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Effective and clinically relevant optimisation of cushioning stiffness to maximise the offloading capacity of diabetic footwear

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ABSTRACT

Introduction: Optimising the cushioning stiffness of diabetic footwear/orthoses can significantly enhance their offloading capacity. This study explores whether optimum cushioning stiffness can be predicted using simple demographic and anthropometric parameters.

Methods: Sixty-nine adults with diabetes and loss of protective sensation in their feet were recruited for this cross-sectional observational study. In-shoe plantar pressure was measured using Pedar® for a neutral diabetic shoe (baseline) and after adding cushioning footbeds of varying stiffness. The cushioning stiffness that achieved maximum offloading was identified for each participant. The link between optimum cushioning stiffness and plantar loading or demographic/anthropometric parameters was assessed using multinomial regression.

Results: People with higher baseline plantar loading required stiffer cushioning materials for maximum offloading. Using sex, age, weight, height, and shoe-size as covariates correctly predicted the cushioning stiffness that minimised peak pressure across the entire foot, or specifically in the metatarsal heads, midfoot and heel regions in 70%, 72%, 83% and 66% of participants respectively.

Conclusions: Increased plantar loading is associated with the need for stiffer cushioning materials for maximum offloading. Patient-specific optimum cushioning stiffness can be predicted using five simple demographic/anthropometric parameters. These results open the way for methods to optimise cushioning stiffness as part of clinical practice.

1. Introduction

People with diabetes can gradually lose the protective sensation of pain in their feet due to peripheral neuropathy. As a result, they tend to repeatedly overload and seriously injure their feet, causing the development of diabetic foot ulceration (DFU) [1]. DFU is an open wound with limited capacity for healing, it can get infected and even lead to amputation. It is estimated that worldwide there is one amputation every twenty seconds due to diabetes (85 % of all lower-limb amputations) [2]. The severity of this fact becomes even more pronounced considering that eight out of ten people die within five years of having an amputation [3] (survival rate lower than prostate or breast cancer). At the same time, the cost of DFU to healthcare systems worldwide is higher than the cost of the three most common types of cancer put together [4].

Due to the key role repetitive overloading plays in the development of DFU, one of the main therapeutic objectives in its clinical management is the offloading of overloaded areas [5]. To this end, therapeutic footwear and orthoses are commonly used to redistribute plantar loading and to protect critical areas of the foot from high pressures [5,6]. According to current international guidelines, the use of cushioning materials with appropriate stiffness in diabetic footwear or orthoses is very important for effective offloading [5]. If a cushioning material is too stiff, then it will not be able to deform enough to redistribute loading and absorb energy during activities of daily living. If it is too soft, it will prematurely bottom-out which can diminish its capacity to offer any cushioning [7]. Amidst these extremes, there is an optimum stiffness that enables the cushioning materials to deform just enough to achieve maximum offloading [7–9].

Our previous research showed that patient-specific optimisation of

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the stiffness of cushioning materials can significantly improve the pressure relieving capacity of footwear in people with diabetes and peripheral neuropathy [8]. However, to date, there is no clinically relevant method to identify optimum cushioning stiffness on a patient-specific basis.

It might appear intuitive to assume that patient-specific optimum cushioning stiffness would be dictated by the patient-specific stiffness of plantar soft tissues [9–11] . However, no evidence is available in the literature to support this hypothesis [9]. On the contrary, strong evidence indicates that patient-specific plantar loading plays a key role in determining optimum cushioning stiffness [7–9]. More specifically, combined experimental and numerical analyses have demonstrated that optimum cushioning stiffness increases with the magnitude of loading [7,9]. These findings indicate that people who load their feet more heavily also tend to need stiffer cushioning materials for maximum offloading. Moreover, preliminary in vivo studies in people without diabetes [7] and in people with diabetes [8] found significant correlations between optimum cushioning stiffness and body mass or body mass index (BMI) [7,8]. These findings indicate that the prediction of optimum cushioning stiffness might be possible based on simple anthropometric and demographic parameters that have been linked in the literature to the intensity of plantar loading. Besides body mass and BMI [12–14] these also include age [15,16], sex [16,17], height [16] and shoe size[18].

In this context, the present study explores whether it is feasible to predict optimum cushioning stiffness on a patient-specific basis using simple demographic and anthropometric parameters that are linked to the magnitude of plantar loading (sex, age, body mass, height and shoe size) [12–18]. Answering this question can open the way for the development of simple methods for the selection of optimum cushioning stiffness that can be used in clinics.

