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Comparison of the effects of orthoses on hallux valgus angle and plantar pressure in individuals with hallux valgus

Hüsnanur Çamur[1] and Sena Özdemir Görgü[2]

Abstract

Background: Hallux valgus (HV) is a condition characterized by the lateral deviation of the first phalanx and medial deviation of the first metatarsal, leading to subluxation of the first metatarsophalangeal joint. Various orthotic applications are employed in the treatment of HV deformity. This study aimed to compare the effects of a toe separator (TS) and dynamic orthosis (DO) on hallux valgus angle (HVA), plantar pressure (PP), and quality of life (QoL).

Methods: Thirty individuals aged between 18 and 65 years who had mild to moderate HV deformity were included in our study. Participants were randomized into TS and DO groups. Pretest and post-test evaluations at 4 weeks included goniometric measurement for HVA, PP measurement using the Sensor Medica device, QoL assessment using the American Orthopaedic Foot & Ankle Society-Hallux MTP-IP Scale and Manchester-Oxford Foot Questionnaire, and numerical evaluation scale for orthosis satisfaction.

Results: No statistically significant changes were observed in HVA measurements ($p > 0.05$). In the DO group, significant differences were observed in PP assessment for right rearfoot loading ($p = 0.048$) and total average pressure measurement of the right foot ($p = 0.025$). QoL assessments were observed significant differences in the DO group compared with the TS group ($p < 0.05$).

Conclusions: After a 4-week period of wearing the TS and DO orthoses, no change in HVA was observed. In the DO group, a more balanced load distribution between the right and left foot (50.2% left, 49.8% right) and a more pronounced effect in reducing deformity-related pain and improving QoL by increasing functionality were noted.

Keywords

dynamic orthosis, hallux valgus, hallux valgus angle, plantar pressure analysis, toe separator

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Introduction

Hallux valgus (HV) is painful and complex 3-dimensional deformity characterized by the lateral deviation of the big toe and medial deviation of the first metatarsal.[1–3] Its etiology involves intrinsic factors such as heredity, gender, and pes planus deformity, as well as extrinsic factors such as footwear usage.[2] Moreover, the big toe is the area where the most force is transmitted after the heel, and hallux valgus deformity (HVD) reportedly leads to abnormalities in the plantar pressure (PP) distribution of the foot.[4,5] HVD is troublesome condition that causes functional impairments, psychological issues, and diminished quality of life (QoL), among other problems.[6] Conducting a comprehensive assessment is important to determine the impact of HVD on individuals. In the literature, radiographic or goniometric measurement methods are used to assess the hallux valgus angle (HVA), and the Manchester scale is used to classify its severity. The Manchester scale classifies deformity based on the degree of HVA, categorizing it as healthy, mild, moderate, or severe.[7,8]

Previous studies have reported that orthotic applications, including night splints, insoles, toe separators, and dynamic orthoses, may be effective in conservative treatment of individuals with mild to moderate HVD.[8–11] The corrective biomechanical principle of night splints is to develop resistance strength in contracted muscles by separating first and second phalanges.[12] The corrective biomechanical principle of insoles is to realign the thumb with supination force from the arch support by reducing the force on the hallux and first metatarsal head.[9] Furthermore, toe separator (TS) and dynamic orthosis (DO) are most commonly used in clinics owing to their affordability and accessibility. Unlike other orthoses, TS (Figure 1) do not use straps or bands to separate first and second toes and realign the first metatarsal. Orthosis is effective in reducing friction between shoe and bunion area, thereby reducing pain in the bunion area.[9]

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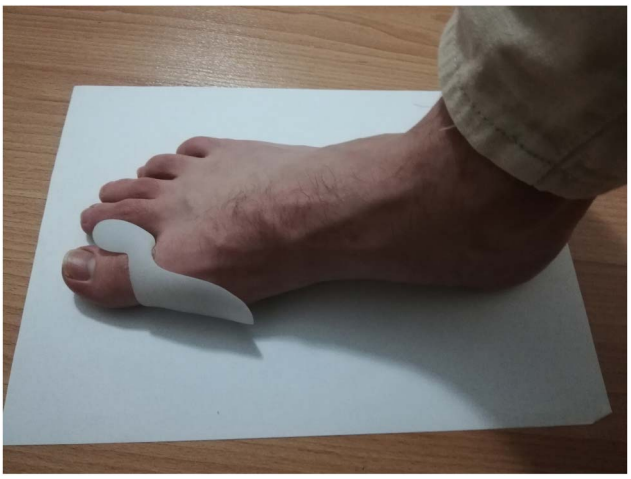

Figure 1. Toe separator.

