



Article

Development and Effectiveness Testing of a Novel 3D-Printed Multi-Material Orthosis in Nurses with Plantar Foot Pain

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Abstract: Plantar foot pain is one of the most common musculoskeletal conditions affecting the foot. It is regularly experienced by the population with occupations that require prolonged standing hours, especially in nurses. The etiology of plantar foot pain remains unclear, but it is likely to be multi-factorial, with many associated risk factors including increased hours of standing. Orthoses and insoles are often recommended to plantar foot pain patients, however with minimal scientific advancements and limited customizations. In this study, a novel 3D-printed multi-material customized foot orthosis was developed, and its effectiveness on plantar foot pain reduction and functional ability improvement was studied in the nursing population. A total of thirty-six subjects were recruited and were randomized into two groups. The experimental group received the novel 3D-printed multi-material customized foot orthosis, whereas the control group received the standard-of-care (or traditional) intervention. Pre-test and the post-test scores of pains, functional ability and plantar pressure were observed using SPSS software. Improvements were observed in both of the groups; however, better improvements were seen in the experimental group. Overall, the novel 3D printing-based customized foot orthosis showed significant efficacy in reducing plantar foot pain and pressure, and also in increasing functional ability in the nursing population as compared to the traditional method.

Keywords: plantar pain; foot orthosis; 3D printing; custom insoles; nurses



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1. Introduction

Plantar foot pain is a common condition that affects the musculoskeletal system, particularly for the population that requires hours of prolonged standing in their occupations [1]. Several causes that lead to plantar foot pain include prolonged standing hours, bad posture, deteriorated gait cycle, increased weight, increased age, weak musculature, etc. [2]. The normal foot anatomy includes fourteen phalanges, five metatarsals and seven tarsals, where the foot structure is commonly divided into three subcategories, i.e., forefoot, midfoot and hindfoot [3,4]. This structure is generally affected by several musculoskeletal disorders that cause foot pain, such as hallux valgus, metatarsalgia in the forefoot; and plantar fasciitis, Achilles tendinopathy, heel fat pad atrophy, calcaneal stress fractures, tarsal tunnel syndrome, and retrocalcaneal bursitis in the mid- and hindfoot [5]. These disorders may or may not be caused by prolonged standing [1,5]. During clinical diagnosis, plantar foot pain is the most commonly reported sign by the affected population [6–8]. As per the literature [9,10], nurses have comparatively increased hours of standing, and require innumerable physical endurance in their jobs. Due to these reasons, foot pain is found to be one of the most frequent complications faced by the nursing population.

Generally, the occurrence of plantar foot pain is indicated by sharp, burning, shock-like, shooting, radiating and localized, and sometimes dull aching pain [6,11]. These

complications can be managed through conservative management techniques which involve modified shoes, over-the-counter orthoses, customized insoles, rest and steroid injections. Choosing amongst these management options is generally based on several factors such as non-invasiveness, affordability, economical acceptability, ease of use, and comfortability [12]. The use of orthotic insoles manages to comprise all of these features, when compared to other management options. The use of orthotic insoles has shown to be effective, and is the most prescribed option for plantar pain management [13].

Orthotic insoles can either be prefabricated or customized according to the subject's measurements. Pain relief and comfort are achieved through customizing the fit and using materials that are soft and adaptable to the foot [14]. There are a variety of materials and fabrication techniques that can be used to fabricate these customized orthotic insoles. A variety of materials, such as evazote, plastazote, polyurethane, leather and P-lite, can be used in fabrication [15,16]. The fabrication techniques can vary from the traditional techniques to recently popular additive manufacturing. The traditional techniques are mostly based on approximation rather than accuracy. Accuracy and precision can be achieved with the use of additive manufacturing techniques. This production technique allows for point-to-point precision, and for the manufacturer to fabricate insoles using a 3D scan of the subject's foot [17]. The digital scans provide exact measurements, and allow for the creation of a replica of the subject's foot [18,19].

The scope of shock absorption and cushioning is usually limited to the available standard insole materials, which may or may not alleviate foot pain in subjects prescribed with them [20–22]. There is some evidence which suggests that customized orthoses are effective in altering plantar heel pain and functional ability in prolonged standing occupations. However, there are limited findings regarding the effect of these orthoses in nursing populations with plantar foot pain [23–25]. Thus, the purpose of this study was to develop and conduct effectiveness testing of a novel 3D printing-based multi-material customized orthosis for reducing the pain, and improving functional ability in nurses with plantar foot pain.

2. Materials and Methods

2.1. Demographics

This study was conducted on the nursing population employed in the Indian Spinal Injuries Center, Delhi, India. Subject recruitment was based on the inclusion criteria, such as female nurses, subjects who experienced pain for more than 6 months, a pain (VAS (Visual Analog Scale)) score between 3–7, a BMI (Body Mass Index) between 19–25 kg/m², normal range of motion in the hip, knee, and ankle, and subjects having pain during walking. The basis of exclusion for the subjects were subjects with chronic pain more than 8 on the 0–10 VAS, a lower extremity injury in the past 6 months, subjects with a history of hip, knee, or ankle surgery, and those receiving a plantar steroid injection within the previous 3 months. The thirty-six subjects who met the inclusion criteria received an informed consent form, and were recruited after they agreed. The mean and standard deviations of age, height, weight and BMI are shown in Table 1.

The baseline characteristics of all of the subjects were approximately the same in both groups. The subjects were randomly divided into two groups; the experimental group 1 received the 3D printing-based customized insoles, and the control group 2 received the standard-of-care insoles, which are usually prescribed in the hospital (Figure 1). A similar body mass index for both groups was observed, which was calculated by weight in kilograms and height in centimeters.

Table 1. Demographic data of all the recruited subjects.

