The key concepts in intra-articular corticosteroid injection therapy for pathology of the first metatarso-phalangeal joint

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Publications

The following publications have been generated from this thesis:

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Reilly, I., Chockallingam, N., & Naemi, R. (2022). The accuracy of first metatarsophalangeal joint palpation guided injections. An arthrography cadaveric study. *Foot & Ankle Surgery: Techniques, Reports & Cases*, 2(3), 1–7. https://doi.org/10.1016/j.fastrc.2022.100219.

List of abbreviations

1st MTP jt	First metatarsophalangeal joint
CEBM	Centre for Evidenced Based Medicine
CS	Corticosteroid
CSI(s)	Corticosteroid injection (plural)
CT	Computed tomography
EBM	Evidence-based medicine
HAV	Hallux abducto valgus
HCP	Health care professional
IL (1β)	Interleukin X, e.g., IL1β
IA	Intra-articular
IAIT	Intra-articular injection therapy
IT	Injection therapy
JIA	Juvenile idiopathic arthritis
MRI	Magnetic resonance imaging
NHFT	Northamptonshire Healthcare Foundation NHS Trust
NICE	National Institute of Clinical Excellence
NSAIDs	Non-steroidal anti-inflammatory drugs
OA	Osteoarthritis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RA	Rheumatoid arthritis
RCT	Randomised controlled trial
ST	Soft tissue
TNF-α	Tissue necrosis factor - alpha
US/S	Ultrasound/Ultrasound scan
USG	Ultrasound-guided
VAS	Visual analogue scale

Cogitatio diei

All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or to postpone the action that it appears to demand at a given time.

Sir Austin Bradford Hill, President's Address, *Royal Society of Medicine*, 1965.

Abstract

The first metatarsophalangeal joint is a synovial articulation in the forefoot comprising the first metatarsal, the hallucal proximal phalanx, and two sesamoid bones. The two most common non-traumatic diseases affecting the joint are osteoarthritis and hallux abducto valgus, but rheumatoid arthritis, gout, and sesamoiditis may also affect the joint. Corticosteroids injection therapy is used in the treatment of musculoskeletal pathology, in particular via intra-articular delivery to treat the pain associated with joint disease.

Given that the first metatarsophalangeal joint corticosteroid injection is one of the most commonly performed infiltrations in the foot, this project aims to identify, synthesise and critique the key concepts for injections in the management of first metatarsophalangeal joint pathology, to highlight gaps in our knowledge, to provide answers where possible, and to generate research questions for future studies.

Whilst providing an overview of injection therapy, local anatomy, joint pathology, and relevant corticosteroid pharmacology, this thesis has attempted to provide a through critical appraisal of the existing literature. The initial scoping review on corticosteroid injections in the management of first metatarsophalangeal joint pathology, identified the range of available evidence for all joint pathologies, and produced three themes:

1. Injection therapy outcomes for a given joint pathology,
2. Injection techniques, dosage, and regimen,
3. Injection accuracy and needle placement.

The initial inquiries into these topics involved a systematic review that centred on the utilisation of corticosteroid injections to address hallux limitus/rigidus. Despite a limited availability of high-level evidence, this indication was identified as the most commonly encountered scenario for injection therapy. Data extracted facilitated the production of a best-practice palpation-guided injection technique. However, the accuracy of such a technique remained uncertain. The next schema of work sought to establish the accuracy of palpation-guided injections using radiopaque contrast media in cadaveric specimens to confirm the needle placement. The study noted the failure of technique in one of the six specimens used and extra-articular injectate leakage in another three specimens. This calls into question the confidence of palpation-guided techniques for injecting the joint.

Whilst the evidence base suggests that corticosteroid injections are safe short- and mid-term treatment options for soft tissue and joint pathology, the specific outcomes in the first metatarso-phalangeal joint warrant further study. It needs to be clarified from the available literature what drug, dose, and at what point in disease regression is optimal for injection therapy in a given patient. Based on the findings of this work, future research should include conducting structured research to establish precise injection therapy protocols for addressing first metatarsophalangeal joint pathology. The primary emphasis of these forthcoming studies should be on osteoarthritis of the great toe, given its prevalence as the most frequently treated condition through injections. Additionally, high-level studies are also needed to assess the efficacy of injection therapy in managing other great toe joint pathologies.

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CHAPTER 1

Introduction to injection therapy

1.1 Introduction to injection therapy

A needle is inserted into a joint for two main indications: aspiration of fluid (arthrocentesis: either for diagnostic purposes or for relief of pressure) or for the injection of medication(s) (De Zordo et al., 2009; Roberts, 2020). Injection therapy (IT) using sodium bicarbonate, potassium phosphate and procaine to treat joint pain has been performed since the 1930s (Miller et al., 1958). Hollander et al. (1951) reported using hydrocortisone and cortisone injections (CSI) following personal communication with Thorn, who they believed was the first to inject a rheumatic joint in 1950. Injected locally (into joints or soft tissues) for their anti-inflammatory effect, the introduction of cortisone injections revolutionised the treatment of several diseases. Further reports were produced by Bornstein et al. (1954) and Fallet and Lambelet (1955), cited by Miller at. (1958). Case reports appear in the podiatric literature (then termed chiropody) from as early as 1954 (Weinstein, 1954) and 1958 (Katz, 1958; Locke, 1958).

CSI IT is now one of musculoskeletal healthcare's most common therapeutic interventions (Rozental & Sculco, 2000; von Stechow & Rittmeister, 2003; Wittich et al., 2009). Intra-articular (IA) and soft tissue (ST) CSIs are the two most frequently performed procedures in rheumatological practice, but techniques and regimens vary (Bamji, 1990). Most injections into joints consist of a glucocorticoid, a local anaesthetic, or a combination of the two (Roberts, 2020), and IT for the relief of vertebrogenic, arthritic and radiculopathic pain is widely accepted (Anitescu et al., 2013; Gray et al., 1981; Martin et al., 2018; Uson et al., 2021).

Injectable glucocorticoids are widely used in foot pathology, in particular for the treatment of osteoarthritis of the great toe: hallux limitus/rigidus (Al-Jabri & Charalambides, 2019; Anderson et al., 2018; Ayral, 2001; Bilstrom et al., 2007; Boxer, 1994; Chiou-tan et al., 2015; Courtney & Doherty, 2005; de Caesar et al., 2017; Grady et al., 2002; Hamid & Parekh, 2015; Kilmartin, 2017; Kunnasegaran & Thevendran, 2015; Lam et al., 2017; Pons et al., 2007; Reilly, 2010; Sahler et al., 2013; Sarkin, 1974; Solan et al., 2001; Tallia & Cardone, 2003; Uthman et al., 2003; Vanore et al., 2003). In a survey of American orthopaedic foot and ankle surgeons, Johnson et al. (2011) found an overall average of 20.6 injections per month per clinician (all conditions).

1.1.1 Indications of injection therapy

Hawker et al. (2010) list the roles of IT:

- Diagnosis
    - Diagnostic synovial fluid analysis,
      Septic arthritis, hemarthrosis, crystal arthritis, differentiation of inflammatory from noninflammatory arthritis,
- Diagnostic studies
    - Arthrography,
    - Synovial biopsy,
    - Small-bore needle arthroscopy,
- Therapy
    - Repeated needle (closed) drainage of septic arthritis,
    - Drainage of large haemorrhagic or tense effusions,
    - Injection of therapeutic agents,
        - Intra-articular corticosteroids,
            - ◊ Local control of inflammatory synovitis,
            - ◊ Relief of pain in joints affected by osteoarthritis,
        - Intra-articular hyaluronate preparations,
        - Intra-articular radioisotopes.

Synovial inflammation is a key feature of much joint pathology. Most notably observed in rheumatoid arthritis (RA) and following joint injury, it is also present in early osteoarthritis (OA) (Berenbaum, 2013). Therapeutic injections - especially those mixed with local anaesthetic - provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, those in whom conservative treatment has failed or those that are awaiting surgery (Chow & Brandser, 1998). Suppression of local joint inflammation by glucocorticoids is rapid and pronounced and may be achieved with only minor systemic effects; however, this suppression is often only temporary (Creamer, 1999; Gossec & Dougados, 2006; Østergaard & Halberg, 1998; Yu & Hunter, 2016).

When performed for the correct indication and using the proper technique, musculoskeletal injections can be beneficial for both patients and rewarding for physicians (Monseau & Nizran, 2013). Diarthrodial joints are well suited to IA injection, and the local delivery of therapeutic substances in this fashion brings several potential advantages to treating a wide range of arthropathies (Evans et al., 2014). Chief of these is a good safety profile (if administered correctly) with less chance of systemic exposure and undesired off-target effects (Nguyen & Rannou, 2017). As well as eliminating many patient-compliance issues, this route of administration overcomes potential problems of bioavailability, uncontrollable drug dosing and the effects of drug binding to systemic molecules that can all limit the efficacy of a substance administered via enteral delivery (Evans et al., 2014; Wehling et al., 2017).

Uson et al. (2021) provide over-arching principles and recommendations for intra-articular IT (IAIT) via a Delphi consensus study:

I. IAITs are recommended and widely used in the management of joint diseases,
II. IAIT aims to improve patient-centred outcomes,
III. Contextual factors are important and contribute to the effect of IAIT,
IV. IAIT should be offered in the frame of full individualised information and a shared decision-making process,
V. A variety of health professionals perform these procedures routinely.

Although CSIs are occasionally used as solitary therapy, they are seldom the primary approach. Genovese (1988) opines that IT should be considered an adjuvant to systemic and local treatment methods, such as oral medication (disease-modifying anti-rheumatic drugs/nonsteroidal anti-inflammatory drugs), use of hot/cold compresses, splints, rest, exercise, and physical and occupational therapy. But while accepted as an important treatment modality, there are no strict rules regarding administration (Fredberg, 1997; Foster et al., 2015; George & Kirwan, 1990; Gross & Lin, 2012; Rifat & Moeller, 2001; Snibbe & Gambardella, 2005).

1.1.2 Evidenced-based injection therapy of the foot

Evidence-based medicine (EBM) is the appropriate application of this research knowledge to practice (Aveyard, 2018), defined by Sackett et al. (1996) as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. It guides and informs practitioners involved in all areas of healthcare to practice according to the best current evidence available and to use this information to support and justify their

actions. By using, critiquing, and applying existing literature, healthcare professionals can be better informed of the options that are available to them so that they can better determine the best evidence-based practice(s) to adopt for their patients.

Burns et al. (2011) state that the cornerstone of EBM is the hierarchical system of classifying evidence, known as the levels of evidence. Several systems exist to systematically rank published literature's evidence levels, which will be helpful in the following critiques. The Centre for Evidenced-based Medicine in Oxford (CEBM, 2009) 'Levels of Evidence' document sets out one approach to systematising this process for different question types – see Table 1.

Table 1: CEBM levels of evidence

Level	Study Design
1a	Systematic review (with homogeneity) of RCTs
1b	Individual RCT (with narrow confidence interval)
1c	All or none
2a	Systematic review (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT)
2c	"Outcomes" research; ecological studies
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual case-control study
4	Case-series (and poor-quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

The quality of evidence base for glucocorticoid injections is of a higher academic level for knee, shoulder, and hip OA, but the evidence base for use in other joints is less robust (He et al., 2017; Kaplan et al., 2020; Najm et al., 2021; Sabha & Hochberg, 2021; Yaftali & Weber, 2019). As will be shown, the quality of that evidence base of IAIT for the first metatarsophalangeal joint (1st MTP jt) is varied and is generally of lower research quality.

1.1.3 The overall aim and the structure of this thesis

This project aims to identify, synthesise and critique the evidence base for using CSIs in managing 1st MTP jt pathology, to highlight gaps in our knowledge and generate research questions for future study. This thesis is presented in eight chapters. The research project begins by examining the existing knowledge about corticosteroid injections (CSI) for the first metatarsophalangeal joint (1st MTP jt) through a comprehensive scoping review (Chapter 2). This review identifies three primary themes: the outcomes of injection therapy for joint pathology, the techniques, dosage, and regimen of injections, and the accuracy and placement of needles during injections.

Following the scoping review, the research progressed with several significant components:

- Systematic Review: An investigation into the use of corticosteroid injections for managing hallux limitus/rigidus, which highlights the lack of high-level evidence while acknowledging the specific criteria inherent to systematic reviews. This review has been published in both preprint and print versions (Chapter 3).
- Best Practice Technique: The development of a best practice injection technique for the 1st MTP jt, intended to guide novice injectors while considering safety concerns. This technique is published as a print version (Chapter 4).
- Cadaveric Study: A study involving cadavers to assess the accuracy of palpation-guided injections for the 1st MTP jt, revealing significant failures in the technique (Chapter 5).

While corticosteroid injections are generally considered safe for various soft tissue and joint pathologies, specific outcomes for the great toe remain uncertain, prompting the need for further study. Future work includes compiling a case series on short- and mid-term outcomes of standard corticosteroid injection therapy for hallux rigidus, as well as planned cohort analysis to identify optimal injection therapy regimens for different pathologies (Chapter 6). The thesis concludes (Chapter 7) by providing comprehensive conclusions and recommendations and offering a reflective analysis of the research journey (Chapter 8). To ensure reader comprehension, the thesis introduces the subject by outlining the general and local anatomy of the 1st MTP jt, discussing relevant joint pathologies, and covering the pharmacology of drugs used to treat these pathologies, all as part of introducing intra-articular injection techniques (IAIT).

1.2 Anatomy

This thesis will concentrate on IAIT, and therefore the general features of synovial joints and detailed local anatomy of the 1st MTP jt will be presented.

1.2.1 Articular surfaces

The joint surfaces of the bones at synovial joints are of many different shapes to allow particular movements and prevent others (Koshi, 2017a). The articular surfaces are composed of hyaline cartilage, which provides a wear-resistant, low-friction, lubricated surface. It is compressible and elastic and accommodates enormous compression and shear forces during weight bearing

and muscle action. The cartilage is closely moulded to the bone, thicker on central convex surfaces and thinning at the edges (Koshi, 2017a).

The articular cartilage may weep synovial fluid from its microscopic porous surface or trap fluid pools in the valleys of its undulating surface. Young cartilage is white and glistening, and older cartilage becomes thinner and becomes yellowish. The cartilage contains neither nerves nor blood vessels. It derives its nutrition from the vascular net in the synovial membrane, the synovial fluid itself and blood vessels in the underlying marrow space (Percival, 2001); see Fig. 1 (author's image from Foot and Ankle Injection Techniques, Reilly, 2010). Note the joint space, which is the target for injectate placement.

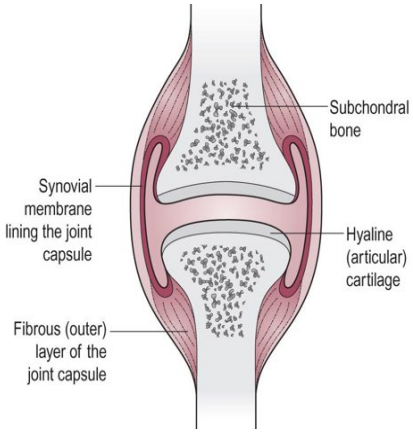

Figure 1: Generic anatomy of a synovial joint (Reilly, 2010)

1.2.2 Joint capsule

Outside the cavity, the bones are held together by a tubular sheath of fibrous tissue (the fibrous capsule or fibrous membrane), which is sufficiently loose to permit movement. The fibrous capsule may be strengthened by ligaments, strong bands of inelastic fibrous tissue connecting bones at joints (Khoshi, 2017a). It forms a cuff attached around the articular ends of the bones concerned in the joint. Nerves and blood vessels perforate it. It may have

apertures through which the synovial membrane lining the capsule may protrude to form a sac or pouch. The capsule generally exhibits thickenings in its substance which are named according to their position or place, e.g., collateral ligaments and sesamoid ligaments. The capsule may be reinforced by tendons or expansions of tendons from neighbouring muscles (Percival, 2001).

1.2.3 Synovial membrane

The synovial membrane lines the inner surface of the fibrous capsule, the intra-capsular non-articular parts of the bone, and intra-capsular tendons and ligaments, when present (Khoshi, 2017a). The pink, smooth, moist, shiny membrane exudes a viscous fluid resembling albumin. Fat pad accumulation is common in the synovial membrane of many joints and forms flexible cushions that fill in joint spaces and increase the surface area of the synovial membrane. The membrane also acts as a sieve; small molecules can pass through to capillaries and venules, and larger particulates pass into the lymphatics. The membrane does not coat any intra-articular discs or menisci. This membrane shows pathological changes in rheumatoid arthritis; it thickens and secretes more fluid resulting in swelling. The membrane contains elastin fibres which impart a recoil in the membrane so that it does not become trapped in joint movement (Percival, 2001).

1.2.4 Synovial fluid

Synovial fluid is secreted by the synovial membrane and is found in the cavities of synovial joints, bursae, and tendon sheaths. It is a dialysate of blood plasma

containing added hyaluronate (hyaluronic acid - a glycosaminoglycan). It shows viscous, elastic, and plastic components. The viscosity, volume and colour vary between different joints: the viscosity decreases in inflammatory conditions mainly to the degree by which polymerisation is reduced by lysosomal enzymes (Brannan & Jerrard, 2006).

1.2.5 1st MTP jt anatomy in detail

Overview

The 1st MTP jt is a condyloid synovial juncture (McSweeney, 2016). It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTP jt in contradistinction to the lesser MTP jts (Hallinan et al., 2020). The metatarso-sesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The six muscles are the abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis. The joint's ligaments are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the intersesamoid ligament and the hood ligament (Alvarez et al., 1984; Khoshi, 2017b).

The First Metatarsal

The head of the 1st metatarsal is large and quadrilateral in general contour, with the transverse diameter exceeding the vertical dimension (see Fig. 2). The articular surface covering the head presents two fields in continuity: a superior

phalangeal and an inferior sesamoidal with a ridge that separates the sesamoids see below (Sarrafian & Kelikian, 2011) (see Fig. 3). The proximal phalanx is directed transversely and has a large base to receive its muscular and ligamentous attachments. It bears an oval, concave articular surface, the glenoid cavity, smaller than the corresponding articular surface of the metatarsal head (Khoshi, 2017b; Sarrafian & Kelikian, 2011).

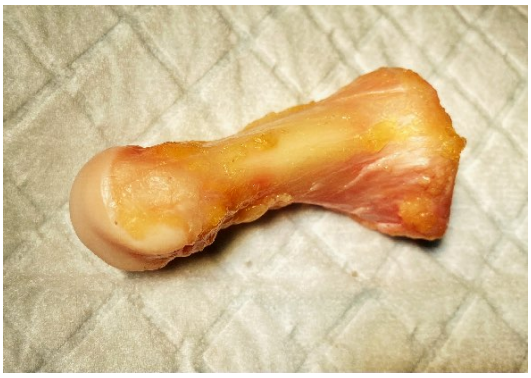

Figure 2: 1st metatarsal (medial view) in a cadaveric specimen

Figure 3: 1st metatarsal (distal view) in a cadaveric specimen

Sesamoids

The sesamoids are often likened in shape to coffee beans, but their overall configuration of the sesamoids is variable: they also may be semi-ovoid or circular in shape. They are embedded in the plantar pad which is a mass of dense fibrous tissue attached firmly to the base of the proximal phalanx. On the plantar surface of the metatarsal, the inferior articular surface is separated into two sloped surfaces by a rounded ridge or crest - the crista - oriented antero-posteriorly (Sarrafian & Kelikian, 2011). The sesamoids function to absorb weight-bearing forces, decrease friction, protect the flexor hallucis brevis tendons, and increase the functional length of the metatarsal in propulsion (Cohen, 2009).

Ligaments

Alvarez et al. (1984) list nine ligaments of the joint. Collateral and suspensory ligaments originate from medial and lateral epicondyles on the head of the first metatarsal. The collateral and sesamoid ligaments run forward and downward to attach to the base of the proximal phalanx and the appropriate sesamoid. The hood ligament is a fibrous expansion from the long extensor tendon, which encloses the tendon and attaches to the sides and plantar surface of the proximal and distal phalanx and blends with the joint capsule. The lateral margins of the plantar pad receive ligamentous and muscular attachments, and the proximal border receives part of the flexor hallucis tendon. The plantar surface of the pad is raised on either side by the two sesamoids to form a groove for the long flexor tendon held in place by a fibrous tunnel (Khoshi, 2017b).

Synovial membrane

Weston (1969) notes that the joint capsule is shaped like a box and cites that the best anatomical description of the synovial cavity of the 1st MTP jt is by Testut and Jacob (1943). The synovial membrane was shown to reflect proximally on the palmar and plantar aspects of the heads and necks of metacarpals and metatarsals.

Movement

Regarding function, the MTP jts permit flexion, extension, abduction, and adduction. The collateral ligaments prevent rotation. Flexion and extension are produced by the long and short flexor and extensor muscles (Khoshi, 2017b).

1.3 Joint pathology of the 1st MTP jt

Appropriate use of IA CSI implies that for the correct diagnosis and appropriate treatment to be instituted, the correct identification of the damaged/diseased structures is mandatory (Theumann et al., 2002). It will be helpful at this point to outline the main pathologies that affect the 1st MTP jt that are amenable to CSIT. Other disease processes from a dermatological, vascular, neoplastic, or traumatic origin that will not benefit from CSIT are beyond the scope of this thesis.

The two most common diseases affecting the 1st MTP jt of the foot are hallux limitus/rigidus (OA) and hallux abducto valgus (HAV) – or bunion (Ajwani et al., 2018; Mann, 1995). Whilst HAV is the most researched topic in 1st ray pathology, IAITs are not commonly used to manage this condition outside of the grey literature. However, their use in post-operative pain management after hallux valgus surgery will be considered. Other common pathologies of the joint include rheumatoid arthritis, gout and sesamoiditis (Tallia & Cardone, 2003). The area is prone to trauma (for example, turf toe) and infection, but this thesis will focus on conditions that are amenable to, or routinely subject to, IA CSI.

1.3.1 Osteoarthritis

OA is the leading cause of disability in adults worldwide and results in significant morbidity. Symptoms arising from osteoarthritis are notoriously difficult to manage with oral analgesics alone: the optimal treatment of osteoarthritis constitutes a combination of non-pharmacological and pharmacological therapeutic modalities. By maximising therapeutic effects locally in the joint and

limiting potential systemic adverse effects, intra-articular injection is an attractive treatment alternative and a good adjunctive therapy (Oo et al., 2018, 2019). Undermanaged osteoarthritis ultimately results in a significant burden on primary care, and there is a growing body of evidence that it is highly disabling (Jordan et al., 2003; Kingsbury & Conaghan, 2012; Paterson & Gates, 2019).

OA was long considered the consequence of any process leading to increased pressure on a particular joint or fragility of the cartilage matrix. The discovery in the 1990's that many mediators, such as cytokines or prostaglandins, can increase the production of matrix metalloproteinases (by chondrocytes) led to the first steps of an "inflammatory" theory, with synovitis later accepted as a critical feature of osteoarthritis (Seller & Berenbaum, 2010). Experimental data have shown that subchondral bone may have a substantial role as a mechanical damper and as a source of inflammatory mediators implicated in the osteoarthritic pain process and the degradation of the deep layer of cartilage. Thus, initially considered cartilage-driven, osteoarthritis is a much more complex disease with inflammatory mediators released by cartilage, bone, and synovium (Berenbaum, 2013).

McSweeney (2016) outlines the two types of OA 1st MTP jt pain are mechanical and inflammatory. He notes that mechanical OA joint pain is aggravated by prolonged functional weight-bearing, excessive range of movement elicited at the joint, and an increased mechanical load but that, in contrast, the onset and frequency of inflammatory OA joint pain is far less predictable. Triggers include

changes in environmental weather conditions, prolonged walking durations, and minor sprains to the joint.

Symptomatic osteoarthritis affects approximately 10% of the adult population, and the prevalence increases with age (as do comorbidities). In the foot, the midfoot and forefoot are often affected by this condition, but the 1st MTP jt is the most affected joint (Roddy & Menz, 2018) – see Fig. 4 (Patient NR, see consent at Appendix 15). Radiographic 1st MTP jt OA with evidence of uneven cartilage loss and exostosis formation is present in approximately 46% of women and 32% of men at 60 years of age – see Fig. 5 (Patient KC, see consent form in Appendix 15).

OA of the 1st MTP jt has been commonly described as either hallux limitus (HL) or hallux rigidus (HR) (Shurnas, 2009). The term used depends on the magnitude of available joint motion and the severity of joint degeneration (Anderson et al., 2018). HL is characterised by restricted sagittal plane motion (primarily dorsiflexion). In contrast, HR lacks joint motion due to end-stage degenerative joint disease and subsequent joint ankylosis (Lucas & Hunt, 2015).

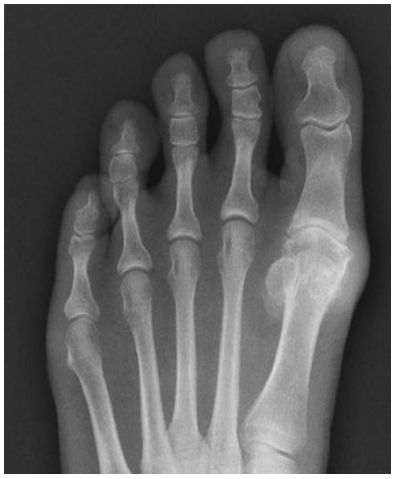

Figure 4: Radiographic features of 1st MTP jt OA demonstrating loss of cartilage and sclerosis

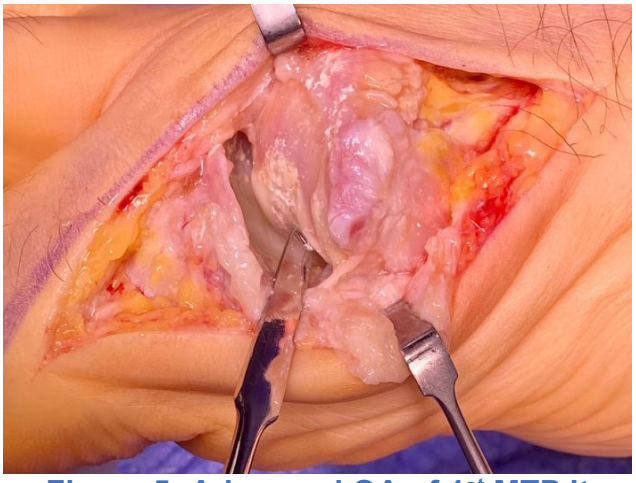

Figure 5: Advanced OA of 1st MTP jt demonstrating loss of cartilage and osteophytosis on intra-operative image for jt arthrodesis

Individuals with 1st MTP jt osteoarthritis experience more foot pain, have greater difficulty performing functional weight-bearing activities, find it more difficult to obtain suitable footwear, and perceive their feet to be in a poorer state of health. Additionally, people with symptomatic 1st MTP jt osteoarthritis have greater difficulty performing a broad range of physical tasks and activities and unmanaged foot pain is an independent risk factor for depression and falls in adults (Awale et al., 2016; Bergin et al., 2012).

Most practitioners use CSIs to treat osteoarthritic or inflammatory conditions that have not been responsive to physical therapy and nonsteroidal anti-inflammatory drugs (Cole & Schumacher, 2005). The National Institute for Health and Care Excellence (NICE, 2014) suggested the following for intra-articular injections in the treatment algorithm of OA:

1.5.12. *Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.*

NICE guidance was updated in 2022 (NICE, 2022a) to state:

> 1.4.10 *Consider intra-articular corticosteroid injections when other pharmacological treatments are ineffective or unsuitable, or to support therapeutic exercise. Explain to the person that these only provide short-term relief (2 to 10 weeks).*

CSIs and hyaluronic acid are the most frequently used IA therapies in OA though many other IA substances have been investigated as potentially therapeutic in treating arthritic joints (Petrella & Cogliano, 2004). These include orgotein, radiation synovectomy, dextrose prolotherapy, silicone, saline lavage, saline injection without lavage, analgesic agents, non-steroidal anti-inflammatory drugs (NSAIDs), glucosamine, somatostatin, sodium pentosan polysulfate, chloroquine, mucopolysaccharide polysulfuric acid ester, lactic acid solution, and thiotepa cytostatica (Uthman et al., 2003).

1.3.2 Rheumatoid arthritis

RA is a chronic, systemic autoimmune disorder that primarily affects the lining of the synovial joints (Cooles & Isaacs, 2011). This results in inflammation and thickening of the joint capsule (Guo et al., 2018). The disease is associated with progressive disability, premature death, and socioeconomic burdens. It typically results in warm, swollen, and painful joints, with pain and stiffness often worsen following rest. The wrist, hands and feet are most commonly involved, with the same joints typically involved on both sides of the body. The disease also affects other parts of the body, which may result in anaemia and pericarditis; fever and lethargy may also be present.

While the cause of rheumatoid arthritis is unclear, it is believed to involve a combination of genetic and environmental factors (Cooles & Isaacs, 2011). Modern pharmacologic therapies (including conventional, biological, and novel potential small molecule disease-modifying anti-rheumatic drugs) remain the mainstay of RA treatment, and there has been significant progress toward achieving disease remission without joint deformity (Guo et al., 2018).

In the rheumatoid foot, the basis of successful management is satisfactory control of inflammation which could include general treatment in combination with early local therapy via a corticosteroid injection (Bálint et al., 2003). CSIs reduce the amount of citrullination in the synovium and induce a long-term decrease in inflammatory markers (Makrygiannakis et al., 20120. The study by Furtado describes IA triamcinolone for treating refractory synovitis in RA patients. Joint swelling was identified as the variable with the best response to this procedure, with the best response to it seen in the knee and the hand. They conclude that more prospective studies are required to define other variables, such as the optimal dose of steroids and the exact duration of response after injection (Furtado et al., 2017).

Green (2001) finds that IA CSIs are an effective treatment for early oligoarthritis, but there is still a high level of long-term morbidity. Failure to respond by two weeks indicates a high likelihood of persistent disease, and this is relevant when producing management guidelines and selecting patients for studies focusing on early intervention (Green et al., 2001). Carrasco et al. (2014) report the common use of CSI in juvenile idiopathic arthritis (JIA). In cases of JIA,

image-guided injections into the joints of the foot have improved symptoms of up to 64 weeks in some patients, with reports of complete resolution in some of these patients (Pekarek et al., 2011). Cleary et al. (2003) suggest 1–2mg of triamcinolone hexacetonide for the 1st MTP jt in JIA; doses are doubled if triamcinolone acetonide is used.

1.3.3 Gout

Gout is the most common form of inflammatory arthritis. It is characterised by disruptions in purine metabolism and decreased urate excretion leading to increased serum uric acid levels, causing monosodium urate crystal formation and deposition, mainly in and near joints (Urits et al., 2020). The 1st MTP jt is a common site for tophus formations and is implicated in over 70% of acute attacks (Scott, 2000, Stewart et al., 2016).

Optimal treatment requires pharmacological and non-pharmacological management. Oral, intra-muscular and IA CSIs have been used to treat acute gout. There is no evidence from RCTs to support the use of IA CSIs treatment in acute gout (Zhang et al., 2006). Wechaleka et al. (2013) note that as the evidence suggests that IA glucocorticoids are a safe and effective treatment in OA and RA, these results may be generalisable to people with acute gout treatment may be beneficial in people when non-steroidal anti-inflammatory drugs or colchicine are contraindicated. Arthrocentesis of acute crystal-induced synovitis such as gout and pseudogout (calcium pyrophosphate deposition disease) and subsequent CSI may rapidly and dramatically alleviate the severe pain caused by such compounds (Caldwell, 1996; Hollander et al., 1951; Scott,

2000). Caldwell's preference is to mix a short-acting and a long-acting steroid to get an immediate and then a longer-term reduction in inflammation: he combines this with a short- and long-acting local anaesthetic for immediate pain relief; he also injects the periarticular issues as he states that these are also affected in gout.

Joint fluid aspiration and IA CSI injection are commonly performed in clinical practice (Sivera et al., 2008), are their use is recommended by rheumatologic societies around the world, including the European League Against Rheumatism (EULAR) (Richette et al., 2016), the British Society of Rheumatology (BSR) (Hui et al., 2017) and the American College of Rheumatology (ACR) (Khanna et al., 2014):

> '*Joint aspiration and injection of a corticosteroid are highly effective in acute monoarticular gout and may be the treatment of choice in patients with acute illness and co-morbidity'* (Hui et al., 2017).

NICE guidance was updated in 2022 (NICE, 2022b) to state:

> 1.3.3 *Consider an intra-articular or intramuscular corticosteroid injection to treat a gout flare if NSAIDs and colchicine are contraindicated, not tolerated or ineffective*.

McCarty (1977) suggests that IA CSIs may be of additional help in cases of recurrent synovitis with pseudo-gout: calcium pyrophosphate dihydrate deposition disease (CPDD).

1.3.4 Sesamoiditis

Sesamoiditis is a generic term for numerous conditions involving the 1st MTP jt sesamoids, including osteonecrosis, chondromalacia, infection, mechanical overload, acute trauma - or repetitive injuries that may cause stress fractures (Hallinan et al., 2020; Lepage-Saucier et al., 2013; Ross, 2016). Patients can also present with a painful swollen plantar 1st MTP jt adventitious bursitis and sesamoiditis secondary to a malalignment in HAV deformity due to erosion on the plantar metatarsal head crista (Reilly, 2010). Diagnostic imaging may demonstrate sesamoid inflammation without radiographic changes, avascular changes of the sesamoids, fragmentation, fracture, or sclerosis (Cohen, 2009). CSIs (+/- local anaesthetic injections) can be both diagnostic and therapeutic in sesamoiditis (Kilmartin, 2017; Ross, 2016; Shin et al., 2013, Sims & Kurup, 2014), though Cohen (2009) counsels against repeated injections.

1.3.5 Arthrofibrosis

Arthrofibrosis is restricted joint motion - typically painful - and is thought to result from an exaggerated fibrotic response after joint trauma or surgery (Bosch et al., 1999; Yu et al., 2001). Patients experiencing arthrofibrosis often experience a heightened immune response after an injury, allowing the excessive activation of inflammatory cells and subsequent induction and proliferation of undifferentiated cells residing in the synovial tissue (Feuerstein et al., 2016). It is commonly seen post open hallux abducto valgus surgery.

1.3.6 Post-operative pain control after HAV surgery

Salerno and Herman (2006) note that while IA CSIs for treating inflammatory joint pain and swelling following surgery have received little attention in the orthopaedic literature, some surgeons perform subcutaneous steroid injections to reduce pain and inflammation after foot surgery.

1.4 The pharmacology of corticosteroids

The relevant pharmacology will be highlighted below. The adrenal glands produce four major classes of hormones (Zaloga & Marik, 2001):

1. Glucocorticoids,
2. Mineralocorticoids,
3. Adrenal androgens (sex hormones),
4. Catecholamines (primarily epinephrine).

Glucocorticoids and mineralocorticoids are collectively known as corticosteroids (CS). Naturally occurring corticosteroids are produced in the adrenal cortex. They are critical mediators in the maintenance of normal physiology and in the complex adaptive mechanisms that protect an organism from internal or external stressors (Bornstein & Chrousos, 1999). Mineralocorticoids maintain normal fluid and electrolyte balance; glucocorticoids primarily enhance glucose production (hence their name) and reduce other metabolic activity (Zaloga & Marik, 2001). Glucocorticoids also suppress the immune system and possess a potent anti-inflammatory effect (Rhen & Cidlowski, 2005). Endogenous corticosteroids are produced from cholesterol building blocks (see Fig. 6), with natural cortisol production

regulated by the hypothalamus-anterior pituitary-adrenal (HPA) cortex axis (Kaplan et al., 2020).

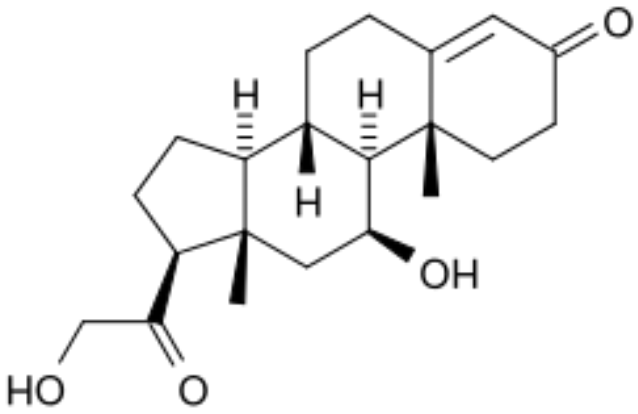

Figure 6: The generic steroid molecule, which is based on the cholesterol molecule (http://en.wikipedia.org/wiki/Corticosteroid)

1.4.1 Injectable corticosteroids

Modern injectable compounds are typically longer-acting, synthetic derivatives of prednisolone (an analogue of cortisol), produced either by methylation (e.g., methylprednisolone) or fluorination (e.g., triamcinolone, betamethasone, and dexamethasone) (Anitescu et al., 2013). Most proprietary drug solutions contain water-insoluble corticosteroid esters and present as microcrystalline suspensions. In contrast, phosphate preparations such as dexamethasone phosphate are free of corticosteroid esters and appear clear and non-particulate (Kaplan et al., 2020).

The most commonly used corticosteroids in the UK are triamcinolone acetonide (Kenalog), methylprednisolone acetate (Depo-Medrone), and dexamethasone (Decadron) (Shar et al., 2019). Other steroids used include triamcinolone hexacetonide (the 21-t-butyl acetate of triamcinolone acetonide, its biologically active metabolite), betamethasone acetate, and hydrocortisone. The

physiological duration of action of an injectable medication depends on the biological and pharmacologic half-lives of the compound. In particulate preparations, the biologically active moiety is released locally by the action (by hydrolysis) of cellular esterases. It, therefore, has the potential to increase the duration of activity at the point of placement, e.g., IA injection (MacMahon et al., 2009). Conversely, water-soluble solutions are taken up quickly by the cells: they have a quicker onset of action but a reduced duration of action (Benzon et al., 2007).

Cortisol has a half-life of only 70 to 90 minutes. In contrast, the injectable compounds used in clinical practice have longer half-lives based on slower metabolism rates (see Table 2, adapted from Deer et al., 2009).

Table 2: Properties of synthetic cortisol analogues

Steroid	Half-Life (hours)	Relative Glucocorticoid Activity	Relative Mineralocorticoid Activity	Glucocorticoid Dose (mg) Equivalency	Relative Anti-inflammatory Activity
Short Term					
Cortisone	8-12	1	1	25	Not given
Hydrocortisone	8-12	0.8	0.6	20	1
Intermediate Acting					
Prednisone	8-36	4	0.8	5	Not given
Prednisolone	8-36	4	0.8	5	3
Methylprednisolone	18-36	5	0.5	4	6.2
Triamcinolone	18-36	5	0	4	5
Long Acting					
Dexamethasone	36-54	20-30	0	0.75	26
Betamethasone	36-54	20-30	0	0.6	Not given

Short-acting synthetic glucocorticoids (hydrocortisone) have durations of action of 8 to 12 hours. The intermediate-acting glucocorticoids (prednisone, prednisolone, methylprednisolone, and triamcinolone) have half-lives of 24 to

36 hours, and the longest-acting glucocorticoids (dexamethasone and betamethasone) have half-lives longer than 48 hours (Melby, 1977). Short-acting synthetic glucocorticoids (hydrocortisone) have durations of action of 8 to 12 hours. Fluorinated corticosteroids have a fluorine group added to their structure. This modification decreases solubility and therefore increases the duration of action (Kaplan et al., 2020; Wakefield, 2016). All glucocorticoids have some mineralocorticoid effect: the shorter-acting glucocorticoids have the highest mineralocorticoid potency, and the long-acting agents have the weakest potency (Anitescu et al., 2013).

1.4.2 The physiological and therapeutic effects of corticosteroids

Glucocorticoids are used to relieve pain, increase mobility, and reduce deformity in joint disease because of their anti-inflammatory effects (NICE, 2014). They act via the glucocorticoid receptor, which resides in the cytoplasm, sequestered in a heat-shock protein complex (Beato et al., 1995). Glucocorticoids modulate the immune response at many levels and are potent and effective in controlling inflammation through numerous mechanisms, including effects on cytokines, inflammatory mediators, inflammatory cells, nitric oxide synthase, and adhesion molecules (Anitescu et al., 2013; Chen et al., 2018; Lim et al., 2007; Schleimer, 1993).

1.4.3 Effects on cytokines

Cytokines are important mediators of inflammation: their expression pattern largely determines the magnitude and persistence of the inflammatory response. Pro- and anti-inflammatory cytokines facilitate and inhibit inflammation, respectively (Chen et al., 2018). CSs have potent inhibitory

effects on cytokine transcription and synthesis, TNF-α and granulocyte-macrophage colony-stimulating factor (Chen et al., 2018; Guyre et al., 1988; Li et al., 2017).

1.4.4 Effects on inflammatory mediators

Phospholipase A_2 leads to the hydrolysis of arachidonic acid and the production of arachidonic acid metabolites from cell membrane phospholipids. Arachidonic acid metabolism produces prostaglandins and thromboxanes via the cyclo-oxygenase pathway and leukotrienes through the lipoxygenase pathway. Glucocorticoids increase the synthesis of annexin A_1 (lipocortin 1), a phospholipase A_2 inhibitor. This decreases the production of inflammatory mediators (Barnes & Adcock, 1993). Glucocorticoids also upregulate the transcription of other anti-inflammatory genes (such as neutral endopeptidase and inhibitors of plasminogen activator and suppress the transcription of genes involved in inflammation (such as collagenase, elastase, plasminogen activator, cyclo-oxygenase-2 and most chemokines) (Schwiebert et al., 1996).

1.4.5 Effects on inflammatory cells

Glucocorticoids modulate macrophage activity by impairing phagocytosis, intracellular digestion of antigens, and macrophage release of IL-1b, IL-6, IL-12 and TNF-α (Lim et al., 2007). By inhibiting the expression of chemokines, glucocorticoids prevent the activation and recruitment of inflammatory cells, including eosinophils, basophils, and lymphocytes (Schwiebert et al., 1996). Glucocorticoid administration blocks the cytokine effects that eosinophil activity depends on, leading to apoptosis (programmed cell death). Glucocorticoids

also interfere with T-cell-mediated immunity and inhibit the release of T-lymphocyte cytokines (Coutinho & Chapman, 2011).

1.4.6 Effects on nitric oxide synthase

Cytokines induce nitric oxide synthase, resulting in increased production of nitric oxide, increasing plasma exudation in inflammatory sites. Steroids inhibit the inducible form of nitric oxide synthase in macrophages; pre-treatment prevents the induction of NOS expression by endotoxins (Barnes & Adcock, 1993).

1.4.7 Effects on adhesion molecules

Adhesion molecules facilitate the trafficking of inflammatory cells to sites of inflammation. The expression of the adhesion molecules E-selectin, P-selectin, and intracellular adhesion molecule-1 on the surface of endothelial cells is induced by the cytokines IL-1β and TNF-α (Barnes & Adcock, 1993). These adhesion molecules enable the endothelium to recruit leukocytes actively and non-selectively (Schwiebert et al., 1996).

1.5 Chapter summary

A needle is inserted into a joint either for aspiration of joint fluid or for administering medications, very often a CS. Therapeutic injections provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, those in whom conservative treatment has failed or those that are awaiting surgery. Typically considered an adjuvant to systemic and local treatment methods, their use is widely accepted as an important treatment

modality. Steroid injections are used for various foot pathologies, notably HL/HR though the evidence base behind their use is weak.

The general features of a synovial joint and detailed anatomy of the 1st MTP have been presented to help the reader visualise the structures involved. The main pathologies of the joint have been discussed concerning those that are amenable to treatment with an injectable CS. The two most common diseases affecting the 1st MTP jt of the foot are HL/HR and HAV. HAV is seldom treated with CSIT, but common joint pathologies that do receive a CSI include RA, gout and sesamoiditis. CSI use in post-operative pain management after hallux valgus surgery will also be considered.

An overview of the pharmacology of glucocorticoids has been presented, which is necessary when considering how these drugs may be employed clinically to treat joint disease. Glucocorticoids control metabolism, suppress the immune system and possess a potent anti-inflammatory effect. Modern injectable compounds are typically long-acting, synthetic derivatives of prednisolone. Understanding relative potency and strength is helpful in their application in clinical practice.

Having outlined the pathology affecting the joint, attention will now turn to the literature to see what is known about CSI of the 1st MTP jt. This will be identified via a scoping review.

CHAPTER 2

IAIT of the 1st MTP jt

Publications: Reilly, I. N. (2021). Key concepts for intra-articular corticosteroid injections for pathology of the first metatarsophalangeal joint: a scoping review protocol. *Open Science Framework PrePrints*. Available from: https://osf.io/vrebq.

Reilly, I. (2022). Hit and miss: The accuracy of intra-articular injections of the first metatarsophalangeal joint. *The Journal of the International Foot & Ankle Foundation*, 1(11), 1–18. https://doi.org/10.55067/jifaf.v1i11.38.

Reilly, I., & Botchu, R. (2022). Use of intra-articular injection corticosteroid injections to the first metatarsophalangeal joint. First theme of a scoping review. *PrePrint,* 1–21. https://www.preprints.org/manuscript/202210.0484/v1

2.1 Introduction

Scoping reviews (ScR) are used to identify, map, or discuss the characteristics or concepts in a field (Peters, 2020a). They are a form of knowledge synthesis that addresses an exploratory research question and maps the key concepts underpinning a research area by systematically searching, selecting, and synthesising existing knowledge (Arksey & O'Malley, 2005; Levac et al., 2010; Colquhoun et al., 2014). ScRs are helpful when a body of literature has yet to be comprehensively reviewed or exhibits a large, complex, or heterogeneous nature that is not amenable to a more thorough systematic review (Peters et al., 2015).

This ScR followed the framework and process set out by the Joanna Briggs Institute (JBI) (Pearson et al., 2005; Khalil et al., 2020). Using a framework ensures that the study is rigorously conducted, transparent, and trustworthy (Peters, 2020b). The JBI recommends developing an a-priori protocol before undertaking the ScR (Peters, 2020a). An ScR protocol is essential as it pre-defines the objectives and methods of the ScR. It is a systematic approach to the conduct and reporting of the review and allows transparency in the process. The objectives, inclusion criteria and methods for this ScR are specified in advance and documented in the protocol (see Appendix 2). This review protocol was registered with Open Science Framework (Reilly, 2021a) and is also available as a preprint (Reilly, 2021b).

The ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews’ – PRISMA-ScR (Tricco et al., 2018) was used to guide the reporting of the review (See Appendix 1).

2.2 Aims and objectives

To overall aim of this work is to establish what is known about IA CSI therapy for the pathology of the 1st MTP jt.

The objectives of the ScR are to:

1. establish the key concepts about IA CSI therapy for the pathology of the 1st MTP jt., and to group the data into thematic areas
2. identify key gaps in the existing evidence base and suggest the most urgent questions for future research.

2.2.1 Inclusion and exclusion criteria

Inclusion and exclusion criteria were established to enable the aims and objectives of the research question to be met (Aveyard, 2018). The JBI recommend using the PCC framework (‘Population – Concept - Context’) for scoping reviews to identify the main factors in review questions (Peters et al., 2020a); see Table 3.

Table 3: Population-concept-context inclusion and exclusion criteria

Inclusion criteria	Rationale for inclusion and exclusion
Population	Human subjects (patients)
Concept	This scoping review will consider literature that provides information related to treatment with an intra-articular (IA) CSI
Context	IA CSI for pathology of the 1st MTP jt
Types of evidence to be included:	• Published papers or published conference abstracts reporting empirical or qualitative data from primary research or service evaluations. All research designs pertaining to the scoping review objectives will be considered. • Grey literature will be excluded for primary searching as published sources will be most useful and appropriate – and likely more rigorous. This is also to limit the number of hits as there are an unmanageable number of grey articles/websites. Selected sources found through secondary reference lists may be considered. • To ensure a wide-ranging review, as per JBI guidelines, there will be no date or language restrictions. • Studies that do not use IA (e.g., peri-articular, or systemic) CSI for the 1st MTP jt, or for which the original manuscript could not be retrieved, will be excluded.

2.2.2 Methodological approach

The search strategy for a scoping review should ideally aim to be as comprehensive as possible within the constraints of time and resources to identify appropriate literature. To achieve the research aim, a strategy that involves searching for research evidence via the following different sources was adopted:

a) Electronic databases,
b) Google Scholar,
c) Reference lists.

Step 1: The following databases were searched via the NHS Healthcare Advanced Database Search (HDAS) search engines using MeSh terms/free text (see Appendix 3):

- CINHAL (Cumulative Index to Nursing and Allied Health Lit.: 1981 – 01.01.2021),
- EMBASE (Excerpta Medica Database: 1974 – 01.01.2021),
- MEDLINE (Medical Literature Analysis and Retrieval Online: 1946 – 01.01.2021).

Search terms

"((GLUCOCORTICOIDS/ OR (Steroid*).ti,ab OR (glucocorticoid*).ti,ab) AND ("INJECTIONS, INTRA-ARTICULAR"/ OR (Injection*).ti,ab)) AND (HALLUX/ OR (hallux).ti,ab OR ("big toe*").ti,ab OR ("great toe*").ti,ab OR (arthrofibrosis).ti,ab OR (gout).ti,ab OR (sesamoid*).ti,ab)"

Step 2: Google Scholar was searched using keywords identified from an analysis of the text words contained in the title and abstract of retrieved papers, and these keywords were used to search for articles.

Step 3: Examination of the reference lists of all identified sources from steps 1 and 2.

Following the execution of the search strategy, the identified records were retrieved and included or excluded according to the inclusion and exclusion criteria listed above, see Appendix 4. Various study designs are included to support the greater breadth of data for scoping reviews. Scoping reviews are designed to provide an overview of the existing evidence base regardless of

research quality. Therefore, a formal assessment of the methodological quality of the included studies was not performed.

Following retrieval (database and snowball referencing), charting and sorting of material according to key issues and themes were performed. A data extraction instrument for study details, characteristics and results extraction is provided in Appendix 5, adapted from the template provided by Peters et al. (2020a) was used for themes one and three. The themes developed are tabulated and summarised to present a narrative account of the existing literature, see Appendix 6.

Due to the heterogeneity of data, ScR do not synthesise the results/outcomes of included sources of evidence, as this is more appropriately done within a systematic review (Peters et al., 2015). The results of this scoping review are presented as a map of the data extracted from the included literature as three themes and a tabular form (Appendix 5) and in a narrative descriptive summary that aligns with the review's objectives.

This final stage of the JBI process refers to stakeholder consultation and is considered optional (Peters et al., 2020a). Two or more researchers usually undertake ScRs to ensure balance; external consultation does not apply to an academic review written by a single researcher (Peters et al., 2020b).

2.3 Results

The search yielded 193 articles (see Appendix 4), 48 of which appeared of potential relevance. After removing duplicate articles, this total was reduced to 37 (see Appendix 4). Many of the abstracts – and more so the titles – did not make it clear whether the article was relevant to the research question. After scanning the content, 27 were excluded to leave ten articles. Twenty-eight further articles were found through related author research, examination of reference lists and free text searches of Google Scholar. One reference was unobtainable. The final count of papers for review was 37 (see Fig. 7 for PRISMA-ScR flowchart).

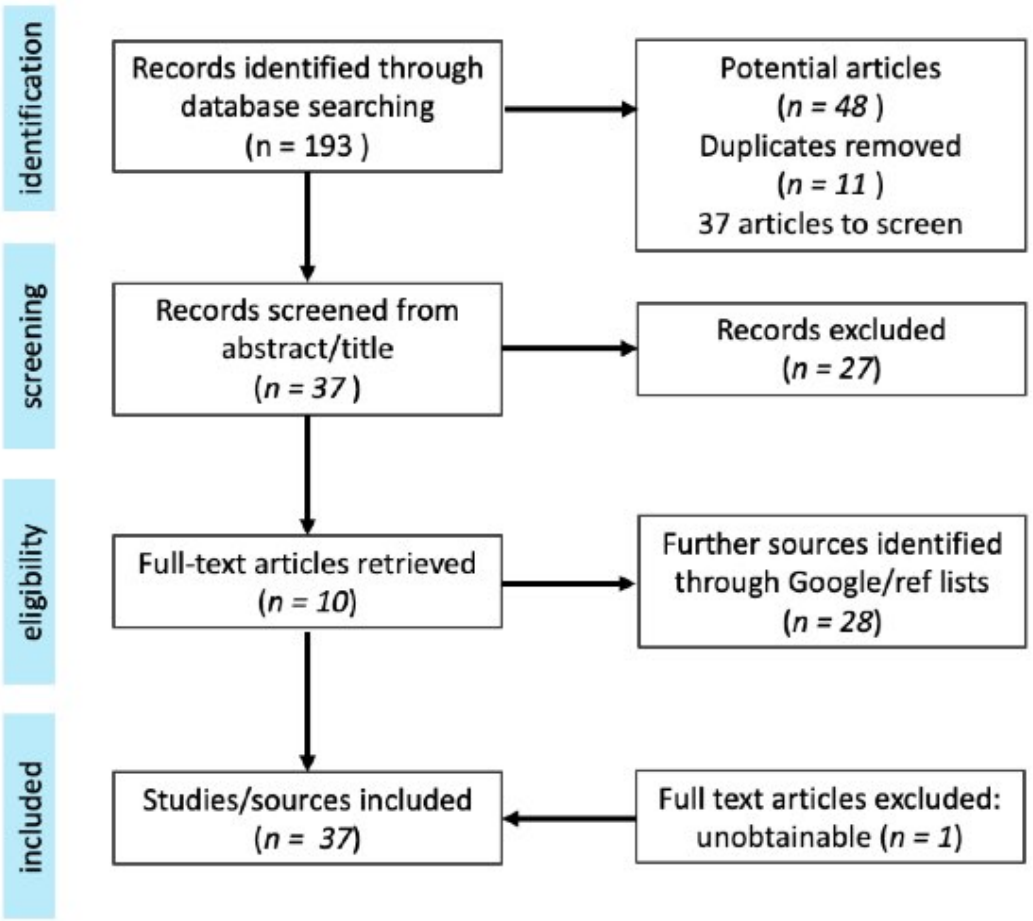

Figure 7: PRISMA-ScR flowchart

Iterative charting of the literature yields three broad and overlapping themes:

1. Injection therapy outcomes for a given joint pathology,
2. Injection techniques, dosage, and regimen,
3. Injection accuracy and needle placement.

Nineteen articles developed Themes 1 and 3 (two also appear in Theme 2) and are summarised in Appendix 5. Twenty articles (plus one, one unreferenced, and one found after the initial search) were technical/technique articles that developed into Theme 2 and led to the development of a best practice IT guideline.

2.4 Theme 1: injection therapy outcomes for a given joint pathology

2.4.1 Osteoarthritis

Sarkin (1974), in the earliest reference that was identified, describes his results of 300 patients with OA of the ankle and 1st MTP jt injected 6mg of betamethasone given weekly, until all symptoms had disappeared, up to a maximum of three injections. This is a low-quality level IV case series but from his experience, Sarkin believes the following three points were important: (i) the type, site and severity of symptoms; (ii) concurrent HAV deformity; (iii) the range movement present in the 1st MTP jt. He concludes that for IA steroid injections to be of value, there must be no HAV deformity and at least 45° of free movement retained in the affected joint.

Solan et al. (2001) report the results of MUA in combination with an IA CSI carried out on 37 joints, with a minimum follow-up of one year using 40mg of depo-medrone in 3ml 0.5% bupivacaine for patients with varying regression of

joint disease. Patients with mild (grade-I) changes gained symptomatic relief for a median of six months, and only one-third in this group went onto surgery. Two-thirds of patients with moderate (grade-II) disease underwent open surgery and only had symptomatic relief for three months. Little symptomatic relief was obtained in advanced (grade-III) HR, and all those patients required operative treatment. The authors recommend that joints are graded before treatment and that manipulation under anaesthetic (MUA) and CSI should be only used only in early (grades I and II) hallux rigidus. This paper is regularly quoted in the literature: it is 22 years old and has not been repeated, but it is considered a landmark study to predict outcomes from CSI in patients cross-referenced by their radiological disease presentation. We do not know whether the steroid, the anaesthetic, the manipulation, or a combination, is responsible for the benefits seen, however short term. The lower numbers (five) in the grade III sample further limit confidence in the conclusions drawn but the results do echo the early work of Sarkin (1974) who also believed that the OA need to be mild for the effects of the CSI to be beneficial.

In a retrospective analysis of 772 patients with symptomatic HL by Grady et al. (2002), 428 patients (55%) of the cohort were successfully treated with conservative care alone. Twenty-four patients (6% of those treated conservatively) were given IA CSIs. Of these patients, 18 received one injection; five received two injections; and one had three injections; injections were given four weeks apart where required (more than 50% but less than 80% improvement). The generalisability from this paper for CSIs is marginal given that n = 24 for IAIT and data on disease progression and regimen is limited.

However, it does point to a potential role of IAIT in the overall management of the pathology.

Ward et al. (2008) looked at the long-term efficacy of CSIs in foot and ankle joints, acknowledging that most evidence for the efficacy of IA CSIs comes from studies confined to the knee, with fewer studies considering the joints of the foot and ankle. Eighteen patients were enrolled in their prospective study and a foot-related quality of life questionnaire completed before injection and at seven set points post infiltration. They found a statistically significant score improvement following CSI up to and including six months post-injection and that the magnitude of the response at two months was found to predict a sustained response at nine months and one year. Many patients were lost to follow-up, and the authors admitted that their sample size was small, and that injections were not performed to a standardised technique. All pathologies were aggregated into toe results: only one MTP jt is included (which may or may not be the 1st MTP jt). It is difficult to draw conclusions from this paper for 1st MTP IAIT given this paper's sample size of n=1 but the predictive value of an early response to the sustained response is noteworthy.

In a similar manner to Ward et al. (2008) (though that paper is not referenced), Grice et al. (2017) performed a retrospective notes review and a telephone questionnaire of all patients who underwent a US-guided CSI of the foot or ankle (all conditions) over a one-year timescale. All injections were performed by a consultant musculoskeletal radiologist and reviewed at least two years post-treatment. 314 out of 365 (86%) of patients included in the study had

significant improvement in symptoms, but the longevity of outcome varied across the range of pathology injected: soft tissue ankle impingement fared best overall. Short-term benefit was seen for HR: 20 of 22 (91%) patients reported benefit from the injection, but only three patients (14%) reported that the improvement lasted longer than six months. At two years post-treatment, only two patients (9%) remained asymptomatic; 12 patients (55%) had undergone surgery. The authors concluded that injections should be reserved for those with mild OA, but they did not break down the HR group by disease regression (i.e., mild, moderate, or severe), so it is unclear how they reached that conclusion.

The level of evidence was level IV case series, with a potential for reporting bias through telephone consultation only. The applicability of context and clinician (image-guided injection performed by a consultant musculoskeletal radiologist) is open to further debate as 1st MTP jt injections are commonly performed non-guided. Nonetheless, this echoes the work by Sarkin (1974) and Solan et al. (2001) who believe that IAIT is of more use in early disease presentation. Kilmartin (2017) also believes that CSIs can be a very effective treatment for joint pain associated with mild-to-moderate HL and HAV, and for continued pain and stiffness following surgical intervention to the 1st MTP joint. He believes that because of potential risk to the joint cartilage, water-soluble betamethasone is a better choice of drug.

Pons et al. (2007) evaluated the effectiveness and safety of IA sodium hyaluronate (Ostenil® mini) compared to IA triamcinolone acetonide in 37 patients with early HR. One group received an injection of 1.0ml sodium hyaluronate; the other received an injection of 1.0ml triamcinolone acetonide. Effectiveness was measured on joint pain at rest or on palpation, passive motion and gait pain, American Orthopedic Foot and Ankle Society (AOFAS) hallux MTP scores, the use of analgesics, and global assessment of the treatment by both the patient and investigator. The AOFAS total score improved significantly in the visco-supplementation group compared to the corticosteroid group. No between-group differences were seen regarding the use of analgesics. The global assessment of treatment by patients was good in both groups, and there was a significant between-group difference favouring visco-supplementation and thus authors concluded that IA injections of sodium hyaluronate are effective and safe in decreasing HR pain.

This paper was poorly titled in that use of a CSI was not mentioned. The trial had a small sample size with a female gender bias. All participants had mild joint disease, potentially limiting the application of conclusions drawn from this to other patient populations, but the most significant limitation with this trial was that interventions were administered to participants with 1st MPJ OA and HAV with no sub-group analysis provided according to condition. The lack of blinding in data collection and evaluating adverse effects associated with the interventions administered poses a significant bias risk. From this trial, it was impossible to determine the efficacy of CSIs as an intervention to treat OA of the 1st MPJ.

Zammit et al. (2010) produced a Cochrane Review of controlled trials evaluating interventions for OA of the 1st MTP jt to determine the optimum intervention(s). Only one trial satisfactorily fulfilled the inclusion criteria and was included in their review: that trial evaluated the effectiveness of two physical therapy programs. The paper by Pons et al. (2007) was excluded from their analysis as both HR and HAV patients were included in that cohort, and therefore, the Cochrane Review will not be considered further.

The most up to date work is a comprehensive review of the non-operative management of HR by Kon Kam King et al. (2017) who found insufficient evidence to support the use of IA injections for pain relief beyond three months and adequate evidence against the use of IA injections for long-term efficacy. However, the methodology was not systematic or comprehensive: only a single database was searched for clinical trials and the risk of pertinent literature having been missed is high. The authors' recommendations were made based on an appraisal system that allocates a level of evidence for an intervention based solely on the design of studies identified; it did not consider the methodological quality of trials or the risk of bias. The IT trials identified in this review lacked heterogeneity regarding injectates tested and the design of trials. Despite this, the authors grouped six trials relating to IT together for data analysis and a collective level of evidence was allocated to IT as a whole.

It is clear that the evidence base for 1st MTP jt OA CSI is weak in strength, with case series predominating, and trials limited by sample size and design. Many other sources make only a passing comment about the use of IA CSIs in the

treatment of HL/HR but make a minimal contribution to the evidence base. For example, Vanore et al. (2003) note that *'judicious use of may provide rapid relief of pain even in recalcitrant cases of HR*'. It is difficult to draw conclusions from the data, but the inference is that mild disease fares better that a later presentation. A more systematic review of the literature is thus required.

2.4.2 Rheumatoid arthritis

While many articles cite the use of CSIs for inflammatory arthritis (RA or spondyloarthropathies), very little is written on foot pathology, even less for the great toe (Bálint et al., 2003; Green et al., 2001; Roberts, 2020). Norberg et al. (2018) included all five MTP jt CSIs in their study to investigate whether US in combination with clinical examination, is better at identifying joints that will benefit from IA CSIs compared to identification by clinical examination alone, as well as identifying the efficacy of US-guided versus palpation-guided procedures, but the data is aggregated and not broken down by anatomical site. It is therefore difficult to draw any conclusions on the role of IAIT for rheumatoid 1st MTP jts and warrants further study.

2.4.3 Gout

The ScR identified only two papers that consider IAIT for gout. Fernandez et al. (1999) reported on a case series of 19 patients who received IA triamcinolone acetonide for acute gout attacks in 11 knees, four 1st MTP jts, three ankles and two wrists. Patients were given 10mg in knees and 8mg in small joints. Based on visual analogue scores (VAS), 11 joints were resolved within 24 hours, and the remaining nine joints were resolved by 48 hours. No

patients presented for return of pain in the initial joint within the next 30 days. Kang et al. (2014) published a trial with 21 patients evaluating the safety and efficacy of IA CSIs for acute gout flare of the 1st MTP jt. The affected joint was injected with 0.5ml (20mg) triamcinolone acetonide with 0.5ml of 2% lidocaine under US guidance. All 21 patients experienced significant improvement in pain, general disability, and walking disability within 48-h post-treatment. No adverse events occurred within the first seven days post injection, the duration of the study.

Excluding low quality trails and case series, the Cochrane review by Wechalekar et al. (2013) found no evidence from randomised clinical trials (RCTs) to support the use of IA CSIs treatment in acute gout but that as the evidence suggests CSIs may be a safe and effective treatment in OA and RA, that those results may be generalisable to people with acute gout, especially when non-steroidal anti-inflammatory drugs or colchicine are contraindicated. NICE (National Institute for Health and Care Excellence, 2018) suggest that IA CSIs are an option if the diagnosis is certain and that only one or two (particularly large) joints are affected but note that IA CSIs are not specifically licensed for the treatment of gout.

In contrast, a consensus statement by the American College of Foot and Ankle (ACFAS) Surgeons via a Delphi study (Mirmiran et al., 2018), the panel could not reach a consensus on the statement: *Joint injections are preferred over oral steroids as initial treatment of acute gout*. The panel reviewed the literature and could not locate any high-level evidence of randomised or controlled studies in

the use of IA CSIs for the treatment of gout, citing the two studies mentioned above.

As with OA and RA, the evidence does not strongly support the use of CSIs for acute gout and this warrant further study. For example, the paper by Kang et al. (2014) had good methodology but a small sample size and no control group. This design would benefit from a larger, multicentre study that was randomised, prospective and had a control group.

2.4.4 Sesamoiditis

The evidence base of sesamoiditis CSI is sparse. Kilmartin (2017) suggests that 1ml of depo-medrone (40mg) can placed in the soft tissues just superficial to the involved sesamoid but not into the plantar fat pad and repeated on up to three occasions. This makes for an IA injection and contrasts to his earlier statement to use Betnesol (as a non-particulate injection) for joints. Wempe et al. (2012) demonstrates that the metatarsophalangeal-sesamoid complex is continuous and can therefore be approached through a standard 1st MTP jt IA technique. Sims and Kurup (2014) suggest that injections are usually done under radiological guidance to improve the accuracy of needle placement but that they should not be used in presence of a sesamoid fracture or avascular necrosis. Even more so than for the evidence base for IAIT in gout, the evidence base for CSIs for sesamoiditis is much sparser and methodologically weaker. This is further complicated is the range of pathologies that may bl classified as sesamoiditis, see section 1.3.4.

