Title: Optimised cushioning in diabetic footwear can significantly enhance their capacity to reduce plantar pressure

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Background: Plantar pressure reduction with the use of cushioning materials play an important role in the clinical management of the diabetic foot. Previous studies in people without diabetes have shown that appropriate selection of the stiffness of such materials can significantly enhance their capacity to reduce pressure. However the significance of optimised cushioning has not been yet assessed for people with diabetic foot syndrome.

Research question: What is the potential benefit of using footwear with optimised cushioning, with regards to plantar pressure reduction, in people with diabetes and peripheral neuropathy?

Methods: Plantar pressure distribution was measured during walking for fifteen people with diabetic foot syndrome in a cohort observational study. The participants were asked to walk in the same type of footwear that was fitted with 3D-printed footbeds. These footbeds were used to change the stiffness of the entire sole-complex of the shoe; from very soft to very stiff. The stiffness that achieved the highest pressure reduction relative to a no-footbed condition was identified as the patient-specific optimum one.

Results: The use of the patient-specific optimum stiffness reduced, on average, peak pressure by 46% (± 14%). Using the same stiffness across all participants reduced pressure reduction by at least nine percentile points (37% ± 17%); a statistically significant difference (paired samples t-test, t(13)= -3.733, p= 0.003, d= 0.997). Pearson correlation analysis also indicated that patient-specific optimum stiffness was significantly correlated with the participants' body mass index (BMI), with stiffer materials needed for people with higher BMI (rs(14)= 0.609, p= 0.021).

Significance:

This study offers the first quantitative evidence in support of optimising cushioning in diabetic footwear as part of standard clinical practice. Further research is needed to develop a clinically applicable method to help professionals working with diabetic feet identify the optimum cushioning stiffness on a patient-specific basis.

1. Introduction:

People with diabetes tend to gradually lose the protective sensation of pain in their feet and can overload and injure them without noticing it. This can lead to foot ulcers that do not heal and even to a lower-limb amputation. In England alone, 135 people/ week have an amputation due to diabetes but up to 80% of them could be prevented with correct management[1].

Ulcerating for the first time is a particularly important negative milestone because it significantly increases the risk for ulcerating again[2–4]. Preventing primary ulcers is the most effective way for helping people avoid getting trapped in this vicious circle of ulceration leading to increased risk for re-ulceration and eventually to amputation.

One of the key therapeutic objectives for the management of DFU is to reduce the likelihood of soft tissue injury in the foot with the help of specialised footwear or orthoses[5,6]. The use of cushioning materials in diabetic footwear/orthoses play an important role in this direction by redistributing plantar loading[7].

Cushioning itself as a concept appears to be deceivingly simple. Intuitively one can easily understand that walking on a layer of a soft material will result in lower plantar pressures compared to walking on a rigid surface that offers no cushioning; simply because in the first case the same external forces will be distributed over larger areas. This leads to the intuitive conclusion that cushioning materials need to be relatively compliant to reduce pressure. On the other hand, if a cushioning material is too soft then it will immediately bottom-out, it will become effectively rigid and lose its capacity to offer any cushioning[8]. Therefore, cushioning materials should not be either too stiff or too soft. What is not clear however is how soft or how stiff they should be, and which parameters are important for defining their optimum stiffness. This gap in knowledge is reflected onto clinical practice too where material selection is still based on empirical or anecdotal evidence[9,10].

A finite element analysis aiming to provide some initial insight on optimum cushioning indicated that appropriate selection of material stiffness in footwear could significantly improve their pressure relieving capacity[11]. The effect of plantar soft tissue stiffness, thickness and loading on the optimum stiffness of cushioning materials was investigated to conclude that only loading had a significant effect[11]. Optimum cushioning stiffness appeared to be completely insensitive to changes in plantar soft tissue stiffness or thickness.

A follow-up, *in vivo* investigation in people without diabetes confirmed that optimising the stiffness of cushioning materials could indeed improve significantly the pressure relieving capacity of footwear[8]. It was also found that optimum stiffness was correlated to the participant's body mass (BM) and body mass index (BMI); with stiffer footbeds needed in the case of heavier participants to minimise pressure.

These studies point to a strong relationship between the magnitude of plantar loading and the optimum stiffness of cushioning materials. They also suggest that optimum cushioning stiffness could potentially be identified based on simple parameters linked to plantar loading (e.g. BM); with substantial potential applications for diabetic foot care[8,11]. However, the potential benefit of optimum cushioning has not yet been quantified for people with diabetic foot disease.

Advanced manufacturing techniques, such as additive manufacturing, enable the production of bespoke insoles, footbeds or orthotics that have personalised geometry as well as personalised stiffness[12,13]. This unique capability opens the way for directly producing cushioning materials with optimum stiffness, provided of course that optimum stiffness is known.

