Original Article

Effectiveness of Prefabricated Silicone Toe Separator on Hallux Valgus

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ABSTRACT

Objectives: To determine effectiveness of a prefabricated silicone toe separator to decrease hallux valgus angle (HVA) |and hallux pain, and also investigate possible complications, compliance, and users' satisfaction.

Study design: Prospective cohort analytical study design

Setting: Foot Clinic, Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital

Subjects: Forty patients with hallux valgus deformity at moderate level (HVA 20°- 40°) were recruited from February to March 2019.

Methods: The participants were asked to wear a prescribed prefabricated silicone toe separator in proper shoes 6 hours a day for 12 months, and continue their current medication and treatment regimen. They had to record the duration of wearing the toe separator and complications in a logbook on a weekly basis. Follow-up pain numeric rating scale (pain NRS) and HVA measured from radiography were evaluated at 6 months, and 12 months after receiving the device.

Results: Thirty-eight participants returned for follow-up at a 6-month and 33 participants continued until the end of the study. Based on per protocol and intention to treat analyses, the results showed no progression of HVA. Pain at the 1st metatarsophalangeal joint decreased with a statistically significant difference ($p < 0.001$) at 12 months. Nearly 60% of participants had minor complications. The common complication was discomfort at the 1st web space.

Conclusion: Wearing a prefabricated silicone toe separator in proper shoes for a year in patients with a moderate degree of hallux valgus could prevent the progression of hallux valgus angle and decrease hallux pain without serious complications.

Keywords: hallux, hallux valgus, pain, orthotic device, foot

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Introduction

Hallux valgus is a common forefoot deformity described as a static subluxation of the first metatarsophalangeal (MTP) joint, characterized by lateral deviation of the great toe and medial deviation of the first metatarsal bone.(1) Intrinsic factors include age,(2) female,(3-4) pes planus,(5-6) tightness of the Achilles tendon,(7) degenerative joint disease at the first MTP joint,(6) ligamentous laxity,(8) and first-ray hypermobility.(9) A family history is a major risk factor of the disease.(10,11) Extrinsic factors include shoe-wearing behaviors,(12) and wearing ill-fitting shoes.(13-15) A heel height of 6 cm or above could also be related to hallux valgus formation.(16) In addition, hallux valgus is associated with excessive walking and weight-bearing.(17)

Goals of treatments for those with hallux pain and progression of hallux deformity are symptomatic pain relief and correction or prevention of the progression of hallux deformity. Conservative treatments relieve patients' symptoms, reduce operative rates and potential operative complications.(10) However, conservative treatments cannot reverse hallux valgus deformity,(18) but decrease progression of disease.(19,20) The conservative treatments include well-fitting shoes with a wide and deep toe box,(21) and foot orthoses.(22) Additional options are soft tissue stretching and muscle strengthening/ retraining exercises, and also therapeutic cold modality.(22) Various orthoses, such as insoles, hallux valgus strap, and toe separators, have been prescribed.(23) Previous literatures reported the effectiveness of a total contact insole with fixed toe separator in relieving pain,(19,20) and improving toe alignment and walking ability.(19)

Our previous study revealed that wearing a custom-mold room temperature vulcanizing (RTV) silicone toe separator for a year decreased the hallux valgus angle (HVA) and hallux pain in patients who had a moderate degree of hallux valgus.(24) In general practice, this orthotic device has to be prescribed by a physician and made by an orthotist. This makes it difficult for patients to access to the treatment. For convenience, many physicians prefer to prescribe prefabricated orthotic devices with acceptable prices. However, there are no studies reporting effectiveness of a prefabricated silicone toe separator to decrease the HVA progression. Therefore,

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the primary objective of this study was to determine the effectiveness of the prefabricated silicone toe separator in decreasing the HVA progression in individuals diagnosed with hallux valgus. In addition, this study would also monitor hallux pain (pain of the great toe), related complications, patient's compliance and satisfaction with the prefabricated silicone toe separator.

Methods

The study protocol was reviewed and approved by the Institutional Review Board at Siriraj Hospital, Bangkok, Thailand (Si597/2018) and supported by the Research Division, Faculty of Medicine Siriraj Hospital, Mahidol University.