2.4.5 Post-operative arthrofibrosis

MUA of the 1st MTP jt joint was first described by Watson Jones in 1927 (Jones, 1927) with the aim of breaking down the capsular adhesions that restricted movement. Ajwani et al. (2018) report their findings to determine the effectiveness of manipulation under anaesthesia (MUA) and CSI to treat stiffness of the 1st MTP jt following surgery for HR or HAV. The injection used was a mixture of 40mg of methylprednisolone in 0.5% bupivacaine. The modal volume used was 1ml but ranged from 0.5ml to 4ml. The authors analysed 35 patients in 38 feet: 27 post-HR surgery and 11 post-HAV corrections. The total range of movement of the joint improved by an overall mean of 44.7°. They concluded that MUA with an IA CSI is an effective way of treating stiffness following first-ray surgery and that treatment results in an improved range of movement of the joint, and patients report good function post-operatively. While the range of motion was reported to improve, the measurements were performed by registrars and consultants without the use of a goniometer. This points to inter- and intra-rater variability and repeatability of data collection, but nevertheless, the trend was clear. Of note, 78% of the HR group had grade III disease: this will be a more difficult-to-manage patient cohort. What we cannot determine from the study is whether the manipulation (breaking down the arthrofibrosis), the local anaesthesia (blocking the pain reception) or the steroid (the effects and/or side effects of the CS) - or a combination - was/were responsible for the favourable outcome.

Feuerstein et al. (2016) investigated the outcomes of 1st MTP jt CSI and manipulation for arthrofibrosis that occurred as a complication of HAV surgery.

53 feet in 38 patients underwent intravenous sedation and regional nerve block and had their 1st MTP jt distracted; repeated attempts were made to forcibly dorsiflex and plantarflex the toe until the capsular adhesions were restricting motion had loosened, and the motion was improved in the toe. The joint was then injected was a mixture of 80mg of methylprednisolone acetate with 3mL of 0.5% plain bupivacaine. A significant increase in range of motion and a decrease in pain scores was seen, and the authors suggest that their technique is a useful modality in patients who experience arthrofibrosis after surgical correction of hallux valgus. As with Ajwani et al. (2018), it is impossible to say which part of the technique is the most important for the overall outcome.

2.4.5 Discussion of theme 1

This theme must be considered against the wider literature for IAIT. OA is the main indication for IAIT of the 1st MTP jt, and such injections fit into the wider discussion on using CSIs for OA.

Osteoarthritis

Cole and Schumacher (2005), Saunders and Longworth (2018b) and Wise (2003) note the breadth of the literature regarding all aspects of IT, with most of the published work based on low-level evidence and author experience, as noted above for the great toe. Much of the IT literature is level four/five, though, as Jacobs et al. (2013) point out, the lack of evidence is not equivalent to evidence of lacking relevance or efficacy. He believes that the efficacy of injection depends on various patient and physician variables. Nordberg et al. (2018) indicate that the efficacy of IAIT varies according to US findings at the

time of injection, supporting the use of US as a tool to select joints that will benefit from IAIT.

A Delphi panel (Shibuya et al., 2020) reached a consensus that the statement: “Intra-articular steroidal injection is a viable option for treatment of ankle arthritis,” was appropriate. Throughout the review, it was appreciated that the use of IA injections was identified in many forms of arthritis, including JIA, RA, acute gout, and OA. Most studies, however, were identified for managing JIA and RA. Even fewer studies looked specifically at foot and ankle injections. Most were retrospective studies, and the only prospective study had a small sample size.

Uthman et al. (2003) note that despite the lack of reproducible evidence that IAIT significantly alters the progression of OA, CSIs are widely used in patients who have failed other therapeutic modalities while Urits et al. (2020) state that injections provide an effective alternative in chronic pain alleviation. However, they also note as other authors do (Matzkin et al., 2017; Orchard, 2020), that the current evidence is limited and that the benefit described from IT is usually short-lived. Jüni et al. (2015) reported on the use CSIs for knee OA. They concluded that the clinically important benefits beyond six weeks remain unclear in view of the overall quality of the evidence, the heterogeneity between trials, and the evidence of small-study effects. They found that most identified trials that compared IA CSIs with sham or non-intervention control were small and hampered by low methodological quality. An analysis of multiple time

points suggested that the effects of the injections decrease over time, and their analysis provided no evidence that an effect remains six months after a CSI.

Smith et al. (2000) reported on the long-term follow-up of 22 patients (24 feet) treated non-surgically for HL/HR, with a mean follow-up of 14 years. They aimed to assess the outcomes from non-operative care, emphasising the patients' perspective. The pain level of the cohort remained constant in 92% of cases 75% of patients stated they would make the same choice for non-operative care if they had to make the decision again. Patients could tolerate their pain via self-care or shoe gear methods. For patients who elect to avoid surgery, using CSIs may be a useful adjunct to other non-surgical methods. But with such a variety of regimes following IA CSIs, there are no firm conclusions that can be drawn from the wider literature to influence IAIT of the 1st MTP jt.

Other joint pathology

The focus of IA injections to relieve the pain of inflammatory joint disease from RA and gout in the 1st MTP jt is very slim. Tan (2012) reports an impressive 68,460 patients who had been treated with CSIs over a 34-year period. While hallux interphalangeal joints and MTP jts are mentioned (n = 656), it is unclear how this number relates to the 1st MTP jt infiltrations. This requires further study. Ongzalima et al. (2016) used CS in combination with local anaesthesia for a Mayo block, while Bryant et al. (1999), Curda (1983), Miller and Wertheimer (1998) and Tiberia et al. (1987) infiltrated 'the operative site' post HAV surgery, which may or may not have resulted in an IA injection. Aasboe

et al. (1998) used intra-muscular Betnesol after HAV surgery and found that patients treated with steroids experienced significantly less post-operative pain in the first twenty-four hours after surgery. All these injection options warrant further study.

Future research

A note for future research: many trials evaluating the efficacy of IA-administered therapies commonly use IA saline injections as a placebo comparator arm. Altman et al. (2016) reviewed the literature to identify the clinical benefit associated with use of IA saline in trials of therapies in the treatment of patients with painful knee OA. They note that joint lavage, whether performed by the closed-needle-hole technique or through arthroscopic intervention does appear to be effective for brief periods of time perhaps through the removal of pain-mediating molecules. They suggest that aspiration of a joint prior to injection may lead to removing these markers prior to introducing the saline into the joint, hypothetically providing a similar effect to lavage. They concluded that IA saline injection, though often used as a “placebo” treatment in clinical trials for knee OA demonstrated the potential to provide substantial pain relief in several studies and that pain relief observed with IA saline should prompt healthcare providers to consider the additional effect of current IA treatments that use saline comparators in clinical studies, challenging saline injection as a placebo. Thus, a comparator arm for a prospective RCT might need to be a sham injection.

IAIT research for joint pathology is further complicated because of the rapid egress of injected materials from the joint space. This elimination is true of both small molecules, which exit via synovial capillaries, and of macromolecules, which are cleared by the lymphatic system (Evans et al., 2014). This questions the use of soluble over insoluble compounds.

Summary

Shoor (2004) notes that the review by Arroll et al. (2004) raises questions about which group of OA patients are likely to respond to CSIs, for example, those with less severe disease or those with clinical evidence of inflammation, such as an effusion. To what degree is the apparent success of IA CSIs affected by how the procedure is performed? For example, how much fluid is withdrawn if lavage is used rather than saline instillation? At what point in the treatment regimen should IA CSIs be used (i.e., after or before NSAID or physical therapy)? What is the effective and safe interval for repeat injections? These questions remain unanswered, even more so for the 1st MTP jt and more so again for conditions other than OA. More than 70 years after the first IA CSIs were given, there is a paucity of level-one evidence regarding their use. The relative efficacy of all injectable therapies is far from definitive and warrants further high-quality comparative trials (Vannabouathong et al., 2018). The literature on CSIT therapy presents little systematic evidence to guide the medication selection, technique, and regimen for therapeutic injections (Tallia and Cardone, 2003; Dahl & Hammert, 2012,). The medication used and the injection frequency should therefore be guided by the goal of the injection

(Reilly, 2010). The challenge is to apply the available evidence in a safe and effective manner.

2.5 Theme 2: injection techniques and regimen

2.5.1 Drug dosages

For common drugs and suggested dosages used in the United Kingdom (UK) taken from Product Information Leaflets (PILs), and from United States (US) (Kaplan et al., 2020), see Tables 4 and 5, respectively.

Table 4: Common drugs and their dosages (UK values)

Drug	Dose	Notes
Hydrocortisone	5–50 mg	Select dose according to size of patient and joint; where appropriate dose may be repeated at intervals of 21 days. Not more than 3 joints should be treated on any one day, for details consult product literature
Methyl-prednisolone	4–80 mg	Select dose according to size; where appropriate dose may be repeated at intervals of 7–35 days, for details consult product literature.
Triamcinolone acetonide	5–40 mg (max 80 mg)	Where appropriate dose may be repeated when relapse occurs, for further details consult product literature, select dose according to size. For doses below 5 mg use Adcortyl®.
Triamcinolone hexacetonide	2–20 mg	Adjusted according to size of joint, no more than 2 joints should be treated on any one day, where appropriate, may be repeated at intervals of 3–4 weeks. No more than 2 joints should be treated on any one day.
Betamethasone	Off-licence	Soft tissue only - not licensed for joint injections.
Dexamethasone	0.3–3.3 mg	Where appropriate, dose may be repeated at intervals of 3–21 days according to response, dose given according to size - consult product literature.

Table 5: Suggested dosages based on target of injection (US values)

Generic Name	Large Jt (mg)	Intermediate Jt (mg)	Soft Tissue (mg)
Betamethasone sodium phosphate	6-12	1.5-3	Varies with location
Dexamethasone sodium phosphate	7.5-15	2-4	Varies with location
Methylprednisolone acetate	40-80	10-20	Varies with location
Triamcinolone acetonide	40-80	10-20	Not recommended
Triamcinolone hexacetonide	40-80	10-20	Not recommended

The results are synthesised below in Table 8. The full descriptions for CSI techniques for the 1st MTP jt are in Appendix 7. These 20 references (plus one that is un-referenced, and a further reference found after the initial search) are expert opinion pieces describing the authors' preferred technique and are qualitative and unsuitable for formal critique/meta-analysis.

Table 6: Synthesised technique data

Reference	Pt. Position	Equipment	Drug	Technique (key points)
Al-Jabri & Charalambides (2019)	Supine with pillows	Not stated	Not stated	Use of the sulcus sign with fluoroscopy; the angle of insertion is 60 to 70 degrees with the tip of the needle aimed distally with a dorsolateral entry point
Bilstrom et al. (2007)	Supine with the foot in a neutral position	5-mL syringe/1-inch 22-25 gauge needle	15 mg of prednisone or 10mg of methyl-prednisolone/1 mL of 1% lidocaine	Traction on the affected toe and locate the resulting recess between the respective phalanges and metatarsal bones; dorsomedially or dorsolaterally to the extensor tendon
Courtney & Doherty (2005)	Not stated	25-gauge needle	7.5 mg of triamcinolone or equivalent	The joint line is identified by palpation and the joint is injected from the medial side with the point of the inserted under the extensor tendon
de Cesar Netto et al. (2018)	Supine to facilitate injection through a dorsomedial approach	25-gauge needle	Not stated	Insert into the joint medially to the EHL tendon, angling 15º-30º distally to avoid chondral injury to the first metatarsal head. Longitudinal traction with a toe trap may facilitate intraarticular placement of the needle
Goncalves et al. (2011)	Seated on an examination table with the knee flexed (45◦)	Not stated	Not stated	The needle was advanced avoiding extensor tendons. A subtle traction in opposite direction of the needle was helpful to slightly open the joint space
Gross & Lin (2012)	Supine with their knee flexed and supported with a pillow	25-gauge 1.5-inch needle	Not stated	The syringe is inserted on the dorsomedial or dorso-lateral surface at an angle of approximately 60 to 70° to the plane of the foot
Hansford et al. (2019)	Supine, with affected knee bent and plantar aspect of the foot on the table	Not stated	Not stated	aim for the medial edge of the joint along the curved surface of the metatarsal head to avoid dorsal osteophytes
Kilmartin (2017)	Not stated	Not stated	Not stated	The joint is accessed either from central dorsal or dorsolateral aspect
Kilmartin (2017)	Not stated	Not stated	1ml (40mg) (? Betnesol)	placed in the soft tissues just superficial to the involved sesamoid but not into the plantar fat pad
Lungu & Moser (2015)	The hand/foot of the patient is positioned prone	A 5/8-inch (1.6-cm) 25-gauge needle	Not stated	Arthrography of the metacarpophalangeal, metatarsophalangeal, and interphalangeal joints can be performed by targeting the dorsal articular recess
Maher & Price (2007)	Not stated	21-gauge needle	Sodium hyaluronate 1.0%	The hallux is held in plantarflexion whilst the needle was introduced towards the plantar proximal medial aspect of the 1st MTPJ above the tibial sesamoid
Millard & Dillingham (1995)	Not stated	25-gauge one-half- to five-eighth-inch needle	Not stated	Dorsomedial approach
Newman (2004)	Not stated	23-gauge needle	Not stated	The needle should be angled distally from a location just proximal to the joint line to avoid the dorsal lip of the proximal phalanx

Pekarek et al. (2011)	supine position with the knee flexed and supported with a pillow	24–26 gauge by ½–5/8 in. needle	Not stated	The needle is directed dorsal medial or dorsal lateral to the extensor tendon without penetrating it, as to minimize trauma. The needle is angled 60–70◦ to the plane of the foot and pointed distally to match the slope of the joint
Reilly (2010)	The patient is typically positioned sitting up or supine, depending on patient preference.	2.5- or 5-ml syringe; 25mm (1 inch) 23G (blue) needle	20-40mg of triamcinolone mixed with local anaesthetic	The approach is through a dorsal medial incision, the needle entry point typically 0.5-1 cm medial to the extensor hallucis longus tendon. A medial approach is more painful and does not give as good access to the joint
Sahler et al. (2013)	Supine with the affected side flexed at the knee in order for the plantar aspect of the foot to lie flat on the table	Not stated	Not stated	The needle should pass through the sterile gel and then pierce the skin. The needle is visualized in its entirety, running superficial to the proximal epiphysis, into the joint capsule, stopping short of the opposing cartilaginous surface
Saunders and Longworth (2018a)	Patient lies with foot supported	1-2ml syringe; orange, 25-gauge 0.5 inch (13mm)	10-20mg Kenalog; 0.5-1ml 2% lidocaine	Distract affected toe with one hand, identify and mark joint line, insert needle perpendicularly into joint space, avoiding extensor tendons, deposit the solution as a bolus
Siddiqui et al. (2019)	Supine	Orange 25G or blue 23G needle	Not stated (post LA)	The needle should be directed at 60 to 70 degrees to the plane of the foot and directed distally; this matches the slope of the joint and reduces the risk of chondral injury. Distraction of the toe can help to open up the joint space
Stephen et al. (2010)	Not stated	27-gauge needle	Not stated	The metatarsophalangeal joint can be entered via a dorsomedial or dorsolateral route
Tallia & Cardone (2004)	Supine position with the knee in a supported flexed position	Not stated	Not stated	The needle is inserted on the dorsomedial or dorsolateral surface. The needle should be angled 60 to 70 degrees to the plane of the foot and pointed distally to match the slope of the joint
Wempe et al. (2012)	Not stated	25-gauge, 38-mm stainless steel needle	Latex (cadaveric model)	The needle is advanced into the joint using a medial-to- lateral, out-of-plane approach, during which the needle tip was visualized as an echogenic dot within the articulation
Unknown reference	Not stated	23-gauge needle	5 mg triamcinolone or equivalent	The joint line is identified by gentle palpation and the introduced obliquely under the extensor tendon. The injection should be performed without resistance using. The patient may experience some discomfort as the needle pierces the skin and joint capsule

2.5.2 Discussion of theme 2

The brevity of the references did not allow for formal critical appraisal to be performed, but cross-referencing allowed for the distillation of key aspects of practice. A technique summary (with an emphasis on safe clinical practice) and recommendation for best practice for CSI of the 1st MTP jt has been produced (Reilly, 2020) – see Appendix 8. Such variety in the literature should not come as a surprise. Haslock et al. (1995) questionnaired 200 consultant rheumatologists and showed a wide divergence of practice in almost every aspect of technique, concluding that there was no consensus (in 1995) for CSI technique amongst British consultant rheumatologists. They found that IAITs are the procedures which rheumatologists undertake more frequently, but that there was an almost complete lack of concurrence among practitioners regarding techniques, and that was from just one professional group. Nearly 30 years later, it is apparent that techniques still vary widely and are often experienced-based rather than evidence-based.

During the chronology of the thesis production, literature on improving ScR methodology, particularly that produced by the JBI, necessitated that the author re-format the first iteration of the ScR that followed 2010 methodology. Purposefully, it is hoped that the extensive narrative in the Appendices will provide a repository for future researchers to develop sub-themes, for example, the role of imaging at different time points during a treatment regimen. General considerations for the clinical use and complications of CSIs emerged from the ScR need to be considered with relevance to injection of the great toe and are outlined in Appendix 7.

2.6 Theme 3: injection accuracy and needle placement

Iterative charting indicated that needle placement and accuracy was a common theme across the available literature with various authors highlighting methodology to ensure precise delivery of the injectate.

2.6.1 Techniques

Al-Jabri and Charalambides (2019) describe their 'sulcus sign' technique in a cohort of 30 patients, where the joint line was marked by a surgeon prior to needle insertion. The insertion point was identified as a skin pucker on hallux distraction which was then compared to fluoroscopic identification of the joint line. The distance from the fluoroscopically identified joint line to the 'sulcus sign' was measured and recorded using a technique like that of Manadan et al. (2013). The authors found no difference between the joint lines identified using image guidance versus the 'sulcus sign' technique and no difference in the point of needle entry marked using either technique, with only a single attempt required to establish an IA needle position even in patients with advanced degenerative changes at the joint. They conclude that this technique is reproducible and useful for supplementing image guidance or when it is unavailable. This technique tip paper lacks quantitative data to support the conclusion.

In contrast to Al-Jabri and Charalambides (2019), Heidari et al. (2013) found that the presence of pathologic changes reduces the rate of successful IA puncture, but that the overall frequency of successful IA injections can be improved through experience and the use of imaging. 106 cadaveric 1st MTP

jts were injected with a methylene blue solution and then dissected to distinguish intra- from peri-articular injections. To evaluate the importance of experience, 38 injections were performed by a student, 38 by a trained resident, and 30 by an experienced surgeon. In the second part of the study, the authors examined the relation of pathological findings of the 1st MTP jt and the accuracy of IA injection. The overall rate of unintentional periarticular injections was low (9.4%; 10 of 106 joints). The student achieved a successful IA injection in 86.8% of joints, the resident in 92.1%, and the specialist in 93.3%. The number of extra-articular injections increased significantly with the presence of HAV deformity or OA of the 1st MTP jt.

Manadan et al., 2013 aimed to determine the accuracy of radiocarpal (RC) joint and 1st MTP jt arthrocentesis using fluoroscopy. Ten experienced rheumatologists were asked to mark their usual site of arthrocentesis over fluoroscopically identified joint lines of the right RC and right 1st MTP joints. The sites marked were a mean of 0.85 cm (range, 0–1.6 cm; SD, 0.5 cm) and 0.33 cm (range, 0–1.3 cm; SD, 0.4 cm) from the fluoroscopically identified RC and 1st MTP jts, respectively. The authors concluded that traditional palpation-guided joint aspiration may be inaccurate, and that fluoroscopic guidance has the potential to improve accuracy of arthrocentesis of small joints.

Three studies used cadaveric models with injectate. In their study to ascertain accuracy, Reach et al. (2009) used US-guidance to inject a methylene blue-saline mixture into the 1st and 2nd MTP (and other) jts in 10 fresh cadaveric feet. Dissection was then undertaken to assess injection accuracy. The authors

found that US guidance allowed the avoidance of intervening neurovascular and tendinous structures and that US-guided MTP, ankle, Achilles, PTT and FHL peri-tendinous injections were 100% accurate; US-guided STJ injection was 90% accurate. A similar study for sesamoid pathology was undertaken by Wempe et al. (2012). US guidance was used to accurately inject blue-coloured latex into the 1st MTPJs of five cadavers and later dissected to determine whether the latex was present between the metatarso-sesamoid articulation. In all five cadaveric specimens, US-guided 1st MTP jt injection accurately delivered latex into the joint, and in each specimen, latex was seen between the metatarsal head and both the fibular and tibial sesamoid bones. The authors suggest that clinicians administering diagnostic or therapeutic injections for patients with sesamoid disorders should consider injecting the 1st MTP jt as an alternative to direct metatarso-sesamoid articulation injections.

Sahler et al. (2013) describe a longitudinal US-guided, in-plane approach for injection into the 1st MTP jt and assess its accuracy in a cadaveric model. Ten 1st MTP jts were injected with 0.5 mL of dye under US-guidance and the joints were dissected. Accuracy was classified as accurate, accurate with overflow, or inaccurate with no injectate in the target area. Of the injections, nine were classified as accurate injections, and one was classified as accurate with overflow. The authors concluded that US-guided injections of the 1st MTP jt can be accurately and reproducibly performed with a gel standoff, long-axis in-plane approach. The authors acknowledge the small sample size which was not powered to determine the true accuracy of this technique but considered it

strong enough to recommend as an acceptable alternative to palpation-guided injections.

2.6.2 Discussion of theme 3

Ask with theme one where injection therapy for a given pathology needs to be considered against more general CSI application, so too for theme 3 where injection accuracy for the 1st MTP jt needs to be considered against the wider body literature. Lopes et al. (2008) state that blind injections prove safe and accurate when performed by a trained professional, but without image guidance, how do we ensure the accuracy of injection? In the long history of CSIs, infiltrations have long been performed without image guidance, i.e., using palpation guidance, anatomical landmarks and clinical judgement to direct needle entry and advancement (Bookman & Pereira, 2014; Cunnington et al., 2010; Hartung et al., 2011; Balint et al., 2002). Hawker posits that about 50% of intra-articular and intralesional injections are placed incorrectly (Hawker et al., 2010). Sofka and Adler (2002) posit that CSIs, traditionally performed using anatomic landmarks, can be inaccurate and miss intended targets.

Needle placement may also be confirmed by the use of diagnostic imaging. Typical imaging modalities are computed tomography (CT), ultrasound (US) or fluoroscopy, used alone or in combination (Bansal et al., 2021; Boone et al., 2021; Hynes et al., 2021).

Injection by palpation guidance

Ajwani et al. (2018) and Feuerstein et al. (2016) stated that joint and toe flexion distension were signs of a successful IA injection of the 1st MTP jt. Joint fluid aspiration may aid confirm needle placement (Heidari et al., 2013; Jackson et al., 2002 Khosla et al., 2009) though aspiration of the 1st MTP jt is more difficult as it is a smaller joint with less fluid available to aspirate (Manadan et al., 2015; Balint et al., 2002). Luc et al. (2006) describe a backflow technique, which involves re-positioning the needle (in the knee) until a free backflow of injected lidocaine occurs. This was also demonstrated in the 1st MTP jt by Bhattia (2018) using iohexol contrast media.

In a contrast radiography study of 108 films of multiple anatomical sites, the classic paper on poor needle placement by Jones et al. (1993) reported that 56 injections were intra-articular, 31 extra-articular; and in 21, the location was uncertain because of a lack of contrast in the radiograph. Khoury et al. (1996) found that radiographically guided diagnostic injections of foot and ankle symptomatic patients demonstrated better success in identifying the source of pain, confirming the diagnosis in 90.9% of the patients and predicting the success of surgical treatment with a fusion of the affected joint.

Lungu and Moser (2015) target the articular recess and suggest that the main theoretical advantage of targeting this point is that it facilitates IA injection when the joint space is obscured by patient positioning or degenerative changes to the joint. Moreover, reliable depth estimation can be provided by bone contact. By targeting the articular recess, the needle path is often shorter, thus

diminishing the number of structures whose integrity is compromised, and this approach inflicts less pain to patients, they state. In practical terms, however, the recess of the 1st MTP jt is a small target.

Injection using image guidance

The accuracy of IA injection depends on the joint and the practitioner's skills, many authors feels that imaging may improve accuracy. Sakellariou et al. (2017) state that while joints such as the hip and midtarsal joints demand imaging for the accuracy of steroid placement, joints which have conventionally been injected with an anatomical landmark approach should have image guidance reserved for those cases that have not responded to an injection performed using anatomical landmarks. In contrast, in a Delphi project carried out by Sconfienza et al. (2020), they state that:

- *US and fluoroscopy guidance improves the accuracy of joint injections in the foot and ankle, although these procedures can be safely performed with palpation alone (level of evidence: 4).*
- *9. Intra-articular foot and ankle anaesthetic injections performed under imaging guidance offer precise information about the pain source (level of evidence: 4).*

D'Agostino et al. (2005) al found that using USS frequently led the physician to change his diagnosis of inflammatory lesions in the painful foot and, consequently, the planning of CSIs with a probable improvement in the response to local treatment.

Fluoroscopy

The normal 1st MTP jt arthrogram demonstrates the opaque medium seen as a thin layer over the head of the metatarsal and between it and the base of the proximal phalanx. On the lateral aspects of the joint, the small recess has a waist due to the collateral ligaments. A large recess is noted on the plantar aspect of the metatarsal head and neck, which extends proximally by about 1cm (Weston, 1969). The joint volume will be in the region of 1-1.5ml, negatively affected by joint disease (Hansford et al., 2019).

X-rays can be used to guide and confirm needle placement, with or without the use of contrast media (Andrews, 2015). Careful attention must be paid to the distribution of iodinated contrast to recognize unexpected findings, such as the extracapsular extension of contrast, which may indicate capsular injury or variant joint communications. Trauma to the 1st MTP jt leads to spindle-shaped swelling of the joint capsule; the shape of the capsule also changes from cylindrical to spindle - and joint density increases - in RA (Weston, 1980). Sacculation may also be seen in RA (Perlman, 1988).

Lucas et al. (1997) sought to determine the value of injections of LA and CSIs in the foot and ankle in localising the source of pain, and their effect on clinical confidence and decision-making. The authors concluded that fluoroscopically guided injections of local anaesthetic and steroid in the foot and ankle can improve clinical confidence regarding the site of pain and may be valuable in clinical decision making and patient.

In contrast, Messina et al. (2016a; 2016b) feel that X-rays should be avoided when other radiation-free modalities (such as USS) can be used and note that the European Union directive 2013/59 clearly states that if a radiation-free imaging modality can achieve the same therapeutic and diagnostic results, it should invariably be used (European Commission, 2013). They conclude that:

- *Intra-articular contrast agent injection can be performed using different imaging modalities,*
- *Fluoroscopy is widely used but uses ionizing radiation,*
- *Ultrasound is an accurate, quick, and radiation-free modality for joint injection,*
- *X-rays should be avoided when other radiation-free modalities can be used.*

This is counter to the work of (an older reference) Saifuddin et al. (2005), who used computed tomography (CT). Over a period of 50 months, 28 individuals were referred for diagnostic and therapeutic hind- and mid-foot injections before possible arthrodesis by. The authors concluded that CT is a simple and safe alternative to fluoroscopy for guiding diagnostic and therapeutic foot injections and may be the technique of choice in cases of disordered anatomy.

Ultrasound

The use of US for guidance for interventional radiologic procedures is well known, including guidance for vascular and visceral interventions. Multiple authors state that US-guided injections are more accurate than landmark-guided CS injections (Albano et al., 2017; Balint et al., 2002; Bookman & Pereira, 2014; Daniels et al., 2018; De Zordo et al., 2009; Gilliland et al., 2011; Goncalves et al., 2011; Grassi et al., 1999; Huang et al., 2015; Muir et al., 2011; Raza et al., 2003; Reach et al., 2009; Sibbitt et al., 2009; Sofka & Adler, 2002;

To et al., 2017; Wisniewski et al., 2010; Yablon, 2013; Yaftali & Weber, 2019), though not all clinicians agree (Hall & Buchbinder, 2004; Hirsch et al., 2017; Nordberg et al., 2018).

Balint et al. (2002) demonstrate that using US to localise joint and soft tissue fluid collection greatly improved the rate of diagnostic synovial fluid aspiration rate, particularly in small joints, over conventional injections. Successful aspiration was achieved in 10 (32%) joints in the conventional group compared to 31 (97%) joints in the US-guided group.

Schumacher (2003) provides a narrative review regarding the variety of IA therapies are available and need comparison for indications, routes used for aspiration and injection, ease of use, benefits, and adverse reactions. This review addresses all these aspects but focuses on neglected technical concerns.

In a systematic review, Gilliland et al., (2011) found that accuracy is improved with the use of US-guided over palpation-guided IA injection, independent of the anatomical site. They also confirm that short-term outcome improvements are presented more quickly using US guidance, but no difference in long-term outcome measures using either technique. They also found that small joint injections in the hands and feet were more accurate using guidance compared to a larger joint where the difference was minimal.

The findings of the position statement by the American Medical Society for Sports Medicine (Finnoff et al., 2015) indicate strong evidence that US-guided injections are more accurate than landmark-guided, moderate evidence that they are more efficacious preliminary evidence that they are more cost-effective. They also note that If an injectate is misplaced, it may lead to complications such as skin depigmentation, subcutaneous fat atrophy, tendon rupture, neurovascular injury, increased procedural and postprocedural pain, or intra-arterial injection.

Beard and Gousse (2018) suggest that using US to guide for interventions in the musculoskeletal system, specifically the foot and ankle, yields accurate placement of the needle tip and subsequent anaesthetic/steroid injection, as well as diagnostic aspiration of tendon sheaths, joint spaces, and bursae. They suggest that US is distinctly more accurate than landmark guidance for small joints. Fredberg (2001) used air for correct needle placement before injection - the sterile air contained in the capped vial is used as a contrast medium.

Daniels et al. (2018) performed a comprehensive review of the literature for the accuracy of US-guided injections regardless of anatomic location. In the lower extremity, the authors found that US-guided injections at the knee, ankle, and foot have superior efficacy to landmark-guided injections. Goldschmiedt et al. (2017) describe the injection jet sign as colour Doppler flow that is directed away from the needle tip at the point of entry and the flow within and often outlining the joint capsule or bursa as a method to ensure the desired target

delivery of the injectate. Further, they outline several papers that discuss the benefits of guided over blind injections. But Hall and Buchbinder (2004) ask:

- *Do radiologically guided corticosteroid injections confer any added clinical benefit over blinded injections in the short and long term?*
- *If there are added benefits, is the routine use of imaging to improve the accuracy of steroid placement, cost effective?*

They conclude that while some joints, such as the hip and midtarsal joints, demand imaging for any accuracy of steroid placement, for most joints which have conventionally been injected by rheumatologists following an anatomical landmark approach, imaging-guided injection should be reserved for those cases who have not responded to injection following anatomical landmarks.

Huang et al. (2015) performed a systematic review and meta-analysis of randomised trials for IA and periarticular injections using US-guidance, finding that its use significantly improves the accuracy of joint injections. There was a significant decrease in visual analogue scale scores for up to 6 weeks after injection, but the long-term effect was inconclusive. Khosla et al. (2009) demonstrated that needle placement was only correct in 3 of 14 (21%) and 4 of 14 (29%) cadavers using palpation guidance into 1st and 2nd tarso-metatarsal jts, respectively. US-guidance significantly improved the accuracy of needle placement for both joints.

The study by Nordberg et al. (2018) indicates that the efficacy of IA injections varies according to US findings at the time of injection, supporting the use of

US as a tool to select joints that will benefit from intra-articular injections, however, US needle-guidance was not superior to palpation-guidance.

438 patients with imaging-guided diagnostic or therapeutic injections in a study by Peterson et al. (2011). The proportions of patients reporting clinically relevant pain reduction (≥ 50%) were calculated overall and for specific subgroups, and the risk ratio comparing patients with OA to those without was calculated. Injections into the Lisfranc articulation were significantly more effective than other sites, with 74% of patients obtaining clinically relevant pain relief.

Sconfienza et al. (2020) report the results of a Delphi-based consensus of 53 experts from the European Society of Musculoskeletal Radiology (ESSR). The authors reviewed the literature for evidence on image-guided interventional procedures offered around the foot and ankle to derive their clinical indications and drafted a list of statements. These were graded according to the Oxford CEMB centre for levels of evidence. Sixteen evidence-based statements on clinical indications for image-guided musculoskeletal interventional procedures in the foot and ankle were drafted.

Wisniewski et al. (2010) compared the relative accuracy rates of US-guided versus non-guided ankle (tibiotalar) joint and sinus tarsi injections in a cadaveric model in 12 embalmed and eight unembalmed cadavers (40 ankles). The accuracy rate for US-guided tibiotalar joint injections was 100% (20/20) versus 85% (17/20) for non-guided injections. The accuracy rate for US-guided sinus

tarsi injections was 90% (18/20) versus 35% (7/20) for non-guided injections. Yablon (2013) provides a technical article on CSI considerations. Yaftali & Weber (2019) also note that image guidance can improve the accuracy of IA placement of CSIs or hyaluronic acid injections.

But how much does needle placement matter? The perceived wisdom is that if an injectate misses its target, it is likely to be less effective and lead to false negative reporting of poor outcomes. Lopes et al. (2008) feel that accurate IA placement of the needle is a prerequisite for the achievement of desired results and the avoidance of complications. Cunnington et al. (2010) found that accurate injections led to greater improvement in joint function, as determined by VAS scores, at six weeks, compared to inaccurate injections. Schumaker (2003) considers accuracy critical as we continue assessing joint injections' value. Jones et al. (1993) state that the steroid should be injected into the synovial space for IA infiltrations.

The small joints and peri-tendinous areas of the foot and ankle present a challenge to blind injection accuracy. Imaging is therefore recommended for joints that are difficult to access due to factors including site, degree of deformity and obesity (D'Agostino et al., 2013; Hall & Buchbinder, 2004; Lavelle et al., 2007; Sakellariou et al., 2017; Uson et al., 2021). Without radiological confirmation, it is difficult to ensure the exact location of the needle. Because of this - and perhaps practising defensively - many authors advocate using image guidance.

In contrast, Simkin (2010) suggests that the inflamed synovial tissue may often be the target for the CS, perhaps close is close enough? Cole and Schumaker (2005) note that the effects of IA CS - though variable - are frequently observed on non-injected involved joints, suggesting the importance of systemic effects. Jones et al. (1996) found that almost half of those with extra-articular CS placement experienced good therapeutic response, suggesting that total accuracy of needle placement may not be essential to a satisfactory outcome. Hirsch et al. (2017) found that accurate IA placement of a CSI injection - as determined by positive air-arthrosonogram - did not improve the outcomes compared to a group with a negative arthrosonogram suggested that placement of injection was predominantly extra-articular.

Finally, the 1st MTP jt varies in size and shape, and it may be difficult to palpate in patients with conditions such as advanced degenerative arthritis and osteophyte formation (Bilstrom et al., 2007; Heidari et al., 2013; Tallia and Cardone, 2003). This finding is of considerable importance because it is often the case that patients with pathologic changes who are offered these injections. Of the six joints in Heidari's cadaveric injection study that had combined HAV and HR, two were not successfully punctured (Heidari et al., 2013). Understanding anatomical landmarks of the foot and ankle is, therefore, crucial for correct needle placement (de Cesar Netto et al., 2018).

2.7 Conclusion and limitations of the ScR

Major patterns, themes, and findings were recorded. Thematic analysis consisted of examining text excerpts and asking how this text related to the

research question: to establish what is known about IA CSI therapy for the pathology of the 1st MTP jt. Reflexivity was essential throughout the review process but especially during thematic analysis to capture the codes that arose from examining and interpreting the data (Mak & Thomas, 2022). Coding the results and allowing for overlap created the three themes highlighted above. This, with the wider discussion about injection therapy, demonstrated what is currently known about IAT of the 1st MTP jt, and highlighted where the gaps in our knowledge remain. The ScR delineated why and when we use injection therapy, and how we perform injections. What is less clear is the drug regimen used for a given pathology at a specific time point in disease progression or regression.

This ScR was limited to a completion date as part of a professional doctorate degree course. The review itself was limited to include only those papers that met the criteria set out and were available via the resources outlined in this chapter. Any articles outside of this availability (i.e., the grey literature) have not been used, and no financial budget was set. Therefore, both financial and time constraints have meant that some limitations to the depth and breadth of the review might be extant.

Ideally, there should be two or more researchers assessing the quality of the papers and should any conflicts arise, then a third party would be assigned to adjudicate independently (Aveyard, 2018). Paterson et al. (2001) advocate that two or three individuals code each research paper to create a maximum understanding of the value of the studies. Given the nature of this review - that

it is for an academic thesis - interpretation and discussion of any findings represent the conclusions of only one author and have the potential to represent unintentional bias.

2.8 Chapter summary

Following a ScR, iterative charting of the literature yields three broad and overlapping themes:

1. Injection therapy outcomes for a given joint pathology,
2. Injection techniques, dosage, and regimen,
3. Injection accuracy and needle placement.

This chapter forms a large part of the thesis, and as noted above, scoping reviews do not undergo formal critical analysis: they identify the breadth of the available literature and develop themes. The scoping review was the first part of the overall scheme of work, leading to the need for a more rigorous systematic review process seen in Chapter 3. Given that much 1st MTP jt IAIT is performed without image guidance, Chapter 4 will be a technique guide to develop a best-practice guide, and Chapter 5 Five of this thesis will be a cadaveric experiment to confirm injection accuracy using palpation guidance.

CHAPTER 3

A systematic review of 1st MTP jt CSI for OA

Publication: Reilly, I. N., Bromley, G., & Flanagan, G. (2020). A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint. *The Foot an Ankle Online Journal*, *13*(3). Available from: http://faoj.org/2020/09/30/a-systematic-review-of-injectable-corticosteroid-for-osteoarthritis-of-the-first-metatarsophalangeal-joint/

3.1 Background

A systematic review was performed to critique the available high-quality research to enable clinicians to adopt an evidence-based approach to CSI for treating OA injection of the 1st MTP jt – the most common reason for injection. This part of the thesis was undertaken with the research hub within the Department of Podiatric Surgery – Ian Reilly (IR), Gillian Bromley (GB), and George Flanagan (GF). The study's senior author (IR) orchestrated and conceptualized the research, establishing the systematic review's criteria. The second author (GB) conducted a comprehensive literature search, with consensus on article selection involving the second and third authors (GB/GF). The initial and ultimate drafts were prepared by the senior author, who also handled the formatting for publication.

3.2 Methodology

Systematic reviews follow a structured and pre-defined process that requires rigorous methods to ensure the results are reliable and meaningful to end users (Munn et al., 2018). The authors undertook the review using the PRISMA checklist for systematic reviews (Moher et al., 2009). The research question was: is the use of CSI for OA of the 1st MTP jt joint in adults a safe and effective method of reducing pain and improving joint function? In order to ensure a systematic review, minimise the risk of bias and provide transparency for replication of the process, a pre-determined research methodology protocol was used based on the PRISMA checklist. The review was registered with PROSPERO (Trial registration number: CRD42019135950), available from:

http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42019135950.

3.2.1 Selection criteria

Inclusion

Pre-determined inclusion and exclusion criteria were used. Only systematic reviews, randomised controlled trials (RCTs), quasi-randomised trials and controlled clinical trials were considered for inclusion as they form the hierarchy of evidence and are most likely to provide a robust evidence base suitable for informing clinical practice. Based on the information highlighted in the ScR, papers found were then screened for the following criteria:

- Trials in which an IA CSI into the 1st MTP jt used for the treatment of OA in adults,
- Diagnosis and grading of 1st MTP jt OA in participants could be achieved via clinical examination and/ or via radiological means,
- Any gender or ethnicity was considered.

In order to be able to determine the efficacy of treatment, trials were required to have provided quantitative or qualitative measures both pre- and post-intervention in order to be able to ascertain the mean differences relating to pain and/or joint function outcomes.

Exclusion

Trials in which intradermal, subcutaneous, intramuscular or extracapsular corticosteroid injections were performed were excluded, as were not trials that tested the efficacy of IA CSIs for conditions other than for OA, or tested CSIs at joints other than the 1st MTP jt. Due to the lack of robust evidence and high risk of bias, the following research designs were not considered for inclusion:

- Retrospective studies.
- Cohort studies.
- Case studies.
- Single case reports.
- Articles based on expert opinion.

3.2.2 Search strategy and data sources

To answer the research question, a keyword search of six electronic databases most likely to generate useful information (AMED, CINAHL, EMBASE, MEDLINE, PUBMED, and COCHRANE) up to February 2020 was undertaken by a graduate research podiatrist (GB) to identify clinical trials that had tested the efficacy of IA CSI for the treatment of 1st MPJ OA:

- AMED (1985 to 05.02.2020)
- CINAHL (1982 to 05.02.2020)
- EMBASE (1974 to 05.02.2020)
- MEDLINE (1950 to 05.02.2020)
- PUBMED (1966 to 05.02.2020)
- COCHRANE (1966 to 05.02.2020)

No date or language restrictions were applied. Reference lists were reviewed, and key author searches were made to reduce the risk of any pertinent literature being missed. A list of keywords and results yielded are provided in Table 7.

Table 7: Search terminology and results yielded by database

#	Database	Search term	Results
1	AMED	(osteoarthritis).ti,ab	2945
2	AMED	(hallux).ti,ab	1252
3	AMED	(metatarsophalangeal).ti,ab	771
4	AMED	(injection).ti,ab	2035
5	AMED	(steroid).ti,ab	454
6	AMED	(hallux limitus).ti,ab	62
7	AMED	(hallux rigidus).ti,ab	178
8	AMED	(1 AND 2)	35
9	AMED	(1 AND 3)	37
10	AMED	(6 OR 7 OR 8 OR 9)	272
11	AMED	(4 AND 10)	5
23	CINAHL	(osteoarthritis).ti,ab	21838
24	CINAHL	(hallux).ti,ab	2033
25	CINAHL	(metatarsophalangeal).ti,ab	1197
26	CINAHL	(injection).ti,ab	43132
27	CINAHL	(steroid).ti,ab	15241
28	CINAHL	(hallux limitus).ti,ab	100
29	CINAHL	(hallux rigidus).ti,ab	319
30	CINAHL	(23 AND 24)	63
31	CINAHL	(23 AND 25)	82
32	CINAHL	(28 OR 29 OR 30 OR 31)	472
33	CINAHL	(26 AND 32)	13
34	EMBASE	(osteoarthritis).ti,ab	79498
35	EMBASE	(hallux).ti,ab	5812
36	EMBASE	(metatarsophalangeal).ti,ab	3924
37	EMBASE	(injection).ti,ab	581417
38	EMBASE	(steroid).ti,ab	163137
39	EMBASE	(hallux limitus).ti,ab	153
40	EMBASE	(hallux rigidus).ti,ab	664
41	EMBASE	(34 AND 35)	183
42	EMBASE	(34 AND 36)	258
43	EMBASE	(39 OR 40 OR 41 OR 42)	1068
44	EMBASE	(37 AND 43)	21
45	EMBASE	(38 AND 43)	12
46	CINAHL	(27 AND 32)	5
48	AMED	(5 AND 10)	4
49	Medline	(osteoarthritis).ti,ab	54837
50	Medline	(hallux).ti,ab	4904
51	Medline	(metatarsophalangeal).ti,ab	3209
52	Medline	(injection).ti,ab	449653
53	Medline	(steroid).ti,ab	125109
54	Medline	(hallux limitus).ti,ab	139
55	Medline	(hallux rigidus).ti,ab	586
56	Medline	(49 AND 50)	137
57	Medline	(49 AND 51)	189
58	Medline	(54 OR 55 OR 56 OR 57)	858
59	Medline	(52 AND 58)	13
60	Medline	(53 AND 58)	5
61	PubMed	(osteoarthritis).ti,ab	80277
62	PubMed	(hallux).ti,ab	6554
63	PubMed	(metatarsophalangeal).ti,ab	4096
64	PubMed	(injection).ti,ab	708493
65	PubMed	(steroid).ti,ab	936715
66	PubMed	(hallux limitus).ti,ab	167
67	PubMed	(hallux rigidus).ti,ab	656
68	PubMed	(61 AND 62)	251
69	PubMed	(61 AND 63)	298
70	PubMed	(66 OR 67 OR 68 OR 69)	1054
71	PubMed	(64 AND 70)	26
72	PubMed	(65 AND 70)	10

3.3 Data extraction

Data was extracted from research that fulfilled the inclusion criteria by using a pre-determined list of parameters to determine the efficacy of the intervention and the validity of methods used for testing. These parameters considered: the design of study, sample size, demographics, diagnostic criteria used, disease severity, intervention tested (type, dosage, method of administration), outcomes, follow up and results. Reported adverse effects (type, duration and severity) were recorded to determine the safety of the intervention. Data from these themes was entered into a spreadsheet to be used for discussion.

3.4 Results

A search of electronic databases identified 111 studies for possible inclusion. Sixty-four papers were deduplicated, and 47 titles and abstracts were assessed. Titles and abstracts were assessed independently by the second and third authors (GB/GF) authors and evaluated against their aims. Thirty-six articles were rejected, and 11 full-text articles were retrieved for assessment against the selection criteria. One RCT (Pons et al., 2007) and one systematic review (King et al., 2017) were identified for inclusion in the review, see Fig. 8 for PRISMA flowchart.

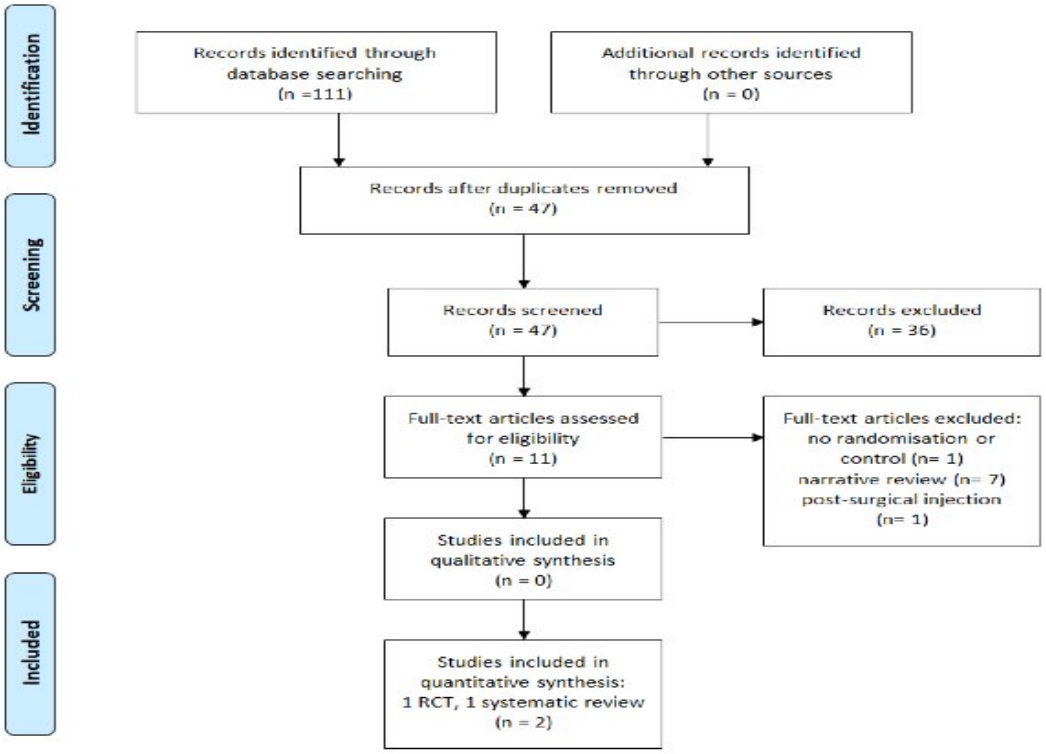

Figure 8: PRISMA systematic review flowchart

Risk of bias

Use of the Grading of Recommendations Assessment, Development and Evaluation for network meta-analysis (GRADE-NMA) was considered to appraise the strength (certainty) of evidence, but discounted due to the low numbers of papers available for review. Similarly, publication bias was also impractical.

In order to assess their validity, RCTs were reviewed using the Critical Appraisal Skills Programme (CASP, 2018) checklist, which uses six quality assessments of studies and considers the risk of (selection, performance, detection, attrition

and reporting) bias. Systematic reviews were appraised using a Centre for Evidence-Based Medicine (CEBM, 2009) appraisal tool for systematic reviews, which uses six quality assessments to determine the validity of reviews based on methodological design, see Table 8. Each quality assessment for data was awarded a 'low', 'high' or 'unclear' risk of bias. GB and GF independently appraised the studies and the results were collated. If there was disparity between results, a discussion was to be raised. If consensus could not be achieved, the senior author (IR) was appointed to make the final decision. Evidence from the identified literature was considered and an appropriate weighting was awarded based on the quality of evidence they provided.

Table 8: Quality assessment of randomised controlled trials (CASP checklist)

Pons et al. (2007)			
Quality Assessment:	**Result:**	**Bias Risk:**	**Quality score:**
Did the trial ask a clearly focused question?	Yes	Screening question	2/2
Was the assignment of patients randomised?	Unclear	Selection bias	1/2
Were all the patients who entered the trial properly accounted for at its conclusion?	Yes	Attrition bias, reporting bias	2/2
Were patients, health care workers and study personnel 'blind' to treatment?	No	Performance bias, detection bias	0/2
Were the groups similar at the start of the trial?	Unclear	Selection bias	1/2
Aside from the experimental intervention, were the groups treated equally?	Yes	Performance bias	2/2

Inter-rater results following an appraisal of studies were 84% consistent between the two reviewers. Following a discussion regarding the variation in quality assessment 100% consensus between reviewers was achieved.

Evidence from the identified literature was considered, and an appropriate weighting was awarded based on the quality of the evidence they provided. Themes regarding joint pain, function and the safety of corticosteroid injections are discussed. Due to only one RCT being identified for inclusion, no meta-analysis was possible.

The one single-blinded RCT was identified for inclusion (Pons et al., 2007) that compared the efficacy of a single dose of IA triamcinolone acetonide (TA) with sodium hyaluronate (SH) delivered without image guidance for mild symptomatic hallux rigidus in thirty-seven adults. A reduction in visual analogue scale (VAS) mean pain scores of the 1st MTP jt at rest 24.6mm, (p.0.01), during dorsiflexion and plantarflexion 22.6mm, (p.0.01) and during gait 22.5mm, (p.0.01) in half of all TA recipients 12 weeks post-intervention was reported. Recipients of TA were reported to have a mean improvement in hallux function of 4.1 on the AOFAS scale for hallux evaluation. However, TA was found to be inferior in terms of the number positive responders to treatment, pain reduction and improvement in hallux function when compared to those treated with SH. Benefits were reported as relatively short lasting in both arms of the trial 52.9% in the TA group and 46.6% in the SH group progressed to surgery within 12 months.

The mean quality score for the RCT reviewed was 66% demonstrating limited methodological quality and potential bias. In this trial, there was no attempt to blind investigators involved in data collection and evaluation of outcome measures. The trial had a small sample size with a significant female gender

bias and all participants had mild joint disease potentially limiting the application of conclusions drawn from this to other patient populations. However, the most significant limitation with this trial was that interventions were administered to participants with 1st MPJ OA and hallux valgus with no sub-group analysis provided according to condition. Given that the underlying pathophysiology of these distinct conditions differs, it is reasonable to expect that treatment outcomes relating to joint pain and function following an IA CSI may vary between recipients with different conditions. Furthermore, the proportion of recipients reported to have progressed to surgery may have been skewed given that the usual treatment for hallux valgus is surgical correction of the deformity. From this trial it was not possible to determine the efficacy of corticosteroids as an intervention to treat osteoarthritis at the 1st MPJ.

Similarly, the lack of blinding in data collection and evaluating adverse effects associated with the interventions administered poses a significant bias risk. Due to the lack of sub-group analysis, it was not possible to determine whether the frequency or type of adverse effects differed by condition. Non-blinded investigators collected data relating to adverse effects post intervention, were mild and arose in just 5% of recipients; no serious adverse effects were reported.

The review by King et al. (2017) set out to provide comprehensive list of evidence-based recommendations regarding conservative treatment modalities for 1st MTPJT OA included a review of CSI. The authors found ‘fair evidence’ to support the use of IA CSIs however, the methodology was neither systematic

nor comprehensive: only a single database was searched for clinical trials and the risk of pertinent literature having been missed was high. The author's recommendations were made based on an appraisal system that allocated a level of evidence for an intervention based solely on the design of studies identified; it did not consider the methodological quality of trials or risk of bias.

The IT trials identified by King et al. (2017) lacked heterogeneity in terms of solutions tested and design of trials. In spite of this, authors grouped six trials relating to injection therapy together for data analysis and a collective level of evidence was allocated to injection therapy as a whole. Since this review did not consider the risk of bias and validity or clinical significance of outcomes from trials it identified, and failed to use a systematic methodology the study was excluded from further review as it was deemed to provide a summary of interventions for healthcare professionals only.

One systematic review was found that considered the efficacy of any treatment modality, including but not limited to injection therapy, for 1st MTP jt OA MPJ (Zammit et al., 2010). This was a comprehensive piece of research with high-quality methodology and low risk of bias. It identified one low-quality study with a high risk of bias to support the use of physical therapy to reduce the pain of osteoarthritis at the big toe joint. It found no evidence to support the efficacy of CSIs for HL/HR. A quality assessment of systematic review (CEBM framework) is at Table 9.

Table 9: Quality assessment of systematic review (CEBM framework)

Quality Assessment:	Result:	Quality Score:
What question did the systematic review address?	Which interventions are optimal for treating osteoarthritis of the big toe?	2/2
Is it unlikely that important, relevant studies were missed?	Yes	2/2
Were the criteria used to select articles for inclusion appropriate?	Yes	2/2
Were the included studies sufficiently valid for the type of question asked?	No, identified a lack of available evidence and high risk of bias.	0/2
Were the results similar from study to study?	One study identified for inclusion only.	0/2

3.5 Discussion

This systematic review was conducted to assess the effectiveness and safety of IA CSIs as a treatment modality for 1st MTP jt OA. A thorough and systematic literature search was completed to identify pertinent literature on the subject area, and forty-seven studies were identified for possible inclusion. After exclusions were applied from the selection criteria to ensure that the correct condition, joint and treatment were being considered, 22 pieces of literature remained. The remaining literature was mainly comprised of studies that provide low-level evidence such as narrative reviews, retrospective and case studies or non-controlled clinical trials.

One single-blind RCT that compared the efficacy of a single corticosteroid injection with hyaluronate was identified. A critical appraisal of this trial found it to have a high risk of bias. Furthermore, the solutions administered to

participants were for two distinct conditions, hallux valgus and hallux rigidus and no details for sub group analysis were provided. It was therefore not possible to determine what influence this may have had on the outcome measures relating to pain reduction and improved joint function for hallux rigidus. From this trial it was not possible to determine with any level of certainty or specificity the efficacy of corticosteroids as an intervention to treat osteoarthritis at the hallux.

Data relating to adverse effects was collected by investigators post-intervention, were mild and arose in just 5% of recipients. It was not possible to determine the quality of reporting of adverse effects in this trial or whether adverse effects arose in HAV and/ or HL/HR. However, the reported rate of adverse effects is homogenous with the 6% rate of mild adverse effects reported by following 1,708 steroid injections into both soft tissue and joints of the foot and ankle and of (Grice et al., 2017) who reported no adverse effects following the administration of sixteen corticosteroid injections for hallux rigidus. Whilst it is recognised that this result has a high risk of bias, it supports the anecdotal view that, in general, CSIs are safe and that adverse effects tend to be mild but cannot be applied specifically to 1st MTP jt OA.

Numerous narrative reviews exist regarding treatments for 1st MTP jt OA and include CSIs but provide no evidence-based recommendations for treatment. An exception to this was a comprehensive review by King et al. (2017), the aim of which was to provide evidence-based recommendations regarding conservative treatment modalities for HR and included a review of CSI.

One systematic literature review included an appraisal of the efficacy of 1st MTP jt CSIs (Zammit et al., 2010). The Cochrane review was well designed, executed and found to have a low risk of bias. The authors did not identify any robust evidence to support the efficacy of CSIs for the treatment of HL/HR and made no recommendations regarding its safety due to the high risk of bias. This view is consistent with the findings of this review that found it was only possible to make generalisations relating to the safety of IA CSIs.

3.6 Conclusion

This review did not find evidence of sufficient quality to confirm whether IA CSIs are an effective intervention for the management of symptomatic 1st MTP jt OA. The current literature that exists was found to be of poor methodological design. In the only randomized controlled clinical trial that tested corticosteroid, Uncertainty regarding variables that may influence treatment outcomes such as concomitant footwear use remains. CSIs were found to be mildly inferior to sodium hyaluronate in terms of pain reduction for patients with mild osteoarthritis. However, in a randomised placebo controlled trial of IA injections for osteoarthritis no benefit was derived from sodium hyaluronate vs saline placebo (Munteanu et al., 2009). What complicates coming to a firm conclusion is an understanding of the severity of the 1st MTP jt OA, and as highlighted by Sarkin (1974) and Solan (2001), the inference that end stage OA does less well with CSI.

There are a number of narrative reviews concerned with the conservative and surgical treatment modalities that can be used for the management of

symptomatic HL/HR. A limited number of case and retrospective studies have evaluated the use of injectable corticosteroids in the foot or ankle but controlled clinical trials in this area are few (see Chapter Two).

Despite the lack of evidence to support their use, IA CSIs remain popular amongst healthcare professionals and patients alike because they are quick and inexpensive to administer with the perception of rapid relief, minimal recovery time and few side effects. In cases of mild OA, some retrospective studies indicate that corticosteroid injections may provide months and, occasionally, years of relief for HL/HR though a significant proportion of recipients of IA CSIs require surgical intervention within two years.

High-quality, randomised, controlled clinical trials that test the efficacy of IA CSIs are required. The severity of 1st MTP jt OA amongst recipients in trials should be classified prior to intervention by clinical and radiological exam and a sub group analysis of outcome measures provided according to disease severity. Further research to determine whether treatment outcomes are improved by the use of image guidance, extrapolation of side effects and whether the use of IAIT in the 1st MTP jt reduces surgical burden would be beneficial.

3.7 Chapter summary

The review did not find evidence of sufficient quality to confirm whether IA CSIs are an effective intervention for managing symptomatic OA of the 1st MTP jt. The current literature that exists was found to be of poor methodological design.

In the only RCT clinical trial, CSI was found to be mildly inferior to hyaluronate injections for pain reduction for patients with mild OA. The authors concluded that despite the frequency of use, no high-quality studies support the use of IA CSI injection of the 1st MTP jt in OA. This omission is central to the identification of future studies that need to be performed in this area.

In contrast, Hammersley notes that good professional practice is more than simply a matter of implementing proven treatments, as against exercising professional expertise, to evaluate what would be best in particular circumstances (Hammersley, 2020). He goes on to expand how systematic reviews can and should be critiqued themselves and that the researcher must be aware of the limitations of (non)-exhaustive searching; the use of explicit criteria to identify relevant studies, assessment of the validity of findings; and synthesis of those findings.

What is known:

- There is wide use of CSI as a treatment modality for degenerative OA of the 1st MTP jt
- Clinical justification is currently based on experiential, anecdotal and low level evidence.

What the review highlights:

- There is little high level evidence to clarify the role for CSI in OA of the 1st MTP jt
- There is a need for robust clinical data to be gathered

The use of PRISMA methodology for both the scoping review and systematic reviews adds to the overall rigour of the thesis. As part of a reflective process, the published systematic review itself is critiqued in Chapter 8.

The absence of high-quality evidence to support the use of IA CSI for OA of the 1st MTP jt is a key finding of this chapter and the thesis in general, and identifies the need for future study in this area. However, the COVID-19 pandemic disrupted the planned experiment to study the outcomes on a cohort of patients, and therefore, in discussion and agreement with my academic supervisors, it was agreed that establishing best practices for injection technique would be the next schema of work.

CHAPTER 4

Best practice CSI technique of the 1st MTP jt

Publication: Reilly, I. (2020). Palpation-Guided intra-articular injection of the first metatarsophalangeal joint: injection technique and safe practice for novice practitioners. *SN Comprehensive Clinical Medicine*, 1-9. https://doi.org/10.1007/s42399-020-00719-w.

4.1 Development of best practice IT technique of the 1st MTP jt

Multiple authors describe generic injection techniques, for example, Wittich et al. (2009) provide a no-touch technique guide (see Table 10); Østergaard & Halberg (1998) provides a generic joint injection technique (see Table 11).

Table 10: Steps for the no touch technique (Wittich et al., 2009)

1. Obtain supplies, including one 1.5-inch 18-gauge needle, one 1.5-inch 22-gauge needle, one 5-mL syringe, a pen, antiseptic swabs, adhesive bandage, gloves, 1 vial of corticosteroid, and 1 vial of anaesthetic
2. Swirl the corticosteroid vial to mix. Shaking can cause bubbles. Draw up the corticosteroid and then the anaesthetic using the 18-gauge needle. Inspect the contents of the syringe to be sure the medications have not flocculated or separated. Drawing up the corticosteroid first reduces the chances of this. Replace the needle with a 22-gauge needle
3. Position the patient on the examination table at a height comfortable for you. Use pillows to support the limb and to improve patient comfort
4. Identify the anatomic landmarks and mark the site of injection with a pen. Also, using the tip of the pen, press gently to make an indentation at the injection point. This will be the guide if the pen mark is erased by the antiseptic
5. Clean the site with the antiseptic. This is a no-touch technique. Do not touch the disinfected area. Gloves should be worn as a universal precaution. However, sterile gloves are unnecessary because this is a no-touch technique
6. Perform a pre procedure pause. Stop and verify the correct patient, correct procedure, and correct site
7. Insert the needle
8. Pull back on the needle to determine if joint fluid is present and to be sure a blood vessel has not been cannulated
9. Inject the contents of the syringe. If correctly positioned, the contents should flow freely with little resistance. All of the medication should be completely expelled from the syringe before removing the needle to help prevent skin atrophy
10. Withdraw the needle and place it in a sharps container
11. Cover the injected area with an adhesive bandage
12. Discuss after care with the patient, including signs of complications and the duration of the anaesthetic and corticosteroid medications, and counsel the patient to avoid overuse of the joint for 2 to 3 days and to avoid submerging the joint in water

Table 11: IA injection technique (Østergaard and Halberg, 1998)

Correct aseptic technique

- Only prepacked sterilised disposable syringes and needles should be used
  Sterilised syringes and needles should be opened just before use (not left on a tray in advance)
- Hands should be domestically cleaned and dried
- The injection site should be swabbed twice with an antiseptic before injection; the skin should dry between the applications
- The site of injection should not be touched after the disinfectant has been applied ('no touch' technique); alternatively, sterile gloves and sterile covers could be used
- Physician and patient should not talk during injection (face mask then not needed)
- Fingers must never guide the needle
- Used syringes and needles should be disposed of safely

Correct corticosteroid injection

- Indications and contraindications should be considered; in particular, infection must be ruled out
- The injection site should be carefully chosen, as far from large vessels and nerves as possible
- The injection site could be marked, e.g., with a ball-point pen, prior to disinfection
  The joint should be carefully positioned and, if possible, extended to increase the target area
- Aspiration of joint fluid before corticosteroid injection will ensure correct intra-articular position of the needle
- Injection should not be carried out if resistance is felt; the needle should be repositioned
- Scratching of the cartilage should be avoided

During the provision of training to post-registration podiatrists on injection therapy, it is important to understand, how quickly and how effectively, students develop and maintain the art and skill of IT. This has never been studied before. This part of the project was to take a cohort of students, teach them the basics of CSIs, and then ascertain their effectiveness in displaying effective technique.

As noted in other parts of this study, the COVID-19 pandemic made this goal impossible as not only were CSIs removed from clinical practice, but social distancing meant that face-to-face teaching was not possible. Having identified the literature injection technique - and noted the variability in the process - it was decided to collate, critique and summarise the practice of 'how to inject the joint' using the 20 articles (plus later findings) identified in Theme 2 of the scoping review. This was done for a palpation-guided method, see Table 8.

4.2 Injection safety

Between January 2005 and June 2006, the National Patient Safety Agency (NPSA) received approximately 800 monthly reports concerning injectable medicines, prompting their publication of 'Promoting Safer Use of Injectable Medicines' (NPSA, 2007). This document highlighted latent system risks and recommended measures to enhance the safety of injectable medicines. These measures include risk assessments for injectable medicine procedures, up-to-date protocols, easy access to technical information, a 'purchasing for safety' policy, training for healthcare staff, and incorporating medication practice audits related to injectable medicines into annual healthcare organization assessments. Additionally, the Specialist Pharmacy Services archives contain

patient safety alerts related to medications published by the NPSA between 2002 and 2012, offering guidance and a template for standard operating procedures for injectable medicines in clinical settings (see Appendix 7).

4.3 Technique

1. The patient is placed in a supine position with the leg relaxed to facilitate injection through a dorso-medial approach.
2. Dorsiflex and plantarflex the great toe to identify the joint space. Look for puckering of the skin over the joint margins. Palpate the anatomical landmarks: the metatarsal head and proximal phalanx and identify any overlying osteophytes (optional: mark the joint margins).
3. The key structures to avoid are the long and short extensor tendons that are dorso- and dorso-laterally placed respectively. Identify the medial aspect of extensor hallucis longus tendon (optional: mark the tendon).
4. The injection site should be carefully chosen, as far from large vessels and nerves as possible.
5. Disinfect the skin according to local guidelines. Allow any solution to dry for two to four minutes to allow time for the solution to reduce the bacterial load.
6. Equipment: 2.5 ml syringe with 25mm (1 inch) 23-gauge (blue) needle. Most steroids are particulate in nature and benefit from a wider gauge needle for injection. A 25-gauge (orange) needle is also suitable.
7. Drug: 20mg of triamcinolone (or other drug per clinician preference) mixed with local anaesthetic (per clinician preference).
8. Perform a pre procedure pause. Stop and verify: the correct patient, correct procedure, and correct site?

