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Biomechanical Evaluation of Custom Foot Orthoses for Hallux Valgus Deformity

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ABSTRACT

The purpose of the present study was to compare the hallux valgus deformity pressure parameters seen in standard footwear (no orthosis) versus the pressure observed in the same footwear with the addition of 3 different length orthoses. The forefoot pressure at a hallux valgus deformity was recorded with pressure sensors placed on the plantar, medial, and dorsal surface of the first metatarsal head. The participants performed walking trials without an orthosis and with orthoses of 3 different lengths. The average pressure and maximum pressure of each area was recorded for each orthosis, and comparisons were made across the groups. The plantar pressures were decreased in the full length and 3/4 length orthoses, and the dorsal pressures were increased with the use of the full-length and sulcus-length orthoses. Significant changes in medial pressure were not seen with the addition of any orthosis compared with standard footwear alone. However, a trend toward increased medial pressures was seen with the full- and sulcus-length orthoses, and the 3/4-length orthoses exhibited a trend toward decreased medial pressures. We were unable to demonstrate that the use of a custom foot orthosis significantly decreases the medial pressures on the first metatarsal head in patients with hallux valgus deformity. The 3/4-length orthosis was less likely to negatively affect the dorsal or medial pressures, which were noted to increase with the sulcus- and full-length orthoses. Our data suggest that if a clinician uses this treatment option, a 3/4-length orthosis might be a better choice than a sulcus- or full-length orthosis.

Hallux valgus deformity is a complex structural malalignment of the foot displaying widening of the forefoot, medial deviation of the distal first metatarsal, lateral deviation and pronation of the hallux relative to the first metatarsal, and lateral deviation of the sesamoids in relation to the first metatarsal head (1–4). Coughlin, with others, developed a classification system based on the magnitude of the hallux valgus angle (HVA) formed between the first metatarsal and the proximal phalanx. They defined the deformity as mild when the HVA was 15° to 20°, moderate when the HVA was 20° to 40°, and severe when the HVA was >40° (5–8).

Multiple causes of hallux valgus have been implicated, and a correlation might be present between a loss of arch height and the development of hallux valgus. In addition, constricting footwear has frequently been cited as being partially responsible for the development of hallux valgus (9–18). Several investigators have suggested that the pressure exerted medially on the hallux and the capsule of the first metatarsophalangeal (MTP) joint, especially in feet with ligamentous laxity and flatfoot deformity, can lead to the development or progression of hallux valgus deformity (11–15,19,20). Some believe that an orthosis has the potential to reduce the medial pressures responsible for producing the hallux valgus deformity and causing some of the associated pain. Such an orthosis might reduce the symptoms associated with hallux valgus, slow progression of the deformity, and possibly delay the need for surgical intervention (12,14,20,21). The objective of the present investigation was to determine whether a foot orthosis, combined with standard footwear, has the potential to reduce the extrinsic pressure at the MTP joint in a patient with hallux valgus deformity.

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Conflict of Interest: None reported.

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Patients and Methods

After approval by the institutional review board of the University of Tennessee College of Medicine, a review of patients' medical records was performed in June 2010, using the International Classification of Disease, 9th edition, diagnostic codes, seeking patients treated for hallux valgus deformity (ICD-9 code 735.0). All participants were part of a fellowship-trained foot and ankle surgeon's practice and had been evaluated and treated nonoperatively within the previous 3 years. The inclusion criteria were a HVA of $\geq 15^\circ$ and a minimum age of 18 years. The subjects were excluded if they had undergone previous operative treatment of hallux valgus deformity, had other foot deformities, or had other comorbid conditions that significantly altered their gait. A total of 25 subjects (23 female, 2 male) with 38 hallux valgus deformities agreed to participate. Of the 25 subjects, 13 with bilateral hallux valgus deformity had both feet included in the present study. The mean age of the participants was 57 (range 25 to 77) years, the mean height was 5 ft, 6 in., and the mean weight was 157.4 (range 125 to 230) lb. The average HVA was $34^\circ \pm 12^\circ$, and the average 1-2 intermetatarsal angle was $14^\circ \pm 4^\circ$. The angles were measured manually on standing weightbearing radiographs by 2 fellowship-trained foot and ankle surgeons. The study included 2 mild (5.3%), 29 moderate (76.3%), and 7 severe (18.4%) cases of hallux valgus deformity, with an equal distribution between the right and left feet.

The custom foot orthoses were fabricated for each of the subjects (patients) by a certified pedorthist. Impressions were taken with the patient in a semi-weightbearing position using biofoam impression system boxes. The heel was pressed to the floor, followed by the lateral forefoot and toes, and, finally, the first metatarsal. The impression was analyzed for sufficient arch elevation and preservation of the plantar surface of the first metatarsal before pouring plaster into the impression box. Fabrication began with a double layer of stockinet pulled over the plaster mold to adjust for compression of the Microcel Puff® (MCP) (ACOR Orthopedic Inc., Cleveland, OH) under vacuum. The 5/32-in. Thermoplastic Elastomer (TPE) (PolyOne Corp., Avon Lake, OH), 1/16-in. MCP, and a 5/32-in. TPE neutral heel post were cut to size. The TPE was heated for 7 minutes, and MCP was heated for 5 seconds on each side. Next, the TPE was pulled over the MCP after it had cooled, and the neutral heel post was added while the plastic was hot.

