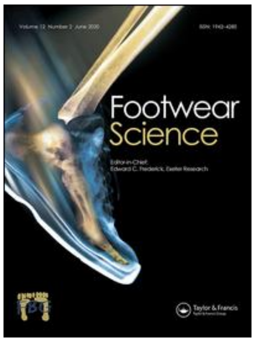

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No change in foot soft tissue morphology and skin sensitivity after three months of using foot orthoses that alter plantar pressure

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ABSTRACT

Altering plantar load using foot orthoses (FOs) may alter the mechanical work required of internal structures and change the size of muscle and connective tissues. Skin sensitivity might also change as a result of altering mechanoreceptor stimulation. This study investigated the effects of FOs on foot soft tissue morphology and skin sensitivity over three months of use. Forty-one healthy participants wore prefabricated FOs ($n = 23$) or no insert ($n = 18$) for three months. The FOs were prescribed specific to each participant, using criteria of a change in peak pressure of 8% in the medial arch (pressure increase) and medial heel (pressure decrease). Ultrasound images were recorded pre- and post-FOs use to derive cross-sectional area and thickness of: abductor hallucis, flexor hallucis brevis, flexor digitorum brevis and the Achilles tendon at the insertion and mid-portion. Plantar fascia thickness was measured at the insertion and midfoot. The minimal detectable difference was established in piloting ($n = 7$). Skin sensitivity was measured with monofilaments at the dorsum (between the hallux and second toe), medial and lateral heel, medial and lateral arch and the 1st metatarsal head. The FOs increased peak pressure by 15% in the medial arch and reduced it by 21% in the medial heel. None of the changes in soft tissue measurements was greater than the minimal detectable difference and there were no effects of group and time. Skin sensitivity decreased over time at the 1st metatarsal head for both groups, but there was no group effect. Using FOs over three months did not change the foot tissues nor skin sensitivity. This study challenges the notion that FOs make muscles smaller.

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Foot orthoses; muscle morphology; skin sensitivity; ultrasound; plantar pressure

Introduction

The effect of foot orthoses (FOs) has not been well studied with respect to adaptations to the internal foot structures and skin sensitivity over time. Plantar pressure is altered with FOs (Farzadi et al., 2015; Hodgson et al., 2006; McCormick et al., 2013; C. J. Nester et al., 2003; Sweeney, 2016; Telfer et al., 2013), consequently altering the distribution of resultant force through foot tissues. Muscles and tendons can change their activity, size and structure as a result of a change in loading with training (Folland & Williams, 2007; Magnusson et al., 2008; Reeves et al., 2004) and intrinsic foot muscles can also change size in response to modified loading of the foot with altered footwear (Bruggemann et al., 2005; Johnson et al., 2016). Therefore, redistributing the external loading of the foot with FOs could alter muscle and connective tissue morphology. It has been suggested that FOs and arch support from footwear leads to smaller and weaker foot muscles (Lieberman et al., 2010; McClinton et al., 2016; McKeon et al., 2015). However, intervention studies on the effect of FOs on muscle are limited (Jung et al., 2011; Protopapas & Perry, 2020). Although there is evidence for altered tissue thickness and stiffness of the Achilles tendon and plantar fascia in pathologies such as diabetes (Khor et al., 2021), which will influence the distribution of plantar stress (Cheung et al., 2005), the effect of FOs on these connective tissue also requires investigation.

Foot orthoses can alter the contact area at specific regions of the foot, like increase the contact area in the medial arch (Farzadi et al., 2015; McCormick et al., 2013), which could influence

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skin sensitivity. Skin sensitivity is comprised of both peripheral (alterations to the cutaneous mechanoreceptor activation or transmission) and central influences (cortical plastic changes based on input). Changes in contact area could alter, and potentially increase, the capacity for cutaneous mechanoreceptors to detect mechanical stimuli. There are four different classes of mechanoreceptors in glabrous skin, like on the foot sole, which respond to stretch, contact forces, vibration and pressure (Johansson et al., 1982; N. D. Strzalkowski et al., 2018). Cortical plasticity allows for the potential for increased skin sensitivity through increasing the relevant area in the primary somatosensory cortex (Björkman et al., 2009) and neurophysiological changes with training has been shown in primates following stroke (Plautz et al., 2016). Increased pressure in the medial arch could increase sensitivity due to the increases in the relative weighting given to receptors from that region, or skin sensitivity could decrease if the receptors become desensitised (Hao & Delmas, 2010). Altered stimulation of mechanoreceptors can modulate afferent feedback to the central nervous system, influencing muscle activity and movement of the lower and upper limbs (Bent & Lowrey, 2013; Fallon et al., 2005; Howe et al., 2015; Nurse & Nigg, 2001; Perry et al., 2008). Consequently, the skin's contribution to gait and posture could be influenced with use of FOs through long term stimulation of mechanoreceptors (a response to mechanical load being elicited in mechanoreceptors repetitively over time).