Studies have reported that the use of TS may be challenging in individuals with severe HVD or a narrow space between the big and second toes.[12] Conversely, DO (Figure 2) is reported to have a free hinge that does not restrict movement of first metatarsophalangeal (MTP) joint and increases passive range of motion of first MTP joint during walking.[13] The principle of orthosis involves facilitating the healing of deformities by applying low torque and prolonged stretching. It exerts opposing force on the connective tissue contributing to the deformity, reducing contracture and enabling plantarflexion and dorsiflexion of first MTP joint. As a result, it is reported to be effective in reducing HVA by realigning hallux.[13,14]

The existing literature lacks studies comparing the effectiveness of TS and DO on HVA and PP of the foot, as well as comparing their effects on QoL. The primary aim of this study was to investigate effect of TS and DO orthoses on HVA in people with HVD. The secondary aim was to investigate effect of the orthoses on PP, QoL, and orthosis satisfaction.

Method

Study design

This study was designed as a pretest–post-test experimental randomized research. Ethical approval was obtained from Non-Interventional Clinical Research Ethics Committee of affiliated institution with approval number E-10840098-772.02-5228 dated October 15, 2021. The study was conducted in accordance with Helsinki Declaration and registered on www.clinicaltrials.gov with registration number NCT06128642.

Participants

A foot evaluation was conducted at Prosthesis Orthosis Center at Istanbul Medipol University between February and December 2022. The participants of study were selected by advertising all students, academics, and staff of the university via social media, and performing a foot evaluation. Individuals who provided consent and endorsed the informed consent form after being briefed on the study's objectives and characteristics were enrolled. Individuals aged between 18 and 65 with mild to moderate severity of HVD were included. Individuals with cognitive impairments, those who had previously received orthotic treatment for HVD, those with a history of foot surgery, rheumatic diseases, diabetes, and rigid HVD were excluded from the study. In total, 37 individuals with HVD were evaluated for this study, and 34 participants (31 females/3 males) who met inclusion criteria were included.

TS orthosis is composed of soft silicone with a Shore A hardness value and features a gel-filled bunion protector on the portion separating the first and second toes.[9] DO is comprised of Shore D hard plastic, a polyurethane gel cushion, and neoprene velcro.[15]

In our study, preprepared sealed envelopes containing numbers from 1 to 34 were used to randomize participants. Each participant sequentially selected 1 sealed envelope. Participants who drew odd numbers were assigned to the TS group (n = 17), whereas those who drew even numbers were assigned to the DO group (n = 17). Two participants from each group discontinued their participation, resulting in completion of the study with 30 participants (28 females/2 males). The participants' selection flowchart is shown in Figure 3.

Participants were provided with TS and DO based on their group assignment. The suitability of the footwear was assessed, participants were instructed to walk for 5 minutes with the orthoses to identify any discomfort. Once participants reported comfort, they were informed about the proper cleaning procedures and began using the orthoses. It was recommended that they wear devices for at least 7 hours a day for 4 weeks.[9] Weekly telephone, face-to-face, and online follow-up interviews were conducted to ensure that orthoses were being used correctly and regularly.[16]

Procedure

This study was completed with a total of 30 participants (28 females/2 males). Pes planus was found in 70% (n = 21) of the participants, and a family history of HV was observed in 90% (n = 27) of them. The participants included in our study were instructed to wear the orthoses for a minimum of 7 h per day over a span of 4 weeks.[9] All participants' HVA, PP, and QoL were recorded through pretest evaluations before participating in the study and post-test evaluations after a 4-week follow-up period.