	Group	Number of Subjects	Mean	Standard Deviation	Standard Error Mean
Age *	1	18	26.66	4.22	0.99
	2	18	26.16	4.24	1.00
Height *	1	18	156.83	10.28	2.42
	2	18	156.33	5.25	1.23
Weight *	1	18	59.00	10.14	2.39
	2	18	58.22	12.99	3.06
BMI *	1	18	21.62	2.28	0.88
	2	18	21.73	1.43	0.23

Note: * Indicates a 95% confidence interval.

**Figure 1.** Standard-of-care insole used in the study.

2.2. Design and Fabrication of Orthosis

Compared to over-the-counter orthoses which consist of fixed geometries to fit the foot arch and other areas, our study included actual foot geometries of the subjects. Firstly, the foot regions of all subjects were scanned using a 3D scanner (3D Systemes, Stone Mountain, SC, USA). The scanned files were exported in STL format (stereolithography format). The artifacts and scanned deformities were smoothened using a mesh editing software, Meshmixer (Autodesk, Mill Valley, CA, USA). Other minor additions such as heel alignment and correction in the arches of the foot were carried out to obtain the corrected foot model. Figure 1 represents the scanned and smoothened model of one of the subjects. The scanned model was then imported to 3D CAD software (SolidWorks 2020, Dassault Systemes, Vélizy-Villacoublay, France). Based on the foot geometries, a negative mold was prepared for casting polyurethane as the hard and flexible base. The mold was 3D-printed using a 3D printer (Creality Ender 3, Shenzhen, China) with polylactic acid (PLA) material. The design of the insole included 4 layers of different materials used for fabrication. The first layer was made of plastazote with a 2 mm dimension; the second layer of evazote had a 5 mm dimension; the third layer was of made of rexine, a layering fabric 1mm in dimension; the most distal or base part comprised the 3D printing-based polyurethane (PU) layer, which was designed subject-specifically using 3D printing. The second layer of evazote had the cut-out for pouring silicone, as per the subject's requirement.

The insoles were fabricated using a combination of both conventional and 3D printing. The fabrication procedure began with scanning and tracing of the subject's foot (Figure 2).

The scan was captured using a 3D scanner (3D systems, USA), and a stereolithography (STL) file was modified using Autodesk Meshmixer software.

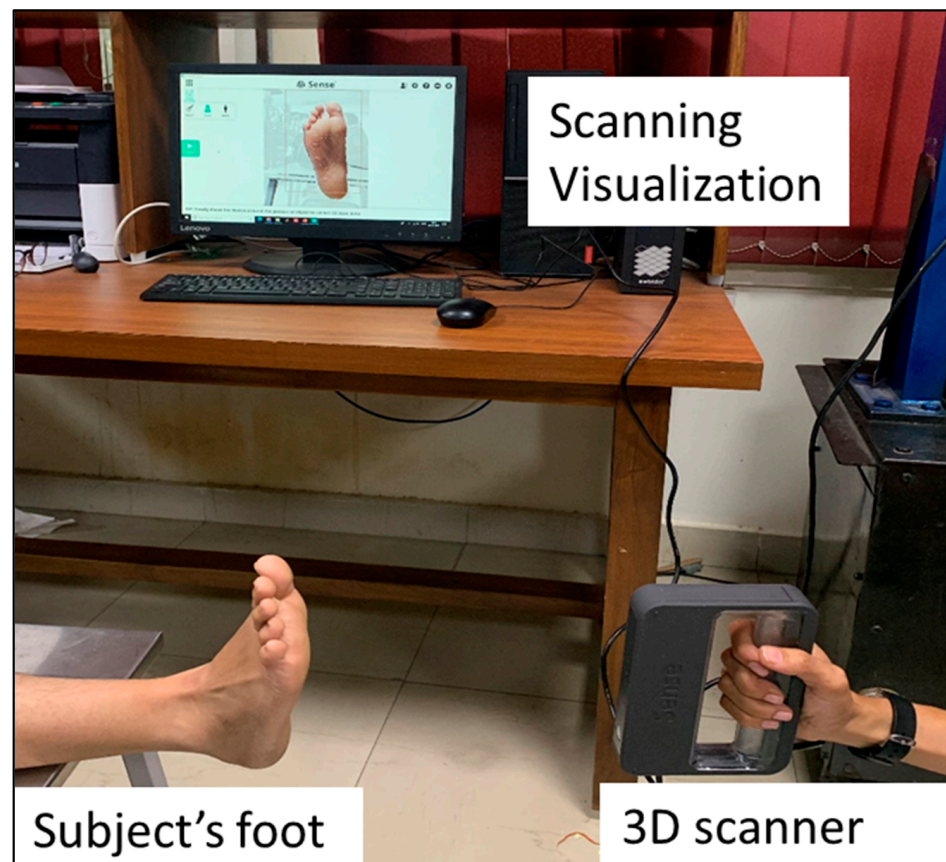


Figure 2. 3D scanning of the subject.

The foot model terminated just below the metatarsals. The STL file was then transformed into a CAD file. It was reversed, and a negative CAD file was obtained using Solidworks software. A 3D-printed solid mold was obtained using PLA (polylactic acid) material with a fused deposition modelling technique (FDM) after 3D printing with a Creality Ender 3 (Shenzhen, China) printer [25]. PU with shore 40A was used as the pouring material in the PLA mold to obtain the base layer. The basis for selecting PU 40 was from its characteristic of rigidity for motion control [26]. The aim to provide the rigid base was to accommodate the deformities and application of the corrections within the foot [27]. The PU material was left for 24 hours to cure, and then it was taken out from the PLA mold.

