Children's Off-the-Shelf Stability Therapeutic Footwear: a mixed method analysis to define their design and purpose.

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"The beginning of wisdom is the definition of terms" - Socrates

Abstract

Footwear is commonly used within the first line of clinical intervention option in children with mobility impairments. It has been used in many roles to assist mobility, from correction of congenital skeletal alignment to support of foot and ankle structures. However, an evidence-based consensus of the different roles and types of clinical footwear has never been achieved. Off-the-shelf stability therapeutic footwear (OSSTF) is a range of commercial clinical footwear that is not bespoke but is taken from stock that is available immediately. Manufacturers propose that this footwear assists stability in gait for mobility-impaired children, however, as identified through scoping and systematic reviews within this thesis this footwear has not been defined. There is a paucity of information on the terms and definitions to identify this footwear and for what mobility impairments it should be prescribed including the purpose of treatment. Also, the design characteristics that will influence its effect as an intervention are not defined. A lack of uniform understanding of intervention leads to inconsistent practice for all stakeholders, clinicians, researchers, and manufacturers.

This thesis has utilised a mixed method approach across a series of studies to provide consistency to the disparate nature of the evidence base concerning footwear interventions, with a specific focus on OSSTF. A conceptual framework for children's clinical footwear has been established with definitions for therapeutic footwear and its groups/subgroups provided. Assessment of the design and material characteristics of a range of available OSSTF informed a Delphi study which provided expert consensus on prescription criteria, purpose, and clinical outcomes for OSSTF. It also provided consensus on salient design characteristics of OSSTF to assist stability and ergonomic function. The effect of these design characteristics were then quantitatively tested in-situ on footwear using a novel mechanical testing methodology. The testing demonstrated which design characteristics had the greatest effect on the stiffness of OSSTF to simulated foot and ankle movements. Building on these results a preliminary assessment tool to assist clinicians in identifying and scoring OSSTF footwear was developed.

This collective work in this thesis has provided consistent terms and definitions to define and group children's therapeutic footwear. It has also provided an expert consensus preliminary criteria prescription for OSSTF and objectively identified how this footwear will act as an intervention. Although further in-vivo testing of the effects of OSSTF on children identified from the prescription criteria is still required, the conceptual basis of OSSTF established in this thesis will inform clinical decision-making, research reporting and manufacturing of OSSTF for children living with mobility impairments.

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Glossary

AFO	Ankle Foot Orthoses
AH	Aoife Healy (Secondary Supervisor)
Angle of Gait	Angle formed between the long axis of the foot and the longitudinal line of progression of movement.
Base of Support	Is the area between an object's point of contact with the supporting surface.
Cadence	Number of steps taken per minute.
Cemented Construction	A shoe construction in which the upper of a shoe is cemented, rather than stitched, to the sole of the shoe.
Cerebral Palsy	Congenital neurological condition involving interruption of blood supply to upper motor neurones resulting in varying degrees of mobility impairment.
Eyelet	A hole through which a lace is threaded; may be reinforced with a metal ring.
Facing	The part of the shoe where the shoelace eyelets are located.
Gait	Repeated sequence of limb movements that bring about locomotion of the body (e.g., walking and running).
Heel Counter/Stiffener	A stiff piece of material placed at the heel of a shoe between the lining and upper to provide support and help the upper wrap around the foot.

Hysteresis	Viscoelastic response to loading (stress) the loading strain does not follow the unloading strain.
Mobility Impairment	Inability of a person to use one or more of their limbs or spine to enable locomotory movement or activities of daily living.
MH	Matthew Hill (PhD Scholar)
Modular Footwear	Standard range of dimensional adaptations e.g., width, girth, (maximum 3) to the upper of stock footwear.
NC	Nachiappan Chockalingam (Primary Supervisor)
Off the Shelf Footwear	Footwear taken from stock or supplies and not individually designed.
OSSTF	Off the Shelf Stability Therapeutic Footwear.
Outsole	The part of the sole that touches the ground, usually made of rubber or PU.
PU	Polyurethane
Rocker	The curvature of the sole from the heel to the toe of a boot to facilitate walking.
Step Length	Distance between the initial ground contact of one foot and the successive initial ground contact of the opposite foot.
Stiffness	Is the extent to which an object resists change in its geometry in response to an applied force
Strain	Change in dimension of an object in response to stress.
Stress	Force per unit area; Newton metres squared N/m^2.

Stride Length	Distance between two successive ground contacts of the same foot (in walking this is usually between two heel contacts of the same foot).
Talipes Equinovarus	Congenital deformity fixation of the foot and ankle in downward and inward orientation.
Topline	The opening in the shoe upper through which the foot enters. Positioned at the rearfoot and ankle.
Upper	The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole
Welt Construction	A shoe construction, in which the upper and sole of the shoe are stitched together with a visible seam that runs around the outside of the shoe, where the upper and outsole meet.
WHO ICF-CY	World Health Organisation International Classification of Function for Child and Youth framework.

Publications arising from this Thesis

Hill, Matthew, Aoife Healy, and Nachiappan Chockalingam. 2019. "Key Concepts in Children's Footwear Research: A Scoping Review Focusing on Therapeutic Footwear." *Journal of Foot and Ankle Research* 12(1): 25. https://jfootankleres.biomedcentral.com/articles/10.1186/s13047-019-0336-z (April 29, 2019).

Hill, Matthew, Aoife Healy, and Nachiappan Chockalingam. 2020. "Effectiveness of Therapeutic Footwear for Children: A Systematic Review." *Journal of Foot and Ankle Research* 13(1): 23. https://jfootankleres.biomedcentral.com/articles/10.1186/s13047-020-00390-3 (May 22, 2020).

Hill, Matthew, Aoife Healy, and Nachiappan Chockalingam. 2021. "Defining and Grouping Children's Therapeutic Footwear and Criteria for Their Prescription: An International Expert Delphi Consensus Study." *BMJ Open* 11(8): e051381. https://bmjopen.bmj.com/content/11/8/e051381 (August 10, 2021).

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1. Introduction

1.1. Background

Mobility impairments are relatively common disabilities affecting children globally (UNICEF, 2013). These mobility impairments create health inequalities with deleterious effects throughout all aspects of the World Health Organisation International Classification of Function Child and Youth version, (ICF-CY) including physical, psychological, and social health (Hwang et al., 2014; World Health Organization, 2007). These inequalities in childhood may impact the risk of secondary morbidity and life expectancy in adult life (Logan et al., 2016; Rimmer et al., 2007; Smith et al., 2021). Integrated Care Systems recognise children's mobility impairments as a serious barrier to health and well-being in the United Kingdom (NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015; NIHR, 2020).

Assistive devices such as orthoses, crutches and walking frames have the potential benefits for individuals living with a mobility impairment, enabling them to achieve a meaningful quality of life if an evidence-based targeted service can be provided (Eddison, Scott, et al., 2022; NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015). It is paramount that children and young people needing assistive devices get the appropriate, effective aid swiftly to account for the changes in skeletal size and geometry and motor development and avoid unnecessary immobility and pain (Eddison, Scott, et al., 2022; Gijon-Nogueron et al., 2019; NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015).

Amongst the many assistive devices available to improve mobility in childhood footwear has been used as a clinical intervention (Kanatlı et al., 2016; Staheli, 1991). Children's clinical footwear consist of a number of footwear modifications that may be either bespoke or off-the-shelf (footwear is taken from stock or supplies with stock standard dimensions to the shoe's upper and outsole (width, girth, height) for any given shoe length (Tyrrell & Carter, 2009). These modifications of footwear are thought to aid walking and lower limb development in children with a range of clinical conditions such as flat feet, talipes equinovarus, toe walking, cerebral palsy and delays in the development of motor skills (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Bartkowlak et al., 2008; Gould et al., 1989; Ivanyi et al., 2015; Wesdock & Edge, 2003). There appears to be a wide range of disparate clinical roles footwear has proffered to act on, including correcting children's skeletal geometry, accommodating foot or ankle deformity or to promote a stable foot posture to allow efficient mobility (Grueger et al., 2009; Morrison, Price, et al., 2018; I. Rotter et al., 2009; Staheli, 1996, 1999).

Off-the-shelf stability footwear is a range of commercially available clinical footwear, it is available from a range of manufacturers including Piedro® Reeds Medical®, Schein®, and Nimco®. The description of these footwear are only available from the manufacturers' sales information and there is little or no scientific quantification of their claims within the peer reviewed evidence base. The shoe designs have apparent similarities amongst the manufacturers cited in that the topline of the shoes extend above the malleoli, with extended medial and lateral heel counter stiffeners (Figure 1-1). The central premise is that the footwear design influences foot and ankle movement to assist stability in gait. As this footwear is available off-the-shelf, they should be readily available to children requiring them without undue delay in treatment, as opposed to the time required for the design and manufacture of bespoke footwear (NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015).

Footwear can serve an immediate functional role in aiding children's mobility (Abd Elkader et al., 2013; Aboutorabi et al., 2014), indicating that off-the-shelf stability footwear may play a role as an assistive aid. While clinical footwear are routinely prescribed for mobility issues (Nester et al., 2018; Staheli & Giffin, 1980), there is no agreed terminology or definitions relating to their purpose, nor prescription criteria related to the specific mobility impairments that would benefit from this footwear or the expected treatment outcomes. Additionally, the specifics of the design characteristics to fulfil their therapeutic role are unclear. Finally, there is no apparent focused review of the evidence base for children's clinical footwear to inform relevant stakeholders of their use in children. This has led to disparate clinical practice, with footwear often used ineffectively for unrequired correction of normal skeletal development and unwarranted lowering of children's self-esteem (Driano et al., 1998; Evans et al., 2022; Rome et al., 2010; Staheli, 1996). Outdated beliefs of footwear requirements for children still persists amongst health professionals and parents (C. M. Williams, Banwell, et al., 2022). Uncertainty about prescription criteria and treatment goals can lead to inconsistent practice and a lack of confidence in providing assistive devices to mobility-impaired children (Kane et al., 2019; Owen, 2019).

Figure 1-1 Standard construction of Off-the-Shelf stability clinical footwear Intervention (Source www.piedro-therapy.com/children).

1.2. Defining and analysing an intervention

Any phenomenon requires consistent terminology and definitions of such terminology for it to be conceptualised (Green, 2014). Consistent terminology and definitions provide a statement expressing the essential nature of something allowing a common understanding to evaluate its potential importance. There is currently inconsistency in terminology and understanding of clinical footwear as a whole, and not just those footwear designs that may offer improved mobility to children without protracted manufacture, such as off-the-shelf stability footwear (Eddison, Scott, et al., 2022; NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015; Tyrrell & Carter, 2009).

Where there is contradictory or insufficient information, the ability to formulate effective clinical reasoning can be affected (Keeney et al., 2006). Mixed methodology is a useful initial research approach where there is limited or unstructured information combining qualitative and quantitative methodology (Tariq & Woodman, 2013). The qualitative aspect of mixed methodology can develop through inductive reasoning, opinion and hypothesises in a standardised approach to provide a conceptual framework of formally developed and organised ideas and improve a common understanding of a clinical phenomenon (Tariq & Woodman, 2013). The hypothesis and ideas within the qualitative concepts may be tested and corroborated through quantitative deductive reasoning to provide a theoretical framework and higher evidence base for potential application (Imenda, 2014; Schoonenboom & Johnson, 2017). The Medical Research Council (MRC) provides a structured approach to define and analyse a clinical intervention through a conceptual and theoretical framework as detailed in Figure 1-2 (Craig et al., 2008; Skivington et al., 2021).

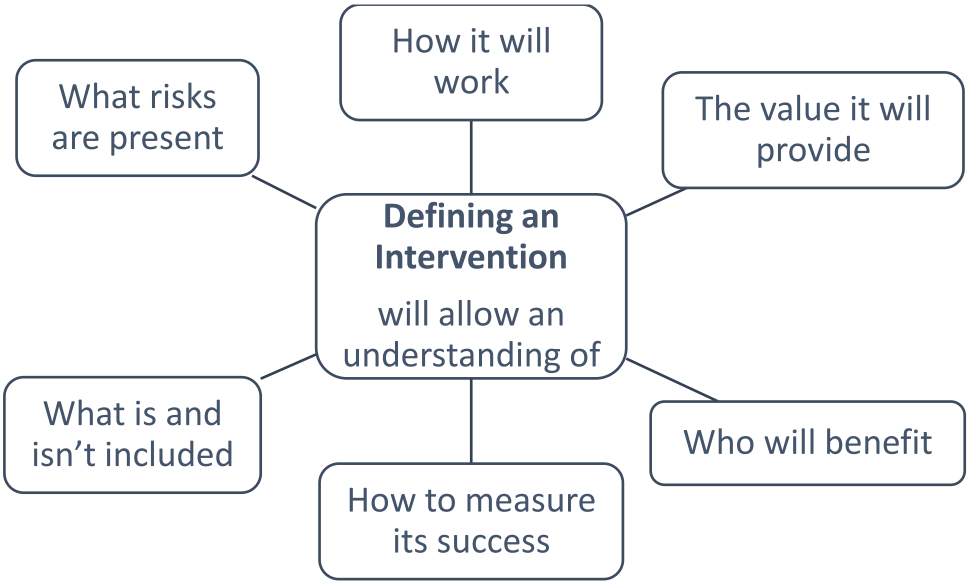


Figure 1-2 Medical Research Council framework for defining and analysing a clinical intervention.

The MRC recognises it is central for any clinical intervention framework to define and provide consistent terms for the intervention as it allows it to be conceptualised and provides a common understanding amongst relevant stakeholders such as clinicians, researchers, patients, and the healthcare industry Figure 1-2. More detailed definitions and analysis of an intervention following MRC guidelines (Moore et al., 2015; Skivington et al., 2021) allow :

- Consistent targeted prescription and assessment aimed at suitable populations
- Allows for an understanding of the purpose and value of the intervention
- Allow clinicians, researchers, and manufacturers to recognise and understand the key functional components of an intervention.
- Provides an understanding to measure the effects of an intervention by identifying the relevant clinical outcomes.
- Facilitate between study comparisons and meta-analyses of future research by using identified salient outcomes to measure its effectiveness.

Previously other assistive aids, such as ankle foot orthoses (AFOs), have also suffered from limited and inconsistent information within the evidence base (Eddison, Mulholland, et al., 2017). With no standardised description of the design or material used or understanding of the salient outcomes to measure its effectiveness (Eddison et al., 2015). By providing a theoretical framework approach to analyse AFOs as an intervention, researchers have demonstrated and defined that an AFO which is optimised or tuned to individual children's lower limb needs improved the mobility and energy expenditure in children with cerebral palsy (Eddison, Chockalingam, et al., 2020; Eddison, Healy, Needham, et al., 2020; Eddison, Mulholland, et al., 2017; Eddison & Chockalingam, 2013). By adopting a similar staged framework to define and analyse off-the-shelf stability footwear for children, this current proposed work would seek to offer clarity for clinical practice to aid function in children with mobility impairments.

1.3. Gaps in current knowledge

Within the current evidence base concerning children's off-the-shelf stability footwear as a clinical intervention, there is a paucity of overall understanding, even compared to other assistive devices, such as AFOs, for children's mobility impairments. The significant shortfalls are:

1) Lack of definition of off-the-shelf stability footwear in terms of

- **Terminology**
- **Components:** no standard design characteristics regarding structure and material properties of off-the-shelf stability footwear.

2) No clinical Protocols: no clear consensus on the clinical indications for the provision of this footwear in mobility-impaired children, inclusive of:

- The specific conditions
- The grade of the conditions
- Purpose of intervention
- The outcomes of treatment

3) Poor understanding of the effects of off-the-shelf stability footwear**:** limited research on the effects of stability footwear relating to biomechanical data on the gait of children with mobility impairments.

4) No focused review on clinical footwear: no summative work using systematic searching and validated synthesis tools to improve the understanding of inconsistencies in diverse evidence. This is necessary to define the phenomena and examine the effects of the phenomenon. No body of work to identify gaps in the research evidence to define future research agendas (Grant & Booth, 2009; Kastner et al., 2012; Lucas et al., 2007).

1.4. Aim and Objectives

The overall aim of this program of work is to establish a conceptual and theoretical foundation for children's off-the-shelf stability footwear. This program will conduct both quantitative and qualitative evaluations of the footwear's design, leading to the creation of an evidence-based framework for clinical interventions catering to this specific population. The work will be carried out collaboratively with all relevant stakeholders.

Objectives

This study will attain its aim by focusing on the following objectives:

I. To define and achieve from the existing body of research and further expert consensus what constitutes off-the-shelf stability footwear designated by:

- Terminology: Standard statement of what identifies it and its intended clinical role
- Specifics of its design: Both structural and material characteristics.
- Its potential clinical effects.

II. To establish expert consensus clinical protocols for the prescription of off-the-shelf stability footwear in children living with a mobility impairment. In terms of:

- The specific type of mobility impairment
- The grade of the mobility impairment
- The proposed outcomes of treatment

III. Design and validate methodology to mechanically test the salient expert consensus design characteristics of off-the-shelf stability footwear to inform on their effects on the stiffness of the footwear.

- Provide a valid and consistent laboratory protocol to mechanically test the expert consensus design characteristics of off-the-shelf stability footwear in situ of the shoe

- Quantify the effects the suggested expert design characteristics have on enhancing the stability properties of this footwear
- Identify the design characteristics likely to influence stability.
- Provide preliminary objective evidence of how off-the-shelf stability footwear will act as an intervention

IV. Design a screening tool to practically assess and identify the salient design characteristics of off-the-shelf stability footwear:

- Provide a simple checklist of the validated design characteristics of off-the-shelf stability footwear established from objectives I and III to be readily used by clinicians, researchers, and footwear manufacturers.
- Pilot the tool for consistency and reliability.

1.5. Scope and Boundaries

The study will concentrate on the terminology and design features of children's off-the-shelf stability footwear, including clinical criteria for paediatric patients up to 18 years old (with no lower age limit other than the onset of walking). However, the proposed research will not conduct any biomechanical or in-vivo investigation into the effects of these footwear on children.

1.6. Framework

A mixed methodology research design was used to allow the gaps in knowledge concerning off-the-shelf stability footwear to be filled. Before embarking on mixed method research Tariq and Woodman (2013) highlight it is important to consider

- The methods used
- The priority of the methods
- The Sequence in which the methods are to be used

The work used a staged mixed-method research design, using quantitative and qualitative methods across a series of studies (see Figure 1-3)

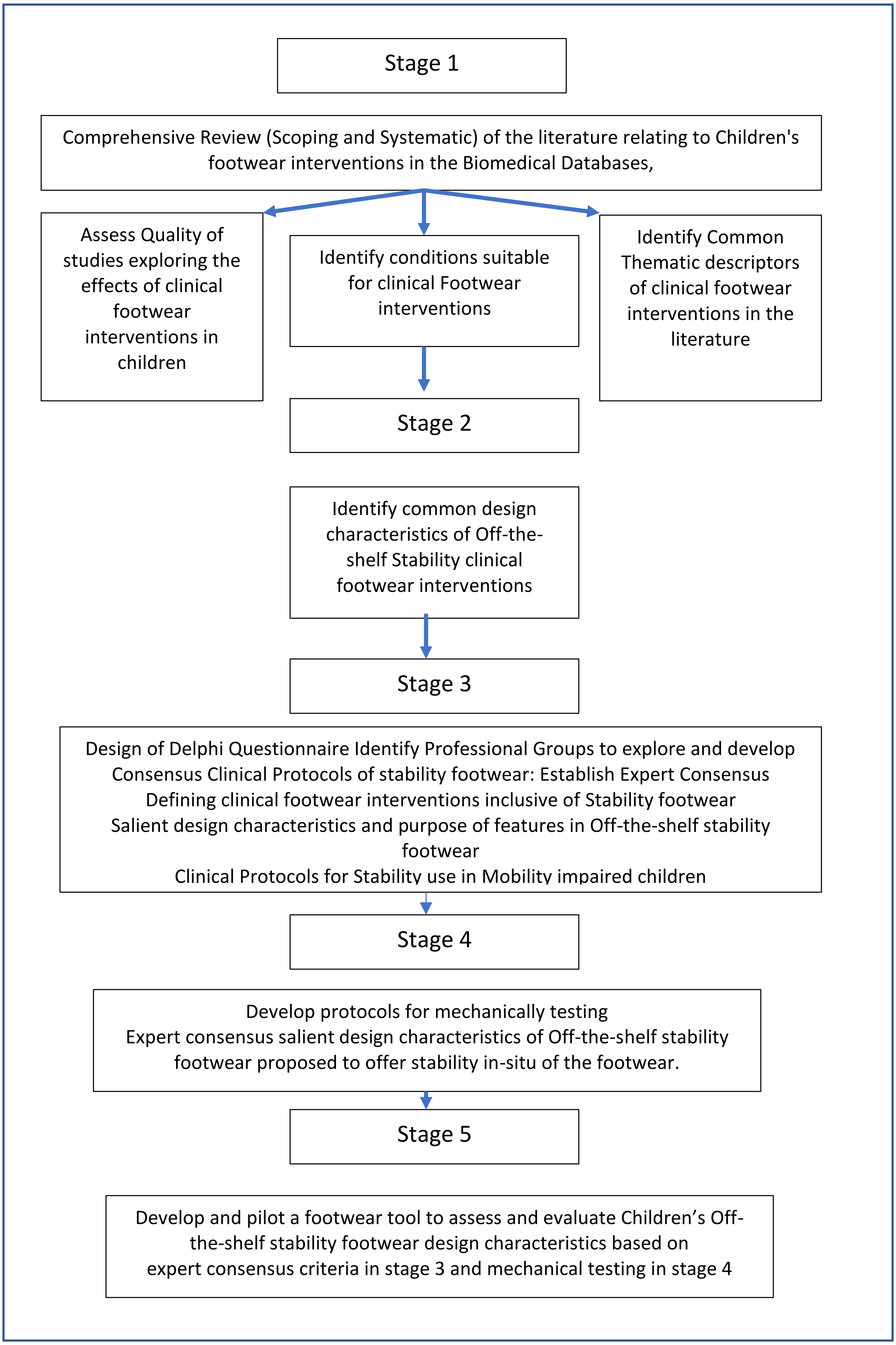


Figure 1-3 Framework of study to assess Off-the-shelf stability clinical footwear interventions

Exploratory qualitative methodology was used to identify terms and definitions for off-the-shelf stability footwear. Additionally, the qualitative work has provided hypotheses such as children's mobility impairments suitable for treatment and the proposed outcomes. The qualitative work has also explored the salient design characteristics of off-the-shelf stability footwear and the perceived purpose of these, with subsequent testing of the hypotheses and identified variables using quantitative research (Schoonenboom & Johnson, 2017; Tariq & Woodman, 2013).

Stage 1 (Chapters 2 & 3) consisted of a scoping review using qualitative analysis to synthesise suggested terms and definitions and conditions that had been used for clinical footwear. It also analysed the current quality of the evidence base concerning the effectiveness of clinical footwear on children's mobility impairment via qualitative analysis has the disparity in the reporting of the evidence precluded quantitative meta-analysis.

Stage 2 (Chapter 0) used qualitative and quantitative methodology to identify design characteristics of a range of off-the-shelf stability footwear for children, to inform on its potential to act as an assistive aid to children living with mobility impairment.

Stage 3 (Chapter 5) gathered expert opinion, using a Delphi study design to corroborate and develop the preliminary definitions provided by stage 1 of this study which has provided consistent language amongst relevant stakeholders in clinical footwear. it also gained insight from the experts on the design and purpose of off-the-shelf stability footwear that had been identified from the preliminary analysis of off-the-shelf stability footwear in stage 2. Additionally, the Delphi explored expert opinion on protocols and outcomes for its use in children living with mobility impairment. Qualitative analysis was employed in the Delphi to synthesise speculative opinion together with quantitative analysis, such as the frequency and strength of consensus of opinion (Hasson & Keeney, 2011). Proposed protocols and outcomes identified variables such as the children's mobility impairments suitable for treatment and the expected physical benefits (outcomes) of using off-the-shelf stability footwear. Although this work has not directly explored these outcomes on mobility-impaired children, the data obtained from stage 3 will inform future research streams studying the in-vivo effectiveness of off-the-shelf stability clinical footwear on children with mobility impairment. The project additionally utilised the data from stage 3 to provide expert consensus design characteristics of off-the-shelf stability clinical footwear that propose to offer stability. These expert consensus design characteristics of the footwear were tested to quantify their effects on mechanical stiffness in stage 4 of the study (Chapters 6 & 7). Testing of the design characteristics were performed in-situ of footwear via novel mechanical testing protocols developed in this study. This provided quantitative data which corroborated and refuted the consensus design characteristics generated in stage 3 and has provided an understanding of how off-the-shelf stability footwear may work as a clinical intervention for children. The corroborated design characteristics of off-the-shelf stability footwear from the mechanical testing in stage 4 were synthesised alongside the other consensus characteristics to develop a survey tool in stage 5 (Chapter 8) to allow relevant stakeholders in clinical footwear to rapidly recognise and assess the relevant design characteristics of off-the-shelf stability footwear to improve clinical practice and research reporting (Craig et al., 2008; C. M. Williams, Morrison, et al., 2022)

1.7. Structure of the thesis

This thesis is structured as a set of individual manuscripts each with individual aims and objectives. The findings from each chapter have been combined as detailed in the stages described above to meet the overall aims and objectives of the thesis.

1.8. Effect of the COVID-19 pandemic on this thesis

Initially, this thesis intended to develop and test a prescription protocol for OSSTF from the expert consensus that identified children's mobility impairments and expected physical benefits (outcomes). These variables were originally proposed to be tested through a quantitative biomechanical study on children identified as suitable from the protocol in stage 4 of the thesis. Pilot testing using biomechanical outcomes and children who fit the characteristics identified from the Delphi protocol would provide an appropriate evidence-based approach to test the protocols. However, the work presented as a part of thesis was conducted during the COVID-19 pandemic and restrictions on participant recruitment pushed this proposed stage beyond the scope of this current study. Therefore, stage 4 of the thesis was modified to explore and test the suggested and hypothesised expert consensus design characteristics of OSSTF through the development and application of novel footwear mechanical testing protocols (Figure 1-3).

2. Key Concepts in Children's Footwear Research: A scoping review focusing on therapeutic footwear

Aspects of this chapter have been published:

Matthew Hill, Aoife Healy, and Nachiappan Chockalingam. 2019. "Key Concepts in Children's Footwear Research: A Scoping Review Focusing on Therapeutic Footwear." *Journal of Foot and Ankle Research* 12(1): 25.

2.1. Background

A United Nations report on disability provided an estimate of 93 million children in the world with moderate or severe disability. This equates to five percent of the global population under 15 years of age (UNICEF, 2013). A further report from the United Kingdom highlighted that children represent the fastest growing group amongst the population of people with disabilities (Disability Rights Commision, 2006). Of these childhood disabilities, over 30% are related to mobility or coordination impairment (Blackburn et al., 2010). Mobility issues in children represent a significant social and health problem (Blackburn et al., 2010) which may require appropriate physical and rehabilitation medicine interventions to assist in their daily activities (Bartkowlak et al., 2008; Ivanyi et al., 2015). Assistive devices such as orthoses, crutches and walking frames have been found to benefit individuals with mobility impairment in activities of daily living (Bartkowlak et al., 2008; Ivanyi et al., 2015). Footwear is the primary interface between the individual and the ground and as such will contribute to how ground reaction forces generated in gait are applied to the foot and ankle (Wegener, Hunt, et al., 2011). Considering this, it is logical that footwear has been postulated to offer a role as a mobility aid for children with locomotory impairment since the 18th Century (Eek et al., 2017; Ivanyi et al., 2015; Staheli, 1996; Staheli & Giffin, 1980). Research has shown that footwear is the key extrinsic factor affecting children's gait with studies on conventional footwear in healthy children demonstrating that it modifies: lower limb movements, forces and sensory stimulus acting through the foot (Carlos González et al., 2005; Colloud et al., 2012; Kristen et al., 1998; Oeffinger et al., 1999; Wegener, Hunt, et al., 2011). As children are still growing and developing their feet demonstrate differing structural and functional characteristics in comparison to adult feet (McKay et al., 2017; Parikh et al., 2012; Stolze et al., 1997). These differences will also vary within childhood depending on the developmental stage taking into account the: plasticity of the foot, growth rate, allometry, and motor ability (Gould et al., 1990; Morrison et al., 2009; Walther et al., 2008). It is therefore considered that foot development is a fundamental factor underlying the requirements of children's footwear (Morrison, Price, et al., 2018; Wegener, Hunt, et al., 2011). However, there is still uncertainty on the long-term effects of footwear on child development and the specifics of children's footwear design in terms of support and flexibility (Adolph et al., 2003; Morrison, Price, et al., 2018; Wegener, Hunt, et al., 2011). These uncertainties concerning footwear are further confounded when considering the developmental needs of children living with a physical disability (Aboutorabi et al., 2014; Davies et al., 2015; Morrison, Price, et al., 2018).

Therapeutic footwear for children consists of a number of footwear modifications that may be either bespoke or off-the-shelf (Aboutorabi et al., 2014; Kanatlı et al., 2016). These modifications have been used in an attempt to achieve efficient walking patterns or to correct skeletal alignment in children with a range of clinical presentations such as: flat feet, talipes equino varus, toe walking, cerebral palsy, and developmental delay (Abd Elkader et al., 2013; Aboutorabi et al., 2014; W. Chen et al., 2015; C. M. Williams et al., 2016). Footwear intended for therapeutic use ranges in design and application from those whose role is to simply accommodate a foot orthosis to those that act as an independent mobility or corrective device (Holt, 1991; Kanatlı et al., 2016; Staheli, 1996). Therapeutic footwear is widely prescribed by healthcare professionals, as evidenced by a recent survey in the United Kingdom (Nester et al., 2018); however, there is lack of scientific evidence on the specifics of the design and purpose of this footwear for children.

Conventional children's footwear in typically developing children has been examined in a number of reviews, including the effects of footwear on gait and the requirements of athletic and school footwear (Hettigama et al., 2016; Walther et al., 2008; Wegener, Hunt, et al., 2011). Although children's therapeutic footwear has previously been considered in a number of reviews, some of these have focussed on individual pathological conditions and others have provided an overview rather than a structured synthesis of the body of research (Rome et al., 2010; Staheli, 1991; Uden & Kumar, 2012). Therefore, it is important to establish the range, and scope of research focussing on therapeutic footwear to support future evidence base in this area. However, it is unclear how footwear intended for therapeutic purposes in children has been defined in the literature. Thus, in order to identify the scope of work concerning therapeutic footwear it is first essential to establish the terminology used for this intervention within the general body of children's footwear research.

A systematic search was undertaken to compile the key concepts pertaining to children's footwear that is facilitative of daily wear, and activity to demonstrate the volume, and progress of work in this area. It was also performed to highlight the gaps in knowledge whilst considering therapeutic footwear alongside the body of children's footwear research. In addition, it was important to include all areas of research and not just limit to either the design and manufacturing aspects of footwear or their influence on locomotory function.

2.1.1. Aims and objectives

The review set out to achieve the following objectives:

- Explore how children's footwear has been studied in the literature; specifically, the intended purpose of the footwear and the chosen methodology.
- Identify how therapeutic footwear has been defined and studied in terms of its design and intended therapeutic role.

With the overall aim to summate the current state and scope of knowledge in relation to both conventional and therapeutic children's footwear and to inform further research streams on the role of footwear as a therapy for children with a mobility impairment.

2.2. Methods:

The scoping review followed the staged methodological guidance of Arksey & O'Malley (Arksey & O'Malley, 2005) and Colquhoun et al. (2014) this met the preferred reporting guidelines extension for scoping reviews PRISMA-ScR (Tricco et al., 2018) (Appendix 1.1 PRISMA-ScR Checklist) . The inclusion and exclusion criteria for the systematic search is detailed below:

2.2.1. Inclusion and exclusion criteria.

2.2.1.1. Types of Study and Publication

Inclusion

- Studies where footwear was the intervention or where its effects were explored independently if it was used as an adjunct to an orthotic intervention.
- Studies examining characteristics relating to ergonomic footwear design and fit.
- Studies exploring the effects of footwear on child health
- Studies exploring the effects of footwear on child development.
- All study designs were considered from peer-reviewed journals and conference proceedings
- Studies with an available English language abstract.

Exclusion

- Studies where footwear was not the preliminary or secondary focus of the research question.
- Commercial based study design customisation which was not related to fit or function.
- Textbook entries, poster presentations.
- Non-English language abstract.

2.2.1.2. Participants

Inclusion

- Infant, children, and adolescents of typical walking and shod age 9 months-18 years of age.

Exclusion

- Less than 9 months of age.
- Greater than 18 years of age.

Gross motor milestones indicates that the normal range of onset of walking is at 9-18 months (World Health Organization, 2006), with onset of walking associated with the introduction of shoe wear (C. M. Williams, Morrison, et al., 2022). Additionally, skeletal development of the foot is considered to be essentially complete by 18 years of age (Hettigama et al., 2016). Therefore, the age range included in this review protocol would feasibly capture all articles where footwear has been considered across the growth and development of the child's foot and ankle.

2.2.1.3. Footwear Type

Inclusion

- Footwear that facilitates typical daily activities (e.g., walking running, jumping)

Exclusion

- Footwear modified for specific sporting task precluding daily wear and activities (e.g., studs, cleats, spikes, ski-boots, and skates)

2.2.2. Search Strategy

The following electronic databases were searched for eligible studies: MEDLINE, CINAHL, PubMed, SPORTdiscus, and Scopus. MeSH headings and free text terms for children and footwear were used to capture all research in this area. Search strategy including the search terms is provided in supplementary material (Appendix 1.2 Example search strategy). The search strategy was adapted across the databases to capture eligible articles published from database inception to 1st February 2018.

2.2.3. Screening and Selection of Studies

Prior to screening all duplicates were removed using referencing software (Mendeley, Elsevier B.V.) and supplemented by a manual check by the principal investigator (MH). One reviewer (MH) independently screened the titles and abstracts yielded by the search against the eligibility criteria; with any uncertainty regarding eligibility resolved through discussion with a 2nd (AH) and 3rd (NC) reviewer.

2.2.4. Data Extraction and Synthesis

Data were extracted from the abstracts by the Author (MH) using a form developed and tested by the Author. Information on study design, footwear style, age range of participants, methodology, outcomes of the study and topics discussed were extracted. Textual narrative synthesis (Kastner et al., 2012; Lucas et al., 2007) was used to chart the evidence into sectioned homogeneous research groupings dependent on the topics discussed or the methodology used within the studies. The charting process took an iterative approach, with groupings of the research reached by structured discussion and consensus between all reviewers (MH, AH, NC). As data was extracted solely from the abstracts, i.e., the full texts of the included studies were not analysed, a quality assessment of the included studies were not performed.

2.3. Results

The search yielded 10,608 articles, after removing duplicate articles this total was reduced to 5,003 articles. Three further articles were found through related author research (Wegener et al., 2012, 2013b; Wegener, Smith, et al., 2011). Following screening, a total of 287 articles were included for synthesis (Figure 2-1). A full list of the included studies and results of individual sources of evidence are provided in Appendix 1.3 (n= number of papers from included studies).

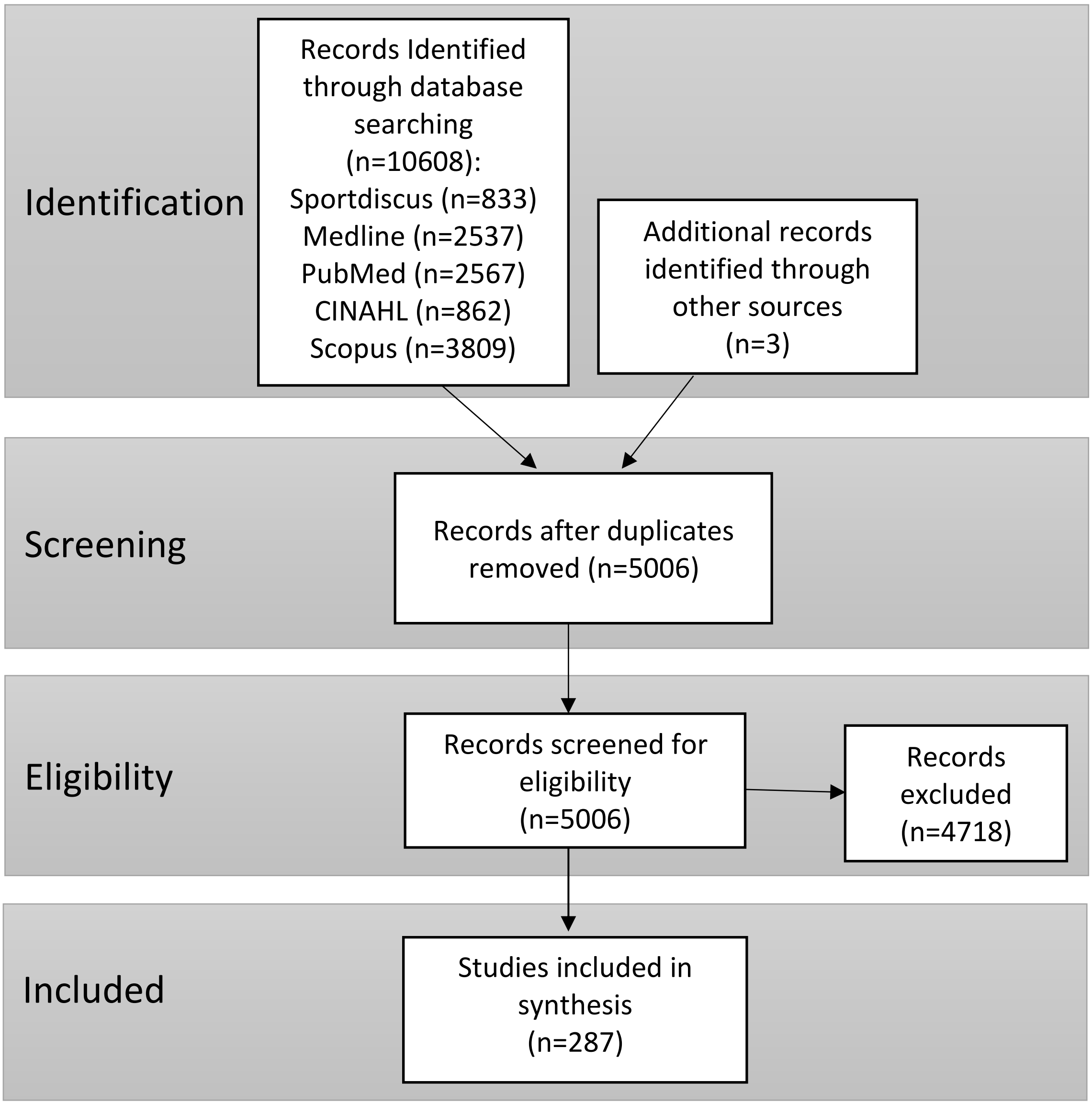


Figure 2-1 Flow diagram for selection of studies included in the scoping review (n=number of papers)

When articles were grouped by year of publication (Figure 2-2), it was evident that children's footwear is an increasing area of research with 56% of articles (n=161) identified in this search published in the past 10 years. There were 211 empirical studies amongst the articles sourced, with 137 of these reporting the age range of the participants in the abstract; age range was from 9 months to 18 years. Articles were grouped by age into 3 ranges: 1) **infant and preschool** (9mths-5Yrs), 2) **primary school** (6-12Yrs) and 3) **adolescents** (13-18Yrs). Although a number of articles considered more than one of the age groupings in the population sampled the majority of the research involved primary school aged children (n=93), followed by adolescents (n=56), then infants and pre-schoolers (n=53).

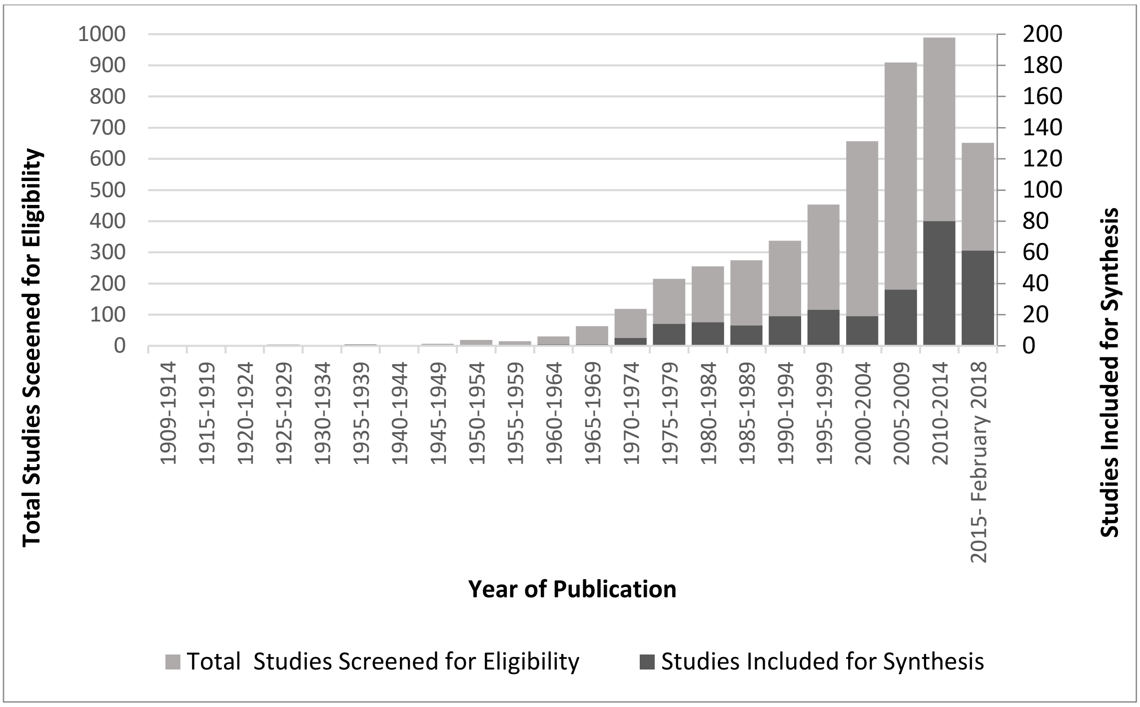


Figure 2-2 Scoping review search results by year of publication.

2.3.1. Overarching areas: Footwear design and Effects of footwear

Charting of the included articles yielded two overarching areas of research in children's footwear:

1) **Footwear design** (n=146) this was in terms of both ergonomics (refining the dimensional fit and functional properties of footwear to meet the daily demands of the child's foot in both typical and atypical development) and the material components of footwear (upper, lining, sole and tanning agents).

2) **Effects of footwear** (n=216) This was the effects of footwear on the child (effects on gait, protective benefits, risk factor for injury/pathology and therapeutic effects). Amongst these two overarching areas, eight general groupings were further charted. Figure 2-3 provides an overview of the charted groupings and how the articles in each group were apportioned amongst the two main areas. The articles were not exclusive to each of the eight groupings or two overarching areas with many articles overlapping across both areas and groupings.

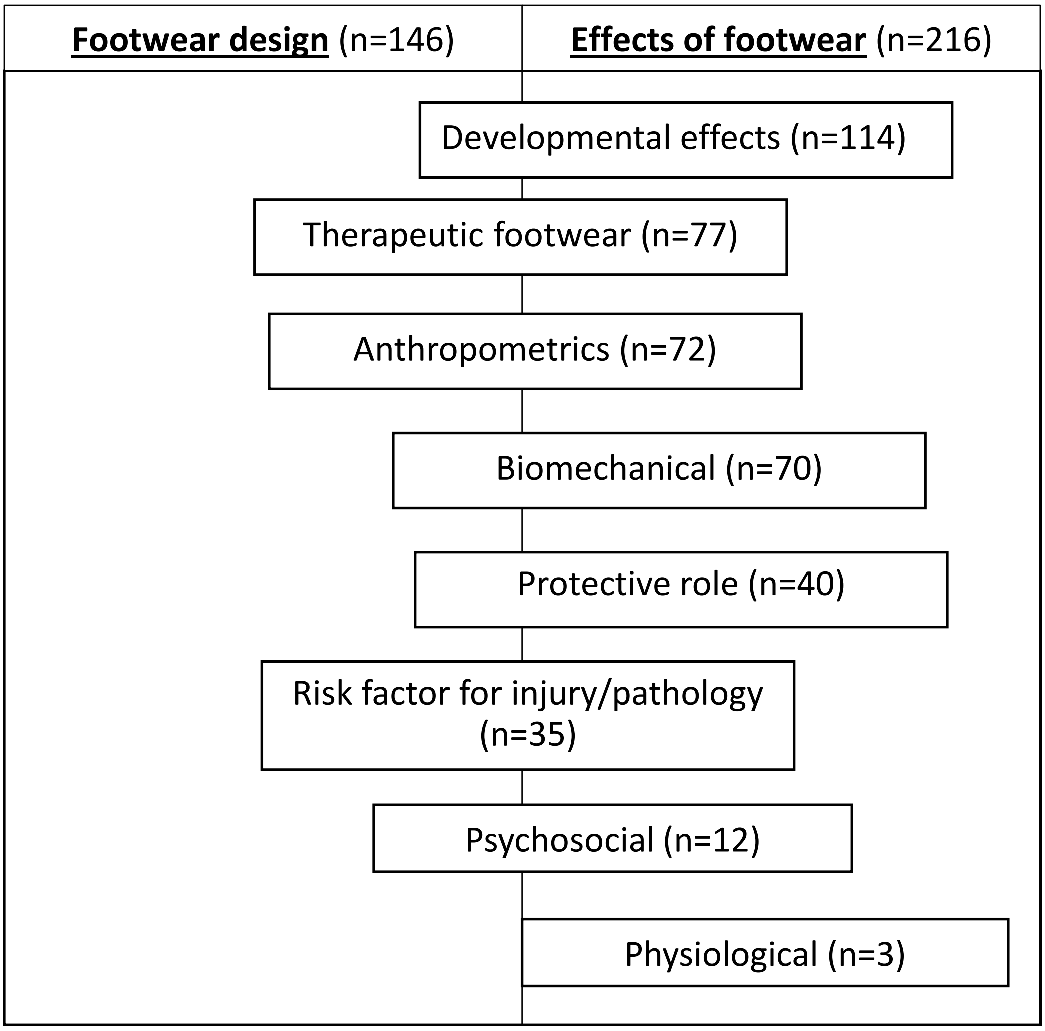


Figure 2-3 Charting of studies within overarching areas (footwear design and effects) and groupings (ordered by volume of studies) (n=number of studies)

2.3.1.1. Developmental Effects

These articles explored the effects or perceived effects of footwear and footwear design on typical and atypical child development; this represented the largest research grouping (n=114). Ninety-four of the studies were empirical in design with age range reported in 63 of the articles, infant and preschool (n=28), primary school (n=40) and adolescents (n=19). Earlier research in this grouping focused on skeletal foot development (n=35) inclusive of the medial longitudinal arch and digital deformity (Abolarin et al., 2011; Basta et al., 1977; Coughlin, 1995; Echarri & Forriol, 2003; Klein et al., 2009; P. Q. X. Lim et al., 2015). However the recent focus of this research grouping has considered the potential effects on neuromuscular development in terms of gait and other motor tasks (n=45) (Abd Elkader et al., 2013; Aibast et al., 2017; Hillstrom et al., 2013; Hollander et al., 2018; Lythgo et al., 2009; Wegener, Hunt, et al., 2011; Wolf et al., 2008). The remaining articles (n= 35) were in relation to the ideal attributes of footwear design and application for the child in both typical and atypical development, with a broad range study design including opinion base, cross-sectional survey through to systematic review (Baba, 1976; Davies et al., 2015; Walther et al., 2005; Yurt et al., 2014).

2.3.1.2. Therapeutic Footwear

This grouping focused on footwear that was designed for the treatment of childhood musculoskeletal or neurological locomotor disability with the underlying principle of last and sole modification to influence the structure and function of the child's foot (Aboutorabi et al., 2014; Bleck, 1971; Cohen & Cowell, 1989; Eddison & Chockalingam, 2013; Kanatlı et al., 2016; Staheli, 1991, 1996). Numerous terms were used to define therapeutic footwear throughout the literature including orthopaedic shoes, shoe corrections, rehabilitative boots, modified shoes, arch support footwear, supportive shoes, special shoes, medical shoes and wedged shoes_(Abd Elkader et al., 2013; Aboutorabi et al., 2014; Bailey-Van Kuren et al., 2005; Bleck, 1971; Bordelon, 1990; Cowell, 1977; Gould et al., 1989; Knittel & Staheli, 1976; Yi et al., 2007). Of the 77 articles in this group, 23 explored the effects of therapeutic footwear empirically with the age range given in 9 of these articles; age groups were roughly equally represented in these studies: infant and preschool (n=6), primary school (n=7) and adolescent (n=5).

Figure 2-4 compares the number of therapeutic footwear articles by year of publication to the total articles considered for synthesis in this review. Although the volume of articles on children's therapeutic footwear has increased annually since the 1970s, when compared to the total volume of research in children's footwear its proportion of this total volume has decreased; from 35% of the total articles from 1998-2007 to 17% of the total articles from 2008-2018.

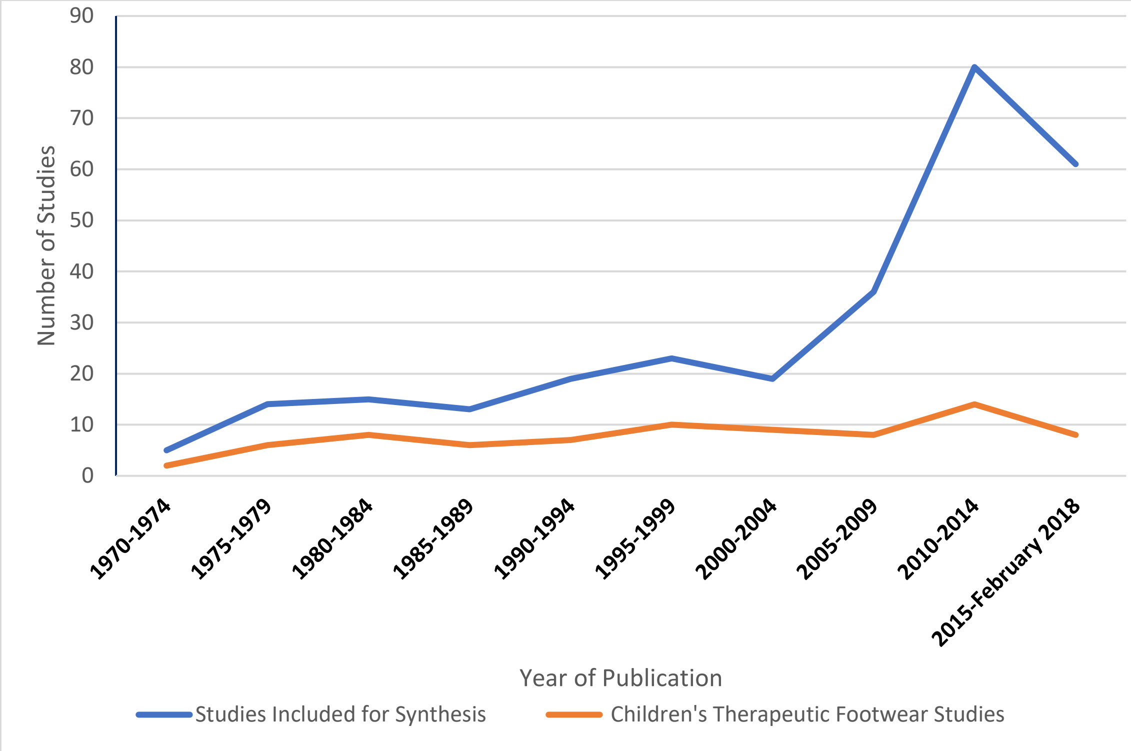


Figure 2-4 Volume of children's therapeutic footwear articles compared to the total volume of children's footwear articles published annually

Therapeutic footwear was charted, based on the information provided within the abstract, into three separate subgroupings (corrective, accommodative, and functional) according to the perceived therapeutic role of the footwear (Figure 2-5). Of the 77 articles, 38 were related to corrective footwear, 34 functional, 2 to accommodative, 5 articles did not specify the direct clinical aims or outcomes of the footwear. One paper discussed corrective, functional and accommodative therapeutic footwear (Holt, 1991).

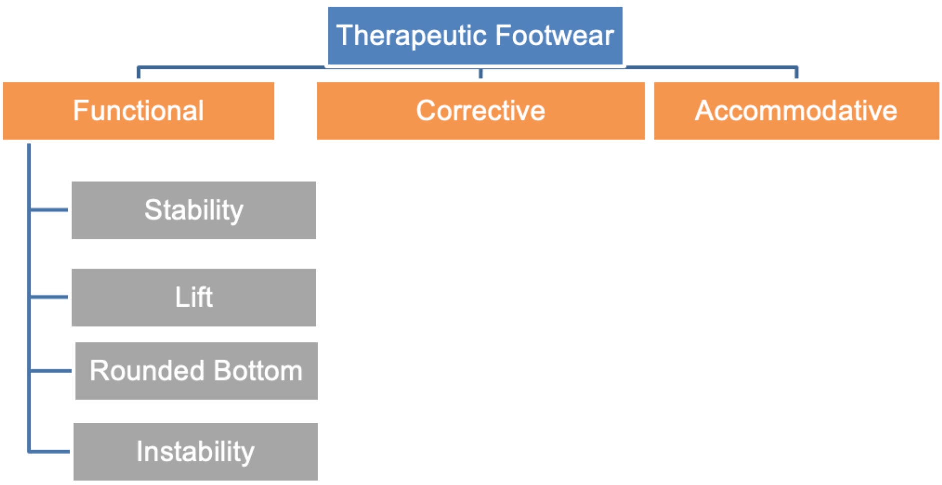


Figure 2-5 Grouping and subgroupings of children's therapeutic footwear suggested from textual narrative synthesis of the literature

2.3.1.2.1. CORRECTIVE FOOTWEAR

Corrective footwear was defined in this review as footwear that was designed to bring about correction of congenital skeletal lower limb alignment (Chong et al., 2014; Staheli, 1996). Corrective footwear research yielded several footwear design modifications that were used to treat a range of structural lower limb issues (e.g., Talipes Equino Varus, genu varum, genu valgum, tibial torsion, paediatric pes planus, metatarsus adductus and hallux valgus) (Basta et al., 1977; Bleck, 1971; W. Chen et al., 2015; Kraemer, 1980; Y. H. Li & Leong, 1999; Sass & Hassan, 2003). The types of footwear included Thomas heel, high topped, reverse last, straight last, in-built arch support, reinforced steel shank, and loop sandals (Basta et al., 1977; Bleck, 1971; Gould et al., 1989; Kraemer, 1980; Staheli & Giffin, 1980).

The effects of corrective footwear have been mainly assessed by prospective studies (n=11) examining anthropometric measures of the medial longitudinal arch including radiographic, laser scanning, and footprint analysis (Basta et al., 1977; Bleck, 1971; W. Chen et al., 2015; Coll Bosch et al., 1999; García-Rodríguez et al., 1999; Gould et al., 1989; Kanatlı et al., 2016; Murri & Zechner, 1994; Pandey et al., 2013; Wenger et al., 1989). Other articles (n=13) included expert opinion on corrective footwear in terms of design and conditions treated (Cowell, 1977; Hutchinson, 2010; Staheli, 1986, 1999), review articles (n=7) (Y. H. Li & Leong, 1999; Rome et al., 2010; Staheli, 1991; C. M. Williams et al., 2013), psychosocial considerations (n=4) (Driano et al., 1996; I. Rotter et al., 2009) and clinical prescription surveys (n=3) (García-Rodríguez et al., 1999; Staheli & Giffin, 1980).

2.3.1.2.2. ACCOMMODATIVE FOOTWEAR

This was defined within this review as footwear that was designed (modular or bespoke) to reduce compression and shearing stresses on the child's foot deformity through dimensional matching of footwear upper, insole, and sole to that of the child's foot (Holt, 1991; Talusan et al., 2013). There was a dearth of research (n=2) in terms of children's accommodative therapeutic footwear (Holt, 1991; Talusan et al., 2013). Of the two articles, one was an opinion piece on suggested indications for therapeutic footwear in terms of "misshapen feet" (Holt, 1991) the second article sourced was a review where accommodative footwear was considered as part of the suggested management for digital deformity in childhood (Talusan et al., 2013).

2.3.1.2.3. FUNCTIONAL FOOTWEAR

This subgrouping was defined as footwear designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns (Abd Elkader et al., 2013; Ivanyi et al., 2015). Functional therapeutic footwear consisted of four further subgroupings which were charted dependent on design and the perceived functional role: **stability** (n=25), **lift** (n=8), **rounded bottom sole** (n=1) and **instability** (n=1) (Figure 2-5).

Stability therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb in order to maintain a controlled displacement of the centre of force during gait (Aboutorabi et al., 2014; Holt, 1991). Various footwear designs (toplines that extend above malleoli, stiffened extended heel counters, stiffened sole, wedged sole, and torqheel) (Holt, 1991; Knittel & Staheli, 1976; Mendelewich & Pitkin, 1989; Yi et al., 2007) have been used to impart stability and these may be used in isolation or in combination with ankle-foot orthosis tuning (Eddison & Chockalingam, 2013). The range of childhood mobility disorders where they have been used includes: cerebral palsy, muscular dystrophy, toe walking, in-toeing, spina bifida, pes planus, haemophilic arthropathy and developmental delay (Abd Elkader et al., 2013; Bakker et al., 1997; Bartkowlak et al., 2008; Caselli et al., 1988; Ivanyi et al., 2015; Knittel & Staheli, 1976; Muller et al., 1999).

Research on the effects of stability therapeutic footwear, on body posture and gait, was limited (n=9) but has included case studies through to cross-sectional study of anthropometrics and biomechanical parameters (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Eddison, Healy, et al., 2017; Hobbs et al., 1980; Knittel & Staheli, 1976; Penneau et al., 1982; Yi et al., 2007). Other articles included opinion based pieces (n=8) on the design and clinical use of stability footwear (Bailey-Van Kuren et al., 2005; Holt, 1991; Mendelewich & Pitkin, 1989; Roye & Raimondo, 2000), review articles (n=7)

(Bartkowlak et al., 2008; Eddison & Chockalingam, 2013; Ivanyi et al., 2015; Uden & Kumar, 2012; C. M. Williams et al., 2014) and a survey of their use in muscular dystrophy (n=1) (Bakker et al., 1997).

Lift therapeutic footwear was defined as a unilateral modular footwear sole addition to conservatively achieve postural and functional symmetry in individuals with limb length inequality (Steen et al., 1997), this included both functional and structural limb length difference of 1cm or greater found in such conditions as cerebral palsy and idiopathic scoliosis (Eek et al., 2017; Zabjek et al., 2001). The effects of lift therapeutic footwear have been reported (n=4) in relation to spinal posture, objective gait parameters and symptomatic relief (Eek et al., 2017; Kayani et al., 2017; Raczkowski et al., 2010; Zabjek et al., 2001). Other articles were opinion based with respect to clinical indications and the degree of lift required (Holt, 1991; Mueller & Boltze, 1975; Vogel Jr, 1984).

The effect of **rounded bottom therapeutic footwear** on gait was studied in one conference proceeding abstract (Hafez, 2017). This footwear consists of a sole with a forefoot rocker design proposed to assist sagittal plane progression of the foot and toe clearance in stiff knee gait associated with cerebral palsy.

Instability therapeutic footwear consists of a sole designed to promote imbalance with the intention of training the individuals motor coordination. The effects on static and reactive balance and directional control in children with developmental delay were assessed in one pilot study (Ramstrand et al., 2008).

2.3.1.3. Anthropometrics

This grouping of articles was in reference to the methods employed in the research which involved the objective study of the human body in relation to dimension, geometry and proportions. The majority of articles (n=66) were of foot measures (length, width, height, circumference, toe flex angle); however the effects of heel height on spinal posture was also reported in the literature (n=6) (de Oliveira Pezzan et al., 2011; Zabjek et al., 2001). Methods involved direct measurement of anatomy or measurements from imaging modalities; these included callipers, inked and pressure foot-printing, radiological imaging, and 3D dynamic laser scanning (Abolarin et al., 2011; Bari et al., 2010; Barisch-Fritz, Schmeltzpfenning, Plank, & Grau, 2014). Forty-four of the abstracts reported the age range in these studies with the age groups represented in the following number of articles, infant and preschool (n=20), primary school (n=29), and adolescents (n=22).

The anthropometric grouping of articles were distributed into articles of footwear design (n=36) which related anthropometric data to ergonomic design of children's footwear taking into consideration the age and perceived rate of foot growth (Barisch-Fritz et al., 2016; Delgado-Abellán et al., 2014; Gould et al., 1990; Küper et al., 2005; Pavlackova et al., 2015; Rajchel-Chyla et al., 2012; A. Yamamoto & Imamatsu, 1990), gender (Delgado-Abellán et al., 2014), geographic region (Mauch et al., 2008), body type (Jiménez-Ormeño et al., 2013), and developmental pathology (P. Q. X. Lim et al., 2015). The other articles (n=2) considered the use of anthropometrics to formulate footwear assessment scores to quantify footwear fit in children (Byrne et al., 1998; Yurt et al., 2014). A considerable number of articles (n=34) used anthropometric methods to study the immediate or potential long term consequence of footwear on children's anatomy, including the medial longitudinal arch, forefoot width, digital deformity, and lumbar lordosis (Bhaskara Rao et al., 1992; Dai et al., 2015; Klein et al., 2009; Thompson & Zipfel, 2005).

2.3.1.4. Biomechanical

Like the anthropometrics grouping, this grouping was in relation to the methods used in the research. These studies involved the mechanical effects of footwear on the child's locomotory system, including gait (running, walking), and motor tasks (jumping, balance) (Au et al., 2018; Wegener et al., 2013a; Wolf et al., 2008; S. Yamamoto, 1985). These studies utilised, kinetic, kinematic, electromyography, and spatio-temporal assessments (Lythgo et al., 2009; Wegener, Hunt, et al., 2011; Wolf et al., 2008; Zhou et al., 2015). Footwear designs studied included "*school footwear*," athletic footwear, therapeutic footwear, and thong style flip-flops (Abd Elkader et al., 2013; Chard et al., 2013; Wegener, Hunt, et al., 2011).

A focus on biomechanics involving children's footwear has been an increasing area of research with a total of 55 of the included 70 articles published in the past 10 years. Fifty of the abstracts reported the age range in these studies: infant and preschool (n=15), primary school (n=38), and adolescents (n=16). Biomechanical studies have chiefly been used to assess the potential effects of footwear on both typical and atypical motor development (n=46) (Lythgo et al., 2009; Ramstrand et al., 2008). Other studies assessed the short term biomechanical effects of footwear (n=6) (Aboutorabi et al., 2014; Au et al., 2018), the potential biomechanical design requirements of footwear (e.g., fastenings, fit, heel height, and upper and sole material stiffness) (n=15) (Herbaut, Roux, Guéguen, Chavet, et al., 2017; Imaizumi et al., 2015; Kristen et al., 1998; Robinson et al., 2011; Van Hamme et al., 2013), or explored footwear as a secondary experimental variable to orthotic intervention (n=3) (Desloovere et al., 2006; Neto et al., 2014; Pasin Neto et al., 2017).

2.3.1.5. Protective Role

The research in this grouping studied the role of children's footwear in reducing the risk of injury or pathology. This was divided into three subgroupings: 1, infection articles 2, environmental articles and 3, functional articles. **Infection articles** (n=30) this subgrouping examined the role footwear played in the reduction of childhood parasitic disease in developing countries (Bird et al., 2014; Ilechukwu et al., 2010; Tomono et al., 2003; Walker et al., 2017). **Environmental articles** (n=4) this subgrouping explored footwears role in the prevention of lacerations, puncture wounds, and environmental irritants (Makary, 1998; Molla et al., 2012) **Functional articles** (n=6) this subgrouping examined the potential of footwear to reduce injury or pain through increased traction, stability, and cushioning (Baker & Bell, 1991; Fong et al., 2007; Herbaut, Roux, Guéguen, Barbier, et al., 2017; James et al., 2016).

2.3.1.6. Risk Factor for injury/pathology

This grouping considered the role of footwear as a potential cause of injury or pathology. This was divided into three subgroupings: 1, dermatology articles, 2, injury articles and 3, Infection articles. **Dermatology articles** this subgrouping (n=23) focused on the material properties of footwear leading to reactive skin pathologies (Cockayne et al., 1998; Koch & Nickolaus, 1996; Trevisan et al., 1992). **Injury Articles** this subgrouping (n=7) discussed features such as design, fit or "ageing" of the footwear, that increases the likelihood of trauma from activity or the environment (Herbaut, Chavet, et al., 2017; W. H. O. Lam et al., 2011; Simon et al., 2005). **Subgrouping infection articles** this subgrouping (n=5) examined the effect of the material properties of footwear in creating an internal environment of the footwear that is conducive to increased risk of microbial infection (Becerril-Chihu et al., 1999; H. Li et al., 2011).

2.3.1.7. Psychosocial

This grouping involved articles that discussed and studied personal or parental beliefs of footwear design in terms of child development, protective function, and social identity. Parents were surveyed (n=6) on their views and understanding of footwear and potential effects on foot development (Dohi & Koike, 2000; Kolsek et al., 2011; I. Rotter et al., 2009; Weiss et al., 1981). Adolescents were surveyed (n=2) on what influenced their selection of athletic footwear (Enke et al., 2009; Yoh, 2006). Concerning social identity (n=4) the effect of the type or design of footwear on self-image, self-esteem, and social isolation were examined (Ayode et al., 2013; Branthwaite et al., 2013; Driano et al., 1998; Taeho, 2005).

2.3.1.8. Physiological

These articles (n=3) compared the cardiovascular, respiratory, and metabolic effects between shod and unshod walking and running in children (Butler et al., 1984; MJ et al., 2002; Shultz et al., 2016). Parameters studied included the Physiological Cost Index (PCI), oxygen consumption and calorific cost. Both children with typical development and cerebral palsy have been amongst the populations studied (Butler et al., 1984; MJ et al., 2002). This was the only research grouping where there was no apparent discussion or comparison of footwear design within the articles.

2.4. Discussion

This current scoping review demonstrated that children's footwear in general is an increasing area of research with most of the articles in this area published within the past 10 years. It has also highlighted the range of research evidence has developed from opinion base to more objective and structured research methodologies.

In consideration of the two overarching areas, footwear design and effects of footwear**,** the articles tended to discuss and study the effects of footwear on the child; however, there was a sizable number of articles (n=70) that considered footwear design in terms of the fit of the footwear. Footwear fit relates to the ergonomic purpose of footwear, a significant factor of its function is how it fits the foot (Goonetilleke et al., 2000). Even though fit appeared to be a prominent area of research, there was a limited number of empirical studies (n=4) exploring the effects of incorrectly fitted footwear on children (Imaizumi et al., 2015; Klein et al., 2009; P. Lim et al., 2017; P. Q. X. Lim et al., 2015).

The protective role of footwear was considered in a number of articles; however, this has chiefly been in relation to reduced risk of parasitic infection with only a limited number of articles exploring protection from physical sources.
Growth and development are a defining characteristic of childhood consequently developmental effects of footwear were noted to be the largest of the general research groupings in the sourced literature (n=114). Consistent with the overall trend of research in children's footwear 65% of the total articles from this grouping were published in the past 10 years and there has been a shift in the studies from opinion base towards empirical research, with this now representing 78% of the available literature in this research grouping.

The methods used in children's footwear research both in their design and to explore their effects on the child mainly consisted of biomechanical and anthropometric studies, with a minority of studies considering the physiological and psychosocial effects. In consideration of typical development a number of biomechanical studies now exist which compare barefoot and shod conditions on children's gait and other motor tasks

(Buckland et al., 2014; Kristen et al., 1998; Lythgo et al., 2009; Pomarino et al., 2016; Wegener, Hunt, et al., 2011). The majority of these biomechanical studies were carried out in children of primary school age compared to the other age groupings.

In consideration of atypical development both foot deformity and neuromuscular conditions have a demonstrable effect on a child's daily activity (Ivanyi et al., 2015; Morris et al., 2007). Since footwear is the primary interface between the foot and the ground these conditions may require specific footwear needs in relation to fit and function (Ivanyi et al., 2015), with footwear having the potential to act as a therapeutic aid to assist locomotion in childhood disability (Blitz et al., 2014; Desloovere et al., 2006).

Therapeutic Footwear appears to have been well documented in the literature but in contrast to the trend of research in children's footwear, which has increased substantially in recent years, less than a third of the articles were produced in the past ten years (Figure 2-4). The majority of the earlier research is based on dated opinion (Bordelon, 1983; Caselli et al., 1988; Holt, 1991; Staheli, 1986) with empirical studies on the effects of therapeutic footwear limited to 30% of the available research (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Kanatlı et al., 2016; Wenger et al., 1989).

There are numerous terms, design, and therapeutic roles attributed to footwear in the literature and this scoping review attempted to form groupings and consistent terminology to structure this research area. The narrative charting of the articles suggested the terminology of children's therapeutic footwear to cover all aspects of children's footwear that is designed with the specific purpose to assist mobility impairment in childhood. With therapeutic footwear being divided into the subgroupings of corrective, accommodative and functional dependent on the perceived role of the footwear. may potentially offer clarity to further research and clinical usage in this area.

Amongst the subgroupings of therapeutic footwear corrective and functional footwear were the most studied. The emphasis of recent research in children's therapeutic footwear appears to be shifting towards a functional intervention on children's walking rather than correction of foot postures such as pes planus, however, articles in these subgroupings still demonstrated a relatively low volume of studies compared to the total volume of recent children's footwear research. The literature in relation to children's therapeutic footwear appears to show a number of gaps in knowledge in terms of empirical study of its effects, the definition and design of this footwear and clear guidelines for their use as a therapeutic intervention.

It is considered best practice to manage healthcare conditions holistically in terms of physiological, psychological, and sociological consideration (Ivanyi et al., 2015; Stucki et al., 2002). The International Classification of Functioning, Disability and Health-Children and Youth version devised by the World Health Organisation (World Health Organization, 2007) provides a logical framework to assess how a child's condition and environment may allow or restrict them to function in a multitude of everyday activities. Further research which objectively establishes the effects of therapeutic footwear in terms of body function and daily activities are needed to support the development of guidelines for clinical populations which would benefit from footwear interventions. This approach will allow children with mobility impairment to achieve their fullest level of function and participation in daily life, whilst avoiding prescription of interventions that may be of little effect, reducing unnecessary healthcare costs and potential psychosocial detriment to the child (Driano et al., 1998; García-Rodríguez et al., 1999; Kanatlı et al., 2016; I. Rotter et al., 2009).

Although this review has fulfilled its objectives in order to define and categorise children's therapeutic footwear and showcase the progress of the work in this area the limitations of the current study are recognised. Whilst agreement of the research groupings and included studies were met through consensus amongst the reviewers, the exclusion of studies and data extraction was performed independently by the author MH, which may have opened these processes to personal bias. The review only analysed the abstracts from each study. While this increased the scope of the review, it provided a source of data omission, since this precluded any quality assessment of the included studies and a full description and understanding of the footwear designs used within the studies. Additionally, this review has considered only those articles with an available English language abstract, which may have impacted the scope of the research.

2.5. Conclusion

This scoping review has established that children's footwear has become an increasing area of research in the past decade. Although therapeutic footwear has been discussed in a considerable number of articles it has represented a smaller proportion of the recent impetus in empirical research into children's footwear.

The articles were narratively grouped into eight general groups with the overarching areas of footwear design and footwear effects; most of the articles examined the biomechanical and anthropometric aspects of footwear. However, in relation to children's therapeutic footwear, there is still limited empirical research in children and ambiguity in the terminology used to define this type of footwear.

To offer potential clarity to future research in this area; this scoping review suggests the term children's therapeutic footwear be used as the common term for footwear that is designed specifically with the purpose to support or alleviate locomotor disability in childhood. With the sub groupings of corrective, accommodative, and functional to be applied dependent on the intended therapeutic role of the footwear. While this scoping review will inform further methodology development within this thesis, such as reaching Delphi consensus on definitions and prescription criteria for therapeutic footwear, a more focused systematic review is still needed to assess the quality of evidence on therapeutic footwear and guide future research efforts.

3. Effectiveness of therapeutic footwear for children: A systematic review

Aspects of this chapter have been published:

Matthew Hill, Aoife Healy, and Nachiappan Chockalingam. 2020. "Effectiveness of Therapeutic Footwear for Children: A Systematic Review." *Journal of Foot and Ankle Research* 13(1): 23.

3.1. Background

Mobility impairment in children consists of a range of congenital or acquired conditions that may be neurological, musculoskeletal or combined in nature, representing a spectrum of moderate to severe disability (Blackburn et al., 2010). Mobility impairment affects the body structure and function of a child which may lead to considerable social and health detriments (Blackburn et al., 2010; contact.org.uk, 2015; World Health Organization, 2007). Limitations to walking affect a sizable number of children with 2% of the childhood population estimated to be living with some form of mobility impairment (Blackburn et al., 2010; contact.org.uk, 2015; DWP, 2016; UNICEF, 2013; World Health Organization, 2007). As previously alluded to in Chapter 2 a number of these mobility impairments require supportive intervention to aid ambulation (Bartkowlak et al., 2008; Ivanyi et al., 2015).

The previous scoping review (Chapter 2) highlighted that footwear is used as an intervention to aid ambulation in mobility-impaired children (Bartkowlak et al., 2008; Eek et al., 2017; Ivanyi et al., 2015; Staheli, 1996; Staheli & Giffin, 1980). Footwear intended for therapeutic purposes in children consists of a broad range of designs and clinical applications including pes planus, talipes equino varus, toe walking, cerebral palsy and developmental delay (Abd Elkader et al., 2013; Aboutorabi et al., 2014; W. Chen et al., 2015; Holt, 1991; Kanatlı et al., 2016; Staheli, 1996; C. M. Williams et al., 2016). Footwear appears to be widely prescribed as an assistive device by some healthcare professionals (Nester et al., 2018), and a number of studies demonstrate that conventional footwear has significant effects on typically developing children's gait (Wegener, Hunt, et al., 2011; Wolf et al., 2008). However, as highlighted in Chapter 2, in contrast to other assistive aids such as ankle-foot orthoses which have seen an increase in research (Aboutorabi et al., 2017; Betancourt et al., 2019; Eddison & Chockalingam, 2013; Lintanf et al., 2018), there appears to be a dearth in current therapeutic footwear research with a consequent lack of understanding on the design, effects and purpose of therapeutic footwear on children living with a mobility impairment (Davies et al., 2015; Hill et al., 2019; Morrison, Price, et al., 2018).

Chapter 2 highlighted that children's footwear research has shown a rapid increase in the past 10 years. However, footwear intended for therapeutic purposes was represented in just a small proportion of the recent literature, with limited empirical work and no focused review exploring its effects in comparison to that of conventional children's footwear. There was also no precise terminology to define therapeutic footwear and the specifics of its role in children living with mobility impairment. The scoping review suggested that the term children's therapeutic footwear be used as the standard definition for footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood. Further to this, subgroupings of therapeutic footwear were suggested dependent on the intended therapeutic role: Corrective (footwear designed to bring about the correction of congenital skeletal lower limb alignment); Accommodative (footwear designed to reduce compression and shearing stresses on children's foot deformities through the dimensional matching of footwear to the child's foot); and Functional (footwear designed to improve dynamic gait parameters of children with mobility impairment). In addition, the scoping review highlighted the need for a systematic assessment of the level and quality of evidence of children's therapeutic footwear research.

3.1.1. Aims and objectives

The overall aim of the systematic review was to establish the effectiveness of therapeutic footwear in the treatment of mobility impairment in children.

The objectives are to:

1. systematically search the published literature to identify studies that have explored the physical or psychosocial effects of therapeutic footwear on children with mobility impairment.

2. establish the levels of evidence and quality of evidence of the available research literature concerning children's therapeutic footwear.

3. explore the benefits and/or adverse effects of therapeutic footwear interventions.

3.2. Methods

The systematic review followed the staged methodological PRISMA guidelines (Moher et al., 2009), with the PRISMA checklist provided in Appendix 2.1. Consideration was also given to recommendations for conducting systematic reviews on paediatric participants (Farid-Kapadia et al., 2017; Kapadia et al., 2016). The protocol for the review was registered with PROSPERO: International prospective register of systematic reviews (CRD42018097038) (Hill et al., 2018).

3.2.1. Searches

The search strategy using medical subject headings (MeSH) and free-text terms related to children and footwear was used from Chapter 2. The databases used in this search were MEDLINE, PubMed, CINAHL, SCOPUS, and Sportdiscus. An example of the search strategy for MEDLINE can be found in Appendix 1.2. As previously discussed in Chapter 2, the search strategy was adapted across the databases to capture eligible articles published from database inception to February 1st, 2018.

3.2.2. Eligibility of studies

3.2.2.1. Study Design

Study designs considered for this review included randomised control trials (RCTs), non-randomised controlled trials, experimental before-after studies, prospective and retrospective comparative cohort studies, and case-control studies. Case series and case report studies were not considered for inclusion. All articles to be available in full English language text.

3.2.2.2. Participants

Participants in included studies were infants, children and adolescents of typical walking and shod age (9 months to 18 years of age) with some form of mobility impairment (defined as a musculoskeletal or neurological condition that affects motor performance). Individuals must be able to ambulate independently or with an assistive device (e.g., arm or underarm crutches, walking frames).

3.2.2.3. Interventions

Interventions included the provision of therapeutic footwear to children with a mobility impairment that facilitates and allows ambulation. Studies were included where therapeutic footwear was provided and assessed separately as an independent variable. Therapeutic footwear that did not permit ambulation during wear (e.g., nocturnal braced footwear) were excluded. Comparators included studies that compare therapeutic footwear to barefoot, standard retail footwear, orthotic interventions, and different types of therapeutic footwear.

3.2.2.4. Outcomes

Primary outcomes considered biomechanical and skeletal geometric measures assessing the effects of therapeutic footwear on lower limb development and function. Secondary outcomes considered measures assessing the effect of therapeutic footwear on children's quality of life, including, physical activity, societal participation, self-esteem, and pain. Reports of adverse effects (e.g., footwear fit related pain/discomfort) in the included studies were also considered.

3.2.3. Study selection

Prior to screening, all duplicates were removed using referencing software (Mendeley, Elsevier BV) and supplemented by a manual check by one reviewer (MH). Screening followed on from the scoping review in Chapter 2, where one reviewer (MH) had independently identified studies that considered children's footwear from a therapeutic perspective amongst the total records sourced. These abstracts were then screened by two reviewers (MH, AH) against the eligibility criteria of the systematic review with any uncertainty resolved through discussion with the third reviewer (NC). Full texts were located for all studies that appeared to meet the inclusion criteria and those studies where there was uncertainty regarding eligibility.

Two reviewers (MH and AH) independently screened the full-text articles to assess whether these met the eligibility criteria. Any disagreements regarding study eligibility between the reviewers were resolved through mediation with a third reviewer (NC).

3.2.4. Data extraction

A data extraction form was developed, and information relevant to the review question was extracted from the included studies (Munn et al., 2014). These included author names, date of publication, study design, participant characteristics (number of participants, age, sex, height, mass), description of intervention and comparison, experimental methodology, duration of follow-up, primary and secondary outcomes, adverse events and key results. Data were extracted by one reviewer (MH). The extracted data were checked for correctness and completeness against the full-text articles by a second reviewer (AH).

3.2.5. Levels of evidence and quality assessment

The levels of evidence of each included study were assessed by two reviewers (MH and AH) using the Oxford Centre for Evidence-Based Medicine level of evidence version 2 (OCEBM) (OCEBM Levels of Evidence Working Group, 2011). The quality of the studies was assessed independently by two reviewers (MH and AH). Quality assessment was completed using the modified Downs and Black quality assessment index (QI) of randomised and non-randomised studies (Downs & Black, 1998; Trac et al., 2016), which has been used in previous systematic reviews of footwear and orthoses (Jane MacKenzie et al., 2012; Wegener, Hunt, et al., 2011). Questions that were not applicable to the study under assessment were not applied (i.e., non-longitudinal studies, studies with only one testing group). Scores were therefore adjusted to an overall percentage to mitigate for the differing total scores. In line with Trac et al. (2016) (Trac et al., 2016) the percentage scores were grouped into the following four QI levels: excellent (92 to 100%), good (71 to 91%), fair (50 to 70%), and poor (less than 50%). Survey studies were assessed separately using the tool suggested by Burns and Kho (K. E. A. Burns & Kho, 2015); this was carried out independently by two reviewers (MH and AH).

Outcome measures from individual trials with acceptable levels of homogeneity in participant characteristics and experimental protocols were planned to be combined through meta-analysis. Where a meta-analysis was not possible, the results from clinically comparable trials were synthesised qualitatively. Data was grouped primarily on therapeutic footwear classification established in the previous scoping review (Chapter 2) with subgrouping of the included studies dependent on the type of outcomes measures (biomechanical, skeletal geometry, quality of life), and pathology/medical condition.

3.3. Results

Database searches yielded 5003 unique articles (Figure 3-1) with 3 further papers found through screening the reference lists of related reviews sourced from the previous scoping review (Chapter 2). From these, 80 articles were identified as discussing children's therapeutic footwear with 23 articles identified for full-text eligibility screening. Ten studies were excluded: Two studies were excluded as the full texts could not be sourced (Driano et al., 1996; Valmassy & Terrafranca, 1986), One article explored adults' retrospective opinion of therapeutic footwear use in childhood (Driano et al., 1998), One article studied the effect of a removable orthotic raise rather than one fixed to the footwear (Raczkowski et al., 2010). Two articles did not explore any effects of therapeutic footwear on the participants (Bleck, 1971; García-Rodríguez et al., 1999) One article did not present the original data, only a summary of the statistical findings (Penneau et al., 1982). One article studied a combined sample of adult and child participants with no separate analysis of the effects of therapeutic footwear on the child participants (Pandey et al., 2013) One article only provided case series study evidence (Lampe et al., 2004) One article did not study children with a mobility impairment or a condition that was perceived to affect mobility, children who were all classified as typical developing (Gould et al., 1989). Thirteen studies met the eligibility criteria for inclusion. A summary of the findings are presented in Table 3-1

Table 3-2Table 3-3Table 3-4Table 3-5 with supplementary results found in Appendix 2.2 . Details of the levels of evidence and quality assessment of the included studies are provided in Appendix 2.3, 2.4. None of the studies offered an acceptable level of homogeneity to allow the data to be combined for meta-analysis. This was due to a number of factors including, lack of sufficient detail to assure similar footwear design between studies, and incomplete description of the participants' characteristics (Table 3-1

Table 3-2). These issues precluded a combined analysis even for those studies with the same footwear grouping, clinical condition and outcomes (Kanatlı et al., 2016; Wenger et al., 1989); therefore, only a qualitative analysis of the included studies was possible.

Analysis and synthesis of the studies were performed according to the grouping/subgrouping of footwear interventions, with further subdivision by the medical condition of the study participants (Table 3-1).

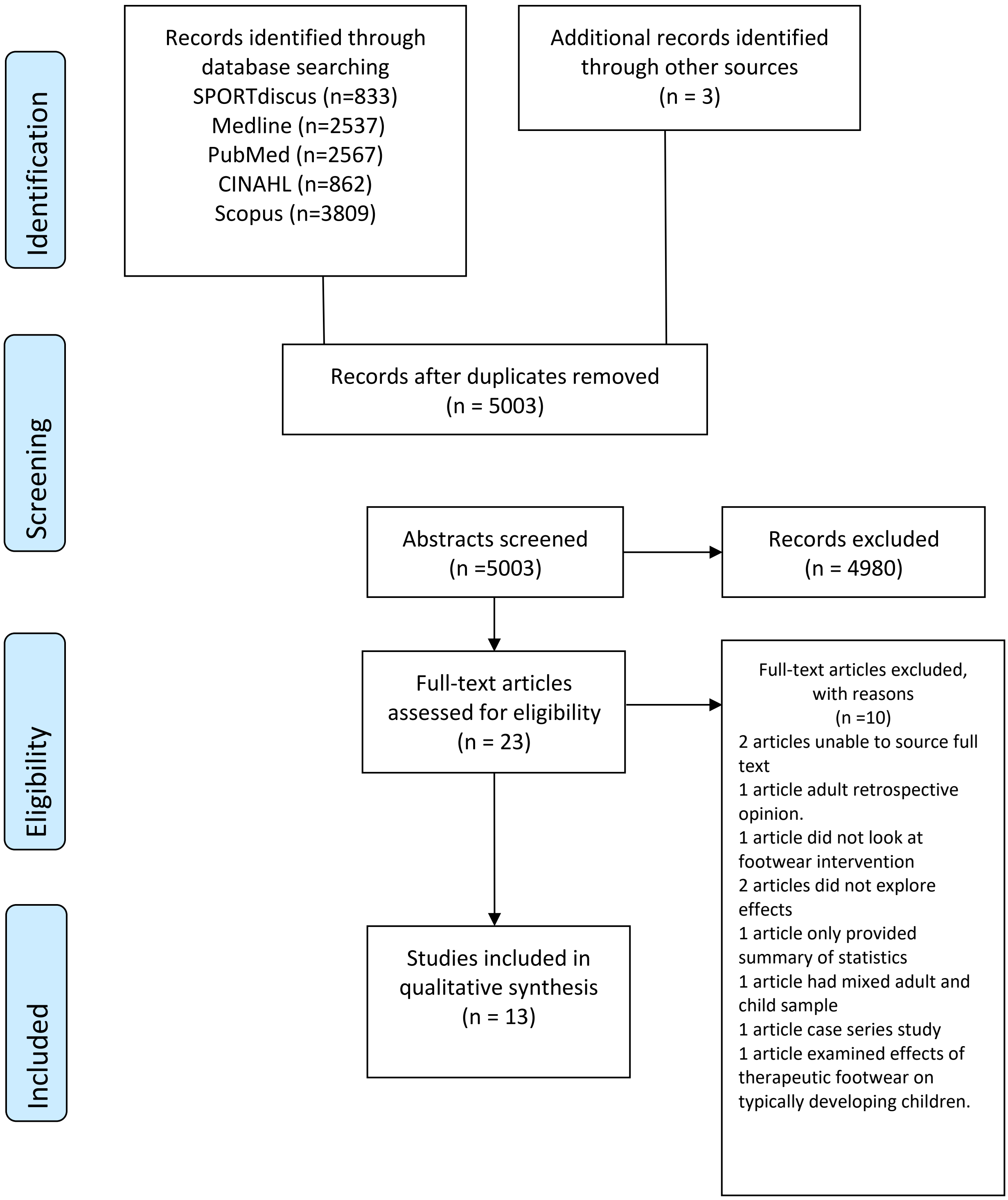


Figure 3-1 PRISMA flow diagram n=number of papers

3.3.1. Therapeutic footwear interventions

The types of therapeutic footwear interventions that were explored in the 13 studies fell into 2 of the previously defined groupings from the scoping review (Chapter 2), corrective (n=3) and functional (n=10) (Table 3-1). Of these, none of the studies explored the effects of accommodative therapeutic footwear on children. Also, no studies reported adverse events or stated if such events were considered within the study plan.

Table 3-1 Details of the participants in the included studies.

Study	**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**Sex** No. (%)	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m² ± SD+/-)**	**Outcomes**
					Corrective Therapeutic Footwear					
Chen et al. (2015)	44 months	Group 1 CTF and DB	20	Group 1 to 3 CTEV (not stated if idiopathic) DiMeglio score ≤Moderate	♂12 (60) ♀ 8 (40)	4.9 yrs. ±1.1*	19.2 3.6	1.10 0.11	Not reported	Skeletal geometry (3D laser scanning) Biomechanical (Plantar pressure)
		Group2 DB and Own footwear	15		♂9 (60) ♀ 6 (40)	4.7 yrs. ±0.7*	17.7 2.5	1.06 0.74		
		Group 3 FAS and CTF	18		♂8 (44) ♀10 (56)	4.9 yrs. ±1*	19.3 3.8	1.10 0.11		
Kanatali et al. (2016)	mean 34.6 ± 10.9 months	Group 1 CTF	21	Flexible pes planus asymptomatic,	♂33 (73) ♀12 (27) †	41.6 months‡	Not reported	Not reported	Not reported	Skeletal geometry (radiographic)
		Group 2 Own footwear	24			36 months‡				

Table 3-1 Details of the participants in the included studies (continued).

Study	**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**Sex** **No. (%)**	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m² ± SD+/-)**	**Outcomes**
				Corrective Therapeutic Footwear						
Wenger et al. (1989)	3 years	Group 1 CTF	28§	Flexible pes planus	♂16 (57) ♀12 (43)	32.2 months ±17‡	Not reported	Not reported	Not reported	Skeletal geometry (radiographic)
		Group 2 SLF	21§		13 (62) ♀8 (38)	27.2 months ±11.6‡				
		Group 3 CTF with Helfet Heel Cup	27§		♂22 (81) ♀5 (19)	28.7 months ±13.5‡				
		Group 4 SLF with UCBL	22§		9 (41) ♀13 (59)	28.2 months ±10.7‡				

Table 3-1 Details of the participants in the included studies (continued).

Study		**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**Sex** No. (%)	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m² ± SD+/-)**	**Outcomes**
	Functional Therapeutic Footwear										
	Functional Stability										
Abd Elkader et al. (2013)		Within 1 day	Group 1 BF, FSTF	15	Down syndrome with flexible pes planus	♂11 (36) ♀14 (47) †,|	3.67 yrs. ±0.72	16.46 2.74	1.01 0.069	16.01 1.67	Biomechanical (spatiotemporal)
			Group 2 BF, Foot Taping	15			4.06 yrs. 0.88	15.61 1.99	0.99 0.032	15.49 1.47	
Aboutorabi et al. (2014)		Within 1 day	Group 1 BF, FSTF, SLS with FO	30	Flexible pes planus	♂18 (67) ♀12 (33)	7.87 yrs. ±1.45	31.4 5.74	123.06 10.25	20.2 1.58	Biomechanical (spatiotemporal)
			Group 2, BF, FSTF, SLS with FO	20	Control, typically developing	♂12 (60) ♀8 (40)	7.8 yrs. ±1.31	32.81 6.66	1.28 .11	19.87 1.4	
Bakker et al. (1997)		16 Months	Group 1 FSTF	7	Duchenne muscular dystrophy	♂48 (100)	Age range 5 to 12 ¶	Not reported	Not reported	Not reported	Secondary outcomes
			Group 2 AFO	20							
			Group 3 SF	6							
			Group 4 KAFO	5							
			Group 5 Own footwear	41							

Table 3-1 Details of the participants in the included studies (continued).

Study	**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**Sex** **No. (%)**	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m² ± SD+/-)**	**Outcomes**
Functional Therapeutic Footwear										
Functional Stability										
Basta et al (1977)	4 years	Group, 1, BF, FSTF, FSTF with CNP	10	Symptomatic flexible pes planus	Not reported	Age Range 6.5 to 7 years ¶	Not reported	Not reported	Not reported	Skeletal geometry (radiographic)
		Group 2, BF, FSTF, FSTF with CNP,	10							
		Group 3, BF, FSTF, FSTF with CNP, FSTF with PCNP,	10							
		Group 4, BF, S, SLF with HB, SLF with CNP, FSTFWS	6							
		Group 5 and 6 formed from groups 1 to 4, Four participants lost to follow up.								
		Group 5, BF, FSTF, FSTF with CNP Group	16							
		6, BF, CNP, with Own footwear	16							
		Group 7, BF, FSTF, FSTF with CNP,	14							

Table 3-1 Details of the participants in the included studies (continued).

Study	**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**Sex No. (%)**	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m^2 ± SD+/-)**	**Outcomes**
Functional Therapeutic Footwear										
Functional Stability										
Jagadamma et al (2009)	Within 1 day	One group AFO and SSF, FSTF+AFO,	5	CP	♂3 (60) ♀2 (40)	9.7 yrs. ±3.5 Range 5.6 to 12.6yrs.	Not reported	Not reported	Not reported	Biomechanical (kinematic, kinetic, spatiotemporal)
Knittel and Staheli (1976)	Not Stated	One group, SSF, Various forefoot and Rearfoot sole wedges, Torqheel,	10	In toeing	♂4 (40) ♀6 (60)	6.25 yrs. ±2.35 Range 3.5 to 10 yrs.	Not reported	Not reported	Not reported	Biomechanical (kinematic)
Wesdock & Edge (2003)	8 weeks	One group, SSF, SSF and AFO, FSTF+AFO	11	CP	♂4 (36) ♀7 (64)	7 yrs. ±2.7 Range 4 to 13.5 yrs.	Not reported	Not reported	Not reported	Biomechanical (spatiotemporal)
		Subset of Group 1 SSF, SSF and AFO, FSTF+AFO	4	CP Initial standing balance ≥15 seconds	♂3 (75) ♀1 (25)	6.5 yrs. ±2 Range 4.6 to 9.3 yrs.	Not reported	Not reported	Not reported	

Table 3-1 Details of the participants in the included studies (continued).

Study	**Duration of Study**	**Group** Intervention and Comparators	**n**	**Condition**	**<u>Sex</u> No. (%)**	**Age (mean ± SD)**	**Mass (mean kg ± SD**	**Height (mean m ± SD**	**BMI (mean kg/m^2 ± SD+/-)**	**Outcomes**
Functional Therapeutic Footwear										
Functional Instability										
Ramstrand et al (2008)	8 weeks	One Group FITF 8wk training program	10	CP + other #	♂6 (60) ♀4 (40)	13.8 yrs. ±2.7 Range 10 to 17 yrs.	51.71 11.18	1.59 0.11	Not Reported	Biomechanical (balance: static, dynamic)
Functional Lift										
Eek et al (2017)	Within 1 day	Group 1 BF, SSF, FLTF	10	Spastic CP with LLD ≥1cm	♂6 (60) ♀4 (40)	10.9 yrs. Range 7.8 to 12.8	38.6 Range 25.7-59.0	1.42, Range 1.24-1.52	Not Reported	Biomechanical (kinematic, spatiotemporal)
		Group 2 BF, SSF	10	Control typically developing	♂5 (50) ♀5 (50)	10.7yrs Range 7.1 to 14	35.1 Range 18.7-49	1.48 Range 1.20-1.67		
Zabjek et al (2001)	Within 1 day	One Group, BF, FLTF	46	Idiopathic scoliosis	♂9 (19.6) ♀37 (80.4)	12yrs. ±2	Not Reported	Not Reported	Not Reported	Skeletal Geometry (3D stereovideographic)

Key to table 3-1

♂Male, ♀ Female **AFO** Ankle Foot Orthosis, **BF** Barefoot, **CNP** Customised Navicular Pad, **CP** Cerebral Palsy, **CTEV** Congenital Talipes Equino Varus, **CTF** Corrective Therapeutic Footwear, **DB** Dennis Brown Splinted Footwear, **FAS** Forefoot Abduction Night Shoe, **FIFT** Functional Instability Therapeutic Footwear, **FLTF** Functional Lift Therapeutic Footwear, **FSTF** Functional Stability Therapeutic Footwear, **FSTFWS,** Functional Stability Therapeutic Footwear Without Steel Shank , **GMSF** Gross Motor Functioning Score**, HB**, heel block, **KAFO** Knee Ankle Foot Orthoses , **LLD** Limb Length Difference , **PNP** Prefabricated Navicular Pad, **SF** Standing Frame, **SLF** Standard Last Footwear, **SSF** Standard Sole

Footwear, **UCBL** University of California Biomechanics Laboratory custom moulded Insert, *Age When tested, † Sex distribution amongst groups not reported, ‡ Age at entry of study, §Numbers at end of study, |missing 17% Sex distribution not accounted for, ¶ age range distribution amongst groups not reported, # variety of neurological and developmental conditions within group.

