
Title	Immediate comfort perception of 3D-printed foot orthoses in individuals with unilateral heel pain
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The immediate comfort perception of 3D printed foot orthoses in individuals with unilateral heel pain.

Abstract

Background:

Custom-made foot orthoses (FOs) play an integral part in managing foot disorders. Traditional FO fabrication is time-consuming and labour intensive. 3D printing FOs save time and costs compared with the traditional manufacturing process. To date, the differences in dimensions and comfort perception of these orthoses have not been compared in a pathological population.

Objective:

Compare the dimensions between 3D printed and traditionally-made FOs and comfort perception between 3D printed, traditionally-made and no FOs in individuals with flat feet and unilateral heel pain.

Study Design:

Within-subject single-blinded randomised crossover study design

Methods:

Thirteen participants had custom-made FOs using 3D printing and traditional processes. Orthotic lengths, widths, arch heights and heel cup heights were compared. Participants performed walking trials under three conditions 1)no orthoses, 2)3D printed orthoses and 3)traditionally-made orthoses. Comfort perception was recorded. Orthotic dimensions were compared using paired t-tests and comfort perception were compared using one-way MANOVA, and Bonferroni post hoc tests.

Results:

3D printed orthoses are wider, have higher arch heights and heel cup heights compared to traditionally-made FOs (medium to large effect sizes). There was a difference in comfort perception between the three orthotic conditions, $F(12,62)=1.99$, $p=0.04$; Wilk's $\Lambda=0.521$, $\eta_p^2=0.279$. Post hoc tests show that there is no difference in comfort perception between the 3D and traditionally-made FOs. Both FOs were significantly more comfortable than no orthoses.

Conclusion:

3D printing appears to be a viable alternative orthotic fabrication option. Future studies should compare the biomechanical effects of 3D printed and traditionally-made FOs.

Abstract word count: 245

Keywords

3D printed, custom made, foot orthoses, flat feet, orthotic dimensions, comfort perception, heel pain

Background:

The foot can be classified into three foot postures – the high-arched, normal-arched and low-arched or flat-foot.¹ Foot posture plays an important role in the function of the lower limb and has been associated with the development of musculoskeletal injuries.² Individuals with high-arched feet have an increased likelihood of impact related injuries due to reduced foot joint mobility³ while individuals with flat-feet have an increased likelihood of foot⁴, knees⁵ and hip⁶ pain due to excessive foot mobility. Foot orthoses (FOs) play an integral part in the management of foot disorders.⁷ FOs were found to be effective in improving foot function⁸ and reducing heel pain⁹ associated with flat-feet.

There are many categories of FOs including off-the-shelf and custom-made FOs.¹⁰ Custom-made FOs are made according to the shape of the foot and to manage an individual's specific foot pathology.^{11,12} Traditional manufacturing of custom-made FOs is time consuming, labour-intensive and the quality and effectiveness of the final product is largely dependent on the skill level of the manufacturing technician.¹³

Three-dimensional (3D) printing has the potential to improve the manufacturing process of FOs.^{14,15} This approach to FO manufacture is increasingly adopted by commercial central orthotic fabrication facilities (COFFs). 3D printing of orthoses has many purported benefits, including less time spent on manual labour, potential costs savings over the long term¹⁶, and may produce devices with better fit.¹⁷ There are also initial studies that show that 3D printed FOs are effective in managing heel pain^{18,19} and altering lower limb biomechanics.^{20,21}

Many COFFs are embracing 3D printing of FOs and gradually phasing out the traditional method of FO manufacture. Studies are required to ensure that 3D printed orthoses are at least similar to traditionally-made FOs in dimension and comfort. This study aimed to compare the dimensions and comfort of 3D printed FOs and traditionally-made FOs. The hypothesis is that 3D printed and traditionally-made FOs have similar dimensions as they are made from the same foot image.