The trace of the patient's foot was used as a reference for the cutout of three other layers. These layers were fabricated with the prominently used materials in many lower extremity orthotic devices. The materials included evazote, plastazote and rexine [10,28,29]. These cutouts were then grinded for a smoother structure. The plastazote layer was just a simple cut-out as per the trace taken; it was used as the base layer of the evazote layer. The evazote layer was given grinded grooves for pouring the silicone material, due to its extra cushioning and shock absorption properties. The location of the grooves was decided as per the pressure measurements of each patient. The evazote and plastazote layers were then stuck together using adhesive. After the complete adhesive drying process, silicone polymer was poured, and was left to cure for the next 6–8 hours. After the curing process was complete, the last layer of rexine material was applied using adhesive. The uppermost layer consisted of anti-fungal and perspiration absorption properties, thus making it most suitable for the layer that was directly in contact with the skin. The PU layer was then applied to the base of the fabricated insole using adhesive, and was left to dry. The fabricated insole was then grinded and smoothened overall to make it even.

It was made sure that no unevenness was present, as this could exaggerate the pain and discomfort, thereby affecting the subject's functionality. The plantar surface of the foot and the uppermost layer of the fabricated insole had to have an even topology for better adaptation, and to placate the subject's specificity [30] (Figure 3).

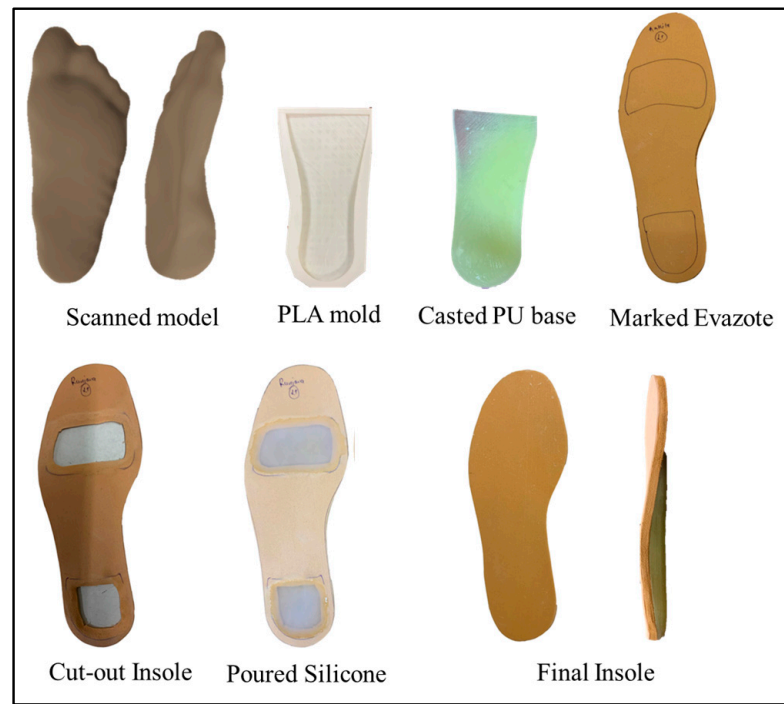


Figure 3. Fabrication procedure of the insole.

2.3. Material Selection

The materials were selected due to their performance and physical properties, as shown in the literature. PU was used as the rigid base layer, with the purpose of motion control, heel alignment and arch support in the foot. Several studies from the literature have shown the use of PU with a shore hardness of 40 to 70A as being effective for foot orthoses [31]. The rationale for selection of evazote and plastazote were for their cushioning effects [29,30]. The patented silicone simulants were implemented into the insole, depending on the requirement for each patient. The location of the silicone groove in the evazote layer was decided based on pain location and pressure distribution in the subject's foot. The shore hardness of the silicone polymer was varied as per the subject's need, and the shore hardness of silicone polymer ranged between 5A to 30A, where the softness decreased with increasing shore hardness. However, the hardness of the silicone polymer with shore 30A was softer when compared to the plantar region of the skin [32].

2.4. Validation

A pressure sensor-based smart insole was used to obtain the pressure values for objective assessment of the 3D-printed insoles. This device was used to calculate the pressure prior to insole application, and after the insole application across the considered groups. The pressure measurements were taken for both standing and walking conditions. The subject was allowed to stand for 60 s, and subjects were asked to walk for 5 min after a break of 5 min (Figure 4). An array consisting of 114 pressure values were extracted from the device every 5 milliseconds.



Figure 4. Subject walking with the smart insole.

2.5. Measures

The subjective and objective data were collected for all of the subjects recruited in the study. For subjective data collection, pain and functional ability were assessed using the visual analog scale (VAS) [33] and foot and ankle ability measure (FAAM) [34] questionnaires, respectively. The VAS questionnaire contains a 10 cm line, where one end demonstrates no pain, and the other extreme end denotes worst pain. The subject must mark the level of pain felt on the line ranging from no pain to worst pain in this questionnaire. The FAAM questionnaire assesses the foot and ankle ability to perform the activities conducted by the subjects. The scale is broadly divided into two sections, where one section has several questions to assess daily activities through the FAAM activities and daily living subscale, whereas the sports activities of the subjects are assessed using the FAAM sports subscale. These questionnaires are widely accepted as the standard measures to quantify the pain and functional ability. The nursing occupation requires long standing hours which affect plantar pressures, and lead to elevations in these pressure values. Therefore, the pressure values were calculated for standing as well as during walking. The objective data were collected using pressure measurements in the plantar foot region while standing and walking.

2.6. Data Analysis

The statistical analysis was performed using SPSS statistics 26.0. An independent *t*-test was used to analyze the results obtained from both of the insole groups. Both of the insoles were compared according to their performance on the VAS and FAAM questionnaires, at p -value < 0.5 . The data were analyzed using SPSS software. Mean and standard deviation were computed for each study variable. An independent *t*-test was used to analyze the post-test data within the insole groups. The hypothesis was tested at a significance level of p -value < 0.5 and confidence interval of 95%.

3. Results

This section deals with the results obtained after the data analysis of the outcome values from the objective and subjective assessments. The following sections discuss each measure with respect to values obtained before the implication of the orthotic intervention, and after the application of the orthotic intervention for four weeks. A thorough follow up was carried out each week to observe the progression of the insoles on plantar pain mitigation. The baseline scores were taken as pre-test and post-test values, for all of the measures. Subjects from each group were assessed for pain, functionality, standing and

walking plantar pressures. These scores were analyzed using SPSS software for the paired sample t-test within group results, which are discussed below.