2. Subjects, materials and methods

2.1. Participants

Sixty-nine (male:40, female:29) adults with diabetes and loss of protective sensation (LOPS) were recruited from the population attending diabetic foot clinics at the main general hospital of Malta for this cross-sectional observational study. Ethical approval was granted by the University of Malta Research Ethics Committee and written informed consent was obtained from each participant before testing.

Inclusion criteria: a) age $\geq$ 18 years, b) diagnosis of diabetes (Type-1 or 2), c) diagnosis of LOPS, d) ability to walk unaided for at least 10 m. Exclusion criteria: a) history of a major operation in the foot including amputation, b) active DFU (anywhere in the foot), c) active Charcot's osteoarthropathy, d) local or systemic infection, e) inability to provide informed consent or to follow the study's instructions (as assessed by the recruiting clinician), f) shoe size < 38 or > 43 (standard European).

The study was limited to people with shoe sizes 38 to 43 to account for the range of available sizes of plantar pressure sensors in our lab. Shoe size was measured using a Brannock device. Screening for sensory loss was performed using a 10 g Semmes-Weinstein monofilament (Bailey 10 g Calibrated Monofilament) at five different sites: plantar tip of hallux, heel, 1st,3rd and 5th metatarsal head (MetHead). The inability to sense pressure in one or more sites was considered indicative of LOPS [20,21]. The participants' feet were visually inspected for the presence of active DFU or Charcot foot. An active DFU was defined as "a break of the skin of the foot that involves as a minimum the epidermis and part of the dermis" [22].

2.2. Plantar pressure measurements

Plantar pressure distribution was measured during walking at self-selected speed using the Pedar® in-shoe system (Novel®, Munich, Germany). The sensors were calibrated according to the manufacturer's instructions. During data collection, the participants were wearing a neutral shoe (Pullman®) which is often used in diabetic foot conditions (Fig. 1).

Plantar pressure was measured without any additional cushioning material in the shoe (baseline condition), and after adding flat 10 mm thick footbeds [7]. Seven bespoke polyurethane foams were used which had similar qualitative mechanical characteristics but their stiffness ranged from very soft to very stiff [7] (Fig. 1). The bespoke footbeds were tested in random order.

Following familiarisation, the participants were asked to walk along a straight line and plantar pressure distribution was recorded for at least six mid-gait steps [8]. The time it took to cover a predefined distance was measured using a stopwatch to ensure walking speed remained the same between conditions [23]. Measurements were repeated if walking speed differed more than 5 % from baseline [24].

Following testing, the maximum peak plantar pressure (PPP), maximum pressure and pressure time interval (PTI) for each condition were averaged over all mid-gait steps. PPP corresponds to the maximum pressure registered by a single sensor-cell within a predefined region of interest. Pressure is the spatial average at any given time of the measurements of all sensor-cells within the region of interest. PPP and pressure were plotted over time and their maximum values for each mid-gate step were identified and averaged across steps to produce the final measurement of average maximum PPP and average maximum pressure. PTI was calculated as the area below the pressure – time graph for each step and was also averaged across all mid-gait steps [25]. For