During the foot assessment of the participants, HVA and the presence of pes planus were evaluated. A goniometer was used to

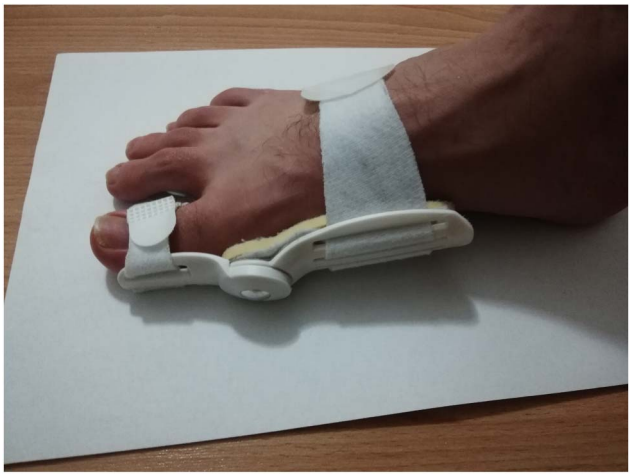

Figure 2. Dynamic orthosis.

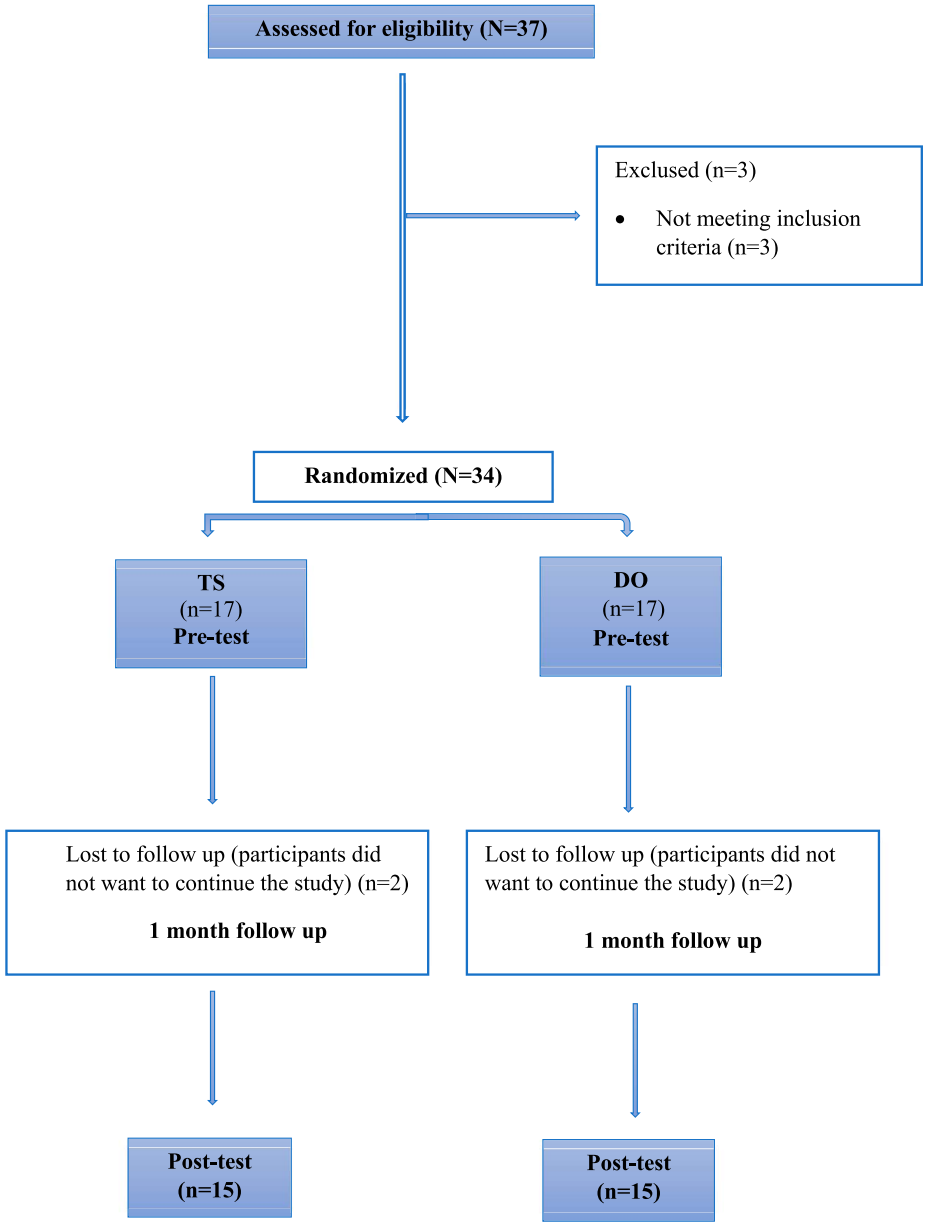

Figure 3. Participants' selection flowchart.