3.1. Pain

The nursing population requires a lot of physical endurance and muscular strength for standing and running between wards as part of their daily routine. In this study, pain was assessed using the VAS questionnaire, where the subjects marked their pain values from 0 to 10 on the VAS scale. The results were compared between the pre-test and post-test data of both groups, with and without the 3D-printed foot orthosis. The pretest pain scores were 3.94 ± 1.76 , and the post-test scores were 1.22 ± 0.87 in the experimental group, representing a reduction of approximately 69% in the pain level scores [35,36] in subjects using the 3D-printed insoles. The pain scores for group 2, i.e., the control group with the standard-of-care insole, were also assessed at the same confidence interval and *p*-value. The pre-test score obtained was 4.16 ± 1.91 , and the post-test score was 2.66 ± 1.78 , representing an approximately 36% reduction. The comparison of pre-test and post-test data for the experimental and control group is shown in Figure 5.

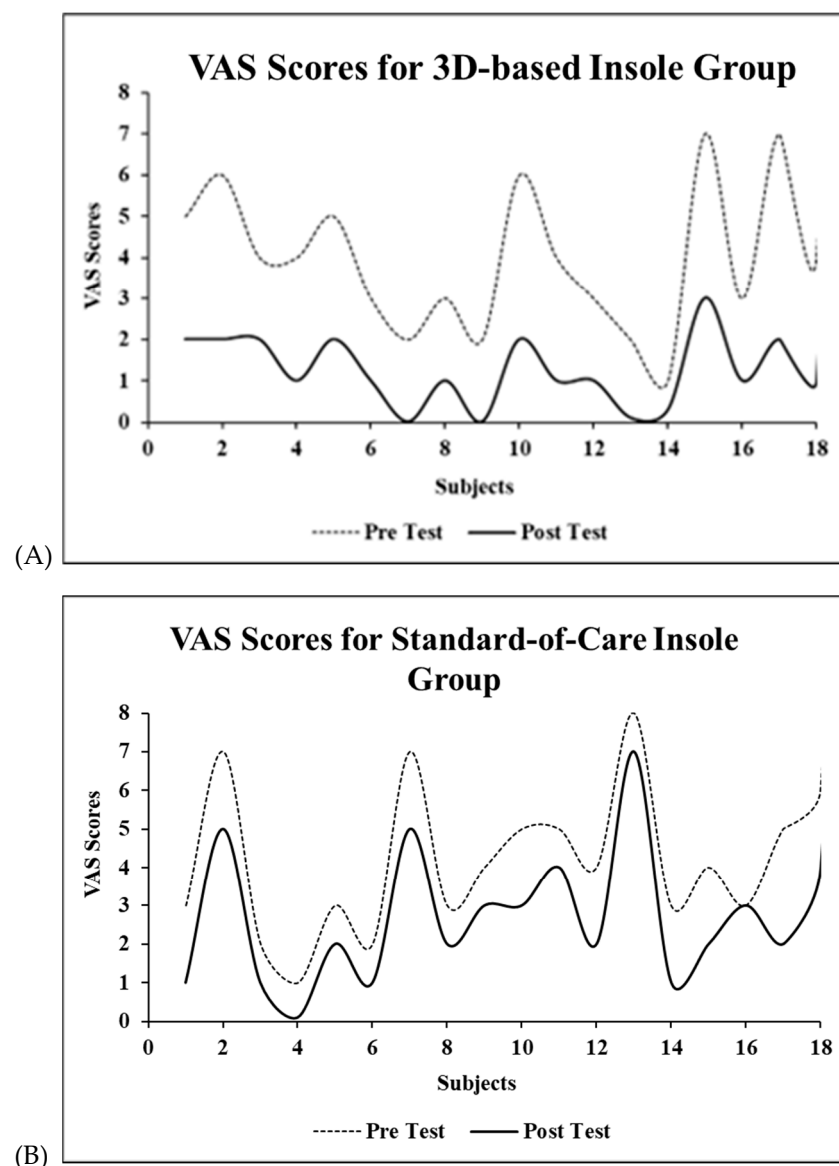


Figure 5. Pre-test and post-test values of VAS for pain in groups wearing (A) 3D printing-based customized and (B) standard-of-care insoles.

The post-test values of both groups were compared using the paired sample *t*-test with SPSS. This comparison could provide better evidence regarding the efficacy of the 3D printing-based customized insole group. The paired *t*-test result demonstrated that the reduction in the pain scores of 3D printing-based group 1 was 2.72 ± 1.01 , whereas in standard-of-care insole group 2, the reduction was just 1.50 ± 0.70 . These results demonstrate the better effectiveness of the 3D printing-based multi-material customized insole, as a greater reduction in pain scores was observed. This pain score reduction is possibly due to customization of the 3D-printed insole. The rectified pain areas of each patient were provided with soft silicone cushioning for pressure reduction and shock absorption. Since all of the pain areas were cushioned for shock absorption, therefore a reduction in the pain scores was observed (Figure 5) in the 3D printing-based insole group.

3.2. Functionality

Prolonged standing hours are known to affect the functionality of the nurses, affecting their activities of daily living. The FAAM questionnaire was used to assess the functional ability of the subjects of the experimental group prescribed with the 3D-printing-based customized insole. The pre-test score obtained was 55.80 ± 20.84 , and the post-test value was 76.19 ± 14.46 , representing an increase of approximately 37% in the functional level scores [35,36]. The same functional assessment was conducted in the control group, i.e., group 2 with standard-of-care insole. The pre-test value obtained was 54.88 ± 20.12 , and the post-test value was 66.11 ± 17 , representing an approximately 20% increase. The scores obtained are described in graphical form in Figure 6.