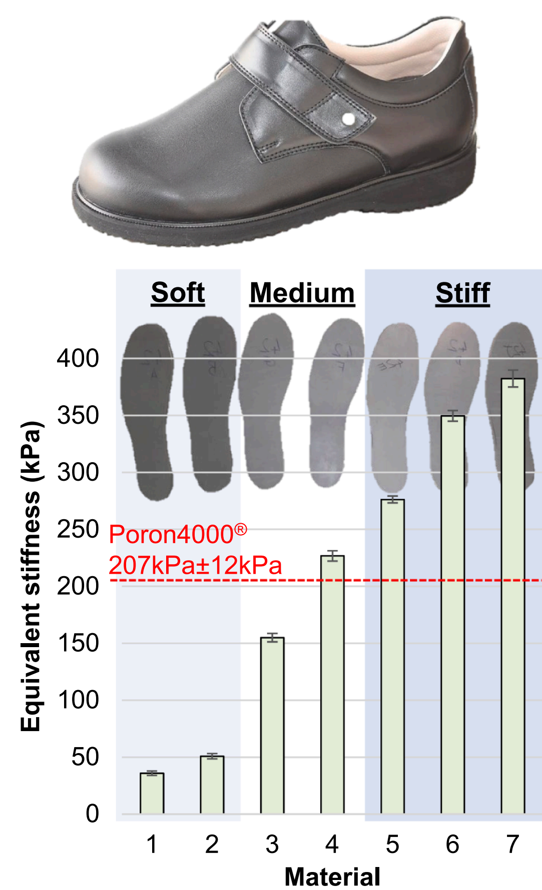

Fig. 1. The diabetic shoe and bespoke footbeds (materials 1 to 7) that were used in this study. The range of equivalent stiffness of the bespoke footbeds is shown in the graph [7]. Their grouping into "soft", "medium" and "stiff" for the regression analyses and the equivalent stiffness of a reference cushioning material commonly used in diabetic footwear/orthoses (Poron4000®) are also shown on the graph.

simplicity, average maximum PPP, average maximum pressure and average PTI will be, from this point on, referred to simply as PPP, pressure and PTI respectively. PPP, pressure and PTI were calculated for the entire foot as well as for four separate regions of the foot: toes, MetHeads, midfoot and heel.

2.3. Footbed materials

The seven footbed materials that were used in this research were selected from a set of ten bespoke polyurethane foams previously produced by authors of this study [7]. These materials were selected to create a continuous range of stiffnesses centred around materials commonly used in diabetic foot care. To this end, equivalent material stiffness was assessed for all bespoke footbed materials in a series of mechanical tests [7]. More specifically, cylindrical samples were subjected to dynamic compression at a loading rate that was relevant to everyday activities (30 mm/sec) [26,27]. The minimum pressure needed to compress the samples by 50 % was used as an assessment of equivalent stiffness [7]. The included footbed materials will be called materials 1 to 7 with material 1 being the softest and 7 being the stiffest. Poron 4000® was used as reference (Fig. 1).

2.4. Identification of optimum cushioning

The capacity of each footbed to reduce PPP and PTI was assessed as the percentage difference relative to the baseline condition (i.e., no additional footbed) [28]. This assessment of offloading was performed separately for the entire foot, the toes, MetHeads, midfoot and the heel region. The footbeds that achieved maximum PPP reduction or maximum PTI reduction were identified separately for each foot and each one of the abovementioned foot regions. This was because of previous research which indicated that optimum cushioning can significantly differ between limbs [7,8] and foot regions [8]. Following the method used previously by Chatzistergos et al. [7,8], subject-specific optimum footbed materials were identified for each participant by focusing on the most heavily loaded foot; namely the foot with the highest baseline PPP or PTI. In the end, ten separate calculations of subject-specific optimum materials were recorded in total for each participant: five for the materials that maximised PPP reduction in the entire foot, toes, MetHeads, midfoot and heel region and five for the material maximising PTI reduction in the same regions.

2.5. Statistical analyses

The hypothesis underpinning this study is that subject-specific optimum cushioning stiffness can be predicted based on subject-specific measurements of plantar loading or based on anthropometric/ demographic parameters associated with the magnitude of plantar loading. Two series of multinomial logistic regression analyses were performed to test this hypothesis. During the first series, individual measurements of baseline plantar loading were used as predictors (Table 1). In the case of regional PPP optimum stiffness (i.e., for toes, MetHeads, midfoot or heel), the region-specific baseline measurements of PPP and the baseline PPP measurement for the entire foot were used as predictors in separate regression analyses. For the PTI optimum materials, baseline measurements of PTI and pressure were explored as potential predictors. Like PPP, region-specific measurements and measurements for the entire foot were also considered for the prediction of region specific PTI optimum stiffness (Table 1).

The covariates that were used during the second series of regression analyses were: sex, age, body mass, height, and shoe size [12–18]. All covariates were screened for collinearity. Considering that the maximum number of independent predictors in these analyses was five a threshold of a minimum sample size of fifty was defined based on the rule of ten [29].

Wilcoxon signed rank test was used to test whether the optimum cushioning materials that were calculated based on PPP reduction were significantly different to those that were calculated based on PTI

Table 1
Multinomial regression results for the prediction of the level of stiffness (soft, medium, hard) that achieved maximum PPP reduction (PPP optimum) or maximum PTI reduction (PTI optimum) in the entire foot or in different areas of the foot based on measurements of baseline loading (i.e., no additional footbed). In the case of regional optimums, the significance of regression models using region-specific or whole-foot measurements of baseline loading are presented separately. For models that achieve predictions that are statistically significantly better than an intercept-only model (Sig. < 0.05) the values of X^2(df) and the % of people with correct predictions are also presented.