9. Plantarflex and distract the toe distally to open up the joint space (see fig 3). The approach is through a dorso-medial entry point, the needle entry point is typically 0.5-1cm medial to the extensor hallucis longus tendon (see fig 2).
10. Insert the needle at 90^0 to the skin, then angle 15^0-30^0 distally to avoid chondral injury to the first metatarsal head but not too distally to injure the base of the proximal phalanx.
11. A slight 'give' is usually felt as the needle enters the joint cavity but difficulty advancing the needle suggests that it is in the wrong position.
12. A medial approach, dorsal or dorso-lateral approach may be of use if the dorso-medial entry fails, for example in the presence of osteophytosis. However, there is a concern that leakage of steroid down the needle track from a dorso- or dorso-lateral approach will enter the extensor tendon sheaths.
13. Aim to have a third of the length of the needle deep to the skin (see fig 2). Aspiration of joint fluid it not typically performed for this joint, however its presence before corticosteroid injection will ensure correct intra-articular position of the needle.
14. The injection should not be carried out if resistance is felt; the needle should be repositioned. Inject the solution slowly.
15. All of the medication should be completely expelled from the syringe before removing the needle to help prevent leakage under the skin which may cause skin atrophy.
16. Withdraw the needle, apply compression and a local dressing.

4.4 Chapter summary

The primary aim of this paper is to describe the author's technique for palpation-guided injection of the 1st MTP jt with technique tips incorporated from key authors identified by the scoping review.

The secondary aim of this paper is to promote injection safety. The technique presented incorporates elements of the NPSA documentation as detailed above and in Appendix 7 and gives references for further reading. Accurate and safe injection technique must become the standard for patient care.

Noting that many clinicians can and do inject this joint without image guidance, further work will now be undertaken to validate injection placement accuracy.

CHAPTER 5

Accuracy of 1st MTP jt palpation-guided injection technique

Publication: Reilly, I., Chockallingam, N., & Naemi, R. (2022). The accuracy of first metatarsophalangeal joint palpation guided injections. An arthrography cadaveric study. *Foot & Ankle Surgery: Techniques, Reports & Cases*, 2(3), 1–7. https://doi.org/10.1016/j.fastrc.2022.100219.

5.1 Injection accuracy

This section of this thesis presents the results of the investigations into the accuracy of 1st MTP jt palpation-guided injection technique. The aim of this experiment was to ascertain injection accuracy of 1st MTP jt infiltration using palpation guidance, confirmed using an injection of a radio-opaque contrast media. As highlighted above, COVID-19 constraints led to the development of a cadaveric-based study. Arthrography has been considered in detail under the scoping review outcomes.

5.2 Ethical approval

Ethical approval was sought and received before the start of this study. The study was authorised by Innovation and Research Department, Northamptonshire Healthcare NHS Foundation Trust (NHFT) on 06.07.20; and approved by the Ethics Committee of Staffordshire University on 04.11.20 (see Appendix 12) as part of a professional doctorate programme. Consent for imaging and use in publication(s) was given by the patients seen in Figs. 24-31 (see Appendix 15).

5.3 Equipment

The injection equipment consisted of a green (21-gauge needle) to draw up the injectate, a 2.5ml Luer lock syringe and a blue (23-gauge needle) needle to inject the joint contrast media (see Fig. 8). The injectate was iohexol [N,N´-Bis(2,3-dihydroxypropyl)-5-[N-(2,3-dihydroxypropyl)-acetamido]-2,4,6-triiodoisophthalamide], a non-ionic, water-soluble radiographic contrast medium, with a molecular weight of 821.14 and iodine content 46.36%.nn: Omnipaque

(GE Healthcare AS, Buckinghamshire, UK). Immediately prior to the study six identical syringes were prepared with 2.5ml of Omnipaque 300 (see Fig. 9).

Figure 9: Injection equipment consists of Omnipaque, 2 x hypodermic needles and 2.5ml Luer syringe

Figure 10: Prepared injectate – 6 identical syringes for the 6 cadavers, seen with Omnipaque

5.4 Location of the study

The procedure room at Danetre Hospital, Daventry, was used with access to handwashing and sharps disposal (see Fig. 10). The X-ray machine used was the InSight mini-C-arm fluoroscan (Holologic International). Personal protective equipment (PPE) consisted of a standard lead x-ray gown and thyroid protector, sterile gown gloves, and eye protection. The Principal Investigator (PI) was Ian Reilly, with assistance from a team member for additional photography. The PI is a Radiation Protection Supervisor and IR(ME)R-operator with authority and responsibility to direct and expose radiographic images (see Appendix 13). Standard safety precautions were followed as per the NHFT C-Arm protocol.

Figure 11: Room layout demonstrating equipment layout

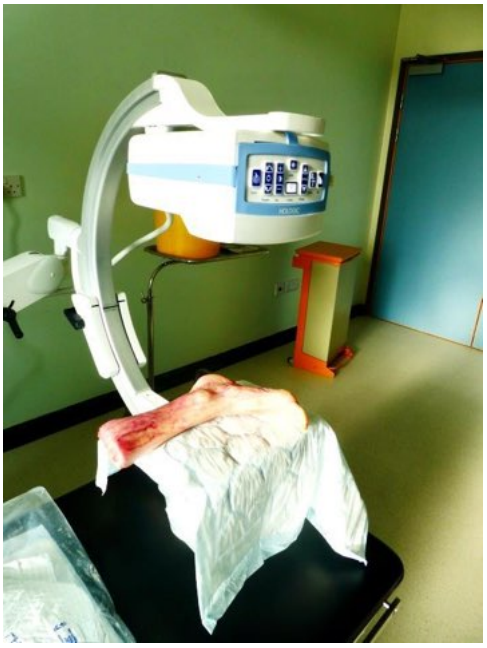

Figure 12: Cadaver set up on the C-arm prior to injection

5.5 Cadaveric specimens

A total of six cadaveric feet were used for this investigation, which was the maximum number that were available at the time of the study: six individual donors in total (see Fig. 11). All cadaveric feet were fresh-frozen, anonymous specimens, thawed overnight, and obtained from the Procedural Skills Laboratory at Nottingham City Hospital (NCH) and delivered via anatomy technologists to the Department of Podiatric Surgery, Danetre Hospital. The anatomy technologists were responsible for the transporting, safety, and safe return of all cadavers and at all times the feet were the responsibility of the NCH anatomical team. The cadavers were free from major deformity, trauma, or surgical changes. Three feet were right-sided, three were left-sided.

5.6 Injection technique for the 1st MTP jt

The injection technique is outlined at Appendix 10 (Reilly, 2020). All injections were performed by the PI using the following sequence:

1. The PI placed a blue, 23-gauge hypodermic needle in the first metatarsophalangeal joint in six cadaveric specimens using palpation-guidance (see Figs. 12 and 13),
2. A pre-injection X-ray was taken but no change in position or further ingress of the needle was made (see Fig. 14),
3. 2ml of iohexol dye was injected into the joint space under live (cine) view using safe distancing from the X-ray beam
4. Following each injection, the cadaveric foot was X-rayed in the dorsal-plantar (DP) and lateral (LAT) planes to confirm the final location of dye placement (see Fig. 15 – AP view),
5. The injectate was considered accurate if the dye coated the inside of the synovial membrane and/or outlined the joint shape,
6. The injectate was considered inaccurate if the dye did not coat the inside of the synovial membrane or outline the joint shape but spread beyond the confines of the articulation,
7. Each injection/X-ray sequence took between 3-5 minutes,
8. All X-rays were stored on a secure NHS server for further assessment,
9. The results were tabulated and subject to further analysis (see Table 9).

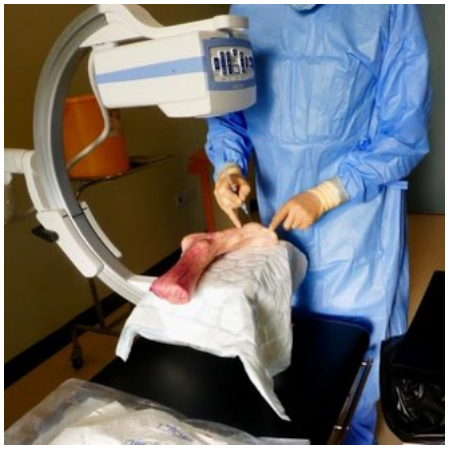

Figure 13: Needle placement in the 1st MTP jt prior to X-ray

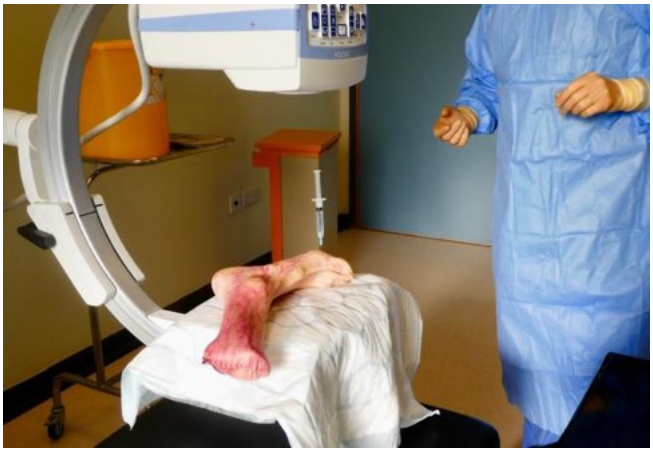

Figure 14: Image taken using foot pedal pre contrast placement (PI at a safe distance)

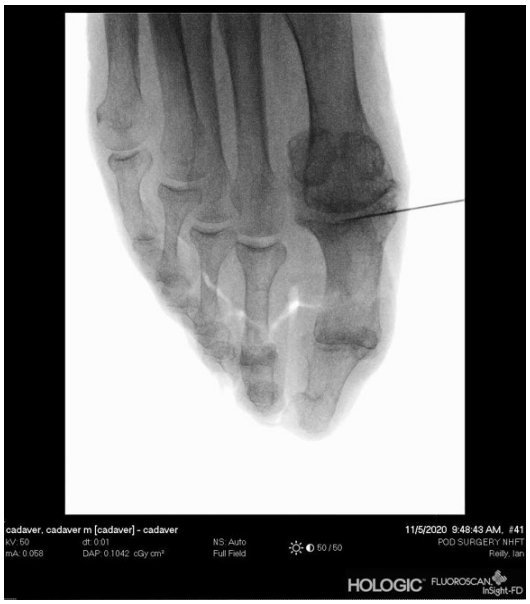

Figure 15: Pre-injection image with needle in situ

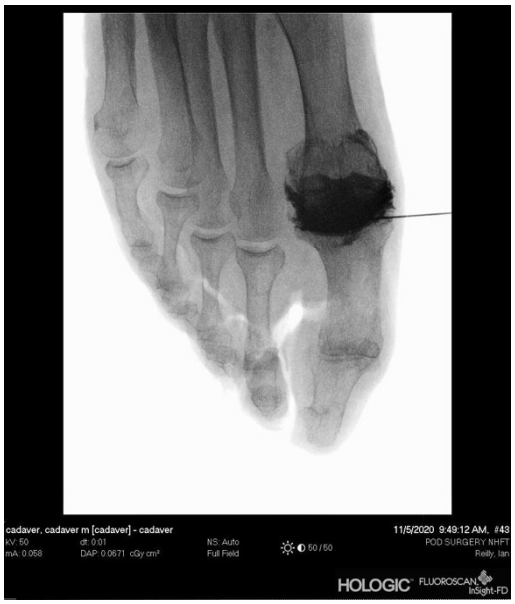

Figure 16: Post-injection image of injected Omnipaque into jt space

5.7 Results

The results are at Table 10 (see Figs. 16-21). An extra, pre-infiltration, lateral view was taken of case one only prior to the injection of the dye. No lateral view was taken for case 2 owing to the surprising failure in technique. Five out of the six injections were accurate, but three of the five accurate injections showed some extravasation of the dye: two 2 plantar-proximally and one dorso-medially and proximally.

Table 12: Results of IA accuracy

Case	Accurate?	Remarks
1	Yes	Extra X-ray taking in lateral view demonstrating good needle placement prior to injection
2	No	Significant extra-capsular leakage medially, and proximally via a digital vessel; no lateral view taken
3	Yes	Accurate injection but slight leakage of dye plantar-proximally
4	Yes	Accurate injection but moderate leakage dorso-medial and proximally
5	Yes	Accurate injection but slight leakage of dye plantar-proximally
6	Yes	Dorsal joint mouse seen on encircled with dye on lateral view but within synovial membrane

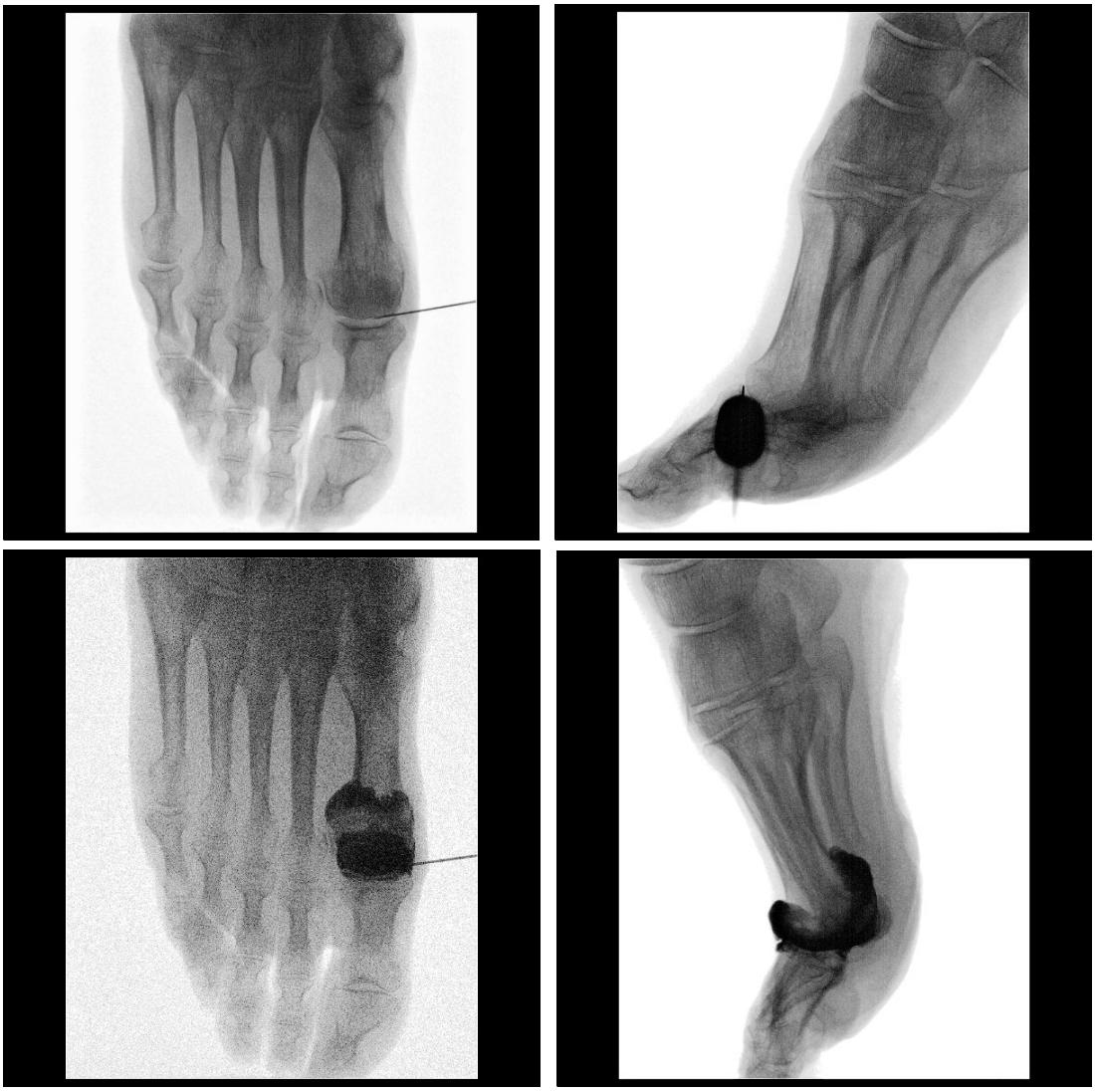

Figure 17: a-d, case 1 pre, during and post-injection

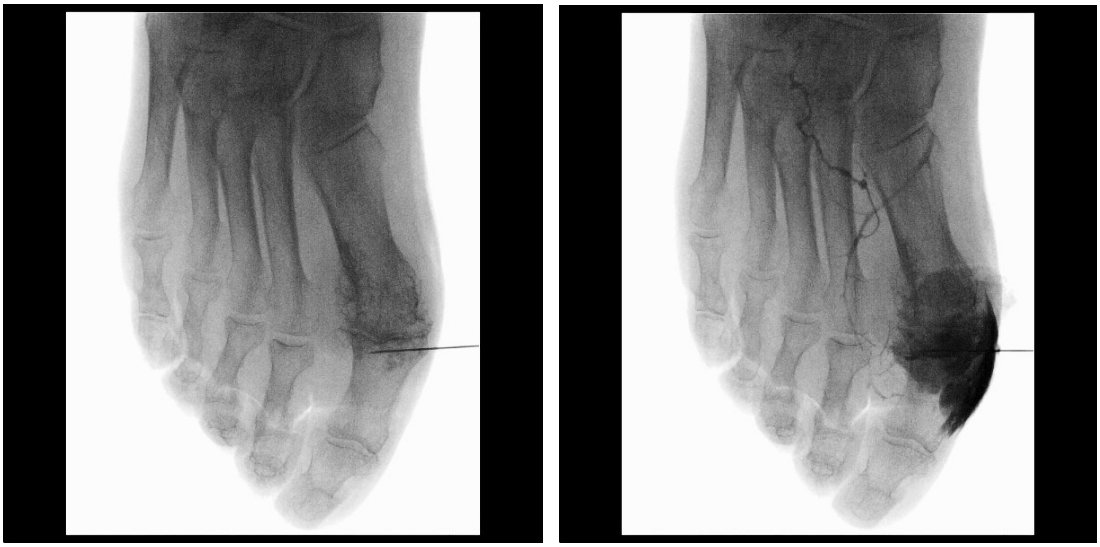

Figure 18: a-b, case 2 pre and during injection

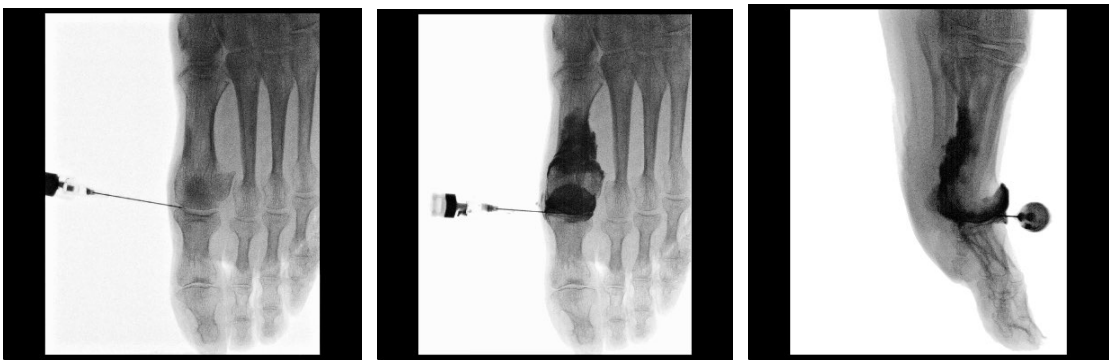

Figure 19: a-c, case 3 pre, during and post-injection

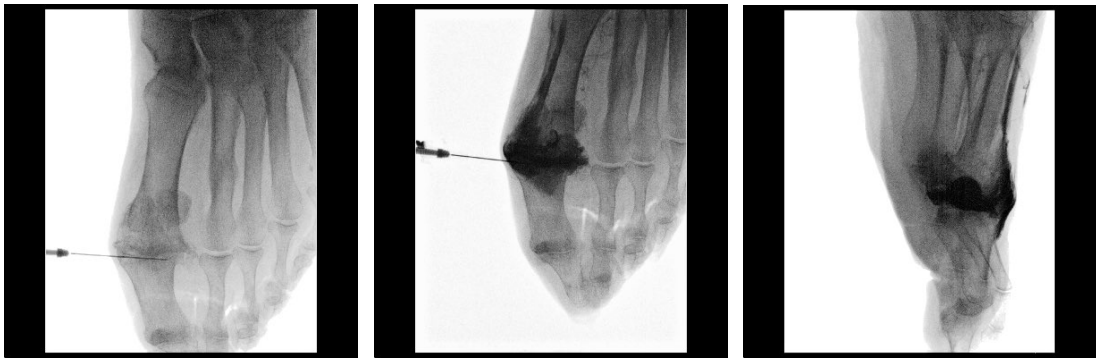

Figure 20: a-c, case 4 pre, during and post-injection

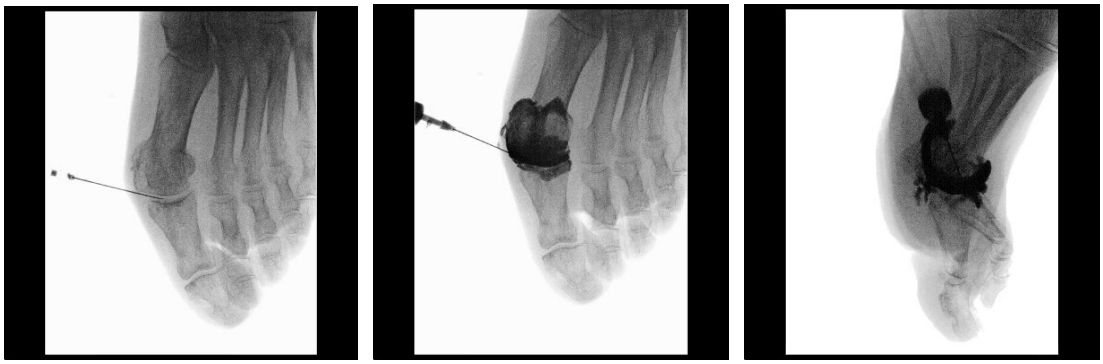

Figure 21: a-c, case 5 pre, during and post-injection

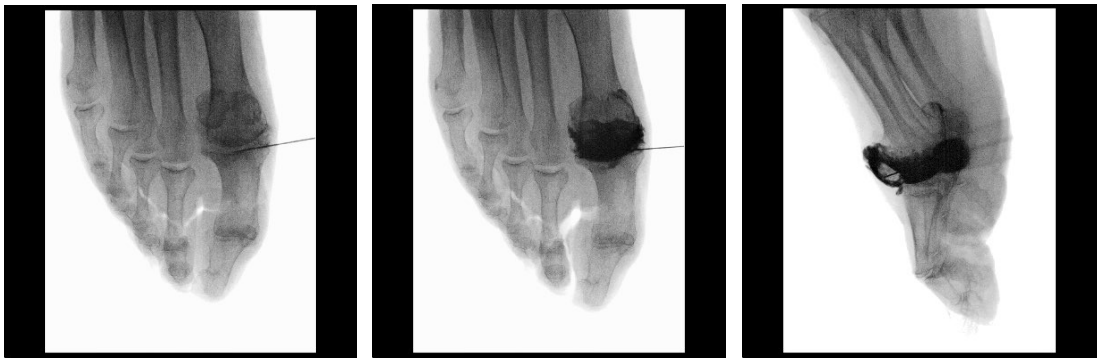

Figure 22: a-c, case 6 pre, during and post-injection

The cadavers were subsequently used as part of a cadaveric surgery teaching course for podiatric surgery students. On one of the feet, following the dissection of the soft tissues and subcutaneous layer away from the joint capsule and periosteum, a 1.0mm Kirschner (K-) wire was inserted into the joint using the standard injection technique (Reilly, 2020). With minimal extra pressure, the K-wire was inserted further into the joint and exited the capsule dorso-laterally (see Figs. 22 and 23).

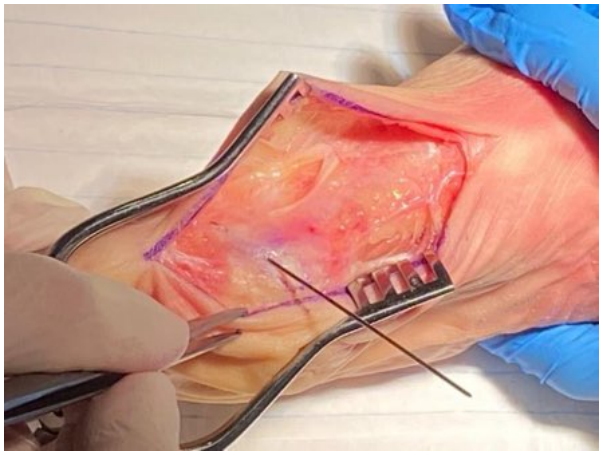

Figure 23: K-wire pass through on a dissected cadaver 1st MTP jt

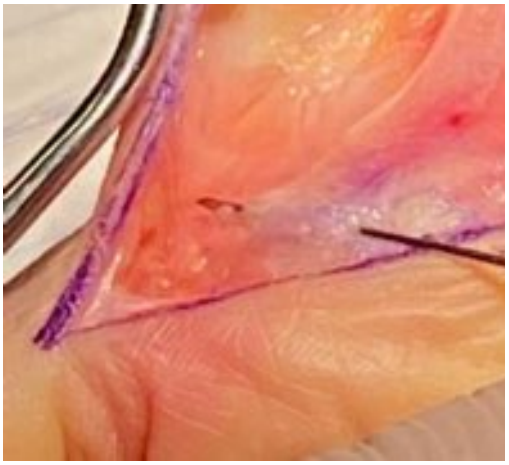

Figure 24: Close view of the K-wire pass through on the jt

5.8 Discussion

The failure of the technique in case two was a surprise to the PI. The live (cine) view of Fig 17-b demonstrates the dye infiltrating the medial tissues, then entering - intravenously (IV) - one of the digital vessels and coursing proximally. This has implications for an under-reported risk of accidental IV injection for IT of the foot. Of note in this study, two of the five successful injections had significant extra-capsular leakage. Depo infiltrations of extra-capsular injectate can remain in the tissues for some time with obvious implications for injection complications. Further work is now required to identify the reasons for - and management of - injection technique failure.

Koski et al. (2006) state that palpation-guided injection s an important clinical skill used by clinicians in several speciality fields. Supporting this, Naylor et al. (2017) had emergency medicine residents perform four US, and four landmark (LM) guided aspirations each of 1st MTP jt simulated effusions in fresh-frozen cadavers. One hundred and forty-four joint aspirations were attempted: 72 by US and 72 by LM guidance. In their study, US did not prove superior to LM for first-pass aspiration of 1st MTP jt effusions.

Derian et al. (2018) state that smaller joints, such as the 1st carpometacarpal (CMC) are often affected by degenerative joint conditions that may benefit from therapeutic injections. They hypothesised that image guidance may be useful for accurate needle placement in these smaller joints but in an US vs palpation-guided latex dye injection cadaveric study of the 1st CMC, they found no difference between the two methods in embalmed specimens. However,

injectate placement accuracy - judged on a four-point scale after dissection of the joint - found that most of the injections (59.7%) were 50%, or less, accurate.

Regarding the use of contrast media, Wang et al. (2007) note that most patients in whom extravasations occur recover without significant sequelae however, McAlister and Palmer (2007) note that extravasated iodinated contrast media can result in injury to surrounding tissues, particularly to the skin, producing an acute local inflammatory response may not peak for 24 to 48 hours. Figs 24 shows a patient six months post IA CSI for HR (Patient LT, see consent form at Appendix 15) that had CS injectate leakage into the subcutaneous tissue from a previous IA CSI. Intra-operatively, during an arthrodesis procedure to the 1st MTP jt, insoluble particulates from the previous injection were noted in the subcutaneous tissues (circled).

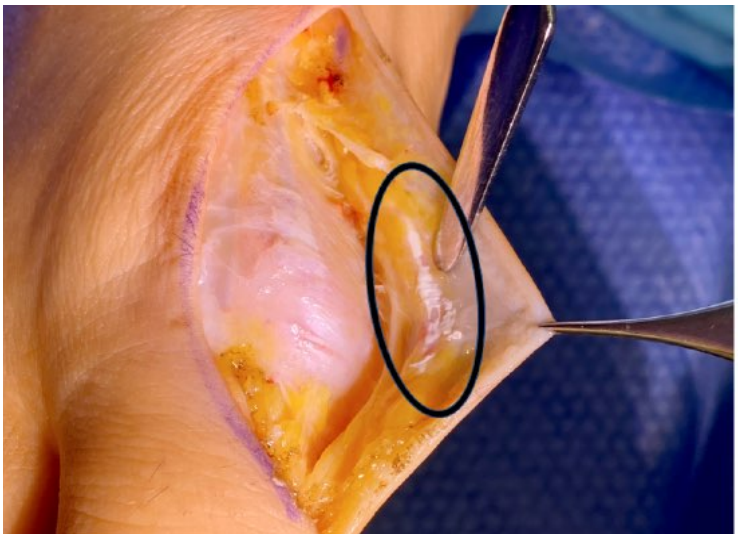

Figure 25: CSI leakage (circled) in the sub-cutaneous tissue, superficial to the synovial membrane, post IA injection

On the hand, Pollard et al. (2007) investigated the accuracy of IA injection of the CMC and determined the rate of soft-tissue extravasation of injected material in successful IA injection. The authors injected 30 cadaveric hands with radiopaque dye (with fluoroscopy-guided needle placement in 8 cases) and then used fluoroscopy to check injection accuracy. The results were recorded depending on the location of the injected dye on fluoroscopic examination. The rates of IA accuracy and soft-tissue extravasation for successful IA injections were 100% and 25% for the fluoroscopy-guided group and 81.8% and 33% for the "blind" group. This study's accuracy rate for IA injection of the CMC is comparable to the rates reported for the injection of larger joints.

Pollard et al. (2007) discuss that this is a relatively high soft tissue extravasation rate for successful IA injection, with the implications for drug extravasation into the surrounding extra-articular space presumed to be similar to those cited for failed needle placement. The authors also recommend injecting a drug at an appropriate volume. In their study, 0.2-0.5mL were injected; a palpable endpoint was difficult to detect but they suggest that forcing excess fluid into the joint space may induce a painfully distended capsule. Care must be exercised during injections to prevent excessive internal pressurization of the capsule, but they accept the shortcomings of this study viz using preserved cadaveric specimens for injection where surface anatomy (and joint mobility) is more difficult to identify in stiff, embalmed specimens.

A narrative review by Saha et al. (2023) and systematic reviews by Gilliland et al. (2011) and Huang et al. (2014) demonstrate that injection accuracy is

improved using US-guidance over palpation-guidance. The authors also found improvements in short-term outcomes but could not confirm a difference in long-term outcome measures using either technique.

The experience of the clinician is relevant to this field of study. Looking more proximally, Curtiss et al. (2011) found that the accuracy of supero-lateral, palpation-guided knee injections were significantly influenced by experience, with a less-experienced investigator demonstrating an accuracy rate of only 55% compared to a more experienced investigator demonstrating an accuracy rate of 100%. At the time of the investigation, the author had 19 years of experience in injection therapy of the foot and ankle, including 14 years of experience in teaching injection techniques to podiatrists and trainee podiatric surgeons nationally and internationally. Therefore, the implication of this 1st MTP jt study is that palpation guidance has a significant failure rate in this series despite the author's experience.

Reflecting on the potential reasons for failure, the author realised his technique had changed over the years in being active in the teaching of such techniques. Looking back at instruction given on the topic from 2006 to 2010, the emphasis was on visualising the needle being within the joint in the centre of the articulation using a dorsal-to-plantar approach angled at 45 degrees to the transverse plane. Over the last 10 years, the authors' technique had evolved to become more horizontal, with the visualisation of the needle tip being just within the synovial membrane/joint recess, as put forward by Lungu and Moser (2015) and Wempe et al. (2012), for example. The reason for this, as alluded

to in an earlier study, is that this made for an easier injection, given the condyloid nature of the joint, reduced joint space, and joint regularity/exostosis typically found with the average arthritic 1st MTP jt undergoing injection. However, if the injection angle is slightly oriented vertically and/or penetrates too far laterally, the joint capsule can be exited on the dorso-lateral aspect by the needle.

The use of joint distraction is helpful in allowing accurate IA positioning. Note in Fig. 25 (Patient NB) the needle angle with respect to the curvature of the metatarsal head, done with the author's preferred medial to lateral technique. Note in Fig. 26 how much space can be created with distal distraction on the proximal phalanx - also note how the first metatarsal-cuneiform joint also opens, medially.

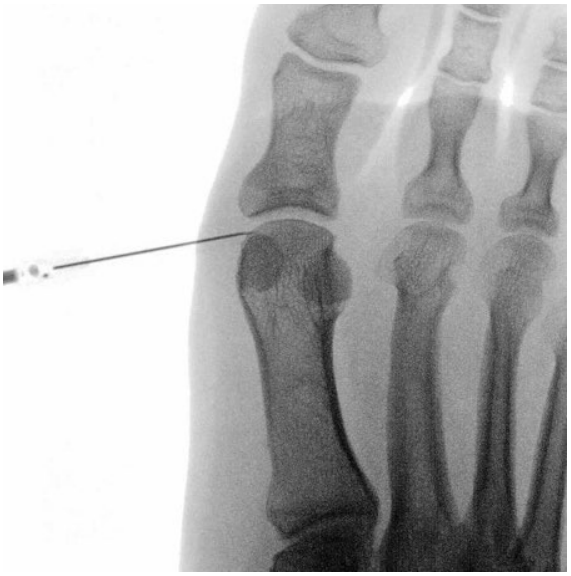

Figure 26: The ideal angle of entry is parallel to the joint space

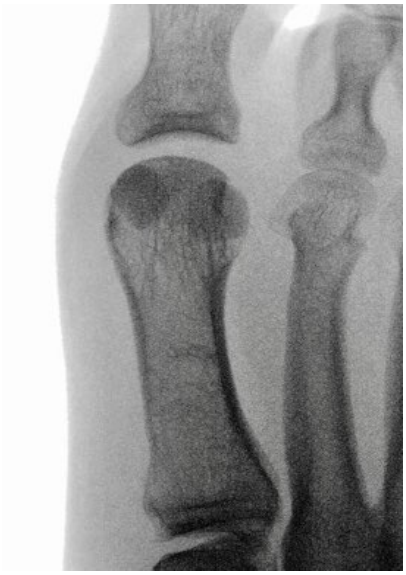

Figure 27: Hallux distraction further increases the potential space for needle entry

Figs. 27 and 28 demonstrate the same concept in the first carpo-metacarpal joint (CMC jt) of the hand. The PI suffered from 1st CMC jt pain and had a CSI

performed under image guidance. Needle placement was confirmed with fluoroscopy, but Fig. 28 shows how the joint space increased with abduction and distraction of the thumb. Fig. 28 also shows what would have been a more effective direction for the needle to follow to enter the joint space (red line).

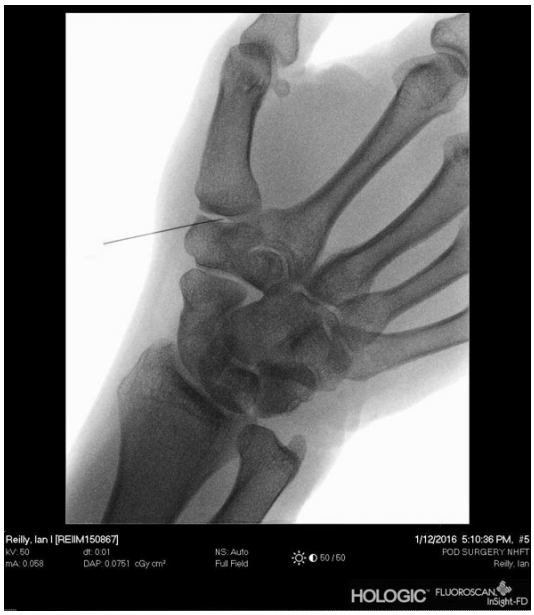

Figure 28: Poor needle placement in the 1st CMC jt

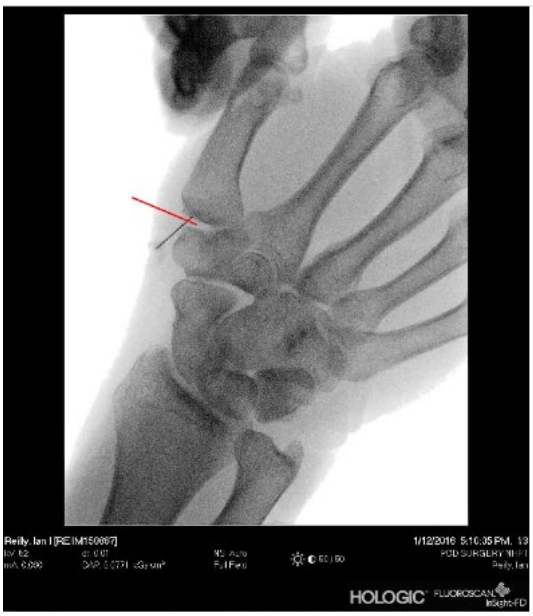

Figure 29: Joint distraction and better needle angle - red line

Fig. 30 shows two options for the joint injection of a more dorsal to plantar approach (orange needle) and a more medial to lateral (blue needle) approach; dorso-lateral (Hawker et al., 2010) and plantar-medial approaches are also supported in the literature (Maher & Price, 2007). Chow and Brandser (1998) note when approaching the joint under fluoroscopic guidance, the joint space that is visible is not directly accessible with a vertical needle approach because the dorsal lip of the proximal phalanx may block needle advancement into the joint. He states that the needle should be inserted 5mm proximal to the visible joint line and advanced in a proximal-to-distal direction to enter the joint, as is

seen with the orange needle in Fig. 29 (patient NB, see consent at Appendix 15).

Fig. 30 (Patient KC, see consent form at Appendix 15) demonstrates an example of dorsal exostosis - albeit an extreme one where the use in intra-articular injections might be of limited use - but serves to demonstrate how irregular joint architecture will impede advancement of the needle into the joint space. In fact, this patient has responded well to IA CSI.

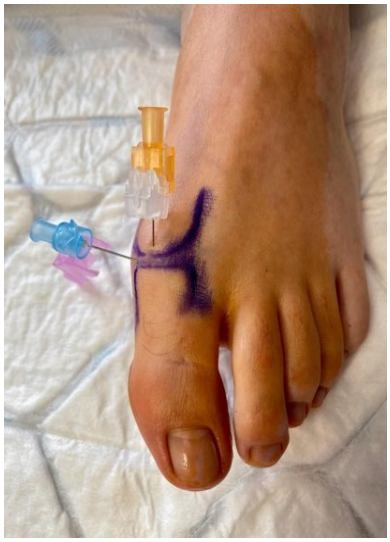

Figure 30: Options - dorso-plantar (orange) and medio-lateral (blue) approaches to jt injection of the 1st MTP jt

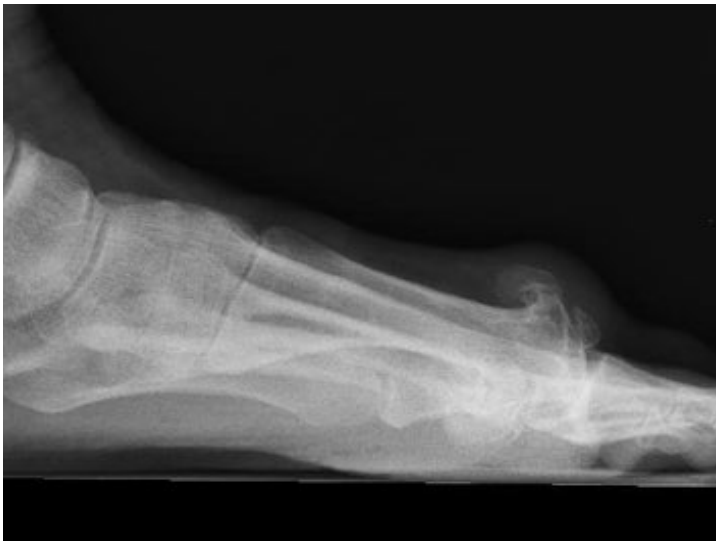

Figure 31: Dorsal exostosis will impede needle entry, especially if utilising a dorso-plantar approach to the 1st MTP jt

This part of the study had several limitations that warrant discussion. The first consideration is the sample size. Only six specimens were available at the time of the study, which was insufficient to carry out statistical analysis. Consideration was given to performing a post-hoc power calculation, but as the main effort of this study was to look at needle accuracy, this was discounted. Future studies would benefit not only from having a larger sample size and performed using actual patients with confirmed metatarsal phalangeal joint

pathology (rather than cadaver specimens). The use of fresh frozen over embalmed specimens was considered to be as close to a realistic clinical scenario as possible, and the injection equipment used was exactly that used by the author in clinical practice. As Smith et al. (2010; 2011) state in their studies, clinicians may wish to exercise caution when extrapolating these cadaveric data to clinical populations.

The results of this call into question the accuracy of palpation-guidance. Over-advancement of the needle into and out of the joint could be one reason for technique failure. Options to mitigate for failure use of image guidance and with or without the application of contrast media. Compounding the failure could be the length of the needle. Typically, the author recommends a 1¼ inch 23-gauge (blue) needle as the standard for 1st MTP jt injections. A shorter needle, for instance, the shorter ¾ inch 25-gauge (orange) needle, might be less prone to 'overshooting the target'.

5.9 Chapter summary

This experiment aimed to ascertain the accuracy of 1st MTP jt infiltration using palpation guidance, confirmed using an injection of a radio-opaque contrast media on cadaveric feet. Failure of accurate needle placement was noted in one of six cadavers, and extra-capsular extravasation of dye beyond the joint was seen in another two, calling into question the use of palpation-guided injection techniques. Having established the potential for failure of a 1st MTP jt palpating-guided injection using a best-practice technique, it is necessary to consider clinical applications and areas for future research.

CHAPTER 6

A case series analysis to inform future research

6.1 Introduction

A key goal of the thesis is to identify gaps in the literature to answer these where possible and to generate questions for future research and analysis. Through a presentation of case series and cohort analysis, this chapter provides an argument on how the work outlined within this program of work can be furthered and translated into clinical practice.

6.2 Case series

The earlier work of Solon et al. (2001) suggested that IA CSIs were of little use in end-stage arthritis. In their study, all patients with grade 3 HR previously treated with IAIT went on to surgery. However, in clinical practice, there are several situations in which patients that present with end-stage arthritis might not otherwise want or necessarily benefit from a joint destructive procedure such as an arthrodesis or an implant arthroplasty (Perler et al., 2013). For example, a fusion or an implant in younger patients will often see them develop further problems elsewhere in the foot within five to ten years. Some patients will not commit to surgery because of medical, social or familial constraints, and as the work by Grady et al. (2002) showed, there is a cohort of patients that primarily seek to avoid surgical intervention. The role of a CSI in end-stage arthritis should be further explored and examined; the initial step will be a case series.

It is the practice of the author to attempt IA CSI even in end-stage arthritis, and it is not unusual for some patients to have effective pain control for several years, allowing surgery to be delayed until a more appropriate time. The

author's best experience is of a five-year cessation of pain after one injection of CSI before the patient returned for a repeat infiltration. The cases presented below will form part of a case series for the use of CSI in advanced cases of OA of the 1st MTP jt (Figs. 31-32 - Patient KC; Figs. 33-34 - Patient RH, Figs. 35-36 - Patient RF, Fig. 37 - Patient DP; see consent forms at Appendix 15). The patients have responded well in the mid- to long-term to IA CSI.

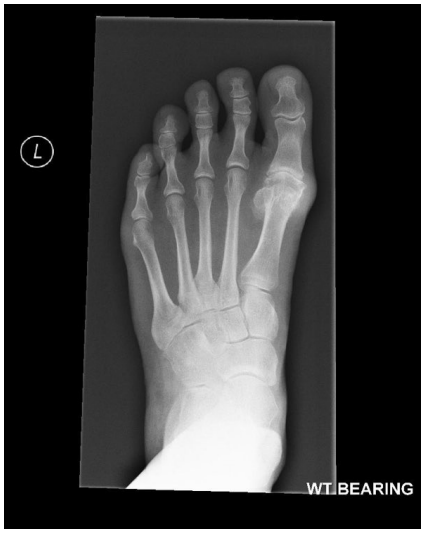

Figure 32: Advanced OA demonstrating loss of jt space and sclerosis

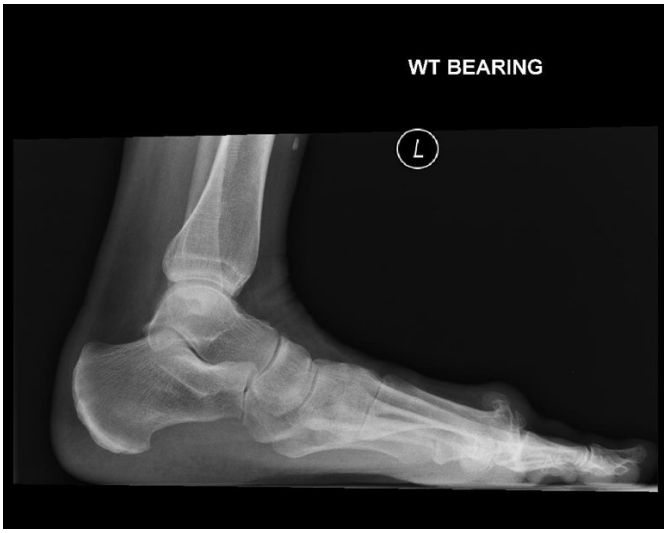

Figure 33: Advanced OA demonstrating loss of jt space and sclerosis

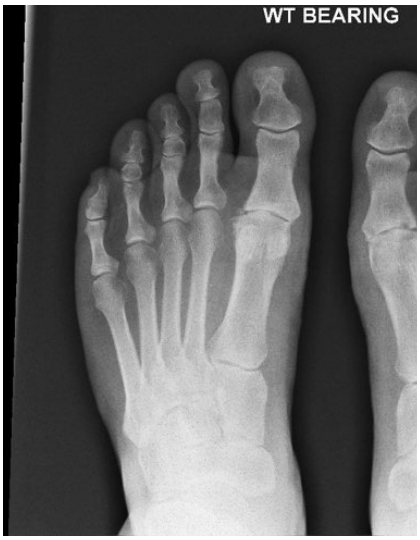

Figure 34: Advanced OA demonstrating reduced jt space and sclerosis

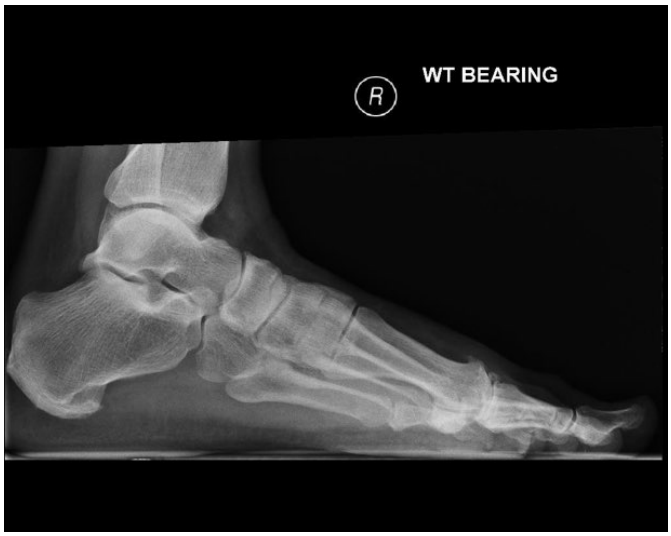

Figure 35: Advanced OA demonstrating reduced jt space and sclerosis

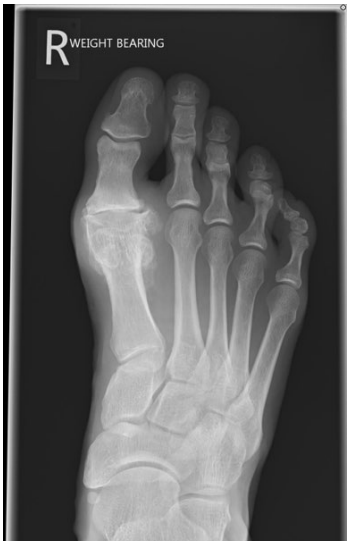

Figure 36: Advanced OA demonstrating loss of jt space and sclerosis

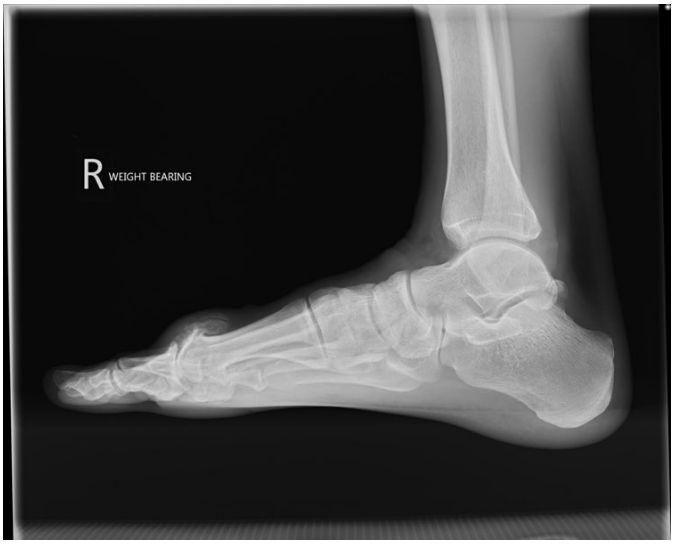

Figure 37: Advanced OA demonstrating loss of jt space and sclerosis

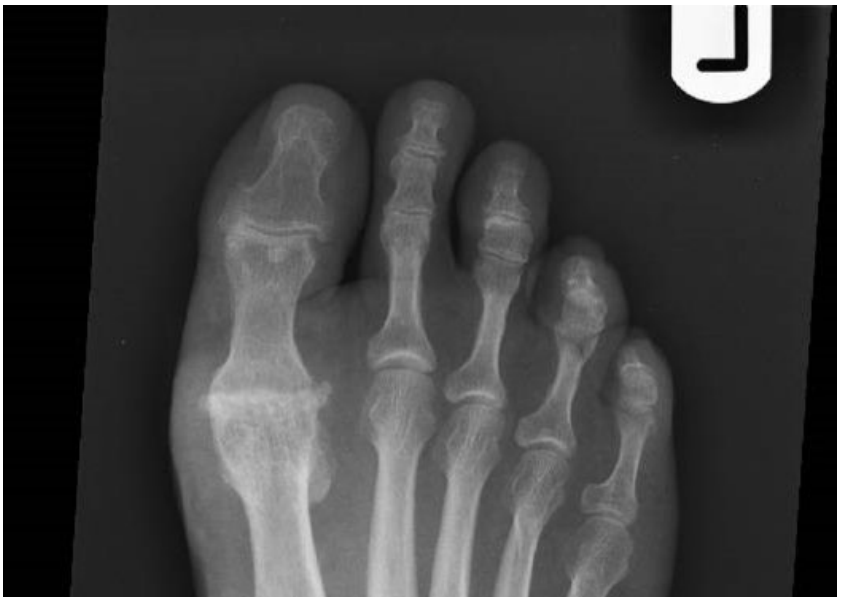

Figure 38: 2020 X-ray - late OA demonstrating complete loss of jt space, osteophytosis and sclerosis

The patient (Patient AR, see consent form at Appendix 15) in Figs. 38-44 underwent bilateral shortening Youngswick osteotomies for hallux limitus in 2016. Three years later, she developed hallux rigidus of the right 1st MTP jt with pain and stiffness, a visual-analogue pain scale of 8/10, and a regression of radiographic parameters, as shown in the images. She underwent a CSI

using 30mg IA CSI triamcinolone acetonide/local anaesthetic with manipulation under anaesthesia in 2020, and now rates her pain at 2/10 on a visual-analogue scale. At the time of completing this thesis some two years later she remains "comfortable". She is 46 years of age and keen to avoid an arthrodesis procedure for as long as possible. She has a preference to wear a moderately high heel shoe and she knows that fusion of the joint will preclude this.

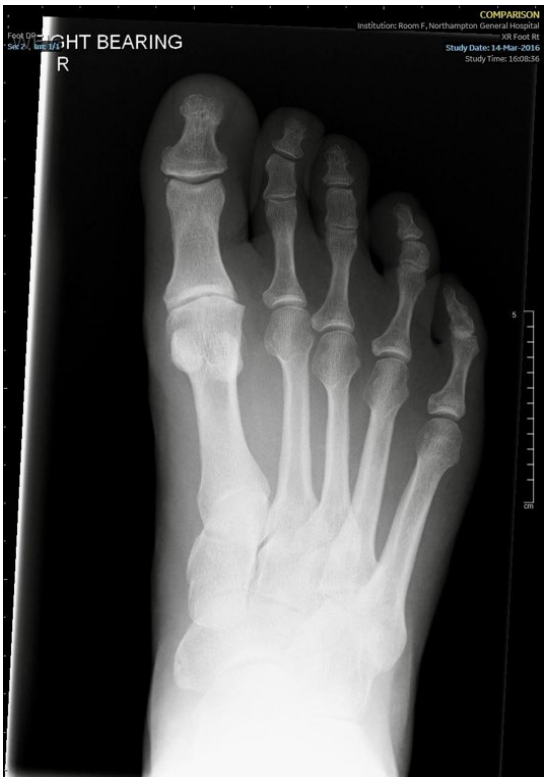

Figure 39: 2016 Pre-operative X-ray demonstrating reduced jt space and sclerosis

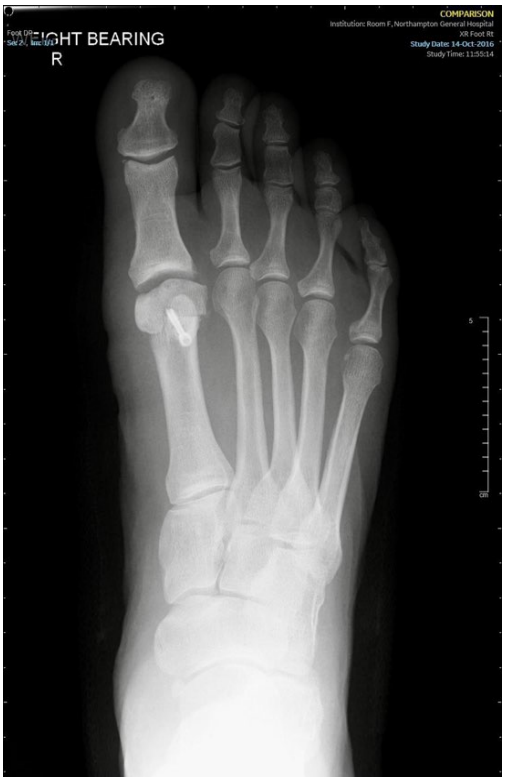

Figure 40: 2016 Post-operative X-ray demonstrating decompression osteotomy of 1st ray

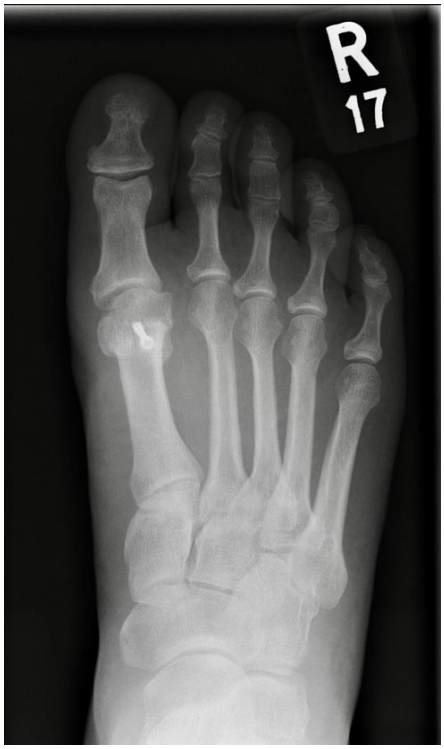

Figure 41: 2019 X-ray - demonstrating loss of jt space and sclerosis - moderate OA

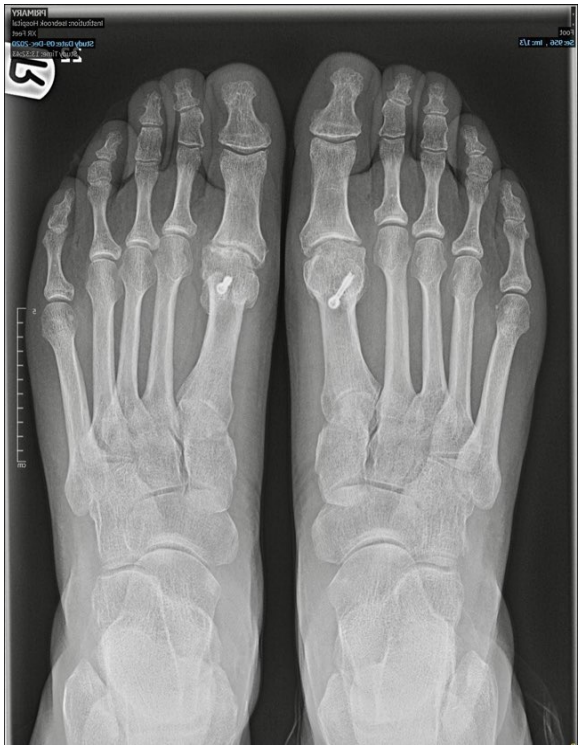

Figure 42: 2020 X-ray - demonstrating loss of jt space and sclerosis - late OA

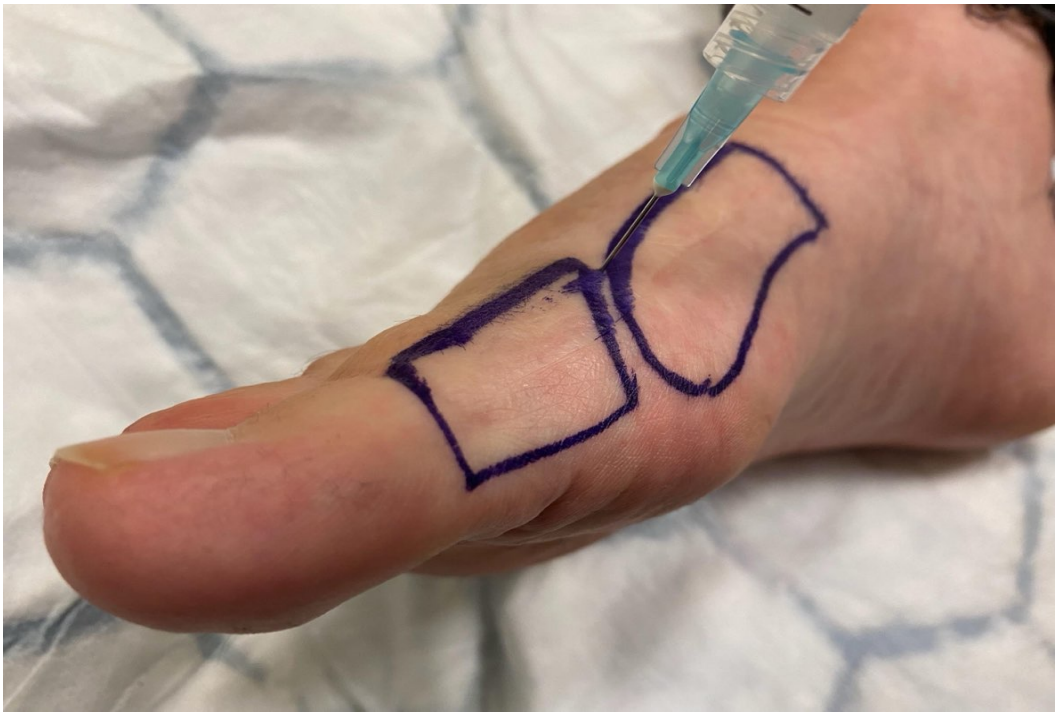

Figure 43: Oblique view demonstrating needle angle and entry of the needle to the 1st MTP CSI

The patient in Fig. 43 (Patient MH, see consent form at Appendix 15) underwent magnetic resonance arthrography for a partially ruptured medial collateral ligament and partial plantar plate tear following a football (turf toe) injury. Gadolinium, injected as a contrast medium into the joint prior to scanning, can be seen as a collection of fluid in the plantar aspect of the synovial membrane. He was given a small (10mg) dose of IA triamcinolone acetonide which completely ameliorated his symptoms. As with the cases presented above, these will be fully discussed in a future publication.

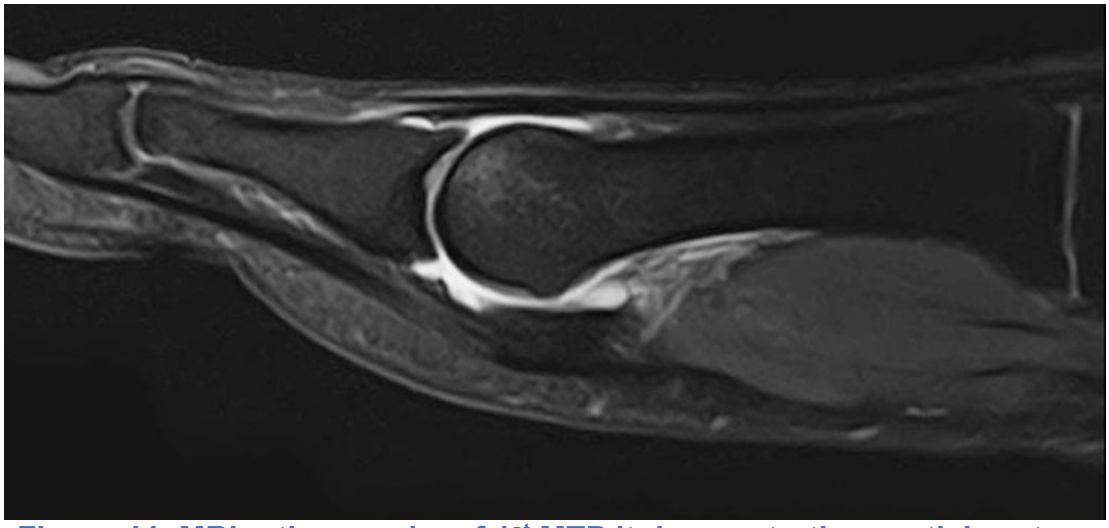

Figure 44: MRI arthrography of 1st MTP jt demonstrating partial rupture at the plantar distal jt capsule

Due to the longitudinal nature of data collection for a case series, the patients are only presented here in outline and the outcomes continued to be monitored. Journals accepting case reports typically require at least one, and in some cases three, years of post-treatment follow-up before accepting literature for publication. The case series will be produced using the CARE guidelines format (Riley et al., 2017).

6.2 Recommendations for a prospective study

To identify the potential benefits of IA CSI for 1st MTP jt OA, it is proposed that a single-blind, placebo-controlled, RCT be designed and conducted after the completion of this thesis. An outline design is detailed below as part six of this thesis, which will test if the null hypotheses can be accepted or rejected. An RCT design will allow the aims and hypothesis to be evaluated and the findings compared by statistical means and patient-reported pain analysis.

Participants to be included in the study will be recruited according to pre-determined inclusion and exclusion criteria. On identifying a subject for study inclusion, the clinician will explain the nature of the study, the role of the participant, the researchers and the duration of their participation in the study they have been blinded to. Clinical information to be given to the patient should include:

- The diagnosis and nature of their condition,
- The details of the proposed treatment and the alternatives,
- The nature and effects of drugs to be given,
- The likely benefits of IA CSI,
- The most likely possible side effects and incidences,
- The plans for follow-up and aftercare.

Without coercion, if the patient agrees to participate in the study, the subject will be given a consent form to complete and a patient information leaflet (on IA CSI). The subject will be given time to read and understand the written literature provided to make an informed decision about their enrolment in the study. If

the patient agrees to become a subject, they will be sent for X-ray assessment of the foot (weight-bearing antero-posterior and lateral views) and allocated a consecutive study number. The sample size, as determined by a power calculation, will highlight the time required for sufficient recruitment of subjects.

CHAPTER 7

Conclusion and recommendations

7.1 Conclusion

The literature suggests that CSIs of joints and periarticular structures are safe and effective, particularly when administered by an experienced physician. IA CSIs are effective for short-term pain relief in OA but accurately predicting the best responders is not currently possible. Specific corticosteroids are recommended for different joints by various authors according to their size, but exact dosages have not been scientifically established. In general, for:

- Smaller joints: methylprednisolone/hydrocortisone is recommended,
- Larger joints: methylprednisolone or triamcinolone is recommended.

This thesis set out to review and develop the evidence base for IA CSI of the 1st MTP jt and identify gaps in our knowledge. The absence of high-quality evidence to support the use of IA CSI of the 1st MTP jt is a key finding of this thesis and identifies the need for future study in this area.

The end destination was not what was initially envisaged, as predicted by Black in his articulate opinion piece (Black, 1998). In particular, the ambition was to examine the effect and outcomes of a cohort of patients, but due to the moratorium on CSI use during the COVID-19 pandemic, it was not possible to advance this concept. Consequently, in discussion with my academic mentors, cadavers were employed, and though one must be careful to extrapolate the results of cadaveric studies into the general population, it allowed for a novel area of research with radio-opaque dyes to be injected into cadaveric joints. This is new knowledge and builds upon a detailed scoping review, a systematic review and an expert treatise of injection technique. The overall contribution to the body of science serves to marshal the literature into one document. It has

been a challenge to gather information from multiple sources and was only effectively achieved through the examination of reference lists (snowball referencing). It is hoped that this project will serve as a useful document if only to present a list of appropriate references for others to use in their own endeavours. Further work is now required to identify the reasons for - and management of - injection technique failure seen in the cadaveric experiment.

The variability in outcomes following injection for 1st MPJ OA raises numerous questions that have not been sufficiently answered: to what extent is pain reduced? Is joint function or range of motion increased? Which patients are most likely to benefit from this treatment? What is the frequency and dose with which corticosteroids should be administered, and whether ultrasound-guided injections enhance treatment outcomes? The key information to delineate is:

1. Which CS drug to use,
2. In what dose,
3. Targeting which patient at which point in their disease process,
4. With or without the use of local anaesthesia,
5. With which injection technique,
6. With or without image guidance (or contrast media),
7. In which regimen (how many injections over what period),
8. With what post-injection advice/follow-up,
9. What short- and long-term complications are seen with CSIs?

