Original Article

An Observational Longitudinal Study Investigating the Effectiveness of Adjustable Splint on Individuals with Hallux Valgus

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ABSTRACT

Objectives: To explore the effectiveness of an adjustable splint to decrease hallux valgus angle and pain at the first metatarsophalangeal joint. In addition, to discover complications and participants' satisfaction

Study design: Prospective cohort analytical study design

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

Subjects: Thirty-eight patients with hallux valgus deformity at moderate to severe degrees (hallux valgus angle 30°- 50°) were recruited from March to May 2021.

Methods: The participants were asked to use an adjustable splint for 6 hours daily for 12 months and continue their current treatment regimen. They were also asked to record the duration of wearing the splint and complications in a logbook every week. Hallux valgus angle measured from radiography and pain numeric rating scale (pain NRS) were evaluated at baseline, 6 months, and 12 months after getting the splint.

Results: Thirty-two participants returned for follow-up at the end of the study. Per protocol and intention to treat, analyses showed a decreased hallux valgus angle and pain at the first metatarsophalangeal joint with a statistically significant difference (p = 0.001). The satisfaction scores with the adjustable splint were high in every domain. No participant had serious complications. The common complication was splint slip (33.3%).

Conclusions: Wearing an adjustable splint for 12 months in patients with moderate to severe degrees of hallux valgus could decrease hallux valgus angle and pain at the first metatarsophalangeal joint without serious complications.

Keywords: foot deformity, hallux valgus, pain, adjustable splint, orthotic device

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Introduction

Hallux valgus is a common forefoot problem. This deformity is described as a static subluxation of the first metatarsophalangeal joint, characterized by lateral deviation of the first toe and medial deviation of the first metatarsal bone.[1] This condition is a slow progressive deformity.[2]

The severity of hallux valgus can be classified into mild, moderate, and severe degrees from clinical presentations (such as degree of the first toe rotation) and hallux valgus angle from radiography.[3]

The causes of hallux valgus deformity are multifactorial such as age,[4] female,[5] pes planus,[6] tightness of the Achilles tendon,[7] degenerative of the first metatarsophalangeal joint, ligamentous hyperlaxity, first-ray hypermobility,[8] and cerebral palsy. Family history is a major risk factor. Improper shoe-wearing behaviors, especially pointed, high-heeled shoes, are also important causes.[9,10] Hallux valgus occurs in women 15 times more than in men.

Many problems occur with the hallux valgus deformity, such as pain at the first metatarsophalangeal joint, friction between bunion and shoe, friction at the first web space, neuropathic pain from over-stretching of medial cutaneous nerve, bursitis, callus, metatarsalgia and overriding of the second toe on the first toe.

The primary objectives of treating individuals with hallux valgus are to alleviate symptomatic pain and correct or prevent the progression of the deformity. Conservative treatment options include wearing properly fitting shoes with a wide toe box, as well as utilizing foot orthoses. Previous studies have demonstrated the effectiveness of total contact orthoses with fixed toe separators in relieving pain,[11,12] improving toe alignment, and enhancing walking ability.[11] Other conservative measures encompass soft tissue stretching, muscle strengthening exercises, and therapeutic modalities. Various orthoses such as toe separators, hallux valgus splints, and hallux valgus straps have been prescribed.

In a previous study conducted by Chadchavalpanichaya N, it was found that wearing a custom-mold room temperature vulcanizing silicone toe separator for a duration of one year resulted in a decrease in hallux valgus angle and alleviation of big toe pain in patients with a moderate degree of hallux valgus.[13] However, this device required customization by a

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skilled orthotist and came at a cost of approximately 50 USD per piece. This posed a challenge for patients seeking access to the device. For more convenience, many physicians prefer to prescribe prefabricated orthotic devices. The study from Kandang C discovered that wearing a prefabricated silicone toe separator for a year can decrease the progression of the hallux valgus angle. However, this prefabricated device is suitable only for patients with mild to moderate hallux valgus.[14] Another study from Chadchavalpanichaya N and Chueluecha C revealed that wearing a prefabricated elastic hallux valgus strap for a year can decrease pain at the first metatarsophalangeal joint. However, this device cannot decrease the progression of the hallux valgus angle more than using only wide-toe box shoes.[15]

An alternative prefabricated orthotic device is an adjustable hallux valgus splint. This device is made of plastic and lined with soft foam to provide cushioning. This splint has two soft bands for strapping it with a foot and a big toe. Since this orthotic device has a joint, it can be adjusted along the angle of hallux deformity.