Table 3-2 Description of footwear interventions in included studies.

Study	**Description provided of therapeutic footwear intervention (s)**
	Corrective Therapeutic Footwear
Chen et al (2015)	Orthopaedic shoe with an orthopaedic insole and hard heel cup (CTF)
Kanatli et al (2016)	Custom made orthopaedic shoe, 0.5-0.9cm longitudinal arch support, 3-4mm heel wedges. (CTF)
Wenger et al (1989)	Orthopaedic shoe, steel shank, Thomas heel, long medial heel counter, navicular pad (CTF)
	Functional Therapeutic Footwear
Functional Stability	
Abd Elkader et al (2013)	Medical shoes same brand and model (brand/model not stated) with prefabricated arch insert (FSTF)
Aboutorabi et al (2014)	Custom made, High-top shoes, wide toe box, internal heel counter, arch inlay (FSTF)
Bakker et al (1997)	No details other than off the shelf orthopaedic footwear (FSTF)
Basta et al (1977)	High topped, Steel Shank, firm counter (FSTF)
Jagadamma et al (2009)	Custom made heel to forefoot wedged EVA sole adhesion, used alongside AFO. Wedges adjusted until shank to vertical angle reached 12°. (FSTF+AFO)
Knittel and Staheli (1976)	Low cut shoe with 9 various sole modifications, medial forefoot wedge only (FSTF 1), lateral forefoot wedge only (FSTF 2), medial forefoot and medial rearfoot wedge (FSTF 3), lateral forefoot and medial rearfoot wedge (FSTF 4), lateral forefoot and lateral rearfoot wedge (FSTF 5), medial rearfoot wedge only (FSTF 6), lateral rearfoot wedge only (FSTF 7), parallel torqheel (FSTF 8), circular torqheel (FSTF 9).
Wesdock & Edge (2003)	Custom made Styrofoam wedged sole adhesion, wedge = vertical distance of posterior inferior elevated heel of the unaltered shoe from the floor when subject with crouch gait stood as erect as possible. (FSTF+AFO)

Table 3-2 Description of footwear interventions in included studies (continued).

Study	Description provided of therapeutic footwear intervention (s)
	Functional Therapeutic Footwear
Functional Instability	
Ramstrand et al (2008)	Masai Barefoot Technologies, MBT unstable sole shoe. (FITF)
Functional Lift	
Eek et al (2017)	12 mm EVA sole adhesion divided into two parts heel and forefoot, (FLTF)
Zabjek et al (2001)	Various sole lift adhesion 5mm, 10mm,15mm, (FLTF)

Key to table 3-2

AFO Ankle Foot Orthosis, **CTF** Correctional therapeutic footwear, **FSTF** Functional stability therapeutic footwear, **FITF** Functional instability therapeutic footwear, **FLTF** Functional lift therapeutic footwear

Table 3-3 Outcome measures skeletal geometry

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Corrective Therapeutic Footwear			
3D Laser scanning						
Bean shaped ratio	**Chen et al. (2015)**	CTEV	Group 1 CTF and DB	N/A	0.29 (0.27-0.30) *	One-way MANOVA: **p=0.002**
			Group 2 DB and Own footwear	N/A	0.31 (0.29-0.33) *	Post hoc: Group 3 vs. 1 **p<0.01**
			Group 3 FAS and CTF	N/A	0.27 (0.25-0.28) *	Group 3 vs. 2 **p<0.01** |
Bimalleolar angle (°)	**Chen et al. (2015)**	CTEV	Group 1 CTF and DB	N/A	75.59 (73.98-77.21) *	One-way MANOVA: **p=0.032**
			Group 2 DB and Own footwear	N/A	72.98 (69.03-6.92) *	Post hoc: Group 2 vs. 3 **p<0.01** |
			Group 3 FAS and CTF	N/A	77.55 (75.57-79.53) *	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
			Corrective Therapeutic Footwear			
Radiographic (Anterior-Posterior view)						
Talo calcaneal angle (°)	**Kanatli et al. (2016)**	Mobile pes planus	Group 1 CTF	34§ (22-53) †	23§ (12-37) †	Wilcoxon signed rank: Group1 **p=0.002**; Group 2 p=**0.003**
			Group 2 Own footwear	33§ (20-45) †	30§ (13-37) †	Mann Whitney U: Group 1 vs.2 p=0.19
	Wenger et al. (1989)	Mobile pes planus	Group 1 CTF	36.2 (1.2) ‡	29.4 (0.74) ‡	One Way ANOVA: p>0.5
			Group 2 SLF	36.3 (0.99) ‡	31.5 (1.2) ‡	
			Group 3 CTF with Helfet heel cup	37.1 (0.84) ‡	30 (0.77) ‡	
			Group 4 SLF with UCBL	36.8 (0.97) ‡	30.1 (0.82) ‡	
Radiographic (Lateral view)						
Calcaneal pitch (°)	**Kanatli et al. (2016)**	Mobile pes planus	Group 1 CTF	12§ (2-20) †	15§ (4-20) †	Wilcoxon signed rank: Group 1 **p=0.002**; Group 2 **p=0.001**
			Group 2 Own footwear	10§ (1-16) †	14§ (4-22) †	Mann Whitney U: Group 1 vs. 2 p=0.18

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Corrective Therapeutic Footwear						
Radiographic (Lateral view)						
Talar 1st metatarsal angle (°)	**Kanatli et al. (2016)**	Mobile pes planus	Group 1 CTF	16§ (7-29) †	10§ (0-26) †	Wilcoxon signed rank: Group 1 **p=0.001**; Group 2 **p=0.001**
			Group 2 Own footwear	18.4§ (6-35) †	9.3§ (0-34) †	Mann Whitney U: Group 1 vs. 2 p=0.72
	Wenger et al. (1989)	Mobile pes planus	Group 1 CTF	19.1 (0.75) ‡	11.7 (0.84) ‡	One-way ANOVA: p>0.5
			Group 2 SLF	16.7 (0.87) ‡	11.8 (0.91) ‡	
			Group 3 CTF with Helfet heel cup	16.8 (0.76) ‡	11.5 (0.67) ‡	
			Group 4 SLF with UCBL	19.7 (0.83) ‡	11.3 (0.98) ‡	
Talo calcaneal angle (°)	**Kanatli et al. (2016)**	Mobile pes planus	Group 1 CTF	46§ (27-56) †	44§ (32-57) †	Wilcoxon signed rank: Group1 p=0.736; Group 2 p=0.113
			Group 2 Own footwear	46§ (34-55) †	43§ (32-51) †	Mann Whitney U: Group 1 vs. 2 p=0.24

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Corrective Therapeutic Footwear						
Radiographic (Lateral view)						
Talar horizontal angle (°)	**Kanatli et al. (2016)**	Mobile pes planus	Group 1 CTF	34§ (16-49) †	29§ (19-42) †	Wilcoxon signed rank: Group 1 **p=0.003**; Group 2 **p=0.001**
			Group 2 Own footwear	35§ (21-52) †	27§ (21-44) †	Mann Whitney U: Group 1 vs. 2 p=0.09
	Wenger et al. (1989)	Mobile pes planus	Group 1 CTF	40.5 (0.70) ‡	34 (0.66) ‡	One Way ANOVA: p>0.4
			Group 2 SLF	39.8 (0.71) ‡	34.7 (0.73) ‡	
			Group 3 CTF with Helfet heel cup	39.5 (0.6) ‡	34.7 (0.61) ‡	
			Group 4 SLF with UCBL	41.8 (0.78) ‡	34.2 (0.84) ‡	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Radiographic (Anterior-Posterior view)						
Talocalcaneal angle (°)	**Basta et al. (1977)**	Symptomatic mobile pes planus	Group 1 Change from BF wearing FSTF	-4.2		No Statistical test for significance performed
			Group 1 Change from FSTF wearing FSTF + CNP		-1	
			Group2 Change from BF with FSTF	-3.8		
			Group 2 Change from FSTF wearing FSTF+CNP		-1.5	
			Group 3 -6	No Data Reported	No Data Reported	
			Group 7 Change from BF wearing FSTF	-4.1		
			Group 7 Change from FSTF wearing FSTF + CNP		-1.4	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Stability Therapeutic Footwear			
Radiographic (Lateral view)						
Calcaneal pitch (°)	**Basta et al. (1977)**	Symptomatic mobile pes planus	Group 1 Change from BF wearing FSTF	1.8		No Statistical test for significance performed
			Group 1 Change from FSTF wearing FSTF + CNP		2.1	
			Group2 Change from BF with FSTF	1.8		
			Group 2 Change from FSTF wearing FSTF+CNP		2	
			Group 3 -6	No Data Reported	No Data Reported	
			Group 7 Change from BF wearing FSTF	2.1		
			Group 7 Change from FSTF wearing FSTF + CNP		1.55	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Radiographic (Lateral view)						
Longitudinal arch angle (°)	**Basta et al. (1977)**	Symptomatic mobile pes planus	Group 1 Change from BF wearing FSTF	-2.75		No Statistical test for significance performed
			Group 1 Change from FSTF wearing FSTF + CNP		-0.9	
			Group2 Change from BF with FSTF	-2.5		
			Group 2 Change from FSTF wearing FSTF + CNP		-0.9	
			Group 3 -6	No Data Reported	No Data Reported	
			Group 7 Change from BF wearing FSTF	-2.6		
			Group 7 Change from FSTF wearing FSTF+CNP		-1.2	
			Group 7 Change from FSTF wearing FSTF+CNP		-1.3	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Radiographic (Lateral view)						
Talo calcaneal angle (°)	**Basta et al. (1977)**	Symptomatic mobile pes planus	Group 1 Change from BF wearing FSTF	0.9		No Statistical test for significance performed
			Group 1 Change from FSTF wearing FSTF + CNP		-1.35	
			Group2 Change from BF with FSTF	0.7		
			Group 2 Change from FSTF wearing FSTF + CNP		-1.25	
			Group 3 -6	No Data Reported	No Data Reported	
			Group 7 Change from BF wearing FSTF	0.8		
			Group 7 Change from FSTF wearing FSTF+CNP		-1.3	

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Lift Therapeutic Footwear						
3D stereovideographic						
Anteroposterior shift of sacral 1 (mm)	**Zabjek et al. (2001)**	Idiopathic scoliosis	BF vs. FLTF	12 (19)	7 (5)	Paired t test: p>0.05
Anteroposterior shift thoracic 1 (mm)			BF vs. FLTF	32 (20)	7 (7)	**p<0.05**
Anteroposterior shift shoulders/pelvis (mm)			BF vs. FLTF	20 (18)	6 (5)	**p<0.05**
Diff in height left-right tibia (mm)			BF vs. FLTF	-3 (5)	11 (4)	**p<0.05**
Diff in height left-right trochanter (mm)			BF vs. FLTF	-10 (10)	15 (6)	**p<0.05**
Kyphosis (%)			BF vs. FLTF	7 (3)	0.6 (0.6)	p>0.05
Lateral shift sacral 1 (mm)			BF vs. FLTF	1 (10)	9 (6)	**p<0.05**
Lateral shift shoulder/pelvis (mm)			BF vs. FLTF	12 (10)	4 (3)	p>0.05
Lateral shift thoracic 1 (mm)			BF vs. FLTF	13 (15)	9 (7)	p>0.05
Lordosis (%)			BF vs. FLTF	4 (2)	0.5 (0.5)	p>0.05
Pelvic rotation (°)			BF vs. FLTF	0.4 (4)	2 (2)	p>0.05
Pelvic tilt (°)			BF vs. FLTF	3 (1)	3 (1)	**p<0.05**

Table 3-3 Outcome measures skeletal geometry (continued).

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Lift Therapeutic Footwear						
3D stereovideographic						
Rotation shoulder/pelvis (°)	**Zabjek et al. (2001)**	Idiopathic scoliosis	BF vs. FLTF	1 (4)	1 (1)	p>0.05
Shoulder rotation (°)			BF vs. FLTF	1 (4)	2 (2)	p>0.05
Shoulder tilt (°)			BF vs. FLTF	0.4 (2)	0.8 (0.6)	**p<0.05**
Tilt shoulder/pelvis (°)			BF vs. FLTF	-2 (2)	3 (2)	**p<0.05**
Vertical height of sacral 1 (mm)			BF vs. FLTF	897 (84)	5 (3)	**p<0.05**
Vertical height of thoracic 1 (mm)			BF vs. FLTF	1279 (117)	6 (3)	**p<0.05**
Version left iliac bone (°)			BF vs. FLTF	-11 (4)	1 (1)	**p<0.05**
Version right iliac bone (°)			BF vs. FLTF	-10 (4)	2 (1)	**p<0.05**
Diff in version right and left iliac (°)			BF vs. FLTF	-0.5 (2)	2 (1)	**p<0.05**

Key to table 3-3

BF Barefoot, **CNP** Customised Navicular Pad, **CTEV** Congenital Talipes Equino Varus, **CTF** Corrective Therapeutic Footwear, **DB** Denis Brown Barred Night Boot, **FAS** Forefoot Abduct Night Shoe, **FLTF** Functional Lift Therapeutic Footwear, **N/A** Not Applicable, **SLF** Standard Last Footwear, **SSF** Standard Sole Footwear, **UCBL** University of California Biomechanics Laboratory, *****95% Confidence Interval, †Min-Max, ‡Standard Error, §Median,

Table 3-4 Outcome measures biomechanical

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Corrective Therapeutic Footwear						
Plantar pressure						
Average peak pressure (kPa): Lateral midfoot	**Chen et al. (2015)** *	CTEV	Group 1 CTF and DB	N/A	62.21 (53.35-71.06) †	One-way MANOVA: **p=0.005**
			Group2 DB and Own footwear	N/A	94.97 (66.38-123.59) †	Post hoc: Group 1 vs. Group 2 **p<0.01**
			Group 3 FAS and CTF	N/A	60.9 (49.26-72.54) †	Group 2 vs. Group 3 **p<0.01**
Maximum peak pressure (kPa): Hindfoot			Group 1 CTF and DB	N/A	148.71 (135.49-161.94) †	One-way MANOVA: **p<0.001**
			Group2 DB and Own footwear	N/A	105.51 (85.73-125.29) †	Post hoc: Group 1 vs. Group 2 **p<0.01**
			Group 3 FAS and CTF	N/A	164.05 (148.22-179.90) †	Group 2 vs. Group 3 **p<0.001**

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
			Corrective Therapeutic Footwear			
Plantar pressure						
Peak pressure ratio: Heel/forefoot	**Chen et al. (2015)** *	CTEV	Group 1 CTF and DB	N/A	0.72 (0.58-0.87) †	One-way MANOVA: **p=0.009**
			Group2 DB and Own footwear	N/A	0.44 (0.29-0.58) †	Post hoc Group 1 vs. Group 2 **p<0.01;** Group 2 vs. Group 3 **p<0.01**
			Group 3 FAS and CTF	N/A	0.73 (0.61-0.86) †	
Peak pressure ratio: Heel/lateral midfoot			Group 1 CTF and DB	N/A	1.45 (1.19-1.72) †	One-way MANOVA: **p<0.001**
			Group2 DB and Own footwear	N/A	0.77 (0.47-1.08) †	Post hoc: Group 1 vs. Group2 **p<0.01;** Group 1 vs. Group 3 **p<0.01**; Group 2 vs. Group3 **p<0.001**
			Group 3 FAS and CTF	N/A	1.98 (1.68-2.29) †	
			SSF		1.21‡ (0.22) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
Functional Stability Therapeutic Footwear						
Kinematic						
Angle of gait (°)	**Knittel and Staheli (1976)**	In toeing	SSF	- 17.3 (11.9)		ANOVA: **p<0.05**
			FSTF1		- 18.3 (12.4)	Post hoc FSTF1 vs. SSF **p<0.05** FSTF7 vs. SSF **p<0.05** FSTF8 vs. SSF **p<0.05** FSTF9 vs. SSF **p<0.05**
			FSTF2		- 17.7 (13.9)	
			FSTF3		- 16.7 (12.7)	
			FSTF4		- 17.1 (12.5)	
			FSTF5		- 16.7 (14.2)	
			FSTF6		- 17.0 (14.3)	
			FSTF7		- 16.9 (12.4)	
			FSTF8		- 15.6 (14.1)	
			FSTF9		- 10.7 (14.9)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Kinematic						
			FSTF+AFO		3.7 (3.3)	
Knee flexion (°) initial contact			AFO and SSF	13.7 (8.4)		p=0.14
			FSTF+AFO		17.2 (5.1)	
Max. knee flexion (°) stance			AFO and SSF	19.7 (9.3)		p=0.06
			FSTF+AFO		25.2 (5.3)	
Shank to vertical angle (SVA) (°)			AFO and SSF	5.6 (3)		**p=0.005**
			FSTF+AFO		10.8 (1.8)	
Kinetic						
Peak knee flexion moment (N m) stance	**Jagadamma et al. (2009)**	Cerebral palsy	AFO and SSF	0.59 (0.31)		Wilcoxon signed rank: p=0.25
			FSTF+AFO		0.7 (0.32)	
Peak Knee extension moment (N m) stance			AFO and SSF	- 0.44 (0.2)		p=0.14
			FSTF+AFO		- 0.29 (0.24)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Spatiotemporal						
Base of support (cm)	**Abd Elkader et al. (2013)**	Mobile pes planus	Group 1 BF	11.80 (1.06)		Paired t test: Group 1 **p<0.05;** Group 2 **p<0.05**
			Group 1 FSTF		9.10 (1.31)	
			Group 2 BF	12.63 (1.96)		Independent t test BF p=0.12; FSTF vs. FT p=0.86
			Group 2 FT		9.20 (1.17)	
Cadence (Steps/min)	**Jagadamma et al. (2009)**	Cerebral palsy	AFO and SSF	122.5 (16.6)		Paired t test: p=0.97
			FSTF+AFO		122.3 (12.4)	
CoP displacement (mm)	**Aboutorabi et al. (2014)**	Mobile pes planus	BF	6.55 (6.40)		Repeated measures ANOVA: **p=0.016**
			FSTF		5.84 (6.15)	Post hoc: FSTF vs. BF **p<0.05**
			SLS+FO		5.87 (6.40)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Spatiotemporal						
Standing balance (s)	**Wesdock and Edge (2003)**	Cerebral palsy Crouch gait	Group1 SSF (after 4 weeks wear of solid AFO)	11 (13)		Mixed model maximum likelihood estimate: p>0.05
			Group 1 SSF + AFO (after 4 weeks wear of solid AFO)	18 (23)		
			Group 1 FSTF+AFO (after 4 weeks wear of solid AFO)	50 (68)		
			Group 1 SSF (after 4 weeks wear of FSTF+AFO)		14 (23)	
			Group 1 SSF + AFO (after 4 weeks wear of FSTF+AFO)		11 (24)	
			Group 1 FSTF+AFO (after 4 weeks wear of FSTF+AFO)		49 (70)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Spatiotemporal						
Difference in standing balance (s)	**Wesdock and Edge (2003)**	Cerebral palsy	Group 1 SSF vs. SSF+AFO (after 4 weeks wear of solid AFO)	(-6)-20 †		No Statistical test for significance performed
			Group1 SSF+AFO vs. FSTF+AFO (after 4 weeks wear of solid AFO)	(-2)-66†		
			Group1 SSF vs. FSTF+AFO (after 4 weeks wear of solid AFO)	7 -73†		
			Group1 SSF vs. SSF+AFO (after 4 weeks wear of solid AFO)		(-19)-13†	
			Group 1 SSF+AFO vs. FSTF+AFO (after 4 weeks wear of solid AFO)		3-73 †	
			Group1 SSF vs. FSTF+AFO (after 4 weeks wear of solid AFO)		0-70 †	
		Cerebral palsy Subset of Group1 all participants who could stand ≥15s	SSF vs. SSF+AFO (after 4 weeks wear of solid AFO)	14 (6)		after 4 weeks wear of solid AFO SSF vs. FSTF+AFO **p<0.05;** SSF+AFO vs. FSTF+AFO **p<0.05**; after 4 weeks wear of solid FSTF+AFO SSF vs. FSTF+AFO **p<0.05;**
			SSF+AFO vs. FSTF+AFO (after 4 weeks wear of solid AFO)	84 (41)		
			SSF vs. FSTF+AFO (after 4 weeks wear of solid AFO)	98 (47)		
			SSF vs. SSF+AFO (after 4 weeks wear of FSTF+AFO)		- 8 (7)	

			SSF+AFO vs. FSTF+AFO (after 4 weeks wear of FSTF+AFO)		101 (25)	SSF+AFO vs. FSTF+AFO **p<0.05**
			SSF vs. FSTF+AFO (after 4 weeks wear of FSTF+AFO)		93 (33)	(Sig based on 95% Confidence Interval of Group 1 differences in standing balance)

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Stability Therapeutic Footwear			
Spatiotemporal						
Step length (cm)	**Abd Elkader et al. (2013)**	Down Syndrome mobile pes planus	Group 1 BF	26.53 (3.72)		Paired t test: Group 1 **p<0.05** Group 2 **p<0.05**
			Group1 FSTF		30.83 (4.28)	
			Group 2 BF	25.63 (4.62)		Independent t test: BF Group 1 vs. 2 p=0.62; FSTF vs. FT p=0.95
			Group 2 FT		30.73 (5.51)	
	Aboutorabi et al. (2014)	Mobile pes planus	BF	37.99 (3.82)		Repeated measures ANOVA: p=0.478
			FSTF		38.85 (4.97)	
			SLS+FO		39.05 (4.68)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Stability Therapeutic Footwear						
Spatiotemporal						
Step symmetry (%)	**Aboutorabi et al. (2014)**	Mobile pes planus	BF	-4.90 (4.66)		Repeated measures ANOVA: **p=0.000**
			FSTF		-2.70 (25.54)	Post hoc FSTF vs. SLS+FO **p<0.05**
			SLS+FO		16.08 (31.25)	
Step width (cm)	**Aboutorabi et al. (2014)**	Mobile pes planus	BF	8.87 (1.61)		Repeated measures ANOVA: p=0.170
			FSTF		8.91 (1.99)	
			SLS+FO		9.41 (1.69)	
Stride length (m)	**Abd Elkader et al. (2013)**	Down Syndrome mobile pes planus	Group 1 BF	0.448 (0.06)		Paired t test: Group 1 **p<0.05** Group 2 **p<0.05**
			Group 1 FSTF		0.504 (0.064)	
			Group 2 BF	0.455 (0.071)		Independent t test:

			Group 2 FT		0.524 (0.078)	BF Group 1 vs. 2 p=0.82; FSTF vs. FT p=0.44
	Jagadamma et al. (2009)	Cerebral palsy	AFO and SSF	1.08 (0.19)		Paired t test: p=0.54
			FSTF+AFO		1.06 (0.20)	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
			Functional Stability Therapeutic Footwear			
Spatiotemporal						
Velocity (m/s)	**Abd Elkader et al. (2013)**	Down Syndrome mobile pes planus	Group 1 BF	0.674 (.059)		Paired t test: Group 1 **p<0.05** Group 2 **p<0.05**
			Group 1 FSTF		0.775 (0.035)	
			Group 2 BF	0.672 (0.109)		Independent t test: BF Group 1 vs. 2 p=0.95; FSTF vs. FT p=0.61
			Group 2 FT		0.762 (0.090)	
	Aboutorabi et al. (2014)	Mobile pes planus	BF	0.727 (0.136)		Repeated measures ANOVA: **p=0.000**
			FSTF		0.847 (0.156)	Post hoc: FSTF vs. BF **p<0.05;** SLF +FO vs. BF **p<0.05**
			SLS+FO		0.779 (0.128)	

	Jagadamma et al. (2009)	Cerebral palsy	AFO and SSF	1.08 (0.1)		Paired t test: p=0.80
			FSTF+AFO		1.07 (0.14)	
			SSF		1.21‡ (0.22) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
Functional Instability Therapeutic Footwear						
Balance (Dynamic)						
Anterior posterior control (CoP)	**Ramstrand et al. (2008)** *	Cerebral Palsy + mixed developmental disability	BF Medium (at 4 weeks)		45.7 (25.5-66.5) †	Wilcoxon signed rank BF vs. FITF Medium at week 4 **p<0.05**
			FITF Medium (at 4 weeks)		51.44 (33.7-69.2) †	
Mediolateral control (CoP)			BF Slow (baseline)	57.2 (47.0-67.2) †		Friedman ANOVA: BF Slow **p<0.05**
			BF Medium (baseline)	66.4 (52.6-80.1) †		Post hoc BF Slow at week 8 vs. week 4 and baseline **p<0.05**

						Wilcoxon signed rank BF vs. FITF Slow at 8 weeks **p<0.05;** BF vs. FITF Medium at 4- and 8-weeks **p<0.05**
			BF Slow (at 4 weeks)		69.2 (59.9-78.5) †	
			BF Medium (at 4 weeks)		75 (67.4-82.6) †	
			FITF Slow (at 4 weeks)		55.1 (36.3-73) †	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Instability Therapeutic Footwear			
Balance (Dynamic)						
Mediolateral control (CoP)	**Ramstrand et al. (2008)** *	Cerebral Palsy + mixed developmental disability	FITF Medium (at 4 weeks)		67 (54.3-79.2) †	Friedman ANOVA: BF Slow **p<0.05**
			BF Slow (at 8 weeks)		74.89 (64.9-84.8) †	Post hoc BF Slow at week 8 vs. week 4 and baseline **p<0.05** Wilcoxon signed rank BF vs. FITF Slow at 8 weeks **p<0.05;**
			BF Medium (at 8 weeks)		72.44 (55.1-89.9) †	

			FITF Slow (at 8 weeks)		57.56 (40.3-74.8) †	BF vs. FITF Medium at 4- and 8-weeks **p<0.05**
			FITF Medium (at 8 weeks)		65.33 (44.5-86.2) †	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Range	Final Range	Statistical Result (Significant values given in bold)
Functional Instability Therapeutic Footwear						
Balance (Dynamic)						
Number of falls toes up condition	**Ramstrand et al. (2008)** *	Cerebral Palsy + mixed developmental disability	Subject 1,2,6,9,10	0		Chi Square: Between testing occasions **p<0.05**
			Subject 3	2		
			Subject 4	3		
			Subjects 5,8	4		
			Subject 7	10		
			Subjects 1,5, 8 -10 (at 4 weeks)		0	
			Subjects 2, 6 (at 4 weeks)		Did not participate	

			Subjects 3 ,4 (at 4 weeks)		1	
			Subject 7 (at 4 weeks)		2	
			Subjects 1,2, 4 - 10 (at 8 weeks)		0	
			Subject 3 (at 8 weeks)		1	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Lift Therapeutic Footwear			
Kinematic						
Ankle dorsiflexion at initial contact (°)	**Eek et al. (2017)**	Cerebral palsy	BF Long leg	-2.3‡ (7.9) §		Wilcoxon signed rank: Comparison long to short BF **p = 0.009;** FLTF **p= 0.017;** SSF **p=0.009**
			BF Short leg	-9.2‡ (13.6) §		
			FLTF Long leg		4.3‡ (9.1) §	
			FLTF Short leg		-2‡ (17) §	
			SSF Long leg		3.5‡ (9.) §	
			SSF Short leg		-6.2‡ (11.3) §	

Ankle dorsiflexion in stance (°)			BF Long leg	11.9‡ (11.6) §		Comparison long to short BF p = 0.22; FLTF p=0.241; SSF **p=0.022**
			BF Short leg	6.5‡ (6.4) §		
			FLTF Long leg		15.1‡ (4.9) §	
			FLTF Short leg		14.4‡ (8.6) §	
			SSF Long leg		16.5‡ (2.8) §	
			SSF Short leg		11.4‡ (10.7) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Lift Therapeutic Footwear			
Kinematic						
Ankle dorsiflexion in swing (°)	**Eek et al. (2017)**	Cerebral palsy	BF Long leg	3.7‡ (5.8) §		Comparison long to short BF **p = 0.007;** FLTF **p=0.037;** SSF p=0.13
			BF Short leg	3.2‡ (5.5) §		
			FLTF Long leg		6.5‡ (10.9) §	
			FLTF Short leg		2.6‡ (9.3) §	
			SSF Long leg		5.8‡ (7.8) §	
			SSF Short leg		0.5‡ (10.7) §	
Hip			BF Long leg	8.4‡ (6.4) §		Comparison long to short

adduction in stance (°)			BF Short leg	7.4‡ (4.4) §		BF p = 0.959; FLTF p=0.646; SSF p=0.646
			FLTF Long leg		6.6‡ (2.9) §	
			FLTF Short leg		9.3‡ (7.5) §	
			SSF Long leg		7.0‡ (4.8) §	
			SSF Short leg		6.3‡ (4.8) §	
Hip extension in stance (°)			BF Long leg	9.6‡ (6.2) §		Comparison long to short BF p = 0.114 FLTF p=0.241 SSF p=0.203
			BF Short leg	11.3‡ (3.7) §		
			FLTF Long leg		12.8‡ (8) §	
			FLTF Short leg		12.3‡ (5.70§	
			SSF Long leg		11.9‡ (7.3) §	
			SSF Short leg		12.5‡ (5.7) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Lift Therapeutic Footwear						
Kinematic						
Hip flexion at initial contact (°)	**Eek et al. (2017)**	Cerebral palsy	BF Long leg	36.3‡ (9.1) §		Comparison long to short BF **p = 0.005;** FLTF p=0.139; SSF **p=0.005**
			BF Short leg	29.8‡ (5.1) §		
			FLTF Long leg		34.9‡ (5.4) §	
			FLTF Short leg		34.1‡ (4.1) §	
			SSF Long leg		36.3‡ (4.3) §	
			SSF Short leg		30.5‡ (8.3) §	

Hip flexion in swing (°)			BF Long leg	37.3 (6.9) §		Comparison long to short BF **p = 0.009;** FLTF p=0.139; SSF **p=0.028**
			BF Short leg	33.0 (5.5) §		
			FLTF Long leg		38.7 (7.3) §	
			FLTF Short leg		36.9 (6.1) §	
			SSF Long leg		36.3 (7.5) §	
			SSF Short leg		33.3 (6.4) §	
Knee extension in stance (°)			BF Long leg	7.0‡ (9.6) §		Comparison long to short BF **p = 0.007;** FLTF **p=0.028;** SSF **p=0.007**
			BF Short leg	4.8‡ (12.6) §		
			FLTF Long leg		4.9‡ (10.2) §	
			FLTF Short leg		1.9‡ (10.9) §	
			SSF Long leg		8.8‡ (10.6)	
			SSF Short leg		1.6‡ (8.7) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final Mean (SD +/-)**	**Statistical Result (Significant values given in bold)**
			Functional Lift Therapeutic Footwear			
Kinematic						
Knee flexion at initial contact (°)			BF Long leg	13.4‡ (6.8) §		Comparison long to short BF p = 0.508; FLTF p=0.114; SSF p=0.386;
			BF Short leg	11.9‡ (7.8) §		
			FLTF Long leg		7.7‡ (7.5) §	
			FLTF Short leg		9.4‡ (6.7) §	
			SSF Long leg		7.3‡ (11.5) §	
			SSF Short leg		8.10‡ (7.5) §	

Knee flexion in swing (°)			BF Long leg	63.8‡ (5.0) §		Comparison long to short BF p = 0.203; FLTF p=0.445; SSF p=0.093
			BF Short leg	62.2‡ (12.7) §		
			FLTF Long leg		64.2‡ (5.2) §	
			FLTF Short leg		60.8‡ (13.4) §	
			SSF Long leg		65.6‡ (2.7) §	
			SSF Short leg		62.5‡ (15.3) §	

Table 3-4 Outcome measures biomechanical continued.

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
			Functional Lift Therapeutic Footwear			
Spatiotemporal						
Cadence steps/min	**Eek et al. (2017)**	Cerebral palsy	BF	100.6‡ (17.8) §		Friedman ANOVA: p>0.05
			FLTF		98.4‡ (25.7) §	
			SSF		99.3‡ (24.9) §	
Stance phase %			BF Long leg	61.1‡ (2.03) §		Wilcoxon signed rank: Comparison long to short BF **p = 0.022;** FLTF p=0.241;
			BF Short leg	56.8‡ (4.0) §		
			FLTF Long leg		60.8‡ (292) §	
			FLTF Short leg		60.0‡ (4.16) §	
			SSF Long leg		62.5‡ (1.91) §	

			SSF Short leg		58.9‡ (3.90) §	SSF **p=0.005**
Stride length (m)			BF	1.12‡ (0.13) §		Friedman ANOVA: **p<0.05**
			FLTF		1.24‡ (0.12) §	Post hoc: BF vs. FLTF **p<0.05;** BF vs. SSF **p<0.05**
			SSF		1.24‡ (0.12) §	
Velocity (m/s)			BF	1.18‡ (0.16) §		Friedman ANOVA: **p<0.05**
			FLTF		1.24‡ (0.12) §	Post hoc: BF vs. FLTF **p<0.05**
			SSF		1.21‡ (0.22) §	

Key to Table 3-4

AFO Ankle Foot Orthosis, **BF** Barefoot, **CoP** Centre of Pressure, **CTEV** Congenital Talipes Equino Varus, **CTF** Corrective Therapeutic Footwear, **DB** Denis Brown Barred Night Boot, **FAS** Forefoot Abduct Night Shoe, **FITF** Functional Instability Therapeutic Footwear, **FLTF** Functional Lift Therapeutic Footwear, **FO** Foot Orthoses, **FSTF** Functional Stability Therapeutic Footwear, **N/A** Not Applicable, **SLF** Standard Last Footwear, **SSF** Standard Sole Footwear, ***** supplementary results in Appendix 2.2, **†** 95% Confidence Interval, **‡** Median, **§** Inter Quartile Range.

Table 3-5 Secondary outcome measures

Outcome	**Study**	**Condition**	**Group**	**Baseline Mean (SD +/-)**	**Final* Mean (SD +/-)**
		Functional Stability Therapeutic Footwear			
Pain whilst using device 1=no pain 5=great deal of pain	**Bakker et al. (1997)**	DMD	FSTF	N/A	1.42 (0.53)
			Own footwear	N/A	1.02(0.51)
			KAFO	N/A	3.0 (1.87)
			SF	N/A	2.33 (1.03)
			AFO	N/A	2.20 (1.39)

Reluctance to use device 1=not reluctant 5=great deal of reluctance			FSTF	N/A	2.28 (1.25)
			Own footwear	N/A	1.29 (1.35)
			KAFO	N/A	3.0 (1.58)
			SF	N/A	3.66 (1.21)
			AFO	N/A	2.85 (1.53)

AFO Ankle Foot Orthosis, **DMD** Duchenne Muscular Dystrophy, **FSTF** Functional Stability Therapeutic Footwear, **KAFO** Knee Ankle Foot Orthosis, **N/A** Not Applicable, **SF** Standing Frame, * No statistical test for significance performed,

3.3.2. Corrective Footwear

These three studies focused on the effects of the footwear on lower limb alignment pes planus (n=2) (Kanatlı et al., 2016; Wenger et al., 1989) and congenital talipes equino varus (CTEV) (n=1)(W. Chen et al., 2015) (Table 3-1). The studies were all randomised controlled trials (level II evidence). Two of the studies were of fair QI (W. Chen et al., 2015; Wenger et al., 1989) and one of poor QI (Kanatlı et al., 2016). A total of 196 children were examined across the studies with an age range from 11 months to 5 years (Table 3-1, **Error! Reference source not found.**). One study failed to report the sex distribution amongst the experimental groups (Kanatlı et al., 2016), and the height and mass of the participants were only reported in one study (W. Chen et al., 2015). Two of the studies (W. Chen et al., 2015; Wenger et al., 1989) had sufficient sample size to detect a medium effect size of 0.3 at 0.05 significance and 80% power (Cunningham & McCrum-Gardner, 2007). However, one of the studies suffered a loss to follow up >20% (Wenger et al., 1989) with no intention to treat factored into the analysis.

Various design characteristics were reported for the corrective footwear (

Table 3-2) in the three studies. Consistent features appeared to be some form of reinforced or lengthened heel counter or arch inlay (W. Chen et al., 2015; Kanatlı et al., 2016; Wenger et al., 1989). The common comparator to corrective footwear interventions across all three studies were daily wear of standard retail footwear (

Table 3-2). One study also considered orthotic arch support or heel cups (Wenger et al., 1989). Assessors were blinded in only one of the three studies (Wenger et al., 1989). Primary outcomes focused on skeletal geometric measures which were presented in the three studies included in this grouping (Table 3-3). These were radiographic measures of the skeletal alignment of the foot in two studies considering pes planus (Kanatlı et al., 2016; Wenger et al., 1989), and 3D scanned images of the foot and ankle for the study considering CTEV (W. Chen et al., 2015). Only one study in this grouping (W. Chen et al., 2015) considered biomechanical outcomes (Table 3-4) consisting of pressure ratios of the heel to forefoot and heel to lateral midfoot in walking conditions. Secondary outcomes, as determined by this current review, were not reported in any study amongst the corrective footwear grouping. Results indicated that there was no significant effect of corrective footwear versus readily available retail footwear in the developmental of asymptomatic paediatric pes planus. Daily wear of corrective footwear in combination with nocturnal wear of Dennis Brown splint did not appear to offer any difference to the 3D scans of the trans-malleolar axis, and the bean-shaped ratio of CTEV in comparison to daily wear of standard footwear and nocturnal wear of Dennis Brown (W. Chen et al., 2015). However, the study did demonstrate statistically significant improvements in 4 of the 13 plantar pressure measures (Table 3-4) indicating a reduction of equinus and varus deformity with the daily wear of corrective footwear and nocturnal use of Dennis Brown splint. Results for the nine plantar pressure measures that were not significant concerning CTEV and corrective footwear, but highlighted the effects of different nocturnal splints, can be found in Appendix 2.2340.

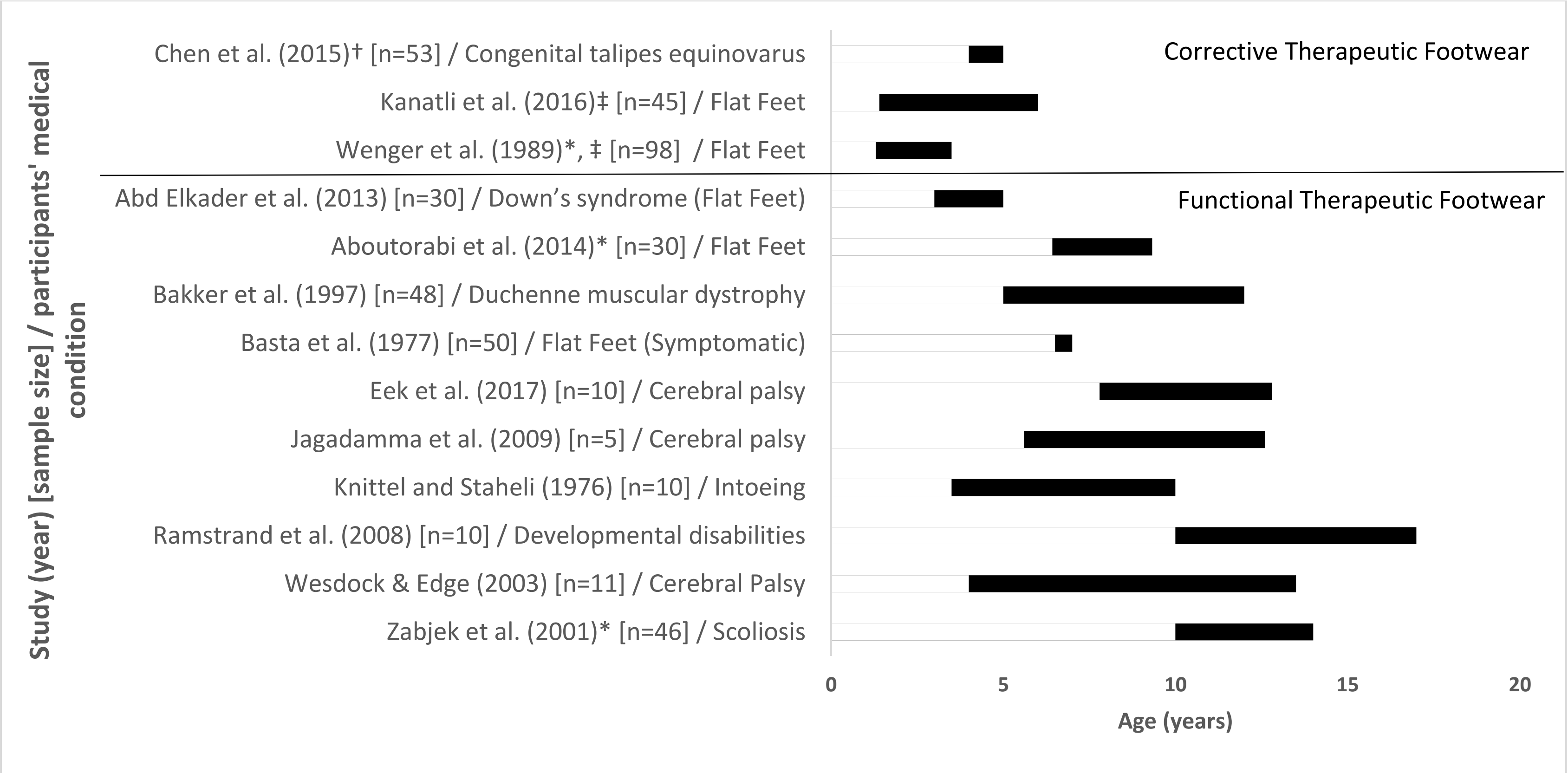


Figure 3-2 Age ranges for children with mobility impairment in the included studies.

*Mean (+/- SD), † Age when tested, ‡ Age at entry of study

3.3.3. Functional Footwear

Functional footwear intervention studies focused chiefly on biomechanical primary outcomes (kinematic, kinetic, spatiotemporal, balance) (Table 3-4, Appendix 2.2) which were considered in 7 of the 10 studies (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Eek et al., 2017; Jagadamma et al., 2009; Knittel & Staheli, 1976; Ramstrand et al., 2008; Wesdock & Edge, 2003). Skeletal geometry primary outcomes (Table 3-3) were considered in only two of the studies (Basta et al., 1977; Zabjek et al., 2001). Secondary outcomes were considered in two studies (Bakker et al., 1997; Basta et al., 1977) but empirically reported in one (Bakker et al., 1997) (Table 3-5). A total of 311 children were considered amongst the studies with an age range from 3 to 17 years Table 3-1, Figure 3-2 Reporting of the participants' height and mass was provided in four studies (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Eek et al., 2017; Ramstrand et al., 2008) Table 3-1. It was noted that the small sample size affected the statistical power (Appendix 2.3) in all but two of the experimental studies amongst the functional footwear grouping studies (Aboutorabi et al., 2014; Raczkowski et al., 2010). None of the studies blinded the participants to the intervention, with only one study blinding the assessor (Abd Elkader et al., 2013). Sufficient information on the participant recruitment strategy was provided in only two studies (Bakker et al., 1997; Eek et al., 2017). Three of the studies stipulated a brief wearing in period to allow the child to become accustomed to walking in the interventions (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Eek et al., 2017). Functional footwear was split into three design characteristic subgroups: Stability, Instability, and Lift as defined by the previous scoping review (Chapter 2)

3.3.3.1. Stability footwear

There were seven studies in this subgrouping with various footwear designs used amongst the studies (

Table 3-2). Five studies involved footwear offering some form of medial-lateral stability with arch inlay and/or reinforced heel counter(Abd Elkader et al., 2013; Aboutorabi et al., 2014; Bakker et al., 1997; Basta et al., 1977; Knittel & Staheli, 1976) and two studies involved footwear with anterior-posterior sole wedging that work alongside Ankle Foot

Orthoses (AFO) to offer sagittal stability (Jagadamma et al., 2009; Wesdock & Edge, 2003).

In relation to footwear that offered mediolateral stability, the study designs consisted of four before-after studies (level III evidence) (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Basta et al., 1977; Knittel & Staheli, 1976) and one survey study (level IV evidence) (Bakker et al., 1997). Two of these studies were of fair QI (Abd Elkader et al., 2013; Aboutorabi et al., 2014) and two poor QI (Basta et al., 1977; Knittel & Staheli, 1976). The survey study met 64% of the survey quality criteria (Bakker et al., 1997). The medical conditions of the participants were mobile pes planus, Down syndrome, in-toeing and Duchenne muscular-dystrophy (Table 3-1) (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Bakker et al., 1997; Basta et al., 1977; Knittel & Staheli, 1976). Various comparators were considered (Table 3-1). Barefoot conditions, walking or stance, was the baseline assessment in three of the five studies (Abd Elkader et al., 2013; Aboutorabi et al., 2014; Basta et al., 1977). Standard unmodified footwear was considered in three of the studies (Bakker et al., 1997; Basta et al., 1977; Knittel & Staheli, 1976). Arch inlays/foot orthosis was a comparator either fitted to stability footwear in one paper (Basta et al., 1977) or to standard footwear in another paper (Aboutorabi et al., 2014). AFOs, Knee Ankle Foot Orthoses (KAFO), and standing frames were additionally considered in one study (Bakker et al., 1997). Medical taping was a consideration in one study (Abd Elkader et al., 2013). Stability footwear with various sole modifications were compared in one study (Knittel & Staheli, 1976).

Primary outcomes considered both biomechanical (Table 3-4) and skeletal geometric measures (Table 3-3). One study demonstrated statistically significant changes in spatiotemporal parameters (increase in velocity and stride length, reduction in the base of support) in children with Down syndrome whilst wearing stability footwear compared to the barefoot condition (Abd Elkader et al., 2013). However, no differences were noted between the stability footwear group and the taping comparator group in this study (Abd Elkader et al., 2013). One study demonstrated a statistically significant reduction in the centre of pressure (CoP) displacement and increased step velocity in the stability footwear compared to the barefoot condition for individuals with pes planus

(Aboutorabi et al., 2017). No significant difference was found in step symmetry in this study between barefoot and stability footwear conditions. However, the regular shoe with orthosis demonstrated a significant increase in step symmetry compared to stability footwear conditions (Aboutorabi et al., 2014). Mediolateral wedged sole modifications were shown to have no statistically significant effect on in-toed angle of gait. Torqheels (circular sole additions that impart a torque on ground contact (Rodenberger, 1981) did show a significant reduction of the in-toed angle of gait (approximately 33%) compared to a standard soled footwear (Knittel & Staheli, 1976). Skeletal geometry outcomes used were immediate weight-bearing radiographic alignment changes to the medial longitudinal arch in participants with symptomatic pes planus. Skeletal alignment was seen to improve in stability footwear vs. barefoot conditions (Basta et al., 1977). However, no statistical analysis was performed on these effects. Additionally, there was absent reporting of the changes to these angles in standard footwear conditions (Basta et al., 1977).

Secondary outcomes, as outlined by this review, were explored in two of the mediolateral stability footwear studies. Reduction of foot fatigue and pain in pes planus were investigated in one paper (Basta et al., 1977). This paper demonstrated these outcomes improved for the stability footwear intervention compared to standard footwear and arch inlay. However, no statistical analysis was performed on these findings. The second paper considered surveying parents of children with Duchenne's muscular dystrophy (DMD) as to the reluctance to use the prescribed assistive device and pain whilst using the device (Bakker et al., 1997) (Table 3-5). This demonstrated that stability footwear was associated with less reluctance to wear, and less pain experienced compared to AFOs, KAFOs and standing frames. This study failed to provide information on the design or testing of the questionnaire. Additionally, there was no statistical analysis performed, and it was unclear as to the severity of the DMD amongst the different interventions or if the pain measured was from the device or from the condition itself.

In relation to footwear that offered sagittal stability, study design consisted of one before-after design (Jagadamma et al., 2009) and one cross over study (Wesdock &

Edge, 2003); both studies were of fair QI. The medical conditions of the participants consisted of spastic cerebral palsy with knee hyperextension (Jagadamma et al., 2009) or crouch gait (Wesdock & Edge, 2003) (Table 3-1). Comparators consisted of standard footwear in one study (Wesdock & Edge, 2003) and AFO worn with standard footwear combination in both studies (Jagadamma et al., 2009; Wesdock & Edge, 2003) (Table 3-1). Biomechanical outcomes were considered in both these studies (Jagadamma et al., 2009; Wesdock & Edge, 2003) (Table 3-4). One study demonstrated a significant improvement on knee hyperextension and shank to vertical angle (SVA) kinematics in sagittal wedged soled footwear in combination with AFO compared to the standard sole footwear with AFO (Jagadamma et al., 2009). However, no kinetic or spatiotemporal variable reached statistical significance (Jagadamma et al., 2009). Standing balance was considered in the second study. This study found statistically significant improvement for differences in standing balance in a sub-set analysis of diplegic individuals with Gross Motor Function Scores (GMFS) 2-3 for AFOs and anteroposterior sagittal wedged footwear combination intervention compared to both standard footwear and AFO standard footwear combination (Wesdock & Edge, 2003).

3.3.3.2. Instability footwear

This subgrouping consisted of one study that considered commercially available MBT® footwear (Ramstrand et al., 2008). This footwear consists of a rounded sole shoe with a midfoot pivot (Ramstrand et al., 2008) (

Table 3-2). The study was a before-after design (level III evidence) of poor QI. The health conditions considered were highly varied in the group and consisted of cerebral palsy, Prader Willi, unspecified motor and development delay, Cornelia de Lange syndrome and Attention Deficit Hyperactive Disorder (ADHD) (Table 3-1). The grading and degree of the mobility impairments of the participants were not fully described. All individuals wore the MBT footwear for the 8-week period and were tested barefoot and in the MBT footwear (Table 3-1 Table 3-4).

Biomechanical outcomes of static and dynamic balance were considered in this study (Table 3-4). No spatiotemporal kinematic or kinetic outcomes were considered. This footwear did not demonstrate any statistically significant effects on static balance and a number of dynamic balance outcomes; these results are presented in Appendix 2.2. However, two of the dynamic balance outcomes were seen to improve statistically significantly, with a reduction in the number of falls seen over the course of the study and improvement in the mediolateral control of the centre of pressure displacement. It must be noted that two of the participants were unavailable for the four-week testing point and one other participant failed to understand the instructions for the control aspect of dynamic balance testing. Intention to treat analysis was not reported to account for this drop off in participation.

3.3.3.3. Lift footwear

Lift footwear was described as consisting of unilateral outer-sole adhesions (

Table 3-2) (Eek et al., 2017; Zabjek et al., 2001). This subgroup consisted of two before and after studies; one fair QI (Eek et al., 2017) and one poor QI (Zabjek et al., 2001). Poor reporting of the intervention and the participants affected the QI of one study (Zabjek et al., 2001). Conditions considered were limb length inequality in combination with either, idiopathic scoliosis (Zabjek et al., 2001) or spastic cerebral palsy (Eek et al., 2017) (Table 3-1).

Barefoot conditions, walking or stance, was considered as a comparator in both studies (Eek et al., 2017; Zabjek et al., 2001), with standard sole footwear also considered in one study (Eek et al., 2017) (Table 3-1). Spatiotemporal and kinematic variables were considered in individuals with spastic cerebral palsy and limb length inequality, in one of the studies (Eek et al., 2017) (Table 3-4). Statistically significant differences seen between stance time in the long and short leg in barefoot and unmodified shod conditions were not seen in the lifted footwear intervention. Velocity was also significantly increased in the lifted footwear compared to the barefoot conditions. Statistically significant kinematic differences between hip flexion at initial contact and swing and ankle dorsiflexion in stance seen between the long and short limb in the barefoot condition were no longer significant in the lifted footwear condition.

The second study considered skeletal geometric measures of acute changes on, lower limb, pelvic, and spinal posture through radiographs and 3D marker system of first barefoot, then lifted sole conditions (Zabjek et al., 2001) (Table 3-3). Sole lifted conditions significantly reduced the Cobb angle, pelvic tilt, version between right and left iliac bones, and shoulder tilt compared to barefoot conditions. These findings according to Zabjek et al.(2001) demonstrate acute improvements in idiopathic scoliosis posture.

3.4. Discussion

The review identified 13 empirical studies that explored the effects of therapeutic footwear in children with mobility impairment. Study quality was negatively affected in most studies by the reporting strategy, with a lack of descriptions of basic participant anthropometrics and inadequate blinding of participants and assessors impacting on generalisability and internal and external validity. Another consideration that may impact on long term conservative footwear management is compliance with the intervention (Sangiorgio et al., 2016); this was not accounted for or was inconsistently measured in the studies potentially introducing confounding bias (Nielsen et al., 2020; Spencer EA, 2018).

The medical conditions with the highest number of studies were pes planus (five studies) and cerebral palsy (four studies). It must be noted three studies, considering pes planus appeared to only acknowledge the postural presentation with no apparent symptoms or other underlying pathology identified (Aboutorabi et al., 2014; Kanatlı et al., 2016; Wenger et al., 1989). Therapeutic interventional studies should consider expanding on the descriptors of inclusion for pes planus in children (Banwell et al., 2018; Dars et al., 2018; Uden et al., 2017) to avoid the possibility of medicalising healthy physiological development (Kaczmarek, 2019) and potential detriment to the health economy and the individual (Carli et al., 2012; Driano et al., 1998). The effects of footwear as a therapeutic intervention on other noteworthy conditions that impact on children's mobility such as joint hypermobility syndrome (Scheper et al., 2017), spina bifida (Schoenmakers et al., 2005), developmental coordination disorder (Wilson et al., 2013), juvenile idiopathic arthritis (Hendry et al., 2008), and Charcot Marie Tooth (Kennedy et al., 2016) were not considered in the included studies.

The age of the participants showed distinct differences between the two main footwear groupings with corrective footwear considering a younger age range (11 months to 5 years) and functional footwear a broader age range (3 to 15 years) (Figure 3-2). This may be explained by the increased percentage of cartilage in the infant skeleton having the perceived potential to be influenced by conservative intervention (Brewster et al., 2008; C. M. Williams et al., 2013) in relation to corrective footwear, and the broader age range in functional footwear linked to the ongoing need for assistive aid for children with mobility issues in daily activity. Primary outcomes were focused on skeletal geometry in all of the corrective footwear studies as would be expected since the aim of treatment is to bring about realignment of the skeletal system in the lower limb as discussed in the subgrouping corrective therapeutic footwear papers (Chapter 2). Primary outcomes for functional footwear were focused on biomechanical variables in 7 out of the 10 studies. This again would be expected since the purpose of functional footwear is to assist children's gait parameters as discussed in the subgrouping functional therapeutic footwear papers (Chapter 2). Of the remaining three articles in the functional footwear grouping studies, two considered skeletal geometry and one considered quality of life measures.

In consideration of corrective footwear grouping**,** the studies explored their effects for asymptomatic flexible pes planus and CTEV alongside nocturnal barred footwear post serial casting. One fair quality study, for a relatively large sample size, would suggest that corrective footwear offers no effect on mobile asymptomatic pes planus in children (Wenger et al., 1989). One fair quality controlled group study (W. Chen et al., 2015) suggests daily use of corrective footwear alongside nocturnal splinted footwear can improve the equinus and varus positioning of the forefoot. However, caution must be observed as CTEV is a heterogeneous pathology (David, 2011), and this study failed to report the aetiologies of the participants' deformities, thus affecting the generalisability of the study's findings.

The studies across the subgroupings of functional footwear were mainly experimental before and after design and one survey (Appendix 2.3, 2.4). The significance of the changes observed in these studies could have been a short term effect (MacLean et al., 2008) due to an insufficient wearing in and accommodation period. A learning effect could also impact on the findings (Wu et al., 2003) with participants able to anticipate factors such as those that required dynamic balance (Ramstrand et al., 2008). Further research with suitable wearing in periods and a control group study design would be beneficial to corroborate the findings of these studies. Stability footwear was seen to comprise of two general designs; one to assist mediolateral stability (Abd Elkader et al., 2013; Aboutorabi et al., 2014) and one to work alongside AFOs to assist sagittal stability (Jagadamma et al., 2009; Wesdock & Edge, 2003). For mediolateral stability design, one fair quality study demonstrated significant effects on velocity and mediolateral CoP displacement in children with pes planus between stability footwear intervention and barefoot (Aboutorabi et al., 2014) with one further fair quality study demonstrating significant effects on velocity, stride length, and base of support for stability footwear vs. barefoot conditions in individuals with Down syndrome (Abd Elkader et al., 2013). However, both the studies did not compare these effects with a standard children's footwear condition that has also demonstrated significant effects on spatiotemporal measures in children compared to barefoot conditions (Wegener, Hunt, et al., 2011). This opens the significance of the spatiotemporal findings for this footwear to debate and precludes any recommendations advocating this intervention over standard footwear in clinical practice for children with flexible pes planus or Downs syndrome. There is poor quality evidence that sole modification reduces the in-toed angle of gait by a third compared to standard sole footwear; however, the need to treat this developmental variant conservatively is debatable (Uden & Kumar, 2012). One survey indicated that stability footwear was associated with less reluctance to use and less pain than other assistive devices in individuals with DMD. However, the severity of the condition amongst those using the various devices was not stated; this precluded any informed clinical recommendation for the use of stability footwear in this condition. Those studies that considered sagittal stability demonstrated fair quality evidence in two studies that this footwear combined with a customised AFO can improve, knee and shank vertical angle in spastic CP (Jagadamma et al., 2009) or standing balance in spastic diplegic GMFS 2-3 crouch gait (Wesdock & Edge, 2003). Therefore, sagittal stability footwear could tentatively be recommended over standard retail footwear for AFO footwear combination in children with spastic CP. Evidence indicated that instability footwear improves dynamic balance (number of falls and control of mediolateral CoP displacement) in a range of children's developmental disabilities. However, the quality of this study was poor, with failure to account for dropout across the testing period, and a diverse range of mobility impairments considered in the sample (Table 3-1) questioning the validity of the central trend analysis obtained (Ramstrand et al., 2008).

Lift footwear offered fair quality evidence in one study to improve the symmetry of a wide range of kinematic and spatiotemporal gait parameters between the long and short limb in individuals with spastic cerebral palsy potentially supporting its use for individuals with this clinical presentation(Eek et al., 2017). Spinal and pelvic skeletal geometry were seen to improve in individuals with idiopathic scoliosis; however, this was of poor quality with no standard footwear comparator and insufficient information provided on the participants and recruitment strategy opening the significance and generalisability of the findings to debate (Zabjek et al., 2001).

It was noted that a number of studies amongst the functional footwear grouping contained a degree of heterogeneity in the participant's age ranges and variable motor impairment. There were over seven year age ranges in some studies (Jagadamma et al., 2009; Ramstrand et al., 2008; Wesdock & Edge, 2003); since development affects biomechanical parameters (McKay et al., 2017; Wegener, Hunt, et al., 2011), this should be considered when averaging biomechanical outcome data. Further consideration should be given to the studies that averaged biomechanical outcome data amongst individuals with cerebral palsy (Eek et al., 2017; Jagadamma et al., 2009; Wesdock & Edge, 2003) as this condition has a significant range of motor impairment that may not be amenable to central trend analysis (Domagalska-Szopa & Szopa, 2014; Domagalska–Szopa & Szopa, 2019; Kim et al., 2018; Tugui & Antonescu, 2013).

There is relatively limited research concerning any grouping of therapeutic footwear. Level of evidence ranged from II to IV, but no study exceeded a quality assessment of fair, due to methodology that affected both internal and external validity. This entails a conservative recommendation from the current evidence base concerning clinical usage of therapeutic footwear. There appears to be evidence that corrective footwear is not recommended as an intervention for developmental pes planus since there is no apparent favourable outcome compared to standard footwear in infants and young children. With an unnecessary prescription of corrective footwear leading to potential over-medicalisation of typical development and psychosocial detriment in early adult life (Driano et al., 1998; Kaczmarek, 2019). Functional footwear appears to be able to play a role in assisting children with mobility impairment across a broader age range than corrective footwear; however, these studies invariably suffer from a small sample size potentially being underpowered to detect any significant effect. Future studies for functional therapeutic footwear must consider a comparison with standard footwear, as suggested by Wegener et al. (Wegener, Hunt, et al., 2011), to factor in the effects of regular footwear on children's gait in comparison to barefoot conditions. Further comparison to other assistive devices such as foot orthoses is warranted in order to inform when stability footwear should be used as an alternative or in combination with foot orthoses; or where lift therapy for limb length inequality is best addressed with removable inlays/orthoses or external modifications to the outsole of the shoe.

Other recommendations for general therapeutic footwear research include clear reporting of participant characteristics and the distribution of demographics between treatment groups, to include, sex, height and mass which have demonstrated effects on foot function and skeletal geometry in previous studies (Barisch-Fritz, Schmeltzpfenning, Plank, Hein, et al., 2014; Jiménez-Ormeño et al., 2013; Morrison, McCarthy, et al., 2018). Consideration of participant recruitment strategies is required; being mindful of institutional bias in the samples selected, and more transparent recruitment reporting to inform on the external validity of the work (Downs & Black, 1998). The lack of consideration of adverse events across the studies warrants comment since it is imperative intervention studies declare adverse events or the measures taken to capture these, as appropriate evidence base should identify the potential harms as well as benefits of any therapeutic intervention (Ioannidis, 2009).

The psychosocial impact of therapeutic intervention is an important consideration for mobility-impaired children (Guerette et al., 2013). The World Health Organisation's international classification of function for children living with disabilities considers a number of factors to ensure the child can achieve the highest quality of life (World Health Organization, 2007). The current evidence base concerning therapeutic footwear has chiefly focused on the body structure and functional aspects of the ICF-CY but has not attempted to assess the long-term or psychosocial effects the intervention may have on the child's quality of life in terms of the ability to participate in daily activities or relief of pain.

3.4.1. Limitations of the current study

The initial screening of the studies that identified children's therapeutic footwear was performed independently by the one author (MH) during the preceding scoping review (Chapter 2) which may have opened these processes to personal bias. The review has considered only those articles with an available English language abstract which may have impacted on the scope of research. Incomplete description of the therapeutic footwear together with the lack of information on basic anthropometrics (height, mass, BMI), heterogeneity of the participants, and the broad range of outcomes precluded a quantitative analysis of the aggregated results which could be perceived as a limitation. There were 76 different outcome measures considered across the included studies with few reporting on the same outcome measures. The definition and adoption by researchers to minimum sets of condition-specific outcome measures, such as those presented by the International Consortium for Health Outcome Measurement (ICHOM) (*ICHOM | Overall Pediatric Health Standard Set | Measuring Outcomes*, 2020); in particular those outcomes focusing on walking velocity which is predictive of health and neurological function (Kennedy et al., 2020; Middleton et al., 2015) will enable between study comparisons and meta-analyses of future research.

3.5. Conclusion

There are a limited number of studies exploring the effects of children's therapeutic footwear; these have mainly been studied on children with pes planus and cerebral palsy. Limited fair quality level II evidence is available that corrective footwear has no significant effect on apparent typical developmental pes planus. Conversely, there is limited fair quality level II evidence that it can offer a corrective effect in mild to moderate cases of CTEV in infancy. Functional therapeutic footwear offers limited fair quality level III evidence on apparent improvement to gait parameters in pre-school and primary school-aged children with pes planus, Down syndrome or CP. Included studies explored body structure and functional aspects of the WHO ICF-CY (biomechanical and skeletal geometry outcomes). However, psychosocial aspects of the ICF-CY concerning the quality of life appears largely absent in the research.

Review findings suggest that further research on therapeutic footwear with robust study designs is warranted. The outcome measures should consider a full range of ICF-CY aspects, and the reporting should include a clear description of the footwear interventions inclusive of the design characteristics, participant characteristics, recruitment strategy and measures of adverse events. These recommendations will improve the current evidence base for therapeutic footwear as an intervention for children living with a mobility impairment

4. Design Characteristics of Off-the-Shelf Children's Stability Footwear

4.1. Background

The effectiveness of assistive aids for mobility impairment, such as orthosis, is dictated by their design and material components (Chatzistergos et al., 2023; Eddison, Healy, et al., 2022; Eddison & Chockalingam, 2013). As outlined in Chapter 2, off-the-shelf stability therapeutic footwear (OSSTF) is a range of children's therapeutic footwear that is postulated to act as an assistive aid to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns. However, as outlined in Chapters 2 and 3, there is no clear identification in the evidence base of the design and material components for OSSTF and the potential purpose of these design components. This has led to inconsistent reporting of this intervention in the current evidence base, with researchers lacking clarity on the salient features to report. Relatively minor variations in orthotic design can produce marked differences in mechanical properties and potentially affect their function as an assistive aid (Bregman et al., 2009; Chatzistergos et al., 2023; Kerkum et al., 2016; Major et al., 2004; Sumiya et al., 1996). In addition to their mechanical properties to improve stability and limb function, the consequences of comfort and ergonomics should also be considered for the usability of assistive aids (Bakker et al., 1997; Eddison, Healy, & Chockalingam, 2020). A lack of understanding of the salient design characteristics of an assistive aid leads to poor reporting in the research with reduced confidence in the findings and precludes effective knowledge synthesis resulting ultimately in poor clinical decision-making (Eddison, Mulholland, et al., 2017; Malas, 2011). Therefore to improve clinical decision-making and assist in defining and analysing OSSTF as an intervention in children, it would be beneficial to understand common characteristics of this footwear and how they differ from standard retail footwear and hypothesise the potential purpose of these design characteristics to improve daily activity in mobility impaired children (Craig et al., 2008).

4.1.1. Aim and objectives

The overall aim of this study was to develop a protocol to assess the design and material characteristics of OSSTF to inform on their standard design and potential purpose.

The objectives were to:

1. Assess the design components of the OSSTF:

   Qualitatively:

   By describing the components, architecture, construction, and material of the footwear

   Quantitatively:

   By measuring the dimension and geometry of footwear
2. Compare qualitative and quantitative measures to standard retail children's footwear
3. Thematically analyse the footwear design characteristics into hypothesised functional purpose

4.2. Methods

4.2.1. Footwear samples

Thirteen samples of children's OSSTF (EU size range 19-41) from five leading therapeutic footwear manufacturers Schein®, Ortho Europe (FitKidz) ®, TSM Fondi Srl®, Nimco® and Piedro® were examined (Figure 4-1, Figure 4-2). These samples were sourced directly from the manufacturers and were thought to offer the typical characteristics of their OSSTF range. Additionally, a Kicker boot Model Kick Hi Core KF 409 was taken as representative of a standard retail shop children's boot for comparative analysis with the OSSTF (Figure 4-3). This standard retail boot comes in a range of colours that could be used for a variety of purposes, such as play and school, as would be comparable for OSSTF daily use, and are a popular choice of footwear amongst children and parents (kickers.co.uk, 2024; Lovedbyparents.com, 2021; Shoe Master, 2021; C. M. Williams, Morrison, et al., 2022).

Figure 4-1 Schein and OrthoEurope (FitKidz) OSSTF used in the study.

Figure 4-2 TSM, Nimco and Piedro OSSTF used in the study.

Figure 4-3 Standard retail children's boot Kickers Kick Hi Core

4.3. Qualitative assessment of OSSTF components characteristics

This involved identifying specific footwear design components using standard footwear design terminology, e.g., heel counter, topline, facings, fastening, toe box, pull tab and heel stiffener (Figure 4-4). Where appropriate components such as the topline, heel counter, facings and collar could be further described, such as reinforced, padded, cut away, contoured, extended to footwear, an anatomical or footwear landmark (ankle, midfoot, toe box). Additionally, the construction technique of some of the components, such as the outsole, was also described, e.g., cemented or welted.

The standard retail children's boot was assessed against the same qualitative criteria and compared against the collective findings of the OSSTF samples.

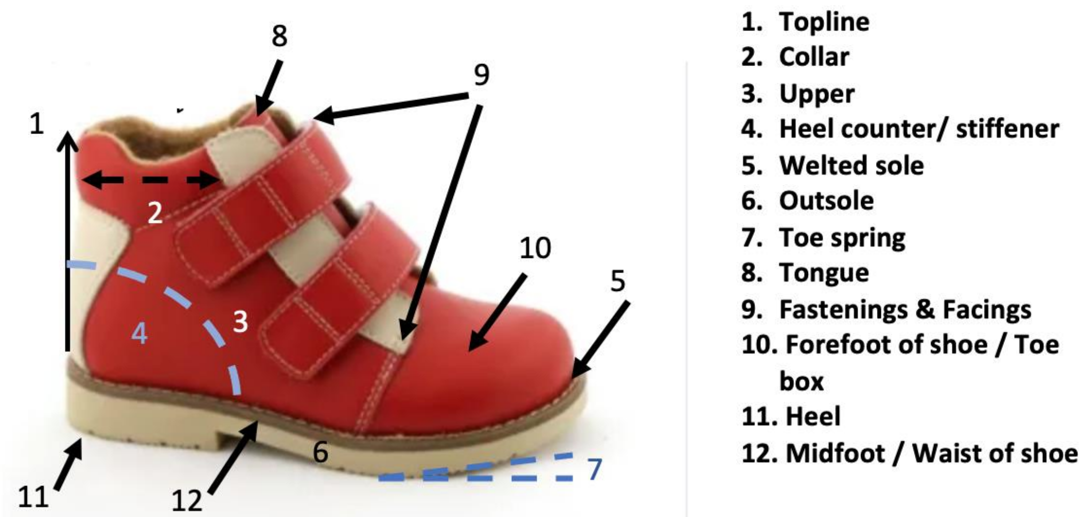


Figure 4-4 Descriptors of OSSTF components and characteristics (Image adapted from www.made-in-china.com)

4.4. Quantitative assessment of OSSTF components characteristics

Quantitative measures of the footwear samples considered the dimensions and geometry of shoe components: topline height, heel stiffener length, total footwear length, footwear width, toe rocker angle, toe flex length and outsole depth (Figure 4-5). Measures of footwear length and width and topline height followed appropriate international standards (ISO, 2021). Measures of the heel counter involved palpating the heel counter through the footwear upper to locate its highest point and furthest extension (Figure 4-6). The height of the heel counter was measured from the highest marked point of the heel counter to the seam of the upper to the outsole via calliper. The length of the heel counter was taken from the back of the heel of the shoe to the furthest point of the heel counter via calliper. The mass of each shoe was also recorded. The quantitative measures were normalised to overall footwear length to allow ratio comparison between various shoe sizes obtained in the sample. Descriptive statistics of the OSSTF (Mean, standard deviation, range) were also taken for comparison to the standard retail footwear sample.

Figure 4-5 Quantitative measures of OSSTF

Figure 4-6 (A) Palpating the top edge of the heel counter through the shoe, (B) Tracing the top edge of the heel counter to its highest point (C)Tracing the top edge of the heel counter to its most distal aspect.

4.4.1. Analysis

The footwear samples' findings were discussed and qualitatively assessed between the author (MH) and principal and secondary supervisor (NC, AH). The discussion involved generating consensus on the hypothesised functional purpose of the design characteristics, e.g., a padded collar may provide comfort around the ankle region, or an increased heel counter height may improve ankle stability. From the hypothesised functions, common groupings of the design features, such as stability, comfort, and security, were then defined by consensus amongst the research team. Design features of the OSSTF were then placed into these groupings.

4.5. Results

The main qualitative and quantitative findings are presented in Table 4-1**Error! Reference source not found.**; the full results are found in appendix 3.

Twelve of the OSSTF consisted of a leather upper with only one canvas material (Schein 1). The standard retail boot also consisted of a leather upper. The topline was extended above the malleoli in all footwear; the mean OSSTF value was 44% of total shoe length (range 39-53%), with the standard retail boot value at 41%. The Nimco and Schein shoes were seen to have the highest toplines of 46-53%. Padding of the topline collar was common to all footwear designs. The topline was also contoured above the medial and lateral malleoli in 7 designs (Piedro 1-2, TSM 1-2, FitKidz 3-5) and the Achilles tendon in 6 designs (Schein 1, Fitkidz 3-5, Piedro 1-2). The standard retail boot was not contoured around the malleoli or Achilles tendon.

Eleven OSSTF designs, in addition to the standard retail boot, had facings and fastenings extended into the toe box. The fastening in the remaining two OSSTF designs extended to the forefoot (Fitkidz 1-2). Eight of the OSSTF consisted of lace fastening and 5 of Velcro, and the standard retail boot was lace fastening. The Velcro fastening consisted of a double over and a “D ring” thread hole. Lace fastening consisted of a metal ring eyelet, with three designs (Piedro 1-2, Nimco 2) having hook eyelets around the upper facing towards the topline. Two designs also contained additional medial side zip fastening (Nimco 1, Schein 2).

All designs consisted of an extended heel counter into the midfoot mean medial and lateral expansions of 51 and 42% of total foot length, respectively. The range of values for the OSSTF heel counter was 33-63% medially and 34-54% laterally. The Piedro and FitKidz range had the most extended medial heel counter extension, with the Nimco range and the Piedro 1 having the most extended lateral heel extensions. The medial heel counter for OSSTF was seen to be 42% in the standard retail boot and 38% for the lateral heel counter although this was seen to be less than the mean value for the OSSTF samples it still fell within the Max-Min range of OSSTF values. The mean value for the heel counter height was 26% of the total footwear length, with a range of 18-34%, with the Nimco 1 and Piedro 1 having the highest value. Heel counter height was the most marked difference between the OSSTF and standard retail boot (16% of total footwear length). All OSSTF designs demonstrated a higher %heel counter height, with the Nimco 1 and Piedro 1 demonstrating over double the standard retail boot value.

Twelve of the OSSTF designs consisted of an arch contoured removable inlay/insole; the FitKidz 1 and the standard retail boot did not have a removable inlay. Outsole material of the OSSTF range consisted of PU (6 designs) or other rubber (7 designs), with 11 of the designs consisting of stitched outsole adhesion (7 Welted and 4 Internal stitch) and two cemented. The standard retail boot had a rubber outsole with a welted outsole adhesion. Nine outsoles were built around a curved last with the Nimco 1 TSM 1 FitKidz 2 and 5, and the standard retail boot was built around a straight last. All outsoles consisted of a sagittal toe rocker with a deepened tread pattern. The average normalised mass of the OSSTF was 1.44g/mm and ranged from 0.99 to 2.10, with the welted sole adhesion OSSTF designs being amongst the densest OSSTF footwear. The standard retail boot mass was 1.18g/mm with most of the OSSTF footwear samples (11 of 13) of greater normalised mass.

Table 4-1 Qualitative assessment of children's OSSTF range and children's standard retail boot

Footwear Range	Upper Material	Topline Collar	Contoured Collar Achilles Tendon Region	Collar contoured to malleoli region	Fastening	Fastening Eyelet	Fastening Facing	Upper Outsole Adhesion	Outer Sole Material	Sole Last
Schein 1	Leather	Padded	Yes	No	Doubled Over Velcro	D Ring Hook	Extended to the Toe box	Cemented	PU Foam	Curved
Schein 2	Canvas	Padded	No	No	Lace & Zip	Ring Eyelet	Extended to the Toe box	Cemented	PU Foam?	Curved
FitzKidz 1	Suede / Nubuck	Padded	No	No	Lace	Ring Eyelet	To Midfoot	Welt	Plastic/Rubber	Curved
FitzKidz 2	Suede / Nubuck	Padded	No	No	Doubled Over Velcro	D Ring Hook	To Midfoot	Welt	Rubber	Straight
FitzKidz 3	Suede Nubuck/Leather Mix	Padded	Yes	Yes	Lace	Ring Eyelet	Extended to Toe box	Littleway Lasting Internal Stitch	Rubber	Curved
FitzKidz 4	Leather	Padded	Yes	Yes	Lace	Ring Eyelet	Extended to Toe box	Littleway Lasting Internal Stitch	Rubber	Curved
FitzKidz 5	Patent Leather	Padded	Yes	Yes	Doubled Over Velcro	D Ring Hook	Extended to Toe box	Welt	Rubber	Straight
TSM 1	Leather	Padded	No	Yes	Doubled Over Velcro	D Ring Hook	Extended to Toe box	Littleway Lasting Internal Stitch	Rubber	Straight
TSM 2	Suede/Canvas	Padded	No	Yes	Lace & Velcro	Ring Eyelet	Extended to Toe box	Littleway Lasting Internal Stitch	Rubber	Curved
Nimco 1	Patent Leather	Padded	No	No	Lace & Zip	Ring Eyelet	Extended to Toe box	Welt	PU Foam	Straight
Nimco 2	Leather	Padded	No	No	Lace	Ring Eyelet & Hook	Extended to Toe box	Welt	PU Foam	Curved
Piedro 1	Leather	Padded	Yes	Yes	Lace	Ring Eyelet & Hook	Extended to Toe box	Welt	PU Foam	Curved
Piedro 2	Leather	Padded	Yes	Yes	Lace	Ring Eyelet & Hook	Extended to Toe box	Welt	PU Foam	Curved
Kicker SRB	Leather	Padded	No	No	Lace	Ring Eyelet	Extended to Toe box	Welt	Rubber	Straight

Table 4-2 Quantitative assessment of children's OSSTF range and children's standard retail boot

Footwear Range	Size (EU)	Mass* (g/mm)	Top Line height *	Medial heel counter length*	Lateral heel stiffener length*	Stiffener height*	Medial rocker angle (°)	Lateral rocker angle (°)	Heel-forefoot height differential (cm)
Schein 1	38	1.56	48%	54%	46%	29%	15	15	1.32
Schein 2	36	1.19	49%	46%	40%	22%	10	10	1.60
FitKidz 1	35	1.72	40%	58%	38%	24%	8	8	2.08
FitKidz 2	35	1.74	42%	57%	34%	27%	10	10	1.71
FitKidz 3	28	1.37	40%	53%	41%	23%	15	10	1.55
FitKidz 4	26	1.35	40%	51%	35%	23%	15	10	1.60
FitKidz 5	19	0.99	43%	55%	43%	29%	10	10	1.50
TSM 1	28	1.60	39%	54%	40%	18%	10	10	1.33
TSM 2	21	1.12	42%	50%	36%	34%	15	10	1.33
Nimco 1	41	1.77	46%	33%	54%	33%	15	10	1.85
Nimco 2	32	1.50	53%	43%	46%	22%	15	10	1.73
Piedro 1	38	2.10	44%	63%	54%	34%	10	10	1.93
Piedro 2	27	1.49	46%	51%	36%	18%	14	14	2.00
Mean		1.50	44%	52%	42%	26%	12.46	10.54	1.67
SD+/-		0.30	4%	7%	7%	6%	2.76	1.85	0.26
Min		0.99	39%	33%	34%	18%	8	8	1.32
Max		2.10	53%	63%	54%	34%	15	15	2.08
Kicker SRB	32	1.18	41%	42%	38%	16%	13	12	1.47

* Percentage of overall footwear length SRB standard Retail Boot

4.6. Discussion

Based on the observations, the following grouped themes of functional purpose were suggested from the preliminary assessment of OSSTF components and design characteristics and comparison with standard retail children's footwear.

Stability: Design characteristics to maintain inversion and eversion movements of the foot and ankle within a controlled range (Liu et al., 2017; Menz et al., 2006; Su et al., 2017).

- Extended heel counter height reinforcement above the ankle mean value of 26% of total footwear length
- Extended heel counter length reinforcement medially and laterally (50 and 40% of total footwear length, respectfully).
- Extended topline height above malleoli mean value 44% total footwear length.
- Provision of arch contoured removable inlay
- Deepened tread pattern for greater traction.

Durability: Longevity to resist deterioration or wear from use in daily mobility (Barton et al., 2009; Byrne et al., 1998).

- Leather or canvas upper with welted or cemented outsole adhesion.
- Hard-wearing rubber or PU foam outsole and reinforcement of the toe box.

Security: Grip the footwear upper to the anatomy of the child's foot and ankle during mobility (Buldt & Menz, 2018; Ellis et al., 2022).

- Lace or doubled-over Velcro fastening extended along the mid and forefoot with some form of reinforced metal fastening eyelet allowing for application of tension for a secure fit.

Accessibility: Ability to easily don and doff footwear. This is a crucial point due to mobility-impaired children having a limited range of motion in the foot and ankle joints and having difficulty in angling the foot and ankle into footwear (Bakker et al., 1997; Ivanyi et al., 2015).

- Wide opening fastening and facings extended to the toe box of footwear.
- Pull tab on the heel collar.
- Other design considerations to improve accessibility are hook eyelet fastening at the topline, making for ease of fastening and unfastening.
- Zip fastenings at the Medial aspect of the rearfoot.

Comfort: Footwear design characteristics that are adapted to conform or are cushioned to reduce stress on the anatomy of the foot and ankle during wear and use (P. Q. X. Lim et al., 2015; Menz & Bonanno, 2021).

- Padded topline collar.
- Contoured collar to malleoli and Achilles tendon
- Padded tongue
- Padded inner lining of upper

It must be recognised that a comparison was made to one model of popular standard retail footwear, and there may be variation across different manufacturers similar to that seen across the OSSTF samples used in this study. Obtaining other samples of standard children's retail boots would have also allowed for a mean comparison analysis of statistical significance. Further qualitative, quantitative and functional assessment of OSSTF is required to substantiate these initial proposed functional purposes of their design characteristics (ISO, 2021; Tariq & Woodman, 2013; Wegener, Hunt, et al., 2011). However, observations presented within this study provide an initial framework for further qualitative studies to develop an expert consensus protocol to assess children's therapeutic footwear (Ellis et al., 2022; Keeney et al., 2010). Further substantiating these observations will be necessary for a clinician to assess the footwear's quality and function and provide informed advice to their patients (Menz & Bonanno, 2021; Morrison, Price, et al., 2018).

4.7. Conclusions

This preliminary qualitative and quantitative OSSTF analysis has identified several design characteristics that differ from a popular model of standard retail footwear. These include increased length and height of the heel counters and height of the topline. These identified characteristics of OSSTF may impart a stability effect on the child’s foot and ankle during standing and walking. The analysis has provided a preliminary hypothesised framework for the design features of OSSTF to inform further qualitative and quantitative assessment of the features and functional purpose of OSSTF design characteristics

5. Defining and grouping children's therapeutic footwear and criteria for their prescription: An international expert Delphi consensus study

Aspects of this chapter have been published:

Matthew Hill, Aoife Healy, and Nachiappan Chockalingam. 2021. "Defining and Grouping Children's Therapeutic Footwear and Criteria for Their Prescription: An International Expert Delphi Consensus Study." *BMJ Open* 11(8).

5.1. Background

As noted from the scoping review (Chapter 2) footwear is a fundamental common boundary between the ground and the foot in daily activities; it modifies forces and sensory stimulus with demonstratable effects on children's gait (Carlos González et al., 2005; Cranage et al., 2019; Wegener, Hunt, et al., 2011). Correspondingly footwear has been used both historically and in modern health care practice as an assistive aid for children with mobility impairment (Nester et al., 2018; Staheli & Giffin, 1980). However, has demonstrated in the scoping review (Chapter 2) footwear as a clinical intervention for children lacks a common understanding of terms and definition as to the specifics of its clinical role. The development of recognised terms, definitions and characteristics of a health care intervention afford an understanding of how it should work, the value it should provide, who should benefit, how to measure its success, what risks are present and what is and isn't included within the intervention (Craig et al., 2008; Owen, 2018). The scoping review (Chapter 2) demonstrated that numerous terms have been used in the literature concerning clinical footwear interventions, including orthopaedic shoes, rehabilitative boots, modified shoes, supportive shoes and special shoes. Additionally, there was no clear definition of the clinical role and outcome measures to classify and group the range of available children's footwear interventions. The results of the scoping review (Chapter 2) suggested therapeutic footwear as a potential overarching term to represent the myriad roles and designs of children's clinical footwear interventions, with three primary groupings of therapeutic footwear categorised according to common identified clinical roles. The groupings were corrective (footwear designed to bring about the correction of congenital skeletal lower limb alignment), accommodative (footwear designed to reduce stresses on children's foot deformity through the matching of footwear dimensions to the child's foot) and functional (footwear designed to improve dynamic gait parameters of mobility-impaired children, reducing pathological movements and facilitating typical walking patterns inclusive of stability).

Amongst the therapeutic footwear groupings suggested in the scoping review (Chapter 2) those that offered a stabilising role were the most studied. The systematic review (Chapter 3) has demonstrated potentially beneficial clinical outcomes to children with mobility impairment with increased velocity and lowered mediolateral excursions of the centre of mass in walking (Abd Elkader et al., 2013; Aboutorabi et al., 2014). Children's stability footwear may be bespoke or have uppers that come in a range of modular adaptions but are most commonly made to a manufacturer's standard stock model, which are termed off-the-shelf (Abd Elkader et al., 2013; ISO, 2017; Tyrrell & Carter, 2009). The body of research concerning off-the-shelf stability footwear has chiefly focused on its biomechanical effects. However, the specific standard design characteristics for this footwear that are requisite for stability were not clearly identified or consistently reported in the literature has highlighted in the scoping and systematic review (Chapter 2, Chapter 3). The lack of recognised characteristics of an intervention prevents a common understanding of how it should work clinically (Craig et al., 2008; Owen, 2018), and preclude a meaningful comparison throughout any evidence-based research as highlighted in the systematic review (chapter 3). Thus, it is important that a consensus understanding of design characteristics required to enhance stability during gait is obtained, from both a manufacturing and clinical perspective, for this footwear.

In respect to who may benefit from this intervention (Craig et al., 2008; Owen, 2018), there were seven childhood mobility impairments considered for OSSTF amongst the research identified through the scoping review (Chapter 2): cerebral palsy, pes planus, toe walking, Duchenne muscular dystrophy, spina bifida, Down syndrome and intoeing. However, both the systematic and scoping review (Chapter 2, Chapter 3) highlighted that there appeared to be no clear prescription criteria for the use of off-the-shelf stability footwear in these conditions. Specific gaps in prescription criteria included the stated clinical role, the grade/severity of the condition when this footwear should be used as a sole assistive aid or an adjunct to other aids such as Ankle Foot Orthoses (AFOs) and the suitable age range for intervention. In addition, the systematic review (Chapter 3) highlighted that there appears to be no standardised set of agreed outcome measures, both physical and psychosocial, to ascertain the effectiveness of this footwear. Identification and consensus agreement of outcome measures for both research and clinical practice allows for a unified measure of the effectiveness of an intervention, informing on value-driven health care and the development of a consistent evidence base (*ICHOM | Overall Pediatric Health Standard Set | Measuring Outcomes*, 2020).

Although terminology and means of grouping clinical footwear interventions as a whole have been suggested by a synthesis of the available research (Chapter 2, Chapter 3), a common understanding and usage of these terms would require an opinion on their practical application from experts who provide footwear to children with mobility impairment. Once the overall groupings and terminology of clinical footwear interventions have been established amongst experts in this area, it will be possible to identify and define individual intervention footwear categories for childhood mobility impairment, such as stability footwear. Off-the-shelf stability footwear appears to offer a beneficial effect on the broadest range of childhood mobility impairments as demonstrated in the scoping and systematic review (Chapter 2, Chapter 3). However, as stated in both reviews, a common understanding of the specifics and purpose of their design and the proposed clinical outcomes of this treatment is not apparent in the research (Chapter 2, Chapter 3).

Where there is contradictory or insufficient information, the ability to formulate effective clinical reasoning can be affected, here consensus surveys such as the Delphi offers a valid and reliable method of determining expert opinion to inform on these areas (Keeney et al., 2006, 2010; McPherson et al., 2018). Delphi surveys incorporate the collective opinion of a panel of experts fed back to the panel through a series of iterative rounds in an anonymised and controlled manner, with the underlying goal to achieve expert consensus on a certain issue where no agreement previously existed. This technique has been used successfully to achieve professional consensus on school footwear design (Davies et al., 2015) and the use of orthoses for mobility impairment (Dars et al., 2018; Hijmans & Geertzen, 2006). The only previous study relating to the synthesis of expert opinion on footwear interventions was performed by Staheli et al. in 1980 (Staheli & Giffin, 1980). This was a single round cross-section survey of practice and opinion that lacked the staged systematic approach of a Delphi survey and was restricted to the correction of musculoskeletal alignments that are mainly found in typically developing children. The survey did not consider the footwear terminology used, the purpose of the specific designs of footwear or any effects on children's gait (Staheli & Giffin, 1980). Establishing a common understanding of terms, definitions and groupings of clinical footwear as a whole, alongside design characteristics and prescription criteria for specific footwear groupings, may be achieved by conducting a Delphi consensus with experts in the field of clinical footwear provision and design. The consensus opinion may then be used to develop consistent terms and definitions for footwear interventions and prescription criteria and design characteristics for off-the-shelf stability footwear for children with mobility impairment.

5.1.1. Aims and Objectives

The overall aim of this study was to achieve an expert consensus on how to define and group clinical footwear interventions for children, with a further focus on the design characteristics and clinical prescription of off-the-shelf stability footwear for children with mobility impairment.

The objectives were:

- To establish expert consensus on the terms, definitions, and groupings of children's clinical footwear interventions, providing a consistent and common clinical understanding to identify and categorise the purpose of these footwear types as an assistive aid for children.

- To establish a consensus of expert opinion of the ideal design characteristics of off-the-shelf stability footwear and the purpose of these characteristics.

- To develop expert consensus recommendations for the prescription criteria and outcome measures for OSSTF.

5.2. Method

This Delphi consensus study followed the methodological and reporting recommendations suggested by Keeney, Hasson and Mckenna (Hasson et al., 2000; Hasson & Keeney, 2011). The development and purpose of this survey were informed by the scoping and systematic reviews performed in Chapters 2 & 3 and benchtop analysis of design characteristics of a range of off-the-shelf footwear proposed to offer a stabilising effect on mobility impaired children (Chapter 4).
Ethical approval was sought and gained from Staffordshire University Ethics Committee. All panellists provided written informed consent to participate in this study.

5.2.1. Identifying Panellists

Experts were recruited by the purposeful sampling of individuals meeting specific criteria:

- Registered practitioner in healthcare or clinical footwear manufacture.

- ≥10 years of practice in clinical footwear provision/manufacture.

- ≥25% clinical caseload involving the provision of footwear interventions to children with mobility impairment or ≥ 25% of their workload involved with the design or manufacture of footwear intended for therapeutic use in children with mobility impairment.

Recruitment was initially through professional networks of the research team and subsequently recruited experts were asked to identify additional experts who they felt met the criteria for this study. A multinational sample of professionals from clinicians, researchers and those involved in the footwear industry was sought to ensure a spectrum of opinions were included. Although there are no agreed definitions for an effective size convention ranging from 10 – 100 panellists within the literature (Akins et al., 2005), researchers have suggested a sample size of 10 will provide a diversity of expert opinion (Novakowski & Wellar, 2008).

5.2.2. Contacting experts

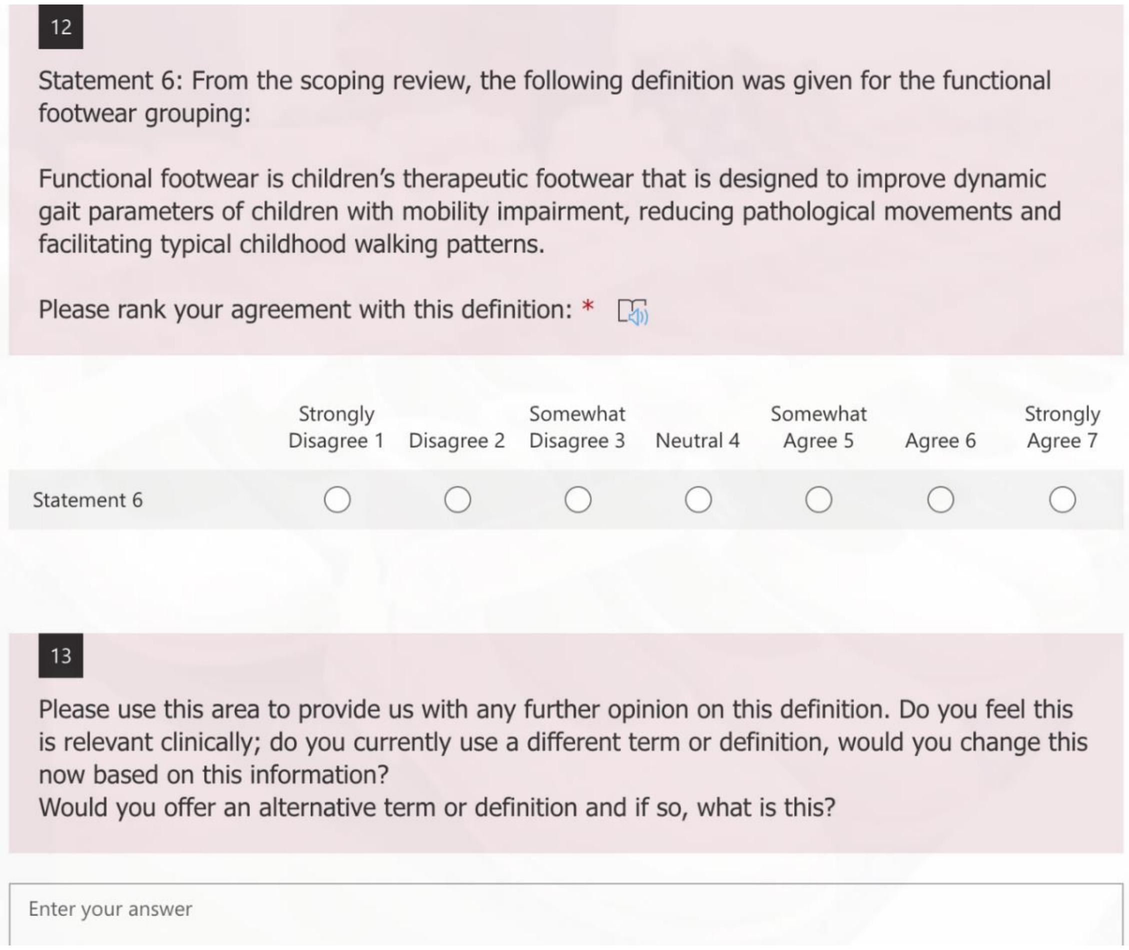
Experts were contacted with the information sheet by email, with consent and a participant professional characteristic survey captured by Microsoft® Forms.

5.2.3. Questionnaire design

The study took the form of a modified Delphi (Keeney et al., 2010), the first round was informed by scoping and systematic reviews of research in relation to children's clinical footwear interventions (Chapter 2, Chapter 3) and benchtop analysis of design characteristics of a range of off-the-shelf footwear proposed to offer a stabilising effect on mobility impaired children (Chapter 4). This approach allowed the development of informed questions from the available evidence. The survey consisted of closed-ended ranked and option questions, with ranked questions using a seven-point Likert scale. Open-ended questions were also provided to explore the panellists' opinions on the statements and questions posed and to allow them to offer alternatives or raise further salient items in relation to children's clinical footwear interventions. The first round of the survey, therefore, captured qualitative and quantitative data. This generated a combined synthesis of the current literature evidence base in relation to children's clinical footwear interventions alongside that of the experts' opinions from working in the area of clinical footwear provision.

