Original Article

Clinical Outcomes between Using Prefabricated Toe Sleeve versus Toe Separator in Patients with Painful Hallux Valgus: A Single-Blinded Randomized Control Trial

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ABSTRACT

Objectives: To compare clinical outcomes between using a prefabricated foot-toe orthosis, a toe sleeve and a toe separator in treating painful hallux valgus/bunion.

Study design: A single-blinded randomized controlled trial.

Setting: Ramathibodi Hospital, Bangkok, Thailand.

Subjects: Patients with painful hallux valgus/bunion aged between 25 and 70 years old

Methods: Patients were randomly divided into two groups: a toe separator and a toe sleeve group, both received the same treatment protocols. Primary outcomes were pain using a visual analog scale (VAS) and functions using visual analog scale-foot and ankle (VAS-FA) at one- and three-month follow-ups, and patient compliance with adherence to daily use of the orthosis as a secondary outcome.

Results: Compared with the baseline, the mean VAS at one- and three-month follow-ups statistically significantly decreased in both groups [the toe sleeve group: 55.72, 21.72 and 19.33 (p < 0.01); the toe separator group: 66.00, 42.67 and 42.17 (p < 0.01) respectively]. The mean VAS-FA at both follow-ups statistically significantly increased in both groups [the former toe sleeve group:75.89, 88.67 and 83.83 (p = 0.01), the toe separator group: 53.72, 65.33 and 71.17 (p < 0.01), respectively]. The toe sleeve group showed significantly lower VAS scores than the toe separator group at both follow-ups, whereas the VAS-FA did not differ.

Conclusions: The toe sleeve significantly reduced pain better than the toe separator did in patients with hallux valgus at 1 and 3 months after usage. The VAS-FA also significantly improved in both groups without a significant inter-group difference. Both, a toe sleeve and a toe separator, improved functions.

Keywords*:* bunion, foot orthoses, hallux valgus, pain

ASEAN J Rehabil Med. 2022; 32(2): 69-73.

Introduction

Hallux valgus represents the most common forefoot deformity. The prevalence of this disease is 23-35 percent in the population aged over 18 years old.[1] The overall deformities of hallux valgus are a valgus deviation of the big toe, a pronation of the big toe, and a prominent medial aspect of the first metatarsophalangeal joint formed by a pronation of the first metatarsal bone with imbalanced intrinsic-extrinsic foot muscles and a ligamentous structure of the first ray.[2] The etiology of this disease is still not fully understood, but the predisposing factors of the disease include types of footwear, occupations, history of trauma, pes planus, and ligamentous laxity.[2] Hallux valgus can be both symptomatic and asymptomatic. Up to 75% of symptomatic patients complain about bunion pain or pain on the medial prominent of the first metatarsophalangeal joint.

The first-line treatments of hallux valgus/bunion are conservative methods,[3-5] such as modification of footwear, a specific hallux night splint,[6] a toe separator,[6-8] kinesiotaping,[9-10] manipulative therapy,[11] and a toe sleeve. A toe separator helps reduce the abduction of the big toe with a less prominent bunion. A custom-molded toe separator and a combined toe separator with a custom-molded insole are reported to help reduce pain and improve patients' abilities.[6,8] A toe sleeve is a silicone tube expanded to cover the bunion area and acts as a bumper between the bunion and the footwear.[12] Combined with the footwear modification, the toe sleeve can reduce compression and attrition between the footwear and the bunion, alleviating bunion pain as a result.[12]

Nowadays, there are many prefabricated foot-toe orthoses for treatment of hallux valgus or painful bunion available. People can buy at drug stores without need of doctor's prescription. Based on our observation, the toe sleeve might reduce the pain at the bunion better than the toe separator

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Received: 4th July 2021 Revised: 1st October 2021 Accepted: 31st January 2022

due to direct reduction of attrition between bunion and shoe. However, there have been no studies comparing between the use of a prefabricated toe sleeve and a prefabricated toe separator. This study aimed to compare clinical outcomes between the above-mentioned foot-toe orthoses.

Methods

We conducted a single-blinded randomized controlled trial at Ramathibodi Hospital, Thailand, between 2015-2017. After approved by the Institute Review Board of Ramathibodi Hospital, and the trial was registered in the Thai Clinical Trials Registry with the ID TCTR20200506003.

Participants

We enrolled patients with hallux valgus. The diagnosis of hallux valgus was confirmed by the weightbearing foot radiograph demonstrating either an intermetatarsal angle over 9 degrees or hallux valgus angle over 15 degrees.[12] The inclusion criteria were age between 25 and 70 years old, and a complaint of bunion pain. We excluded patients with osteoarthritic changes of the first metatarsophalangeal joint, a history of significant foot injury that affected their normal abilities, neuromuscular disorders, inflammatory joint disease, post infection of the first metatarsophalangeal joint, and allergies to non-steroidal anti-inflammatory drug (NSAIDs) acetaminophen and silicone. Drop out criteria were the patient who did not use foot-toe orthoses or not come to follow-up as schedule.