The study from Plaass C revealed that wearing an adjustable hallux valgus splint in patients who had big toe pain for three months can decrease the pain. This orthosis cannot decrease the hallux valgus angle.[16] Another study from Moulodi N compared the effectiveness of an adjustable hallux valgus splint and a non-adjustable one.[17] The study presented that wearing an adjustable splint can decrease the hallux valgus angle and pain at the first metatarsophalangeal joint when walking more than wearing a non-adjustable one. However, this study collected the data after wearing the splint for only a month and used a goniometer instead of a radiograph for monitoring hallux valgus angle. Furthermore, the average age of the population in this study was 22 years old. This age group is not the expected population in clinical practice.

However, no study reports the effectiveness of an adjustable hallux valgus splint to decrease the hallux valgus angle progression in patients with a moderate to severe degree of hallux valgus.

Therefore, the primary objective of this study was to determine the effectiveness of the adjustable hallux valgus splint in decreasing the hallux valgus angle progression in individuals diagnosed with moderate to severe degree hallux valgus. In addition, this study would also monitor pain at the first metatarsophalangeal joint, related complications, patient compliance, and satisfaction with the adjustable hallux valgus splint.

Methods

The study protocol was reviewed and approved by the Institutional Review Board at Siriraj Hospital, Bangkok, Thailand (Si 1063/2020).

Study design

Prospective cohort analytical study design

Participants

Thirty-eight patients who had hallux valgus and visited the Foot Clinic, Siriraj Hospital from March to May 2021 were recruited to participate in this study. A physiatrist performed a foot examination and provided the clinical diagnosis and severity of hallux valgus.

Inclusion criteria

- Age not less than eighteen years old
- Having moderate to severe degree of hallux valgus (hallux valgus angle: 30°– 50°)
- Be detected hallux valgus for more than 5 years.

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

Exclusion criteria

- Having acute inflammation of the first metatarsophalangeal joint
- Having limitation of the first metatarsophalangeal joint ROM
- Having active foot numbness or foot ulcer
- Having ulcer or maceration at the first web space
- Continuous usage of any type of hallux valgus strap or toe separator in a past year
- History of hallux valgus surgery
- Having a condition that cannot answer the questionnaire

Sample size calculation

To determine the proper sample size, the Independent Student's t-test was utilized, taking into account the results of a previous study.[13] Based on a power of 0.80 to detect a significant difference with a 5% type I error (p = 0.05, two-sided), and a clinically significant difference in hallux valgus angle of 5°,[13-15] a sample size of 33 patients was calculated for this study. Ultimately, a sample of 38 participants was recruited, with a predictable 15% drop-out rate.

Materials

An adjustable splint selected for this study was a dynamic bunion splint, universal size Tynor Orthotics® brand. (Figure 1) It is made of plastic with a joint, and a cushioned pad provides cushioning for enhanced comfort. There are two soft straps for strapping a splint with a big toe and foot. It is easy to use and maintain.

Study protocol

An information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained before the study.

In the beginning, demographic data such as age, gender, type/ height of daily-used shoes, side of foot deformity, duration of hallux valgus, as well as problems related to hallux valgus such as pain at the first metatarsophalangeal joint, toe friction, and paronychia were collected. Then, a physiatrist

performed a foot examination to record the point of tenderness and callus.

After that, the participants were recommended how to use an adjustable splint and asked to wear it every day for at least six hours per day during daytime and/or nighttime and recommended to wear proper shoes: low-heel shoes with a wide-and-deep toe box. The participants were also asked to record the duration of wearing the adjustable splint and complications caused by the device in a weekly logbook. They were instructed to contact the research team directly if any complications, such as abrasion, pain, or discomfort, occurred.

The primary outcome was the hallux valgus angle, which was assessed at baseline, 6-month, and 12-month follow-up. The hallux valgus angle was measured with a weight-bearing anteroposterior radiograph. (Figure 2)[1] It was measured by two well-trained physiatrists who did not assess the participants. The angles evaluated by the two assessors were averaged and used for further analyses.

The secondary outcomes were the first metatarsophalangeal pain, friction at the bunion, friction at the first web space, compliance, complications related to the adjustable splint, and the participant's satisfaction. At baseline, 6-month follow-up, and 12-month follow-up, pain and friction experienced within the last 24 hours were scored from 0 (no pain/ friction) to 10 (worst pain/ friction). Patient compliance was measured with daily usage of the adjustable splint, which was then averaged as weekly use and recorded in the logbook. Any complications caused by the device were also recorded. At the end of the study, patient satisfaction in five sub-domains - pain reduction, convenience in wearing, cosmetic appearance, maintenance, durability, and overall satisfaction, were recorded. The NRS was scored as 0 (dissatisfaction) to 10 (most satisfaction).