The survey was designed by the first author with calibration and modification of questions amongst all authors. The survey was also piloted on an expert in clinical footwear provision to ensure the questions were appropriately framed and phrased to avoid ambiguity or multiple events within any question (Glenn & Gordon, 2009). The first round consisted of three sections:

Section 1 asked the panellists for their opinion on consistent terms, definitions, and groupings of clinical footwear interventions for children with mobility impairment. An example of the type and structure of the questions is provided in Figure 5-1, with the full section 1 survey rounds 1-3 available in Appendix 4.1.



12

Statement 6: From the scoping review, the following definition was given for the functional footwear grouping:

Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns.

Please rank your agreement with this definition: *

	Strongly Disagree 1	Disagree 2	Somewhat Disagree 3	Neutral 4	Somewhat Agree 5	Agree 6	Strongly Agree 7
Statement 6	○	○	○	○	○	○	○

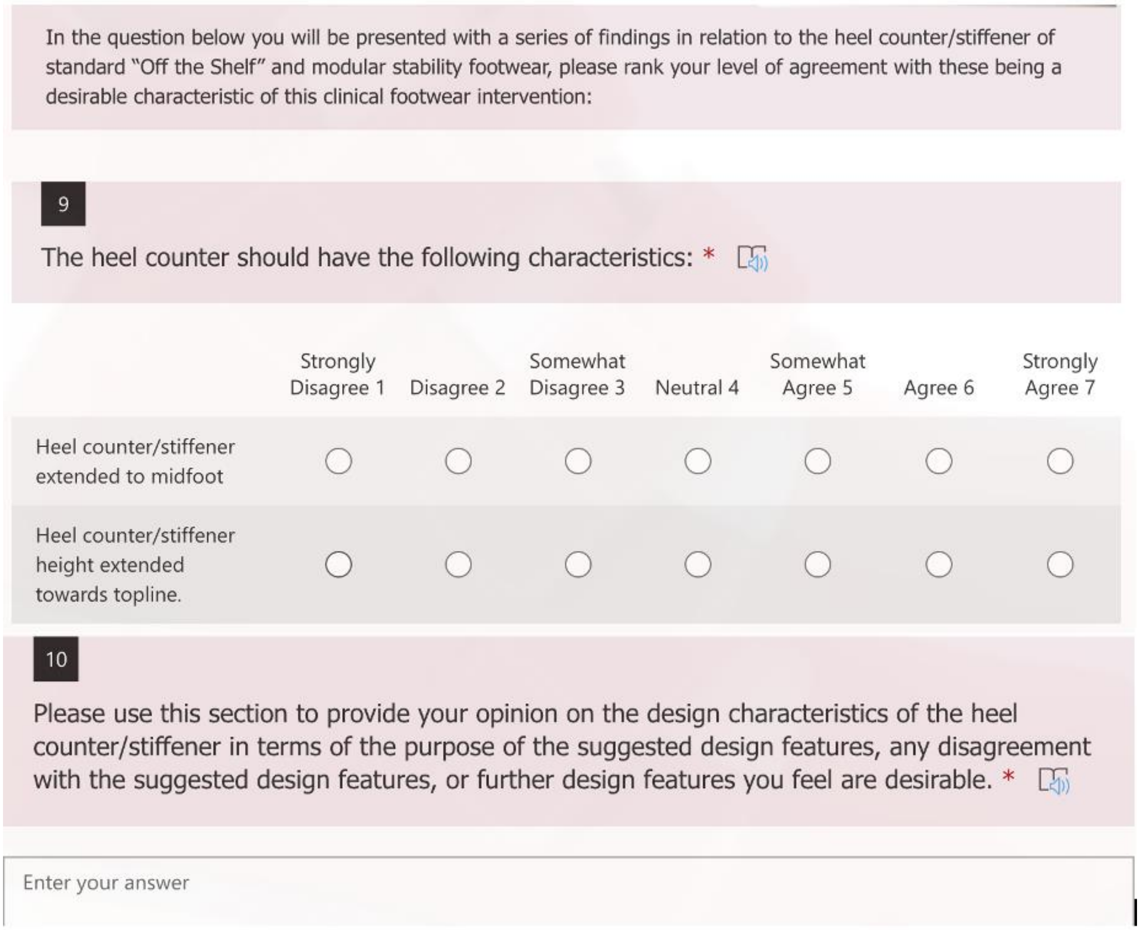
13

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term or definition, would you change this now based on this information?
Would you offer an alternative term or definition and if so, what is this?

Enter your answer

Figure 5-1 An example of a question from section 1 exploring consistent terms and definition of clinical footwear interventions. (indicates required answer)*

Section 2 asked the panellists for their opinion on the ideal design characteristics of off-the-shelf stability footwear and the purpose of these characteristics. An example of the type and structure of the questions is provided in Figure 5-2, with the full Section 2 survey rounds 1-3 available in Appendix 4.2.



In the question below you will be presented with a series of findings in relation to the heel counter/stiffener of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

9

The heel counter should have the following characteristics: *

	Strongly Disagree 1	Disagree 2	Somewhat Disagree 3	Neutral 4	Somewhat Agree 5	Agree 6	Strongly Agree 7
Heel counter/stiffener extended to midfoot	○	○	○	○	○	○	○
Heel counter/stiffener height extended towards topline.	○	○	○	○	○	○	○

10

Please use this section to provide your opinion on the design characteristics of the heel counter/stiffener in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Enter your answer

Figure 5-2 An example of a question from section 2 exploring recognised design characteristics of children's off-the-shelf stability footwear. (indicates required answer)*

Section 3 asked the panellists for their opinion on the prescription criteria of issuing commercially available off-the-shelf stability footwear in a range of mobility impairments and the outcome measures to be used to assess the effectiveness of this footwear. An example of the type and structure of the questions is provided in Figure 5-3, with the full section 3 survey rounds 1-3 available in Appendix 4.3.

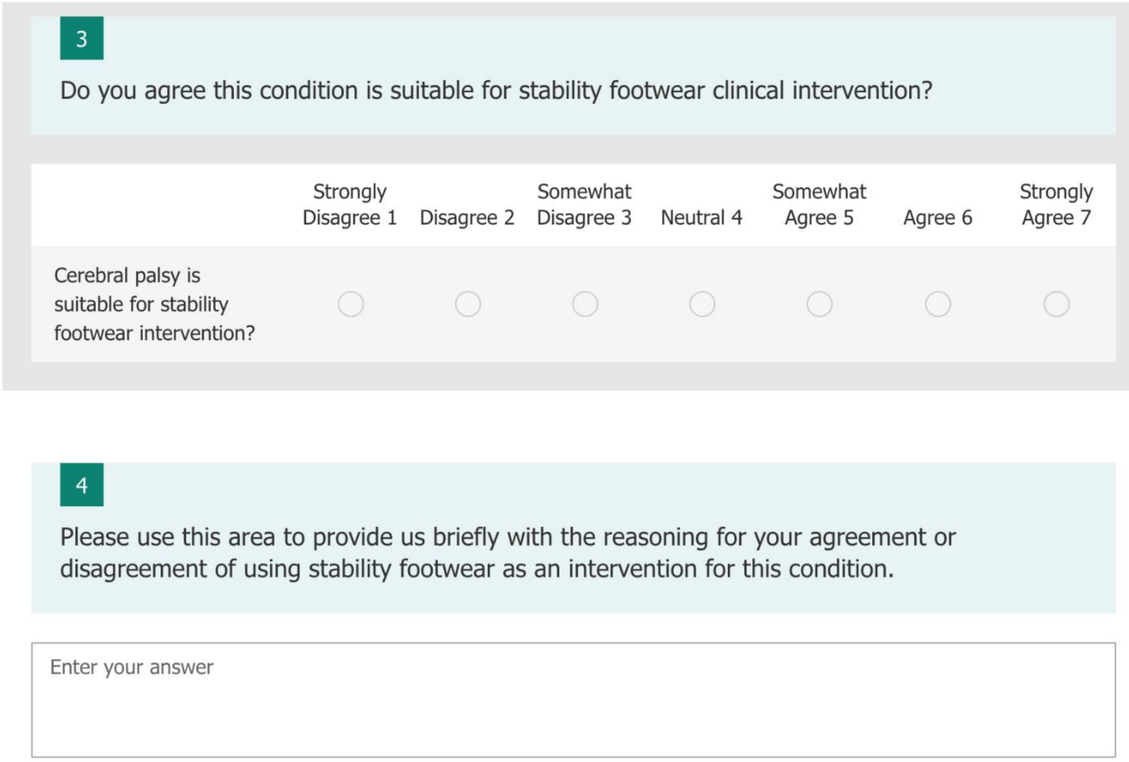


Figure 5-3 An example of a question from section 3 exploring prescription criteria for the provision of children's off-the-shelf stability footwear.

The panellists were given instructions on how to complete the survey in the introduction of each section.

5.2.4. Distribution

The survey was distributed amongst panellists electronically via Microsoft Forms. Panellists were reminded to complete the survey one week before the deadline. Late responders were followed up and offered an appropriate extension if required.

5.2.5. Analysis of Results

Analysis followed a standard mixed-method approach for Delphi consensus surveys and employed both qualitative and quantitative analysis. The combined findings were used to inform the development of subsequent rounds of Delphi (two and three) in addition to the final results.

Analysis of open-ended questions involved an inductive themed content analysis framework performed by the author (Burnard, 1991). The process involved the identification of statements that were the same or could be constructed to mean the same thing. These statements were grouped together, and themes developed around similar statements. Once statements were grouped under a common theme, a decision was made amongst the research team as to whether these themes should be collapsed into one statement to be presented to the Delphi panel in the subsequent round. Unique statements that did not fall into any common theme were kept as the original statements. The wording of all statements was assessed by the research team for potential multi-clauses and ambiguity.

The grouped themed and unique statements were presented to the panellists alongside a summary of the collective panellists' reasoning in round 2 and 3. These were in a series of ranked Likert scale questions or options alongside the original statements from round 1 or 2. Rounds 2 and 3 followed the same format of round 1 with three sections (Appendix 4.1, 4.2, 4.3).

Descriptive statistics: central tendency and dispersion of the responses (Median analysis, IQR) and % frequency to the ranked questions were fed back to the panellists in round 2 and 3 for an estimation of the general response of the other expert panellists. (Appendix 4.1, 4.2, 4.3). The quantitative values were also recorded for consistency analysis across the rounds.

5.2.6. Consensus:

There is no agreed guidance on consensus but is often achieved through generating a pre-determined percentage level of consensus of ranked questions or panellists preferred option (frequency) (Keeney et al., 2006, 2010). The range of pre-set agreement is variable amongst Delphi studies; however, a value of 75% is a commonly reported value (Diamond et al., 2014) and the one chosen to define consensus amongst the recruited panel in the present study. Statements would reach consensus when there was 75% or greater frequency of response for a preferred option or ranked questions of “agree” to “strongly agree”.

5.2.7. Cut Off:

The Delphi was set *a-priori* to run over three rounds or if there was a greater than 30% drop off of panellists.

5.3. Results

Thirty panellists were contacted in January 2020, of which 24 consented to participate; 6 participants withdrew from the study prior to commencement of the first round. Eighteen panellists participated in Round 1; the panel consisted of orthotists, podiatrists, and a physiotherapist with a range of experience and roles in clinical footwear provision for children, including direct patient contact, education, research, and commercial sales and manufacture. The international panel comprised of panellists from the U.K., Australia, and the U.S.A. a full breakdown of the panellists' characteristics are provided in (

Table 5-1). For this sample size, consensus was achieved with 14 of the 18 panellists for Round 1 (75% of panellists).

Table 5-1 Participant Characteristics

Participant Characteristics		
Sex	7 Females 11 Males	39% 61%
Experience with clinical footwear provision for children	Median 18 Years	IQR 11.75
% Workload dedicated to either: assessment, manufacture or commercial distribution of footwear interventions for children with mobility impairment	Median 36.5%	IQR 25%
<u>Profession:</u>		
Orthotist	10	55.6%
Physiotherapist	1	5.6%
Podiatrist	7	38.8%
<u>Professional Role</u>		
Clinician	5	27.8%
Clinician; Researcher	3	16.7%
Clinician; Education	3	16.7%
Clinician; Education; Researcher	3	16.7%
Clinician; Commercial (Sales and Manufacture)	2	11.1%
Clinician; Researcher; Commercial (Sales & Manufacture)	1	5.6%
Clinician; Education; Commercial (Sales & Manufacture)	1	5.6%
<u>Highest qualification</u>		
PhD/Professional Doctorate	5	27.8%
Master's Degree	5	27.8%
Bachelor's Degree	6	33.3%
Professional Diploma	2	11.1%

Of the 18 panellists, 16 completed all rounds of the Delphi survey resulting in an 11% drop off from the initial round (Figure 5-4). For these sample sizes, consensus was achieved with 13 of the 17 panellists for Round 2 and 12 of the 16 panellists for Round 3 (75% of panellists). From the initial 45 statements (11 in section 1, 27 in Section 2 and 7 in Section 3), a further 238 statements were developed or modified from panellist feedback (Figure 5-4) for a total of 283 statements. Consensus agreement amongst the panel was reached on a total of 150 statements (**Error! Reference source not found.**). The statements for each section inclusive of the original, modified and those that reached consensus are found in supporting information files (Appendix 4.4, 4.5, 4.6). The results for each section are presented and discussed separately.

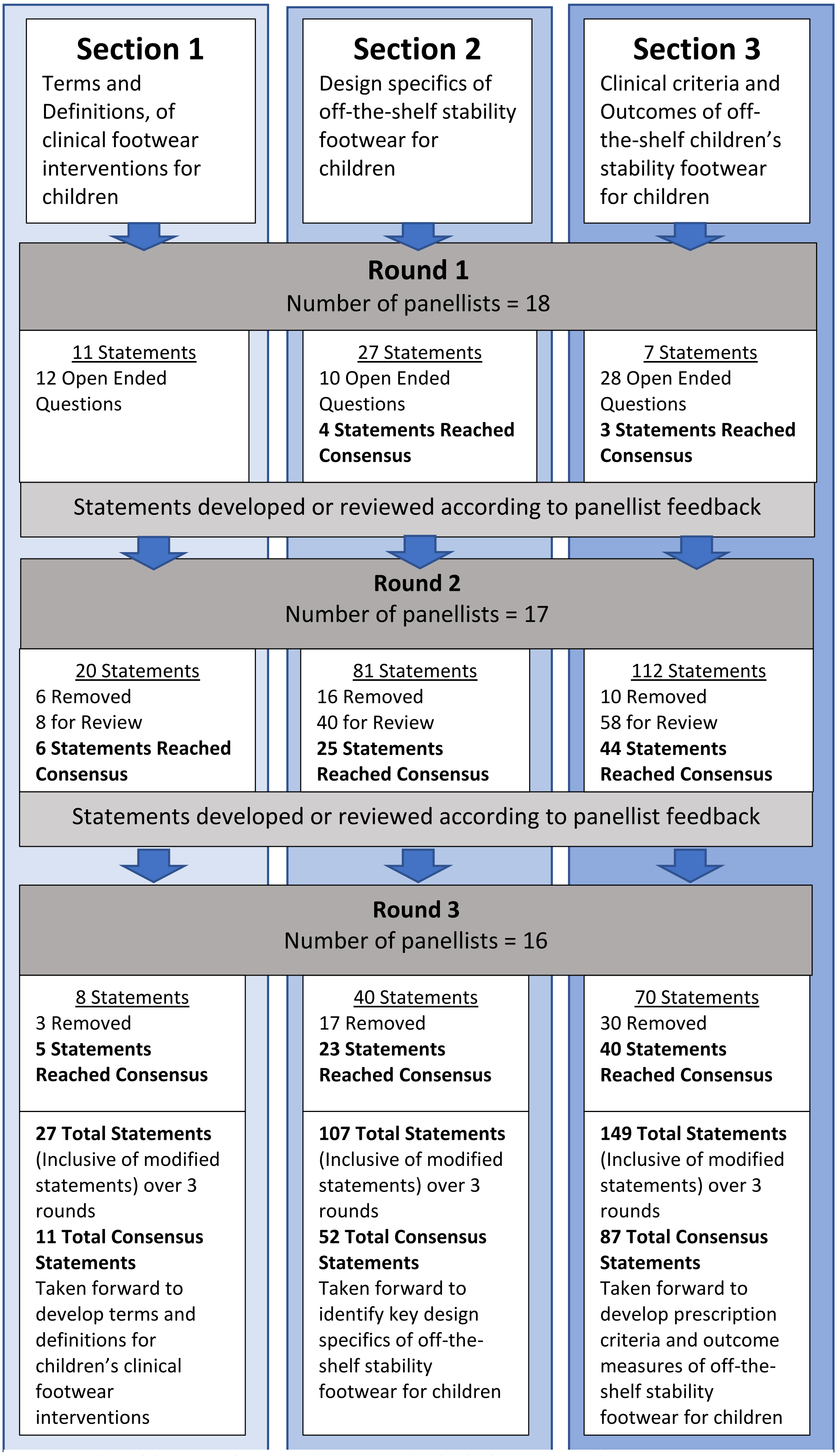


Figure 5-4 The Delphi survey three-round process and individual sections results.

5.3.1. Section 1

The 11 consensus statements from section 1 were taken forward to establish consistent terms and definitions to broadly group and categorise children's clinical footwear interventions. There was a considerable majority consensus of the panel (81% agreement) who favoured therapeutic footwear as the overarching term for children clinical footwear interventions (Figure 5-5). This term was felt by the majority of the panel to reflect the holistic aspect of footwear interventions on childhood mobility rather than be limited to aspects of aligning body structure that would be suggested by "orthopaedic" and "orthotic". A broad overarching definition was established by panellists (82% agreement) for these interventions as:

"Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children."

This definition comprised of the scope of the potential role of footwear as a clinical intervention whilst also recognising that designs may incorporate specific therapeutic footwear or standard shoes that are adapted to meet a clinical purpose. Groupings of footwear fell under the overarching term therapeutic footwear (100% agreement) and panellists felt they should be grouped and categorised according to intended clinical outcomes of the components of the footwear (100% agreement). This was modified from the suggested method of groupings from the scoping review [6] in which the groupings assigned footwear as an individual design. The current grouping recognised that footwear might have more than one clinical role, i.e., footwear may have both a direct functional component on gait and an accommodative component of the child's foot deformity. The main groupings of therapeutic footwear were those offered in Round 1, which were taken from the scoping review (Chapter 2): Accommodative, Corrective and Functional (Figure 5-5). However, the definitions were modified by panellist's feedback with all achieving consensus in the second round:

"Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot." (76% agreement)

"Corrective footwear is footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children. This may be secondary to a primary corrective measure such as serial casting or surgery." (82% agreement)

"Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children." (76% agreement)

Panellists felt that functional footwear could be placed into subgroupings dependent on the design and intended clinical outcomes of the footwear similarly to that suggested for the main groupings of therapeutic footwear (76% agreement). The panellists favoured the subgrouping of stability footwear suggested from the scoping review provided in Round 1 (94% agreement) (Figure 5-5). However, the definition was modified by panellists' feedback and did not achieve consensus until the third round:

"Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle." (94% agreement)

Panellists felt that the separate subgroupings of lift (raise*), rounded bottom (rocker bottom*) suggested from the scoping review in Round 1 should be considered to fall collectively under one subgrouping. Therefore, a new separate subgrouping of functional footwear adapted sole was suggested from panellist feedback, this reached consensus in round 2 (76% agreement) (*preferred alternative terminology suggested by the majority of panellists in round 1) (Figure 5-5). This was defined as:

"A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children."

From panellist feedback, the subgrouping of adapted sole recognised that there is a range of sole adaptions offering varied functional roles broader than stability. However, it was beyond the scope of the current Delphi to fully categorise and define the many sole adaptions that could fall into this subgrouping. Further detail on panellist opinion in the development of the subgrouping adapted sole may be found in Appendix 4.4.

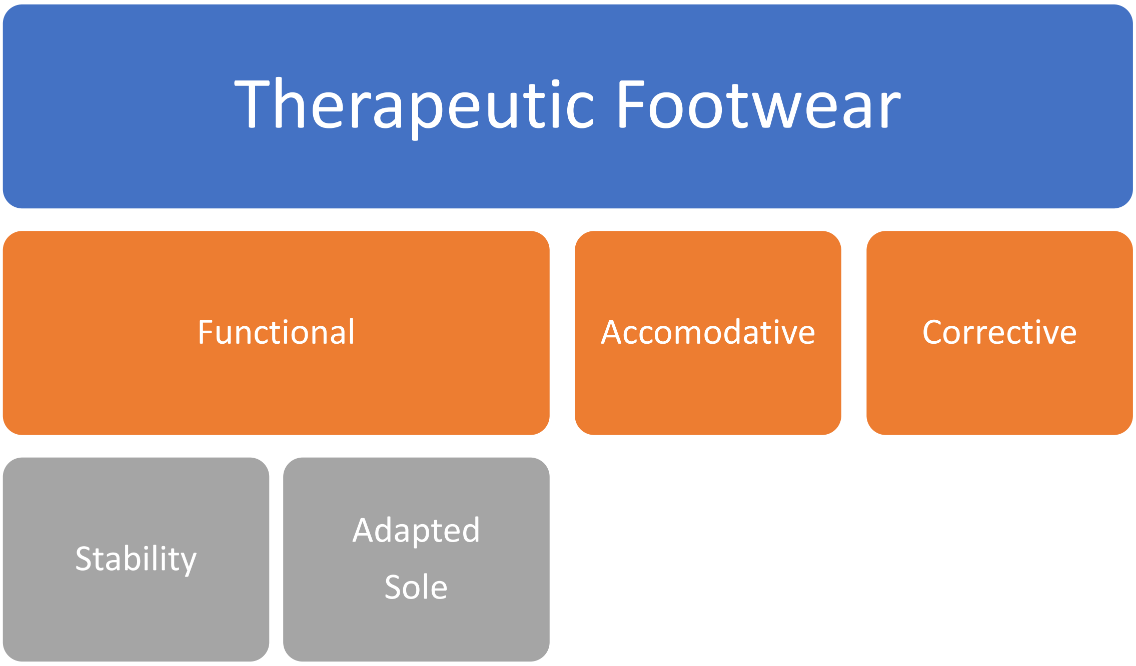


Figure 5-5 Terms and groupings of clinical footwear interventions for children derived from Section 1.

5.3.2. Section 2

The 52 consensus statements from section 2 concerning the specific ideal design characteristics and purpose of OSSTF were distributed in nine regions of the shoe: topline, upper, facings and fastenings, heel counter/stiffener, heel, inlay, sole unit, sole rocker, in addition to overall consideration of the footwear's mass (Table 5-2). Three key themes emerged from panellist feedback concerning the ideal design characteristics and their purpose those of stability, ergonomics, and aesthetics (Table 5-2). Stability was felt to be achieved by material stiffens of the heel counter (81% agreement), which may be assisted by an increased topline height in offering mediolateral stability to the foot and ankle (81% agreement). Panellists also felt that the fitting of the shoe inlay/insole to the child's heel should not be overlooked to increase vertical ground reaction forces in this area in addition to the firm anchorage of the counter to the welt and outer sole (88% agreement) (Table 5-2). Although a proprioceptive effect of the heel counter and topline was suggested by some panellists, full consensus (69% agreement) could not be achieved as a number of panellists were not convinced that the current evidence base supported the design components influence on proprioception. Other design characteristics that were thought to impart stability and reached consensus were the:

width of the heel in relation to the upper (87% agreement), stiffness of the outsole at the midfoot and rearfoot (88% agreement), tread depth of the outsole (87% agreement), lace fastenings (81% agreement) and leather upper of high tensile strength properties (93% agreement). The overall mass of the shoe was not thought to improve the stability properties of the shoe; it was, however, proposed and achieved consensus as a potential cause of instability in the swing phase of gait if too heavy.

The second key theme concerning the ideal design characteristics of OSSTF was in relation to ergonomics**.** Ergonomic aspects considered the fit and comfort of the shoe during wear and the ease in which the shoe could be donned and doffed on a child's foot with limited mobility. Originally in round, 1 specific statements were presented to the panellists in relation to the design of this footwear, for example, *"Extended topline height above the ankle." and "The fastening should have the following characteristics: Lace".* However, panellist opinion and feedback established a consensus preference to a pragmatic range of ergonomic options based on the child's ability, age, and clinical need over the course of rounds 2-3, for example:
"The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs." (93% agreement), and *"The Fastenings should be Optional dependent on patient's ability and desired goal (e.g., Velcro for limited hand dexterity, lace for greater stability)"* (93% agreement).

Panellists felt that the upper (93% agreement) and heel counter (80% agreement) should be available in a range of dimensions for any given size of OSSTF to accommodate a child's foot and ankle anatomy. The material of the upper should come in a range of materials to include breathable and wipeable fabrics for warm climates and issues with continence (100% agreement). The topline should be padded at the collar (88% agreement) and contoured to the ankle anatomy (80% agreement) to minimise mechanical stress to this region. Facings should be offered extended to the toe box to allow easy access (donning and doffing of the footwear) for children with limited movement of the foot and ankle (93% agreement).

Fastening should be in both lace and Velcro fastening to accommodate children's manual dexterity and allow a degree of independence (93% agreement). The mass of the footwear should be the lowest reasonable to reduce the physiological cost of walking (100% agreement). However, it was recognised that older children might require heavier footwear to account for increased mobility or enhanced stability requirements such as a stiffened outsole or extended heel counter that may additionally increase the footwear's mass (93% agreement). A consensus of the panellist was reached concerning the inlay/insole of off-the-shelf stability footwear, in that contouring at the heel improves rearfoot fit (81% agreement), and the inlay should be removable and thick enough to represent replacement by a possible adjunct orthosis (100% agreement). However, the specifics of the design in relation to contouring to the arch and heel failed to reach a consensus (63% agreement). Similarly, the purpose of a forefoot rocker to facilitate forward progression in gait and not affect the swing phase of gait reached a consensus (93% agreement). However, the standard design requirements of the rocker did not reach a consensus (56% agreement). Aesthetics of the footwear was proposed by the panellists in recognition of the psychosocial needs of children and felt that the visual appeal of the shoe was important to facilitate social interaction with peers with this statement receiving 100% agreement amongst the panel on initial consideration in round two.

Table 5-2 Themes of the ideal design specifics and purpose of off-the-shelf therapeutic stability footwear derived from Section 2.

Theme	Region	Dimension/Manufacture	Material/Properties
Stability	Heel counter/stiffener	Extended to midfoot and towards topline Robust anchorage to welt and outsole	Stiffened material
	Topline	Extended above ankle To assist leverage of heel counter	Leather
	Outer sole	Wider than heel cup of upper Range of tread depths Deepened tread for uneven terrain Shallower for indoor use to avoid catching on the walking surface Minimal heel forefoot differential to maximise stability	Stiffer at the heel and midfoot Hard Wearing Sole material
	Upper		Leather with stiffened material properties
	Inlay/Insole	Contoured to cup the child's heel to improve the rearfoot fit	
	Fastenings/Facings	Facings extended to Midfoot	Lace fastenings
	Forefoot rocker	Should not be so large to affect ground clearance in swing	
Ergonomics	Heel counter/stiffener	Range of available extensions to accommodate ankle anatomy	
	Topline	Padded collar and contoured to ankle anatomy	
	Outer sole	Flexibility focused at the toe flex line	
	Upper	Range of available dimensional adaptions to accommodate foot anatomy Tongue adapted to avoid slippage under fastenings Tongue length to provide comfort from fastenings	Range of materials to allow breathability in warm climates Wipeable material dependent on user's continence
	Fastening/Facings	Facings extended to toe box to allow greater access to footwear for limited foot and ankle mobility	Velcro or lace dependent on the patient's dexterity
	Inlay/Insole	Contoured to cup the child's heel to improve rearfoot fitting Deep enough to simulate potential prescriptive orthoses	
	Footwear kept to the lowest reasonable mass to reduce the physiological cost to a child in mobility		
Aesthetics	Upper	Range of colours	Range of material

5.3.3. Section 3

The 87 consensus statements concerning children's mobility impairments suitable for OSSTF resulted in consensus recommendations for the prescription criteria and outcome measures for five of the initial seven conditions: Cerebral Palsy (92% agreement), Mobile symptomatic pes planus (86% agreement), Duchenne Muscular Dystrophy (92% agreement), Spina Bifida (80% agreement) and Down Syndrome (85% agreement) (Table 5-3,

Condition	Indications for treatment	Sole or adjunct treatment
Spina Bifida	Where mediolateral stability is required for standing and walking	**Adjunct** Used simultaneously with: 1) Foot orthoses to assist foot and ankle stability in sacral leve 2) AFO's and walking frames to assist walking and standing in Myelomeningocele) 3) HKAFO or KAFO and walking frames to assist walking and st (Meningocele, Myelomeningocele).
Symptomatic Mobile Pes Planus	Secondary line intervention to improve mediolateral stability in walking **where foot orthoses** have not resolved associated symptoms.	**Adjunct** Used simultaneously with foot orthoses in: 1) children with significant foot and ankle instability associate 2) children with insufficiency of posterior tibialis function 3) children with conditions associated with motor delay
AFO: Ankle Foot Orthoses; GMFCS: Gross Motor Functioning Classification Score; HKAFO: Hip Knee Ankle F * Other assistive devices to include AFO's, crutches, foot orthoses, standing frames and walking frames. † Adjunct AFO with stability footwear intervention requires a review of prescription of the sole to address a knee hyperextension in midstance**.**		

Table 5-4). Five further conditions were suggested and reached a consensus amongst the panel: Charcot Marie Tooth (92% agreement), Hypermobility (Ehlers Danlos Type) (92% agreement), Developmental Coordination Disorder (100% agreement), Rett's Syndrome (80% agreement), Chronic Lateral Ankle Instability (77% agreement) (Appendix 4.6). However, the prescription criteria and outcome measures for the treatment of these further conditions were unable to be explored without further extending the Delphi survey and risking panellist fatigue (Keeney et al., 2006).

In relation to the prescription criteria for OSSTF, there were three areas that reached a general consensus for the five conditions:

1) The footwear provides mediolateral stability at the foot and ankle in walking and standing. Meaning it could act as both a walking aid and transfer aid (range 79-88% agreement) (Table 5-3).

2) The provision of OSSTF should only be issued to children with mobility impairment after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications and with clear clinical outcomes (range 86-92% agreement). Panellists voiced their concern that this footwear had been historically uncritically prescribed in the conditions exampled. Panellists felt foot orthoses serving similar function are less obtrusive and potentially cheaper. Consequently, a consensus (86% agreement) was reached that OSSTF should only be used as a secondary line of intervention for symptomatic pes planus where foot orthoses had failed to resolve symptoms.

3) In relation to the suitable age range for OSSTF footwear intervention, a pragmatic approach to initiation and endpoints reached consensus in that it should be based on the functional ability and the mobility needs of the child rather than a specified age (range 77-94% agreement).

Other areas suggested by panellists were concerning the use of this footwear as a sole aid or adjunct to other assistive devices. Most indications for the use of OSSTF were as an adjunct to other assistive devices (range 77-92% agreement) to aid mediolateral stability in walking and standing (Table 5-3). These other assistive devices included foot orthoses, AFO's (ankle foot orthoses), KAFO's (knee ankle foot orthoses), HKAFO (hip knee ankle foot orthoses), and walking and standing frames. Indications for OSSTF as a sole aid were limited to low-grade cerebral palsy with no tonal issues (81% agreement) and the early walking stage of individuals with Down syndrome (94% agreement). It was also noted by panellists that the foot anatomy of Down syndrome children presents a challenge with footwear fitting. Therefore, the practitioner should consider available last adaptions to accommodate the dimensions of these children during prescription (85% agreement).

Two of the seven originally proposed conditions suggested from the scoping review toe walking and intoeing failed to reach any consensus statements concerning the suitability and clinical indications for stability footwear intervention. However, it must be noted that idiopathic toe walking moved closer towards consensus statements for clinical indications (range 60-67% agreement) than intoeing (range 25-44% agreement).

Outcome measures proposed by the panellist were broadly aligned to – biomechanical, physiological, gross motor proficiency and quality of life measures. In relation to biomechanical measures, ankle range of motion reached consensus as an outcome measure for cerebral palsy, symptomatic pes planus, and Duchenne muscular dystrophy (range 80-88% agreement). Spatiotemporal outcome measures including walking velocity, six-minute walk test and Timed Up and Go reached consensus amongst the five conditions (range 77-90% agreement). Kinematic outcome measures also achieved consensus amongst the five groupings (range 77-90% agreement); these were in relation to optimising gait movement patterns of the foot and ankle against disease-specific scores, Edinburgh Gait Score and Hoffer Ambulation Score or normal available data sets. None of the suggested kinetic outcome measures achieved a consensus level of agreement (range 60-67% agreement). Physiological outcome measures concerning cardiovascular and metabolic exertion were proposed and reached consensus (range 75-91% agreement) for cerebral palsy, spina bifida and mobile pes planus. Outcome measures based on the child's ability to perform activities via measures of gross motor skills reached a consensus amongst the five conditions (range 75-88% agreement) (

Condition	**Indications for treatment**	**Sole or adjunct treatment**
Spina Bifida	Where mediolateral stability is required for standing and walking	**Adjunct** Used simultaneously with: 1) Foot orthoses to assist foot and ankle stability in sacral leve 2) AFO's and walking frames to assist walking and standing in Myelomeningocele)

		3) HKAFO or KAFO and walking frames to assist walking and st (Meningocele, Myelomeningocele).
Symptomatic Mobile Pes Planus	Secondary line intervention to improve mediolateral stability in walking **where foot orthoses** have not resolved associated symptoms.	**Adjunct** Used simultaneously with foot orthoses in: 1) children with significant foot and ankle instability associate 2) children with insufficiency of posterior tibialis function 3) children with conditions associated with motor delay
AFO: Ankle Foot Orthoses; GMFCS: Gross Motor Functioning Classification Score; HKAFO: Hip Knee Ankle Fo * Other assistive devices to include AFO's, crutches, foot orthoses, standing frames and walking frames. † Adjunct AFO with stability footwear intervention requires a review of prescription of the sole to address a knee hyperextension in midstance.		

Table 5-4). Consensus was also reached by the panel in that suitability of physical outcome measures must consider the stage/grade of Duchenne muscular dystrophy and the capability of the child to perform the tasks (88% agreement). Quality of Life (QoL) measures, pain and activities of daily living outcome measures for off-the-shelf stability footwear intervention reached consensus agreement for all five conditions to a relatively high level (range 79–100% agreement). With the majority of QoL outcome measures reaching consensus on initial consideration in round 2.

Table 5-3 Prescription Criteria for Off-the-shelf Stability Therapeutic Footwear

Condition	Indications for treatment	Sole or adjunct treatment
Cerebral Palsy	Where mediolateral stability is required for standing and walking	**Sole aid** maybe used to assist both foot and ankle walking stability in children with GMFCS 1 and no significant tonal issues. **Adjunct** Used simultaneously with other assistive aids* to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues Used simultaneously with other assistive aids* to assist standing in non-ambulant children GMFCS 4
Down Syndrome		**Sole aid** In pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones **Adjunct** Used simultaneously with: 1) Foot orthoses to assist walking in individuals with ankle instability 2) AFO's to assist walking in individuals with knee instability
Duchenne Muscular Dystrophy		**Adjunct** Used simultaneously with: 1) Foot orthoses to assist foot and ankle stability in early ambulatory stages 2) AFO's and walking frames to assist walking in late ambulatory stages 3) AFO's and standing frames to assist standing and transfer in early non-ambulatory stages
AFO: Ankle Foot Orthoses; GMFCS: Gross Motor Functioning Classification Score; HKAFO: Hip Knee Ankle Foot Orthoses * Other assistive devices to include AFO's, crutches, foot orthoses, standing frames and walking frames. † Adjunct AFO with stability footwear intervention requires a review of prescription of the sole to address any potential exacerbation of knee hyperextension in midstance**.**		

Table 5-3 Prescription Criteria for Off-the-shelf Stability Therapeutic Footwear Continued

Condition	Indications for treatment	Sole or adjunct treatment
Spina Bifida	Where mediolateral stability is required for standing and walking	**Adjunct** Used simultaneously with: 1) Foot orthoses to assist foot and ankle stability in sacral level 1 (Meningocele) 2) AFO's and walking frames to assist walking and standing in lumbar level 4-5 (Meningocele, Myelomeningocele) 3) HKAFO or KAFO and walking frames to assist walking and standing in lumbar level 1-3 (Meningocele, Myelomeningocele).
Symptomatic Mobile Pes Planus	Secondary line intervention to improve mediolateral stability in walking **where foot orthoses** have not resolved associated symptoms.	**Adjunct** Used simultaneously with foot orthoses in: 1) children with significant foot and ankle instability associated with tripping and falling 2) children with insufficiency of posterior tibialis function 3) children with conditions associated with motor delay
AFO: Ankle Foot Orthoses; GMFCS: Gross Motor Functioning Classification Score; HKAFO: Hip Knee Ankle Foot Orthoses * Other assistive devices to include AFO's, crutches, foot orthoses, standing frames and walking frames. † Adjunct AFO with stability footwear intervention requires a review of prescription of the sole to address any potential exacerbation of knee hyperextension in midstance**.**		

Table 5-4 Clinical outcome measures for off-the-shelf Stability Therapeutic Footwear in children with mobility impairment

Biomechanical	Physiological	Gross Motor Proficiency	Quality of Life Measures
Kinematic Optimising gait movement patterns (foot and ankle) Edinburgh Gait Score† Hoffer Ambulation Score‡ <u>*Static Ankle Range of Motion:*</u> Passive§: Measured with the knee flexed and extended within the child's limits Weightbearing Lunge|: Provided child can safely stand and get the heel to the ground **Spatiotemporal:** Walking velocity TUG 6MWT 10 Metre Walk Test	Physiological Cost Index¶ Perceived Exertion¶ (BORG)	Number of falls BOT2# Hoffer Ambulation Score‡ Four square step test	Paediatric pain scale Daily mobility and social interaction
6MWT Six-Minute Walk Test, TUG, Timed Up and Go. *Outcomes must consider the stage/grade of the condition and the capability of the child to perform the tasks. † Specific Outcome for Cerebral Palsy ‡ Specific Outcome for Spina Bifida § Range of Motion Outcome for Cerebral Palsy and Symptomatic Mobile Pes Planus | Range of Motion Outcome for Cerebral Palsy, Symptomatic Mobile Pes Planus and Duchenne Muscular Dystrophy ¶ Physiological Outcomes for Cerebral Palsy, Symptomatic Mobile Pes Planus and Spina Bifida # Gross Motor Proficiency Outcome for Cerebral Palsy, Symptomatic Mobile Pes Planus, Down syndrome			

5.4. Discussion

Despite the historical and relatively common usage of clinical footwear interventions in children with mobility impairment (Chapter 2), there has been a lack of common understanding of how to define and characterise this intervention. The collective opinion of the expert panel and the consensus formed through the inductive and iterative process of this study allowed novel ideas to be synthesised alongside previously published information. Clinical footwear interventions for children with mobility impairment reached a common understanding and were collectively grouped and defined under the overarching term therapeutic footwear. This allowed the identification and categorisation of one of the more potentially effective of these interventions, stability footwear (Chapter 3) as a subgrouping of functional footwear. The process also provided a consensus understanding of the ideal design characteristics for OSSTF and how this intervention may be used in a range of childhood mobility impairments. As stated, only one previous study had explored expert opinion on footwear as a clinical intervention for children (Staheli & Giffin, 1980). The current study has provided a more detailed synthesis of expert opinion providing consensus on terms and definitions for children's clinical footwear interventions in addition to identifying the specifics and purpose of OSSTF design and criteria for clinical prescription for children.

Section 1 sought to obtain consensus on definitions terms and groupings for clinical footwear interventions in children. Although this represented the smallest section in the total number of statements and open-ended questions in round 1, it received the most detailed and rich comments for qualitative analysis, underlining the potential contentiousness of this section. However, this was the only section that received a consensus statement for each area presented to the panel. It is highlighted that a consistent language of terms and definitions is required in health care practice to improve interprofessional communication, health care research and provide optimal patient outcomes (Owen, 2010, 2018). The suggested terms definitions and groupings, incorporating children's footwear interventions from this study have been obtained using a valid consensus approach (Keeney et al., 2010).

The survey also sought to focus on OSSTF which is a potentially effective footwear intervention for children's mobility impairment (Chapter 3) The survey provided consensus agreement of a number of ideal design characteristics that should be offered on OSSTF for children, and the purpose of these. Identification of the key design specifics of an assistive aid affords an understanding of how and where the aid should support and assist mobility and has been used to help develop interventions such as AFOs (Eddison, Mulholland, et al., 2017; Eddison & Chockalingam, 2013; Owen, 2010). However, the panellists pointed out there was a limited evidence base to support these stability design characteristics. Some panellist proposed potential neurodynamic properties of the footwear through proprioceptive feedback at the heel counter and extended topline. However, panellists felt that further evidence was required to justify this claim. In comparison to stability features of the footwear, the panellists appeared more certain with their opinion on ergonomic factors as this achieved consensus in earlier rounds and is probably due to the established body of work in footwear science that relates comfort and fit to function (Branthwaite & Chockalingam, 2019; Goonetilleke, 2013; Goonetilleke et al., 2000; Witana et al., 2009). Although there is a lack of evidence to substantiate the design characteristics purported to offer stability, the identification of these areas will inform further mechanical testing of OSSTF.

In addition to the design characteristics of children's OSSTF, the survey sought to gain opinion and consensus on the clinical criteria for providing this footwear, and the outcome measures to ascertain its effectiveness. Uncertainty on prescription criteria and goals of treatment can lead to inconsistent practice and lack of confidence in providing assistive aids to mobility impaired children (Kane et al., 2019; Owen, 2019). This section initially started with the least number of statements in round 1 but went on to generate a total of 149 statements for panellist consideration. Criteria for prescription were largely to improve mediolateral stability in mobility and standing. OSSTF may often be prescribed by clinicians as a first line intervention based on historical practice. However, expert consensus recommends that prescription of this footwear be assessed critically against the mobility needs of the child and the evidence base of other assistive devices, with the most suitable intervention being issued. OSSTF was to be used simultaneously with other assistive devices (AFO's KAFO's walking frames) in more severe gradings (GMFCS 2-4) with only minor gradings indicated for sole line treatment with OSSTF (GMFCS 1). The exception to this was symptomatic pes planus where it may be used only as a secondary line intervention after foot orthoses had failed to resolve symptoms. Body structure and function outcome measures were chiefly focused on spatiotemporal and kinematic measures in addition to the physiological cost. Kinetic measures did not reach consensus; however, this was largely due to the perceived compliance with in-shoe measurement devices and availability of force plates in clinical settings rather than the validity of these outcome measures. It was, therefore, uncertain if the panellists considered if outcomes were inclusive of research settings as well as daily clinical practice. Quality of life measures appeared to be considered an important outcome for OSSTF intervention in children with mobility impairment as these reached a higher frequency of strongly agree and in earlier rounds compared to the other outcomes. Conversely, the current body of research is limited, exploring the effects of footwear interventions on the quality of life of children Chapter 3.

Idiopathic toe walking and intoeing did not achieve any consensus for clinical criteria of OSSTF provision. Idiopathic toe walking was not felt by the panel to be completely unsuitable for OSSTF. It was noted that it presented with a nebulous aetiology with variable responses to many interventions (C. M. Williams et al., 2016). The establishment of criteria therefore required more complex stratification than the closed-ended statements offered in the current survey. Intoeing again was cited as heterogeneous in nature (Uden & Kumar, 2012) however this achieved the highest frequency of panellists scoring disagree or strongly disagree with panellists reaching a general consensus there was no clear evidence base to indicate OSSTF for this clinical presentation even in the subcategories suggested by the modified statements offered across rounds 2 and 3.

Five further conditions were suggested through consensus of the panellists; however, it was beyond the capacity of the current survey to explore the clinical criteria and proposed outcomes for OSSTF in these additional conditions. This will require further exploratory work amongst experts in the area of clinical footwear provision to establish this.

The Medical Research Council (Medical Research Council, 2006) provide a list of recommendations in developing and evaluating complex interventions. Paramount to the development process is that an intervention should be able to be fully defined in what it is expected to do and under what situations. There should be a full understanding of the components of the intervention, and how these should act, who the intervention is aimed at and what the salient outcome measures expected to be achieved (Craig et al., 2008; Medical Research Council, 2006). The results of the Delphi consensus process have outlined and defined the spectrum of roles footwear may play as a clinical intervention. Further to this, the results of the study provided an expert consensus of OSSTF including the identification of the design characteristics purported to enhance mediolateral stability in children's gait, the childhood mobility impairments that may benefit from stability footwear intervention and the necessary outcomes to evaluate the footwears effectiveness in these children. While this consensus has identified several design characteristics, which the experts considered pertinent for OSSTF, further consideration should be given on how to assess these characteristics using mechanical testing procedures and in turn link them to ISO standards.

The Delphi technique has limitations in that it does not necessarily produce the right or definitive answers; instead, it produces a valid consensus of expert opinion (Hasson & Keeney, 2011). The method utilises both qualitative and quantitative analysis in a mixed-method approach; however, the data provided from Delphi's is of inductive Level 5 evidence (OCEBM Levels of Evidence Working Group, 2011) and is not authoritative requiring further deductive empirical research to support the findings of the work (Keeney et al., 2010).
The recruitment to the Delphi panel was limited to countries with English as their first language, and potential differences in expert opinions may exist outside the selected experts' countries (Australia, UK and USA).

The themes were derived by content analysis performed by one author. This may potentially have introduced some bias in interpretation of the expert opinions; however, this was mitigated by a collective agreement of statement generation between the authors from the themes, and the opportunity for panellists to correct any misrepresentation or omission of their opinions in the subsequent Delphi rounds.

This study has achieved an expert consensus on defining and grouping clinical footwear interventions for children, where none previously existed. Additionally, the ideal design characteristics for OSSTF for children with mobility impairment and suitable clinical populations for their provision have been identified.

The consensus will facilitate:

- A common understanding of therapeutic footwear terminology to facilitate communication between clinicians, researchers and manufacturers.
- Research-informed evidence for selection of appropriate OSSTF based on identified design characteristics.
- Research-informed evidence for dispensing OSSTF to suitable clinical populations.
- Standardised outcome measures for clinical assessment of the effectiveness of OSSTF.
- Identification of the salient design characteristics for further mechanical testing of OSSTF.

5.5. Conclusion

The current study is the first to establish a structured synthesis of expert opinion on defining and grouping children's therapeutic footwear, in addition to identifying the design characteristics of OSSTF and relevant criteria for clinical prescription. Further, this study has provided an expert consensus on the design characteristics of OSSTF proposed to influence stability and the relevant outcomes to assess their effectiveness on children's mobility. These findings will provide a framework for developing appropriate testing methods for OSSTF, both mechanical stiffness testing of their design and in-vivo testing of their effects on children's mobility.

6. Establishing a protocol to bench test children's "Off the shelf" stability therapeutic footwear (OSSTF).

6.1. Background

Therapeutic footwear is a frequently used assistive aid to facilitate children living with a mobility impairment (Hill et al., 2019; Nester et al., 2018). As outlined earlier in the thesis (see Chapter 2), children's OSSTF is thought to enhance stability in these children through design modifications from standard retail footwear. However, as established in the conducted systematic review (see Chapter 3), there was no consistent common understanding of the design characteristics of this footwear. Consequently, through expert consensus gained through a standardised Delphi process, the ideal design characteristics of OSSTF were identified (see Chapter 5). The consensus design characteristics of OSSTF from a functional aspect were characterised into stability and ergonomics. Stability with respect to biomechanics may be defined as the property of a body when disturbed from a static or steady state of motion to develop forces that restore the original state (Meyer & Ayalon, 2006). From a mechanical perspective, the experts thought stability and ergonomics were linked to the stiffness of the components of OSSTF in specific regions of the footwear (see Chapter 5). With stability thought to be enhanced with increased resistance to movement (stiffness) in a mediolateral direction (coronal plane) (Figure 6-1), and ergonomics thought to be enhanced by a lowered resistance to movement (flexibility/lower stiffness) in an anterior-posterior direction (sagittal plane) (Figure 6-1).

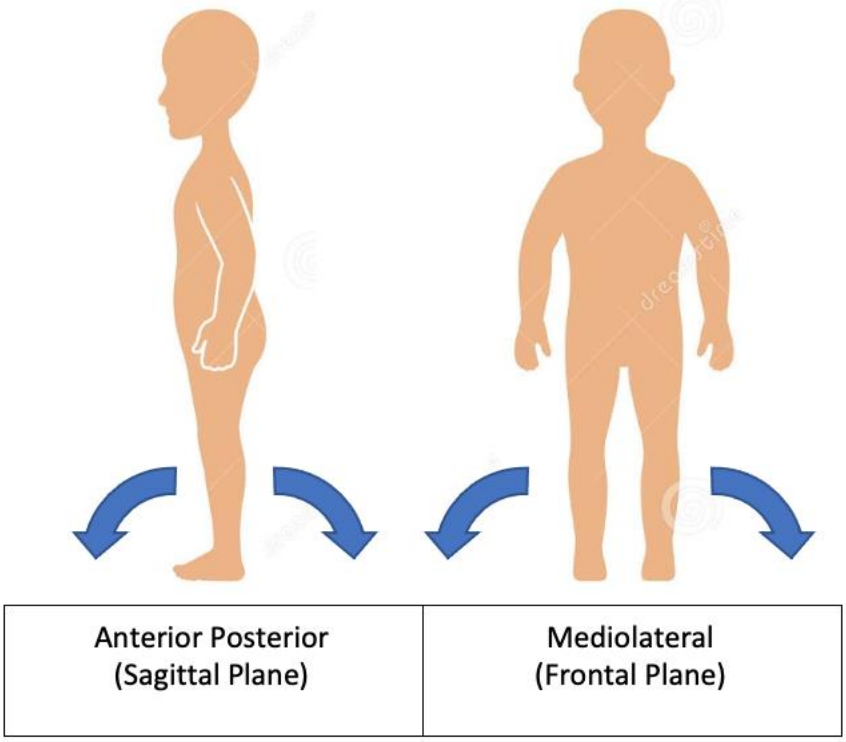


Figure 6-1 Planes of motion

Design characteristics suggested by the experts (see Chapter 5) to enhance stability by offering increased stiffness to movements in a mediolateral direction included (Figure 6-2):

S1. Increased height and length of the heel counter/stiffener

S2. Increased height of the topline

S3. Reduced outsole width ratio of the forefoot and heel

S4. Increased outsole heel width ratio to the width of the heel cup of upper

S5. Lace fastening

S6. Stiffer fixation of the upper to the outsole.

S7. Increased stiffness of the outsole at the midfoot area

Design characteristics thought to enhance ergonomics by offering lower stiffness to movements in an anterior-posterior direction included (Figure 6-2):

E1. Flexibility of the outsole at the forefoot

E2. Flexibility of the topline

The design characteristics to enhance stability would be required to be stiffer than standard retail footwear, whilst those design characteristics of ergonomics should offer comparable stiffness to standard retail footwear (see Chapter 5).

It must be noted that design characteristics S1-S5 to enhance stiffness were specifically defined by the experts. In contrast, the remaining characteristics for stability (S6&7) and those of ergonomics (E1&E2) only stated the characteristic should offer increased stiffness or flexibility with no suggestion of what design would achieve this. Although it would be logical to postulate that these design characteristics are related to the shore strength of the material used, the manufacturing process (stitching, glued) and the dimensions of the characteristic (length, width, depth) (Ji, 2003).

Figure 6-2 Design characteristics of children's "Off the shelf" stability therapeutic footwear (OSSTF).

Although these design characteristics reached expert consensus, this only provided opinion-based evidence for the design characteristics of OSSTF as an assistive aid for children. It would be beneficial for researchers, clinicians, and manufacturers to quantify the effects these design characteristics may have on mechanical stiffness to inform how they may assist children's mobility.

6.1.1. Mechanical stiffness testing of footwear

Numerous test methods for footwear manufacture and design exist (ISO, 2021; Technology Centre, 2020). However, there is not currently a complete range of tests available to test the effect of the Delphi postulated design characteristics on the stiffness of footwear. Established international mechanical stiffness testing standards have mainly focused on analysing the individual design components separately (ex-situ) and not within the shoe as a whole (in-situ) (ISO, 2021). Studies that have looked at the stiffness of footwear design components in-situ have tended to focus on the compressive stiffness of the outsole in relation to the cushioning properties of the footwear (Polomé et al., 2022; Price et al., 2014; Schwanitz et al., 2010). Conversely there has been relatively limited assessment of ankle and midfoot torque stiffness (Böhm & Hösl, 2010; Zifchock et al., 2017), that would be applicable to assess the stability properties of OSSTF proposed from the Delphi expert consensus (Chapter 5). Since it is known that the mechanical stiffness of a structure will be affected not only by the materials used but the architecture (manufacturing process, dimensions) of the complete structure (Ji, 2003), in order to mechanically assess how these design characteristics work within the shoe, it is necessary to formulate a standardised and repeatable range of testing methods.

In order to inform on the stiffness of OSSTF, testing should be focused on the typical movements that an individual would perform whilst using this footwear, with this largely involving angular movements in the sagittal and coronal planes (Figure 6-1) and the forces required to cause this movement (torque Nm) (Böhm & Hösl, 2010; Colloud et al., 2012). The systems to measure the angular movement and torque may be highly precise (ISO 2021); however, the materials utilised in footwear will exhibit viscoelastic properties (Papanicolaou & Zaoutsos, 2010) and may require repeated cycles of loading and unloading (stress-strain cycles) to reach a consistent stiffness value. Additionally, the positioning and securing of the footwear may be open to operator variation, so any validation of the testing method would also require a repeated number of testing episodes or runs to establish a more precise representative value (acceptable variation) of the footwear's stiffness (Bury, 1999).

The development of a standardised, repeatable range of test methods to quantify the stiffness of the design characteristics of children's OSSTF in situ of the shoe will inform on its potential role for children living with a mobility impairment across research, manufacturing, and clinical practice.

6.1.2. Aim and Objectives

The overall aim of this study was to develop a standardised method to quantify the in-situ effects that expert consensus-recommended design characteristics have on the mechanical stiffness of OSSTF:

The objectives of the research are:

- To provide a series of mechanical testing protocols to quantify the effects on mechanical stiffness of the expert consensus OSSTF design characteristics.
- To establish for each testing protocol how many loading cycles are required to establish a consistent value for mechanical stiffness.
- To provide a level of precision for each testing protocol by establishing how many repeated separate testing episodes (test runs) are required to provide an acceptable level of variation.

6.2. Method

6.2.1. Footwear samples for testing

A children's OSSTF was taken from the Nimco range Model 07556 as representative of OSSTF (Figure 6-3).

Figure 6-3 Children's footwear used for mechanical stiffness testing

A left shoe of EU size 32 was used; this was representative of an eight-year-old child's foot (Delgado-Abellán et al., 2014). At this age, children demonstrate increased mobility in daily life yet still demonstrate comparable foot gender anthropometrics for unisex comparison (Delgado-Abellán et al., 2014; Schmidt et al., 2017).

Dimensional measures were taken of the sample OSSTF that ascribed to the design characteristics experts thought would influence the stability and ergonomics of the footwear (Table 6-1). The methods of measuring footwear dimensions followed ISO standards where appropriate (ISO, 2021) and those described in Chapter 4.

6.2.2. Testing Apparatus:

Mechanical testing was carried out on a bespoke torque platform system. This consisted of two platforms, one stationary that was connected to a torque load cell (Applied Measurements Ltd, DTD-F-50Nm, sensitivity: 1.0mV/V, accuracy: ±0.05Nm) and one rotating platform connected to a motor. The motor was controlled using a custom software system that also measured the angle of rotation (Figure 6-4). The system could be set to move through a specified angle of rotation at a given speed (min/max), a given number of rotation cycles, and a given measurement rate (min/max). The software system was also employed to record angles of rotation (°) and torque (Nm).

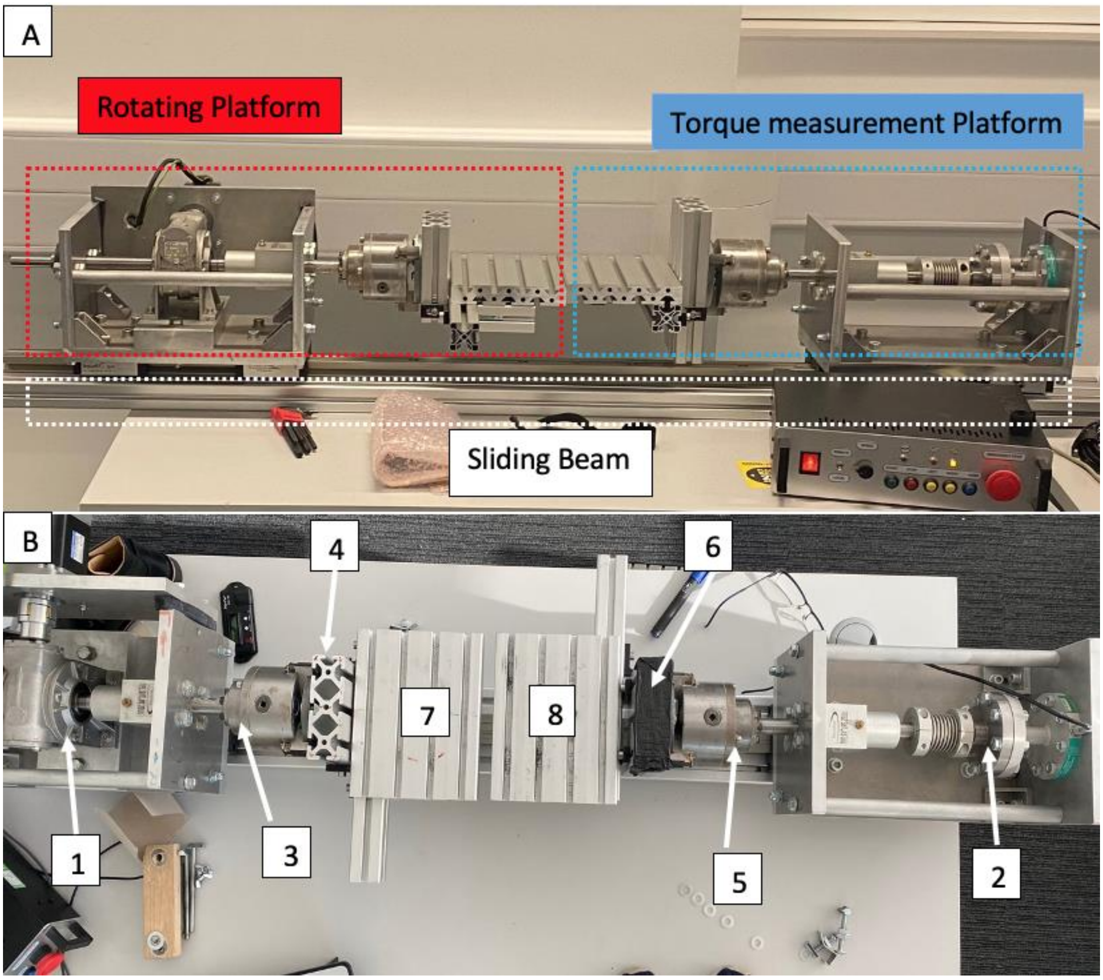


Figure 6-4 A, Torque platform system set up. B, Torque Platform Components, 1 Rotating motor and angle measurement system, 2 Torque Measurement system, 3 Rotating arm, 4 Rotating arm mounting beam, 5 Torque measurement arm, 6 Torque measurement arm mounting beam,

Although the torque system rotates about a fixed axis, the platform system is capable of being adjusted along the sliding beam, mounting beams and footwear support platforms (Figure 6-4 A, B). The adjustments in the platform system, together with a realignment of the footwear, allows torque loading of the footwear in both the coronal and sagittal plane.

6.2.3. Footwear load testing

Four types of torque loading scenarios were considered for mechanical testing of the expert design characteristics of OSSTF.

1. Forefoot flexion loading
2. Midfoot torsion loading
3. Ankle inversion/eversion loading

4. Ankle plantar/dorsi flexion loading

For each of the loading scenarios, testing was conducted along the long axis of the footwear for coronal plane movements or perpendicular to the long testing axis for sagittal plane movements. The determination of the long axis of the footwear followed the methodology detailed by ISO standards (ISO, 2021).

1. The footwear was placed on a horizontal surface and alongside a vertical plane so that the edges of the outsole touch the vertical plane points A and B on the medial side of the footwear. (Figure 6-5)
2. Two further vertical planes were defined perpendicular to the first vertical plane so that they are tangent to the sole at points X (toe point) and Y (heel point).

A line was drawn from X and Y on the outsole of the footwear to derive the test axis for the footwear.

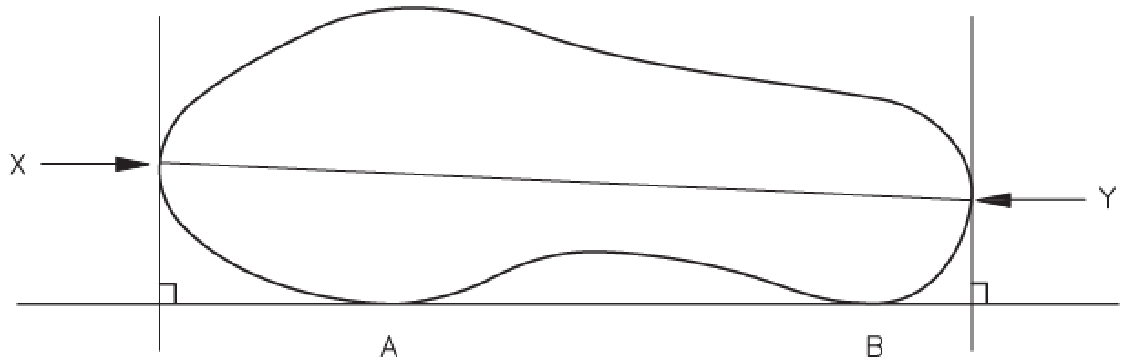


Figure 6-5 Long testing axis of the footwear ISO. ISO 20344: 2021 (en), Personal protective equipment — Test methods for footwear.

The platform can rotate to a given angle (loading period), then back to zero (unloading period), then rotate to the same angle in the opposite direction (loading period), then back to zero (unloading period) so that one complete cycle of footwear loading consisted of two loading and two unloading periods (Figure 6-6). The torque (Nm) at the maximum angle in either direction was taken as representative of the footwear's equivalent maximum stiffness for the given type of torque loading scenario (Figure 6-6). The torque measurements for stiffness were taken during the loading periods to avoid any inertial effects in the change of rotation direction of the system in the unloading period.

The speed of rotation was set at 2°/s for safety purposes. Testing was conducted at room temperature (20-23°C).

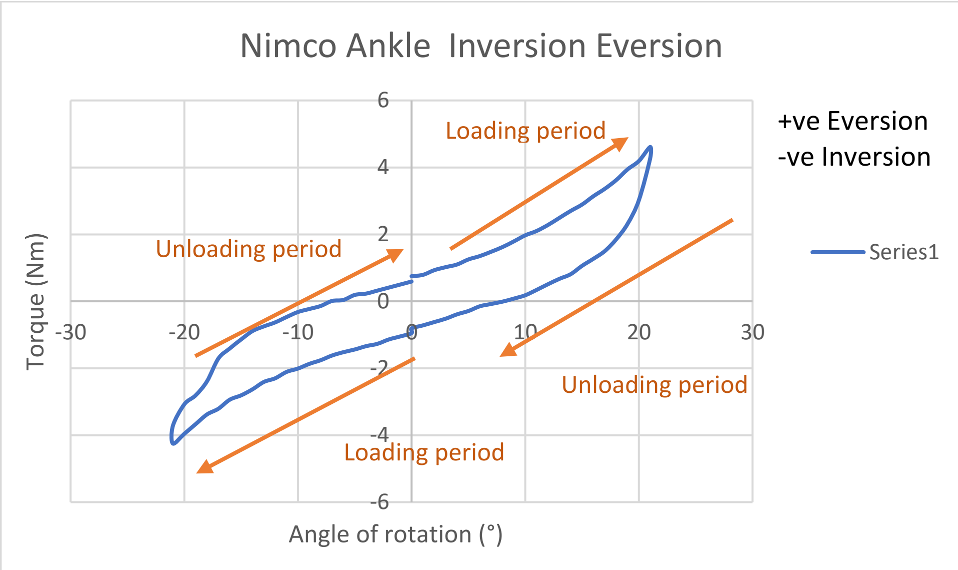


Figure 6-6 Long testing axis of the footwear ISO. ISO 20344: 2021 (en), Personal protective equipment — Test methods for footwear,

For each of the loading scenarios, the footwear was secured to the respective footwear support platforms by screws clamps. Fixation of the footwear on the platform was adjusted and optimised through an iterative approach to reduce additional movement of the footwear on the platform other than the motion under test to avoid movement artefact affecting the results.

The footwear was taken through a range of angular rotations for each of the loading scenarios that represented the foot and ankle motion of mobility-impaired children (Amene et al., 2019; Kruger et al., 2017). Due to the variable clinical pattern of spasticity in children with cerebral palsy, reliance solely on the central trend data may not be ideal for informing clinical decisions (Domagalska–Szopa & Szopa, 2019; Kim et al., 2018). Therefore, the general range of kinematic data was utilised, which approximated 20° inversion and eversion of the forefoot and ankle and 20° dorsiflexion and plantarflexion of the ankle (Amene et al., 2019; Kruger et al., 2017).

The protocol for each of the loading scenarios would consist of an individual testing episode (test run) which would consist of a set number of repeated loading cycles.

One of the objectives of the study was to establish that a consistent value of maximum stiffness was reached for each of the loading scenarios by identifying a saturation point of drop-off for torque stiffness. A testing run would therefore have repeated cycles; these were performed initially in increments of ten cycles; these were then analysed for a saturation point of drop-off for maximum stiffness torque values. The second objective was to establish a degree of precision for the methodology by calculating how many repeated testing episodes would be required to provide an acceptable level of variation and an increased precision of equivalent stiffness value offered. Therefore, each loading scenario had ten individual testing episodes (testing runs) whereby the shoe would be repositioned and fixated according to each loading scenario protocol. The torque values were then subject to descriptive and inferential statistical analysis to estimate the variability and precision of the loading scenario. Runs were also performed periodically with no footwear set up on the platform to ensure there was no residual stiffness (Torque) from the platform system affecting the results.

Key to Loading Protocol Testing
Loading Cycle = Two loading and unloading periods each in opposite directions
Test Run = Separate testing episodes consisting of a set number of loading cycles

6.2.3.1. Forefoot Flexion Loading

1. Area of Footwear Tested: Forefoot area of Outsole

2. Function Aspect Tested: Ergonomic

3. Test Plane of Rotation: Sagittal

4. Structures and Design Characteristics Tested: Width and thickness of the outsole, fixation of the upper to the outsole (welt, stitched, cemented), and the upper material.

5. Platform Set-Up: The platform system was set up by adjusting the footwear support platforms and sliding the rotating motor and rotating arm along the sliding beam, the outer edges of both footwear support platforms seen in Figure 6-4 B were alongside each other with a 1cm gap (Figure 6-7 A and B).

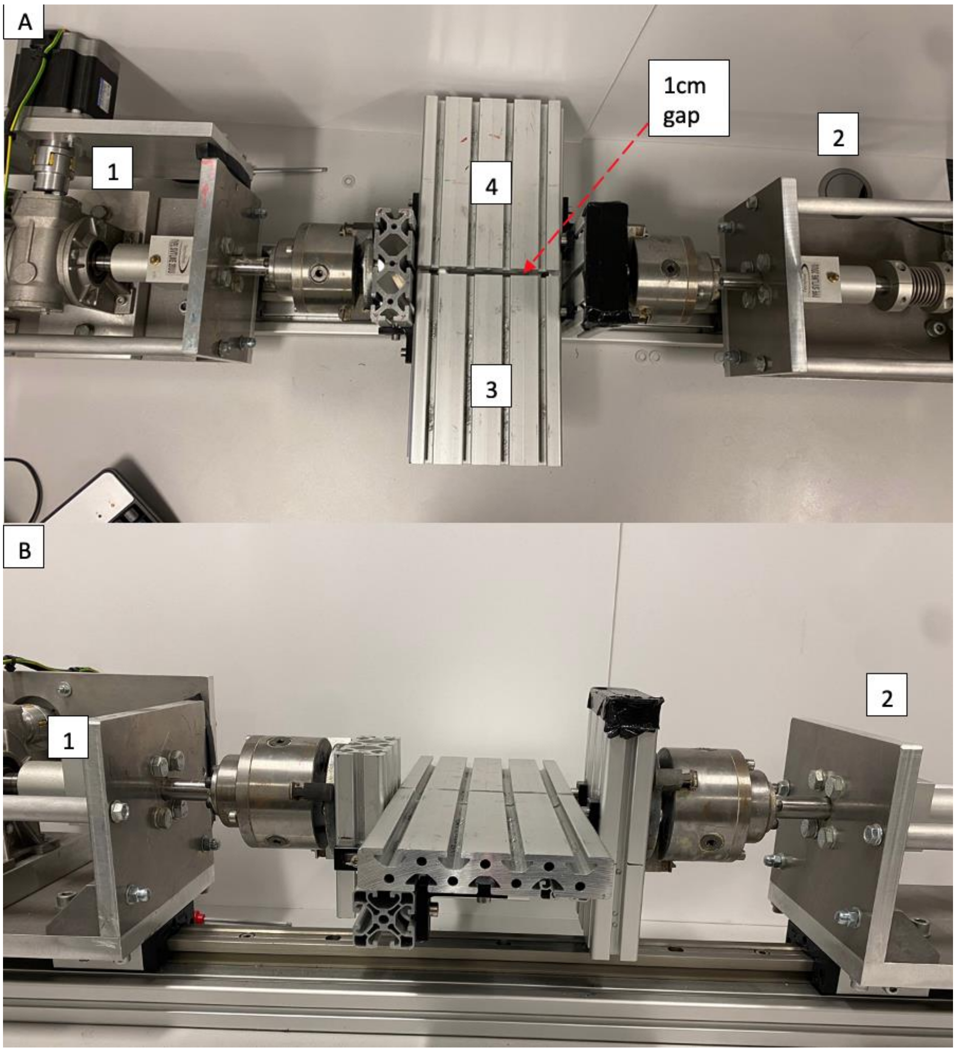


Figure 6-7 A B Platform system set up for forefoot flexion loading, A 1 Rotating arm, and angular measurement system, 2, Torque measurement system, 3 Rotating support platform, 4, Torque measurement support platform

6. Footwear Axis Set-Up: Followed recommendations laid out by ISO 20344:2021(ISO, 2021).The position of rotation of the forefoot of the outsole occurred at a point along the long axis of the footwear following Figure 6-8 ISO 20344:2021 this was 33.33% the length of the axis X-Y from the front of the shoe and perpendicular to the long axis (**line A-C** Figure 6-8).

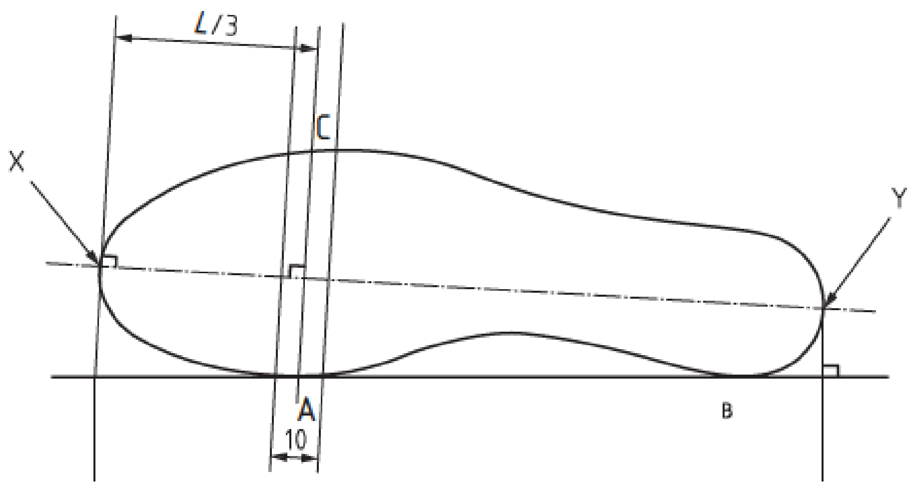


Figure 6-8 Line of Forefoot flexion of Outsole. ISO. ISO 20344: 2021 (en), Personal protective equipment — Test methods for footwear,

7. Footwear Platform Positioning and Loading Cycle Set up: For a cycle of forefoot loading, the forefoot of the shoe would be required to flex 40° in an upward direction, then back to the shoe's unloaded position to simulate 40° of dorsiflexion of the forefoot (ISO, 2021). The platform could be set up by the software to rotate through a given angle of rotation; however, as previously discussed, a complete loading cycle would occur in both directions. Since the forefoot loading procedure only wished to measure 40° of dorsiflexion of the forefoot[5], this required a modified set-up procedure of the footwear and the platform.

a. The footwear was positioned and secured so that the forefoot of the shoe was placed on the stationary foot torque measurement platform, and the rearfoot of the shoe was positioned on the rotating platform set at the horizontal (Figure 6-9 A).
b. The flex point of the forefoot of the outsole Line A-C (Figure 6-8) was positioned to align parallel and along the 1cm gap between the two platforms and along the rotating axis of the torque platform system (Figure 6-9 B).
c. The rotating platform was then rotated anticlockwise so that the torque measurement platform was tangent to the toe spring of the outer sole (Figure 6-27); this was then marked as zero on the software system (Figure 6-10 C). The footwear was secured to the platform, as in (Figure 6-10 D).
d. The rotating platform was then rotated 20° further anticlockwise, this was then reset by the software as zero, but this zero value would be a position of 20°

forefoot dorsiflexion of the footwear from the set-up toe spring angle in step c (Figure 6-11 E).

e. The software system was then set up to run through 20° from the 0° position established in step d, which would allow the forefoot of the footwear to be dorsiflexed 40° (ISO, 2021) (Figure 6-11 F) from the toe flex angle (Figure 6-10 D).
f. The platform was set up to run for 2 x 10 cycles to establish saturation of maximum torque stiffness drop-off.
g. Ten separate test runs were performed for variance and precision analysis.

Figure 6-9 (A) Shoe and platform set up for forefoot flexion; (B) Forefoot flex line of shoe aligned along 1cm gap of rotating axis of the system.

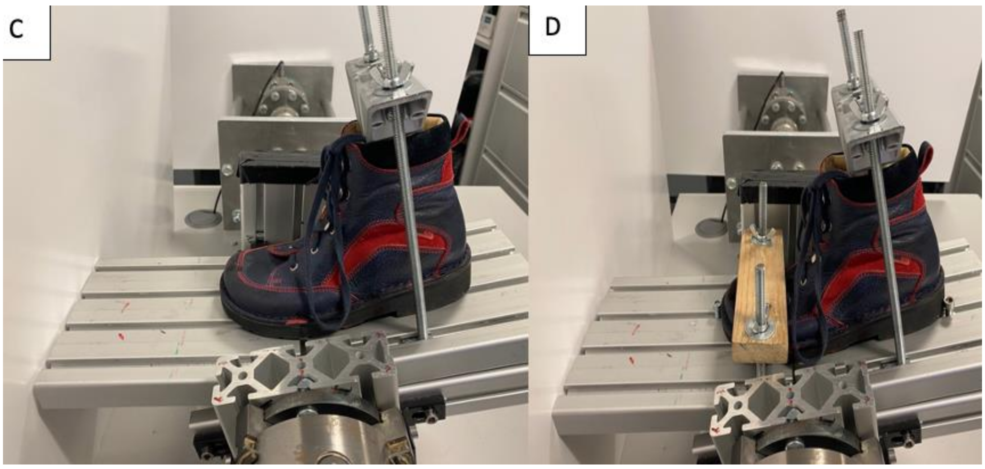


Figure 6-10 (C) Rotating platform elevated so that the toe spring of the shoe's forefoot is tangent with the stationary torque measurement platform.; (D) Securing the shoe to the platform system.

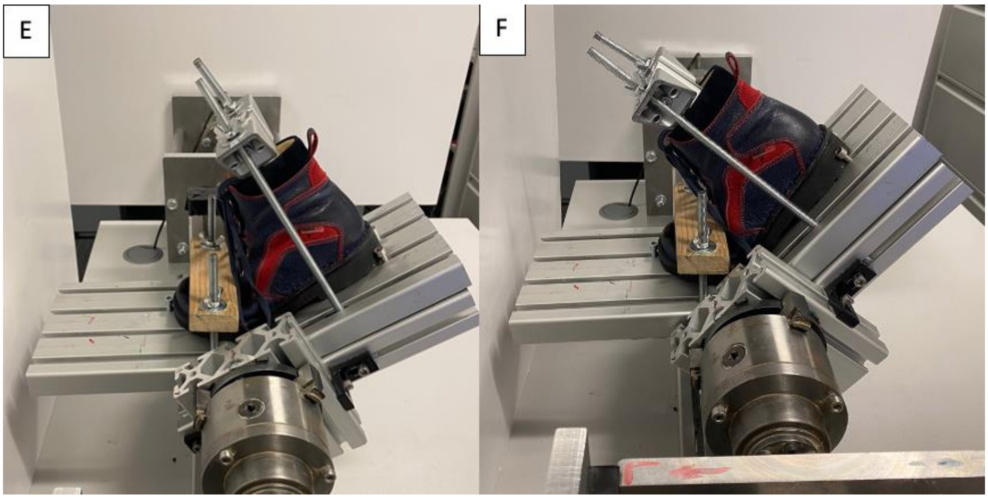


Figure 6-11 (E) Zero value for platform system with the shoe at 20° forefoot dorsiflexion; (F) Shoe at full 40° forefoot dorsiflexion.

6.2.3.2. Midfoot Torsion Loading

1. Area of Footwear Tested: Midfoot area of outsole

2. Function Aspect Tested: Stability

3. Test Plane of Rotation: Coronal

4. Structures and design characteristics tested: Width and thickness of the outsole at the midfoot, fixation of the upper to the outsole (welt, stitched, cemented), the material of the upper shank and heel counter if it extended into the midfoot.

5. Platform Set-Up: The torque platform system was set up in a similar configuration to Figure 6-4 A and B with a 1cm gap left between the footwear support platforms (Figure 6-12 A and B).

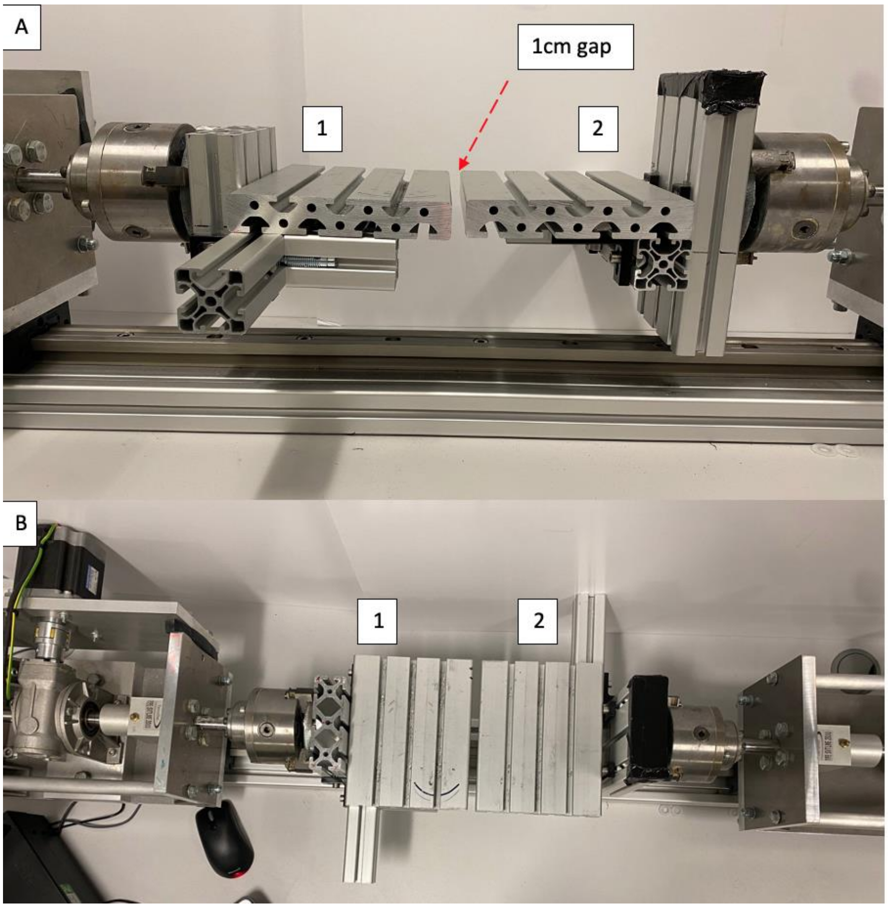


Figure 6-12 A and B Platform system set up for midfoot torsion loading (1) rotating and angular measurement support platform; (2) Stationary torque measurement support platform

6. Footwear Axis Set-Up: This loading scenario conducts torque loading along the long axis of the footwear (Figure 6-5) but is focused on the region of the midfoot. The midfoot position was marked on the medial and lateral aspect of the outsole of the shoe at 40% of the total outsole length from the posterior aspect of the heel. This was to approximate the position of the midtarsal joint (Hill et al., 2017) (Figure 6-13 A, B). The footwear was set up so that the long axis of the footwear aligned along the rotating axis of the system (Figure 6-14).

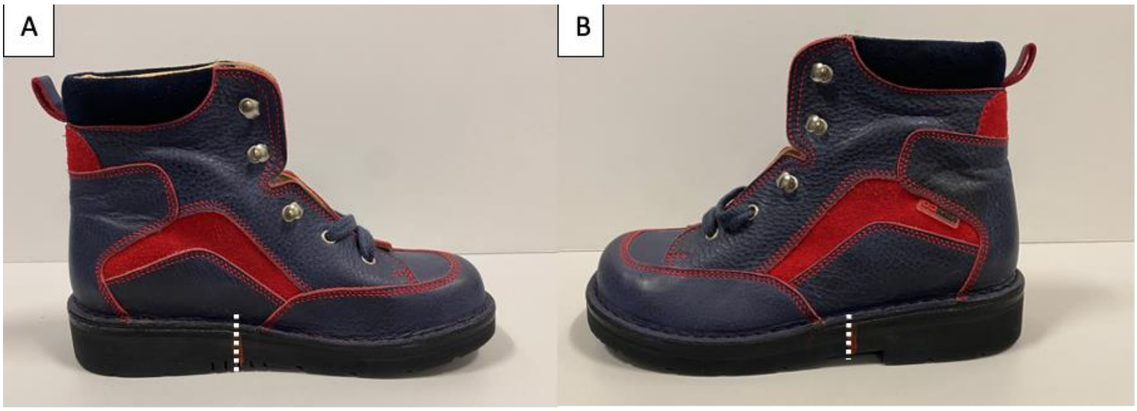


Figure 6-13 Midfoot Outsole marker on Children's OSSTF, (A) Medial marker position; (B) Lateral marker position.

Figure 6-14 Alignment of the long axis of the footwear along the axis of the rotating system 1 Axis of the rotating system

7. Footwear Platform Positioning and Loading Cycle Set-Up:

a. The midfoot marker on the outsole was positioned so that it aligned in the centre of the 1cm gap between the rotating and torque measurement support platforms and was then secured in place by screws and clamps, as detailed in Figure 6-15 A and B. This was set up as the 0° position (Figure 6-16 A).
b. The software system was then set up to run through 20° of motion; this would run in both a clockwise and anticlockwise direction to simulate 20° midfoot inversion (Figure 6-16 B) and 20° midfoot eversion of the midfoot (Figure 6-16 C) (Amene et al., 2019; Kruger et al., 2017).
c. The platform was set up to run for 2 x 10 cycles to establish saturation of maximum torque stiffness drop offTen0 separate test runs were performed for variance and precision analysis.

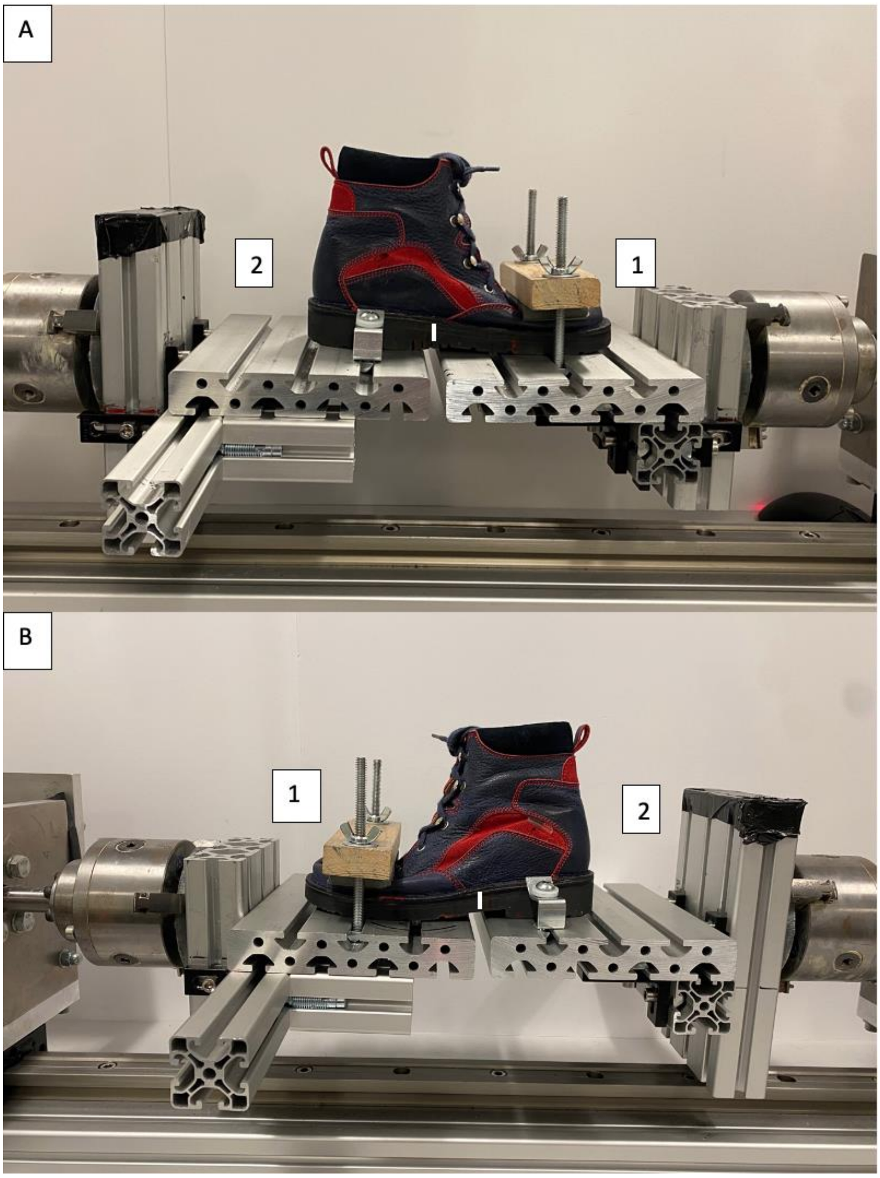


Figure 6-15 Positioning and securing of the footwear on the supporting platforms for midfoot torsion loading A medial aspect B Lateral aspect. 1, Rotating platform; 2, Torque measurement platform.

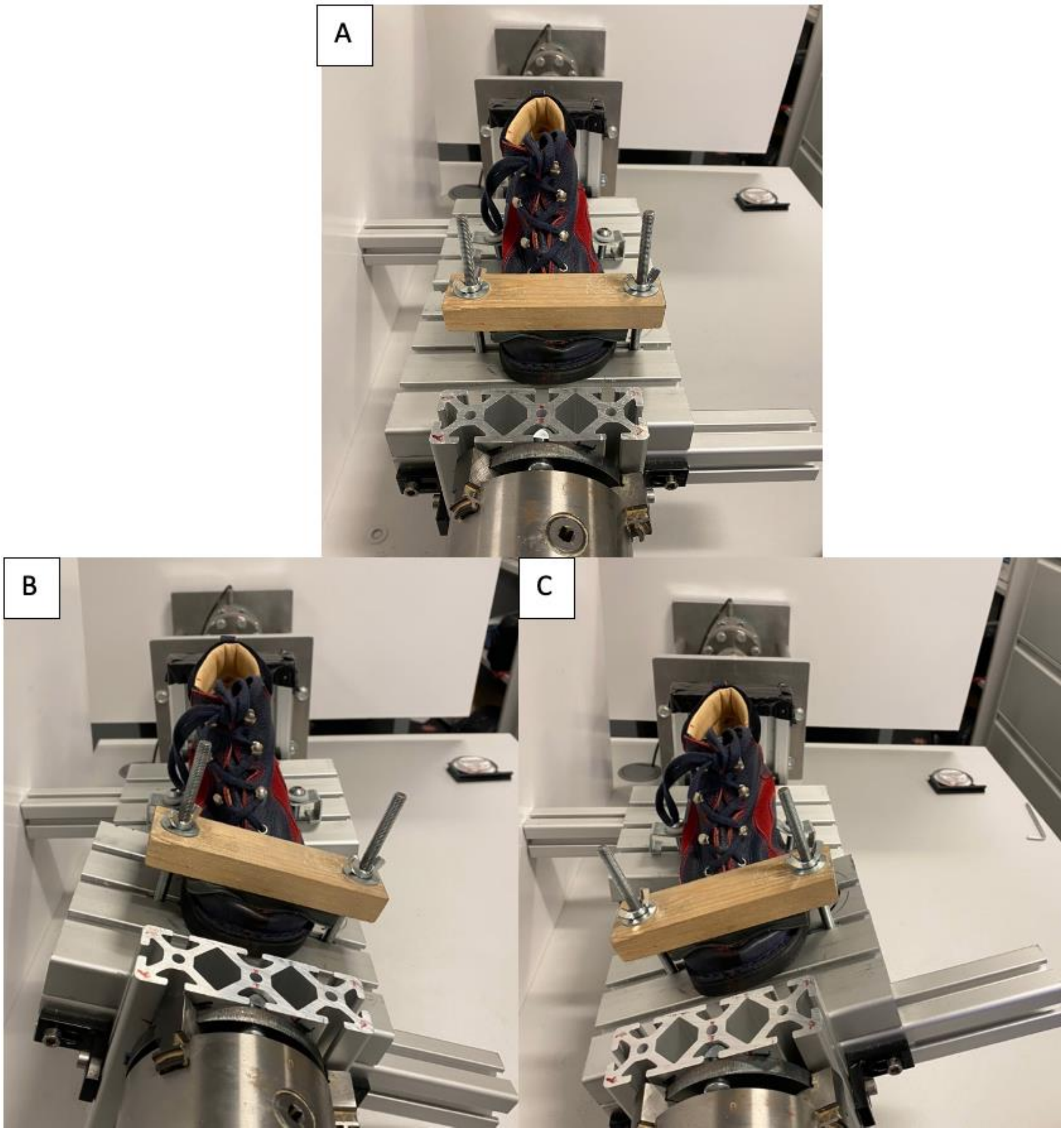


Figure 6-16 Midfoot torsion loading A 0° position B 20° Inversion C 20° Eversion

6.2.3.3. Ankle Inversion/Eversion loading

1. Area of Footwear Tested: Rearfoot area of the upper and outer sole of the heel

2. Function Aspect Tested: Stability

3. Test Plane of Rotation: Coronal

4. Structures Design Characteristics Tested: Height and length of the heel counter, the height of the topline, the material of the upper, the fastenings and the adhesion of the shoe upper to the outsole.

5. Platform Set-Up: For ankle inversion/eversion, the rotating footwear support platform was removed, and a frame structure was secured onto the rotating arm and mounting beam (Figure 6-17). The frame consisted of a vertical metal structure with a plastic moulded attachment to represent the shank and ankle. The moulded shank and ankle attachment was tapered along one edge to represent the shape of the posterior aspect of the shank and ankle; this was positioned on the frame for ankle inversion/eversion loading so that it aligned along the rotating axis of the torque system (Figure 6-18).

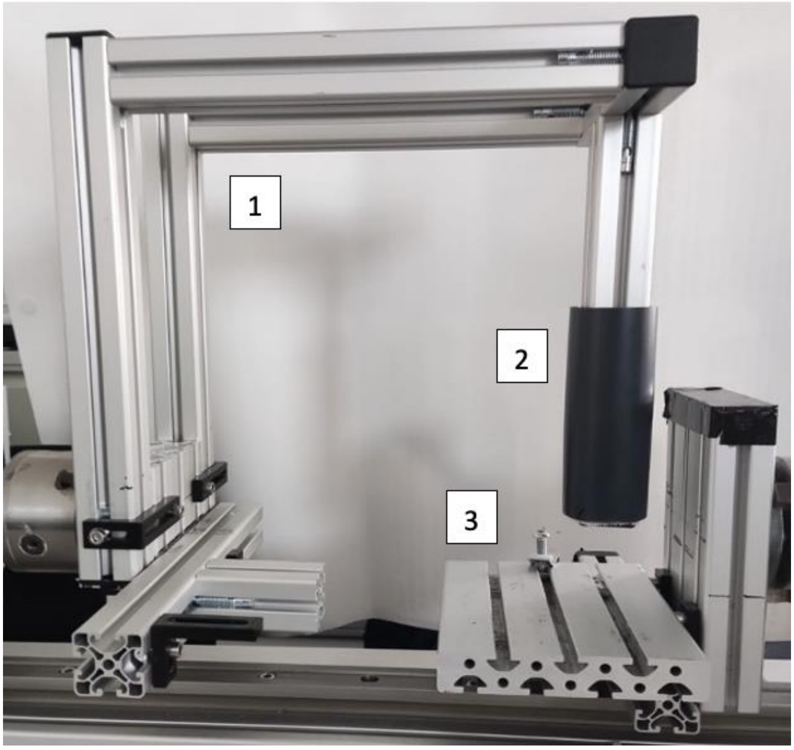


Figure 6-17 Shank and ankle frame model for Ankle Inversion and eversion; (1) Rotating frame; (2) Shank and ankle representative model; (3) Torque measurement platform.

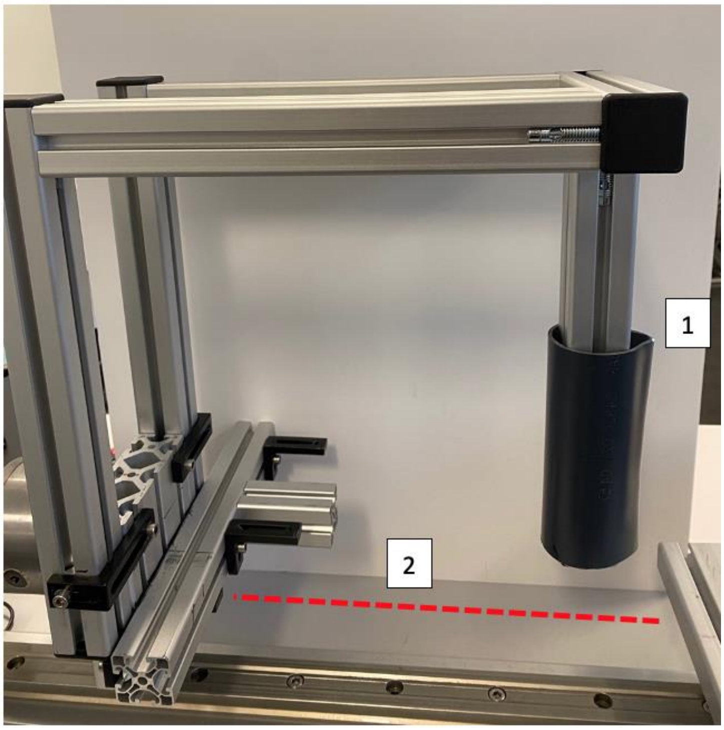


Figure 6-18 Alignment of the tapered edge of the shank model along the rotating axis of the system, 1 tapered edge of the shank model, 2 Axis of the rotating system.