Preliminary work ($n = 12$) has shown using a metatarsal bar to increase pressure can increase skin sensitivity in the forefoot (Vie et al., 2015), however, the effect of increases in pressure on skin sensitivity in other regions of the foot with FOs has not been investigated. Skin sensitivity in the medial arch may adapt differently to pressure changes from the forefoot because the medial arch is not normally loaded, and is the most sensitive region of the foot, despite having potentially fewer mechanoreceptors than other regions (N. D. Strzalkowski et al., 2018). The arch region of the foot is of particular interest as it is frequently loaded in FOs interventions (Williams & Nester, 2010). The arch region also has the lowest perceptual threshold (greatest sensitivity), while the heel has the greatest perceptual threshold (N. D. J. Strzalkowski et al., 2015).

Prefabricated FOs were used by 93% of responders to a national survey of clinicians prescribing FOs in the UK and ethylene vinyl acetate (EVA) and rigid plastic were the most commonly used materials for prefabricated FOs (C. Nester et al., 2017). The effect of FOs that affect loading under the heel and medial arch on soft tissue size and structure and foot/ankle skin sensitivity is unknown. The purpose of this study was to enhance our understanding of the mechanisms behind the effect of prefabricated FOs by investigating whether skin sensitivity and soft tissue morphology would be altered when plantar loading was changed with FOs.

Materials and methods

Participants

Fifty-three healthy participants (Females = 36, mean ± SD age: 29 ± 9 years; height: 1.67 ± 0.07 m; mass: 68.6 ± 12.9 kg) were allocated to a FOs group, who wore prefabricated EVA or thermoplastic FOs (Salfordinsole) for three months ($n = 27$), or a control group, who received no insert ($n = 26$). Exclusion criteria were: (1) having lower limb injury in the last three months or foot/ankle with pathology/deformity; (2) having cardiovascular, musculoskeletal or neurological condition or disease; (3) walking with an aid; (4) wearing FOs in the last six months and (5) having a pair of footwear being worn during the day unsuitable for FOs. All participants provided written informed consent prior to participation. Participants were recruited from the University of Salford and the University of Guelph and the study received ethical approval at both institutions (HSR1718-009 and REB Number: 17-08-019, respectively).

Protocol

Height, body mass, shoe size, static foot type and leg dominance were recorded at baseline. Foot type was classified using the Foot Posture Index (FPI) described previously (Redmond et al., 2006). Ultrasound measurements, skin sensitivity testing and an assessment of physical activity levels were conducted at baseline and after three months of

Figure 1. Salfordinsole foot orthosis. The majority of participants ($n = 18$) wore medium density ethylene vinyl acetate (EVA) or thermoplastic (Shore A 70) depicted.

wearing FOs or normal footwear with existing inserts. Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ), Short Form. Participants were considered 'active/inactive' based on the World Health Organisation (2011) guidelines.

Foot orthoses

Participants wore thermoplastic or EVA FOs for at least 4 h a day, following a previous protocol (Hossain et al., 2011). Participants were given the option whether or not to wear the FOs in physical activities other than walking. Participants received weekly emails checking on FOs condition, whether the FOs were comfortable, FOs wear time and any substantial changes in physical activity. Additionally, participants were asked compliance questions after the three months regarding typical daily FOs wear.

Participants were issued FOs that generated a minimum 8% increase in peak pressure in the medial arch and 8% decrease in peak pressure in the medial heel (compared to walking in their normal shoes) determined by in shoe pressure measurements. A threshold of 8% was chosen based on the mean reduction in peak plantar pressure at the medial heel previously shown with the Salfordinsole (Sweeney, 2016), which is also consistent with the mean reduction in plantar pressure at baseline in the medial heel with other FOs with a medial arch support (Hodgson et al., 2006). The rationale was to ensure a suitable change in external loading of the foot as a necessary precursor to changes in the internal (soft tissue and sensitivity) response to the change in load. The change in pressure was evaluated using Pedar insoles (Mobile, Novel Electronics Inc., GmbH Munich, Germany), which were calibrated prior to data collection. Data was recorded after two minutes of habituation with the FOs (Melvin et al., 2014). Successful trials were those with a walking speed within ±5% of self-selected speed. The arch region occupied the middle third of the footprint (Cavanagh & Rodgers, 1987).