Comfort evaluation is important as the perception of poor comfort may lead to poor user compliance. There are some previous studies comparing comfort perception in asymptomatic participants with normal foot postures.²⁰ As custom-made FOs are usually prescribed to flat footed individuals for management of heel pain,¹⁰ studies examining individuals with these two conditions would be clinically relevant. Foot pain can affect one foot (unilateral) or both feet (bilateral). In the general population, unilateral heel pain is more prevalent than bilateral heel pain.²² In this study, the comfort perception of 3D printed, traditionally-made and no FOs on flat-footed individuals with unilateral heel pain was investigated. As this study is exploratory in nature, there may be

a possibility that the comfort perception of the 3D printed or traditionally-made FO may be similar to not using any FOs. Therefore, a control condition of 'No FO' was included. The hypothesis is that the 3D printed and traditionally-made FOs would be perceived as equally comfortable, and both would be more comfortable than the 'no FO' condition.

The results could show initial evidence that 3D printed FOs may be a viable alternative to traditionally-made FOs. This study may also pave the way for future studies to investigate the biomechanical and longitudinal effects of 3D printed orthoses in patients with musculoskeletal foot conditions.

Method:

The study employed a within-subject single-blinded randomised crossover design and was approved by CQUniversity Human Research Ethics Committee. Participants were recruited from the university staff and attendees of the university health clinic via email, and advertisements placed prominently on the clinic notice boards. Social media posts were also used to recruit individuals from the public. Interested participants contacted the Principal Investigator who arranged an appointment for an initial assessment for suitability for inclusion. All participants provided written informed consent before they were assessed by two podiatrists registered with the Australian Health Practitioner Regulation Agency (AHPRA).

Inclusion criteria

Participants' age, height, weight, Foot Posture Index (FPI) score, pain location, self-reported pain duration (in months) and pain intensity (using a 10 cm Visual Analogue Scale (VAS)) were collected. The inclusion criteria were over 18 years of age, a BMI of less than 36 kg.m⁻², flat feet (score of +6 to +12) as classified by the FPI,²³ and unilateral heel pain for more than three months. The heel pain must be deemed clinically suitable for orthotic therapy based on the opinion of the assessing podiatrists. Exclusion criteria were pain at other sites (e.g.knee), existing medical conditions affecting joints (e.g.arthritis), and neurological conditions affecting gait (e.g.Parkinson's disease), on medication(s) that may reduce their ability to sense pain or discomfort (e.g.analgesia), and current or previous use of orthoses. This is to minimise extraneous factors that may affect comfort perception of the FOs.

Digital scanning and casting

All participants were seated on a podiatry couch. The podiatrist held the non-weight bearing foot in a subtalar joint neutral position with the midtarsal joint pronated and locked.²⁴ For the digital scanning process, the foot was held near the foot scanner (Orthotech 3D Edge Scanner, Orthotech Laboratories, Blackburn, Australia) mounted vertically on a stand, and the assessor scanned the foot by activating a foot pedal. For the

casting process, plaster-of-paris impregnated gauze was placed on the foot to obtain a negative cast of the foot.²⁵ Scans and casts were sent to the same COFF which produced a 3D printed FO (using the digital scan) and a traditionally-made FO (using the plaster cast).

To reduce bias in the manufacturing process, the digital scans and plaster casts were given unique identifier codes to blind the COFF to the participant. The same prescriptions were made for both orthoses according to the needs of each individual participant and each foot. All participants had orthoses ordered and fitted bilaterally. Completed orthoses were sent to the university health clinic via standard post.

Orthotic Dimensions

Dimensions were measured using standard Vernier callipers. Three measurements were taken at least one day apart and the average of three measurements were recorded. All measurements were conducted by the same assessor to reduce inter-rater discrepancies. Measurements of the orthotic length, width, and arch and heel cup heights were taken. There are currently no standardised guidelines on orthotic dimension measurements. Rather, a good orthotic fit is one that aligns with the patient's weight bearing foot.²⁶ As feet vary in proportion, to provide a standardised set of measurements for all orthoses in this study, orthotic length is defined by the vertical distance between the posterior midpoint of the heel, to midpoint of the anterior edge of the orthotic device. Orthotic width is defined as the perpendicular horizontal measurement taken at the widest part of the orthotic device (Figure 1).