6. Footwear Axis Set-Up: The footwear was set up so that the long axis of the footwear (Figure 6-5) was aligned along the rotating axis of the system, as detailed in Figure 6-19.

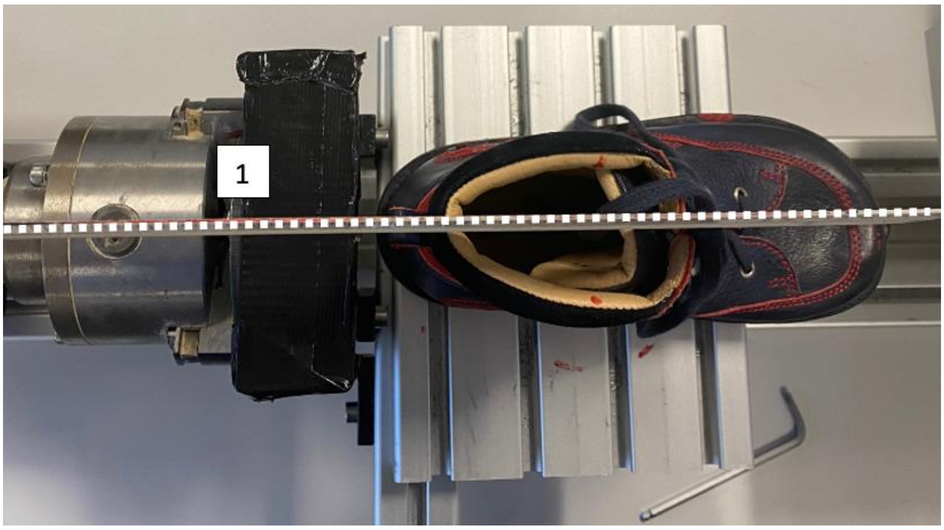


Figure 6-19 Alignment of the long axis of the footwear along the axis of the rotating system (1) Axis of the rotating system

7. Footwear Platform Positioning and Loading Cycle Set-Up:

a. The ankle shank representative model was positioned approximately 22% of the shoe length and 4cm above the inlay of the footwear. This was a size 32 scaled approximation of the ankle from previous foot and ankle laser scans (Hill et al.,

2017) and was proposed to represent closed kinetic chain movements of the shank and ankle when the footwear was fixed securely to the torque measurement footwear support platform (Figure 6-20) with the shank and frame rotated around the fixed footwear.

d. The footwear was secured to the rotating frame and shank model by the lace fastening of the shoe, and the outsole was secured to the torque measurement footwear mounting platform, as detailed in Figure 6-21 A and B. This was set up as the 0° position (Figure 6-22 A). The positioning of the shank and footwear would simulate the longitudinal axis of the ankle and rearfoot joints.
b. The software system was then set up to run through 20° of motion; this would run in both a clockwise and anticlockwise direction to simulate 20° ankle inversion (Figure 6-22**Error! Reference source not found.** B) and 20° ankle eversion (Figure 6-22 C) (Amene et al., 2019; Kruger et al., 2017)
c. The platform was set up to run for 2 x 10 cycles to establish saturation of maximum torque stiffness drop off
d. Ten separate test runs were performed for variance and precision analysis.

Figure 6-20 Positioning of ankle shank rotating frame in test footwear, (1) Shank ankle representative model, 2 Torque measurement footwear support platform

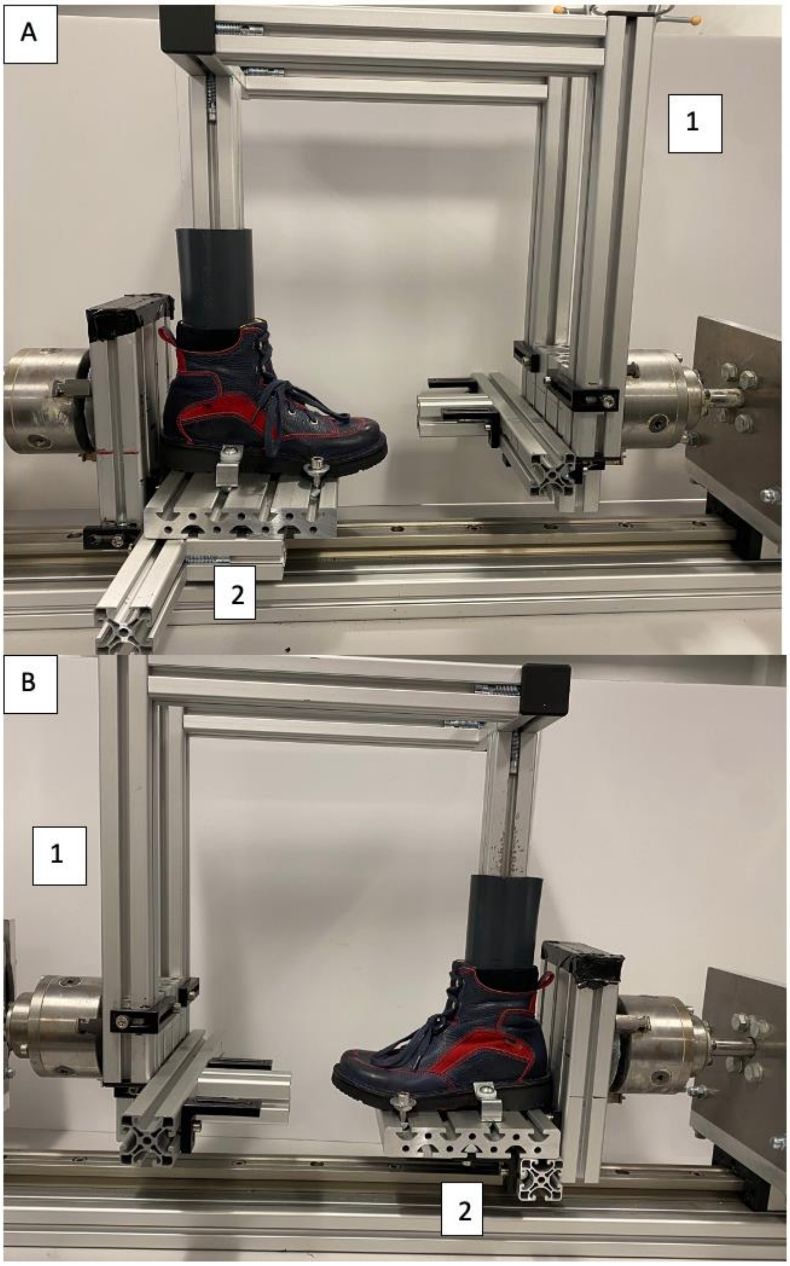


Figure 6-21 Positioning of the rotating frame ankle and shank model and securing of the footwear on the torque measurement support platform for Ankle inversion/eversion loading. A Medial view C Lateral view, 1 Rotating frame, 2 Torque measurement platform

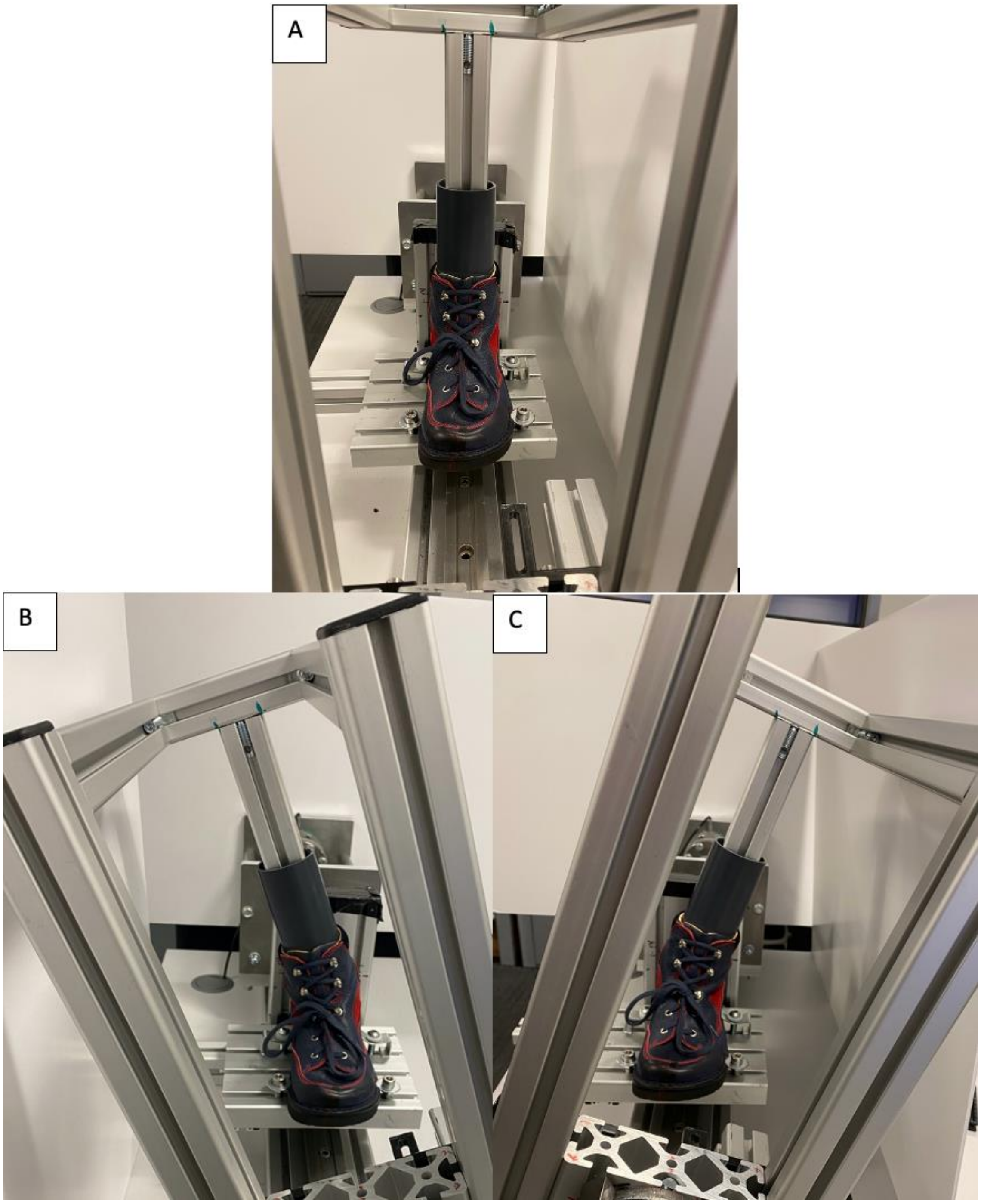


Figure 6-22 Ankle inversion/Eversion loading A 0° Position B 20° Inversion C 20° Eversion

6.2.3.4. Ankle plantar/dorsi flexion loading

1. Area of Footwear Tested: Rearfoot and midfoot area of the upper and Outsole

2. Function Aspect Tested: Ergonomic

3. Test Plane of Rotation: Sagittal

4. Structures Design Characteristics Tested: Height and length of the heel counter, the height of the topline, the material of the upper, the fastenings and the adhesion of the shoe upper to the outsole.

5. Platform Set-Up: For ankle plantar/dorsi flexion consisted of the same platform set-up detailed in 6.2.3.3 Ankle inversion/eversion step 5 (Figure 6-17). However, the vertical shank component of the model was repositioned on the frame through 90° from the inversion eversion set-up so that the tapered edge shank model was perpendicular to the rotating axis of the torque system (Figure 6-23).

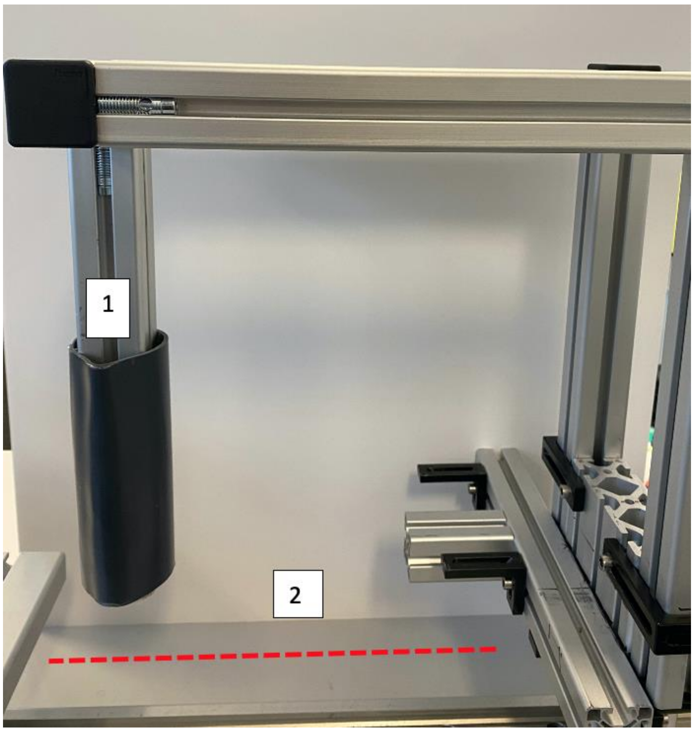


Figure 6-23 Alignment of the tapered edge of the shank model perpendicular to the rotating axis of the system, 1 tapered edge of the shank model, 2 Axis of the rotating system

6. Footwear Axis Set-Up. The long axis of the footwear (Figure 6-5) was positioned perpendicular to the rotating axis of the system. The footwear was then aligned so that the rotating axis of the system passed through the approximated position of the ankle joint (Figure 6-24).

Figure 6-24 Alignment of the long footwear axis (dotted line) perpendicular to the rotating platform axis (solid line).

7. Footwear Platform Positioning and Loading Cycle Set-Up:

a. The rotating frame was positioned in the approximated ankle joint position as previously detailed in Figure 6-20 and section 6.2.3.3 step 7a (22% of the length of the footwear and 4cm above the inlay). The footwear was secured onto the shank model by lace fastening and onto the platform by screws and clamps, detailed in Figure 6-25 A and B. This was set up as the 0° position (Figure 6-26 A). The positioning set-up would simulate the lateral axis of the ankle and rearfoot joints.
b. The software system was then set up to run through 20° of motion; this would run in both an anticlockwise and clockwise direction to simulate 20° shank and ankle plantarflexion (Figure 6-26 B) and 20° shank and ankle dorsiflexion (Figure 6-26 C) (Amene et al., 2019; Kruger et al., 2017)
c. The platform was set up to run for 2 x 10 cycles to establish saturation of maximum torque stiffness drop off
d. Ten separate test runs were performed for variance and precision analysis.

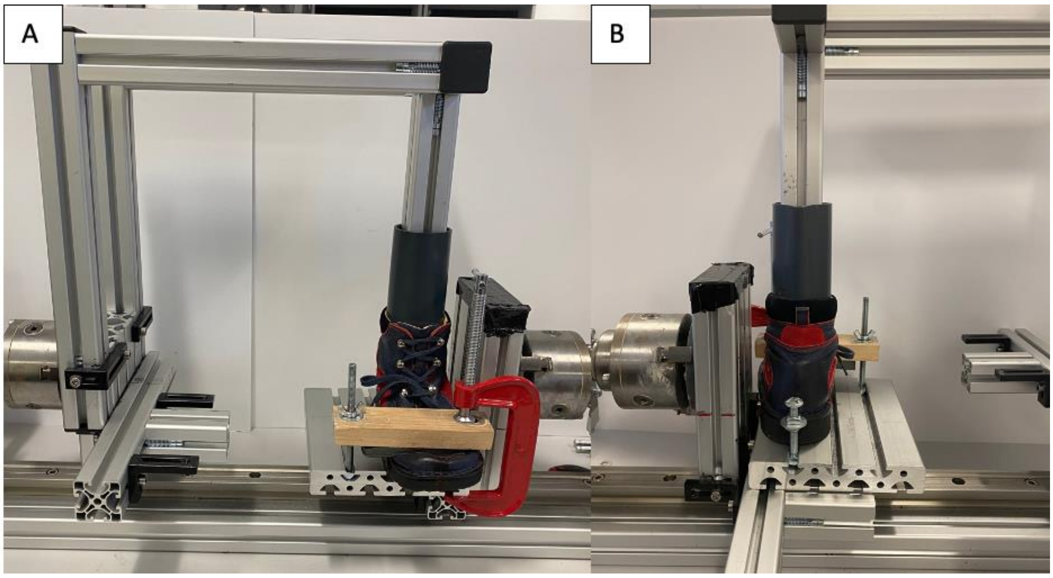


Figure 6-25 Positioning of the rotating frame ankle and shank model and securing of the footwear on the torque support platform for ankle plantar/dorsi flexion loading. A Anterior view, B Posterior view

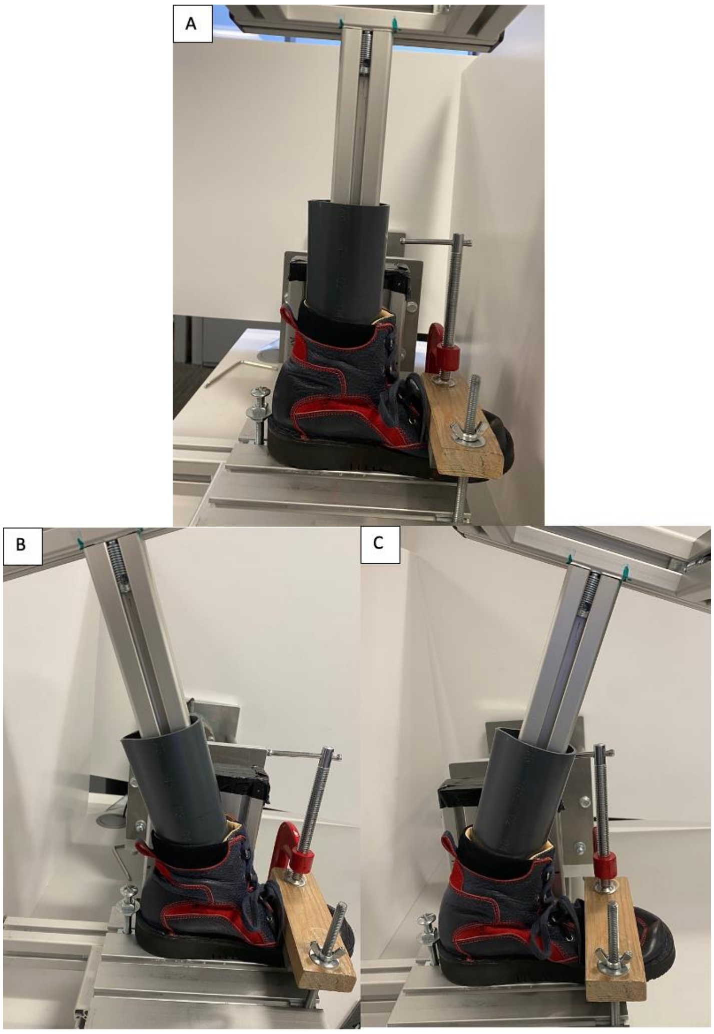


Figure 6-26 Ankle plantar/dorsi flexion loading A 0° Position B 20° Plantarflexion C 20° Dorsiflexion

6.2.4. Statistical Analyses

Statistical analyses were performed in Excel (Microsoft® version 16.60) and SPSS (IBM® version 28.0.1.1). Descriptive statistics (mean, standard deviation) were taken for repeated cyclic loading between test runs. The standard error of the mean (SEM) was used as a measure of variation and equivalent measure of consistency (precision) amongst the repeated test runs for each loading scenario. For multiple measures to be representative of the maximum torque, the number of repeated measures to reach a tolerance level of SEM ≤5% was agreed to be sufficient. An additional measure of consistency was performed by calculating the successive means of the repeated runs with a proportional comparison with the mean of the tenth run. Consistency was agreed to be achieved when the proportional ratios equalled one.

6.3. Results

6.3.1. Dimensional measures of OSSTF sample

Table 6-1 demonstrates the dimensional and mass measures of the OSSTF sample used in this study. The design characteristics proposed to enhance stability, such as topline height and heel counter height and length, demonstrated proportional dimensions within one standard deviation of the mean values of a sample of OSSTF measured in Chapter 4.

Table 6-1 Dimensional and mass measures of OSSTF shoe sample

FOOTWEAR	Size EU	Length Total (mm)*	Forefoot Width (mm)*	Mass (g)	Topline Height (mm)	Heel Stiffener Length Medial (mm)	Heel Stiffener Length Lateral (mm)	Stiffener Height (mm)	Heel Depth (mm)	Forefoot Outer Sole Depth (mm)	Heel / Forefoot Ratio	Waist (Midfoot) Outer Sole Depth (mm)	Heel / Midfoot Depth Ratio	Waist Area (mm)	Waist (Midfoot) Outer Sole width (mm)	Heel Cup Width (mm)	Heel Outer sole width (mm)	Outersole Heel width to Heel Cupwidth ratio	Outersole forefoot width to outersole heel width ratio
OSCTSF Nimco	32	226	92	340	120	102	105	50	28	15	1.87	22.00	0.79	53.00	74.00	65	73	1.12	1.26
* Taken from Outersole Tracing																			

Figure 6-27 Dimensional measures of footwear

6.3.2. Saturation maximum stiffness drop off

The first part of establishing the testing protocol was to obtain the number of cycles within a test run that would reach a consistent value for the maximum stiffness for the respective loading scenario. This consistent value was predefined when a saturation point was reached for drop-off for the maximum stiffness. This was performed by observing the respective maximum torque values over repeated cycles in increments of ten; it was noted that a saturation of drop-off for maximum stiffness occurred for all loading scenarios between cycles 11-20 (Figure 6-28,Figure 6-29,Figure 6-30,Figure 6-31) except for midfoot torsion loading maximum eversion torque, this was reached at cycle 3 (8.18 Nm) conversely before the highest value at cycle 5 (9.24 Nm). All loading patterns had achieved a stable linear pattern by cycle 20; it was noted there was still a degree of unevenness to the ankle inversion and eversion loading between cycles 11-20, but this demonstrated only +/-3.5% variation from the central trend.

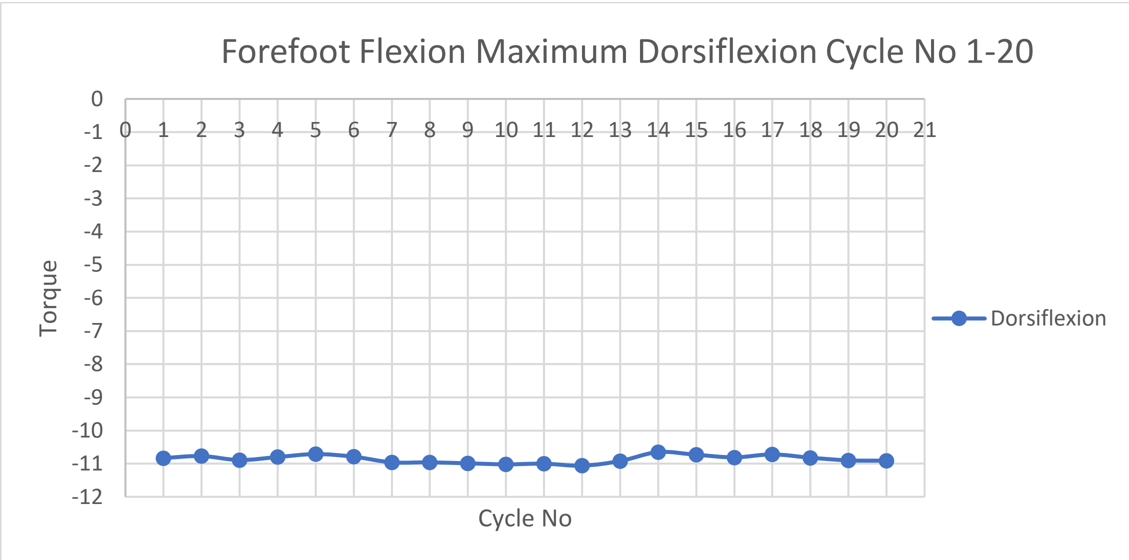


Figure 6-28 Forefoot flexion loading maximum dorsiflexion torque cycle 1-20.

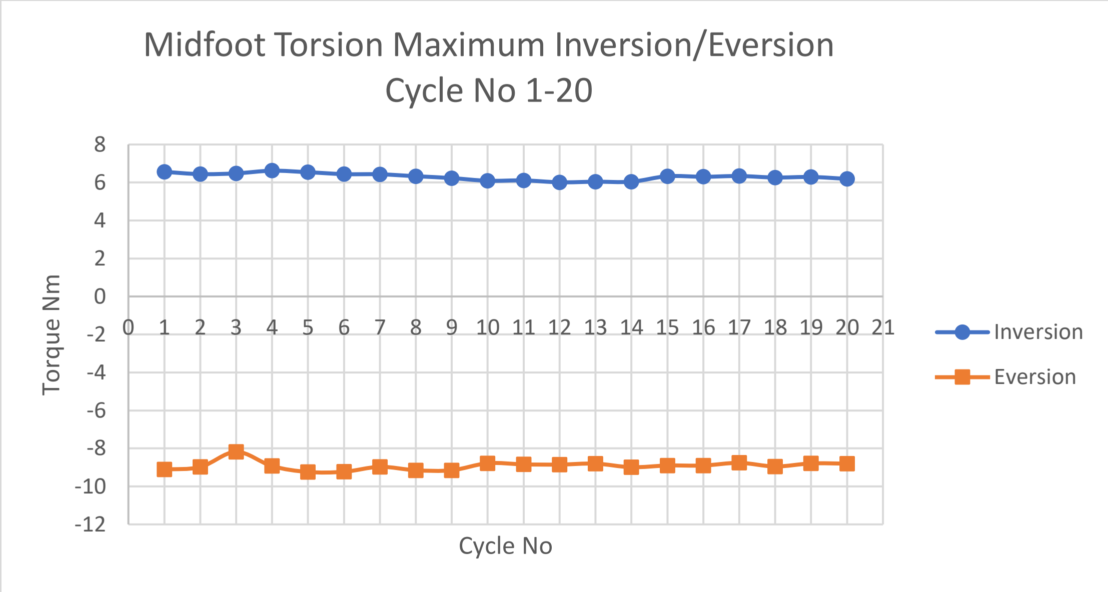


Figure 6-29 Midfoot torsion maximum inversion and eversion torque cycles 1-20.

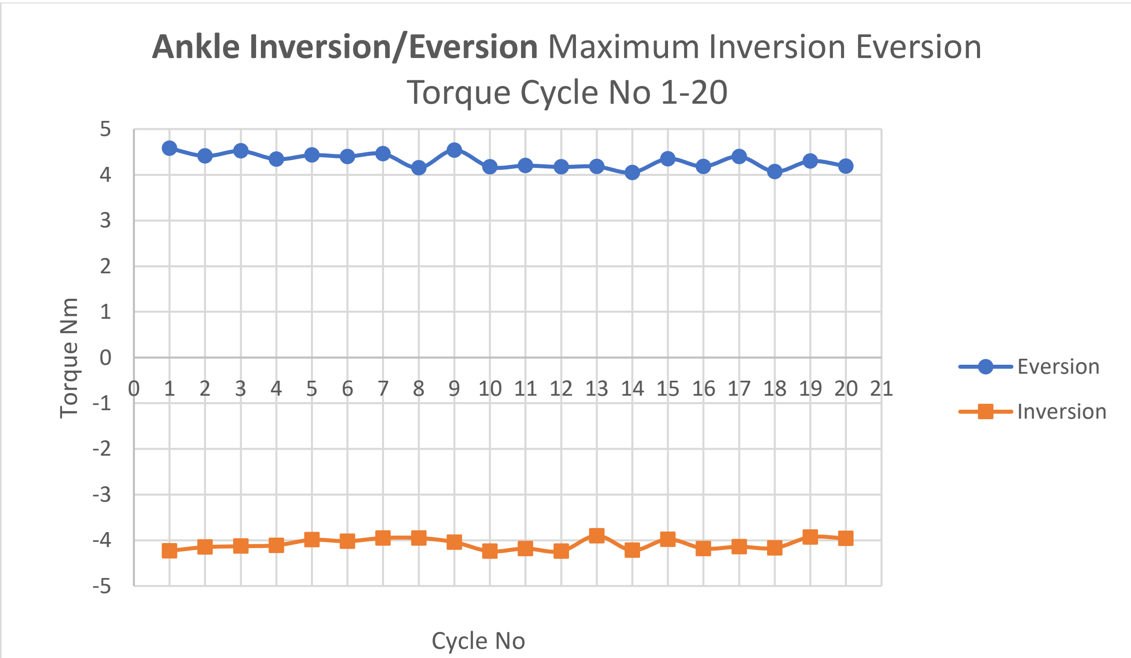


Figure 6-30 Ankle inversion/eversion maximum eversion and inversion torque Cycle 1-20.

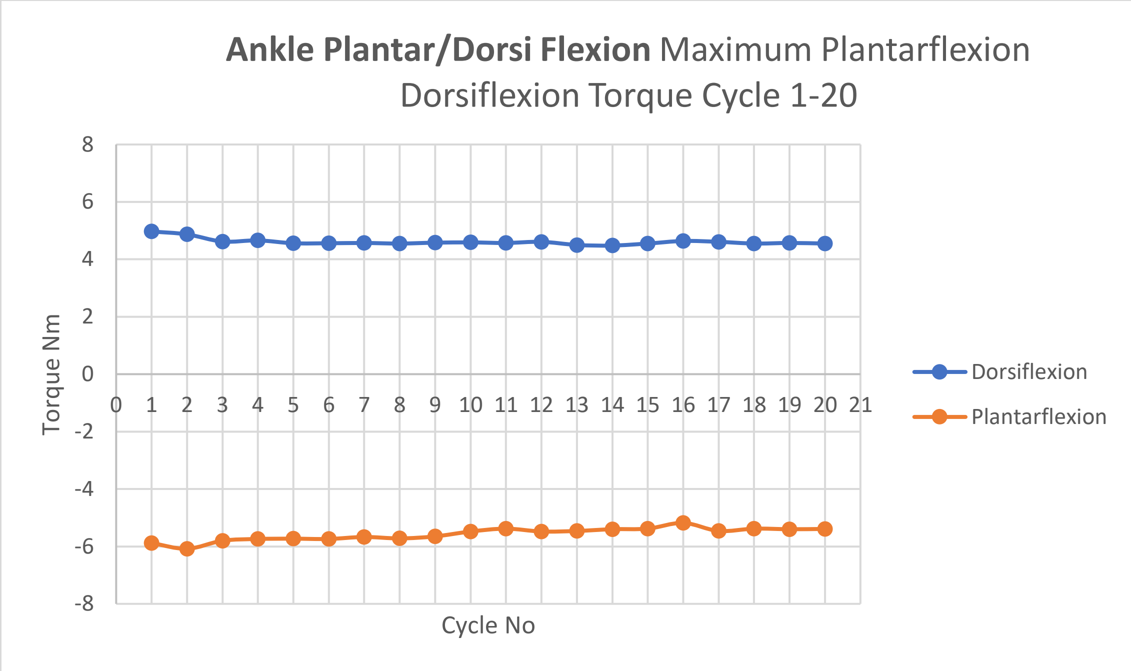


Figure 6-31 Ankle plantar/dorsi flexion maximum plantarflexion and dorsiflexion torque Cycle 1-20.

6.3.3. Reliability and consistency of testing protocol

The second objective was to establish a degree of precision and consistency for the methodology by calculating how many repeated testing runs would be required to provide an acceptable level of variation and an increased precision of the equivalent stiffness value offered. Ten separate test runs were performed for each loading scenario, and the maximum torque value at cycle 20 was taken from each test run for descriptive and inferential statistical analysis Table 6-2.

Table 6-2 Percentage, standard deviation and error of the mean of loading scenarios between test runs 1-10.

Loading Scenario	Nimco (OSSTF) Test Run 1-10				
	Mean	SD +/-	% Deviation from mean	Standard Error of the mean	% Error of the mean
Forefoot Flexion					
Maximum Dorsiflexion Torque (Nm)	-10.91	0.25	-2.32	0.08	0.73
Midfoot Torsion					
Maximum Inversion Torque (Nm)	6.07	0.19	3.14	0.06	0.99
Maximum Eversion Torque (Nm)	-8.48	0.53	-6.24	0.17	1.97
Ankle Inversion/Eversion					
Maximum Inversion Torque (Nm)	-3.77	0.28	-7.56	0.09	2.39
Maximum Eversion Torque (Nm)	3.80	0.41	10.73	0.13	3.39
Ankle Plantarflexion/Dorsiflexion					
Maximum Plantarflexion Torque (Nm)	-6.42	0.46	-7.11	0.14	2.25
Maximum Dorsiflexion Torque (Nm)	4.71	0.18	3.85	0.06	1.22

The standard error of the mean fell within a +/- 4% range for all loading scenarios providing an acceptable margin of error (McHugh, 2008). The largest variations of SEM were seen for both ankle loading scenarios.

An additional measure of consistency was performed by a proportional comparison of successive means with the mean value of the total 10 test runs. The projection of the ratio comparison of successive means against the mean of the total 10 test runs is presented in Figure 6-32, Figure 6-33,Figure 6-34, Figure 6-35. The proportional comparison of successive means was seen to approach a ratio of 1 for all loading scenarios within 9-10 runs for all loading scenarios.

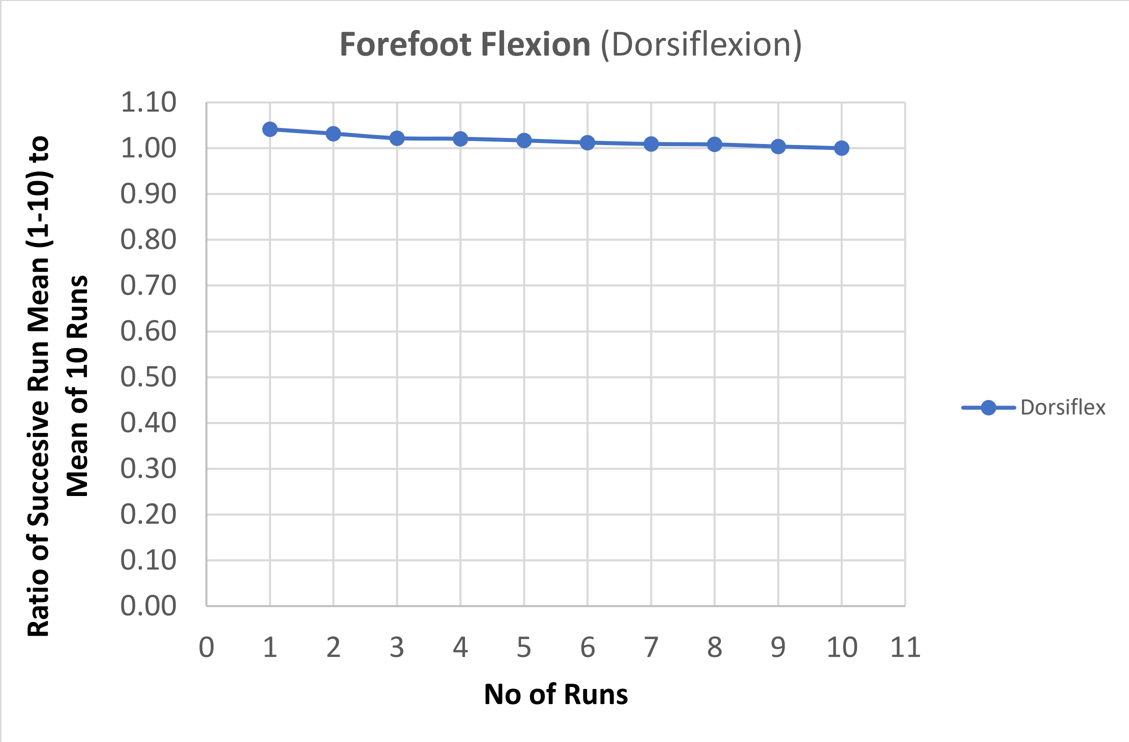


Figure 6-32 Forefoot Flexion Ratio of Maximum Dorsiflexion Torque Successive Means Test Run 1-10 to mean of 10th test run

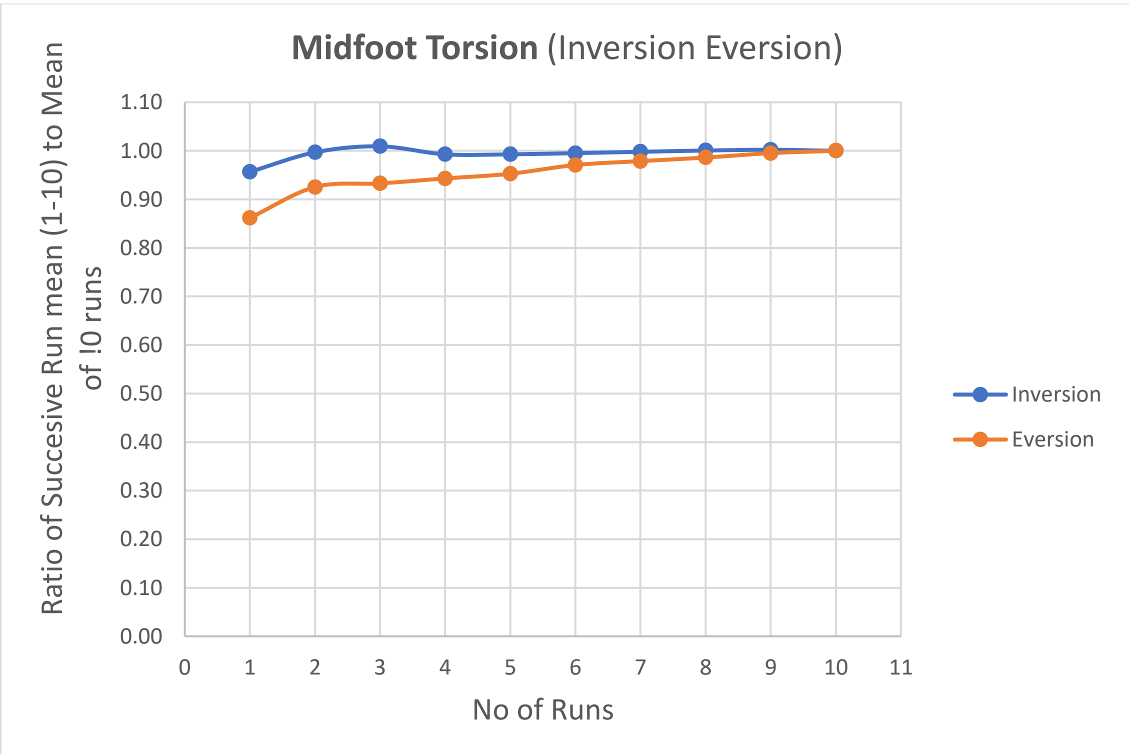


Figure 6-33 Midfoot Torsion Ratio of Maximum Inversion Eversion Torque Successive Means Test Run 1-10 to mean of 10th test run

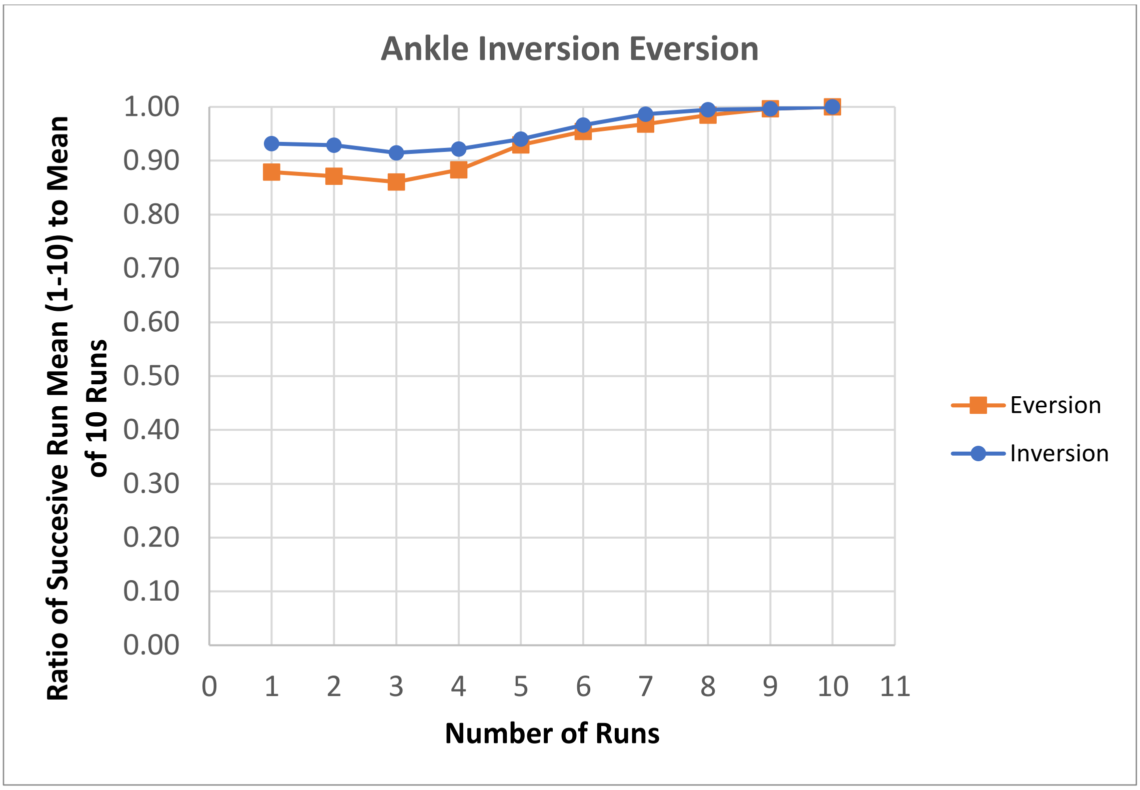


Figure 6-34 Ankle Inversion Eversion Ratio of Maximum Inversion Eversion Torque Successive Means Test Run 1-10 to mean of the 10th test run

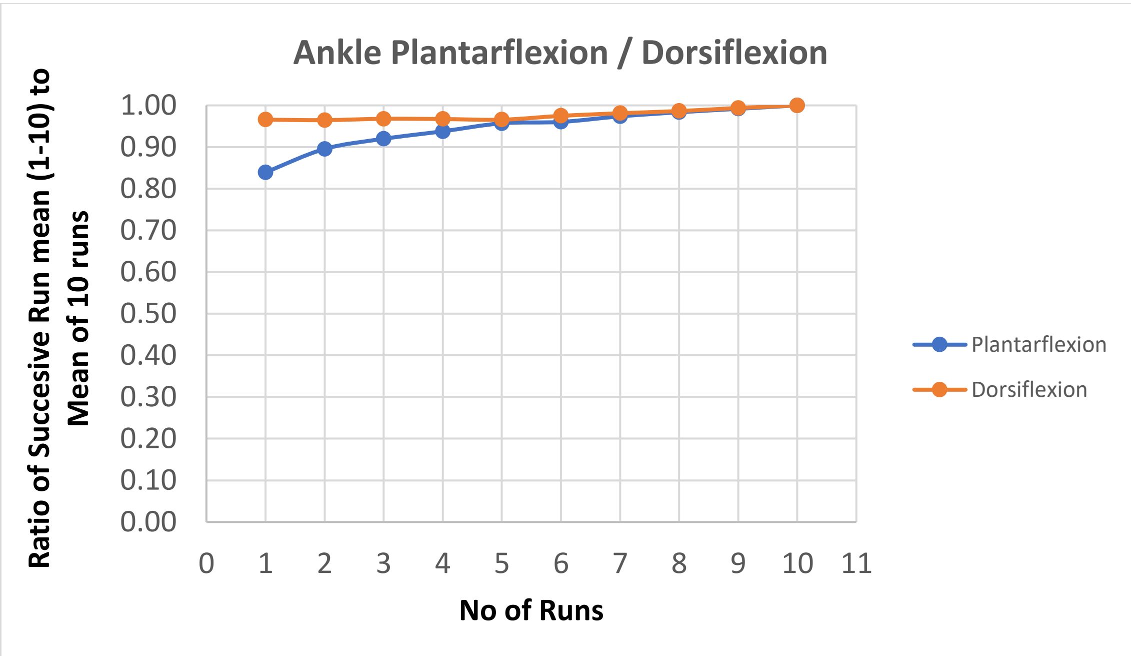


Figure 6-35 Ankle Plantarflexion Dorsiflexion Ratio of Maximum Dorsiflexion Plantarflexion Torque Successive Means Test Run 1-10 to mean of the 10th test run

6.4. Discussion

The aim of this study was to formulate a standardised method to quantify the in-situ effects that expert consensus design characteristics for OSSTF would have on the footwear's mechanical stiffness. The overall objectives were to provide a series of testing protocols to assess the consensus design characteristics in different loading scenarios from both a stability and ergonomic perspective in the coronal and sagittal plane, respectfully. A series of torque loading scenarios were developed on a bespoke torsion platform that would be representative of foot and ankle angular movement of children living with a mobility impairment (Amene et al., 2019; Kruger et al., 2017). Four torque loading scenarios were considered to capture the most important angular displacement that the footwear would be required to offer increased flexibility for ergonomics of the footwear (forefoot flexion and ankle plantar/dorsiflexion) and increased stiffness for stability (midfoot torsion and ankle inversion/eversion). These loading scenarios involved torque loading through the sole (forefoot flexion and midfoot torsion) and via the sole and a representative ankle/shank model (ankle inversion/eversion and plantar/dorsiflexion). Testing of the OSSTF incorporated international standardised footwear testing protocols where appropriate such as determining the long testing axis of the footwear and the forefoot flexion position (ISO, 2021).. Any testing protocol should produce results that accurately represent the concept under test and also provide consistent and repeatable measures to allow for meaningful analysis and comparison (Krumm et al., 2013; Patino & Ferreira, 2018). Therefore, in addition to providing torsional testing protocols that would simulate angular movements of the foot and ankle of children with mobility impairments, the objectives of the study also sought to provide testing protocols that would provide consistent and reliable representative values of the footwear's mechanical stiffness. The potential for a drop-off in mechanical stiffness through repeated torque cyclic loading was acknowledged. Consequently, a second objective of the testing protocol was to establish how many loading cycles would be required to reach a consistent value of maximum stiffness. From observations of the results in Figure 6-28Figure 6-29Figure 6-30Figure 6-31, it was noted that generally, maximum stiffness for the loading scenarios was higher in the initial cycles, but values reached a roughly linear pattern

between cycles 11-20, Although ankle inversion/eversion demonstrated a more undulating pattern than the other loading scenarios this variation was seen to be consistent at +/- 3.5% of the central trend. It was therefore concluded that the maximum torque value at cycle 20 would offer a consistent value for equivalent maximum stiffness and should be incorporated into the protocol for future footwear testing. It was also acknowledged that the maximum torque values would be open to variation between setting up the footwear for separate testing episodes (test runs). Measurement precision can be improved by taking multiple separate measurements of the same testing condition and averaging the value; with the more values averaged, the better the precision of the average (Koo & Li, 2016). Therefore, a third objective of the testing protocol was to provide a degree of precision for each loading scenario by establishing how many repeated testing episodes are required to provide an acceptable level of variation of the mean. The percentage standard error of the mean ranged from 0.73 to 3.49% across the torque loading scenarios providing a Margin of error of less than <7% over 10 test runs (McHugh, 2008; Wonnacott & Wonnacott, 1990).
Correspondingly a proportional comparison of successive means demonstrated a ratio that approached 1 within 9 test runs. Therefore, it was concluded from the results that the protocol would require the mean calculated from 10 separate test runs to provide an acceptable level of precision for the torque loading scenarios.

This study has provided a series of torque loading protocols to consistently measure the mechanical stiffness of OSSTF. These protocols should allow a quantitative assessment of the effects of variation of OSSTF design characteristics on the mechanical stiffness of this footwear. This will inform on the ability of this footwear to act as an assistive aid for children living with a mobility impairment. As previously discussed, one of the key principles in developing an intervention is to develop an understanding of how it should work (Craig et al., 2008). Providing a protocol to measure the design characterises in situ of the shoe architecture will allow clinicians, researchers and manufacturers to recognise and understand the key functional components of this intervention with the potential to facilitate patient care research reporting and study design, and manufacturing design (Eddison et al., 2015; Eddison, Healy, et al., 2022; Eddison, Mulholland, et al., 2017).

Although the protocols proposed in this study may facilitate an improved understanding of how OSSTF design characteristics may act as an assistive aid, the potential limitations of the protocol must be acknowledged. From the results, it was noted that torque loading scenarios involving ankle motion had a larger % standard error and took more testing cycles and runs to approach a consistent and precise value. This may be explained by the within-operator variation in securing the lace fastening of the OSSTF to the shank model of the rotating frame. Additionally, although the frame was contoured to simulate the shape of the lower tibia, it was not an accurate representation of the foot and ankle. Therefore, validity, consistency and precision of the ankle torque loading scenarios may be improved by adapting a prosthesis representing an EU size 32 foot and ankle with two degrees of freedom at the ankle joint. The precision of the protocol for the ankle inversion/eversion torque loading scenario would give a 95% confidence interval of the margin of error +/- 6.8% meaning the protocol could not precisely evaluate characteristic design effects on stiffness below 14% of ankle inversion eversion torque. In contrast, forefoot flexion may precisely evaluate design characteristics effects on stiffness above 4% dorsiflexion torque, and midfoot torsion may precisely evaluate effects on stiffness above 8 % inversion, eversion torque. The current protocol was only carried out on one sample of OSSTF, footwear with different mechanical stiffness properties may demonstrate different measures of consistency and precision for the protocol; therefore, further work should assess the protocol on various footwear to ensure similar levels of precision are provided across a range of OSSTF. In terms of the apparatus, the current platform system had no graduated means of adjusting the platform or positioning the footwear. This was done by simple markup on the platform to ensure repeatability of positioning with a more standardised method of platform adjustment and positioning, reducing the variability of the protocol. Additionally, the current method of securing the outsole to the support platforms required an appropriate extension of the outsole from the upper, meaning the current protocol would only allow OSSTF with a welted type of outsole construction to be assessed. Improvements to the system would include a universal securing setup to allow differing outsole designs to be assessed. Despite these limitations, this study has provided a protocol to study the in-situ effects of the design characteristics of OSSTF on their mechanical stiffness where none had previously existed.

6.5. Conclusion

This study has provided a protocol consisting of a series of torque loading scenarios to quantify the effects of the mechanical stiffness of OSSTF. The loading scenarios have demonstrated an acceptable degree of consistency and precision of torque measurement (> +/- 4% SEM) on the OSSTF sample to movements expected in the gait of a child living with a mobility impairment. The methodology developed can be used to further identify which design characteristics of OSSTF may influence stability and inform future applications in research, manufacturing, and clinical practice.

7. The effect of design characteristics on the mechanical stiffness of children's off-the-shelf stability therapeutic footwear

Aspects of this chapter have been published:

Hill, Matt, Aoife Healy, Panagiotis Chatzistergos, and Nachiappan Chockalingam. 2023. "The Effect of Design Characteristics on the Mechanical Stiffness of Children's off-the-Shelf Stability Therapeutic Footwear." Footwear Science, Proceedings of the Sixteenth Footwear Biomechanics Symposium (Osaka, Japan, 2023); 15(sup1): S158–60.

7.1. Background

Identification of how an intervention may act therapeutically is crucial to its understanding of research and development (Craig et al., 2008). Chapter 4 highlighted that there are numerous designs and styles of OSSTF; however, from the review of the available literature, it appears the general purpose of this footwear (Chapters 2 and 3) is to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait. The expert panel further developed the purpose in Chapter 5 "Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle". Further to this, the experts offered design characteristics that may influence the function of OSSTF during its use by children living with a mobility impairment, including both stability and ergonomic design characteristics. These design characteristics were linked to mechanical stiffness in two body planes, coronal (mediolateral) for stability and sagittal (anteroposterior) for ergonomics. With OSSTF designed to offer increased stiffness for **stability**, thereby limiting movements mediolaterally and offering flexibility (reduced stiffness) for **ergonomics** in an anterior-posterior direction (Chapter 5). The design characteristics suggested by the experts are summarised in Chapter 6 Figure 6-2

As previously stated in Chapter 6, the recommendations obtained from the Delphi study were based on expert opinion with no objective evidence to support the design characteristics suggested. It was proposed in the previous chapter that a means to objectively evaluate these design characteristics' effects on the mechanical stiffness when they were in-situ of OSSTF would enhance the understanding of this intervention as an assistive aid for children (Eddison, Mulholland, et al., 2017).

The methodology developed and proposed in Chapter 6 offered a potentially consistent and precise protocol to assess the torsional stiffness of these design characteristics within OSSTF. However, the protocol was only tested on one design of OSSTF, and there is a potential for the consistency of such a protocol to be affected by OSSTF of differing design and stiffness characteristics (Krumm et al., 2013). Therefore, further assessment of the protocol was suggested across a range of OSSTF to evaluate the consistency and precision of this method. As previously discussed in Chapter 6, the mechanical stiffness of a structure is affected by several factors, including the shore hardness of the material used, the manufacturing process (cemented, stitched, layered) and its architecture (dimensions, geometry) (Ji, 2003). Therefore, when exploring the effects of design characteristics of OSSTF, it would be necessary to explore the factors that can potentially affect stiffness independently of each other to quantify their effects.

Stiffness is the extent to which an object resists change in its geometry (strain) in response to an applied force (stress), with stiffer objects requiring greater force for the same change in geometry (Vaidya & Pathak, 2019). Recognising this, the desirable design characteristic of OSSTF to enhance stability would be stiffer relative to standard retail children's footwear, whilst those to allow ergonomic function would offer comparable stiffness to standard retail children's footwear. Therefore, for researchers, manufacturers, and clinicians to understand how OSSTF may influence stability in children living with a mobility impairment, the mechanical stiffness of OSSTF should be benchmark tested to comparable standard retail footwear. This lack of comparison of stability therapeutic footwear to standard footwear was highlighted as a limitation of the current body of research in Chapter 3.

7.1.1. Aim and Objectives

The aim of this study was to quantify the in-situ effects of the design characteristics of OSSTF on their mechanical stiffness and inform stakeholders of their potential to act as a clinical intervention for children living with a mobility impairment.

The objectives of this research are:

- To use the developed loading scenario protocols to quantify the in-situ effects of architectural (dimension, geometry) and fastening design characteristics of children's OSSTF on their mechanical stiffness independent of material and manufacturing process via a comparative analysis study.
- Establish which design characteristics may influence the mechanical stiffness of OSSTF via comparative analysis of maximum torque values.
- Establish the precision and consistency of the developed loading scenario protocols across a range of footwear.
- Compare the equivalent relative mechanical stiffness of a range of OSSTF footwear with comparable standard retail children's footwear.

7.2. Methods

7.2.1. Footwear samples for testing

The study was carried out using a range of OSSTF from two manufacturers of OSSTF, Nimco® and Piedro®. The left shoe EU size 32 was chosen as previously discussed in Chapter 6 as being representative of a child aged 8; this age is associated with an increase in social mobility and participation involving more physical activity (Delgado-Abellán et al., 2014; Schmidt et al., 2017).

The Nimco Made4You Cool shoe range was used. The Cool Catalogue standard was used as the control for comparative analysis: this had a standard height and length heel counter/stiffener, lace fastening, and standard rubber outsole. The Catalogue Cool range also offered the following modifications to the standard design (Figure 7-1,Table 7-1); increased heel counter length and height, increased topline, Velcro fastenings, polyurethane (PU) outsole and combination PU Rubber outsole, both outsole modifications offered a thickened solid outsole at the midfoot region in comparison to the stepped heel section of the standard rubber outsole (Figure 7-2).

For Piedro, the catalogue range 2480-2580 was used; this again offered a catalogue standard 2480 Rehab, which would be used as a control for comparative analysis which had standard height and length heel counter, lace fastening, standard rubber outsole and standard width of the outsole. The catalogue range also offered the following modifications to the catalogue standard; increased heel counter length and height, Velcro fastenings, and narrower outer sole (Figure 7-3,Table 7-1). The relative mechanical stiffness of the control footwear was compared with their respective design modifications for each manufacturer. The control footwear would allow the study to investigate the effects of dimensional and fastening design modifications on mechanical stiffness independent of the materials and the manufacturing process. The study also assessed if the design modifications effects on mechanical stiffness were consistent across manufacturers.

Table 7-1 Nimco and Piedro OSSTF Design Modifications

OSSTF MANUFACTURER	HEEL COUNTER	FASTENINGS	OUTSOLE	TOPLINE
NIMCO				
N1	Standard	Lace	Rubber with Heel	Standard
N2	Increased Height and Length	Lace	Rubber with Heel	Standard
N3	Standard	Velcro	Rubber with Heel	Standard
N4	Standard	Lace	Rubber with Heel	Extended
N5	Standard	Lace	PU with solid midfoot infill	Standard
N6	Standard	Lace	PU / Rubber with solid midfoot infill	Standard
PIEDRO				
P1	Standard	Lace	Rubber with Heel	Standard
P2	Increased Height and Length	Lace	Rubber with Heel	Standard
P3	Standard	Velcro	Rubber with Heel	Standard
P4	Standard	Lace	Rubber with Heel, Narrower Outsole width	Standard

Figure 7-1 Nimco OSSTF design modifications N1, Standard, N2 Increased height and length of heel counter, N3 Velcro fastening, N4 Increased topline height, N5 PU outsole with solid midfoot infill, N6 PU/Rubber outsole with solid midfoot infill

Figure 7-2 A) Outsole with solid midfoot infill, B) Outsole with a stepped heel section

Figure 7-3 Piedro OSSTF design modifications P1 Standard P2 Increased height and length of heel counter, P3 Velcro fastening, P4 Narrower outsole width

An EU size 32 left Kicker boot Model Kick Hi Core KF 409 (Figure 7-4**Error! Reference source not found.**) was taken as being

representative of a standard retail children's boot for relative stiffness comparative analysis with the OSSTF ranges. This standard retail boot (SRB) is a popular choice in children's footwear being marketed as "durable" and comes in a range of colours that could be used for a variety of purposes such as play and school as would be comparable for OSSTF daily use (Lovedbyparents.com, 2021; Shoe Master, 2021; C. M. Williams, Morrison, et al., 2022). Other brands of standard retail children's boots that could be used for school and social activities, including Clarks® and Dr Martin®, were considered for comparison with OSSTF. However, these brands only offered lace boots in children's EU sizing 32 with side zip fastenings, which may have affected the integral stiffness of the heel counter and precluded direct comparison with OSSTF samples.


Figure 7-4 Standard retail children's boot Kickers Kick Hi Core

Dimensional measures of the design characteristics experts considered would influence the stability and ergonomics of the footwear were taken of the OSSTF and standard retail footwear. The methods of measuring footwear dimensions followed ISO standards where appropriate (ISO, 2021) and those described in Chapter 0. The mass of the footwear was also recorded for comparison.

7.2.2. Mechanical stiffness testing of footwear samples

Mechanical stiffness testing of the footwear samples followed the protocols outlined in the methodology section of Chapter 6.

7.2.3. Statistical analysis

Statistical analyses were performed in Excel (Microsoft® version 16.60) and SPSS (IBM® version 28.0.1.1). Descriptive statistics (mean, standard deviation) were taken from the ten test runs for each loading scenario for each footwear sample. The mean value and standard deviation were used for comparative analysis between the footwear samples to observe the effects of design modifications on the representative mechanical stiffness. The standard error of the mean (SEM) was also obtained and compared to the findings in Chapter 6, to ascertain if the protocol outlined in Chapter 6 presented consistent variation across other footwear designs.

7.3. Results

7.3.1. Dimension measures of OSSTF and standard retail boot samples

Table 7-2 demonstrates the dimensional and mass measures of the OSSTF samples and standard retail footwear used in this study. Within design analysis of dimensional measures demonstrated that for the Nimco range, heel counter height was considerably higher in the N2 design modification representing a 50% increase from the other designs, the medial and lateral extension of the heel counter stiffener was also greater by 135mm, except for the standard model which had the same medial extension but a lateral extension that was comparable with the rest of the Nimco range. The N4 had the lowest dimensions of heel counter extensions. Other notable variations were the thickness of the outsole at the waist region of the footwear, with N5 and N6 being almost 100% thicker than the other Nimco OSSTF. N3 was the heaviest of the Nimco OSSTF, 413g, with the PU outsole shoes N5 and N6 being the lightest, 309g and 331g, respectfully. Other design characteristics that the experts considered may have affected stability, such as outsole width and depth at the heel and forefoot, were consistent amongst the Nimco range. Amongst the Piedro range, the P2 had the highest heel counter extension, similar to the Nimco stability N2; this was approximately 50% greater than the other Piedro footwear. However, it did not have the longest medial extension; this was the P4 at 129mm. Again, similar to the Nimco range, the Velcro

Table 7-2 Dimensional and mass measures of OSSTF and standard retail footwear shoe samples

FOOTWEAR	*Size EU*	*Length Total (mm)**	*Forefoot Width (mm)**	*Mass (g)*	*Top Line Height (mm)*	*Heel Counter/ Stiffener Length Medial (mm)*	*Heel Counter/ Stiffener Length Lateral (mm)*	*Heel Counter/ Stiffener Height (mm)*	*Heel Depth (mm)*	*Forefoot Outer Sole Depth (mm)*	*Heel / Forefoot Ratio*	*Waist (Midfoot) Outer Sole Depth (mm)*	*Heel / Midfoot Depth Ratio*	*Waist Area (mm)*	*Waist (Midfoot) Outer Sole width (mm)*	*Heel Cup Width (mm)*	*Heel Outer sole width mm*	*Outsole Heel width to Heel Cupwidth ratio*	*Outsole forefoot width to Outsole heel width ratio*
Nimco																			
N1	32	**240**	93	397	121	**135**	106	50	27	13	2.08	12.00	0.44	54.00	72	**64**	70	1.09	1.33
N2	32	235	93	407	123	**135**	**135**	**75**	27	13	2.08	12.00	0.44	52.00	73	**64**	70	1.09	1.33
N3	32	237	94	**413**	122	120	106	45	26	13	2.00	13.00	0.50	52.00	73	63	**73**	1.16	1.29
N4	32	235	94	406	**142**	105	95	45	26	14	1.86	12.00	0.46	**57.00**	71	62	70	1.13	1.34
N5	32	236	93	309	122	121	111	50	**30**	**15**	2.00	**25.00**	0.83	0.00	73	63	72	1.14	1.29
N6	32	236	**95**	331	117	107	105	50	28	14	2.00	23.00	0.82	0.00	73	63	**73**	1.16	1.30
Piedro																			
P1	32	232	**97**	424	118	127	**90**	45	**28**	13	2.15	12.00	0.43	**55.00**	**73**	64	**72**	1.13	1.35
P2	32	230	**97**	415	118	117	**90**	**70**	27	13	2.08	10.00	0.37	50.00	71	**67**	71	1.06	1.37
P3	32	235	96	**454**	118	122	74	45	**28**	13	2.15	12.00	0.43	52.00	**73**	65	71	1.09	1.35
P4	32	**237**	94	396	118	**129**	74	47	27	13	2.08	**13.00**	0.48	**55.00**	71	62	68	1.10	1.38
Kicker																			
SRB†	32	224	86	264	92	93	85	35	25	17	1.47	15	0.60	40.00	67.00	60	64	1.07	1.34

** Taken from Outsole Tracing † SRB standard retail boot, largest value for respective brand dimensional value given in bold*

Fastening P3 was the heaviest footwear at 454g. Additional features that the experts considered to impart an effect on stability, such as outsole width and depth at the heel and forefoot, were generally consistent amongst the Piedro range and has previously been observed in the Nimco range; this consistency amongst the design modifications would limit the effect of extraneous design variables affecting the results of representative mechanical stiffness other than the design variable of interest, i.e. heel counter height. Comparison amongst the range of OSSTF and the standard retail footwear demonstrated that the Piedro footwear was generally the heaviest, with only the P4 being lighter than four of the shoes in the Nimco range; all OSSTF were considerably heavier than the standard retail boot which was 264g. The heel counter dimensions were generally greater in the OSSTF compared to the standard retail boot, with the heel counter height being 25 to 100% greater in the OSSTF, and medial extension of the heel counter height greater in the OSSTF from 10 to 42 mm. The lateral extension of the heel counter was generally greater in OSSTF compared to the standard retail boot other than P3 and P4, where the expansion was 10 mm less than the standard retail boot.

7.3.2. Mechanical stiffness measures of OSSTF and standard retail footwear samples

The results of the mechanical testing of footwear samples are presented with respect to the four torque loading scenarios, forefoot flexion, midfoot torsion, ankle inversion/eversion and ankle plantar/dorsi flexion. The effects of the design characteristics of the footwear on their mechanical stiffness will be considered through a comparison of the max mean torque compared to the respective control for the OSSTF range N1 for Nimco and P1 for Piedro, given as % of the control. Comparison will also be given with respect to the standard retail boot SRB to the control of each OSSTF footwear range. The significance of the design characteristics will be inferred from the standard deviation. The consistency and precision of the testing protocol will be considered through the % standard error of the mean across the range of footwear with agreed tolerance of +/- 5% as agreed in the protocol outlined in Chapter 6.

7.3.2.1. Forefoot flexion torque loading

The maximum mean dorsiflexion torque for forefoot flexion torque loading for both ranges of OSSTF (Piedro and Nimco) and the SRB are presented in Table 7-3. For the Nimco range, the control N1 had the highest mean torque value at 12.39 Nm however, most of the range was approximately 95% of the control value. Only in the N3 did there appear to be a notable difference. All of the Nimco footwear appeared to be stiffer than the SRB by up to 15% (Table 7-3) There was a greater range of values in the Piedro range than Nimco, -12.84 (P1) to -10.39 (P4), with the control P1 being almost 20% stiffer in forefoot flexion than P4. However, samples P2 to P3 were roughly comparable 91 -97% of. the P1 control value. Generally, the Piedro range was significantly stiffer in forefoot flexion than the SRB by up to 18%, except the Piedro shoe with the narrower outsole P4. In consideration of the precision of the forefoot flexion torque measurement protocol across various footwear ranges and designs, the % standard error of the mean for forefoot flexion torque loading across all the footwear ranges ranged between 1.29 and 0.48%; this was comparable with the values in the protocol and within the tolerance values set.

Table 7-3 Mean, standard deviation and standard error of maximum Forefoot flexion torque loading scenarios for OSSTF and standard retail boot samples

Forefoot Flexion					
Footwear	Max Mean Dorsiflexion Torque (Nm)	Standard Deviation +/- (Nm)	Standard Error of mean +/- (Nm)	% Error of the mean	% Torque of control
Nimco					% Torque N1
N1	-12.39	0.19	0.06	0.48%	
N2	-12.12	0.49	0.15	1.24%	97.82%
N3	-11.74	0.22	0.07	0.60%	94.77%
N4	-12.23	0.17	0.05	0.41%	98.71%
N5	-12.13	0.28	0.09	0.74%	97.85%
N6	-12.22	0.30	0.09	0.77%	98.65%
Piedro					% Torque P1
P1	-12.84	0.44	0.14	1.08%	
P2	-11.75	0.18	0.06	0.51%	91.49%
P3	-12.42	0.51	0.16	1.29%	96.74%
P4	-10.39	0.22	0.07	0.67%	80.89%
Kicker					% Torque of N1, P1
SRB	-10.49	0.32	0.1	0.95%	84.69%
					81.74%

7.3.2.2. Midfoot torsion torque loading

The maximum mean inversion and eversion values for midfoot torque loading for both ranges of OSSTF and SRB are presented in Table 7-4. For the Nimco range, the footwear with the solid midfoot outsole infill was considerably stiffer than the control in inversion torque +37% for N6 and +20% for N5, these designs also appeared to be stiffer than the other Nimco range, other than N5 compared to N2. All the Nimco range appeared significantly stiffer than SRB except for N4, which had a slightly lower mean inversion torque stiffness than the SRB. For eversion midfoot torque in the Nimco range, N2 was seen to have the highest torque value, 26% of the control N1, with the next stiffest Nimco shoe being the N5 at 15%, with the N2 and N6 stiffer. Midfoot eversion in comparison to midfoot inversion, all the Nimco range were stiffer than the SRB, representing 72% of the value of N1.

In the Piedro range, the control P1 was the stiffest in midfoot inversion torque 9.20Nm, being 16-25% stiffer than the rest of the range (Table 7-4). All of the Piedro range were stiffer in midfoot inversion torque than the SRB, with the SRB representing 56% torque of P1 (Table 7-4) In eversion midfoot torque for the Piedro range, the stability footwear P2 was the stiffest at -9.75 Nm, but this was only 8% greater than P1 (Table 7-4). Both P1 and P2 appeared to be stiffer in eversion midfoot torque than the P3 and P4 -9.01 and -9.75 Nm vs -6.74 and -7.60 Nm, respectfully. The SRB represented 81% of the P1 value for midfoot eversion torque. However, only P1 and P2 in the Piedro range appeared to be stiffer than SRB in midfoot eversion with the P3 offering 7% less stiffness than the SRB for this loading scenario. In consideration of the precision of midfoot torque measurement protocol across various footwear ranges and designs, the % standard error of the mean for midfoot torque loading across all the footwear ranged from 0.81-2.42% for inversion and 0.55-1.33% for eversion, this was comparable with the values in the initial protocol and within the tolerance values set.

Table 7-4 Mean standard deviation and standard error of maximum Midfoot torsion torque loading scenarios for OSSTF and standard retail boot samples

Footwear	Max Mean Inversion Torque Nm	Standard Deviation +/-(Nm)	Standard Error of mean +/- (Nm)	% Error of the mean	% Torque of control
Inversion					
Nimco					% Torque N1
N1	7.13	0.18	0.06	0.81%	
N2	7.68	0.39	0.12	1.56%	107.80%
N3	6.06	0.28	0.09	1.48%	85.08%
N4	4.96	0.39	0.12	2.42%	69.55%
N5	8.61	0.26	0.08	0.93%	120.83%
N6	9.79	0.47	0.15	1.53%	137.44%
Piedro					% Torque P1
P1	9.20	0.64	0.20	2.21%	
P2	7.68	0.39	0.12	1.56%	83.45%
P3	6.87	0.18	0.06	0.87%	74.60%
P4	6.83	0.56	0.18	2.64%	74.17%
Kicker					% Torque of N1, P2
SRB	5.13	0.21	0.07	1.37%	71.92%
					55.69%
Eversion					
Nimco					% Torque N1
N1	-10.13	0.41	0.13	1.27%	
N2	-12.77	0.49	0.15	1.17%	126.04%
N3	-10.46	0.30	0.09	0.86%	103.30%
N4	-9.49	0.26	0.08	0.84%	93.67%
N5	-10.92	0.17	0.06	0.55%	107.81%
N6	-11.60	0.31	0.1	0.86%	114.56%
Piedro					% Torque P1
P1	-9.01	0.37	0.12	1.33%	
P2	-9.75	0.40	0.13	1.33%	108.11%
P3	-6.74	0.17	0.05	0.74%	74.76%
P4	-7.60	0.48	0.15	1.97%	84.35%
Kicker					% Torque of N1, P2
SRB	-7.33	0.26	0.08	1.09%	72.40%
					81.35%

7.3.2.3. Ankle inversion/eversion torque loading

The maximum mean inversion and eversion torque values for ankle inversion/eversion torque loading for both ranges of OSSTF and SRF are presented in

Table 7-5. For the Nimco range, the footwear design with the increased dimensions of the heel counter N2 was stiffer in ankle inversion torque than the control N1, -12.32Nm versus -6.34 Nm, this contributed to increase in the stiffness by 94% (

Table 7-5). A review of the distribution of values in indicates the significance of the N2 design characteristic on ankle inversion torque with all the other design variations for the Nimco range clustering around similar values. All the Nimco range was stiffer than the SRB in ankle inversion torque, with the SRB representing only a 1/3rd of the stiffness of N1 control (

Table 7-5). In ankle eversion torque for the Nimco range, the design with increased heel counter N2 was again found to be stiffer than the control N1 11.70 vs 5.42 Nm, increasing the stiffness by +116%. A review of the distribution of the values indicates the significance of the design of N2 with all the other Nimco range clustering around the control N1 value. All the Nimco range were significantly stiffer than the SRB for ankle eversion torque, with the SRB representing 29% of the eversion torque of Nimco control N1.

For the Piedro range, the footwear design with the increased heel counter dimensions P2 was markedly stiffer in ankle inversion torque than the control P1, -8.90Nm versus -5.64Nm, representing a 58% increase in inversion torque (

Table 7-5). The P4 design variation represented a 22% increase compared to the control P1, -6.90 versus -5.64 Nm. Analysis of the distribution of the values for ankle inversion torque demonstrated that the P2 design variation was stiffer in ankle inversion torque than the rest of the range. All design variations of the Piedro OSSTF were stiffer in ankle inversion torque than the SRB, with the SRB representing 36% of the control P1 value

Table 7-5,. For ankle eversion torque, the P2 increased heel counter dimension was markedly stiffer than the control P1 value, 9.71 versus 5.42Nm, representing a +107% increase. The P4 narrower outsole dimension was also seen to be 33% stiffer than the control P1, 6.22 versus 5.42Nm. Analysis of the distribution of values for ankle eversion torque indicates the P2 design variation was stiffer in ankle eversion torque than the other Piedro design variations. All Piedro designs were stiffer than the SRB in ankle eversion torque, with the SRB representing 33% of the P1 control value (

Table 7-5). In consideration of the precision of the ankle inversion/eversion torque measurement protocol across the various footwear ranges, the % standard error of the mean for ankle inversion/eversion torque loading across all the footwear ranged from 1.04-3.89% for inversion and 1.06-4.49% for eversion. This was comparable with the values in the initial protocol and within the tolerance values set.

Table 7-5 Mean, standard deviation and standard error of maximum Ankle inversion/eversion torque loading scenarios for OSSTF and standard retail boot samples

Ankle Inversion/Eversion					
Footwear	Max Mean Inversion Torque (Nm)	Standard Deviation +/-	Standard Error of mean +/-	% Error of the mean	% Torque of control
Ankle inversion					
Nimco					% Torque N1
N1	-6.34	0.17	0.13	2.03%	
N2	-12.32	0.47	0.15	1.22%	194.38%
N3	-6.08	0.25	0.08	1.32%	95.87%
N4	-6.15	0.21	0.07	1.14%	97.03%
N5	-6.70	0.24	0.07	1.04%	105.71%
N6	-6.34	0.21	0.07	1.10%	100.05%
Piedro					% Torque P1
P1	-5.64	0.63	0.20	3.53%	
P2	-8.90	0.38	0.12	1.35%	157.93%
P3	-5.66	0.18	0.06	1.06%	100.39%
P4	-6.90	0.29	0.09	1.30%	122.45%
Kicker					% Torque of N1, P2
SRB	-2.06	0.15	0.08	3.89%	32.44%
					36.47%
Ankle Eversion					
Nimco					% Torque N1
N1	5.42	0.25	0.06	1.06%	
N2	11.70	0.46	0.15	1.28%	215.81%
N3	4.68	0.19	0.06	1.28%	86.33%
N4	4.68	0.29	0.09	1.92%	86.44%
N5	6.15	0.21	0.07	1.14%	113.42%
N6	5.65	0.31	0.15	2.65%	104.26%
Piedro					% Torque P1
P1	4.69	0.18	0.06	1.18%	
P2	9.71	0.65	0.2	2.06%	207.30%
P3	5.44	0.28	0.09	1.65%	116.07%
P4	6.22	0.62	0.2	3.22%	132.65%
Kicker					% Torque of N1, P2
SRB	1.56	0.19	0.07	4.49%	28.75%
					33.25%

7.3.2.4. Ankle plantar/dorsi flexion torque loading

The maximum mean plantarflexion and dorsiflexion torque values for ankle plantar/dorsi flexion torque loading for both ranges of OSSTF and SRB are presented in

Table 7-6. For the Nimco range, maximum plantarflexion torque was markedly reduced in the Velcro N3 design variation compared to the control N1 value, -4.98 versus -8.21 Nm, representing 61% of the N1 value. Although the increased topline height model N4 represented the highest plantarflexion torque value (-9.58Nm), which represented a 17% increase on the control, there was a high degree of crossover of standard deviation for plantarflexion torque amongst the Nimco designs other than the N3 design variant. All the Nimco shoes except the N3 Velcro fastening were stiffer in ankle plantarflexion torque than the SRB, with the SRB representing 48% of the N1 control value

Table 7-6. In ankle dorsiflexion torque, the model with the increased heel counter dimensions N2 was stiffer in dorsiflexion torque than the control value N1, 11.30 versus 5.11Nm, representing a 121% increase from the control value. The Velcro N3 and PU sole N5 were stiffer than the control, 6.54 Nm and 6.70 Nm, respectfully, representing a 28% and 31% increase from the control value (

Table 7-6). On reviewing the distribution of values, the N2 design variant was significantly larger than the Nimco range. All of the Nimco range were significantly stiffer in ankle dorsiflexion torque than the SRB, with the SRB representing 48% of the N1 control value (

Table 7-6).

For the Piedro range ankle plantarflexion torque, the creased heel counter design model P2 was stiffer than the control value P1, -13.40 versus -8.55 Nm, representing a 57% increase in plantarflexion torque stiffness (

Table 7-6). The Velcro design P3 offered less stiffness than the control P1 value, -7.11 versus -8.55 Nm, representing a 17% decrease from the control P1 value (

Table 7-6). On review of the distribution of values in the P2 had the greatest effect on an increase in ankle plantarflexion torque, with the P3 variant having a lesser effect on a decrease in ankle plantarflexion torque. All Piedro footwear was stiffer in ankle plantarflexion torque than the SRB, with the SRB representing 47% of the P1 control value (

Table 7-6). For ankle dorsiflexion torque, the increased heel counter dimension design P2 was stiffer than the control value P1, 9.11 vs 5.37 Nm, representing a 70% increase on the P1 control value

Table 7-6. However, both the Velcro P3 and Narrower outsole P4 models were found to be stiffer, 6.96 and 8.28Nm, respectfully representing a 30% and 54% increase on the ankle dorsiflexion torque stiffness (

Table 7-6). On reviewing the distribution of ankle dorsiflexion torque values, P2 and P4 had the greatest effects on increasing the torque value. All Piedro footwear was significantly stiffer in ankle dorsiflexion torque than the SRB, with the SRB representing 45% of the P1 control value (

Table 7-6). In consideration of the precision of the ankle plantar/dorsi flexion torque measurement protocol across the various footwear ranges; the % standard error of the mean for ankle plantar/dorsi flexion torque loading across all the footwear ranged from 0.50-3.13% for plantarflexion and 0.82-3.96% for dorsiflexion this was comparable with the values in the initial protocol and within the tolerance values set.

Table 7-6 Mean, standard deviation and standard error of maximum Ankle Plantar/Dorsi flexion torque loading scenarios for OSSTF and standard retail boot samples

Footwear	Max Mean Torque (Nm)	Standard Deviation (Nm)	Standard Error of mean (Nm)	Mean error (%)	% Torque of control
Ankle Plantarflexion					
Nimco					% Torque N1
N1	-8.21	0.47	0.15	1.81%	
N2	-9.27	0.91	0.29	3.13%	112.95%
N3	-4.98	0.27	0.09	1.81%	60.63%
N4	-9.58	0.41	0.13	1.34%	116.71%
N5	-9.19	0.74	0.23	2.50%	111.93%
N6	-9.41	0.53	0.17	1.81%	114.70%
Piedro					% Torque P1
P1	-8.55	0.37	0.12	1.39%	
P2	-13.40	0.72	0.23	1.70%	156.77%
P3	-7.11	0.14	0.04	0.56%	83.18%
P4	-8.56	0.57	0.18	2.10%	100.13%
Kicker					% Torque of N1, P2
SRB	-3.99	0.34	0.02	0.50%	48.66%
					46.70%
Ankle Dorsiflexion					
Nimco					% Torque N1
N1	5.11	0.25	0.11	2.15%	
N2	11.30	0.87	0.28	2.48%	221.20%
N3	6.54	0.43	0.13	1.99%	127.98%
N4	5.76	0.47	0.15	2.60%	112.82%
N5	6.70	0.23	0.07	1.04%	131.19%
N6	5.63	0.23	0.07	1.24%	110.26%
Piedro					% Torque P1
P1	5.37	0.67	0.21	3.96%	
P2	9.11	0.56	0.18	1.93%	169.78%
P3	6.96	0.18	0.06	0.86%	129.63%
P4	8.28	0.53	0.17	2.05%	154.18%
Kicker					% Torque of N1, P2
SRB	2.43	0.25	0.02	0.82%	47.55%
					45.26%

7.4. Discussion

The overall aim of this study was to quantify the in-situ effects of the design characteristics of children's OSSTF on their mechanical stiffness, in order to inform researchers, clinicians and footwear manufacturers on how these design characteristics may potentially act as a clinical intervention for children living with a mobility impairment.

In reference to the consistency of the loading scenario protocols, similar standard errors were observed from those in the initial protocol across all the loading scenario protocols. Again, the ankle loading scenarios, both Inversion/eversion and plantar/dorsi flexion loading, offered the most variability. The SRB offered the highest variability in ankle inversion and eversion torque +/- 3.89 % and 4.49%, respectfully the N2 in ankle plantarflexion +/- 3.13% and the P1 in ankle dorsiflexion, and values that are within 16 and 18% of the torque value of SRB for ankle inversion, and within 12% for N2 ankle plantarflexion and 14% for P1 ankle dorsiflexion. Again, this was interpreted as potential user variability of tightening the fastenings of the footwear and securing it to the rotating shank model for the ankle loading scenarios Figure 6-20 The data therefore obtained from the loading scenarios in this study met the criteria for precision and consistency set out in the initial protocol detailed in Chapter 6.

In Chapter 5, expert consensus on the design characteristics that would enhance stability through increased stiffness in a mediolateral direction (coronal plane) would be increased height and length of the heel counter, lace fastenings, increased topline height, increased ratio of outsole heel width compared to the forefoot outsole heel width and heel cup width. The experts also felt that OSSTF should be stiffer in the midfoot to mediolateral movements (inversion/eversion) but did not elaborate on what design feature or characteristic would increase this. The loading scenarios that would reflect stability were midfoot torsion and ankle inversion/eversion.

The design feature that appeared to affect the stiffness of midfoot torsion in inversion in the Nimco range was the thickness of the outsole in the midfoot. With doubling the midfoot thickness giving a 20% (N5) to (37%) N6 increase in relative stiffness compared to the control N1. Although the PU outsole material had a lower shore hardness than the rubber outsole the outsole dimension that has an area at a greater distance away from the rotating axis through its centroid will have a larger moment of inertia. The material thickness of the outsole at the midfoot therefore also affects the stiffness with the PU rubber sole mix N6 having the larger % increase in stiffness to midfoot inversion. It must also be noted that the N4 shoe had a considerable decrease of 30% from the N1 control, with the N4 having the shortest medial heel counter extension of the Nimco range. This, again, would be explained by the moment of inertia. For midfoot torsion eversion in the Nimco range, the footwear with the greater lateral extension of the heel counter N2 increased the stiffness by 26%; however, one of the thickened outsoles, N6, still demonstrated an approximate 15% increase on the control.

For midfoot torsion inversion in the Piedro range, the control P1 demonstrated a greater relative stiffness, approximately 16-25% stiffer than the other design. It was not readily apparent what features may have affected this since the dimension of the medial extension of the heel counter and midfoot outsole depth seemed similar amongst the Piedro samples. For midfoot torsion eversion, the relevant stiffness for the P3 and P4 shoes was 25% and 16% reduced, respectfully from that of the control P1; P1 had a longer lateral heel counter extension than P3 and P4. Both the P3 and P4 had the same lateral heel counter extensions; since it was the midfoot area of the footwear under test, it was unclear how the difference in fastenings would impact the findings. For the majority of OSSTF, both Piedro and Nimco provided greater stiffness in midfoot torsion than the SRB, with the control values N1 and P1 being 28% and 46% greater respectfully in inversion and 28% and 19% greater respectfully in eversion. Only N4 was of a similar value for SRB in midfoot inversion, 69.55% versus 71.92% of the control N1 value, respectfully, and P3 and P4 for midfoot eversion torque, 74.76% and 84.35% of the P1 value with SRB being 81.35% of the P1 value. It must be noted that the N4 had the lowest of the medial extensions of the heel counter amongst the Nimco range, and the P3 and P4 had lower lateral extensions of the heel counter than the SRB.

Comparison of the OSSTF ranges indicated that the Nimco were equivalent in midfoot inversion but generally stiffer in midfoot eversion, with the Nimco range having a longer lateral heel counter extension than the Piedro range except for N4, which was equivalent to the P1 and P2 extension with similar in eversion torque. From initial analysis, it appeared that an increase in heel counter length into the midfoot and an increase in midfoot outsole depth were the design characteristics that increased midfoot torsion stiffness through an increase in area moment of inertia.

The design characteristics that appeared to affect the stiffness of ankle inversion torque in the Nimco range appeared to be the height of the heel counter, with an increase of 25mm in heel counter height of N2 dramatically increasing the torque value by 94% of the control N1 value. All the other design variants were of comparable stiffness to the N1 value with similar heel counter height dimensions. Increased topline height was thought by the expert panel to influence stiffness to ankle inversion; however, this was seen to be of a similar value to the N1 control value. Velcro fastening was thought by the expert panel to reduce stiffness for ankle inversion; however, this was seen to be of similar value to that of the N1 control. For ankle eversion torque, again, the height of the heel counter was seen to dramatically increase the stiffness, with the N2 design increasing the torque value by 116% of the control N1 value. Although the N3 and N4 design variants were seen to be lower than the N1 control, this was differences were not as large.

For ankle inversion torque for the Piedro range, heel counter height appeared to have a dramatic effect on increasing stiffness with a 58% increase from the P1 control value. The P4 design variant also increased the stiffness of ankle inversion by 22% of the P1 control value but P4 and P1 appeared to have similar design characteristics at the ankle region of the footwear that the experts felt could influence stiffness to mediolateral movements. The P3 Velcro offered similar stiffness to the P1 control as was also seen in the Nimco range. For ankle eversion, again heel counter height dramatically increased torque stiffness, with the P2 demonstrating a 107% increase on the P1 control value. The P4 also demonstrated a 33% increase from the P1 control value; however, design characteristics were similar between P1 and P4. The Velcro design P3 was 16% stiffer than the control P1 value.

All the OSSTF footwear range were stiffer than the SRB in both ankle inversion and ankle eversion, with both control shoes N1 and P1 being approximately three times stiffer than the SRB in ankle inversion/eversion torque loading. The design variant that offered the greatest increase in stiffness was the height of the heel counter, with the increase in the area of moment of inertia at the heel counter likely to explain this finding. It was noted that the N2 increased heel counter was 2 to 3 Nm stiffer than the P2 increased heel counter; this may have been due to differences in material. However, it was noted that the heel counter of the N2 range increased from the posterior of the heel to reach its height point at the malleoli. In contrast, the P2 heel counter was highest at the posterior of the heel and curved downwards to the midfoot, indicating the position of the highest point may also be a factor. Velcro fastenings and increased topline height did not affect the torque stiffness at the ankle.

For the forefoot flexion torque loading scenario in the Nimco range, there were similar values across the design variables for maximum dorsiflexion torque. Similar maximum dorsiflexion torque values were also observed across the majority of the range of Piedro OSSTF except for the P4 shoe, which was 19% reduced from the control P1 torque value; this may be explained by the reduced cross-sectional area of the P4 shoe compared to the P1 control and the subsequent effects of area moment of inertia. The N control footwear (N1 and P1) were both seen to be stiffer than the SRB by 15 to 18% respectfully; even though the cross-sectional area of the OSSTF was similar to the SRB, however, the N1 and P1 had a uniform depth in the forefoot. In contrast, the SRB had a marked deepened tread with greater variability of the depth of the outsole. It must also be noted that the density and material of the OSSTF footwear could affect these findings, with the N1 and P2 shoe mass being 133 to 160g heavier than the SRB.

Velcro fastening N3 appeared to affect the stiffness of plantarflexion torque for ankle plantar/dorsi flexion loading scenario in the Nimco OSSTF range, with a 39% reduction from the N1 control value. Other design characteristics that appeared to affect the ankle plantarflexion torque was the increased height of the topline, with a 16% increase compared to the control value N1. For dorsiflexion torque, the increased heel counter N2 had the largest effect, with a 121% increase in stiffness compared to the control N1 value. This could be explained by the increased height providing an increased area moment of inertia. The Velcro N3 was seen to be 28% stiffer than the control N1. This may be explained by the cross-sectional area of the Velcro fastening as compared to the lace fastenings. The thickened outsole at the midfoot design N5 was 31% stiffer than the control N1, inferring that increased midfoot stiffness might impart a stiffening effect to forward flexion at the ankle region of the footwear. For the Piedro OSSTF range, the design characteristic with the most dramatic effect on ankle plantarflexion torque was the increased heel counter height P2 design, which increased the stiffness by 57% of the control P1 value. The Velcro fastening P3 design was again seen to reduce the stiffness to ankle plantarflexion torque compared to the control P1 with a 17% reduction. For ankle dorsiflexion torque, the increased heel counter design P2 was seen to have the largest effect on stiffness, being 70% of the P1 control value. The P3 Velcro fastening was 30% stiffer than the control P1 value, which again could be accounted for by the cross-sectional area of the Velcro fastening.

Interestingly the P4 was 54% stiffer than the control P1 value in ankle dorsiflexion torque, although there did not appear to be a variation of design characteristic that could account for this. In comparison to the SRB, the Nimco N1 and Piedro P1 control were approximately twice as stiff in both ankle plantarflexion and dorsiflexion torque, and this is most probably linked to the increased heel counter and topline height, increasing the area moment of inertia to these movements. The Velcro fastening appeared to decrease the ankle plantarflexion torque and increase the dorsiflexion torque on both ranges. Interestingly the increased heel counter height in the Piedro range P2 was 4 Nm stiffer than the increased heel counter height in the Nimco range. As discussed previously the maximum heel counter height was located at the posterior aspect of the P2 shoe; however, the N2 shoe had a lower contour at the posterior aspect comparable with the other Nimco shoes of approximately 50mm, indicating that the shape and geometry of the heel counter influence the stiffness as well as the dimension.

7.4.1. Implications for research and clinical practice

The study has used the protocol developed in Chapter 6 to quantify the effects of expert consensus design characteristics of OSSTF had on their mechanical stiffness. The results indicated that increases in heel counter height had the most dramatic effect on increasing ankle inversion and eversion stiffness. The geometry of the heel counter also appeared to affect stiffness; stiffer values were found when the highest point centred around the malleoli. The experts considered that the midfoot area of the outsole in OSSTF should be stiffer to inversion and eversion; however, it was not identified in Chapter 5 what design specifics would achieve this, This study demonstrated that increases in thickness of the outsole at the midfoot together with the extension of the heel counter into the midfoot were the design characteristics that increased stiffness to midfoot inversion and eversion. Topline height did not increase ankle inversion/eversion stiffness, and Velcro fastenings did not decrease ankle inversion eversion stiffness, as suggested by the expert panel. This study indicates the possible areas of importance for researchers to report for OSSTF in future research to allow comparison across studies. In clinical practice and manufacturing, this work provides evidence on what might improve stability in the child living with a mobility impairment. The design characteristics of OSSTF appeared to offer stiffness in the areas that the experts felt were important in improving stability compared to standard retail footwear. Although increasing heel counter dimensions increased mediolateral stiffness, it also reduced flexibility in dorsiflexion and plantarflexion, which the experts felt may not be ergonomically desirable. Increased topline height was also seen to increase ankle plantarflexion stiffness. Additionally, it was noted that Velcro fastenings reduced the stiffness in ankle plantarflexion. OSSTF was also stiffer in forefoot dorsiflexion than the SRB, which the experts felt might also reduce the ergonomics of the footwear.

Although the experts acknowledged that children with mobility impairment such as cerebral palsy tend to exhibit instability in the mediolateral direction (Hsue, Miller, and Su 2009; Wist et al. 2022,), it must be noted that stability is a combination of anteroposterior and mediolateral control (Rival et al., 2005; Verbecque et al., 2016) and individuals may require assistance with stability in the anteroposterior direction additionally (Meyns, Duysens, and Desloovere 2016; Pavone et al. 2017). Considering the effects heel counter and topline height and Velcro fastening have on ankle plantarflexion stiffness together with the stiffness in forefoot dorsiflexion may potentially be clinically relevant if using footwear as an intervention for individuals with a tendency of equinus gait or ataxia (Caserta et al., 2019; Pavone et al., 2017; C. M. Williams et al., 2014).

Although the OSSTF ranges were seen to be stiffer than the SRB, which may enhance stability, they were also considerably heavier than the SRB, with the experts indicating that increased mass of the footwear may impact on the ergonomics and stability of the footwear that was independent of the footwear's stiffness. In consideration of the mass of the footwear, the PU (N5) sand Sports sole N6 appeared to be the lightest in the Nimco range whilst offering an increased stiffness to midfoot torsion. Clinicians may therefore use this information to choose a Sports sole Nimco shoe with increased heel counter dimension to maximise midfoot and ankle inversion eversion stiffness, while maintaining a low footwear mass.

7.4.2. Limitations of current work

The torque loading applied to footwear is an oversimplification of those that would be applied in-vivo, where the rate of loading would be highly variable occurring simultaneously in all cartesian planes and with variable angular velocity and degrees of freedom (Bianco et al., 2023; Price et al., 2014; Wade et al., 2022). The clinical relevance of the loading rate applied in this study could therefore be called into question. However, the context of this study was a comparative analysis that allows comparison between the OSSTF designs for various loading conditions. Loading rate will differ between individuals, due to the viscoelasticity of footwear materials the absolute values of stiffness will also change, but the significance of the results of the comparative analysis between the OSSTF designs would remain the same. Stiffness is assumed to be equivalent to stability, and although research indicates foot and ankle movements can be affected by the dimensions and stiffness of footwear interventions (Chicoine et al. 2021; Desmyttere et al. 2020; Hajizadeh et al. 2020), this study did not consider the proprioceptive effects that the design characteristics such as increased top line height or tension from lacings may have on the user (Liu et al., 2017; Lord et al., 1999; Menant et al., 2008a). All the aforementioned considerations will require further triangulation with in-vivo experimentation to support the findings of this study.

It must also be noted findings of reduced ankle joint plantarflexion torque in the Velcro fastening footwear may have been due to the limitations of the simple ankle shank model projecting through the gaps between successive Velcro straps, and a more accurate anatomical ankle-hinged model would be required to support these tentative findings. The scope of the study also looked at the loading patterns over a short period of time and did not take into consideration the effects of ageing through repetitive loading on mechanical stiffness on the footwear's design and material which may have impacted on the comparative stiffness (Chambon et al., 2014; Cornwall & McPoil, 2017).

