The Effects of a New Foot-Toe Orthosis in Treating Painful Hallux Valgus

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Objective: To assess the effects of a new foot-toe orthosis on painful hallux valgus.

Design: Uncontrolled intervention study.

Setting: An outpatient clinic in a tertiary medical center with an orthotic laboratory in Taiwan.

Participants: Seventeen patients with painful hallux valgus.

Intervention: Application of a new total contact insole with fixed toe separator.

Main Outcome Measures: The hallux valgus angle, an 11-point numeric rating scale (NRS-11) for pain assessment, and walking ability scale.

Results: The average hallux valgus angle reduction ± standard deviation was 6.5°±3.8° after insole application (P<.001). An improvement on the NRS-11 pain scale from 4.06±2.8 to 0.88±1.17 (P<.001) was noted after immediate insole application and was .42±.67 (P=.002) 3 months later for the 12 patients who completed the study. The walking ability scale improved at least 1 grade or more after the insole was worn for 3 months (P=.002). All patients tolerated the insole well without any clinical evidence of skin ulcers or blisters.

Conclusion: Our new total contact insole with fixed toe separator reduced pain, and improved walking ability and the hallux valgus angle. It is an effective alternative treatment for patients with painful hallux valgus.

Key Words: Foot; Hallux valgus; Orthotic devices; Rehabilitation; Toes; Walking.

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Hallux valgus is a foot disorder manifested by lateral deviation of the great toe and medial deviation of the first metatarsal. Usually, the deformity is caused by progressive subluxation of the first metatarsophalangeal joint. Onset of the deformity is often during the fifth or sixth decade of life, a fact that implicates constricting footwear as a cause of hallux valgus.1,2 The cause of hallux valgus is multifactorial.3 Constricting footwear appears to be the major extrinsic cause, but intrinsic factors also play a role. Inman4 suggested that pronation of the hindfoot (rearfoot valgus) is a major cause of bunion formation. Mann and Coughlin5 reported that pes planus also contributes to bunion formation. An increased angle between the first and second metatarsals (metatarsus primus varus) is often associated with hallux valgus deformity. Other intrinsic causes of hallux valgus include contracture of the Achilles’ tendon, generalized joint laxity, hypermobility of the first metatarsocuneiform joint, and neuromuscular disorders (including cerebral palsy and stroke). Heredity is also thought to influence the development of hallux valgus in many individuals.6

Nonoperative care is always the first treatment option for patients with hallux valgus deformity.1 Pain, blistering, and bursal inflammation can be relieved by eliminating friction over the medial eminence. Shoes with a wider toe box may reduce symptoms substantially.7 Patients with pes planus, forefoot varus, and rearfoot valgus deformity can be managed with foot orthoses and the possible addition of posting on the plantar aspect of the insole.8 If surgery is performed, its goal is to correct all pathologic elements while maintaining a biomechanically functional forefoot.1

Currently, commercial toe separators are available that can be placed between the first and second toes.9 However, because of the external rotation component of the first toe, it is extremely difficult to keep the toe separator in place. Dislodgment often occurs during walking, especially in patients wearing shoes with modified large toe boxes.

In this study, we applied our newly designed foot-toe orthosis (total contact insole with fixed toe separator) to every recruited individual with hallux valgus. The purpose of this study was to test the hypothesis that application of an insole with a toe separator decreases pain, reduces hallux valgus angle, and improves walking ability.

METHODS

This study was approved by our hospital’s medical ethics and the human clinical trial committee. Clinical diagnosis of hallux valgus was made based on observation of great toe lateral deviation and a high prevalence rate of bunion formation. To calculate the hallux valgus angle using foot roentgenography, we measured the angle formed by lines drawn to bisect the first metatarsal bone and the proximal phalanx of the great toe9 (fig 1).

Participants

Seventeen woman ranging in age from 14 to 75 years (mean, 42.59±16.52y) with painful hallux valgus gave informed consent to participate in the study. Inclusion criteria were hallux valgus angle of at least 20°, single or bilateral hallux valgus, and no history of foot operations. Fifteen had bilateral hallux valgus, 1 had right side involvement and 1 had left side involvement. The apparent cause of hallux valgus in 14 pa-
tients was constricting footwear. Hallux valgus in the remaining 3 patients was because of rheumatoid arthritis, osteoarthritis, and pronated foot. Osteoarthritis of the foot was confirmed by x-ray findings of joint space loss, sclerosis of the subchondral bone, and osteophyte formation at the margins of the articular surfaces.