Insert Figure 1 here

Heel cup height is taken as the measurement between the ground and the highest edge of the posterior aspect of the heel cup (Figure 2). Orthotic length, width and heel cup height were measured as these formed the edges of the orthoses and a poor fit could potentially cause discomfort. Height at the arch is measured as the vertical distance from the ground to the highest point of the orthotic arch area. Height at the start of the arch is measured as the vertical distance from the ground to the highest point of the orthoses at the distal aspect of the heel cup and the start of the arch (Figure 2). This corresponds to the sustentaculum-tali of the foot. The two arch height points were deemed important as the extent of the arch heights at these two areas would determine orthotic support provided to the inner longitudinal arch of the foot and in controlling excessive foot pronation.²⁷

Insert Figure 2 here

Data collection

The participants attended a second session at the university's biomechanics laboratory where comfort ratings were collected. The participants' symptoms (side of painful foot and intensity) were checked again to

ensure that there were no changes between the two assessment sessions. All participants were provided with a pair of standard canvas lace-up sneakers and were required to walk along a corridor under three conditions: (1) no FO, (2) with 3D printed FO, and (3) with traditionally-made FO, in a randomised order. All orthoses are covered with a black leather top cover to blind the participant from knowing which orthoses they were using for each trial. No adjustments were made to the orthoses before, during or after the trials. To ensure that participants were walking at a similar speed for all trials, participants walked barefoot along a 3-metre walkway five times and the average time was recorded using electronic timing gates (Smartspeed Pro, Fusion Sport, Colorado, USA). During the data collection, participants had to walk within 5% of this recorded average speed for the trial to be accepted. Each participant walked along the walkway approximately 20 times per condition.

Comfort ratings

Participants were asked to complete a comfort survey²⁸ following each condition. The assessor followed a predetermined script to explain the survey to each participant. Participants rated their comfort perception on six criteria: overall comfort, heel cushioning, forefoot cushioning, medio-lateral control, arch support and heel cup fit.²¹ The scale was 100mm ranging from -50, being “not comfortable at all”, to +50, being “the most comfortable condition imaginable”. A score of ‘zero’ indicates the exact point at which the individual’s feeling transitioned from discomfort to comfort (i.e., “neither comfortable nor uncomfortable”). Participants were required to mark a line anywhere along the scale that represented the comfort level they experienced. This type of survey has been shown to be valid and reliable in evaluating patient-reported outcome measures.²⁹

Statistical analysis

Paired t-tests were used to compare the dimensions of the 3D printed orthoses and traditionally-made orthoses for each participant. The effect size (Cohen’s d) is reported as small ($d = 0.2$), medium ($d = 0.5$) and large ($d = 0.8$)³⁰. Bonferroni adjusted p-value was set at 0.01. One-way multiple analysis of variance (MANOVA) and Bonferroni post hoc tests were used to examine the differences in comfort perception variables between the three conditions. Significance was accepted when $p < 0.05$. Data was analysed using SPSS V25 (IBM Corp., Armonk, NY, USA).

Results:

Twenty participants volunteered for the study. After the initial assessment, 7 individuals were excluded for the following reasons: bilateral foot pain ($n=4$); pain in other parts of the body ($n=1$); not having a diagnosis of flat feet as classified by the FPI ($n=1$); and foot pathology unsuitable for orthotic therapy ($n=1$). Thirteen participants (5 males, 8 females; mean age 45.8 ± 9.1 years; BMI $28.6 \pm 6.0 \text{ kgm}^{-2}$) were included in the study.

The mean FPI for the symptomatic foot was 7.0 ± 1.4 and for the asymptomatic foot was 7.2 ± 1.4 . The pain level on the symptomatic foot was 4.9 ± 2.9 (out of 10) on the VAS. The duration of symptoms ranged from 6 months to 8 years.

Table 1 shows the comparison of dimensions of 3D printed orthoses and traditionally-made orthoses. 3D printed orthoses are wider and higher heel cup heights (large effect sizes) and higher height at arch and at start of arch (medium effect sizes) compared to traditionally-made orthoses.