Dependent variable		Predictor		Sig.	X^2(df)	Correct prediction
PPP optimum *(soft/ medium/ stiff)*	Whole foot	Baseline PPP	Whole foot	0.090	–	–
	Toes	Baseline PPP	Region-specific	0.310	–	–
			Whole foot	0.990	–	–
	MetHeads	Baseline PPP	Region-specific	0.037	6.571(2)	64 %
			Whole foot	<0.001	14.407(2)	69 %
	Midfoot	Baseline PPP	Region-specific	0.763	–	–
			Whole foot	0.389	–	–
	Heel	Baseline PPP	Region-specific	0.004	10.989(2)	51 %
			Whole foot	0.046	6.150(2)	51 %
PTI optimum *(soft/ medium/ stiff)*	Whole foot	Baseline PTI	Whole foot	0.760	–	–
	Toes	Baseline PTI	Region-specific	0.654	–	–
			Whole foot	0.471	–	–
	MetHeads	Baseline PTI	Region-specific	0.332	–	–
			Whole foot	0.642	–	–
	Midfoot	Baseline PTI	Region-specific	0.920	–	–
			Whole foot	0.430	–	–
	Heel	Baseline PTI	Region-specific	0.957	–	–
			Whole foot	0.528	–	–
	Whole foot	Baseline pressure	Whole foot	0.947	–	–
	Toes	Baseline pressure	Region-specific	0.748	–	–
			Whole foot	0.620	–	–
	MetHeads	Baseline pressure	Region-specific	0.189	–	–
			Whole foot	0.217	–	–
	Midfoot	Baseline pressure	Region-specific	0.645	–	–
			Whole foot	0.041	4.167(1)	84 %
	Heel	Baseline pressure	Region-specific	0.660	–	–
			Whole foot	0.864	–	–

reduction. The same statistical test was also used to assess the significance of differences between foot regions.

3. Results

The participants' average (±standard deviation) age, body mass, height, BMI and shoe size (standard European) was 67y (±11y), 75 kg (±19 kg), 1.67 m (±0.10 m), 26.8 kg/m^2 (±5.7 kg/m^2) and 40 (±2) respectively. An initial screening of results led to the exclusion of participants and foot regions within participants due to missing data or due to having fewer than six mid gait steps. This led to differences in sample sizes between regions and measurements. However, the threshold of at least fifty participants for each measurement was exceeded in all cases. The specific sample size for each foot region and measurement can be found in Fig. 2. The average number of recorded mid-gait steps in the included participants was 11 ± 2.

3.1. Optimum cushioning

Materials in the middle of the selected stiffness range (i.e., materials 3 and 4) were the most common optimum materials (group optimums) based on PPP reduction for the entire foot, toes, MetHead and heel regions (Fig. 2left). Material 1 was the group-optimum material for the midfoot. Wilcoxon signed rank test indicated that the materials maximising PPP reduction at the midfoot were significantly softer than the rest of the examined foot regions (2-tailed, $p < 0.001$).

The maximum PPP reduction that was achieved by the PPP group-optimum materials for the entire foot, the toes, MetHead, midfoot and heel regions was 20 %(±26 %), 27 %(±34 %), 34 %(±19 %), 46 %(±20 %) and 20 %(±18 %) respectively. When the patient-specific optimum materials were used the achieved PPP reduction increased to 30 %(±19 %), 40 %(±24 %), 40 %(±18 %), 52 %(±16 %) and 28 %(±13 %) respectively. This constitutes a 13 %-50 % increase in average PPP reduction.

The distribution of optimum materials across participants changed when optimum cushioning was defined based on maximum PTI reduction instead of maximum PPP reduction (Fig. 2right). In this case, material 2 was the group-optimum for the entire foot, material 4 was the group optimum for the toes and material 1 was the group-optimum material for the MetHeads, midfoot and heel regions (Fig. 2right).

The maximum PTI reduction that was achieved by the PTI group-optimum materials for the entire foot, the toes, MetHead, midfoot and heel regions was 18 %(±18 %), 17 %(±58 %), 20 %(±25 %), 45 %(±28 %) and 8 %(±22 %) respectively. When the patient-specific optimum material was used the achieved PTI reduction increased to 23 %(±13 %), 39 %(±42 %), 28 %(±24 %), 51 %(±26 %) and 20 %(±24 %) respectively. This constitutes a 13 %-150 % increase in average PTI reduction.