Participants

Forty patients who had hallux valgus and visit the Outpatient Foot Clinic, Siriraj Hospital from February to March 2019 were recruited to participate in the study. A physiatrist performed a complete foot examination and provided the clinical diagnosis of hallux valgus.

Inclusion criteria

- Age not less than 18 years old
- A moderate degree of hallux valgus (HVA: 20°- 40°)

Exclusion criteria

- Having foot numbness or foot ulcers
- Having acute inflammation of the first MTP joint
- Having hallux rigidus or hallux limitus
- Continuous usage of any types of toe separator or hallux valgus strap in the past year
- Having silicone allergies
- History of hallux valgus surgery

If the condition presented on both sides, the one with a greater HVA measured with a goniometer was selected.

Sample size calculation

The sample size was determined by using Independent Student's t-test. Sample size calculation was based on the results of a previous study.[24] based on a power of 0.80 to detect a significant difference (5% type I error, $p = 0.05$, two-sided), 33 patients were required for this study. The recruited sample size was 40 subjects with an estimated 20% drop-out. The clinically important difference in HVA was 5°.

Materials

Two different sizes of a prefabricated silicone toe separator (size M and L) (Figure 1) The prefabricated silicone toe separator selected for this study was 00-120 toe retractors, I-M® brand. It is a single unit of a toe separator and made of medical-grade silicone to maximize comfort when used. Size M was selected for those who had a foot length of 22.5-26 cm and size L for a foot length of 26-30 cm.

Study protocol

Once the study was approved, an information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained prior to the study. Correspondingly, the participants were recommended to wear a prefabricated silicone toe separator every day for at least 6 hours per day during daytime or nighttime, and recommended to wear proper shoes; i.e. low-heel shoes with a wide-and-deep toe box without termination of current drug use.

To ensure that the device fit properly for each participant, a trial was provided for each participant to wear it and walk for 5 to 10 minutes, and then an appropriate size was prescribed accordingly. The participants were asked to record the duration of wearing the toe separator and complications caused by the device in a log book on a weekly basis. If irritation or discomfort occurred, they were instructed to contact the researcher immediately.

At baseline, demographic data were collected, as well as, average hours of wearing walking shoes, current types of daily-used shoes, side of hallux deformity, duration of hallux valgus, family history, and complications/ problems related to hallux valgus.

The primary outcome measured in this study was the HVA, which was measured with a weight-bearing anteroposterior radiograph (Figure 2).[1] The progress evaluation on HVA was done at baseline, 6-month and 12-month follow-up. The HVA was measured by two well-trained physiatrists who did not assess nor treat the participants. The angles measured by the two assessors were averaged and used for further analyses.

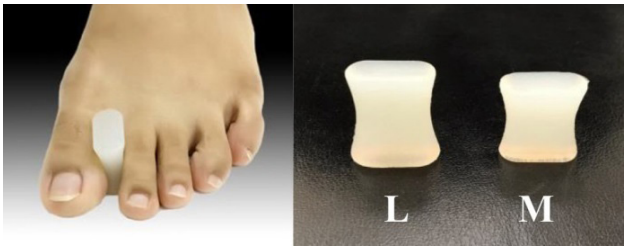

Figure 1. The prefabricated silicone toe separator between the great and the second toes (left), and two different sizes: L (large) and M (medium) (right)

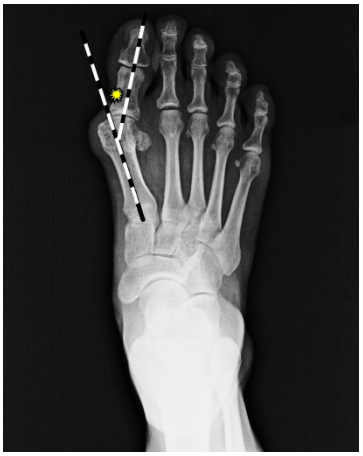

Figure 2. The hallux valgus angle (HVA) measures demonstrated on a weight bearing anteroposterior (AP) radiographs.