measure HVA. In the literature, HVA is classified as normal (<15°), mild (15–20°), moderate (20–40°), and severe (>40°).[17] The Manchester scale was used to classify the severity of deformity in participants.[7] This visual scale categorizes HVD into 4 levels: no HVD (A), mild (B), moderate (C), and severe (D). In our study, participants with HVD classified as groups B and C based on goniometer results were included. In addition, the Feiss line method was employed for pes planus assessment on both feet.[18]

A review of the literature reveals that dynamic pressure analysis is employed with greater frequency in the assessment of HVD, whereas the use of static pressure analysis is less prevalent.[9,15] Consequently, our study employed static pressure analysis to examine the impact of orthosis use on PP distribution in individuals with HVD. Static pressure analysis was used to elucidate the distribution of body weight on foot PP during standing in individuals with HVD and to assess the efficacy of orthoses by evaluating abnormal pressure distribution.[5] In our study, PP analysis was performed using the Sensor Medica (Italy) device, which consists of pressure-sensitive sensors. The platform of the device was the FreeMed Maxi Baropodometric Platform. The software used with the device was Free Step software, which included static baropodometry. During the analysis, participants were directed to remove their shoes and socks and stand barefoot on the platform while facing forward. Participants were asked to stand in a fixed position on the platform for 5 seconds with their eyes open to allow the device to record the required data.[19,20]

For the assessment of QoL, the AOFAS-Hallux Metatarsophalangeal-Interphalangeal (AOFAS Hallux MTP-IP) scale and Manchester-Oxford Foot Questionnaire (MOXFQ) were used. The AOFAS Hallux MTP-IP scale is a validated assessment method in Turkish and other languages, proven for its validity and reliability. The

scale evaluates foot function, pain, and alignment. Pain is evaluated out of 40 points, function out of 45 points, and alignment out of 15 points, with a total score of 100 points. Moreover, lower scores indicate a more severe deformity and poorer prognosis, whereas higher scores indicate a milder deformity and a better prognosis.[21] MOXFQ is a validated questionnaire in Turkish and other languages. The questionnaire evaluates the functional and social impacts of pain, walking, standing, and QoL on individuals with HVD. Each question is scored from 0 to 4, with 0 indicating the best clinical condition and 100 indicating the worst condition for each subcategory.[22]

To assess the participants' satisfaction with the orthoses, a numerical evaluation scale was used. Orthotic satisfaction was evaluated based on 4 subparameters: quality of orthosis, comfort during orthotic use, ease of wearing and removing, and suitability of the material. After using the orthosis, participants were asked to rate these subparameters on a scale from 0 to 5 (0 = not satisfied at all, 3 = neutral; 5 = very satisfied).[9]

Statistical analysis

The study by Moulodi et al was referenced to determine the strength of our study.[13] To examine the effectiveness of orthotic applications in individuals with HVD, the change in HVA selected as the primary evaluation criterion. To ensure the reliability of the results, power analysis was conducted using the G*Power 3.1 program to assess the sensitivity of the outcomes. To achieve a study power exceeding 80%, a sample size of 26 participants was required, with a 5% significance level and an effect size of 0.744 (degrees of freedom = 12; t = 1.782). To account for potential losses and to aim for a higher testing power, 30 participants were included in the study. The participants were divided into groups in a 1:1 ratio, with at least 15 participants in each group.

The data obtained in the research were analyzed using the Statistical Package for Social Sciences for Windows 22.0 program. Descriptive statistical methods such as count, percentage, mean, and standard deviation were used for data evaluation. Chi-square and Fisher exact tests were employed to analyze differences in the proportions of categorical variables between the TS and DO groups. Independent *t*-tests were used to compare continuous quantitative variables between the 2 independent groups. Paired samples *t*-tests were used for comparing measurements within groups.

Results

The demographic information and clinical characteristics of the participants are shown in Table 1.