In this context, the overall aim of this study was to set the basis for a method to calculate optimum cushioning stiffness for diabetic footwear. As a first step the potential benefit of optimum cushioning properties for reducing plantar pressure in people at risk for ulcerating for the first time will be quantified to see whether stiffness optimisation is something worth doing. The validity of a previously found relationship between BM/ BMI and optimum stiffness will also be tested for people with diabetic foot.

2. Methods

2.1 Participants

Ethical approval was granted by the University of Malta Research Ethics Committee and written informed consent was obtained from each participant before testing.

Fifteen people (male:6, female:9) were recruited for this study from the population attending diabetic foot clinics at the main general hospital of Malta. Their average(±stdev) age was 65y(±9y) and their average(±stdev) BM and BMI was 88kg(±12kg) and 34kg/m^2 (±5kg/m^2) respectively.

Inclusion criteria: a) age ≥18years, b) diagnosis of diabetes (Type-2), c) diagnosis of peripheral sensory neuropathy. Exclusion criteria: a) lower extremity amputation, b) active/ history of DFU, c) active/ history of Charcot's osteoarthropathy, d) shuffling gait or inability to walk unaided for at least 10m, e) inability to provide informed consent or follow the study's instructions.

Screening for sensory loss was performed using a 10g Semmes-Weinstein monofilament (Bailey 10g Calibrated Monofilament) at five different sites (plantar tip of hallux, heel, 1st,3rd and 5th metatarsal head). Inability to sense pressure in one or more site was considered indicative of loss of large-fibre nerve function[14].

2.2 Cushioning materials

Flat, 10mm thick footbeds were produced using fused layer deposition 3D-printing from a soft thermoplastic polyurethane filament (Filaflex TPU A72, Recreus Industries). The density of the printing pattern was increased from 10% to 20% in increments of 2% to produce six different cushioning materials (footbeds 1 to 6) (Figure 1). Their stiffness ranged from soft to stiff but was comparable to available cushioning materials used in footwear manufacturing[15](Figure 2). Relative stiffness was assessed using a load-frame (3kN INSTRON ElectroPuls™ E3000) by measuring the pressure that was needed to compress samples from the different materials by 50%.

Footbeds of different sizes were designed to fit in a typical neutral comfort shoe often used in diabetic foot conditions (Pullman®) below their thin fabric insole (Figure 1).

2.3 Plantar pressure measurements

Plantar pressure distribution was measured during walking at self-selected speed using in-shoe sensors for all six footbeds (F-Scan, TekScan, USA). The condition of no-footbed was also tested as reference. Two walking trials were performed for each condition with at least six mid-gait steps per foot in total. Self-selected speed was determined and monitored for each participant using a stopwatch[16] and measurements were repeated if walking speed differed more than 5% from that.

Following testing, the maximum peak pressure for each condition was averaged over all mid-gate steps. For simplicity, average maximum peak pressure will be, from this point on, referred to simply as pressure.

The capacity of each footbed to reduce pressure was assessed as the percent difference relative to reference[17]. This calculation of pressure reduction was performed for the entire foot (i.e. overall pressure reduction) and for four specific regions of the foot; namely heel, midfoot, metatarsal head (MetHead) and toe region (figure 3).

The footbed that offered optimum cushioning was initially identified separately for each foot as the one achieving maximum pressure reduction for the entire foot. This was based on previous research which indicated that optimum cushioning can significantly differ between limbs[8]. Following the method used by Chatzistergos et al. [8], a single, patient-specific optimum footbed was identified for each participant by focusing on the most heavily loading foot; namely the foot with the highest reference pressure. The footbed that achieved on average the maximum pressure reduction for all participants was identified as the group’s optimum. The effect of patient-specific optimum and group’s optimum on pressure time integral (PTI) was also assessed.

2.4 Statistical analysis

The normality of data was assessed using the Shapiro-Wilk test. Normally and non-normally distributed data will be presented with their mean(±stdev) and median(min, max) values respectively.

The significance of the difference in the capacity to reduce plantar pressure between the patient-specific and the group’s optimum footbed was assessed using paired sample’s t-test. The purpose of this comparison was to test whether optimising cushioning stiffness on a patient-specific basis can indeed significantly enhance pressure reduction relative to using the same material across.

The ability of the patient-specific optimum footbed to reduce pressure in individual foot regions was also assessed. One sample t-test was used to test whether the reduction achieved by the patient-specific optimum footbed was significantly greater than zero in the heel, midfoot, MetHead or toe regions.

Finally, a Pearson’s correlation analysis was run to assess the significance of the relationship between BM or BMI and patient-specific optimum stiffness[8].

3. Results

Data from fourteen participants were analysed. One female participant was excluded from the analysis (participant #8) because of a damaged sensor.

The median of pressure for the most heavily loaded foot was equal to 775kPa (min:406kPa, max:1802kPa) for the reference condition and it was significantly reduced with the use of the cushioning footbeds (Table 1). On average, footbeds-1 to -4 (infill density 10%-16%) appear to be the best performing ones with very small difference in the achieved overall pressure reduction between them. Indeed, the average pressure reduction that was achieved by the first four footbeds ranged between 34%(±14%) and 37%(±17%). Footbed-4 achieved the highest pressure reduction for the entire plantar surface and it could be considered as the group's optimum. The capacity to reduce pressure dropped for footbed-5 and 6 (Figure 3a).