The secondary outcomes were hallux pain, compliance, complications related to using the toe separator, and satisfaction. At baseline, 6-month follow-up, and 12-month follow-up, hallux pain experienced within the last 24 hours was scored from 0 (no pain) to 10 (worst pain). Patient compliance was measured with daily usage of the toe separator, which was then averaged as weekly use and recorded in the logbook. Any complications caused by the device such as abrasions or rashes were also recorded. At the end of the study, patient's satisfaction in seven sub-domains - pain reduction, cosmetic appearance of the device, convenience in wearing, maintenance, durability, fitting and overall satisfaction, were recorded. The NRS was scored as 0 (dissatisfaction) to 10 (most satisfaction). Intentions for future use as well as suggestions for improving the quality of the device were also reported.

Statistical analysis

All statistical analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA) and a *p* value of less than 0.05 was considered as statistically significant difference. Age, BMI, HVA and patient compliance in using the prefabricated silicone toe separator (hours/day) were calculated by means and standard deviations (SD). The median (range) was calculated for duration of hallux valgus problem (months), pain at the 1st MTP joint and patient satisfaction (NRS from 0 to 10). Gender, daily activities, current types of daily-used shoes, sides, complications and problems from hallux valgus, results from foot examinations and any complications from the toe separator usage were calculated as a number and percentage. For demographic data, an unpaired t-test and Mann–Whitney test were used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Additionally, Fisher's exact test and chi-square test were performed to analyze the differences of categorical data. To explore the primary outcome of HVA, as measured in degrees, were reported by both per protocol (PP) and intention-to-treat (ITT) analysis. A repeated-measures analysis of variance (ANOVA) was used to analyze the differences between at baseline, 6-month and 12-month follow-up. To explore the secondary outcomes of hallux pain, compliance, complication, and satisfaction, the Friedman test was performed, and Bonferroni correction for multiple comparisons was used to analyze the difference of the data at baseline, 6-month and 12-month follow-up.

Results

Forty participants enrolled in the study. Thirty-eight and 33 participants returned to follow-up at 6-month and 12-month, respectively. Two participants lost contact at 6-month follow-up. Five participants dropped out at 12-month follow-up, two of them due to pain, one of them due to difficult to transport and two of them lost contact. The characteristic data and foot problems of the participants are shown in Table 1. The majority

Table 1. Demographic data of all 40 participants

Characteristics	
Age (year)[1]	52.3 (13.5)
Gender[2]	
Female	36 (90)
Body mass index (kg/m^2)[1]	23.0 (3.2)
Daily activity/working[2]	
Mostly standing/ walking with shoes wearing	20 (50)
Mostly sitting	17 (42.5)
Mostly standing/ walking with bare feet	3 (7.5)
Current types of daily-used shoes	
Types[2,*]	
Closed toe	24 (60)
Open toe	10 (25)
Wide toe box	26 (65)
Narrow toe box	6 (15)
Shoe height (inch)[2,*]	
< 2	33 (82.5)
≥ 2	2 (5)
Hallux vulgus	
Side[2]	
Right	9 (22.5)
Left	12 (30.0)
Bilateral	19 (47.5)
Duration (month)[3]	120 (6, 840)
Family history[2]	
Yes	23 (57.5)
Complications related to hallux valgus[2,**]	
Pain	
Pain at the 1st metatarsophalangeal joint	18 (45)
Metatarsalgia	10 (25)
Pain at bunion from shoe compression	26 (65)
Friction ulcer at	
Bunion from shoe compression	3 (7.5)
1st web space Maceration at 1st web space	2 (5)
Paronychia	2 (5)
Nail thickening	2 (5)
Callus	1 (2.5)
Toe riding (when wearing shoe)	8 (20)
Shoes-fitting problems	7 (17.5)
Cosmetic problem	18 (45.0)
	17 (42.5)
Foot examination[2, **]	
Tenderness at	
1st metatarsal head	3 (7.5)
2nd-5th metatarsal head	5 (12.5)
Callus at	
Medial side of 1st toe	22 (55)
1st metatarsal head	25 (62.5)
Tip of 2nd-5th toes	3 (7.5)
2nd-5th metatarsal heads	18 (45.0)
Callus at	
Medial side of 1st toe	22 (55)
1st metatarsal head	25 (62.5)
Tip of 2nd-5th toes	3 (7.5)
2nd-5th metatarsal heads	18 (45.0)
Maceration at 1st web space	2 (5)