Hallux valgus angle and static plantar pressure analysis

The HVA, static analysis of PP loading percentages, and total average pressure measurements of the groups included in the study are shown in Table 2. No statistically significant difference was observed in intragroup or intergroup pretest and post-test comparisons in HVA measurements for the TS and DO groups ($p > 0.05$).

The static PP analysis revealed no statistically significant difference between the groups in the left forefoot loading percentage in post-test results ($p = 0.332$). However, a statistically significant difference was observed in right forefoot loading percentage ($p = 0.040$). The post-test measurements for the right forefoot were higher in the TS group than in the DO group. When the pretest and post-test measurements were compared within the groups, although the left hindfoot loading percentage was not significant in the DO group ($p = 0.266$), a statistically significant difference was found in the right hindfoot loading percentage ($p = 0.048$). In contrast, no statistically significant difference was observed in the TS group ($p > 0.05$).

Assessments of quality of life

The measurements of AOFAS Hallux MTP-IP scale and the MOXFQ for the groups included in the study are presented in Table 3. Statistically significant differences were found in the measurements of pain, function, and total values of the AOFAS Hallux MTP-IP scale in the DO group ($p = 0.009$, $p = 0.048$, $p = 0.007$). Statistically significant differences were also found in the measurements of walking and standing, foot pain, social interaction, and total values of the MOXFQ in the DO group ($p = 0.005$, $p = 0.006$, $p = 0.046$, $p = 0.006$).

Assessment of orthosis satisfaction

In the assessment of orthosis satisfaction, no statistically significant differences were observed between the groups in quality of orthosis, comfort, ease of wearing and removal, material suitability, and overall satisfaction scores ($p > 0.05$).

Discussion

The objective of the present study was to compare the effects of TS and DO on HVA, PP, and QoL in individuals with HVD. Our findings revealed that, although no change in HVA was observed in all participants, after 4 weeks of DO use, the percentage load values for right and left foot were almost equal (50.2% left, 49.8% right), and QoL improved.

Table 1. Basic demographic and clinical information of the groups.

Outcome Measures	TS (n = 15)		DO (n = 15)		*t*	df	*p*
	Avg	SD	Avg	SD			
Age (y)	33.533	12.409	34.333	13,351	−0.170	28	0.866
Weight (kg)	65.200	10.325	72.667	12,579	−1.777	28	0.086
Height (cm)	165.933	6.088	163.933	6029	0.904	28	0.374
BMI (kg/m^2)	23.709	3.685	27.115	5092	−2.099	28	**0.045**
Shoe size	38.133	1.187	38.400	1639	−0.510	28	0.614

Abbreviations: Avg, average; BMI: Body Mass Index; df, degrees of freedom; n, number of people; SD, standard deviation; Shoe size, EU shoe size; t, independent means *t*-test. Bold values are statistical singificant to $p < 0.05$.

Table 2. HV angle, static analysis PP loading percentages, and total pressure average pretest and post-test measurements.

Outcome Measures	TS (n = 15) Avg ± SD	DO (n = 15) Avg ± SD	t[a]	*p*
HVA (°)				
Left				
Pretest	19.290 ± 2.498	18.630 ± 2.387	—	—
Post-test	19.290 ± 2.498	18.630 ± 2.387	—	—
P	—	—		
Right				
Pretest	17.920 ± 2.392	23.290 ± 3.200	—	—
Post-test	17.920 ± 2.392	23.290 ± 3.200	—	—
P	—	—		
Forefoot load (%)				
Left				
Pretest	22.200 ± 4.475	22.800 ± 4.329	−0.373	0.712
Post-test	22.200 ± 4.960	20.470 ± 4.658	0.987	0.332
P	0.973	0.070		
Right				
Pretest	21.000 ± 4.359	21.600 ± 3.906	−0.397	0.694
Post-test	22.733 ± 3.150	19.867 ± 4.069	2.158	**0.040**
P	0.145	0.165		
Rearfoot load (%)				
Left				
Pretest	28.467 ± 4.809	28.733 ± 4.079	−0.164	0.871
Post-test	27.333 ± 4.402	29.733 ± 4.317	−1.507	0.143
P	0.401	0.266		
Right				
Pretest	28.333 ± 4.030	26.867 ± 4.086	0.990	0.331
Post-test	28.400 ± 4.748	29.933 ± 5.405	−0.825	0.416
P	0.786	**0.048**		
Total load (%)				
Left				
Pretest	50.667 ± 2.498	51.533 ± 3.204	−0.826	0.416
Post-test	49.600 ± 2.971	50.200 ± 3.950	−0.470	0.642
P	0.423	0.471		
Right				
Pretest	49.333 ± 2.498	48.467 ± 3.204	0.826	0.416
Post-test	50.400 ± 2.971	49.800 ± 3.950	0.470	0.642
P	0.423	0.471		
Total Pavg (g/cm^2)				
Left				
Pretest	316.867 ± 53.354	312.000 ± 39.645	0.284	0.779
Post-test	304.400 ± 42.827	328.667 ± 47.231	−1.474	0.152
P	0.084	0.092		
Right				
Pretest	299.933 ± 45.402	297.933 ± 40.732	0.127	0.900
Pro-test	291.467 ± 34.602	321.333 ± 48.776	−1.934	0.063
P	0.503	**0.025**		