Comparison against the respective results for PPP and PTI indicated that significantly softer materials are needed to maximise PTI reduction in the entire foot, MetHeads or heel region relative to the ones that maximise PPP reduction in the same regions (Wilcoxon signed rank test, 2-tailed, $p < 0.001$).

3.2. Regression analyses

During the regression analyses, the cushioning materials were combined into three groups (or stiffness levels) to enable a more intuitive interpretation of results. To this end, materials 1 and 2 were grouped together and classed as "soft", materials 3 and 4 as "medium" and materials 5, 6 and 7 as "stiff" (Fig. 1).

The first series of regression analyses showed that measurements of plantar loading were able to predict the optimum PPP materials at the MetHead and heel regions (Table 1). These models were statistically significantly better than intercept-only models and were able to correctly predict the MetHead and heel PPP optimums in a minimum of 64 % and 51 % of participants respectively (Table 1). Regarding the effect of different plantar loading measures, it was found that the likelihood of a "soft" material being the PPP optimum for the MetHeads decreased by a factor of 0.983 per unit increase in baseline PPP pressure at MetHeads (i.e., region-specific PPP). Moreover, the likelihood of having a "soft" or "medium" PPP optimum decreased by a factor of 0.965 and 0.983 respectively per unit increase in baseline PPP pressure in the entire foot. Similarly, in the case of the heel, the likelihood of a "soft" PPP optimum decreased by a factor of 0.974 per unit increase in region-specific baseline PPP. The likelihood of a "medium" PPP optimum decreased by a factor of 0.987 per unit increase in baseline PPP pressure in the entire foot.

The trend of increased loading being associated with stiffer optimum materials was also observed with regards to the PTI optimums. In this case, statistically significant improvement relative to an intercept-only model was found only for the midfoot (Table 1). Using baseline pressure for the entire foot as the only predictor enabled this regression model to correctly predict the midfoot PTI optimum material in 84 % of participants. This model also showed that the likelihood of a "soft" PTI optimum decreased by a factor of 0.957 per unit increase in baseline pressure in the entire foot. The use of region-specific measurements of baseline pressure or measurements of baseline PTI (region-specific or for the entire foot) did not produce any statistically significant results for the prediction of PTI optimum level of stiffness (Table 1).

Replacing measurements of baseline plantar loading with sex, age, weight, height, and shoe size as covariates led to regression models that were statistically significant improvements to intercept-only models for the prediction of PPP optimum materials for the entire foot, as well as for the MetHeads, midfoot and heel regions (Table 2). These models were able to correctly predict the optimum level of footbed stiffness for maximum PPP reduction in these areas for 70 %, 72 %, 83 % and 66 % of participants respectively (Table 2).

Shoe size, age, body mass and sex appeared to have a significant effect on optimum PPP stiffness. More specifically, the likelihood of having a "soft" PPP optimum at the MetHeads or of a "medium" PPP optimum at the heel decreased by a factor of 0.420 or 0.502 per unit increase in shoe size. At the heel, the likelihood of "soft" or "medium" PPP optimum increased by a factor of 1.179 and 1.103 per unit increase in age. The likelihood of a "medium" PPP optimum at the heel or the entire foot decreased by a factor of 0.923 or 0.945 per unit increase in body mass respectively. In the case of the whole foot optimum, being a woman also significantly reduced the likelihood of a "medium" material being optimum.

Statistically significant prediction of PTI optimum stiffness using demographic covariates was achieved only for the toes (Table 2). This regression model was able to correctly identify the optimum level of stiffness in 64 % of people. In this case, body mass, height and sex appeared to have significant effects on optimum stiffness level. More specifically, the likelihood of a "soft" or "medium" PTI optimum was reduced by a factor of 0.870 and increased by a factor of 1.520 per unit increase in body mass and height respectively. The likelihood of a "medium" PTI optimum was reduced by 0.874 and increased by 1.484 per unit increase in body mass and height respectively. Being a woman significantly increased the likelihood of a "soft" or "medium" stiffness being optimal. Please refer to supplementary material for a detailed description of the statistically significant regression models and a demonstration of their predicting capacity.