Initially, participants wore either medium density EVA or the 'flex' thermoplastic Salfordinsole FOs (Shore A 70) (Figure 1). If either were uncomfortable participants were given low density EVA Salfordinsole FOs (Shore A 30). Plantar pressures were then compared with those when walking without FOs. If the pressure decrease in the heel was below 8% a higher density EVA or the harder thermoplastic FOs (Shore A 85) were worn, so as to increase load in the medial arch and thereby offload the medial heel. The predominant FOs used to achieve the required pressure changes were medium density EVA or thermoplastic, reflecting clinical practice (C. Nester et al., 2017).

The measurement of the soft tissue thickness and cross-sectional areas

Ultrasound images were recorded with either: MyLab 70 Xvision with a 13 MHz linear array transducer (Type, LA523, Esoate Europe, UK), Venue 40 (GE Healthcare, UK) or M-turbo musculoskeletal ultrasound system (Sonosite, Bothell, WA, USA) with a 6 cm linear array probe (HFL50x, 15–6 MHz wideband). Images for each individual were recorded with the same machine pre and post 3-months.

Measurements focussed on structures associated with foot posture and function (Angin et al., 2014; Kelly et al., 2014; Murley et al., 2014; Semple et al., 2009) that could be reliably imaged based on pilot work and a previous study of test and retest reliability (Crofts et al., 2014). The protocol included the measurement of the thickness of abductor hallucis (ABH), flexor digitorum brevis (FDB), flexor hallucis brevis (FHB), proximal plantar fascia (PFINS) and mid-portion plantar fascia (PFMID)

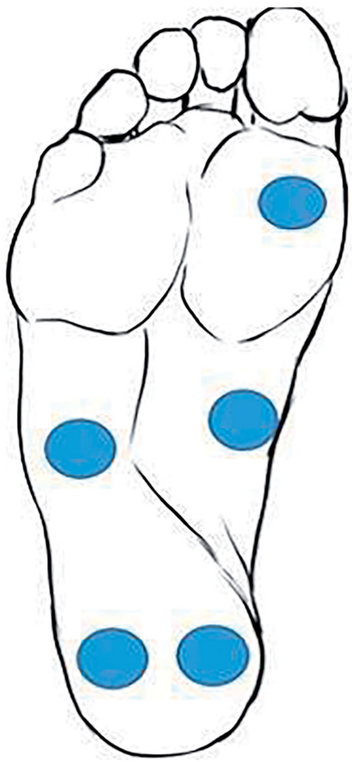

Figure 2. The foot sole with blue dots depicting the approximate locations of skin sensitivity testing. An additional site was on the dorsum at approximately the level of the distal interphalangeal joint between the hallux and second toe.

as outlined previously (Angin et al., 2014; Crofts et al., 2014). The cross-sectional area (CSA) was also measured for ABH and FDB (Angin et al., 2014; Crofts et al., 2014). Thickness and CSA of the Achilles tendon were taken at the insertion on the calcaneus (ATINS) and the mid-portion, (ATMID) where the underlying soleus was visible. Two images were taken per structure.

A pilot test and retest reliability study established the minimal detectable difference (MDD) from which to contextualise any differences pre and post FOs use. Two researchers collected data and they undertook the same training. Inter-rater reliability was assessed using images taken from the same seven individuals by both researchers. The standard error of measurement (SEM) was calculated as the square root of the sum of squares of the between-subjects standard deviation. The MDD was calculated as 1.5*SEM (Hopkins, 2000).

Skin sensitivity

Skin sensitivity was tested prone with feet in a relaxed, neutral position. The regions assessed were the dorsum (around the level of the distal interphalangeal joint between the hallux and second toe), medial and lateral heel, medial and lateral arch and the 1st metatarsal head (Figure 2). The staircase method was employed to determine perceptual threshold (Dyck et al., 1993) using Semmes-Weinstein monofilaments (North Coast Medical Inc, Gilroy, CA). The monofilaments were applied perpendicular to the skin until they buckled. Each monofilament is calibrated so as the diameter relates precisely to the force being applied (across a range of 0.008–300 g). The smallest diameter monofilament detected with 75% accuracy was determined as the threshold and the steps to arrive at this threshold have been previously described (Lowrey et al., 2014; N. D. Strzalkowski Lowrey, 2015; N. D. J. Strzalkowski et al., 2015). Importantly, the afferent firing response of cutaneous mechanoreceptors in the foot sole is very variable below 20 °C (Lowrey, 2012). Skin temperature was therefore measured using a handheld infra-red thermometer (Brannan Thermometers, Cumbria, UK) or (Thermoworks, USA). If skin temperature fell below 20 °C the participant was asked to put their sock back on to rewarm the foot and testing resumed once skin temperature returned to above 20 °C.