The sample size was calculated by using the mean visual analog scale (VAS) score from a study of Tehraninasr et al.[6] with alpha = 0.05 and beta = 0.10. The calculated sample size was 18 participants per group.

Randomization

The randomization was done by using a block size of four, generated by STATA 11.0 and concealed by an opaque envelope.

Intervention

The recruited patients were divided into two groups: a toe sleeve and a toe separator group. All participants were instructed to use the prescribed orthosis for at least 7 hours a day, 5 days a week, especially while doing physical activities, such as walking, running, or standing for a long period of time, and record the duration of usage in the logbook. Both groups were advised to wear shoes of one size larger to prevent overstuffing of the foot-toe orthosis and instructed to take either 500 mg of acetaminophen orally every 6 hours or 250 mg of naproxen twice a day after every meal for severe pain and record in a logbook.

The participants' baseline characteristics were recorded. The participants were followed up at one- and three- month for assessment of VAS and visual analog scale-foot and ankle (VAS-FA) after using the prescribed orthosis.

Materials

In the toe separator group, the participants were instructed to wear a prefabricated toe separator, a standard size firm curve silicone rubber (e-life orthopedic, Taiwan) (Figure 1 A).

In the toe sleeve group, the participants were instructed to wear a soft, stretchable fabric fully coated with proprietary polymer gel and one-sided recess to cover the bunion area, size L/XL (SILIPOS, USA) (Figure 1 B). Both foot-toe orthoses were approved by the Thai-FDA.

Outcomes

VAS and the Thai version of VAS-FA were the primary outcomes of the study. VAS was rated by the participants to quantify bunion pain, ranged from 0 (no pain) to 100 (extreme pain). The Thai version of VAS-FA is a validated functional scale which consists of 20 questions about pain (4 questions), functions/abilities (11 questions) and other complaint (5 questions).[13] The total point for entire scaling system is 2,000 points which is then divided by 20, resulting in score ranging 0 (extreme pain and limited function) to 100 (no pain and normal functions).[13]

In addition, patient adherence to the instruction of using the prescribed orthosis, the daily usage (hours), was recorded by participants in a provided logbook.

Statistical methods

The means of both VAS and VAS-FA at baseline were compared by student's t-test. The mean adherence in terms of usage hour was compared by student's t-test. Comparison the mean of VAS and VAS-FA in each group at baseline, and 1 and 3 months after treatment was done using repeated ANOVA. Comparison the mean of VAS and VAS-FA between the toe sleeve and the toe separator groups was done using ANCOVA, taking into account the significant difference at baseline of VAS-FA and possible confounding effects by

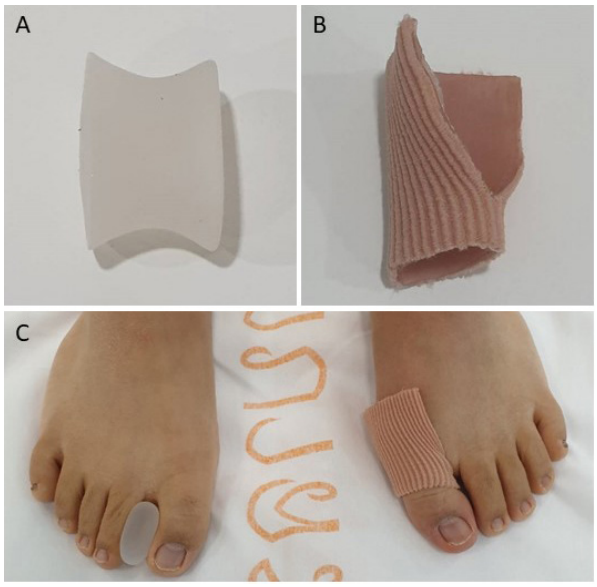

Figure 1. Two types of foot-toe orthoses used in this study: (A) a toe separator, (B) a toe sleeve and (C) showing how the orthoses are used

adherence to treatment. All statistical analyses were done by SPSS version 15 with statistical significance defined as $p < 0.05$. The participants were analyzed based on the intention-to-treat principle.

Results

Thirty-six participants were included in this study. All were female except one male participant in the toe separator group. There was no significant difference in the mean values of the baseline characteristics, hallux valgus angle, intermetatarsal angle, and VAS as shown in Table 1. The ranges of VAS were 13 to 84 in the toe sleeve group and 21 to 91 in the toe separator group. The baseline VAS-FA was, however, significantly different between the two groups, with the means of 53.72 and 75.89 ($p < 0.01$) in the group treated with a toe separator and the group treated with a toe sleeve, respectively (Table 1). There was no participant dropout during the study (Figure 2).