[1]Mean (SD), [2] number (%), [3]median (min, max)
[*]Some patients wore more than one type of shoes,
[**]Some patients had more than one problem

Table 2. Hallux valgus angle at baseline, 6 and 12-month follow-up

	Per protocol (n=33)		*p*-value	Intention to treat (n=40)		*p*-value
Hallux valgus angle (degrees)	Baseline	29.3 (5.4)	0.846[a]	Baseline	28.7 (5.6)	0.797[a]
	Month 6	29.3 (7.1)		Month 6	28.5 (7.6)	
	Month 12	28.9 (6.9)		Month 12	28.2 (7.5)	

Mean (SD)

[a]*p*-value analyzed by repeated-measure analysis of variance (ANOVA) with the use of Bonferroni correction for multiple comparisons, statistically significant at $p < 0.05$

of the participants were females with a mean age of 52.3 (SD 13.5) years. Half of the patients had hallux valgus on both sides. The duration of hallux valgus was 120 (range 6, 840) months. The present study found that at base line the patients spent their time standing or walking while wearing shoes with an average of 7.9 (SD 4.2) hours per day. The top three most common problems from hallux valgus were pain at bunion from shoe compression (65%), pain at the 1st MTP joint (45%) and shoes-fitting problems (45%). The hallux valgus associated findings were tenderness at the metatarsal head, callus, and skin maceration at the 1st web space.

Primary outcome

The results demonstrated no progression of HVA at baseline, 6-month and 12-month follow-up, and were reported in both PP and ITT analysis as shown in table 2. From the PP analysis, means (SD) of the HVA were 29.3 (5.4) at baseline, 29.3 (7.1) at a 6-month and 28.9 (6.9) at a 12-month follow-up with no statistically significant difference ($p = 0.846$).From the ITT analysis, means (SD) of the HVA were 28.7 (5.6) at baseline, 28.5 (7.6) at a 6-month and 28.2 (7.5) at a 12-month follow-up with no statistically significant difference ($p = 0.797$).

Subgroup analyses were analyzed to evaluate whether factors: the BMI, daily activity, types of daily-used shoes, severity of HVA at baseline and compliance with the device usage, had any effects on the HVA progression. The results showed that the differences of HVA at baseline, 6 months and 12 months after treatment remained no statistical significance.

Secondary outcomes

Based on the PP and the ITT analyses, the result showed a statistically significant decrease in pain at the1st MTP joint at 12-month follow-up when compared with the baseline ($p = 0.001$) as shown in Figure 2, and when compared at 6-month follow-up. However, there was no a statistically significant decrease in pain at 6-month follow-up when compared with the baseline.

Regarding compliance with the usage of prefabricated silicone toe separator, the data from participants' logbook showed that the highest compliance was seen in the first 3 months with mean (SD) of 6.8 (1.8) hours per day and 41.3 (16.0) hours per week. The lowest compliance was in the last 3 months with mean (SD) of 6.5 (1.9) hours per day and only 37.3 (17.7) hours per week.

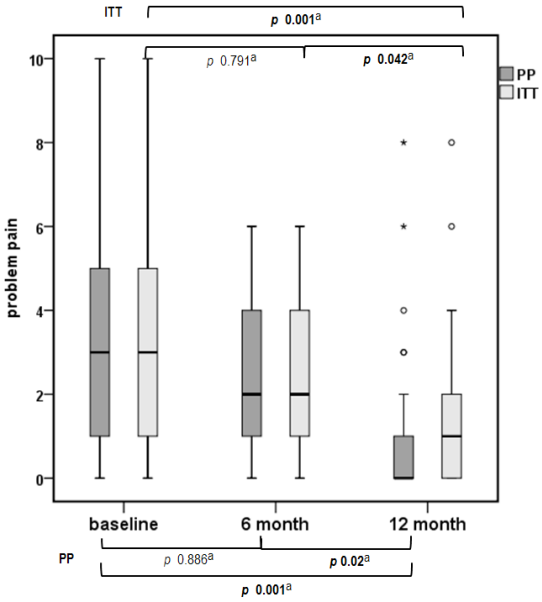

Figure 3. Pain at the 1st metatarsophalangeal joint
Measured by numeric rating scale (0- no pain, 10-the worst pain)
PP, per protocol analysis; ITT, intention to treat analysis
[a]*p*-value analyzed by Friedman test, statistically significant at $p < 0.05$

Table 3 indicates that 14 (42%) of participants had minor complications while using the device. Some patients had more than one complication; however, they did not register them as serious complications. The most common complication reported was discomfort or mild pain at the 1st web space.