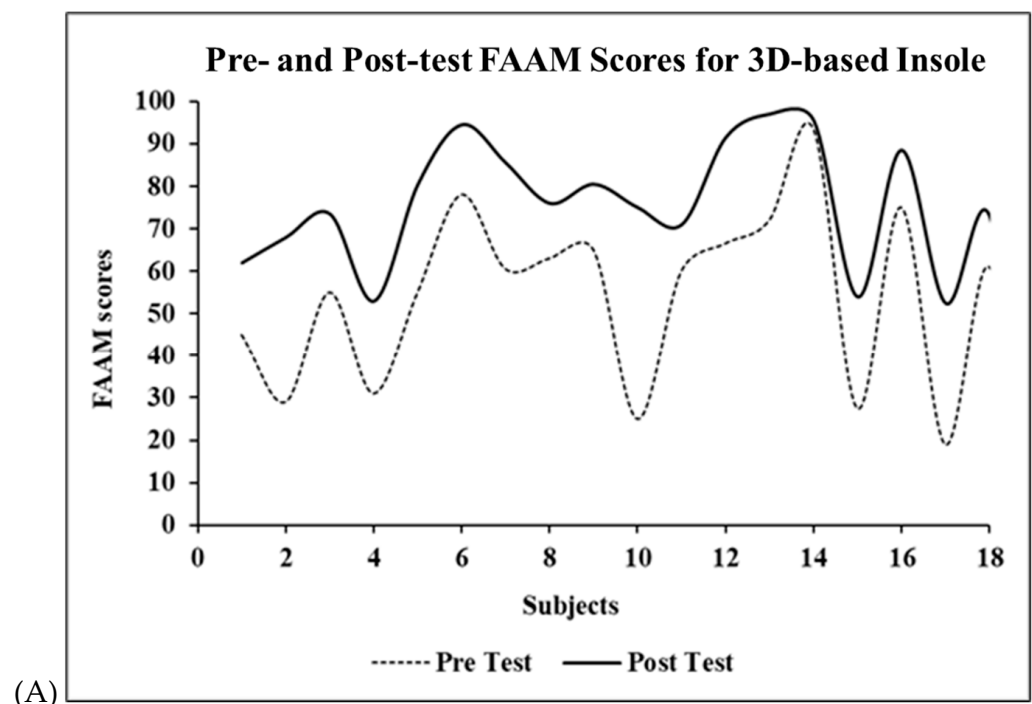


Figure 6. Cont.

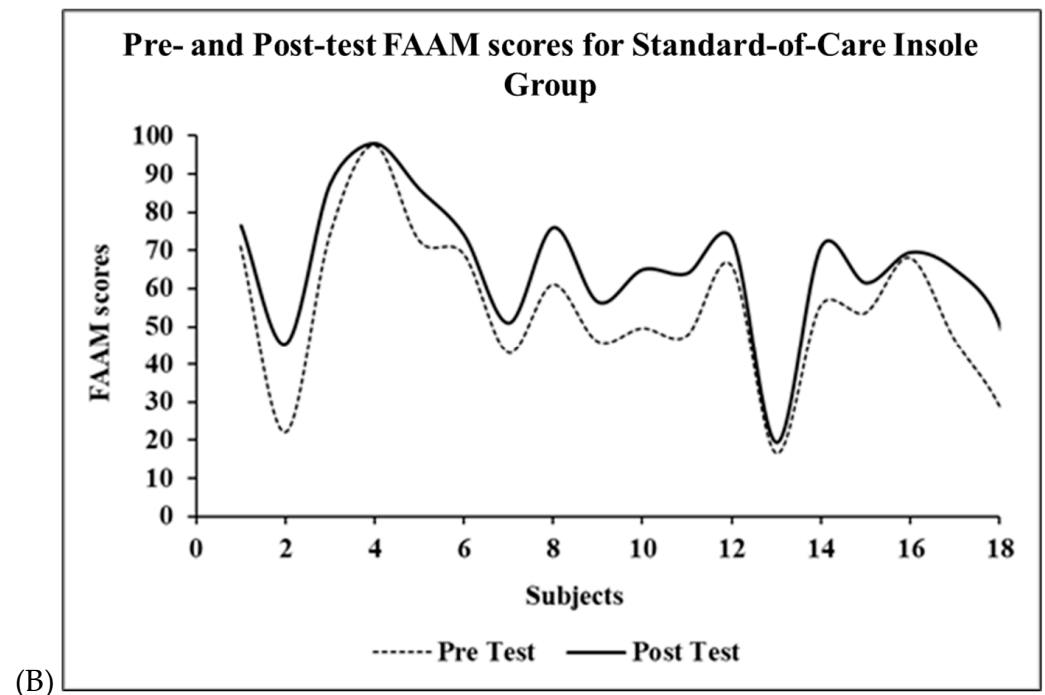


Figure 6. Pre-test and post-test functionality scores of subjects wearing (A) 3D-printing-based customized and (B) standard-of-care insoles.