Insert Table 1 here

Table 2 shows a comparison of immediate comfort ratings when participants walked with under the three conditions.

Insert Table 2 here

There was a statistically significant difference in comfort ratings based on the orthotic condition, $F(12,62)=1.99$, $p=0.04$; Wilk's $\Lambda=0.521$, $\eta_p^2=0.279$. There were significant differences between no FO and the 3D printed orthoses condition, and no FO and the traditionally-made foot orthoses conditions for all criteria of comfort (Table 2). There were no differences found between the 3D printed and traditionally-made FO.

Discussion:

The study aim was to investigate if there were dimensional differences and if there were differences in immediate comfort perception ratings between using no FO, 3D printed FOs and traditionally-made FOs. The results within this study indicate that 3D printed orthoses were wider, have higher arch heights and have higher heel cup heights compared to traditionally-made FOs. Despite dimensional differences between the 3D printed and traditionally-made FOs, there were no differences in immediate comfort perception according to individuals who have flat feet and unilateral heel pain.

Orthoses Dimensions

3D printed orthoses were wider than traditionally-made FOs (Table 1). During the traditional manufacture process, the orthotic width is determined by the podiatrist or orthotic technician grinding the device to the desired width. For the 3D printed orthoses, the width may be determined by the orthotic template used by the software. Wider orthoses may result in shoe fitting issues while narrower orthoses may cause discomfort. Clinically, the 3.8 mm difference in orthotic width between the two devices did not seem to have a detrimental clinical effect as both orthoses were equally comfortable (Table 2) and fitted into the footwear provided in this study.

Although both orthotic prescriptions were the same, there were differences in both measured orthotic arch heights which could have resulted from variations in the modification processes. In the traditional process, this involves the application of additional plaster to the positive cast to smooth out the arch. A gradual curve of the arch fill will allow the thermoplastic material to mould to the cast without creases. With the digital scan, the digitised geometry of the foot is used by specialised orthotic design software to produce a surface representation of the foot on a template of an orthotic device. The resulting file containing instructions on the orthotic shape is sent to a 3D printer for manufacturing.³¹ As such, the arch geometry of the 3D printed orthoses might be closer to the actual shape of the foot arch. The arch height differences between the two types of orthoses were less than 2 mm (medium effect size) (Table 1) with no difference in comfort perception (Table 2). Although the arch heights are statistically different, the clinical implications may be minimal.

Orthoses with higher heel cup heights have been found to be effective in providing better balance in the older population.³² A higher heel cup also keeps the heel fat pad contained under the heel bone to provide better natural cushioning during weight bearing³³ which may decrease the peak force produced at initial contact during locomotion.³⁴ The mean heel cup height for the traditionally-made orthoses were 14.1mm and the 3D printed orthoses was 17.5mm (Table 1). This may infer that the higher heel cup height in the 3D printed orthotic device may provide the wearer with more stability and more heel cushioning. Although comfort perception was similar, actual biomechanical studies could be conducted to see if there were differences in stability and impact forces during gait.

We hypothesised that two FOs would have similar dimensions, but findings show the 3D printed FOs were statistically significantly larger in all dimensions except length, compared to traditionally-made FOs.

Comfort perception ratings

As the dimensions of both 3D printed and traditionally-made FOs were different, the immediate comfort perception would be expected to differ. However, this was not the case. This is consistent with the findings of Mo et al.²¹ which concluded that 3D printed and traditionally-made FOs provided a greater sense of medio-lateral control and heel cushioning amongst flat footed individuals compared to no orthoses during running. This is potentially because the differences in dimensions were small, and not sufficient to cause a difference in comfort perception.

From a clinical perspective, it is important to know if a significant difference in comfort ratings was clinically meaningful. A study on comfort perception in footwear reported that a clinically meaningful change in comfort is at least 10.2mm on a 100mm scale.³⁵ A statistical difference in comfort rating was found between the

no FO, and the 3D printed and traditionally-made orthoses conditions respectively (Table 2). These differences were more than 10.2 mm for all criteria, which indicates a plausible clinical difference. The difference between the 3D printed and traditionally-made orthoses conditions for all comfort criteria were less than 10.2 mm, inferring that regardless of which manufacturing process used, both orthoses improved immediate comfort ratings clinically. There was a substantial amount of variability in the comfort ratings for all criteria which may reflect the variability in the general population.

