Immediate Effect of Customized Foot Orthosis on Plantar Pressure and Contact Area in Patients with Symptomatic Hallux Valgus

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Abstract: Foot orthotics are recommended for the treatment of hallux valgus. The effects of customized foot orthoses (FOs) designed with both medial longitudinal and transverse arch supports are poorly understood, however. This study aimed to investigate the immediate effect of customized FOs on the plantar pressure and contact area in patients with symptomatic hallux valgus.

We recruited 18 patients with a mean hallux valgus angle of 27.3 ± 11.1°. Plantar pressure while walking with FOs or flat insoles (FIs) was monitored with a wireless in-shoe plantar pressure-sensing system. Peak pressure (PP), peak force (PF), pressure-time integral (PTI), force-time integral (FTI), and contact area with FOs and FIs were compared. The PF, PTI, and FTI of the midfoot were significantly higher (p < 0.05), and the PP and PTI of the rearfoot were significantly lower (p < 0.05) with the FOs than the FIs. The FOs significantly increased the contact area of the midfoot and rearfoot (p < 0.05) and reduced the contact area of the forefoot (p < 0.05). These results suggest that customized FOs redistribute plantar pressure and the contact area of the midfoot and rearfoot, improving the functional support of the midfoot for patients with hallux valgus.

Keywords: hallux valgus; customized foot orthotic; insole; plantar pressure

1. Introduction

Hallux valgus occurs when the proximal phalanx deviates laterally and the first metatarsal head deviates medially, and it is associated with a widened forefoot [1]. Plantar pressure parameters can be used to detect abnormal foot lesions or lower extremity problems [2,3]. Hida et al. [4] have reported that the peak force, contact time, contact area, and force-time integral of the hallux during walking in patients with hallux valgus are all lower than in those without, indicating that the function of the hallux during walking is inhibited in patients with hallux valgus. In addition, peak pressure and peak force in the second metatarsal area of patients with hallux valgus are greater, leading to increased load on the forefoot and possibly producing metatarsalgia [4,5].

Customized total contact insoles are used to increase the contact area and support of the foot arch [6]. The plantar pressure in the hallux and forefoot areas is significantly reduced, and the plantar contact area is maximized to disperse plantar pressure [7]. Total contact insoles can reduce the valgus of the rearfoot and the peak pressure on the toes, lateral metatarsals, lateral foot, and heel [8] and increase the peak pressure on the midfoot and the peak force under the medial forefoot and hallux [9]. In patients with foot pain, customized insoles can move the peak pressure from metatarsal heads II to V and the
The material used to construct insoles influences their effectiveness. Softer material can more effectively absorb the impact of walking, whereas harder material provides faster ground reaction force feedback and greater support [17]. Previous insole studies have mainly described the production principles and materials of the insoles used in the experimental groups but not of those in the control groups [5,9,18]. However, in examining the effects of insoles, using the same material compositions and designs in the control and experimental groups reduces variable factors and is thus beneficial [19]. Accordingly, the present study investigated the immediate effect of customized foot orthoses (FO) designed with both medial longitudinal and transverse arch supports on the plantar pressure and contact area in patients with symptomatic hallux valgus.

2. Materials and Methods

2.1. Participants

A total of 18 participants were recruited from the outpatient and inpatient clinics of a medical center in Taipei, Taiwan. The inclusion criteria were (1) age of ≥20 years and (2) mild-to-moderate hallux valgus (HVA: 15 to 40°) [20] with metatarsalgia. Patients with neurological diseases (e.g., stroke or Parkinson’s disease), diabetic peripheral neuropathy, leg-length discrepancy following lower limb fracture or joint replacement, osteoporotic vertebral compression fractures, or other lower limb joint deformity or pain impeding study participation were excluded. The study protocol was approved by the Institutional Review Board of Taipei Veterans General Hospital. All participants provided written informed consent prior to participating.

2.2. Procedure

Each patient’s HVAs, defined as the angle between the first metatarsal and proximal phalangeal axes, were measured using a goniometer in a non-weight-bearing sitting position [14] by the same physical therapist with 6 years of experience. Pain was measured by the Taiwanese version of the Brief Pain Inventory (BPI) [21,22]. The 4-item intensity scale assesses the worst, least, average, and current pain intensity, and the 7-item interference scale...
assesses the interference of pain in 7 life domains (general activity, mood, walking ability, normal work, relations with others, sleep, and enjoyment of life) on a 0 to 10 rating scale.

Plantar pressure was monitored with the F-Scan System® (Tekscan, Boston, MA, USA) at a sampling rate of 60 Hz. The F-Scan 3000E sensor comprised of 960 sensing elements was placed on top of the tested insole. Validity and repeatability of the F-Scan System® was generally acceptable [23]. The test–retest reliability was dependent on the measure and region of the foot; the forefoot and toes regions displayed good to high reliability for all plantar pressure variables, and that contact area had high reliability for all regions of the foot [24].