Within group analysis

The mean VAS-FA of both groups increased significantly at both follow-ups (Table 2). respectively. When using repeated-measure ANOVA, both groups were significantly different across the three time points. Post-hoc analysis shown a significant increase of VAS-FA at 1-month follow-up compared to baseline in the toe sleeve group whereas in the toe separator group VAS-FA was increased significantly at 3 months follow-up (Table 3).

Comparison between groups

By using ANCOVA, mean VAS was significant difference between the two groups at 1-month ($p = 0.01$) and 3-month follow-up ($p < 0.01$) (Table 4).

When comparing the mean VAS-FA between two groups at 1-month and 3-month follow-ups (Table 4), no significant difference was observed between the two groups at both time points ($p = 0.10$ and 0.59).

Table 1. Baseline characteristics, baseline disease profile and adherence: mean and standard deviation.

	Toe-sleeve (N = 18)	Toe-separator (N = 18)	*p*-value
Age (years)	51.50 (12.00)	48.00 (12.00)	0.38
Body mass index (Kg/m^2)	21.44 (2.06)	20.61 (2.09)	0.23
IMA (degree)	14.50 (2.40)	14.11 (1.50)	0.56
HVA (degree)	28.11 (5.00)	28.22 (4.00)	0.94
VAS (mm)	55.72 (20.86)	66.00 (14.68)	0.09
VAS-FA (mm)	75.89 (14.01)	53.72 (10.65)	< 0.01*

IMA, intermetatarsal angle; HVA, hallux valgus angle; VAS, Visual analoque scale; VAS-FA. visual analogue scale-Foot and ankle (Thai)
p-value comparing the mean between two groups.

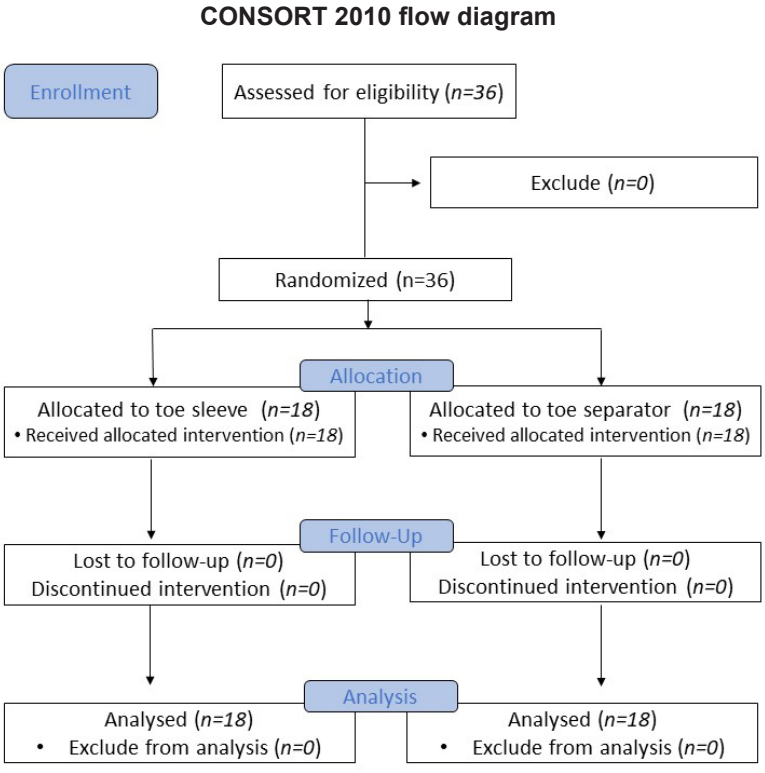

Figure 2. Flowchart of the trial

Table 2. Comparison of VAS and VAS-FA in each group: mean and standard deviation

	Toe sleeve group		Toe separator group	
	VAS	VAS-FA	VAS	VAS-FA
Baseline[1]	55.72 (20.86)	75.89 (14.01)	66.00 (14.68)	53.72 (10.65)
at 1-month FU	21.72 (11.64)	88.67 (12.03)	42.67 (25.72)	65.33 (18.11)
at 3-month FU	19.33 (9.61)	83.83 (11.78)	42.17 (24.58)	71.17 (12.65)
p-value*	< 0.01	0.01	< 0.01	< 0.01

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
p-value comparing the same device at different times

Table 3. Post-hoc analysis (pairwise comparisons)