4. Discussion

The results of this study confirm previous findings on the importance of evidence-based selection of cushioning materials in diabetic footwear/ orthoses for effective offloading [7–9] and, for the first time, show that patient-specific optimisation of cushioning stiffness can be achieved using simple demographic and anthropometric parameters.

When patient-specific optimum cushioning materials were compared

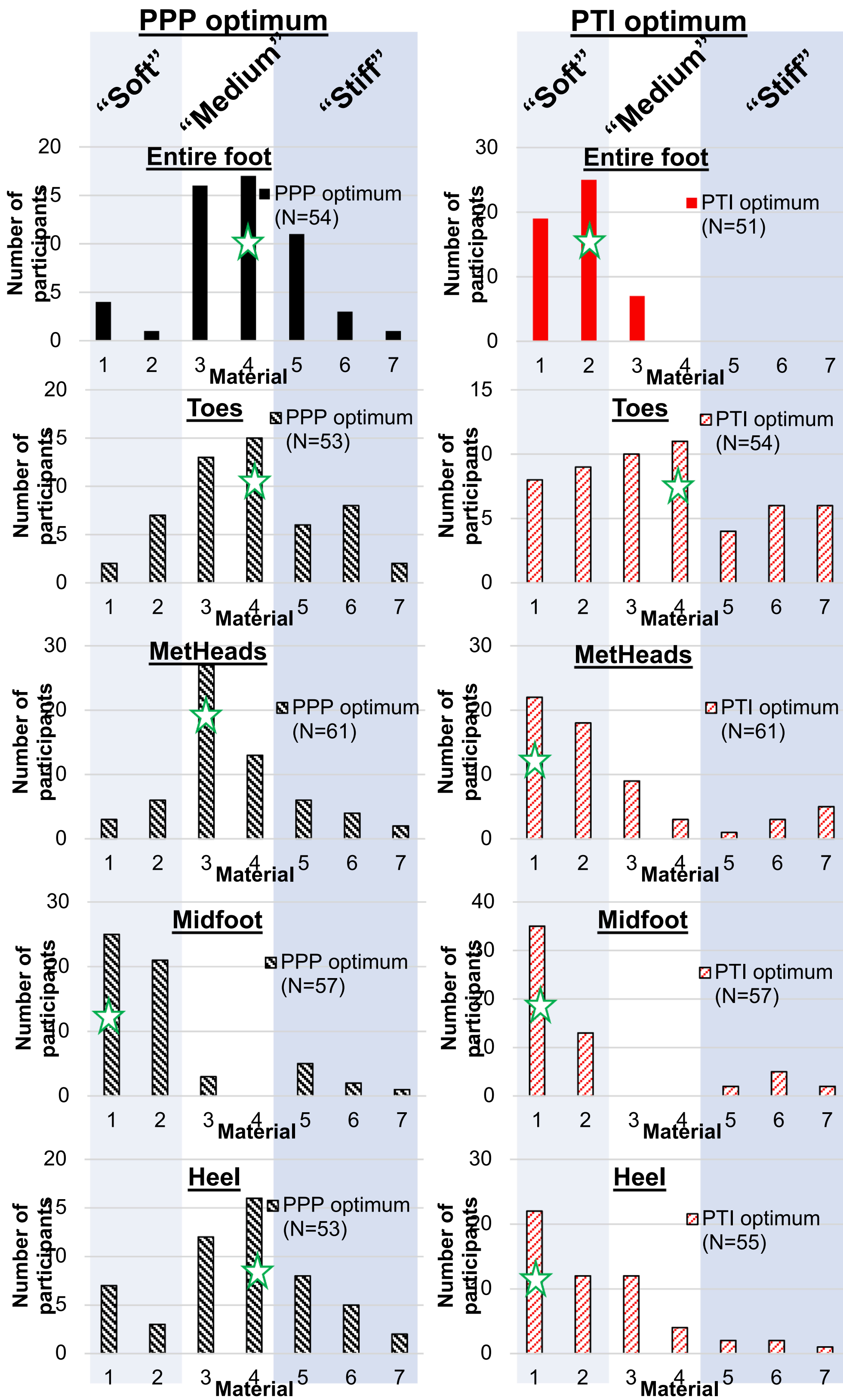

Fig. 2. The frequency with which each bespoke footbed material achieved maximum PPP reduction (left) and maximum PTI reduction (right). The distribution of PPP optimum and PTI optimum materials is separately presented for the entire foot as well as for the toes, MetHeads, midfoot and heel region. The grouping of materials as "soft", "medium" and "stiff" and the sample size (N) that was included in the calculations for each graph are also shown. The material that was found to be optimum for most participants in each case is indicated with (★).