Including only one design of standard retail children's boot (Kicker Hi Kick) for stiffness comparison with the OSSTF may not represent stiffness for the full retail children's footwear market. However, as previously discussed, boots from other manufacturers in the sizing considered in this study (EU 32) had zip fastenings through the heel counter that would preclude direct comparison with the OSSTF samples used in this study.

7.5. Conclusion

This study intended to quantify the effects expert-recommended design characteristics would have on in situ mechanical stiffness of children's OSSTF. This study concluded that the design characteristics that most enhanced stiffness of inversion and eversion of the ankle and midfoot were increases in heel counter height and length and thickness of the outsole material in the midfoot. For a 50% increase in heel counter height up to 95% and 115% increase in ankle inversion and eversion torque was seen, respectfully. For an increase in midfoot outsole thickness by 100%, an approximate 40% increase in midfoot inversion torque was seen, and for a 27% increase in heel counter length, a proportionate increase in midfoot eversion torque was seen. It was also noted that the mechanical testing protocols developed in Chapter 6 held a similar margin of error throughout the various footwear designs. This indicates that the developed protocols can be used to reliably predict the effects of footwear design characteristics on their in-situ mechanical stiffness. The clinical significance of these findings will require further in-vivo biomechanical testing on children living with a mobility impairment. However, knowledge of these mechanical effects will inform researchers, clinicians, and footwear manufacturers of the design characteristics of OSSTF to acknowledge when considering them as a mobility aid for children living with a mobility impairment.

8. Development and a pilot investigation of a screening tool to assess the clinical suitability of Off the Shelf Stability Therapeutic Footwear (OSSTF) for mobility-impaired children

8.1. Background

Footwear is generally agreed to play an important contribution to foot function and health in children and adults (Barton et al., 2009). Consequently, it is important for those individuals dealing with foot and ankle function of children living with a mobility impairment to be able to recognise the features of footwear that may contravene or contribute to foot health (Ellis et al., 2022). There exists a number of validated screening tools to assess footwear for such purposes in children and adults who do not have mobility impairment (Barton et al., 2009; Byrne et al., 1998; Ellis et al., 2022). These tools generally consist of a series of questions about the qualities (e.g., fastenings and padded collar), dimensions (e.g., topline height, outsole width), material (Leather, synthetic) and fit of the footwear in relation to the wearer's foot and ankle anatomy. These tools have demonstrated validaty by allowing clinicians and researchers to measure and assess footwear fit and suitability for daily mobility in children and people with arthritis (Byrne et al., 1998; Silvester et al., 2010; Yurt et al., 2014). Addtionally these tools have allowed clinical researchers to identfy design characteristics that may increase the risk of falling in older adults or impact on motor skill performance in children or enhance walking kinematics and kinetics in people with arthritis (Khajooei et al., 2020; Menant et al., 2008b; Stewart et al., 2014). Children living with mobility impairments have unique foot and ankle needs, and footwear is often cited as a requirement that needs special consideration (Morrison et al., 2019). It is important that clinicians, therapeutic footwear manufacturers and researchers, can readily and easily recognise the relevant OSSTF design features that can assist stability to inform clinical decision-making and appropriate reporting of the intervention in clinical research (Craig et al., 2008). Therefore, it would be helpful for those providing OSSTF to children to have a simplified and reliable method to assess OSSTF's potential effectiveness, like those tools developed for standard retail footwear.

8.1.1. Aims and objectives

The aim of the current study is to develop and pilot a screening tool for footwear to reliably assess the design characteristics of OSSTF to support appropriate treatment interventions for children living with a mobility impairment.

Objectives of the study:

- To develop a screening tool that can be used in a clinical setting to assess and score the potential effectiveness of OSSTF.
- To test the intra and inter-rater agreement for the screening tool.

8.2. Methods

8.2.1. Ethics

Ethical approval was obtained prior to the study through Staffordshire University's Ethics Committee (SU22-052).

8.2.2. Development of the tool:

The development of the tool consisted of a survey/questionnaire design and followed recommended item generation for questionaries (K. E. A. Burns et al., 2008; K. E. A. Burns & Kho, 2015). Item generation for the tool utilised the findings from the Delphi study which identified the desirable design characteristics of OSSTF alongside the mechanical testing that quantitively examined a range of OSSTF in terms of dimension, mass and mechanical stiffness (Chapters 5 & 7). The expert consensus criteria on the desirable design characteristics were grouped into three key themes dependent on their purpose:

I. Ergonomics considered the fit and comfort of the shoe during wear, the ease in donning and doffing of the shoe and the ability to allow forward flexion of the foot and ankle during walking. These consisted of the material, mechanism, height, and width of the components, along with measures of stiffness of the components.

II. Aesthetics considered the visual appeal of the shoe to facilitate psychosocial well-being and social interaction with peers.

III. Stability is considered the shoe's ability to limit excessive mediolateral displacement of the child's foot and ankle during walking. These consisted of measures of the stiffness of the components alongside the height and width of the components.

The tool is designed for clinicians to assess OSSTF against the functional aspects of ergonomics and stability obtained from the expert consensus criteria and mechanical testing data (Chapter 5 & 7). The aesthetics of footwear, whilst identified by the experts as being important for children's values and quality of life, would be criteria that would be most aptly interpreted and assessed by the personal preferences of the child or adolescent rather than the clinician (Branthwaite et al., 2013; Kumar & Garg, 2010; Lahoud et al., 2021; Orsborn et al., 2009; Price et al., 2021b; Taeho, 2005). Additionally, the recommendations from the experts for aesthetics of OSSTF requested that there is an available catalogue range of design offers (colour, material). The tools' purpose is to allow a clinician to assess an individual shoe at hand and not the catalogue range. The tool, therefore, limited its focus to the ergonomics and stability themes recommended by the experts.

The tool consists of a qualitative assessment of the footwear via identifying the component or design feature of the OSSTF and, where appropriate, a description of its dimension with respect to the footwear or the foot and ankle anatomy. A previously validated qualitative method to assess the stiffness of children's footwear, which the thesis author had contributed to, was also used (C. M. Williams, Morrison, et al., 2022). A summation of the assessment method used in the tool is presented in

Table 8-1.

Table 8-1 Design characteristic themes and proposed methods to assess

Themes OSCSTF design characteristics	Method to assess
	Qualitative
Ergonomic	1. Identify the presence or availability of ergonomic component 2. Description of dimensions of a component with respect to the shoe or foot and ankle anatomy 3. Qualitative assessment of stiffness of structural region area of a footwear component
Stability	1. Identify the presence or availability of stability component 2. Description of dimensions of a component with respect to the shoe or foot and ankle anatomy 3. Qualitative assessment of stiffness of structural region area of a footwear component

The tool was developed alongside an accompanying instruction user manual (Appendix 5.1) which provides instructions on identifying the OSSTF components and the tests to be performed to enable reliable interpretation of the items/questions in the tool. The design of the tool and the manual were calibrated and modified through an iterative approach. An expert in therapeutic footwear provision piloted the tool and accompanying manual to ensure the questions and instructions are appropriately framed and phrased to avoid ambiguity or multiple events within any question or instruction. The survey tool was designed to contain no deceptive or psychometric elements. The final survey tool consisted of 26 closed-ended questions, 14 questions relating to ergonomic factors (E1-E14) (Figure 8-1 and 12 relating to stability (S1-S12) (Figure 8-2). The questions were distributed into five regions of the footwear: topline, outsole, upper, fastening and facings and inlay/insole, with the heel counter a sixth region considered for stability only. The ergonomics questions were limited to two responses, with the question scored 0 or 1, resulting in a maximum total ergonomic score of 14. The stability questions consisted of 9 questions with two responses scored 0 or 1 and 3 questions with three responses scored 0, 1 or 2, resulting in a total stability score of 15. Higher scores indicated footwear meeting more of the desirable expert design characteristics for OSSTF. The maximum score for each section was divided into three ranges for interpretation, with the lower 1/3rd representing “poor”, the middle 1/3rd representing “moderate” and the upper 1/3rd representing “good” qualities for the OSSTF against the expert criteria.

Children's Off-the-Shelf Stability Therapeutic Footwear (OSSTF) Footwear Tool

Please refer to accompanying manual to answer the questions detailed in the Footwear Tool. There are no mandatory questions.

Footwear brand/name: _______________

Ergonomic
Topline
Question E1 Padded Collar A) Yes (1) ☐ B) No (0) ☐
Question E2 Contoured to Tibia and Fibula anatomy A) Yes (1) ☐ B) No (0) ☐
Question E3 Contoured to Achilles tendon A) Yes (1) ☐ B) No (0) ☐
Question E4 Pull Tab to the back of the collar A) Yes (1) ☐ B) No (0) ☐
Outsole
Question E5 Toe Spring / Forefoot Flexibility A) Flexible (1) ☐ B) Rigid (0) ☐

Upper
Question E6 Breathable Material A) Yes (1) ☐ B) No (0) ☐
Question E7 Wipeable Material A) Yes (1) ☐ B) No (0) ☐
Question E8 Tongue with fastening loop or Velcro to avoid slippage under fastenings A) Yes (1) ☐ B) No (0) ☐
Question E9 Tongue length above the line of top fastenings to provide comfort from fastenings A) Yes (1) ☐ B) No (0) ☐

Ergonomic score interpretation:
0- 4 = Poor
5 - 9 = Moderate
10 - 14 = Good

Fastening and Facings
Question E10 Facings extended to the toe box to allow greater access to footwear for limited foot and ankle mobility A) Yes (1) ☐ B) No (0) ☐
Question E11 Velcro fastening for limited hand dexterity A) Yes (1) ☐ B) No (0) ☐
Inlay/Insole
Question E12 Available removable Inlay/Insole A) Yes (1) ☐ B) No (0) ☐
Question E13 Contoured to cup heel anatomy to improve rearfoot fitting A) Yes (1) ☐ B) No (0) ☐
Question E14 Deep enough to simulate potential prescriptive orthoses A) Yes (1) ☐ B) No (0) ☐
Total Score Ergonomic: / 14

Figure 8-1 OSSTF Tool ergonomic questions

Children's Off-the-Shelf Stability Therapeutic Footwear (OSSTF) Footwear Tool

Please refer to accompanying manual to answer the questions detailed in the Footwear Tool. There are no mandatory questions.

Stability

Heel Counter/Stiffener

Question S1
Length extension of heel counter:
A) Extended to forefoot (2) ☐
B) Extended into midfoot (1) ☐
C) Extended to length of Heel (0) ☐

Question S2
Height extension of heel counter
A) Extended above Malleoli (2) ☐
B) Extended to midline height of Malleoli (1) ☐
C) Extended below Malleoli (0) ☐

Question S3
Heel Counter Stiffness
A) Rigid (1) ☐
B) Flexible (0) ☐

Topline

Question S4
Topline Extended
A) Above Malleoli (2) ☐
B) In line with Malleoli (1) ☐
C) Below Malleoli (0) ☐

Outersole

Question S5
Material
A) Non-compressible (e.g., rubber or polyurethane (PU) (1) ☐
B) Compressible (e.g., EVA) (0) ☐

Question S6
Outer sole flexibility at the midfoot
A) Rigid (1) ☐
B) Flexible (0) ☐

Question S7
Heel outersole wider than heel cup of upper
A) Yes (1) ☐
B) No (0) ☐

Question S8
The thickness of the outersole at the midfoot
A) Solid infill (1) ☐
B) Separate Heel (0) ☐

Question S9
Deepened tread
A) Yes (1) ☐
B) No (0) ☐

Stability score interpretation:
0 - 4 = Poor
5 - 10 = Moderate
11 - 15 = Good

Upper

Question S10
Material
A) Leather (1) ☐
B) Other material (0) ☐

Inlay/Insole

Question S11
Contoured to cup heel anatomy to improve rearfoot fitting
A) Yes (1) ☐
B) No (0) ☐

Fastening and Facings

Question S12
Fastenings
A) Laces (1) ☐
B) Velcro (0) ☐

Total Score Stability: / 15

Figure 8-2 OSSTF Tool stability questions

8.2.3. Testing of the tool

The testing of the tool involved a repeated agreement measure study by professionals who regularly prescribe OSSTF to children on a range of OSSTF samples. A purposeful sample of six orthotists was recruited from professional contacts to the research team against the following specific criteria:

- Registered practitioner in healthcare or clinical footwear manufacture.
- ≥25% clinical caseload involving the provision of footwear interventions to children with mobility impairment
- No vested interest in the footwear samples used.

Participants were recruited via email invitation and provided with an overview of the aims, purpose and what to expect from the project to provide informed consent. The participants were provided with the same five designs of OSSTF marked A-E (see Figure 8-3). OSSTF samples with varied design characteristics were chosen to capture the range of instructions and questions in the developed tool and user manual.

Figure 8-3 OSSTF samples used in the rater percentage agreement study

The participants assessed each shoe using the tool and submitted their results electronically via email.

Each participant assessed the five pairs of OSSTF at two different time frames, with a gap of at least one week between each assessment. Categorical data was taken from the clinician's responses from the tool for each question and each shoe. The data was then analysed within rater between sessions and between raters in the same session. Categorical data were analysed for consistency using percentage agreement for intra and inter-rater agreement, with the mean average percentage agreement average for the five OSSTF samples for each question. Mean values for percentage agreement were set at 80% for a high level of agreement (Birkimer & Brown, 1979; Kottner et al., 2011).

8.2.4. Practical use of the tool

In addition to the tool, the clinicians were also asked their thoughts on its use and clinical applicability through a short survey. The survey comprised of five Likert Scale levels of agreement and five linked open-ended Figure 8-4 &Figure 8-5 (Appendix 5.2). These questions were in relation to the ease of the use of the tool, the scoring of the tool, the range of OSSTF design characteristics considered, and if they felt it was a practical tool to support prescribing OSSTF for children with a mobility impairment. An additional open-ended question was provided for any other considerations the participants felt were important. The Likert scale responses were analysed by frequency of level of agreement. Analysis of open-ended questions was by inductive themed content analysis performed by the author and another member of the research team (Burnard, 1991). The process involved the identification of statements that were the same or could be constructed to mean the same thing. These statements were grouped, and themes developed around similar statements. Once statements were grouped under a common theme, a comparison was made between the author's and research team members' findings; a decision was made amongst the research team if the themes generated by the author and the other team member could be collapsed into the same theme.

Question 1

Thinking about using the Footwear Tool together with the manual to clinically assess OSSTF for children living with a mobility impairment, do you agree it was practical to use?
Please rank your agreement below.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 1, and possible suggestions on how you feel the tool and manual might be improved for practicality (You may also provide suggestions if you scored higher than 3)

Question 2

Thinking about the Footwear Tool, do you agree it is a useful method to clinically assess and inform how OSSTF may act as an assistive aid to improve mobility?
Please rank your agreement below.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 2, and possible suggestions on how you feel the tool might be improved to clinically assess OSSTF as a suitable assistive aid (You may also provide suggestions if you scored higher than 3)

Question 3

Thinking about the design components of OSSTF included in the Footwear Tool. Do you agree that the tool considered all the important design components of OSSTF that may clinically influence ergonomics and stability when used by a child with mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 3, and possible suggestions of any further design components of OSSTF that should be considered (You may also provide suggestions if you scored higher than 3, specifically if you feel there were too many components considered)

Figure 8-4 Rater survey of practicality of OSSTF footwear tool

Question 4

Thinking about the score ranking (0-4 Poor) (5-9 Medium) (10-14 Good) of ergonomic aspects of OSSTF used in the footwear tool. Do you agree that this is an appropriate score ranking ergonomic factors of OSSTF to be used clinically for children living with a mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 4, and possible suggestions of any further means to rank the score of ergonomic factors of OSSTF that should be considered (You may also provide suggestions if you scored higher than 3)

Question 5

Thinking about the score ranking (0-4 Poor) (5-10 Medium) (11-15 Good) of stability aspects of OSSTF used in the footwear tool. Do you agree that this is an appropriate score ranking for stability factors of OSSTF to be used clinically for children living with a mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 5, and possible suggestions of any further means to rank the score of stability factors of OSSTF that should be considered (You may also provide suggestions if you scored higher than 3)

Thank you for completing this survey. If you have any further comments on the tool or manual, you may add them in the section below

Figure 8-5 Rater survey of practicality of OSSTF footwear tool (cont'd)

8.3. Results

The total results for the participant's response to the OSSTF screening tool for each section, ergonomic and stability and each of the two sessions are presented in Appendices 0, 0, 0, and 0.

8.3.1. Percentage agreement inter-rater

The results of the mean measure of agreement between participants (raters) are given for each section of the screening tool ergonomics and stability in Table 8-2 & Table 8-3. The results are further stratified into individual questions and ranked score.

There was a higher level of agreement among participants for the ergonomic section of the survey than the stability section, with 10 of the 14 ergonomic questions reaching the boundary of a high level of agreement (>80%) compared to 6 of the 12 stability questions. Similarly, the overall ranked score for ergonomics met a high level of agreement, whilst the stability section had 65% agreement for the ranked score.

The stability question for extension of the heel counter had the lowest between rater agreement (43%). All questions relating to heel cup and counter dimensions tended to have lower levels of agreement between raters, S2 (64%) and S7 (57%). Questions relating to compressibility reached a high percentage agreement between S3 and S5 (83%), whereas questions relating to the stiffness of the outsole did not E5 (69%) and S6 (79%). Questions that required estimation and/or interpretation of stiffness, dimension, or shape tended not to reach the higher threshold level of agreement (E2, E3, E5, E14, S1, S2, S6, S7, S10, S11). In contrast, questions that required identification of the presence of a design characteristic, e.g., lace or Velcro fastening or a removable inlay, reached a perfect level of agreement (E11, E12, and S12). It was noted that although E13 and S11 were the same questions, E13 met the threshold value of 80% agreement, whereas S11 only provided 60% agreement between raters.

When considering the percentage agreement for the questions against the footwear designs, shoe C reached the most consistent percentage agreement for ergonomic questions, and Shoe E reached the most consistent percentage agreement for stability questions. Shoe B had the least consistent percentage agreement for both stability and ergonomic questions.

8.3.2. Percentage agreement intra-rater

Intra-rater mean percentage agreement demonstrated near-perfect levels of agreement for all questions and ranked score for the ergonomic section of the tool between testing sessions (see Table 8-4). For the stability section, 11 of the questions reached the threshold for a high mean percentage agreement, with eight of these questions being near perfect levels of agreement (Table 8-5). The ranked score achieved a mean of 100% agreement for stability. Only question S1 did not meet the criteria percentage agreement for intra-rater (67%); similarly, this was the lowest scoring percentage agreement for inter-rater agreement.

Table 8-2 OSSTF footwear tool ergonomic section Inter-rater percentage agreement

Question	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	Ranked Score
Shoe A	67	67	73	53	47	100	100	100	100	67	100	100	100	100	67
Shoe B	33	100	73	100	100	47	100	53	40	73	100	100	40	40	33
Shoe C	100	67	47	100	100	100	67	100	100	100	100	100	100	53	100
Shoe D	100	67	100	100	60	67	53	100	100	67	100	100	100	53	100
Shoe E	100	67	40	53	40	100	100	100	100	100	100	100	67	60	100
Mean % Agreement	**80**	73	67	**81**	69	**83**	**84**	**91**	**88**	**81**	**100**	**100**	**81**	61	**80**

Values in bold indicate a threshold 80% high level of agreement met

Table 8-3 OSSTF footwear tool stability section Inter-rater percentage agreement

Question	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	Ranked Score
Shoe A	47	40	47	100	100	60	67	100	100	100	67	100	27
Shoe B	20	67	100	100	100	33	47	67	47	53	33	100	47
Shoe C	47	67	67	100	47	100	67	100	100	53	67	100	100
Shoe D	47	47	100	47	67	100	40	100	100	73	67	100	53
Shoe E	47	100	100	100	100	100	67	100	100	100	67	100	100
Mean % Agreement	41	64	**83**	**89**	**83**	79	57	**93**	**89**	76	60	**100**	65

Values in bold indicate a threshold 80% high level of agreement met

Table 8-4 OSSTF footwear tool ergonomic section Intra-rater percentage agreement

Question	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	Ranked Score
Mean % Agreement	97	100	97	93	97	90	97	100	97	97	100	97	97	93	93

Table 8-5 OSSTF footwear tool stability section Intra-rater percentage agreement

Question	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	Ranked Score
Mean % Agreement	67	87	97	93	97	97	90	97	100	83	97	97	100

Table 8-6 Survey of raters ranked level of agreement with the usability of the OSSTF tool

	Question 1	Question 2	Question 3	Question 4	Question 5
	Number of raters	Number of raters	Number of raters	Number of raters	Number of raters
Strongly Agree	1	0	2	1	1
Agree	5	0	4	3	3
Neutral	0	5	0	0	1
Disagree	0	1	0	2	1
Strongly Disagree	0	0	0	0	0

8.3.3. Analysis of raters' opinions of the usability of the OSSTF tool

In addition to assessing the consistency of the OSSTF tool through percentage agreement, the study also looked to understand the raters' opinion on how easy and practical the tool was to use, and how applicable it was for clinical decision-making when prescribing OSSTF for children living with a mobility impairment. The clinicians were asked five questions and asked to score their levels of agreement on a five-point Likert scale ranging from (Strongly disagree to Strongly agree) (Figure 8-4 & Figure 8-5).

Results for the number of raters and levels of agreement are presented in Table 8-6. The raters all agreed it was a useful and practical tool to assess OSSTF. They were mostly neutral, 5 out of 6, that it was a useful method to assess how OSSTF would act as an assistive aid to improve mobility for children. All raters agreed that all the appropriate design characteristics of OSSTF were considered. Although 4 out of the six raters agreed the ergonomic and stability factors scoring was appropriate for clinical assessment, there could not be a consensus as there was still a sizable proportion (33%) who disagreed or were neutral. To further explore the reasoning behind the rater's level of agreement with the usability of the OSSTF, the survey also offered open-ended questions.

The open-ended questions were explored using thematic analysis. The results are presented in Table 8-7Table 8-7 The responses were grouped into two overarching themes and seven subthemes. The two overarching themes were advantages of the tool and areas for improvement of the tool; three subthemes were grouped into the advantages overarching theme and four subthemes in the areas for improvement. Considering the advantages, the raters felt the user manual was informative and helpful, with incrustations on how to apply the questions within the OSSTF tool. They felt that practice perfected the use of the tool and that all the design characteristics to facilitate stability and ergonomics were considered. Areas for improvement presented a consistent theme: although the tool was useful in assessing the footwear, it was too simplistic to translate directly on its clinical application as it would depend on the condition and the individual as to what may be considered good or poor as an intervention. The raters also felt that there were some contradictions in the scoring and requested the reasoning behind the scores be elaborated on in the user manual. There was also a request for an abridged version of the user manual to assist as a prompt for the more experienced user without referring to a large document. A final theme requested consideration of sole adaptions. However, this would preclude the footwear from meeting the definition of off-the-shelf and was discarded.

Table 8-7 Thematic analysis of raters' opinion of the usability of the OSSTF tool

Overarching Themes	Sub Themes
Advantages of tool	**Theme 1** User Manual was informative and helpful
	Theme 2 Practice perfected the use of the tool
	Theme 3 All design characteristics of OSSTF were considered that impact on Ergonomics and Stability
Areas for improvement of the tool	**Theme 4** Tool is useful in assessing the properties of OSSTF design but not entirely on its clinical application dependent on patient and condition
	Theme 5 User Manual requires some more explanation as to the reason behind the low and high scores for OSSTF design to clear up contradictions
	Theme 6 Abridged User manual prompt sheet for Confident users
	Theme 7 requested sole adaptions to be considered.

8.4. Discussion

The aim of this current study were to develop and validate a practical screening tool to reliably assess the design characteristics of OSSTF against the expert consensus and mechanical testing criteria laid out in chapters 5 and 7 of this thesis for use by clinicians, researchers and manufacturers of OSSTF footwear.

From the results, the raters felt the tool was practical and easy to use, with a relatively comprehensive and easily understandable supporting user manual.

Reliability for the tool indicated that the ergonomic section was more robust to interrater use than stability. Consequently, the ergonomic score ranking reached the threshold % of agreement, and stability did not. Intra-rater reliability demonstrated full agreement between testing session for all questions and score ranking in the ergonomic section and 11 of the 12 questions in the stability section. Cosistenecy reliability and validity are essential components of any tool that is purported to be used for research or clinical purposes to ensure phenomena are repeatable between different users and time frames and also the tool is appropriately measuring the phenomena under observation (Downham et al., 2005). Validity and reliability of an assessment tool allows for effective and consistent understanding and communication between users and measurement over time (Eddison, Healy, et al., 2022; Jarl et al., 2014). Therefore, it is essential to further analyse and develop any form of assessment method that may offer face validity but displays inconsistencies between users (Bolarinwa, 2015).

From the identified design characteristics that may offer stability, only midfoot outsole thickness met the threshold 80% agreement between raters. The questions that did not reach a satisfactory agreement were based on semi-quantified values that required a physical examination of the footwear and interpretation rather than an absolute observation of the presence or absence of a component. It was also noted that two of these measures had three response options, which may have decreased the percentage agreement. Semi-quantified measures may improve with appropriate practice, clear, unambiguous instructions and an iterative process in their design (Redmond et al., 2006). It was noted during assessment of the OSSTF that the distal edge of the heel counter extension might be confused with the inlay/insole of the footwear, so removal of this if possible, may improve the accuracy of this assessment. Consistency of agreement may also be improved if the estimate of the heel counter dimension was kept to a binary choice as the raters showed 100% agreement on the OSSTF where the heel counter was above the malleoli (Shoe E), and demonstrated inconsistencies on the interpretation of OSSTF where the footwear sat in line or below the malleoli.

One of the themes highlighted by the raters to improve the tool was to explain the purpose of the question and design characteristics in the user manual. There was evidence that there were errors in the interpretation of the tool and user manual. Specifically, in question E14, two of the raters misinterpreted that this referred to the space within the shoe as offering adequate depth for a prescriptive orthotic and not the thickness of the inlay/insole itsel. Since it was noted they correctly identified there was no removable inlay/insole in footwear D and C yet they stated there was adequate depth of the inlay on question E14 for footwear D and C. There was also evident misinterpretation in question S11; one rater had interpreted that the inlay was shaped at the rearfoot in the ergonomics section of the tool E 13 but chose the negative option for S11. Raters were also unclear about how design characteristics such as Velcro scored positively in the ergonomic section and negatively in the stability section and vice versa. Some raters were also unsure as to why the flexibility of the forefoot was a positive value as stiffness may sometimes be required here; therefore, an explanation in the manual that experts in a Delphi consesus reasoned that this assisted general forefoot mobility may clear any ambiguity for users of the OSSTF tool.

Another consistent theme that emerged from the raters in areas to improve the OSSTF screening tool was in consideration of its application to children with mobility impairment. Raters felt it was a practical and useful way to assess the ergonomic and stability components of the OSSTF; however, mobility impairments in children present a heterogeneous group of disorders, and within these, there are variations (Ivanyi et al., 2015; Maltais et al., 2006; Morrison et al., 2019) and the raters highlighted that the tool did not capture the complexity of the mobility impaired childhood population. The raters, therefore, felt the tool's purpose and instructions for the tool be tailored to the assessment of OSSTF if the clinician had previously decided that OSSTF was a suitable intervention.

8.4.1. Limitations to the current study

It is recognised that there are issues relating to the reliability of sections of the screening tool. However, this is the first tool developed for assessing OSSTF against valid criteria, and the data gained from this study will provide the structure for further iteration to improve its reliability for use in the clinical and research setting.

Percentage agreement studies are open to a chance agreement. However, this study selected an acceptable threshold level of percentage agreement to mitigate this effect (Birkimer & Brown, 1979; Kottner et al., 2011). Further work would involve increasing the number of footwear assessed to allow measures of reliability which reduce the effect of chance agreement influencing the results.

8.5. Conclusion

This study intended to develop a screening tool to assess the design characteristics of OSSTF against validated criteria previously laid out in this thesis from expert consensus and mechanically testing that may influence stability in children with a mobility impairment. Findings demonstrated that professional users felt that it was a practical and useful tool to assess the design of OSSTF, and the tool demonstrated itself to be consistent between time frames for the same user. Although, it is important not that the design characteristics to enhance stiffness and stability at the ankle and midfoot (heel counter height and length) did not reach a satisfactory agreement between users. This will require further iteration of the tool to improve assessment of heel counter characteristics. Raters also felt that the form should be used to assess and inform on the design characteristics of OSSTF where it had been previously clinically reasoned that OSSTF would be a suitable intervention; rather than the tool be the means to dictate if OSSTF should be prescribed as an assistive aid to a child. However, this is the first screening tool to be developed for OSSTF use in children living with a mobility impairment against evidence-based criteria and will, with further iteration, seek to inform clinical practice and future research reporting in this area.

9. Summative Discussion

9.1. Introduction

Prior to this thesis, it was identified that children's OSSTF was a commercial range of shoes with design adaptions that manufacturers' postulate will assist the gait of children living with mobility impairments. Since it is known that standard footwear has demonstratable effects on non-pathological children's gait (Wegener et al., 2013b; Wegener, Hunt, et al., 2011) it is reasonable to presume that footwear could be designed to provide stability during daily mobility. Additionally, since OSSTF is readily available from a standard stock supply, this would avoid unnecessary delay in a child's access to an assistive aid that would be associated with the manufacture of bespoke footwear (Eddison, Scott, et al., 2022; NHS England. Improving the Quality of Orthotics Services in England. NHS England; 2015., 2015). However, as identified in the scoping review (Chapter2), there was a lack of research examining footwear as a clinical intervention. This dearth of research provided little consistency in defining it within an intervention framework identified by the MRC; such as what are the perceived effects, how will it have its effect, how to measure these effects and who should benefit (Figure 1-2) (Craig et al., 2008; Skivington et al., 2021)? This was exampled in the current evidence base with clinical footwear for children as a whole being poorly defined and categorised. In particular, there was no clear consensus on the terminology, clinical purpose, specific design characteristics, specific childhood mobility conditions suitable for treatment or the salient treatment outcomes. These issues were apparent through the findings of the systematic review (Chapter 3), with poor and inconsistent reporting of the footwear interventions, participants, and disparate outcome measures precluding any form of meta-analysis.

This thesis focused on filling in the identified research gaps concerning OSSTF, through a systematic analysis of the intervention in a similar process that had been incorporated for tuned AFOs for children and alongside that of the Medical Research guidelines for evaluating a complex intervention (Craig et al., 2008; Eddison, Healy, Needham, et al., 2020; Eddison, Mulholland, et al., 2017; Skivington et al., 2021).

The overall aim of this program of work was to provide a conceptual and theoretical basis for children's off-the-shelf therapeutic footwear through a mixed-method approach of quantitative and qualitative evaluation of their design and purpose to provide a preliminary evidence-based framework for researchers, clinicians, and footwear manufacturers. The following discussion will integrate the findings and highlight the impact the work will have on the provision of OSSTF to children living with a mobility impairment.

9.2. Impact of work

9.2.1. Terminology, Definition and Purpose of OSSTF

Since it was unclear how footwear has been utilised as a clinical intervention for children, a scoping review on the entirety of children's footwear research was performed. It identified a grouping of footwear research designed to treat childhood musculoskeletal or neurological mobility impairments with the underlying principle of last and sole modification to influence the structure and function of the child's foot. Many terms were used throughout the research with a wide variety of treatment goals. Therefore, to define and term OSSTF amongst the many different clinical footwear, this research proposed to group the many footwear interventions under one overarching term, therapeutic footwear. The textual narrative synthesis of the therapeutic footwear research performed in chapter 2 identified three separate therapeutic roles: **Corrective, Accommodative** and **Functional**. Amongst functional therapeutic footwear, there were further sub-branches identified, which were termed and defined according to their design and role: **Stability, Instability, Rounded Bottom** and **Lift.** The textual narrative synthesis of the research performed in the scoping review allowed the rudiments of a conceptual framework of children's therapeutic footwear in which OSSTF may be identified and defined as a subgrouping of functional therapeutic footwear. However, for this framework to gain acceptance and use amongst the various stakeholders (clinicians, researchers and manufacturers), expert opinion and agreement would be required (Glenn & Gordon, 2009).

Where there are inconsistencies and uncertainty in areas of knowledge, inductive reasoning by expert opinion may provide direction and formulation of conceptual frameworks and hypotheses for further deductive reasoning to test through a mixed-method approach (Tariq & Woodman, 2013). The opinion of multiple experts is deemed to have greater face validity than a singular opinion, which may be structured via a combined qualitative and quantitative standardised approach using a Delphi technique (Keeney et al., 2010). The initial findings from the scoping review (Chapter 2) concerning the terms definitions and groupings of therapeutic footwear and the design characteristics of OSSTF were presented to a selected group of 18 experts in clinical footwear for children (Chapter 5) via the Delphi technique. The experts modified the preliminary conceptual framework for clinical footwear suggested by the scoping review. Their combined working knowledge of clinical footwear has now been qualitatively analysed and quantified to provide a consensus conceptual framework of terms, definitions, and groupings of clinical footwear. The experts reported that therapeutic footwear could be footwear designed for a therapeutic purpose or standard retail footwear that had been adapted to fulfil a therapeutic purpose. Although the experts agreed with the proposed groupings for therapeutic footwear, they recognised that each grouping was not a specific design of footwear, but that components of the footwear could allow it to fall into multiple groupings, i.e., therapeutic with stability components may have modular adaptions to the upper and sole that would allow it to fall under the accommodative and functional stability grouping. They also proposed that three of the previous subgroupings of functional therapeutic footwear (instability, rounded bottom and lift), should fall under a subgrouping termed **adapted sole**. A refined conceptual framework for therapeutic footwear was developed using the expert consensus technique (Chapter 5 Figure 5-5).

From this framework, it is possible to conceptualise the various therapeutic footwear, what is and isn't included in its clinical role, and the potential benefit it may provide as an assistive aid for children. The consensus conceptual framework of terms and definitions allows a common understanding of therapeutic footwear terminology to facilitate communication between clinicians, researchers and manufacturers.

9.2.2. Design Characteristics

It was noted in the scoping and systematic reviews (Chapters 2 and 3) there was a wide variety of design characteristics reported amongst the therapeutic footwear designs, such as orthopaedic insole, hard heel cup, longitudinal arch support, heel wedges, steel shank, Thomas heel, long medial heel counter, navicular pad, prefabricated arch insert, High-top shoes, internal heel counter, and arch inlay. Additionally, there was no elaboration of the purpose of these design characteristics. It is essential for any therapeutic intervention that there is an understanding of how it will act (Craig et al., 2008). Uncertainty about the specifics of how an intervention will act can lead to inconsistent practice and a lack of confidence in providing assistive devices to mobility-impaired children (Kane et al., 2019; Owen, 2019).

The design characteristics of OSSTF were preliminary explored in Chapter 4; compared to standard retail children's footwear, OSSTF was demonstrated proportionally higher and longer heel counters and higher toplines. These footwear design modifications are seen to benefit stability in athletic and elderly populations (Liu et al., 2017; Lord et al., 1999). To further improve upon the inconsistencies and uncertainty of the characteristics of OSSTF design and their purpose, a conceptual framework was gained through a Delphi consensus (Chapter 5). The identified design characteristics were grouped under three overarching themes **aesthetics**, **ergonomics,** and **stability**.

This thesis further corroborated the consensus conceptual design framework of OSSTF by quantifying the in-situ effects of the design characteristics of OSSTF on mechanical stiffness using novel mechanical testing protocols (Chapters 6 and 7). Four loading scenarios were developed: two focused on the stiffness on the outsole (forefoot flexion and midfoot torsion), and two focused on the rearfoot of the upper of the shoe through a rudimentary but novel ankle shank (ankle inversion/eversion and ankle dorsi/plantar flexion). The torque loading protocols were shown to provide consistent methods to test the mechanical stiffness of OSSTF both in the initial piloted OSSTF footwear sample (Chapter 6) and across a range of OSSTF (Chapter 7), with all testing protocols providing values within an acceptable margin of error.

The validated torque loading protocols were then used in a comparative analysis to quantify the effects the identified OSSTF design characteristics had on the mechanical stiffness of the footwear. This comparison was made against a standard catalogue model in two manufacturer ranges of OSSTF and against a standard retail children's boot.

Ankle inversion/eversion torque loading corroborated that increases in heel counter height increased torque stiffness to inversion and eversion torque, with the greatest effect noted if the height is focused in the malleoli region. Increased topline height did not demonstrate any effect on ankle inversion/eversion torque. Midfoot torsion loading corroborated extending the heel counter along the midfoot of the OSSTF increased stiffness to midfoot inversion eversion torque. Midfoot torsion loading also identified that increasing the thickness of the outsole at the midfoot increased stiffness to midfoot inversion eversion torque loading. However, it was also noted that increasing the height of the heel counter also increased the stiffness of ankle plantar/dorsi flexion torque loading, which was thought by the experts to be counterproductive to ergonomic function. The OSSTF ranges sampled in Chapter 7 demonstrated comparatively increased stiffness in ankle inversion/eversion and midfoot torsion torque compared to retail footwear, which may benefit mobility-impaired children by resisting extreme movement of the foot and ankle (Amene et al., 2019; Kruger et al., 2017). The OSSTF were generally stiffer in anterior-posterior torque loading scenarios lowering their ergonomics from the experts' opinion. However, it must be noted that although it is hypothesised that stiffening the sole of footwear and increasing topline height may alter the function of the foot and ankle, the effects these may have on children's gait are still uncertain (Cranage et al., 2019; G. W. K. Lam et al., 2015; Wegener, Smith, et al., 2011). Human balance and stability are a composite of control of the displacement of the centre of gravity anterior-posterior and mediolateral centre direction (Blanchet et al., 2019; Ganapathy et al., 2021; Meyns et al., 2016; Verbecque et al., 2016). Stiffness of the OSSTF in the anterior-posterior direction at the ankle and forefoot may enhance mobility in conditions such as toe walking and cerebral palsy (Aboutorabi et al., 2017; Caserta et al., 2019; Chatzistergos et al., 2023; de Jong et al., 2022; Jagadamma et al., 2014). In addition, there was also expert consensus that the footwear should be kept to the lowest reasonable mass to reduce potential physiological cost and potential loss of stability in the swinging limb (Chapter 5). It was noted that the OSSTF samples were markedly heavier than the standard retail boot. These factors require further In-vivo laboratory work observing the effects of OSSTF on children's gait to corroborate the findings of the Delphi and mechanical testing performed in Chapters 5 and 7. The data obtained from the mechanical testing of OSSTF has corroborated that heel counter height and length extensions, together with increased thickness of the outsole at the midfoot, influence the stiffness of the midfoot and ankle regions of the footwear to mediolateral movement. The findings also indicated that OSSTF was heavier and stiffer in anterior-posterior movements, which may impede children's mobility identifying what potential risks are present for this intervention in line with the MRC theoretical framework (Craig et al., 2008; Skivington et al., 2021).

It is crucial in clinical practice to follow care pathways that are evidence-based and provide a uniform care policy to provide effective care (Panella et al., 2003; T. Rotter et al., 2017). In addition, importance is also placed in clinical research to consistently report on the characteristics of an intervention so that clinicians have an understanding of how this applies to their clinical practice and allowing practical combined analysis in knowledge synthesis (Page et al., 2021; J. A. Sterne et al., 2016; J. A. C. Sterne et al., 2019). Defining and evaluating an intervention allows a consistent understanding of how it will work and the potential value and benefit to health care it will provide (Skivington et al., 2021). The thesis has provided a consensus conceptual framework of OSSTF design characteristics (Chapter 5) and corroborated these through further mechanical assessment (Chapter 7). However, a consistent understanding and recognition of these design characteristics may not be readily accessible by clinicians, researchers or manufacturers who have a relevant interest in the prescription or assessment of OSSTF for children.

Therefore, a survey tool was developed to cover salient design characteristics for ergonomics and stability of OSSTF identified from Chapters 5 and 7. This was further piloted amongst a group of orthotists who frequently prescribe OSSTF to children with a mobility impairment (Chapter 8). The tool was demonstrated to be a practical and easy method to assess OSSTF. The clinicians felt that all the salient design characteristics that would affect the ergonomics and stability of OSSTF were identified. The tool may also be used by the same user consistently. Unfortunately, of the design factors corroborated by mechanical testing that affected mechanical stiffness, only the thickness of the midfoot reached the required percentage agreement between users. Due to the apparent importance of the heel counter design characteristics on stiffness from the mechanical testing data in Chapter 8, further iterative and piloting work will be required to refine these questions and instructions to improve user agreement. Once fully developed, the tool will allow an assessment of OSSTF against the consensus conceptual and theoretical framework of OSSTF design developed in this thesis. This should improve clinical decision-making for OSSTF and reporting of stability therapeutic footwear design characteristics in research.

9.2.3. Preliminary prescription criteria

The scoping and systematic reviews performed in Chapters 2 and 3 indicated that there were a number of mobility impairment conditions in children that could be considered for the use of OSSTF, including cerebral palsy, spina bifida, toe walking, muscular dystrophy, pes planus and children with Down syndrome. The systematic review illustrated that there was tentative evidence that stability footwear benefits spatiotemporal and centre-of-pressure gait parameters of children living with mobility impairment (children with Down syndrome, Pes planus). However, there was no apparent professional consensus on which conditions were suitable for this treatment intervention and the criteria for their prescription, inclusive of the grade/severity of the condition, the age for initiation of treatment, overall goals of intervention and the outcomes of treatment. All the outlined factors are prerequisites in defining and assessing a healthcare intervention (Craig et al., 2008). Additionally, therapeutic footwear such as OSSTF may be used as a single line of treatment or simultaneously with another assistive aid such as AFOs (Eddison et al., 2015; Ivanyi et al., 2015). It was unclear in the literature where OSSTF would be used in isolation or in addition to another assistive aid.

To clarify the uncertainties noted in the evidence base, this thesis gained a consensus opinion of experts in clinical footwear provision for children concerning the prescription of OSSTF and the salient treatment outcomes to measure its effectiveness. A consensus was established on the suitability of treatment for cerebral palsy, spina bifida, muscular dystrophy and children with Down syndrome. In contrast, of the umbrella mobility impairment terms toe walking and intoeing pes planus, only pes planus reached consensus. However, this was refined to stipulate that the suitability of OSSTF for pes planus was based on it being symptomatic rather than being injudiciously prescribed simply based on foot posture that had been customary of historic practice, as noted in Chapters 2 and 3. Although toe walking did not reach consensus, this was not because the experts considered it unsuitable for OSSTF intervention, it was due to the complex myriad aetiologies involved that required further stratification which was beyond the cut-off point of the current Delphi's three rounds. Intoeing failed to reach or even approach a consensus on suitability for OSSTF intervention even with modified criteria suggested from the content analysis of the experts' opinions. There was a general trend for Likert scores of disagreement, with the emergent consensus that OSSTF should not be used as an intervention for the clinical presentations of intoeing.

There was consensus that the overall purpose OSSTF was to offer mediolateral stability to children with the mobility impairments considered in the Delphi. In addition, there was consensus that OSSTF was only to be prescribed to these children after a critical reflection of the child's mobility needs with respect to other assistive aids and with clear intervention outcomes. Generally, a consensus was reached that OSSTF could be prescribed as a single primary intervention in the mild or early cases of neurologically influenced mobility impairments such as cerebral palsy, spina bifida and muscular dystrophy. When these conditions presented with more severe motor limitation, OSSTF may be considered simultaneously with higher levels of control such as ankle, knee and hip orthoses or walking frames. Conversely, OSSTF was to be considered a secondary line of treatment for symptomatic pes planus if foot orthoses had failed to resolve symptoms or were associated with tripping and falling or any linked gross motor delay. Children with Down syndrome had a collection of indications for primary and secondary use, primarily in early walking children with Down syndrome who needed assistance in standing and ambulating, and as a secondary intervention with foot orthoses in elder children. Although the expert panel recognised children with Down syndrome may have other therapeutic footwear needs in addition to stability, such as accommodative footwear for their different foot anthropometrics. Therefore, OSSTF may require a number of modular adaptions to be offered in the range to accommodate children with Down syndrome. In consideration of the age range suitable for clinical intervention for the various mobility-impaired conditions, there was again a general consensus that the age of the patient should not dictate the use of OSSTF, instead, the initiation and end points of OSSTF intervention should be indicated by functional ability and the mobility needs of the child.

In relation to the expert consensus proposed outcomes, these tended to be of a functional nature rather than anthropometric, as identified in the methodologies to examine the effects of footwear in the scoping review Chapter 2 and the body structure function and activities aspects of the WHO ICF-CY (World Health Organization, 2007, 2010). The functional outcomes were grouped into biomechanical, physiological and gross motor proficiency. Amongst the biomechanical measures, simple spatiotemporal outcomes that were readily available to be used in a clinical setting were those that swiftly reached expert consensus. Validated measures such as the timed up and go 6-minute walk test and 10-metre walk test (Eichinger et al., 2017; Mohamed & Appling, 2020) were those most commonly suggested by the panel and would encapsulate the predictive effects of walking on general health (Middleton et al., 2015). A consensus was also reached throughout the mobility impairment conditions on pain and quality of life outcomes that would capture the participation of environmental and personal factors of the ICF-CY (World Health Organization, 2007, 2010). It is recognised that mobility demonstrated in a clinic or laboratory setting not be representative of how they typically move, termed "Motor Capacity", as it does not always mirror how children mobilise in daily life, termed "Motor Performance" (Carcreff et al., 2020; Gerber et al., 2020; Halma et al., 2020). It is essential to identify the benefits via validated quality of life measures of assistive aids to improve societal participation and activity in daily life (Morris et al., 2007; Sivaratnam et al., 2020; C. M. Williams et al., 2020), as mobility-impaired children commonly experience disadvantages socioeconomically and earlier morbidity and mortality from lifestyle diseases (Logan et al., 2016; Smith et al., 2021). The findings of Chapter 5 have provided expert consensus on three of the prerequisites from the MRC guidance on defining and assessing a clinical intervention: who will benefit, how to measure its success, and the value it will provide (Craig et al., 2008). It is noted that the evidence to support the prescription and assessment of OSSTF has only provided the qualitative aspect of the mixed method approach and will require further objective work to corroborate the findings. However, the preliminary prescription criteria offer some initial clarity to clinical decision-making where none existed previously and will inform the development of further quantified research streams.

9.3. Limitations

The current work has limitations that should be acknowledged. The work has provided findings based on level 5 evidence, qualitative expert opinion and quantitative bench research (P. B. Burns et al., 2011).

It is recognised that although Delphi studies provide valid qualitative and quantitative data in relation to expert opinion, this data is inductive and not authoritative, requiring further objective deductive research to support or refute the findings (Hasson & Keeney, 2011). Therefore, the findings concerning prescription criteria derived from the Delphi will require in-vivo testing on consensus suitable childhood mobility impairments. As indicated in Chapter 11.8 the effects of COVID-19 pandemic had restructured the initial proposed framework of study which precluded biomechanical testing of children during the course of this thesis.

Although some of the expert consensus design characterises of OSSTF were corroborated through quantitative mechanical testing, their importance cannot be fully validated until their effects on children's gait have been studied. Other factors to consider that were beyond the scope of comparative mechanical testing to corroborate the experts' opinion are the possible proprioceptive effects of design characteristics of OSSTF, such as increased topline height and lacing tension. This, again, will require further validation through in-vivo biomechanical studies.

10. Recommendations

10.1. Research

Consensus terms and definitions for therapeutic footwear: It is recommended that the terms and definitions provided in this thesis be incorporated into a common taxonomy to aid an understanding of the role and purpose of the therapeutic footwear under investigation. This should assist research reporting when collating and synthesising the evidence base to inform clinical practice (C. M. Williams, Morrison, et al., 2022).

Quantification of the salient design characteristics of OSSTF that influence mechanical stiffness: The research identified that heel counter height and length, as well as the thickness of the outsole at the midfoot, are the primary components of OSSTF to increase mechanical stiffness in mediolateral movements. Therefore the specifics of these design characteristics should be reported in future research to ensure appropriate and consistent reporting of the OSSTF interventions implementing an effective and comparable evidence base (J. A. Sterne et al., 2016; J. A. C. Sterne et al., 2019).

Standardisation of assessing OSSTF design characteristics: The OSSTF footwear tool was piloted and developed within the thesis. While it did not achieve inter-rater agreement for the salient design characteristics that influence stability, namely heel counter dimensions and midfoot stiffness, possible solutions to improve these areas through further iteration and testing of the tool were identified. Further development will seek to provide a standardised approach to report OSSTF in future research for clarity of communication (C. M. Williams, Morrison, et al., 2022).

Validating prescription criteria and evaluating the effectiveness of OSSTF: The thesis has provided a provisional consensus conceptual framework for the prescription of OSSTF for a number of mobility impairments, together with a range of outcome measures to assess the effectiveness and purpose of this intervention. These conceptual, preliminary prescription criteria from inductive methods will need to be triangulated and potentially corroborated or refuted with deductive quantitative methods (Schoonenboom & Johnson, 2017). However, the concepts postulated in this thesis will inform further in-vivo gait laboratory research using the consensus-validated spatiotemporal measures TUG, 6MWT, 10 Metre Walk Test (Mcdonald et al., 2013; Pane et al., 2014) alongside kinematic analysis with comparison to normative data sets (Chester et al., 2007; Lythgo et al., 2011; Tingley et al., 2002).

From an analysis of the current body of general children's footwear research in combination with that exploring children's therapeutic footwear, this study has identified previous biomechanical analyses of stability footwear that had failed to use standard footwear as a comparator. Since it is now well documented that footwear of any design has a number of significant effects on gait in children (J.-P. P. Chen et al., 2015; Wegener, Hunt, et al., 2011) future work is recommended to be carried out where possible with barefoot and standard retail footwear comparison to observe the possible beneficial effects on gait parameters. The work not only identified the mobility-impaired conditions that may benefit from OSSTF but the grade of the condition that may involve OSSTF as a single line of treatment to assist mobility or used simultaneously with other assistive such as AFOs which again would require a standard footwear comparator to establish the possible benefit of using OSSTF alongside other assistive aids. Other outcomes to study include the effects of OSSTF on functional motor tasks, which will help predict how OSSTF may assist children in other aspects of mobility (Estilow et al., 2019).

Physiological indexes have also been absent in previous research exploring footwear interventions; experts had suggested and reached a consensus that estimated perceived metabolic cost would be a viable outcome to explore the effectiveness of OSSTF intervention (Butler et al., 1984; Marinov et al., 2008; MJ et al., 2002; J. G. Williams et al., 1994). In addition to exploring the potential benefits of OSSTF on children's mobility, the physiological outcomes could also explore the potential risk of this intervention, as it was observed in Chapter 7 that OSSTF was heavier than standard retail children's footwear and was identified as a potential impediment to children's mobility. Outcomes to measure quality of life were identified and reached a consensus by the expert panel. These outcomes go beyond the body structure and functional aspects of the ICF-CY that may be accounted for in motor capacity and explore goals and outcomes of an intervention that may be perceived to be necessary for the child in daily life that enriches their social and long-term physical health (Keawutan et al., 2014; The "F-Words" in Childhood Disability: I Swear This Is How We Should Think, 2012; C. M. Williams et al., 2020). It would also be essential for future research in OSSTF to involve the opinion of the child and parent concerning comfort aesthetics and function and how these may be modified to meet user acceptance and improved outcomes across the ICF-CY (Hodgson et al., 2021; Price et al., 2021b, 2021a)

Toe walking was a suggested condition for OSSTF that did not reach expert consensus. However, it was identified that the panel were close to achieving a consensus here. Still, a further systematic breakdown of this nebulous condition was felt required to establish how OSSTF may benefit specific clinical presentations (C. M. Williams et al., 2010). The data and modified statements obtained from the Delphi Chapter 5 concerning toe walking may be further analysed to evolve future statements placed before an expert panel to reach a consensus on its suitability for OSSTF intervention.

Five further mobility impairments were suggested and reached consensus by the expert panel, Charcot Marie Tooth, hypermobility (Ehlers Danlos type), developmental coordination disorder, Rett's syndrome and chronic lateral ankle instability. Exploration of the prescription criteria for OSSTF for these conditions will require further study but the consensus protocols that have been developed for the previous conditions could inform the development of future expert consensus.

Mechanical testing provided data that increased heel counter height increased stiffness to mediolateral torque, which was desirable according to expert consensus to improve stability. However, increased heel counter height also increased stiffness to ankle dorsiflexion and plantarflexion torque which expert consensus hypothesised would reduce the ergonomics of the footwear. This may indicate a risk of treatment. Further in-vivo testing would identify if this increased stiffness of ankle sagittal plane motion impeded children's mobility or, in some conditions, potentially enhanced it (Caserta et al., 2019; Ganapathy et al., 2021; Meyns et al., 2016). These combined recommendations will facilitate the development of a higher-level evidence-based OSSTF prescription protocol to aid in clinical decision-making and facilitate the potential mobility of these children.

Further Mechanical testing of OSSTF: A novel ankle loading protocol was developed in this thesis and quantified the effect of design characteristics on mechanical stiffness. However, this employed a rudimentary ankle shank model, which, although it provided an acceptable margin of error, it was the largest of the loading scenarios. There were also observations of differing effects of lace and Velcro fastenings on ankle plantarflexion that may have been due to the shank model stressing the tongue between the Velcro straps. Future work could potentially employ a more accurate ankle rearfoot anatomical model. This could be an ankle-foot prosthesis with two degrees of freedom to potentially lower the margin of error and further explore the tentative findings of differing fastening on sagittal ankle loading.

10.2. Clinical practice

Definitions and purpose of OSSTF: This work, through a mixed method approach, has provided a level 5 evidence base of consensus expert opinion to provide a conceptual framework of footwear as a clinical intervention for children with agreed terms, definitions and groupings dependent on the therapeutic role of the footwear. This framework should assist clinicians in prescribing OSSTF as it identifies that the purpose is immediately functional in nature, assisting stability in children's gait and is not intended as long-term correction of skeletal structural alignment.

Assessment of OSSTF design: The salient design characteristics have been identified by expert consensus with corroboration of their effects on mechanical stiffness to enhance the stability or ergonomics of the footwear through further quantitative. The identification and assessment of these design characteristics of OSSTF have been developed into the OSSTF tool. A further iteration of the tool with improved inter-rater reliability will allow clinicians to readily identify the design characteristics of OSSTF to inform on their potential to act as an assistive aid in clinical practice.

10.3. Footwear manufacture

The current work through mixed methodology has identified the salient design characteristics of OSSTF through structured consensus methodology of a combined group of experts in clinical footwear interventions inclusive of clinicians and researchers alongside footwear manufacturers to provide unbiased consensus opinion evidence base (Hasson & Keeney, 2011; Keeney et al., 2010). Further mechanical testing has corroborated and quantified that heel counter dimensions in height can influence stiffness to ankle inversion eversion torque, and length can influence midfoot inversion eversion torque. Lighter weight PU foam and combination PU rubber outsoles demonstrated increases in midfoot inversion eversion torque based on being thicker at the outsole in the midfoot in comparison to heavier and higher shore outsole materials such as rubber (ISO, 2010; Naveen et al., 2022) which were comparatively thinner in the outsole in the Midfoot. This data should provide a preliminary evidence base to inform future design and marketing information for OSSTF by manufacturers.

11. Conclusions

This thesis aimed to provide a conceptual and theoretical basis for children's OSSTF with a combined quantitative and qualitative evaluation of their design and purpose to provide a preliminary evidence-based framework for assistive aid stakeholders.

From the subsequent studies in this thesis, the following concepts can be concluded for OSSTF:

Terms and Definitions

- Children's Therapeutic footwear should be the overarching term for children's footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity or to assist mobility and standing in children.
- Children's therapeutic footwear should be termed, defined, and grouped according to its intended therapeutic role
- The three main groupings of children's therapeutic footwear are **Accommodative, corrective** and **functional.**

    - Accommodative footwear is children's therapeutic footwear that is designed to prevent the deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot.
    - Corrective footwear is footwear that is designed or adapted to support the correction of congenital or acquired foot and ankle deformities in children. This may be secondary to a primary corrective measure such as serial casting or surgery
    - Functional footwear is children's therapeutic footwear designed or adapted to directly assist mobility and standing in children.
- Functional therapeutic footwear consists of two further subgroupings **Adapted sole** and **Stability**
    - Adapted sole is a range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children.
    - Stability therapeutic footwear is children's therapeutic footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle.

Design characteristics

- OSSTF tends to have higher toplines and higher and longer heel counters compared to standard children's retail footwear.
- The salient design characteristics of OSSTF, which increase mediolateral stiffness (inversion and eversion) at the ankle region of the footwear, is increased heel counter height.
- The salient design characteristics of OSSTF, which increase mediolateral stiffness at the midfoot region of the footwear, are extended heel counters across the midfoot of the footwear and increased thickness of the outsole at the midfoot.

Prescription purpose and outcomes of treatment.

- Corrective therapeutic footwear is an ineffective treatment to correct pes planus in typically developing children.

- Corrective therapeutic footwear may play a role in maintaining skeletal geometry in CTEV subsequent to prior serial casting or surgery in young children
- OSSTF should not be prescribed to children with intoeing.
- The purpose and indications for treatment of OSSTF are to provide mediolateral stability to the child's foot and ankle in standing and walking.
- The provision of OSSTF should only be issued to children with mobility impairment after a critical assessment of the child's mobility needs with respect to other assistive aids or footwear modifications and with clear clinical outcomes.
- Outcomes to assess the effectiveness of OSSTF in children should consider Body structure and function and activity aspects of the ICF (Biomechanical, Physiological) alongside personal and participation aspects (Quality of Life measures, pain).
- Biomechanical and physiological testing of OSSTF should consider a standard retail footwear comparator as well as barefoot to account for the known effects of standard footwear on children's gait.
- Further, In-vivo, testing is required to validate and assess the effectiveness of OSSTF against the consensus prescription criteria obtained from this work.

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Appendix

1. Chapter 2

1.1. PRISMA-ScR Checklist

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	Reported on Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Reported on Page 2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	Reported on Page 3-6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	Reported on Page 5
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	Reported on Page 6-8
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	Reported on Page 6-7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	Reported on Page 7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Reported in Additional File 2
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	Reported on Page 8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and	Reported on Page 8

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Reported on Page 8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	Not Performed
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	Reported on Page 8
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Reported on Page 9 and Figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Reported in Additional File 3
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	Not Performed
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Reported Additional File 3
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	Reported in Page 9-16 and Figure 3
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	Reported on Page 16-19
Limitations	20	Discuss the limitations of the scoping review process.	Reported on Page 19
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	Reported on Page 19
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	Reported on Page 20

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med.;169:467–473. doi: 10.7326/M18-0850

1.2. Example of Medline (EBSCO) search strategy

1. Child*.ti,ab.
2. Infant*ti,ab.
3. Adolescent *ti,ab.
4. Paediatric*ti,ab.
5. Pediatric*ti,ab.
6. Schoolchild*ti,ab.
7. Toddler*ti,ab.
8. Preschool*ti,ab.
9. teenage*ti,ab.
10. Exp Child/
11. Exp Infant/
12. Adolescent/
13. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12
14. Shoe*.ti,ab.
15. Footwear*.ti,ab.
16. Boot.ti,ab.
17. Boots.ti,ab.
18. Sandal*.ti,ab.
19. Exp Shoes/
20. 14 OR 15 OR 16 OR 17 OR 18 OR 19
21. 13 AND

1.3. Results of individual sources of evidence.

Article	**Study Design**	**Age/Age Range**	**Charted:** **Area/ Grouping/ Sub Grouping**
1. Abd Elkader, S. M., Abd Elhafz, Y. N. & Al-Abdulrazaq, S. S. Foot taping versus medical shoes on kinematic gait parameters in children with down's syndrome. World Appl. Sci. J. 27, 311–317 (2013).	Randomised Control Trial	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic-Footwear Stability
2. Abera, B., Alem, G., Yimer, M. & Herrador, Z. Epidemiology of soil-transmitted helminths, Schistosoma mansoni, and haematocrit values among schoolchildren in Ethiopia. J. Infect. Dev. Ctries. 7, 253–260 (2013).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
3. Abolarin, T., Aiyegbusi, A., Tella, A. & Akinbo, S. Predictive factors for flatfoot: The role of age and footwear in children in urban and rural communities in South West Nigeria. Foot 21, 188–192 (2011).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear
4. Aboutorabi, A. et al. Immediate effect of orthopedic shoe and functional foot orthosis on center of pressure displacement and gait parameters in juvenile flexible flat foot. Prosthet Orthot Int 38, 218–223 (2014).	Before-and-after study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability
5. Adams, D. W. & Marshall-Battle, M. R. Shoe contact dermatitis: a case report of an acute severe reaction to potassium dichromate. Foot 22, 141–145 (2012).	Case Study	Not Reported in Abstract	Risk Factor Injury/Pathology, Risk Factor Dermatology, Effects of Footwear, Footwear Design

6. Aibast, H. et al. Foot Structure and Function in Habitually Barefoot and Shod Adolescents in Kenya. Curr. Sport. Med. Reports (Lippincott Williams Wilkins) 16, 448–458 (2017).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Biomechanics, Developmental Effects, Effects of Footwear
7. Aimpun, P. & Hshieh, P. Survey for intestinal parasites in Belize, Central America. Southeast Asian J Trop Med Public Heal. 35, 506–511 (2004).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
8. Akiko, Y. A Study of the Foot Form for Footwear Design. Part 4: The Application of Principal Component Analysis to the Property of Foot Form of Children Aged 3 to 6. J. JAPAN Res. Assoc. Text. END-USES 31, 533–538 (1990).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
9. Al-Delaimy, A. K. et al. Epidemiology of intestinal polyparasitism among Orang Asli school children in rural Malaysia. PLoS Negl Trop Dis 8, e3074–e3074 (2014).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
10. Alelign, T., Degarege, A. & Erko, B. Soil-Transmitted Helminth Infections and Associated Risk Factors among Schoolchildren in Durbete Town, Northwestern Ethiopia. J. Parasitol. Res. 2015, 641602 (2015).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
11. Alemu, A. et al. Soil transmitted helminths and schistosoma mansoni infections among school children in zarima town, northwest Ethiopia. BMC Infect. Dis. 11, 189 (2011).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
12. Alemu, A., Tegegne, Y., Damte, D. & Melku, M. Schistosoma mansoni and soil-transmitted	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Effects of Footwear, Protective Role, Protective Role Infective

helminths among Preschool-aged children in Chuahit, Dembia district, Northwest Ethiopia: prevalence, intensity of infection and associated risk factors. BMC Public Health 16, 1–9 (2016).			
13. Als, C. & Marugg, S. Exclusive wearing of shoes of impregnated cloth by an adolescent girl during a cold winter: Late effects in osseous tomoscintigraphy and in magnetic resonance imaging. Med. Nucl. 33, 658–661 (2009).	Case Study	14 years	Effects of Footwear, Footwear Design, Risk Factor Injury/Pathology, Risk Factor Injury
14. Au, I. P. H. et al. Immediate and short-term biomechanical adaptation of habitual barefoot runners who start shod running. J Sport. Sci 36, 451–455 (2018).	Randomised Control Trial	Adolescent 13-18yrs	Biomechanics, Effects of Footwear
15. Ayala, F. et al. A multicentre study of contact sensitization in children. Gruppo Italiano Ricerca Dermatiti da Contatto e Ambientali (GIRDCA). Contact Dermatitis 26, 307–310 (1992).	Cross Sectional Study	Not Reported in Abstract	Risk Factor Injury/Pathology, Risk Factor Dermatology, Effects of Footwear, Footwear Design
16. Ayode, D. et al. A Qualitative Study Exploring Barriers Related to Use of Footwear in Rural Highland Ethiopia: Implications for Neglected Tropical Disease Control. PLoS Negl Trop Dis 7, e2199–e2199 (2013).	Survey	Not Reported in Abstract	Protective Role, Psychosocial, Effects of Footwear, Protective Role Infective
17. Baba, K. Shoes as a necessity for children. J Hum Ergol 5, 82–83 (1976).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
18. Bailey-Van Kuren, M., Gillette, S., Mejia, P., Stoever, T. & Walker, A. Design considerations for a wearable pediatric rehabilitative boot. in 2005 IEEE 9th International Conference on	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design

Rehabilitation Robotics, ICORR 2005 2005, 400–403 (2005).			
19. Baker, M. D. & Bell, R. E. The role of footwear in childhood injuries. Pediatr Emerg Care 7, 353–355 (1991).	Cross Sectional Study	Not Reported in Abstract	Protective Role, Protective Role Functional. Risk Factor Injury/Pathology, Risk Factor Injury, Footwear Design, Effects of Footwear
20. Bakker, J. P. J., De Groot, I. J. M., De Jong, B. A., Van Tol-De Jager, M. A. & Lankhorst, G. J. Prescription pattern for orthoses in The Netherlands: use and experience in the ambulatory phase of Duchenne muscular dystrophy. Disabil. Rehabil. 19, 318–325 (1997).	Survey	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design, Effects of Footwear
21. Bari, S. B., Othman, M. & Mohd Salleh, N. Foot anthropometry for shoe design among Preschool children in Malaysia. Pertanika J. Soc. Sci. Humanit. 18, 69–79 (2010).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
22. Barisch-Fritz, B., Plank, C. & Grau, S. Evaluation of the rule-of-thumb: calculation of the toe allowance for developing feet. Footwear Sci. 8, 119–127 (2016).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
23. Barisch-Fritz, B., Schmeltzpfenning, T., Plank, C., Hein, T. & Grau, S. The effects of gender, age, and body mass on dynamic foot shape and foot deformation in children and adolescents. Footwear Sci. 6, 27–39 (2014).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design

24. Barisch-Fritz, B., Schmeltzpfenning, T., Plank, C. & Grau, S. Foot deformation during walking: Differences between static and dynamic 3D foot morphology in developing feet. Ergonomics 57, 921–933 (2014).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
25. Bartkowlak, Z. et al. Orthopedic equipment applied in children with cerebral palsy. Fizjoterapia / Physiother. 16, 99–113 (2008).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
26. Basta, N. W. et al. A comparative study of the role of shoes, arch supports, and navicular cookies in the management of symptomatic mobile flat feet in children. Int. Orthop. 1, 143–148 (1977).	Cohort Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design, Effects of Footwear
27. Beattie, P. E., Green, C., Lowe, G. & Lewis-Jones, M. S. Which children should we patch test? Clin Exp Dermatol 32, 6–11 (2007).	Case Series	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
28. Becerril-Chihu, G. et al. How often are dermatophytes present in apparently normal versus scaly feet of children? Pediatr Dermatol 16, 87–89 (1999).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Risk Factor Injury/Pathology, Risk Factor Infective, Effects of Footwear, Footwear Design
29. Benbella, I. et al. [Cutaneous larva migrans syndrome on a malformed foot (a case report)]. Pan Afr. Med. J. 23, 50 (2016).	Case Study	15 months	Effects of Footwear, Protective Role, Protective Role Infective
30. Berger, C. Children's shoe: a miniature version of the adult shoe? Sport. Sport. 7, 183–186 (1993).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design

31. Bernardczyk, K. The influence of the footwear on the health status of the child's foot. Chir Narzadow Ruchu Ortop Pol 38, 233–238 (1973).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
32. Bernhard, M. K. & Merkenschlager, A. Does barefoot walking influence the prevalence of idiopathic toe walking? Differences between German and Bengal children. Padiatr. Prax. 72, 301–305 (2008).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
33. Bhaskara Rao, U., Joseph, B., Rao, U. B. & Joseph, B. The influence of footwear on the prevalence of flat foot. A survey of 2300 children. J Bone Jt. Surg Br 74, 525–527 (1992).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear, Footwear Design
34. Bird, C., Ame, S., Albonico, M. & Bickle, Q. Do shoes reduce hookworm infection in school-aged children on Pemba Island, Zanzibar? A pragmatic trial. Trans R Soc Trop Med Hyg 108, 297–304 (2014).	Randomised Control Trial	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
35. Bleck, E. E. The Shoeing of Children: Sham or Science? Dev. Med. Child Neurol. 13, 188–195 (1971).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear, Footwear Design
36. Blitz, J. R., Stern, S. & Marzan, K. A. B. A110: The Impact of Shoe Wear on the 6 Minute Walk Test in Adolescents with Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 66, S146–S146 (2014).	Pilot Study	Adolescent 13-18yrs	Biomechanics, Effects of Footwear, Protective Role, Protective Role Functional, Footwear Design,

37. Böhm, H. et al. Effect of floor reaction ankle-foot orthosis on crouch gait in patients with cerebral palsy: What can be expected? Prosthet Orthot Int 42, 309364617716240–309364617716240 (2017).	Before-and-after study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Effects of Footwear
38. Bordelon, R. L. Hypermobile flatfoot in children: present status of diagnosis and treatment. Semin. Orthop. 5, 13–22 (1990).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Developmental Effects, Effects of Footwear
39. Bordelon, R. L. Hypermobile flatfoot in children. Comprehension, evaluation, and treatment. Clin Orthop Relat Res NO. 181, 7–14 (1983).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear, Developmental Effects
40. Branthwaite, H., Chockalingam, N., Grogan, S. & Jones, M. Footwear choices made by young women and their potential impact on foot health. J Heal. Psychol 18, 1422–1431 (2013).	Survey	Adolescent 13-18yrs	Psychosocial, Effects of Footwear, Footwear Design
41. Buckland, M. A. et al. The Effect of Torsional Shoe Flexibility on Gait and Stability in Children Learning to Walk. Pediatr Phys Ther 26, 417 (2014).	Before-and-after study	Preschool and Infants 9mths-5yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
42. Butler, P. et al. Physiological cost index of walking for normal children and its use as an indicator of physical handicap. Dev Med Child Neurol 26, 607–612 (1984).	Before-and-after study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Physiological, Effects of Footwear

43. Byrne, M. et al. The development and use of a footwear assessment score in comparing the fit of children's shoes. Foot 8, 215–218 (1998).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Effects of Footwear, Footwear Design
44. Camper, P. The classic: Dissertation on the best form of shoe, Pieter Camper. Clin Orthop Relat Res No. 110, 2–5 (1975).	Opinion Piece	Not Reported in Abstract	Therapeutic Footwear, Footwear Design
45. Carstensen, H. & Baumann, J. U. Orthopedic care of the feet in patients with cerebral disorders of motion. Ther. Umschau 31, 18–22 (1974).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design
46. Caselli, M. A., Rzonca, E. C. & Lue, B. Y. Habitual toe-walking: evaluation and approach to treatment. Clin Pod. Med Surg 5, 547–559 (1988).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
47. Chard, A., Greene, A., Hunt, A., Vanwanseele, B. & Smith, R. Effect of thong style flip-flops on children's barefoot walking and jogging kinematics. J Foot Ankle Res 6, 8 (2013).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
48. Chen, J.-P. P., Chung, M.-J. J., Wu, C.-Y. Y., Cheng, K.-W. W. & Wang, M.-J. J. Comparison of Barefoot Walking and Shod Walking Between Children with and Without Flat Feet. J Am Pod. Med Assoc 105, 218–225 (2015).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Developmental Effects

49. Chen, W. et al. Correcting Congenital Talipes Equinovarus in Children Using Three Different Corrective Methods: A Consort Study. Med. (United States) 94, e1004–e1004 (2015).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Biomechanics, Effects of Footwear, Footwear Design
50. Choy, S. H. et al. Prevalence and associated risk factors of Giardia infection among indigenous communities in rural Malaysia. Sci Rep 4, 6909 (2014).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
51. Cockayne, S. E., Shah, M., Messenger, A. G. & Gawkrodger, D. J. Foot dermatitis in children: causative allergens and follow-up. Contact Dermatitis 38, 203–206 (1998).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
52. Coll Bosch, M. D., Viladot Perice, A. & Suso Vergara, A. Follow-up study of flat feet in children. Rev. Ortop. y Traumatol. 43, 213–220 (1999).	Non-Randomised Control Trial	Preschool and Infants 9mths-5yrs	Anthropometrics, Biomechanics, Effects of Footwear, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective
53. Colloud, F. et al. Shoes effect on young children gait with the increase of displacement velocity. Mov. Sport. Sci. - Sci. Mot. 75, 97–105 (2012).	Before-and-after study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
54. Coughlin, M. J. Juvenile Hallux Valgus: Etiology and Treatment. Foot Ankle Int 16, 682–697 (1995).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear
55. Cowell, H. R. Shoes and shoe corrections. Pediatr Clin North Am 24, 791–797 (1977).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic, Developmental effects, Footwear Corrective, Footwear Design

56. Da Rocha, E. S., Bratz, D. T. K., Gubert, L. C., De David, A. & Carpes, F. P. Obese children experience higher plantar pressure and lower foot sensitivity than non-obese. Clin. Biomech. 29, 822–827 (2014).	Cross Sectional Study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
57. Dai, M. et al. High-heeled-related alterations in the static sagittal profile of the spino-pelvic structure in young women. Eur Spine J 24, 1274–1281 (2015).	Before-and-after study	Not Reported in Abstract	Anthropometrics, Footwear Design, Developmental Effects, Effects of Footwear
58. Davies, N., Branthwaite, H. & Chockalingam, N. Where should a school shoe provide flexibility and support for the asymptomatic 6- to 10-year-olds and on what information is this based? A Delphi yielded consensus. Prosthet. Orthot. Int. 39, 213–8 (2015).	Survey	Primary School 6-12yrs	Footwear Design, Developmental Effects,
59. Davis, I. What Can We Learn from Watching Children Run? AMAA J. 24, 7–8 (2011).	Opinion Piece	Not Applicable	Footwear Design, Developmental Effects
60. de Oliveira Pezzan, P. A. & de Freitas Lopes, D. M. in Posture: Types, Exercises and Health Effects 171–191 (Nova Science Publishers, Inc., 2014).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear
61. de Oliveira Pezzan, P. A. et al. Postural assessment of lumbar lordosis and pelvic alignment angles in adolescent users and nonusers of high-heeled shoes. J Manip. Physiol Ther 34, 614–621 (2011).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear

62. De Vetten, A. L. & Heesters, P. J. J. The qualities of children's shoes (Dutch). Ned Tijdschr Geneeskd 120, 2044–2049 (1976).	Opinion Piece	Not Reported in Abstract	Footwear Design, Developmental Effects
63. Delgado-Abellán, L. et al. Foot morphology in Spanish school children according to sex and age. Ergonomics 57, 787–797 (2014).	Cross Sectional Survey	Primary School 6-12yrs	Anthropometrics, Footwear Design
64. Desloovere, K. et al. How can push-off be preserved during use of an ankle foot orthosis in children with hemiplegia? A prospective controlled study. Gait Posture 24, 142–151 (2006).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear
65. Desmons, F. Contact dermatitis in children. Allergol Immunopathol (Madr) 3, 35–42 (1975).	Case Series	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
66. Dias, M. P. et al. IDENTIFICAÃÃO DOS FATORES DE RISCO PARA ACIDENTES NA PRIMEIRA INFÃNCIA NO CONTEXTO CRECHE. Rev. Atencao Primaria a Saude 16, 20–26 (2013).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Injury, Footwear Design
67. Dohi, M. & Koike, M. Consumers' awareness concerning the selection of infant shoes. J. JAPAN Res. Assoc. Text. END-USES 41, 39–48 (2000).	Survey	Preschool and Infants 9mths-5yrs	Psychosocial, Footwear Design, Developmental Effects
68. Driano, A. N., Staheli, L. T. & Staheli, L. R. The psychosocial effects of childhood corrective shoe wearing. J. Investig. Med. 44, 101A (1996).	Cross Sectional Study	Not Reported in Abstract	Psychosocial, Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design, Effects of Footwear
69. Driano, A. N., Staheli, L. T. & Staheli, L. T. Psychosocial development and corrective shoewear use in childhood. J. Pediatr. Orthop. 18, 346–349 (1998).	Cross Sectional Study	Not Reported in Abstract	Psychosocial, Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design, Effects of Footwear

70. Echarri, J. J. & Forriol, F. Development of footprint morphology in congolese children in relation to footwear use. Rev. Ortop. y Traumatol. 47, 395–399 (2003).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear, Cross Sectional Study
71. Echarri, J. J. & Forriol, F. The development in footprint morphology in 1851 Congolese children from urban and rural areas, and the relationship between this and wearing shoes. J. Pediatr. Orthop. Part B 12, 141–146 (2003).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear, Cross Sectional Study
72. Eddison, N. & Chockalingam, N. The effect of tuning ankle foot orthoses-footwear combination on the gait parameters of children with cerebral palsy. Prosthet. Orthot. Int. 37, 95–107 (2013).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
73. Eddison, N., Healy, A., Needham, R. & Chockalingam, N. Shank-to-Vertical Angle in Ankle-Foot Orthoses: A Comparison of Static and Dynamic Assessment in a Series of Cases. J. Prosthetics Orthot. 29, 161–167 (2017).	Case Series	Not Reported in Abstract	Biomechanics, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability
74. Eek, M. N., Zügner, R., Stefansdottir, I. & Tranberg, R. Kinematic gait pattern in children with cerebral palsy and leg length discrepancy: Effects of an extra sole. Gait Posture 55, 150–156 (2017).	Before-and-after study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift
75. Eiff, M. P., Steiner, E., Judkins, D. Z. & Winkler-Prins, V. Clinical inquiries. What is the appropriate evaluation and treatment of children who are ‘toe walkers’? J Fam Pr. 55, 447 (2006).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear

76. Elyana, F. N. et al. A tale of two communities: intestinal polyparasitism among Orang Asli and Malay communities in rural Terengganu, Malaysia. Parasites and Vectors 9, 398 (2016).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
77. English, M. P., Gibson, M. D. & Duncan, E. H. L. Studies in the epidemiology of tinea pedis. Br Med J 2, 573–576 (1960).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Infective, Footwear Design
78. Enke, R. C., Laskowski, E. R. & Thomsen, K. M. Running shoe selection criteria among adolescent cross-country runners. PM R J. Inj. Funct. Rehabil. 1, 816–819 (2009).	Survey	Adolescent 13-18yrs	Psychosocial, Footwear Design
79. Espinosa-Muñoz, D. Y., Gómez-Gómez, N. E., Polanco, L. C., Cardona-Arias, J. A. & Ríos-Osorio, L. A. Prevalence of gastrointestinal parasite in the indigenous community of Seminke of Wiwa shelter, in Sierra Nevada de Santa Marta, 2014. Arch. Med. 11, (2015).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
80. Evans, A. M. & Rome, K. A Cochrane review of the evidence for non-surgical interventions for flexible pediatric flat feet. Eur. J. Phys. Rehabil. Med. 47, 69–89 (2011).	Systematic Review	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear Developmental Effects
81. Flores, J. M., Castillo, V. B., Franco, F. C. & Huata, A. B. Superficial fungal infections: Clinical and epidemiological study in adolescents from marginal districts of Lima and Callao, Peru. J. Infect. Dev. Ctries. 3, 313–317 (2009).	Cross Sectional Study	Adolescent 13-18yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Infective, Footwear Design

82. Foiasi, T. & Pantazi, M. Children's footwear - Health, comfort, fashion. Leather Footwear J. 10, 45–60 (2010).	Opinion Piece	Not Applicable	Footwear Design, Developmental Effects
83. Fong, D. T.-P. P. et al. Cushioning and lateral stability functions of cloth sport shoes. Sport. Biomech 6, 407–417 (2007).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Footwear Design, Protective Role, Protective Role Functional
84. Forrest, D., Dufek, J. S. & Mercer, J. A. Impact Characteristics of Female Children Running in Adult Versus Youth Shoes of the Same Size. J Appl Biomech 28, 593–598 (2012).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Footwear Design
85. Freeman, S. Shoe dermatitis. Australas J Dermatol 24, 63–68 (1983).	Technical Report	Not Applicable	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology,
86. Frigerio, S. et al. Knowledge, Attitudes, and Practices Related to Schistosomiasis Among Children in Northern Senegal. Ann. Glob. Heal. 82, 840–847 (2016).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
87. Fritz, B., Schmeltzpfenning, T., Plank, C. & Grau, S. Development of well-fitting shoes for children and adolescents. Footwear Sci. 5, S93–S94 (2013).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
88. Ganesh, M. S. P. & Magnani, B. The Influence of Footwear on the Prevalence of Flat Foot. Indian J. Physiother. Occup. Ther. 10, 157–159 (2016).	Cross Sectional Study	Primary School 6-12yrs,	Anthropometrics, Developmental Effects, Effects of Footwear
89. Ganjehie, S., Saeedi, H., Farahmand, B. & Curran, S. The efficiency of gait plate insole for children with in-toeing gait due to femoral	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Developmental Effects, Effects of Footwear

antetorsion. Prosthetics Orthot. Int. (Sage Publ. Ltd.) 41, 51–57 (2017).			
90. García-Rodríguez, A. et al. Flexible flat feet in children: a real problem? Pediatrics 103, 1278 (1999).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
91. George, D. A. & Elchert, L. The influence of foot orthoses on the function of a child with developmental delay. Pediatr. Phys. Ther. 19, 332–336 (2007).	Case Study	19 months	Biomechanics, Effects of Footwear, Developmental Effects
92. Gilmore, A. & Thompson, G. H. Common childhood foot deformities: to treat, to wait, or to refer? Many are benign and self-correcting, but parental concerns must be addressed. J. Musculoskelet. Med. 19, 287–295 (2002).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear Developmental Effects
93. Gould, N. Shoes versus sneakers in toddler ambulation. Foot Ankle 6, 105–107 (1985).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
94. Gould, N., Moreland, M., Alvarez, R., Trevino, S. & Fenwick, J. Development of the child's arch. Foot Ankle 9, 241–245 (1989).	Randomised Control Trial	Preschool and Infants 9mths-5yrs	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design, Effects of Footwear
95. Gould, N. et al. Foot growth in children age one to five years. Foot Ankle 10, 211–213 (1990).	Before-and-after study	Preschool and Infants 9mths-5yrs	Preschool and Infants 9mths-5yrs, Anthropometrics, Footwear Design
96. Grieve, D. W. & Gear, R. J. The relationships between length of stride, step frequency, time of	Before-and-after study	Adolescent 13-18yrs, Preschool and Infants	Biomechanics, Effects of Footwear, Developmental Effects

swing and speed of walking for children and adults. Ergonomics 9, 379–399 (1966).		9mths-5yrs, Primary School 6-12yrs	
97. Grueger, B., Leung, A., Otley, A., Society, C. P. & Committee, G. Footwear in children. Paediatr. Child Health 14, 121–122 (2009).	Narrative Review	Not Reported in Abstract	Footwear Design, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective
98. Hafez, E. Effect of rounded bottom profile shoes on foot clearance in children with stiff knee gait. Gait Posture 57, 239–240 (2017).	Pilot Study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Rounded-Bottom-Sole, Footwear Design
99. Hailegebriel, T. Prevalence of intestinal parasitic infections and associated risk factors among students at Dona Berber primary school, Bahir Dar, Ethiopia. BMC Infect. Dis. 17, 1–8 (2017).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
100. Helfand, A. E. Basic considerations for shoes, shoe modifications, and orthoses in foot care. Clin Pod. 1, 431–440 (1984).	Opinion Piece	Not Applicable	Footwear Design, Therapeutic Footwear
101. Herbaut, A. et al. Influence of minimalist shoes on lower-limb overuse injuries risk in children. Sci. Sport. 32, 119–128 (2017).	Narrative Review	Adolescent 13-18yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Functional, Footwear Design
102. Herbaut, A. et al. The influence of shoe aging on children running biomechanics. Gait Posture 56, 123–128 (2017).	Before-and-after study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Injury
103. Herbaut, A. et al. Determination of optimal shoe fitting for children tennis players: Effects of	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Footwear Design

inner-shoe volume and upper stiffness. Appl Erg. (2017). doi:10.1016/j.apergo.2017.05.016			
104. Herkt, R. The Forest Town boot as an aid in treatment of cerebral palsy. Krankengymnastik 27, 367–368 (1975).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design
105. Herro, E. & Jacob, S. E. p-tert-Butylphenol formaldehyde resin and its impact on children. Dermatitis 23, 86–88 (2012).	Technical Report	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
106. Hettigama, I. S., Punchihewa, H. K. G. & Heenkenda, N. K. Ergonomic footwear for Sri Lankan primary schoolchildren: A review of the literature. Work 55, 285–295 (2016).	Narrative Review	Primary School 6-12yrs	Footwear Design, Developmental Effects
107. Hicks, J. F. FITTING A POPULATION OF FEET. J. Test. Eval. 16, 404–406 (1988).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Footwear Design
108. Hillstrom, H. et al. Torsional shoe flexibility effects on functional performance of children learning to walk. Footwear Sci. 1, 73–75 (2009).	Before-and-after study	Preschool and Infants 9mths-5yrs	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
109. Hillstrom, H. J. et al. Effect of shoe flexibility on plantar loading in children learning to walk. J Am Pod. Med Assoc 103, 297–305 (2013).	Before-and-after study	Preschool and Infants 9mths-5yrs	Biomechanics, Effects of Footwear, Developmental Effects, Footwear Design
110. Hobbs, S. A., Altman, K. & Halldin, M. A. Modification of a child’s deviant walking pattern:	Case Study	3.5 years	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic

An alternative to surgery. J. Behav. Ther. Exp. Psychiatry 11, 227–229 (1980).			Footwear Functional Stability, Effects of Footwear, Footwear Design
111. Hollander, K. et al. Growing-up (habitually) barefoot influences the development of foot and arch morphology in children and adolescents. Sci Rep 7, 8079 (2017).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Effects of Footwear
112. Hollander, K. et al. Foot Strike Patterns Differ Between Children and Adolescents Growing up Barefoot vs. Shod. Int. J. Sports Med. 39, 97–103 (2018).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Effects of Footwear, Developmental Effects
113. Hollander, K., Riebe, D., Campe, S., Braumann, K.-M. M. & Zech, A. Effects of footwear on treadmill running biomechanics in preadolescent children. Gait Posture 40, 381–385 (2014).	Before-and-after study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Effects of Footwear, Developmental Effects
114. Hollander, K. et al. The effects of being habitually barefoot on foot mechanics and motor performance in children and adolescents aged 6-18 years: study protocol for a multicenter cross-sectional study (Barefoot LIFE project). J Foot Ankle Res 9, 36 (2016).	Research Protocol	Adolescent 13-18yrs, Primary School 6-12yrs	Developmental Effects, Effects of Footwear
115. Holt, K. S. Mobility aids and appliances for disabled children. Bmj 302, 105–107 (1991).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Therapeutic Footwear Functional Stability, Footwear Design, Therapeutic

			Accommodative, Developmental effects
116. Hon, K. L. E. et al. Does age or gender influence quality of life in children with atopic dermatitis? Clin Exp Dermatol 33, 705–709 (2008).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Pathology
117. Hulstaert, E. et al. Contact dermatitis caused by a new rubber compound detected in canvas shoes. Contact Dermatitis 78, 12–17 (2018).	Cross Sectional Study	Adolescent 13-18yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
118. Hutchinson, B. Pediatric metatarsus adductus and skewfoot deformity. Clin Pod. Med Surg 27, 93–104 (2010).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear, Developmental Effects
119. Ilechukwu, G. C. et al. Some behavioural risk factors for intestinal helminthiasis in nursery and primary school children in Enugu, south eastern Nigeria. Niger. J. Clin. Pract. 13, 288–293 (2010).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
120. Imaizumi, K., Akimoto, M., Kobayashi, Y., Hobara, H. & Kouchi, M. Effects of oversized footwear on gait parameters in children. Footwear Sci. 7, S16–S18 (2015).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Footwear Design, Developmental Effects
121. Ivanyi, B. et al. The effects of orthoses, footwear, and walking aids on the walking ability of children and adolescents with spina bifida: A systematic review using International Classification of Functioning, Disability and Health	Systematic Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear

for Children and Youth (ICF-CY) as a ref. Prosthet Orthot Int 39, 437–443 (2015).			
122. Jafarnezhadgero, A., Majlesi, M. & Madadi-Shad, M. The effects of low arched feet on lower limb joints moment asymmetry during gait in children: A cross sectional study. Foot 34, 63–68 (2018).	Cross Sectional Study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Footwear Design
123. James, A. M., Williams, C. M. & Haines, T. P. Effectiveness of footwear and foot orthoses for calcaneal apophysitis: a 12-month factorial randomised trial. Br J Sport. Med 50, 1268–1275 (2016)	Randomised Control Trial	Adolescent 13-18yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Functional
124. Jane MacKenzie, A., Rome, K. & Evans, A. M. The efficacy of nonsurgical interventions for pediatric flexible flat foot: A critical review. J. Pediatr. Orthop. 32, 830–834 (2012).	Systematic Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear, Developmental Effects
125. Jelić, M. Orthopedic devices for children. Paediatr. Croat. Suppl. 44, 205–210 (2000).	Opinion Piece	Not Reported in Abstract	Therapeutic Footwear, Footwear Design
126. Jiménez-Ormeño, E. et al. Foot morphology in normal-weight, overweight, and obese schoolchildren. Eur. J. Pediatr. 172, 645–652 (2013).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Footwear Design

127. João, S. M. A., Cardillo, C., Kieling, I., de Oliveira Pezzan, P. A. & Sauer, J. F. Analysis of the medial longitudinal arch in adolescents user of high heeled shoes. Fisioter. e Pesqui. 19, 20–25 (2012).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Developmental Effects, Effects of Footwear, Footwear Design
128. Joffe, M., Torrey, S. B. & Baker, M. D. Fire hydrant play: injuries and their prevention. Pediatrics 87, 900–903 (1991).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Environmental
129. Jones, S. K., English, J. S. C., Forsyth, A. & Mackie, R. M. Juvenile Plantar Dermatosis—an 8-year follow-up of 102 patients. Clin Exp Dermatol 12, 5–7 (1987).	Cohort Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Cohort Study
130. Jung, J. H., McLaughlin, J. L., Stannard, J. & Guin, J. D. Isolation, via activity-directed fractionation, of mercaptobenzothiazole and dibenzothiazyl disulfide as 2 allergens responsible for tennis shoe dermatitis. Contact Dermatitis 19, 254–259 (1988).	Case Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
131. Kanatlı, U. et al. Do corrective shoes improve the development of the medial longitudinal arch in children with flexible flat feet? J. Orthop. Sci. 21, 662–666 (2016).	Non-Randomised Control Design	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
132. Kato, T. & Watanabe, S. The etiology of Hallux Valgus in Japan. Clin Orthop Relat Res No.157, 78–81 (1981)	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
133. Kayani, B. et al. Orthopaedic manifestations of congenital indifference to pain with anhidrosis (Hereditary Sensory and Autonomic Neuropathy	Case-Series	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic

type IV). Eur. J. Paediatr. Neurol. EJPN Off. J. Eur. Paediatr. Neurol. Soc. 21, 318–326 (2017).			Footwear Functional Lift, Effects of Footwear
134. Kebede, S. W., Beyene, D. A., Meshesha, A. G. & Sinishaw, M. A. Two thirds of hookworm infected children were anemic at the outpatient department in Jimma Health Center, Jimma, Southwest Ethiopia. Asian Pacific J. Trop. Dis. 6, 691–694 (2016).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
135. Ketema, H., Biruksew, A. & Mekonnen, Z. Prevalence of Necator americanus infection and risk factors among school-age children in Mirab Abaya District, South Ethiopia. Asian Pacific J. Trop. Dis. 5, 363–368 (2015).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
136. Khan, M. Y. An analytical study of factors related to infestation by intestinal parasites in rural school children (report of a pilot study). Public Health 93, 82–88 (1979).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
137. Khieu, V. et al. Strongyloides stercoralis infection and re-infection in a cohort of children in Cambodia. Parasitol. Int. 63, 708–712 (2014).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
138. Klein, C., Groll-Knapp, E., Kundi, M. & Kinz, W. Increased hallux angle in children and its association with insufficient length of footwear: a community based cross-sectional study. BMC Musculoskelet Disord 10, 159 (2009).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear

139. Knittel, G. & Staheli, L. T. The effectiveness of shoe modifications for intoeing. Orthop. Clin. North Am. 7, 1019–1025 (1976).	Before-and-after study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design
140. Koch, P. & Nickolaus, G. Allergic contact dermatitis and mercury exanthem due to mercury chloride in plastic boots. Contact Dermatitis 34, 405–409 (1996).	Case Study	5 years	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
141. Kolsek, T., Jurca, A. & Vidic, T. Survey on parents' selection of children's footwear. Footwear Sci. 3, S88–S90 (2011).	Survey	Not Reported in Abstract	Anthropometrics, Footwear Design, Psychosocial
142. Kraemer, J. Loop sandals for early functional treatment of hallux valgus. Orthopadische Prax. 16, 882–884 (1980).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design, Effects of Footwear, Developmental Effects
143. Kristen, H. Wholesome shoes for children. The role of the doctor in this problem. Osterr. Arzteztg. 29, 1299–1314 (1974).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
144. Kristen, K. H. et al. [Functional evaluation of shoes for children based on gait analysis of children in the learning to walk stage]. Z Orthop Ihre Grenzgeb 136, 457–462 (1998).	Before-and-after study	Preschool and Infants 9mths-5yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design

145. Krol, R. Treatment of deformities associated with congenital absence of the fibula. Chir Narzadow Ruchu Ortop Pol 45, 161–165 (1980).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Design
146. Kung, S. M., Fink, P. W., Hume, P. & Shultz, S. P. Kinematic and kinetic differences between barefoot and shod walking in children. Footwear Sci. 7, 95–105 (2015).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear, Cross Sectional Study
147. Küper, K. et al. Evaluation of inner shoe dimensions by computed tomography. Fuss und Sprunggelenk 3, 159–163 (2005).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Footwear Design
148. Kurup, H. V, Clark, C. I. M. & Dega, R. K. Footwear and orthopaedics. Foot Ankle Surg 18, 79–83 (2012).	Narrative Review	Not Reported in Abstract	Developmental Effects, Footwear Design, Effects of Footwear
149. Lachapelle, J. M. & Tennstedt, D. Juvenile plantar dermatosis: a report of 80 cases. Am J Ind Med 8, 291–295 (1985).	Case Series	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
150. Lago, D. C. F., Coutinho, C. A., Kochi, C. & Longui, C. A. Reported shoes size during gh therapy: Is foot overgrowth a myth or reality? Arch Endocrinol Metab 59, 414–421 (2015).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Footwear Design
151. Lam, W. H. O., Lui, T. H. & Chan, K. M. The Epidemiology of Ankle Sprain During Hiking in	Cross Sectional Study	Adolescent 13-18yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Injury, Footwear Design