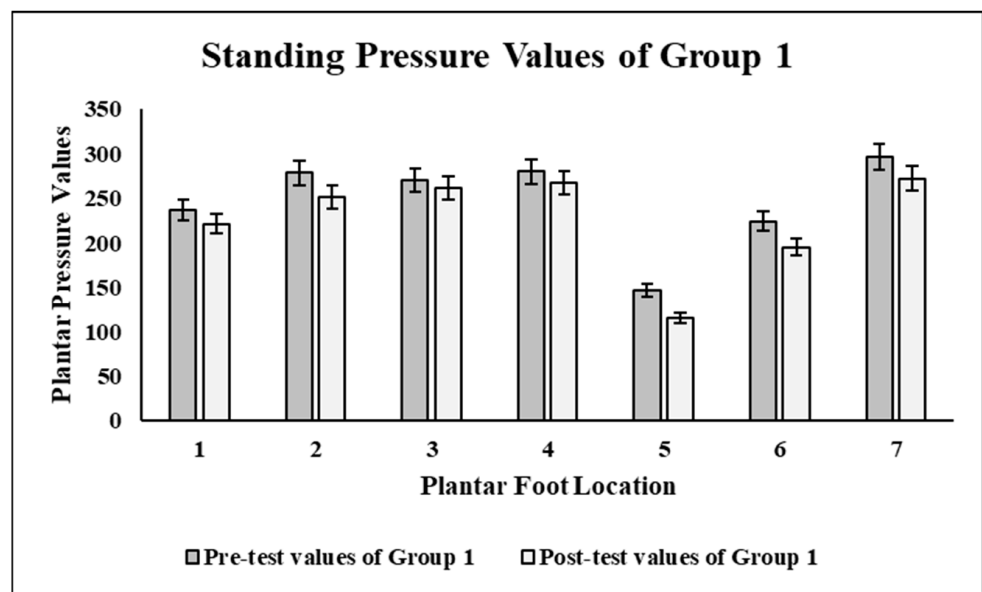
The post-test values of functional ability for both groups were compared using the paired sample *t*-test with SPSS. The comparative post-test functional ability could provide better evidence of the efficacy regarding the 3D-printing-based customized insole group. The paired *t*-test result demonstrated that the improvements in the functional scores of groups 1 was 21.69 ± 11.23 , whereas in group 2 it was 11.22 ± 6.80 . This result demonstrated the prominence of the 3D-printing-based customized insole, as a greater improvement in functional ability scores was observed.

3.3. Plantar Pressure

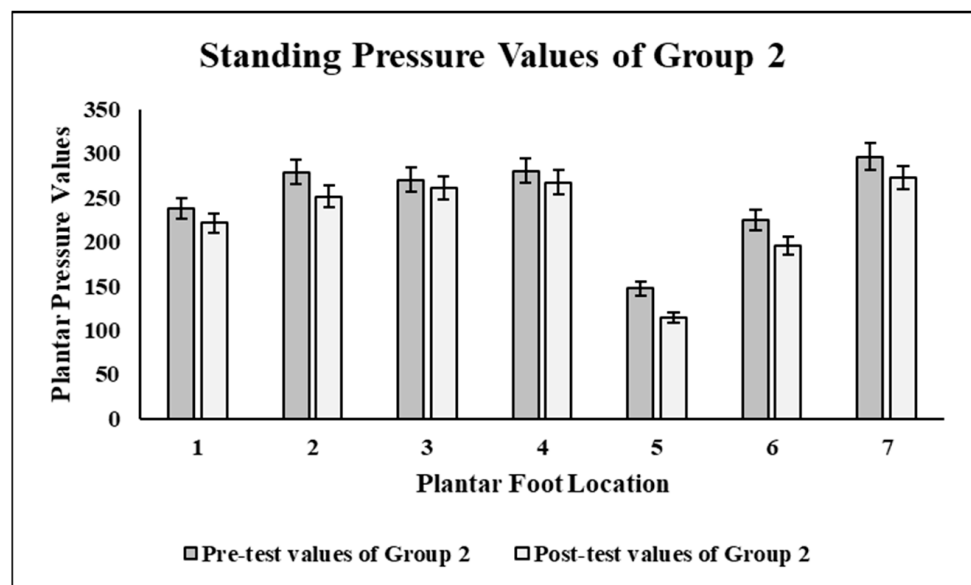
Plantar pressure was observed throughout the plantar areas of the foot. The pressure values were obtained for seven different locations in the plantar region of the foot, i.e., hallux, first metatarsal, third metatarsal, fifth metatarsal, medial midfoot, lateral midfoot and heel.

3.3.1. Standing

The mean pre-test plantar pressure values for standing in group 1 at the aforementioned locations were 238.16 kPa, 278.61 kPa, 273.55 kPa, 282.55 kPa, 143.66 kPa, 222.83 kPa and 293.83 kPa, respectively (Figure 7A). The post-test means values obtained after application of the insole for four weeks were 197.61 kPa, 222.44 kPa, 222.22 kPa, 226.55 kPa, 98.94 kPa, 137.72 kPa and 237 kPa, respectively. The pressure values for group 2 are demonstrated in Figure 7B. The mean pre-test plantar pressure values at the same seven locations were 237.38 kPa, 278.94 kPa, 270.22 kPa, 280.22 kPa, 147.05 kPa, 224.50 kPa and 296.38 kPa, respectively. The mean post-test pressure values were 221.55 kPa, 251.50 kPa, 261.50 kPa, 267.44 kPa, 115.00 kPa, 195.33 kPa and 272.50 kPa, respectively. Both the pre-test and post-test values are shown in Figure 7.



(A)



(B)

Figure 7. Pressure values taken in standing position in 3D-printing-based group 1 (A) and standard-of-care insole group 2 (B) at seven different locations in the plantar region, 1: hallux, 2: first metatarsal, 3: third metatarsal, 4: fifth metatarsal, 5: medial mid-foot, 6: lateral mid-foot and 7: heel, for (A) experimental group and (B) control group.

The distribution of the standing plantar pressure is represented in Figure 8 for both the experimental as well as the control group. In the case of the experimental group, the peak values ranged from 98.94 to 237 kPa, whereas in the control group, the peak values ranged from 115.00 to 272.50 kPa.