The Total Contact Insole With Fixed Toe Separator

The negative cast was obtained by the same physiatrist (SFT). Patients sat in an upright position with knees flexed at 90°. With the subtalar joint under neutral and non-weight-bearing position, the foot was placed on the foam box impression system. The negative cast was molded by the physiatrist who pushed the knee vertically downward with 1 hand while fixing the subtalar joint with the other hand. A positive mold was then fabricated from the negative cast, and the total contact insole was made according to the positive mold.

The contact layer of the total contact insole was made with plastazote poron, the middle layer with microcell pull, and the bottom layer with semirigid material of plastazote no. 3. The fixed toe separator, a thermoplastic plate with a vertical bar was inserted between the contact layer and the bottom layer at the forefoot area (fig 2). The vertical bar was perpendicular to the thermoplastic plate and situated between the first and second toes. A Silipos toe separator was used to wrap around the vertical bar (fig 3). This toe separator was selected because of its fine cushioning effect. It is made of mineral oil–based polymer gel and can lubricate and moisturize the skin.

For the patient with an overriding second toe, the vertical bar was extended in a horizontal direction to cover the second, third, and fourth toes. The extended bar was also covered with the Silipos toe separator (fig 3).

We advised our patients to purchase shoes 1 size larger than their normal shoe size so that the total contact insole would fit inside the shoe. Patients with more severe hallux valgus angle and bunion formation were given special modified shoes with extra-depth and larger toe boxes. A modified shoe was given to the patient with the overriding second toe to accommodate the extended horizontal bar from the second to fourth toes.

Walking Ability Evaluation

The pain felt during walking was recorded by an 11-point numeric rating scale (NRS-11). It consists of pain intensities, which range from 0 to 10, reflecting an increase in pain. We modified the walking ability scale of Pun et al with grade 1 to 4 to evaluate the patients’ walking ability. The walking ability scale was subjective. Grade 1 indicated poor walking ability; patients could walk for less than 10 minutes. Grade 2 indicated fair walking ability, in that the patient could walk for more than 10 minutes, but for less than an hour. Grade 3 indicated good walking ability with the patient able to walk well over an hour. Grade 4 indicated an excellent walking ability, with the patient able to walk normally.

The NRS-11 was evaluated before and immediately after the application of the insole and again 3 months later.

For patients with moderate (30°) and severe (40°) hallux valgus angles, the insoles were first removed from the shoes during the donning process. The first and second toes were separated manually to place the fixed toe separator in between. After the toes, the fixed toe separator, and the total contact insole were correctly aligned, they were inserted together into the shoes.

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Abbreviations: HV, hallux valgus; R, right side; L, left side; B, before orthotic intervention; I, immediately after orthotic intervention; F, follow-up

NOTE. Patients 2, 7, 9, 11, and 17 did not complete the study.

1. The same pairs of shoes were used during the entire 3-month study period. We did not observe any serious tearing or wearing of the shoes that would alter patients’ gait patterns.

2. Roentgenographic Studies

Roentgenographic studies showing the different degrees of hallux deformity were obtained before and immediately after the shoes with the total contact insole with fixed toe separator were worn (fig 1).

3. Statistical Analysis

The paired t test was used to compare the hallux valgus angle correction before and after wearing the total contact insole. The nonparametric Wilcoxon signed-rank test was used to compare changes in NRS-11 pain and walking ability scales. The NRS-11 pain scale results were first compared before and immediately after patients wore the total contact insole. These results were compared again before and after the patients had worn the total contact insole for 3 months. The walking ability scale results were compared before and after patients had worn the total contact insoles for 3 months. The statistical comparison of the NRS-11 pain and walking ability scales after the 3-month period was performed for 12 patients because 5 patients refused further participation. It was not known whether the 5 continued to wear the insoles after dropping out of our study. Statistical significance was set at P≤.05.

4. RESULTS

Immediate Effects of the Total Contact Insole With Fixed Toe Separator

The hallux valgus angle was reduced from 31.04°±6.4° to 25.25°±7.14° in the right toe (P<.001) and from 33.38°±7.73° to 26.19°±6.91° in the left toe (P<.001) immediately after subjects wore our insole with fixed toe separator. The NRS-11 pain scale score was reduced from 4.06±2.8 to 0.88±1.17 (P<.001). The rheumatoid arthritis patient with the overriding second toe had the highest NRS-11 pain score (8) before wearing the insole. The score improved to 2 immediately after insole application (table 1). The overriding in the second toe was prevented with the second, third, and fourth toes placed under the extended horizontal bar.