The participants wore the same shoes (ARWR92280, Arnor, Taipei, Taiwan) and socks and were instructed to walk at a self-selected comfortable pace along a 7 m gait way under 2 testing conditions, implemented in random order: (1) walking with FOs and (2) walking with flat insoles (FIs); a 5-min rest period between the FOs and FIs testing conditions was provided. For each testing condition, five consecutive walking trials were collected. The first and last strides were excluded, and the rest of the strides were analyzed for each trial. The plantar pressure parameters of the foot with the larger HVA were analyzed. For feet with equal HVAs, the data from the dominant leg were selected. The dominant leg was determined in relation to the foot normally used to kick a ball [25]. Eighteen participants with a total of 18 feet were selected for subsequent analyses.

2.3. Insoles

The customized FOs were fabricated by a prosthetist with 19 years of experience at the Rehabilitation and Technical Aid Center of Taipei Veterans General Hospital. A mold of the foot was produced from a foam-box foot impression taken in a non-weight-bearing sitting position with 90-degree knee flexion and the subtalar joint in a neutral position, and without pushing downward on the feet. The negative foam mold was filled with liquid plaster to obtain a positive mold, on which the transverse arch, medial longitudinal arch, and lateral longitudinal arch were contoured to fabricate the insole (Figure 1).

![Positive foot mold for making customized foot orthosis.](image1.png)

The positive plaster cast was placed into a vacuum. The FOs used in this study (Figure 2) comprised 3 layers: a full-length 2 mm-thick medium EVA shell (heated to 100 °C for 20 s), full-length 1.55 to 1.65 mm Relion G-18 rigid polyester (heated to 100 °C for 3 min) layer, and two-thirds-length 1.1 to 1.2 mm Relion G-12 rigid polyester (heated to 100 °C for 1 min) layer shaped to mirror the contours of the foot. The advantages of our FOs are as follows: (1) simple and rapid construction (about 4-h manufacturing process); (2) thin and light design (3 mm thickness at the forefoot and 5 mm thickness at the rearfoot; 54 to 79 g
weight; (3) elastic material with mechanical properties providing arch support and impact absorption during walking; and (4) transverse arch support reinforced by a third layer of polyester fabric (about 5 to 7 mm height) [26,27].

![Positive foot mold for making customized foot orthosis.](image1.jpg)

**Figure 1.** Positive foot mold for making customized foot orthosis.

![Example of customized foot orthosis used in the study.](image2.jpg)

**Figure 2.** Example of customized foot orthosis used in the study.

The FIs used in this study (Figure 3) also comprised 3 layers and were made of the same materials as the FOs but had no arch supports.

![Example of flat insole used in the study.](image3.jpg)

**Figure 3.** Example of flat insole used in the study.

2.4. Data Processing

Tekscan software (Tekscan Inc., Boston, MA, USA) was used to analyze the peak pressure, peak force, pressure-time integral, force-time integral, and contact area of the
toes, forefoot, midfoot, and heel. The foot was divided into 12 regions: the hallux (T1), the second through fifth toes (T2, T3, and T45), metatarsals I to V (M1–M5), the midfoot (MF), the medial heel (MH), and the lateral heel (LH; Figure 4).

![Figure 4](image)

**Figure 4.** Foot divided into 12 regions for analysis of plantar pressure parameters: big toe (T1), second through fifth toes (T2, T3 and T45), metatarsals I–V (M1–M5), midfoot (MF), medial heel (MH), and lateral heel (LH).

### 2.5. Statistical Analysis

Statistical analysis was performed using SPSS 18.0 (SPSS, Chicago, IL, USA). The Wilcoxon signed-rank test was employed for comparison of outcome variables of interest between the FO and FI conditions. Statistical significance was set to $\alpha = 0.05$. Effect sizes (ESs) for nonparametric data were calculated with the formula $r = Z/\sqrt{n}$ and classified as small ($r = 0.1$), medium ($r = 0.3$), or large ($r = 0.5$) [28].

### 3. Results

In total, 16 women and 2 men (age, $53.4 \pm 16.4$ years; height, $159.9 \pm 7.8$ cm; weight, $57.8 \pm 10.8$ kg) participated in the study. The mean HVA was $27.3 \pm 11.1^\circ$. Scores for the BPI intensity subscale ranged from $1.11 \pm 1.49$ for the least-pain item to $4.67 \pm 2.40$ for the worst-pain item. The average pain and now pain were $3.56 \pm 2.12$ and $2.44 \pm 2.18$, respectively. For the BPI interference subscale, the most affected domains were walking ability ($3.61 \pm 3.27$) and normal work ($3.28 \pm 3.29$); the least affected domain was sleep ($1.11 \pm 1.75$).