Abbreviations: Avg, average ortalama; n, number of people; Pavg, average pressure; SD, standard deviation; t[a]: independent means *t*-test.
—, not significant.
Bold values are statistical singificant to $p < 0.05$.

Table 3. AOFAS Halluks MTP-IP scale and MOXFQ pretest and post-test measurements.

Outcome Measures	TS (n = 15) Avg ± SD	DO (n = 15) Avg ± SD	t[a]	*p*
AOFAS Hallux MTP-IP				
Pain				
Pretest	32.000 ± 5.606	28.000 ± 6.761	1.764	0.089
Post-test	32.000 ± 5.606	32.000 ± 6.761	0.000	1.000
t[b]	0.000	−3.055		
P	1.000	**0.009**		
Function				
Pretest	41.267 ± 4.367	42.533 ± 3.441	−0.882	0.385
Post-test	41.800 ± 3.968	43.467 ± 2.949	−1.306	0.202
t[b]	−1.835	−2.168		
P	0.088	**0.048**		
Total				
Pretest	81.267 ± 7.704	78.533 ± 8.692	0.911	0.370
Post-test	81.800 ± 7.523	83.467 ± 8.758	−0.559	0.581
t[b]	−0.297	−3.175		
P	0.771	**0.007**		
MOXFQ				
Walking/standing				
Pretest	24.487 ± 19.683	37.580 ± 20.776	−1.772	0.087
Post-test	17.240 ± 18.256	24.907 ± 19.066	−1.125	0.270
t[b]	2.710	3.287		
P	**0.017**	**0.005**		
Pain				
Pretest	24.487 ± 19.683	39.667 ± 20.999	−2.043	0.051
Post-test	24.000 ± 23.315	26.333 ± 14.326	−0.330	0.744
t[b]	0.114	3.274		
P	0.911	**0.006**		
Social interaction				
Pretest	10.833 ± 11.443	14.583 ± 14.108	−0.800	0.431
Post-test	7.917 ± 11.197	8.333 ± 11.492	−0.101	0.921
t[b]	1.606	2.185		
P	0.131	**0.046**		
Total				
Pretest	25.087 ± 15.167	32.457 ± 16.797	−1.261	0.218
Post-test	17.685 ± 16.304	21.217 ± 13.572	−0.645	0.524
t[b]	3.304	3.212		
P	**0.005**	**0.006**		

Avg: average; n, number of person; SD, standard deviation; t[a], independent means *t*-test; t[b], dependent groups *t*-test.
Bold values are statistical singificant to $p < 0.05$.

The frequency of HVD occurrence is reported to be higher in females compared with males.[15,23,24] In our study, 93.3% of the participants were female. Literature reviews indicate a higher likelihood of deformity occurrence in individuals with a family history of HVD.[25] In our study, 90% of the participants reported a family history of HVD. Several studies have suggested that pes planus affects HVD.[26] In our study, 70% of the participants were found to have pes planus. The findings of our study regarding participants' sex, family history of HV, and pes planus deformity align with the literature.