7.2 Implications for practice

IA CSIs are recommended for pain management of hip and knee OA (OA) in patients who have not responded to oral or topical analgesics (Guermazi et al.,

2021), but the position is less clear in the foot. Menz et al. (2023) found that a significant proportion of individuals with 1st MTP jt OA report symptoms suggestive of neuropathic pain, which may partly explain the suboptimal responses to commonly used treatments for this condition, and that screening for neuropathic pain may assist in the selection of targeted interventions and improve clinical outcomes. Atrophy of subcutaneous tissues and local skin depigmentation may occur from peri-articular leakage of corticosteroid. The risk is greatest if large or repeated doses of a long-acting, potent corticosteroid are given. CSIs' role in the advancement of 1st MTP OA remains a concern.

The focus of future research should be on the use of CSIs for 1st MTP OA, but as highlighted above, high-level studies also need to be conducted for the role of IA CSI in the management of HAV, acute gout, sesamoiditis and arthrofibrosis. It is unclear why IAIT is not more readily used to manage the synovitis of HAV. Karzon et al. (2022) report on a prospective study of patients aged 25 to 75 years undergoing surgical management of either HAV or HR. Tissue samples from the synovium were collected at the time of the procedure and sent for histology: the samples were graded in a blinded fashion based on the degree of inflammation. Morphological features of the synovectomy specimens undergoing histopathologic analysis were scored by synovial lining cell layer hyperplasia, the extent of inflammatory synovium infiltration, as well as pannus formation via activation of synovial stroma and resident cells. The amount of inflammation in the synovial tissue of hallux valgus patients in this study was similar to that of patients with hallux rigidus, suggesting that there is IA inflammation in patients with hallux valgus. This raises the question of the

potential role of CSIs in the management of bunion joint pain. Arthrofibrosis is one of the most seen complications after HAV surgery and specifically warrants further consideration for research and evaluation of treatment outcomes.

While the best practice methodology has been put forward with an emphasis on injection safety and best practice for novice injectors, it would be useful to repeat the work of Haslock (1990) for CSIs of the 1st MTP jt, and compare practice between professional groups (i.e., orthopaedic/podiatric surgeons, radiologists, rheumatologists, etc.) for both technique and regimen. The summarised results in Appendix 5 show the diversity of professions that have contributed to the literature in the field. A Delphi approach would lend itself to this to agree on best practices across a range of clinical professions and might partly answer some of the softer aspects of CSI around regimen, post-procedure care and outcomes.

In the cadaveric study of six feet injected with a radio-opaque contrast media using palpation guidance, failure of technique was seen in one of six feet and extravasation of dye noted in three out of six feet. Further study using a larger sample of 'live' patients, with a range of joint pathology, is required to expand the confidence of these findings, but the implication is that even technically straightforward injections may not be as accurate as previously assumed. The clinician should therefore be persuaded of the benefits of using image guidance to aid need placement and await further research to guide and refine the therapeutic regimen.

While more and better evidence must be a goal, it seems prudent to recall the thoughts of Black (1988) "*we are more commonly persuaded by a balance of likelihoods than we are driven forward by the iron laws of evidence*."

7.3 Summary

The thesis has outlined the history and indication of injection therapy, described the pharmacology of the commonly used drugs, detailed the anatomy of the 1st MTP jt and the diseases that affect it, reviewed the available literature for CSIT of the joint before systematically reviewing CSIT of OA in detail. A best practice injection technique building on early work was developed, that was examined using a cadaveric model. Concurrently, longitudinal case theories is being collated for the use of CSIT advanced HR, with a perspective future study on CSIT outcomes designed. Concepts for other research areas are suggested. To quote Hill (1965), the work is incomplete, but we must build on the knowledge that we already have.

CHAPTER 8

Reflective analysis

8.1 Reflection

The author's primary goal was to produce a piece of work built on a strong scientific base that credibly adds to the evidence base for 1st MTP jt CSI. The challenge of this project is to provide a useful narrative that will help to inform practice, even if that narrative will take some time to filter down to remote and distal clinical interventions. One assumes that even though the systematic review failed to produce any high-level evidence for using CSIs in 1st MTP jt OA, its publication has not made many clinicians question its use in clinical practice. Few clinicians will have embarked on a four-year academic journey to examine the literature in greater detail.

The methodologies outlined above were applied to establish the rigour and integrity of the process and to ensure that what has been produced is valid. To maintain academic rigour, literature searches concentrated on peer-reviewed, published papers. Scoping reviews often look at the grey literature, but primarily for the manageability of an academic study, it was decided upon to exclude the grey literature in these search strategies. It is apparent from a quick Google search that IAIT is considered useful in clinical practice.

An academic partner will now be sought to undertake the prospective RCT outlined in the previous chapter. Future work will incorporate up-to-date literature searches as new information (published after the initial literature searches) is already available, e.g., Enami Razavi et al. (2021). Much of the thesis data had been published, as noted above, with a critique of the systematic review (Reilly et al., 2020b) shown at Table 11.

Table 13: Critique of "A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint"

Point	Page	Comment
Systematic reviews were appraised using a CEBM appraisal tool for systematic reviews	2	This should have been included detailing the extent of compliance
Inclusion criteria	2	The language of paper, the country in which research was carried out, and date range should have been a predetermined criterion
Mean differences	2	Qualitative data cannot have a mean value
Risk of bias	3	Other quality measures could have been considered
Quality weighting award	3	This should have been clarified
Pons et al. paper	4	This paper should not have been found via initial search
King et al. paper	6	Why discuss this paper if rejected?
Discussion	6	Too much information that should have been in the introduction

8.2 Previous research experience

The secondary goal of this project was to sustainably develop my research skill set to progress from being a research-aware to a research-informed practitioner. I had undertaken two research roles previously but had not consolidated that experience into my everyday practice.

Honorary Visiting Research Fellow

Lancaster University (1998 - 2000)

Following a successful bid for funding from the Northwest Regional Office (£41,000), a research initiative was commenced for six months in June 1998. I was one of four non-medics seconded to Lancaster University for a six-month R&D training programme. This led to the role of R&D Facilitator for the Morecambe Bay Trust from 1999 – 2000 (I took on an academic/surgery post at University College Northampton 2000).

Research Grant Funding

Designated Research Team (2004 - 2006)

I was part of a 3-podiatrist team for a two-year project: Northampton Primary Care Trust (PCT) Designated Research Team (DRT). We successfully gained a £30k training and research grant from the Trent Focus Group (DRSU). The training was provided by the Sunley Management Centre, the University of Northampton, followed by a project to develop an EBM nail surgery guideline.

8.3 Recent research activity

Concurrently during the duration of this course, several preprints and publications have been produced with members of my NHFT research hub with injection therapy and minor surgery as key themes:

Anton, A. L., Reilly, I. N., & Bridgen, A. (2022). The management of ingrown toenails with soft tissue/periungual resection without nail resection or matricectomy: A scoping review. The Journal of the International Foot & Ankle Foundation, 1(11), 1–8. https://doi.org/https://doi.org/10.55067/jifaf.v1i11.36

Clee, S., Flanagan, G., Pavier, J., & Reilly, I. (2021). Scarf and Akin osteotomies for correction of hallux abducto valgus. A ten-year retrospective patient evaluation from five podiatric surgery centres using PASCOM PSQ-10. Research Square. https://doi.org/10.21203/rs.3.rs-1108625/v1

Clee, S., Flanagan, G., Pavier, J., & Reilly, I. (2022). Correction of hallux abducto valgus by scarf osteotomy. A ten-year retrospective multicentre review of patient reported outcomes shows high satisfaction rates with podiatric surgery. Journal of Foot and Ankle Research, 15(1), 44. https://doi.org/10.1186/s13047-022-00546-3

Flanagan, G., Burt, N., & Reilly, I. (2020). Intralesional fenestration and corticosteroid injection for symptomatic Ledderhose disease of the foot: two case reports. Research Square. https://doi.org/10.21203/rs.3.rs-123430/v1

Flanagan, G., Burt, N., & Reilly, I. N. (2021). Intralesional fenestration and corticosteroid injection for symptomatic Ledderhose disease of the foot: Two case reports. SAGE Open Medical Case Reports, 9, 1–6. https://doi.org/10.1177/2050313X211011813

Kontos, A., & Reilly, I. (2022). Podiatry and post-injury fracture management. The Podiatrist, 22(Sept/Oct), 42–45.

Nischal, N., Chandra, L. K., Iyengar, K. P., Reilly, I., & Botchu, R. (2022). Angle of BRINK — a new way to measure Haglund's deformity. Skeletal Radiology, 1–6. https://doi.org/10.1007/s00256-022-04169-4

Reilly, I. (2020). The Fowler total nail avulsion procedure: a case study. J British Dermatological Nursing Group, 19(3), 33–35.

Reilly, I. (2021a). Key concepts for intra-articular corticosteroid injections for pathology of the first metatarsophalangeal joint: a scoping review protocol. https://osf.io/vrebq

Reilly, I. (2021b). Toenail surgery: Indications, options and techniques. Dermatological Nursing, 20(1), 10–18. www.bdng.org.uk

Reilly, I. (2021c). Palpation-guided intra-articular injection of the first metatarsophalangeal joint: Injection technique and safe practice for novice practitioners. SN Comprehensive Clinical Medicine. https://doi.org/10.1007/s42399-020-00719-w

Reilly, I. (2022a). Hit and miss: The accuracy of intra-articular injections of the first metatarsophalangeal joint. The Journal of the International Foot & Ankle Foundation, 1(11), 1–18. https://doi.org/https://doi.org/10.55067/jifaf.v1i11.38

Reilly, I. (2022b). The use of homeopathy in the treatment of hallux abducto valgus and bunion deformities. A systematised review of the application of pseudo-crem. SMAE Journal, 4(Spring), 28–36. www.smaeinstitute.co.uk

Reilly, I., & Blandford, T. (2021a). An update for UK podiatrists performing toenail surgery on patients who are taking anti-thrombotic medications. It's about bleeding time. SMAE Journal, 3(Autumn), 24–30. www.smaeinstitute.co.uk

Reilly, I., & Blandford, T. (2021b). An update for UK podiatrists performing toenail surgery on patients who are taking antithrombotic medications: it's about bleeding time. PrePrint, 2021050559. https://doi.org/10.20944/PREPRINTS202105.0559.V1

Reilly, I., & Botchu, R. (2022). Use of intra-articular injection corticosteroid injections to the first metatarsophalangeal joint. First theme of a scoping review. PrePrint, 1–21. https://doi.org/10.20944/preprints202210.0484.v1

Reilly, I., Bromley, G., & Flanagan, G. (2020). A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint. Research Square PREPRINT. https://doi.org/10.21203/rs.3.rs-105785/v1

Reilly, I., & Burt, N. (2021). Periungual soft tissue resection. The Podiatrist, 24(2), 44–48.

Reilly, I., Burt, N., Reilly, R., & Swami, A. (2020). An update on the chemistry, pharmacology and dose calculations of mepivacaine hydrochloride for Podiatrists in the United Kingdom. PREPRINT, 2020120555. https://doi.org/10.20944/PREPRINTS202012.0555.V1

Reilly, I., Chockallingam, N., & Naemi, R. (2022). The accuracy of first metatarsophalangeal joint palpation guided injections. An arthrography

cadaveric study. Foot & Ankle Surgery: Techniques, Reports & Cases, 2(3), 1–7. https://doi.org/10.1016/j.fastrc.2022.100219

Reilly, I., Longhurst, B., & Chadwick, P. (2022). A cut above. A deeper dive into the development of a College-accredited module on skin surgery. The Podiatrist, 25(1), 37–41.

Reilly, I. N. (2019a). Continuing Professional Development. Nail Surgery. Podiatry Now, 22(11), Supp-undefined.

Reilly, I. N. (2019b). Corticosteroid injection for Podiatrists. A little bit of reflection. Reflective Podiatric Practice, 2(9), 60–63.

Reilly, I. N. (2023). Sharp resection of hypergranulation tissue from only one sulcus in a bilateral stage 3 onychocryptosis: A case report. PrePrints, 1–8.

Reilly, I. N., Bromley, G., & Flanagan, G. (2020). A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint. The Foot and Ankle Online Journal, 13(3). https://doi.org/10.3827/faoj.2020.1303.0012

Reilly, I. N., Ousey, J., & Blandford, T. (2022). A literature review of the use of phenol for nail matrix ablation on pregnant and breastfeeding patients: implications for safe use. The Journal of the International Foot & Ankle Foundation, 1(8), 1–8.

Reilly, I., & Uddin, A. (2021). High volume injection (hydrodissection) for tarsal tunnel syndrome using peripheral nerve stimulation: treatment protocol. Preprint, 202101.0366. https://doi.org/10.20944/preprints202101.0366.v1

Shetty, R., Reilly, I., Iyengar, K. P., Gallagher, M., & Botchu, R. (2022). Survey of knowledge about anatomy and management of plantar fasciitis. The Journal of the International Foot & Ankle Foundation, 1(10), 1–9.

Uddin, A., Flanagan, G., & Reilly, I. (2020). Surgical excision of complex lipoma from the foot: a case report. Research Square PREPRINT. https://doi.org/10.21203/rs.3.rs-99671/v3

Uddin, A., Flanagan, G., & Reilly, I. (2022a). Surgical excision of complex lipoma from the foot: A case report. Clinical Case Reports, 10(6), 1–9. https://doi.org/10.1002/ccr3.5953

Uddin, A., Flanagan, G., & Reilly, I. N. (2022b). Surgical excision of complex lipoma from the foot: a case report. Authorea PrePrint.

Vibhakar, A., Reilly, I., & Shah, A. (2023). Infection. In H.-U. Kauczor, P. M. Parizel, W. C. G. Peh, & J. L. Lu (Eds.), Medical Radiology. Diagnostic Imaging (pp. 1–29). Springer. https://doi.org/10.1007/174_2023_406

The use of ORCID, ResearchGate and Publons websites has been useful in supporting the process of becoming a credible researcher, as has the use of Mendeley reference management software.

- https://orcid.org/0000-0002-2786-5739
- https://www.researchgate.net/profile/Ian_Reilly3
- https://publons.com/researcher/1758282/ian-reilly/

Enrolling on this course in 2019 was the impetus to develop my research skill set. Instead of research-active, perhaps research-hyperactive would be a more appropriate term.

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APPENDIX 1: PRISMA-ScR

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.	44
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.	NA
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.	Appendix 2
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.	48
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.	46
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.	49
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.	50
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Appendix 4
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	50
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 whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	51
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Appendix 5
Critical appraisal of individual	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how	NA

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
sources of evidence§		this information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	Appendix 5
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.	52-53
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Appendix 5
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	NA
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.	53
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	54-122
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.	Appendix 5
Limitations	20	Discuss the limitations of the scoping review process.	1123
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.	121-122
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.	NA

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 at. PRISMA Extension for Scoping Reviews (PRISMA ScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

APPENDIX 2: Scoping review protocol

Introduction

Injection therapy

A needle is inserted into a joint for two main indications: aspiration of fluid (arthrocentesis) for diagnosis or for relief of pressure, or injection of medications (Roberts, 2020). Injection therapy for the treatment of joint pain has been performed since the 1930's. The introduction of cortisone revolutionized the treatment of several medical diseases and injections of glucocorticoids for the relief of vertebrogenic, arthritic and radiculopathic pain are widely accepted (Anitescu et al., 2013). Diarthrodial joints are well suited to intra-articular injection and the local delivery of therapeutics in this fashion brings several potential advantages to the treatment of a wide range of arthropathies (Evans et al., 2014). As well as eliminating many patient-compliance issues, this route of administration overcomes potential problems of bioavailability, uncontrollable drug dosing and the effects of drug binding to systemic molecules that can all limit the efficacy of a substance administered via enteral delivery.

The first metatarsophalangeal joint

The first metatarsophalangeal (great toe) joint (1st MTP jt) is a condyloid synovial juncture (McSweeney, 2016). The metatarso-sesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The base of the proximal phalanx is concave and has a large base to receive its muscular and ligamentous attachments (Percival, 2001). The six muscles are abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis. The ligaments of the joint are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the inter-sesamoid ligament, and the hood ligament (Alvarez et al., 1984). It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTP jt in contradistinction to the lesser MTP jts (Hallinan et al., 2020).

Pathology

The two most common diseases affecting the 1st MTP jt of the foot are hallux limitus/rigidus (osteoarthritis [OA]) and hallux valgus (bunion) (Ajwani et al., 2018; Mann, 1995). Other common pathologies include rheumatoid arthritis, gout and sesamoiditis (Tallia & Cardone, 2003). There are a range of treatments for these conditions: one treatment option is intra articular (IA) injection therapy. Therapeutic injections - especially corticosteroid mixed with anaesthetic - provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, in those in whom conservative treatment has failed or those that are awaiting surgery (Chow & Brandser, 1998). They are accepted as an important treatment modality, but currently there are no evidenced-based guidelines about administration technique or regimen of the 1st MTP jt.

Reilly et at. (2020) performed a systematic review of injectable corticosteroid for OA of the 1st MTP jt (Reilly et al., 2020). The aim of their review was to determine if good quality research exists to enable clinicians to adopt an evidenced based approach to corticosteroid injection (CSI) of the jt. They undertook a review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. A search of electronic databases identified 111 studies for possible inclusion. 64 duplicates were excluded, and 47 titles and abstracts were assessed. Titles and abstracts were assessed and evaluated against their aims. 36 articles were rejected, and 11 full text articles were retrieved for assessment against the selection criteria. One randomised control trial and one systematic review were identified for inclusion in their review. The authors concluded that despite the frequency of use, no high-quality studies support the use of IA CSI of the 1st MTP jt in osteoarthritis.

The planned coping review will take a wider approach to gathering data for the use of IA CSI for all 1st MTP jt pathologies to chart themes and identify gaps in the evidence base.

Methods

Scoping reviews

All literature review methods offer a set of tools that researchers need to use appropriately. The method adopted for identifying literature for this review needs to achieve in-depth and broad results regardless of study design. In 2009, Grant and Booth identified 14 different types of literature reviews (Grant and Booth, 2009), one of which was the 'scoping review'. Scoping reviews are used to assess and understand the extent of the knowledge in an emerging field or to identify, map, report, or discuss the characteristics or concepts in that field. (Peters, 2020a).

A scoping review is commonly used for 'reconnaissance' of an area; to map out and clarify working definitions and conceptual boundaries of a topic or field (Davis et al., 2009). It is a form of knowledge synthesis that addresses an exploratory research question and maps the key concepts underpinning a research area by systematically searching, selecting, and synthesizing existing knowledge (Arksey & O'Malley, 2005; Colquhoun et al., 2014). They are useful when a body of literature has not yet been comprehensively reviewed, or exhibits a large, complex, or heterogeneous nature that is not amenable to a more precise systematic review (Peters et al., 2015).

Munn et at. (2018) listed the indications for scoping reviews:

- As a precursor to a systematic review,
- To identify the types of available evidence in a given field,
- To identify and analyse knowledge gaps,
- To clarify key concepts/ definitions in the literature,
- To examine how research is conducted on a certain topic or field,
- To identify key characteristics or factors related to a concept.

A scoping review was therefore considered to be the most suitable approach to answer the research question looking at the wider themes about injection therapy of this jt.

Scoping review design

A scoping review methodological framework was first proposed by Arksey and O'Malley and Colquhoun (Arksey & O'Malley, 2005; Colquhoun et al., 2014) and amended by Levac et at. (Levac et al., 2010). The six stages of the frameworks they produced for conducting a scoping study were:

- Stage 1: identifying the research question
- Stage 2: identifying relevant studies
- Stage 3: study selection
- Stage 4: charting the data
- Stage 5: collating, summarizing, and reporting the results
- Stage 6: consultation

Arksey and O'Malley scoping methodological framework

Arksey and O'Malley Framework Stage (2005)	Description
1: Identifying the research question	Identifying the research question provides the roadmap for subsequent stages. Relevant aspects of the question must be clearly defined as they have ramifications for search strategies. Research questions are broad in nature as they seek to provide breadth of coverage.
2: Identifying relevant studies	This stage involves identifying the relevant studies and developing a decision plan for where to search, which terms to use, which sources are to be searched, time span, and language. Comprehensiveness and breadth is important in the search. Sources include electronic databases, reference lists, hand searching of key journals, and organizations and conferences. Breadth is important; however, practicalities of the search are as well. Time, budget, and personnel resources are potential limiting factors and decisions need to be made upfront about how these will impact the search.
3: Study selection	Study selection involves post hoc inclusion and exclusion criteria. These criteria are based on the specifics of the research question and on new familiarity with the subject matter through reading the studies.
4: Charting the data	A data-charting form is developed and used to extract data from each study. A 'narrative review' or 'descriptive analytical' method is used to extract contextual or process-oriented information from each study.
5: Collating, summarizing, and reporting results	An analytic framework or thematic construction is used to provide an overview of the breadth of the literature but not a synthesis. A numerical analysis of the extent and nature of studies using tables and charts is presented. A thematic analysis is then presented. Clarity and consistency are required when reporting results.
6: Consultation (optional)	Provides opportunities for consumer and stakeholder involvement to suggest additional references and provide insights beyond those in the literature.

Levac et at. recommendations for clarification/additional steps

Arksey and O'Malley Framework Stage	Levac et al (2010) recommendations for clarification/additional steps
1: Identifying the research question	1. Clearly articulate the research question that will guide the scope of inquiry. Consider the concept, target population, and health outcomes of interest to clarify the focus of the scoping study and establish an effective search strategy. 2. Mutually consider the purpose of the scoping study with the research question. Envision the intended outcome (e.g., framework, list of recommendations) to help determine the purpose of the study. 3. Consider rationale for conducting the scoping study to help clarify the purpose.
2: Identifying relevant studies	1a. Research question and purpose should guide decision-making around the scope of the study. 1b. Assemble a suitable team with content and methodological expertise that will ensure successful completion of the study. 1c. When limiting scope is unavoidable, justify decisions and acknowledge the potential limitations to the study.
3: Study selection	1. This stage should be considered an iterative process involving searching the literature, refining the search strategy, and reviewing articles for study inclusion. 2a. At the beginning of the process, the team should meet to discuss decisions surrounding study inclusion and exclusion. At least two reviewers should independently review abstracts for inclusion. 2b. Reviewers should meet at the beginning, midpoint and final stages of the abstract review process to discuss challenges and uncertainties related to study selection and to go back and refine the search strategy if needed. 2c. Two researchers should independently review full articles for inclusion. 2d. When disagreements on study inclusion occur, a third reviewer can determine final inclusion.
4: Charting the data	1a. The research team should collectively develop the data- charting form and determine which variables to extract in order to answer the research question. 1b. Charting should be considered an iterative process in which researchers continually extract data and update the data- charting form. 1c. Two authors should independently extract data from the first five to ten included studies using the data-charting form and meet to determine whether their approach to data extraction is consistent with the research question and purpose. 2. Process-oriented data may require extra planning for analysis. A qualitative content analysis approach is suggested.
5: Collating, summarizing, and reporting results	Researchers should break this stage into three distinct steps: 1a. Analysis (including descriptive numerical summary analysis and qualitative thematic analysis). 1b. Reporting the results and producing the outcome that refers to the overall purpose or research question. 1c. Consider the meaning of the findings as they relate to the overall study purpose; discuss implications for future research, practice and policy.
6: Consultation (optional)	1. Consultation should be an essential component of scoping study methodology. 2a. Clearly establish a purpose for the consultation. 2b. Preliminary findings can be used as a foundation to inform the consultation. 2c. Clearly articulate the type of stakeholders to consult and how data will be collected, analysed, reported, and integrated within the overall study outcome. 2d. Incorporate opportunities for knowledge transfer and exchange with stakeholders in the field.

The Joanna Briggs Institute (JBI) is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide (Pearson et al., 2005). The JBI develops and delivers evidence-based information, software, education, and training and its guidance is widely cited across a range of disciplines, academic fields, and professional backgrounds (Khalil et al., 2020). This scoping review will follow the JBI process, which provides for the review to be rigorously conducted, transparent, and trustworthy (Peters, 2020b). Building on the guidance developed by Arksey and O'Malley (2005) and Levac et at. (2010), the JBI framework (Peters, 2020a) recommends organising the review process into nine stages:

1. Defining and aligning the review objectives and questions,
2. Developing the inclusion criteria with the objective and questions,
3. Describing the planned approach to evidence searching, selection, extraction, and charting,
4. Searching for the evidence,
5. Selecting the evidence,
6. Extracting the evidence,
7. Charting the evidence,
8. Summarising the evidence in relation to the objectives and questions.
9. Consultation.

The JBI framework informs the overall conduct of the scoping review. The 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews' (Tricco et al., 2018) will be used to guide the reporting of this protocol and will also subsequently be used to structure the reporting of the full review (PRISMA-ScR).

Protocol

The JBI recommend that an a-priori protocol must be developed before undertaking the scoping review (Peters, 2020a). A scoping review protocol is important as it pre-defines the objectives and methods of the scoping review. It is a systematic approach to the conduct and reporting of the review and allows transparency of process. The objectives, inclusion criteria and methods for this scoping review are specified in advance and documented in this protocol.

1. Defining and aligning the review objectives and questions.

Scoping study research questions are broad in nature as the focus is on summarizing the breadth of evidence. Arksey and O'Malley (Arksey & O'Malley, 2005) suggest an iterative process for developing research questions, i.e., the process is not linear and requires researchers to engage with each stage in a reflexive way and, where necessary, repeat steps to ensure that the literature is covered comprehensively. The scoping review question guides and directs the development of the specific inclusion criteria for the scoping review. Clarity of the review question assists in developing the protocol, facilitates effectiveness in the literature search, and provides a clear structure for the development of the scoping review (Peters et al., 2020).

2. Developing the inclusion criteria with the objective and questions

Aim

To establish what is known about intra-articular cortico-steroid injection therapy for pathology of the 1st MTP jt.

Objectives

1. To establish the key concepts about IA CSI therapy for pathology of the 1st MTP jt.,
2. To map or chart the data obtained to identify themes,
3. To identify key gaps in the existing evidence base and suggest the most urgent questions for future research.

The JBI recommends the PCC framework ('Population–Concept–Context') for scoping reviews to identify the main concepts in review questions (Peters et al., 2020a), see table 1.

Inclusion criteria	Rationale for inclusion and exclusion
Population	Human subjects (patients)
Concept	This scoping review will consider literature that provides information related to treatment with an intra-articular (IA) CSI
Context	IA CSI for pathology of the 1st MTP jt
Types of evidence to be included:	Published papers or published conference abstracts reporting empirical or qualitative data from primary research or service evaluations. All research designs pertaining to the scoping review objectives will be considered Grey literature will be excluded for primary searching as published sources will be most useful and appropriate – and likely more rigorous. This is also to limit the number of hits as there are an unmanageable number of grey articles/websites. Selected sources found through secondary reference lists may be considered. To ensure a wide-ranging review, as per JBI guidelines, there will be no date or language restrictions. Studies that do not use IA (e.g., peri-articular, or systemic) CSI for the 1st MTP jt, or for which the original manuscript could not be retrieved, will be excluded.

Table 1: PCC inclusion and exclusion criteria

3. Describing the planned approach to evidence searching, selection, extraction, and charting

The search strategy for a scoping review should ideally aim to be as comprehensive as possible within the constraints of time and resources to identify appropriate literature. To achieve the research aim, a strategy that involves searching for research evidence via the following different sources will be adopted:

a) Electronic databases

b) Google scholar

c) Reference lists

4. Searching for the evidence

Step 1: "The following databases will be searched via the NHS Healthcare Advanced Database Search (HDAS) search engines using MeSh terms/free text:

- CINHAL (Cumulative Index to Nursing and Allied Health Lit.: 1981 - 2021)
- EMBASE (Excerpta Medica Database: 1974 - 2021)
- MEDLINE (Medical Literature Analysis and Retrieval Online: 1946 - 2021)

Search terms

"((GLUCOCORTICOIDS/ OR (Steroid*).ti,ab OR (glucocorticoid*).ti,ab) AND ("INJECTIONS, INTRA-ARTICULAR"/ OR (Injection*).ti,ab)) AND (HALLUX/ OR (hallux).ti,ab OR ("big toe*").ti,ab OR ("great toe*").ti,ab OR (arthrofibrosis).ti,ab OR (gout).ti,ab OR (sesamoid*).ti,ab)"

Step 2: Google Scholar will be searched using key words identified from an analysis of the text words contained in the title and abstract of retrieved papers, and these key words used to search for articles.

Step 3: Examination of reference lists of all identified sources from step 1 and 2.

5. Selecting the evidence

Following the execution of the search strategy, the identified records will be retrieved and included or excluded according to the inclusion and exclusion criteria listed above. To support the greater breadth for scoping reviews, a variety of study designs will be included: scoping reviews are designed to provide an overview of the existing evidence base regardless of research quality and therefore a formal assessment of the methodological quality of the included studies is generally not performed.

6. Extracting the evidence

Following retrieval (database and snowball referencing), charting and sorting of material according into key issues and themes will be performed. A data extraction instrument for study details, characteristics and results extraction is provided in Appendix 1, adapted from the template provided by Peters et al. (2020a):

a) Author(s), source, and year of publication,
b) Type of evidence,
c) Origin/country of origin (where the study was published or conducted),
d) Profession,
e) Population,
f) Concept,
g) Context,

h) Aims,
i) Methodology,
j) Intervention,
k) Outcomes,
l) Key findings that relate to the scoping review question.

7. Charting the evidence

The themes will be tabulated and summarized to present a narrative account of the existing literature. Data synthesis is not normally undertaken in scoping reviews because of the heterogeneity of the data (Peters et al., 2015).

8. Summarising the evidence in relation to the objectives and questions

Due to the heterogeneity of data, scoping reviews do not synthesize the results/outcomes of included sources of evidence as this is more appropriately done within the conduct of a systematic review (Peters et al., 2020a). The results of this scoping review will be presented as a map of the data extracted from the included literature in a tabular form and in a narrative descriptive summary that aligns with the objectives of the review. It is expected that the evidence will be further refined toward the end of the review when there is greater awareness of the contents of the included studies.

9. Consultation

This review will be registered with Open Science Framework and be available as a preprint. Findings will be presented to explore speciality-specific and profession-specific commonalities and differences. The scoping review results will be disseminated via publication in peer-reviewed journals (it is envisaged that at least two publications will be developed) and presentation at national/international conferences.

Declarations

Declaration of intertest: The author confirms that he has no competing interests.

This scoping review has been developed as part of the requirements toward completion of a doctoral degree in healthcare science at the University of Staffordshire.

Funding: This research did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

Patient and public involvement: Patients and/or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication: Not required.

References

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APPENDIX 3: Search strategy

HDAS Export
Strategy Prof Doc - 1st MTP joint
Strategy 856181/saved

Current search strategy: Prof Doc - 1st MTP joint search			
	Database(s)	**Search Term**	
	Saved Results	View Results (37)	
1	CINAHL	GLUCOCORTICOIDS/	View Results (9,166)
2	CINAHL	(Steroid*).ti,ab	View Results (26,219)
3	CINAHL	(glucocorticoid*).ti,ab	View Results (6,256)
4	CINAHL	"INJECTIONS, INTRAARTICULAR"/	View Results (2,728)
5	CINAHL	(Injection*).ti,ab	View Results (61,015)
6	CINAHL	"METATARSOPHALANGEAL JOINT"/	View Results (1,380)
7	CINAHL	(hallux).ti,ab	View Results (2,647)
8	CINAHL	("big toe*").ti,ab	View Results (245)
9	CINAHL	("great toe*").ti,ab	View Results (535)
10	CINAHL	(arthrofibrosis).ti,ab	View Results (313)
11	CINAHL	(gout).ti,ab	View Results (3,481)
12	CINAHL	(sesamoid*).ti,ab	View Results (394)
13	CINAHL	(1 OR 2 OR 3)	View Results (36,786)
14	CINAHL	(4 OR 5)	View Results (61,893)
15	CINAHL	(13 AND 14)	View Results (3,915)
16	CINAHL	(6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12)	View Results (7,933)
17	CINAHL	(15 AND 16)	View Results (23)
18	EMBASE	GLUCOCORTICOID/	View Results (83,432)
19	EMBASE	(Steroid*).ti,ab	View Results (316,518)
20	EMBASE	(glucocorticoid*).ti,ab	View Results (87,538)
21	EMBASE	INJECTION/	View Results (135,636)
22	EMBASE	(Injection*).ti,ab	View Results (738,922)
23	EMBASE	HALLUX/	View Results (3,530)
24	EMBASE	(hallux).ti,ab	View Results (6,326)
25	EMBASE	("big toe*").ti,ab	View Results (1,470)
26	EMBASE	("great toe*").ti,ab	View Results (2,563)

27	EMBASE	(arthrofibrosis).ti,ab	View Results (733)
28	EMBASE	(gout).ti,ab	View Results (15,849)
29	EMBASE	(sesamoid*).ti,ab	View Results (1,821)
30	EMBASE	(18 OR 19 OR 20)	View Results (423,032)
31	EMBASE	(21 OR 22)	View Results (747,063)
32	EMBASE	(23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29)	View Results (28,169)
33	EMBASE	(30 AND 31 AND 32)	View Results (116)
34	Medline	GLUCOCORTICOIDS/	View Results (63,307)
35	Medline	(Steroid*).ti,ab	View Results (217,052)
36	Medline	(glucocorticoid*).ti,ab	View Results (67,042)
37	Medline	"INJECTIONS, INTRA-ARTICULAR"/	View Results (7,791)
38	Medline	(Injection*).ti,ab	View Results (564,314)
39	Medline	HALLUX/	View Results (1,892)
40	Medline	(hallux).ti,ab	View Results (5,314)
41	Medline	("big toe*").ti,ab	View Results (1,094)
42	Medline	("great toe*").ti,ab	View Results (2,055)
43	Medline	(arthrofibrosis).ti,ab	View Results (614)
44	Medline	(gout).ti,ab	View Results (12,143)
45	Medline	(sesamoid*).ti,ab	View Results (1,708)
46	Medline	(34 OR 35 OR 36)	View Results (304,278)
47	Medline	(37 OR 38)	View Results (566,943)
48	Medline	(39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45)	View Results (22,354)
49	Medline	(46 AND 47 AND 48)	Viewing (54)

APPENDIX 4: Search results

Contents 37 of 37 results on Saved Results

1. The Impact of Ultrasound on the Use and Efficacy of Intraarticular Glucocorticoid Injections in Early Rheumatoid Arthritis.

Author(s): Nordberg; Haavardsholm, Espen A.; Lillegraven, Siri; Aga, Anna-Birgitte; Sexton, Joe; Lie, Elisabeth; Hammer, Hilde B.; Uhlig, Till; Kvien, Tore K.; Olsen, Inge C.; van der Heijde, Désirée

Source: Arthritis & Rheumatology; Aug 2018; vol. 70 (no. 8); p. 1192-1199

Publication Date: Aug 2018

Publication Type(s): Academic Journal

Database: CINAHL

2. Manipulation under anaesthesia and steroid injection for pain and stiffness after surgery to the first metatarsophalangeal joint.

Author(s): Ajwani ; Kocialkowski, Cezary; Hill, Rebecca; Kurdy, Nasser

Source: Foot; Mar 2018; vol. 34 ; p. 36-39

Publication Date: Mar 2018

Database: CINAHL

3. Managing Gout Flares in the Elderly: Practical Considerations.

Author(s): Abhishek, Abhishek

Source: Drugs & Aging; Dec 2017; vol. 34 (no. 12); p. 873-880

Publication Date: Dec 2017

Database: CINAHL

4. Efficacy of Foot and Ankle Corticosteroid Injections.

Author(s): Grice ; Marsland, Daniel; Smith, George; Calder, James

Source: Foot & Ankle International; Jan 2017; vol. 38 (no. 1); p. 8-13

Publication Date: Jan 2017

Database: CINAHL

5. Intra-articular glucocorticoids for acute gout.

Author(s): Wechalekar MD; Vinik O; Schlesinger N; Buchbinder R

Source: Cochrane Database of Systematic Reviews; Apr 2013 (no. 4)

Publication Date: Apr 2013

Database: CINAHL

6. Predictors of response to a single intra-articular injection of mannitol-modified cross-linked hyaluronic acid (HANOX-M-XL) in patients with first metatarsophalangeal joint osteoarthritis (hallux rigidus)

Author(s): Conrozier T.; Charpentier A.; Bossert M.; Mellac-Ducamp S.; Galois L.

Source: Arthritis and Rheumatology; Sep 2018; vol. 70 ; p. 424-425

Publication Date: Sep 2018

Database: EMBASE

7. Validation of claims-based algorithms for gout flares

Author(s): MacFarlane L.A.; Liu C.-C.; Solomon D.H.; Kim S.C.

Source: Pharmacoepidemiology and Drug Safety; Jul 2016; vol. 25 (no. 7); p. 820-826

Publication Date: Jul 2016

Database: EMBASE

8. Bioresponsive glucocorticoid-loaded microparticles to prevent acute gout flares

Author(s): Stubelius A.; Sheng W.; Lee S.; Almutairi A.; Guma M.

Source: Arthritis and Rheumatology; Oct 2016; vol. 68 ; p. 2966-2967

Publication Date: Oct 2016

Database: EMBASE

9. Sonography of the first metatarsophalangeal joint and sonographically guided intraarticular injection of corticosteroid in acute gout attack

Author(s): Kang M.H.; Moon K.W.; Jeon Y.H.; Cho S.W.

Source: Journal of clinical ultrasound : JCU; Mar 2015; vol. 43 (no. 3); p. 179-186

Publication Date: Mar 2015

Database: EMBASE

10. Adverse events from diagnostic arthrocentesis for suspicion of gout: A systematic analysis in a large multi-centre cohort

Author(s): Taylor W.J.; Fransen J.; Jansen T.; Dalbeth N.; Neogi T.; Schumacher H.R.

Source: Annals of the Rheumatic Diseases; Jun 2015; vol. 74 ; p. 1266-1267

Publication Date: Jun 2015

Publication Type(s): Conference Abstract

Available at Annals of the Rheumatic Diseases - from BMJ Journals - NHS

Available at Annals of the Rheumatic Diseases - from ProQuest (Health Research Premium) - NHS Version

Abstract: Background: Arthrocentesis is a common procedure in

Database: EMBASE

11. Identification of gout flare using an administrative claims based algorithm

Author(s): MacFarlane L.; Solomon D.H.; Kim S.C.

Source: Arthritis and Rheumatology; Oct 2015; vol. 67

Publication Date: Oct 2015

Database: EMBASE

12. Computed tomography-guided bupivacaine and corticosteroid injection for the treatment of symptomatic calcification in the great toe tendon

Author(s): Karatoprak O.; Karaca S.; Karaman O.; Erdem M.N.; Hamzaoglu A.

Source: Local and Regional Anesthesia; Apr 2014; vol. 7 (no. 1); p. 23-25

Publication Date: Apr 2014

Database: EMBASE

13. A novel application of musculoskeletal ultrasound for the diagnosis and the treatment of hallux saltans at the master knot of henry: A case report

Author(s): Lee S.; Poole S.; Onishi K.

Source: PM and R; Sep 2014; vol. 6 (no. 9)

Publication Date: Sep 2014

Publication Type(s): Conference Abstract

Database: EMBASE

14. The risk of intraarticular steroid injections are overestimated

Author(s): Andreasen R.A.; Just S.A.; Hansen I.M.J.

Source: Annals of the Rheumatic Diseases; Jun 2014; vol. 73

Publication Date: Jun 2014

Database: EMBASE

15. Symptomatic hallucal interphalangeal sesamoid bones successfully treated with ultrasound-guided injection

Author(s): Shin H.Y.; Kim H.Y.; Jung Y.S.; An S.; Park S.Y.; Kang D.H.

Source: Korean Journal of Pain; 2013; vol. 26 (no. 2); p. 173-176

Publication Date: 2013

Database: EMBASE

16. The usefulness of high-resolution ultrasonography of the first metatarsophalangeal joint in acute gout

Author(s): Moon K.; Kang M.; Jeon Y.; Kim J.

Source: Annals of the Rheumatic Disease; Jun 2013; vol. 71

Publication Date: Jun 2013

Database: EMBASE

17. GOUT and other crystal diseases

Author(s): Doherty M.

Source: Annals of the Rheumatic Disease; Jun 2013; vol. 71

Publication Date: Jun 2013

Database: EMBASE

18. The rheumatoid foot: Aspects of diagnosis and treatment

Author(s): Stengaard-Pedersen K.

Source: Scandinavian Journal of Rheumatology; 2012; vol. 41 ; p. 15

Publication Date: 2012

Database: EMBASE

19. Corticosteroid injections in rheumatology - A review of 34 years of clinical experience

Author(s): Tan R.F.

Source: International Journal of Rheumatic Diseases; Sep 2012; vol. 15 ; p. 123

Publication Date: Sep 2012

Database: EMBASE

20. Symptomatic hallucal interphalangeal sesamoid bones treated with injection under the ultrasound guidance: A case report

Author(s): Kim H.Y.; Shin H.Y.; Moon J.Y.; Park S.Y.; Kim Y.C.; Lee S.C.

Source: Regional Anesthesia and Pain Medicine; 2012; vol. 37 (no. 5)

Publication Date: 2012

Database: EMBASE

21. Chondrotoxicity of single dose corticosteroid injections

Author(s): Dragoo J.

Source: Arthroscopy - Journal of Arthroscopic and Related Surgery; Oct 2011; vol. 27 (no. 10)

Publication Date: Oct 2011

Database: EMBASE

22. Musculoskeletal corticosteroid and local anesthetic injections; A survey of practice patterns among members of the American college of rheumatology

Author(s): Alon L.; Ramessar N.; Cabas-Vargas J.; Stefanov D.; Lazaro D.M.

Source: Arthritis and Rheumatism; Oct 2011; vol. 63 (no. 10)

Publication Date: Oct 2011

Database: EMBASE

23. Single intramuscular depot methylprednisolone injection: A convenient, efficacious and safe treatment for gouty arthritis in an inpatient setting

Author(s): Ishorari J.; Hassan N.; Dasgupta B.

Source: Rheumatology; Apr 2010; vol. 49

Publication Date: Apr 2010

Database: EMBASE

25. Foot and ankle disorders

Author(s): Balint G.P.; Korda J.; Balint P.V.; Hangody L.

Source: Best Practice and Research: Clinical Rheumatology; Feb 2003; vol. 17 (no. 1); p. 87-111

Publication Date: Feb 2003

Database: EMBASE

26. Manipulation and injection for hallux rigidus

Author(s): Solan M.C.; Calder J.D.F.; Bendall S.P.

Source: Journal of Bone and Joint Surgery - Series B; 2001; vol. 83 (no. 5); p. 706-708

Publication Date: 2001

Database: EMBASE

27. Corticosteroid therapy for the treatment of acute attacks of crystal-induced arthritis: An effective alternative to nonsteroidal antiinflammatory drugs

Author(s): Werlen D.; Gabay C.; Vischer L.

Source: Revue du Rhumatisme (English Edition); 1996; vol. 63 (no. 4); p. 248-254

Publication Date: 1996

Database: EMBASE

28. Acute rupture of the extensor hallucis longus tendon

Author(s): Poggi J.J.; Hall R.L.

Source: Foot and Ankle International; 1995; vol. 16 (no. 1); p. 41-43

Publication Date: 1995

Database: EMBASE

29. Traumatic lesions of the metatarsophalangeal joint of the great toe in athletes

Author(s): Coker T.P.; Arnold J.A.; Weber D.L.

Source: American Journal of Sports Medicine; 1978; vol. 6 (no. 6); p. 326-334

Publication Date: 1978

Database: EMBASE

30. Sesamoiditis

Author(s): Seder J.I.

Publication Date: 1974

Publication Type(s): Article

PubMedID: 4828301

Database: EMBASE

31. Indications for intra-articular steroid in osteoarthritis of the ankle and big toe joints.

Author(s): Sarkin, T L

Source: South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde; Oct 1974; vol. 48 (no. 49); p. 2067-2068

Publication Date: Oct 1974

Database: Medline

32. The efficacy and safety of treatments for acute gout: results from a series of systematic literature reviews including Cochrane reviews on intraarticular glucocorticoids, colchicine, nonsteroidal antiinflammatory drugs, and interleukin-1 inhibitors.

Author(s): Wechalekar, Mihir D; Vinik, Ophir; Moi, John H Y; Sivera, Francisca; van Echteld, Irene A M; van Durme, Caroline; Falzon, Louise; Bombardier, Claire; Carmona, Loreto; Aletaha, Daniel; Landewé, Robert B; van der Heijde, Désirée M F M; Buchbinder, Rachelle

Source: The Journal of rheumatology. Supplement; Sep 2014; vol. 92 ; p. 15-25

Publication Date: Sep 2014

Database: Medline

33. Diagnosis and treatment of gout in primary care.

Author(s): Rakieh, Chadi; Conaghan, Philip G

Source: The Practitioner; Dec 2011; vol. 255 (no. 1746); p. 2-7

Publication Date: Dec 2011

Database: Medline

34. Joint aspiration and injection and synovial fluid analysis.

Author(s): Courtney, Philip; Doherty, Michael

Source: Best practice & research. Clinical rheumatology; Apr 2013; vol. 27 (no. 2); p. 137-169

Publication Date: Apr 2013

Database: Medline

35. Injection Techniques for Common Chronic Pain Conditions of the Hand: A Comprehensive Review.

Author(s): Urits, Ivan; Smoots, Daniel; Anantuni, Lekha; Bandi, Prudhvi; Bring, Katie; Berger, Amnon A; Kassem, Hisham; Ngo, Anh L; Abd-Elsayed, Alaa; Manchikanti, Laxmaiah; Urman, Richard; Kaye, Alan; Viswanath, Omar

Source: Pain and therapy; Jun 2020; vol. 9 (no. 1); p. 129-142

Publication Date: Jun 2020

Database: Medline

36. Symptomatic Hallucal Interphalangeal Sesamoid Bones Successfully Treated with Ultrasound-guided Injection - A Case Report.

Author(s): Shin, Hye Young; Park, Soo Young; Kim, Hye Young; Jung, Yoo Sun; An, Sangbum; Kang, Do Hyung

Source: The Korean journal of pain; Apr 2013; vol. 26 (no. 2); p. 173-176

Publication Date: Apr 2013

Database: Medline

37. Regional musculoskeletal conditions: foot and ankle disorders.

Author(s): Bálint, Géza P; Korda, Judit; Hangody, László; Bálint, Péter V

Source: Best practice & research. Clinical rheumatology; Feb 2003; vol. 17 (no. 1); p. 87-111

Publication Date: Feb 2003

Database: Medline

APPENDIX 5: Extraction instrument

Population, Concept, Context

Study details, characteristics, and results extraction instrument. Adapted from JBI template source of evidence details, characteristics and results extraction instrument (Peters et al., 2020a).

Template

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	xxx
Type of evidence source	xxx
Country/Profession	xxx

Inclusion/exclusion criteria	
Population	yyy
Concept	yyy
Context	yyy

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
Aims: zzz Methodology: zzz Intervention: zzz Outcomes: zzz

https://wiki.jbi.global/display/MANUAL/Appendix+11.1+JBI+template+source+of+evidence+details%2C+characteristics+and+results+extraction+instrument

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Ajwani, S., Kocialkowski, C., Hill, R., & Kurdy, N. (2018). Manipulation under anaesthesia and steroid injection for pain and stiffness after surgery to the first metatarsophalangeal joint. The Foot, 34, 36-39.
Type of evidence source	Retrospective case series
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	38 feet in 35 patients
Concept	IA CSI
Context	Post-operative MUA with CSI

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Aim: To determine the effectiveness of manipulation under anaesthesia and local steroid injection to treat stiffness of the first metatarsophalangeal joint following surgery for hallux rigidus or hallux valgus.

Methods: Patients were identified who had undergone surgery for hallux rigidus or hallux valgus and subsequently were treated with manipulation and steroid injection for stiffness of their joint. Patient records were reviewed to determine the range of movement of the joint pre-operatively, immediately following the procedure and at subsequent follow up. Manchester–Oxford foot questionnaires (MOXFQ) were sent to patients to evaluate symptoms post-operatively.

Results: In total 35 patients were analysed, which included a total of 38 foot operations. Twenty seven had prior surgery for hallux rigidus and 11 for hallux valgus correction. The total range of movement of the joint improved following manipulation by an overall mean of 44.7° ($p < 0.0001$). At subsequent follow up, the total range of movement of the joint was still improved by 22.2° ($p < 0.0001$) overall. The mean post-operative MOXFQ score was 24.8 but no correlation was found between MOXFQ scores and range of movement.

Conclusions: Manipulation under anaesthesia and local steroid injection is an effective way of treating stiffness following first ray surgery. Treatment results in an improved range of movement of the joint and patients report good function post-operatively.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Al-Jabri T., Charalambides C. (2019). First metatarsophalangeal joint injections: the 'sulcus sign' technique. Clin Surg, 4: 2429
Type of evidence source	Case series
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	30 patients
Concept	IA CSI
Context	Description of the 'sulcus sign' technique

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
A first metatarsophalangeal joint injection is a very useful diagnostic and therapeutic technique used in a range of pathologies afflicting this joint. We describe a novel technique for obtaining accurate intraarticular needle positioning which is simple to perform and avoids the morbidity associated with multiple injection attempts.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Fernandez, C., Noguera, R., Gonzalez, J. A., & Pascual, E. (1999). Treatment of acute attacks of gout with a small dose of intraarticular triamcinolone acetonide. The Journal of Rheumatology, 26(10), 2285-2286.
Type of evidence source	Case series
Country/Profession	Rheumatology/Spain

Inclusion/exclusion criteria	
Population	20 joints in 19 men
Concept	IA CSI
Context	Acute monoarticular gout

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
Smaller doses of triamcinolone acetonide in monoarticular arthritis (all confirmed by MSU crystals identification) significatively improved pain (VAS 0-100), CRP levels and patient perception in 48h and were safe and well tolerated in this prospective, uncontrolled study of patients with gout.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Feuerstein, C., Weil Jr, L., Weil Sr, L. S., Klein, E. E., Argerakis, N., & Fleischer, A. E. (2016). Joint manipulation under anesthesia for arthrofibrosis after hallux valgus surgery. The Journal of Foot and Ankle Surgery, 55(1), 76-80.
Type of evidence source	Case series
Country/Profession	US/Podiatry

Inclusion/exclusion criteria	
Population	53 feet in 38 patients
Concept	IA CSI
Context	Post-operative MUA with CSI

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Arthrofibrosis is a known complication of hallux valgus surgery. Joint manipulation under anesthesia has been studied for adhesive capsulitis of the shoulder; however, a paucity of published data exists on the use of this modality in the foot and ankle. The purpose of the present study was to investigate the outcomes of first metatarsophalangeal joint manipulation for arthrofibrosis that occurred as a complication of bunion surgery. The study population consisted of patients attending a single foot and ankle specialty clinic who were evaluated for arthrofibrosis after bunion surgery. Patients who underwent joint manipulation under anesthesia were asked to complete a research visit in which a clinical examination was performed, and the presence and severity of joint pain were assessed. A total of 38 patients (34 females, 4 males, 53 feet), with a mean age of 55.7 +/-11.8 (range 30 to 83) years, agreed to participate. The mean follow-up period was 6.5 +/- 3.4 (range 1 to 17) years. The visual analogue scale scores improved significantly from baseline to the final follow-up visit (baseline 6.5 +/-1.5, range 2 to 10; final follow-up visit 2.3 +/- 1.5, range 0 to 6; $p < .001$). Furthermore, joint motion had increased significantly ($p < .001$) for both dorsiflexion and plantarflexion at the final follow-up examination. The final range of motion (dorsiflexion, r 1⁄4 0.431, p 1⁄4 .002; plantarflexion, r 1⁄4 0.494, p< .001) correlated highly with patient self- reported pain in the first metatarsophalangeal joint. Our findings suggest that joint manipulation could be a useful modality for increasing first metatarsophalangeal joint mobility and alleviating pain in patients who experience arthrofibrosis after surgical correction of hallux valgus.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Grady, J. F., Axe, T. M., Zager, E. J., & Sheldon, L. A. (2002). A retrospective analysis of 772 patients with hallux limitus. Journal of the American Podiatric Medical Association, 92(2), 102-108.
Type of evidence source	Case series
Country/Profession	US/Podiatry

Inclusion/exclusion criteria	
Population	772 patients
Concept	IA CSI (as part of conservative care)
Context	CSI

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

In this retrospective analysis of 772 patients with symptomatic hallux limitus, 428 patients (55%) were successfully treated with conservative care alone; of these 428 patients, 362 (84%) were treated with orthoses. Corticosteroid injections and a change in shoes allowed 24 patients (6% of conservatively treated patients) and 42 patients (10%), respectively, to have less discomfort and return to previous activity levels. Overall, 47% of the patients in this analysis were successfully treated with orthoses. Surgical procedures were performed on 296 patients (38% of all patients) who did not respond to conservative care. In this analysis, 48 of the patients (6% of all patients) who did not respond to conservative care either refused surgery or were not surgical candidates. These data are intended to provide podiatric physicians with expected outcomes for conservative care of hallux limitus. The etiology, symptoms, conservative management, and surgical treatments of hallux limitus and hallux rigidus are also reviewed.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Grice, J., Marsland, D., Smith, G., & Calder, J. (2017). Efficacy of foot and ankle corticosteroid injections. Foot & Ankle International, 38(1), 8-13.
Type of evidence source	Case series
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	22 patients
Concept	IA CSI
Context	Guided CSI

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Background: Corticosteroid injections have been used for a variety of foot and ankle pathologies over the years, and our aim was to evaluate the efficacy and safety of them in our clinic.

Materials and Methods: We performed a retrospective review of notes and a telephone questionnaire on the clinical outcome of all patients who underwent a corticosteroid injection of the foot or ankle in a year. All procedures were performed in an outpatient setting by a consultant musculoskeletal radiologist using either ultrasound or X-ray guidance and had a minimum of 2 years of follow-up.

Results: Overall, 314 of 365 (86%) patients reported a significant improvement in symptoms, and 242 (66%) reported complete resolution of their pain, with 107 (29%) remaining asymptomatic at the 2-year follow-up. The mode time of recurrence of pain was 3 months. Fifty-one (14%) underwent a further injection and 88 (24%) underwent operative intervention within the follow-up period. Complication rates in our series were low. There were no reported infections. Complications occurred in 5 patients (1.3%), including steroid flare, pain, and plantar plate ruptures.

Conclusion: Corticosteroid injections were a safe and effective option for treating a variety of foot and ankle conditions and reduced the need for surgery. They were particularly effective for the treatment of ankle soft tissue impingement. They appear ineffective in providing significant improvement in pain for longer than 3 months in conditions such as plantar fasciitis and HR.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Heidari, N., Kraus, T., Fischerauer, S., Tesch, N., & Weinberg, A. (2013). Do the presence of pathologic changes and the level of operator experience alter the rate of intra-articular injection of the first metatarsophalangeal joint? A cadaver study. Journal of the American Podiatric Medical Association, 103(3), 204-207.
Type of evidence source	Case series
Country/Profession	Austria/Orthopaedics

Inclusion/exclusion criteria	
Population	106 cadaveric joints
Concept	IA dye
Context	Injection success in pathological joints

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Background: injections, punctures, and aspirations of the first metatarsophalangeal joint are common interventions. Accurate intra-articular placement of the needle is a prerequisite for the achievement of desirable results and the avoidance of complications. We evaluated the rate of successful intra-articular injections and the influence of the degree of operator experience in achieving this success.
Methods: A total of 106 cadaveric metatarsophalangeal joints were injected with a methylene blue-containing solution and subsequently dissected to distinguish intra-articular from periarticular injections. To evaluate the importance of experience, 38 injections were performed by a student, 38 by a trained resident, and 30 by an experienced surgeon. In the second part of the study, we examined the relation of pathologic findings of the metatarsophalangeal joint and the accuracy of intra-articular injection.
Results: The overall rate of unintentional periarticular injections remained low (9.4%; 10 of 106 joints). The student achieved a successful intra-articular injection in 86.8% of joints (33 of 38), the resident in 92.1% (35 of 38), and the specialist in 93.3% (28 of 30). The number of extra-articular injections increased significantly with the presence of deformity (hallux valgus) and arthritis of the first metatarsophalangeal joint.
Conclusions: The presence of pathologic changes reduces the rate of successful intra-articular joint puncture. However, the overall frequency of successful intra-articular injections can be improved through experience and the use of imaging.

Evidence source details and characteristics

Citation (author/s, date, title, journal, volume, issue, pages)	Kang, M. H., Moon, K. W., Jeon, Y. H., & Cho, S. W. (2015). Sonography of the first metatarsophalangeal joint and sonographically guided intraarticular injection of corticosteroid in acute gout attack. Journal of Clinical Ultrasound, 43(3), 179-186.
Type of evidence source	Case series
Country/Profession	Korea/Medicine & Radiology

Inclusion/exclusion criteria	
Population	21 patients
Concept	IA CSI
Context	US guided IA CSI

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Objective. The aims of this study were to identify the characteristic ultrasound (US) findings of the first metatarsophalangeal joint (MTPJ1) in acute gout attack and to evaluate the efficacy and safety of US-guided intraarticular corticosteroid injection of the MTPJ1.
Methods. We enrolled 21 patients with acute gout attack involving the MTPJ1 unilaterally. US evaluation of each affected MTPJ1 was compared with radiographic features. US-guided intraarticular corticosteroid (0.5 ml [20 mg] of triamcinolone mixed with 0.5 ml of 2% lidocaine) was injected into the affected MTPJ1s. Pain, general disability, and walking disability were assessed at baseline, 24 hours, 48 hours, and 7 days after injection with visual antilog scales.
Results. The characteristic US findings of MTPJ1 were erosion, joint effusion, synovial hypertrophy, tophus-like lesion, double contour, hyperechoic spots, and increased power Doppler signal in acute gout attack. US was more sensitive than conventional radiograph in detecting erosion and tophus-like lesion. The reductions of mean visual analogue scale scores in pain, general disability, and walking disability were 48 mm (SD, 27), 35 mm (SD, 26) and 39 mm (SD, 26), respectively, 48 hours after US-guided intraarticular corticosteroid injection. There were no adverse events.
Conclusions. US is a sensitive tool to evaluate joint abnormality of the MTPJ1 in acute gout attack and US guided intraarticular corticosteroid injection to this joint is effective and safe.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Kilmartin, T. E. (2017). Corticosteroid injection therapy in Podiatry. Podiatry Now, February, CPD Suppl 1-11.
Type of evidence source	Narrative review
Country/Profession	UK/Podiatry

Inclusion/exclusion criteria	
Population	Not stated
Concept	IA CSI
Context	Narrative review/opinion piece

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
Along with orthotic therapy and joint mobilisation, corticosteroid injection can be a very effective treatment for joint pain associated with mild-to-moderate hallux limitus and hallux valgus. It can also be helpful for continued pain and stiffness following surgical intervention to the first MTP joint. Because of potential risk to the joint cartilage, water-soluble betamethasone is the preferred corticosteroid for this complaint and 2mg (0.5ml) is injected using a 1ml syringe and a 27 gauge needle, which is small enough calibre to allow good access into the reduced joint space.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	King, C. K. K., James Loh, S. Y., Zheng, Q., & Mehta, K. V. (2017). Comprehensive review of non-operative management of hallux rigidus. Cureus, 9(1).
Type of evidence source	Narrative review
Country/Profession	Singapore/Orthopaedics

Inclusion/exclusion criteria	
Population	Literature
Concept	Narrative review
Context	Review of non-operative management of hallux rigidus

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

This article aims to provide an evidence-based literature review for the non-operative management of hallux rigidus. Currently, there is very little article on the evidence for the non-operative management of hallux rigidus. A comprehensive evidence-based literature review of the PubMed database conducted in November 2016, identified 11 relevant articles out of 560 articles assessing the efficacy of non-operative modalities for hallux rigidus. The 11 studies were then assigned to a level of evidence (I-IV). Individual studies were reviewed to provide a grade of recommendation (A-C, I) according to the Wright classification in support of or against the non-operative modality. Based on the results of this evidence-based review, there is poor evidence (grade C) to support use of intra-articular injections for pain relief for a period of three months and fair evidence (grade B) against the use of intra-articular injections for long term efficacy. There is poor evidence (grade C) to support manipulation and physical therapy and poor evidence (grade C) to support modifications in footwear, insoles and orthotics. There were no good evidence (grade A) recommending any interventions. In general, most of the interventions showed improvement. However, the evidence is poor in recommending orthosis, manipulation and intra-articular injections. There is a need for high-quality Level I randomized controlled trials with validated outcome measures to allow for stronger recommendations to be made. There is no study that looked solely at the use of pharmaceutical oral agents for the treatment of hallux rigidus. Non-operative management should still be offered, prior to surgical management.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Manadan, A. M., Mushtaq, S., & Block, J. A. (2015). Radiocarpal and first metatarsophalangeal intraarticular injection site confirmation with fluoroscopy and review of accuracy of intraarticular injections. American Journal of Therapeutics, 22(1), 11-13.
Type of evidence source	Case series
Country/Profession	US/Rheumatology

Inclusion/exclusion criteria	
Population	10 patients
Concept	IA arthrocentesis
Context	Palpation vs fluoroscopic guidance

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
The aim of this study was to determine the accuracy of radiocarpal (RC) joint and first metatarsophalangeal (MTP) joint arthrocentesis using fluoroscopy. Rheumatologists were asked to mark their usual site of arthrocentesis over fluoroscopically identified joint lines of the right RC and right first MTP joints. Ten rheumatologists with a mean of 17.9 years of clinical experience participated. The sites marked were a mean of 0.85 cm (range, 0–1.6 cm; SD, 0.5 cm) and 0.33 cm (range, 0–1.3 cm; SD, 0.4 cm) from the fluoroscopically identified RC and MTP joints, respectively. Traditional palpation guided joint aspiration may be inaccurate. Fluoroscopic guidance has the potential to improve accuracy of arthrocentesis of small joints.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Pons, M., Alvarez, F., Solana, J., Viladot, R., & Varela, L. (2007). Sodium hyaluronate in the treatment of hallux rigidus. A single-blind, randomized study. Foot & Ankle International, 28(1), 38-42.
Type of evidence source	Prospective trial
Country/Profession	Spain/Orthopaedics

Inclusion/exclusion criteria	
Population	37 patients
Concept	IA CSI vs hyaluronate injection
Context	Prospective trail in hallux limitus

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Background: The purpose of this study was to evaluate the effectiveness and safety of intra-articular sodium hyaluronate (Ostenil®mini) compared to intra-articular triamcinolone acetonide (Trigon depot®) in the treatment of painful hallux rigidus. Methods: Thirty-seven patients (ages 40 to 80 years) with painful early stage hallux rigidus were enrolled in the study. One group received an intra-articular injection with 1.0 ml sodium hyaluronate (SH); the other received an intraarticular injection of 1.0 ml triamcinolone acetonide (TA). Patients were evaluated on days 0, 14, 28, 56 and 84. Effectiveness was measured using the following parameters: joint pain at rest or on palpation (VAS), with passive motion, and gait pain; AOFAS hallux metatarsophalangeal score; use of analgesics and global assessment of the treatment by the patient and investigator. Safety was evaluated by the outcome of tolerance to treatment and observation of adverse events. Statistical analyses were performed using the Chi-square test, Mann-Whitney U test, Wilcoxon test and Friedman test. Results: Thirty-seven patients (40 feet) were evaluated. Pain at rest or with palpation and pain on passive mobilization decreased significantly in both treatment groups in comparison to baseline ($p < 0.01$), but no significant between-group differences were observed ($p > 0.05$). Gait pain improved substantially in the sodium hyaluronate group with significant differences compared to the triamcinolone group at days 28 and 56 ($p < 0.05$). The AOFAS total score improved significantly in the SH group compared to the TA group ($p < 0.05$). This was mainly due to improvements in the pain subscale. No between-group differences were seen regarding the use of analgesics. Global assessment of treatment by patients was good in both groups, and there was a significant between-group difference favouring SH when areas

under the curves (AUC) were calculated ($p < 0.05$). Tolerance was good in both groups. Adverse events occurred in three patients. Conclusions: Intra-articular injections of sodium hyaluronate.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Reach, J. S., Easley, M. E., Chuckpaiwong, B., & Nunley, J. A. (2009). Accuracy of ultrasound guided injections in the foot and ankle. Foot & Ankle International, 30(3), 239-242.
Type of evidence source	Case series
Country/Profession	US/Orthopaedics

Inclusion/exclusion criteria	
Population	10 cadavers
Concept	IA dye
Context	US guided injections

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Background: Ultrasonography is an emerging imaging modality which affords dynamic, real-time, cost-effective and surgeon controlled visualization of the foot and ankle. The purpose of this study was to evaluate the accuracy of ultrasound guided injections for common injection sites in the foot and ankle. Materials and Methods: In 10 fresh cadaver feet, ultrasound guidance was utilized to inject a methylene blue-saline mixture into (1) the first MTP joint, (2) the second MTP joint, (3) the tibiotalar joint, (4) the Achilles peritendinous space, (5) the flexor hallucis longus sheath, (6) the posterior tibial tendon sheath, and (7) the subtalar joint. Dissection was then undertaken to assess injection accuracy. Results: Ultrasound guidance allowed the avoidance of intervening neurovascular and tendinous structures. Ultrasound guided MTP, ankle, Achilles, PTT and FHL peritendinous injections were 100% accurate. Ultrasound guided subtalar injection was 90% accurate. Conclusion: Ultrasound appears to be a highly accurate method of localizing injections into a variety of locations in the foot and ankle. Clinical Relevance: Ultrasound's ability to display soft-tissue structures may be an advantage over blind injection and fluoroscopic injection techniques.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Sahler, C. S., Spinner, D. A., & Kirschner, J. S. (2013). Ultrasound-guided first metatarsophalangeal joint injections: description of an in-plane, gel standoff technique in a cadaveric study. Foot & ankle specialist, 6(4), 303-306.
Type of evidence source	Cadaveric study
Country/Profession	US/Medicine

Inclusion/exclusion criteria	
Population	10 cadavers
Concept	IA injection
Context	US-guided in plane

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Objective. To describe a longitudinal ultrasound-guided in-plane approach for injection into the first metatarsophalangeal (MTP) joint and assess its accuracy in a cadaveric model.
Design. A prospective anatomical cadaver study model was used. A total of 10 first MTP joints using the described technique were injected with 0.5 mL of dye under ultrasound guidance. The joints were later dissected, and accuracy was classified as accurate, accurate with overflow, or inaccurate with no injectate in the target area.
Results. Of the injections, 9 were classified as accurate injections, and 1 was classified accurate with overflow.
Conclusion. This cadaveric study suggests that ultrasound-guided injections of the first MTP joint can be accurately and reproducibly performed with a gel standoff, long-axis in-plane approach. This technique attempts to minimize the collateral damage to the surrounding tissue, specifically the articular cartilage. Clinicians should consider using this technique when performing ultrasound-guided injections to the first MTP joint.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Sarkin, T. L. (1973). Indications for intra-articular steroid in osteoarthritis of the ankle and big toe joints. South African Medical Journal, 47(10).
Type of evidence source	Case series
Country/Profession	South Africa/Orthopaedics

Inclusion/exclusion criteria	
Population	200 patients
Concept	IA CSI
Context	OA of the 1st MTP jt

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

The results of treatment with intra-articular steroid in an unselected group of patients with osteo-arthritis of the ankle and metatarsophalangeal joint of the big toe are described. From the results of this trial, it is possible to lay down indications for the use of intra-articular steroid in these conditions. In the ankle joint it is suggested that symptoms must not be so severe as to be disabling, and that the interval of time between the precipitating trauma and the onset of symptoms should be as long as possible, but certainly not less than 2 years.