Limitations

This study looked at the dimensions of the orthoses before use, and the immediate comfort perception of the user. It is acknowledged that most individuals would use an orthosis for an extended period of time. Longitudinal studies investigating deformation of the orthoses and the corresponding comfort ratings would be clinically useful.

In this study, the orthotic measurements were compared between the 3D printed and traditionally-made devices and not anatomical foot measurements. Participant's feet were measured using the FPI and actual vertical foot arch height measurements were not taken. The digital scan and plaster cast of the foot were taken in a non-weight bearing position and in FO manufacture, the geometry of the orthoses would be modified to account for foot and fat pad splay during weight bearing. Therefore, in comparing the fit of the custom-made FO, biomechanical studies using three-dimensional motion capture technology to compare the arch height of the foot during walking gait would be needful. Comparing this dynamic arch height between the three FO conditions would provide information regarding the efficacy of the 3D printed and traditionally-made FO when compared to no FO.

Conclusion:

Despite dimensional differences, there were no differences in immediate comfort ratings between the 3D printed and traditionally-made FO in wearers with flat feet and unilateral heel pain. 3D printing seems a viable alternative orthotic fabrication option. Studies comparing the biomechanical effects of 3D printed orthoses and traditionally-made FOs is needful.

Main body word count: 2883

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List of Figures and Tables

Figure 1: Orthotic length (L) and width (W) measurements. Anterior edge of orthotic device is outlined by a grey line.

Figure 2: Orthotic measurements for arch height (AH), height at the start of the arch (SA) and heel cup height (HH).

Table 1: Dimensional comparison of 3D printed and traditionally-made orthoses.

Table 2: Comfort comparison between no Foot Orthoses, 3D printed and Traditionally-made Orthoses.