The peak force, pressure-time integral, and force-time integral of the MF were substantially higher with the FOs than with the FIs (Figure 5). The FOs also increased the peak pressure of the MF, with a medium ES. The peak pressure and pressure-time integral of the rearfoot (MH and LH) were substantially lower with the FOs than with the FIs (Figure 6). The FOs also reduced the peak force and force-time integral of the heel, with small-to-medium ESs. Regarding the forefoot (i.e., M2 and M3), the FOs reduced the force-time integral, with a medium ES. The peak pressure of the toes was greater with the FOs than with the FIs, with small-to-medium ESs. FOs significantly increased the contact area of the MF (Figure 5) and heel (Figure 7), the contact area of the forefoot decreased, with a medium ES, and reached statistical significance for M2 and M3. The detailed plantar pressure and contact area data are summarized in the Appendix A.
Figure 5. Plantar pressure and contact area of midfoot (MF) with customized foot orthosis (FO) or flat insoles (FI). * p < 0.05.

Figure 6. Plantar pressure of medial heel (MH) and lateral heel (LH) with customized foot orthosis (FO) or flat insoles (FI). * p < 0.05.

Figure 7. Contact area of heel with customized foot orthosis (FO) or flat insoles (FI). * p < 0.05.
4. Discussion

This study investigated the immediate effect of a customized FO designed with both medial longitudinal and transverse arch supports on the plantar pressure in patients with symptomatic hallux valgus. The results indicate that FOs significantly redistribute plantar pressure and contact area and enhance the functional support of the MF.

A large population-based cohort study on hallux valgus and plantar pressure during gait reported lower center of pressure excursion indices and center of pressure excursion to foot width ratios in patients with hallux valgus [29]. Another study observed changes in plantar pressure in young female patients with hallux valgus during walking and found a decrease in lateral pressure, suggesting a tendency toward foot pronation [30]. Research sharing the purpose of the current study—to increase contact area and arch support to improve load distribution at the MF—has demonstrated that 3D-printed customized insoles may reduce the pressure on the metatarsals of patients with flatfoot [18,31].

The peak force, press-time integral, and force-time integral of the MF increased considerably when the patients walked with the FO. These results are in agreement with previous findings indicating that an arch support insole can shift the load from the forefoot and rearfoot toward the MF [5,32–34]. In the current study, we discovered that the force-time integral of the MF increased by 165% with the FO, a result consistent with another demonstrating a 144% increase in the force-time integral of the MF with customized insoles with medial arch support for patients with diabetes mellitus and associated neuropathic pain and foot deformities (including hallux valgus) [35].

Insoles with medial arch support can be used as an effective intervention to correct excessively high pressure in the forefoot area. Another study observed that customized insoles significantly reduced the peak pressure and pressure-time integral of the middle and lateral forefoot regions after 1 month of use [36]. The plantar pressure under the forefoot (metatarsal) area, however, exhibited no significant differences between the FO and FI conditions in the current study. This result may be due to the minor differences between the FI and FO; in the present study, the FI was composed of the same materials and 3 layers as the FO. The third layer was two-thirds length (around the transverse arch). This probably enhanced the support of the transverse arch by increasing the arch height [37].

In the current study, the peak pressure and pressure-time integral of the rearfoot (MH and LH) were substantially reduced when the patients wore FOs. Similarly, a study discovered that wearing customized insoles resulted in a considerable reduction in the peak pressure of the rearfoot, both immediately and at 1 month follow-up, in patients with hallux valgus [36]. Arch support insoles can also considerably reduce the average pressure and peak pressure of the rearfoot in patients with flatfoot [31,32]. Studies have demonstrated that HVA is positively correlated with the pressure under the LH, and patients with hallux valgus exhibit greater pressure under the LH while walking than those without [30,38]; therefore, redistributing plantar pressure and reducing the pressure under the rearfoot may be crucial in hallux valgus interventions.

Regarding the plantar contact area, significant increases of 42.5% in the MF and 18.0% in the rearfoot were observed. Medial arch support orthotics can increase the plantar contact area of the MF and transfer forefoot pressure to the MF in patients with hallux valgus [4], but hallux valgus orthotics (braces) failed to more effectively distribute plantar pressure by increasing total contact area [39]. Furthermore, arch support insoles for flatfoot can increase the contact area of the MF [9,18] and provide support for the medial arch, resulting in a more evenly distributed contact area of the MF, which may help absorb shocks during walking [40]. Thus, the use of arch support insoles appears to be an effective intervention for hallux valgus. Although the current study discovered that the contact area of the second and third metatarsals decreased by 6.5% and 8.3%, respectively, with the FOs, no differences in the peak pressure, peak force, pressure-time integral, or force-time integral of the forefoot were observed.