In osteo-arthritis of the metatarsophalangeal joint of the big toe, for intra-articular steroid injections to be of value there must be no hallux valgus deformity and at least 45° of free movement must be retained in the affected big toe joint.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Sims, A. L., & Kurup, H. V. (2014). Painful sesamoid of the great toe. World Journal of Orthopedics, 5(2), 146.
Type of evidence source	Expert opinion
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	Not stated
Concept	IA CSI
Context	Sesamoiditis

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
The painful sesamoid can be a chronic and disabling problem and isolating the cause can be far from straightforward. There are a number of forefoot pathologies that can present similarly to sesamoid pathologies and likewise identifying the particular cause of sesamoid pain can be challenging. Modern imaging techniques can be helpful. This article reviews the anatomy, development and morphological variability present in the sesamoids of the great toe. We review evidence on approach to history, diagnosis and investigation of sesamoid pain. Differential diagnoses and management strategies, including conservative and operative are outlined. Our recommendations are that early consideration of magnetic resonance imaging and discussion with a specialist musculoskeletal radiologist may help to identify a cause of pain accurately and quickly. Conservative measures should be first line in most cases. Where fracture and avascular necrosis can be ruled out, injection under fluoroscopic guidance may help to avoid operative intervention.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Solan, M. C., Calder, J. D. F., & Bendall, S. P. (2001). Manipulation and injection for hallux rigidus: is it worthwhile? The Journal of bone and joint surgery. British volume, 83(5), 706-708.
Type of evidence source	Prospective study
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	Hallux limitus
Concept	IA CSI with manipulation
Context	MUA with CSI for hallux rigidus

Details/results extracted from source of evidence (in relation to the concept of the scoping review)
Manipulation of the metatarsophalangeal joint and injection with steroid and local anaesthetic are widely practised in the treatment of hallux rigidus, but there is little information on the outcome. We report the results of this procedure carried out on 37 joints, with a minimum follow-up of one year (mean, 41.2 months). Patients with mild (grade-1) changes gained symptomatic relief for a median of six months and only one-third required surgery. Two-thirds of patients with moderate (grade-2) disease proceeded to open surgery. In advanced (grade-III) hallux rigidus, little symptomatic relief was obtained, and all patients required operative treatment. We recommend that joints are graded before treatment and that manipulation under anaesthetic and injection be used only in early (grades I and II) hallux rigidus.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Ward, S. T., Williams, P. L., & Purkayastha, S. (2008). Intra-articular corticosteroid injections in the foot and ankle: a prospective 1-year follow-up investigation. The Journal of foot and ankle surgery, 47(2), 138-144.
Type of evidence source	Prospective study
Country/Profession	UK/Orthopaedics

Inclusion/exclusion criteria	
Population	1 1st MTP joint
Concept	IA CSI
Context	CSI for OA

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Most evidence for the efficacy of intra-articular corticosteroids is confined to the knee, with few studies considering the joints of the foot and ankle. The aim of this study was to identify the long-term efficacy of corticosteroid injection in foot and ankle joints. All patients undergoing intra-articular corticosteroid injections into foot and ankle joints over a 10-month period were recruited into the study. Patients were asked to complete a foot-related quality of life questionnaire, namely the Foot and Ankle Outcome Score, immediately before intra-articular injection and at set points up to 1-year afterward. Eighteen patients, comprising 36 foot and ankle joints, were recruited into the study. There was a statistically significant score improvement following corticosteroid injection up to and including 6 months postinjection. No independent clinical factors were identified that could predict a better postinjection response. The magnitude of the response at 2 months was found to predict a sustained response at 9 months and 1 year. Intra-articular corticosteroids improved symptom scores in patients with foot and ankle arthritis. The duration of this response was varied and patient factors affecting the response remain unclear. Response to the injection at 2 months can be used to predict the duration of beneficial effects up to at least 1 year.

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	Wempe, M. K., Sellon, J. L., Sayeed, Y. A., & Smith, J. (2012). Feasibility of first metatarsophalangeal joint injections for sesamoid disorders: a cadaveric investigation. PM&R, 4(8), 556-560.
Type of evidence source	Prospective study
Country/Profession	US/Physical Medicine

Inclusion/exclusion criteria	
Population	5 cadavers
Concept	IA dye
Context	IAIT for the treatment of sesamoid pathology

Details/results extracted from source of evidence
(in relation to the concept of the scoping review)

Objective: To determine whether accurately placed first metatarsophalangeal joint (MTPJ) injections consistently deliver injectate to the metatarso-sesamoid articulations.
Design: Prospective anatomic cadaver study.
Setting: Procedural skills laboratory at a tertiary care academic institution.
Participants: Five unembalmed cadaveric lower limb specimens, free from trauma, surgery, or major deformity of the medial forefoot.
Methods: Ultrasound guidance was used to accurately inject the first MTPJs of each cadaveric specimen with diluted, blue-coloured latex. At a minimum of 24 hours after injection, each specimen was dissected to determine whether the latex was present between the metatarsal head and sesamoid bones (metatarso-sesamoid articulations).
Main Outcome Measures: The presence or absence of latex within the first MTPJ and both the tibial and fibular metatarso-sesamoid articulations.
Results: In all 5 cadaveric specimens, ultrasound-guided first MTPJ injection accurately delivered latex into the first MTPJ. In addition, in each specimen, latex was seen between the metatarsal head and both the fibular and tibial sesamoid bones.
Conclusions: Accurate first MTPJ injections reliably deliver latex to the articular surfaces of the metatarso-sesamoid articulations. Clinicians administering diagnostic or therapeutic injections for patients with sesamoid dis
orders should consider injecting the first MTPJ as an alternative to direct metatarso-sesamoid articulation injections.

APPENDIX 6: Use of intra-articular injection corticosteroid injections to the first metatarsophalangeal joint. First theme of a scoping review

Reilly and Botchu, 2022

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Use of intra-articular injection corticosteroid injections to the first metatarsophalangeal joint. First theme of a scoping review

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Abstract

Introduction. A needle is inserted into a joint for arthrocentesis or injection of a therapeutic medication(s), commonly a corticosteroid. The aim of this paper is to discuss the first theme identified from a scoping review of corticosteroid injections for the pathology of the first metatarsophalangeal joint.

Pathology. The two most common pathologies affecting the first metatarsophalangeal joint are osteoarthritis and bunions. An arthritic joint is regularly injected with a corticosteroid, but bunions are not. Other pathologies that may receive an injection include rheumatoid arthritis, gout, sesamoiditis and post-operative arthrofibrosis.

Discussion. Most available evidence discusses corticosteroid injections for osteoarthritis, but there is a paucity of high-quality evidence, especially for corticosteroid use in other pathological conditions.

Conclusion. Whilst the evidence base suggests that corticosteroid injections are safe short- and mid-term treatment options for a range of soft tissue and joint pathology, the specific indications, and short/long-term outcomes in the first metatarsophalangeal joint pathologies are not clear and warrant further study.

Keywords. Steroid injection, synovial joint, first metatarsophalangeal joint, hallux limitus, hallux rigidus, hallux valgus, gout, arthrofibrosis.

Introduction

As part of a scoping review, the senior author has discussed[1] the general indications for the intra-articular (IA) insertion of a needle into a joint: for diagnostic arthrocentesis or injection of a therapeutic medication(s)[2–7]. Therapeutic injections of corticosteroids provide a treatment option for patients with joint or

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peri-articular pain, and injection therapy (IT) is now one of the most common and widely performed interventions in musculoskeletal healthcare[8–17], see Fig. 1 (patient of the senior author).

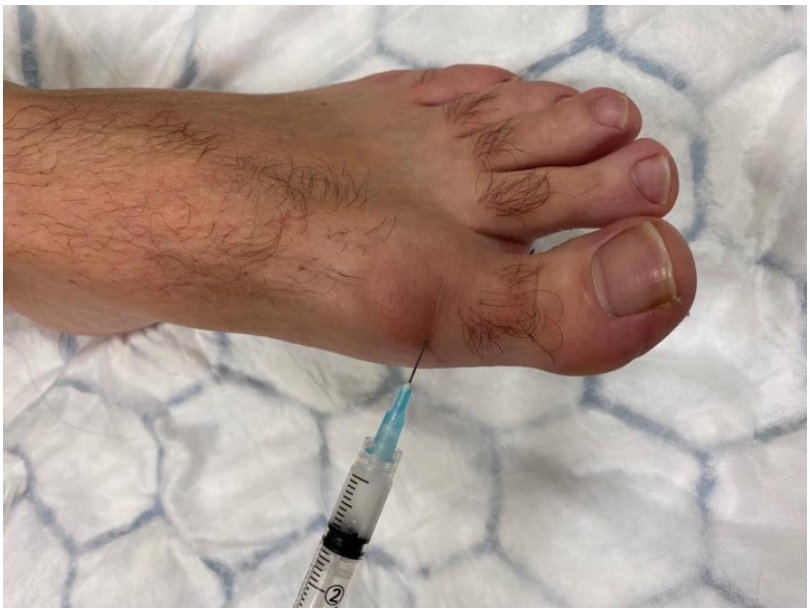

Figure 1: intra-articular CSI for hallux limitus

The objectives of the doctoral project are to identify, synthesise and critique the evidence base for the use of corticosteroid injections (CSIs) in the management of first metatarsophalangeal joint (1st MTP jt) pathology, to highlight gaps in the knowledge base and to generate research questions for future study. The first part of the project was a scoping review (which is being reported more fully elsewhere). The literature search yielded 193 articles, 48 of which appeared of potential relevance. After removing duplicate articles, this total was reduced to 37 articles: 27 were excluded after review to leave ten articles; a further 28 articles were found through related author research, examination of reference lists and free text

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searches of Google Scholar. One reference was unobtainable, giving a final count of papers utilised for review was 37. Iterative charting of the literature yielded three broad and overlapping themes:

1. Evidence of IA CSIs by joint disease/pathology,
2. Non-evidenced based descriptions of injection technique and regimen,
3. Accuracy of 1st MTP jt injection.

Nineteen papers discussed and overlapped to produce themes 1 and 2. This paper aims to discuss the first theme identified from that scoping review.

Pathology of the 1st MTP jt.

The two most common pathologies affecting the first metatarsophalangeal joint (1st MTP jt) of the foot are OA - hallux limitus/rigidus and bunion - hallux abducto valgus (HAV)[18,19]. Injectable CSIs are widely used in hallux limitus[20–45] but they are rarely used in the pre-operative management of HAV joint pain. However, they are employed for post-operative stiffness and pain that can occur as a result of surgery: arthrofibrosis[18,46]. Other pathologies of the joint include rheumatoid arthritis (RA), gout and sesamoiditis[47]. CSIs can be both diagnostic and therapeutic in sesamoiditis[30,48–50]. While joint fluid aspiration and CSI are commonly performed for gout[51,52] its use has not been investigated by controlled trials[53–55]. However, the authors note that intra-articular (IA) CSIs for gout are recommended by the British Society of Rheumatology (BSR)[56], the European League against Rheumatism[57], and the American College of Rheumatology (ACR)[58].

Osteoarthritis

In a retrospective analysis of 772 patients with symptomatic hallux limitus by Grady et al.[28], 428 patients (55%) of the cohort were successfully treated with conservative care alone. Twenty-four patients (six per cent of those treated conservatively) were given CSIs injections. Of these patients, 18 received one

injection; five received two injections, and one had three injections; injections were given four weeks apart where required, i.e., if the patient had more than 50% but less than 80% improvement.

Grice et al.[59] performed a retrospective of all patients who underwent ultrasound (US) guided CSI of the foot or ankle (all conditions) over a one-year timescale in a similar manner to that of Ward et al.[41] (though that paper is not referenced). All injections were performed by a consultant musculoskeletal radiologist and reviewed at least two-years post-treatment. 314 out of 365 (86%) of patients included in the study had significant improvement in symptoms, but the longevity of outcome varied across the range of pathology injected. Short-term benefit was seen for HL/HR: 20 of 22 (91%) patients reported benefit from the injection, but only three (14%) reported that the improvement lasted longer than six months. At two years post-treatment, only two patients (9%) remained asymptomatic; 12 patients (55%) had undergone surgery. The authors concluded that injections should be reserved for those with mild OA, but they did not break down the HL/HR group by the extent of disease, i.e., mild, moderate, or severe OA, so it is not clear how they reached that conclusion. The applicability of context and profession (US-guided CSIs performed by a consultant musculoskeletal radiologist) is open to further debate as 1st MTP jt CSIs are commonly performed non-guided.

Kilmartin[30] writes that CSIs can be a very effective treatment for joint pain associated with mild-to-moderate HL and HAV, and for continued pain and stiffness following surgical intervention to the 1st MTP jt.

In a comprehensive review of the non-operative management of HL/HR, Kon Kam King et al.[45] found insufficient evidence to support the use of IA CSIs for pain relief for three months, and fair evidence against the use of IA CSIs for long-term

efficacy. However, the methodology was neither systematic nor comprehensive: only a single database was searched for clinical trials, and the risk of missing pertinent literature is high. The authors' recommendations were made based on an appraisal system that allocates a level of evidence for an intervention based on the identified studies' design without consideration of the methodological quality of trials, or the risk of bias. The trials identified in this review lacked heterogeneity in terms of solutions tested and the design of trials. Despite this, the authors grouped six trials relating to IT together for data analysis, and a collective level of evidence was allocated to IT as a whole.

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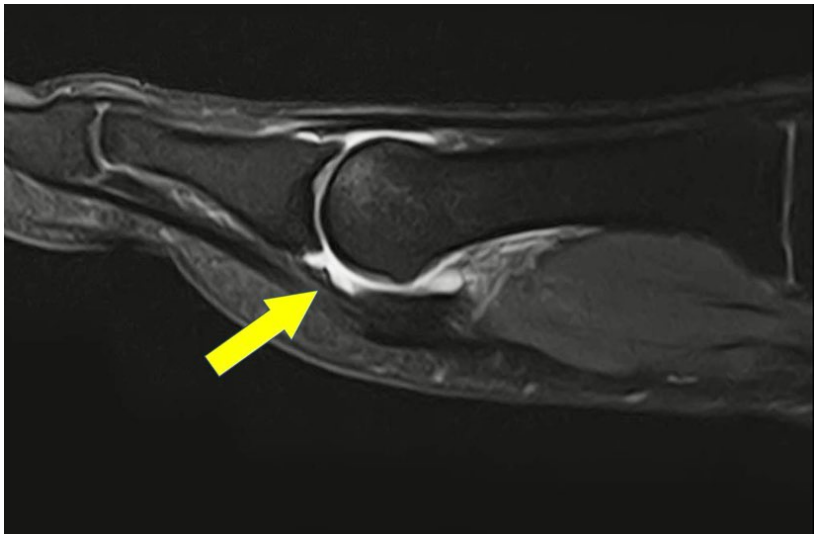

Figure 2: MRI arthrography of 1st MTP jt

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Ajwani et al.[18] reported their findings to determine the effectiveness of MUA and local steroid injection to treat stiffness of the 1st MTP jt following surgery for HR or HAV. Patients who had undergone 1st ray surgery and were subsequently treated for joint stiffness with MUA and CSI were reviewed. The injectate was a mixture of 40mg/1ml of methylprednisolone and 0.5% bupivacaine plain. The modal volume used was 1ml but ranged from 0.5ml to 4ml. Patient records were reviewed to determine the range of movement of the joint pre-operatively, immediately following the procedure and at subsequent follow-up, using the Manchester-Oxford foot questionnaire (MOxFQ) to evaluate symptoms post-operatively. The authors analysed 35 patients in 38 feet: 27 post-HR surgery and 11 post-HAV corrections. The total range of movement of the joint improved following treatment by an overall mean of 44.7°. At subsequent follow-up, the total range of motion of the joint was still improved by 22.2° overall. The mean post-operative MOxFQ score was 24.8 but no correlation was found between MOxFQ

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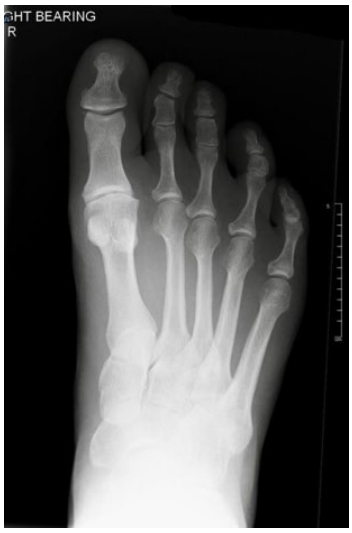
the joint with stiffness and a visual-analogue (VAS) pain scale of 8/10. She underwent a MUA/CSI using 30mg IA TA in 2020 and rates her pain at 2/10 six weeks post-treatment.



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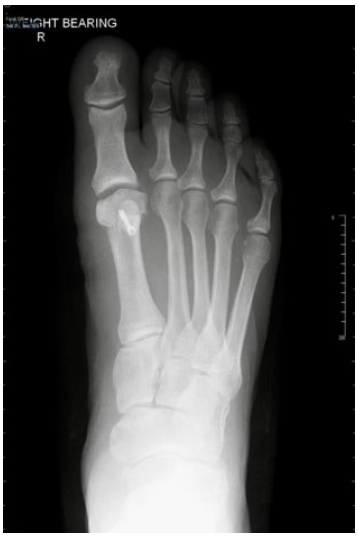

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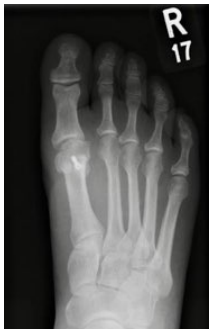

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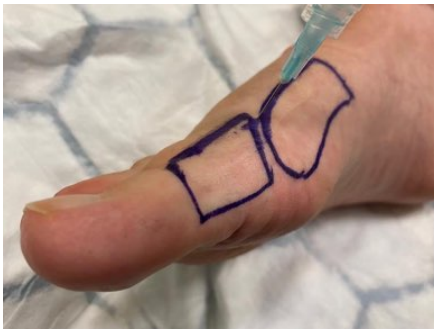

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of value, there must be no HAV deformity and at least 45° of free movement retained in the affected joint.

Manipulation under anaesthesia (MUA) of the 1st MTP jt joint was first described by Watson Jones in 1927[60] to break down the capsular adhesions that restrict movement. Solan et al.[37] report the results of MUA in combination with an IA CSI of 40mg of depo-medrone/3ml 0.5% bupivacaine plain, carried out on 37 joints, with a minimum follow-up of one year across a range of disease staging. Patients with grade I (mild) changes gained symptomatic relief for a median of six months and only one-third in this group went onto surgery. Two-thirds of patients with grade II (moderate) disease proceeded to open surgery and only had symptomatic relief for three months. Little symptomatic relief was obtained in grade III (advanced) HR, and all patients required operative treatment. The authors recommend that joints be graded before treatment and that MUA with CSI should only be used in grades I and II HR. This paper is regularly quoted in the literature and though over 20 years old, it has not been repeated. Nevertheless, it is considered a landmark study to predict outcomes for pedal CSIs with reference to radiological disease presentation. However, we do not know whether CSI, the local anaesthetic, the manipulation, or a combination, is responsible for the benefits seen. The lower numbers (five) in the grade III sample further limit confidence in the conclusions drawn.

Ward et al.[41] studied the long-term efficacy of CSIs in foot and ankle joints, stating that most evidence for the efficacy comes from studies of the knee, with fewer studies considering the joints of the foot and ankle. Eighteen patients were enrolled in their prospective study and a foot-related quality of life questionnaire before CSI and at seven set points post infiltration. They found a statistically significant improvement following CSI up to and including six months post-injection and that the magnitude of the response at two months was found to

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Sesamoiditis

Sims and Kurup[50] suggest that injections are usually done under radiological guidance to improve the accuracy of needle placement but that they should not be used in the presence of a sesamoid fracture or avascular necrosis. Kilmartin[30] suggests that 1ml of depo-medrone (40mg) can be placed in the soft tissues just superficial to the involved sesamoid - but not into the plantar fat pad - and repeated on up to three occasions. This contrasts with his earlier statement in the reference where he recommends betamethasone (as a non-particulate injection) for joints. This contrasts with Wempe et al.[67] who demonstrated that the metatarsophalangeal-sesamoid complex is continuous and can therefore be approached through a standard dorsal 1st MTP jt IA technique. Cohen[68] counsels against repeated injections for sesamoiditis.

The patient in Fig. 2 (a patient of the senior author) underwent magnetic resonance arthrography (MRI) for sesamoiditis and a partially ruptured medial collateral ligament and partial plantar plate tear (yellow arrow) following a football (turf toe) injury. Gadolinium, injected as a contrast medium into the joint before scanning can be seen as a collection of fluid in the plantar-posterior aspect of the synovial membrane. He was given a small (10mg) dose of IA triamcinolone acetonide and was pain-free within seven days.

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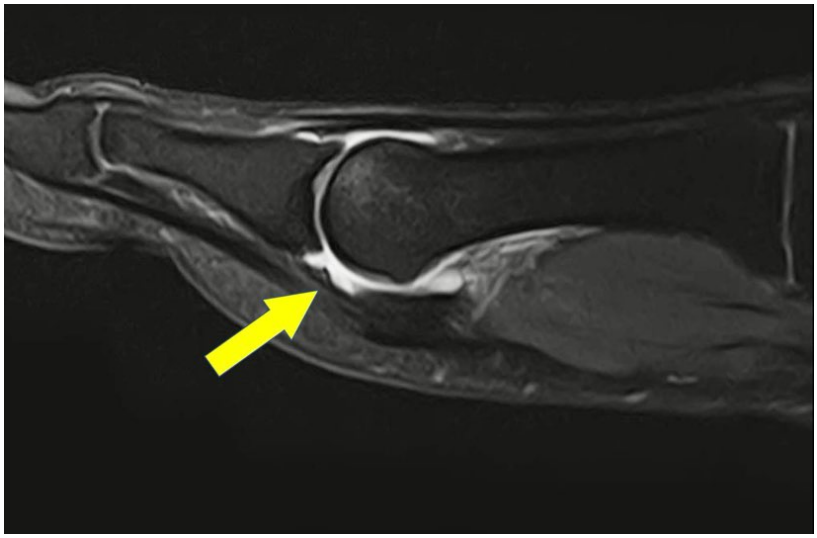

Figure 2: MRI arthrography of 1st MTP jt

Post-operative arthrofibrosis

Ajwani et al.[18] reported their findings to determine the effectiveness of MUA and local steroid injection to treat stiffness of the 1st MTP jt following surgery for HR or HAV. Patients who had undergone 1st ray surgery and were subsequently treated for joint stiffness with MUA and CSI were reviewed. The injectate was a mixture of 40mg/1ml of methylprednisolone and 0.5% bupivacaine plain. The modal volume used was 1ml but ranged from 0.5ml to 4ml. Patient records were reviewed to determine the range of movement of the joint pre-operatively, immediately following the procedure and at subsequent follow-up, using the Manchester-Oxford foot questionnaire (MOxFQ) to evaluate symptoms post-operatively. The authors analysed 35 patients in 38 feet: 27 post-HR surgery and 11 post-HAV corrections. The total range of movement of the joint improved following treatment by an overall mean of 44.7°. At subsequent follow-up, the total range of motion of the joint was still improved by 22.2° overall. The mean post-operative MOxFQ score was 24.8 but no correlation was found between MOxFQ

scores and range of movement. They concluded that MUA/CSI is an effective way of treating stiffness following 1st ray surgery and that treatment results in an improved range of motion of the joint, and patients report good function post-operatively.

While the range of motion was reported to improve, the authors note that measurements were performed by registrars and consultants in a clinic or theatre setting without the use of a goniometer. This could infer inter- and intra-rater variability and repeatability of data collection, but the trend is clear. Of note, 78% of the HR group had grade III OA. As per Solan et al.[37], we cannot determine from the study whether the manipulation (breaking down the arthrofibrosis), the local anaesthesia (blocking the pain reception) or the CSI (the effects and side effects of the CS) - or a combination - was/were responsible for the favourable outcome.

Feuerstein et al.[46] investigated the outcomes of 1st MTP jt CSI and manipulation for arthrofibrosis that occurred as a complication of HAV surgery. The study population consisted of 53 feet in 38 patients. Under sedation and regional nerve block, their 1st MTP jt was distracted; repeated attempts were then made to forcibly dorsiflex and plantarflex the toe until the capsular adhesions restricting motion had loosened and the movement was improved in the toe. The joint was then injected with 2ml of methylprednisolone acetate (40mg/1mL) mixed and 3ml of 0.5% bupivacaine plain. A significant increase in range of motion and a decrease in pain scores was seen, and the authors suggest that their technique is a valuable modality in patients who experience arthrofibrosis after surgical correction of HAV. As mentioned above, it is not possible to say which part of the technique is the most important for the overall outcome.

The patient in Figs. 3-7 (a patient of the senior author) underwent a Youngswick decompressive osteotomy for HL in 2017. Three years later, she developed HR of

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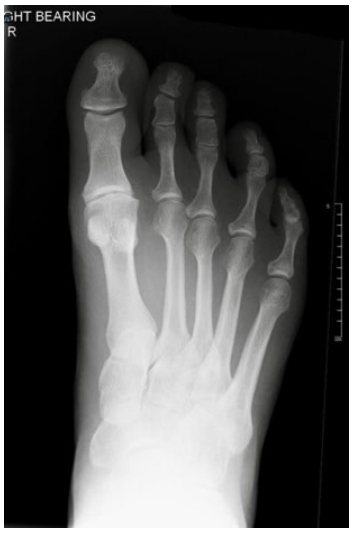
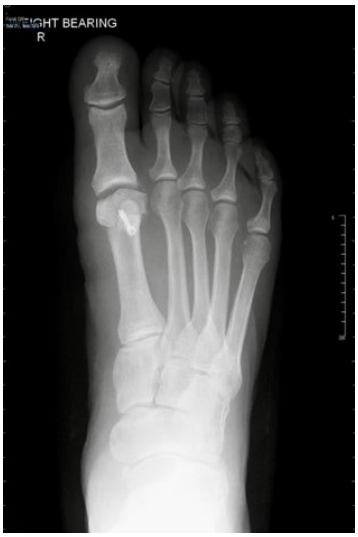


Figure 3: 2016 Pre-operative X-ray



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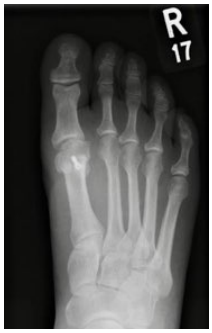

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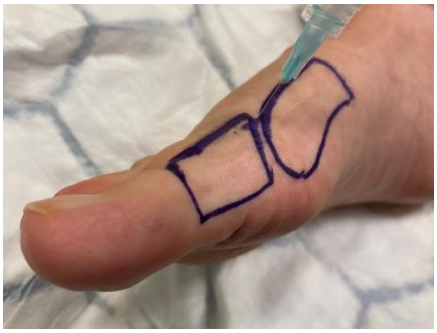

Figure 6: CSI lateral view

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Discussion

IA CSIs are used for a variety of 1st MTP jt pathology with a predominance in the literature for their use in HL/HR. Uthman et al.[38] note that despite the lack of strong, convincing, and reproducible evidence that any of the IA IT significantly alters the progression of OA, CSIs and SH are widely used in patients who have failed other therapeutic modalities. Cole and Schumacher[69] also note that despite the scarcity of high-quality clinical trial data, there is a large body of literature related to injectable CSIs. Urits et al.[13] state that injections provide an effective financial alternative and that some evidence exists that they are effective in chronic pain alleviation. However, they also note that current evidence is limited and that the benefit described by IT is short-lived in most cases. However, the literature shows that CSIs of joints and periarticular structures are safe and effective when administered by an experienced physician.

Reilly et al[70] performed a systematic review to determine if good quality research exists to enable clinicians to adopt an evidence-based approach to 1st MTP jt CSIs for OA. Despite the frequency of use, the review found no high-quality studies that support their use. The wider literature suggests that IA CSIs are effective for short-term relief of pain in OA but predicting the best responders is not currently possible. Specific corticosteroids are recommended for different joints by various authors according to their size. In general, the literature suggests that for:

- For smaller joints: methylprednisolone/hydrocortisone is recommended
- For larger joints: methylprednisolone or triamcinolone is recommended

A key objective of the scoping review was to generate questions for future research studies. The focus of future research should be on the use of CSIs for 1st MTP jt OA as this is the most frequent indication for IT, but high-level studies also need to be conducted for the role of IA CSI in the management of HAV (of which there is an almost total absence from the current literature), acute gout, sesamoiditis and

arthrofibrosis. Arthrofibrosis is one of the most seen complications after HAV surgery and specifically warrants further consideration for research and evaluation of treatment outcomes.

This scoping review was limited to a completion date as part of a professional doctorate degree course and further limited to the inclusion of only those papers that met the criteria set out in the search parameters. Any articles outside of this availability (i.e., the grey literature) were not used, and no financial budget was set. Therefore, both financial and time constraints have meant that some limitations to the depth and breadth of the review might be extant.

Conclusion

The article concludes as many do, that more research is needed. Whilst the evidence base suggests that CSIs are safe short- and mid-term treatment options for a range of soft tissue and joint pathology, the specific outcomes in the 1st MTP jt for a given condition are opaque and warrant further study. It is not clear what drug, at what dose, and at what point in disease regression is optimal for a given patient.

Declarations

This research did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors. The authors have no competing interests to declare. IR conceived the aim and format of the paper. The manuscript has been read and approved by both the authors.

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APPENDIX 7: Additional information from ScR. 1st MTP Jt CSI techniques by author, and general considerations of CSIs

Al-Jabri & Charalambides (2019)
The patient is positioned supine on the operating room table with 2 pillows beneath the knee allowing the foot to rest flat on the table. The foot is prepared and draped using chlorhexidine spray to the skin. The fluoroscopy machine is positioned on the contra lateral side of the table. Distal traction is applied to the great toe. This opens the joint space and a sulcus is visible lateral to the extensor hallucis longus tendon to avoid injury to the medial dorsal branch of the superficial fibular nerve (Figure 1). This is the 'sulcus sign'. Palpation can now be used to identify the base of the proximal phalanx and the metatarsal head. A needle is inserted in the centre of the sulcus between the proximal phalanx and metatarsal. The angle of insertion is 60 to 70 degrees with the tip of the needle aimed distally with a dorsolateral entry point. Intraarticular needle positioning can be confirmed using fluoroscopy. Aspiration of the joint can be performed followed by injection if an injection is planned. A clean dressing is subsequently applied.

Bilstrom et at. (2007)
Suggested supplies:

- 5-mL syringe for aspiration.
- 5-mL syringe with 15 mg of prednisone equivalents (we prefer 10mg of methylprednisolone) and 1 mL of 1% lidocaine.
- 1-inch 22- to 25-gauge needle.
- Alcohol wipes, povidone-iodine, or chlorhexidine for sterilization.
- Local anaesthetic: ethyl chloride topical spray or 1% lidocaine.
- Needle cap or ballpoint pen to mark the site of insertion.
- Nonsterile gloves.
- Gauze pads and bandage.
- Tubes and slides for synovial fluid analysis.

Surface anatomy: Pull traction on the affected toe and locate the resulting recess between the respective phalanges and metatarsal bones. Moving the toe through full plantar flexion and dorsiflexion should allow for identification of the space between the proximal and distal borders of the joint. A mark should be placed either dorsomedially or dorsolaterally to the extensor tendon. In cases of gout, traction/flexion of the first MTP usually is extremely painful; prior injection of local anaesthetic may be required.
Patient position: Have the patient lie supine with the foot in a neutral position.
Procedure: After sterilization and application of local anaesthetic, advance the needle at an angle either dorsomedially or dorsolaterally to the extensor tendon. If bony resistance is met, redirect the needle more distal until fluid is aspirated (usually about ¼ to ½ inch).

Pearls

- Identification of surface anatomy on an inflamed MTP joint can be difficult. Palpate the surface anatomy of the contralateral toe (on the nonaffected side) for comparison.
- Aspirating any fluid from the first MTP joint in a patient with gout can be difficult. Using intra-articular anaesthetic injection first is a good idea because it allows for better positioning and landmark identification; in some cases, the physician can aspirate back the injected anaesthetic and identify crystals in that drop of fluid.
- Even if no frank fluid is aspirated, the diagnosis may lie in the scant amount of fluid in the needle tip or hub. The physician should attempt to examine this fluid by tapping the needle on the glass slide or "spritzing" the contents of the needle on a slide, which may reveal enough fluid or blood for crystal analysis.
- Hypopigmentation with extravasation of corticosteroid through the injection track can be problematic when a superficial joint is injected. Half a ml of air injected at the end can act as a plug to prevent leaking of corticosteroids.

Courtney & Doherty (2005)
The aspiration of fluid may confirm the diagnosis of crystal arthritis or septic arthritis and local injection may help the inflammatory conditions. The joint line is identified by palpation and the joint is injected from the medial side with the point of the 25 gauge needle inserted under the extensor tendon (Figure 11) using 5–7.5 mg of triamcinolone or equivalent.

de Cesar Netto et at. (2018)
1. The patient is placed in a supine position to facilitate injection through a dorsomedial approach.
2. Dorsiflex and plantarflex the 1st toe to identify the joint space, feel the anatomical landmarks like the metatarsal head and proximal phalanx and identify any overlying osteophytes.
3. Identify the extensor hallucis longus (EHL) tendon.
4. Insert a 25-gauge needle into the joint medially to the EHL tendon, angling 15º-30º distally to avoid chondral injury to the first metatarsal head. Longitudinal traction with a toe trap may facilitate intraarticular placement of the needle.

Goncalves et at. (2011)
Patient was placed seated on an examination table with the knee flexed (45◦), ankle and fingers extended. The probe was place in a longitudinal dorso-lateral or dorso-medial position along the articular space (Fig. 24). The needle was advanced avoiding extensor tendons. A subtle traction in opposite direction of the needle was helpful to slightly open the joint space (Fig. 25).

Gross & Lin (2012)
The patient is placed supine with their knee flexed and supported with a pillow. The foot is held in a relaxed position. The first MTPJ is identified by passively flexing and extending the joint. Distal traction and flexion of the hallux will assist in inserting the needle into the joint. The 25-gauge 1.5-inch needle and syringe is then inserted on the dorsomedial or dorso-lateral surface at an angle of approximately 60 to 70° to the plane of the foot. The needle should also point distally to help match the contour

and slope of the joint. The needle may be felt passing through the capsule. Once the needle is intracapsular (as confirmed by aspiration), the anaesthetic and corticosteroid are injected. Postinjection care includes protected weight bearing in a postoperative shoe for 1 week followed by activities of daily living as tolerated in a regular shoe. No sport activity for 4 weeks.

Hansford et at. (2019)
For MTP intra-articular access, the patient should be positioned supine, with affected knee bent and plantar aspect of the foot on the table. The skin is entered dorsally, just off midline and proximal to the joint line. We typically aim for the medial edge of the joint along the curved surface of the metatarsal head to avoid dorsal osteophytes. It is also important to target the metatarsal head in an attempt to avoid the dorsal lip of the proximal phalanx (Fig. 8). The MTP joints are small, with injectate volumes of 0.5–1.5 ml.

Kilmartin (2017)
1st MTP jt: The joint is accessed either from central dorsal or dorsolateral aspect (Figure 7). Medial injections are to be avoided because the soft tissues are often inflamed in that compartment of the joint. Prior to injection the hallux is flexed and extended to identify the joint line and then the hallux is distended and the needle introduced. If the needle is positioned well it will pass into the joint to a depth of 15 to 20mm and, as the corticosteroid is injected, the medial capsule may bulge. If the needle misses the joint space it will hit bone and pass superficially over the joint. If this happens the needle should be withdrawn slightly, the joint distended and the needle redirected. No more than three injections at four-weekly intervals should be given in any episode of care.
Sesamoid: Depo-Medrone 1ml (40mg) is placed in the soft tissues just superficial to the involved sesamoid but not into the plantar fat pad (Figure 14). This is repeated on up to three occasions.

Lungu & Moser (2015)
Arthrography of the metacarpophalangeal, metatarsophalangeal, and interphalangeal joints can be performed by targeting the dorsal articular recess. The following steps are required (Fig. 9):

1. The hand/foot of the patient is positioned prone. The target is the distal aspect of the metacarpal/metatarsal or phalanx proximal to the joint.
2. A 5/8-inch (1.6-cm) 25-gauge needle is inserted until bone contact.
3. Flow of contrast medium away from the needle tip and opacification of the compartment confirm adequate position. The joint capacity is about 1 ml. Alternatively, the dorsal recess is also accessible under ultrasound guidance (Fig. 10).

Maher & Price (2007)
The product used was sodium hyaluronate 1.0% (Ostenil ® Mini) supplied by TRB Chemedica UK LTD as a pre filled 1ml syringe in sterile wrap (Figure 1). This was administered following infiltration of local anaesthetic (Mepivacaine 3% plain solution) at the planned injection site in order to reduce discomfort from the subsequent intra-articular injection. The 1st MTPJ was then approached proximally and plan- tar

medially with a 21 gauge needle. The hallux was held in plantarflexion whilst the needle was introduced towards the plantar proximal medial aspect of the 1st MTPJ above the tibial sesamoid (Figure 2). Once within the joint capsule, 1ml of sodium hyaluronate was deposited. A sterile skin dressing was applied and the patient advised of the possibility of joint discomfort over the next 24 hours.

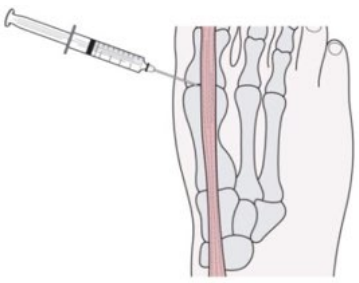
Millard& Dillingham (1995)
A 25-gauge one-half- to five-eighth-inch needle is inserted medial or lateral to the extensor tendon mechanism. Many clinicians prefer the dorsomedial approach for injection of the first metatarsophalangeal joint. Gentle longitudinal traction on the digit to be injected may be helpful to ease intra-articular needle placement

Newman (2004)
First MTP joint arthrography (Fig 13) is per- formed via the dorsal approach using a 23-gauge needle. The needle should be angled distally from a location just proximal to the joint line to avoid the dorsal lip of the proximal phalanx.19 Approximately 1 to 1.5 mL of total volume is injected. Images should be obtained in both anteroposterior and lateral projections and show contrast filling the plantar aspect of the articulation. A separate sesamoid/metatarsal joint injection is generally unnecessary because of their continuity with the first MTP capsule. If requested, directed injection of the sesamoid/metatarsal joint can be performed via an axial approach with the x-ray beam angled perpendicular to the long axis of these joints and the toes slightly dorsiflexed.

Pekarek et at. (2011)
The patient is placed in the supine position with the knee flexed and supported with a pillow. Mild distraction and flexion of the hallux at the MPJ will assist with the ability to get the needle in between the joint. A 24–26 gauge by ½–5/8 in. needle is directed dorsal medial or dorsal lateral to the extensor tendon without penetrating it, as to minimize trauma. The needle is angled 60–70◦ to the plane of the foot and pointed distally to match the slope of the joint. The joint capsule should be penetrated in order for the injection to be intra-articular. However, it is not necessary for the needle to be between the articular surfaces. This may be due to the fact that it is very difficult to get a needle in the small joint.

Reilly (2010)

Condition	Painful 1st metatarso-phalangeal joint
Anatomy	The 1st metatarso-phalangeal joint is a synovial joint comprised of four bones. The first metatarsal is the shortest and thickest of the five metatarsal bones. The distal surface or head of the metatarsal has a large cartilage-covered prominence, wider than the base of the proximal phalanx with which it articulates. On either side the cartilage overlaps onto the lateral aspect of the bone to form a smooth surface for the capsular ligaments of the joint. On the plantar surface of the head, there are two grooves for the articulation of the sesamoid bones which are separated by the sesamoid ridge. The medial sesamoid and groove are larger than the lateral.
Pathology	The most common clinical indication for a corticosteroid injection into the painful 1st metatarso-phalangeal joint is mild to moderate osteoarthritis from hallux limitus (HL). HL can he defined as limitation of motion of the proximal phalanx at the first MPJ in the sagittal plane to less than 65^0 dorsiflexion less than 15^0 plantarflexion. The author has injected steroid into a 1st MPJ for hallux abducto valgus on rare occasions only, and only then as part of an overall treatment plan to quell the worst of an inflammatory episode either prior to surgery or concurrently with orthotic therapy. End stage osteoarthritis is less amenable to the beneficial effects of steroid though its use can be considered – experience suggests that the results are better with mild and moderate disease. Ideally, the diagnosis is confirmed radiographically prior to injection. This is particularly helpful to identify the pattern of the disease and the potential presence of loose bodies thereby influencing the decision to inject.
Equipment	2.5- or 5-ml syringe 25mm (1 inch) 23G (blue) needle
Drug(s)	20-40mg of triamcinolone mixed with local anaesthetic
Positioning	The patient is typically positioned sitting up or supine, depending on patient preference.
Technique	Map out the anatomical land marks. The key structures to avoid are the long and short extensor tendons that are dorsally and dorso-laterally placed respectively. The approach is through a dorsal medial incision, the needle entry point typically 0.5-1 cm medial to the extensor hallucis longus tendon. A medial approach is more painful and does not give as good access to the joint. The dorso-lateral approach is deeper and more difficult overall. There is also a concern that leakage of steroid down the needle track from the dorso-lateral approach will be close to the extensor hallucis brevis tendon. Dorsiflex and plantarflex the toe and palpate the joint line. Distract the toe distally and look for puckering of the skin over the joint margins. Insert the needle perpendicularly to the skin and then change the angle to approximately 45° aiming distally and plantar-laterally. Advance the needle, remembering the curvature of the joint. Aim to have at least half the length of the needle deep to the skin and be careful to do as little trauma to the cartilage of the base of the proximal phalanx as possible.
Comments	Changes in joint morphology from cartilage erosion and osteophytosis can reduce the joint space and change the joint shape making the injection more difficult. Patients normally experience positive results over the next few days but improvement may not be noticed for two weeks. The author reviews patients after six weeks and will consider further injections as indicated.



Sahler et at. (2013)
Injections should begin by proper patient positioning. The patient lays supine with the affected side flexed at the knee in order for the plantar aspect of the foot to lie flat on the table (Figure 3). The clinician then positions himself or herself at the caudad side of the table, facing the patient, with the ultrasound machine adjacent to the examining table (Figure 4). The table height is adjusted to a comfortable level. The skin is prepped with betadine. A sterile ultrasound probe cover and sterile gel is used. The ultrasound probe is oriented in the longitudinal plane (long axis) directly over the dorsa aspect of the MTP joint to identify the EHL tendon. It is then moved medially, so that no overlying structures exist of the joint capsule. A copious amount of sterile gel is then placed under the ultrasound probe. The needle should pass through the sterile gel and then pierce the skin. The needle is visualized in its entirety, running superficial to the proximal epiphysis, into the joint capsule, stopping short of the opposing cartilaginous surface (Figure 5).

Saunders and Longworth (2018a)

Syringe	Needle	Kenalog 40	Lidocaine	Total volume
1–2 ml	Orange, 25 gauge 0.5 inch (13 mm)	10–20 mg	0.5–1 ml, 2%	0.75–1 ml

Anatomy
The first metatarsophalangeal joint line is found by palpating the space produced at the base of the metatarsal on the dorsal aspect while passively flexing and extending the toe. Palpation of the collateral ligaments at the joint line on the sides of the other toes will help identify the affected joint.

Technique
- Patient lies with foot supported
- Distract affected toe with one hand
- Identify and mark joint line
- Insert needle perpendicularly into joint space, avoiding extensor tendons
- Deposit the solution as a bolus

Aftercare. Avoid excessive weight-bearing activities until comfortable, together with taping of the joint and a toe pad between the toes. Care in choice of footwear and orthotic advice will usually be necessary.
Practice point. This treatment may be long-lasting in early degenerative disease of the first metatarsophalangeal joint but less so in advanced cases. The other toe joints are usually more easily injected from the medial or lateral aspect while under traction using a smaller dose and volume, such as 10 mg Kenalog plus 0.5 ml lidocaine (0.75 ml total volume).

Siddiqui et at. (2019)
The patient position is supine. The first MTPJ line is palpated and marked (this can be done by dorsiflexion and plantar flexion). The EHL tendon should be identified and protected. The needle entry point is either medial or lateral to the EHL tendon. An ‘indirect approach’ is useful for this injection. The skin and soft tissue are infiltrated with 5-10mL of 1% lidocaine with orange 25G or blue 23G needle. Blue needle 23G

is used for intra articular placement of steroid. The needle should be directed at 60 to 70 degrees to the plane of the foot and directed distally; this matches the slope of the joint and reduces the risk of chondral injury. Distraction of the toe can help to open up the joint space. There should be minimal resistance during injection; the needle should be re-sited if injection is encountered

Stephen et al. (2010)
The metatarsophalangeal joint can be entered via a dorsomedial or dorsolateral route (Figure 7-19). The joint space is first identified, and then a 27 gauge needle is inserted on either side of the extensor tendon to a depth of 2 to 4 mm. Slight traction on the toe facilitates entry.

Tallia & Cordone (2004)
The patient is placed in a supine position with the knee in a supported flexed position (e.g., with a pillow beneath the knee), and the foot is firmly supported by the table. The physician palpates the joint line on the dorsum of the foot and passively flexes and extend the toe to locate the joint line. Distal traction may be applied to the great toe to open the joint space. The needle is inserted on the dorsomedial or dorsolateral surface (Figure 6). The needle should be angled 60 to 70 degrees to the plane of the foot and pointed distally to match the slope of the joint. The joint space is not deep below the skin surface. The physician should aspirate before injecting; the injectable agent should flow without major resistance when the needle is positioned properly in the joint space.

Wempe et at. (2012)
The setup for completing each US-guided MTPJ injection is shown in Figure 2. The transducer was placed medial to the extensor hallucis longus tendon to image the dorsomedial aspect of the first MTPJ. A 25-gauge, 38-mm stainless steel needle was then advanced into the joint using a medial-to- lateral, out-of-plane approach, during which the needle tip was visualized as an echogenic dot within the articulation (Figure 3A). Once intra-articular placement was confirmed sonographically, 1.5 mL of diluted blue-coloured latex (50% water) was injected into the joint with use of real-time visualization. During each injection, distension of the dorsal first MTPJ recess confirmed intra-articular placement (Figure 3B). The toe was then plantarflexed and dorsiflexed 3 to 5 times to distribute the intra-articular latex throughout the joint.

Unknown reference
The joint line is identified by gentle palpation and the 23 gauge needle introduced obliquely under the extensor tendon. The injection should be performed without resistance using 5 mg triamcinolone or equivalent. The patient may experience some discomfort as the needle pierces the skin and joint capsule. Marked discomfort usually reflects inaccurate placement for example direct contact with periosteum. A slight ‘give’ is usually felt as the needle enters the joint cavity but difficulty advancing the needle suggests that it is in the wrong position. If there is marked resistance or discomfort the syringe and needle should be withdrawn slightly and gently advanced again after reassessment of the anatomical landmarks. When the needle is correctly placed the syringe should be pulled taking care not to dislodge the needle. Aspiration

of synovial fluid confirms correct placement. Correct placement is also suggested by low resistance to injection of local anaesthetic or steroid.

Further references were found after the best practice technique paper was written:

Andrews (2015)
The patient is placed on a radiolucent table in the supine position with the knee flexed and the ankle slightly dorsiflexed on top of a towel roll. Using fluoroscopy, the injection site is located and marked. The foot is then sterilely prepped and draped. Under local anesthesia and fluoroscopic guidance, a 21-gauge inch-and-a-half needle is advanced into the first MTP joint. Slight traction on the great toe while advancing the needle can help open up the joint space to slip the needle in. Proper intra-articular position is confirmed with 1 cc of contrast material (Figure 10). Once the position is confirmed, 40 mg of Depo-Medrol and 1 cc of 1% lidocaine is injected intra-articularly.

Michaelis et at. (2003)
Injection of the metatarsophalangeal (MTP) or interphalangeal joints requires distal angulation of the needle to pass beneath the dorsal lip of the phalangeal base. These joints can be accessed under fluoroscopic visualisation with the foot in a lateral position after marking the area in the anteroposterior position (Fig. 7.1).

Spinner & Eldon (2022)
Injection: In-plane gel-standoff approach
Use copious sterile gel between the transducer and the skin to allow for gel standoff technique (Fig. 69.3). Identify the proximal phalanx, metatarsal, and EHL tendon. Traction and flexion of the proximal phalanx will open up the dorsal MTP joint space. Move the probe just medially off the EHL tendon, and centre the joint space in view. Advance the needle through the gel parallel to the transducer using the in-plane approach, from distal to proximal, and enter the skin just distal to the joint using a superficial angle (Fig. 69.3). When the needle tip is visualized directly in the joint capsule, before reaching the metatarsal, inject 0.5 mL of corticosteroid under direct visualization.

Injection: Short-Axis Out-of-Plane Approach
With patient supine and leg flexed so the foot rests flat on the table. A small footprint linear array transducer is placed in the sagittal plane across the MTP joint. Use a small quantity of sterile gel. Identify the two ends of the joint articulation. Line a small needle up in the centre of the probe at a 45–75° angle directed toward the centre of the joint. Once under the joint capsule, the needle does not needle to be advanced further. The needle will appear as a hyperechoic dot.

General considerations of CSI that emerged from the ScR
Further data drawn from the ScR shows that CSIs accepted as an important treatment modality, but that currently, there are no strict rules regarding the administration regimen, especially in the foot and ankle (Fredberg, 1997; Foster et al., 2015; George & Kirwan, 1990; Gross & Lin, 2012; Rifat & Moeller, 2001; Reilly, 2010; Snibbe & Gambardella, 2005).

General considerations of CSIs

Workman (2000) posits that there are four main considerations regarding injections: the route, site, technique, and equipment, for a given injection:

1. Route: In this field of study, the route is intra-articular. The overall aim is to deposit the injectate into the IA space and many approaches to achieve this. This concept links into injection accuracy, further discussed below (under ScR Theme 2 discussion).
2. Site: the site of the injection is the 1st MTP jt. This concept links into injection accuracy, further discussed below (under Theme 2 discussion).
3. Technique: for convenience, the technique is considered separately to injection accuracy, but these concepts dovetail each other. Various injection techniques and regimen are found through the search strategy are listed above at ScR Theme 1. Variety of techniques is mirrored in other anatomical sites. The aim of the study by Shortt et al. (2009) was to evaluate the range of techniques used by radiologists performing shoulder, hip, and knee arthrography using fluoroscopic guidance. They enquired regarding years of experience, preferred approaches, needle gauge, gadolinium dilution, and volume injected. For each approach, the radiologist was asked their starting and end needle position based on a numbered and lettered grid superimposed on a radiograph. They found that arthrographic approaches for the shoulder, hip, and knee vary among radiologists over a wide range of experience levels.
4. Equipment: in fluid dynamics, the Hagen–Poiseuille equation (also known as the Poiseuille law) is a law of physics that gives the pressure drop for an incompressible Newtonian fluid flowing through a cylindrical pipe of constant cross section in laminar flow (Sutera & Skalak, 1993). It can be applied to the flow of fluid through a hypodermic needle. The relevance is for the clinician to consider the needle gauge: a wider gauge needle will make for an easier (lower pressure) injection for particulate compounds, but this larger needle may make for a more painful injection (Reilly, 2010). For the 1st MTP jt, we do not know the best IA CSI equipment, and the multiple opinion pieces in the literature vary in their recommendations.

Further considerations that emerged from the ScR will be outlined under the following headings:

- Contraindications to an injection,
- Safety and clinical governance,
- Choice and dosage of the steroid,
- Infection control,
- Image guidance,
- Arthrography and use of contrast media,
- Concurrent use of local anaesthesia,
- Post-injection protocol,
- Repetition of the injection,
- Side effects and complications,
- Chondrotoxity.

Contraindications to an injection

The contraindications of steroid injections can be both absolute and relative (Šimurina et al., 2019). Many authors have put forward their (non-EBM) thoughts, for example, Østergaard and Halberg (1998) list:

Relative

- Joint instability
- Severe juxta-articular osteoporosis
- Failure to respond to prior injections
- Prior injection of the same joint more than twice this year or within the last 6/52
- Blood clotting disorders

Absolute

- Intra-articular or periarticular infection (including tuberculous arthritis)
- Bacteraemia
- Intra-articular fracture

Safety and clinical governance

Between January 2005 and June 2006, the National Patient Safety Agency (NPSA) received around 800 reports a month to its National Reporting and Learning System relating to injectable medicines. In their document 'Promoting Safer Use of Injectable Medicines' (National Patient Safety Agency, 2007a). the NPSA has identified several latent system risks and made the following recommendations to make the use of injectable medicines safer:

1. Undertake a risk assessment of injectable medicine procedures and products in all clinical areas to identify high risks and develop an action plan to minimise them,
2. Ensure there are up-to-date protocols and procedures for prescribing, preparing, and administering injectable medicines in all clinical areas,
3. Ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use,
4. Implement a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features,
5. Provide training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring injectable medicines,
6. As part of the annual medicines management audit programme, healthcare organisations should include an audit of medication practice with injectable medicines.

The Specialist Pharmacy Services pages archive all the patient safety alerts that relate to medications that were published between 2002 and 2012 by the NPSA (National Patient Safety Agency, 2007b, 2007c, 2007d) for prescribing, preparation and administration competencies, plus a template standard operating procedure for prescribing, preparing, and administering injectable medicines in clinical areas (National Patient Safety Agency, 2007e).

Choice and dosage of the steroid

As with injection technique, the choice (and dose) of CS varies widely, depending on the injection site and the clinician's practice pattern, often based on professional opinion/experience and manufacturer recommendations (Caldwell, 1996; Centeno & Moore, 1994; Dahl & Hammert, 2012; Kaplan et al., 2020; Uson et al., 2021). Note that 'dose' is a factor of both volume and drug concentration. Authors posit different drug choices in the available literature (Martin & Cody, 2018). For example, Hawker et al. (2010) suggest the following for small joints (e.g., the hands and feet):

- Hydrocortisone acetate - 10–15 mg,
- Methylprednisolone acetate - 5–10mg,
- Triamcinolone hexacetonide - 2.5–5mg.

Rozental and Sculco (2000) also note that there is little consensus in the literature on the appropriate administration technique and that no clinical studies have been performed (at that time) comparing various preparations for safety and effectiveness. Stephen et al. (2010) and Lavelle et al. (2007) state that there is little systematic evidence to guide medication selection for therapeutic injections and that the medication used and the injection frequency should be guided by the goal of the injection.

A systematic review by Garg et al. (2014) and review articles by Foster et al. (2015) and Anderson et al. (2019) highlight that there is a paucity of good quality randomised controlled trials to address the question of which corticosteroid is better for various musculoskeletal conditions. For example, Garg et al. (2014) found limited evidence that favoured triamcinolone hexacetonide over other CS drugs. Triamcinolone hexacetonide is the least soluble and longest-acting of the available CS preparation and has therefore become a favoured agent for joint injection for many clinicians (Derendorf et al., 1986; Genovese, 1998). Derendorf et al. (1986) found that the total absorption amount was similar between triamcinolone hexacetonide and triamcinolone acetonide however, the absorption rates were markedly different, with triamcinolone hexacetonide released more slowly than triamcinolone acetonide, resulting in lower peak plasma levels. Caldwell (1996) found the mean residence time of triamcinolone hexacetonide in the joint is 6.1 days - nearly 50% longer than the mean residence time value of 3.9 days for triamcinolone acetonide. A lower systemic level of CSs generally viewed as a favourable feature because of potential reductions in systemic toxicity. However, lower plasma levels also may reduce inflammation at non-injected sites (Cole & Schumacher, 2005).

Cushman et al. (2019) systematically evaluated the literature examining the effect of CS type, dose, and volume of small- and intermediate-size joint injections on pain and function. A total of 28 articles were included, all studying patients with OA and/or RA. Most studies used 10 to 20mg of methylprednisolone or triamcinolone for small joints, and 20 to 40mg for intermediate joints; wrist joints were the only joint studied that directly compared doses - 20mg was non-inferior to 40mg. Triamcinolone hexacetonide was found to be superior to methylprednisolone in the interphalangeal finger joints in a single randomised controlled trial. The authors found few studies directly examine the effect of CS type or dose; and none on injectate volume on clinical

outcomes for small- or intermediate-size joint arthralgia, concluding that additional research is needed.

Buyuk et al. (2017) found that bilateral steroid injections using either methylprednisolone or triamcinolone hexacetonide is safe and effective at reducing pain in patients with bilateral knee OA and that both compounds had similar efficacy in relieving pain and improving function. The efficacy of the injection was highest two weeks after injection, and the effect continued to 24 weeks after injection. Østergaard & Halberg (1998) note that, in controlled studies, triamcinolone hexacetonide has proved most effective, providing clinical effects for a mean period of up to several months. However, this compound frequently causes local tissue necrosis when injected outside a synovial cavity and believes that it should be used only by experienced clinicians.

Wollstein et al. (2007) evaluated methylprednisolone acetate and a combination of betamethasone diproprionate and betamethasone sodium phosphate for short-term pain, and the predictive value of short-term pain, in a prospective, double-blind, RCT of 85 patients. Short-term pain increased from the baseline for both preparations and decreased from three days to three weeks; pain at three days and three weeks was positively correlated. This study did not support a difference in short-term pain between the two preparations.

Centeno and Moore (1994) surveyed the American College of Rheumatology members about their preference of IAIT for knee OA. Methylprednisolone acetate was favoured by 34.6%, triamcinolone hexacetonide by 31.2% and triamcinolone acetonide by 21.7% of the respondents. The other preparations were favoured much less commonly, and hydrocortisone acetate was used the least (by only 0.2%).

In the study by Gaffney et al. (1995) the authors reported that improvement in a triamcinolone group was greater among patients with clinical evidence of joint effusion and those who had synovial fluid successfully aspirated. Different hypotheses might explain the importance of aspiration: aspiration before steroid injection diminishes the dilution factor of the steroid suspension, which might subsequently be more efficient. The greater pain relief after successful aspiration may relate to better accuracy of the IA CSI confirmed by the visualisation of synovial fluid.

NICE, prior to a 2018 update, suggested the following:

Which corticosteroids are recommended for intra-articular injection?

- *Intra-articular corticosteroid injections should be administered by an appropriately trained and skilled person*
- *Specific corticosteroids are recommended for different sites according to joint size; the dose depends on the severity of the condition. In general, for:*
  - ***Small joints:** use methylprednisolone or hydrocortisone*
  - ***Medium or large joints:** use methylprednisolone or triamcinolone*
- *To limit potential adverse effects, no joint should be treated more than three times a year*
- *Lidocaine is frequently mixed with the steroid to provide immediate pain relief*

- *The injected joint should be rested as much as practicable for 24 hours following the injection as this increases the efficacy of the injection* https://cks.nice.org.uk/osteoarthritis#!prescribinginfosub:2

All these drugs have the potential to produce physiologic toxicity and, therefore, should be administered appropriately and in the smallest dose that will reliably produce the desired effect; an increase in total dose or volume should not be used to compensate for inadequate injection technique (Benzon et al., 2007). As a typical rule of thumb, small volumes of steroids are confined to locations which include smaller joints and, accordingly, larger volumes of steroids for larger joints. Consideration should be given to previous treatment. Conversely, doses can be adjusted based on previous treatment. For example, if limited improvement has been given from a first steroid dose, a higher dose might be considered for subsequent injections (Reilly, 2010). The choice is often guided by clinician preference for both drug and dose (Bird, 1994; Cleary et al., 2003) as well as the availability, cost, versatility, and pharmacokinetics of the agent (Cole & Schumacher, 2005). Personal and institutional preferences may play a larger role in choosing CSs rather than differences in chemical properties between agents (Newman, 2004). However, the small number of reported complications suggests that low intermittent doses pose little risk of significant adverse effects.

In summary, what we do not know is the relative merit of one drug over another for the 1st MTP jt. One can extrapolate the benefit of depot injections over soluble preparations, but this needs to be tested scientifically. Equally, the best dosage warrants further study for a given pathology. In addition to local effects, IA CSIs may elicit dose-related systemic effects. Marked improvements in inflammatory markers, such as erythrocyte sedimentation rate and C-reactive protein level, can occur in patients with RA who receive IA CSIs. The effects of IA CSIs are frequently observed on non-injected RA-involved joints, further suggesting the importance of systemic effects. However, the effect on non-injected joints varies, ranging from no response to a complete response (Cole & Schumacher, 2005).

Infection control

Multiple sources discuss infection control for CSIs, but no papers specifically address it in the 1st MTP jt and therefore, data must be extrapolated from other sources. Many authors discuss this briefly. Lavelle et al. (2007) note that skin preparation prior to injection is as individualised as that seen in surgical site preparation but recommend alcohol then Betadine for the skin with the use of sterile gloves. Dooley & Martin (2002) state that there is no current consensus on preparing patients for joint/soft tissue CSI or arthrocentesis but recommends universal precautions and that an aseptic technique should be practised.

> "*The skin over the area to be injected should be free of any infection. Physicians should wash their hands thoroughly before this procedure. Universal blood and body fluid precautions mandate use of gloves, and sterile gloves also allow physicians to palpate the prepared area without contaminating the field. The area to be injected or aspirated should be wiped first with an antiseptic solution, such as povidone-iodine, and allowed to dry.*

Sterile draping has not been shown to reduce risk of infectious complications. Disposable sterile needles and syringes should be used".

Image guidance

See ScR Theme 2: the use of image guidance overlaps with injection accuracy and will be considered in detail below.

Arthrography and use of contrast media

Linking to Theme 2 for injection accuracy, some authors advocate needle placement confirmation with a radio-opaque contrast media. Direct injection of contrast media comes in two basic forms: injection via percutaneous needle access, such as direct arthrography, and injection via an indwelling catheter or tube, such as in cystography or sinography (Pasternak & Williamson, 2012). Direct contrast injection differs from intravascular injection in that the contrast is not rapidly cleared by the kidneys after image acquisition but is evacuated by natural drainage and absorbed slowly back into the body via the lymphatic system or back through the catheter (when used).

Arthrography is the IA injection of contrast media (with image guidance) to improve the evaluation or visualisation of IA structures (i.e., outline the articular structures and gives information on basic joint architecture) or for confirmation of IA needle placement prior to IA delivery of medication(s) (Carter & Mudigonda, 2009; Masala et al., 2010; Perlman, 1988). Contrast agents have long been used to examine anatomic boundaries and to explore normal and abnormal physiologic findings. These agents have included colourimetric contrast agents (e.g., methylene blue and indocyanine green) and fluorescent contrast agents (e.g., fluorescein). However, the introduction of increasingly faster and more discriminating radiographic imaging techniques has resulted in the need for radiation-attenuating contrast agents that can be used in traditional radiographic imaging or, more recently, in subtraction imaging, both of which can be projected and rotated in three dimensions (Pasternak & Williamson, 2012).

The contrast type delivered into the joint will vary depending on the patient's presenting symptoms and the subsequent imaging modality chosen. Arthrography can be performed as an out-patient technique (Haller et al., 1988) with contrast media alone (single contrast) or in combination with air (double-contrast) though this is done less frequently in joints (Perlman, 1988; Bliddal, 1999). Fluoroscopy requires expensive equipment that is often not portable, exposes the operator and patient to radiation, fails to visualise important neurovascular structures, and exposes the patient to the additional risk of contrast reactions but it remains popular in an orthopaedic setting (Wisniewski et al., 2010).

Iodinated contrast agents (ICAs) have been in use since the 1950s to facilitate radiographic imaging modalities: they have widely applied contrast agents in use today. Physicians in almost all specialities will either administer these agents or care for patients who have received these drugs. Different iodinated contrast agents vary greatly in their properties, uses, and toxic effects. Therefore, clinicians should be familiar with iodinated contrast agents' clinical pharmacology, administration, risks, and adverse effects (Pasternak et al., 2012; Rusundu et al., 2020).

Iohexol: N,N´-Bis(2,3-dihydroxypropyl)-5-[N-(2,3-dihydroxypropyl)-acetamido]-2,4,6-triiodoisophthalamide, is a non-ionic, water-soluble radiographic contrast medium with a molecular weight of 821.14 (iodine content 46.36%). Omnipaque is provided as a sterile, pyrogen-free, colourless to a pale-yellow solution in the following iodine concentrations: 140, 180, 240, 300, and 350mgI/ml. Omnipaque 300/350 is indicated for adult arthrography (General Electric Company, 2017).