Follow-Up at 3 Months

In the 12 patients who wore the total contact insole with fixed toe separator for 3 months, the NRS-11 scale score improved further to 0.4±0.67 (P=.002) (table 1).

The walking ability score improved at least 1 grade or more after patients wore the total contact insole for 3 months (P=.002). Patients could walk for a longer period of time and with greater comfort.

Patients were not told how long they should wear the insoles. We did recommend that they wear them when in weight-bearing circumstances such as standing and walking. Our patients also wore the insoles at home in situations requiring them to stand for long periods. All 12 patients tolerated the insole well and showed no clinical evidence of skin ulcers or blisters.

5. DISCUSSION

A diagnosis of hallux valgus is made in patients with a hallux valgus angle greater than 15°; a slight lateral deviation of the great toe is normal.9,12 Kelikian13 suggested that a measurement of 20° should be considered as mild deformity, 30° a moderate deformity, and more than 40° a severe deformity. Patients recruited for our study had at least a mild deformity of 20°; the most serious deformity was 40°. Regardless of the patient’s level of severity, our newly designed total contact insole with fixed toe separator reduced the average hallux valgus angle by 6.5°±3.8°.

There is an underlying cause for every hallux valgus case. The cause must be determined if treatment is to be effective. In cases caused purely by constricting footwear, treatment with wider toe box shoes is adequate. Such shoes with a wider toe box may substantially reduce the pain, blistering, and bursal inflammation caused by friction over the medial eminence.1,7,8

When hallux valgus is caused by intrinsic factors such as pronation of the hindfoot, forefoot varus, Achilles’ tendon contracture, joint laxity, hypermobility of the first metatarso-
cuneiform joint, or neuromuscular disorders, treatment strategy should focus on restoring an anatomically and biomechanically functional foot. In this patient population, constructing a total contact insole according to the foot’s positive mold, with adequate arch support and posting, would be a better intervention because anatomic alignment of the foot can be correctly restored.\(^1\,^8\)

Nonsurgical intervention is usually considered first in the treatment of hallux valgus. If surgical intervention is considered, the goal is to correct the prominence of medial eminence; to increase the valgus angulation of the proximal phalanx; to increase the first-second intermetatarsal angle; and to ensure the congruency of the metatarsophalangeal joint, the subluxation of the sesamoids, and the pronation of the great toe.\(^1\) However, some foot conditions, such as generalized joint laxity and hypermobility, cannot be corrected surgically. This might explain the high postsurgical recurrence rate of hallux valgus in some patients. In such cases, we recommend postsurgical application of this new total contact insole with fixed toe separator to maintain the foot anatomic alignment.

The main advantage of our insole is the restoration of correct anatomic foot alignment. Overstretched collateral ligaments and bone subluxation could then be improved. The Silipos toe separator material provided cushioning between the first and second toes and had a lubricating and moisturizing effect on the surrounding skin. Shoes with a wider toe box help give immediate relief from pain caused by bunion formation. The design of the fixed toe separator prevents the possibility of dislodge. All these factors contributed to decreased pain, increased walking ability, and decreased hallux valgus angles in our patients.

The disadvantage in our insole design is that manual manipulation is required to separate the first 2 toes in patients with moderate (30°) hallux valgus deformity or worse in order for the fixed toe separator to be placed between the toes. Self-separation of the first 2 toes to accommodate the fixed toe separator is not possible in these patients when the insoles are in the shoes. Therefore, the insole must first be properly aligned with the foot outside the shoe and then inserted together into the shoe. Some patients found this donning process troublesome. In our case of the overriding second toe, manual manipulation was required first to separate the first and second toe and then to push the second to fourth toes beneath the extended bar in order for overriding prevention to be effective.

The limitations to this study were that we do not know how long the total contact insoles with fixed toe separators should be applied to patients with hallux valgus. We also do not know if foot malalignment is a reversible process and can be corrected permanently after wearing the insoles for a certain period of time. In future studies, we will focus more on the biomechanical changes in the foot over time. More patients with different disease entities that cause hallux valgus will also be studied.

**CONCLUSION**

Our foot-toe orthosis should be considered an effective treatment for patients with painful hallux valgus. Use of this orthosis can result in decreased pain, increased walking ability, and decreased hallux valgus angulation.

**References**


**Suppliers**

a. ACOR Orthopaedic Inc, 18530 S Miles Pkwy, Cleveland, OH 44128.
b. Silipos Orthopedic Products, 7049 Williams Rd, Niagara Falls, NY 14304.