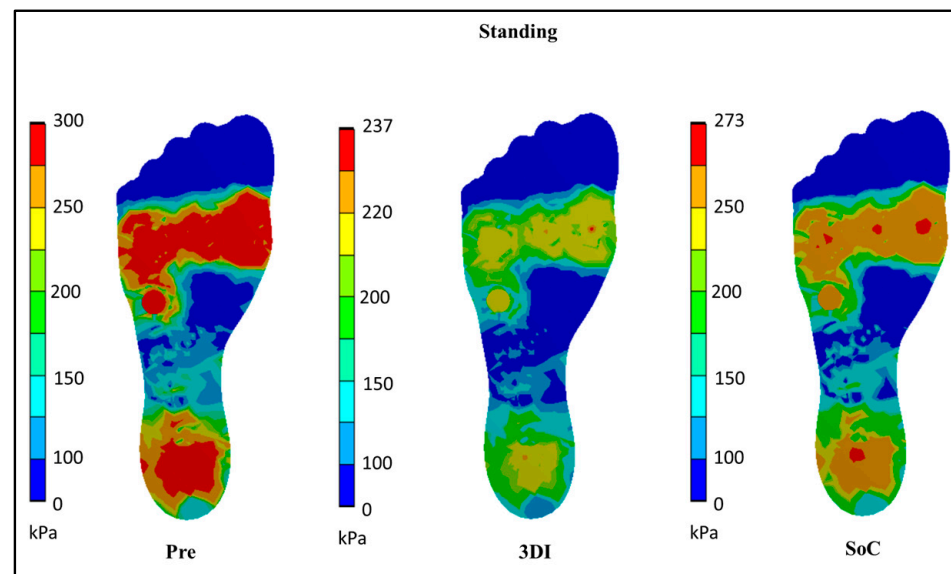
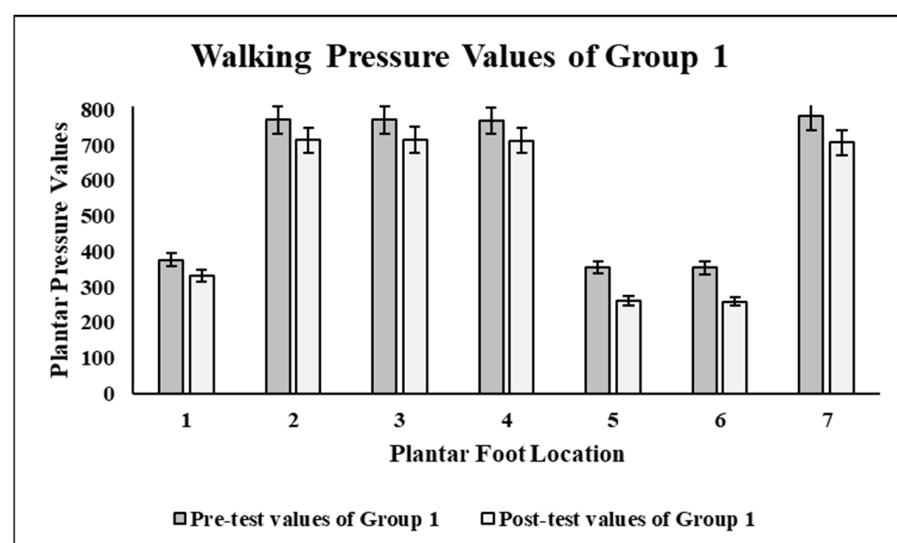


Figure 8. Standing plantar pressure distributions across the experimental (3DI) and control (SoC) groups.

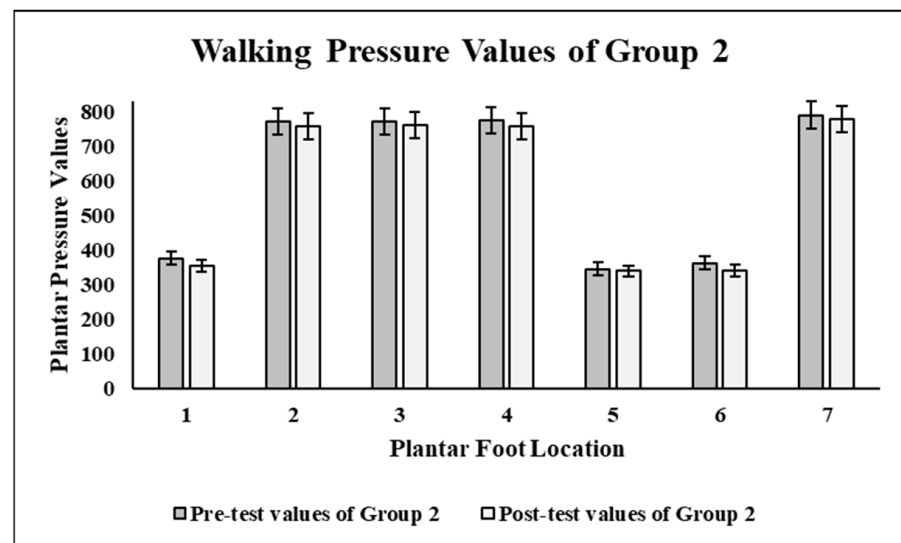
3.3.2. Walking

The pressure values were taken in the walking phase as well. The mean pre-test values for walking with the application of the 3D printing-based insole obtained were 376.33 kPa, 770.61 kPa, 770.38 kPa, 768.38 kPa, 354.88 kPa, 354.50 kPa and 782.05 kPa at the hallux, first metatarsal, third metatarsal, fifth metatarsal, medial mid-foot, lateral mid-foot and heel, respectively. The post-test values obtained for the same group were 332.55 kPa, 714.38 kPa, 714.66 kPa, 712.05 kPa, 260.94 kPa, 259.33 kPa and 707.66 kPa, respectively. The walking pressures for group 2 were also assessed, and the mean pre-test values obtained were 374.72 kPa, 769.50 kPa, 770.33 kPa, 773.55, 345.16, 362.38 and 788.05, respectively. The post-test values obtained were 354.94, 757.94, 758.50, 757.00, 338.44, 339.11 and 776.66 kPa, respectively. Both sets of values obtained were tested using the paired sample *t*-test at 95% confidence interval. The values are demonstrated in Figure 9.



(A)

Figure 9. Cont.