Careful patient positioning before the procedure facilitates patient comfort and safe and efficient access to the joint - for the 1st MTP jt, a supine position is appropriate, with a bent knee to allow the foot to rest flat on the table (or C-arm) (Hansford et al., 2019). A radiopaque object may be placed on the skin overlying the target for fluoroscopy to mark an appropriate skin entry site (Haller et al., 1988; Reilly, 2010). Use of the aseptic technique is mandatory – and its use should be recorded. After skin penetration, the needle is advanced into the joint with either intermittent fluoroscopic guidance (to reduce radiation dosage) or under direct US visualisation. Prior to injection, the joint may be aspirated; some authors inject local anaesthesia at this point. The IA position is confirmed when a contrast medium can be injected with little resistance and flows freely into the joint recesses rather than clustering around the needle tip (Hansford et al., 2019; Rastogi et al., 2016).

Chow and Brandser (1988) inject a small amount of contrast to confirm an IA position. They use a flexible connecting tube from the syringe to the needle to minimise movement of the needle once it has been placed within the joint or the tendon sheath. The injected contrast should flow freely from the needle tip and outline articular surfaces. Spot films are taken for documentation. Images should be obtained in both anteroposterior and lateral projections and show contrast filling the plantar aspect of the articulation. Newman (2004) suggests that to avoid the dorsal lip of the proximal phalanx, the needle should be inserted just proximal to the joint line and angled slightly distally.

Karpman and MacCollum (1988) suggest that longitudinal traction is placed on the hallux, and the contrast media is injected into the joint under fluoroscopic control. The joint is then brought through a passive range of motion several times to allow for proper distribution of the contrast material.

Weston (1969) posits the following for the metacarpo- (and metatarso-) phalangeal joint technique, and is worth noting in full:

> "*The metacarpo-phalangeal joint is flexed to a right angle. The joint space is then easily palpated on the dorso-lateral aspect of the joint on either side of the extensor tendon. Once the space is located, the 26-gauge needle is inserted through the extensor expansion, which fixes the needle. As the opaque medium enters the joint, the synovial cavity is distended. This can be palpated by the left index finger of the operator, which is placed on the palmar aspect of the joint. The distended cavity is tense and cystic, and it displaces the index finger away from the metacarpal head*".

De Caser Netto et al. (2018) note that sesamoiditis or plantar plate injuries are more difficult to identify after injections due to the continuity of capsule and the plantar plate-

sesamoid complex and that 1st MTP jt arthrography can be useful in these cases. Perlman (1988) notes that 1st MTP jt arthrography can be performed to demonstrate sesamoid fractures or RA where a corrugated synovial pattern with saccular joint enlargement is seen.

The use of contrast incurs the additional risk of contrast agent reactions and may reduce the space available within small joints subsequent diagnostic or therapeutic injection (Pasternak et al., 2012). Chemical incompatibility between injectable CSs and other agents can result in flocculation. High-performance liquid chromatographic analysis was used by Shah et al. (2009) to assess the stability of combinations of steroids (triamcinolone and methylprednisolone) and Omnipaque™ (iohexol). Further analysis was also performed to test the stability of adding local anaesthetics (lidocaine and bupivacaine) to these mixtures. The results demonstrated that all combinations were stable when mixed, supporting the continued safe use of these products in combination in clinical practice.

Concurrent use of local anaesthesia

Injectable corticosteroids are often combined with a local anaesthetic (LA). LAs may be applied on the skin, infiltrated in the subcutaneous tissue, infiltrated along the needle path into the joint, injected into the joint alone, or mixed with the steroid. The use of LA not only provides immediate pain relief but also can verify that the site injected was the source of pain: it acts as a diagnostic injection (Crawford et al., 1998; Johnson et al., 2011; Khoury et al., 1996; Lavelle et al., 2007; Peterson et al., 2010, Reilly, 2010). Multiple joints may show arthritic changes at imaging; deciding which joint is the primary source of the pain can be difficult. Anaesthetic injections of the joints and tendon sheaths of the foot and ankle are a valuable adjunct to imaging for evaluating patients whose foot pain is of uncertain origin (Chow & Brandser, 1998; de Cesar Netto et al., 2018; Khoury et al., 1996. Uson et al. (2021) note that using LA in IAIT reduces discomfort during the procedure and extends pain reduction post-procedure. In an older reference, Boxer (1994), states that the effect of LA creates a chemical sympathectomy which results in dilation of the vessels feeding the synovial membrane and capsule and that the passive hyperaemia becomes active, and the inflammatory process is subsequently reduced. This then results in reduced muscular spasms of the joint as an anaesthetic effect is created.

More recently, Saunders and Longworth (2018b) list the following benefits of adding local anaesthetic to a steroid solution:

1. Diagnosis (as above),
2. Analgesia (as above),
3. Dilution of the CS drug,
4. Distension of tissue.

Haslock et al. (1995) found that while about a quarter of the Rheumatologists surveyed used no local anaesthetic, most used LA before or with the CS. Rastogi et al. (2016) suggest that particulate CSs should be mixed only with preservative-free anaesthetics to prevent particulate precipitation. In some cases, combinations of CS and LA are available from the manufacturer. If not, Cole and Schumacher (2005) recommend that the mixture be carefully inspected for the formation of precipitates before injection.

Post injection protocol

Haslock et al. (1995) found that post-injection advice was extremely variable among Rheumatologists. Resting an injected joint for 24 to 48 hours after an injection - particularly large, weight-bearing articulations - reduces the escape of steroids from the joint and improves the anti-inflammatory response (Hawker et al., 2010). Ayral (2001) posits that rest after IA steroids seems logical and that injections in outpatients should be performed before the weekend to allow rest for at least 24 hours, with bed rest for lower limb injection and rigid bandage or splint for fingers or thumb-base injection. Fadale and Wiggins (1994) believe that using CSIs must be accompanied by a well-orchestrated treatment plan, including close follow-up, physical therapy, and limitation of activities.

Neustadt (1985) pointed out the usefulness of a post-injection rest regimen to improve steroid efficacy in inflammatory knee arthritis. His protocol involved bed rest for at least three days, except for time for bathroom and meals, then crutches for three weeks to protect the injected knee. Chakravarty et al. (1994) reported a randomised trial in which patients with knee arthritis were randomised to receive either 24-hour strict, non-weight-bearing bed rest in a hospital following IA CSI (40mg triamcinolone hexacetonide plus 2ml lignocaine 2%) or were treated as outpatients. By 12 weeks, the degree of improvement in the pain score, stiffness score, function score, knee circumference and inflammatory markers was significantly better in the group that experienced 24-hour bed rest, and this difference persisted up to 24 weeks.

Repetition of the injection

Three months have historically been a suggested buffer between IA CSIs, but no current evidence supports shorter or longer periods to be safer or more efficacious. The duration of effect is thought to correlate inversely with the solubility of the preparation, i.e., the less soluble an agent, the longer it remains in the joint and the more prolonged the effect it has, creating lower systemic corticoid levels; and conversely for the insoluble. In general, soluble materials have an IA dwell time measured only in hours (Evans et al., 2014) however, neither type has been shown to be more effective than the other (Safran et al., 2011).

The wider literature on OA recommends that the interval between IA CSIs injections be at least 4-6 weeks, and the number of injections at one site should be limited to three or four per year to minimise the potentially deleterious effects of corticosteroids on articular structures. However, Freire and Bureau (2016) note that these recommendations are mostly empirical. Safran et al. (2011) recommend not having more than three injections of cortisone preparations in the same location in one year and no more than ten injections in a large joint in a patient's lifetime. Honcharuk and Monica (2016) and Handa (2012) recommend that joints should not receive more than 3 to 4 injections per 12 months. However, others have reported that an injection can be repeated after six weeks; Martin and Browne (2019) found no evidence of a lifetime limit of three CSIs.

Ayral (2001) argues that most RCTs deal with small patient populations and use only one CSI, even though, in clinical practice, injections may be repeated in the case of a

partial result and that the CS dose is often lower than those usually injected by many practising clinicians. Injection frequency should be guided by the underlying disease process, the response to past injections, the availability of other treatment options, patient preferences, and clinical judgement (Raynauld et al., 2002). A lack of response to two or three injections forebodes future therapeutic failure, and additional injections into a refractory joint should be omitted (Caldwell, 1996), but further research is required to determine the recommendation of a maximum frequency of IA CSIs for each joint pathology.

Side effects and complications

Complications from CSIs are relatively rare and often minor but can and do occur and are well documented in the literature (Anderson et al., 2019; Brinks et al., 2020; Cassidy & Bole, 1966; Cheng & Abdi, 2007; Cole & Schumacher, 2005; Freire & Bureau, 2016; Habib et al., 1010; Honcharuk & Monica, 2016; Hynes et al., 2021; Kompel et al., 2019; Lavelle et al., 2007; MacMahon et al., 2009; Martin & Browne, 2019; Šimurina et al., 2019). Adverse effects are related to the dose and duration of treatment, the route of administration, and how closely patients are followed after the procedure (Cole & Schumacher, 2005; Dorai-Raj & Schrieber, 1998; Østergaard & Halberg, 1998). Such events may be local or an exaggeration of the normal physiological response: fluid retention, hyperglycaemia, elevated blood pressure, mood changes, menstrual irregularities, gastritis, Cushing's syndrome, increased appetite, weight gain, increased infections, delayed wound healing, and acneiform eruptions. Even short courses of oral GC therapy (less than 2 to 3 weeks) are usually safe, and adverse effects are generally avoided with single injections. However, side effects from single-dose administrations have been reported, and HPA axis suppression may be affected for up to four weeks (Anitescu et al., 2013).

The most common local side effects are post-injection flare, facial flushing, and skin or fat atrophy. A steroid "flare" – significant pain at the injection site prolonged beyond the immediate injection period is caused by insoluble, µm sized cortisone crystals forming on the synovial membrane causing macrophages to collect at the site of crystallisation (Alsop et al., 2016). The immune response leads to the release of synovial fluid, swelling, and pain at the injection site and typically occurs within 1–2 days of injection (Honcharuk & Monica, 2016). The pain can be severe but settles down in a day or two but can be considerably longer with over-the-counter strength painkillers and ice packs used if required (Cole & Schumacher, 2005). Extreme flares have been reported (Young & Homlar, 2016). As noted above, insoluble CSIs such as methylprednisolone tend to have more of an inflammatory response. Anderson et al. (2019) report that the adverse event rate following IA ankle or subtalar joint CSI was 5.8%, with post-injection flare being the most common complication.

Facial flushing may occur 24-48 hours after the injection and will (usually) settle within a day or two. It occurs in up to 15% of patients and is particularly common in women (Caldwell, 1996; Cole & Schumacher, 2005). Fat wasting – a small amount of sub-cutaneous fat may be affected by the injection leaving an indentation at the injection site. An anaphylactic reaction is rare, but its occurrence warrants prompt life support therapy, including resuscitation of airway, breathing, and circulation, with adrenaline,

oxygen support and cardiac life support where indicated (Anitescu et al., 2013; Mace et al., 1997).

CSIs have been shown to be a risk factor for developing influenza compared with non-injected vaccinated control patients (Stysma et al., 2018). Poggi and Hall (1995) provide a case report where a 40-year-old man with a history of previous cheilectomy and two CSIs for 1st MTP jt degenerative joint disease who sustained an acute rupture of the extensor hallucis longus tendon. Dislocation at the 2nd MTP jt has been reported post-injection but not thus far in the 1st MTP jt (Reis et al., 1989). Steroid-induced AVN has been reported after oral steroid administration (Li and Dowell, 1995). More recently, Kompel et al. (2019) note that accelerated OA progression, subchondral insufficiency fractures, complications of osteonecrosis, and rapid joint destruction, including bone loss, have been structurally observed in patients after IA CSIs.

Brook et al. (2017) note that, although the incidence is low, sex-related side effects, such as abnormal menstruation, lactation disturbances, facial flushing, and hirsutism, are associated with CSIs, and therefore clinicians should be aware of these female-specific side effects and relay this information as part of the informed consent process.

The most feared complication post-CSI is an infection, and clinicians must be hyper-alert to septic arthritic because of the reduced cardinal signs of infection via the effect of the CS (see above). The potential for post-operative surgical site infection following a previous IA CSI is even less discussed in the foot. Some information is available in larger joints. Berthelot et al. (2013) believe that the risk of sepsis with a hip or knee implant does not seem to be increased by prior joint injections if the injection and surgery are separated by at least two months. More recently, Bhattacharjee et al. (2021) suggest that total knee arthroplasty performed within four weeks of a CSI may be associated with a higher risk of post-operative infection.

Chondrotoxity

Chondrotoxity merits special mention. The safety of IA-administered CSIs and LAs is controversial because their effects on the cartilage structure and metabolism are not completely elucidated, and studies related to this topic are divergent (Kompel et al., 2019; Wernecke et al., 2015). The overall slant of data suggests that the combinations of certain types of CSs and LAs have a deleterious effect on articular chondrocytes; therefore, it raises the question regarding whether concomitant administration of these two agents is justified in the treatment of OA (Farkas et al., 2010).

Some authors have concerns about the progression of cartilage destruction, but others have shown that CSIs can reduce this progression, suggesting that IA CSIs impede cartilage metabolism and decelerate cartilage breakdown. Some authors balance these conflicting effects by limiting the number of corticosteroid injections into a single joint to four or fewer per year (Caldwell, 1996). Reports of Charcot joints and cartilage destruction have been discussed widely (Mazanec, 1995).

The aim of Klocke et al.'s (2018) study was to look at the response of biomarkers of cartilage and bone metabolism after IA injections in the knee. Eighty subjects with symptomatic knee osteoarthritis underwent routine knee joint injections with 40mg

triamcinolone acetonide and 4ml 1% lignocaine. Knee pain and biomarkers were measured at baseline and three weeks after injection. The radiographic severity of the disease was evaluated using knee radiographs. Median uCTX-II, a cartilage degradation marker, was lower at three weeks post-injection than baseline. Apart from a weak trend of lower cartilage oligomeric matrix protein post-injection, other biomarkers showed no change after injection. This observational study suggests that CSIs in knee OA may reduce cartilage degradation in the short term.

Farkas et al. (2010) asked whether CS and LA combined had any synergistic effects on chondrocyte apoptosis. Cell viability and apoptosis/necrosis assessment of human articular chondrocytes were performed in vitro (chondrocyte cell cultures) and ex vivo (osteochondral specimens) using flow cytometry and TUNEL analysis, respectively. Glucocorticoids and LAs induce apoptosis in chondrocytes at various rates. When combined, the number of dead chondrocytes increased in in-vitro chondrocyte cell cultures and osteochondral ex vivo specimens. They observed a time-dependent decrease in chondrocyte viability after concurrent CS and LA exposure. The combination of CS and LA has an adverse effect on articular chondrocytes, raising a question regarding whether concomitant administration should be used in treating OA.

The goal of Braun et al.'s (2011) study was to evaluate the effect of single injection doses of 1% lidocaine or 0.25% bupivacaine in combination with single injection doses of dexamethasone sodium phosphate, methylprednisolone acetate, betamethasone sodium phosphate and betamethasone acetate, or triamcinolone acetonide on human chondrocyte viability. All solutions were delivered to human chondrocytes in vitro for the medication's respective average duration of action using a bioreactor containing a continuous infusion pump constructed to mimic joint fluid metabolism. A two-colour fluorescence assay was used to evaluate cell viability. A mixed-effects regression model was used to evaluate the mean differences in cell viability between treatment groups. At 14 days, a single injection dose of 1% lidocaine or 0.25% bupivacaine in combination with betamethasone sodium phosphate and betamethasone acetate solution illustrated significant chondrotoxicity when compared with the local anaesthetics alone. Methylprednisolone acetate and triamcinolone acetonide both showed significant evidence of chondrotoxicity when used in combination with 1% lidocaine compared with lidocaine alone but showed no significant chondrotoxicity in combination with 0.25% bupivacaine. The conclusion was that clinicians should use caution when injecting 1% lidocaine or 0.25% bupivacaine in conjunction with betamethasone sodium phosphate and betamethasone acetate solution due to its pronounced chondrotoxic effect.

Guermazi et al. (2020) point out that large prospective studies evaluating the risk of accelerated OA or joint destruction after IA CSIs are needed but given the relatively rare incidence of these adverse outcomes, any clinical trial would be challenging in design and a large number of patients would need to be included.

The subject of chondrotoxicity has not been specifically answered for use of CSI (with or without LA) for the 1st MTP jt. Does the potential chondrotoxicity of the CS - plus or minus LA - have a net negative effect, or is this counteracted to a greater or lesser degree by the potential to reduce synovitis, potentially slowing the arthritic process

within the joint? Lidocaine or ropivacaine should be used rather than bupivacaine, which is cytotoxic to chondrocytes in vitro, and at least theoretically poses a small risk to articular cartilage in vivo. Potential local adverse effects, such as cartilage degradation and tendon weakening, are poorly understood. Critically weighing up the data seems to indicate that CSIS, in modest doses, protect cartilage against the detrimental insults imposed by inflammatory enzymes but excessive CS dosage may impair cartilaginous biochemistry (Grillet & Dequeker, 1990).

APPENDIX 8: Hit and miss: The accuracy of intra-articular injections of the first metatarsophalangeal joint

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Hit and miss: The accuracy of intra-articular injections of the first metatarsophalangeal joint

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Introduction: Therapeutic injections provide a treatment option for patients with joint and periarticular pain, those who are not surgical candidates, whom conservative treatment has failed, or those that are awaiting surgery. Injectable glucocorticoids are one of the most common therapeutic interventions in musculoskeletal healthcare and are widely used in pathologies of the first metatarsophalangeal joint. The aim of this paper is to highlight current concepts around first metatarsophalangeal joint injection injection accuracy.
Anatomy: The first metatarsophalangeal joint is a condyloid synovial juncture and consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones, with associated ligamentous attachments. The joint capsule is shaped like a box.
Methods: To achieve the research aim, a scoping review was undertaken with a search strategy that identified evidence via the following sources: Electronic databases, Google scholar, and Reference lists.
Results: The search yielded 193 articles, 48 of which appeared of potential relevance. After removing duplicate articles this total was reduced to 37 articles. After scanning the content, 27 were excluded to leave 10 articles. Twenty eight further articles were found through related author research, examination of reference lists and free text searches of Google Scholar. One reference was unobtainable. The final count of papers utilised for review was 37 which produced three themes, one of which was injection accuracy.
Injection accuracy: In the long history of injection therapy, infiltrations have often been performed without image guidance, i.e., using palpation guidance, anatomical landmarks and clinical judgement to direct needle entry and advancement. Needle placement may also be confirmed by use of diagnostic imaging. Typical imaging modalities are fluoroscopy or ultrasound, used alone or in combination with contrast media.
Discussion: The perceived wisdom is that if an injectate misses its target it is likely to be less effective and lead to false negative reporting of poor treatment outcomes, but the literature is not equivocal. This article discusses the recent literature in the field.
Conclusions: The literature suggests that steroid injections are safe and effective for the short-term relief of joint pain. When injecting small synovial joints using palpated-guided methods, clinicians must be alert to the potential for failure of technique from the needle penetrating too far into the articulation and exiting the joint on the contralateral side from the entry point. Use of shorter needles and use of imaging, +/- the use of contrast media, might reduce the number of such failures.

Keywords: steroid injection, injection accuracy, synovial joint, hallux limitus

A needle is inserted into a joint for two main indications: aspiration of fluid (arthrocentesis) for diagnosis purposes or for the relief of pressure; or injection of a therapeutic medication [1–6]. Therapeutic injections, especially those mixed with local anesthetic, provide a treatment option for patients with joint or periarticular pain, those who are not surgical candidates, in those in whom conservative treatment has failed, or those that are awaiting surgery [7]. The introduction of injectable cortisone in the early 1950's revolutionised the treatment of several medical diseases. Injection therapy (IT) is now one of the most common therapeutic interventions in musculoskeletal healthcare and injections for the relief of vertebrogenic, arthritic and radiculopathic pain are widely accepted [8–20]. Suppression of local joint inflammation by glucocorticoids is rapid and

pronounced and may be achieved with only minor systemic effects; however, this suppression is often only temporary [21–26].

Despite their frequency of use, there are no strict guidelines regarding the administration of corticosteroid injections (CSIs) and injection regimen vary widely across anatomical injection sites and speciality [27–34]. The dose and frequency of corticosteroid use are similarly opaque and often based on professional opinion/experience and manufacturer recommendations [13,35–39]. A Delphi consensus study by Uson, et al., provided overarching principles and recommendations for intra-articular injection therapy (IAIT), noting their use in improving patient-centred outcomes as part of shared decision making [13].

The two most common diseases affecting the first metatarsophalangeal joint (1st MTPJ) of the foot are hallux limitus/rigidus (osteoarthritis; OA) and hallux abducto valgus (HAV; bunion) [40,41]. Other common pathologies of the joint include rheumatoid arthritis, gout and sesamoiditis [42]. Injectable glucocorticoids are widely used in hallux limitus though high-quality evidence for their use is lacking [4370]. IAIT is rarely used in the pre-operative management of HAV though it is employed for postoperative arthrofibrosis ; restricted joint motion,typically painful as a result from an exaggerated fibrotic response after joint trauma or surgery [40, 71-73]. IAIT (+/- local anaesthetic injections) can be both diagnostic and therapeutic in sesamoiditis [53,74–76], though Cohen [77] counsels against repeated injections. While joint fluid aspiration and CSI injection are commonly performed in clinical practice for gout [78,79] its use has not been investigated by controlled trials [80–82]. Nonetheless, IA CSIs for gout are recommended by rheumatologic societies around the world including the British Society of Rheumatology (BSR) [83], the European League against Rheumatism [84], and the American College of Rheumatology (ACR) [85].

This work forms part of a doctoral thesis. The objectives of the project are to identify, synthesise and critique the evidence base for the use of CSIs in the management of 1st MTPJ pathology, to highlight gaps in our knowledge and to generate research questions for future study. The thesis is presented in six parts as a scoping review for CSIs of the 1st MTPJ; a systematic review of CSIs for OA of the 1st MTPJ; a best practice technique for IA CSI of the 1st MTPJ; a cadaveric experiment on 1st MTPJ injection accuracy, IA CSI case studies, and an outline study design for a high-level prospective study. The aim of this paper (in two parts) is to highlight current concepts in 1st MTPJ injection accuracy with reference to the wider CSI literature.

Anatomy of the 1st MTP Joint

Structure

The 1st MTPJ is a condyloid synovial juncture [86]. It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTPJ in contradistinction to the lesser MTPJs [87,88]. The metatarso-sesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The six muscles are the abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis [89]. The ligaments of the joint are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the intersesamoid ligament, and the hood ligament [88].

Osteology

The head of the first metatarsal is large and quadrilateral in general contour, with the transverse diameter exceeding the vertical dimension (Figure 1). The articular surface covering the head presents two fields in continuity: a superior phalangeal and an inferior sesamoidal [90] (Figure 2).

The proximal phalanx is directed transversely and has a large base to receive its muscular and ligamentous attachments [91]. It bears an oval, concave articular surface, the glenoid cavity, smaller than the corresponding articular surface of the metatarsal head [90]. The sesamoids are often likened in shape to coffee beans, but their overall configuration of the sesamoids is variable: they also may be semi-ovoid or circular in shape. They are embedded in the plantar pad which is a mass of dense fibrous tissue attached firmly to the base of the proximal phalanx.

Figure 1 First metatarsal (distal view) in a cadaveric specimen: right foot.

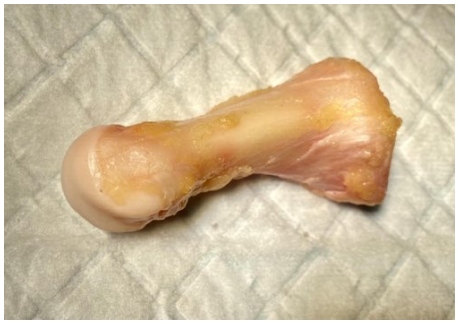


Figure 2 First metatarsal (medial border) in a cadaveric specimen: right foot.

On the plantar surface of the metatarsal the inferior articular surface is separated into two sloped surfaces by a rounded ridge or crest (the crista) oriented antero-posteriorly [92]. The sesamoids function to absorb weight-bearing forces, decrease friction, protect the flexor hallucis brevis tendons, and increase the functional length of metatarsal in propulsion [77].

Ligaments

Alvarez, et al., [88] list nine ligaments of the joint. Collateral and suspensory ligaments originate from medial and lateral epicondyles on the head of the first metatarsal. The collateral and sesamoid ligaments run forward and downward to attach to the base of the proximal phalanx and the appropriate sesamoid.

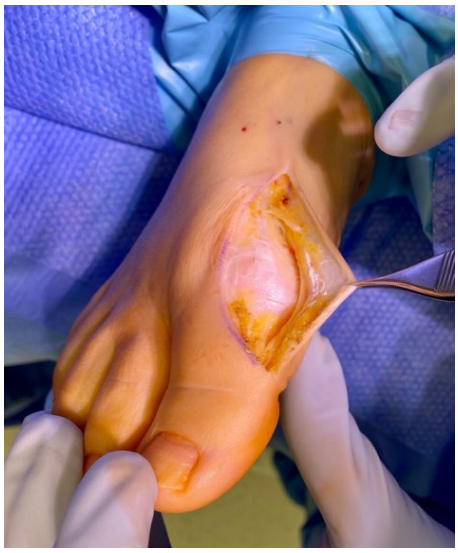


Figure 3 Joint capsule of the 1st MTPJ.

The hood ligament is a fibrous expansion from the long extensor tendon which encloses the tendon and attaches to the sides and plantar surface of the proximal and distal phalanx and blends with the joint capsule (Figure 3). The lateral margins of the plantar pad receive ligamentous and muscular attachments and the proximal border receives part of the flexor hallucis tendon. The plantar surface of the pad is raised on either side by the two sesamoids to form a groove for the long flexor tendon held in place by a fibrous tunnel [91].

Synovial membrane

Weston [93] notes that the joint capsule is shaped like a box and cites that the best anatomical description of the synovial cavity of the 1st MTPJ is by Testut and Jacob in 1943. The synovial membrane was shown to reflect proximally on the palmar and plantar aspects of the heads and necks of metacarpals and metatarsals (Figure 4).

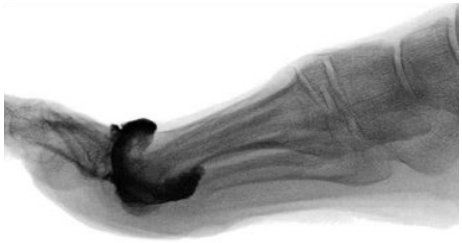


Figure 4 Radio-opaque dye highlighting proximal extension of the 1st MTPJ.

Methodology

Scoping reviews are used to assess and understand the extent of the knowledge in an emerging field or to identify, map, report, or discuss the characteristics or concepts in that field [94]. A scoping review is commonly used to map out and clarify working definitions and conceptual boundaries of a topic or field; it is a 'reconnaissance' of an area [95]. It is a form of knowledge synthesis that addresses an exploratory research question and maps the key concepts underpinning a research area by systematically searching, selecting, and synthesising existing knowledge [96,97].

A scoping review was considered to be the most suitable first step to question the wider themes about injection therapy of the 1st MTPJ. An *a-priori* protocol [98] was developed before undertaking the scoping review. The 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews' – PRISMA-ScR [99] was used to guide the reporting of this protocol and is used to structure the reporting of the full review available for review in the doctoral thesis.

To achieve the research aim, a three-step strategy was adopted that involved searching for research evidence from the following different sources:

I. Electronic databases
II. Google Scholar
III. Reference lists

Step 1: The following databases was searched via the NHS Healthcare Advanced Database Search (HDAS) search engines using MeSh terms/free text:

- CINAHL (Cumulative Index to Nursing and Allied Health Literature: 1981 – 01.01.2021)
- EMBASE (Excerpta Medica Database: 1974 – 01.01.2021)
- MEDLINE (Medical Literature Analysis and Retrieval Online: 1946 – 01.01.2021)

Search terms

"((GLUCOCORTICOIDS/ OR (Steroid*).ti,ab OR (glucocorticoid*).ti,ab) AND ("INJECTIONS, INTRA-ARTICULAR"/ OR (Injection*).ti,ab)) AND (HALLUX/ OR (hallux).ti,ab OR ("big toe*").ti,ab OR ("great toe*").ti,ab OR (arthrofibrosis).ti,ab OR (gout).ti,ab OR (sesamoid*).ti,ab)"

Step 2: Google Scholar was searched using key words identified from an analysis of the text words contained in the title and abstract of retrieved papers, and these keywords were used to search for articles.

Step 3: Examination of the reference lists of all identified sources from steps 1 and 2.

Results

The search yielded 193 articles, 48 of which appeared of potential relevance. After removing duplicate articles this total was reduced to 37 articles. After scanning the content, 27 were excluded to leave 10 articles. 28 further articles were found through related author research, examination of reference lists and free text searches of Google Scholar. One reference was unobtainable. The final count of papers utilised for review was 37.

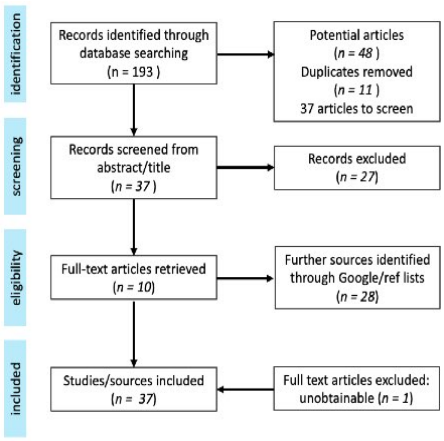


Figure 5 PRISMA-ScR flowchart.

Iterative charting of the literature yielded three broad and overlapping themes:

1. Evidence of IA CSIs by joint disease/pathology,
2. Non-evidenced based descriptions of injection technique and regimen,
3. Accuracy of the injection.

Nineteen articles are summarised Themes 1 and 2 (two articles appear in Theme 2 also) with a systematic review of the result of further work [69]. 20 articles (plus one, one unreferenced, and one found after the initial search) were technical/technique articles (Theme 2) and led to the development of a best practice IT guideline [100]. The cadaveric work that led from the initial scoping review has already been published [101]; part 2 of this paper will look at the wider concepts around injection accuracy of the 1st MTPJ.

Injection Accuracy

Workman [102] posits that there are four main considerations regarding injections: the route, site, technique, and equipment, for a given injection. In the long history of IAIT, the technique is done using palpation guidance, anatomical landmarks and clinical judgement to direct needle entry and advancement [103–105].

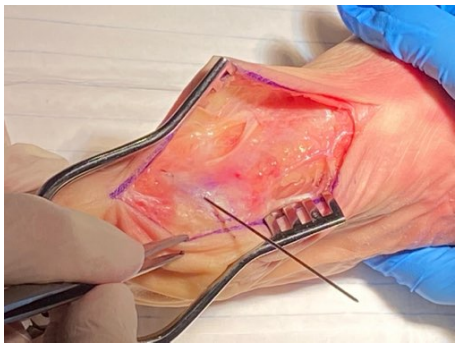
Needle placement may also be confirmed by use of diagnostic imaging. Typical imaging modalities are fluoroscopy or ultrasound (US), used alone or in combination with contrast media [106–109] .

Injection by palpation guidance: options

Ajwani, et al., [40] and Feuerstein, et al., [71] state that distension of the joint and flexion of the toe are signs of a successful IA injection of the 1st MTPJ. Joint fluid aspiration in larger joints may aid confirm needle placement [110–112] though aspiration of the 1st MTPJ is more difficult as it is a smaller joint with less fluid available to aspirate [105,113]. Luc, et al., [114] describe a backflow technique, which involves re-positioning the needle (in the knee) until a free backflow of pre-injected lidocaine occurs. This has been demonstrated in the 1st MTPJ by Bhattia [115] using iohexol contrast media.

Al-Jabri and Charalambides describe their "sulcus sign' technique. The joint line was marked by a surgeon prior to needle insertion in a cohort of 30 patients[43]. The point of insertion was identified using the 'sulcus sign' technique as described in table 8 of their paper (note that Figure 1 of their paper shows a direct dorsal rather than dorso-lateral needle entry as they describe). This was then compared to the actual point of insertion following fluoroscopic identification of the joint line. The distance from the image-guided joint line to the marked joint line identified using the 'sulcus sign' technique and measured and recorded using a technique similar of Manadan, et al., [113]. These authors found no difference between the joint lines identified using image guidance versus the 'sulcus sign' technique and no difference in the point of needle entry marked using either technique, with only a single attempt required to establish an IA needle position, even in patients with advanced degenerative changes at the joint.

In contrast to Al-Jabri and Charalambides , Heidari et al. found that the presence of pathologic changes reduces the rate of successful IA puncture, but that the overall frequency of successful IA injections can be improved through experience and the use of imaging [43, 110]. 106 cadaveric 1st MTPJs were injected with a methylene blue solution and then dissected to distinguish IA from periarticular injections.



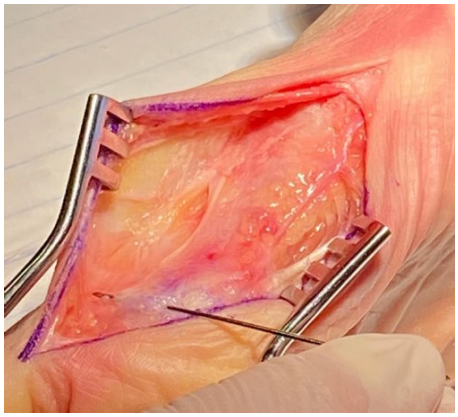
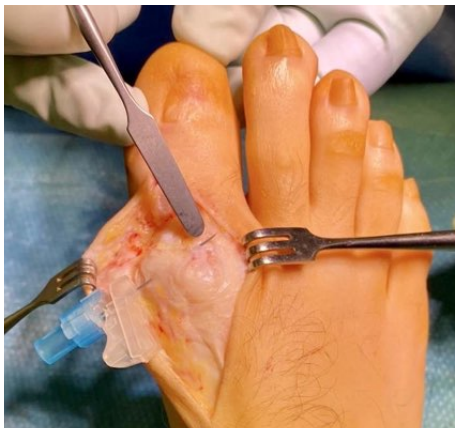
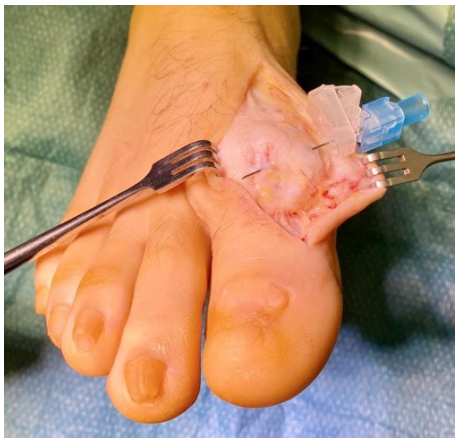


Figure 6 and 7 K-wire passes through 1st MTPJ on cadaver.

To evaluate the importance of experience, 38 injections were performed by a student, 38 by a trained resident, and 30 by an experienced surgeon. In the second part of the study, the authors examined the relation of pathologic findings of the 1st MTPJ and the accuracy of IA injection. The overall rate of unintentional periarticular injections was low (9.4%; 10 of 106 joints). The student achieved a successful IA injection in 86.8% of joints (33 of 38), the resident in 92.1% (35 of 38), and the specialist in 93.3% (28 of 30). The number of extra-articular injections increased significantly with the presence of deformity (hallux valgus) or OA of the 1st MTPJ.





Figures 8 and 9 Needle seen to pass into and through the joint.

The aim of Manadan's study was to determine the accuracy of radiocarpal (RC) joint and 1st MTPJ arthrocentesis using fluoroscopy [113]. Ten rheumatologists with a mean of 17.9 years of clinical experience were asked to mark their usual site of arthrocentesis over fluoroscopically identified joint lines of the right RC and right 1st MTPJs. The sites marked were a mean of 0.85 cm and 0.33 cm from the fluoroscopically identified RC and 1st MTPJs, respectively.

The authors concluded that traditional palpation-guided joint aspiration may be inaccurate, and that fluoroscopic guidance has the potential to improve accuracy of arthrocentesis of small joints.

As noted above, a best practice palpation-guided IT of the 1st MTPJ has been the subject of a previous study with further work evidencing the failure rate of this technique in a cadaveric model [100, 101]. The cadavers were subsequently used as part of a foot and ankle anatomy teaching course for podiatric surgery students. On one of the feet, following dissection of the soft tissues and subcutaneous layer away from the joint capsule and periosteum, a 1.0mm Kirschner wire was inserted into the joint using the senior author's standard technique. With minimal extra pressure the wire was pushed further into the joint and exited the capsule dorso-laterally (Figures 6 and 7).

The patient in Figures 8 and 9 was undergoing open HAV surgery. With consent, prior to dissection of the 1st MTPJ capsule off the bony structures, a 23-gauge (blue) needle was inserted into the joint using the author's standard injection technique. This demonstrates how easy it is to 'overshoot the target' if the needle is orientated slightly too dorsally or inserted too far laterally.

Injections using image guidance: options

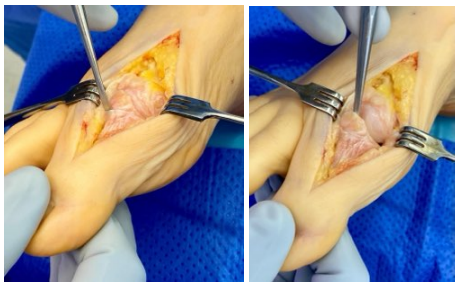
Fluoroscopy

X-rays can be used to guide and confirm needle placement, with or without the use of contrast media [116,117]. Careful patient positioning before the procedure facilitates patient comfort and safe and efficient access to the joint - for the 1st MTPJ a supine position is appropriate, with a bent knee to allow the foot to rest flat on the table or radiography sensor [118]. A radiopaque object may be placed on the skin overlying the target to mark an appropriate skin entry site [57]. After skin penetration the needle is advanced into the joint with intermittent fluoroscopic guidance to reduce radiation dosage. Prior to injection, the joint may be aspirated; some authors inject local anesthesia at this point.

Direct injection of contrast media comes in two basic forms: injection via percutaneous needle access, such as direct arthrography, and injection via an indwelling catheter or tube, such as in cystography or sinography [119]. Arthrography is the IA injection of contrast media with image guidance to improve the evaluation or visualisation of IA structures (i.e., outline the articular structures, and gives information on basic joint architecture) or for confirmation of IA needle placement prior to intra articular delivery of medication(s) [109,115,120,121]. Contrast agents have long been used for the imaging of anatomic boundaries and to explore normal and abnormal physiologic findings. Iodinated contrast agents (ICAs) have been in use since the 1950s to facilitate radiographic imaging modalities and are widely applied contrast agents in use today. Physicians in almost all specialties will either administer these agents or care for patients who have received these drugs. Different iodinated contrast agents vary greatly in their properties, uses, and toxic effects. Therefore, clinicians should be at least superficially familiar with the clinical pharmacology, administration, risks, and adverse effects associated with iodinated contrast agents [119,122].

When a contrast medium is injected, it should flow freely into the joint recesses rather than clustering around the needle tip [7,118,123]. The normal 1st MTPJ arthrogram demonstrates the opaque medium seen as a thin layer over the head of the metatarsal, and between it and the base of the proximal phalanx. On the lateral aspects of the joint the small recess has a waist due to the collateral ligaments. A large recess is noted on the plantar aspect of the metatarsal head and neck which extends proximally by about 1cm [93]. The volume of the joint will be in the region of 1-1.5ml, negatively affected by joint disease [118]. Careful attention must be paid to the distribution of iodinated contrast to recognize unexpected findings such as extracapsular extension of contrast, which may indicate capsular injury or variant joint communications. Trauma to the 1st MTPJ leads to spindle-shaped swelling of the joint capsule; the shape of the capsule also changes from cylindrical to spindle - and joint density increases - in rheumatoid arthritis (RA) [93]. Sacculation may also be seen in RA [121].

Chow and Brandser use a flexible tube connecting the syringe to the needle to minimise movement of the needle once it has been placed within the joint or the tendon sheath and inject a small amount of contrast to confirm IA position. Spot films are taken for documentation [7]. Images should be obtained in both anteroposterior and lateral projections and show contrast filling the plantar aspect of the articulation.



Figures 10 and 11 Osteophytic lip on the proximal phalanx.

Newman suggests that to avoid the dorsal lip of the proximal phalanx, the needle should be inserted just proximal to the joint line and angled slightly distally [124]. Note the osteophytic lip on the dorsal aspect of the base of the proximal phalanx undergoing an arthrodesis procedure seen in Figures 10 and 11, which might impede needle entry into the joint space from a dorsal approach.

Karpman and MacCollum suggested that longitudinal traction is placed on the hallux and the contrast media is injected into the joint under fluoroscopic control [125]. The joint is then brought through a passive range of motion several times to allow for proper distribution of the contrast material.

Khour,y et al., found that radiographically guided diagnostic injections of foot and ankle symptomatic patients demonstrated better success in identifying the source of pain, confirming diagnosis in 90.9% of the patients and predicting success of surgical treatment with fusion of the affected joints [126]. However, in a contrast radiography study of 108 films of multiple anatomical sites in an oft-cited study, Jones et al. reported that 56 injections were intra-articular, 31 extra-articular; and in 21 the location was uncertain because of a lack of contrast in the radiograph [127] .

In contrast, Messina, et al., state that X-rays should be avoided when other radiation-free modalities such as (US can be used and note that the European Union directive 2013/59 clearly states that if a radiation-free imaging modality can achieve the same therapeutic and diagnostic results, it should invariably be used [128,129].

This is countered by the (earlier) work of Saifuddin, et al., who used computed tomography (CT) who concluded that CT is a simple and safe alternative to fluoroscopy for guiding diagnostic and therapeutic foot injections and may be the technique of choice in cases of disordered anatomy [130].

In a classic reference, Weston posits the following for the metacarpo- (and metatarso-) phalangeal joint technique:

> "The metacarpophalangeal joint is flexed to a right angle. The joint space is then easily palpated on the dorsolateral aspect of the joint on either side of the extensor tendon. Once the space is located, the 26-gauge needle is inserted through the extensor expansion, which fixes the needle. As the opaque medium enters the joint, the synovial cavity is distended. This can be palpated by the left index finger of the operator, which is placed on the palmar aspect of the joint. The distended cavity is tense and cystic, and it displaces the index finger away from the metacarpal head" [93].

Ultrasound

The use of US for guidance for interventional radiologic procedures is well known, including guidance for vascular and visceral interventions. Multiple authors state that US-guided injections are more accurate than landmark-guided CSIs though not all clinicians agree [2,105,106,131–150–153]. Sofka, et al., state that regional CSIs, traditionally performed using anatomic landmarks, can be inaccurate and miss their intended target [140]. They posit that the use of USS for guidance for interventional radiologic procedures is well known, and that using sonography to guide for interventions in the musculoskeletal system, specifically the foot and ankle, yields accurate placement of the needle tip and subsequent CS/LA injections (as well as diagnostic aspiration of tendon sheaths, joint spaces, and bursae).

Balint, et al., demonstrate the use of US to localise joint and soft tissue fluid collection greatly improved the rate of diagnostic synovial fluid aspiration, particularly in small joints [105]. 32 joints in 30 consecutive patients, referred for injection to an experienced consultant rheumatologist for joint aspiration and injection were aspirated in a conventional (non-guided) group.

In the US guided group, 31 consecutive patients were examined by US to confirm the presence and location of fluid. Following US examination, aspiration was performed by a second rheumatologist based on the US localization of fluid or under direct US guidance. Successful aspiration was achieved in 10 (32%) joints in the conventional group but in 31 (97%) joints in the US guided group.

Beard and Gousse suggests that using US to guide for interventions in the musculoskeletal system, specifically the foot and ankle, yields accurate placement of the needle tip and subsequent anesthetic/steroid injection, as well as diagnostic aspiration of tendon sheaths, joint spaces, and bursae[154]. They suggest that US is distinctly more accurate than landmark guidance for small joints. Daniels, et al., performed a comprehensive review of the literature for the accuracy of US-guided injections regardless of anatomic location[132]. In the lower extremity, the authors found that US-guided injections at the knee, ankle, and foot have superior efficacy to landmark-guided injections. Fredberg used air for correct placement of the needle before injection - the sterile air that is contained in the capped vial is used as a contrast medium [31]. The needle is guided into the joint space of the distended capsule by US.

Goldschmiedt, et al., describe the injection jet sign as colour Doppler flow that is directed away from the needle tip at the point of entry as well as the flow within, and often outlining the joint capsule or bursa as a method to assure the desired target delivery of the injectate [144].

Khosla, et al., demonstrated that needle placement was only correct in 3 of 14 (21%) and 4 of 14 (29%) cadavers using palpation guidance into 1st and 2nd tarsometatarsal joints, respectively [112]. US-guidance significantly improved the accuracy of needle placement for both joints.

Lucas et al. sought to determine the value of injections of LA and CSIs in the foot and ankle in localising the source of pain, and their effect on clinical confidence and decision making [155]. 106 intra- and extra-articular foot and ankle injections were performed on 47 patients. Questionnaires were completed by the referring surgeon before and after injections to evaluate the level of confidence regarding the source of pain for each site injected and the proposed treatment plan. Forty-three (91%) patients reported pain relief after injections. The level of confidence that the site injected was the source of pain increased in 68 (64%) sites, decreased in 19 (18%) sites, and remained unaltered in 19 (18%) sites. The treatment plan was changed from nonsurgical initially to surgical in three (8%) of 36 patients and was changed from surgical to nonsurgical in three (27%) of 11 patients after injections. Of the remaining eight patients, treatment was altered in three (37%) because of pain relief after the injections. The authors concluded that fluoroscopically guided injections of local anaesthetic and steroid in the foot and ankle can improve clinical confidence regarding the site of pain and may be valuable in clinical decision making and patient.

In a cadaveric mode, Muir, et al., found that US-guided peroneal tendon sheath injections were significantly more accurate than palpation-guided injections [136]. Nordberg, et al., study [152] indicates that the efficacy of IA injections varies according to US findings at the time of injection, supporting the use of US as a tool to select joints that will benefit from intra-articular injections, however, ultrasound needle-guidance was not superior to palpation-guidance. In the hand, Raza, et al., found that IA needle positioning was 59% accurate in palpation-guided injections and that no fluid could be aspirated prior to injection [137]. With US-guidance, initial IA needle placement was intra-articular in 96% of cases and that synovial fluid cells were lavaged from 63% of joints.

Sahler, et al., describe a longitudinal US-guided, in-plane approach for injection into the 1st MTPJ and assess its accuracy in a cadaveric model[58]. Ten 1st MTPJs were injected with 0.5 mL of dye under US-guidance. The joints were later dissected, and accuracy was classified as accurate, accurate with overflow, or inaccurate with no injection in the target area. Of the injections, nine were classified as accurate injections, and one was classified accurate with overflow. The authors concluded that US-guided injections of the 1st MTPJ can be accurately and reproducibly performed with a gel standoff, long-axis in-plane approach. This technique attempts to minimise the collateral damage to the surrounding tissue, specifically the articular cartilage.

The authors acknowledge the small sample size which was not powered to determine the true accuracy of this technique but with a relative accuracy was 100%, considered it strong enough to recommend as an acceptable alternative to palpation-guided 1st MTPJ injections.

Sibbitt, et al., found that sonographic needle guidance improves the performance and outcomes of IA injections in a clinically significant manner [139]. Schumacher provides a narrative review regarding the variety of IA therapies available and need comparison for indications, routes used for aspiration and injection, ease of use, benefits, and adverse reactions [156]. This review addresses all these aspects but focuses on neglected technical concerns.

Sconfienza, et al., report the results of a Delphi-based consensus of 53 experts from the European Society of Musculoskeletal Radiology (ESSR)[157]. The authors reviewed the literature for evidence on image-guided interventional procedures offered around foot and ankle to derive their clinical indications and drafted a list of statements. These were graded according to the Oxford CEMB centre for levels of evidence. 16 evidence-based statements on clinical indications for image-guided musculoskeletal interventional procedures in the foot and ankle were drafted. A consensus was considered strong when > 95% of experts agreed with the statement or broad when > 80% but < 95% agreed. The highest level of evidence was reported for four statements, all receiving 100% agreement.

Simkin suggests that inflamed synovial tissue comprises a large and completely appropriate target for injection by a clinician. In that situation, an injection that missed the pocket of fluid may have accurately hit the site of joint involvement in cases that otherwise would be considered "successful failures [158] . Sofka and Adler posit that regional corticosteroid injections, traditionally performed using anatomic landmarks, can be inaccurate and miss intended targets[140]. The use of ultrasound for guidance for interventional radiologic procedures is well known, including guidance for vascular as well as visceral interventions. Using sonography to guide for interventions in the musculoskeletal system, specifically the foot and ankle, yields accurate placement of the needle tip and subsequent CS/LA injection as well as diagnostic aspiration of tendon sheaths, joint spaces, and bursae.

Needle placement for sesamoid pathology has been considered by Wempe, et al., [159]. US guidance was used to accurately inject the 1st MTPJs of five unembalmed cadaveric lower limb specimens with blue-coloured latex. 24 hours after injection, each specimen was dissected to determine whether the latex was present between the metatarsal head and sesamoid bones (metatarsal-sesamoid articulations). In all 5 cadaveric specimens, US-guided 1st MTPJ injection accurately delivered latex into the joint and in each specimen, latex was seen between the metatarsal head and both the fibular and tibial sesamoid bones. The authors suggest that clinicians administering diagnostic or therapeutic injections for patients with sesamoid disorders should consider injecting the 1st MTPJ as an alternative to direct metatarsal-sesamoid articulation injections.

Discussion

Shoor [160] notes that the review by Arroll, et al,. [161] raises several questions: which group of OA patients are likely to respond to knee CSIs? Those with less severe disease or those with clinical evidence of inflammation such as an effusion? To what degree is the apparent success of intra-articular steroids affected by how the procedure is performed? For example, how much fluid is withdrawn if lavage is used rather than saline instillation? At what point in the treatment regimen should intra-articular corticosteroids be used (i.e., after or before NSAID or physical therapy)? What is the effective and safe interval for repeat injections? These questions remain largely unanswered for the 1st MTPJ.

So, how much does needle placement matter? The perceived wisdom is that if an injectate misses its target it is likely to be less effective and lead to false negative reporting of poor treatment outcomes, but the literature is not equivocal. Lopes, et al., state that blind injections prove safe and accurate when performed by a trained professional but without image guidance, how do we ensure accuracy of injection? [162] Hawker posits that about 50% of intra-articular and intralesional injections are placed incorrectly. The findings of the position statement by the American Medical Society for Sports Medicine indicate that there is strong evidence that US guided CSIs are more accurate than those that are landmark guided, moderate evidence that they are more efficacious, and preliminary evidence that they are

more cost-effective [163]. They also note that If an injectate is misplaced, it may lead to complications such as skin depigmentation, subcutaneous fat atrophy, tendon rupture, neurovascular injury, increased procedural and postprocedural pain, or intra-arterial injection.

Cunnington, et al., found that accurate injections led to greater improvement in joint function, as determined by VAS scores, at 6 weeks, as compared with inaccurate injections [103]. Schumaker considers that accuracy is critical as we continue to assess the value of joint injections[164]. Jones, et al., state that the steroid should be injected into the synovial space for IA infiltrations [165]. Lopes, et al., feels that accurate IA placement of the needle is a prerequisite for the achievement of desirable results and the avoidance of complications [162]. Sibbitt, et al., found that US guidance significantly improved the performance and outcomes of outpatient IA injections. Conversely, Cole and Schumaker note that the effects of IA corticosteroids - though variable - are frequently observed on non-injected involved joints, suggesting the importance of systemic effects [139,165]. Jones, et al., found that almost half of those with extra-articular CS placement experienced good therapeutic response, suggesting that total accuracy of needle placement may not be essential to a satisfactory outcome [165].

Hall and Buchbinder [150] ask:

1. Do radiologically guided corticosteroid injections confer any added clinical benefit over blinded injections in the short and long term?
2. If there are added benefits, is the routine use of imaging to improve the accuracy of steroid placement, cost effective?

They conclude that while some joints such as the hip and midtarsal joints demand imaging for any accuracy of steroid placement, for most joints which have conventionally been injected by rheumatologists following an anatomical landmark approach, imaging guided injection should be reserved for those cases who have not responded to injection following anatomical landmarks. Imaging is therefore recommended for joints by many authors that are difficult to access due to factors including site, degree of deformity and obesity [13,39,145,150,167]. Without radiological confirmation, it is difficult to ensure the exact location of the needle. Because of this - and practising defensively - many authors advocate the use of image guidance. But with Simkin suggesting that inflamed synovial tissue may often be the target for the CS, perhaps close is close enough [158]? Fortuitous, since needle placement is therefore often less accurate than many practitioners would suggest and even in the most experienced hands, large joint injections such as the shoulder and knee have demonstrated accuracy rates that have varied. The small joints and peritendinous areas of the foot and ankle present an even greater challenge to blind injection accuracy.

As the 1st MTPJ varies in size and shape, and it may be difficult to palpate in patients with conditions such as advanced degenerative arthritis and osteophyte formation [42,46,110]. This finding is of considerable importance because it is often the case that patients with pathologic changes who are offered these injections. Of the six joints in Heidari, et al., cadaveric injection study that had combined hallux valgus and hallux rigidus cases, two were not successfully punctured [110]. The understanding of anatomical landmarks of the foot and ankle is therefore relevant for correct needle placement [50]. Lungu and Moser target the articular recess and feel that the main theoretical advantage of targeting this point is that it facilitates IA injection when the joint space is obscured, either by patient positioning or degenerative changes to the joint (*reliable depth estimation can be provided by bone contact*) [62]. By targeting the articular recess, the needle path is often shorter, thus diminishing the number of structures whose integrity is compromised, and that this approach inflicts less pain to patients, they state. In practical terms, however, the dorsal recess of the 1st MTPJ is a small target.

Yablon provides a technical article on CSI considerations [142]. Yaftali & Weber also note that the use of image guidance can improve accuracy of IA placement of CSIs or hyaluronic acid injections[143]. D'Agostino, et al., found that use USS frequently led the physician to change his diagnosis of inflammatory lesions in painful foot, and consequently the planning of CSI injections with a probable improvement in the response to local treatment [168]. While many injections are given with anatomical- or palpation guidance on an outpatient basis, accurate needle placement can be aided by image guidance [138,154]. The accuracy of IA injection depends on the joint and on the skills of the practitioner, but use of imaging may improve accuracy.

Conclusion

The literature shows that CSIs of joints and periarticular structures are safe and effective when administered by an experienced physician. IA CSIs are effective for short-term relief of pain in OA but predicting the best responders is not currently possible. When injecting small synovial joints using palpated-guided methods, clinicians must be alert to the potential for failure of technique from the needle penetrating too far into the articulation and exiting the joint on the contralateral side from the entry point. Use of shorter needles and use of imaging, +/- use of radiopaque dyes, might reduce the number of such failures though as noted above, close might often be close enough.

The variability in outcomes following injection for 1st MPJ OA raises numerous questions: to what extent is pain reduced? Is joint function improved? Which patients are most likely to benefit from this treatment? What is the frequency with which corticosteroid should be administered and whether the use of image-guided injections improves treatment outcomes? The key information to produce would be delineate:

1. Which CS drug to use,
2. In what dose,
3. Targeting which patient at which point in their disease process,
4. With or without the use of local anesthesia,
5. With which injection technique,
6. With or without image guidance (or contrast media),
7. In which regimen (how many injections over what period),
8. With what post injection advice/follow-up,
9. For a given pathological condition (and given disease progression),
10. What short- and long-term complications are seen with CSIs.

The focus on future research should be on the use of CSIs for 1st MTP OA but high-level studies also need to be conducted for the role of IA CSI in the management of hallux abducto valgus, acute gout, sesamoiditis and arthrofibrosis. Arthrofibrosis is one of the most seen complications after hallux abducto valgus surgery and specifically warrants further consideration for research and evaluation of treatment outcomes.

Concurrently, the author has recorded several cases for the use of CSI in advanced cases of OA of the 1st MTPJ and will from part of a case series. Many patients have responded well in the mid-to long-term to IA CSI using 3-400mg IA CSI of triamcinolone acetonide. This case series will be produced according to CARE guidelines [169].

Declarations

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The author has no competing interests to declare.

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APPENDIX 9: A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint

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A systematic review of injectable corticosteroid for osteoarthritis of the first metatarsophalangeal joint

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Intra-articular steroid injection is a common treatment modality for relief of pain and inflammation associated with degenerative joint disease. Use of injectable steroid preparations is widely accepted as safe and effective for the treatment of osteoarthritis of the 1st metatarsophalangeal joint. Despite the frequency of use, literature specific to pathology of the 1st metatarsophalangeal joint is sparse. The aim of this systematic review was to determine if good quality research exists to enable clinicians to adopt an evidenced based approach to corticosteroid injection of the 1st metatarsophalangeal joint. Despite the frequency of use, this review found no high quality studies that support the use of intra-articular corticosteroid injection of the 1st metatarsophalangeal joint in osteoarthritis.

Keywords: steroid injection, first metatarsophalangeal joint, osteoarthritis, hallux rigidus, systematic review.

The use of injectable corticosteroid as part of a treatment strategy for painful joints is a common treatment modality. In degenerative disease the intended aim is to reduce the pain and inflammation associated with osteoarthritis (OA) as well as improve joint function [1]. The use of intra-articular (IA) corticosteroid injections (CSIs) for the treatment of OA is supported by guidelines provided by the United Kingdom (UK) National Institute for Health and Care Excellence (NICE) in patients who experience joint pain that is not adequately controlled by oral and/or topical options or where such treatment is contraindicated [2]. The basis for this guidance is largely derived from conclusions drawn from research into the efficacy of IA CSI's at the knee and shoulder [3,4]: data from these studies has been extrapolated and applied to other synovial joints such as the first metatarsophalangeal joint (1st MPJ).

Osteoarthritis is the leading cause of disability in adults worldwide and results in significant morbidity [5]. Joints in the foot are often affected by this condition with the 1st MPJ being most commonly affected pedal joint [6]. Symptomatic 1st MPJ OA affects approximately 10% of the adult population and the prevalence increases with age - as do comorbidities amongst sufferers – with the result that reduced pharmacological treatment options available for pain relief in these patients [7]. Symptoms arising from OA are notoriously difficult to manage with oral analgesics alone: this ultimately results in a significant burden on primary care services [8]. This provides the niche for IA CSI, i.e. where other conservative treatment has failed, is contraindicated or where there is a desire or requirement to postpone the need for surgical intervention. Unmanaged foot pain is an independent risk factor for depression and falls in adults [9,10,11].

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The authors are experienced injectors and are active in teaching CSI techniques to under- and postgraduate students. Anecdotally, we find that 80-90% of patients experience improvement following IA CSI for 1st MPJ OA but the extent and duration of that improvement varies. The variability in outcomes following CSI for 1st MPJ OA raises numerous questions: to what extent is pain reduced? Is joint function improved? Which patients are most likely to benefit from this treatment? What is the frequency with which corticosteroid should be administered and whether the use of ultrasound guided injections improves treatment outcomes [12,13,14]. Furthermore, there has been debate surrounding whether a steroid based solution, when combined with local analgesia, may even be chondrotoxic [15]. A Cochrane Review from 2010 [16] concerned with identifying optimal treatment modalities for 1st MPJ OA found low level evidence for physical therapy only. A systematic literature review was therefore undertaken (as part of a larger body of work being undertaken by the lead author) in order to identify randomized trials that had used IA CSI for OA of the 1st MPJ.

Methods

The research question is: *is the use of corticosteroid injections for osteoarthritis of the first metatarsophalangeal joint in adults a safe and effective method of reducing pain and improving joint function?*

In order to ensure a systematic review, minimize the risk of bias and provide transparency for replication of the process, a predetermined research methodology protocol was used, based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [17]. This was registered with PROSPERO. (Trial registration number: CRD42019135950. Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42019135950).

Selection criteria

Inclusion

Predetermined inclusion and exclusion criteria were used. Only systematic reviews, randomized controlled trials (RCTs), quasi randomized trials and controlled clinical trials were considered for inclusion as they form the hierarchy of evidence and are most likely to provide a robust evidence base suitable for informing clinical practice [18]. Those papers found were then screened for the following criteria:

- Trials in which an IA CSI into the 1st MPJ used for the treatment of OA in adults,
- Diagnosis and grading of OA in participants could be achieved via clinical examination and/ or via radiological means [19],
- Any gender or ethnicity was considered.

In order to be able to determine the efficacy of treatment, trials were required to have provided quantitative or qualitative measures both pre- and post-intervention in order to be able to ascertain the mean differences relating to pain and/or joint function outcomes.

Exclusion

Trials in which intradermal, subcutaneous, intramuscular or extracapsular corticosteroid injections were performed were excluded, as were not trials that tested the efficacy of IA CSIs for conditions other than for OA, or tested CSIs at joints other than the 1st MPJ. Due to the high risk of bias, cohort and case studies, articles based on expert opinion, retrospective studies and narrative-based literature reviews were excluded [18].

Search strategy and data sources

To answer the research question a keyword search of six electronic databases (AMED, CINAHL, EMBASE, MEDLINE, PUBMED, and COCHRANE) up to February 2020 was undertaken by graduate research podiatrist (GB) to identify clinical trials that had tested the efficacy of IA CSI for the treatment of 1st MPJ OA.

AMED (1985 to 05.02.2020)

CINAHL (1982 to 05.02.2020)

EMBASE (1974 to 05.02.2020)

MEDLINE (1950 to 05.02.2020)

PUBMED (1966 to 05.02.2020)

COCHRANE (1966 to 05.02.2020)

No date or language restrictions were applied. Reference lists were reviewed, and key author searches were made to reduce the risk of any pertinent literature being missed. A list of keywords and results yielded are provided in Table 1.

#	Database	Search term	Results
1	AMED	(osteoarthritis).ti,ab	2945
2	AMED	(hallux).ti,ab	1252
3	AMED	(metatarsophalangeal).ti,ab	771
4	AMED	(injection).ti,ab	2035
5	AMED	(steroid).ti,ab	454
6	AMED	(hallux limitus).ti,ab	62
7	AMED	(hallux rigidus).ti,ab	178
8	AMED	(1 AND 2)	35
9	AMED	(1 AND 3)	37
10	AMED	(6 OR 7 OR 8 OR 9)	272
11	AMED	(4 AND 10)	5
23	CINAHL	(osteoarthritis).ti,ab	21838
24	CINAHL	(hallux).ti,ab	2033
25	CINAHL	(metatarsophalangeal).ti,ab	1197
26	CINAHL	(injection).ti,ab	43132
27	CINAHL	(steroid).ti,ab	15241
28	CINAHL	(hallux limitus).ti,ab	100
29	CINAHL	(hallux rigidus).ti,ab	319
30	CINAHL	(23 AND 24)	63
31	CINAHL	(23 AND 25)	82
32	CINAHL	(28 OR 29 OR 30 OR 31)	472
33	CINAHL	(26 AND 32)	13
34	EMBASE	(osteoarthritis).ti,ab	79498
35	EMBASE	(hallux).ti,ab	5812
36	EMBASE	(metatarsophalangeal).ti,ab	3924
37	EMBASE	(injection).ti,ab	581417
38	EMBASE	(steroid).ti,ab	163137
39	EMBASE	(hallux limitus).ti,ab	153
40	EMBASE	(hallux rigidus).ti,ab	664
41	EMBASE	(34 AND 35)	183
42	EMBASE	(34 AND 36)	258
43	EMBASE	(39 OR 40 OR 41 OR 42)	1068
44	EMBASE	(37 AND 43)	21
45	EMBASE	(38 AND 43)	12
46	CINAHL	(27 AND 32)	5
48	AMED	(5 AND 10)	4
49	Medline	(osteoarthritis).ti,ab	54837
50	Medline	(hallux).ti,ab	4904
51	Medline	(metatarsophalangeal).ti,ab	3209
52	Medline	(injection).ti,ab	449653
53	Medline	(steroid).ti,ab	125109
54	Medline	(hallux limitus).ti,ab	139
55	Medline	(hallux rigidus).ti,ab	586
56	Medline	(49 AND 50)	137
57	Medline	(49 AND 51)	189
58	Medline	(54 OR 55 OR 56 OR 57)	858
59	Medline	(52 AND 58)	13
60	Medline	(53 AND 58)	5
61	PubMed	(osteoarthritis).ti,ab	80277
62	PubMed	(hallux).ti,ab	6554
63	PubMed	(metatarsophalangeal).ti,ab	4096
64	PubMed	(injection).ti,ab	708493
65	PubMed	(steroid).ti,ab	936715
66	PubMed	(hallux limitus).ti,ab	167
67	PubMed	(hallux rigidus).ti,ab	656
68	PubMed	(61 AND 62)	251
69	PubMed	(61 AND 63)	298
70	PubMed	(66 OR 67 OR 68 OR 69)	1054
71	PubMed	(64 AND 70)	26
72	PubMed	(65 AND 70)	10

Table 1 Search terminology and results yielded by database.

Risk of bias

In order to assess their validity, RCTs were reviewed using the Critical Appraisal Skills Programme (CASP) checklist [20], which uses six quality assessments of studies and considers the risk of (selection, performance, detection, attrition and reporting) bias. Systematic reviews were appraised using a Centre for Evidence-Based Medicine (CEBM) appraisal tool for systematic reviews [21] which uses six quality assessments to determine validity of reviews based on methodological design. Each quality assessment for data was awarded a 'low', 'high' or 'unclear' risk of bias. Two reviewers independently (GB, GF) appraised the studies and results were collated. If there was disparity between results, a discussion was to be raised. If consensus could not be achieved the senior author (INR - a consultant podiatric surgeon with a special interest in injection therapy) was appointed to make the final decision. Evidence from the identified literature was considered and an appropriate weighting awarded based on the quality of evidence they provided.

Initial inter-rater results following an appraisal of studies was 84% consistent between two reviewers. Following a discussion regarding the variation in quality assessment, 100% consensus between reviewers was achieved. Evidence from the identified literature was considered and an appropriate weighting awarded based on the quality of evidence they provided. Themes regarding joint pain, function and the safety of CSIs are discussed. Due to only one RCT being identified for inclusion, no meta-analysis was possible.