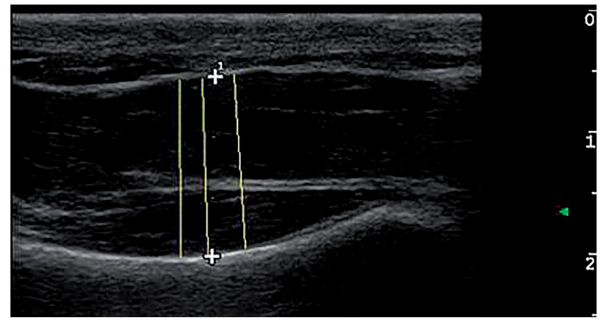

Figure 3. Ultrasound image of the flexor hallucis brevis with three thickness measurements (yellow lines).

Data analysis

Ultrasound

Ultrasound images were assessed blind and analysed by a single assessor using ImageJ (NIH, USA). For thickness, three measurements were taken per image between the deep and superficial aponeurosis in the centre of the image, as per a previous protocol (de Boer et al., 2008) (Figure 3).

Table 1. Mean participant (±SD) characteristics pre- and post-intervention measured pre-intervention.

	Group	Age	(±SD)	Sex		Height (m)	(±SD)	Mass (kg)	(±SD)	Shoe size	(±SD)	Leg dominance		FPI L	(±SD)	FPI R	(±SD)
Pre	FOs ($n=26$[a])	27	7	F = 16	M = 10	1.680	0.078	68.1	13.2	7	2	L = 0	R = 24[a]	3	4	3	4
	Control ($n=26$)	30	11	F = 19	M = 7	1.662	0.069	69.2	12.7	7	2	L = 2	R = 24	2	5	2	4
	Total ($n=52$[a])	29	9	F = 35	M = 17	1.671	0.074	68.6	12.9	7	2	L = 2	R = 48[a]	2	4	2	4
Post	FOs ($n=23$)	28	10	F = 15	M = 8	1.651	0.070	67.8	13.3	7	2	L = 0	R = 23	3	4	3	3
	Control ($n=18$)	28	10	F = 12	M = 6	1.656	0.069	68.7	13.1	7	2	L = 0	R = 18	3	4	3	4
	Total ($n=41$)	28	9	F = 27	M = 14	1.673	0.074	68.1	12.2	7	2	L = 0	R = 41	3	4	3	4

F: female; M: male; L: left; R: right; SD: standard deviation; FPI: foot posture index; FOs: foot orthoses group, [a]denotes missing data.

For CSA two measurements were taken per image as CSA was highly correlated between images (e.g. $r=0.98$ for ABH). Means were calculated from the four measurements for CSA and six measurements for the thickness respectively. Median values of the differences within participants over time were reported, as per previous work (Blazevich et al., 2007, 2009), because the median is less sensitive to extreme values. Therefore, extreme changes due to measurement error in one session, which could occur as a result of variation in probe orientation or the pressure applied (Ihnatsenka & Boezaart, 2010), would affect the median less than the mean.

Statistics

Statistical analysis was performed with SPSS (IBM SPSS Statistics 25). Values beyond the first quartile −3*interquartile range (IQR) or the third quartile +3*IQR were classified as outliers and the participant was excluded for that variable. Two-way mixed model ANOVAs were used (time*group). The monofilament scores were non-normally distributed so were log-transformed before running the ANOVA. An α level of 0.05 was used to determine significance. Interaction effects between time and group were of primary interest as they would indicate that differences between pre- and post-intervention measurements varied between the FOs and control groups.

Results

Participants

Twelve of the 53 participants recruited dropped out, including four from the FOs group. One in the FOs group dropped out due to hip pain which they attributed to the FOs. The other three participants in the FOs group who dropped out did not report an adverse event, but did not respond to the invitation to return for post intervention assessments. Several included participants experienced some foot soreness using the FOs, but this did not persist beyond week one and is typical (Matthews et al., 2020; Woodburn et al., 2002), and these participants continued with the study. Characteristics of all recruited participants are presented in (Table 1).