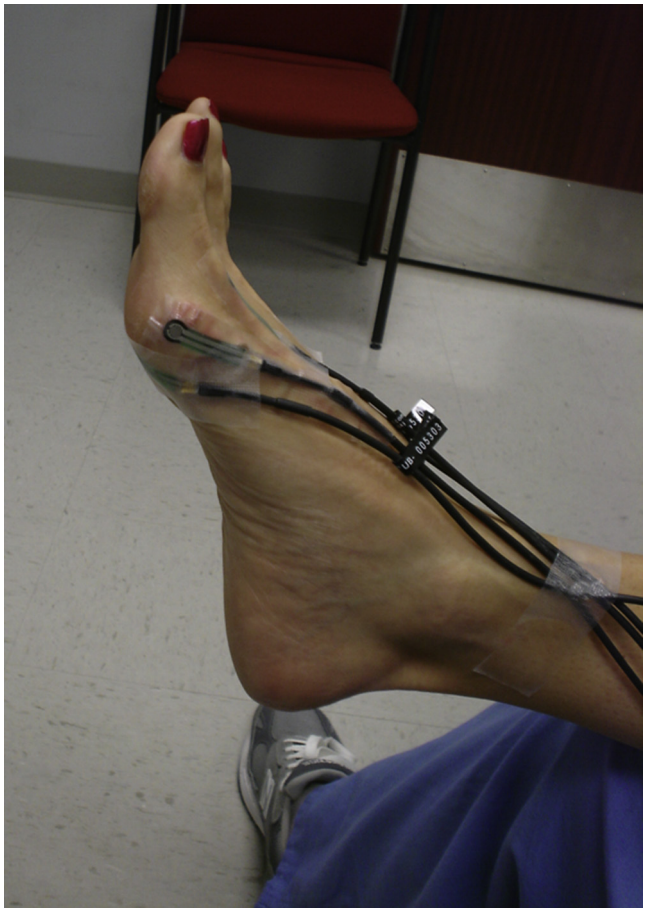

Fig. 1. Pressure sensors were placed on the plantar, medial, and dorsal skin surfaces of the metatarsal head.

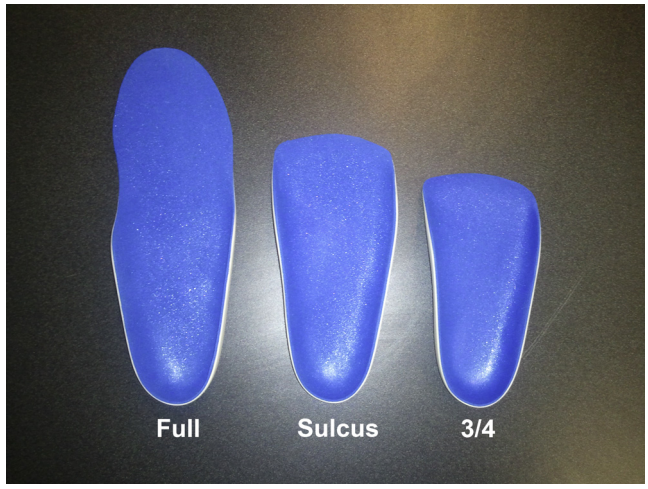

Fig. 2. Three different lengths of orthoses were used for the testing conditions.

Biomechanical Analysis

Biomechanical testing was conducted in the gait laboratory. The patients were instructed to bring the 2 pairs of shoes they felt were most comfortable, they were required to work in, or they would wear the most often if prescribed an orthosis. The shoes were required to have a closed toe box, closed heel, low heel, and removable inserts. These included sneakers, casual shoes, dress shoes, hiking boots, and work boots.

The pressures were monitored using the Tactilus Free Form® Sensor System (Sensor Products, Madison, NJ), which has low-profile pressure sensors to fit flush inside the patients' socks and shoes. Each 4-mm diameter sensor is measured in parallel at a rate of 40 Hz by a data acquisition board on a scale of 0 to 1.72 MPa. Three sensors were used to measure the contact pressure on the medial, plantar, and dorsal surfaces of the hallux valgus deformity. The sensors were placed on the skin at each corresponding location and secured with pliable sports tape (Fig. 1). A thin sock was then applied to the foot to protect the sensors from the shear forces of the shoe. The control pressures for each subject were obtained by testing the subject in 2 pairs of shoes without an orthosis. The process was repeated in the same 2 pairs of shoes to obtain pressures with each of the 3 different length foot orthoses. Each subject was instructed to ambulate for a distance of 4.5 m, which provided a gait cycle of ≥ 4 steps to be evaluated. Data acquisition began during midstride of the initial step and ended during midstride of the final step. The gait cycle was analyzed to calculate the average (mean) pressures and maximum pressures for each testing condition. Testing consisted of 4 conditions, with 3 trials per shoe for each condition:

1. The control without an orthosis
2. The full-length orthosis
3. The sulcus-length orthosis
4. The 3/4-length orthosis (Fig. 2)

Therefore, each patient performed 24 walking trials (12 in each pair of shoes). The factory insole was left in place for the no orthosis, sulcus-length orthosis, and 3/4-length orthosis trials, and the insole was removed to accommodate the full-length orthosis. To maintain consistency from 1 testing condition to the next, the same

Table 1
Power and *p* values for observed pressure differences (N = 38 feet)

Measurement	*p* Value	Observed Power
Plantar average (mean)	.001	0.940
Plantar maximum	.006	0.835
Medial average (mean)	.038	0.630
Medial maximum	.041	0.622
Dorsal average (mean)	.000	1.000
Dorsal maximum	.000	1.000