Data extraction

Data was extracted from research that fulfilled the inclusion criteria by using a predetermined list of parameters to determine the efficacy of the intervention and validity of methods used for testing.

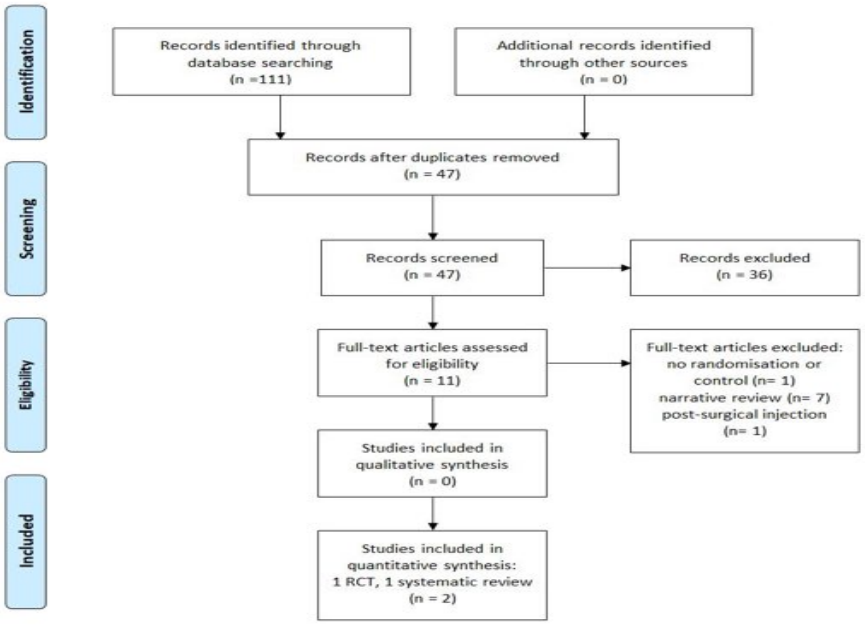

Figure 1 PRISMA flow chart for trials selected for review [17].

These parameters considered: the design of study, sample size, demographics, diagnostic criteria used, disease severity, intervention tested (type, dosage, method of administration), outcomes, follow up and results. Reported adverse effects (type, duration and severity) were recorded to determine the safety of the intervention. Data from these themes was entered into a spreadsheet to be used for discussion.

Results

A search of electronic databases identified 111 studies for possible inclusion. Sixty-four duplicates were excluded and 47 titles and abstracts were assessed. Titles and abstracts were assessed independently (GB and GF) and evaluated against the aims of this study and its predetermined selection criteria. Full-text articles believed to be appropriate were accessed and further assessed for relevance against the predetermined inclusion criteria. If there was a difference in opinion as to whether an article should be included for review, a discussion was raised between the two main authors and if it was not possible to reach a consensus then the senior author was given the final vote on selection. 36 articles were rejected and 11 full-text articles were retrieved for assessment against the selection criteria (Figure 1). One RCT and one systematic review were identified for inclusion in this review.

Randomized controlled trials

One single blinded randomized trial that compared the efficacy of a single dose of intra-articular triamcinolone acetonide (TA) with sodium hyaluronate (SH) delivered without image guidance for mild symptomatic hallux rigidus in thirty-seven adults was identified for inclusion [22] – see Table 2. The title of the paper was misleading (sodium hyaluronate in the treatment of hallux rigidus. A single blind randomized study) in that its use of CSI was not mentioned.

Pons et al. 2007 [22]			
Quality Assessment:	Result:	Bias Risk:	Quality score:
Did the trial ask a clearly focused question?	Yes	Screening question	2/2
Was the assignment of patients randomized?	Unclear	Selection bias	1/2
Were all the patients who entered the trial properly accounted for at its conclusion?	Yes	Attrition bias, reporting bias	2/2
Were patients, health care workers and study personnel 'blind' to treatment?	No	Performance bias, detection bias	0/2
Were the groups similar at the start of the trial?	Unclear	Selection bias	1/2
Aside from the experimental intervention, were the groups treated equally?	Yes	Performance bias	2/2

Table 2 Quality assessment of randomised controlled trials (CASP checklist).

Zammit et al. 2010 [16]		
Quality Assessment:	Result:	Quality Score:
What question did the systematic review address?	Which interventions are optimal for treating osteoarthritis of the big toe?	2/2
Is it unlikely that important, relevant studies were missed?	Yes	2/2
Were the criteria used to select articles for inclusion appropriate?	Yes	2/2
Were the included studies sufficiently valid for the type of question asked?	No, identified a lack of available evidence and high risk of bias.	0/2
Were the results similar from study to study?	One study identified for inclusion only.	0/2

Table 3 Quality assessment of systematic reviews (CEBM framework).

Changes in joint pain and function

A reduction in mean visual analogue scale (VAS) pain scores at rest or on palpation was observed in both treatment groups. Mean VAS scores (n/100 mm) reduced at baseline from 58.7 mm to 34.1 mm in the TA group. A significant decrease in dorsiflexion or plantarflexion VAS pain scores was also observed in both groups: mean VAS scores decreased from 64.2 mm to 41.6 mm in the TA group. TH demonstrated reduced improvement in VAS pain scores on walking 20 metres compared to SH. Recipients of TA were reported to have a mean improvement in hallux function of 4.1 on the American Orthopaedic Foot and Ankle Society Score (AOFAS) for hallux evaluation. Overall, TA was found to be inferior in terms of the number positive responders to treatment, pain reduction and improvement in hallux function when compared to those treated with SH. Benefits were reported as relatively short lasting in both arms of the trial: 52.9% in the TA group and 46.6 % in the SH group progressed to surgery within 12 months.

The mean quality score for the RCT reviewed was 66% demonstrating limited methodological quality and potential bias. In this trial there was no attempt to blind investigators involved in data collection and evaluation of outcome measures. The trial had a small sample size with a significant female gender bias and all participants had mild joint disease potentially limiting the application of conclusions drawn from this to other patient populations. However, the most significant limitation with this trial was that interventions were administered to participants with 1st MPJ OA *and* hallux valgus with no sub-group analysis provided according to condition. This caused the paper to be rejected from the 2015 Cochrane review [16]. Given that the underlying pathophysiology of these distinct conditions differs, it is reasonable to expect that treatment outcomes relating to joint pain and function following an IA SCI may vary between recipients with different conditions. Furthermore, the proportion of recipients reported to have progressed to surgery may have been skewed given that the usual treatment for hallux valgus is surgical correction of the deformity. From this trial it was not possible to determine the efficacy of corticosteroids as an intervention to treat osteoarthritis at the 1st MPJ.

Adverse effects

Similarly, the lack of blinding in data collection and evaluation of adverse effects associated with the interventions administered poses a significant bias risk. Due to the lack of sub group analysis it was not possible to determine whether the frequency or type

of adverse effects differed by condition. Data relating to adverse effects was collected by non-blinded investigators post intervention, were mild and arose in just 5% of recipients; no serious adverse effects were reported.

Systematic reviews

A recent review [14] that set out to provide a comprehensive list of evidence-based recommendations regarding conservative treatment modalities for 1st MPJ OA included a review of injection therapy. Authors of the review found 'fair evidence' to support the use of IA CSIs to treat 1st MPJ OA. However, the methodology was neither systematic nor comprehensive: only a single database was searched for clinical trials and the risk of pertinent literature having been missed was high. The author's recommendations were made based on an appraisal system [23] that allocates a level of evidence for an intervention based solely on the design of studies identified; it does not consider the methodological quality of trials or risk of bias. Rama [24] pointed out that this system is a derivative of the levels of evidence system [25] and cautioned regarding the limitations of this style of review. He highlighted the need to not generalise evidence in order to avoid misleading conclusions being drawn.

The injection therapy trials identified in this review lacked heterogeneity in terms of solutions tested and design of trials. In spite of this, the authors grouped six trials relating to injection therapy together for data analysis and a collective level of evidence was allocated to injection therapy as a whole. Since this review did not consider the risk of bias and validity or clinical significance of outcomes from trials it identified, and failed to use a systematic methodology the study was excluded from this review as it was deemed to provide a summary of interventions for healthcare professionals only [24].

This review identified one systematic review that considered the efficacy of any treatment modality, including but not limited to injection therapy, for 1st MPJ OA [16]. The 2010 systematic review (see table 3) was a comprehensive piece of research with high quality methodology and low risk of bias. It identified one low quality study with a high risk of bias to support the use of physical therapy to reduce the pain of osteoarthritis at the big toe joint. It found no evidence to support the efficacy of corticosteroid injections for hallux rigidus (see note above re Pons et al, 2007).

Discussion

Originally suggested by Cotterill in 1887 [26], hallux rigidus/limitus (1st MPJ OA) are terms used to describe arthritic changes at the 1st MPJ. Many theories regarding the etiology of 1st MPJ OA have been postulated. Traditionally, osteoarthritis was viewed simply as a degenerative condition characterized by the degeneration of joint cartilage over time that resulted in progressive pain, stiffness and loss of joint function. However, a greater understanding of the pathophysiology of osteoarthritis indicates that symptoms arising from the disease are caused by the body's attempt to repair damaged cartilage and that it is this process of repair and remodelling that results in abnormal bone growth and inflammation that involves the entire joint [16].

In a review of 114 patients it was found that irrespective of age, females are twice as likely to develop 1st MPJ OA [27]. A positive family history is strongly associated with bilateral joint disease, whereas unilateral joint involvement is often precipitated by trauma and does not routinely progress to involve both feet. Little consensus exists between studies regarding other possible causes although Coughlin and Shurnas [27] discuss pes planus, Achilles tendon contracture, hallux valgus, hallux valgus interphalangeus, a flat metatarsal head, metatarsus adductus, a long first metatarsal, metatarsus primus elevatus, and first ray hypermobility in the development of this condition. Furthermore, a number of recent retrospective studies that have considered the natural course of 1st MPJ OA suggest that progression of the disease is far more variable than previously thought and that for many it may follow a more benign course with symptoms that can be adequately managed with conservative treatment methods such as physical, mechanical or pharmacological therapy [28]. It is therefore increasingly important for clinicians to understand when to administer IA CSIs and which patients would derive the greatest benefit from treatment.

Corticosteroid is a synthetic version of the endogenous hormone glucocorticoid found in vertebrates that is produced in the adrenal gland cortex. Amongst its other functions in the cardiovascular, metabolic and nervous systems; glucocorticoids provide a feedback mechanism within the immune system to reduce inflammation. Synthetic corticosteroids administered orally or via injection can be exploited to mimic this action and can be used to suppress unwanted, immune mediated

inflammatory responses caused by many disease processes including osteoarthritis. Corticosteroids act to reduce inflammation and suppress the immune response at various levels:

- Leukocytes and monocytes transform into macrophages, a larger and more bactericidal cell that releases lysosomal enzymes that ushers in further inflammatory processes. By suppressing the adhesion of leukocytes, the formation of macrophages is reduced which inhibits the release of lysosomal enzyme and leads to a reduction in further inflammation [29].

- Lymphocytes aid in activation of T cells and macrophages that have been produced causing rapid division and cytokine secretion. Cytokines are associated with both the initial activation and ongoing sensitization of the nociceptive receptors on sensory neurons perceived as chronic pain mediators. By reducing the effect of lymphocytes by depleting the amount of T cells and secretion of cytokines pain is reduced [30].

- Cytokines are also responsible for releasing eicosanoid, a signalling molecule that stimulates other inflammatory mediators including histamine and prostaglandins. Both histamine and prostaglandins cause vasodilation of the surrounding blood vessels. This vasodilation leads to increased swelling and also contributes to the sensitisation of nerves resulting in pain perception. By reducing vasodilation and stimulation of pain receptors swelling and pain are reduced [31].

This systematic review was conducted in order to assess the effectiveness and safety of intra-articular corticosteroid injection as a treatment modality for 1st MPJ OA. A thorough and systematic literature search was completed in order to identify pertinent literature on the subject area and forty-seven studies were identified for possible inclusion. After exclusions were applied from the selection criteria to ensure that the correct condition, joint and treatment were being considered 11 pieces of literature remained of which two have been considered in detail. The remaining literature was mainly comprised of studies that provide low level evidence such as narrative reviews, retrospective case studies or non-controlled clinical trials.

One single blind randomized trial that compared the efficacy of a single corticosteroid injection with hyaluronate was identified [22]. A critical appraisal of this trial found it to have a high risk of bias. Furthermore, the solutions administered to participants were for two distinct conditions, hallux valgus and hallux rigidus and no details for sub group analysis were provided. It was therefore not possible to determine what influence this may have had on the outcome measures relating to pain reduction and improved joint function for hallux rigidus. From this trial it was not possible to determine with any level of certainty or specificity the efficacy of corticosteroids as an intervention to treat osteoarthritis at the hallux.

CSIs are generally considered safe drugs with steroid flare being the most commonly reported adverse event, though rare complications that may arise following administration of intra-articular steroid including anaphylaxis, disturbance of menstrual pattern and avascular necrosis [32]. Data relating to adverse effects was collected by Pons, et al., post intervention were mild, and arose in just 5% of recipients. It was not possible to determine the quality of reporting of adverse effects in this trial or whether adverse effects arose in hallux valgus and/or hallux rigidus joints. However, the reported rate of adverse effects is homogenous with the 6% rate of mild adverse effects reported by following 1,708 steroid injections into both soft tissue and joints of the foot and ankle [33]. The most common side effect reported was a steroid 'flare', an acute inflammatory reaction to the steroid solution which made up 75% of the reported side effects. Vasovagal episodes, facial flushing, local skin reactions, short term paraesthesia and a temporary increase in blood glucose levels were also reported but were rare. No infections were reported by the study, a result consistent with the view that joint infection is a very rare complication resulting in septic arthritis. No adverse effects following the administration of 22 CSIs for hallux rigidus were noted by Grice, et al., [34] although they do report that the positive results (seen in 20 of the 22 patients) only lasted longer than three months in three of that cohort. At two years, two patients (9%) remained asymptomatic, but 12 patients (55%) had undergone surgery. Peterson and Hodler [35] and Kilmartin [36] also note that most adverse effects experienced following an intra-articular joint injection of steroid are mild and transient and can be managed by the patient with self-care advice. These papers support the anecdotal view that in general, CSIs are safe and that adverse effects tend to be moderate and time-limited.

Numerous narrative reviews exist regarding treatments for hallux rigidus and include CSIs but provide no evidence-based recommendations for treatment. An exception to this was a comprehensive review [14], the aim of which was to provide evidence-based recommendations regarding conservative treatment modalities for hallux rigidus and included a review of injection therapy. Authors of the review based their recommendations on an established appraisal system [23] that allocates a level of evidence for an intervention based on the design of studies identified. Rama [24] pointed out that this system is a derivative of the widely established levels of evidence system [25] and cautioned regarding the limitations of this style of review. He highlighted the need to not generalize evidence in order to avoid misleading conclusions being drawn. King, et al., grouped six trials relating to injection therapy together for data analysis regardless of the fact that interventions and trial designs differed. A 'collective' level of evidence was allocated to injection therapy in general rather than by individual solutions. This led to skewed results given that the quality of trial design that had tested hyaluronate was superior to other interventions such as corticosteroid. Given that this review did not use a methodology that considered the risk of bias, validity or clinical significance of results of trials this study was excluded from this review as it was deemed to provide a narrative review.

One systematic literature review that included an appraisal of the efficacy of corticosteroid injections for osteoarthritis at the big toe joint [16] was included in this review. The Cochrane review was well designed, well executed and found to have a low risk of bias. Zammit, et al., [16] did not identify any robust evidence to support the efficacy of corticosteroid injections for the treatment of hallux rigidus and made no recommendations regarding its safety due to the high risk of bias. This view is consistent with the findings of this review that found it was only possible to make generalizations relating to the safety of intra-articular corticosteroid injections.

This review did not find evidence of sufficient quality to confirm whether intra-articular corticosteroid injections are an effective intervention for the management of symptomatic osteoarthritis at the 1st MPJ. The current literature that exists was found to be of poor methodological design. In the only randomized controlled clinical trial that tested corticosteroid, it was found to be mildly inferior to hyaluronate in terms of pain reduction for patients with mild osteoarthritis [22]. However, in a robust randomized placebo controlled [38] trial of intra-articular injections for osteoarthritis no benefit was derived from sodium hyaluronate vs saline placebo.

Conclusion

There are a number of narrative reviews concerned with the conservative and surgical treatment modalities that can be used to inform the management of symptomatic hallux rigidus. A number of cases and retrospective [26,27] studies have evaluated the use of injectable corticosteroids in the foot or ankle but controlled clinical trials in this area are few.

Many interventions exist that are intended to reduce the symptoms associated with OA of the 1st MPJ. In spite of the lack of evidence to support their use, IA CSI remains popular amongst health care professionals and patients alike because they are quick and inexpensive to administer with the perception of rapid relief, minimal recovery time and few side effects [32]. In cases of mild osteoarthritis, some retrospective studies indicate that CSIs may provide months and occasionally, years of relief for hallux rigidus [28]; a retrospective study by Smith, et al., in 2000 [37] found 75% of patients that had previously declined surgical treatment for symptomatic hallux rigidus were happy with this decision, had not experienced an increase in pain undergone despite degeneration of the joint, and were able to manage symptoms with stiff soled shoes and accommodative footwear. It is unclear whether progression to surgery has any association with the administration of intra-articular corticosteroid but given the risk of chondrotoxicity [15] this warrants further investigation.

This review found no high quality evidence to support the use of IA CSI as an effective treatment modality for symptomatic 1st MPJ OA. Uncertainty regarding variables that may influence treatment outcomes such as concomitant footwear use [39] remains. Existing research that tested intra-articular corticosteroid was found to be of poor methodological design with a high risk of bias. High quality, randomized, controlled clinical trials that test the efficacy of IA CSI are required. The severity of 1st MPJ OA amongst recipients in trials should be classified prior to intervention by clinical and radiological examination [19] and a sub group analysis

of outcome measures provided according to disease severity. Further research to determine whether treatment outcomes are improved by the use of image guidance, extrapolation of side effects [40] and whether the use of IA CSI in 1st MPJ reduces surgical burden would be beneficial.

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APPENDIX 10: Best practice CSI technique

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MEDICINE

Palpation-Guided Intra-articular Injection of the First Metatarsophalangeal Joint: Injection Technique and Safe Practice for Novice Practitioners

Ian Reilly [1,2,3]

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Abstract
Injection of a glucocorticoid for the relief of vertebrogenic, arthritic and radiculopathic pain is widely accepted. Diarthrodial joints are especially well suited to intra-articular injection, and the local delivery of therapeutics in this fashion brings several potential advantages to the treatment of a wide range of arthropathies. Injectable glucocorticoids are used in the first metatarsophalangeal joint (1st MTP jt) to treat various forms of joint pathology such as osteoarthritis (hallux rigidus) and gout, but no standard protocol for injection of this joint exists. In their document 'Promoting Safer Use of Injectable Medicines' the National Patient Safety Agency identified a number of latent system risks and produced a series of templates for prescribing, preparing and administering injectable medicines. The two aims of this paper are to promote injection technique safety and to offer a palpation-guided 1st MTP jt injection technique, prior to further work which will be undertaken to validate injection placement accuracy.

Keywords First metatarsophalangeal joint · Steroid injection · Palpation-guided · Injectable medicine safety · Hallux limitus · Hallux rigidus · Osteoarthritis

Introduction

Injection of a glucocorticoid for the relief of vertebrogenic, arthritic and radiculopathic pain is widely accepted [1, 2]. Diarthrodial joints are well suited to intra-articular injection, and the local delivery of therapeutics in this fashion brings several potential advantages to the treatment of a wide range of arthropathies. Chief of these is a good safety profile (if administered correctly) with less chance of systemic exposure and undesired off-target effects [3]. As well as eliminating patient compliance issues, this route of administration overcomes concerns about bioavailability, uncontrollable drug dosing and the effects of drug binding to systemic molecules that can limit the efficacy of a substance administered via enteral delivery [4, 5]. Injectable glucocorticoids are widely used in the first metatarsophalangeal joint (1st MTP jt) to treat various forms of joint pathology such as osteoarthritis (hallux rigidus) and gout [6–21] but no standard protocol for injection of this joint exists. The primary aim of this paper is to describe the author's technique prior to further work which will be undertaken to validate injection placement accuracy.

The secondary aim of this paper is to promote injection technique safety. While the use of injectable medication has many healthcare benefits for patients, the complexities associated with the preparation and administration of injectable medicines mean that there are greater potential risks for patients than for other routes of administration [22]. The four main considerations regarding injections are the route, site, technique and equipment [23]. Weak operating systems increase the potential risk of harm, and safe systems of work are needed to minimize these risks. Between January 2005 and June 2006, the UK National Patient Safety Agency (NPSA: archived on 30.10.17) received around 800 reports per month relating to injectable medicines. That represented approximately 24% of the total number of medication incidents. The

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majority of these resulted in no or low harm to patients; however, there were 25 incidents of death and 28 of serious harm reported between January 2005 and June 2006. In their document 'Promoting Safer Use of Injectable Medicines' [22], the NPSA identified a number of latent system risks and produced a series of templates for prescribing, preparing and administering injectable medicines, which are referenced below. The authors acknowledge that local guidelines may take precedent over parts of the suggested technique, for example the use of skin preparation and donning of gloves varies between authors.

Literature Review and Injection Technique

The following databases were searched via the NHS Healthcare Advanced Database Search (HDAS) search engine: AMED, CINAHL, EMBASE, EMCARE, Medline and PubMed using MeSh terms and free text keywords **steroid* plus *inject** plus *hallux**, with a second search performed on injection safety. A brief overview of the anatomy of the 1st MTP jt will be presented first.

Anatomy of the 1st MTP jt

The 1st MTP jt is a condyloid synovial structure [24]. It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTP jt in contradistinction to the lesser MTP jts [25]. The metatarsosesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The six muscles are abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis. The ligaments of the joint are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the inter-sesamoid ligament and the hood ligament [26].

The metatarsal head has medial and lateral epicondyles from which the collateral and suspensory ligaments originate. The collateral and sesamoid ligaments run forward and downward to attach to the base of the proximal phalanx and the appropriate sesamoid. The hood ligament is a fibrous expansion from the long extensor tendon which encloses the tendon and attaches to the sides and plantar surface of the proximal and distal phalanx and blends with the joint capsule. The base of the proximal phalanx is concave and has a large base to receive its muscular and ligamentous attachments [27].

The sesamoids are often likened in shape to coffee beans and are embedded in the plantar pad which is a mass of dense fibrous tissue attached firmly to the base of the proximal phalanx. On the plantar surface of the metatarsal, there are two grooves for the articulation of the sesamoid bones which are separated by the sesamoid crista. The lateral margins of the plantar pad receive ligamentous and muscular attachments and the proximal border receives part of the flexor hallucis tendon. The plantar surface of the pad is raised on either side by the two sesamoids to form a groove for the long flexor tendon held in place by a fibrous tunnel [27]. The sesamoids' function is to absorb weight-bearing forces, decrease friction, protect the flexor hallucis brevis tendons and increase the functional length of metatarsal in propulsion [28].

A Framework for Safe, Palpation-Guided Injections

The author's technique is based on his earlier work [17], the injection safety frameworks put forward by the NPSA [29–32], and with technique tips incorporated from key authors identified by the literature review [9, 10, 33–41].

Knowledge and Understanding Required by the Clinician

The following is based on the NPSA documentation, modified for this injection technique.

Legislation, Regulations and Guidelines

1. An in-depth understanding of national and local injectable medication guidelines and their application.
2. An in-depth understanding of the national and local prescribing guidelines.
3. A working understanding of the guidelines on the administration of medicines.
4. A working understanding of local guidelines for waste and sharps handling and disposal.
5. A working understanding of risk management, patient safety principles and causes of medication errors.

Clinical Knowledge

6. An in-depth understanding of the indications and contraindications for the injectable medication.
7. An in-depth understanding of principles and practice of administering/prescribing injectable medication.
8. An in-depth understanding of drug dosages, dose dilution and drug delivery appropriate to the injectable medication.
9. An in-depth understanding of the side effects of injectable medicines and their assessment, monitoring, prevention and management.

10. An in-depth understanding of diagnosis, care plans, protocols and guidelines.
11. An in-depth understanding of the normal and pathoanatomy of the 1st MTP jt.

Technical Knowledge

12. A working understanding of injection equipment.
13. A working understanding of administration by the intra-articular route.

Procedures and Patient Management

14. A factual knowledge of the roles and responsibilities of other team members.
15. A working understanding of the limits of one's own knowledge and experience and the importance of not operating beyond these.

Pre-injection Preparation

The following is based on the NPSA documentation, modified for this injection technique.

Pre-injection Checklist

16. Read the patient's notes, drug monologue (available from the manufacturer and/or nation formularies) and any relevant protocols/clinical guidelines
17. Identify any special instructions, investigations (e.g. diagnostic imaging), baseline parameters or issues for which you need to seek advice.
18. Determine the appropriate regimen for the patient: which medication to use, what dose, the frequency and the nature type of post-injection monitoring, e.g. post-injection observation for syncope.
19. Assess the appropriateness of the intended treatment against the patient's current health status and concurrent medication, particularly in relation to intended therapeutic outcomes and potential drug interactions with concurrent medication.
20. Prescribe/administer according to legislation, national and local prescribing guidelines and relevant clinical information to ensure safe and optimal delivery of treatment.
21. If working under a prescription, include the following information:

- the patient's name, hospital number, date of birth and address;
- the allergy status of the patient;
- the date and time;
- the approved name of the injectable medication (in full, do not abbreviate);
- the dose;
- the route of administration (intra-articular);
- the number of doses;
- the prescriber's signature.

22. Explain and confirm understanding of the treatment and potential side effects (and their management) to the patient and/or carer and accurately answer any questions at a level and pace that is appropriate to:

- their level of understanding;
- their culture and background;
- their preferred ways of communicating;
- their needs.

23. Local policy will dictate the method of informed consent, e.g. with/without use of written consent form.
24. Use of patient information leaflets (PILs) will aid (and not replace) the informed consent process.
25. Communicate with appropriate professional colleagues as required by local guidelines.
26. Recognize when you need help and seek advice and support from an appropriate source when the needs of the individual and the complexity of the case are beyond your competence and capability.

Equipment Checklist

27. Assuming all necessary resuscitation equipment is in-date, serviced and to hand, check the medication(s) to be used against the treatment plan, prescription, patient information and local protocol with regard to:

- patient's identification (and on labelled medication where necessary);
- allergy status (where relevant for the medication involved);
- critical test results (including blood results);
- individual medication name, dose and regimen;
- expiry date/time of the medication.

28. Be able to assemble the required materials in a clean location designated for the task. This area should be uncluttered and free from interruption and distraction. Materials will include medication ampoules/vials, needle(s), alcohol wipes, disposable protective gloves, clean re-useable plastic tray and a sharps bin for disposal of waste.

29. Check product/packaging and containers for damage and ensure that the materials have not passed their expiry date. Check that storage up to this point has been as required, for example, temperature controlled.
30. Calculate the volume of medication required to give the desired dose.
31. If multiple preparations of injectable medications are being undertaken, or if there is a delay between preparation and administration, syringes should be labelled immediately, according to local policy.
32. Labels used on injectable medicines prepared in clinical areas should contain the following information:

- name of the medicine;
- strength;
- route of administration;
- diluent and final volume;
- patient's name;
- expiry date and time;
- name of the practitioner preparing the medicine.

33. Do not leave unlabelled syringes in the presence of other unlabelled medication, as this may lead to error.
34. Cleanse hands according to local policy (optional: use of disposable gloves). Disinfect the surface of the plastic tray in which preparation is to be undertaken.
35. Arrange the medication, syringes and needles on the tray and using an aseptic non-touch technique (ANTT), i.e. avoid touching areas where bacterial contamination may be introduced.
36. If required, place the syringe, the empty ampoule/vial in a clean tray for transportation to the patient for immediate administration.
37. Communicate with appropriate professional colleagues, as required by local guidelines.
38. Recognize when you need help and seek advice and support from an appropriate source when the needs of the individual and the complexity of the case are beyond your competence and capability.

Injectate Preparation

39. Prepare the medication according to prescription requirements, with reference to relevant technical information or local guidelines.
40. Use an aseptic non-touch technique (ANTT), i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe-tips, needles, vial tops. Never put down a syringe attached to an unsheathed needle.
41. Withdrawing solution from an ampoule (glass or plastic) into a syringe:

- Tap the ampoule gently to dislodge any medicine in the neck;
- Snap open the neck of glass ampoules, using an ampoule snapper if required;
- Attach a 19-gauge filter needle to a syringe and draw the required volume of solution into the syringe. Tilt the ampoule if necessary;
- The necks of some plastic ampoules are designed to connect directly a syringe without use of a needle, after the top of the ampoule has been twisted off;
- If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe;
- Invert the syringe and tap lightly to aggregate the air bubbles at the needle end;
- Expel the air carefully;
- Remove the needle from the syringe and fit a new needle (23/25 gauge) or sterile blind hub;
- Keep the ampoule and any unused medicine until administration to the patient is complete to enable further checking procedures to be undertaken.

42. Withdrawing a solution or suspension from a vial into a syringe (see Fig. 1):

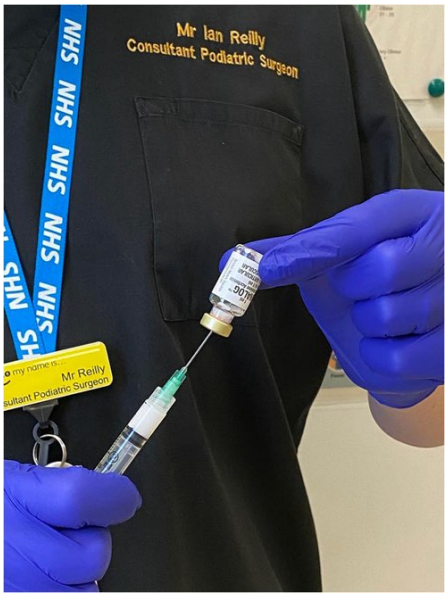

Fig. 1 Withdrawing a solution or suspension from a vial into a syringe

- Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 s;
- With the needle (19/21 gauge) sheathed, draw a volume of air into the syringe equivalent to the required volume of solution to be drawn up;
- If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents, immediately before they are drawn into the syringe;
- Remove the needle cover and insert the needle into the vial through the rubber septum;
- Invert the vial. Keep the needle in the solution and slowly depress the plunger to push air into the vial;
- Release the plunger so that solution flows back into the syringe;
- If a large volume of solution is to be withdrawn, use a push-pull technique. Repeatedly inject small volumes of air and draw up an equal volume of solution until the required total is reached. This 'equilibrium method' helps to minimize the build-up of pressure in the vial;
- Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage;
- With the vial still attached, invert the syringe. With the needle and vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial;
- Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial;
- Expel excess air from the syringe. Remove the needle and exchange it for a new needle (23/25 gauge) or a sterile blind hub;
- The vial(s) and any unused medicine should be kept until administration to the patient is complete.

43. If allowed by local guidelines or national legislation, for mixing two medications in the same syringe (e.g. cortico-steroid and local anaesthesia), follow the stages above for each drug used.
44. Place the final syringe or infusion and the empty ampoule(s)/vials(s) in a clean plastic tray with the prescription for taking to the patient for administration.

Injectate Administration

The author's technique is based on his earlier work and with technique tips incorporated from key authors identified by the literature review.

45. The patient is placed in a supine position with the leg relaxed to facilitate injection through a dorso-medial approach.
46. Dorsiflex and plantarflex the great toe to identify the joint space. Look for puckering of the skin over the joint margins. Palpate the anatomical landmarks: the metatarsal head and proximal phalanx and identify any overlying osteophytes (optional: mark the joint margins. See Fig. 2).
47. The key structures to avoid are the long and short extensor tendons that are dorso- and dorso-laterally placed respectively. Identify the medial aspect of extensor hallucis longus tendon (optional: mark the tendon. See Fig. 2).
48. The injection site should be carefully chosen, as far from large vessels and nerves as possible.
49. Disinfect the skin according to local guidelines. Allow any solution to dry for 2 to 4 min to allow time for the solution to reduce the bacterial load.
50. Equipment: 2.5-ml syringe with 25-mm (1 in.) 23-gauge (blue) needle. Most steroids are particulate in nature and benefit from a wider gauge needle for injection. A 25-gauge (orange) needle is also suitable.
51. Drug: 20 mg of triamcinolone (or other drug per clinician preference) mixed with local anaesthetic (per clinician preference).
52. Perform a pre-procedure pause. Stop and verify: the correct patient, correct procedure, and correct site?
53. Plantarflex and distract the toe distally to open up the joint space (see Fig. 3). The approach is through a dorso-medial entry point, the needle entry point is typically 0.5–1 cm medial to the extensor hallucis longus tendon (see Fig. 2).
54. Insert the needle at 90° to the skin, then angle 15–30° distally to avoid chondral injury to the first metatarsal head (see Fig. 4) but not too distally to injure the base of the proximal phalanx (see Fig. 5).

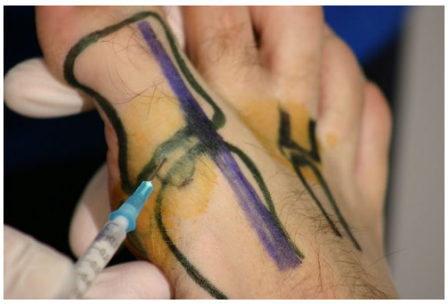

Fig. 2 Marking up helps to orientate the joint space [17]

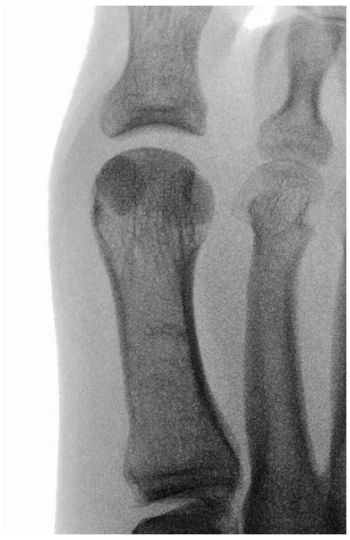

Fig. 3 Note how the 1st MTP jt space increases with plantarflexion and distraction

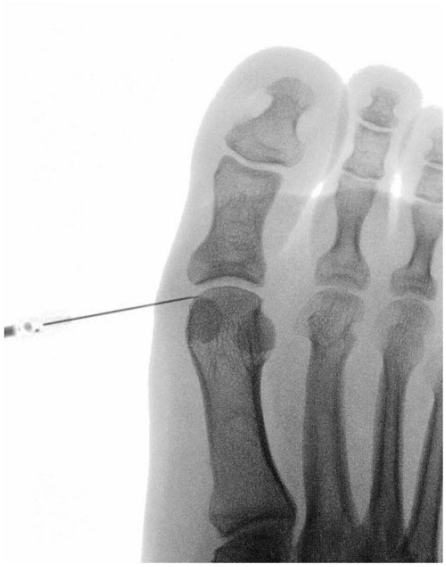

Fig. 4 Needle entry from a dorso-medial approach (prior to plantarflexion and distraction

55. A slight 'give' is usually felt as the needle enters the joint cavity but difficulty advancing the needle suggests that it is in the wrong position.
56. A medial approach, dorsal or dorso-lateral approach may be of use if the dorso-medial entry fails, for example in the presence of osteophytosis (see Fig. 6). However, there is a concern that leakage of steroid down the needle track from a dorso- or dorso-lateral approach will enter the extensor tendon sheaths.
57. Aim to have a third of the length of the needle deep to the skin (see Fig. 2). Aspiration of joint fluid is not typically performed for this joint; however, its presence before corticosteroid injection will ensure correct intra-articular position of the needle.
58. The injection should not be carried out if resistance is felt; the needle should be repositioned. Inject the solution slowly.
59. All of the medication should be completely expelled from the syringe before removing the needle to help prevent leakage under the skin which may cause skin atrophy.
60. Withdraw the needle, and apply compression and a local dressing.

Post Administration

61. After completion of the injection, discard the needle/syringe according to local policy. Discard the empty ampoules/vials from which the injection was prepared and any unused medicine. Ampoules or vials should never be used to prepare more than one injection unless specifically labelled by the manufacturer for 'multi-dose' use.
62. Ask the patient to report promptly any soreness at the injection site or discomfort of any sort.
63. Make a detailed record of the administration including use of PILs.
64. Re-check the administration site for signs of bleeding, steroid leakage or inflammation and continue to monitor the patient, according to local policy.
65. Check that arrangements if follow-up has been made. Ensure that relevant documentation is made available for subsequent monitoring to take place.

Discussion

Injection therapy is one of the most common therapeutic interventions in musculoskeletal healthcare [33, 42, 43]. For intra-articular injections, a needle is inserted for two main indications: 1—aspiration of fluid (arthrocentesis) for diagnosis and relief of pressure, or 2—injection of medication(s) for a therapeutic effect. Most injections into joints consist of a

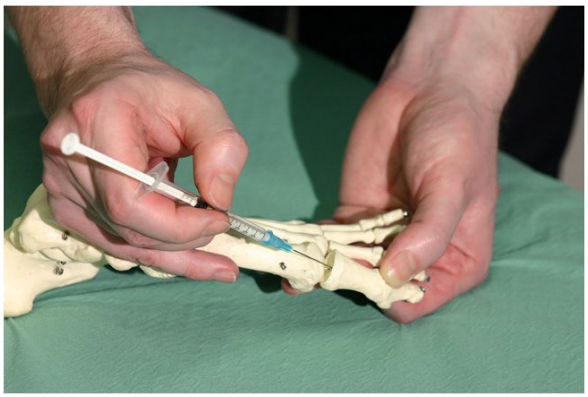

Fig. 5 Avoid chondral injury on the proximal phalanx

glucocorticoid, a local anaesthetic or a combination of the two [44, 45]. The use of viscosupplementation [16, 38, 46] and prolotherapy [47] has also been reported in this joint. Such injections provide a treatment option for patients with joint or peri-articular pain, for those who are not surgical candidates, in those in whom conservative treatment has failed and/or in those that are awaiting surgery [45].

In the long history of intra-articular joint corticosteroid injections, infiltrations have often been performed without image guidance, i.e. using palpation guidance, anatomical landmarks and clinical judgement to direct needle entry and advancement [48]. While the evidence base for the joint injections points towards the benefits of guided (x-ray or ultrasound) injections over blind (palpation guided) injections for accuracy [49], a proportion of surgeons and clinicians will continue to inject the 1st MTP jt using palpation guidance [50]. Hall and Buchbinder, and Sakellariou et al. state that while joints such as the hip and midtarsal joints demand imaging for accuracy of steroid placement, joints which have conventionally been injected with an anatomical landmark approach should have image guidance reserved for those cases who have not responded to an injection performed using anatomical landmarks [50, 51].

The author uses this technique as part of documentation to teaching and record competency to sign-off for students and novice injectors prior to be given autonomy of practice once sufficient skill has been demonstrated (see fig. 7).

For further information on injection safety, see Health and Safety (Sharp Instruments in Healthcare) Regulations [52], the World Health Organization injection toolkit [53] and the First UK Injection Technique Recommendations (2nd edn) [54]. In summary, always ensure the [55]:

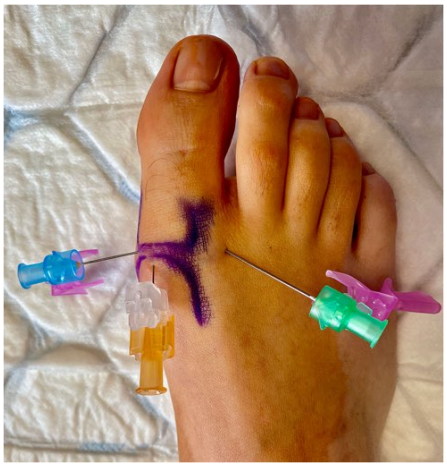

Fig. 6 Options for needle entry–dorso-medial (blue needle), dorsal (orange needle) and dorso-lateral (green needle)

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Appendix 4: Steroid Injection Competency Sign-Off

Team Member	**Name:** ..... **Job Title:** .....
Trainer	**Name:** ..... **Job Title:** .....
Competency Achieved	I confirm that the signatory is competent in the skills and behaviour needed to effectively perform in this role. ..... **Ian Reilly** MSc, FCPodS, FFPM RCPS(Glasg) Consultant Podiatric Surgeon ..... / ..... / .....

Fig. 7 Competency sign off for trained injectors

- Right patient
- Right drug
- Right time
- Right dose
- Right route

Conclusion

The primary aim of this paper is to describe the author's technique for palpation-guided injection of the 1st MTP jt. Noting that many clinicians can and do inject this joint without image guidance, further work will now be undertaken to validate injection placement accuracy on novice injectors. The secondary aim of this paper is to promote injection safety. The technique presented incorporate elements of the NPSA documentation as detailed above and gives references for further reading. Accurate and safe injection technique must become the standard for patient care. It is envisaged that this paper becomes the benchmark for non-guided 1st MTP jt injection technique.

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Data Availability Data sharing is not applicable to this article as no datasets were generated or analysed.

Compliance with Ethical Standards

Competing Interests The author declares that he has no competing interests.

Ethical Approval Ethical approval was not required for this technique description but the author confirms that he adhered to virtue- and principle-based ethics when producing this work. Save for information contained in and adapted from the references, the author confirms that the work is his own.

Consent for Publication Consent for publication has been granted by Elsevier (Figs. 2 and 5) and from the patient seen in Figs. 3, 4 and 6.

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APPENDIX 11: Full ethical review form

RESEARCH ETHICS

Full Ethical Review Form

Full ethical review must be used for research involving above minimal risk and therefore necessitating a more thorough ethical review prior to approval. Further guidance on projects which involve above minimal risk is provided within the University's Ethical Review Policy.

Relevant professional body ethical guidelines should be consulted when completing this form.

Please seek guidance from the School Ethics Coordinator if you are uncertain about any ethical issues arising from this application.

There is an obligation on the researcher and supervisor (if applicable) to bring to the attention of the School Ethics Coordinator any issues with ethical implications not identified by this form.

PART A: TO BE COMPLETED BY RESEARCHER

Name of Researcher:	Ian Reilly
School:	School of Life Sciences and Education

Student/Course Details (If Applicable)			
Student ID Number:		r029538	
Name of Supervisor(s)/Module Tutor:		Profs N. Chockalingam / R. Naemi.	
PhD/MPhil project:	☐		
Taught Postgraduate Project/Assignment:	☒	Award Title:	Professional Doctorate in Healthcare Science
Undergraduate Project/Assignment:	☐	Module Title:	SPOR80004-2019-SPG2-2020-SPG1

Project Title:	An audit of the accuracy of first metatarso-phalangeal joint injections using iohexol after palpation-guided technique		
Expected Start Date:	05.11.20	Expected End Date:	31.02.21

Application Checklist Have the following documents been supplied alongside this application?	Yes	N/A
Participant information sheet(s) in language appropriate to the recipient	☐	☒
Participant consent form(s) in language appropriate to the recipient	☐	☒
Letter/s of invitation to participants in language appropriate to the recipient	☐	☒
Questionnaires (only attach questionnaires that have NOT been validated previously)	☐	☒

Health related projects only: Letters giving permission for access to participants or confirming that full LREC ethical approval is not required	☒	☐
Other relevant information (e.g. tests or product information)	☒	☐

NHS Research	YES	N/A
Will the research involve any of the following: • NHS patients • NHS staff or premises • Confidential patient information • Material consisting of or containing human cells • Patients who are cared for in private and voluntary sector nursing homes • Exposure to ionising radiation • Medical devices that are not CE-marked or CE-marked medical devices that have been modified or are being used for a new purpose • Investigational medicinal products • Practising midwives conducting a clinical trial • Protected information from the Human Fertilisation and Embryology Authority register. If the research will involve any of the above, an IPR (Independent Peer Review) application should be completed INSTEAD of a full ethical review. Please contact the Chair if the IPR panel for advice. The HRA (Health Research Authority) provide a tool to help identify if projects need NHS REC approval: http://www.hra-decisiontools.org.uk/ethics/index.html	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☒ ☒ ☒ ☒ ☒ ☒ ☒ ☒ ☒ ☒

Submission Guidance (for completion by School):

1. Project Outline

Please provide a brief paragraph indicating answers to the following questions where relevant:

i) The aims and objectives of the project.
ii) Its rationale and justification.
iii) The research question or specific hypotheses to be tested.
iv) The background to the project.
v) Where the research is to be carried out.
vi) Names of other individuals or organisations involved in the project.
vii) Whether other approvals have been gained or are to be sought.

INTRODUCTION

Anatomy

The first metatarsophalangeal (great toe) joint (1st MTP jt) is a condyloid synovial juncture (McSweeney, 2016). It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTP jt in contradistinction to the lesser MTP jts (Hallinan et al., 2020). The metatarso-sesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The six muscles are abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis. The ligaments of the joint are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the inter-sesamoid ligament and the hood ligament (Alvarez et al., 1984).

The metatarsal head has medial and lateral epicondyles from which the collateral and suspensory ligaments originate. The collateral and sesamoid ligaments run forward and downward to attach to the base of the proximal phalanx and the appropriate sesamoid. The hood ligament is a fibrous expansion from the long extensor tendon which encloses the tendon and attaches to the sides and plantar surface of the proximal and distal phalanx and blends with the joint capsule. The base of the proximal phalanx is concave and has a large base to receive its muscular and ligamentous attachments (Percival, 2001).

Pathology

The two most common diseases affecting the 1st MTP jt of the foot are hallux limitus/rigidus (osteoarthritis) and hallux valgus/bunion (Ajwani et al., 2018; Mann, 1995). Other common pathologies include rheumatoid arthritis, gout and sesamoiditis (Tallia & Cardone, 2003). There are a range of treatments for each of the conditions mentioned above. One treatment option is intra articular injection therapy and this is one of the most common therapeutic interventions in musculoskeletal healthcare.

A needle is inserted into a joint for two main indications: aspiration of fluid (arthrocentesis) for diagnosis or for relief of pressure, or injection of medications (Roberts, 2020). Most injections into joints consist of a glucocorticoid, a local anaesthetic, or a combination of the two; the use of viscosupplementation has also been reported in this joint. Such injections provide a treatment option for patients with joint or peri-articular pain, for those who are not surgical candidates, in those in whom conservative treatment has failed and in those that are awaiting surgery.

History

Injection therapy for the treatment of joint pain has been performed since the 1930's. Compounds such as sodium bicarbonate, potassium phosphate and procaine have been used from the first half of the twentieth century (J. H. Miller et al., 1958) with case reports in podiatry (chiropody) from as early as 1954 (Weinstein, 1954) and 1958 (Katz, 1958; Locke, 1958). The introduction of cortisone (a purified glucocorticoid preparation) revolutionized the treatment of a number of medical diseases (Anitescu et al., 2013). Hollander et al reported the use of hydrocortisone and cortisone in 1951 following personal communication with Thorn, who they believe was the first to inject a rheumatic joint in 1950 (Hollander et al., 1951). Further reports were produced by Bornstein and Fallet, and Lambelet, cited by MILLER et al (J. H. Miller et al., 1958). Injection therapy is now one of the most common therapeutic interventions in musculoskeletal healthcare (Rozental & Sculco, 2000; von Stechow & Rittmeister, 2003; Wittich et al., 2009). In practical terms, most injections into joints now consist of a glucocorticoid, a local anaesthetic, or a combination of the two (Roberts, 2020).

Rationale

Diarthrodial joints are well suited to intra-articular injection, and the local delivery of therapeutics in this fashion brings several potential advantages to the treatment of a wide range of arthropathies (Evans et al., 2014). Chief of these a good safety profile (if administered correctly) with less chance of systemic exposure and undesired off-target effects (Nguyen & Rannou, 2017). As well as eliminating many patient compliance issues, this route of administration overcomes potential problems of bioavailability, uncontrollable drug dosing and the effects of drug binding to systemic molecules that can all limit the efficacy of a substance administered via enteral delivery. It also removes the concern over patient compliance (Evans et al., 2014; Wehling et al., 2017). Synovial inflammation is a key feature of much joint pathology; most notably observed in rheumatoid arthritis and following joint injury, but it is also present in osteoarthritis (Berenbaum, 2013). Therapeutic injections - especially those mixed with anaesthetic - provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, in those in whom conservative treatment has failed or those that are awaiting surgery (Chow & Brander, 1998).

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Diagnostic aspiration or therapeutic injection can be performed for management of advanced osteoarthritis, rheumatoid arthritis and other inflammatory arthritides such as gout or synovitis of the foot (de Cesar Netto et al., 2018; Genovese, 1998; Tallia & Cardone, 2003; Vanderstraeten et al., 2005). They are accepted as an important treatment modality, but currently there are no guidelines in regard to administration technique. Injectable glucocorticoids are widely used in foot pathology, in particular for the treatment of osteoarthritis of the great toe: hallux limitus/rigidus (Anderson et al., 2018; Ayral, 2001; Bilstrom et al., 2007; Boxer, 1994; Courtney & Doherty, 2005; Grady et al., 2002; Hamid & Parekh, 2015; Kilmartin, 2017; Kunnasegaran & Thevendran, 2015; Lam et al., 2017; Pons et al., 2007; Reilly, 2010; Sahler et al., 2013; Solan et al., n.d.; Tallia & Cardone, 2003; Uthman et al., 2003). However, the benefit of using injectable medication is based on accurate needle placement.

Summary Justification

i. Injection of therapeutic substances into the first metatarsophalangeal joint (great toe joint) is a commonly performed procedure across different clinical specialties. There is a debate whether the injection needs to be performed under image guidance, such as fluoroscopy or ultrasonography, to confirm needle placement.

This is an initial audit of my service (as a sole practitioner). Protocols have already been developed and this is the first step in rolling out a standard technique across other NHS Trusts so that a future audit(s) can be conducted on the effectiveness - using multiple practitioners with cadaver feet - with the longer term aim of assessing the real-world effectiveness i.e. patient outcome in future research projects.

ii. Confirmation that a palpation-guided technique yields accurate injection technique would provide significant cost and convenience advantages.

iii. While much research has been produced on injection therapy of other synovial joints, there are gaps in the literature pertaining to injection therapy of the first metatarsophalangeal joint. We do not know that a palpation-guided technique is accurate. This study will audit my standard technique.

iv. In the long history of intra-articular joint corticosteroid injections, infiltrations have often been performed without image guidance, i.e. using palpation guidance, anatomical landmarks and clinical judgement to direct needle entry and advancement. The evidence base for the joint injections points towards the benefits of guided (x-ray or ultrasound) injections over blind (palpation guided) injections for injection accuracy. The literature suggests that while joints such as the hip and midtarsal joints demand imaging for accuracy of steroid placement, joints which have conventionally been injected with an anatomical landmark approach should have image guidance reserved for those cases who have not responded to an injection performed using anatomical landmarks. Many surgeons and clinicians continue to inject the first metatarsophalangeal joint using palpation guidance. However, an accurate palpation-guided technique is not well proven.

v. Department of Podiatric Surgery, Danetre Hospital, Daventry. NN11 4DY.

vi. N/A.

vii. Approval given by Northamptonshire Healthcare Foundation NHS Trust (NHFT) Research and Innovation Department (email enc).

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39. Wittich, C. M., Ficalora, R. D., Mason, T. G., & Beckman, T. J. (2009). Musculoskeletal injection: Concise review for clinicians. In Mayo Clin Proc (Vol. 84, Issue 9).

2. Research Procedure

Please provide a summary of the procedures that will be followed when carrying out the research project under the following headings.

a) The design of the project (including, where appropriate, issues of statistical power):

This audit project is a part of a taught degree. The academic supervisors have reviewed and looked at the project. Since there is no other study of this nature, it is not possible to calculate a prior sample size but we are aware of the problems of retrospective calculation (Gilbert, G. E., & Prion, S. K. 2016. Making sense of methods and measurement: The danger of the retrospective power analysis. Clinical Simulation in Nursing, 12(8), 303–304. https://doi.org/10.1016/j.ecns.2016.03.001).

Appropriate tests will be carried out. As such I expect to conduct a non-parametric analysis via chi-square test of association. This has been discussed at length with my supervisors.

Injection technique

Dorsiflex and plantarflex the great toe to identify the joint space. Look for puckering of the skin over the joint margins. Palpate the anatomical landmarks: the metatarsal head and proximal phalanx and identify any overlying osteophytes (optional: mark the joint margins)

The key structures to avoid are the long and short extensor tendons that are dorso- and dorso-laterally placed respectively. Identify the medial aspect of extensor hallucis longus tendon (optional: mark the tendon).

The injection site should be carefully chosen, as far from large vessels and nerves as possible.

Equipment: 2.5 ml syringe with 25mm (1 inch) 23-gauge (blue) needle. Most steroids are particulate in nature and benefit from a wider gauge needle for injection.

Drug: lahexol.

Plantarflex and distract the toe distally to open up the joint space. The approach is through a dorso-medial entry point, the needle entry point is typically 0.5-1cm medial to the extensor hallucis longus tendon.

Insert the needle at 90 degrees to the skin, then angle 15-30 degrees distally to avoid chondral injury to the first metatarsal head but not too distally to injure the base of the proximal phalanx.

A slight 'give' is usually felt as the needle enters the joint cavity but difficulty advancing the needle suggests that it is in the wrong position.

A medial approach, dorsal or dorso-lateral approach may be of use if the dorso-medial entry fails, for example in the presence of osteophytosis. However, there is a concern that leakage of steroid down the needle track from a dorso- or dorso-lateral approach will enter the extensor tendon sheaths.

Aim to have at least 1/3 of the length of the needle deep to the skin. Aspiration of joint fluid it not typically performed for this joint, however its presence before corticosteroid injection will ensure correct intra-articular position of the needle.

The injection should not be carried out if resistance is felt; the needle should be repositioned. Then inject the solution slowly.

All of the medication should be completely expelled from the syringe before removing the needle to help prevent leakage under the skin which may cause skin atrophy.
Perform x-rays to conform iohexol placement.

Radio-opaque Dyes
Radiographically guided diagnostic injections of foot and ankle symptomatic patients demonstrated better success in identifying the source of pain, when compared to imaging studies, confirming diagnosis in 90.9% of the patients and predicting success of surgical treatment with fusion of the affected joints. Iohexol, N,N'-Bis(2,3-dihydroxypropyl)-5-[N-(2,3-dihydroxypropyl)-acetamido]-2,4,6-triiodoisophthalamide, is a non-ionic, water-soluble radiographic contrast medium with a molecular weight of 821.14 (iodine content 46.36%). Omnipaque is provided as a sterile, pyrogen-free, colourless to pale-yellow solution, in the following iodine concentrations: 140, 180, 240, 300, and 350 mg/ml. Omnipaque 300/350 is indicated for arthrography in adults.

b) The procedures to be followed:

The study will be performed on 6 cadaveric feet (this is the maximal available at the time of the study).
The cadaveric feet will be supplied from Nottingham City Hospital (NCH) and at all times be the responsibility of the NCH anatomical team.
The anatomy technologists will be responsible for the transporting, safety and return of all cadavers.
Injections will take place in the Podiatric Surgery Dept I Danetre Hospital I London Road I Daventry I Northamptonshire I NN11 4DY.
All injections will be performed by the Principle Investigator (PI), Ian Reilly.
The PI will attempt to place a hypodermic needle in the first metatarsophalangeal joint in all 6 specimens using palpation-guidance.
Iohexol dye will be injected into the joint space.
Following each injection, the cadaveric foot will be X-rayed by the PI to confirm needle and dye placement.
Each injection/X-ray will take between 5-10 minutes: 1-hour total in theatre.
X-rays will be stored on NHS secure server for further assessment.
The results will be tabulated and subject to statistical analysis.

c) The participation of people or animals in the project:

6 cadaveric feet.

d) How the design of the project and the procedures followed are likely to assess the research question or test the hypothesis in question or establish some significant result:

Accurate injection technique confirmed via X-ray and will be accurate, or not accurate. Two orthogonal views will demonstrate if the needle is within the joint space. Using the two views it will be easy to state if the needle placement is accurate.

e) Availability of facilities/resources/equipment to enable the project to be carried out:

Cadaveric feet will be supplied by National Repository Centre I City Hospital I Nottingham I NG5 1PB.

The PI will use NHFT Departmental equipment - procedure room, X-ray machine, injectable disposables and PPE as outlined below.

f) Procedures that will be followed if any adverse event occurs:

NHFT clinical protocols.

3. Participant Recruitment & Characteristics

Please provide clear information regarding the recruitment of participants and their appropriateness to the project:

Please provide answers to the following questions regarding the handling and storage of information and data:
a) How will research data be stored (manually or electronically)? Electronically.
b) How is protection given to the participants (e.g. by being made anonymous through coding and with a participant identifier code being kept separately and securely)? N/A.
c) What assurance will be given to the participant about the confidentiality of this data and the security of its storage? N/A.
d) Is assurance given to the participant that they cannot be identified from any publication or dissemination of the results of the project? N/A.
e) Who will have access to this data, and for what purposes? PI Profs N. Chockalingam / R. Naemi
f) How will the data be stored, for how long, and how will it be discarded? Data will be stored on password protected NHS computers. The data will be analysed by the student and only the student and supervisors will have access to the data. Data will be retained for 10 years according to the Staffordshire University Research Ethics policy.

5. Risk, Harm and Other Ethical Considerations Please provide an estimate of the perceived benefits or outcomes of the project weighed against the possible harms caused to the participants.
Please identify any potential risks or hazards that might be caused to participants or the researcher, in addition to any discomfort, distress or inconvenience to them, together with any ethical problems or considerations that the researcher considers to be important or difficult in the proposed project. Risk Assessment There are two potential risks to this study: 1. A risk of needle injury. As an experienced clinician, the principle investigator is used to working with sharps and this confers no greater risk than from routine clinical practice. 2. A risk of being exposed to ionising radiation.
Please explain how any potential risks or hazards will be dealt with, along with any justificatory statements. This information should highlight any remaining ethical considerations and to respond to them in a way which may assist the Research Ethics Committee in arriving at some judgement upon the proposal. 1. Personal protective equipment (PPE, e.g. gloves) will be used. 2. Lead shielding (body and thyroid) will be worn during needle placement and safe distances will be maintained when exposures are taken. Ionising radiation can cause cancer which may manifest itself after many years or

decades. The risk of developing cancer as a consequence of taking part in this study is very low. For comparison, the natural lifetime cancer incidence in the general population is about 50%.
Has a risk assessment been completed for this project Yes ☒ N/A ☐

6. Supporting Information

Please attach the consent form, information sheet, and questionnaire/interview questions to this application. Further guidance on the design and content of consent forms and information sheets can be found on the University's Research Ethics website.

Researcher Declaration

I undertake to carry out the project described above in accordance with ethical principles. I have completed the application in good faith. I accept that providing false information constitutes scientific fraud and will be subject to appropriate disciplinary procedures.

Signature of Researcher:		Date:	04.11.20

NB: Any departure from the protocol for this research project may mean that the ethical approval decision made by the School Ethics Coordinator is no longer valid and a new ethics proposal will have to be submitted. It is the responsibility of a student researcher to discuss proposed changes to the agreed protocol with their project supervisor as soon as possible so that a revised /new ethics application can be submitted. Research based on any revised / new protocol **MUST** not proceed unless and until the protocol has ethical approval.

Next Step:

STUDENTS: Please submit this form (and supporting documentation) for consideration by your Supervisor/ Module Tutor.

STAFF: Please submit this form for consideration by your Head of Department of a Senior Researcher in the School. This form should then be forwarded to the Research Administrators in RIIS (ethics@staffs.ac.uk) who will arrange for it to be considered by two independent members of the School's College of Ethical Reviewers

PART B: TO BE COMPLETED BY SUPERVISOR/MODULE TUTOR (If student) OR Head of Department/ Senior Researcher (if staff)

I have examined this proposal and confirm that the rationale and methodology is appropriate and that it can proceed to the stage of ethical consideration.	☒
I have checked and approved the key documents required for this proposal (e.g. consent form, information sheet, questionnaire and interview schedule).	☒

Signature of Supervisor/ Head of Department/ Senior Researcher:		Date:	

Next Step:

Please submit this form to the Research Administrators in RIIS (ethics@staffs.ac.uk).

PART C: TO BE COMPLETED BY THE SCHOOL ETHICS COORDINATOR

This research proposal has been considered by two members of the School's College of Ethical Reviewers and **RECEIVED** ethical approval.	☐
This research proposal has been considered by two members of the School's College of Ethical Reviewers and was REFUSED ethical approval on grounds detailed below: **Recommendation (delete as appropriate):** Approve/ Amendments required/ Reject	☐

Signed (School Ethical Coordinator)		Date	

APPENDIX 12: Ethical approval

Life Sciences and Education

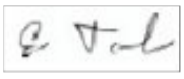
ETHICAL APPROVAL FEEDBACK

Researcher name:	Ian Reilly
Title of Study:	An audit of the accuracy of first metatarso-phalangeal joint injections using Iohexol after palpation-guided technique
Status of approval:	Approved

Thank you for addressing the committee's comments. Your research proposal has now been approved by the Ethics Panel and you may commence the implementation phase of your study. You should note that any divergence from the approved procedures and research method will invalidate any insurance and liability cover from the University. You should, therefore, notify the Panel of any significant divergence from this approved proposal.

You should arrange to meet with your supervisor for support during the process of completing your study and writing your dissertation.

When your study is complete, please send the ethics committee an end of study report. A template can be found on the ethics BlackBoard site.

Signed: 

Date: 4th November 2020

Dr Ed Tolhurst

pp Dr Roozbeh Naemi

Podiatric Surgery Protocol

DIAGNOSTIC IMAGING: USE OF THE MINI C-ARM

Document Details	
NHFT document reference	CLPr032
Version	Version 4
Date ratified	01.04.20
Ratified by	Adult Clinical Governance Directorate
Implementation date	01.04.20
Responsible director	Medical Director
Review date	01.04.23
Related policies and other documents	Podiatric surgery 3: Diagnostic Imaging: Requesting
Freedom of information category	Protocol

DOCUMENT CONTROL SUMMARY

Document Title	Diagnostic Imaging: Mini C-Arm
Document Purpose (executive brief)	This document outlines the Podiatric Surgery protocol for the use of the Mini C-Arm.
Status: New / Update/ Review	Update
Areas affected by the policy	Podiatric Surgery Team
Policy originators/authors	Ian Reilly Consultant Podiatric Surgeon
Consultation and communication with Stakeholders including public and patient group involvement	Chris Wood Medical Physics Department Northampton General Hospital Cliftonville Northampton NN1 5BD
Archiving arrangements and register of documents	The Risk Management Team is responsible for the archiving of this policy and will hold archived copies on a central register
Equality Analysis (including Mental Capacity Act 2007)	NA
Training Needs Analysis	See section 7
Monitoring Compliance and Effectiveness	See section 8
Meets national criteria with regard to	
NHSLA	N/A
NICE	N/A
NSF	N/A
Mental Health Act	N/A
CQC	N/A
Other	N/A
Further comments to be considered at the time of ratification for this policy (i.e. national policy, commissioning requirements, legislation)	None
If this policy requires Trust Board ratification, please provide specific details of requirements	None

INTRODUCTION

The Podiatric Surgery service sits outside of the NGH/KGH district general hospital surgical directorates and structures and has a need to develop its own policies and protocols to support surgical practice. Below is a list specific to Podiatric Surgery:

1. Podiatric Surgery: standard operating procedures
2. Podiatric Surgery: pre-surgical assessment
3. Podiatric Surgery: diagnostic imaging – requesting
4. Podiatric Surgery: diagnostic imaging - use of the mini C-arm
5. Podiatric Surgery: local anaesthesia and steroid injection therapy
6. Podiatric Surgery: prevention of venous thrombo-embolic disease
7. Podiatric Surgery: peri-operative management of diabetic patients
8. Podiatric Surgery: theatre protocols – surgery SOPs and LocSSIPs
9. Podiatric Surgery: theatre protocols – post-operative discharge
10. Podiatric Surgery: post-operative consultations
11. Podiatric Surgery: clinical and surgical emergencies
12. Podiatric Surgery: COSHH register and risk assessments
13. Podiatric Surgery: research, audit and PASCOM

PURPOSE

All diagnostic examination or interventional procedures involving the use of ionising radiation are to be justified. The basis of justification is that the procedure must have an impact on the clinical decision-making process. Any examination that does not affect the clinical decision making is not justifiable.

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R[1] provide for the health protection of individuals undergoing medical exposures involving ionising radiation, including requirements regarding requests for X-ray examinations.

This protocol defines the local rules and safe systems of work for the use the Mini C-Arm for patients of the Podiatric Surgery service. The general principles that apply are[2]:

1. The individual that initiates the original investigation is responsible and accountable for tracking, validating, documenting, acting upon and informing the patient and/or General Practitioner or responsible hospital consultant of the results.
2. There must be a systematic Trustwide approach to the validation of results
3. All staff must be involved in developing explicit local clinical diagnostic testing policies for those elements of the process that they are involved in.
4. There must be staff training about the clinical diagnostic testing process so that each member of staff understands how his or her role contributes to the overall process.
5. Local working practices must not be allowed to diverge from local policies
6. All cases of non-conformance with the local policy should be recorded and brought to the attention of the line manager and a NtPCT incident form completed.

DEFINITIONS

DI – Diagnostic Imaging
II – Image Intensifier
HCPs – Health Care Professionals
NGH – Northampton General Hospital
NHFT – Northamptonshire Healthcare NHS Foundation Trust
RPS – Radiation Protection Supervisor
RPA – Radiation Protection Adviser
SoCaP – the Society of Chiropodist and Podiatrists

DUTIES

This protocol applies to HCPC registered members of the Podiatric Surgery service employed by NHFT who are working outside their basic training and undertaking extended roles that require the use of Diagnostic Imaging (DI) modalities to support their clinical practice. The content of this protocol is based on the NGH Scope document[3] and the requirements of Protocol for Radiology Referrals from Non-Medically Qualified Staff[2]. An extended role is determined as a procedure that is not part of the healthcare professional's pre-registration basic training and competence.