Foot orthoses

The actual mean (± SD) change in peak pressure due to FOs was significantly larger than the minimum requirement. In the medial heel the mean reduction was 21% (± 14%, $p=0.012$) and for the lateral heel 17% (± 14%, $p=0.004$). Mean (± SD) peak pressure at the medial arch was significantly greater at 15% (± 19%, $p=0.005$), though not significantly greater at the lateral arch 7% (± 17%, $p=0.106$).

Compliance

Sixteen of the 23 participants in the FOs group completed the post-intervention compliance questions and all bar one wore the FOs for more than the minimum of 4 h a day (mean ± SD: ∼8.5 ± 3 h). The seven participants who did not complete these questions had confirmed via email that they were wearing the FOs more than the minimum of 4 h a day.

Physical activity levels

In the FOs group, 21/23 (91%) were active pre-intervention and 22/23 (96%) were active post-intervention. In the control group, 14/18 (78%) were active pre-intervention and all remained so.

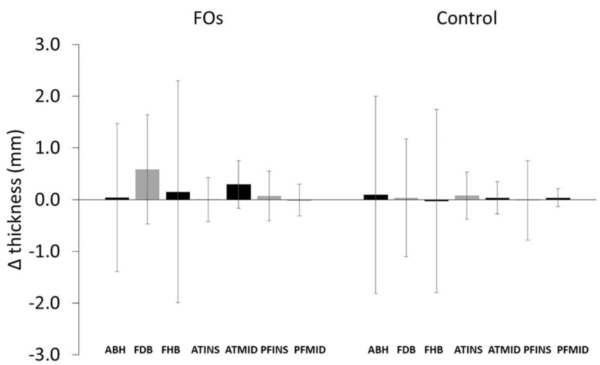

Figure 4. Median difference in ultrasound thickness from pre- to post-three months in the foot orthoses group (FOs) and control group for abductor hallucis (ABH), flexor digitorum brevis (FDB), flexor hallucis brevis (FHB), Achilles tendon at the insertional site on the calcaneus (ATINS) and the mid-portion (ATMID), proximal plantar fascia (PFINS) and mid-portion plantar fascia (PFMID).

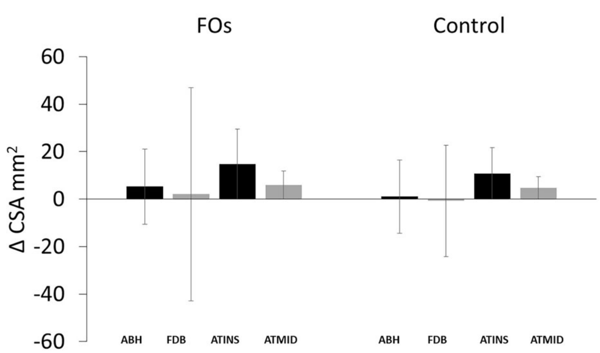

Figure 5. Median difference in ultrasound cross sectional area (CS) from pre- to post-three months in the foot orthoses group (FOs) and control group for abductor hallucis (ABH), flexor digitorum brevis (FDB), Achilles tendon at the insertional site on the calcaneus (ATINS) and the mid-portion (ATMID).

Table 2. Mean ultrasound thickness measurements at pre- and post-intervention.

Thickness (mm)		Pre Mean	Pre SD	Post Mean	Post SD	Difference (median)	MDD
ABH	FOs ($n=19$)	10.639	2.268	10.736	1.720	0.037	0.742
	CO (=16)	10.491	1.739	10.568	2.134	0.092	
ATINS	FOs ($n=19$)	4.339	0.680	4.348	0.657	0.001	0.323
	CO ($n=17$)	4.245	0.581	4.259	0.517	0.076	
ATMID	FOs ($n=19$)	3.577	0.781	3.773	0.831	0.289	0.451
	CO ($n=17$)	3.922	0.882	4.009	0.788	0.034	
FDB	FOs ($n=19$)	8.916	1.437	9.304	1.575	0.581	2.138
	CO ($n=17$)	9.892	2.101	9.745	1.542	0.033	
FHB	FOs ($n=16$)	11.989	2.602	11.682	2.608	0.151	1.032
	CO ($n=12$)	12.902	2.840	11.688	3.352	−0.031	
PFINS	FOs ($n=20$)	2.178	0.457	2.286	0.380	0.070	0.495
	CO ($n=17$)	2.204	0.448	2.100	0.407	−0.018	
PFMID	FOs ($n=20$)	1.652	0.193	1.667	0.260	−0.010	0.302
	CO ($n=17$)	1.600	0.151	1.629	0.183	0.036	

FOs: foot orthoses group; CO: control group; MDD: minimal detectable difference; ABH: abductor hallucis; ATINS: Achilles tendon at the insertional site on the calcaneus; ATMID: Achilles tendon at the mid-portion; FDB: flexor digitorum brevis; FHB: flexor hallucis brevis; PFINS: proximal plantar fascia and PFMID: mid-portion plantar fascia.