Table 2
Multinomial regression results for the prediction of optimum stiffness (PPP optimum and PTI optimum) in the entire foot or in different areas of the foot based on five demographic/ anthropometric covariates. The significance of all regression models is presented separately. For models that achieve predictions that are statistically significantly better than an intercept-only model (Sig. < 0.05) the values of X^2(df) and the % of people with correct predictions are also presented.

Dependent variable		Covariates	Sig.	X^2(df)	Correct prediction
PPP optimum *(soft/ medium/ stiff)*	Whole foot	Sex, age, body mass, height, shoe size	0.002	27.646 (10)	70 %
	Toes		0.591	–	–
	MetHeads		0.029	19.988 (10)	72 %
	Midfoot		0.037	19.353 (10)	83 %
	Heel		<0.001	37.824 (10)	66 %
PTI optimum *(soft/ medium/ stiff)*	Whole foot	Sex, age, body mass, height, shoe size	0.902	–	–
	Toes		<0.001	35.615 (10)	64 %
	MetHeads		0.653	–	–
	Midfoot		0.667	–	–
	Heel		0.268	–	–

against the materials that appeared to be optimum for most people in each foot region (i.e., group-optimum materials), patient-specific optimisation substantially improved PPP reduction and PTI reduction. This finding is in line with literature where patient-specific optimisation improved PPP reduction across the entire foot by 24 % [8]. The equivalent improvement that was observed here was 50 % for the entire foot and ranged between 13 % and 44 % for specific regions of the foot.

Optimised cushioning can enhance the capacity of footwear/ orthoses interventions to offload the foot-at-risk for more effective prevention of DFU and diabetic foot amputations. Increased PPP and PTI have been both linked in the literature with increased risk for DFU [30]. Based on this, PPP and PTI were separately considered regarding optimum cushioning. We found that softer cushioning materials are needed to maximise PTI reduction compared to those that are needed to maximise PPP reduction. This finding means that the specific aim of offloading (i.e., PPP reduction or PTI reduction) needs to be carefully considered in the selection of appropriate cushioning materials.

In this study, optimum cushioning was identified on a patient-specific basis by measuring plantar pressure distribution during gait for different materials with stiffness ranging from very soft to very stiff. Eight separate plantar pressure recordings were needed in total per participant to this end. Even though this methodology is established in the literature [7,8], its time-consuming and resource-intensive nature significantly restricts its applicability outside research. To address this problem and enable patient-specific optimisation of cushioning in clinics, the present study examined whether patient-specific optimum cushioning stiffness can be predicted either based on simpler measurements of baseline plantar loading or based on demographic and anthropometric parameters previously linked to the intensity of plantar loading [12–18].

We found that optimum cushioning stiffness for walking at a self-selected speed can be predicted based on a single recording of baseline plantar loading. In this case increased PPP and pressure were significantly associated with the need for stiffer insoles to maximise PPP reduction or PTI reduction respectively. This finding agrees with previous relevant observations in the literature [7–9]. The link between increased loading and the need for stiffer cushioning materials is further highlighted by the observation that maximising PPP reduction in the least loaded region of the foot, namely the midfoot, requires significantly softer cushioning materials compared to the toes, MetHeads or the heel.

The need for a single recording of plantar loading to predict optimum cushioning stiffness, instead of eight that were needed for this study, significantly reduces the potential burden to patients and clinicians. However, the need for even a single plantar pressure recording makes patient-specific cushioning optimisation inaccessible for most clinical settings.

The results presented here indicate that this does not need to be the case. Optimum cushioning stiffness can be predicted based on the patient's sex, age and simple measurements of body mass, height and shoe size. Multinomial regression analysis showed that this simple model of five covariates is a statistically significant improvement relative to an intercept-only model. In the context of this study, an intercept-only model could be understood as providing all participants with the same material stiffness.