	Toe sleeve group		Toe separator group	
	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value
VAS				
Baseline - 1-month FU	34 (20.33-47.67)	< 0.01	23.33 (9.41-37.25)	< 0.01*
Baseline - 3-month FU	36 (22.94-49.83)	< 0.01	23.83 (10.67-37.00)	< 0.01*
1-month FU - 3-month FU	2.39 (-1.39-6.17)	0.33	0.50 (-37.00- -10.67)	1.00
VAS-FA				
1-month FU - baseline	12.78 (7.85-17.71)	< 0.01	11.61 (-0.23–23.46)	0.55
3-month FU - baseline	7.944 (-0.05–15.93)	0.05	17.44 (9.35–25.54)	< 0.01*
3-month FU - 1-month FU	-4.83 (-11.27–1.60)	0.19	5.83 (1.07-10.59)	0.01*

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
Negative mean difference of VAS-FA means worse

Table 4. Comparison of VAS and VAS-FA between the toe sleeve and the toe separator groups: mean and standard deviation

	Toe sleeve group	Toe separator group	*p*-value
VAS			
at 1-month FU	21.72 (11.64)	42.67 (25.72)	0.01*
at 3-month FU	19.33 (9.61)	42.17 (24.58)	< 0.01*
VAS-FA			
at 1-month FU	88.67 (12.03)	65.33 (18.11)	0.10
at 3-month FU	83.83 (11.78)	71.17 (12.65)	0.59

p-value compared between devices at the same period; FU, follow-up

Patient adherence and use of pain medication

In terms of patient adherence to the instruction of using a toe sleeve/toe separator and taking pain medication, there was no significant difference between the two groups with the mean foot-toe orthosis usage of 38.17 (19.65) hours per week in the toe separator group and 36.63 (22.56) hours per week in the toe sleeve group (p = 0.83). There was no reported use of pain medication nor any problems e.g. discomfort from the foot-toe orthoses during the study.

Discussion

In theory, toe sleeve could reduce the pressure on the bunion by padding that covers the bunion and toe separator could reduce the pressure by reduced the deformities of the hallux valgus.[6,12] Here, our study compared the usage of foot-toe orthoses between a toe sleeve and a toe separator using the pain VAS for self-rating painful bunion and the Thai version of VAS-FA for self-assessment of foot and ankle functions. We found that both orthoses could reduce pain and improve function after using them for a month. A comparison between the two orthoses revealed that the toe sleeve had superior outcomes in terms of VAS and VAS-FA over the toe separator, although the baseline VAS-FA of the toe sleeve treatment group was better than that of the toe separator treatment group.

Tehraninasr et al. concluded that a toe separator could reduce pain after three months of follow-up from baseline.[6] The foot-toe orthoses in their study was custom fabricated and used with semi-rigid insole but our study used prefabricated foot-toe orthoses but still can relieved pain and improved functions of patients.

The data show that there were no differences in the VAS and VAS-FA scores when comparing between at one-month and at three-month follow-ups in both groups. The patients still had pain but less, improved functions but still had some limitation. This might be because the foot-toe orthoses could help relieved the pain from the deformities but not totally corrected them so the pain and limitation of functions were not totally resolved.

In terms of the adherence and pain relievers, we found no significant difference in both outcomes between the two groups. Both could treat hallux valgus patients without any reported problems. The foot-toe orthoses in our study were prefabricated and easy to wear. The mean usage hours per week of both foot-toe orthoses were closed to the report by Chadchavalpanichaya et al. in the 3-month follow-up but after 3 months the adherence from their study was decrease.[8] Our study may need more follow-up time to evaluate the adherence in long term.

Our study is a randomized controlled trial with a specific attention to only painful bunion in hallux valgus patients who completed the protocol. The outcomes of our study were measured in reference to the patients' pain and functions. Our limitations were that the majority of the study participants had mild to moderate degrees of hallux valgus, and could not be extrapolated to the patients with severe hallux valgus. Type of footwear of each patient was not evaluated as a baseline characteristic. The follow-up period was only 3 months. A longer period of follow-up, evaluation the type of footwear and inclusion of more types of prefabricated foot-toe orthoses may need to be studied in the future.

In conclusion, daily use of a prefabricated toe separator or a toe sleeve significantly decreased pain and improved the functional mobility of patients with mild to moderate degree of hallux valgus patients and bunion pain. The toe sleeve better relieved pain than the toe separator did in patients with hallux valgus after one month of usage and the pain reduction was maintained at three months.

Disclosure

The authors declare no related activity with or benefits from companies producing the foot-toe orthoses used in the study.

Acknowledgements

I would like to thank Ms Peeranuch Thibaud and Dr Nattaphong Rattanavirotkul for their helpful efforts as proofreaders for the manuscript.

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