Uniformed Groups. J. Orthop. Trauma Rehabil. 15, 10–16 (2011).			
152. Lampe, R., Mitternacht, J., Gerdesmeyer, L. & Gradinger, R. Plantar pressure measurement in children and youths during sports activities. Klin Padiatr 217, 70–75 (2005).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Biomechanics, Effects of Footwear, Footwear Design
153. Lampe, R. et al. Influence of orthopaedic-technical aid on the kinematics and kinetics of the knee joint of patients with neuro-orthopaedic diseases. Brain Dev. 26, 219–226 (2004).	Before-and-after study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability
154. Latorre Roman, P. A., Balboa, F. R. & Pinillos, F. G. Foot strike pattern in children during shod-unshod running. Gait Posture 58, 220–222 (2017).	Before-and-after study	Adolescent 13-18yrs, Primary School 6-12yrs	Developmental Effects, Biomechanics, Effects of Footwear
155. Leong Lim, K. B. et al. Escalators, rubber clogs, and severe foot injuries in children. J Pediatr Orthop 30, 414–419 (2010).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Injury, Footwear Design
156. Li, H., Zhao, C., Zhou, J., Shao, H. & Chen, W. Isolation, purification and identification of bacteria from the shoes worn by children. African J. Biotechnol. 10, 4133–4137 (2011).	Cross Sectional Study	Primary School 6-12yrs	Risk Factor Injury/Pathology, Risk Factor Infective, Footwear Design, Cross Sectional Study
157. Li, H., Zhou, J., Shi, R. & Chen, W. Identification of fungi from children’s shoes and application of a novel antimicrobial agent on shoe	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Infective

insole. African J. Biotechnol. 10, 14493–14497 (2011).			
158. Li, Y. H. & Leong, J. C. Intoeing gait in children. Hong Kong Med. J. = Xianggang Yi Xue Za Zhi 5, 360–366 (1999).	Narrative Review	Not Reported in Abstract	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
159. Lieberman, D. E. et al. Foot strike patterns and collision forces in habitually barefoot versus shod runners. Nature 463, 531–535 (2010).	Cross Sectional Study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear
160. Lim, P. Q. X. et al. The association of foot structure and footwear fit with disability in children and adolescents with Down syndrome. J Foot Ankle Res 8, 4 (2015).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear
161. Lim, P. et al. Do foot posture, deformity, and footwear fit influence physical activity levels in children with Down syndrome? A prospective cohort study. J. Intellect. Dev. Disabil. 42, 332–338 (2017).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear
162. López Elvira, J. L., López Plaza, D., López Valenciano, A. & Alonso Montero, C. Influencia del calzado en el movimiento del pie durante la marcha y la carrera en niños y niñas de 6 y 7 años. / Influence of footwear on foot movement during walking and running in boys and girls aged 6-7. Retos Nuevas Perspect. Educ. Física, Deport. y Recreación 31, 128–132 (2017).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
163. Lord, M. & Foulston, J. Clinical trial of a computer-aided system for orthopaedic shoe	Cross Sectional Study	Not Reported in Abstract	Footwear Design, Therapeutic Footwear

upper design. Prosthet Orthot Int 15, 11–17 (1991).			
164. Lord, M., Foulston, J. & Smith, P. J. Technical Evaluation of a Cad System for Orthopaedic Shoe-Upper Design. Proc. Inst. Mech. Eng. Part H J. Eng. Med. 205, 109–115 (1991).	Cross Sectional Study	Not Reported in Abstract	Footwear Design, Therapeutic Footwear
165. Louey, M. G. Y. & Sangeux, M. Shod wear and foot alignment in clinical gait analysis. Gait Posture 49, 144–147 (2016).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear
166. Lythgo, N., Wilson, C. & Galea, M. Basic gait and symmetry measures for primary school-aged children and young adults whilst walking barefoot and with shoes. Gait Posture 30, 502–506 (2009).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
167. Mackie, R. M. & Husain, S. L. Juvenile plantar dermatosis: A new entity? Clin Exp Dermatol 1, 253–260 (1976).	Case Series	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology
168. Makary, M. A. Reported incidence of injuries caused by street glass among urban children in Philadelphia. Inj. Prev. 4, 148–149 (1998).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Environmental
169. Malas, B. S. What variables influence the ability of an AFO to improve function and when are they indicated? Clin Orthop Relat Res 469, 1308–1314 (2011).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
170. Martin-Casado, L., Barquin, C., Martín-Casado, L. & Barquín, C. Does a Physical Education lesson affect the foot morphology in school-aged children? Bol. Med. Hosp. Infant. Mex. 74, 357–363 (2017).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Footwear Design

171. Matsuda, S., Kasuga, K., Hanai, T., Demura, T. & Komura, K. The effect of the kindergarten barefoot policy on Preschool children's toes. J Physiol Anthr. 36, 4 (2016).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Developmental Effects, Effects of Footwear
172. Mauch, M., Grau, S., Krauss, I., Maiwald, C. & Horstmann, T. A new approach to children's footwear based on foot type classification. Ergonomics 52, 999–1008 (2009).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Footwear Design
173. Mauch, M. et al. Do the feet of German and Australian children differ in structure? Implications for children's shoe design. Ergonomics 51, 527–539 (2008).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
174. McCarthy, C, et al. The effects of shoe design on gait, stability, and loading in new walkers, Abstracts * of Poster and Platform Presentations at the 2011. Pediatr. Phys. Ther. 23, 49–68 (2011).	Before-and-after study	Preschool and Infants 9mths-5yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
175. McSweeney, S. C., Reed, L. F. & Wearing, S. The effect of sex on measures of foot mobility and stiffness in children and adolescents. Footwear Sci. 9, S138–S139 (2017).	Cross Sectional Study	Primary School 6-12yrs, Adolescent 13-18yrs	Anthropometrics, Footwear Design
176. Mendelewich, I. A. & Pitkin, M. R. Orthopedic shoes for children with cerebral palsy in residual stage and with 'pes equino-varus congenital' which is feebly marked or was	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design

surgically treated. Abstr. XII Congr. Int. Soc. Biomech. 22, 1055 (1989).			
177. Minkin, W., Cohen, H. J. & Frank, S. B. Contact Dermatitis to East Indian Leather. Arch Dermatol 103, 522–523 (1971).	Case Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
178. MJ, I. J., Nene, A. V, Ijzerman, M. J. & Nene, A. V. Feasibility of the physiological cost index as an outcome measure for the assessment of energy expenditure during walking. Arch. Phys. Med. Rehabil. 83, 1777–1782 (2002).	Before-and-after study	Not Reported in Abstract	Physiological, Effects of Footwear
179. Molla, Y. B. et al. Individual correlates of podoconiosis in areas of varying endemicity: a case-control study. PLoS Negl Trop Dis 7, e2554–e2554 (2013).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Environmental
180. Monsia, A. et al. [Surgery of congenital clubfoot in Don Orione, Health Center for physical handicaps of Ivory Coast (About 554 feet)]. Ann Chir Plast Esthet 53, 41–45 (2008).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
181. Moorthy, T. T. & Rajan, V. S. Juvenile plantar dermatosis in Singapore. Int J Dermatol 23, 476–479 (1984).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology Footwear Design
182. Moreno-Hernández, A. et al. Temporal and spatial gait parameters analysis in non-	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear

pathological Mexican children. Gait Posture 32, 78–81 (2010).			
183. Mueller, R. & Boltze, W. H. The conservative equalization of differences in the length of the legs. Ther. Umschau 32, 303–305 (1975).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Footwear Design
184. Mullen, S. & Toby, E. B. Adolescent runners: The effect of training shoes on running kinematics. J. Pediatr. Orthop. 33, 453–457 (2013).	Before-and-after study	Adolescent 13-18yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
185. Muller, S. et al. Conservative treatment measures in hemophilic arthropathy. Orthopade 28, 347–355 (1999).	Case Series	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
186. Muñoz-Antoli, C., Pavón, A., Marcilla, A., Toledo, R. & Esteban, J. G. Prevalence and risk factors related to intestinal parasites among children in Department of Rio San Juan, Nicaragua. Trans R Soc Trop Med Hyg 108, 774–782 (2014).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
187. Munuera, P. V, Castillo, J. M., Dominguez, G. & Lafuente, G. Orthotic devices with out-toeing wedge as treatment for in-toed gait in children. J Am Pod. Med Assoc 100, 472–478 (2010).	Before-and-after study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
188. Murri, A. & Zechner, G. [Corrective dynamic shoe fitting of the functional clubfoot in patients	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear,

with infantile cerebral palsy]. Z Orthop Ihre Grenzgeb 132, 214–220 (1994).			Therapeutic Footwear Corrective, Effects of Footwear
189. Nasr, N. A., Al-Mekhlafi, H. M., Ahmed, A., Roslan, M. A. & Bulgiba, A. Towards an effective control programme of soil-transmitted helminth infections among Orang Asli in rural Malaysia. Part 2: Knowledge, attitude, and practices. Parasit. Vectors 6, 28 (2013).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
190. Neering, H. & Van Dijk, E. Juvenile plantar dermatosis. Acta Derm Venereol 58, 531–534 (1978).	Narrative Review	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology
191. Neto, H. P. et al. Immediate effect of postural insoles on gait performance of children with cerebral palsy: Preliminary randomized controlled double-blind clinical trial. J. Phys. Ther. Sci. 26, 1003–1007 (2014).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear
192. Nordenfelt, P. J. Children's shoes. Acta Pædiatrica 25, 220–226 (1939).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
193. Ocak, B. & Gülümser, G. Foot measurement standardization of adolescent boys in 7-14 age group. Tekst. ve Konfeksiyon 19, 157–162 (2009).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design

194. Oeffinger, D. et al. Comparison of gait with and without shoes in children. Gait Posture 9, 95–100 (1999).	Before-and-after study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear
195. Ortiz-Salvador, J.-M. M. et al. Dermatitis of the Foot: Epidemiologic and Clinical Features in 389 Children. Pediatr Dermatol 34, 535–539 (2017).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
196. Pandey, S. et al. Flatfoot in Indian population. J. Orthop. Surg. (Hong Kong) 21, 32–36 (2013).	Randomised control Trial	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear, Footwear Design
197. Pasin Neto, H. et al. Postural insoles on gait in children with cerebral palsy: Randomized controlled double-blind clinical trial. J. Bodyw. Mov. Ther. 21, 890–895 (2017).	Randomised Control Trial	Primary School 6-12yrs	Biomechanics, Effects of Footwear
198. Pauk, J. & Griškevičius, J. Ground reaction force and support moment in typical and flat-feet children. Mechanika 17, 93–96 (2011).	Cross Sectional Study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Footwear Design
199. Pauk, J., Ezerskiy, V., Raso, J. V & Rogalski, M. Epidemiologic factors affecting plantar arch development in children with flat feet. J Am Pod. Med Assoc 102, 114–121 (2012).	Cross Sectional Study	Adolescent 13-18yrs Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear
200. Pavlackova, J., Egner, P., Mokrejs, P. & Cernekova, M. Verification of toe allowance of children's footwear and its categorisation. Footwear Sci. 7, 149–157 (2015).	Cross Sectional Study	Not Reported in Abstract	Developmental Effects, Footwear Design

201. Penneau, K., Lutter, L. D. & Winter, R. D. Pes planus: radiographic changes with foot orthoses and shoes. Foot Ankle 2, 299–303 (1982).	Before-and-after study	Not Reported in Abstract	Anthropometrics, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
202. Pezzan, P. A. O., Sacco, I. C. N. & João, S. M. A. Foot posture and classification of the plantar arch among adolescent wearers and non-wearers of high-heeled shoes. Brazilian J. Phys. Ther. / Rev. Bras. Fisioter. 13, 398–404 (2009).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Developmental Effects, Footwear Design, Effects of Footwear
203. Phiri, K. S. The prevalence, intensity and ecological determinants of helminth infection among children in an urban and rural community in Southern Malawi. Malawi Med. J. J. Med. Assoc. Malawi 13, 22–26 (2001).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
204. Phiri, K., Whitty, C. J. M., Graham, S. M. & Ssembatya-Lule, G. Urban/rural differences in prevalence and risk factors for intestinal helminth infection in southern Malawi. Ann Trop Med Parasitol 94, 381–387 (2000).	Cross Sectional Study	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective

205. Prasher, V. P., Robinson, L., Krishnan, V. H. R. & Chung, M. C. Podiatric disorders among children with Down syndrome and learning disability. Dev Med Child Neurol 37, 131–134 (1995).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Biomechanics, Effects of Footwear, Footwear Design
206. Puszczałowska-Lizis, E. et al. Foot Structure in Boys with Down Syndrome. Biomed Res. Int. 2017, 7047468 (2017).	Cross Sectional Study	Adolescent 13-18yrs	Anthropometrics, Footwear Design
207. Raczkowski, J. W., Daniszewska, B. & Zolynski, K. Functional scoliosis caused by leg length discrepancy. Arch. Med. Sci. 6, 393–398 (2010).	Cohort Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Effects of Footwear
208. Rajchel-Chyla, B., Skrzyńska, B., Janocha, M. & Gajewski, R. The foot length changes due to age as well as load during ambulation and determintion of the toe allowance. Prz. Wlokienniczy 66, 23–26 (2012).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Footwear Design, Footwear Design
209. Ramstrand, N., Andersson, C. B., Rusaw, D., Björk Andersson, C. & Rusaw, D. Effects of an unstable shoe construction on standing balance in children with developmental disabilities: A pilot study. Prosthet Orthot Int 32, 422–433 (2008).	Pilot Study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Unstable
210. Reichert, F. et al. Prevalence and Risk Factors of Hookworm-Related Cutaneous Larva Migrans (HrCLM) in a Resource-Poor Community in	Cross Sectional Study	Adolescent 13-18yrs Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective

Manaus, Brazil. PLoS Negl Trop Dis 10, e0004514–e0004514 (2016).			
211. Revenga-Giertych, C. & Bulo-Concellón, M. P. Valgus flatfoot: Evolution of the footprint and related factors. Rev. Ortop. y Traumatol. 49, 271–280 (2005).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear
212. Robinson, L. E. et al. Footwear and locomotor skill performance in Preschoolers. Percept Mot Ski. 113, 534–538 (2011).	Randomised Control Trail	Preschool and Infants 9mths-5yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
213. Rocha, E. S. & Pedreira, A. C. [Common orthopedic problems in adolescents]. J. Pediatr. (Rio. J). 77 Suppl 2, S225–S233 (2001).	Narrative Review	Not Reported in Abstract	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
214. Romaguera, C. & Vilaplana, J. Contact dermatitis in children: 6 years experience (1992-1997). Contact Dermatitis 39, 277–280 (1998).	Cross Sectional Study	Adolescent 13-18yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology, Footwear Design
215. Rome, K., Ashford, R. L. & Evans, A. Non-surgical interventions for paediatric pes planus. Cochrane Database Syst Rev 7, Cd006311 (2010).	Systematic Review	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
216. Rotter, I., Wicher, J., Zułtak-Bączkowska, K., Mroczek, B. & Karakiewicz, B. Prevention and correction of faulty postures among children in pre-school age-parents' opinion. Fam. Med. Prim. Care Rev. 11, 471–472 (2009).	Survey	Preschool and Infants 9mths-5yrs	Developmental Effects, Psychosocial, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear

217. Roul, S. et al. Footwear contact dermatitis in children. Contact Dermatitis 35, 334–336 (1996).	Case Series	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology
218. Roye, D. P. J. & Raimondo, R. A. Surgical treatment of the child's and adolescent's flexible flatfoot. Clin. Podiatr. Med. Surg. 17, 515–30, vii–viii (2000).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Footwear Design
219. Sacco, I. C. N., Onodera, A. N., Bosch, K., Rosenbaum, D. & Sacco, I. C. N. Comparisons of foot anthropometry and plantar arch indices between German and Brazilian children. BMC Pediatr. 15, 4 (2015).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
220. Sachithanandam, V. & Joseph, B. The influence of footwear on the prevalence of flat foot. A survey of 1846 skeletally mature persons. J. Bone Jt. Surg. - Ser. B 77, 254–257 (1995).	Cross Sectional Study	Adult Population Retrospective to Childhood	Anthropometrics, Developmental Effects, Effects of Footwear
221. Sah, R. B. et al. Prevalence of intestinal helminthic infections and associated risk factors. Indian J. Community Heal. 25, 134–139 (2013).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
222. Sandoval, N. R. et al. A survey of intestinal parasites including associated risk factors in humans in Panama. Acta Trop 147, 54–63 (2015).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
223. Sanzarello, I., Nanni, M. & Faldini, C. The clubfoot over the centuries. J. Pediatr. Orthop. Part B 26, 143–151 (2017).	Narrative Review	Not Reported in Abstract	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
224. Sass, P. & Hassan, G. Lower extremity abnormalities in children. Am Fam Physician 68, 461–468 (2003).	Opinion Piece	Not Applicable	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Footwear Effects

225. Schaars, A. H. & Postema, K. Conservative treatment of foot deformities in Duchenne Muscular Dystrophy. J. Rehabil. Sci. 3, 49–52 (1990).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
226. Shin, I. S., Kim, E. S. & Kim, J. T. The segemental measurement of foot and its three dimensional modeling. Korean J. Sport Sci. 3, 48–65 (1991).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
227. Shultz, S. P., Houltham, S. D., Kung, S. M., Hume, P. & Fink, P. W. Metabolic Differences between Shod and Barefoot Walking in Children. Int J Sport. Med 37, 401–404 (2016).	Before-and-after study	Primary School 6-12yrs	Developmental Effects, Physiological, Effects of Footwear
228. Silva, A. M., de Siqueira, G. R. & da Silva, G. A. P. Implications of high-heeled shoes on body posture of adolescents. Rev. Paul. Pediatr. Orgao Of. Da Soc. Pediatr. Sao Paulo 31, 265–271 (2013).	Narrative Review	Adolescent 13-18yrs	Anthropometrics, Biomechanics, Developmental Effects, Effects of Footwear, Effects of Footwear, Footwear Design
229. Simon, T. D., Soep, J. B. & Hollister, J. R. Pernio in pediatrics. Pediatrics 116, e472–e475 (2005).	Case Series	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Injury, Footwear Design
230. Society, C. P. Footwear for children. Paediatr. Child Health 3, 373–375 (1998).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design
231. Staheli, L. T. Torsional deformity. Pediatr Clin North Am 33, 1373–1383 (1986).	Opinion Piece	Not Applicable	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear

232. Staheli, L. T. Planovalgus foot deformity. Current status. J Am Pod. Med Assoc 89, 94–99 (1999).	Opinion Piece	Not Applicable	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
233. Staheli, L. T. Corrective shoes for children: are they really necessary? J. Musculoskelet. Med. 13, 11–15 (1996).	Opinion Piece	Not Applicable	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
234. Staheli, L. T. Shoes for children: a review. Pediatrics 88, 371–375 (1991).	Narrative Review	Not Reported in Abstract	Developmental Effects Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
235. Staheli, L. T. & Giffin, L. Corrective shoes for children: a survey of current practice. Pediatrics 65, 13–17 (1980).	Survey	Not Reported in Abstract	Developmental Effects, Psychosocial, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
236. Steen, H., Terjesen, T. & Bjerkreim, I. [Anisomelia. Clinical consequences and treatment]. Tidsskr. Den Nor. Laegeforening Tidsskr. Prakt. Med. Ny Raekke 117, 1595–1600 (1997).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Footwear Design
237. Stricker, S. J. & Sama, A. A. Assessment of angulation and torsion of lower limbs in children. Int. Pediatr. 16, 138–143 (2001).	Narrative Review	Not Reported in Abstract	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
238. Taeho, Y. Parent, peer and TV influences on American teens' athletic shoes purchasing. Int. J. Sport Manag. Mark. 1, 2 (2005).	Survey	Adolescent 13-18yrs	Psychosocial, Footwear Effects
239. Talusan, P. G., Milewski, M. D., Reach Jr, J. S. & Reach Jr., J. S. Fifth Toe Deformities: Overlapping and Underlapping Toe. Foot Ankle Spec. 6, 145–149 (2013).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Accommodative, Footwear Design, Effects of Footwear

240. Theophilos, P. et al. Evaluation of sprinting performance in adolescent athletes with running shoes, spikes and barefoot. J. Phys. Educ. Sport 14, 593–598 (2014).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear
241. Thompson, A. L. T. & Zipfel, B. The unshod child into womanhood -- forefoot morphology in two populations. Foot 15, 22–28 (2005).	Cross Sectional Study	Not Reported in Abstract	Anthropometrics, Developmental Effects, Effects of Footwear
242. Tomono, N. et al. Risk factors of helminthiases among schoolchildren in southern Thailand. Southeast Asian J Trop Med Public Heal. 34, 264–268 (2003).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective
243. Tong, J. W. K., Pui, W. K., Kong, P. W., Pui, W. K. & Kong, P. W. Medial Longitudinal Arch Development of Children Aged 7 to 9 Years: Longitudinal Investigation. Phys Ther 96, 1216–1224 (2016).	Cross Sectional Study	Primary School 6-12yrs	Anthropometrics, Developmental Effects, Effects of Footwear
244. Trevisan, G., Kokeli, E. & Kokelj, F. Allergic contact dermatitis due to shoes in children: a 5 year follow up. Contact Dermatitis 26, 45–45 (1992).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yr	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology , Footwear Design
245. Tulu, B., Taye, S. & Amsalu, E. Prevalence and its associated risk factors of intestinal parasitic infections among Yadot primary school children of South Eastern Ethiopia: A cross-sectional study. BMC Res. Notes 7, 848 (2014).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Infective

246. Uden, H. & Kumar, S. Non-surgical management of a pediatric ‘intoed’gait pattern - a systematic review of the current best evidence. J. Multidiscip. Healthc. 5, 27–35 (2012).	Systematic Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear, Developmental Effects
247. Ujević, D. et al. Standardization, anthropometric surveys and croatian anthropometric system. Tekstil 55, 516–526 (2006).	Cross Sectional Study	Adolescent 13-18yrs Primary School 6-12yrs	Anthropometrics, Footwear Design
248. Unger, H. & Rosenbaum, D. Gender-specific differences of the foot during the first year of walking. Foot Ankle Int 25, 582–587 (2004).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design Developmental Effects
249. Uvelli, K., Neher, J. O. & Safranek, S. Treatment for Calcaneal Apophysitis. Am Fam Physician 96, 126–127 (2017).	Opinion Piece	Not Applicable	Effects of Footwear, Protective Role, Protective Role Functional
250. Van Hamme, A. et al. Is there a predominant influence between heel height, upper height and sole stiffness on young children gait dynamics? Comput. Methods Biomech. Biomed. Engin. 16, 66–67 (2013).	Before-and-after study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
251. Veilleux, L.-N. N., Ballaz, L., Robert, M., Lemay, M. & Rauch, F. Analysing gait using a force-measuring walkway: intrasession repeatability in healthy children and adolescents. Comput Methods Biomech Biomed Engin 17, 1447–1451 (2014).	Before-and-after study	Adolescent 13-18yrs, Primary School 6-12yrs	Biomechanics, Effects of Footwear

252. Vogel Jr, F. Short-leg syndrome. Clin Pod. 1, 581–599 (1984).	Opinion Piece	Not Applicable	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Footwear Design
253. Vrdoljak, J. et al. Antropometric measurements of growing feet. Paediatr. Croat. 48, 117–120 (2004).	Cross Sectional Study	Adolescent 13-18yrs, Primary School 6-12yrs	Anthropometrics, Footwear Design
254. Walker, S. L. et al. The prevalence and association with health-related quality of life of tungiasis and scabies in schoolchildren in southern Ethiopia. PLoS Negl Trop Dis 11, e0005808 (2017).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
255. Walther Richters, M., Wahl, H., Walther-Richters, M. & Wahl, H. Problems in choice of shoes for young children. Beitr Orthop Traumatol 24, 181–184 (1977).	Survey	Preschool and Infants 9mths-5yrs	Developmental Effects, Footwear Design
256. Walther, M. et al. Requirements for children sport shoes, when taking into consideration the evolution of the child's foot. A systematic review of current literature. Fuss und Sprunggelenk 3, 23–33 (2005).	Systematic Review	Not Reported in Abstract	Developmental Effects, Footwear Design
257. Walther, M., Herold, D., Sinderhauf, A. & Morrison, R. Children sport shoes--a systematic review of current literature. Foot Ankle Surg 14, 180–189 (2008).	Systematic Review	Not Reported in Abstract	Developmental Effects, Footwear Design
258. Watanabe, E. et al. Use of footwear and foot condition among rural Ethiopian school children. J Epidemiol Glob Heal. 4, 323–325 (2014).	Cross Sectional Study	Primary School 6-12yrs	Effects of Footwear, Protective Role, Protective Role Environmental

259. Wegener, C. et al. Effect of sports shoes on midfoot power generation in children while walking and running. Footwear Sci. 5, S55–S56 (2013).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
260. Wegener, C. et al. Effect of sports shoes on children's vertical jump performance and midfoot and ankle kinetics. Footwear Sci. 5, S58–S59 (2013).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
261. Wegener, C. et al. In-shoe multi-segment foot kinematics of children during the propulsive phase of walking and running. Hum Mov Sci 39, 200–211 (2015).	Before-and-after study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear
262. Wegener, C. et al. Power generation of the midfoot in children wearing sports shoes. J. Foot Ankle Res. 2013 61 6, O35 (2013).	Before-and-after study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear
263. Wegener, C., Hunt, A. E., Vanwanseele, B., Burns, J. & Smith, R. M. Effect of children's shoes on gait: a systematic review and meta-analysis. J Foot Ankle Res 4, 3 (2011).	Systematic Review	Adolescent 13-18yrs, Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
264. Wegener, C. et al. Three-dimensional ankle kinematics in children's school shoes during running. J. Foot Ankle Res. 5, O20 (2012).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Effects of Footwear, Footwear Design
265. Wegener, C. et al. Children's rearfoot and midfoot motion while walking in school shoes. J. Foot Ankle Res. 4, O49 (2011).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear

266. Weiss, J., De Jong, A., Packer, E. & Bonanni, L. Purchasing infant shoes: attitudes of parents, pediatricians, and store managers. Pediatrics 67, 718–720 (1981).	Survey	Preschool and Infants 9mths-5yrs	Psychosocial, Developmental Effects, Footwear Design
267. Wenger, D. R. & Leach, J. Foot deformities in infants and children. Pediatr Clin North Am 33, 1411–1427 (1986).	Opinion Piece	Not Applicable	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
268. Wenger, D. R. et al. Foot growth rate in children age one to six years. Foot Ankle Int 3, 207–210 (1983).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
269. Wenger, D. R., Mauldin, D., Speck, G., Morgan, D. & Lieber, R. L. Corrective Shoes and Inserts as Treatment for Flexible Flatfoot in Infants and Children. J Bone Jt. Surg Am 71, 953–954 (1989).	Randomised Control Trial	Not Reported in Abstract	Anthropometrics, Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
270. Weston, J. A., Hawkins, K. & Weston, W. L. Foot dermatitis in children. Pediatrics 72, 824–827 (1983).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Footwear Design, Risk Factor Dermatology
271. Williams, C. M., James, A. M. & Tran, T. Metatarsus adductus: development of a non-surgical treatment pathway. J Paediatr Child Heal. 49, E428-33 (2013).	Narrative Review	Not Reported in Abstract	Developmental Effects, Therapeutic Footwear, Therapeutic Footwear Corrective, Effects of Footwear
272. Williams, C. M., Michalitsis, J., Murphy, A., Rawicki, B. & Haines, T. P. Do external stimuli impact the gait of children with idiopathic toe walking? A study protocol for a within-subject randomised control trial. BMJ Open 3, (2013).	Research Protocol	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear

273. Williams, C. M., Tinley, P. & Rawicki, B. Idiopathic toe-walking: have we progressed in our knowledge of the causality and treatment of this gait type? J Am Pod. Med Assoc 104, 253–262 (2014).	Narrative Review	Not Reported in Abstract	Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Effects of Footwear
274. Wolf, S. et al. Foot motion in children shoes: a comparison of barefoot walking with shod walking in conventional and flexible shoes. Gait Posture 27, 51–59 (2008).	Before-and-after study	Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear
275. Xu, M. & Wang, L. [Foot growth and foot types in children and adolescents: a narrative review]. Sheng Wu Yi Xue Gong Cheng Xue Za Zhi 34, 648–652 (2017).	Narrative Review	Not Reported in Abstract	Anthropometrics, Developmental Effects, Footwear Design
276. Yamamoto, A. A Study of the Foot Form for Footwear Design Part 8 :Factor Analysis of the Toes of Male and Female Children of 3 to 6 years old. J. JAPAN Res. Assoc. Text. END-USES 34, 254–260 (1993).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
277. Yamamoto, A. & Imamatsu, R. A Study of the Foot Form for Footwear Design (Part1) —The Property of the Foot Form of Children Ranging from Three to Six in Age on the Basis of the Footprints or the Foot Measurements—. J. JAPAN Res. Assoc. Text. END-USES 31, 231–237 (1990).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design

278. Yamamoto, A. & Imamatsu, R. A Study of the Foot Form for Footwear Design (Part 2) —The Increment of Foot Growth of Children Aged Three to Six Traced and Measured—. J. JAPAN Res. Assoc. Text. END-USES 31, 245–249 (1990).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
279. Yamamoto, S. Studies on upright postural sway in normal and cerebral palsy children. Acta Sch. Med. Univ. Gifu 33, 822–849 (1985).	Cross Sectional Study	Not Reported in Abstract	Biomechanics, Developmental Effects, Effects of Footwear
280. Yi, N. et al. Improved influence of the combination of wedged shoes and ankle foot orthoses on the extension ability of knee joint in cerebral palsy children. J. Clin. Rehabil. Tissue Eng. Res. 11, 900–902 (2007).	Before-and-after study	Not Reported in Abstract	Biomechanics, Effects of Footwear, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Stability, Developmental Effects
281. Yori, P. P. et al. Seroepidemiology of strongyloidiasis in the Peruvian Amazon. Am J Trop Med Hyg 74, 97–102 (2006).	Cross Sectional Study	Not Reported in Abstract	Effects of Footwear, Protective Role, Protective Role Infective
282. Young, E. Forefoot eczema—further studies and a review. Clin Exp Dermatol 11, 523–528 (1986).	Case Series	Not Reported in Abstract	Effects of Footwear, Risk Factor Injury/Pathology, Risk Factor Dermatology
283. Yurt, Y., Sener, G. & Yakut, Y. Footwear suitability in Turkish Preschool-aged children. Prosthetics Orthot. Int. (Taylor Fr. Ltd) 38, 224–231 (2014).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Developmental Effects, Footwear Design, Psychosocial
284. Zabjek, K. F. et al. Acute postural adaptations induced by a shoe lift in idiopathic scoliosis patients. Eur. Spine J. Off. Publ. Eur. Spine Soc. Eur. Spinal Deform. Soc. Eur. Sect. Cerv. Spine Res. Soc. 10, 107–113 (2001).	Before-and-after study	Adolescent 13-18yrs Primary School 6-12yrs	Anthropometrics, Therapeutic Footwear, Therapeutic Footwear Functional, Therapeutic Footwear Functional Lift, Effects of Footwear

285. Zhou, J., Li, T., Xu, B. & Chen, W. Investigation of children’s plantar pressure distribution with varied angle of hallux. Leather Footwear J. 15, 3–14 (2015).	Cross Sectional Study	Preschool and Infants 9mths-5yrs, Primary School 6-12yrs	Biomechanics, Developmental Effects, Effects of Footwear, Footwear Design
286. Žukiené, K., Vilunaité, L. & Milašiené, D. Analysis of Preschool age Lithuania children’s feet measurements: Implications for shoe design. in 4th International Textile, Clothing and Design Conference - Magic World of Textiles, ITC and DC 1047–1051 (2008).	Cross Sectional Study	Preschool and Infants 9mths-5yrs	Anthropometrics, Footwear Design
287. What requirements to make of a well-made child’s shoe? (Dutch). Ned. Tijdschr. voor Fysiother. 86, 117–119 (1976).	Opinion Piece	Not Applicable	Developmental Effects, Footwear Design

2. Chapter 3

2.1. Prisma 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Not applicable
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1-5, Additional File 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Additional File 4 and 5
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Figures 3-5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	10-17
DISCUSSION			

Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	18-23
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	24
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24-25
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	30

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097
For more information, visit: **www.prisma-statement.org**.

2.2. Supplementary biomechanical outcome results

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Corrective Therapeutic Footwear						
Biomechanical outcomes						
Plantar pressure						
Average peak pressure (kPa): Hindfoot	**Chen et al. (2015)**	CTEV	Group 1 CTF and DB	N/A	74.1 (64.02-84.18) *	One-way MANOVA: **p=0.024**
			Group2 DB and Own footwear	N/A	57.48 (39.47-75.49) *	Post hoc: Group 2 vs. Group 3 **p<0.05** §
			Group 3 FAS and CTF	N/A	83.18 (71.78-94.58) *	

Average peak pressure (kPa): Medial midfoot			Group 1 CTF and DB	N/A	55.51 (41.82-69.21) *	One-way MANOVA: p>0.05
			Group2 DB and Own footwear	N/A	59.58 (43.14-76.01) *	
			Group 3 FAS and CTF	N/A	47.5 (41.20-53.80) *	
Average peak pressure (kPa): Lateral forefoot			Group 1 CTF and DB	N/A	55.44 (46.02-64.87) *	One-way MANOVA: p>0.05
			Group2 DB and Own footwear	N/A	66.09 (50.02-82.15) *	
			Group 3 FAS and CTF	N/A	55.15 (42.37-67.94) *	
Average peak pressure (kPa): Medial forefoot			Group 1 CTF and DB	N/A	95.54 (83.89-107.19) *	One-way MANOVA: **p=0.049**
			Group2 DB and Own footwear	N/A	89.34 (66.31-112.33)	Post hoc: Group 2 vs. Group 3 **p<0.05** §
			Group 3 FAS and CTF	N/A	122.58 (100.78-124.38) *	
Maximum peak pressure (kPa): Lateral midfoot			Group 1 CTF and DB	N/A	99.14 (89.06-109.22) *	One-way MANOVA: **p=0.033**
			Group2 DB and Own footwear	N/A	105.89 (84.27-127.52) *	Post hoc: Group 1 vs. Group 3 **p<0.05** § Group 2 vs. Group 3 **p<0.05** §
			Group 3 FAS and CTF	N/A	82.38 (71.87-92.90) *	
Maximum peak pressure			Group 1 CTF and DB	N/A	63.69 (51.88-75.50) *	One-way MANOVA:

(kPa): Medial midfoot			Group2 DB and Own footwear	N/A	56.8 (45.64-67.96) *	p>0.05
			Group 3 FAS and CTF	N/A	56.44 (46.69-66.20) *	
Maximum peak pressure (kPa): Lateral forefoot			Group 1 CTF and DB	N/A	118.48 (105.96-131) *	One-way MANOVA: p>0.05
			Group2 DB and Own footwear	N/A	120.53 (104.55-136.51)	
			Group 3 FAS and CTF	N/A	129.77 (112.98-146.55) *	
Maximum peak pressure (kPa): Medial forefoot			Group 1 CTF and DB	N/A	115 (101.83-128.16) *	One-way MANOVA: **p=0.008**
			Group2 DB and Own footwear	N/A	101.26 (81.02-121.51) *	Post hoc: Group 1 vs. Group 3 **p<0.05** § Group 2 vs. Group 3 **p<0.01** §
			Group 3 FAS and CTF	N/A	135.87 (122.1-149.64) *	
Peak pressure ratio: Medial/lateral forefoot			Group 1 CTF and DB	N/A	1.52 (1.28-1.76) *	One-way MANOVA: p>0.05
			Group2 DB and Own footwear	N/A	1.37 (0.96-1.78) *	
			Group 3 FAS and CTF	N/A	1.52 (1.28-1.75) *	

Outcome	Study	Condition	Group	Baseline Mean (SD +/-)	Final Mean (SD +/-)	Statistical Result (Significant values given in bold)
Functional Instability Therapeutic Footwear						
Biomechanical outcomes						
Balance (Dynamic)						
Anterior posterior control (CoP)	**Ramstrand et al. (2008)**	Cerebral Palsy + mixed developmental disability	BF Slow	51 (33.9-68.1) *		BF p>0.05; FITF p>0.05
			BF Medium	40.67 (15.9-65.5) *		
			BF Fast	35.6 (11.6-59.7) *		
			FITF Slow	33.78 (12.8-54.8) *		
			FITF Medium	31.44 (7.1-55.8) *		
			FITF Fast	36.89 (13.5-60.3) *		
			BF Slow (at 4 weeks)		43 (19.9-66.6) *	
			BF Fast (at 4 weeks)		53.9 (41.9-66.4) *	

			FITF Slow (at 4 weeks)		30.67 (8.2-53.1) *	
			FITF Fast (at 4 weeks)		52.11 (30.3-74.0) *	
			BF Slow (at 8 weeks)		51.6 (36.9-66.1) *	
			BF Medium (at 8 weeks)		62.67 (45.7-79.7) *	
			BF Fast (at 8 weeks)		56.89 (36.1-77.7) *	
			FITF Slow (at 8 weeks)		55.44 (41.4-69.5) *	
			FITF Medium (at 8 weeks)		40.44 (18.0-62.9) *	
			FITF Fast (at 8 weeks)		51.78 (30.5-73.1) *	
Number of falls toes down condition			Subjects 1,2,9	0		Unable to test, requirements for statistical test violated
			Subject 3	7		
			Subjects 4,10	2		
			Subject 5	1		
			Subject 6	5		
			Subject 7,8	9		
			Subject 1 (at 4 weeks)		1	
			Subject 2, 6 (at 4 weeks)		Did not participate	
			Subject 3 (at 4 weeks)		6	
			Subject 4 (at 4 weeks)		8	

			Subject 5 (at 4 weeks)		4	
			Subject 7 (at 4 weeks)		7	
			Subject 8,9,10 (at 4 weeks)		0	
			Subjects 1,2,4,5,8,9,10 (at 8 weeks)		0	
			Subject 3 (at 8 weeks)		3	
			Subject 6 (at 8 weeks)		2	
			Subject 7 (at 8 weeks)		1	
Balance (Static)						
Frequency Hz (revolutions of CoP)	Ramstrand et al. (2008)	Cerebral Palsy + mixed developmental disability	BF Eyes open	0.79 (0.7-0.9) *		Friedman ANOVA: BF p>0.05; FITF p>0.05
			FITF Eyes open	0.85 (0.7-1) *		Wilcoxon signed rank BF vs. FITF p>0.05
			BF Eyes closed	0.7 (0.5-0.9) *		
			FITF Eyes closed	0.61 (0.5-0.7) *		
			BF Eyes open (at 4 weeks)		0.68 (0.6-0.8) *	
			FITF Eyes open (at 4 weeks)		0.68 (0.6-0.8) *	
			BF Eyes closed (at 4 weeks)		0.66 (0.6-0.8) *	

			FITF Eyes closed (at 4 weeks)		0.62 (0.5-0.7) *	
			BF Eyes open (at 8 weeks)		0.69 (0.6-0.8) *	
			FITF Eyes open (at 8 weeks)		0.72 (0.6-0.8) *	
			BF Eyes closed (at 8 weeks)		0.71 (0.6-0.8) *	
			FITF Eyes closed (at 8 weeks)		0.67 (0.6-0.8) *	
Path length (cm/sec) (CoP)			BF Eyes open	2.66 (2.3-3.0)*		Friedman ANOVA: BF p>0.05; FITF p>0.05 Across testing occasions
			FITF Eyes open	3.94 3.3-4.6)*		Wilcoxon signed rank BF vs. FITF **p<0.05** Across testing occasions
			BF Eyes closed	3.28 (2.8-3.7)*		
			FITF Eyes closed	5.82 (4.5-7.1)*		
			BF Eyes open (at 4 weeks)		2.56 (2.1-3.0)*	
			FITF Eyes open (at 4 weeks)		3.64 (2.7-4.5)*	
			BF Eyes closed (at 4 weeks)		3.04 (2.3-3.7)*	
			FITF Eyes closed (at 4 weeks)		4.51 (3.8-5.3)*	
			BF Eyes open (at 8 weeks)		2.63 (2.2-3.0)*	
			FITF Eyes open (at 8 weeks)		4.14 (5.0-4.1)*	
			BF Eyes closed (at 8 weeks)		3.29 (2.8-3.7)*	
			FITF Eyes closed (at 8 weeks)		4.7 (4.1-5.4) *	

Radial displacement (cm) (CoP)			BF Eyes open	0.59 (0.5-0.7)*		Friedman ANOVA: p>0.05; FITF p>0.05 Across testing occasions
			FITF Eyes open	0.86 (0.6-1.1)*		Wilcoxon signed rank BF vs. FITF **p<0.05** Across testing occasions
			BF Eyes closed	0.85 (0.7-1.0)*		
			FITF Eyes closed	1.56 (1.2-1.9)*		
			BF Eyes open (at 4 weeks)		0.64 (0.5-0.8)*	
			FITF Eyes open (at 4 weeks)		0.92 (0.6-1.2)*	
			BF Eyes closed (at 4 weeks)		0.79 (0.6-1)*	
			FITF Eyes closed (at 4 weeks)		1.22 (0.9-1.5) *	
			BF Eyes open (at 8 weeks)		0.67 (0.5-0.9)*	
			FITF Eyes open (at 8 weeks)		0.99 (0.7-1.3)*	
			BF Eyes closed (at 8 weeks)		0.83 (0.6-1.1)*	
			FITF Eyes closed (at 8 weeks)		1.28 (0.9-1.6)*	

AFO Ankle Foot Orthosis, **BF** Barefoot, **CoP** Centre of Pressure, **CTEV** Congenital Talipes Equino Varus, **CTF** Corrective Therapeutic Footwear, **DB** Denis Brown Barred Night Boot, **FAS** Forefoot Abduct Night Shoe, **FITF** Functional Instability Therapeutic Footwear, **FLTF** Functional Lift Therapeutic Footwear, **FO** Foot Orthoses, **FSTF** Functional Stability Therapeutic Footwear, **N/A** Not Applicable, **SLF** Standard Last Footwear, **SSF** Standard Sole Footwear, ***** 95% Confidence Interval, **†** Median, **‡** Inter Quartile Range § Post Hoc Test

2.3. Evidence level and quality assessment of experimental studies

Author Year	**Level of Evidence OCEBM Study Design**	**Quality Assessment, Modified Downs and Black**																											
		Reporting										**External validity**			**Internal validity bias**							**Internal Validity-Confounding (Selection bias)**						**Power**	**Total Score % Score**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	
Corrective																													
Chen et al (2015)(W. Chen et al., 2015)	2 RCT	Y	Y	Y	Y	Y	Y	Y	N	Y	N	UTD	UTD	Y	N	N	Y	UTD	Y	N	Y	UTD	UTD	UTD	UTD	Y	Y	Y	57%
Kanatli et al (2016)(Kanatlı et al., 2016)	2 RCT	Y	Y	N	Y	N	Y	Y	N	Y	Y	UTD	UTD	UTD	N	UTD	Y	N	Y	UTD	Y	UTD	UTD	N	N	Y	Y	N	43%
Wenger et al (1989)(Wenger et al., 1989)	2 RCT	Y	Y	Y	Y	P	Y	Y	N	N	N	Y	UTD	Y	N	Y	Y	N	Y	UTD	UTD	Y	Y	Y	N	N	N	Y	57%
Functional Stability																													
Abd Elkader et al (2013)(Abd Elkader et al., 2013)	3 Before-after Study	Y	Y	Y	N	P	Y	Y	N		Y	UTD	UTD	Y	N	Y	Y		Y		Y	Y	UTD	N	N	Y		N	58%
Aboutorabi et al (2014)(Aboutorabi et al., 2014)	3 Before-after Study	Y	Y	Y	N	Y	Y	Y	N		Y	UTD	UTD	UTD	N	UTD	Y		Y		Y	UTD	UTD	UTD	N	Y		Y	54%
Basta et al (1977)(Basta et al., 1977)	3 Before-after Study	Y	Y	N	Y	N	N	N	N		N	UTD	UTD	Y	N	UTD	Y		N		Y	UTD	N	N	N	N		N	25%
Jagadamma et al (2009)(Jagadamma et al., 2009)	3 Before-after Study	Y	Y	Y	Y		Y	Y	N		Y	UTD	UTD	UTD	N	N	Y		Y		Y			N	N			N	53%

Knittel and Staheli (1976)(Knittel & Staheli, 1976)	3 Before-after Study	Y	Y	N	N		Y	Y	N		N	UD	UD	UD	N	UTD	Y		Y		Y			N	N			N	36%
Wesdock & Edge (2003)(Wesdock & Edge, 2003)	3 Cross Over Study	Y	Y	Y	Y		Y	Y	N	Y	N	UTD	UTD	UTD	N	N	Y	Y	Y	UTD	Y			N	N		Y	N	52%
Functional Instability																													
Ramstrand et al (2008)(Ramstrand et al., 2008)	3 Before-after Study	Y	Y	Y	N		Y	Y	N	Y	N	UTD	UTD	UTD	N	N	Y	Y	Y	UTD	Y			N	N		Y	N	48%
Functional Lift																													
Eek et al (2017)(Eek et al., 2017)	3 Before-after Study	Y	Y	Y	Y	Y	Y	Y	N		Y	Y	UTD	Y	N	N	Y		Y		Y	Y	UTD	N	N	Y		N	67%
Zabjek et al (2001)(Zabjek et al., 2001)	3 Before-after Study	Y	Y	N	N		Y	Y	N		N	UTD	UTD	Y	N	N	Y		Y		Y			N	N			Y	47%

Yes (Y) Score = 1 except Item 5 score = 2 No (N) Score = 0 Partially (P) Score = 1 Unable to determine (UTD) Score = 0 , RCT Randomised Control Trial

2.4. Level of evidence and quality assessment of survey study.

Author Year	**Level of Evidence Study Design OCEBM**	**Quality Assessment Burns and Kho Assessment Tool for Surveys**																					
		1) Question	2) Population		3) Develop Questionnaire			4) Testing Questionnaire		5) Administration		6) Response				7) Results Reporting							
		1 a	2a	2b	3a	3b	3c	4a	4b	5a	5b	6a	6b	6c	6d	7a	7b	7c	7d	7e	7f	7g	7h
Functional Stability																							
Bakker (1997)(Bakker et al., 1997)	4 Survey	Y	Y	Y	N	Y	N	N	N	Y	N	Y	Y	UTD	Y	Y	N	N	Y	Y	Y	Y	Y

Y =Yes, N =No

3. Chapter 4

3.1. Qualitative analysis of OSSTF and Standard Retail Boot design

3.1.1. Upper components: Materials and segments

Shoe Manufacturer / Design	Size (EU)	Width	Upper	
			Material	Segments
Schein				
1	38	TN2	Leather	Vamp, Tongue, Heel Counter, Quarter, Stitched Toe Box Covering
2	36	TN2	Canvas	Vamp, Tongue, Heel Counter, Quarter, Rubber Toe Box Covering, Collar
FitzKidz				
1	35	EW	Suede / Nubuck	Vamp, Tongue, Heel Counter, Quarter, Collar
2	35	MC	Suede / Nubuck	Vamp, Tongue, Heel Counter, Quarter, Collar
3	28	M	Suede / Nubuck/Leather Mix	Vamp, Tongue, Heel Counter, Quarter, Collar
4	26	M	Leather	Vamp, Tongue, Heel Counter, Quarter, Collar
5	19	M	Patent Leather	Vamp, Tongue, Heel Counter, Quarter, Collar
TSM				
1	28	Not Stated on Shoe	Leather	Vamp, Tongue, Heel Counter, Quarter, Stitched Toe Box Covering
2	21	M	Suede/Canvas	Vamp, Tongue, Quarter,
Nimco				
1	41	TN4	Patent Leather	Vamp, Tongue, Heel Counter, Quarter
2	32	TN4	Leather	Vamp, Tongue, Heel Counter, Toe Box Covering
Piedro				
1	38	Not Stated on Shoe	Leather	Vamp, Tongue, Heel Counter, Toe Box Covering
2	27	Not Stated on Shoe	Leather	Vamp, Tongue, Heel Counter, Toe Box Covering
Kicker				
SRB	32	Available in one width fitting	Leather	Vamp, Tongue, Heel Counter, Quarter, Collar

3.1.2. Upper components, Characteristics of topline and toebox

Shoe Manufacturer / Design	Upper	
	Topline	**Reinforced Toe Box**
Schein		
1	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Pull Tab, Extended Tongue	Yes
2	Extended Topline above malleoli, Padded Collar, Pull Tab, Zip Entry	Yes
FitzKidz		
1	Extended Topline above malleoli, Padded Collar, Pull Tab,	Yes
2	Extended Topline above malleoli, Padded Collar, Pull Tab	No
3	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Medial and Lateral Ankle Scoop	Yes
4	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Medial and Lateral Ankle Scoop	Yes
5	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Medial and Lateral Ankle Scoop	Yes
TSM		
1	Extended Topline above malleoli, Padded Collar, Medial and Lateral Ankle Scoop	Yes
2	Extended Topline above malleoli, Padded Collar, Medial and Lateral Ankle Scoop	Yes
Nimco		
1	Extended Topline above malleoli, Padded Collar, Pull Tab, Zip Entry	Yes
2	Extended Topline above malleoli, Padded Collar, Pull Tab, Extended Tongue	Yes
Piedro		
1	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Pull Tab, Extended Tongue, Medial and Lateral Ankle Scoop	Yes
2	Extended Topline above malleoli, Padded Collar, Achilles Tendon Cut-Away, Pull Tab, Extended Tongue, Medial and Lateral Ankle Scoop	Yes
Kicker		
SRB	Extended above malleoli, Padded No pull tab Topline Extended Nil Achilles tendon Cut Away Nil Scoop Medial and Lateral Ankle Scoop	No

3.1.3. Upper Components: Characteristics of footwear fastening,

Shoe Manufacturer / Design	Upper		
	Fastening Type	**Fastening Eyelet**	**Fastening Facing**
Schein			
1	Velcro	D Ring Hook	Extended to Toebox
2	Lace & Zip	Ring Eyelet	Extended to Toebox
FitzKidz			
1	Lace	Ring Eyelet	To Midfoot
2	Velcro	D Ring Hook	To Midfoot
3	Lace	Ring Eyelet	Extended to Toebox
4	Lace	Ring Eyelet	Extended to Toebox
5	Velcro	D Ring Hook	Extended to Toebox
TSM			
1	Velcro	D Ring Hook	Extended to Toebox
2	Lace & Velcro	Ring Eyelet	Extended to Toebox
Nimco			
1	Lace & Zip	Ring Eyelet	Extended to Toebox
2	Lace	Ring Eyelet & Hook	Extended to Toebox
Piedro			
1	Lace	Ring Eyelet & Hook	Extended to Toebox
2	Lace	Ring Eyelet & Hook	Extended to Toebox
Kicker			
SRB	Lace	Ring Eyelet	Extended to Toebox

3.1.4. Sole and Inner components and construction

Shoe Manufacturer / Design	Sole		Inner
	Upper/ Sole Adhesion	**Outer Sole Material**	**Removable Contoured Inlay**
Schein			
1	Cemented	PU Foam	Yes
2	Cemented	PU Foam?	Yes
FitzKidz			
1	Welt	Plastic/Rubber	No
2	Welt	Rubber	Yes
3	Cemented	Rubber	Yes
4	Cemented	Rubber	Yes
5	Welt	Rubber	Yes
TSM			
1	Littleway Lasting Internal Stitch	Rubber	Yes
2	Littleway Lasting Internal Stitch	Rubber	Yes
Nimco			
1	Welt	PU Foam	Yes
2	Welt	PU Foam	Yes
Piedro			
1	Welt	PU Foam	Yes
2	Welt	PU Foam	Yes
Kicker			
SRB	Welt	Rubber	No

3.2. Quantitative analysis of OSSTF and Standard Retail Boot Design

3.2.1. Length Width and Normalized Mass measures

Shoe Manufacturer / Design	**Size EU**	**Length Total (mm)***	**Forefoot Width (mm)***	**width per mm length**	**Mass (g)**	**g per mm length**
Schein						
1	38	274	103	0.38	427	1.56
2	36	253	102	0.40	302	1.19
FitzKidz						
1	35	250	101	0.40	430	1.72
2	35	242	89	0.37	420	1.74
3	28	203	86	0.42	279	1.37
4	26	191	78	0.41	257	1.35
5	19	146	67	0.46	145	0.99
TSM						
1	28	203	80	0.39	324	1.60
2	21	149	71	0.48	167	1.12
Nimco						
1	41	290	104	0.36	512	1.77
2	32	226	99	0.44	340	1.50
Piedro						
1	38	263	99	0.38	553.5	2.10
2	27	196	90	0.46	292	1.49
Mean	-------	-------	-------	**0.41**	-------	**1.50**
St Dev +/-	-------	-------	-------	**.04**	-------	**0.30**
Min Val	-------	-------	-------	**0.36**	-------	**0.99**
Max Val	-------	-------	-------	**0.48**	-------	**2.10**
Kicker						
SRB	**32**	224	86	0.38	264	1.18

3.2.2. Measures of: Topline and toe rocker dimensions and geometry

Shoe Manufacturer / Design	Top Line Height (mm)	Top Line Height per mm length	Medial Toe Pivot Point mm**	Lateral Toe Pivot Point mm**	Rocker Angle Medial (°)	Rocker Angle Lateral (°)
Schein						
1	132	0.48	130	125	15	15
2	123	0.49	155	155	10	10
FitzKidz						
1	99	0.40	162	165	8	8
2	102	0.42	160	160	10	10
3	82	0.40	130	127	15	10
4	77	0.40	120	116	15	10
5	63	0.43	89	93	10	10
TSM						
1	80	0.39	123	121	10	10
2	63	0.42	102	98	15	10
Nimco						
1	133	0.46	182	157	15	10
2	115	0.51	150	146	15	10
Piedro						
1	117	0.44	165	165	10	10
2	90	0.46	117	117	14	14
Mean	-------	**0.44**	-------	-------	**12.46**	**10.54**
St Dev +/-	-------	**0.04**	-------	-------	**2.76**	**1.85**
Min Val	-------	**0.39**	-------	-------	**8**	**8**
Max Val	-------	**0.51**	-------	-------	**15**	**15**
Kicker						
SRB	92	0.41	136	0.61	128	0.57

3.2.3. Heel Stiffener length dimensions and normalized measures

Shoe Manufacturer / Design	Heel Stiffener Length Medial (mm)	Heel Stiffener Medial per mm Total length	Heel Stiffener Length Lateral	Heel Stiffener Lateral per mm Total length
Schein				
1	147	0.54	125	0.46
2	117	0.46	102	0.40
FitzKidz				
1	145	0.58	94	0.38
2	137	0.57	82	0.34
3	108	0.53	83	0.41
4	98	0.51	66	0.35
5	81	0.55	63	0.43
TSM				
1	110	0.54	81	0.40
2	74	0.50	54	0.36
Nimco				
1	97	0.33	157	0.54
2	98	0.43	104	0.46
Piedro				
1	165	0.63	141	0.54
2	100	0.51	70	0.36
Mean	-------	**0.51**	-------	**0.42**
St Dev +/-	-------	**0.07**	-------	**0.07**
Min Val	-------	**0.33**	-------	**0.34**
Max Val	-------	**0.63**	-------	**0.54**
Kicker				
SRB	93	0.42	85	0.38

3.2.4. Ratio of Lateral to Medial heel stiffeners, and Heel Stiffener height dimensions and normalized measures.

Shoe Manufacturer / Design	Lateral/Medial Heel Stiffener	Heel Stiffener Height (mm)	Heel Stiffener Height per mm Total Length
Schein			
1	0.85	80	0.29
2	0.87	55	0.22
FitzKidz			
1	0.65	60	0.24
2	0.60	65	0.27
3	0.77	47	0.23
4	0.67	43	0.23
5	0.78	43	0.29
TSM			
1	0.74	36	0.18
2	0.73	50	0.34
Nimco			
1	1.62	95	0.33
2	1.06	50	0.22
Piedro			
1	0.85	90	0.34
2	0.70	35	0.18
Mean	**0.84**	-------	**0.26**
St Dev +/-	**0.26**	-------	**0.06**
Min Val	**0.60**	-------	**0.18**
Max Val	**1.62**	-------	**0.34**
Kicker			
SRB	1.09	35	0.16

4. Chapter 5

4.1. Delphi Survey Section 1 Rounds 1-3

WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

Delphi survey Round 1
Introduction

Thank you for participating in this Delphi survey for the consensus on children's clinical footwear interventions.
Please note this is Round 1 of the survey and will be the lengthiest in respect to your time.

This first round aims to:

1) Gather information and seek consensus for the general definition of clinical footwear interventions in children.
These will be: The specific terms to be used, the categorisation of the footwear, and the proposed clinical role of these footwear.

2) To gather specific information on "off the shelf"* and modular** clinical footwear interventions that would be considered to offer a stability effect on children with mobility impairment. This would be in terms of design characteristics and suggested clinical protocols (guidelines) for the prescription of stability footwear as an assistive aid.

* Footwear taken from stock or supplies and not individually designed.
** Standard range of dimensional adaptations (maximum 3) to stock upper.

Your responses from this round will be analysed and collated into statements. These will be returned to you along with the anonymised responses of the other panellists, and you will be asked to rank your agreement or non-agreement with them. You can review the previous information you provided, and considering the information provided by the other panellists, maintain or change your opinion.

Please note you are free to withdraw from the study at any time.

For withdrawal from the study or any further questions, please contact:
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OVERVIEW OF SURVEY

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1)

Name *

There are three sections in round 1 of this survey which will be available in a separate link.

The first section is aimed at determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of your ideas and opinions on design characteristics of "off the shelf" and modular clinical footwear that offers stability to children with mobility impairment.

The third section will consist of your ideas and opinions on clinical protocols and outcomes for the provision of "off the shelf" and modular footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1 Round 1

Hill et al. Journal of Foot and Ankle Research (2019) 12:25
https://doi.org/10.1186/s13047-019-0336-z

Journal of Foot and Ankle Research

REVIEW — Open Access

Key concepts in children's footwear research: a scoping review focusing on therapeutic footwear

Matthew Hill*, Aoife Healy and Nachiappan Chockalingam

Abstract

Background: Reports suggest that children with mobility impairment represent a significant proportion of the population living with a disability. Footwear is considered to be the key extrinsic factor affecting children's gait and footwear modifications have been historically postulated to assist with locomotory difficulty. Although therapeutic footwear has been considered within the literature, there is a lack of consistency on terminology and paucity on the overall understanding. A scoping review was performed to chart the key concepts in children's footwear and to establish the range of studies that considered therapeutic footwear.

Methods: A systematic search of MEDLINE, CINAHL, PubMed, SPORTdiscus, and Scopus electronic databases was performed using MeSH headings and free text terms in relation to children's footwear. All studies that used footwear as an intervention in children aged 9 months to 18 years with the outcome measures including design, fit, and the effects on development and health were included. Studies were charted by textual narrative synthesis into research groupings dependent on the topics discussed and the methods used in the studies.

Results: The search yielded a total of 5006 articles with 287 of these articles meeting the inclusion criteria. Two overarching areas of research were identified; articles that discussed footwear design and those that discussed the effects of footwear. Eight further general groupings were charted and apportioned between the overarching areas and therapeutic footwear was charted into three subgroupings (corrective, accommodative and functional).

Conclusion: Children's footwear has become an increasing area of research in the past decade with a shift towards more empirical research, with most of the included articles examining biomechanical and anthropometric aspects. However, children's therapeutic footwear has not shared the same recent impetus with no focused review and limited research exploring its effects. Empirical research in this area is limited and there is ambiguity in the terminology used to describe therapeutic footwear. Based on the findings of this review the authors suggest the term children's therapeutic footwear be used as the standard definition for footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood; with subgroupings of corrective, accommodative and functional dependent on the intended therapeutic role.

Keywords: Shoes, Orthotic devices, Disability, Child, Adolescent, Paediatric, Mobility limitation, Assistive devices

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BMC

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

Definition together with standard terminology is essential for any intervention to allow a consistent understanding of who will benefit, the value it will provide, what is and isn't included, how it will work and how to measure its success.

The work in this section has been informed from the results of our recently published scoping review, https://rdcu.be/b1tKM

We derived general terminology definitions and groupings of footwear that had been used from a therapeutic perspective from the collective body of research considering children's footwear.
We will ask you to rate your agreement with these proposed terms, definitions and groupings. These will be in the form of a Likert scale where you will rank your level of agreement on a scale of 1-7 ranging from Strongly Disagree (1) to Strongly Agree (7).

We will provide you with the opportunity to offer your opinion to modify these proposed terms, definitions and groupings. All answers will be anonymised and will not be identifiable as your responses.

What can you base your answers on?

The validity of the data obtained relies on your answers, being your opinion. This may be based on research or your own clinical or manufacturing experience.

How do you provide detail to your answer?

It is recommended that your answers be clear and unambiguous. You should provide enough detail to qualify what you are basing your opinion on. General comments are therefore not recommended. On some answers, you may wish to provide more information.

i.e., The following statement provides insufficient information
"Stability footwear would improve children's gait ."

A qualified statement may read:

"Stability footwear would potentially increase children's walking velocity, stride length and reduce mediolateral (side to side) displacement of the centre of mass "

The answers and rationale you provide may influence the opinion of other panellists. i.e., a panellist may change their opinion dependent on the strength of your response.

* Required Filed

2)

From the collective body of research, various terms have been used in relation to clinical footwear interventions in childhood. Statement 1: The scoping review recommended the term "Children's Therapeutic Footwear" as the standard terminology to be used for clinical footwear interventions for children with mobility impairment. Please rank your agreement with the term children's therapeutic footwear as a standard term for this purpose. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 1	☐	☐	☐	☐	☐	☐	☐

3)

Please use this area to provide us with any further opinion on this terminology. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

4

Statement 2: The term therapeutic footwear was defined in the scoping review as: "footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood." Please rank your agreement with this Definition. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 2	☐	☐	☐	☐	☐	☐	☐

5)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

6)

Statement 3: From the scoping review footwear for clinical interventions in childhood was categorised into groupings dependent on their intended therapeutic role. Please rank your agreement for this approach to categorise clinical footwear interventions.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 3	☐	☐	☐	☐	☐	☐	☐

7)

Please use this area to provide us with any further opinion on this method of categorisation. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

8)

Statement 4: From the scoping review, the following definition was given for the corrective footwear grouping: Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment. Please rank your agreement with this definition:*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 4	☐	☐	☐	☐	☐	☐	☐

9)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

10)

Statement 5: From the scoping review, the following definition was given for the accommodative footwear grouping: Accommodative footwear is children’s therapeutic footwear that is designed (modular or bespoke) to reduce compression, and shearing stresses on children’s foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child’s foot. Please rank your agreement with this definition: *						
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 5	☐	☐	☐	☐	☐	☐	☐

11)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

12)

Statement 6: From the scoping review, the following definition was given for the functional footwear grouping: Functional footwear is children’s therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns. Please rank your agreement with this definition: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 6	☐	☐	☐	☐	☐	☐	☐

13)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

14)

Statement 7: From the scoping review functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role. Please rank your agreement with this method of categorisation. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 7	☐	☐	☐	☐	☐	☐	☐

15)

Please use this area to provide us with any further opinion on this method of categorisation. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

16)

Statement 8: From the scoping review the following definition was given for the stability footwear subgrouping

Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 8	☐	☐	☐	☐	☐	☐	☐

17)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

18)

Statement 9: From the scoping review, the following definition was given to lift footwear subgrouping:

Lift functional therapeutic footwear is a range of footwear designed with a unilateral modular outer or midsole addition to conservatively achieve postural and functional symmetry in individuals with limb length inequality.

Please rank your agreement with this definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 9	☐	☐	☐	☐	☐	☐	☐

19)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

20)

Statement 10: From the scoping review the following definition was given for rounded bottom (rocker sole)

Rounded bottom (rocker sole) is a range of functional therapeutic footwear with a forefoot rocker design to assist the sagittal plane progression of the lower limb.

Please rank your agreement with this definition.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 10	☐	☐	☐	☐	☐	☐	☐

21)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

22)

Statement 11: From the scoping review, the following definition was given for instability footwear:

Instability therapeutic functional footwear consists of a sole designed to promote imbalance to train the individuals motor coordination.

Please rank your agreement with this definition.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Statement 11	☐	☐	☐	☐	☐	☐	☐

23)

Please use this area to provide us with any further opinion on this definition. Do you feel this is relevant clinically; do you currently use a different term, would you change this now based on this information? Would you offer alternative terminology and if so, what is this? *

END OF SECTION 1 ROUND 1

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

ROUND 2 (S1) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

Delphi survey Round 2
Introduction

Thank you for participation in Round 1 of this Delphi survey for the consensus on children's clinical footwear interventions.

Please note this is Round 2 of the survey which will provide you with the collective responses from Round 1 of the expert panel. The panel consisted of 18 participants (orthotists, podiatrists and physiotherapists) with clinical expertise in footwear provision including research, commercial distribution as well as clinical practitioners. The panel is international comprising of panellists from the UK, Australia and the U.S.A.

The feedback from responses will be presented as the median and distribution of level of agreement, as well as a summary of the reasoning for panellists' answers.

This second round aims to:

1) Seek consensus for the general definition of footwear used as a clinical intervention for children. These will be: The specific terms to be used, the categorisation of the footwear, and the proposed clinical role of these footwear.

2) To gain consensus on "off the shelf"† clinical footwear interventions that would be considered to offer a stability effect on children with mobility impairment. This would be in terms of design characteristics and suggested clinical protocols (guidelines) for the prescription of stability footwear as an assistive aid.

†Footwear taken from stock or supplies and not individually designed.

This questionnaire is completed differently to the first round, and the instructions within the form will guide you through this process. Please read the instructions carefully and complete the Delphi questionnaire as fully as you can.

You will receive the original statements from Round 1 alongside modified statements that have been informed by yours and other panellists' responses.

You will be asked to give your preferential option or your level of agreement with them. You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, maintain or change your opinion.

Please note you are free to withdraw from the study at any time.

For withdrawal from the study or any further questions, please contact:
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Ph +44 1782 294122
Email: Matthew.Hill@research.staffs.ac.uk1)

* Required Filed

Name *

OVERVIEW OF SURVEY

There are three sections in round 2 of this survey which will be available in three separate links.

The first section will consist of yours and the panellists' collective opinions on determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of yours and the panellists' collective opinions on design characteristics of "off the shelf" clinical footwear that offers stability to children with mobility impairment.

The third section will consist of yours and the panellists' collective opinions on clinical protocols and outcomes for the provision of "off the shelf" footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

The original statements concerning terminology, definitions and groupings of footwear that had been used from a therapeutic perspective for children suggested by the scoping review are listed alongside modified statements informed from the opinions gained from yourself and the other panellists in round 1. You will be asked to give your preferential option or your level of agreement or non-agreement with them (Strongly Disagree to Strongly Agree).
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, You may maintain your position with the original statement or change your opinion and align yourself with the new statement

We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

* Required Filed

2)

From Round 1 panellists were presented with Statement 1: "The scoping review recommended the term Children's Therapeutic Footwear as the standard terminology to be used for footwear used as a clinical intervention for children with mobility impairment." The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree". From panellist feedback there was support for this term in preference to orthopaedic footwear as some felt this term had negative social connotations and could be associated with over-medicalisation. Other feedback indicated that therapeutic may be ambiguous inferring that the footwear healed the disease. Some panellists suggested alternate terms that matched International Organisation for Standardisation (ISO) terminology, with Orthopaedic footwear matching ISO 9999:2016 and more recently Orthotic footwear matching ISO 21064:2017. It was also discussed that ISO terminology aligned footwear with orthotic therapies. Please choose your preferred standard term for footwear that is used as a clinical intervention for children with mobility impairment. *	
☐	Therapeutic Footwear (Term from Round 1)
☐	Orthopaedic Footwear
☐	Orthotic Footwear
☐	Prescriptive Footwear
☐	Other

3)

You may use this optional area if you wish to provide any further information for your response.

4)

From Round 1 panellists were presented with Statement 2 which offered the following definition for footwear used as a clinical intervention for children:

“footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.”

The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "neutral" to "agree".

From panellist feedback suggestions were made to improve the definition. Alleviate was seen as an ambiguous term that may be misinterpreted as curing the problem. The terminology should include that standard retail footwear may be adapted to offer a therapeutic role as well as therapeutic footwear that is specifically designed. The definition should also recognise the role footwear may play to accommodate or prevent foot deformities and the role it can offer to assist standing as well as mobility. Some panellist also requested the definition Follow ISO or World Health Organisation (WHO) terminology and be more biomechanically specific.

From panellist feedback, the following modified definitions for footwear used as a clinical intervention in children were derived.

Statement 2a: "Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children."

Please choose your preferred definition. *	
☐	Statement 2 (Original statement)
☐	Statement 2a
☐	Other

5)

You may use this optional area if you wish to provide any further information for your response.

6)

From Round 1 panellists were presented with Statement 3:

"footwear for clinical interventions in childhood should be categorised into groupings dependent on their intended therapeutic role."

The median level of agreement amongst the panellists was " agree" with the majority of responses between "somewhat agree" to "strongly agree".

Panellist feedback suggested that this was a suitable method of grouping clinical footwear interventions as it recognised the different characteristics and requirements for footwear prescriptions in a similar manner to orthoses. Suggestions to improve this method of grouping footwear included ensuring the therapeutic role had measurable outcomes. The method should recognise that footwear may offer more than one therapeutic role e.g. "accommodative and stability", therefore the method to classify should address that they are not separate footwear groupings, but potential therapeutic components of the footwear and a coding method could be employed to classify multiple therapeutic components of the footwear.

From panellist feedback, the following modified statement has been offered as an alternate method to group clinical footwear interventions for children.

Statement 3a: "Footwear used as a clinical intervention in childhood should be classified via the intended therapeutic outcomes of its components."

Please choose your preferred method for classifying footwear as a clinical intervention for children. *

☐	Statement 3 (Original statement)
☐	Statement 3a
☐	Other

7)

You may use this optional area if you wish to provide any further information for your response.

8)

From Round 1, panellists were presented with Statement 4 as a definition for the corrective footwear grouping:

"Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."

The median level of agreement amongst the panellists was "Neutral" with the majority of responses between "somewhat disagree" to "agree".

Panellist feedback suggested modifications to improve the definition. It was noted that footwear could not act as a curative intervention on its own and should be used alongside other corrective interventions (serial casting, surgery). Correction of lower limb alignment is misleading as footwear can only affect the foot and ankle. The definition should also include acquired deformity.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 4a: "Corrective footwear is children's therapeutic footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children."

Please choose your preferred definition.*

☐	Statement 4 (Original statement)
☐	Statement 4a
☐	Other

9)

You may use this optional area if you wish to provide any further information for your response.

10)

From Round 1, panellists were presented with Statement 5 as a definition for the accommodative footwear grouping:

"Accommodative footwear is children's therapeutic footwear that is designed (off the shelf or bespoke) to reduce compression, and shearing stresses on children's foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child's foot."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree".

Panellist feedback suggested modifications to the definition. This included the role accommodative footwear may play in preventing deterioration of the child's foot deformity and reducing excessive details of the footwear design.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 5a: "Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot."

Please choose your preferred definition.*

☐	Statement 5 (Original statement)
☐	Statement 5a
☐	Other

11)

You may use this optional area if you wish to provide any further information for your response.

12)

From Round 1, panellists were presented with Statement 6 as a definition for the functional therapeutic footwear grouping:

"Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "neutral" to "agree".

Panellist feedback suggested that the definition represented the direct dynamic role footwear may play in supporting walking in children with mobility impairment. Suggested modifications to improve the definition included avoiding ambiguous terms such as pathological movement and typical patterns. Recognise the role functional footwear may play in assisting standing as well as mobility. Two panellists suggested disagreement with the term functional as all therapeutic footwear groupings had a function, however, no alternate term was suggested to represent this grouping.

From panellist feedback, the following modified statement has been offered as an alternate definition.

Statement 6a: "Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children."

Please choose your preferred definition.*

☐	Statement 6 (Original statement)
☐	Statement 6a
☐	Other

13)

You may use this optional area if you wish to provide any further information for your response.

14)

From Round 1, panellists were presented with Statement 7 as a method to categorize functional footwear into subgroupings:

"Functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role."

The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "strongly agree". Panellist feedback was similar to the previous statement on methods of grouping footwear, in that footwear may offer more than one therapeutic role. The classification should recognise that they are not separate footwear groupings but therapeutic components of the footwear. From panellist feedback, the following modified statement has been offered as an alternate method to subgroup functional therapeutic footwear for children. Statement 7a "Functional therapeutic footwear should be classified via its design and the intended therapeutic outcomes of its components." Please choose your preferred method for classifying functional therapeutic footwear for children.*

☐	Statement 7 (Original statement)
☐	Statement 7a
☐	Other

15)

You may use this optional area to provide us with any further information for your response.

16)

From Round 1, panellists were presented with Statement 8 as a definition for the stability footwear subgrouping. "Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait." The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "somewhat disagree" to "agree". Feedback from the panellists suggested that the definition attempted to represent the effects of this footwear. Suggestions for improvement of the definition included avoiding ambiguous terms such as extreme movements, and recognising that this footwear would only effectively control forces at the foot and ankle but not the knee. The definition should recognise the potential proprioceptive effect of the footwear and the additional ability to assist standing in children. From panellist feedback, the following modified statement has been offered as an alternate definition. Statement 8a: "Stability therapeutic footwear is a range of footwear that is designed to assist mobility and standing in children by enhancing proprioception and influencing movements of the foot and ankle." In the section below, please choose your preferred definition.*

☐	Statement 8 (Original statement)
☐	Statement 8a
☐	Other

17)

You may use this optional area if you wish to provide any further information for your response.

18)

From the feedback of panellists, there was a collective suggestion that a number of the groupings offered in the first round, (lift, rounded bottom, instability) should fall under another Functional Footwear subgrouping termed Adapted Sole.

Panellists suggested this represented footwear either therapeutic or standard retail footwear that had a custom adaption to the sole which would facilitate gait or standing posture in children with mobility impairment.

Panellist feedback also suggested alternative terms for adapted soles that would fall under this subgrouping, raise instead of lift and rocker sole instead of rounded bottom.

The following term and definition were derived from panellist feedback.

Term: Adapted Sole

Definition: "A range of customised sole adaptions to standard retail or children's therapeutic footwear that would assist mobility or standing in children."

In the section below please rank your agreement with the term and definition: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Term Adapted sole	☐	☐	☐	☐	☐	☐	☐
Definition of Adapted sole	☐	☐	☐	☐	☐	☐	☐

19)

You may use this optional area if you wish to provide any further information for your response.

END OF SECTION 1 ROUND 2

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 2 attached to the Delphi survey email.

STAFFORDSHIRE UNIVERSITY

ROUND 3 (S1) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

* Required Filed

Name *

To recognise the valued work you have provided on this project the research team would like to acknowledge you as a panel member on any report or publication generated from the completed work. Please indicate your consent to your name and profession being released as an expert panel member below.. *	
☐	I consent to my name and profession being included in the acknowledgment section of any publication generated from the completed work
☐	I do not consent to my name being acknowledged in this work

OVERVIEW OF SURVEY

There are three sections in round 3 of this survey which will be available in three separate links.

The first section will consist of yours and the panellists' collective choices and opinions on determining how to define clinical footwear interventions for children with mobility impairment. This will be the terminology used, categorisation and the proposed clinical role of the footwear.

The second section will consist of yours and the panellists' collective choices and opinions on design characteristics of "off the shelf" clinical footwear that offers stability to children with mobility impairment.

The third section will consist of yours and the panellists' choices and collective opinions on clinical protocols and outcomes for the provision of "off the shelf" footwear that offers stability for children with mobility impairment.

Please note!
There is no "save and complete later" option available for the survey; therefore, you must complete and most importantly submit your answers for each section in one sitting. You may, however, complete each of the three sections on separate occasions if you wish.

Section 1

Defining clinical footwear interventions for children with mobility impairment. Terms, Categorisation and Proposed clinical roles.

You will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning terminology, definitions and groupings of footwear that had been used from a clinical perspective for children. You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

* Required Filed

1)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for standard terminology to be used for footwear used as a clinical intervention for children with a mobility impairment :

The relative frequency of response is detailed below:

Term “Therapeutic Footwear” 59%
Term "Orthotic Footwear" 23%
Term "Prescriptive Footwear" 12%
Term "Orthopaedic Footwear" 6%

From panellist feedback:
The reasoning for choosing "Therapeutic Footwear" was that it was felt that orthotic and orthopaedic footwear would appear to be limited to the body structure aspect of the WHO ICF-CY as it still implies a “straightening” approach to care and did not embrace a holistic approach of health care delivery, as also outlined in the WHO ICF-CY, such as those involved with Quality of Life, activity and participation. They also felt that orthotic "straightening" could be misleading for some treatment goals such as accommodative footwear. It was also pointed out Prescriptive Footwear may not be applicable if using unmodified “off the shelf footwear”. It was felt that Therapeutic Footwear was consistent with the language used in the research literature. The importance of embracing consistent international terminology as outlined by the ISO was proposed, however, even here there has been inconsistency with both the terms Orthopaedic footwear (ISO 9999:2016) and Orthotic footwear ISO (21064:2017) being used.

The reasoning for choosing "Orthotic footwear" was that it embraced reputable terminology from ISO without the perceived negative social connotations of orthopaedic footwear.

The reasoning for choosing "Prescriptive Footwear" evoked setting out specific parameters of footwear treatment that were potentially measurable.

No specific reasoning was given for choosing "Orthopaedic footwear"

One panellist suggested overall term could be interchangeable dependent on clinical preference as long as there was an agreed definition and understanding of how footwear could be applied and used for the treatment of mobility impairment in childhood.

Considering the collective panellist feedback please choose your preferred standard term for footwear that is used as a clinical intervention for children with mobility impairment.

☐	Therapeutic Footwear (Term from Round 1)
☐	Orthopaedic Footwear
☐	Orthotic Footwear
☐	Prescriptive Footwear

2)

You may use this optional area if you wish to provide any further information for your response.

3)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel which offered a definition for footwear used as a clinical intervention for children:

The relative frequency of response is detailed below:

Statment 2a “Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children." (82%)

Statement 2 “footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.” (12%)

Other (6%)

A Consensus was reached to Statement 2a

Panellist feedback from those who chose "Other"
One panellist objected to the aligning and corrective aspect in the definition due to limited evidence base for this and suggested the following definition: "Footwear that is designed or adapted specifically to protect, support or assist mobility and standing in children".
One preferred a definition that encompassed ISO and WHO terminology and suggested the following definition: “Footwear intended to address the effect of a neuromusculoskeletal impairment(s). These can encompass the ankle joint. They can be custom made or prefabricated”

4)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the process of categorising clinical footwear interventions for children.

The relative frequency of response is detailed below:

Statement 3a: "Footwear used as a clinical intervention in childhood should be classified via the intended therapeutic outcomes of its components." (70%)

Statement 3 "footwear for clinical interventions in childhood should be categorised into groupings dependent on their intended therapeutic role." (18%)

Other (12%)

From panellist feedback, there was agreement throughout the panel that it was important that the method of classification/grouping of the footwear relates to the intended clinical role or outcome, However, consensus failed to be reached due to the terminology used within the statement. Panellists who did not choose therapeutic footwear as a preferred term objected to the reference to therapeutic in the statement, others wanted WHO terminology to be included within the definition.

Slight modification to the statement has been made to this definition to address panellist feedback and gain consensus within the panel, please rank your agreement with the following statement *

"Footwear used as a clinical intervention in childhood should be classified by the intended outcomes of its components."

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

"Footwear used as a clinical intervention in childhood should be classified by the intended outcomes of its components."	☐	☐	☐	☐	☐	☐	☐

5)

If your level of agreement was "somewhat agree" or lower please use this optional area to provide us with your reasoning.

6)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition of Corrective footwear.

The relative frequency of response is detailed below:

Statement 4a: "Corrective footwear is children's therapeutic footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children."* (82%)

Other (18%)

Statment 4 "Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."(0%)

A Consensus was reached to Statement 4a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the corrective footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

Even those panellists who agreed to the new definition advocated that the definition needs to be clearer that this footwear works as a subsequent step to support and maintain primary corrective interventions such as serial casting and surgery,

*(To respect panellists variation in preferred overarching terminology for clinical footwear interventions reference to therapeutic, orthotic, orthopaedic and prescriptive will be removed from all definitions including those that have reached consensus)

In light of panellist feedback concerning corrective footwear's role in supporting primary corrective measures, a slight modification to this statement has been made.

"Corrective footwear is footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children. This may be secondary to a primary corrective measure such as serial casting or surgery."

Please indicate if you agree to this modified statement below.*	
☐	Yes I agree
☐	No I don't agree

7)

You may use this optional area if you wish to provide any further information for your response.

8)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition Accommodative footwear

The relative frequency of response is detailed below:

Statement 5a:
"Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot." (76%)

Statement 5
"Accommodative footwear is children's therapeutic footwear that is designed (off the shelf or bespoke) to reduce compression, and shearing stresses on children's foot deformities through the dimensional matching of footwear upper, insole, and sole to that of the child's foot." (12%)

Other (12%)

A Consensus was reached to Statement 5a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the Accommodative footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

9)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the grouping and definition Functional footwear

The relative frequency of response is detailed below:

Statement 6a: "Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and standing in children." (76%)

Statement 6"Functional footwear is children’s therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns." (12%)

Other (12%)

A Consensus was reached to Statement 6a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the Functional footwear grouping established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.

One panellist who agreed to statement 6a questioned if psychosocial factors such as cosmesis should be considered in function for those individuals who are immobile.

10)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the process of categorising functional footwear into subgroupings:
The relative frequency of response is detailed below:

Statement 7a "Functional therapeutic footwear should be classified via its design and the intended therapeutic outcomes of its components." (76%)

Statement 7 "Functional therapeutic footwear was divided into subgroupings which are categorised dependent on the design and functional role." (12%)

Other (12%)

A Consensus was reached to Statement 7a

From panellists who chose "Other" one objected to the inclusion of the term therapeutic footwear in the statement*. One panellist did not agree to the footwear groupings established from the research literature and advocated for different groupings based on a different structural tree however no alternative suggestions were offered.
The panellist who queried the psychosocial aspect missing from the functional footwear group definition in 6a felt this method of subgrouping would address their suggestion.

11)

From Round 2 panellists were presented with a series of options from the original scoping review and suggestions from the panel for the subgrouping and definition Stability footwear

The relative frequency of response is detailed below:

Statement 8a "Stability therapeutic footwear is a range of footwear that is designed to assist mobility and standing in children by enhancing proprioception and influencing movements of the foot and ankle." (65%)

Other (23%)

Statement 8 "Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait." (12%)

From panellists who chose "Other" one objected to the term therapeutic footwear in the statement. A number of panellists were uncertain of the evidence for the footwear influencing proprioception and

that by placing this prior to its role on influencing movements in the definition may imply that this was the footwear's primary role. It was suggested to move proprioception to the end of the definition to deemphasize its role in this footwear subgrouping A slight modification has been made to this definition to address panellist feedback and gain consensus within the panel, please rank your agreement with the following statement "Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle."

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
"Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle."	☐	☐	☐	☐	☐	☐	☐

12)

If your level of agreement was "somewhat agree" or lower please use this optional area to provide us with your reasoning.

13)

From Round 2 panellists were presented with a new subgrouping of functional footwear and definition for this subgrouping suggested by panellist feedback in Round 1, this was "Adapted sole". This subgrouping would incorporate raise, rocker sole and possibly instability footwear. The median level of agreement and relative frequency of response for both the term and definition is presented below. Term "Adapted Sole" Median level of agreement 6 ("Agree") Relative frequency of agreement: 6% "Somewhat Disagree", 6% "Neutral", 12% "Somewhat Agree", 41% "Agree", 35% "Strongly Agree" Panellist Consensus reached (76%) Definition "A range of customised sole adaptions to standard retail or children's therapeutic footwear that would assist mobility or standing in children." Median level of agreement 6 ("Agree") Relative frequency of agreement: 6% "Somewhat Disagree", 6% "Neutral", 23% "Somewhat Agree", 41% "Agree", 24% "Strongly Agree" From Panellist feedback reasons for lack of agreement with the statement

is that the definition should include a reference to the heel as well as the sole to ensure heel modifications are represented in the subgrouping of functional footwear.
Also, therapeutic footwear was not every panellist's preferred terminology for clinical footwear interventions,

A slight modification has been made to this definition to address panellist feedback and gain consensus within the panel; please rank your agreement with the following definition for Adapted Sole Footwear

"A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children."

In the section below, please rank your agreement with the modified definition.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
"A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children."	☐	☐	☐	☐	☐	☐	☐

14)

You may use this optional area if you wish to provide any further information for your response.

END OF SECTION 1 ROUND 3

Thank you for taking the time to complete section 1. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM? (SECTION2 ROUND 1)

4.2. Delphi Survey Section 2 Rounds 1-3

The second section asks for your ideas and opinions on identifiable and or desirable design characteristics of “off the shelf” and modular clinical footwear interventions that offers stability to children with mobility impairment.

Section 2

Establishing identifiable and desirable design characteristics for "off the shelf"* and modular** footwear clinical interventions that offer stability to children with mobility impairment.
* Footwear taken from stock or supplies and not individually designed.
** Standard range of dimensional adaptations e.g. width, girth, (maximum 3) to stock upper.

This section consists of a series of ranked and open-ended questions concerning identifiable or desirable characteristics of standard "off the shelf" and modular clinical stability footwear interventions.

The information provided in this section was informed by a study of the design and dimensional characteristics of a sample of standard children's off-the-shelf footwear (EU size range 19-41*) from a range of manufacturers that are currently marketed to offer stability to children with some form of mobility impairment.

We will ask you to rate your agreement with the findings of the characteristics identified from the sample. These will be in the form of a Likert scale where you will rank your level of agreement on a scale of 1 Strongly Disagree to Strongly Agree 7.

We will provide you with the opportunity to offer your opinion on these characteristics and to suggest their possible purpose to facilitate stability in children with mobility impairment. You will also be free to suggest additional aspects you view as important and your reasons for this. All answers will be anonymised and will not be identifiable as your responses.

Example of answers to a series of questions concerning a specific area of "off the shelf" modular stability footwear.

Please rate your agreement with the following findings of the topline of "off the shelf" modular stability footwear.

1) "Off the shelf" and modular stability footwear should have an extended topline height

Agree (6)

2) "Off the shelf" and modular stability footwear should have a padded foam collar.

Agree (6)

3) Please provide your opinion and the possible purpose of these characteristics

Answer:
The topline should extend above the ankle. The purpose of this is to offer a degree of proprioceptive stability and increased leverage at the ankle and rearfoot. This has been shown to help in previous studies on the elderly. High topped shoes appear to improve stability in comparison to lower toplines on children in my clinical practice. The padding of the collar allows for a reduction of shearing during ambulation, enhancing the ergonomics of the shoe design.

Please note when answering the following questions we are asking you to consider the characteristics of standard stability footwear and not adaptations for specific clinical presentations.

Required Field *
1)

Name: *

Glossary of Footwear Anatomy

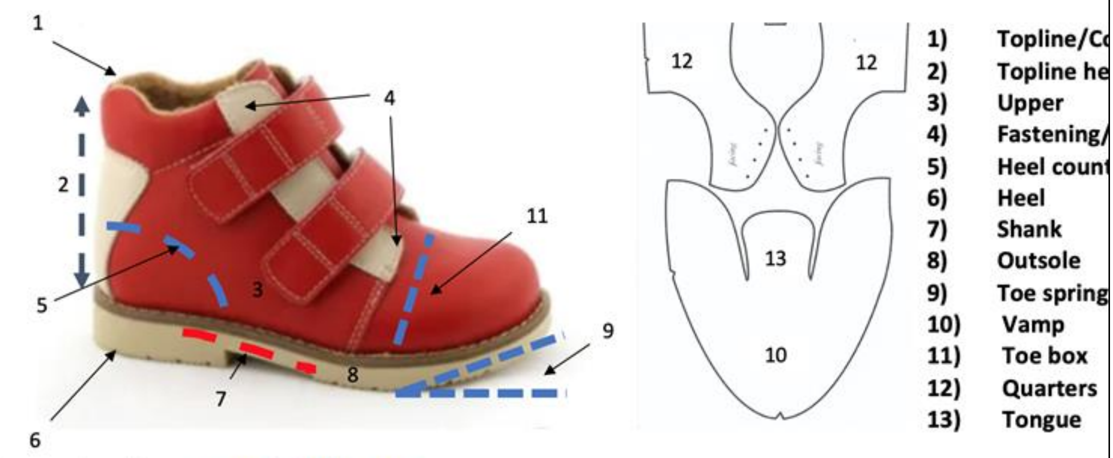


Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the question below you will be presented with a series of findings in relation to the topline/collar of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

2)

The topline or collar should have the following characteristics: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Extended topline height above ankle	☐	☐	☐	☐	☐	☐	☐
Foam padded collar	☐	☐	☐	☐	☐	☐	☐
Collar contoured to malleoli	☐	☐	☐	☐	☐	☐	☐
Collar contoured to Achilles tendon	☐	☐	☐	☐	☐	☐	☐
Pull tab to back of collar	☐	☐	☐	☐	☐	☐	☐

3)

Please use this section to provide your opinion on the design characteristics of the topline/collar in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Upper


In the question below you will be presented with a series of findings in relation to the upper of standard “Off the Shelf” and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

4)

The upper should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Leather material	☐	☐	☐	☐	☐	☐	☐
Tongue in line with topline	☐	☐	☐	☐	☐	☐	☐
Tongue extended above topline	☐	☐	☐	☐	☐	☐	☐

5)

Please use this section to provide your opinion on the design characteristics of the upper in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Fastening and Facing 
In the question below you will be presented with a series of findings in relation to the Fastening and Facing of standard “Off the Shelf” and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

6)

The fastening should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option) *	
☐	Velcro
☐	Lace
☐	No Preference
☐	Other

7)

The facings should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option)*	
☐	Facings extended to the midfoot
☐	Facings extended to just behind the toe box
☐	No Preference
☐	Other

8)

Please use this section to provide your opinion on the design characteristics of the fastening and facing in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Heel counter/stiffener

In the question below you will be presented with a series of findings in relation to the heel counter/stiffener of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

9)

The heel counter should have the following characteristics: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Heel counter /stiffener extended to midfoot	☐	☐	☐	☐	☐	☐	☐
Heel counter/ stiffener height extended towards topline.	☐	☐	☐	☐	☐	☐	☐

10)

Please use this section to provide your opinion on the design characteristics of the heel counter/stiffener in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Heel

In the question below you will be presented with a series of findings in relation to the heel of standard “Off the Shelf” and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

11)

The heel should have the following characteristics: (You may suggest an alternative by typing your suggestion in the other option)*	
☐	Heel width in line with heel counter width
☐	Heel width extended wider than heel counter width
☐	No Preference
☐	Other

12)

Please use this section to provide your opinion on the design characteristics of the heel in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Inlay

In the question below you will be presented with a series of findings in relation to the inlay of standard “Off the Shelf” and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

13)

The Inlay unit should have the following characteristics: *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should come with a standard removable inlay.	☐	☐	☐	☐	☐	☐	☐
The inlay should be contoured to simulate the medial longitudinal arch.	☐	☐	☐	☐	☐	☐	☐

14)

Please use this section to provide your opinion on the design characteristics of the inlay in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Sole unit

In the question below you will be presented with a series of findings in relation to the heel counter/stiffener of standard "Off the Shelf" and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

15)

The sole unit should have the following characteristics: *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
A deepened tread	☐	☐	☐	☐	☐	☐	☐
Be made of hard wearing material	☐	☐	☐	☐	☐	☐	☐

16)

Please rank the degree of flexibility for the sole unit you feel would constitute a desirable characteristic of this clinical footwear intervention. *

0	1	2	3	4	5	6	7	8	9	10

0-Completely flexible 10-Completely rigid

17)

Please use this section to provide your opinion on the design characteristics of the inlay in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable. *

Toe spring forefoot/heel rocker 
In the question below you will be presented with a series of findings in relation to the toe spring/forefoot rocker and heel rocker of standard “Off the Shelf” and modular stability footwear, please rank your level of agreement with these being a desirable characteristic of this clinical footwear intervention:

18)

*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should have a reasonable forefoot rocker.	☐	☐	☐	☐	☐	☐	☐
Stability footwear should have a heel rocker.	☐	☐	☐	☐	☐	☐	☐

19)

Please use this section to provide your opinion on the design characteristics of the toe spring forefoot heel rockers in terms of the purpose of the suggested design features, any disagreement with the suggested design features, or further design features you feel are desirable.*

Weight of the footwear
In the question below, we will ask you your opinion on the weight of "Off the Shelf" and modular stability footwear when considering these as a clinical intervention:

20)

*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The weight of the stability footwear is an important consideration when issuing footwear to children with mobility impairment?	☐	☐	☐	☐	☐	☐	☐

21)

Please use this section to provide your opinion on the weight of stability footwear and how you feel it may impact on the gait of children with mobility impairment or may change with the age of the patient.*

Optional Further Information
You may use this additional section to provide further suggestions that you feel are important characteristics of children's "Off the Shelf" and modular stability footwear. Please remember to detail your answer where appropriate with the following information: Constituents or area of the footwear Material Shape or dimension Degree of rigidity flexibility. Purpose

22)

Which other areas do you feel are important design characteristics of children's "Off the Shelf" and modular stability footwear?

END OF SECTION 2 ROUND 1

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for next section of Round 1 attached to the Delphi survey email.

ROUND 2(S2) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The second section will present the feedback of panellists opinions from Round 1 on the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.

Section 2

Establishing desired design characteristics of “off the shelf”† stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.
†*Footwear taken from stock or supplies and not individually designed.*

The original statements provided from the study of a range of children's "off the shelf" stability footwear is listed alongside modified statements informed by the collective opinions gained from the panellists in round 1. The panel in this section consisted of 17 experts in the clinical provision of footwear for children with mobility impairment.

You will be asked to give your preferred option or your level of agreement with the original or modified statements (Strongly Disagree to Strongly Agree)

You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, You may maintain your position with your original statement or change your opinion and align yourself with the new statement

We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements at the end of each section (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

Required Field *

1)

Name*

Glossary of Footwear Anatomy

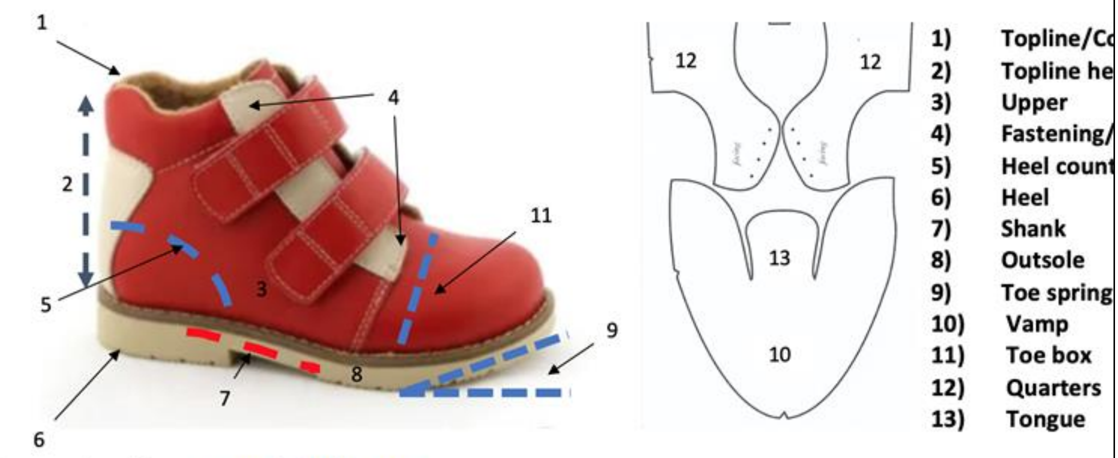


Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the topline/collar of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:
Please rank your level of agreement with the following purpose or potential adverse effects suggested from panellists' feedback of an extended topline.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: An extended topline height increases proprioception input at the rearfoot and ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: An extended topline height assists heel counter leverage to resist frontal plane movement of the rearfoot and ankle.	☐	☐	☐	☐	☐	☐	☐
Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle.	☐	☐	☐	☐	☐	☐	☐

2)

"Extended topline height above the ankle":
The median level of agreement amongst the panellists was "agree" with the majority of responses between "somewhat agree" to "agree".