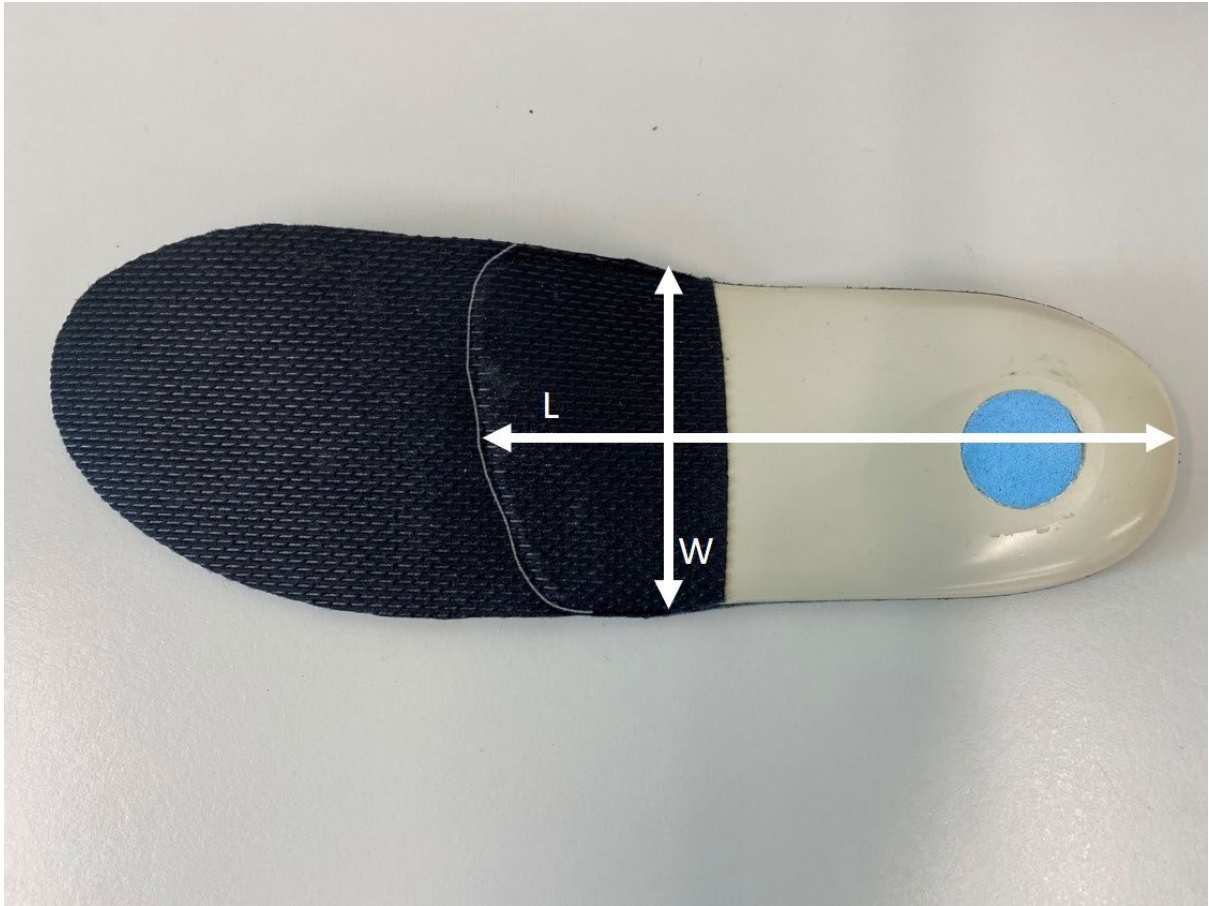


Figure 1

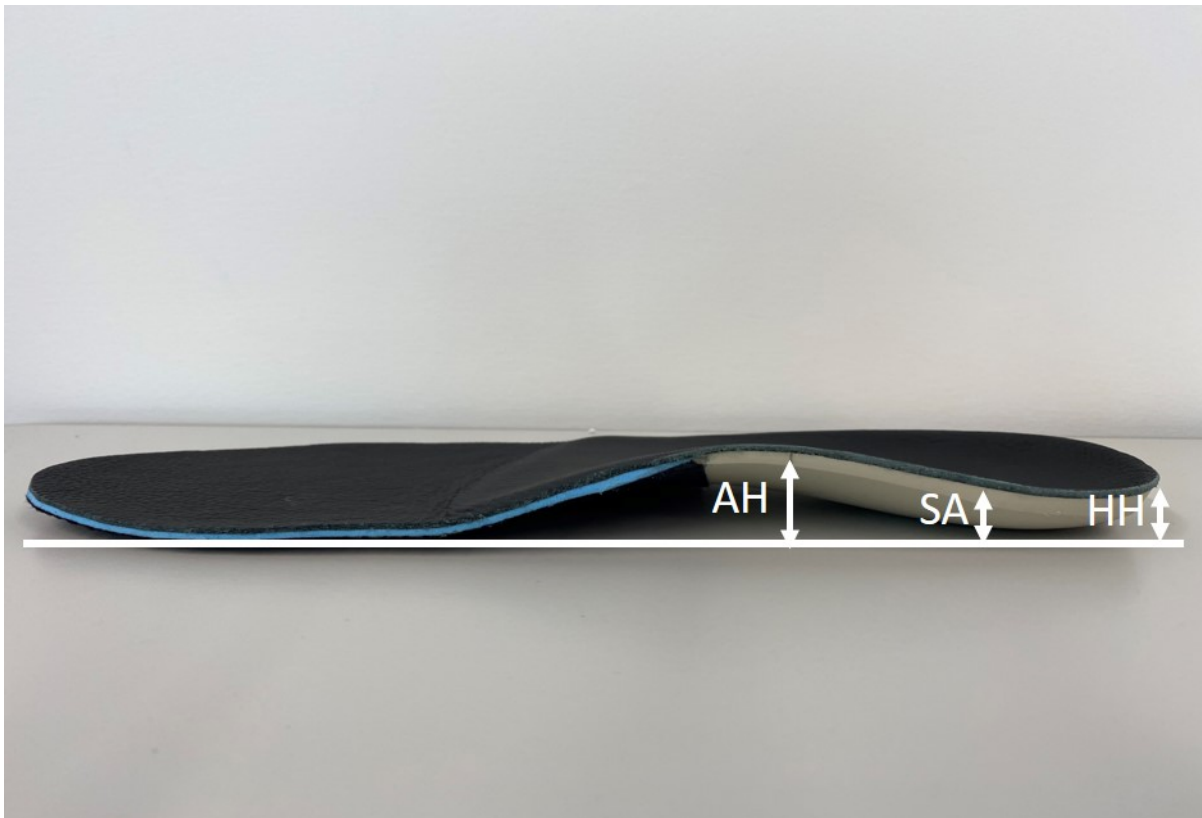


Figure 2

Table 1: Dimensional comparison of 3D printed and traditionally made orthoses.

Orthotic Dimension	3D Printed orthoses (Mean \pm SD)	Traditionally made orthoses (Mean \pm SD)	Mean difference (95%CI)	<i>t</i>	<i>p</i>	<i>d</i>
Length (mm)	167.7 \pm 15.6	169.0 \pm 15.0	1.3 (-1.1, 3.8)	1.091	0.286	0.21
Width (mm)	79.8 \pm 5.7	76.1 \pm 5.2	-3.8 (-5.2, -2.3)	-5.322	<0.001	1.04
Height at arch (mm)	24.2 \pm 2.7	22.8 \pm 3.0	-1.4 (-2.2, -0.5)	-3.078	0.005	-0.60
Height at start of arch (mm)	28.1 \pm 3.9	26.5 \pm 4.5	-1.5 (-2.5, -0.6)	-3.351	0.003	0.66
Heel cup height (mm)	17.5 \pm 3.9	14.1 \pm 3.0	-3.4 (-5.1, -1.5)	-4.201	<0.001	-0.82

95%CI – 95% confidence intervals, degrees of freedom = 25, Cohen's *d* (*d*) small = 0.2, medium = 0.5, large = 0.8, Significant differences (Bonferroni adjusted *p* <0.01) are presented in bold type

Table 2: Comfort comparison between no Foot Orthoses, 3D printed and Traditionally-made Orthoses.