Looking at the effect that each footbed had in different foot regions highlights a clear difference between the heel and MetHead regions on one hand and the midfoot and toes on the other. As shown in figure 3b,c all cushioning footbeds achieved, on average, a positive pressure reduction in the first two regions. On the contrary, the average pressure reduction was either very close to zero or even negative in the latter two (Figure 3d,e). The footbeds that achieved maximum pressure reduction was footbed-2 for the toes and midfoot and footbed-1 and 3 for the MetHead and heel regions respectively (Figure 3).

When averaged for all participants, the patient-specific optimum footbed achieved a reduction in pressure for the entire area of the foot of 46%(±14%). Paired samples t-test indicated that using the patient-specific optimum instead of the group's optimum led to higher pressure reduction, a statistically significant improvement (t(13)=-3.733,p=0.003, d=0.997).

The group's optimum and the patient-specific optimum footbeds were also able to substantially reduce PTI. More specifically the median PTI for the reference condition was equal to 86kPa*sec (min:53hPa*sec, max:200kPa*sec) and it reduced by 40%(±12%) and 32%(±19%) by the group's and patient-specific optimum footbeds respectively.

Pearson's correlation analysis revealed a statistically significant, strong positive correlation between BMI and patient-specific optimum footbed stiffness (rs(14)=0.609,p=0.021). BM was not significantly correlated to optimum stiffness (rs(14)=0.497,p=0.070).

The use of the patient-specific optimum footbed reduced pressure by 28%(±29%) and 39%(±17%) in the heel and MetHead regions respectively. This reduction was significantly different to zero (p<.001,two tail). On the contrary no significant reduction was achieved by the patient-specific optimum footbed in the toes (p=0.375,two tail) or midfoot regions (p=0.490,two tail) (figure 4a). Also, a similar trend was observed in the case of PTI (figure 4b).

As expected, loading under the heel and MetHeads was significantly higher compared to the toes and midfoot regions. When averaged between limbs and for all participants, the net force applied on the heel and MetHead regions was equal to 83%(±20%) and 105%(±30%) of the participants' body weight (BW) leading to median peak pressures of 442kPa (min:318kPa, max:693kPa) and 567kPa (min:366kPa, max:1447kPa) respectively. On the other hand the net force applied in the toe and midfoot regions was equal to 22%(±10%) and 12%(±10%) of BW which led to peak pressures of 343kPa (min:93kPa, max:841kPa) and 174kPa (min:110kPa, max:720kPa) respectively. Friedman's analysis of variance with a Bonferroni correction showed that the difference between the areas of low and high loading was statistically significant in terms of net force ($\chi^2(3)=36.870, p<.001$) and pressure ($\chi^2(3)=19.114, p<.001$).

4. Discussion:

The results presented here indicate that using cushioning materials with stiffness that has been optimised on a patient-specific basis can reduce plantar pressure significantly more compared to using the same cushioning material for everyone. That was shown to be true even when the common material used across all participants was the one that achieved on average the highest pressure reduction for the entire group of participants (i.e. group's optimum). Indeed, the patient-specific optimum stiffness reduced pressure by 46%(±14%) while the group's optimum by 37%(±17%). This substantial reduction in plantar pressure is in line with a similar study in people without diabetes where optimising cushioning reduced pressure by 31%(±13%)[8].

Using the optimum footbed as reference can also provide a better understanding of the relationship between footbed stiffness and pressure reduction. As it can be seen in figure 5, the capacity for pressure reduction drops substantially as one moves away from the patient-specific optimum towards softer or stiffer footbeds. Indicatively, using the 1st softer or 1st stiffer footbed relative to the optimum one reduced pressure reduction to 37%(±15%) and

30%(±14) respectively; a statistically significant drop in the capacity to reduce pressure according to one-way repeated measures ANOVA with Bonferroni correction (Wilks' Lambda=0.275,F(1,9)=104.532,p<0.005,ηp^2=.921). This non-monotonous relationship between stiffness and pressure reduction is in agreement with previous computational findings[11] and results for non-diabetic volunteers[8].

These findings highlight the potential benefit optimised cushioning can have for people with diabetic foot. Realising, however, this potential requires being able to optimise cushioning as part of clinical practice, which in essence means: a) being able to calculate optimum cushioning stiffness and b) to have the capacity to manufacture footbeds with said stiffness. 3D-printing with its unprecedented capabilities for producing materials with prescribed stiffness can help meet the latter prerequisite[12,13]. However, there is still a need for reliable methods for finding optimum stiffness as part of clinical practice.