From panellist feedback, it was proposed the purpose of a topline extended above the ankle (supra-malleolar) increases proprioceptive input around the rearfoot and ankle in addition to assisting the leverage of the heel counters. This was thought to assist in reducing frontal plane movements at the foot and ankle. Other panellists suggested toplines extended above the ankle may adversely affect ankle plantarflexion and dorsiflexion power generation and limit mobility in some patients.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the topline height for stability footwear. *

☐	The topline should be extended above the ankle (Original)
☐	The topline should not be extended above the ankle
☐	The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs.

3)

"Padded collar"

The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree".
A consensus was reached in Round 1 with respect to this design feature being an ideal characteristic.

Panellist feedback suggested that the purpose of this design feature was to lower compression and shear stress to structures to the sides and the back of the supra-malleolar region. Some panellists indicated that foam padding may increase shear therefore the padded area should be covered in a low shear material.

Please rank your level of agreement with the following purpose or characteristic suggested from panellists' feedback of a padded collar. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam padded collar should be covered with low shear material.	☐	☐	☐	☐	☐	☐	☐
Purpose: Foam Padding reduces compression to lower limb anatomy from an extended topline height	☐	☐	☐	☐	☐	☐	☐

5)

"Collar contoured to Malleoli"

The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree".
A consensus was reached in Round 1 with respect to this design feature being an ideal characteristic.

Although a consensus was reached on this design characteristic panellist feedback suggested there is potential ambiguity with "contoured to malleoli" if the topline is extended above the ankle (supra-malleolar), therefore, the description of the contouring is dependent on the topline height (supra or inframalleolar). Concerning the suggested purpose of the design, panellists felt that due to the increased topline height the contoured padding would ergonomically incorporate ankle structures to reduce shear and compression.

Based on panellist feedback a modified description and purpose of the desired design characteristic is offered, please rank your agreement with these. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam	☐	☐	☐	☐	☐	☐	☐

padded collar should be covered with low shear material.							

6)

"Collar contoured to the Achilles tendon" The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree". From the feedback of panellists, there did not appear to be any specific reason for only a partial level of agreement other than a lack of research to support the design adaption. There was no feedback to suggest an ideal modified design characteristic. Concerning the purpose of the suggested characteristic, it was proposed contouring to the Achilles tendon would reduce shear and compression to the area. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of contouring of the collar at the Achilles tendon for stability footwear.*	
☐	Collar contoured to Achilles tendon (Original)
☐	Collar contoured to Achilles tendon is not a desired design characteristic.

7)

Please rank your level of agreement with the following purpose suggested from panellists feedback of a collar contoured to the Achilles tendon. *							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring the collar to the Achilles tendon reduces shear and compression to the tendon.	☐	☐	☐	☐	☐	☐	☐

8)

"Pull tab to the back of collar": The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree". Panellist feedback suggested that the purpose of pull-tab was to assist donning of the footwear; however, a number of panellists stated that they had never seen a child use the pull-tab to don stability footwear. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of a collar pull tab for stability footwear.*

☐	Pull tab to back of collar (Original)
☐	Pull tab to back of collar is not a desired design characteristic.

9)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of a pull tab to the collar. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: A collar pull tab aids the child in donning the shoe.	☐	☐	☐	☐	☐	☐	☐

10)

You may use this optional area to provide us with any further information to your responses on the topline/collar.

Upper

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the upper of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

11)

"The Upper should be constructed of leather:" The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree". From panellist feedback, it was suggested that the purpose and advantages of leather material was that it adapts to foot structures over time and can enhance stability adaptions of the footwear through material stiffness. A number of panellists suggested that the upper should be available in optional materials, such as breathable materials for hot climates or sweaty feet, in addition, wipeable washable fabric for issues with incontinence. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the material of the upper for stability footwear. *	
☐	Upper should be constructed of leather (Original)
☐	Optional range of upper material to include; leather, breathable material and wipeable material.

12)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of leather as an upper material.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Leather adapts to foot structures over time	☐	☐	☐	☐	☐	☐	☐
Leather enhances material stiffness of the footwear	☐	☐	☐	☐	☐	☐	☐

13)

"Tongue to topline relationship:" "Tongue in line with the topline:" The median level of agreement amongst the panellists was "agree" with the majority of responses being between "neutral" to "agree". "Tongue extended above topline:" this reached the same level of agreement with the median level amongst the panellists being "agree" with the majority of responses being between "neutral" to "agree". Panellist feedback concerning the tongue being in line with the topline suggested that this would cause less irritation to the front of the ankle than an extended tongue. However, panellists who were in favour of an extended topline suggested that an extended tongue allowed comfort with lacing and the ability for the patient to pull up the tongue to stop slippage of the tongue during wear. Other

feedback suggested that the tongue length should be optional depending on the patient's preference and manual dexterity. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the tongue to topline relationship for stability footwear. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the material of the upper for stability footwear.*	
☐	Tongue extended above topline (Original)
☐	Tongue should be in line with topline (Original)
☐	Tongue length optional dependent on patient's preference and manual dexterity

14)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the Tongue to topline relationship.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows for comfort with lacing	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear	☐	☐	☐	☐	☐	☐	☐

15)

From panellist feedback other suggestions for the upper design were offered these included:

An option for an open upper in the form of a high topped sandal for standard stability footwear ranges for hotter climates.
The upper design should consider the effects and location of the internal seams in relation to compression and shearing of children's foot anatomy.
A slit or loop be placed in the tongue for the fastening (lace or Velcro strap) to pass through to minimise tongue slippage in the shoe.

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the uppers of stability footwear.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
High topped sandals to be offered as an option for stability footwear ranges for warm weather	☐	☐	☐	☐	☐	☐	☐
Ergonomic consideration of internal seams to reduce skin irritation	☐	☐	☐	☐	☐	☐	☐
Slit or loop in tongue for fastening to minimise tongue slippage	☐	☐	☐	☐	☐	☐	☐

16)

You may use this optional area to provide us with any further information to your responses on the upper.

Fastening and Facing 
In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Fastenings and Facings of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

17)

"The type of fastenings"

Most panellists (53%) choose "other", next was Velcro (23%), no preference (18%) and lace (6%).

Those panellists that chose the other option suggested that the chosen fastenings be optional depending on the ability of the child or the desired therapeutic goal (e.g. Velcro for limited hand dexterity to enhance independence, lace if greater stability is required).

From panellist feedback Velcro fastenings were proposed to assists with independence making it easier for children to don/doff the shoes. A number of panellists proposed that lace fastenings allowed a firmer grip to the contours of the foot to enhance the stability offered by the shoe.

Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the type of fastenings for stability footwear.*

☐	Velcro (Original)
☐	Lace (Original)
☐	No Preference (Original)
☐	Optional dependent on patient's ability and desired goal (e.g. Velcro for limited hand dexterity, lace for greater stability)

18)

Please rank your level of agreement with the following purpose suggested from panellists' feedback for the type of fastenings.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of Velcro fastenings: Assists independence with limited hand dexterity in donning and doffing	☐	☐	☐	☐	☐	☐	☐
Purpose of lace fastenings: Enhances stability through potential firmer grip to contours of the foot	☐	☐	☐	☐	☐	☐	☐

19)

"Position of the facings"

Most panellists (47%) choose 'extended to just behind the toebox, 23% choose "other", 18% suggested "facings extended to the midfoot" and 12% had no preference.

From panellist feedback facings extended to the toe box were suggested to allow greater access into the footwear with patients who had limited foot and ankle ROM. Whereas facings extended to the midfoot allowed the upper to offer greater stability.
Similar to the fastenings a number of panellists felt the facings of stability footwear should be offered in an optional range dependent on the ability of the patient and desired therapeutic role. Extended to the toebox for limited patient foot and ankle mobility, extended to the midfoot for greater shoe stability.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the position of the facings for stability footwear.*

☐	Facings extended to the midfoot (Original)
☐	Facings extended to just behind the toe box (Original)
☐	No Preference (Original)
☐	Optional dependent on patient's foot and ankle mobility or therapeutic goal (i.e. facings extended to toe box for ease of foot and ankle access, extended to midfoot for greater upper stability)

20)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the position of the facings.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Facings extended to just behind the toe box allows greater access into the footwear for the child with limited foot and ankle range of motion	☐	☐	☐	☐	☐	☐	☐
Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.	☐	☐	☐	☐	☐	☐	☐

21)

Other considerations suggested by the panellist in relation to the facings and fastenings were the gap between facings should be enough to allow an adequate range of fastening adjustment. A side zip along the rearfoot was suggested alongside a lace fastening to allow easy donning and doffing to pre-tightened laced footwear. Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the fastenings and facings of stability footwear.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The gap between facings should allow an adequate range of fastening adjustment.	☐	☐	☐	☐	☐	☐	☐

Side zip lace combination fastening	☐	☐	☐	☐	☐	☐	☐

22)

You may use this optional area to provide us with any further information to your responses on fastening and facing.

Heel counter/stiffener

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Heel Counter/Stiffener of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

23)

The heel counter/stiffener extension

"Heel counter/stiffener extended to midfoot:"
The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

"Heel counter/stiffener extended towards the topline."
The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses being between "somewhat agree" to "agree".

From panellist feedback, it was suggested that this was one of the most important design characteristics to enhance the stability of this footwear. It was thought the material stiffness of the counter and its extension could resist frontal plane movements of the foot and ankle and the midfoot if extended to this region. It was also suggested that this design feature can enhance proprioception at the rearfoot and ankle. Some panellists suggested that heel counters should come in a range of extensions both in length and height dependent on the therapeutic need (high to moderate stability) and to account for any impingement on the varied foot and ankle anatomy of patients.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the heel counter/ stiffener extensions for stability footwear.*

☐	Heel counter/stiffener extended to the midfoot only
☐	Heel counter/stiffener extended towards the topline only
☐	Heel counter stiffener, extended to the midfoot and towards topline
☐	Optional range of heel counter extensions dependent on therapeutic need and the patient's foot and ankle anatomy

24)

Please rank your level of agreement with the following purpose suggested from panellists’ feedback of the heel counter/stiffener:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Purpose: Heel counter/stiffener extensions can enhance proprioception at the foot and ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Heel counter/stiffener extension offers material stiffness to restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.	☐	☐	☐	☐	☐	☐	☐

25)

You may use this optional area to provide us with any further information to your responses on heel counter/stiffener.

Heel

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Heel of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

26)

"Heel width in relation to the heel counter" The majority (47%) felt that the heel should be extended wider than the heel counter followed by 23% who felt it should be in line, the remaining 30% chose no preference or other. Feedback from the panellists suggested that the purpose of an increased heel width allowed greater medial-lateral stability. Panellists suggested that a welted sole construction provided a slight width increase from standard retail footwear. Others suggested that wider heels affect aesthetics and the mass of the shoe or potentially cause weakening to the upper and sole adhesion. Other feedback stated that heel width extension needs to be quantified and come in a range of prescriptive adaptions (heel float) dependent on clinical need rather than a standard characteristic. Please consider the following options suggested by panellists' feedback in relation to the desired design characteristic of the heel to heel counter width relationship for stability footwear.*	
☐	Heel width in line with heel counter width (Original)
☐	Heel width extended wider than heel counter width (Original)
☐	No preference (Original)
☐	Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam.

27)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of an extended heel width:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Heel width extensions assist medial-lateral stability of the foot and ankle through an increased base of support	☐	☐	☐	☐	☐	☐	☐

28)

Other heel design considerations suggested by the panellists were the heel pitch; heel pitch should not be so high as to impart instability at the ankle or be incompatible with the fitting of adjunct orthotic therapy:

Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the heel of stability footwear:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Heel Pitch should not increase ankle instability	☐	☐	☐	☐	☐	☐	☐
Heel pitch should	☐	☐	☐	☐	☐	☐	☐

allow for adjunct orthotic therapy							

29)

You may use this optional area to provide us with any further information to your responses on the heel

Inlay

In the questions below, you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Inlay of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

30)

The inlay should have the following characteristics:

"Stability footwear should come with a standard removable inlay."
The median level of agreement amongst the panellists was "strongly agree" with the majority of responses being between "agree" to "strongly agree".
Consensus was reached on this design feature in Round 1.

"The inlay should be contoured to simulate the medial longitudinal arch. "
The median level of agreement amongst the panellists was "neutral" with the majority of responses being between "somewhat disagree" to "somewhat agree".

From panellist feedback, it was suggested that a removable inlay would allow for soft covering over the inner base layer of the sole and be thick enough to allow replacement with a prescriptive foot orthotic device if required. The majority of panellists did not feel contouring to the arch was necessary as this not be representative of an early walkers foot; however, panellists did suggest contouring to the heel cup to improve rearfoot fitting in the footwear.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the inlay for stability footwear.*

☐	The inlay should be contoured to simulate the medial longitudinal arch (Original)
☐	The inlay should be contoured to cup the heel but not the medial longitudinal arch
☐	The inlay should be contoured to simulate the medial longitudinal arch and to cup the heel

31)

Please rank your level of agreement with the following purpose suggested from panellists' feedback of the inlay.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Removable Inlay should be thick enough to allow for a potential prescriptive foot orthoses.	☐	☐	☐	☐	☐	☐	☐
An inlay contoured to cup the heel improves rearfoot fitting	☐	☐	☐	☐	☐	☐	☐

32)

You may use this optional area to provide us with any further information to your responses on the inlay.

Sole unit

In the questions below you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the sole unit of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

33)

The sole unit should have "A deepened tread"
The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses being between "neutral" to "agree".

Panellist feedback suggested that a deepened tread allows for greater traction over different terrains however it may also be a trip hazard especially with low ground clearance in some mobility impairments.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the tread depth for stability footwear.*

☐	A deepened tread (Original)
☐	The tread depth should come in an optional range dependent (on the ability of the child and the environment where the footwear is to be used.

34)

The sole unit should: "Be made of hard-wearing material"
The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

Panellist feedback suggested the benefit of a hard-wearing sole unit is that it would resist abnormal sole wear from pathological gait and prolong the stability effect of the footwear. Other suggestions indicated that hard-wearing soling material may not be so important for younger children as growth would entail replacement before significant wear. There was also the suggestion that hard-wearing soling material may increase walking effort in early walkers.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the wear resilience of the sole material for stability footwear.*

☐	Hard-wearing material (Original)
☐	Optional wear resilience of the sole material dependent on the age and ability of the patient.

35)

In relation to a hard wearing sole material please rank your level of agreement with the following purpose or characteristic suggested from panellists feedback.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Hard wearing sole material will prolong the stability effect of the footwear by resisting wear patterns associated with gait pathologies.	☐	☐	☐	☐	☐	☐	☐

36)

"The degree of flexibility" for the sole unit. The value range for flexibility 10 completely rigid and 0 completely flexible the median level of flexibility amongst the panel was 6 with the majority of values falling between 5 and 7. Panellist feedback suggested that although a rigid sole may enhance stability, flexion of the metatarsophalangeal joints (MPJ) is a requisite of the Hick's windlass and potential development of the arched complex of the foot. It was suggested that the sole stiffness may come in a range dependent on the ability of the child and therapeutic goals. Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the sole unit flexibility for stability footwear.*	
☐	The sole unit should come in a range of sole stiffness dependent on the patient's ability or the therapeutic goals, with flexibility of the sole focused at the MPJ area
☐	Other: (Please state)

37)

Other sole unit design considerations suggested by the panellists were: That the rearfoot to forefoot sole width should be kept to the lowest practical ratio to manage mediolateral stability of the footwear. That the sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions Please rank your agreement with the following panellists' suggestions in relation to further desired design characteristics for the sole unit of stability footwear.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Rearfoot to Forefoot width of the sole unit kept to	☐	☐	☐	☐	☐	☐	☐

lowest practical ratio to assist medial-lateral stability							
The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.	☐	☐	☐	☐	☐	☐	☐

38)

You may use this optional area to provide us with any further information to your responses on the sole unit.

Toe spring forefoot/heel rocker

In the questions below, you will be presented with the collective opinion of panellists to the findings form Round 1 in relation to the Toe spring forefoot/heel rocker of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment, please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

39)

"Stability footwear should have a reasonable forefoot rocker."

The median level of agreement amongst the panellists was "agree" with the majority of responses being between "somewhat agree" to "agree".

Panellist feedback suggested that forefoot rockers should come in a range depending on the patient's condition from increased in Charcot Marie Tooth to avoid tripping in propulsion and swing, to reduce in conditions such as Idiopathic toe walking to reduce the 3rd rocker (MPJ) loading. It was pointed out a range of forefoot rockers would also be required dependent on the stiffness of the sole. Panellists suggested the purpose of an appropriate rocker was to facilitate sagittal progression in propulsion without impacting on stability and also allowing for adequate ground clearance in swing phase.

Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the forefoot rocker for stability footwear.*

☐	Stability footwear should have a reasonable forefoot rocker. (Original)
☐	Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole.

40)

In relation to the forefoot rocker please rank your level of agreement with the following purpose or characteristic suggested from panellists feedback.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of forefoot rocker: Should facilitate forward progression in terminal stance without impacting on stability	☐	☐	☐	☐	☐	☐	☐
Design characteristic of forefoot rocker: Should allow adequate ground clearance in swing	☐	☐	☐	☐	☐	☐	☐

41)

"Stability footwear should have a heel rocker." The median level of agreement amongst the panellists was "neutral" with the majority of responses being between "somewhat disagree" to "somewhat agree". Panellist feedback suggested that a heel rocker may speed up the 1st rocker and cause instability during the initial loading phase of gait. A number of panellists suggested that heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design. Please consider the following options suggested by the panellists' feedback in relation to the desired design characteristic of the heel rocker for stability footwear.*	
☐	Stability footwear should have a heel rocker. (Original)
☐	Heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design of stability footwear.

42)

You may use this optional area to provide us with any further information to your responses on toe spring forefoot/heel rocker.

Weight of the footwear
In the questions below you will be presented with the collective opinion of panellists to the findings from Round 1 in relation to the weight of "Off the Shelf" Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics:

20)

"The weight of stability footwear is an important consideration when issuing footwear to children with mobility impairment?"
The median level of agreement amongst the panellists was "agree" with the majority of responses being "agree."
Consensus was reached in Round 1 with respect to this being an important design characteristic.

Panellist feedback suggested that the footwear should be the lowest reasonable mass to reduce physiological cost during mobility. The design should, however, consider the mass of the child and the stability requirements of the child's condition, with more stabilising features associated with a higher mass. It was also highlighted some mobility-impaired conditions might allow the child to become more mobile with age; therefore, requiring sturdier footwear conversely other conditions may entail the child becoming weaker requiring lighter footwear. It was suggested that heavier shoes could assist stability in stance and the pendular motion in swing. Others noted that the perceived increased weight of stability footwear by children might be due to its stiffness rather than the actual mass.

The following design considerations in respect to the weight of stability footwear and its purpose have been formed from panellist feedback; please rank your agreement with these.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should be the lowest reasonable mass to reduce physiological cost during mobility.	☐	☐	☐	☐	☐	☐	☐
The mass of the shoe should be dependent on the mass and age of the child.							
The mass of the shoe should be dependent on the child's stability needs.							
Purpose of increased mass: Assist stability in stance							
Purpose of increased mass: Assists pendular							

motion in swing							

21)

You may use this optional area to provide us with any information for your responses on the weight of the footwear.

Further Design Considerations
The following section provides additional design considerations for "Off the Shelf" Stability footwear suggested by the panellists.

45)

Children's "Off the Shelf" stability footwear should come in a range of last dimensions to accommodate proportional differences in foot types. Please rank your agreement with the following panellists' suggestion in relation to further desired design characteristics for stability footwear.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Children's stability footwear should be available in a range of last dimensions to accommodate different foot types.	☐	☐	☐	☐	☐	☐	☐

46

Children's "Off the Shelf" stability footwear should come in a range of colours and styles to appeal to children's preferences. Please rank your agreement with this design feature suggested from the panellists' feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should come in a range of colours and styles to appeal to children's aesthetics.	☐	☐	☐	☐	☐	☐	☐

47)

You may use this optional area to provide us with any information for your responses.

END OF SECTION 2 ROUND 2

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

You can find the link for the next section of Round 2 attached to the Delphi survey email.

ROUND 3(S2) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The second section will present yours and the panellists' collective choices and opinions from Round 2 on the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.

Section 2

Establishing desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment.
* Footwear taken from stock or supplies and not individually designed.

In this section, you will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning the desired design characteristics of “off the shelf” stability footwear and the purpose of these as a clinical intervention for children with mobility impairment. You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

Required Field *

1)

Name*

Glossary of Footwear Anatomy

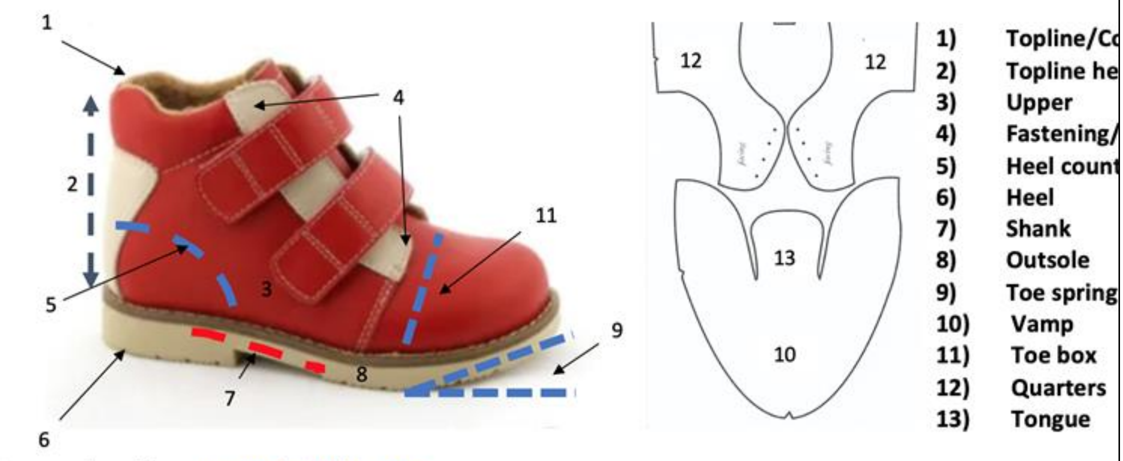


Image adapted from www.made-in-china.com

This section provides a brief glossary to the footwear terms used in this survey.

1) Topline: the opening of the shoe at the rearfoot and ankle region,
Collar: Sometimes padded, a strip of material attached to the topline/opening of a shoe.

2) Topline height, The height between the base of the upper at the heel cup to the topline.

3) Upper: The part of a shoe that covers the entire top, sides and back of the foot and attaches to the insole and outsole

4) Fastening: The part of the shoe that can adjust and secure the fitting of the vamp and the quarters to the foot.
Facing: The area of the shoe where the fastenings are located.

5) Heel counter: stiffened material placed between the shoe's inner lining and the upper located at the heel cup region of the shoe just above the heel.

6) Heel: The part of the outsole that raises the rear of the shoe (maybe part/or a separate attachment of the outsole)

7) Shank: The Reinforced strip of material located between the insole and the sole of the shoe running from the heel region to the midfoot.

8) Outsole: The base of the shoe that is attached to the upper and contacts the ground.

9) Toe spring: The elevation angle from the ball region of the shoe to the distal aspect of the toe box.

10) Vamp: The area of the upper that covers the front part of the shoe,

11) Toe box: Distal region of the shoe upper that provides space and protection for the toes.

12) Quarters: The back half of the upper. Attached at the front to the vamp, making up both sides of a shoe, and wrapping around the rear of the shoe.

13) Tongue: Flap of material attached to the vamp shoe, extending centrally along the instep from the forefoot to the topline.

Topline/collar

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the topline/collar of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

2)

rom Round 2 panellists were presented with a series of options from suggestions from the panel and the original study of stability footwear in relation to the height of the topline.
The relative frequency of response is detailed below:

Option 1: The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs. (93%)
Option 2: The topline should be extended above the ankle (Original) (7%)
Option 3: The topline should not be extended above the ankle (0%)

A Consensus was reached to Option 1.

Panellist feedback suggested that it was difficult to recommend standard design as different foot types (pes planus, pes cavus) will affect the efficacy of the topline and collar options

3)

Panellists were asked to rank their agreement with the following purpose and potential adverse effects of an extended topline in Round 2.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Extended topline increases proprioception at the Foot and Ankle
Median level of Agreement 5 ("Somewhat Agree")
20% "Neutral", 33% "Somewhat Agree", 40% "Agree", 7% "Strongly Agree"

Purpose: Extended topline assist heel counter leverage to resist frontal plane motion at foot and ankle
Median level of Agreement 6 ("Agree")
13% "Neutral", 34% "Somewhat Agree", 40% "Agree", 13% "Strongly Agree"

Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle
Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 20% "Neutral", 40% "Somewhat Agree"
13% "Agree", 20% "Strongly Agree"

Panellist Feedback suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose of the design characteristics.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of an extended topline.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: An extended topline height may increase proprioception input at the rearfoot and ankle.	☐	☐	☐	☐	☐	☐	☐
Purpose: An extended topline height may assist heel counter leverage to resist frontal plane movement of the rearfoot and ankle.	☐	☐	☐	☐	☐	☐	☐
Adverse Effect: An extended topline height may reduce sagittal plane power generation at the ankle.	☐	☐	☐	☐	☐	☐	☐

4)

"Padded collar"
The panellists were presented with the following design characteristic and purpose of a foam padded collar in Round 2
The median level of agreement and the relative distribution of response is detailed below.

Design Characteristic: Foam Padded collar covered with low sheer material

Median level of Agreement 6 ("Agree")
13% "Neutral", 20% "Somewhat Agree", 47% "Agree", 20% "Strongly Agree"

Purpose Foam padding collar reduces compression from an extended topline height.
Median level of Agreement 6 ("Agree")
7% "Disagree", 13% "Neutral", 27% "Somewhat Agree", 33% "Agree"
20% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the design characteristics and their purpose. It was difficult to recommend standard design as different foot types (pes planus, pes cavus) will affect the efficacy of the topline and collar options.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of a foam padded collar.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Design Characteristic: The foam padded collar should be covered with low shear material.	☐	☐	☐	☐	☐	☐	☐
Purpose: Foam Padding may reduce compression to lower limb anatomy from an extended topline height.	☐	☐	☐	☐	☐	☐	☐

5)

The panellists were presented with the following purpose to the contouring of the topline to the ankle region in Round 2

The median level of agreement and relative distribution of response is detailed below.

Purpose: contouring of topline reduces compression and sheer to ankle region.
Median level of Agreement 6 ("Agree")
13% "Somewhat Disagree", 7% "Neutral", 20% "Somewhat Agree", 47% "Agree", 13% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose. However, some panellists did acknowledge contouring to anatomical structures above or below the ankle improves tolerance fit and comfort.
The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption.

Based on your clinical experience please rank your level of agreement with these proposed purposes of a contoured topline.*							
The panellists were presented with the following purpose to the contouring of the topline to the ankle region in Round 2 The median level of agreement and relative distribution of response is detailed below. Purpose: contouring of topline reduces compression and sheer to ankle region. Median level of Agreement 6 ("Agree") 13% "Somewhat Disagree", 7% "Neutral", 20% "Somewhat Agree", 47% "Agree", 13% "Strongly Agree" Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose. However, some panellists did acknowledge contouring to anatomical structures above or below the ankle improves tolerance fit and comfort. The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption. Based on your clinical experience please rank your level of agreement with these proposed purposes of a contoured topline.							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring of topline may reduce shear and compression stress to the ankle region.	☐	☐	☐	☐	☐	☐	☐

6)

The panellists were presented with the following options in relation to the contouring of the collar to the Achilles tendon in Round 2 The relative distribution of response is detailed below: Option 1: Collar contoured to Achilles tendon (Original) (80%) Option 2: Collar contoured to the Achilles tendon is not a desired design characteristic (20%) A Consensus was reached to Option 1.*

7)

The following purpose was presented to the panellists in Round 2 in relation to contouring the collar to the Achilles tendon. The median level of agreement and relative distribution of response is detailed below. Purpose: Contouring the collar to the Achilles tendon reduces shear and compression to the tendon. Median level of Agreement 6 (Agree) 13% "Neutral", 27% "Somewhat Agree", 53% "Agree", 7% "Strongly Agree"

Panellist Feedback again suggested that partial agreement could only be reached due to limited peer-reviewed evidence to support the purpose. However, some panellists did acknowledge contouring to anatomical structures above or below the ankle improves tolerance fit and comfort. The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption. Based on your clinical experience please rank your level of agreement with these proposed purposes of a topline contoured to the Achilles tendon.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Contouring the collar to the Achilles tendon may reduce shear and compression to the tendon.	☐	☐	☐	☐	☐	☐	☐

8)

The panellists were presented with the following options in relation to the pull tab at the back of the collar in Round 2 Option 1: Pull tab to back of collar (Original) 53% Option 2: Pull tab to back of collar is not a desired design characteristic 47% Panellist feedback suggested that the pull tab may aid the child or those offering assistance to the child in donning the shoe. The pull tab may inadvertently assist sliding of an AFO into the boot. Please consider again the following options.*	
☐	Pull tab to back of collar (Original)
☐	Pull tab to back of collar is not a desired design characteristic.

9)

The following purpose was presented to the panellists in Round 2 in relation to the pull tab to the back of the collar. The median level of agreement and relative distribution of response is detailed below. Purpose: A collar pull tab aids the child in donning the shoe Median level of Agreement 5 ("Somewhat Agree") 7% "Disagree", 33% "Neutral", 26% "Somewhat Agree", 27% "Agree" 7% "Strongly Agree" The statement has been slightly modified based on panellist feedback please rank your level of agreement with this.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Purpose: A collar pull tab may aid the child or those offering assistance in donning the stability shoe	☐	☐	☐	☐	☐	☐	☐

10)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the topline/collar please use this optional area to provide us with your reasoning.

Upper

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the upper of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.

Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

11)

The panellists were presented with the following options in relation to the ideal material for the upper in Round 2
The relative distribution of response is detailed below:

Option 1: Optional range of upper material to include; leather, breathable material and wipeable material. 100%

Option 2: Upper should be constructed of leather (Original) 0%

A Consensus was reached for Option 1

12)

The following purpose was presented to the panellists in Round 2 in relation to leather as an upper material.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Leather adapts to foot structures over time
Median level of Agreement 6 ("Agree")
7% "Neutral", 20% "Somewhat Agree", 53% "Agree", 20% "Strongly Agree"

Purpose: Leather enhances material stiffness of the footwear
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 20% "Somewhat Agree",
53% "Agree"

Panellist feedback suggested that Leather material do not have uniform tensile strength. The upper material needs to account for the mass of the patient and the potential for increased mechanical stress.

The statements have been slightly modified based on panellist feedback please rank your level of agreement with these.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Leather may adapt to foot structures over time dependent on the tensile strength of the leather.	☐	☐	☐	☐	☐	☐	☐
Purpose: Leather may enhance material stiffness of the footwear dependent on the tensile strength of the leather.	☐	☐	☐	☐	☐	☐	☐

13)

The panellists were presented with the following options in relation to the desired design characteristic of the tongue to topline relationship for stability footwear In Round 2.
The relative distribution of response is detailed below:

Option 1: Tongue length optional dependent on patient's preference and manual dexterity 67%
Option 2:Tongue extended above topline (Original) 33%
Option 3:Tongue should be in line with topline (Original) 0%

No specific panellist feedback was given to inform any further modification of these options.

Please consider the following two options in reference to the tongue to topline relationship.*	
☐	Option 1:Tongue length optional dependent on patient's preference and manual dexterity
☐	Option 2: Tongue extended above topline (Original)

14)

The following purposes were presented to the panellists in Round 2 in relation to the tongue to topline relationship.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle.
Median level of Agreement 5 ("Somewhat Agree")
13% "Somewhat Disagree", 13% "Neutral", 40% "Somewhat Agree",
27% "Agree", 7% "Strongly Agree"

Purpose: Tongue extended above topline allows for comfort with lacing
Median level of Agreement 6 ("Agree")
13% "Neutral", 27% "Somewhat Agree", 40% "Agree", 20% "Strongly Agree"

Purpose: Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear
Median level of Agreement 6 ("Agree")
13% "Somewhat Disagree", 13% "Neutral", 13% "Somewhat Agree",
40% "Agree", 21% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of these statements, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statements from Round 2 in relation to the purpose of the tongue to topline relationship and rank your agreement with them..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows for comfort with lacing	☐	☐	☐	☐	☐	☐	☐
Purpose: Tongue extended above topline allows the wearer to	☐	☐	☐	☐	☐	☐	☐

minimise slippage of the tongue under the fastenings during wear							

15)

The panellists were presented with following design considerations for the upper of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and relative distribution of response is detailed below.

High topped sandals to be offered as an option for stability footwear ranges for warm weather.
Median level of Agreement 6 ("Agree")
13% "Neutral", 33%, "Somewhat Agree", 27% "Agree", 27% "Strongly Agree"

Ergonomic consideration of internal seams to reduce skin irritation
Median level of Agreement 6 ("Agree")
67% "Agree", 33% "Strongly Agree"
A Consensus was reached for this design option

Slit or loop in the tongue for fastening to minimise tongue slippage
Median level of Agreement 6 ("Agree")
13% "Somewhat Agree", 60% "Agree", 27% "Strongly Agree"
A Consensus was reached for this design option

No specific panellist feedback was given to inform any further modification of the design option of high topped sandals, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statement from Round 2 in relation to the design option for the upper.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
High topped sandals to be offered as an option for stability footwear ranges for warm weather	☐	☐	☐	☐	☐	☐	☐

16)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the upper please use this optional area to provide us with your reasoning.

Fastening and Facing 
In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Fastenings and Facings of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

17)

The panellists were presented with the following options in relation to the desired design characteristic of the type of fastening in Round 2 The relative distribution of response is detailed below: Option 1: Optional dependent on patient's ability and desired goal (e.g. Velcro for limited hand dexterity, lace for greater stability) 93% Option 2: Velcro (Original) 7% Option 3: Lace (Original) 0% Option 4:No preference (Original) 0% A consensus was reached for Option 1. Panellist feedback suggested that having combination fastenings on offer may also assist donning with adjunct assistive aids such as AFO's

18)

The following purposes were presented to the panellists in Round 2 for the type of fastenings.
The median level of agreement and relative distribution of response is detailed below.

Purpose of Velcro fastenings: Assists independence with limited hand dexterity in donning and doffing.
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 46% "Agree", 47% "Strongly Agree"
A Consensus was reached for this purpose

Purpose of lace fastenings: Enhances stability through potential firmer grip to contours of the foot.
Median level of Agreement 6 (Agree)
7% "Somewhat Disagree", 7% "Neutral", 13% "Somewhat Agree", 47% "Agree", 26% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of the purpose of lace fastenings. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following statement from Round 2 in relation to the purpose of a lace fastening.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose of lace fastenings: Enhances stability through potential firmer grip to the contours of the foot	☐	☐	☐	☐	☐	☐	☐

19)

The panellists were presented with the following options in relation to the desired design characteristic of the Position of the facings in Round 2
The relative distribution of response is detailed below:

Option 1: Optional dependent on patient's foot and ankle mobility or therapeutic goal (i.e. facings extended to toe box for ease of foot and ankle access, extended to midfoot for greater upper stability) 93%
Option 2: Facings extended to just behind the toe box (original)
7%
Option 3: Facings extended to midfoot (original) 0%
Option 4: No Preference (original) 0%

A consensus was reached for Option 1.

20)

The following purposes were presented to the panellists in Round 2 in relation to the position of the facings.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Facings extended to just behind the toe box allows greater access into the footwear for the child with limited foot and ankle range of motion
Median level of Agreement 6 ("Agree")
7% "Neutral", 66% "Agree", 27% "Strongly Agree"
A consensus was reached for this Purpose

Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 20% "Somewhat Agree"
, 53% "Agree"

No feedback was given to explain the lack of consensus agreement to the purpose of the facings extended to the midfoot, or to suggest further modification of the statement, although a strong majority of the panel advocated for an optional range of facing extensions to be incorporated in Question 19.

Please consider the following statement from Round 2 in relation to the purpose of facings extended to the midfoot..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle.	☐	☐	☐	☐	☐	☐	☐

21)

The panellists were presented with following design considerations for the fastenings and facings of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and the relative distribution of response is detailed below.

The Gap between the facings should allow adequate range of fastening adjustment
Median level of Agreement 6 ("Agree")
13% "Somewhat Agree", 40% "Agree", 47% "Strongly Agree"
A consensus was reached for this statement

Side Zip combination fastening
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 20% "Neutral", 13% "Somewhat Agree", 47% "Agree", 13% "Strongly Agree"

Panellist feedback suggested potential difficulty with side zip fastening including easy to damage zip mechanism, dangers of damaging skin or nails, and difficulty in fastening zip if lace fastenings are tightened tight enough to contour to the foot and ankle. Considering panellist feedback please rank your level of agreement to side zip lace combination fastening..*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Side zip lace combination fastening	☐	☐	☐	☐	☐	☐	☐

22)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the fastening and facings please use this optional area to provide us with your reasoning.

Heel counter/stiffener

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Heel counter/stiffener of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

23)

The panellists were presented with the following options in relation to the desired design characteristic of the heel counter/stiffener extension in Round 2.
The relative distribution of response is detailed below:

Option1: Optional range of heel counter extensions dependent on therapeutic need and the patient's foot and ankle anatomy (80%)
Option 2: Heel counter/stiffener extended to the midfoot only (13%)
Option 3: Heel counter stiffener, extended to the midfoot and towards topline (7%)
Option 4: Heel counter/stiffener extended towards the topline only (0%)

A Consensus was reached for Option 1:

Panellist Feedback suggested a concern that requesting too many optional features may present manufactures with difficulty in providing a stock boot. Additionally, heel counter changes may affect the fixation of the upper to the sole unit.

24)

The following purposes were presented to the panellists in Round 2 in relation to the heel counter/stiffener.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Heel counter/stiffener extensions can enhance proprioception at the foot and ankle
Median level of Agreement 5 ("Somewhat Agree")
20% "Neutral", 46% "Somewhat Agree", 27% "Agree", 7% "Strongly Agree"

Purpose: Heel counter/stiffener extension offers material stiffness to restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.
Median level of Agreement 6 ("Agree")
7% "Neutral", 40% "Somewhat Agree", 40% "Agree", 13% "Strongly Agree"

Panellist feedback suggested partial agreement due to the limited evidence base to support the purpose of the heel counter. Additionally, it was felt control at the heel counter area of the shoe should also consider the vertical ground reaction force component through increased contact area between the inner sole of the shoe and the plantar surface of the child's heel. The research team appreciates that there is a paucity of scientific or structured clinical research but we would ask you to consider your years of clinical experience and expertise as to the perceived role of this design adaption. Based on your clinical experience please rank your level of agreement with these proposed purposes and design considerations of the Heel counter/stiffener:*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Purpose: Heel counter/stiffener extensions may enhance proprioception at the foot and ankle.	☐	☐	☐	☐	☐	☐	☐
Purpose: Heel counter/stiffener extension offers material stiffness that may restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile.	☐	☐	☐	☐	☐	☐	☐
Control of frontal plane movements of the foot and ankle at the heel counter area should also consider vertical ground reaction force contact area, through close contact between the plantar surface of the child's heel and the inner sole of the shoe.	☐	☐	☐	☐	☐	☐	☐

25)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the heel counter/stiffener please use this optional area to provide us with your reasoning.

Heel

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Heel of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

26)

The panellists were presented with the following options in relation to the desired design characteristic of the "Heel width in relation to the heel counter" in Round 2.
The relative distribution of response is detailed below:

Option 1: Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam. (53%)
Option 2: Heel width extended wider than heel counter width (Original) (40%)
Option 3: No preference (Original) (7%)
Option 4: Heel width in line with heel counter width (Original) 0%

No specific panellist feedback was given to inform any further modification of the options of heel width in relation to the heel counter. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please consider the following 3 options from Round 2 of the heel width in relation to the heel counter.*

☐	Heel width in line with heel counter width (Original)
☐	Heel width extended wider than heel counter width (Original)
☐	No preference (Original)

☐	Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam.

27)

The following purpose was presented to the panellists in Round 2 in relation to an extended heel width The median level of agreement and relative distribution of response is detailed below. Purpose: Heel width extensions assist medial-lateral stability of the foot and ankle through an increased base of support. Median level of Agreement 6 ("Agree") 7% "Neutral", 7% "Somewhat Agree:, 53% "Agree", 33% "Strongly Agree" A consensus was reached for this statement. Panellist feedback suggested for a wide sole to offer increased stability maximum contact with the insole of the shoe and the plantar surface of the foot is required to maximise vertical GRF contact area:*

28)

The panellists were presented with following design considerations for the heel of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1. The median level of agreement and relative distribution of response is detailed below. Heel Pitch should not increase ankle instability Median level of Agreement 6 ("Agree") 13% "Somewhat Agree", 67% "Agree", 20% "Strongly Agree" A consensus was reached for this statement Heel pitch should allow for adjunct orthotic therapy Median level of Agreement 6 ("Agree") 7% "Somewhat Agree", 73% "Agree", 20% "Strongly Agree" A consensus was reached for this statement Panellist feedback suggested that ankle Instability would be inevitable due to plantarflexion in propulsion.

29)

You may use this optional area to provide us with any further information to your responses on the heel

Inlay

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Inlay of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

30)

The panellists were presented with the following options in relation to the desired design characteristic of the Inlay in Round 2. The relative distribution of response is detailed below: Option 1: The inlay should be contoured to simulate the medial longitudinal arch and to cup the heel 54% Option 2: The inlay should be contoured to cup the heel but not the medial longitudinal arch 33% Option 3: The inlay should be contoured to simulate the medial longitudinal arch (Original) 13% Panellist feedback suggested, That "off the shelf" stability footwear not just for early walkers therefore contouring to MLA may be required for larger sizes. Mild arch contour similar to that offered in standard retail footwear would be appropriate. The Arch may be easily reduced by clinician to control blistering in low arch feet. Ambiguous statement unsure if heel cupping would improve the fit of inlay to shoe or inlay and shoe to patient’s foot Slight modification to the options have been addressed panellist based on panellist feedback.*	
☐	The inlay should cup the child's heel to improve rearfoot fit and be appropriately contoured to the medial longitudinal arch
☐	The inlay should cup the child's heel to improve rearfoot fit but not be contoured to the medial longitudinal arch
☐	The inlay should be appropriately contoured to the medial longitudinal arch

31)

The following purpose and design characteristics were presented to the panellists in Round 2 in relation to inlay The median level of agreement and the relative distribution of response is detailed below. Removable Inlay should be thick enough to simulate a potential prescriptive foot orthoses Median level of Agreement 6 ("Agree") 67% "Agree", 33% "Strongly Agree" A consensus was reached for this statement Purpose: An inlay contoured to cup the heel improves rearfoot fitting Median level of Agreement 5 ("Somewhat Agree") 7% "Somewhat Disagree", 13% "Neutral", 34% "Somewhat Agree", 33% "Agree", 13% "Strongly Agree" Panellist feedback suggested ambiguity if cupping of the heel would improve the fit of inlay to shoe or the inlay and shoe to the patient’s foot The statement has been slightly modified based on panellist feedback please rank your level of agreement with this.*							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

An inlay contoured to cup the heel improves rearfoot fitting of the child's foot to the shoe	☐	☐	☐	☐	☐	☐	☐

32)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the Inlay please use this optional area to provide us with your reasoning.

Sole unit

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the Sole unit of standard "Off the Shelf" stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

33)

The panellists were presented with the following options in relation to the desired design characteristic of the tread depth of the sole unit in Round 2.
The relative distribution of response is detailed below:

Option 1: The tread depth should come in an optional range dependent on the ability of the child and the environment where the footwear is to be used. (87%)

Option 2: A deepened tread (Original) 13%

A consensus was reached for Option 1

34)

The panellists were presented with the following options in relation to the desired design characteristic of the wear characteristics of the sole unit in Round 2.
The relative distribution of response is detailed below:

Option 1: Optional wear resilience of the sole material dependent on the age and ability of the patient. (87%)

Option 2: Hard-wearing material (Original) (13%)

A consensus was reached for Option 1

35)

The following purpose was presented to the panellists in Round 2 in relation to hard wearing sole material.
The median level of agreement and relative distribution of response is detailed below.

Purpose: Hard-wearing sole material will prolong the stability effect of the footwear by resisting wear patterns associated with gait pathologies.
Median level of Agreement 6 ("Agree")
7% "Neutral", 7% "Somewhat Agree", 79% "Agree", 7% "Strongly Agree"

A consensus was reached for this Statment.

36)

"The panellists were presented with the following options in relation to the desired design characteristic of the degree of flexibility for the sole unit. in Round 2.
The relative distribution of response is detailed below:

Option 1: The sole unit should come in a range of sole stiffness dependent on the patient's ability or the therapeutic goals, with flexibility of the sole focused at the MPJ area
(100%)
Option2 (Other)
(0%)

A consensus was reached for option 1.

37)

The panellists were presented with following design considerations for the sole unit of off the shelf stability footwear in Round 2 based on panellist suggestions in Round 1.
The median level of agreement and relative distribution of response is detailed below.

Rearfoot to Forefoot width ratio’s kept to lowest practical ratio to assist medial lateral stability
Median level of Agreement 5 ("Somewhat Agree")
27% "Neutral", 27% "Somewhat Agree', 40% "Agree", 6% "Strongly Agree"

The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.
Median level of Agreement 5 (Somewhat Agree)
7% "Somewhat Disagree", 20% "Neutral", 26% "Somewhat Agree", 20% "Agree", 27% "Strongly Agree"

Panellist feedback suggested the width ratio of forefoot and rearfoot was ambiguous and required further explanation.

The statement in relation to the sole unit rearfoot to forefoot ratio has been slightly modified based on panellist feedback No specific feedback was offered to offer modification of the statement concerning the stiffness at midfoot and rearfoot sole unit, However, you may consider the distribution of the panel's response to either change or maintain your previous choice to this statement.

Please rank your level of agreement with these statements..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
The ground contact area ratio between the rearfoot and forefoot of the sole unit should be kept to the lowest practical ratio to assist	☐	☐	☐	☐	☐	☐	☐

medial-lateral stability							
The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions.	☐	☐	☐	☐	☐	☐	☐

38)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the sole unit please use this optional area to provide us with your reasoning.

Toe spring forefoot/heel rocker	

In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the toe spring forefoot/heel rocker of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment.
Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

39)

The panellists were presented with the following options in relation to the desired design characteristic of the forefoot rocker in Round 2.
The relative distribution of response is detailed below:

Option 1: Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole. (73%)

Option 2: Stability footwear should have a reasonable forefoot rocker. (Original) (27%)

Panellist feedback suggested that although the variation of rocker's and sole stiffeners offered for conditions such as Charcot Marie Tooth and toe walking were important these should be offered as a sole adaption prescription rather than a standard design on stability footwear.

A modified option as been offered based on panellist feedback.*

☐	Option 1: Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole.
☐	Option 2: Stability footwear should have a reasonable forefoot rocker as a standard design. With forefoot rocker adaption prescriptions available to meet patient's needs.

40)

The following purposes were presented to the panellists in Round 2 in relation to the forefoot rocker
The median level of agreement and relative distribution of response is detailed below.

Purpose of forefoot rocker: Should facilitate forward progression in terminal stance without impacting on stability.
Median level of Agreement 6 ("Agree")
7% "Somewhat Agree", 66% "Agree", 27% "Strongly Agree"
A consensus was reached for this statement

Design characteristic of forefoot rocker: Should allow adequate ground clearance in swing Median level of Agreement 6 ("Agree") 7% "Somewhat Agree", 66% "Agree', 27% "Strongly Agree" A consensus was reached for this statement

41)

The panellists were presented with the following options in relation to the desired design characteristic of the heel rocker in Round 2. The relative distribution of response is detailed below: Option 1: Heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a standard design of stability footwear. (100%) Option 2: Stability footwear should have a heel rocker. (Original) (0%) A Consensus was reached for Option 1

42)

You may use this optional area to provide us with any further information to your responses on toe spring forefoot/heel rocker.

Weight of the footwear
In the questions below you will be presented with the collective choices and opinions from Round 2 in relation to the weight of the footwear of standard “Off the Shelf” stability footwear used as a clinical intervention for children with mobility impairment. Please consider the options offered or rank your level of agreement with the suggested characteristic or purpose of these design characteristics some of which may have been slightly modified based on panellist feedback in Round 2:

43)

The following purpose and design characteristics were presented to the panellists in Round 2 in relation to the weight of the footwear The median level of agreement and relative distribution of response is detailed below. Stability Footwear should be the lowest reasonable mass to reduce physiological cost during mobility Median level of Agreement 6 ("Agree") 33% 'Somewhat Agree", 40% "Agree", 27% 'Strongly Agree' Mass of shoe should be dependent on the mass and age of the child Median level of Agreement 6 ('Agree") 13% "Neutral", 20% "Somewhat Agree", 54% "Agree", 13% "Strongly Agree" The mass of the shoe should be dependent on the child’s stability needs. Median level of Agreement 6 ("Agree") 7% "Neutral", 13% "Somewhat Agree", 67% "Agree", 13% "Strongly Agree" A consensus was reached for this statement Purpose of Increased mass assists stability in stance, Median level of Agreement 5 ("Somewhat Agree") 40% "Neutral", 20% "Somewhat Agree", 40% "Agree" Purpose of Increased Mass Assists pendular motion in swing Median level of Agreement 5 ("Somewhat Agree") 7% "Somewhat Disagree", 40% "Neutral', 26% "Somewhat Agree"

20% "Agree", 7% "Strongly Agree"

Panellist feedback suggested that pendular motion may be assisted but increased mass may also cause an adverse effect with instability in swing and preloading increasing difficulty in navigating obstacles and stair climbing.
The increased mass of the footwear may unintentionally provide a benefit in strengthening limbs but also may induce early fatigue.

A new statement was generated from panellist feedback concerning a potential adverse effect of the weight of the shoe. No specific panellist feedback was given to inform further modification of the other statements, However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your level of agreement with these statements..*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should be the lowest reasonable mass to reduce physiological cost during mobility.	☐	☐	☐	☐	☐	☐	☐
The mass of the shoe should be dependent on the mass and age of the child.	☐	☐	☐	☐	☐	☐	☐
Purpose of increased mass: Assist stability in stance	☐	☐	☐	☐	☐	☐	☐
Purpose of increased mass: Assists pendular motion in swing	☐	☐	☐	☐	☐	☐	☐
Adverse Effect: Increased mass of the shoe may lead to difficulty in swing phase with ground clearance, navigating	☐	☐	☐	☐	☐	☐	☐

obstacles and stair climbing.							

44)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to the weight of the footwear please use this optional area to provide us with your reasoning.

Further Design Considerations
The following section provides additional design considerations for "Off the Shelf" Stability footwear suggested by the panellists.

45)

The Following design consideration was presented to the panellist in Round 2
The median level of agreement and relative distribution of response is detailed below.

Children's "Off the Shelf" stability footwear should come in a range of last dimensions to accommodate proportional differences in foot types.
Median level of Agreement 6 ("Agree")
7% "Neutral", 46% "Agree", 47% "Strongly Agree",

A consensus was reached for this statement.

46

The Following design consideration was presented to the panellist in Round 2
The median level of agreement and relative distribution of response is detailed below.

Children's "Off the Shelf" stability footwear should come in a range of colours and styles to appeal to children's preferences.
Median level of Agreement 7 ("Strongly Agree")
40% "Agree", 60% "Strongly Agree"

A consensus was reached for this statement.

END OF SECTION 2 ROUND 3

Thank you for taking the time to complete section 2. Your time and participation in this survey are greatly appreciated.

Please remember to submit your answers before closing this form.

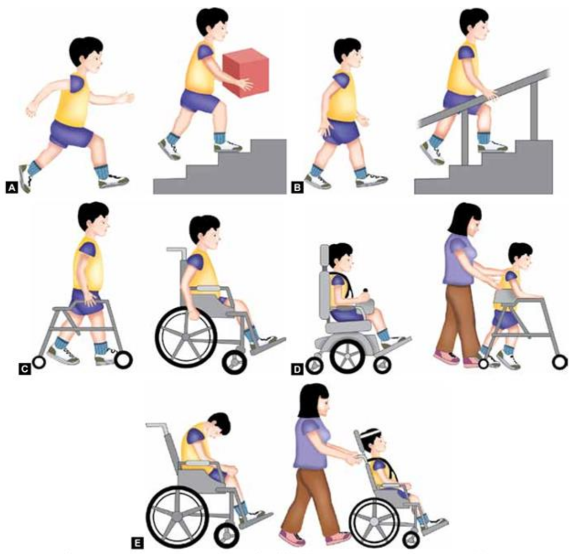
You can find the link for the next section of Round 2 attached to the Delphi survey email.

4.3. Delphi Survey Section 3 Rounds 1-3

WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM? (SECTION 3 ROUND 1)

The third section will consist of your ideas and opinions on clinical protocols and outcomes for the provision of "off the shelf" modular stability clinical footwear interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" and modular stability footwear clinical interventions for children with mobility impairment.

This section consists of a series of closed-ended and structured open-ended questions concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (ankle foot orthoses (AFO*), walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear.

*Please remember to qualify any abbreviation for mobility aids.

The conditions presented were suggested from the research sourced in the scoping review. However, you will be given the opportunity to suggest further conditions you treat or that you consider from your manufacturing experience may benefit from stability footwear intervention.

For each condition, a range of topics will be considered, and you will be free to suggest additional aspects you view as necessary, and your reasons for these.

- Do you have experience of treating or from a manufacturing perspective recommending footwear for This condition?
- Do you feel that this condition is appropriate for stability footwear intervention?
- Degree of mobility impairment (qualify if the footwear is to be used as a sole aid or in combination with another assistive aid).
- Age of patient, i.e. at what age do you consider appropriate to use this footwear as a mobility intervention.
- Clinical Outcomes: Changes in gait e.g. reduction/increase in velocity/stride length/ side to side movement.

An example of answers to a series of questions in relation to a specific condition that would benefit from the clinical prescription of "off the shelf" and modular stability footwear is presented below.

Cerebral palsy

1) Do you have experience in treating this condition

Answer: (Yes)

2) Do you feel this condition is appropriate for stability footwear intervention

Answer: (Strongly Agree 7)

3) The degree of mobility impairment would be:

Answer: For sole use of footwear: Gross Motor Function Classification Score level 1, mild hemiplegia or diplegia where the child is capable of independent ambulation
For combined use with walking frame Level: Gross Motor Function Classification Score level 3 where independent ambulation is extremely limited,

4) Concerning this condition, the age range would be:

Answer: 1-18 years

5) Concerning this condition, the clinical outcomes of "off the shelf" and modular stability footwear intervention would be:

Answer: Increase in: gait velocity, stride length. Reduce side to side sway. Improved walking distance and participation in daily life activities such as play, family outings, walking to school.

Required Field*

1)

Name: *

Cerebral Palsy
From the research stability footwear has been proposed as a clinical intervention for children with cerebral palsy. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

2)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 8). *	
☐	Yes
☐	No

3)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Cerebral palsy is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

4)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

5)

The degree of mobility impairment that would be suitable for this condition is: *Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

6)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

7)

Clinical outcomes:

Pes Planus
From the research stability footwear has been proposed as a clinical intervention for children with pes planus. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

8)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 14). *	
☐	Yes
☐	No

9)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Pes planus is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

10)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

11)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

12)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

13)

Clinical outcomes:

Toe Walking
From the research stability footwear has been proposed as a clinical intervention for children with toe walking. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

14)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 20). *	
☐	Yes
☐	No

15)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Toe walking is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

16)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

17)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

18)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

19)

Clinical outcomes:

Duchenne Muscular Dystrophy
From the research stability footwear has been proposed as a clinical intervention for children with Duchenne muscular dystrophy. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

20)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 26). *	
☐	Yes
☐	No

21)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Duchenne muscular dystrophy is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

22)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

23)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

24)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

25)

Clinical outcomes:

Spina Bifida
From the research stability footwear has been proposed as a clinical intervention for children with spina bifida. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

26)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 31). *	
☐	Yes
☐	No

27)

Do you agree this condition is suitable for stability footwear clinical intervention?							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Spina bifida is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

28)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

29)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

30)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

31)

Clinical outcomes:

Down Syndrome
From the research stability footwear has been proposed as a clinical intervention for children with Down syndrome. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

32)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 38). *	
☐	Yes
☐	No

33)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Down syndrome is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

34)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

35)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

36)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

37)

Clinical outcomes:

Intoeing
From the research stability footwear has been proposed as a clinical intervention for children with Duchenne muscular dystrophy. In the questions below, please consider the following in reference to clinical protocols for issuing "off the shelf" and modular stability footwear as a mobility aid for children: Experience treating this condition Agreement on the suitability of stability footwear as a treatment for this condition Degree of mobility impairment The age range of patients Clinical outcomes

38)

Do you have experience in treating this condition? If your answer is no move to the next condition (Q 44). *	
☐	Yes
☐	No

39)

Do you agree this condition is suitable for stability footwear clinical intervention?

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Intoeing is suitable for stability footwear intervention?	☐	☐	☐	☐	☐	☐	☐

40)

Please use this area to provide us briefly with the reasoning for your agreement or disagreement of using stability footwear as an intervention for this condition.

41)

The degree of mobility impairment that would be suitable for this condition is: †Please qualify if stability footwear is to be used as a sole aid or in combination with another assistive aid.

42)

Please indicate in years the age range this footwear intervention should be prescribed clinically for this condition: e.g. 1-5 years.

43)

Clinical outcomes:

44)

Optional Further Information
Please use the additional area to provide further conditions where you feel "off the shelf" modular stability footwear would act as a mobility aid. Please try to detail your answer with the following considerations • Condition • Severity / Grade of the condition if applicable, • The age of the patient • Clinical Outcomes

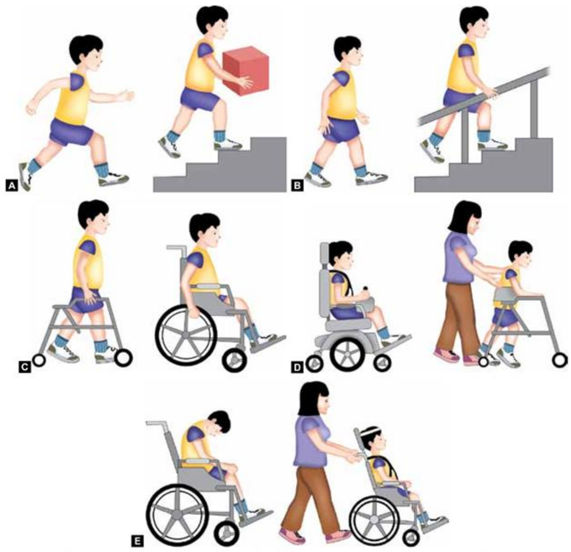
END OF SECTION 3 ROUND 1

Thank you for taking time to complete section 3 of round 1. You have now completed all sections of round 1 of this Delphi survey. Your time and participation is greatly appreciated. Please note that the following rounds will be less time consuming and will be sent in the same format as round 1. Remember to submit your answers before closing this form.

ROUND 2(S3) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The third section will present the feedback of panellists opinions from Round 1 on clinical protocols and outcomes for the provision of “off the shelf” stability footwear clinical interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" stability footwear clinical interventions for children with mobility impairment.

This section consists of a series of closed-ended and ranked questions concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (ankle foot orthoses AFO†, walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear interventions.

† *Please remember to qualify any abbreviation for mobility aids.*

The original information provided in this section sourced from the scoping review are listed alongside modified statements informed from the responses gained from panellists in round 1.

You will be asked to give your preferred option or your level of agreement with these statements (Strongly Disagree to Strongly Agree).

We will provide you with the opportunity to offer your reasoning for your stance or to suggest any further amendments to the statements (You may also leave these areas blank in this round). All answers will be anonymised and will not be identifiable as your responses.

Required Field*

1)

Name: *

Cerebral Palsy

Panellists were asked if cerebral palsy (CP) was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "strongly agree" with the majority of responses between "agree" and "strongly agree.
A Consensus was reached with respect to this condition being suitable for stability footwear intervention in Round 1

Panellist feedback suggested the reasons for stability footwear as an assistive aid for CP were: it could be used alongside other assistive devices such as foot orthoses and walking frames to assist in standing and walking. It assists with mediolateral stability and proprioception to reduce falls. Other feedback stated that footwear could be issued to children with CP but should be thoroughly assessed for its suitability with clear, measurable outcomes. One panellist felt ankle foot orthoses (AFO) and foot orthoses (FO) used with regular footwear or other footwear modifications such as "tuned" footwear were more applicable interventions. However, a number of panellists felt that stability footwear would offer greater ankle stability than regular footwear and foot orthoses combinations. Other panellists suggested stability footwear as an interim stability aid in some cases when not using their AFO and could make mobility easier than their AFO for some tasks such as getting up off the floor.

The following statements have been devised form panellist feedback in relation to the suitability of stability footwear for this condition; please rank your agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with CP.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used alongside other assistive aids to assist standing and walking in children with CP.	☐	☐	☐	☐	☐	☐	☐
Stability footwear should only be issued to children with CP after a critical	☐	☐	☐	☐	☐	☐	☐

assessment of the child's mobility needs in respect to other assistive aids or footwear modifications, and with clear intervention outcomes.							

From the research stability footwear has been proposed as a clinical intervention for children with cerebral palsy.
In the questions below, you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention.

13 of the 15 (86%) panellists had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition, please move to the next condition Question 7)

2)

3)

Panellists were asked the degree of mobility impairment in children with CP that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested Stability footwear may be used as a sole aid to assist foot and ankle stability in walking at GMFCS-1 with no significant tone issues. Stability footwear may also be used alongside other assistive devices (AFO's walking frames) to assist stability in walking and standing from GMFCS 1-3 in ambulant children with tonal issues. May be used alongside other assistive devices as a positioning transfer standing aid in non-ambulant GMFCS 3-4 children.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with CP suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive intervention to assist both foot and ankle walking stability in children with GMFCS 1 and no significant tonal issues.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used	☐	☐	☐	☐	☐	☐	☐

alongside other assistive aids to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues.							
Stability footwear may be used alongside other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4.	☐	☐	☐	☐	☐	☐	☐

4)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in CP

From panellists feedback, a range of ages was stated varying from 1-4 years for initiation and 16 years -adulthood for an endpoint, however from the reasoning; it was decerned even those panellists who indicated an endpoint of 16 years envisioned the potential for ongoing stability footwear intervention into adulthood if required. Some feedback indicated that footwear should only be used in mild cases (GMFCS 1) in the learning to walk stages then should focus on other orthotic aids. In moderate cases (GMFCS 2-3) where surgery was not indicated in teenage years, supportive footwear may be used alongside orthoses. Other panellists felt initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than specific age ranges such as displaying the potential to stand and endpoint defined as the need for differing assistive aids.

The following options have been suggested by panellist feedback:

☐	1-18 years (with assessed adult transition care)
☐	3-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

5)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with CP:

From panellist feedback outcomes were grouped into therapeutic goals alongside the World Health Organisation International Classification of Functioning Child and Youth version (WHO ICF-CY). These were goals based on body structures and function and those based on Quality of Life measures (QoL). Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the Edinburgh Gait Scale. Spatiotemporal

outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor proficiency measures were also suggested including, motor milestones and Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), frequency of falls was also suggested as a measure of the child's motor performance. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed. QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers. The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Edinburgh Gait Scale)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

6)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with CP.

Pes Planus
From the research stability footwear has been proposed as a clinical intervention for children with pes planus. In the questions below, you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 15 of the 15 panellists 100% had clinical experience with this condition and provided the information for this section.

7)

Panellists were asked if Pes Planus was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "somewhat agree" with the majority of responses between "neutral" and "agree".

Panellist feedback suggested that stability footwear may be used to assist foot and ankle stability in children but only in cases that required more control than could be offered by foot orthoses alone. This was thought to be where mobile symptomatic pes planus is associated with significant ankle instability (hypermobility) leading to tripping and falling or developmental delay in gross motor skills.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition; please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may assist foot and ankle stability in children with symptomatic mobile pes planus	☐	☐	☐	☐	☐	☐	☐
Stability footwear is a suitable secondary line intervention for symptomatic mobile pes planus in children where foot orthoses have not resolved associated symptoms	☐	☐	☐	☐	☐	☐	☐

8)

Panellists were asked the degree of mobility impairment in children with pes planus that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid. Panellist feedback suggested that stability footwear should be used alongside orthoses in severe symptomatic pes planes. Severe or extreme was characterised by the panellists if the pes planus was associated with marked insufficiency of the posterior tibialis function (accessory navicular, muscle atrophy), significant foot and ankle instability that lead to tripping or falling or if pes planus was associated with developmental conditions that affected gross motor development. The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with symptomatic pes planus suitable for stability footwear intervention.							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be used alongside foot orthoses in children with insufficiency of posterior tibialis function.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside foot orthoses in children with significant foot and ankle instability associated with tripping and falling.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used alongside foot orthoses in children with conditions associated with motor delay	☐	☐	☐	☐	☐	☐	☐

9)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for Pes Planus, Panellists feedback suggested a range of ages were stated varying from 1-5 years for initiation and 15-21 years for an endpoint, however, like in CP from reasoning; it was decerned even those panellists who indicated an endpoint of 15 years envisioned assessment for ongoing support in adulthood if required. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than a specific age range such as displaying the potential to stand and endpoint defined as the need for ongoing stability footwear assistance. The following options have been suggested by panellist feedback:

☐	1-18 years (with assessed adult transition care)
☐	5-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with pes planus: From panellist, feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures. Concerning body structure, monitoring foot posture using the FPI was suggested. Body function outcomes included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns, specifically those of the foot and ankle. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG. Gross motor proficiency measures were also discussed, Gross motor milestones, BOT-2 and frequency of falls. QoL measures suggested by the panellists included pain rating and measures of ADL, walking to school, shops, playparks and interaction with peers. The following outcomes have been suggested from panellist feedback; please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot Posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Foot and ankle)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increase walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐

QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with pes planus.

Toe Walking
From the research stability footwear has been proposed as a clinical intervention for children with toe walking. In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 15 of the 15 panellists 100% had clinical experience with this condition and provided the information for this section.

12)

Panellists were asked if toe walking was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "neutral" with the majority of responses between "neutral" and "somewhat agree".

Panellist feedback suggested that the issue with the suitability for stability footwear used as an intervention for this condition was the highly heterogeneous nature of toe walking. Some panellist stated that it may only be used in mild to moderate idiopathic toe walking (ITW) it was not to be used if toe walking was severe or associated with Autistic Spectrum Disorder or hypertonia. Other suggestions were the stability footwear should have a stiffened sole or used alongside carbon plate insole addition to limit 3rd rocker engagement. If the toe walking was associated with hypermobility and foot posture issues stability footwear may be used. Other panellist felt there was limited evidence for this intervention even in ITW.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be a suitable treatment if used alongside other stiffened components (insole, sole) for	☐	☐	☐	☐	☐	☐	☐

ITW with no associated hypertonia							
Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay	☐	☐	☐	☐	☐	☐	☐

13)

Panellists were asked the degree of mobility impairment in children with toe walking that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used in combination with restrictive components (reduced forefoot rocker, carbon fibre insole plate) in type 1-2 ITW patients, the child must be able to achieve a standing plantargrade position. Other panellist felt the use for this footwear only if the child's own footwear could not accommodate an AFO.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with toe walking suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used alongside other stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position	☐	☐	☐	☐	☐	☐	☐

14)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in toe walking

Panellists feedback suggested a range of ages were stated varying from 1-4 years for initiation and 8-18 years for an endpoint. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific.

The following options have been suggested by panellist feedback

☐	1-18 years
☐	4-18 years
☐	4-8 years

☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

15)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Toe Walking:

From panellist, feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures. Concerning body structure, passive ankle ROM was suggested to monitor any flexural contracture. Body function outcomes included kinematic, kinetic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns including heel and forefoot contact timing ankle ROM, Kinetic outcomes purposed in-shoe pressure measurements of heel and forefoot loading. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG.
QoL measures suggested by the panellists included pain rating and measures of ADL walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

16)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children who toe walk.

Duchenne Muscular Dystrophy
From the research stability footwear has been proposed as a clinical intervention for children with Duchenne Muscular Dystrophy (DMD). In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 11 of the 15 panellists 73% had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition please move to the next condition Question 22)

17)

Panellists were asked if DMD was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was "somewhat agreel" with the majority of responses between "neutral" and "strongly agree".

Panellist feedback suggested there was a dispersion of responses concerning the suitability of stability footwear for this condition. Some panellist felt there were no significant foot posture issues with DMD and if there were that foot orthoses were a more cost-effective measure. Whereas others felt it could help stabilise rearfoot and ankle motion in early stages and could be used in later stages if there was a loss of ankle range of motion or assist standing balance alongside other assistive aids (AFO). Some felt it may hinder walking in later stages due to muscle weakness and knee extension ability.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear should only be issued to children with DMD after a critical assessment of the child's mobility needs in respect to other assistive aids	☐	☐	☐	☐	☐	☐	☐

18)

Panellists were asked the degree of mobility impairment in children with DMD that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used as a sole aid or in combination with foot orthosis for foot and ankle instability in early ambulatory stage DMD (walks with some limitations to velocity and balance, can stair climb). In late ambulatory stage DMD, (Loss of ankle ROM, difficulty with walking distances and stair climbing) stability footwear may be used in combination with an AFO and walking frames to assist with mobility. In Early non-ambulatory DMD, (Mobility requires a wheelchair, but the child may still weight-bear for a limited time) stability footwear may be used with AFOs and standing frames to assist with standing and transfer tasks. The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with DMD suitable for stability footwear intervention; please rank your level of agreement.							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be used alongside foot orthoses to assist foot and ankle stability in early ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and walking frames to assist walking in late ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and standing frames to assist standing and transfer in early non ambulatory stages.	☐	☐	☐	☐	☐	☐	☐

19)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in DMD

Panellists feedback suggested a range of ages were stated varying from 1-5 for initiation and 9-18 for an endpoint. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than chronological. The following options have been suggested by panellist feedback

☐	1-18 years
☐	4-18 years
☐	4-9 years
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

20)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with DMD: From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures. Concerning body structure, passive ankle ROM was suggested to monitor any flexural contracture. Body function outcomes included kinematic, kinetic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns including heel and forefoot contact timing and ankle ROM, Kinetic outcomes purposed in-shoe pressure measurements of heel and forefoot loading. Spatiotemporal outcomes included increased walking velocity, 6MWT. Gross motor proficiency measures were suggested such as frequency of falls and the four square step test. QoL measures suggested by the panellists included pain rating and measures of ADL walking to school, shops, playparks and interaction with peers. The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Heel and forefoot contact timing, ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: four square step test	☐	☐	☐	☐	☐	☐	☐

Gross motor proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

21)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with DMD.

Spina Bifida
From the research stability footwear has been proposed as a clinical intervention for children with spinal bifida. In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 10 of the 15 panellists 66% had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition please move to the next condition Question 27)

22)

Panellists were asked if spina bifida (SB) was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " agree" with the majority of responses between "agree" and "strongly agree.
A Consensus was reached with respect to this condition being suitable for stability footwear intervention in Round 1

Panellist feedback suggested that although stability footwear was suitable for children with SB even with low-level spinal involvement other assistive aids would be required alongside stability footwear. Additionally, stability footwear would have to offer a range of dimensional measures to the last to accommodate foot deformity with underlying sensory neuropathy.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Stability footwear should only be issued to children with SB after a critical assessment of the child's mobility needs in respect to other assistive aids.	☐	☐	☐	☐	☐	☐	☐

23)

Panellists were asked the degree of mobility impairment in children with SB that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used with other assistive aids such as AFO's and Walking Frames to assist standing and walking for lumbar level 1-5 dysraphisms. In mild dysraphism at lumbar level 5, stability footwear used alongside foot orthoses may offer adequate mobility assistance.

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with SB suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used alongside foot orthoses to assist foot and ankle stability in mild level lumbar 5 vertebral involvement.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside AFO's and walking frames to assist walking and standing in lumbar 1-5 vertebral involvement.	☐	☐	☐	☐	☐	☐	☐

24)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in SB Panellists feedback suggested an age range 1-2 years for initiation and 18-21 years for an endpoint with assessment for adult need. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific. The following options have been suggested by panellist feedback	
☐	1-18 years (with assessed adult transition care)
☐	3-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

25)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear in children with Spina Bifida:

From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures. Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal biomechanical measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the Hoffer Ambulation Scale. Spatiotemporal outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor proficiency measures were also suggested including, motor milestones and Hoffer Ambulation Scale. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed. QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: (Hoffer Ambulation Score)	☐	☐	☐	☐	☐	☐	☐

Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with SB.

Down Syndrome
From the research stability footwear has been proposed as a clinical intervention for children with Down Syndrome. In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention 13 of the 15 panellists 87% had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition please move to the next condition Question 32)

27)

Panellists were asked if Down Syndrome was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " agree" with the majority of responses between "agree" and "strongly agree.
A consensus was reached in Round 1 with respect to this condition being suitable for stability footwear intervention.

Panellist feedback suggested that this footwear could assist the mediolateral stability of the foot and ankle due to low tone and hypermobility. This would aid gross motor skill acquisition and mobility in these children. Other panellist suggested only consider stability footwear if the child's foot dimensions were outside a standard last. There was also the discussion that stability footwear offer modular sizing to accommodate altered foot anthropometrics in these children.

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7

Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with Down syndrome	☐	☐	☐	☐	☐	☐	☐
Stability footwear design should consider last adaptions to accommodate the foot dimensions of children with Down syndrome	☐	☐	☐	☐	☐	☐	☐

28)

Panellists were asked the degree of mobility impairment in children with Down syndrome that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid.

Panellist feedback suggested that stability footwear may be used as a sole intervention in children with delayed motor skills alongside hypermobility and hypotonia in the pre-walking and early walking stages. If associated with ankle instability (tripping, falling) in older children use stability footwear to support foot orthoses interventions. If associated with knee instability stability footwear may be used to support AFO interventions

The following statements have been devised from panellist feedback in relation to the degree of mobility impairment in children with Down syndrome suitable for stability footwear intervention, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used	☐	☐	☐	☐	☐	☐	☐

alongside foot orthoses to assist walking in individuals with ankle instability							
Stability Footwear may be used alongside AFO's to assist walking in individuals with knee instability	☐	☐	☐	☐	☐	☐	☐

29)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in Down syndrome Panellists feedback suggested an age range 1-4 for initiation and 18 for an endpoint with ongoing assessment for adult need. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific. The following options have been suggested by panellist feedback	
☐	1-18 years (with assessed adult transition care)
☐	4-18 years (with assessed adult transition care)
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

30)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Down syndrome:

From panellist feedback outcomes were grouped into therapeutic goals alongside the World Health Organisation International Classification of Functioning Child and Youth version (WHO ICF-CY). These were goals based on body structures and function and those based on Quality of Life measures (QoL). Concerning body structure, passive ankle range of motion (ROM) was suggested to monitor any flexural contracture. The majority of outcomes were focused on body function. These included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait movement patterns using referenced scales such as the Edinburgh Gait Scale. Spatiotemporal outcomes included increased walking velocity, 6-minute walk test (6MWT) Timed Up and Go (TUG), stride length, and cadence. Gross motor proficiency measures were also suggested including, motor milestones and Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), frequency of falls was also suggested as a measure of the child's motor performance. Physiological outcomes such as perceived exertion measures (BORG) with motor tasks were also purposed.
QoL outcome measures suggested included pain rating and measures of activities of daily living (ADL) walking to school, shops, playparks and interaction with peers.

The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (foot and ankle)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increase Velocity, 6MWT	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL Comfort with Footwear	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

31)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with Down syndrome.

Intoeing
From the research stability footwear has been proposed as a clinical intervention for children with intoeing. In the questions below you will be presented with the collective opinion of panellists from Round 1 in relation to the suitability of stability footwear as a clinical intervention. 12 of the 15 panellists 80% had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition please move to Question 36)

32)

Panellists were asked if Intoeing was a suitable condition for stability footwear intervention in children and their reasoning for this.

The median level of agreement amongst the panellists was " somewhat disagree" with the majority of responses between "disagree" and "neutral".

Feedback form panellists suggested that intoeing was generally a skeletal rotational issue associated with typical development and stability footwear has no effect on the natural progression on this.
Panellist suggested that only significant cases of metatarsus adductus required footwear intervention and this was corrective footwear (reverse last and straight last) not stability footwear.
Some panellists suggested that if the intoeing was associated with a neuromuscular pathology or tripping stability footwear may be considered. (These indications were also the same as the suggested level of mobility impairment)

The following statements have been devised from panellist feedback in relation to the suitability of stability footwear for this condition, please rank your level of agreement.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may a suitable intervention for intoeing if associated with tripping	☐	☐	☐	☐	☐	☐	☐
Stability footwear may a suitable intervention for intoeing if associated with an underlying neurological condition	☐	☐	☐	☐	☐	☐	☐

33)

Panellists were asked the age range they felt this footwear intervention should be prescribed clinically for in Intoeing

The age range was only given by a limited number of panellist as the majority of panellists did not feel this condition was a suitable indication for stability footwear intervention.

3 years was given for the initiation of intervention. Other panellists suggested initiation and endpoints of treatment should be functionally based on the child's abilities and needs rather than age-specific.

☐	3 years onwards
☐	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked what clinical outcomes would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear in children with Intoeing:

From panellist feedback outcomes were grouped into therapeutic goals alongside the WHO ICF-CY. These were goals based on body structures and function and those based on QoL measures. Body function outcomes included kinematic and spatiotemporal measures. Kinematic outcomes suggested optimising or normalising gait patterns specifically Angle of Gait. Spatiotemporal outcomes included increased walking velocity, 6MWT and TUG, Motor skills proficiency was discussed in relation to the frequency of tripping. QoL measures suggested by the panellists included pain rating, perceived comfort with footwear and measures of activities of daily living (walking to school, shops, playparks and interaction with peers). The following outcomes have been suggested from panellist feedback please rank your agreement with these.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Angle of Gait)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: reduction in tripping	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

You may use this optional area if you wish to provide any further information on stability footwear intervention in children with intoeing.

Additional Conditions:

36)

	I have no clinical experience with this condition	Disagree	Neutral	Agree
Charcot Marie Tooth, Hereditary Motor Sensory Neuropathy	☐	☐	☐	☐

Hypermobility (Ehlers Danlos Type)	☐	☐	☐	☐
Developmental Coordination Disorder	☐	☐	☐	☐
Rett's Syndrome	☐	☐	☐	☐
Foetal Alcohol syndrome	☐	☐	☐	☐
Accessory navicular	☐	☐	☐	☐
Chronic lateral ankle instability	☐	☐	☐	☐

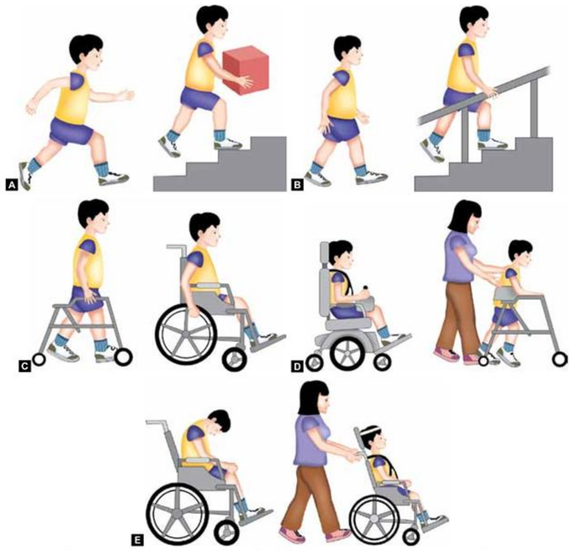
END OF SECTION 3 ROUND 2

Thank you for taking the time to complete section 3 of round 2. You have now completed all sections of round 2 of this Delphi survey. Your time and participation is greatly appreciated.
Remember to submit your answers before closing this form.

ROUND 3(S3) WHAT ARE CHILDREN'S CLINICAL FOOTWEAR INTERVENTIONS AND HOW TO PRESCRIBE THEM?

The third section will present yours and the panellists' collective choices and opinions from Round 2 on clinical protocols and outcomes for the provision of “off the shelf” stability footwear clinical interventions for children with mobility impairment.

Section 3



Opinion on prescription and clinical outcomes of "off the shelf" stability footwear clinical interventions for children with mobility impairment.

In this section, you will be presented with the collective preference (Median, relative frequency of response) and opinions of the panellists to the modified and original statements from round 1 and 2 of the survey concerning clinical protocols for the issuing of stability footwear as a sole assistive aid or in combination with other assistive aids (Ankle Foot Orthosis (AFO)*, walking frames) for children with mobility impairment, and the expected clinical outcomes of these footwear interventions.

* Please remember to qualify any abbreviation for mobility aids.

You will again be asked to give your preferential option or your level of agreement or non-agreement with them ("Strongly Disagree" to "Strongly Agree").
You can review the previous information you provided (in the document emailed to you), and considering the information provided by the other panellists, you may maintain your option or level of agreement with your chosen statement or change your opinion.

Full consensus for a statement is reached when a statement gains ≥75% of panellists with a level of agreement of "agree" or above, or ≥ 75% of panellists preferred option.

If you choose a level of agreement below "agree" we would ask that you provide us with the reason for your choice in the optional open-ended section provided.

Required Field*

1)

Name: *

Cerebral Palsy
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

2)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with Cerebral Palsy (CP) in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Purpose: Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with CP.
Median level of Agreement 6 (Agree)
7% "Somewhat Disagree", 7% "Neutral", 7% "Somewhat Agree", 36% "Agree", 43% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear may be used alongside other assistive aids to assist standing and walking in children with CP.
Median level of Agreement 7 ("Strongly Agree")
14% "Neutral", 29% "Agree", 57% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear should only be issued to children with CP after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications and with clear intervention outcomes.
Median level of Agreement 6 ("Agree")
14% "Neutral", 36% "Agree", 50% "Strongly Agree"
A consensus was reached for this statement.

Panellists feedback suggested there may be potential overlap between stability footwear and oversplint footwear, and that stability footwear was only to be issued to provide further stability and not just to accommodate the adjunct assistive aid such as an Ankle Foot Orthosis (AFO) or Knee Ankle Foot Orthosis (KAFO).

The following statement has been added based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear is only to be issued as an adjunct to AFO's KAFO's where additional medio-lateral stability is required, and not just to	☐	☐	☐	☐	☐	☐	☐

accommodate the orthotic.							

3)

Panellists were asked to rank their agreement with the following statements concerning the degree of mobility impairment in children with CP that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used as a sole assistive intervention to assist both foot and ankle stability in walking in children with Gross Motor Functioning Classification Score (GMFCS) 1 and no significant tonal issues.
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 7% "Neutral", 14% "Somewhat Agree", 43% "Agree", 29% "Strongly Agree"

Stability footwear may be used alongside other assistive aids to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues.
Median level of Agreement 6 ("Agree")
14% "Neutral", 7% "Somewhat Agree", 43% "Agree", 36% "Strongly Agree"
A consensus was reached for this statement.

Stability footwear may be used alongside other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4.
Median level of Agreement 6 ("Agree")
14% "Neutral", 14% "Somewhat Agree", 43% "Agree", 29% "Strongly Agree"

Panellists feedback suggested there was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been slightly modified based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive intervention to assist both foot and ankle stability in walking in children with GMFCS 1 and no significant tonal issues.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used simultaneously with other assistive aids to assist standing and transfer in non-ambulant	☐	☐	☐	☐	☐	☐	☐

children GMFCS 3-4. This footwear must be issued to assist stability and not just to accommodate the associated assistive aid							

4)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for CP in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).69%
Option 2, 1-18 years (with assessed adult transition care) 15%
Option 3, 3-18 years (with assessed adult transition care) 8%
Option 4, N/A I do not feel this condition is suitable for stability footwear intervention 8%

No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.

☐	Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2, 1-18 years (with assessed adult transition care)
☐	Option 3, 3-18 years (with assessed adult transition care)
☐	Option 4, N/A I do not feel this condition is suitable for stability footwear intervention.

5)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with CP in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Passive Ankle ROM
Median level of Agreement 6 ("Agree")
7% "Somewhat Disagree", 14% "Neutral", 22% "Somewhat Agree", 43% "Agree"
14% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Edinburgh Gait Scale)
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree"
A consensus was reached for this statement

Spatiotemporal: Increased walking velocity, 6 Minute Walk Test (6MWT), Timed Up and Go (TUG), stride length, cadence
Median level of Agreement 6 ("Agree")
14% "Somewhat Agree", 50% "Agree", 36% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency: Number of falls

Median level of Agreement 6 ("Agree")
14% "Neutral", 7% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 ("Agree")
14% "Neutral", 14% "Somewhat Agree", 50% "Agree", 22% "Strongly Agree"

Physiological: Perceived exertion (Borg)
Median level of Agreement 5 ("Somewhat Agree")
7% "Neutral", 43% "Somewhat Agree", 36% "Agree", 14% "Strongly Agree"

Quality of Life (QoL): Pain
Median level of Agreement 6 ("Agree")
7% "Neutral", 14% "Somewhat Agree", 50% "Agree", 29% "Strongly Agree"
A consensus was reached for this statement

QoL: Activities of Daily Living (ADL) (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 50% "Agree", 29% "Strongly Agree"
A consensus was reached for this statement

Panellist feedback suggested the following additional outcomes be included:
Passive Ankle Range of Motion (ROM) includes measures with the knee flexed and extended. Weight-bearing lunge may be used if the child can get the heel to ground in addition to passive Ankle ROM. Physiological cost index also to be considered. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐
Physiological: Perceived exertion (BORG)	☐	☐	☐	☐	☐	☐	☐
Physiological: Physiological Cost Index	☐	☐	☐	☐	☐	☐	☐

6)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with CP please use this optional area to provide us with your reasoning.

Pes Planus
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

7)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with mobile pes planus in Round 2. The median level of agreement and the relative distribution of response is detailed below. Suitability and Purpose Stability footwear may assist foot and ankle stability in children with symptomatic mobile pes planus Median level of Agreement 6 ("Agree") 7% "Disagree", 7% "Neutral", 7% "Somewhat Agree", 57% "Agree", 22% "Strongly Agree" A consensus was reached for this statement. Stability footwear is a suitable secondary line intervention for symptomatic mobile pes planus in children where foot orthoses have not resolved associated symptoms Median level of Agreement 7 ("Strongly Agree") 14% "Neutral", 29% "Agree", 57% "Strongly Agree" A consensus was reached for this statement.

8)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with pes planus that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2. The median level of agreement and the relative distribution of response is detailed below. Stability Footwear may be used alongside foot orthoses in children with insufficiency of posterior tibialis function. Median level of Agreement 6 ("Agree") 14% "Neutral", 14% "Somewhat Agree", 65% "Agree", 7% "Strongly Agree"   Stability Footwear may be used alongside foot orthoses in children with significant foot and ankle instability associated with tripping and falling. Median level of Agreement 6 ("Agree") 14% "Neutral", 7% "Somewhat Agree", 43% "Agree", 36% "Strongly Agree" A consensus was reached for this statement. Stability footwear may be used alongside foot orthoses in children with conditions associated with motor delay Median level of Agreement 6 ("Agree") 7% "Disagree", 29% "Somewhat Agree", 50% "Agree", 14% "Strongly Agree" There was also potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid. The following statements have been slightly modified based on panellist feedback. *

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree

	1	2	3	4	5	6	7
Stability Footwear may be used simultaneously with foot orthoses in children with insufficiency of posterior tibialis function.	☐	☐	☐	☐	☐	☐	☐
Stability footwear may be used simultaneously with foot orthoses in children with conditions associated with motor delay	☐	☐	☐	☐	☐	☐	☐

9)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for mobile pes planus in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).77%
Option 2, 1-18 years (with assessed adult transition care) 15%
Option 3, N/A I do not feel this condition is suitable for stability footwear intervention 8%
Option 4, 5-18 years (with assessed adult transition care) 0%

A consensus was reached to Option 1,

10)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with mobile pes planus in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Foot Posture FPI-6
Median level of Agreement 5 ("Somewhat Agree")
7% "Disagree", 7% "Somewhat Disagree", 22% "Neutral", 14% "Somewhat Agree", 36% "Agree", 14% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and ankle)
Median level of Agreement 6 ("Agree")
23% "Somewhat Agree", 62% "Agree", 15% "Strongly Agree"
A consensus was reached for this statement

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
7% "Neutral", 21% "Somewhat Agree", 36% "Agree", 36% "Strongly Agree"

Motor skill proficiency: Number of falls
Median level of Agreement 6 ("Agree")
29% "Somewhat Agree", 57% "Agree", 14% "Strongly Agree"

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 43% "Agree", 21% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 58% "Agree", 21% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 43% "Agree", 21% "Strongly Agree"

Panellist feedback suggested that the FPI-6 is a semi-quantitative description of foot posture and should not be considered as an outcome measure. Panellist suggested the following further outcomes to be included: Passive Ankle ROM including measures with the knee flexed and extended within the child's limits of knee extension. Weight-bearing lunge may also be used to measure ankle ROM if the child can get their heel to the ground. 10-meter walk test as a valid spatiotemporal measure. Physiological Cost Index also to be considered. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot Posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increase walking velocity, 6MWT, TUG 10 meter walk test	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency:	☐	☐	☐	☐	☐	☐	☐

Gross Motor Skills (BOT-2)							
Physiological: Physiological Cost Index	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Mobile Pes Planus please use this optional area to provide us with your reasoning.

Toe Walking
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (100%) panellists in Round 2 had clinical experience with this condition and provided the information for this section.

12)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with toe walking in Round 2.
The median level of agreement and relative distribution of response is detailed below.

Stability footwear may be a suitable treatment if used alongside other stiffened components (insole, sole) for ITW with no associated hypertonia
Median level of Agreement 6 ("Agree")
21% "Neutral", 21% "Somewhat Agree", 37% "Agree", 21% "Strongly Agree"

Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay
Median level of Agreement 6 ("Agree")
43% "Somewhat Agree", 29% "Agree", 28% "Strongly Agree"

Panellist feedback suggested better alternative assistive aids from their clinical experience with all cases of Idiopathic Toe Walking (ITW); such as Dynamic AFOs that inhibit plantarflexion and stimulate dorsiflexion offering more effective treatment than stiffened footwear, however, no specific feedback was given to inform modification of the statements.

Based on panellist feedback please rank your agreement with the following statements.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may	☐	☐	☐	☐	☐	☐	☐

be a suitable treatment if used simultaneously with other stiffened components (insole, stiffened sole) for ITW with no associated hypertonia							
Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay	☐	☐	☐	☐	☐	☐	☐

13)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility of impairment in children with toe walking that would be suitable for stability footwear, both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used alongside other stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position
Median level of Agreement 5 ("Somewhat Agree")
7% "Disagree", 14% "Neutral", 43% "Somewhat Agree", 22% "Agree", 14% "Strongly Agree".

Panellist feedback suggested stability footwear may cause issues with knee hyperextension if used in conjunction with AFO's and suggested their use only if gait requires mediolateral stability.

The following statements have been slightly modified based on panellist feedback.*

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used to provide mediolateral stability when used simultaneously with stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position	☐	☐	☐	☐	☐	☐	☐

14)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for toe walking in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).77%
Option 2, 4-8 years (15%)
Option 3, 4-18years (8%)
Option 4 1-18 years (0%)
Option 5 N/A I do not feel this condition is suitable for stability footwear intervention (0%)

A Consensus was reached for Option 1

15)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with toe walking in Round 2:
The median level of agreement and the relative distribution of response is detailed below.

Passive Ankle ROM
Median level of Agreement 6 ("Agree")
8% "Neutral", 38% "Somewhat Agree", 46% "Agree"
8% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and Ankle)
Median level of Agreement 6 ("Agree")
21% "Somewhat Agree", 36% "Agree", 43% "Strongly Agree"

Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)
Median level of Agreement 5 ("Somewhat Agree")
7% "Somewhat Disagree", 29% "Neutral", 21% "Somewhat Agree", 29% "Agree"
14% "Strongly Agree"

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
7% "Neutral", 29% "Somewhat Agree," 50% "Agree", 14% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 ("Agree")
14% "Somewhat Agree", 72% "Agree", 14% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
36% "Somewhat Agree", 50% "Agree", 14% "Strongly Agree"

Panellist feedback suggested modifications and additions to the outcomes.
The weight bearing lunge test to measure Ankle ROM in addition to Passive ROM in children who can get the heel to the floor. Consider adding 10-metre walk test as a valid spatiotemporal measure. Finally the addition of plantar callus patterns and sole wear patterns of the footwear. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing lunge provided child can get heel to ground	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	☐	☐	☐	☐	☐	☐	☐
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal Increased walking velocity, 6MWT, TUG 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

16)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Toe Walking please use this optional area to provide us with your reasoning.

Duchenne Muscular Dystrophy
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(93%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition, please move to the next condition)

17)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear for individuals with Duchenne Muscular Dystrophy (DMD) in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear should only be issued to children with DMD after a critical assessment of the child's mobility needs in respect to other assistive aids
Median level of Agreement 7 ("Strongly Agree")
8% "Neutral", 31% "Agree", 61% "Strongly Agree"
A consensus was reached for this statement.

18)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with DMD that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability Footwear may be used alongside foot orthoses to assist foot and ankle stability in early ambulatory stages.
Median level of Agreement 6 ("Agree")
8% "Neutral", 23% "Somewhat Agree", 54% "Agree", 15% "Strongly Agree"

Stability Footwear may be used alongside AFO's and walking frames to assist walking in late ambulatory stages.
Median level of agreement 6 ("Agree")
15% "Somewhat Disagree", 23% "Somewhat Agree", 54% "Agree", 8% "Strongly Agree"

Stability Footwear may be used simultaneously with AFO's and standing frames to assist standing and transfer in early non-ambulatory stages.
Median level of Agreement 5 ("Somewhat Agree")
15% "Somewhat Disagree", 8% "Neutral", 31% "Somewhat Agree", 31% "Agree", 15% "Strongly Agree"

Panellist feedback indicated there was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been slightly modified based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability Footwear may be used simultaneously with foot orthoses to assist foot and ankle stability in early ambulatory stages.	☐	☐	☐	☐	☐	☐	☐

Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking in late ambulatory stages.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with AFO's and standing frames to assist standing and transfer in early non ambulatory stages.	☐	☐	☐	☐	☐	☐	☐

19)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention DMD in Round 2. The relative distribution of response is detailed below. Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).68% Option 2, 1-18 years 8% Option 3, 4-9 years 8% Option 4, 4-18 years 8% Option 5, N/A I do not feel this condition is suitable for stability footwear intervention 8% No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.