Comfort Variable	No Orthoses (Mean \pm SD)	3D Printed orthoses (Mean \pm SD)	Traditionally made orthoses (Mean \pm SD)	Manova Values			Bonferroni		
				<i>F</i>	<i>p</i>	η_p^2	<i>post-hoc</i>	<i>p</i>	
Overall Experience	-8.1 \pm 22.8	11.3 \pm 18.6	13.0 \pm 15.8	4.81	0.014	0.211	C<D C<T D=T	0.043 0.025 1.000	
Heel Cushioning	-12.3 \pm 21.7	11.5 \pm 21.5	11.8 \pm 17.7	6.20	0.005	0.256	C<D C<T D=T	0.013 0.012 1.000	
Forefoot cushioning	-5.7 \pm 21.8	13.2 \pm 13.1	16.0 \pm 14.6	6.30	0.004	0.259	C<D C<T D=T	0.022 0.007 1.000	
Medio-lateral support	-7.8 \pm 17.6	12.5 \pm 15.1	16.1 \pm 15.1	8.17	0.001	0.312	C<D C<T D=T	0.009 0.002 1.000	
Arch Support	-13.1 \pm 19.0	13.8 \pm 18.1	17.4 \pm 16.7	11.16	<0.001	0.383	C<D C<T D=T	0.002 <0.001 1.000	
Heel Cup Fit	-14.5 \pm 19.8	16.9 \pm 17.3	15.1 \pm 22.8	12.45	<0.001	0.409	C<D C<T D=T	<0.001 0.001 1.000	

MANOVA- Multiple Analysis of Variance, η_p^2 Partial Eta Square
Significant difference (*p* <0.05) are presented in bold type