PROCESS

The Trust recognises that every healthcare professional is accountable for their practice and that it is their professional judgement that can provide innovative solutions to meeting the needs of patients and clients in a health service that is constantly changing. Extending the role of the practitioner is encouraged and supported for the improvement in patient care and the development of healthcare services.

The principles that must underpin a practitioner's approach to taking on the responsibilities beyond the traditional boundaries of practice are that the clinician must:

1. Be satisfied that patient and client needs are uppermost in line with Trust policy and service developments
2. Keep up to date and develop knowledge, skills and competence
3. Recognise the limits to personal knowledge and skill and remedy deficiencies
4. Ensure that existing care is not compromised by new developments and responsibilities
5. Acknowledge personal and professional accountability
6. Avoid inappropriate delegation

The development of extended roles is to enhance the patient journey and to deliver a holistic patent centred approach to care. All practitioners must comply with Trust and SoCaP guidance on expanding roles.

LOCAL RULES FOR IONISING RADIATION SAFETY

These Local Rules have been drawn up in accordance with Regulation 17 of the Ionising Radiations Regulations, 1999[4]. They cover podiatry work with a Mini C-arm within theatres at Danetre Hospital. These local rules are applicable to all staff members who work with this equipment. Every member of staff to whom these rules apply must read these local rules. A copy must be readily available to all staff working in the controlled area covered by these local rules.

These rules should be reviewed at least annually by the RPS, or after any major changes to the X-ray equipment or the use of the X-ray equipment. Any changes should be discussed with the RPA.

RADIATION PROTECTION SUPERVISORS

The RPS will supervise work with ionising radiation within the department and ensure that the local rules are observed. They should be informed and their advice sought whenever a matter concerning radiation protection arises. The RPS for the department are:

Ian Reilly
Consultant Podiatric Surgeon. NHFT

Ganesh Baliah
Clinical Asst, Podiatric Surgery. NHFT

RADIATION PROTECTION ADVISER

The appointed RPA for the department is:

Chris Wood.
NGH (01604 54 4371)

DESIGNATED AREAS (SEE DEFINITIONS IN APPENDIX FOR DETAILS)

A controlled area exists within 2m of the X-ray unit when the X-ray unit is in use.

ENTERING AND WORKING IN CONTROLLED AREAS

Podiatry staff are not classified radiation workers. They may enter controlled areas under Written Arrangements for Entry into Controlled Areas (see appendix) and can work in controlled areas provided that they follow the key work instructions contained within these local rules. This will ensure that a person's exposure to ionising radiation is suitably restricted.

During examinations, no unauthorised person, other than the patient, is permitted to enter the controlled area, except in exceptional circumstances where patient assistance is necessary (see Key Work Instructions below).

All staff members issued with a personal monitoring badge must wear their badge on the trunk, under a lead apron or other protective device if one is being worn, whenever working with X-ray equipment. Any other monitoring devices issued to staff must be worn. All monitoring devices must be returned when requested.

If a member of staff becomes pregnant, she should inform the RPS and the head of her department in writing as soon as possible. The RPS should contact the personal monitoring service.

Engineering staff and medical physics staff may work unsupervised within the controlled area if permission has been given to them from pain relief clinic staff and they follow the key work instructions listed in the appendix.

Staff Dose Investigation Level

The staff dose investigation level is set at 0.5 mSv per badge.

Key Work Instructions

- During X-ray exposures all non-essential staff should retire from the vicinity and be at least 2m (3m preferably) from the X-ray unit and patient.
- No member of staff should remain in the controlled area while X-ray exposures are being made unless it is essential or, in exceptional circumstances, they are required to support the patient. In these cases, protective lead aprons must be worn at all times. Protective aprons do not provide adequate protection from the primary beam.
- The operator should take care to ensure when initiating the exposure that everyone in the vicinity is safely positioned and that they can see the patient and the extent of the controlled area.
- When the X-ray equipment is left unsupervised, the person who was in charge of the last examination must ensure that it is left so that others may enter without fear of accidental irradiation. If practicable, the X-ray equipment should be isolated from the mains supply.
- If practicable, mechanical aids should be used if the patient is in need of support.
- A record must be kept within the department of all who support patients. It must include type of examination and radiographic factors. The RPS should regularly inspect this record to ensure that no one person is performing this duty repeatedly.
- Users should be aware that some X-ray units do not emit an audible warning when X-rays are emitted.
- Use of high dose fluoroscopy and magnified fields should be reduced as far as practicable.
- Staff should avoid standing on the same side of the patient as the X-ray tube during lateral views.
- X-ray exposures must only be initiated by staff who have been adequately trained.
- The Mini C-arm must not be handled or moved whilst X-rays are being emitted.

Contingency Plan

If the X-ray unit fails to terminate the production of X-rays at the end of the set time, or if the operator believes there may be a fault with the X-ray unit, it must immediately be isolated from the mains supply. The unit should be taken out of use and a notice indicating the problem should be attached to it. The RPS

must be informed. The unit should not be used again until the incident has been investigated and the cause rectified.

If an employee suspects that they have received an overexposure of radiation, or if the radiation monitoring indicates that an overexposure has been received, the RPS must be informed. They must ensure that an investigation is carried out in conjunction with the RPA as required by the Regulations.

If it is suspected that a patient has received a dose much greater than intended, the RPS must be informed. They must ensure that an immediate investigation is carried out and must notify the RPA. If the incident is confirmed and found to be due to equipment fault or malfunction, the RPA will advise the employer of the need to inform the Health and Safety Executive as required under the Regulations and a full investigation will be carried out. If the incident is due to operator error, the Medical Physics Expert should be informed (via the RPA) and they will advise the employer on whether external notification to the Care Quality Commission is necessary.

TRAINING

MANDATORY TRAINING

All operators and practitioners must have:

- IR(ME)R certification.
- Training in the use of the Mini C-Arm (e.g. Pulvertaft course).
- Training on equipment-specific applications.
- Further training for the RPS(s) via NGH.

Each applicant will sign a copy of the authorisation produced in Appendix 1, sponsored by the Senior Clinician with the Department of Podiatry (lead Podiatric Surgeon).

AUDIT

AUDIT LOG

All justification, doses and views will be recorded and kept on a spreadsheet. Annual audits of this date will be made available to the Medical Physics department (Appendix 5).

MONITORING COMPLIANCE WITH THIS DOCUMENT

The table below outlines the Trusts' monitoring arrangements for this document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

Aspect of compliance or effectiveness being monitored	Method of monitoring	Individual responsible for the monitoring	Monitoring frequency	Group or committee who receive the findings or report	Group or committee or individual responsible for completing any actions
Duties	To be reviewed by team leader and consultants annually and updated 3-yearly via Directorate Clin Gov Cmtee.				

REFERENCES AND BIBLIOGRAPHY

1. Department of Health. The Ionising Radiation (Medical Exposure) Regulations 2000/17 (together with notes on good practice). London: DH. 2000. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957
2. Protocol for Radiology Referrals from Non-Medically Qualified Staff.
3. NGH Policy: Expanding the Scope of Professional Practice Clinical Guideline No: 014. NMCTB. August 2004.
4. Ionising Radiations Regulations 1999 and Work with Ionising Radiation (Approved Code of Practice and Guidance) (S. I. 1999/3232).
5. Ionising Radiation (Medical Exposure) Regulations 2000 (and Amendments) Medical and Dental Guidance Notes 2002.

RELATED TRUST POLICY

Podiatric Surgery protocol no 3: diagnostic imaging – requesting

INTERNAL DOCUMENT MANAGEMENT

1	22.03.15	22.03.17	31.03.15	New protocol
2	19.03.19	19.03.19	31.03.20	Review and update
3	05.11.19	05.11.19	31.03.20	Extra Review and update
4	31.03.20	01.04.20	01.04.23	Review and update

C-Arm Appendix 1

DIAGNOSTIC IMAGING PROTOCOL: MINI C-ARM

Task	Date Completed	Signature
Switch On / Off		
Log on to System / Password Protection		
Manual Input of patient details / Search for work list & Select Correct Patient		
II Controls and Movements		
Selection of target size /iris function		
Send images to PACS and informing radiographer of patient dosage		
Print images		
Radiation Protection issues to consider (local rules)		
Procedure for equipment breakdown / unattended machine (continuous screening what to do)		
Supervised practice		

I have been shown how to use the Vertec Mini C-Arm. I believe I am adequately trained and competent to use this unsupervised.

Signed: ……
(Practitioner)

Date: ……

The above person has demonstrated adequate competence, understanding and knowledge to use the Vertec Mini-C-Arm unsupervised.

Signed: ……
(Named Senior Practitioner)

Name: Ian Reilly, Consultant Podiatric Surgeon

Date: ……

Trust register notified (date): ……

Copy to personal file (date): ……

C-Arm Appendix 2

WRITTEN ARRANGEMENTS FOR ENTRY INTO CONTROLLED AREAS

In compliance with the Ionising Radiations Regulations 1999, all persons, prior to entering a controlled area, except patients and persons supporting the patient, are required to read, and comply with, the conditions detailed in this document.

No one should assume responsibility for authorising entry to a controlled area unless they have been designated to act by the RPS. Individuals delegated this responsibility are required to refer unusual requests for entry to the RPS.

Conditions of entry for radiation workers

1.1) You have read the local rules and agreed in signature to abide by the protocols set out therein.

or

You are accompanied by, or have received instructions from, the RPS or a person designated by the RPS who can ensure the local rules are obeyed.

or

1.3) You have received specific authorisation to enter into a controlled area from the RPS or a person designated by the RPS.

and

1.4) You are wearing a valid personal dosemeter if one has been issued to you.

FEMALES OF REPRODUCTIVE CAPACITY

If you are pregnant, or believe you might be pregnant, it is important that you inform, in writing, the RPS and the Radiation Protection Service or the RPA.

CONDITIONS OF ENTRY FOR PERSONS SUPPORTING THE PATIENT (NURSES, PORTERS, RELATIVES OF THE PATIENT ETC.

The RPS or a person designated by the RPS who can ensure the local rules are obeyed, requests the person required to support the patient to enter into the controlled area with the patient. It should be ensured that persons supporting patients are adequately protected such that they do not receive a dose in excess of 300 uSv in any one year. Special written arrangements agreed with the RPA shall be made in the case of persons designated as comforters and carers who are expected to receive more than the above dose.

CONDITIONS OF ENTRY FOR OTHER PERSONS

1.1) You are identified by name in the local rules as an authorised person.

or

1.2) You have received authorisation to enter into a controlled area from the RPS or a person designated by the RPS.

and

1.3) The X-ray set is isolated from the mains electricity supply.

or

1.4) You are accompanied by, or instructed by, the RPS or a person designated by the RPS to ensure X-rays are not produced.

MAINTENANCE WORKERS OR CONTRACTORS

If you are either required to enter into a controlled area whilst X-rays are produced (e.g. ventilation engineers), or are required to carry out structural work on the boundaries of a controlled area, you must first obtain permission and instructions from the RPS on advice from the RPA.

C-Arm Appendix 3

INTRODUCTION TO LOCAL RULES FOR IONISING RADIATIONS

The Ionising Radiation Regulations 1999 (IRR99), require ionising radiation local rules to be established and followed for areas that have been designated as controlled (or supervised) areas. A Radiation Protection Supervisor (RPS) is appointed to ensure personnel comply with the local rules. A Radiation Protection Adviser (RPA) is appointed to advise the Trust on compliance with the requirements of IRR99. These local rules set out the general principles and description of the means of complying with IRR99.

CONTROLLED AREAS (IRR99 REG. 16 (1))

An area must be designated as a controlled area where special procedures are required to restrict significant exposure or to prevent or limit the probability and magnitude of radiation accidents or their effects, or, the effective dose to a person working in the area is likely to exceed 6mSv per year or an equivalent dose greater than three-tenths of a relevant annual dose limit. (For dose limits refer to Schedule 4 of IRR99).

SUPERVISED AREAS (IRR99 REG. 16 (3))

An area must be designated as supervised area, unless designated as a controlled area, where:
the status of the area must be kept under review to ensure it does not need to become designated as a controlled area, or,
any person is likely to be exposed to an effective dose of more than 1 mSv per year or an equivalent dose greater than one-tenth of any relevant dose limit.

CLASSIFIED PERSONS (IRR99 REG. 20) AND WRITTEN ARRANGEMENTS (IRR99 REG. 18 (2))

If it is likely that an employee during the course of their work will receive an effective dose in excess of 6 mSv per year or an equivalent dose that exceeds three-tenths of any relevant annual dose limit, they have to be designated as a classified person. Only classified persons or those complying with the written arrangements for entry into controlled radiation areas for non-classified persons may enter and remain in a controlled area. Only employees aged 18 years or over may be designated as classified persons. Designation of an employee as a classified person must take into account the potential exposure from likely accidents or if it is foreseeable that the employee could receive a dose greater than a dose limit within several minutes. The Trust does not have any designated classified persons.

PRINCIPLES OF RADIATION PROTECTION

Radiation Protection is based on the three principles:

1. Justification: No practice shall be adopted unless its introduction produces a net benefit.
2. Optimisation: All exposures shall be kept as low as reasonably practicable (ALARP).
3. Limitation: The dose equivalent to individuals shall not exceed the dose limits.

An investigation will be initiated by the RPA should any employee record an effective dose greater than expected and in any case where the recorded dose is greater than 0.5 mSv in any one year.

DUTIES ON EMPLOYEES (IRR99 REG. 34)

Every employee and other persons to whom the regulations apply has the following obligations:

- To abide by the local rules.
- Not to expose themselves or any other person to radiation to an extent greater than is reasonably necessary for the purposes of their work and to exercise reasonable care while carrying out such work.
- To make full and proper use of any protective equipment (including film badges), to return such equipment after use, and, to report any defect in the equipment to their manager.
- To inform their manager of any suspected incident such as an overexposure or loss of a source.

PERSONNEL MONITORING

All necessary staff are issued with personal dosemeters. All doses are recorded to check:

- The annual dose does not approach 3/10 of annual dose limit.
- The dose for any person is not at variance to other workers undertaking similar duties or showing any rise in dose level.
- Environmental dose level, as determined by the dose levels of all staff, does not appreciably alter from previously recorded doses.

C-Arm Appendix 4

RULES FOR ENGINEERING AND MEDICAL PHYSICS STAFF

Engineering and medical physics staff can work in controlled areas providing they have permission from radiology department staff and have signed any necessary handover forms.

During equipment servicing or medical physics tests, the responsibility for the controlled area rests with the engineer or physicist.

Any handover forms provided by the department must be completed.

LOCAL RULES FOR THE TEMPORARY HANDOVER OF CONTROLLED AREA (UNLESS PROVIDED BY ENGINEER/PHYSICIST)

The departmental local rules must be obeyed.

When making exposures, staff should remain behind the protective screen if one is present. If this is not possible due to the nature of the work, a protective lead apron must be worn if staff members are required to remain in the controlled area.

The engineers/physicists personal dosimeter must be worn at all times.

When work is completed, responsibility for the controlled area should be handed back to the department. The need for any further work or action needed should be discussed with the RPS. Any necessary exposure checks should be completed before the equipment is handed back.

If any protective systems or safety features have been overridden during the course of the work, these must be returned back to normal control and checked prior to the controlled area being handed back.

If the equipment cannot be left in full working order, it should be isolated from the mains supply, a notice indicating that the equipment is not working should be placed on the control desk and the departments RPS must be informed.

C-Arm Appendix 5

RISK ASSESSMENT

Area/Ward	Operating Theatre Danetre Hospital – Podiatric Surgery	Directorate	Adult Therapies

People at Risk	
All theatre/ Day Surgery personnel	
Document reference	CLPr030
Issue date	28.02.17
Review frequency	Annual
Author(s)	Ian Reilly, Radiation Protection Supervisor Chris Wood, Radiation Protection Adviser
References	The Ionising Radiations Regulations 1999 (IRR99) Work with Ionising Radiation – ACoP Medical and Dental Guidance Notes

DESCRIPTION OF RISK

Risk of fluoroscopic exposure using a mini c-arm
Nature of Source of Ionising Radiation (ACoP 44(a))
50 to 120 kV X-rays, either as primary, transmitted, secondary or leakage radiation from the X-ray tube and patient.
Exposed Groups and Dose Constraints
Staff involved – Podiatrists, theatre staff, service engineers, medical physicists.
Other persons involved – patient.
Dose constraints – as stated in Schedule 4 of IRR99.

ESTIMATED DOSE RATES TO STAFF/MEMBERS OF THE PUBLIC (ACOP 44(B))

There is no public access to the gait analysis room. The controlled area is designated such that dose to staff will be less than 0.3mSv per year.
Results of previous dosimetry and/or area monitoring (ACoP 44(e))
Not applicable - this is a new service.
Advice from the equipment manufacturer/supplier (ACoP 44(e))
Equipment is serviced in line with manufacturer's advice.

SYSTEMS OF WORK (ACOP 44(G))

Local rules are available as required by IRR99 Regulation 17.

PERSONAL PROTECTIVE EQUIPMENT REQUIREMENTS (ACOP 44(I))

Lead aprons should be equivalent to not less than 0.25mm lead for use with X-rays up to 100kV and not less than 0.35mm lead for X-rays over 100kV (MDGN 3.119).

RESTRICTION OF ACCESS (ACOP 44(J))

Access to the theatre is controlled by fob access.

CONTINGENCY ARRANGEMENTS (ACOP 44(K),(M))

Possible accident – Unit fails to terminate X-ray production at end of set time.
Likelihood – Rare.
Likely dose to staff/member of public – Minimal (staff will be wearing personal protective equipment).
Contingency arrangement - Exposure must be terminated using emergency stop button. The RPS must be informed and the equipment must be taken out of use.
Measures to prevent or limit accident – Regular servicing of equipment.

Possible accident - Unauthorised person in controlled area during exposure.
Likelihood – Rare
Likely dose to staff/member of public – Less than 10μSv per exposure.
Contingency arrangement - exposure halted if possible (with due regard to examination requirements), person to be removed or provided with protection as appropriate. The RPS must be informed.
Measures to prevent or limit accident – Operator can see the extent of the controlled area and terminate the exposure if necessary.

Possible accident – Operator's hand inadvertently enters primary or transmitted radiation field.
Likelihood – Possible.
Likely dose to staff – Less than 10mSv for a 5-second exposure to primary radiation.
Contingency arrangements - Operator to remove hand and reposition. The RPS must be informed.
Measures to prevent or limit accident – Operator training.

DESIGNATION OF AREAS (IRR99 REG.16)

A controlled area is defined as being within 2m of the patient and X-ray tube when X-rays are being emitted.

DESIGNATION OF WORKERS (IRR99 REG.20)

The doses likely to be received during normal work and in any reasonably foreseeable incident, where staff follow the contingency arrangements in the local rules, are likely to be well below three-tenths of the annual dose limits. Designation as classified workers is therefore not required.

Risk Score (Using Risk Scoring Matrix)		
Severity (S) = 6	Likelihood (L) = 1	Risk (S X L) = 6

Conclusion/Justification for Rating				
Due to the environment / nature of the work and large equipment/sets the risk is a moderate				
Adequately controlled	YES/NO	Risk Assessor	Sign (wet signature)	Date
If no add risk onto risk register/action plan. All recommendations to further control risk must also go onto the risk register/action plan.	YES	Ian Reilly		28.02.17

Review Date		
December 2019		
Print name	Sign	Date

	Likelihood				
Likelihood score	**1**	**2**	**3**	**4**	**5**
	Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

- 1 - 3 Low risk
- 4 - 6 Moderate risk
- 8 - 12 High risk
- 15 - 25 Extreme risk

C-Arm Appendix 6
AUDIT LOG

Mini C-arm Log/Audit

Date	Pregnant	Clinician	Patient no.	Anatomy	Justification	Views	Screening time	Dose (mSv)	Outcome

C-Arm Appendix 7

RECOMMENDED STEPS FOR USE OF THE FLUROSCAN INSIGHT

1. Locking of the C arm should be done as a first priority to protect the vital component of the Fluroscan Diagnostic Tool.
2. The Monitor should always be folded down when the Fluroscan machine is being transported, to help with better vision as well as protecting the screen.
3. When logging in to the Fluroscan, the “Admin and Field service” is only meant for the Consultant Podiatric Surgeon.
4. For better functionality, it is recommended that the Fluroscan has time to warm up before being used.
5. While logging in, 3 fields including a study description need to be filled. These would include, the patients name, surname, DOB, gender and PASCOM number (in CAPS).
6. The use of the snap shot on the screen more commonly used than continuous loop, please ensure that the Noise record is off.
7. Cine record only runs for 10 seconds.
8. Noise suppression ultra is best used for foreign body identification.
9. Tag as reference is used for choosing sides.
10. Time reset, simply tap the button for it to stop.
11. Operating foot paddle has to be stored with the black button facing out.
12. Applications are for image tools.
13. Brightness and contrast must be constantly monitored to avoid radiation abuse.
14. The field marker on Fluroscan C arm has to be on end scale gauge.
15. Images can be shared on the Fluroscan Insight, or saved on a USB or on a CD-ROM.
16. 'End session' has a saving reminder for the Practitioner, by clicking the review button, it goes back.
17. The C arm has locks and is capable of being rotated around, however with time, these can lose their grip and technical advice will have to be sought.
18. The C arm sterile applications field works around review and performance.
19. The laser beam is for central location and the bottom pad can be manipulated to suit the position of the target (Foot).
20. DAP (Dose/Area/Product) report, records the amount of exposure of radiation per patient. It has legal implications that are governed by the CQC, including a built in Audit log on system.

APPENDIX 14: The accuracy of first metatarsophalangeal joint palpation guided injections. An arthrography cadaveric study

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Original Research

The accuracy of first metatarsophalangeal joint palpation guided injections. An arthrography cadaveric study

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ARTICLE INFO

Keywords:
First metatarsophalangeal joint
Steroid injection
Hallux limitus
Hallux rigidus
Injection accuracy

ABSTRACT

Background: Injectable glucocorticoids are widely used in the management of foot pathology, in particular for the treatment of osteoarthritis of the great toe - hallux limitus/rigidus. Injections can be performed using anatomical (blind) guided methods or performed with needle placement aided by the use diagnostic imaging with ultrasound or fluoroscopy, with or without the use of contrast media.
Aim: Palpation and image guided injection techniques have been studied in other joints of the body but less so for the first metatarsophalangeal joint of the foot, where palpation guidance is commonly performed. The aim of this study was to investigate the injection accuracy of palpation guided injections of the first metatarsophalangeal joint in six cadaveric feet using radio-opaque contrast media.
Methods: The injection equipment consisted of a 2.5 ml Luer lock syringe and a 23-gauge needle used to inject iohexol (Omnipaque 300) into the first metatarsophalangeal joint in six cadaveric specimens. The needle was placed into the joint space by a single practitioner using palpation guidance. The contrast media was injected under live (cine) view without further movement or ingress of the needle. The injectate was considered accurate if the media coated the inside of the synovial membrane and/or outlined the joint shape.
Findings: Failure of technique was seen in one of six feet, and extravasation of contrast media beyond the joint margins noted in three out of six feet.
Conclusions: Further study on a large sample of live subjects using a variance of technique is required to expand the confidence of these findings but the high failure rate calls into question the confidence of palpation guided techniques for injection of the first metatarsophalangeal joint.

Introduction

Background

Injection therapy for joint pathology is one of the most common therapeutic interventions in musculoskeletal healthcare.[1] Most therapeutic injections into joints consist of a glucocorticoid, a local anaesthetic, or a combination of the two, and are widely used in the treatment of foot pathology, in particular for the treatment of osteoarthritis of the first metatarsophalangeal joint (1st MTP jt) - hallux limitus/rigidus.[2] Injections into the joint can be performed using anatomical (palpation-guided) guided methods[3] or performed with needle placement aided by diagnostic imaging from ultrasound (US) or fluoroscopy, with or without the use of contrast media.[4,5]

Arthrography

Injection of contrast media comes in two basic forms: injection via percutaneous needle access, such as direct arthrography, or injection via an indwelling catheter or tube, such as in cystography or sinography.[6] Arthrography is the intra-articular (IA) injection of contrast media to improve the evaluation or visualisation of joint structures under imaging (i.e., outline the articular structures, and gives information on basic joint architecture) or for confirmation of needle placement prior to the intra articular delivery of medication(s).[7]

Aim

Palpation and image-guided techniques have been studied in other joints of the body but less so for the 1st MTP jt, where palpation

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guidance is commonly performed.[8] Production of a best practice injection technique for the 1st MTP Jt by novice injectors has already been presented as part of this schema of work.[3] The aim of this experiment was to investigate the accuracy of that technique and injectate placement using radio-opaque contrast media.

Methods

Ethical approval

The study was authorised by Innovation and Research Department, Northamptonshire Healthcare NHS Foundation Trust (NHFT) and approved by the Ethics Committee of Staffordshire University (ref: SPOR80004-2019-SPG2-2020-SPG1) as part of a professional doctorate programme.

Location of the study

The procedure room at Danetre Hospital, Daventry was used with access to handwashing and sharps disposal. The X-ray machine used was the InSight mini-C-arm fluoroscan (Holologic International). Personal protective equipment (PPE) consisted of a standard lead x-ray gown and thyroid protector, sterile gown gloves, and eye protection. The Principal Investigator (PI) was Ian Reilly, with assistance from a Podiatric Surgery team member for additional photography. The PI is a Radiation Protection Supervisor (RPS) with authority and responsibility to direct and expose radiographic images. Standard safety precautions were followed, as per the (Northamptonshire Healthcare Foundation NHS Trust (NHFT) C-Arm protocol.

Cadaveric specimens

A total of six cadaveric feet from six individual donors were used for this investigation, which was the maximum number that were available at the time of the study. All cadaveric feet were anonymous, fresh-frozen specimens, thawed overnight, and obtained from the Procedural Skills Laboratory at Nottingham City Hospital (NCH), and delivered via anatomy technologists to the NHFT Department of Podiatric Surgery, Danetre Hospital. The anatomy technologists were responsible for the transporting, safety, and safe return of all cadavers and at all times the feet were the responsibility of the NCH anatomical team. The specimens were noted to be free from major deformity, trauma, or surgical changes. Three feet were right-sided, three were left-sided.

Procedure

A green (21-gauge needle) was used to draw up the injectate into a 2.5 ml Luer lock syringe, and a blue (23-gauge needle) needle to inject the contrast media. The injectate was iohexol [N,N′-Bis(2,3-dihydroxypropyl)−5-[N-(2,3-*dihydroxypropyl*)-*acetamido*]−2,4,6-triio-doisophthalamide], a non-ionic, water-soluble radiographic contrast medium, with a molecular weight of 821.14 and iodine content 46.36%. nn (Omnipaque, GE Healthcare AS, Buckinghamshire, UK). Immediately prior to the study six identical syringes were prepared with 2.5 ml of Omnipaque 300.

All injections were performed by the PI using the following sequence:

1. The PI placed a blue, 23-gauge hypodermic needle in the 1st MTP jt in six cadaveric specimens using a standard palpation guided technique,
2. A pre-injection anterior-posterior (AP) x-ray was taken of the foot but with no change in position or further ingress of the needle (see Fig. 1),
3. 2 ml of iohexol was injected into the joint space under live (cine) view ensuring safe distancing of the PI from the x-ray beam,
4. Following each injection, the foot was x-rayed in the AP and lateral (LAT) planes to confirm the location of contrast media placement (see Fig. 2),
5. The injectate was considered accurate if the contrast media coated the inside of the synovial membrane and/or outlined the joint shape,
6. The contrast media was considered inaccurate if the dye did not coat the inside of the synovial membrane or outline the joint shape,
7. Each injection/x-ray sequence took between 3 and 5 min,
8. All X-rays were stored on secure NHS server for further assessment,
9. The results were tabulated and subject to further analysis (see Table 1).

See supplementary video material.

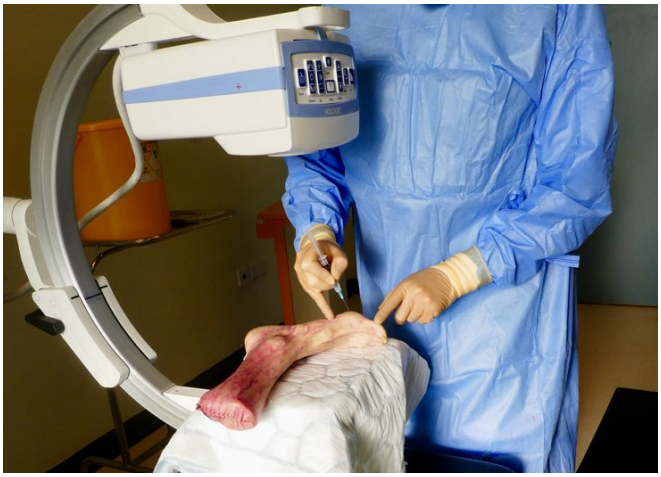

Fig. 1. Needle placement in the 1st MTP jt prior to X-ray.

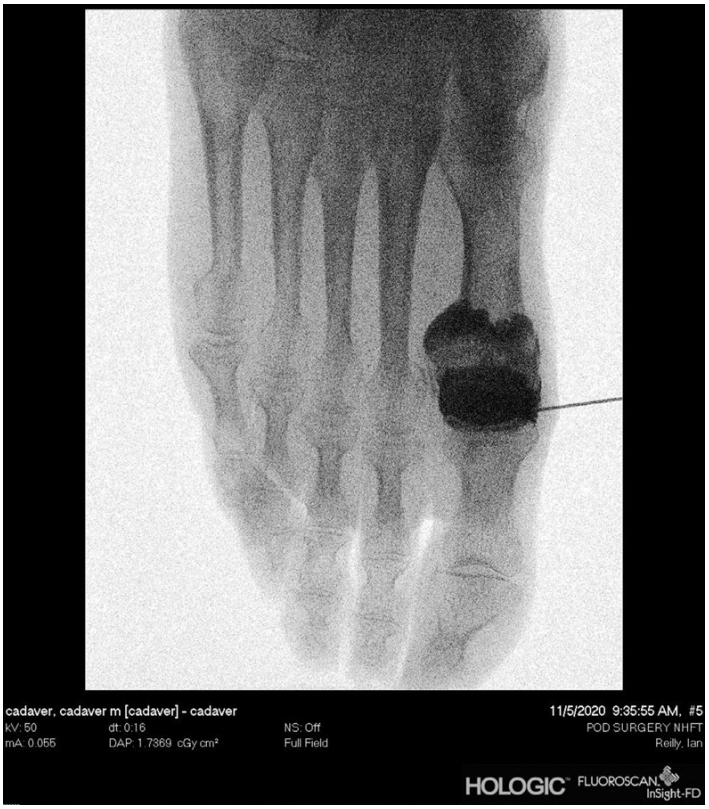

Fig. 2. Needle placement in the 1st MTP jt (specimen 1) post infiltration.

Results

The results are at Table 1 (see supplementary images). An extra, pre-infiltration, lateral x-ray was taken of specimen 1 only, prior to injection of the contrast media. No lateral view was taken for specimen 2 owing to the surprising failure in technique causing the PI to omit this step (see Fig. 3). Five out of the six injections were accurate with the contrast media coating the inside of the synovial capsule. However, three of five accurate injections (specimens 3, 4 and 5) showed some extravasation of the contrast media beyond the joint space: two plantar-proximally and one dorso-medially and proximally (see Fig. 4).

Table 1
Results of contrast media placement.

Specimen	Accurate?	Leakage	Remarks
1	Yes	No	One extra pre-injection lateral X-ray view demonstrating good needle placement prior to injection
2	No	NA	Significant extra-capsular leakage medially, and proximally via a digital vessel; no lateral view taken
3	Yes	Yes	Accurate injection but slight leakage of dye plantar-proximally
4	Yes	Yes	Accurate injection but moderate leakage dorso-medial and proximally
5	Yes	Yes	Accurate injection but slight leakage of dye plantar-proximally
6	Yes	No	Dorsal joint mouse seen on encircled with dye on lateral view but within synovial membrane

The cadavers were subsequently used as part of a cadaveric surgery dissection course for podiatric surgery students. On specimen 1, following dissection of the soft tissues and subcutaneous layer away from the joint capsule, a 1.0 mm Kirschner (K) wire was inserted into the joint using the standard palpation guided technique. With minimal extra advancement of the K-wire, the tip punctured and exited the capsule dorso-laterally (see Fig. 5). A wider discussion around technical failure will be the subject of a subsequent article.

Discussion

Koski et al.[9] state that palpation guided injection of joints and soft tissues is an important clinical skill used in everyday work by clinicians in several speciality fields. Naylor et al.[8] had 18 emergency medicine residents perform four US and four landmark (LM) guided aspirations each of 1st MTP jt simulated effusions in fresh-frozen cadavers. A total of 144 joint aspirations were attempted: 72 by US and 72 by LM guidance. In

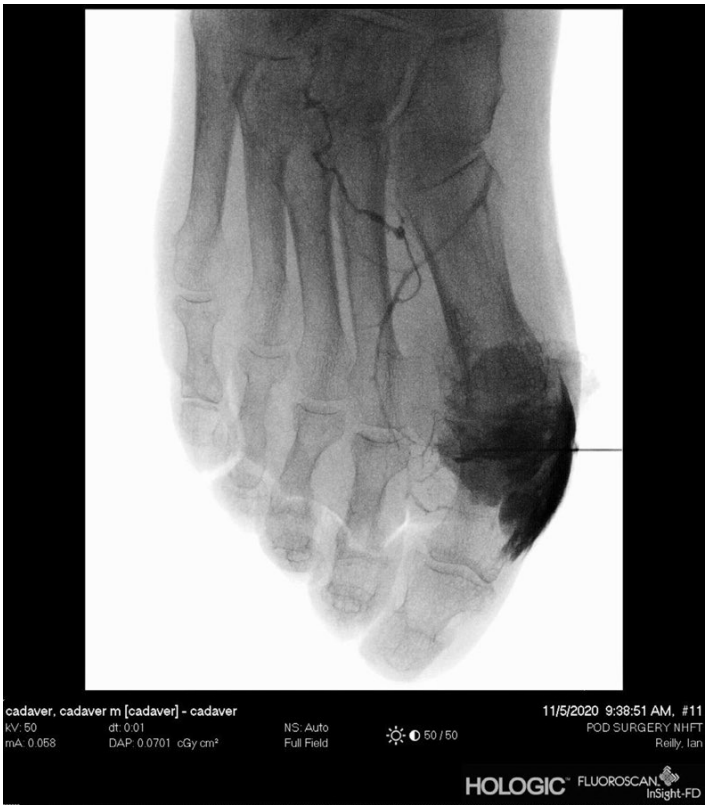

Fig. 3. Inaccurate injection and leakage into local vessels (specimen 2).

their study, US did not prove superior to LM for first-pass aspiration of 1st MTP jt effusions. The PI was expecting to see 100% accurate injections in this study and therefore the complete failure of technique in specimen two was surprising. Further work is now planned to identify the reasons for - and management of - injection technique failure. Three of the five accurate injections had extra-capsular leakage which may predispose to complications such as atrophy and tendon rupture. Further, the live (cine) view demonstrates the contrast media infiltrating the medial tissues then intravenously entering one of the digital vessels and coursing proximally. This has implications for the under-reported risk of accidental intravenous injection. Regrading contrast media, Wang et al.[10] note that most patients in whom extravasations of nonionic iodinated contrast medium occur rarely result in moderate or severe adverse effects but McAlister and Palmer[11] note that an acute local inflammatory response from contrast media may not peak until 24 to 48 h post procedure.

Derian et al.[12] state that smaller joints, such as the first carpometacarpal joint (CMC) are often affected by degenerative joint conditions that may benefit from therapeutic injections. They hypothesised that image guidance may be useful for accurate needle placement in these smaller joints but in an ultrasound vs palpation guided latex dye injection cadaveric study of the 1st CMC jt, they found no difference between the two methods. However, injectate placement accuracy - judged on a four-point scale after dissection of the joint - found that most of the injections (59.7%) were 50%, or less, accurate.

Pollard et al.[13] investigated the accuracy of IA injection of the basal thumb joint and to determine the rate of soft-tissue extravasation of injected material in successful IA injection. The authors injected 30 cadaveric hands with radiopaque dye - with fluoroscopy-guided needle placement in 8 specimens - and then used fluoroscopy to check injection accuracy. The results were recorded depending on the location of the injected dye under fluoroscopic examination. The rates of IA accuracy and soft-tissue extravasation for successful IA injections were 100 and 25% for the fluoroscopy guided group and 81.8 and 33% for the "blind" group. The authors discuss that this is a relatively high soft tissue extravasation rate for successful IA injection with the implications for drug extravasation into the surrounding extra-articular space presumed to be similar to those cited for failed needle placement. The authors also recommend injecting a drug at an appropriate volume. In their study, 0.2–0.5 mL were injected; they note that a palpable endpoint was difficult to detect but they suggest that forcing excess fluid into the joint space may induce a painfully distended capsule and that care must be exercised during injections to prevent excessive internal pressurization of the capsule. The authors accept the shortcomings of their study viz using preserved cadaveric specimens for injection where surface

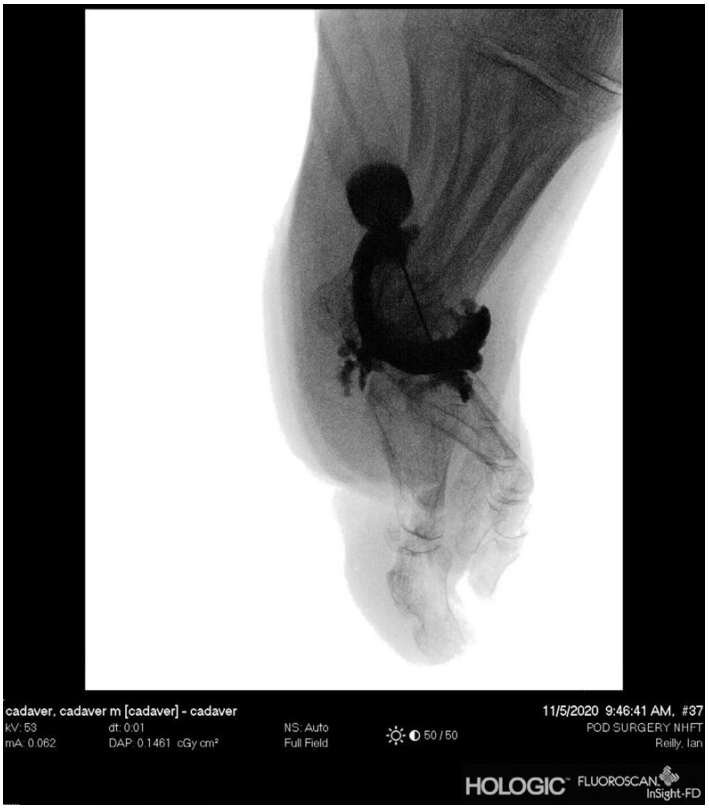

Fig. 4. Extra-articular leakage of injectate (specimen 5).

anatomy (and joint mobility) is more difficult to identify in stiff, embalmed specimens.

The local pathological changes and the experience of the clinician are also relevant. Heidari et al.[14] found that the presence of pathologic changes reduces the rate of successful IA puncture, but that the overall frequency of successful IA injections can be improved through experience and the use of imaging. In their study a total of 106 cadaveric 1st MTP jts were injected with a methylene blue solution and then dissected to distinguish IA from periarticular injections. To evaluate the importance of experience, 38 injections were performed by a student, 38 by a trained resident, and 30 by an experienced surgeon. In the second part of the study, the authors examined the relation of pathologic findings of the MTP jt and the accuracy of IA injection. The overall rate of unintentional periarticular injections was low (9.4%; 10 of 106 joints). The student achieved a successful IA injection in 86.8% of joints (33 of 38), the resident in 92.1% (35 of 38), and the specialist in 93.3% (28 of 30). The number of extra-articular injections increased significantly with the presence of deformity (hallux valgus) or osteoarthritis of the 1st MTP jt.

Curtiss et al.[15] found that the accuracy of supero-lateral, palpation-guided knee injections were significantly influenced by experience, with a less-experienced investigator demonstrating an accuracy rate of only 55% compared to a more experienced investigator demonstrating an accuracy rate of 100%. At the time of the investigation, the senior author had 19 years of experience in injection therapy of the foot and ankle, including 14 years' experience in teaching injection techniques to podiatrists and trainee podiatric surgeons, nationally and internationally. The overall implication of our study is therefore that palpation guided injections of the 1st MTP jt has a significant failure rate, in this series despite the experience of the PI. This calls into question the accuracy of palpation guidance for the 1st MTP Jt.

Multiple systematic reviews by confirm that injection accuracy is improved with the use of US guidance over palpation-guidance. Over advancement of the needle into and out of the joint could be one reason for technique failure. Compounding the failure could be the length of the needle. Typically, the senior author recommends a 1¼ inch 23-gauge (blue) needle as the standard for 1st MTP jt injections. A shorter needle, for instance the ¾ inch 25-gauge (orange) needle might be less prone to 'overshooting the target'. These factors will be discussed in greater detail in a subsequent paper.

This study had several limitations that warrant discussion. The first consideration is the sample size. Only six specimens were available at the time of the study, which was insufficient to carry out statistical analysis. Consideration was given to performing a post-hoc power calculation but as the main effort of this study was to look at needle accuracy, and this was

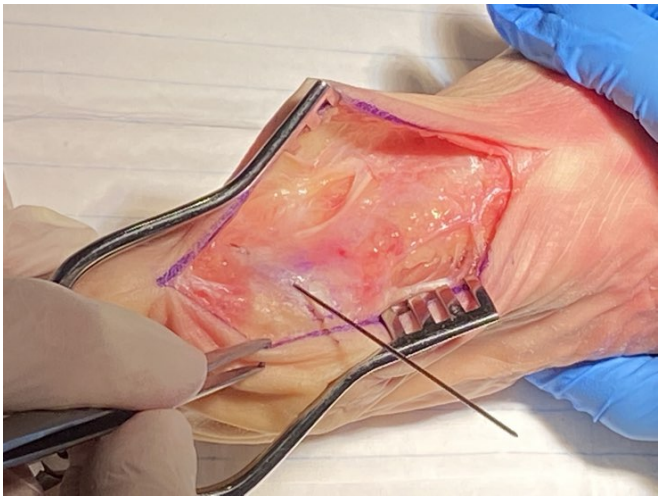

Fig. 5. Needle placement in the 1st MTP jt.

therefore discounted. Future studies would benefit not only from having a larger sample size and performed using live subjects with confirmed metatarsal phalangeal joint pathology (rather than cadaver specimens). Use of fresh frozen over embalmed specimens was considered to be as close to a realistic clinical scenario as possible, and injection equipment used was exactly that as used by the author in clinical practice but as Pollard et al.[13] (and other authors) state in their studies, clinicians may wish to exercise caution when extrapolating cadaveric data into clinical populations.

Conclusion

The accuracy of palpation-guided injections of the 1st MTP jt was assessed in an arthrography cadaveric study. In this study there was a complete failure of technique in one of six specimens and extra-capsular leakage in three out of six specimens. Further work is required to identify the reasons for - and management of - injection technique failure.

Ethics approval and consent to participate

Ethical approval was sought and received from Staffordshire University Ethics committee.

Consent for publication

Not applicable.

Availability of data and material

Data for this paper is available on request.

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Declaration of Competing Interest

The authors have no competing interests to declare.

CRediT authorship contribution statement

Ian Reilly: Conceptualization, Methodology, Visualization, Investigation, Writing – original draft, Writing – review & editing. **Nachiappan Chockalingam:** Visualization, Writing – review & editing. **Roozbeh Naemi:** Visualization, Writing – review & editing.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.fastrc.2022.100219.

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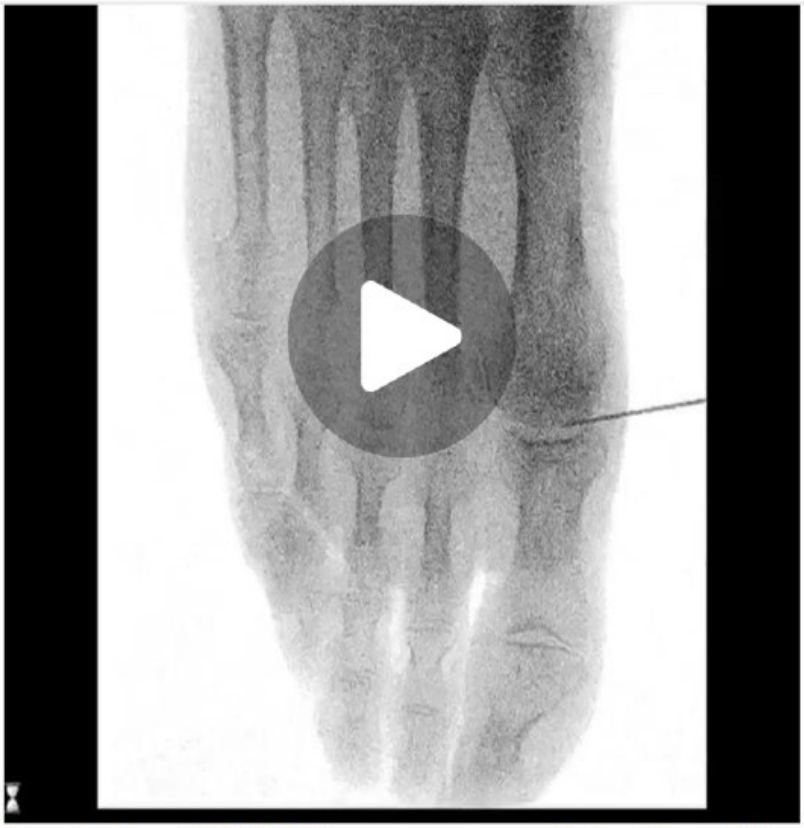

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Help with .mp4 files

APPENDIX 15: Patient consent for digital photographs (redacted)

Patient AR

Phot Consent Form Sheet
Ver 04 updated 17.05.19

Northamptonshire Healthcare NHS
NHS Foundation Trust

Department of Podiatric Surgery – AV Consent Form
Audio Visual Recording (including photographs)

Patient Details

Name: .....[redacted].....

Date of Birth: .....[redacted].....

Address: .....[redacted].....

Clinic	Department of Podiatric Surgery, Danetre Hospital/Isebrook Hospital
Clinician	

We are making this recording/taking photographs to help train future healthcare professionals and for educational purposes. These images will be used within Northamptonshire Healthcare NHS Foundation Trust but may also be accessible to other parties outside the Trust. XRAYS FOR PUBLICATION

Your involvement with this is entirely voluntary and needs your consent. Any images shared outside of the Trust will be anonymised (your name/personal details will not appear and you will not be identified). We will not be able to withdraw any of these recordings/photographs from circulation as all personal details will have been removed prior to use.

To be completed by patient:

I understand a recording and/or photographs will be taken for the reasons stated above. I confirm that I understand the information given to me about the process and hereby give my consent for a recording/photographs to be taken today.

Patient signature: .....[redacted]..... 20/10/21.

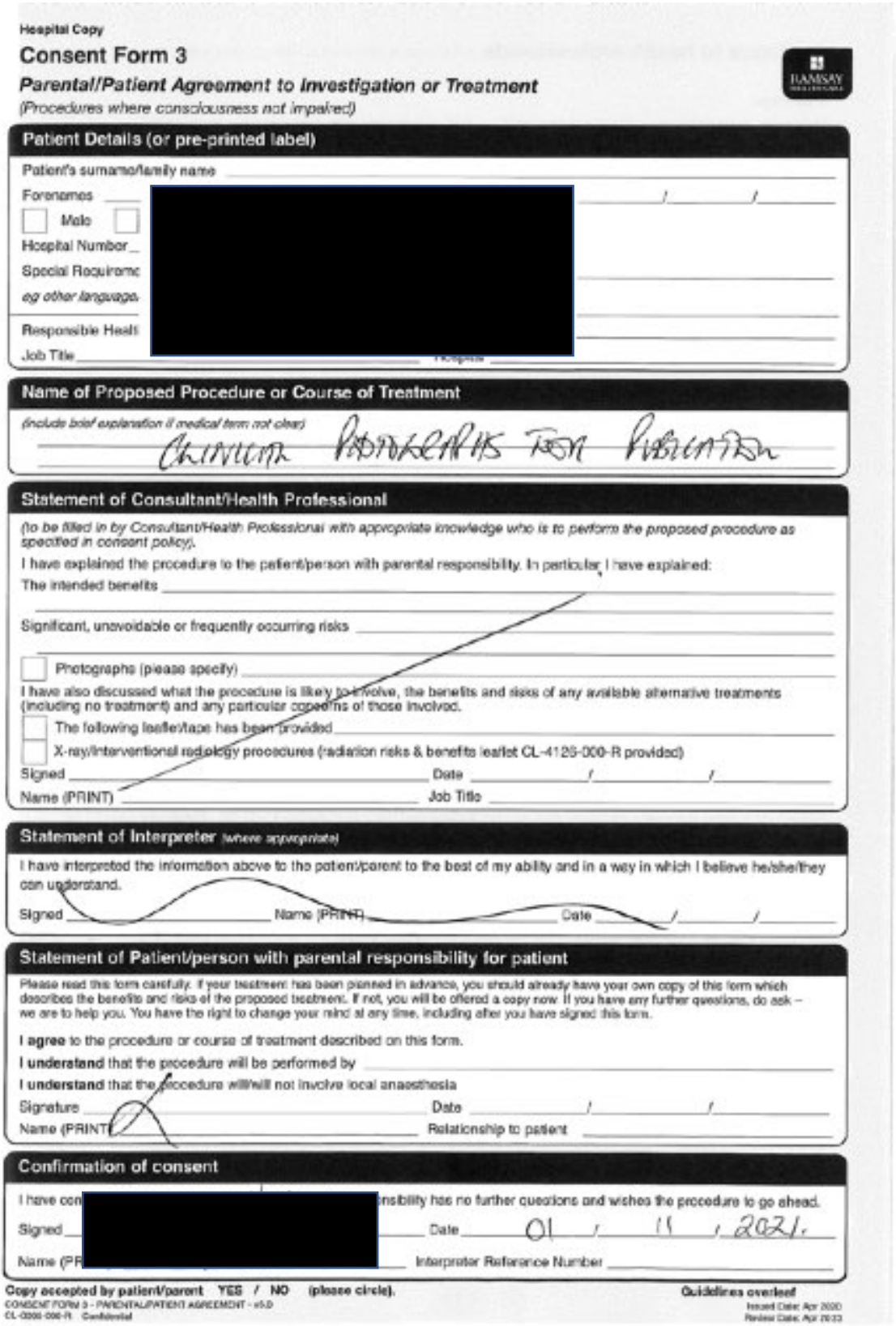
Clinician signature: .....

Date recording/photographs taken ..... 20.10.21.

This form to be retained in patient's case notes/S1.

The Podiatric Surgery Service Danetre Hospital, London Road Daventry, Northants. NN11 4DY
Telephone: (01327) 708102. Email: podiatric.surgery@nhft.nhs.uk

Patient DP



Hospital Copy

Consent Form 3

Parental/Patient Agreement to Investigation or Treatment

(Procedures where consciousness not impaired)

Patient Details (or pre-printed label)

Patient's surname/family name

Forenames

☐ Male ☐

Hospital Number

Special Requirements

eg other language

Responsible Healt

Job Title

Name of Proposed Procedure or Course of Treatment

(include brief explanation if medical term not clear)

Statement of Consultant/Health Professional

(to be filled in by Consultant/Health Professional with appropriate knowledge who is to perform the proposed procedure as specified in consent policy).

I have explained the procedure to the patient/person with parental responsibility. In particular I have explained:

The intended benefits

Significant, unavoidable or frequently occurring risks

☐ Photographs (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.

☐ The following leaflet/tape has been provided

☐ X-ray/Interventional radiology procedures (radiation risks & benefits leaflet CL-4125-000-R provided)

Signed Date / /

Name (PRINT) Job Title

Statement of Interpreter *(where appropriate)*

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe he/she/they can understand.

Signed Name (PRINT) Date / /

Statement of Patient/person with parental responsibility for patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of this form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that the procedure will be performed by

I understand that the procedure will/will not involve local anaesthesia

Signature Date / /

Name (PRINT) Relationship to patient

Confirmation of consent

I have con nsibility has no further questions and wishes the procedure to go ahead.

Signed Date 01 / 11 / 2021.

Name (PR Interpreter Reference Number

Copy accepted by patient/parent YES / NO (please circle).

Guidelines overleaf

CONSENT FORM 3 - PARENTAL/PATIENT AGREEMENT - v5.0

CL-0000-000-R Confidential

Issued Date: Apr 2020

Review Date: Apr 2023

Patient KC

Phot Consent Form Sheet
Ver 04 updated 17.05.19

Northamptonshire Healthcare NHS
NHS Foundation Trust

Department of Podiatric Surgery – AV Consent Form
Audio Visual Recording (including photographs)

Patient Details

Name: [redacted]

Date of Birth:

Address:

Clinic	Department of Podiatric Surgery, Danetre Hospital/Ledbrook Hospital
Clinician	IAN ITEM

We are making this recording/taking photographs to help train future healthcare professionals and for educational purposes. These images will be used within Northamptonshire Healthcare NHS Foundation Trust but may also be accessible to other parties outside the Trust. [redacted]

Your involvement with this is entirely voluntary and needs your consent. Any images shared outside of the Trust will be anonymised (your name/personal details will not appear and you will not be identified). We will not be able to withdraw any of these recordings/photographs from circulation as all personal details will have been removed prior to use.

To be completed by patient:

I understand a recording and/or photographs will be taken for the reasons stated above. I confirm that I understand the information given to me about the process and hereby give my consent for a recording/photographs to be taken today.

Patient signature: .....

Clinician signature: .....

Date recording/photographs taken ..... 13/10/21.

This form to be retained in patient's case notes/S1.

The Podiatric Surgery Service Danetre Hospital, London Road Daventry, Northants. NN11 4DY
Telephone: (01327) 708102. Email: podiatric.surgery@nhft.nhs.uk

Patient LT

Patient Copy

Consent Form 3

Parental/Patient Agreement to Investigation or Treatment

(Procedures where consciousness not impaired)

RAMSAY HEALTH CARE

Patient Details (or pre-printed label)

Patient's surname/family name

Forenames

☐ Male ☐ Female

Hospital Number

Special Requirements

eg other language/other com

Responsible Health Professic

Job Title

[redacted]

Name of Proposed Procedure or Course of Treatment

(include brief explanation if medical term not clear)

CONSENT FOR PHOTOGRAPH FOR PUBLISHING

Statement of Consultant/Health Professional

(to be filled in by Consultant/Health Professional with appropriate knowledge who is to perform the proposed procedure as specified in consent policy).

I have explained the procedure to the patient/person with parental responsibility. In particular I have explained:

The intended benefits CLINICAL EDUCATION

Significant, unavoidable or frequently occurring risks

☐ Photographs (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.

☐ The following leaflet/tape has been provided

☐ X-ray/Interventional radiology procedures (radiation risks & benefits leaflet CL-4126-000-R provided)

Signed Date

Name (PRINT) Job Title

Statement of Interpreter *(where appropriate)*

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe he/she/they can understand.

Signed Name (PRINT) Date

Statement of Patient/person with parental responsibility for patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of this form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that the procedure will be performed by MR (CM)

I understand that the procedure will/will not involve local anaesthesia

Signature Date 16 / 10 / 21

Name (PRINT) Relationship to patient

Confirmation of consent

I have confirmed that the patient/person with parental responsibility has no further questions and wishes the procedure to go ahead.

Signed Date 16 / 10 / 21

Name (PRINT) [redacted] Interpreter Reference Number

Copy accepted by patient/parent YES / NO (please circle).

CONSENT FORM 3 - PARENTAL/PATIENT AGREEMENT - v5.0
CL-0005-000-R Confidential

Guidelines overleaf

Issued Date: Apr 2020
Review Date: Apr 2023

Patient MH

BMI Three Shires Hospital
The Avenue, Cliftonville
Northampton NN1 5DR

Secretary: Vicki Elwill
Tele: 01604 885003

Date of Clinic: 14 October 2021
Date of Transcription: 19 October 2021

[redacted]

Dear Dr [redacted]

Re:	[redacted]	**DOB:**	[redacted]
		NHS No.	
		Hosp. No	[redacted]

Diagnosis:	Right 1st turf toe
Co-morbidities:	Unstable ankle
Medication:	Nil of note
Suggested mgnt:	Cortisone injection
Review date:	Thursday 21st October at 5:30pm

I have had a telephone consultation with [redacted] following his scan. He has had ultrasonography with gadolinium and MRI, which shows an attenuated medial collateral ligament and partial rupture of the plantar plate (*he will kindly let me use images for an academic article i am currently writing on 1st MTP jt pathology*).

The conundrum is knowing how much to do for [redacted] to try and make him better without making him worse. Surgically, it would be a very difficult fix and I am concerned that the trauma of surgery would negate any potential improvement, so I have therefore recommended that we try a cortisone shot. We will do this for him next week and I will do a small injection of cortisone into the joint, which will hopefully settle down some of his discomfort. The major concern is to take the joint and make it unstable when it is currently not – overuse of steroid is implicated in joint laxity and rupture. I will therefore use a small amount of cortisone to try to improve symptoms and I will do this for him under ultrasound guidance next week.

With best wishes

Yours sincerely

(checked by Mr Reilly but sent unsigned to avoid delay)

Mr Ian Reilly MSc, FRCPodS, FFPM RCPS(Glasg)
Consultant Podiatric Surgeon

c.c. [redacted] – for your information

Patient NB

Consent form

I [redacted] [Name] give my consent for information about myself/my child or ward/my relative (circle as appropriate) to be published in ……. [redacted]. ……

[Name of journal, manuscript number and corresponding author].

I understand that the information will be published without my/my child or ward's/my relative's (circle as appropriate) name attached, but that full anonymity cannot be guaranteed.

I understand that the text and any pictures or videos published in the article will be freely available on the internet and may be seen by the general public. The pictures, videos and text may also appear on other websites or in print, may be translated into other languages or used for commercial purposes.

I have been offered the opportunity to read the manuscript.

Signing this consent form does not remove my rights to privacy.

Name… [redacted]

Date… 22/04/2020

Signed… [redacted]

Author name… Ian Reilly

Date… 22/04/20

Signed… Ian Reilly

Please keep this consent form in the patient's case files. The manuscript reporting this patient's details should state that 'Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient. A copy of the consent form is available for review by the Editor of this journal.

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Patient NR

Consent form

I [redacted] [Name] give my consent for information about myself/my child or ward/my relative (circle as appropriate) to be published in [redacted]

[Name of journal, manuscript number and corresponding author].

I understand that the information will be published without my/my child or ward's/my relative's (circle as appropriate) name attached, but that full anonymity cannot be guaranteed.

I understand that the text and any pictures or videos published in the article will be freely available on the internet and may be seen by the general public. The pictures, videos and text may also appear on other websites or in print, may be translated into other languages or used for commercial purposes.

I have been offered the opportunity to read the manuscript.

Signing this consent form does not remove my rights to privacy.

Name [redacted]

Date 22/04/2020

Signed [redacted]

Author name Ian Reilly

Date 22/04/20

Signed Ian Reilly

Please keep this consent form in the patient's case files. The manuscript reporting this patient's details should state that 'Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient. A copy of the consent form is available for review by the Editor of this journal.

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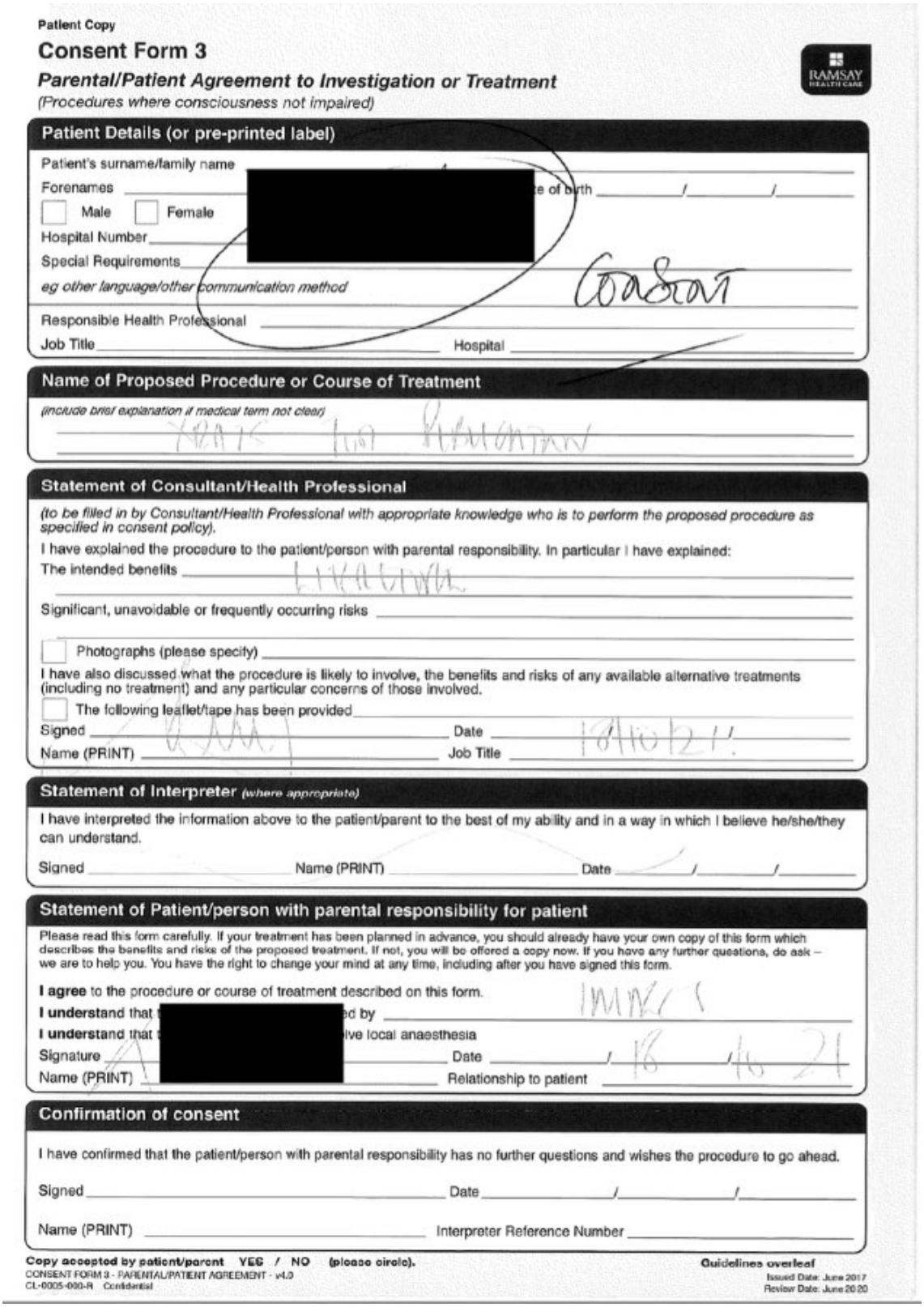
Patient RH



Patient Copy

Consent Form 3

Parental/Patient Agreement to Investigation or Treatment

(Procedures where consciousness not impaired)

RAMSAY HEALTH CARE

Patient Details (or pre-printed label)

Patient's surname/family name

Forenames [redacted] e of birth / /

☐ Male ☐ Female

Hospital Number

Special Requirements

eg other language/other communication method Cobalt

Responsible Health Professional

Job Title Hospital

Name of Proposed Procedure or Course of Treatment

(include brief explanation if medical term not clear)

Statement of Consultant/Health Professional

(to be filled in by Consultant/Health Professional with appropriate knowledge who is to perform the proposed procedure as specified in consent policy).

I have explained the procedure to the patient/person with parental responsibility. In particular I have explained:

The intended benefits

Significant, unavoidable or frequently occurring risks

☐ Photographs (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.

☐ The following leaflet/tape has been provided

Signed Date 18/10/21

Name (PRINT) Job Title

Statement of Interpreter *(where appropriate)*

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe he/she/they can understand.

Signed Name (PRINT) Date / /

Statement of Patient/person with parental responsibility for patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of this form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that [redacted] ed by

I understand that [redacted] ive local anaesthesia

Signature Date / /

Name (PRINT) Relationship to patient

Confirmation of consent

I have confirmed that the patient/person with parental responsibility has no further questions and wishes the procedure to go ahead.

Signed Date / /

Name (PRINT) Interpreter Reference Number

Copy accepted by patient/parent YES / NO (please circle).

Guidelines overleaf

CONSENT FORM 3 - PARENTAL/PATIENT AGREEMENT - v4.0

CL-0005-000-R Confidential

Issued Date: June 2017

Review Date: June 2020

Patient RF

Phot Consent Form Sheet
Ver 04 updated 17.05.19

Northamptonshire Healthcare NHS
NHS Foundation Trust

Department of Podiatric Surgery – AV Consent Form
Audio Visual Recording (including photographs)

Patient Details

Name: .....[redacted]...

Date of Birth: .....[redacted]...

Address: .....[redacted]...

Clinic	Department of Podiatric Surgery, Danetre Hospital/Isebrook Hospital
Clinician	[redacted]

We are making this recording/taking photographs to help train future healthcare professionals and for educational purposes. These images will be used within Northamptonshire Healthcare NHS Foundation Trust but may also be accessible to other parties outside the Trust.

Your involvement with this is entirely voluntary and needs your consent. Any images shared outside of the Trust will be anonymised (your name/personal details will not appear and you will not be identified). We will not be able to withdraw any of these recordings/photographs from circulation as all personal details will have been removed prior to use.

To be completed by patient:

I understand a recording and/or photographs will be taken for the reasons stated above. I confirm that I understand the information given to me about the process and hereby give my consent for a recording/photographs to be taken today.

Patient signature: [redacted]

Clinician signature: .....

Date recording/photographs taken 29/10/21

This form to be retained in patient's case notes/S1.

The Podiatric Surgery Service Danetre Hospital, London Road Daventry, Northants. NN11 4DY
Telephone: (01327) 708102. Email: podiatric.surgery@nhft.nhs.uk