☐	Option1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)
☐	Option 2, 1-18 years
☐	Option 3, 4-9 years
☐	Option 4, 4-18 years
☐	Option 5, N/A I do not feel this condition is suitable for stability footwear intervention.

20)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with DMD in Round 2: The median level of agreement and the relative distribution of response is detailed below. Passive Ankle ROM Median level of Agreement 5 ("Somewhat Agree") 8% "Somewhat Disagree", 8% "Neutral", 61% "Somewhat Agree", 15% "Agree" 8% Strongly Agree

Kinematics: Optimising gait movement patterns (Foot and Ankle)
Median level of Agreement 6 ("Agree")
23% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement.

Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)
Median level of Agreement 5 ("Somewhat Agree")
8% "Somewhat Disagree", 16% "Neutral", 30% "Somewhat Agree", 30% "Agree"
16% "Strongly Agree"

Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence
Median level of Agreement 6 ("Agree")
8% "Neutral", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Gross motor proficiency: four square step test
Median level of Agreement 6 ("Agree")
15% "Neutral", 31% "Somewhat Agree", 46% "Agree", 8% "Strongly Agree"

Gross motor proficiency: Number of falls
Median level of Agreement 6 ("Agree")
8% "Neutral", 15% "Somewhat Agree", 69% "Agree", 8% "Strongly Agree"
A consensus was reached for this statement

QoL: Pain
Median level of Agreement 6 ("Agree")
8% "Neutral", 8% "Somewhat Agree", 76% "Agree", 8% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 ("Agree")
15% "Somewhat Agree", 70% "Agree", 15% "Strongly Agree"
A consensus was reached for this statement

Panellist feedback suggested the following modifications to the outcomes.
Use weight bearing lunge test to measure Ankle ROM in addition to Passive ROM in children who can get their heel to the floor. Consider adding the 10-meter walk test as a valid spatiotemporal measure. A pragmatic point was raised in relation to degenerative conditions and outcomes, in that they need to consider the stage of the condition in light of the capability of the child to perform the tasks required. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Passive Ankle ROM measured with knee flexed and extended within child's limits	☐	☐	☐	☐	☐	☐	☐
Ankle ROM Weight Bearing	☐	☐	☐	☐	☐	☐	☐

lunge provided child can get heel to ground							
Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: four square step test	☐	☐	☐	☐	☐	☐	☐
Outcomes for a degenerative condition must consider the stage of the condition and the capability of the child to perform the tasks.	☐	☐	☐	☐	☐	☐	☐

21)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with DMD please use this optional area to provide us with your reasoning.

Spina Bifida
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (86%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition, please move to the next condition)

22)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Spina Bifida (SB) from Round 2. The median level of agreement and the relative distribution of response is detailed below. Stability footwear should only be issued to children with SB after a critical assessment of the child's mobility needs in respect to other assistive aids. Median level of Agreement 6 ("Agree")

8% "Neutral", 42% "Agree", 50% "Strongly Agree" A consensus was reached for this statement.

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with SB that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be used alongside foot orthoses to assist foot and ankle stability in mild level lumbar 5 vertebral involvement.
Median level of Agreement 5 ("Somewhat Agree")
8% "Strongly disagree", 42% "Somewhat Agree", "50% Agree",

Stability Footwear may be used alongside AFO's and walking frames to assist walking and standing in lumbar 1-5 vertebral involvement.
Median level of agreement 6 ("Agree")
8% "Strongly disagree", 8% "Somewhat Disagree", 26% "Somewhat Agree", 50% "Agree", 8% "Strongly Agree"

Panellist feedback suggested the recommendations should consider actual severity of dysraphism as well as spinal level (Occulta, Meningocele, Myelomeningocele) and incorporate assistive aid recommendations from 'Orthoses for Myelomeningocele' in the Atlas of Orthoses and Assistive Devices, 2019. L1-3 level lesions would need Hip Knee Ankle Foot Orthosis (HKAFO) or Knee Ankle Foot Orthoses (KAFO) to be able to stand/walk. Level L4-5 lesions would walk with AFOs and S1 walk without AFO.

There was potential ambiguity with the term "alongside"; panellists questioned did this mean stability footwear was to be used at different times or simultaneously with the other assistive aid.

The following statements have been modified and developed based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used simultaneously with foot orthoses to assist foot and ankle stability in sacral level 1 (Meningocele).	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking and standing in lumbar level 4-5 (Meningocele, Myelomeningocele).	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used simultaneously with HKAFO or KAFO and walking frames to assist walking and standing in lumbar	☐	☐	☐	☐	☐	☐	☐

level 1-3 (Meningocele, Myelomeningocele).							

24)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for SB in Round 2. The relative distribution of response is detailed below. Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (73%) Option 2, 1-18 years (with assessed adult transition care) (18%) Option 3, 4-18 years (with assessed adult transition care) (9%) Option 4, N/A I do not feel this condition is suitable for stability footwear intervention (0%) No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.

☐	Option 1 Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2, 1-18 years (with assessed adult transition care)
☐	Option 3, 4-18 years (with assessed adult transition care)
☐	Option 4, N/A I do not feel this condition is suitable for stability footwear intervention.

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with SB in Round 2: The median level of agreement and the relative distribution of response is detailed below. Kinematics: Optimising gait movement patterns (Hoffer Ambulation Scale) Median level of Agreement 6 ("Agree") 18% "Neutral" 9% "Somewhat Agree", 64% "Agree", 9% "Strongly Agree" Spatiotemporal: Increased walking velocity, 6MWT, TUG, Median level of Agreement 6 ("Agree") 9% "Somewhat Agree", 82% "Agree", 9% "Strongly Agree" A consensus was reached for this statement Motor skill proficiency: Hoffer Ambulation Score Median level of Agreement 6 ("Agree") 9% "Neutral", 9% "Somewhat Agree", 73% "Agree", 9% "Strongly Agree" A consensus was reached for this statement Physiological Perceived exertion (BORG) Median level of Agreement 6 ("Agree") 9% "Neutral", 82% "Agree", 9% "Strongly Agree" A consensus was reached for this statement QoL: Pain Median level of Agreement 6 ("Agree") 9% "Somewhat Agree", 82% "Agree", 9% "Strongly Agree" A consensus was reached for this statement QoL: ADL (daily mobility and social interaction) Median level of Agreement 6 ("Agree") 18% "Somewhat Agree", 73% "Agree", 9% "Strongly Agree" A consensus was reached for this statement

No specific panellist feedback was given to inform any further modification of the outcomes for SB. However, you may consider the distribution of the panel's response to either change or maintain your previous level of agreement with the following outcome.							
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	☐	☐	☐	☐	☐	☐	☐

25)

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with SB please use this optional area to provide us with your reasoning.

Down Syndrome
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition. (93%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section. (If you have no clinical experience in treating this condition, please move to the next condition)

27)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Down Syndrome from Round 2. The median level of agreement and the relative distribution of response is detailed below. Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with Down syndrome Median level of Agreement 6 ("Agree") 15% "Somewhat Agree", 62% "Agree", 23% "Strongly Agree" A consensus was reached for this statement. Stability footwear design should consider last adaptions to accommodate the foot dimensions of children with Down syndrome Median level of Agreement 6 (Agree) 8% "Neutral", 42% "Agree", 50% "Strongly Agree"

A consensus was reached for this statement.

28)

Panellists were asked to rank their agreement with the following statements concerning the grade of mobility impairment in children with Down Syndrome that would be suitable for stability footwear both as a sole aid or in combination with another assistive aid in Round 2.
The median level of agreement and relative distribution of response is detailed below.

Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.
Median level of Agreement 6 (Agree)
8% "Strongly disagree", 42% "Somewhat Agree", 50% "Agree",

Stability Footwear may be used alongside foot orthoses to assist walking in individuals with ankle instability
Median level of agreement 6 (Agree)
8% "Somewhat Agree", 69% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Stability Footwear may be used alongside foot orthoses to assist walking in individuals with knee instability
Median level of agreement 6 (Agree)
8% "Strongly disagree", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Although consensus was reached in respect to knee instability and the use of stability footwear a potential adverse event was elaborated from panellist feedback in that associated knee hyperextension would contraindicate stiffened sole therapy in combination with AFO, as this would increase hyperextension in midstance,

The following statements have been modified and developed based on panellist feedback

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones.	☐	☐	☐	☐	☐	☐	☐
Stability Footwear may be used alongside foot orthoses to assist walking in individuals with ankle instability	☐	☐	☐	☐	☐	☐	☐
Stability Footwear with a stiffened sole is contraindicated with	☐	☐	☐	☐	☐	☐	☐

simultaneous AFO use in individuals with knee hyperextension.							

29)

Panellists were presented with the following options in relation to the suitable age range for stability footwear intervention for Down Syndrome in Round 2.
The relative distribution of response is detailed below.

Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (77%)
Option 2, 1-18 years (with assessed adult transition care) (15%)
Option 3, 4-18 years (with assessed adult transition care) (8%)
Option 4, N/A I do not feel this condition is suitable for stability footwear intervention (0%)

A consensus was reached for Option 1

30)

Panellists were asked to rank their agreement with the following statements in relation to the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with Down Syndrome in Round 2:
The median level of agreement and relative distribution of response is detailed below.

Foot Posture FPI-6
Median level of Agreement 5 (Somewhat Agree)
8% "Disagree", 15% "Somewhat Disagree", 15% "Neutral", 23% "Somewhat Agree", 31% "Agree", 8% "Strongly Agree"

Kinematics: Optimising gait movement patterns (Foot and ankle)
Median level of Agreement 6 (Agree)
8% "Somewhat Disagree", 23% "Somewhat Agree", 46% "Agree", 23% Strongly Agree

Spatiotemporal: Increased walking velocity, 6MWT,
Median level of Agreement 6 (Agree)
8% "Neutral", 15% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement.

Gross Motor skill proficiency: Number of falls
Median level of Agreement 6 (Agree)
8% "Neutral", 8% "Somewhat Agree", 61% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

Motor skill proficiency:
Gross Motor Skills (BOT-2)
Median level of Agreement 6 (Agree)
31% "Somewhat Agree", 61% "Agree", 8% "Strongly Agree"

QoL: Pain
Median level of Agreement 6 (Agree)
8% "Somewhat Agree", 69% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

QoL: Comfort with Footwear
Median level of Agreement 6 (Agree)
23% "Somewhat Agree", 54% "Agree", 23% "Strongly Agree"
A consensus was reached for this statement

QoL: ADL (daily mobility and social interaction)
Median level of Agreement 6 (Agree)
15% "Somewhat Agree", 62% "Agree", 23% "Strongly Agree"
A consensus was reached with this statement.

Panellist feedback suggested that the FPI-6 is a semi-quantitative description of foot posture and should not be considered as an outcome measure. Panellist suggested adding 10-meter walk test as a valid spatiotemporal measure. No specific panellist feedback was given to inform further modification of the other outcomes that did not reach consensus. However, you may consider the distribution of the panel's response to either change or maintain your previous choice.

Please rank your agreement with the following outcomes.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Foot posture FPI-6	☐	☐	☐	☐	☐	☐	☐
Kinematics: Optimising gait movement patterns (foot and ankle)	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal 10-meter walk test	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: number of falls	☐	☐	☐	☐	☐	☐	☐
Motor skill proficiency: Gross Motor Skills (BOT-2)	☐	☐	☐	☐	☐	☐	☐

31)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Down Syndrome please use this optional area to provide us with your reasoning.

Intoeing
In the questions below you will be presented with the collective choices and opinions from Round 2 concerning suggested protocols and measurable outcomes of stability footwear as a clinical intervention for this condition.

(86%) of panellists in Round 2 had clinical experience with this condition and provided the information for this section.

(If you have no clinical experience in treating this condition, please move to the next condition)

32)

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Intoeing from Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be a suitable intervention for in-toeing if associated with tripping
Median level of Agreement 4 (Neutral)
17% "Disagree", 17% "Somewhat Disagree", 41% "Neutral", 8% "Somewhat Agree", 17% "Agree",

Stability footwear may be a suitable intervention for in-toeing if associated with an underlying neurological condition
Median level of Agreement 4 (Neutral)
8% "Disagree", 8% "Somewhat Disagree", 26% "Neutral", 17% "Somewhat Agree", 33% "Agree",
8% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of the statements. However, you may consider the distribution of the panel's response to either change or maintain your previous level of agreement with the following statements.

Panellists were asked to rank their agreement with the following statements concerning the issuing of stability footwear children with Intoeing from Round 2.
The median level of agreement and the relative distribution of response is detailed below.

Stability footwear may be a suitable intervention for in-toeing if associated with tripping
Median level of Agreement 4 (Neutral)
17% "Disagree", 17% "Somewhat Disagree", 41% "Neutral", 8% "Somewhat Agree", 17% "Agree",

Stability footwear may be a suitable intervention for in-toeing if associated with an underlying neurological condition
Median level of Agreement 4 (Neutral)
8% "Disagree", 8% "Somewhat Disagree", 26% "Neutral", 17% "Somewhat Agree", 33% "Agree",
8% "Strongly Agree"

No specific panellist feedback was given to inform any further modification of the statements. However, you may consider the distribution of the panel's response to either change or maintain your previous level of agreement with the following statements.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Stability footwear may a suitable intervention for intoeing if associated with tripping	☐	☐	☐	☐	☐	☐	☐
Stability footwear may a suitable	☐	☐	☐	☐	☐	☐	☐

intervention for intoeing if associated with an underlying neurological condition							

33)

Panellists were presented with the following options concerning the suitable age range for stability footwear intervention for intoeing in Round 2. The relative distribution of response is detailed below. Option 1, Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual). (73%) Option 2, N/A I do not feel this condition is suitable for stability footwear intervention (27%) Option 3, 3 years onwards (0%) No specific panellist feedback was given to inform any further modification of these options. However, you may consider the distribution of the panel's response to either change or maintain your previous option.

☐	Option 1 Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).
☐	Option 2 N/A I do not feel this condition is suitable for stability footwear intervention.

10)

Panellists were asked to rank their agreement with the following statements concerning the clinical outcomes that would be used to evaluate the effectiveness of "Off the Shelf" Stability footwear for children with intoeing in Round 2: The median level of agreement and the relative distribution of response is detailed below. Kinematics: Optimising gait movement patterns (Angle of Gait) Median level of Agreement 5 (Somewhat Agree) 18% "Neutral", 37% "Somewhat Agree", 37% Agree, 8% Strongly Agree Spatiotemporal: Increased walking velocity, 6MWT, TUG2 Median level of Agreement 5 (Somewhat Agree) 46% "Neutral", 18% "Somewhat Agree", 27% "Agree", 9% "Strongly Agree" Gross Motor skill proficiency: Number of falls Median level of Agreement 6 (Agree) 36% "Somewhat Agree", 46% "Agree", 18% "Strongly Agree" QoL: Pain Median level of Agreement 6 (Somewhat Agree) 27% "Neutral" 27% "Somewhat Agree", 46% "Agree" QoL: ADL (daily mobility and social interaction) Median level of Agreement 6 (Agree) 46% "Somewhat Agree", 46% "Agree", 8% "Strongly Agree" There was minimal feedback in relation to modifying the outcomes, other than the suggestion that standing Foot Progression Angle (Fick Angle) may be compared with foot progression angle in gait. No specific panellist feedback was given to inform further modification of the other outcomes. However, you may consider the distribution of the panel's response to either change or maintain your previous choice. Please rank your agreement with the following outcomes

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	1	2	3	4	5	6	7
Kinematics: Optimising gait movement patterns (Angle of Gait). Comparison of standing foot progression angle with walking foot progression angle .	☐	☐	☐	☐	☐	☐	☐
Spatiotemporal: Increased walking velocity, 6MWT, TUG	☐	☐	☐	☐	☐	☐	☐
Gross motor proficiency: reduction in tripping	☐	☐	☐	☐	☐	☐	☐
QoL: Pain	☐	☐	☐	☐	☐	☐	☐
QoL: ADL (daily mobility and social interaction)	☐	☐	☐	☐	☐	☐	☐

11)

If your level of agreement was "somewhat agree" or lower for any of the statements in relation to stability footwear intervention in children with Intoeing please use this optional area to provide us with your reasoning.

Additional Conditions:
A number of additional conditions were presented to the panellists in Round 2 based on suggestions made from panel members in Round 1.
Panellists were asked if they agreed with the suitability of stability footwear as an assistive aid for the suggested conditions.
The relative distribution of responses are detailed below,

(Panellists who had no clinical experience of the condition were discounted from the frequency calculation)

Charcot Marie Tooth, Hereditary Motor Sensory Neuropathy
Agree 92%, Neutral 0%, Disagree 8%

A consensus was reached for this statement

Hypermobility (Ehlers Danlos Type)
Agree 92%, Neutral 8%, Disagree 0%
A consensus was reached for this statement

Developmental Coordination Disorder
Agree 100%, Neutral 0%, Disagree 0%
A consensus was reached for this statement

Rett's Syndrome
Agree 80%, Neutral 0%, Disagree 20%
A consensus was reached for this statement

Foetal Alcohol Syndrome
Agree 50%, Neutral 0%, Disagree 50%

Accessory navicular
Agree 31%, Neutral 46%, Disagree 23%

Chronic lateral ankle instability
Agree 77%, Neutral 15%, Disagree 8%
A consensus was reached for this statement

Concerning the conditions below concerning their suitability for stability footwear clinical intervention.

36)

	I have no clinical experience with this condition	Disagree	Neutral	Agree
Foetal Alcohol syndrome	☐	☐	☐	☐
Accessory navicular	☐	☐	☐	☐

END OF SECTION 3 ROUND 3

Thank you for taking the time to complete section 3 of round 2. You have now completed all sections of round 2 of this Delphi survey. Your time and participation is greatly appreciated.
Remember to submit your answers before closing this form.

4.4. Complete Results Section 1 Rounds 1-3 Consensus Terms, Definitions and Grouping of Children's Footwear Interventions

Section 1						
Term, Definition, Grouping, Method of Grouping	Round 1		Round 2		Round 3	
Standard overall terminology to be used for clinical footwear interventions for children with mobility impairment		% Frequency of ≥Agree		Relative % Frequency		Relative %Frequency
	"Therapeutic Footwear"	66.67%	Therapeutic Footwear (Term from Round 1)	58.82	Therapeutic Footwear (Term from Round 1)	81.25
			Orthotic Footwear	23.53	Orthotic Footwear	18.75
			Orthopaedic Footwear	5.88	Orthopaedic Footwear	0
			Prescriptive Footwear	11.76	Prescriptive Footwear	0
			Other	0		
Overall Definition for Children's		% Frequency of ≥Agree		Relative % Frequency		

Clinical Footwear Interventions	“Footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.”	50%	Original Round 1 “Footwear that is designed specifically with the purpose to support or alleviate mobility impairment in childhood.”	5.88		
			Modified Round 2 "Footwear that is designed or adapted specifically to protect, support, align, prevent, or correct foot deformity, or to assist mobility and standing in children."	82.35		
			Other	11.76		
Method to Group and Categorise		% Frequency of ≥Agree		Relative % Frequency		% Frequency of ≥Agree

Children's Clinical Footwear Interventions	"Footwear for clinical interventions in childhood is categorised into groupings dependent on their intended therapeutic role."	72.22%	Original Round 1 "Footwear for clinical interventions in childhood is categorised into groupings dependent on their intended therapeutic role."	17.65	Modified Round 3 "Footwear used as a clinical intervention in childhood should be classified by the intended outcomes of its components."	100%
			Modified Round 2 "Footwear used as a clinical intervention in childhood should be classified via the intended therapeutic outcomes of its components."	70.59		
			Other	11.76		
Grouping and Definition		% Frequency of ≥Agree		Relative % Frequency	**Although Consensus reached in Round 2 a number of panellists requested addendum to the statement**	

"Corrective Footwear"	"Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."	44.44%	Original Round 1 "Corrective footwear is children's therapeutic footwear that is designed to bring about the correction of congenital skeletal lower limb alignment."	0	Modified Round 3 "Corrective footwear is footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children. This may be secondary to a primary corrective measure such as serial casting or surgery."	Relative % Frequency
			Modified Round 2 "Corrective footwear is children's therapeutic footwear that is designed or adapted to support correction of congenital or acquired foot and ankle deformity in children."	82.35	Yes: I agree to Round 3 Modified Statement	100
			Other	17.65	No: I don't agree to Round 3 Modified Statement	0

Grouping and Definition of "Accommodative Footwear"		% Frequency of ≥Agree		Relative % Frequency	
	"Accommodative footwear is children's therapeutic footwear that is designed (modular or bespoke) to reduce compression, and shearing stresses on children's foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child's foot."	72.22%	Original Round 1 "Accommodative footwear is children's therapeutic footwear that is designed (modular or bespoke) to reduce compression, and shearing stresses on children's foot deformities through dimensional matching of footwear upper, insole, and sole to that of the child's foot."	11.76	

			Modified Round 2 "Accommodative footwear is children's therapeutic footwear that is designed to prevent deterioration of children's foot deformities through the dimensional matching of the footwear to the child's foot."	76.47	
			Other	11.76	
Grouping and Definition		% Frequency of ≥Agree		Relative % Frequency	

"Functional Footwear"	"Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns."	55.50%	Original Round 1 "Functional footwear is children's therapeutic footwear that is designed to improve dynamic gait parameters of children with mobility impairment, reducing pathological movements and facilitating typical childhood walking patterns."	11.76	
			Modified Round 2 "Functional footwear is children's therapeutic footwear that is designed or adapted to directly assist mobility and	76.47	

			standing in children."		
			Other	11.76	
Method to subgroup and categorise Functional Footwear		% Frequency of ≥Agree		Relative % Frequency	
	"Functional therapeutic footwear is divided into subgroupings which are categorised dependent on the design and functional role."	66.67%	Original Round 1 "Functional therapeutic footwear is divided into subgroupings which are categorised dependent on the design and functional role."	11.76	

			Modified Round 2 "Functional therapeutic footwear should be classified via its design and the intended therapeutic outcomes of its components."	76.47		
			Other	11.76		
Subgrouping and Definition "Stability Footwear"		% Frequency of ≥Agree		Relative % Frequency		% Frequency of ≥Agree
	"Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of	50%	Original Round 1 "Stability functional therapeutic footwear is a range of footwear that is designed to limit extreme movements of the lower limb to maintain a controlled displacement of the centre of force during gait."	11.76	Modified Round 3 "Stability Footwear is footwear that is designed to assist mobility and standing in children by influencing movements and potentially proprioception of the foot and ankle."	93.75%

	force during gait."		Modified Round 2 "Stability therapeutic footwear is a range of footwear that is designed to assist mobility and standing in children by enhancing proprioception and influencing movements of the foot and ankle."	64.71		
			Other	23.53		
Sub-Grouping and Definition "Lift Footwear"		% Frequency of ≥Agree	From Panellist opinion **Lift "Raised"* Footwear**, **Rounded Bottom "Rocker Sole"* Footwear** and **Instability Footwear,** to collectively fall under new subgrouping "**Adapted Sole**" †			

	"Lift functional therapeutic footwear is a range of footwear designed with a unilateral modular outer or midsole addition to conservatively achieve postural and functional symmetry in individuals with limb length inequality."	38.89%	* Panellists' preferred term from Round 1 content analysis
Sub-Grouping and Definition "Rounded		% Frequency of ≥Agree	

Bottom (Rocker Sole)"	"Rounded bottom (rocker sole) is a range of functional therapeutic footwear with a forefoot rocker design to assist the sagittal plane progression of the lower limb."	33.33%			
Grouping and Definition "Instability"	"Instability therapeutic functional footwear consists of a sole designed to promote imbalance to train the individuals motor coordination."	% Frequency of ≥Agree 38.89%			
Sub-Grouping "Adapted Sole"†	**N/A see comment †**		**Sub-Grouping**	% Frequency of ≥Agree	
			"Adapted Sole"	76.47%	

Definition "Adapted Sole"†		Definition	% Frequency of ≥Agree		% Frequency of ≥Agree
		"A range of customised sole adaptions to standard retail or children's therapeutic footwear that would assist mobility or standing in children. "	64.71%	Modified Round 3 "A range of customised sole or heel adaptions to any suitable children's footwear, with the adaptions designed to assist mobility or standing in children.'	100%

Text in Red Indicates: Consensus Statement ≥75% Relative Frequency ≥75% Panel ≥Agree

4.5. Complete Results Section 2 Rounds 1-3 Consensus design characteristics of “off the shelf” Stability clinical footwear interventions

Section 2					
Area of Footwear	Round 1		Round 2		Round 3
Topline	Design Characteristic "Topline Extension"	% Frequency of ≥Agree	Design Characteristic "Topline Extension"	Relative %Frequency	
	"Extended topline height above the ankle"	58.82	Original Round1 “Extended topline height above the ankle"	6.67	

			Modified Round 2: "The topline extension should come in an optional range both above and below the ankle dependent on the patient's ability and needs."	93.33		
			Modified Round 2: "The topline should not be extended above the ankle"	0.00		
			Purpose of Design "Topline Extension"	% Frequency of ≥Agree	**Purpose of Design "Topline Extension"**	% Frequency of ≥Agree
			"An extended topline height increases proprioception input at the rearfoot and ankle"	40.67	Modified Round 3: "An extended topline height may increase proprioception input at the rearfoot and ankle. "	68.75
			"An extended topline height assists heel counter leverage to resist frontal plane movement of the rearfoot and ankle "	53.33	Modified Round 3: "An extended topline height may assist heel counter leverage to resist frontal plane movement of the rearfoot and ankle."	81.25

			Adverse Effect of Design: Topline Extension	% Frequency of ≥Agree	**Adverse Effect of Design: Topline Extension**	% Frequency of ≥Agree
			"An extended topline height may reduce sagittal plane power generation at the ankle."	33.33	Original Round 2: "An extended topline height may reduce sagittal plane power generation at the ankle."	62.50
	Design Characteristic "Collar Material "	% Frequency of ≥Agree	**Design Characteristic "Collar Material"**	% Frequency of ≥Agree	**Design Characteristic "Collar Material"**	% Frequency of ≥Agree
	"Topline Should have a padded Collar"	88.40				
			"The foam padded collar should be covered with low shear material."	66.67	Original Round 2 "The foam padded collar should be covered with low shear material."	68.75
			Purpose of Design "Collar Material"	% Frequency of ≥Agree	**Purpose of Design "Collar Material"**	% Frequency of ≥Agree
			Foam Padding reduces compression to lower limb anatomy from an extended topline height	53.33	Modified Round 3: "Foam Padding may reduce compression to lower limb anatomy from an extended topline height."	81.25

	Design Characteristic "Collar Contouring "	% Frequency of ≥Agree	Design characteristic "Collar Contouring "	Relative %Frequency		
	"Topline Collar should be contoured to the supra or infra malleoli region dependent on topline height"	76.47				
	"Topline should have a Collar contoured to the Achilles tendon"	70.59	Original Round 1: "Topline should have a Collar contoured to the Achilles tendon"	80.00		
			Modified Round2: "Collar contoured to Achilles tendon is not a desired design characteristic."	20.00		
			Purpose of Design "Collar Contouring "	% Frequency of ≥Agree	**Purpose of Design "Collar Contouring "**	% Frequency of ≥Agree
			"Contouring of topline reduces shear and compression stress to the ankle region"	60.00	Modified Round 3: "Contouring of topline may reduce shear and compression stress to the ankle region."	93.75
			"Contouring the collar to the Achilles tendon reduces shear and	60.00	Modified Round 3: "Contouring the collar to the Achilles tendon may	81.25

			compression to the tendon."		reduce shear and compression to" the tendon.	
	Design Characteristic “Collar Pull Tab "	% Frequency of ≥Agree	**Design Characteristic “Collar Pull Tab "**	Relative %Frequency	**Design Characteristic “Collar Pull Tab "**	Relative %Frequency
	"Topline should have a Pull tab to back of collar"	52.94	Original Round 1: "Topline should have a Pull tab to back of collar"	53.33	Original Round 1: Topline should have a Pull tab to back of collar	75.00
			Modified Round 2: "Pull tab to back of collar is not a desired design characteristic"	46.67	Original Round 2:Pull tab to back of collar is not a desired design characteristic	25.00
			Purpose of Design "Collar Pull Tab "	% Frequency of ≥Agree	**Purpose of Design "Collar Pull Tab "**	% Frequency of ≥Agree
			A collar pull tab aids the child in donning the shoe	33.33	Modified Round 3: A collar pull tab may aid the child or those offering assistance in donning the stability shoe	75.00
Upper	**Design Characteristic “Upper material"**	% Frequency of ≥Agree	**Design Characteristic “Upper material"**	Relative %Frequency		
	"The Upper should be constructed of leather"	52.94	Original Round 1: "Upper should be constructed of leather"	0.00		

			Modified Round 2: "Optional range of upper material to include; leather, breathable material and wipeable material"	100.00		
			Purpose of Design "Upper material"	% Frequency of ≥Agree	**Purpose of Design "Upper material"**	% Frequency of ≥Agree
			"Leather adapts to foot structures over time"	73.33	Modified Round 3: "Leather may adapt to foot structures over time dependent on the tensile strength of the leather."	93.25
			"Leather enhances material stiffness of the footwear"	53.33	Modified Round 3:"Leather may enhance material stiffness of the footwear dependent on the tensile strength of the leather."	93.25
	Design Characteristic "Tongue Extension"	% Frequency of ≥Agree	**Design Characteristic "Tongue Extension"**	Relative %Frequency	**Design Characteristic "Tongue Extension"**	Relative %Frequency
	"Tongue in line with topline"	47.06	Original Round 1" Tongue in line with topline"	0.00		

	"Tongue extended above topline"	47.06	Original Round 1" Tongue extended above topline"	33.33	Original Round 1" Tongue extended above topline"	6.25
			Modified Round 2 "Tongue length optional dependent on patient's preference and manual dexterity "	66.67	Original Round 2 "Tongue length optional dependent on patient's preference and manual dexterity "	95.75
			Purpose of Design" Tongue Extension"	% Frequency of ≥Agree	**Purpose of Design" Tongue Extension"**	% Frequency of ≥Agree
			"Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle"	33.33	Original Round 2 "Tongue in line with topline is to minimise irritation to the anterior aspect of the ankle"	62.50
			"Tongue extended above topline allows for comfort with lacing"	60.00	Original Round 2 "Tongue extended above topline allows for comfort with lacing"	81.25
			"Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear'	60.00	Original Round 2 "Tongue extended above topline allows the wearer to minimise slippage of the tongue under the fastenings during wear'	81.25

			Design Characteristic “Tongue Loop"	% Frequency of ≥Agree		
			"Slit or loop in tongue for fastening to minimise tongue slippage"	86.67		
			Design Characteristic “High Topped Sandals"	% Frequency of ≥Agree	**Design Characteristic “High Topped Sandals"**	% Frequency of ≥Agree
			"High topped sandals to be offered as an option for stability footwear ranges for warm weather"	53.33	Original Round 2 "High topped sandals to be offered as an option for stability footwear ranges for warm weather"	81.25
			Design Characteristic “Internal Seams"	% Frequency of ≥Agree		
			"Ergonomic consideration of internal seams to reduce skin irritation"	100.00		
Fastenings and Facings	**Design Characteristic “Fastenings" The fastening should have the following characteristics:**	Relative %Frequency	**Design Characteristic “Fastenings" The fastening should have the following characteristics:**	Relative %Frequency		
	Velcro	23.53	Original Round 1 Lace	0.00		

	Lace	5.88	Original Round 1 "Velcro"	6.67		
	No Preference	17.65	Original Round 1 "No Preference"	0.00		
	Other	52.94	"Optional dependent on patient's ability and desired goal (e.g. Velcro for limited hand dexterity, lace for greater stability)"	93.33		
			Purpose of Design " Fastening"	% Frequency of ≥Agree	**Purpose of Design " Fastening"**	% Frequency of ≥Agree
			Velcro fastenings: Assists independence with limited hand dexterity in donning and doffing	93.33		
			"lace fastenings: Enhances stability through potential firmer grip to contours of the foot"	73.33	Original Round 2: "lace fastenings: Enhances stability through potential firmer grip to the contours of the foot"	81.25
			Design Characteristic “Fastening Side Zip"	% Frequency of ≥Agree	Design Characteristic “Fastening Side Zip"	% Frequency of ≥Agree
			"Side zip lace combination fastening"	60.00	Original Round 2 "Side zip lace combination fastening"	68.75

	Design Characteristic “Facing Extension" The facings should have the following characteristics:	Relative %Frequency	**Design Characteristic “Facing Extension" The facings should have the following characteristics:**	Relative %Frequency		
	Facings extended to just behind the toe box	47.06	Original Round 1 "Facings extended to just behind the toe box"	6.67		
	Facings extended to the midfoot	17.65	Original Round 1"Facings extended to the midfoot"	0.00		
	No Preference	11.76	Original Round 1 "No Preference"	0.00		
	Other	23.53	Optional dependent on patient's foot and ankle mobility or therapeutic goal (i.e., facings extended to toe box for ease of foot and ankle access, extended to midfoot for greater upper stability)	93.33		
			Purpose of Design "Facing Extension"	% Frequency of ≥Agree	**Purpose of Design "Facing Extension"**	% Frequency of ≥Agree
			"Facings extended to just behind the toe box allows greater access	93.33		

			into the footwear for the child with limited foot and ankle range of motion"			
			"Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle."	53.33	Original Round 1: "Facing extended to the midfoot allows the upper to offer greater stability to the foot and ankle."	87.50
			Design Characteristic "Facings"	**% Frequency of ≥Agree**		
			"The gap between facings should allow an adequate range of fastening adjustment."	86.67		
Heel Counter	**Design Characteristic "Heel Counter Extension"**	% Frequency of ≥Agree	**Design Characteristic "Heel Counter Extension"**	Relative %Frequency		
	"Heel counter/stiffener extended to midfoot"	70.59	Modified Round 2:"Heel counter/stiffener extended to the midfoot only"	13.33		
	"Heel counter/stiffener height extended towards topline."	47.06	Modified Round 2: "Heel counter/stiffener extended towards the topline only"	0.00		

			Modified Round 2: "Heel counter stiffener, extended to the midfoot and towards topline"	6.67		
			Modified Round 2: "Optional range of heel counter extensions dependent on therapeutic need and the patient's foot and ankle anatomy"	80.00		
			Purpose of Design "Heel Counter Extension"	% Frequency of ≥Agree	**Purpose of Design "Heel Counter Extension"**	% Frequency of ≥Agree
			"Heel counter/stiffener extensions can enhance proprioception at the foot and ankle"	33.33	Modified Round 3: "Heel counter/stiffener extensions may enhance proprioception at the foot and ankle."	68.75
			"Heel counter/stiffener extension offers material stiffness to restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile."	53.33	Modified Round 3: "Heel counter/stiffener extension offers material stiffness that may restrict frontal plane movements at the foot, ankle and midfoot dependent on the extension profile."	81.25

					Design Characteristic “Heel Counter"	% Frequency of ≥Agree
					"Control of frontal plane movements of the foot and ankle at the heel counter area should also consider vertical ground reaction force contact area, through close contact between the plantar surface of the child's heel and the inner sole of the shoe. "	87.50%
Heel	**Design Characteristic “Heel Width" The heel should have the following characteristics:**	Relative %Frequency	**Design Characteristic “Heel Width" The heel should have the following characteristics:**	Relative %Frequency	**Design Characteristic “Heel Width" The heel should have the following characteristics:**	Relative %Frequency
	"Heel width in line with heel counter width"	23.53	Original Round 1:"Heel width in line with heel counter width"	0		
	"Heel width extended wider than heel counter width"	47.06	Original Round 1: Heel width extended wider than heel counter width	40.00	Original Round 1: "Heel width extended wider than heel counter width"	25
	"No preference"	17.65	Original Round 1: "No preference"	6.67	Original Round 1 "No preference"	0

	"Other"	11.76	Modified Round 2: Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam.	53.33	Original Round 2: "Heel width extensions should be provided as an optional sole adaption with the heel width extension on standard stability footwear being no wider than the welted seam."	75
			Purpose of Design "Heel Width"	% Frequency of ≥Agree		
			" Heel width extensions assist medial-lateral stability of the foot and ankle through an increased base of support"	86.67		
			Design Characteristic "Heel Pitch"	% Frequency of ≥Agree		
			"Heel Pitch should not increase ankle instability"	86.67		
			"Heel pitch should allow for adjunct orthotic therapy"	93.33		

Inlay / Insock/ Insole	Design Characteristic: "Removable Inlay"	% Frequency of ≥Agree	Design Characteristic: "Removable Inlay"	% Frequency of ≥Agree		
	"Stability footwear should come with a standard removable inlay."	88.23	"Removable Inlay should be thick enough to allow for a potential prescriptive foot orthoses."	100		
	Design Characteristic: "Insole Contouring"	% Frequency of ≥Agree	**Design Characteristic: "Insole Contouring"**	Relative %Frequency	**Design Characteristic: "Insole Contouring"**	Relative %Frequency
	"The inlay should be contoured to simulate the medial longitudinal arch. "	23.52	Original Round 1: "The inlay should be contoured to simulate the medial longitudinal arch"	13.33	Modified Round 3 "The inlay should be appropriately contoured to the medial longitudinal arch"	6.25
			Modified Round 2:"The inlay should be contoured to cup the heel but not the medial longitudinal arch"	33.33	Modified Round 3 "The inlay should cup the child's heel to improve rearfoot fit but not be contoured to the medial longitudinal arch"	31.25
			Modified Round 2 "The inlay should be contoured to simulate the medial longitudinal arch and to cup the heel"	53.33	Modified Round 3 "The inlay should cup the child's heel to improve rearfoot fit and be appropriately contoured	62.50

					to the medial longitudinal arch"	
			Purpose of Design “Insole Contouring"	% Frequency of ≥Agree	**Purpose of Design “Insole Contouring"**	% Frequency of ≥Agree
			"An inlay contoured to cup the heel improves rearfoot fitting"	47.67	Modified Round 3 "An inlay contoured to cup the heel improves rearfoot fitting of the child's foot to the shoe"	81.25
Outsole	**Design Characteristic “Tread"**	% Frequency of ≥Agree	**Design Characteristic “Tread"**	Relative %Frequency		
	"Outsole should have a deepened tread"	35.29	Original Round 1 "Outsole should have a deepened tread"	13.33		
			Modified Round 2 "The tread depth should come in an optional range dependent (on the ability of the child and the environment where the footwear is to be used.)"	86.67		
	Design Characteristic “Material"	% Frequency of ≥Agree	**Design Characteristic “Material"**	Relative %Frequency		

	"Outsole should be made of hard-wearing material"	64.72	Original Round 1: Outsole should be made hard-wearing material"	13.33	
			Modified Round 2 "Optional wear resilience of the sole material dependent on the age and ability of the patient."	86.67	
			Purpose of Design "Material"	% Frequency of ≥Agree	
			"Hard wearing sole material will prolong the stability effect of the footwear by resisting wear patterns associated with gait pathologies."	86.67	
	Design Characteristic "Flexibility" Degree of flexibility Ranked , 10 Firm - 1 Flexible	Relative %Frequency	**Design Characteristic "Flexibility"**	Relative %Frequency	

	10	5.88	The Degree of Flexibility of the Sole Unit: "The sole unit should come in a range of sole stiffness dependent on the patient's ability or the therapeutic goals, with flexibility of the sole focused at the MPJ area"	100		
	9-8	0				
	7	41.18				
	6	23.53				
	5	23.53				
	4-2	0				
	1	5.88	Other	0		
			Design Characteristic “Regional Stiffness of Outsole"	% Frequency of ≥Agree	**Design Characteristic “Regional Stiffness of Outsole"**	% Frequency of ≥Agree
			"The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions."	46.67	Original Round 2: "The sole unit should be stiffer at the midfoot and rearfoot to assist stability in these regions."	87.5
			Design Characteristic “Regional Dimensions of Outsole"	% Frequency of ≥Agree	**Design Characteristic “Regional Dimensions of Outsole"**	% Frequency of ≥Agree

			"Rearfoot to Forefoot width of the sole unit kept to lowest practical ratio to assist medial-lateral stability"	46.67	Modified Round 3 "The ground contact area ratio between the rearfoot and forefoot of the sole unit should be kept to the lowest practical ratio to assist medial-lateral stability"	93.75
Toe Spring Sole Rocker	**Design Characteristic "Forefoot Rocker"**	% Frequency of ≥Agree	**Design Characteristic "Forefoot Rocker"**	Relative %Frequency	**Design Characteristic "Forefoot Rocker"**	Relative %Frequency
	"Stability footwear should have a reasonable forefoot rocker. "	52.94	Original Round 1:"Stability footwear should have a reasonable forefoot rocker."	26.67	Modified Round 3: Stability footwear should have a reasonable forefoot rocker as a standard design. With forefoot rocker adaption prescriptions available to meet patient's needs.	56.25
			Modified Round 2 "Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole."	73.33	Original Round 2: "Stability footwear should come in a range of forefoot rockers dependent on the patient's condition and the stiffness of the sole."	43.75

			Design Characteristic "Forefoot Rocker"	% Frequency of ≥Agree	
			forefoot rocker: "Should allow adequate ground clearance in swing"	93.33	
			Purpose of Design "Forefoot Rocker"	% Frequency of ≥Agree	
			Forefoot rocker: "Should facilitate forward progression in terminal stance without impacting on stability"	93.33	
	Design Characteristic “Heel Rocker"	% Frequency of ≥Agree	**Design Characteristic “Heel Rocker"**	Relative %Frequency	
	"Stability footwear should have a heel rocker."	11.76	Original Round 1: "Stability footwear should have a heel rocker"	0	
			Modified Round 2: "Heel rockers should be offered as a sole adaption prescription dependent on the child's condition rather than a	100	

<table>
<tr><td></td><td></td><td></td><td>standard design of stability footwear."</td><td></td><td colspan="2"></td></tr>
<tr><td rowspan="6">Mass of Footwear</td><td>Design Characteristic “Mass of Footwear"</td><td>% Frequency of ≥Agree</td><td>Design Characteristic “Mass of Footwear"</td><td>% Frequency of ≥Agree</td><td>Design Characteristic “Mass of Footwear"</td><td>% Frequency of ≥Agree</td></tr>
<tr><td rowspan="3">"The weight of the stability footwear is an important consideration when issuing footwear to children with mobility impairment"</td><td rowspan="3">82.35</td><td colspan="4"></td></tr>
<tr><td>"The mass of the shoe should be dependent on the mass and age of the child."</td><td>66.67</td><td>Original Round 2 "The mass of the shoe should be dependent on the mass and age of the child."</td><td>93.75</td></tr>
<tr><td>"The mass of the shoe should be dependent on the child's stability needs."</td><td>80</td><td colspan="2"></td></tr>
<tr><td colspan="2" rowspan="2"></td><td>Purpose of Design "Mass of Footwear"</td><td>% Frequency of ≥Agree</td><td>Purpose of Design "Mass of Footwear"</td><td>% Frequency of ≥Agree</td></tr>
<tr><td>"Stability footwear should be the lowest reasonable mass to</td><td>66.67</td><td>Original Round 2: "Stability footwear should be the lowest reasonable mass to</td><td>100</td></tr>
</table>

		reduce physiological cost during mobility."		reduce physiological cost during mobility."	
		"Increased mass: Assist stability in stance"	40	Original Round 2: increased mass: Assist stability in stance	68.75
		"Increased mass: Assists pendular motion in swing"	26.67	Original Round 2: "increased mass Assists pendular motion in swing"	68.75
				Adverse Effect "Increased Mass of Footwear"	% Frequency of ≥Agree
				"Increased mass of the shoe may lead to difficulty in swing phase with ground clearance, navigating obstacles and stair climbing."	87.5
Other Considerations		**Design Characteristic "Last Dimensions"**	% Frequency of ≥Agree		
		"Children's stability footwear should be available in a range of last dimensions to accommodate different foot types."	93.33		

		Design Characteristic "Aesthetics"	% Frequency of ≥Agree	
		"Children's Stability footwear should come in a range of colours and styles to appeal to children's aesthetics."	100	

Text in Red Indicates: Consensus Statement ≥75% Relative Frequency ≥75% Panel ≥Agree

4.6. Complete Results Section 3 Rounds 1-3: Consensus Prescription Criteria and Outcomes for Off the shelf stability footwear clinical interventions

Section 3				
Condition	Round 1		Round 2	Round 3
Cerebral Palsy	**Suitability for Intervention**	% Frequency of ≥Agree		
	"Cerebral palsy is suitable for stability footwear intervention?"	92.31		

		Criteria for Treatment	% Frequency of ≥Agree	Criteria for Treatment	% Frequency of ≥Agree
		"Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with CP."	78.57		
		"Stability footwear may be used alongside other assistive aids to assist standing and walking in children with CP."	85.71		
		"Stability footwear should only be issued to children with CP after a critical assessment of the child's mobility needs in respect to other assistive aids or footwear modifications, and with clear intervention outcomes."	85.71		

		"Stability footwear may be used as a sole assistive intervention to assist both foot and ankle walking stability in children with GMFCS 1 and no significant tonal issues."	71.43	Original Round 2 "Stability footwear may be used as a sole assistive intervention to assist both foot and ankle stability in walking in children with GMFCS 1 and no significant tonal issues."	81.25
		"Stability footwear may be used alongside other assistive aids to assist walking and standing in ambulant children GMFCS 1-3 with tonal issues."	78.57		
		"Stability footwear may be used alongside other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4."	71.43	Modified Round 3: "Stability footwear may be used simultaneously with other assistive aids to assist standing and transfer in non-ambulant children GMFCS 3-4. This footwear must be issued to assist stability and not just to accommodate the associated assistive aid"	87.50

				"Stability footwear is only to be issued as an adjunct to AFO's KAFO's where additional medio-lateral stability is required, and not just to accommodate the orthotic. "	68.75
		Age Range for Stability Footwear Intervention	Relative %Frequency	**Age Range for Stability Footwear Intervention**	Relative %Frequency
		1-18 years (with assessed adult transition care)	15.38	1-18 years (with assessed adult transition care)	6.25
		3-18 years (with assessed adult transition care)	7.69	3-18 years (with assessed adult transition care)	0.00
		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)	69.23	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)	87.50
		N/A I do not feel this condition is suitable for stability footwear intervention	7.69	N/A I do not feel this condition is suitable for stability footwear intervention	6.25
		Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree
		Passive Ankle ROM	57.15	Modified Round 3: Passive Ankle ROM measured with knee flexed and extended within child's limits	87.50

					Ankle ROM Weight Bearing lunge provided child can get heel to ground	87.50
			Kinematics: Optimising gait movement patterns (Edinburgh Gait Scale)	78.57		
			Spatiotemporal: Increased walking velocity, 6MWT, TUG, stride length, cadence	85.71		
			Motor skill proficiency: Number of falls	78.57		
			Motor skill proficiency: Gross Motor Skills (BOT-2)	71.43	Motor skill proficiency: Gross Motor Skills (BOT-2)	75.00
			Physiological: Perceived exertion (Borg)	50.00	Physiological: Perceived exertion (Borg)	75.00
					Physiological: Physiological Cost Index	81.25
			QoL: Pain	78.57		
			QoL: ADL (daily mobility and social interaction)	78.57		
Pes planus	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree		
	"Pes planus is suitable for stability footwear intervention?"	46.67	"Stability footwear is a suitable secondary line intervention for symptomatic mobile pes planus in children where foot orthoses have not	85.72		

			resolved associated symptoms"			
			Criteria for Treatment	% Frequency of ≥Agree	**Criteria for Treatment**	% Frequency of ≥Agree
			"Stability footwear may assist foot and ankle stability in children with symptomatic mobile pes planus"	78.57		
			"Stability Footwear may be used alongside foot orthoses in children with insufficiency of posterior tibialis function."	71.43	Modified Round 3: "Stability Footwear may be used simultaneously with foot orthoses in children with insufficiency of posterior tibialis function."	87.50
			"Stability Footwear may be used alongside foot orthoses in children with significant foot and ankle instability associated with tripping and falling."	85.72		
			"Stability footwear may be used alongside foot orthoses in children with conditions associated with motor delay"	64.29	Modified Round 3: Stability footwear may be used simultaneously with foot orthoses in children with	93.75

				conditions associated with motor delay	
		Age Range for Stability Footwear Intervention	Relative %Frequency		
		1-18 years (with assessed adult transition care)	15.38		
		5-18 years (with assessed adult transition care)	0.00		
		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).	76.92		
		N/A I do not feel this condition is suitable for stability footwear intervention.	7.69		
		Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree
		Foot Posture FPI-6	50.00	Foot Posture FPI-6	62.50
				Passive Ankle ROM measured with knee flexed and extended within child's limits	80.00

					Ankle ROM Weight Bearing lunge provided child can get heel to ground	87.50
			Kinematics: Optimising gait movement patterns (Foot and ankle)	76.92		
			Spatiotemporal: Increase walking velocity, 6MWT, TUG	71.42	Modified Round 2: Spatiotemporal: Increase walking velocity, 6MWT, TUG 10 meter walk test.	87.50
			Gross motor proficiency: (BOT-2)	64.29	Gross motor proficiency: (BOT-2)	75.00
			Gross motor proficiency: number of falls	71.42	Motor skill proficiency: Number of falls	87.50
					Physiological: Physiological Cost Index	75.00
			QoL: Pain	78.57		
			QoL: ADL (daily mobility and social interaction)	64.29	QoL: ADL (daily mobility and social interaction)	100.00
Toe Walking	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree
	"Toe walking is suitable for stability footwear intervention?"	26.67	"Stability footwear may be a suitable treatment if used alongside other stiffened components (insole, stiffened sole) for ITW with no associated hypertonia"	57.14	Modified Round 3 "Stability footwear may be a suitable treatment if used simultaneously with other stiffened components (insole,	60.00

					stiffened sole) for ITW with no associated hypertonia"	
			Criteria for Treatment	% Frequency of ≥Agree	**Criteria for Treatment**	% Frequency of ≥Agree
			"Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay"	57.14	Original Round 2 "Stability footwear may be used for toe walking in developmental conditions with hypermobility and gross motor delay"	66.67
			"Stability footwear may be used alongside other stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position"	35.72	Modified Round 3 "Stability footwear may be used to provide mediolateral stability when used simultaneously with stiffened components for ITW Type 1-2, when the child is able to achieve a plantargrade position"	66.67
			Age Range for Stability Footwear Intervention	Relative %Frequency		
			1-18 years	0.00		
			4-18 years	7.69		
			4-8 years	15.38		

		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)	76.92		
		N/A I do not feel this condition is suitable for stability footwear intervention.	0.00		
		Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree
		Passive Ankle ROM2	53.84	Modified Round 3: Passive Ankle ROM measured with knee flexed and extended within child's limits	66.67
				Ankle ROM Weight Bearing lunge provided child can get heel to ground	73.33
		Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	57.14	Kinematics: Optimising gait movement patterns (Heel forefoot contact timing ankle ROM)	80.00
		Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	42.86	Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	60.00
		Spatiotemporal Increased walking velocity, 6MWT, TUG	64.29	Modified Round 3: Spatiotemporal Increased	80.00

					walking velocity, 6MWT, TUG, 10-metre walk test	
			QoL: Pain	85.72		
			QoL: ADL (daily mobility and social interaction)	64.29	QoL: ADL (daily mobility and social interaction)	86.67
					Callus and outer sole wear patterns	66.67
Duchenne Muscular Dystrophy	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree		
	Duchenne muscular dystrophy is suitable for stability footwear intervention?	54.54	"Stability footwear should only be issued to children with DMD after a critical assessment of the child's mobility needs in respect to other assistive aids"	92.31		
			Criteria for Treatment	% Frequency of ≥Agree	**Criteria for Treatment**	% Frequency of ≥Agree
			"Stability Footwear may be used alongside foot orthoses to assist foot and ankle stability in early ambulatory stages"	69.23	Modified Round 3: "Stability Footwear may be used simultaneously with foot orthoses to assist foot and ankle stability in early ambulatory stages."	87.50

		"Stability Footwear may be used alongside AFO's and walking frames to assist walking in late ambulatory stages."	61.54	Modified Round 3 "Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking in late ambulatory stages."	87.50
		"Stability Footwear may be used alongside AFO's and standing frames to assist standing and transfer in early non ambulatory stages."	66.25	Modified Round 3 "Stability Footwear may be used simultaneously with AFO's and standing frames to assist standing and transfer in early non ambulatory stages."	87.50
		Age Range for Stability Footwear Intervention	Relative %Frequency	**Age Range for Stability Footwear Intervention**	Relative %Frequency
		1-18 years	7.69	1-18 years	6.25
		4-9 years	7.69	4-9 years	0.00
		4-18 years	7.69	4-18 years	0.00
		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)	69.23	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual)	87.50
		N/A I do not feel this condition is suitable for stability footwear intervention.	7.69	N/A I do not feel this condition is suitable for stability footwear intervention.	6.25
		Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree

		Passive ankle ROM	69.23	Modified Round 3: Passive Ankle ROM measured with knee flexed and extended within child's limits	68.75
				Ankle ROM Weight Bearing lunge provided child can get heel to ground	81.25
		Kinematics: Optimising gait movement patterns (Heel and forefoot contact timing, ankle ROM)	76.93		
		Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	46.15	Kinetic: In-shoe pressure measurement (Heel and Forefoot loading)	62.50
		Spatiotemporal Increased walking velocity, 6MWT	76.93		
				Spatiotemporal: 10-metre walk test	75.00
		Gross motor proficiency: four square step test	53.84	Gross motor proficiency: four square step test	81.25
		Gross motor proficiency: Number of falls	76.93		
		QoL Pain	84.61		
		QoL ADL (daily mobility and social interaction)	84.61		

					"Outcomes for a degenerative condition must consider the stage of the condition and the capability of the child to perform the tasks."	87.50
Spina Bifida	**Suitability for Intervention**	% Frequency of ≥Agree				
	Spina bifida is suitable for stability footwear intervention?	80				
			Criteria for Treatment	% Frequency of ≥Agree	**Criteria for Treatment**	% Frequency of ≥Agree
			"Stability footwear should only be issued to children with SB after a critical assessment of the child's mobility needs in respect to other assistive aids."	91.67		
			"Stability footwear may be used alongside foot orthoses to assist foot and ankle stability in mild level lumbar 5 vertebral involvement."	50.00	Modified Round 3: "Stability footwear may be used simultaneously with foot orthoses to assist foot and	87.50

				ankle stability in sacral level 1 (Meningocele)"	
		"Stability Footwear may be used alongside AFO's and walking frames to assist walking and standing in lumbar 1-5 vertebral involvement."	58.33	Modified Round 3 "Stability Footwear may be used simultaneously with AFO's and walking frames to assist walking and standing in lumbar level 4-5 (Meningocele, Myelomeningocele)."	87.50
				Modified Round 3 "Stability Footwear may be used simultaneously with HKAFO or KAFO and walking frames to assist walking and standing in lumbar level 1-3 (Meningocele, Myelomeningocele)."	81.25
		Age Range for Stability Footwear Intervention	Relative %Frequency	**Age Range for Stability Footwear Intervention**	Relative %Frequency
		1-18 years (with assessed adult transition care)	18.18	1-18 years (with assessed adult transition care)	6.25
		4-18 years (with assessed adult transition care)	9.09	4-18 years (with assessed adult transition care)	0.00
		Initiation and end points of treatment indicated by functional ability and the	72.73	Initiation and end points of treatment indicated by functional ability and the	93.75

			mobility needs of the child (potential or actual).		mobility needs of the child (potential or actual).	
			N/A I do not feel this condition is suitable for stability footwear intervention.	0.00	N/A I do not feel this condition is suitable for stability footwear intervention.	0.00
			Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree
			Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	72.73	Kinematics: Optimising gait movement patterns (Hoffer Ambulation scale)	87.50
			Spatiotemporal: Increased walking velocity, 6MWT, TUG	90.91		
			Gross motor proficiency: (Hoffer Ambulation Score)	81.82		
			Physiological Perceived exertion (Borg)	90.91		
			QoL: Pain	90.91		
			QoL ADL (daily mobility and social interaction)	90.91		
Down Syndrome	**Suitability for Intervention**	% Frequency of ≥Agree				

	Down syndrome is suitable for stability footwear intervention?	84.62				
			Criteria for Treatment	% Frequency of ≥Agree	**Criteria for Treatment**	% Frequency of ≥Agree
			"Stability footwear may assist mediolateral stability and proprioception of the foot and ankle in standing and walking in children with Down syndrome"	84.62		
			"Stability footwear design should consider last adaptions to accommodate the foot dimensions of children with Down syndrome"	84.62		
			"Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones."	53.84	Original Round 2 "Stability footwear may be used as a sole assistive aid in pre-walking and learning to walk stages with associated hypotonia and delayed motor milestones."	93.75
			"Stability Footwear may be used alongside foot orthoses	92.31		

		to assist walking in individuals with ankle instability"			
		Stability Footwear may be used alongside AFO's to assist walking in individuals with knee instability	76.92	Addendum to Consensus Statement Round 2 "Stability Footwear with a stiffened sole is contraindicated with simultaneous AFO use in individuals with knee hyperextension."	62.50
		Age Range for Stability Footwear Intervention	Relative %Frequency		
		1-18 years (with assessed adult transition care)	15.38		
		4-18 years (with assessed adult transition care)	7.69		
		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual) rather than specific age.	76.92		
		N/A I do not feel this condition is suitable for stability footwear intervention.	0.00		

			Outcomes	% Frequency of ≥Agree	Outcomes	% Frequency of ≥Agree
			Foot posture FPI-6	38.43	Foot posture FPI-6	50.00
			Kinematics: Optimising gait movement patterns (foot and ankle)	69.23	Kinematics: Optimising gait movement patterns (foot and ankle)	87.50
			Spatiotemporal Increase Velocity, 6MWT	76.92		
					Spatiotemporal: 10 Metre Walk Test	81.25
			Gross motor proficiency: (BOT-2)	69.23	Gross motor proficiency: (BOT-2)	75.00
			Gross motor proficiency: number of falls	84.62		
			QoL Pain	92.31		
			QoL Comfort with Footwear	76.92		
			QoL ADL (daily mobility and social interaction)	84.62		
Intoeing	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree	**Suitability for Intervention**	% Frequency of ≥Agree
	Intoeing is suitable for stability footwear intervention?	8.33	"Stability footwear may be a suitable intervention for intoeing if associated with tripping"	16.67	Original Round 2: "Stability footwear may be a suitable intervention for intoeing if associated with tripping"	25.00

		"Stability footwear may be a suitable intervention for intoeing if associated with an underlying neurological condition"	41.67	Original Round 2: "Stability footwear may be a suitable intervention for intoeing if associated with an underlying neurological condition"	43.75
		Age Range for Stability Footwear Intervention	Relative %Frequency	**Age Range for Stability Footwear Intervention**	Relative %Frequency
		3 years onwards	0.00		
		Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).	72.73	Initiation and end points of treatment indicated by functional ability and the mobility needs of the child (potential or actual).	81.25
		N/A I do not feel this condition is suitable for stability footwear intervention.	27.27	N/A I do not feel this condition is suitable for stability footwear intervention.	18.75
		Outcomes	% Frequency of ≥Agree	**Outcomes**	% Frequency of ≥Agree
		Kinematics: Optimising gait movement patterns (Angle of Gait)	45.45	Modified Round 3: Kinematics: Optimising gait movement patterns (Angle of Gait). Comparison of standing foot progression angle with walking foot progression	62.50
		Spatiotemporal: Increased walking velocity, 6MWT, TUG	36.36	Spatiotemporal: Increased walking velocity, 6MWT, TUG	56.25

		Gross motor proficiency: reduction in tripping	63.63	Gross motor proficiency: reduction in tripping	68.75
		QoL: Pain	45.45	QoL: Pain	75.00
		QoL ADL (daily mobility and social interaction)	54.54	QoL ADL (daily mobility and social interaction)	75.00
Other Conditions		**Suitable for Stability Footwear Intervention**	Relative %Frequency	**Suitable for Stability Footwear Intervention**	Relative %Frequency
		Charcot Marie Tooth, (Hereditary Motor Sensory Neuropathy)			
		Agree	92.31		
		Neutral	0.00		
		Disagree	7.69		
		Hypermobility (Ehlers Danlos Type)			
		Agree	92.31		
		Neutral	7.69		
		Disagree	0.00		
		Developmental Coordination Disorder			
		Agree	100.00		
		Neutral	0.00		
		Disagree	0.00		
		Rett's Syndrome			
		Agree	80.00		
		Neutral	20.00		

		Disagree	0.00		
		Foetal Alcohol syndrome		**Foetal Alcohol syndrome**	
		Agree	50.00	Agree	44.44
		Neutral	50.00	Neutral	55.56
		Disagree	0.00	Disagree	0.00
		Accessory navicular		**Accessory navicular**	
		Agree	30.77	Agree	50.00
		Neutral	46.15	Neutral	31.25
		Disagree	23.08	Disagree	18.75
		Chronic lateral ankle instability			
		Agree	76.92		
		Neutral	15.38		
		Disagree	7.69		

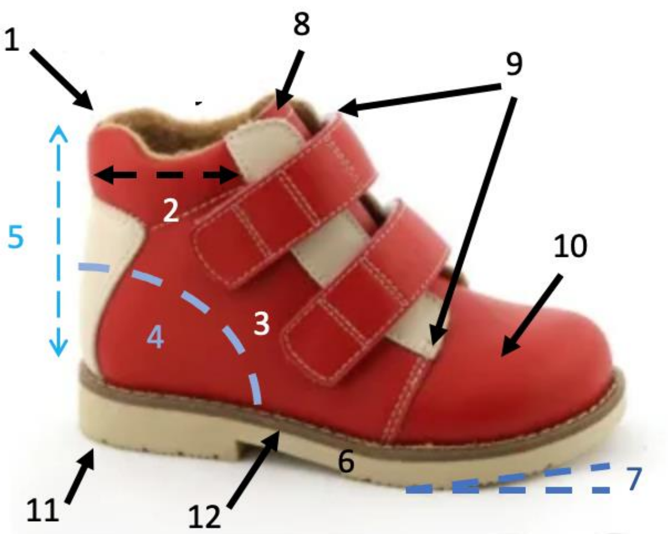
Text in Red Indicates: Consensus Statement ≥75% Relative Frequency ≥75% Panel ≥Agree

5. Chapter 8

5.1. Footwear tool user manual

Children's "Off-the-Shelf" Stability Therapeutic Footwear (OSSTF) Assessment Tool Manual.

The following manual will guide the clinician in using the accompanying footwear survey tool to assess and rate any given children's off-the-shelf stability therapeutic footwear (OSSTF) for its suitability as an assistive aid for children living with a mobility impairment. The tool is based on consensus expert criteria and validated by mechanical testing of OSSTF design (Hill et al., 2021). The tool will ask the clinician to assess the various components of the footwear against **ergonomic** and **stability** criteria. A higher score for each criterion indicates that the shoe offers more ergonomic features or greater stability, respectfully. A glossary of the various terms used in the tool and manual is found in figure 1.



1. **Topline**
2. **Collar**
3. **Upper**
4. **Heel counter/ stiffener**
5. **Topline height**
6. **Outersole**
7. **Toe spring**
8. **Tongue**
9. **Fastenings & Facings**
10. **Forefoot of shoe / Toe box**
11. **Heel**
12. **Midfoot / Waist of shoe**

Figure 1 Glossary of stability therapeutic footwear components

<u>Ergonomic Criteria</u>
Component Topline:

Question E1

Does the topline of the OSSTF have a padded collar, as seen in figure 2(A) (Result A Yes), or an unpadded collar, as seen in figure 2(B) (Result B No)

Figure 2(A) Padded Collar   Figure 2(B) Unpadded Collar

Question E2

Is the topline of the OSSTF contoured around the areas of the tibia and fibula, as seen in figure 3(A) (Result A Yes), or flat, as seen in figure 3(B) (Result B No)

Figure 3 (A) Tibia and fibula contoured topline; (B) No contour to the topline

Question E3

Is the topline of the OSSTF contoured around the areas of the Achilles tendon, as seen in figure 4(A) (Result A Yes), or flat, as seen in figure 4(B) (Result B No)

Figure 4 (A) Contour to the Achilles Tendon 4(B) No contour to the Achilles Tendon

Question E4

At the back of the collar, is there a pull tab to allow the child or parent to pull on the shoes, as seen in figure 5(A) (Result A Yes), or no pull tab, as seen in figure 5(B) (Result B No)

Figure 5 (A) Pull tab to the back of the collar (B) No pull tab to the back of the collar

Component Outsole:
Toe spring / Forefoot flexibility

Question E5
The following instructions to assess the flexibility of the toe spring and forefoot of the outsole are adapted from Williams et al. 2022 (C. M. Williams, Morrison, et al., 2022). With one hand, hold the outsole at the rearfoot and with the other hand, hold outsole at the forefoot. Now with your hand at the forefoot, try to bend it upwards as in Figure 6 (A-B). Note the change in angle caused by bending should be estimated from the resting toe spring angle, which may vary from shoe to shoe (figure 7).

1. When the outersole can bend an estimated greater than 10° at the forefoot Figure 6(A): The outersole at the forefoot is described as **flexible** (Result A Flexible)

2. When the outersole can bend an estimated 10° or less at the forefoot: Figure 6(B): The outersole at the forefoot is described as **rigid (**Result B Rigid)

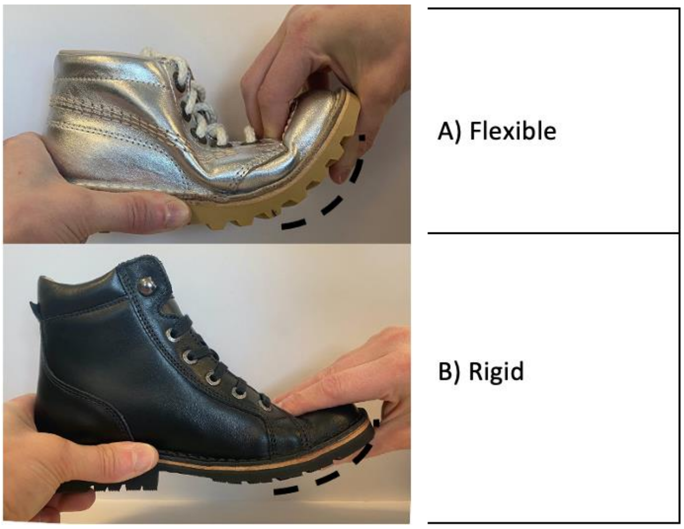


Figure 6 How to describe outsole flexibility in the toe spring and forefoot (A) Flexible (B) Rigid

Figure 7 Resting toe spring angle of the shoe

Component Upper:

Question E6

Is the material of the upper made from a breathable material such as leather or Gore-Tex (Result A Yes), or is it made of non-breathable material such as PVC (Result B No)?

Question E7

Is the material of the upper made from a wipeable material such as leather or rubber (Result A Yes), or is it made of a non-wipeable material such as canvas or suede (Result B No)?

Question E8
Does the tongue of the shoe have a fastening loop or Velcro fastening on it to reduce slippage of the tongue under fastenings Figure 8(A) (Result A Yes), or is it a plane tongue with no method to secure to the upper Figure 8(B) (Result B No)?

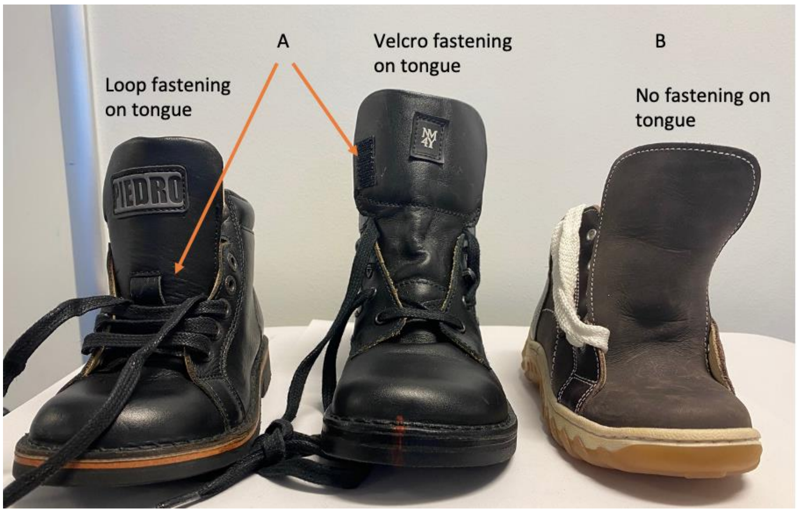


Figure 8 (A) With a loop or Velcro fastening on the tongue (B) No fastening on the tongue.

Question E9

Does the length of the tongue come above the line of top fastenings to provide comfort when the fastenings are tightened (Result A Yes), or is the tongue below or in line with the top fastening (Result B No)?

Component Fastenings and Facings:

Question E10

Are the facings of the shoe extended along the length of the shoe into the toe box beyond the start of the toe spring to allow ease of access to the footwear Figure 9(A) (Result A Yes), or are the facings extended just to the length of the midfoot Figure 9(B) (Result B No)?

Figure 9(A) Facings extended into the toe box beyond the start of the spring, (B) Facings extended to the length of the midfoot

Question E11

Are the fastenings of the shoe Velcro allowing for fastening and unfastening for individuals with limited hand dexterity (Result A Yes), or are the fastenings lace or buckle fastening (Result B No)?

Component Inlay/Insole:

Question E12

Is the shoe's inlay/insole able to be easily removed without tearing it from the inner base (Result A Yes), or is the shoe's insole glued into the shoe and requires tearing to remove (Result B No)?

Question E13

Is the shoe's inlay/insole contoured to cup the anatomy of the heel, as seen in Figure 10(A) (Result A Yes), or is the shoe's inlay flat, as seen in Figure 10(B)(Result B No)?

Figure 10(A) Inlay/Insole cupped at the heel and deep at the rearfoot, midfoot and forefoot.
(B) Inlay/Insole Flat at rearfoot and midfoot.

Question E14

Is the shoe’s inlay/insole deep enough at the rearfoot, midfoot and forefoot to simulate a potential required prescriptive foot orthoses for the child, as seen in Figure 10(A) (Result A Yes)? Or is the shoe’s inlay flat and of limited depth as seen in Figure 10(B) (Result B No)?

Total Ergonomic Score and Interpretation

Total up the score for a maximum **Ergonomic Value** of 14. Ergonomic score interpretation:
0- 4 = Poor 5 - 9 = Moderate 10 - 14 = Good

<u>**Stability Criteria**</u>

Component Heel Counter/Stiffener:

Question S1

Press into the heel region of the upper of the shoe until you find the top edge of the heel counter, as seen in Figure 11(A); now trace the edge of the heel counter along its length until it curves down to meet the edge of the outsole as seen in Figure 11(B). Do this for both the medial (inside) and lateral (outside) sides of the shoe and estimate the length of the extension with respect to the shoe. Is the heel counter extended to the forefoot/toe box Figure 12(A) (Result A), extended into the midfoot Figure 12(B) (Result B), or is it only extended to the length of the heel Figure 12(C)?

Figure 11(A) Palpating the top edge of the heel counter through the shoe, (B) Tracing the top edge of the heel counter to its most distal aspect of the shoe.

Figure 12 (A) Heel counter extending to the forefoot/toe box, (B) Heel counter extending into the midfoot, (C) Heel counter extending to the length of the heel.

Question S2
Press into the heel region of the upper of the shoe until you find the top edge of the heel counter, as seen in Figure 13(A); now trace the edge of the heel counter through the shoe until you find the highest point of the heel counter, as seen in Figure 13(B). Do this for both the medial (inside) and lateral (outside) sides of the shoe.

Figure 13(A) Palpating the top edge of the heel counter through the shoe, (B) Tracing the top edge of the heel counter to its highest point.

Now estimate the height of the extension with respect to the imagined child's ankle anatomy; note the height of the third eyelet or hook lace fastening; this is equivalent to the ankle joint Figure 14(A). If the fastening is Velcro, note the height from the base of the front of the second fastening Figure 14(B). Is the heel counter height above the respective: eyelet, hook, or Velcro fastening Figure 15(A) (Result A)? Is the heel counter height in line with the: eyelet, hook, or Velcro fastening figure 15(B) (Result B), or is the heel counter height below the respective: eyelet, hook, or Velcro fastening Figure 15(C) (Result C)?

Figure 14 Estimated height of the ankle joint. (A) From the third eyelet or hook lace fastening (B) From the base of the front of the second Velcro fastening

Figure 15(A) Heel counter above the respective fastening (B) Heel counter in line with the respective fastening (C) Heel counter extending below the respective fastening.

Question S3

How to describe heel counter stiffness

The following instructions are modified from Williams et al. 2022 (C. M. Williams, Morrison, et al., 2022)
Hold the forefoot and rearfoot of the shoe.
Try to bend the heel counter at the back of the shoe with your thumb, as in Figure 16 (A) (B)

1. If the heel counter bends towards the sole at an estimated <10°, the heel counter is classified as **rigid** (Figure 16 Heel A)
2. If the heel counter bends towards the sole at an estimated 10 to 45°, the heel counter is classified as **flexible** (Figure 16 Heel B)

Figure 16 Heel (A) Heel counter stiffness rigid, Heel (B) Heel counter stiffness flexible

Component Topline:

Question S4

Consider the total height of the topline (Figure 1 item 5) and estimate the height of the topline with respect to the child's ankle anatomy. Is the topline height extended above the malleoli Figure 17 (A) (Result A), extended in line with the malleoli Figure 17(B) (Result B) or extended below the malleoli Figure 17(C) (Result C)?

Figure 17-(A) Topline extending above the malleoli (B) Topline in line with the malleoli (C) Topline below the malleoli

Component Outersole:

Question S5

Consider the material of the outersole. Try to compress the material at the heel with your thumb, as in Figure 18 (A). If you cannot compress the material with your thumb, this will likely be Rubber or Polyurethane (Result A). If it is slightly compressible with your thumb, as in Figure 18(B), (Result B)

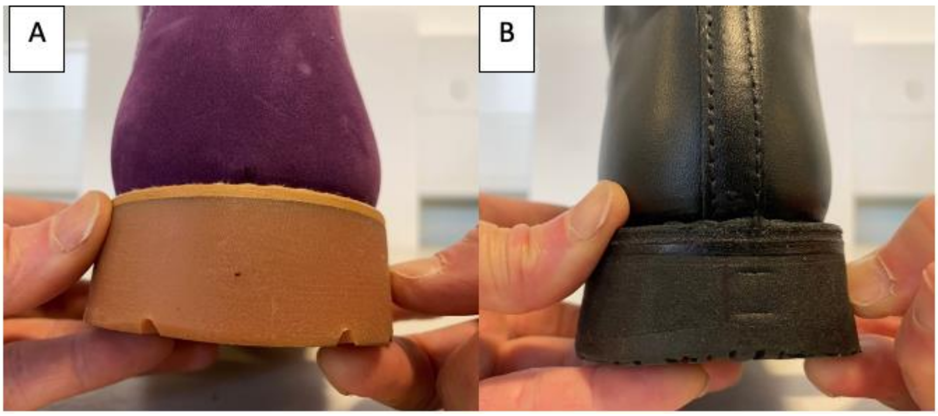


Figure 18 (A) Outersole material incompressible with thumb, (B) Outersole material partially compressible with thumb

Question S6

How to describe outersole flexibility at the midfoot
The following instructions are adapted from Williams et al. 2022 (C. M. Williams, Morrison, et al., 2022).
With one hand, hold the outsole at the rearfoot and with the other hand, hold outsole at the forefoot. Now try to twist the shoe in opposite directions at the forefoot and rearfoot to create a torsion around the midfoot of the shoe (Figure 19). Now estimate the amount of twist at the midfoot.

1. When outersole can twist an estimated less than 10° at the midfoot: The outersole at the midfoot is described as **rigid** Figure 19 (A) (Result A)
2. When outersole can twist an estimated 10-45° at the midfoot: The outersole at the midfoot is described as **flexible** Figure 19(B) (Result B)

A - Rigid

B - Flexible

Figure 19 (A) Rigid outersole at the midfoot (B) Flexible outersole at the midfoot

Question S7

Observe the footwear from the posterior aspect. Evaluate the heel cup width of the upper compared to the heel width of the outersole use a ruler and place it next to the outersole of the heel, as represented by the red lines in figure 20. Is the heel outersole width wider than the width of the upper heel cup Figure 20 (A) Yes or Figure 20 (B)No?

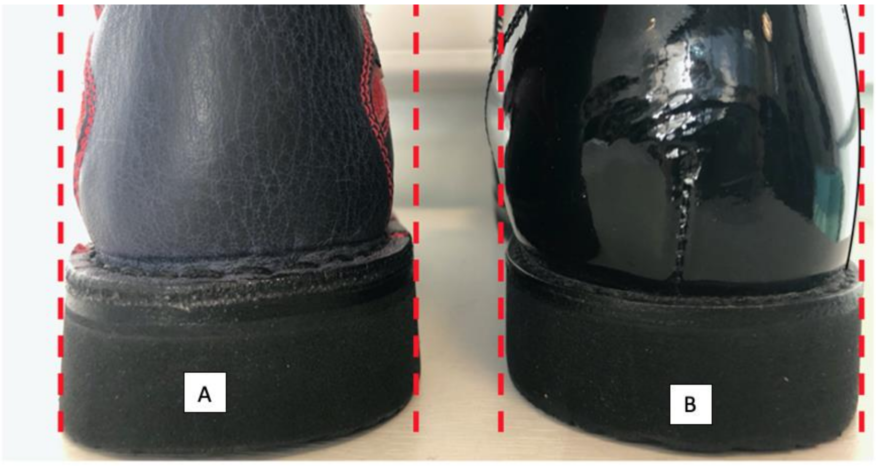


Figure 20 Outersole heel wider than upper heel cup (A) Outersole heel not wider than upper heel cup (B)

Question S8

Consider the thickness of the outersole at the midfoot/waist of the shoe (Figure 1, item 12). Is there a solid infill from the heel to the midfoot see Figure 21(A) (Result A) or a separate heel from the heel of the shoe to the midfoot see Figure 21(B) (Result B)?

Figure 21(A) Solid infill of the outersole at the midfoot/waist of the shoe, (B) Stepped cutaway of the outersole at the midfoot

Question S9

Consider the depth of the tread of the outersole of the forefoot. Is there a deepened tread pattern (estimated 3-4mm or greater) see Figure 22(A) (Result A) or a shallow tread pattern (estimated 2mm or less) see Figure 22(B) (Result B)?

Figure 22 A Outersole with a deepened tread pattern B Outersole with a shallow tread pattern

Component Upper:

Question S10

Consider the material of the upper of the shoe; is the material leather (Result A) or another material such as suede, polyester, or canvas (Result B)?

Component Inlay/Insole:

Question S11

Is the shoe's inlay/insole contoured to cup the anatomy of the heel, as seen in Figure 10(A) (see in ergonomic section question E13) (Result A Yes), or is the shoe's inlay flat, as seen in Figure 10(B) (Result B No)?

Component Fastening and Facings:

Question S12

Are the fastenings of the shoe laces to allow a firmer, tighter fastening of the upper of the shoe to the child's foot (Result A) or Velcro (Result B)?

Total Stability Score and Interpretation

Total up the score for a maximum Stability Value of 15. Stability score interpretation: 0- 4 = Poor 5 - 10 = Moderate 11 - 15 = Good

References

Hill, M., Healy, A., & Chockalingam, N. (2021). Defining and grouping children's therapeutic footwear and criteria for their prescription: an international expert Delphi consensus study. *BMJ Open*, *11*(8), e051381. https://doi.org/10.1136/BMJOPEN-2021-051381

Williams, C. M., Morrison, S. C., Paterson, K., Gobbi, K., Burton, S., Hill, M., Harber, E., & Banwell, H. (2022). Young children's footwear taxonomy: An international Delphi survey of parents, health and footwear industry professionals. *PLOS ONE*, *17*(6), e0269223. https://doi.org/10.1371/journal.pone.0269223

5.2 Children's Off-the-shelf Stability Therapeutic Footwear (OSSTF) Footwear Tool Usability Survey

Children's Off-the-shelf Stability Therapeutic Footwear (OSSTF) Footwear Tool Usability Survey

Below are a limited number of questions seeking your opinion on the use of this footwear tool and manual for children's OSSTF. This is inclusive of how easy it is to use and how applicable it is to your clinical practice when offering this footwear as an assistive aid for children living with a mobility impairment.

The questions will be firstly closed-ended Likert scale ranked agreement as detailed below.

Ranked Responses
Ranked responses are based on Likert scales where you will rank your level of agreement on a scale of 1-5

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Following each ranked agreement scale, there will be an open-ended question where you may offer your opinion. We would encourage you to elaborate on your response so that we may understand your reasoning and reflect on the clinical applicability of the footwear tool's design.

All answers will be anonymised and will not be identifiable as your responses.

Question 1

Thinking about using the Footwear Tool together with the manual to clinically assess OSSTF for children living with a mobility impairment, do you agree it was practical to use?
Please rank your agreement below.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 1, and possible suggestions on how you feel the tool and manual might be improved for practicality (You may also provide suggestions if you scored higher than 3)

Question 2

Thinking about the Footwear Tool, do you agree it is a useful method to clinically assess and inform how OSSTF may act as an assistive aid to improve mobility?
Please rank your agreement below.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 2, and possible suggestions on how you feel the tool might be improved to clinically assess OSSTF as a suitable assistive aid (You may also provide suggestions if you scored higher than 3)

Question 3

Thinking about the design components of OSSTF included in the Footwear Tool. Do you agree that the tool considered all the important design components of OSSTF that may clinically influence ergonomics and stability when used by a child with mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 3, and possible suggestions of any further design components of OSSTF that should be considered (You may also provide suggestions if you scored higher than 3, specifically if you feel there were too many components considered)

Question 4

Thinking about the score ranking (0-4 Poor) (5-9 Medium) (10-14 Good) of ergonomic aspects of OSSTF used in the footwear tool. Do you agree that this is an appropriate score ranking ergonomic factors of OSSTF to be used clinically for children living with a mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 4, and possible suggestions of any further means to rank the score of ergonomic factors of

OSSTF that should be considered (You may also provide suggestions if you scored higher than 3)

Question 5

Thinking about the score ranking (0-4 Poor) (5-10 Medium) (11-15 Good) of stability aspects of OSSTF used in the footwear tool. Do you agree that this is an appropriate score ranking for stability factors of OSSTF to be used clinically for children living with a mobility impairment?

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1) ☐	2 ☐	3 ☐	4 ☐	5 ☐

Please provide further details for your reasoning if you score 3 or less in question 5, and possible suggestions of any further means to rank the score of stability factors of OSSTF that should be considered (You may also provide suggestions if you scored higher than 3)

Thank you for completing this survey. If you have any further comments on the tool or manual, you may add them in the section below

5.3 Total results for OSSTF Screening Tool ergonomics section session one

	Topline				Outsole	Upper				Fastenings and Facings		Inlay/Insole			Total Ergonomic Score	Ranked Score
	Question E1	Question E2	Question E3	Question E4	Question E5	Question E6	Question E7	Question E8	Question E9	Question E10	Question E11	Question E12	Question E13	Question E14		
Shoe A Rater 1	A	A	B	B	B	A	A	B	A	A	A	A	A	A	10	Good
Shoe A Rater 2	A	A	B	B	B	A	A	B	A	B	A	A	A	A	9	Moderate
Shoe A Rater 3	A	A	B	B	B	A	A	B	A	A	A	A	A	A	10	Good
Shoe A Rater 4	A	B	A	B	A	A	A	B	A	A	A	A	A	A	11	Good
Shoe A Rater 5	A	A	B	A	A	A	A	B	A	A	A	A	A	A	12	Good
Shoe A Rater 6	A	A	B	A	B	A	A	B	A	A	A	A	A	A	11	Good
Shoe B Rater 1	A	B	B	A	A	B	A	A	A	A	B	A	B	B	8	Moderate
Shoe B Rater 2	A	B	B	A	A	A	A	A	A	A	B	A	B	A	10	Good
Shoe B Rater 3	A	B	B	A	A	A	A	B	B	A	B	A	B	A	8	Moderate
Shoe B Rater 4	A	B	A	A	A	A	A	B	A	B	B	A	A	A	10	Good
Shoe B Rater 5	A	B	B	A	A	B	A	A	B	A	B	A	B	B	7	Moderate
Shoe B Rater 6	A	B	B	A	A	B	A	A	A	A	B	A	A	A	10	Good
Shoe C Rater 1	A	A	A	A	B	A	A	B	A	A	A	B	B	B	9	Moderate
Shoe C Rater 2	A	A	A	A	B	A	A	B	A	A	A	B	B	B	9	Moderate
Shoe C Rater 3	A	A	B	A	B	A	B	B	A	A	A	B	B	A	8	Moderate
Shoe C Rater 4	A	B	A	A	B	A	A	B	A	A	A	B	B	A	9	Moderate
Shoe C Rater 5	A	A	A	A	B	A	A	B	A	A	A	B	B	B	9	Moderate
Shoe C Rater 6	B	A	B	A	B	A	A	B	A	A	A	B	B	B	7	Moderate

Shoe D Rater 1	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe D Rater 2	**A**	**A**	**A**	**B**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe D Rater 3	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**B**	**A**	**B**	**B**	**A**	**8**	**Moderate**
Shoe D Rater 4	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**B**	**A**	**9**	**Moderate**
Shoe D Rater 5	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**9**	**Moderate**
Shoe D Rater 6	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe E Rater 1	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**12**	**Good**
Shoe E Rater 2	**A**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**A**	**10**	**Good**
Shoe E Rater 3	**A**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**11**	**Good**
Shoe E Rater 4	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**10**	**Good**
Shoe E Rater 5	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**12**	**Good**
Shoe E Rater 6	**A**	**A**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**11**	**Good**

5.4 Total results for OSSTF Screening Tool ergonomics section session two

	Topline				**Outsole**	**Upper**				**Fastenings and Facings**		**Inlay/Insole**			**Total Ergonomic Score**	**Ranked Score**
	Question E1	**Question E2**	**Question E3**	**Question E4**	**Question E5**	**Question E6**	**Question E7**	**Question E8**	**Question E9**	**Question E10**	**Question E11**	**Question E12**	**Question E13**	**Question E14**		
Shoe A Rater 1	**A**	**A**	**B**	**B**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**11**	**Good**
Shoe A Rater 2	**A**	**A**	**B**	**B**	**B**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**9**	**Moderate**
Shoe A Rater 3	**A**	**A**	**B**	**B**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**10**	**Good**
Shoe A Rater 4	**A**	**B**	**A**	**B**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**11**	**Good**
Shoe A Rater 5	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**13**	**Good**
Shoe A Rater 6	**A**	**A**	**B**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**12**	**Good**

Shoe B Rater 1	**A**	**B**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**B**	**8**	**Moderate**
Shoe B Rater 2	**A**	**B**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**A**	**9**	**Moderate**
Shoe B Rater 3	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**B**	**A**	**8**	**Moderate**
Shoe B Rater 4	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**10**	**Good**
Shoe B Rater 5	**A**	**B**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**9**	**Moderate**
Shoe B Rater 6	**A**	**B**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**10**	**Good**
Shoe C Rater 1	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe C Rater 2	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**B**	**B**	**B**	**9**	**Moderate**
Shoe C Rater 3	**A**	**A**	**B**	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**B**	**A**	**8**	**Moderate**
Shoe C Rater 4	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**B**	**B**	**A**	**9**	**Moderate**
Shoe C Rater 5	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**B**	**B**	**B**	**9**	**Moderate**
Shoe C Rater 6	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**A**	**A**	**A**	**B**	**B**	**A**	**10**	**Good**
Shoe D Rater 1	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe D Rater 2	**A**	**A**	**A**	**B**	**B**	**B**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**7**	**Moderate**
Shoe D Rater 3	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**B**	**A**	**B**	**B**	**A**	**8**	**Moderate**
Shoe D Rater 4	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**B**	**A**	**9**	**Moderate**
Shoe D Rater 5	**A**	**A**	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**8**	**Moderate**
Shoe D Rater 6	**A**	**A**	**A**	**B**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**B**	**B**	**A**	**9**	**Moderate**
Shoe E Rater 1	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**12**	**Good**
Shoe E Rater 2	**A**	**A**	**B**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**B**	**A**	**9**	**Moderate**
Shoe E Rater 3	**A**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**11**	**Good**
Shoe E Rater 4	**A**	**B**	**A**	**B**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**10**	**Good**

Shoe E Rater 5	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**B**	**12**	**Good**
Shoe E Rater 6	**A**	**A**	**B**	**A**	**B**	**A**	**A**	**A**	**A**	**A**	**B**	**A**	**A**	**A**	**11**	**Good**

5.4 Total results for OSSTF Screening Tool stability section session one

	Heel Counter/Stiffener			Topline	Outsole					Upper	Inlay/Insole	Fastenings and Facings	Total Stability Score	Ranked Score
	Question S1	Question S2	Question S3	Question S4	Question S5	Question S6	Question S7	Question S8	Question S9	Question S10	Question S11	Question S12		
Shoe A Rater 1	B	B	A	A	A	A	A	B	A	A	A	B	11	Good
Shoe A Rater 2	B	B	A	A	A	A	B	B	A	A	B	B	9	Moderate
Shoe A Rater 3	B	C	A	A	A	A	A	B	A	A	A	B	10	Moderate
Shoe A Rater 4	B	C	B	A	A	A	A	B	A	A	A	B	9	Moderate
Shoe A Rater 5	C	C	B	A	A	B	A	B	A	A	A	B	7	Moderate
Shoe A Rater 6	C	B	A	A	A	A	A	B	A	A	A	B	10	Good
Shoe B Rater 1	C	A	A	A	B	A	B	A	B	A	B	A	9	Moderate
Shoe B Rater 2	C	B	A	A	B	B	B	B	B	A	B	A	7	Moderate
Shoe B Rater 3	A	A	A	A	B	A	B	A	B	A	A	A	12	Good
Shoe B Rater 4	A	A	A	A	B	B	A	A	A	A	A	A	13	Good
Shoe B Rater 5	B	A	A	A	B	A	A	A	A	B	B	A	11	Good
Shoe B Rater 6	B	A	A	A	B	B	B	A	B	B	A	A	10	Good
Shoe C Rater 1	B	C	B	C	B	A	A	A	A	A	B	B	6	Moderate
Shoe C Rater 2	A	B	A	C	B	A	B	A	A	A	B	B	7	Moderate
Shoe C Rater 3	B	C	A	C	A	A	A	A	A	B	A	B	7	Moderate
Shoe C Rater 4	A	C	A	C	B	A	A	A	A	B	B	B	7	Moderate
Shoe C Rater 5	B	C	A	C	B	A	A	A	A	A	B	B	7	Moderate

Shoe C Rater 6	B	C	A	C	A	A	A	A	A	A	B	B	8	Moderate
Shoe D Rater 1	B	B	A	B	B	A	A	A	A	B	B	B	8	Moderate
Shoe D Rater 2	B	A	A	B	B	A	B	A	A	B	B	B	8	Moderate
Shoe D Rater 3	A	A	A	A	B	A	B	A	A	B	A	B	10	Good
Shoe D Rater 4	A	A	A	A	B	A	A	A	A	A	B	B	12	Good
Shoe D Rater 5	B	B	A	A	B	A	A	A	A	B	B	B	9	Moderate
Shoe D Rater 6	B	A	A	A	A	A	B	A	A	B	B	B	9	Moderate
Shoe E Rater 1	B	A	A	A	A	A	B	B	A	A	A	A	11	Good
Shoe E Rater 2	A	A	A	A	A	A	A	B	A	A	B	A	13	Good
Shoe E Rater 3	B	A	A	A	A	A	A	B	A	A	A	A	13	Good
Shoe E Rater 4	A	A	A	A	A	A	A	B	A	A	A	A	14	Good
Shoe E Rater 5	A	A	A	A	A	A	A	B	A	A	A	A	14	Good
Shoe E Rater 6	A	A	A	A	A	A	A	B	A	A	A	A	14	Good

5.5 Total results for OSSTF Screening Tool stability section session two

	Heel Counter/Stiffener			Topline	Outsole					Upper	Inlay/Insole	Fastenings and Facings	Total Stability Score	Raked Score
	Question S1	Question S2	Question S3	Question S4	Question S5	Question S6	Question S7	Question S8	Question S9	Question S10	Question S11	Question S12		
Shoe A Rater 1	B	C	A	A	A	A	A	B	A	A	A	B	10	Good
Shoe A Rater 2	B	B	A	A	A	A	B	B	A	A	B	B	9	Moderate
Shoe A Rater 3	B	C	A	A	A	A	A	B	A	A	A	B	10	Good
Shoe A Rater 4	A	C	B	A	A	A	A	B	A	A	A	B	10	Good
Shoe A Rater 5	C	C	B	A	A	B	A	B	A	A	A	B	7	Moderate
Shoe A Rater 6	A	B	A	A	A	A	A	B	A	A	A	B	12	Good
Shoe B Rater 1	B	A	A	A	B	A	A	A	B	A	B	A	11	Good

Shoe B Rater 2	C	B	A	A	B	B	B	A	B	B	B	A	6	Moderate
Shoe B Rater 3	A	A	A	A	B	A	B	A	B	A	A	A	12	Good
Shoe B Rater 4	A	A	A	A	B	B	A	A	A	A	A	A	13	Good
Shoe B Rater 5	A	A	A	A	B	A	A	A	A	B	A	A	13	Good
Shoe B Rater 6	A	A	A	A	B	A	B	A	B	B	A	A	11	Good
Shoe C Rater 1	B	C	A	C	B	A	A	A	A	B	B	B	6	Moderate
Shoe C Rater 2	A	B	A	C	B	A	B	A	A	B	B	B	7	Moderate
Shoe C Rater 3	B	C	A	C	A	A	A	A	A	B	A	B	8	Moderate
Shoe C Rater 4	A	C	A	C	B	A	A	A	A	B	B	B	7	Moderate
Shoe C Rater 5	B	C	A	C	B	A	A	A	A	A	B	B	7	Moderate
Shoe C Rater 6	B	C	A	C	B	A	A	A	A	B	B	B	7	Moderate
Shoe D Rater 1	B	A	A	A	B	A	A	A	A	B	B	B	10	Good
Shoe D Rater 2	B	A	A	B	B	A	B	A	A	B	B	B	8	Moderate
Shoe D Rater 3	A	A	A	A	B	A	B	A	A	B	A	B	11	Good
Shoe D Rater 4	A	A	A	A	B	A	A	A	A	A	B	B	12	Good
Shoe D Rater 5	C	B	A	A	B	A	A	A	A	A	B	B	9	Moderate
Shoe D Rater 6	A	A	A	A	A	A	B	A	A	B	B	B	11	Good
Shoe E Rater 1	C	A	A	A	A	A	A	B	A	A	A	A	12	Good
Shoe E Rater 2	A	A	A	A	A	A	A	B	A	A	B	A	13	Good
Shoe E Rater 3	A	A	A	A	A	A	A	B	A	A	A	A	13	Good
Shoe E Rater 4	A	A	A	A	A	A	A	B	A	A	A	A	14	Good
Shoe E Rater 5	A	B	A	A	A	A	A	B	A	A	A	A	13	Good
Shoe E Rater 6	A	A	A	A	A	A	A	B	A	A	A	A	14	Good