Among conservative treatments for HVD, TS and DO are commonly used.[8–10,13] Moulodi et al examined the effects of static and dynamic orthotics on the HVA after 4 weeks, suggesting that longer-term use may be beneficial.[13] Our study assessed the use of TS and DO for at least 7 hours a day over 4 weeks in individuals with HVD, referencing existing literature.[9] Although goniometric measurement is widely used in clinics to assess HVA, it has limitations.[13,27,28] These including difficulties in stabilization, potential for larger angle readings because of bunion effects, and insufficient sensitivity to detect minor changes in short-term

studies.[6,26,29] Radiographic evaluation is traditionally considered the gold standard for HVA assessment with this recently, mobile phone–based protractors have emerged, offering a modern measurement approach. Studies indicate that radiography is more effective in detecting changes in HVA.[30,31] In our study, we used goniometric measurement method and observed no change in HVA after 4 weeks of orthosis usage. This suggests that relying solely on goniometric methods, along with the lack of more sensitive techniques like radiography and the limited duration of use, may be inadequate. To observe a change in HVA, it would be necessary to use long-term orthosis use and more sensitive measurement methods in short-term studies.

The severity of lateral deviation of hallux because of HVD can disrupt weight transfer between feet, leading to abnormal PP distribution.[5,32] In this study, minimal differences in weight bearing were observed between feet, with no significant changes after 4 weeks of orthotic use. All participants initially showed higher forefoot loading. In the participants using DO, the percentages of loading and mean pressure values were equalized after 4 weeks of follow-up, with a decrease in percentages of right and left forefoot loading. The results of this study support the previous studies and show that the use of DO is more effective in regulating PP distribution in people with HVD. The effectiveness of orthotics may relate to their biomechanical properties: DO (Shore D, hard plastic) enhances the first MTP joint's range of motion during walking, whereas TS (Shore A, soft silicone) primarily separates the big toe from the second toe but lacks sufficient force to reposition the big toe effectively.[9,13] This softness may limit TS's corrective capacity for HVD and its influence on forefoot loading. Previous studies indicate that individuals with HVD may impair big toe function during gait, potentially increasing forefoot load.[33] In light of our findings and existing literature, we recommend further research to investigate the effects of these orthoses on static and PP distribution during gait in individuals with HVD. In addition, given that our study examined the effect of orthoses over a relatively short period of 4 weeks, we recommend that longer-term studies be conducted to assess the change in pressure analysis.

Studies have reported that pain caused by HVD can adversely affect an individual's QoL.[34] In our study, the AOFAS Hallux MTP-IP scale and MOXFQ were used to assess participants' QoL.[8,35] After 4 weeks of TS usage, no changes were observed in participants' QoL parameters; however, after DO usage, improvement was observed in all subparameters of both questionnaires. As a result of our study, indicate that use of orthotics for a 4-week short-term period resulted in a reduction in foot pain and an improvement in the functionality and QoL of the participants. Further studies are required to examine the effects of long-term orthotic use.

In our study, participants' satisfaction with orthoses was evaluated. DO was preferred for its ease of use and fit. However, its bulky design and width limited its compatibility with various footwear. Therefore, subjects wore a fixed shoe compatible with the orthosis throughout the study. Participants also reported that DO's straps deformed from washing, complicating hygiene maintenance. Although TS orthosis was appreciated for its shoe compatibility, it caused irritation, discoloration, and odor between the toes. The feedback indicates a need for more effective, comfortable, and technologically advanced orthosis designs for HVD. To create more effective orthoses for HVD and HVA, investigate existing orthoses for new designs, consider material compatibility, and design them to be compatible with every shoe.

The present study is limited by the absence of radiographic evaluation of HVA. Furthermore, the relatively brief duration of the orthotic intervention (4 weeks) and lack of longer-term follow-up of the orthosis are among limitations of this study. Finally, the use of nonuniform shoes with varying materials, sole heights, and heel softness may have influenced the observation of PP changes, and the lack of a uniform shoe to increase orthotic fit represent further limitations of this study.

Conclusion

The results of the study demonstrated that there was no alteration in HVA after utilization of TS and DO orthoses over a 4-week period. In addition, a more balanced distribution of load between right and left foot (50.2% on left, 49.8% on right) was observed in participants using DO. Furthermore, a more pronounced effect was observed in reduction of forefoot pain because of HVD and in improvement of QoL by increasing functionality. In light of these findings, it can be concluded that DO may have more beneficial effects on pain, functionality, and QoL in individuals with HVD. These results suggest that effect of orthoses on HVD should be further investigated after long-term use.

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Supplemental material

No supplemental digital content is available in this article.

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