Table 3. Mean ultrasound cross-sectional area measurements at pre- and post-intervention.

CSA (mm^2)		Pre Mean	Pre SD	Post Mean	Post SD	Difference (median)	MDD
ABH	FOs ($n=17$)	204.332	62.368	203.705	57.624	5.232	7.229
	CO ($n=15$)	198.601	53.211	197.935	48.367	1.062	
ATINS	FOs ($n=17$)	68.460	13.890	69.971	12.591	1.808	11.963
	CO ($n=16$)	66.365	16.741	67.263	14.149	−2.716	
ATMID	FOs ($n=15$)	53.495	13.717	55.527	9.472	1.829	14.169
	CO (n = 16)	47.986	7.826	51.044	9.347	2.108	
FDB	FOs ($n=17$)	200.401	44.741	204.332	46.820	2.086	40.360
	CO ($n=14$)	195.531	55.193	199.157	57.221	−0.790	

FOs: foot orthoses group; CO: control group; MDD: minimal detectable difference; ABH: abductor hallucis; ATINS: Achilles tendon at the insertional site on the calcaneus; ATMID: Achilles tendon at the mid-portion and FDB: flexor digitorum brevis.

Ultrasound

Difference in ultrasound measurements pre- and post-intervention are presented in Figures 4 and 5 for thickness and CSA respectively and mean values pre- and post-intervention are presented in Tables 2 and 3. No average difference in ultrasound measurement was greater than the MDD (Tables 2 and 3). There was a trend for an effect of time for ATMID thickness ($p = 0.056$, $\eta p^2 = 0.103$) and a main effect of group for ATMID CSA ($p = 0.049$, $\eta p^2 = 0.127$) and other effect sizes were also small (<0.1).

Skin sensitivity

Mean skin temperature was 26.3 °C (± 1.6 °C) pre- and 29.8 °C ± 1.3 °C post-intervention, both above the recommended minimum threshold of 20 °C. The monofilament results are presented in Table 4 and Figure 6. There was a main effect of time for the 1st metatarsal head. Monofilament threshold increased with time for both control (0.34 ± 0.53 to 0.60 ± 0.55 g) and FOs groups (0.27 ± 0.42 g to 0.55 ± 0.62 g, $p = 0.003$, $\eta p^2 = 0.211$). There were no significant effects in other locations, with effect sizes <0.1 and large variability in thresholds across regions.

Discussion

This study investigated whether skin sensitivity and selected soft tissue morphology were altered when plantar loading changed due to use of FOs. Despite successfully altering pressure across the foot sole, the FOs did not significantly change soft tissue

Table 4. Mean monofilament thresholds from pre- to post-three months in the foot orthoses group (FOs, $n = 23$) and control group (CO, $n = 18$) for each region of the foot.

		Pre		Post		Difference	
		Mean	SD	Mean	SD	Mean	SD
Dorsum	FOs	0.34	0.42	0.51	0.65	0.17	0.56
	CO	0.22	0.25	0.46	0.59	0.24	0.59
1st metatarsal head	FOs	0.27	0.42	0.55*	0.62	0.28	0.59
	CO	0.34	0.53	0.60*	0.55	0.26	0.52
Medial arch	FOs	0.08	0.09	0.17	0.26	0.09	0.23
	CO	0.12	0.22	0.12	0.14	0.00	0.28
Lateral arch	FOs	0.55	1.27	0.64	0.69	0.09	1.28
	CO	0.23	0.31	0.25	0.29	0.02	0.45
Medial heel	FOs	0.92	1.03	0.88	0.78	−0.04	0.99
	CO	0.93	0.75	0.94	0.70	0.01	0.90
Lateral heel	FOs	1.14	0.96	1.18	0.79	0.04	0.90
	CO	0.86	0.73	0.84	0.72	−0.01	0.65

*denotes main effect of time ($p < 0.05$).