The satisfaction scores with the prefabricated silicone toe separator were high in every domain. The median (min, max) satisfaction score of the overall satisfaction was 8 (2, 10). The three subdomains with highest scores were durability, pain reduction and maintenance as shown in table 4. Concerning the intention to use this device in the future, 20 participants (60%) would continue using it, 10 (30.3%) might continue using it and 3 (9.1%) would stop using it due to pain.

Table 3. Complications from using the prefabricated silicone toe separator

Complications	N (%)
No	19 (58)
Yes*	14 (42)
Discomfort or mild pain at the hallux and second toe	13
Rash/ pruritus	2
Metatarsalgia	1

N (%); number of participants = 33
*Some patients had more than one complication

Table 4. Satisfaction with the prefabricated silicone toe separator (n=33)

Categories	Satisfaction score
Pain reduction	8 (0,10)
Cosmetic appearance	7 (0,10)
Convenience	7 (0,10)
Maintenance	8 (6,10)
Durability	9 (4,10)
Fitting	7 (0,10)
Overall satisfaction	8 (2,10)

Median (min, max)
Measured with numeric rating scale (0, dissatisfied; 10, mostly satisfied)

Discussion

Over time, hallux valgus usually progresses to hallux valgus deformity by increasing the HVA because of the instability of the 1st MTP joint. Wearing proper shoes seems not prevent such deformity as our study followed the HVA of those who had a moderate degree of hallux valgus for 12 months and found significantly increased HVA in the control group and but those who used a custom-mold silicone toe separator had the HVA reduction in 6 months.[24] In Thailand, an access to a custom-mold silicone toe separator is limited.

Therefore, in this present study, we focused on evaluating effectiveness of wearing a prefabricated silicone toe separator which is available at drug stores with affordable price, around 250 Baht. We assumed that the custom-mold and the prefabricated silicone toe separators have a similar effect in decreasing the progression of HVA and hallux pain as both allow soft tissues and nerves on the medial and the lateral aspects of the hallux to return to a more anatomical position,[20] thus prevent shortening of the soft tissues on the lateral aspect of the hallux, and overstretching of the soft tissues and the nerves located on the medial aspect, and subsequently reducing the hallux pain.

The results from using the prefabricated silicone toe separator in the present study showed no progression of HVA at 6 and 12 months whereas the previous study revealed that the custom-mold RTV silicone toe separator could reduce the HVA.[24] The reason may be due to the fact that the prefabricated silicone toe separator could not exactly fit each patient's toes. When compared with the custom-mold toe separator,[24] our study showed higher rate of complications (42% vs 20%) especially in discomfort and lower compliance (6.5 vs 7 hours/day, 37.3 vs 45 hours per week). This might be caused by slippage or incorrect position of the device causing shearing force and leading to pain over affected toes in long term use.[24] However, such problems were resolved by decreasing the duration of use or wearing socks. And, thus more than half of the participants intended to continuously use this device.

Although the prefabricated silicone toe separator used in this study could not reduce the HVA but it could effectively reduce hallux pain. In addition, it has some advantages as one could buy it over the counter and it costs less than a custom-mold one.

The present study had some limitations in. as its design was a cohort analytical study and has no control group. For stronger evidence a randomized controlled trial should be conducted.

In conclusion, using a prefabricated silicone toe separator for a year in patients with a moderate degree of hallux valgus could prevent the progression of hallux valgus angle and decrease hallux pain with mild complications.

Disclosure

The authors declared no potential conflicts of interest with respect to the materials used in this research study, authorship, and/or publication of this article.

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