In this study, stiffness optimisation was performed by measuring plantar pressure distribution for footbeds that had different stiffness (figure 2). For each condition at least six mid-gait steps were recorded. As a result, the total duration of the data collection protocol was between 45 and 60 min. Previous research has indicated that at least three midgait steps are needed for a reliable measurement of peak pressure but that at least twelve steps are needed for an accurate assessment of pressure in custom-made footwear in high-risk diabetic neuropathic patients[22]. Considering the substantial burden to patients, the exact number of steps that are needed to reliably identify the patient-specific optimum stiffness must be assessed before any clinically relevant optimisation method is proposed. Regardless of the number of steps that are required, the need for multiple plantar pressure measurements itself will remain a major barrier for widespread clinical use.

Previous studies have demonstrated significant correlations between a person's BMI and optimum footbed stiffness[8]. This correlation was also confirmed here for people with diabetic foot where stiffer footbeds were found to be needed to maximise pressure reduction in people with higher BMI. This indicates that predicting optimum cushioning stiffness could potentially be feasible based on simple demographic measurements[8].

Even though plantar loading plays a key role in identifying the patient-specific optimum footbed, more evidence is needed for the development of a clinically relevant optimisation method. To this end, the present study provides baseline data to support follow-up research to identify the range of parameters that are required to explain the observed variability in optimum cushioning. This can be the first step towards developing a method to predict optimum footbed stiffness without the need for in-shoe plantar pressure measurements.

Analysing the effect of optimum cushioning in different regions of the foot showed that the achieved pressure reduction was not uniform across the foot. More specifically, the patient-specific optimum footbed significantly reduced pressure under the heel and MetHeads but not under the midfoot or toes (Figure 4).

Reducing pressure in one area of the foot only to see it increasing in another is not uncommon in footwear or orthotic interventions[23,24]. However, in this study plantar pressure under the toes and midfoot appeared to reduce in some participants and to increase in some others in almost equal measures. As a result, the change in pressure in these areas was on average practically zero (Figure 4). Based on that it can be inferred that using a uniform cushioning material across the foot could be an effective way to reduce pressure in the heaviest loaded regions of the foot without necessarily increasing pressure in other foot regions.

The modern therapeutic footwear has a complex, layered, structure including an outersole, midsole and insole. Each layer has its own distinctive mechanical role but together they contribute to the overall stiffness of the sole complex. In this study flat footbeds were used to adjust the stiffness of the surface that supports the foot. These materials offered only cushioning and were not meant to change how a person walks in any specific way[25]. As a result, the findings of this study are directly relevant to optimising the cushioning properties of individual layers as well as of the entire sole complex.

This study focused on people at high risk of ulcerating for the first time. For this reason, people with history of DFU or of amputation were excluded. Having said that, the findings about the potential benefit of optimum cushioning should be transferrable to any group where reduction in plantar pressures is needed. Further research will be needed however to find the best way of integrating cushioning optimisation in existing protocols for the design of bespoke footwear/orthoses.

Although foot deformity was not an exclusion criterion, the recruited participants did not have any severe foot deformity. Deformity can significantly affect plantar loading[26,27] and therefore should be taken into account in any follow-up study aiming to develop a clinical technique for cushioning optimisation.

5. Conclusions

Optimising cushioning on a patient-specific basis can significantly improve the pressure relieving capacity of footwear. 3D printing with its unique capacity to produce materials with prescribed mechanical properties brings the prospect of patient-specific stiffness optimisation closer to becoming clinical reality. This study verified that stiffer cushioning materials are needed in the case of people with higher BMI to minimise plantar pressure. Further research is needed however to develop a reliable clinical method to calculate optimum cushioning stiffness on a patient-specific basis.

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Tables:

Table 1: The demographic characteristics and key results for all participants that were included in the analysis (participant 8 was excluded due to a damaged sensor). The reference peak pressure (PP) values (i.e. no footbed) and the %reduction achieved by each 3D-printed footbed are presented separately for left and right foot. Data indicating maximum pressure reduction in each foot are highlighted. The reference condition is used to identify the most heavily loaded foot (*) and the overall optimum material (bold, underlined) for each participant.