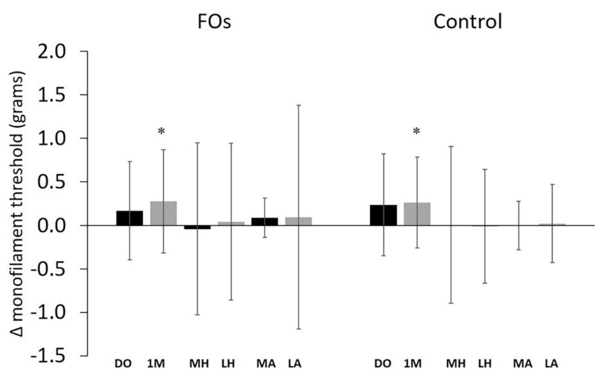

Figure 6. Median difference in monofilament threshold from pre- to post-three months in the foot orthoses group (FOs) and control group for the dorsum (DO), the 1st metatarsal head (1 M), medial heel (MH), lateral heel (LH), medial arch (MA) and lateral arch (LA), * denotes main effect of time ($p < 0.05$). An increase in threshold represents a decrease in sensitivity.

morphology or skin sensitivity when compared to the control group. There may be a number of reasons why this was the case. The neurophysiological and active and passive systems of the foot are thought to be flexible in coping with changing demands (McKeon et al., 2015). So the change of demand with altered plantar loading due to FOs may have been accommodated without changing soft tissue morphology or sensory function. However, effects could have occurred in muscles other than those we could reliably assess with ultrasound, or other muscle properties or aspects of skin sensitivity that we did not measure. The daily wear time of FOs and study duration might also have been insufficient to cause changes. However, mean FOs wear time (8.5 h/day) was arguably close to what could be expected in clinical practice and comparable to previous research (McPoil et al., 2011; Munteanu et al., 2015) and might therefore be considered a pragmatic dose of altered plantar loading. Several participants reported not wearing the FOs some days on weekends when indoors, which also likely reflects clinical practice. In a trial of custom FOs for patients with rheumatoid arthritis, FOs were worn six days/week on average (Woodburn et al., 2002). Increases in muscle CSA have been documented after 8–12 weeks (Folland & Williams, 2007), so it is conceivable that a 12 week FO intervention would be long enough to see change in intrinsic foot muscle CSA. Physical activity levels were comparable throughout and so unlikely to confound results.

Soft tissue measures

A lack of change in the FOs group conflicts with previous research investigating FOs, whereby CSA decreased in the FOs group and not the control group (Protopapas & Perry, 2020) and an earlier study that found an increase in CSA of ABH with FOs with and without the addition of short foot exercises (Jung et al., 2011). However, the study by Jung et al. is difficult to interpret without a control group. The study by Protopapas and Perry only evaluated the cross-sectional area of five participants in each of a control and intervention group, reporting that FDB reduced 9.6% and ABH reduced 17.4% over 12 weeks (Protopapas & Perry, 2020). However, the MDDs of measures was not reported and the reduction in FDB CSA was smaller than the MDD in this study. Given the small sample size the reported change might be measurement error and not meaningful. Furthermore, the results from this and earlier reliability work (2014) showed better measurement reliability for thickness rather than CSA. For example, limits of agreement were 13% and 13.5% for ABH and FDB thickness respectively, and 16% and 17% for ABH and FDB CSA (Crofts et al., 2014). Using prefabricated FOs in this study rather than customised FOs (Protopapas & Perry, 2020) could also explain the different outcomes, if match between FOs and foot shape influences neuromuscular adaptations. However, prefabricated and customised FOs have similar effects on peak plantar pressure and can be equally effective in reducing pain in a clinical population (Almeida et al., 2009; Redmond et al., 2009). Without knowledge of the change in plantar pressures or the material of the FOs in the earlier study (Protopapas & Perry, 2020), we cannot compare the changes in loads achieved. In the current study the mean percent 21% decrease in peak pressure at the medial heel and 15% increase in peak pressure at the medial arch with prefabricated FOs were similar or greater than a previous study using custom FOs that reflect common clinical practice, in which there was a 13% reduction in the medial heel and 15% increase in the medial midfoot (McCormick et al., 2013).

Skin sensitivity

As participants were young, healthy and mostly active it is possible that they had little capacity to increase skin sensitivity. Baseline monofilament threshold in the medial arch was low, indicating high sensitivity (~0.1 g vs. ~1.0 g at the heel), which reflects the level of sensitivity previously reported in the literature (N. D. J. Strzalkowski et al., 2015). In this young healthy population, it may be that increased loading in this area would not increase sensitivity because it was already very sensitive. Alternatively, decreased sensitivity in one region could have increased sensitivity in another region that perhaps was not measured (Björkman et al., 2009). Previous preliminary work has shown increased forefoot sensitivity following the use of a hard metatarsal pad (Vie et al., 2015). This differs from our results here. Differences could be attributed to the different methods of measuring skin sensitivity (the previous study used a bespoke loading device), different regions of pressure change (they used the forefoot, which is less sensitive than the medial arch) and/or the density of FOs material.