The current study has several limitations. First, our participants included only patients seeking medical care for their foot ailments. The sample size was small due to the
coronavirus (COVID-19) pandemic. Second, the immediate effects of customized insoles on pain were not measured. It was speculated that redistributing plantar pressure would reduce foot pain. Third, we did not conduct follow-up measurements. The short-term and long-term effects of both medial and transverse arch supports on plantar pressure and contact area may differ after prolonged wear. Moreover, the actual ascertainment of pain can enable clinical practices. Fourth, the inclusion criteria did not account for the potential presence of different foot types (e.g., the normal, planus, and cavus foot). Although the findings of this study improve the clinical knowledge of the effects of medial longitudinal and transverse arch support orthotics on plantar pressure distribution in hallux valgus, future studies with a larger sample size are warranted to determine the optimal clinical practice.

5. Conclusions

Customized foot orthoses designed with both medial longitudinal and transverse arch supports redistribute the plantar pressure and contact area of the midfoot and rearfoot and improve the functional support of the midfoot in patients with hallux valgus.


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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Taipei Veterans General Hospital (Approval Number 2020-02-005C and date of approval 27 February 2020).

Informed Consent Statement: Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding authors on reasonable request.

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

Table A1. Plantar Pressure data.

<table>
<thead>
<tr>
<th></th>
<th>FO</th>
<th>FI</th>
<th>FO</th>
<th>FI</th>
<th>FO</th>
<th>FI</th>
<th>FO</th>
<th>FI</th>
<th>FO</th>
<th>FI</th>
<th>FO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Pressure (KPa)</td>
<td>291.52 ± 175.64</td>
<td>280.79 ± 182.38</td>
<td>14.61 ± 10.04</td>
<td>13.59 ± 9.82</td>
<td>30.48 ± 16.11</td>
<td>28.86 ± 14.84</td>
<td>2.32 ± 1.57</td>
<td>2.15 ± 1.49</td>
<td>5.05 ± 2.41</td>
<td>5.19 ± 2.38</td>
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<tr>
<td>Peak Force (%BW)</td>
<td>156.57 ± 83.11</td>
<td>137.23 ± 62.08</td>
<td>5.09 ± 3.09</td>
<td>4.6 ± 2.92</td>
<td>18.74 ± 6.74</td>
<td>18.71 ± 7.44</td>
<td>0.71 ± 0.42</td>
<td>0.67 ± 0.45</td>
<td>2.95 ± 1.41</td>
<td>2.86 ± 1.11</td>
<td></td>
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<tr>
<td>Plantar Pressure-Time Integral (Kpa*s)</td>
<td>137.33 ± 57.35</td>
<td>143.02 ± 84.86</td>
<td>3.89 ± 1.86</td>
<td>4.38 ± 2.77</td>
<td>16.7 ± 6.62</td>
<td>18.45 ± 10.45</td>
<td>0.57 ± 0.27</td>
<td>0.62 ± 0.45</td>
<td>2.63 ± 1.21</td>
<td>2.86 ± 0.87</td>
<td></td>
</tr>
<tr>
<td>Force-Time Integral (%BW*s)</td>
<td>115.36 ± 76.04</td>
<td>96.06 ± 42.98</td>
<td>3.09 ± 2.44</td>
<td>2.83 ± 2.04</td>
<td>13.71 ± 6.54</td>
<td>13.35 ± 6.73</td>
<td>0.46 ± 0.36</td>
<td>0.43 ± 0.36</td>
<td>2.39 ± 1.37</td>
<td>2.26 ± 1.36</td>
<td></td>
</tr>
<tr>
<td>Contact Area (cm²)</td>
<td>294.81 ± 190.29</td>
<td>294.93 ± 189.12</td>
<td>22.45 ± 11.6</td>
<td>23.03 ± 12.08</td>
<td>36.45 ± 23.73</td>
<td>35.03 ± 18.55</td>
<td>4.27 ± 2.37</td>
<td>4.51 ± 2.51</td>
<td>8.96 ± 2.38</td>
<td>9.46 ± 2.22</td>
<td></td>
</tr>
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</table>

FO = customized foot orthosis, FI = flat insole, T1 = big toe, T2 = second toe, T3 = third toe, T45 = fourth and fifth toes, M1–M5 = metatarsals I–V, MH = medial heel, LH = lateral heel, FF = forefoot, MF = midfoot. * p < 0.05, ** ES < 0.3 (small), *** ES = 0.3–0.5 (medium), 1 ES > 0.5 (large).