(B)

Figure 9. Pressure values taken in the walking position in 3D-printing-based group 1 (A) and standard-of-care insole group 2 (B) at seven different locations in the plantar region, 1: hallux, 2: first metatarsal, 3: third metatarsal, 4: fifth metatarsal, 5: medial mid-foot, 6: lateral mid-foot and 7: heel.

The distributions of the walking plantar pressure are represented in Figure 10 for both the experimental as well as the control group. In the case of the experimental group, the peak values ranged from 259.33 to 714.66 kPa, whereas in the control group the values ranged from 338.44 to 776.66 kPa. Better improvements in the plantar pressures could be observed in the post-test scores of standing and walking plantar pressures in the 3D-printing-based customized insole group. The figures demonstrating the plantar pressure distribution also show evidence of these improvements.

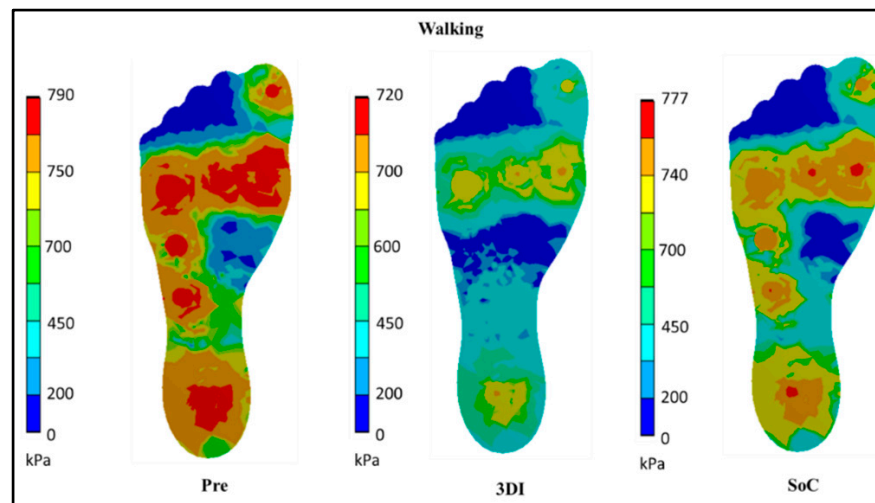


Figure 10. Walking plantar pressure distributions across the experimental (3DI) and control (SoC) groups.

4. Discussion

The current study demonstrated the fabrication of a 3D-printed customized orthosis for subjects with plantar foot pain. The target population chosen was subjects with an occupation of long-standing and walking hours, specifically the nursing population. The experimental group was compared with a control group that was prescribed a traditional standard-of-care insole. The foot of the subjects was scanned using a 3D scanner, and

using 3D printing and other manufacturing techniques, a novel multi-material customized insole was developed. The insole was prescribed to the subjects for an intervention period of four weeks. The data of the groups were assessed using SPSS based on the values obtained using certain measures for the pain, functionality and pressure in the plantar region of the foot. The developed customized orthoses were found to be more effective in alleviating the plantar pain amongst nurses as compared to the standard treatment which were earlier provided.

The results demonstrated the efficacy of both insoles in the experimental and the control groups. However, the differences in all the measures, pain using VAS, functional ability using FAAM, and pressures using a validation device with pressure sensors, were higher in the experimental group when compared to the control group. While the pre-test values of both groups seemed to be similar, when the post-test values were compared, a more significant improvement was seen in the 3D-printing-based customized insole group. Peak foot pressures were found to correlate and provide an objective measure of pain. The VAS and FAAM values shown in this study represented a significant difference between the groups, with and without the 3D-printed foot orthosis, and greater improvement in functional ability of the 3D-printed insole group. These differences in scores could be considered significant, and in line with literature studies reporting similar significant differences [35,36].

The maximum pain and pressures were observed in the heel and the metatarsal regions. This may be possible evidence of the fact that the maximum weight is borne on these two plantar regions prominently. The physical properties of shock absorption and cushioning offered by the silicone material were tuned to maximize cushioning in these regions. The reduction in pain and pressure improved the functional activity of the subjects, hence improving their work performance. The subjects reported that they were able to improve their work productivity after wearing the customized insoles, thereby confirming the efficacy of the 3D-printing-based customized insoles.

A few limitations of this study should be reported. Although the developed insole was found to produce significant reduction in plantar pain, increased thickness led to the replacement of the already pasted insoles which came with the footwear. Finding ways of minimizing the thickness of the insoles while providing the same amount of cushioning will be beneficial for future studies. Secondly, the population size was moderate; for further testing, a larger sample size needs to be recruited.

5. Conclusions

This study found that the novel 3D-printing-based multi-material customized insole could be a better possible line of conservative management for subjects with plantar foot pain. The efficacy of the insole was tested by prescribing it to a nursing population, and observing its effect on an occupation with maximum standing hours. The results showed significant reductions in the pain and pressure scores; moreover, there was an increased functional level in all of the subjects. Therefore, it can be concluded that these novel insoles can help subjects with prolonged standing occupations to improve their job performance. Further testing of this insole on individuals with other standing occupations such as teachers, guards, etc., is anticipated to help better understand the improvements required for commercialization.

Author Contributions: K.C.: methodology, validation, investigation, formal analysis, writing—original draft and writing—review and editing. S.S.S.: methodology, investigation, formal analysis. S.G.: methodology, data curation, formal analysis and investigation. S.S.: data curation, investigation and formal analysis. C.K.: data curation, investigation and formal analysis. A.C.: conceptualization, methodology, formal analysis, supervision, and writing—review and editing. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by Ethical Committee of Indian Spinal Injuries Centre, New Delhi (protocol code New Delhi ISIC/RP/2022/023 and date of approval was 13 July 2022).

Informed Consent Statement: The subject provided a signed consent form before the study was conducted.

Data Availability Statement: The datasets generated during and/or analyzed during the current study are not publicly available, due to being large datasets; however, data are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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