Mean skin temperature at the time of measurement increased by ~3.5 °C from pre- to post-intervention assessments, possibly due to seasonal weather variation, but remained within the typical range (Lowrey, 2012; N. D. Strzalkowski et al., 2015; Sun et al., 2005). This was not felt to mask any underlying change in sensitivity. The increase in monofilament threshold at the 1st metatarsal head with time in both groups could be interpreted simply as noise in the measurement.

It is conceivable that changes in skin sensitivity occurred outside of those mechanisms tested using monofilaments, which target fast adapting type I receptors (FAIs) (Johansson et al., 1982; N. D. J. Strzalkowski et al., 2015). Perceptually, it is known that FAIs are responsible for the sensation of touch using monofilaments, so it is possible that we missed changes that were experienced by other mechanoreceptors in the glabrous skin. No change in perceptual threshold measured with monofilaments was reported following space flight, despite some changes in vibration sensitivity at frequencies that target other receptors, namely fast adapting type II receptors and slow adapting type I receptors (Lowrey et al., 2014). If monofilaments were insensitive to changes in skin sensation following the large pressure changes that occurred due to microgravity, it seems unlikely monofilaments would be sensitive enough to detect changes in skin sensitivity following ~20% changes in pressure due to FOs at a localised area. So perhaps if minor changes in skin sensitivity occurred, the monofilaments were not able to detect the change. The increased pressure in the medial arch and arch curvature of the FOs may have changed the sensitivity of slow adapting type I (SAI) receptors, which are not tested by monofilaments (N. D. J. Strzalkowski et al., 2015). Development of a validated measure of spatial acuity would enable testing of these receptors. Participants reported 'getting used to' the FOs after around a week, so anecdotally it appeared some neurological adaptation to the redistribution of plantar pressure occurred that was not captured using monofilaments.

Limitations

For ultrasound measurements the MDD was relatively high, especially for CSA, which could have impacted on the ability to detect an effect of FOs. Less measurement error could be achieved with MRI, however this was not accessible or financially feasible. Additionally, the measurement protocol we used could have contributed to the variability in skin sensitivity. Monofilament tests have demonstrated low reliability (ICC 0.46–0.61) on the back (Ellaway & Catley, 2013). Additionally, testing sites were defined as regions, not as precise points as previously (N. D. Strzalkowski et al., 2015), so as there is not a uniform distribution of mechanoreceptors, different mechanoreceptors could have been targeted pre- and post-intervention. However, the method used was designed to give a practical measure of skin sensitivity of functional regions of the foot similar to clinical practice.

Nil effects could have been due to sample size, characteristics or group allocation. The sample was pseudorandomised as at one site participants were randomly allocated into groups ($n = 39$) whereas at the other they were allocated on convenience ($n = 14$), based on the sizes of FOs that were available at that location. There were no statistical differences in participant characteristics between the FOs and control groups for the latter sample, which refutes the idea that a lack of randomisation contributed to a nil effect. The nil effects are unlikely due to a lack of power, as effect sizes were typically less than small (≤ 0.1). Although on visual inspection no differences in responses were observed between foot types, recruitment did not target specific foot types and so most participants had a neutral foot posture. Given the potential importance of sub-groups (Selfe et al., 2016), perhaps the mixed sample of foot postures masked an effect of FOs for a specific foot type, as foot type and medial arch height in particular will influence the contact area of FOs with the foot and may also influence soft tissue size (Angin et al., 2014; Murley et al., 2014). Our sample size was insufficient to account for the effect of foot posture on foot soft tissue morphology or skin sensitivity. However, we used plantar pressure measures to ensure all participants experienced minimum changes in pressure independent of foot type. We were also not able to account for any changes in skin thickness which partially influences skin sensitivity (N. D. Strzalkowski et al., 2015).

Conclusion

This study found no detectable change in foot soft tissue morphology nor skin sensitivity after three months of FOs use. Future study on the effects of FOs on the neuromuscular system could consider using alternative measurement techniques and foot posture sub groups. Although this study does not explain the mechanism of FOs benefits, it challenges the notion that FOs reduce muscle size.

Disclosure statement

CN owns equity in Salfordinsole Healthcare Ltd. (Nuneaton, UK) that manufactures foot orthoses. Other authors have no conflicts of interest to declare.

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