At this point it should be noted that this investigation focused on walking at self-selected speed because this was considered to be the most relevant dynamic loading scenario for people with diabetes and LOPS. Walking faster or slower would lead to higher or lower plantar pressures respectively [31]. However, this does not mean that the selected material would automatically stop being effective. Due to their inherent viscoelastic nature, the foam and rubber materials of therapeutic footwear/ orthoses naturally become stiffer or softer when loading speed increases or decreases respectively [32]. The fact that optimum cushioning stiffness also increases with the magnitude of plantar pressure means that it could be feasible to achieve optimum cushioning for a range of loading scenarios using the same material. To achieve that, the material's viscoelastic mechanical properties will have to be optimised for the entire range of relevant loading scenarios. This process was beyond the scope of the present study, but it should be considered in future research.

For the regression analyses presented here, results from the seven individual footbeds that were included in this study were grouped into three categories or levels of stiffness, namely "soft", "medium" and "stiff". Considering that Poron4000® would be classed as having "medium" stiffness, a "soft" or a "stiff" optimum material could be interpreted as a material that is significantly softer or stiffer than Poron4000®. This grouping enables a more intuitive interpretation of results to demonstrate the feasibility of cushioning optimisation without the use for plantar pressure measurements. Moving forward, measuring the equivalent stiffness of the cushioning materials that are currently available for the manufacturing of bespoke diabetic footwear or orthoses can open the way for the development of clinically applicable guidelines for evidence-based material selection. Such an extensive investigation of the mechanical properties of commercially available cushioning materials was also beyond the scope of this study.

Besides informing the selection of the most appropriate foam material, this research also lends itself to improving the effectiveness of bespoke 3D printable footbeds or orthoses. This is because of the unique capability of 3D printing to produce an almost continuous spectrum of different material stiffnesses based on the type of the 3D printing material, the infill pattern and the infill density that is used [8,33]. The findings presented here indicate that it is possible to inform the selection of these parameters to achieve optimum cushioning in individual regions of the foot on a patient-specific basis.

Regarding the limitations of this study, only uniform stiffness footbeds were used in this analysis. Because of this, no conclusion can be drawn at this stage about the simultaneous optimisation of cushioning stiffness for both limbs and all foot regions. Further research involving the use of footbeds with regional variations in stiffness is needed to this end.

Flat footbeds were used to adjust the cushioning stiffness of the surface that supports the foot. These footbeds offered only cushioning and were not meant to change how a person walks [34]. As a result, the findings of this study are directly relevant to optimising the cushioning properties of a shoe's insole. The cushioning properties of the entire sole complex (i.e. outer sole, midsole and insole combined) could also be optimised, but in this case optimum cushioning has to be considered alongside the desired effect on gait biomechanics [35–38].

This study focused on people with diabetes who are at risk of DFU due to plantar soft tissue overloading [19]. Considering the risk stratification system proposed by the International Working Group on the Diabetic Foot (IWGDF), the risk for DFU in the recruited population ranged from low (category 1) to high (category 3), but the distribution of participants in these three risk groups was not recorded. People with peripheral arterial disease who don't have LOPS could also belong to the same IWGDF risk categories. However, emphasis was given to people with LOPS due to the established effect of neuropathy on the intensity and distribution of plantar loading [39–41]. Moreover, people with peripheral arterial disease and no LOPS would be at risk of developing ischemic ulcers. These ulcers usually develop on the tips of the toes or the lateral borders of the foot and not on the plantar surface of the foot [19].

People with a lower limb amputation would also be at high risk for DFU [19]. However, they had to be excluded to avoid the confounding effect a missing limb, foot or toe would have on plantar loading and therefore on optimum cushioning results. People with active DFU or Charcot foot were also excluded because the neutral diabetic shoe used here would be contraindicated in these cases. Even though the overall findings about the link between plantar loading and optimum cushioning are transferable, further research is needed to verify and to (potentially) adapt the predictive models presented here for different sections of the diabetic population.

The key strength of this study is the production of specific information that inform evidence-based selection of cushioning materials in everyday clinical practice for the design of effective footwear/ orthoses interventions. More specifically, according to the results presented here, softer cushioning materials should be used in interventions aiming to reduce PPP at the midfoot compared to interventions aiming to reduce PPP in other regions of the foot. Interventions aiming to reduce PTI also appear to require the use of softer materials for effective offloading relative to interventions that are focused on PPP reduction. For the first time, this study demonstrated that patient-specific optimisation of cushioning stiffness is achievable even without access to plantar pressure measurements. Building on these results, simple-to-use clinical tools can be developed for the selection of the most appropriate foam material or the design-optimisation of bespoke 3D-printable footbeds and orthoses.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2023.110914.

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