Participants	Sex (M/F)	Weight (kgr)	BMI (kgr/ m^2)	Foot (L/R)	Reference PP (kPa)	PP reduction (%)					
						Footbed 1	Footbed 2	Footbed 3	Footbed 4	Footbed 5	Footbed 6
1	M	80	29.3	L*	406	**60.7**	3.7	15.0	6.5	-43.3	-37.5
				R	372	61.5	11.7	22.2	2.0	1.9	-8.5
2	F	116	43.6	L	516	17.3	13.8	3.4	39.8	11.6	22.7
				R*	610	33.5	38.6	**41.9**	40.5	34.6	39.1
3	M	97	31.6	L	609	-38.5	2.2	-25.7	11.7	-7.4	-46.4
				R*	777	46.1	**51.7**	48.0	48.1	39.1	50.2
4	F	83	33.2	L*	1433	**51.0**	46.7	43.7	50.3	34.0	21.9
				R	901	47.1	46.0	43.2	68.6	54.6	46.4
5	F	79	38.6	L*	549	27.1	6.0	**28.2**	8.7	-9.9	20.9
				R	401	35.5	3.2	17.7	27.2	16.7	29.5
6	M	96	34.4	L*	774	46.9	46.2	47.4	**52.6**	30.6	39.8
				R	550	34.5	44.7	45.0	43.5	36.8	40.8
7	M	70	22.0	L*	1095	**28.8**	21.8	2.5	4.6	3.0	3.3
				R	1024	58.3	64.2	63.5	70.3	51.9	62.9
9	M	87	30.1	L	474	30.8	37.1	20.4	30.0	18.4	-148.4
				R*	857	6.4	23.8	25.9	**35.5**	29.4	11.0
10	F	95	37.5	L*	550	27.8	**37.6**	29.6	27.0	24.3	25.3
				R	495	30.2	27.2	29.7	29.5	29.8	18.0
11	F	83	31.6	L	520	13.6	12.0	39.8	45.1	30.8	39.1
				R*	538	11.6	**30.4**	30.3	27.7	21.5	24.0
12	F	104	41.4	L	941	44.4	51.4	50.3	58.7	50.5	43.7
				R*	1802	64.7	48.3	41.1	65.4	63.5	**76.8**
13	F	74	33.7	L*	876	44.6	41.2	48.7	**62.0**	50.1	58.2
				R	562	16.9	22.5	14.9	22.0	7.0	6.9
14	F	89	31.9	L	559	16.1	33.6	31.0	34.1	37.8	47.8
				R*	641	42.2	43.6	**44.8**	28.8	25.6	30.9
15	M	89	33.0	L	689	16.5	12.0	22.9	1.3	-9.5	-10.4
				R*	778	29.0	**37.4**	29.6	35.5	-17.6	12.0

Figure legends:

Figure 1: A representative footbed and the infill pattern for different densities (10% to 20%). The comfort shoe that was used was used and its thin fabric insole is also shown.

Figure 2: Comparison between the stiffness of the 3D printed footbeds for different infill densities and typical off-the-self foam materials. Relative stiffness is assessed as the pressure needed to compress the footbed by 50%. *Off-the-self properties are calculated from Shariatmadari et al. [15].

Figure 3: The average pressure reduction (%) relative to the reference condition (i.e. no footbed) that was achieved by each footbed for all participants for the entire plantar surface (a) and for different foot regions (b-e). The specific foot regions used in this analysis are also shown on a typical plantar pressure map (f).

Figure 4: The %reduction in pressure (a) and in PTI (b) relative to the reference condition that was achieved by the patient-specific optimum footbed for the entire plantar surface (overall) and for different foot regions (i.e. toes, midfoot, MetHeads and heel).

Figure 5: The relationship between (%) reduction in peak pressure and footbed stiffness relative to the patient-specific optimum. The patient-specific optimum is used as reference to identify the patient-specific next softer or stiffer footbeds (e.g. in a patient where footbed-3 is optimum, footbeds 2 and 4 will be the 1st softer and 1st stiffer respectively etc.).

For each footbed condition, pressure reduction is averaged between participants. Footbed conditions with fewer than three participants have been excluded. The number of averaged values is also shown in brackets (n).

Figure 1:

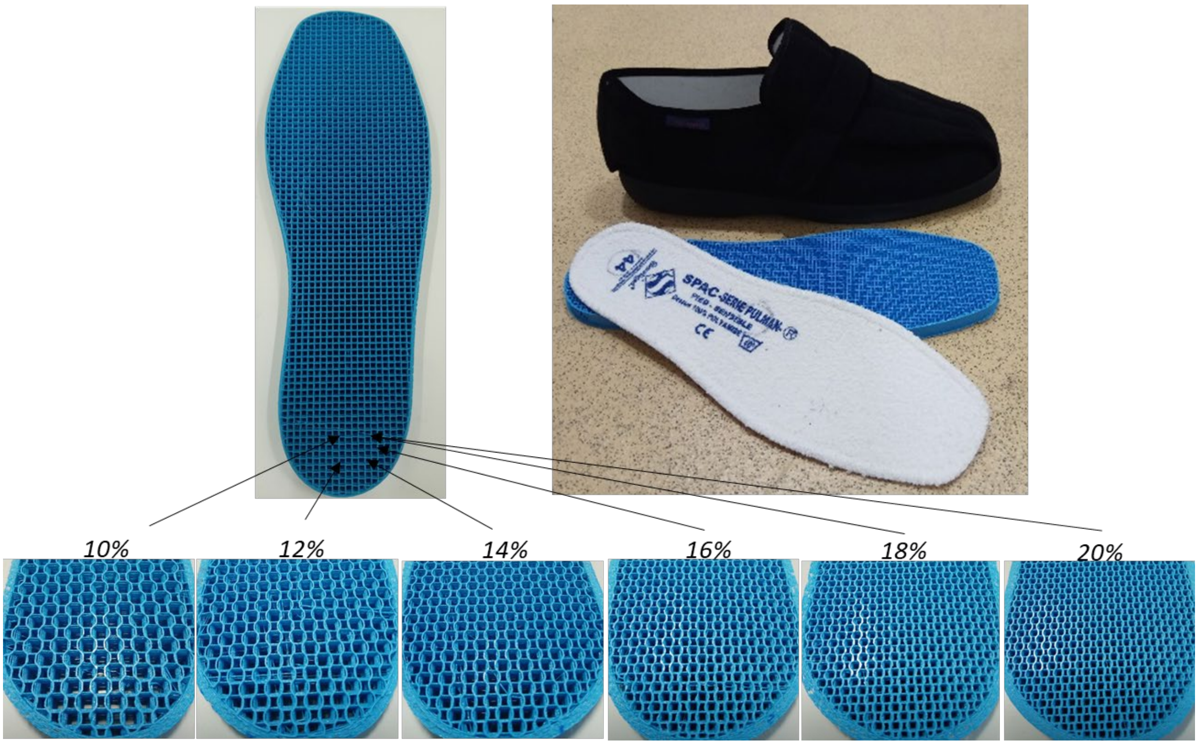


Figure 2:

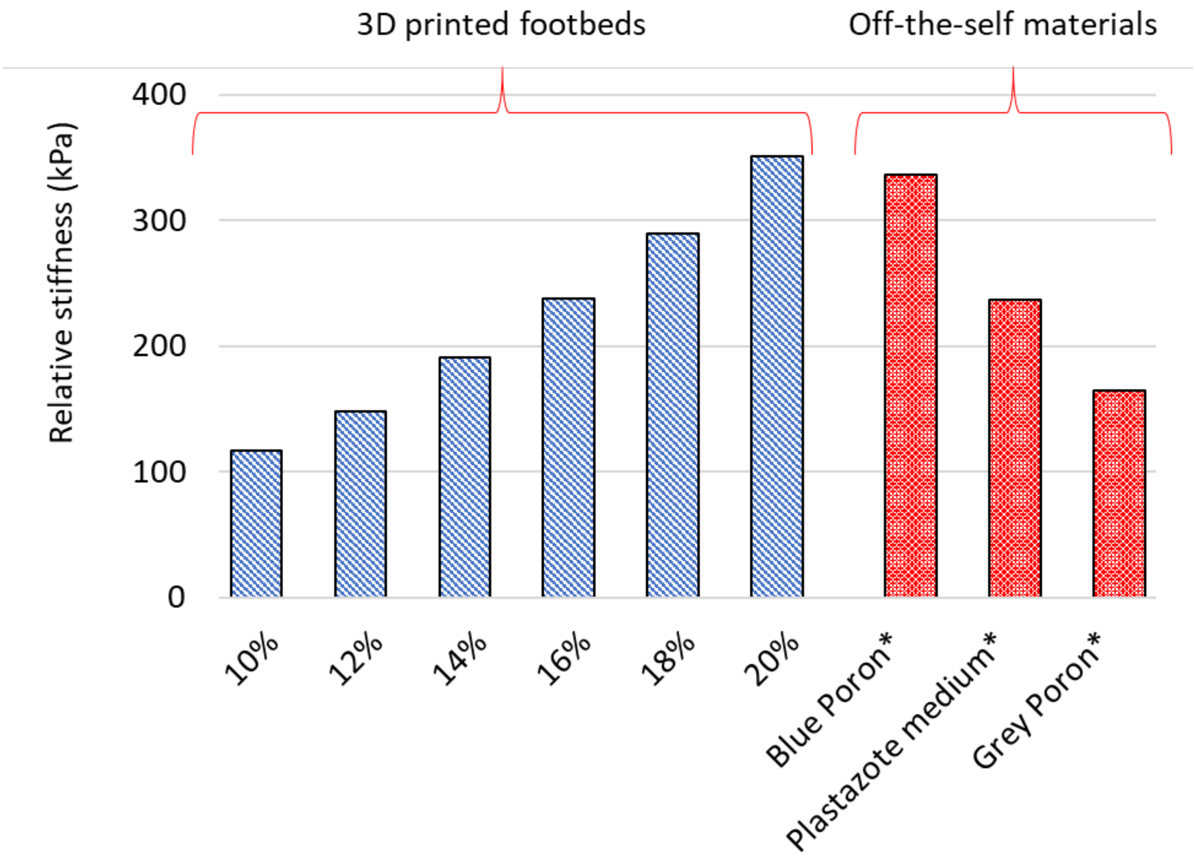

3D printed footbeds
Off-the-self materials
Relative stiffness (kPa)
400
300
200
100
0
10%
12%
14%
16%
18%
20%
Blue Poron*
Plastazote medium*
Grey Poron*

Figure 3:

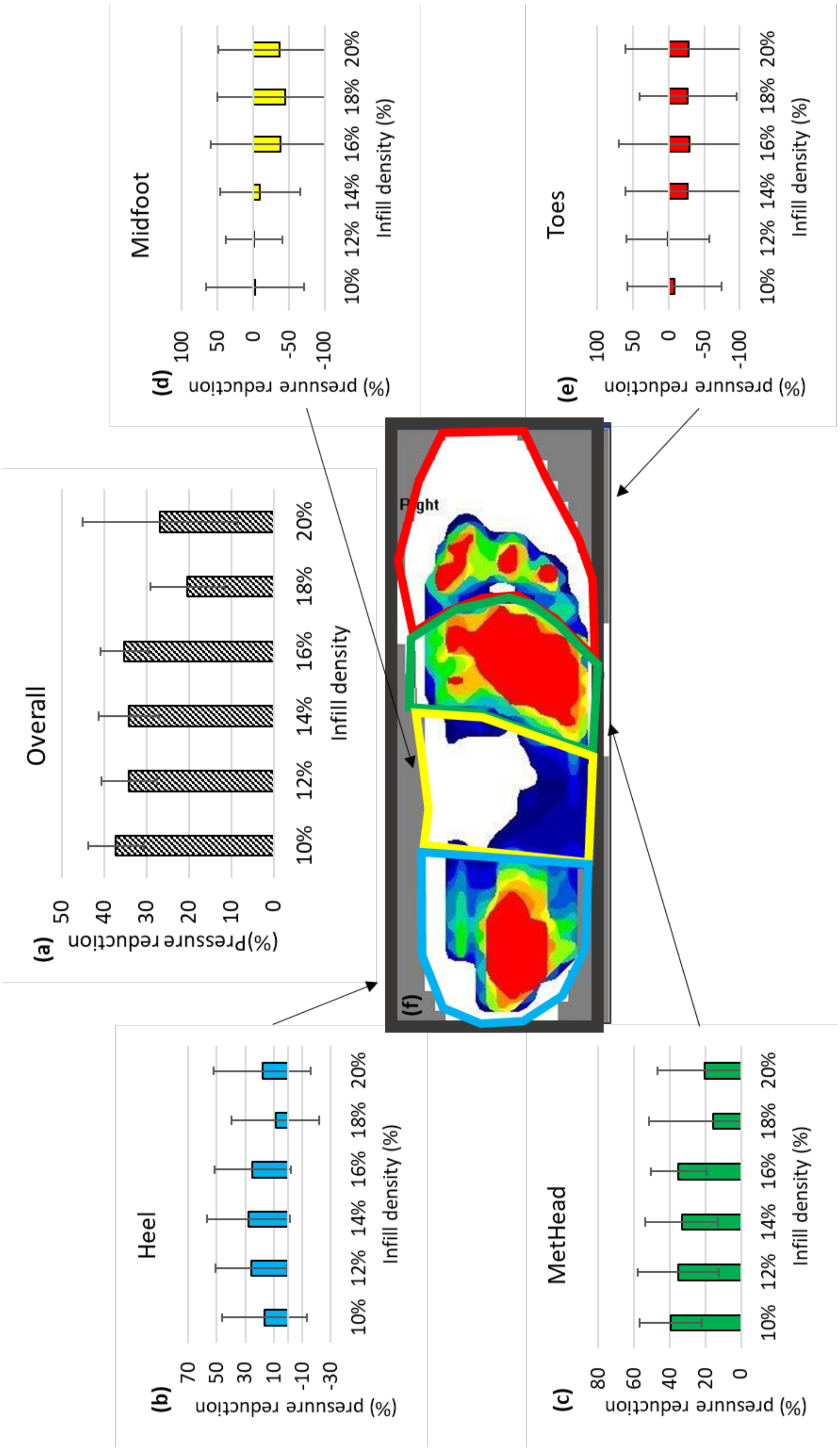

(a)
Overall
(%)Pressure reduction
50
40
30
20
10
0
10%
12%
14%
16%
18%
20%
Infill density
(b)
Heel
(%) pressure reduction
70
50
30
10
-10
-30
10%
12%
14%
16%
18%
20%
Infill density (%)
(c)
MetHead
(%) pressure reduction
80
60
40
20
0
10%
12%
14%
16%
18%
20%
Infill density (%)
(d)
Midfoot
(%) pressure reduction
100
50
0
-50
-100
10%
12%
14%
16%
18%
20%
Infill density (%)
(e)
Toes
(%) pressure reduction
100
50
0
-50
-100
10%
12%
14%
16%
18%
20%
Infill density (%)
(f)
Right

Figure 4:

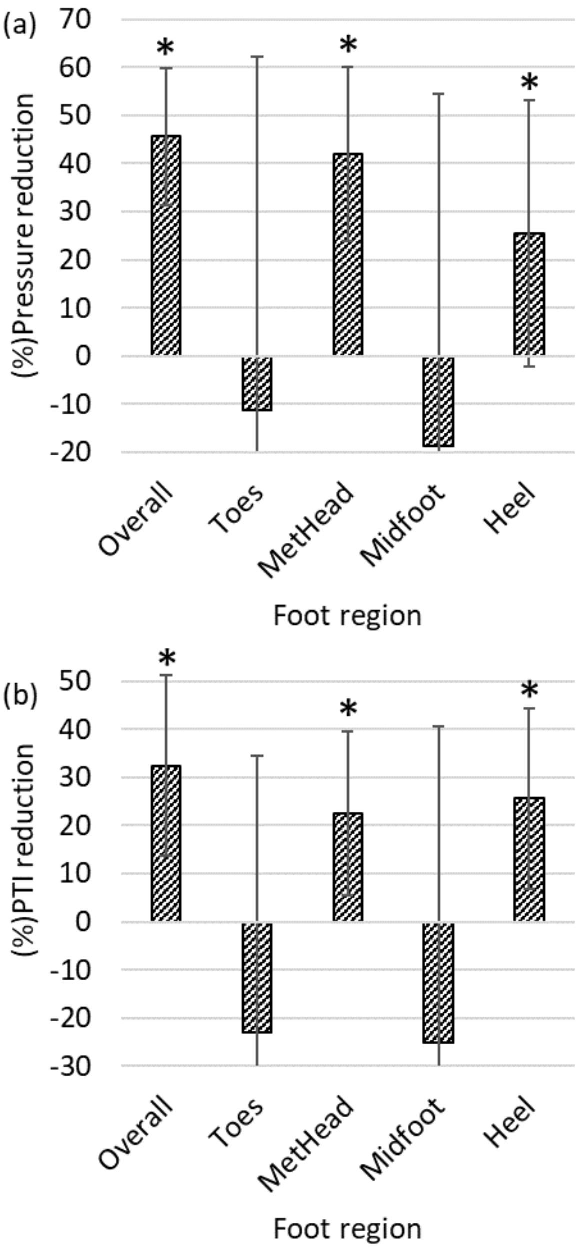
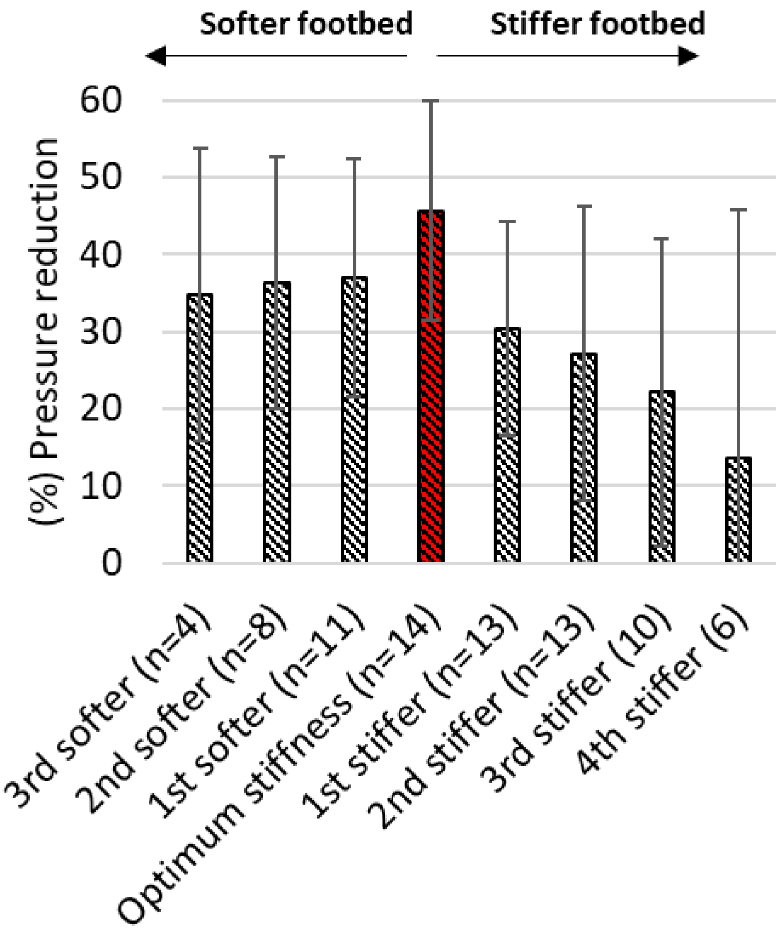

(a)
70
60
50
40
30
20
10
0
-10
-20
(%)Pressure reduction
*
*
*
Overall
Toes
MetHead
Midfoot
Heel
Foot region
(b)
50
40
30
20
10
0
-10
-20
-30
(%)PTI reduction
*
*
*
Overall
Toes
MetHead
Midfoot
Heel
Foot region

Figure 5:


Softer footbed
Stiffer footbed
(%) Pressure reduction
0
10
20
30
40
50
60
3rd softer (n=4)
2nd softer (n=8)
1st softer (n=11)
Optimum stiffness (n=14)
1st stiffer (n=13)
2nd stiffer (n=13)
3rd stiffer (10)
4th stiffer (6)