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 a statistically significant difference. Age, body mass index, hallux valgus angle, and patient compliance using the adjustable splint (hours/day) were calculated by means and standard deviations (SD). The median (IQR) was calculated for the duration of hallux valgus problem (months), the first metatarsophalangeal pain, friction at the bunion, friction at the first web space, and patient satisfaction (NRS from 0 to 10). Gender, daily-used shoes, sides, hallux valgus problems, foot examination results, and any complications from the adjustable splint usage were calculated as a number and percentage.

As measured in degrees, the primary outcome of hallux valgus angle was 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 baseline, 6-month, and 12-month follow-up. The Friedman test was performed to determine the secondary outcomes of pain at the first metatarsophalangeal joint. Bonferroni correction for multiple comparisons was used to analyze the difference of the data at baseline, 6-month, and 12-month follow-up.

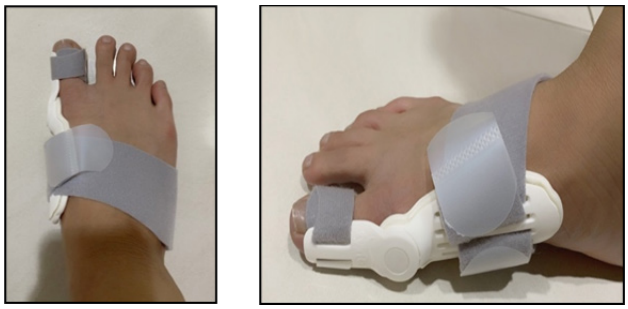


Figure 1. An adjustable splint, universal size; Tynor Orthotics® brand.

Results

Thirty-eight participants joined in the study. Thirty-three and 32 participants returned to follow-up at the hospital six months and twelve months, respectively. Five participants dropped out at 6-month follow-up: one of them due to pain, one of them due to itching, two of them due to the COVID-19 situation, and one of them lost contact. Thirty-three participants answered the questionnaires, but 32 returned to x-ray at the 12-month follow-up because one participant denied going to the hospital due to COVID-19. (Figure 3)



Figure 2. The hallux valgus angle measures were demonstrated on weight-bearing anteroposterior radiographs.

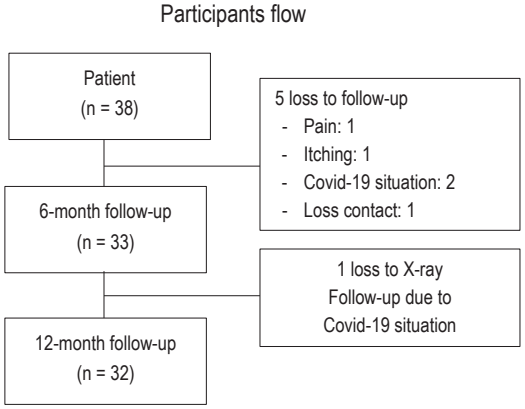


Figure 3. Participant flow

The characteristic data and foot problems of the participants are shown in Table 1. Most participants were females (97.4%) with a mean age of 63.5 years. Nearly all of the patients had hallux valgus on both sides. The median duration was 10 years. Thirty participants wore closed shoes (78.6%), and 27 were used to wearing narrow-toe box shoes (71.1%).

The top four most common problems from hallux valgus were callus (65.7%), friction at the bunion or friction at the first web space (57.8%), shoes-fitting problems or difficulty in finding comfortable shoes (52.6%), and pain at bunion from shoe compression (50%). The hallux valgus associated findings were callus at the first metatarsal head (73.7%), calluses at the medial side of the big toe (57.9%), and tenderness at the first metatarsal head (13.2%).

Table 1. Demographic data (38 patients)

Characteristics	
Age (years)[1]	63.5 (9.8)
Gender[2]	
Female	37 (97.4)
Body mass index (kg/m^2)[1]	23.2 (3.57)
Hallux valgus problem	
Duration[3]	10 (7.8, 20)
Side[2]	
Right	1 (2.6)
Bilateral	37 (97.4)
History type of used shoes[2]	
Closed toe box	30 (78.9)
Opened toe box	8 (21.1)
Wide toe box	11 (28.9)
Narrow toe box	27 (71.1)
Shoe height (inch)[2*]	
Low heel	17 (44.7)
1-2 inch	15 (39.5)
2-4 inch	4 (10.5)
> 4 inch	2 (5.3)
Complications related hallux valgus[2*]	
Pain	
Pain at bunion from shoe compression	19 (50.0)
Pain at the first metatarsophalangeal joint	8 (21.0)
Redness/ friction	22 (57.8)
Bursitis	0 (0.0)
Paronychia	4 (10.5)
Callus	25 (65.7)
Overriding toe	9 (23.6)
Cosmesis problems	14 (36.8)
Shoe fitting problems	20 (52.6)
Foot examination 2[*]	
Tenderness at	
1st metatarsal head	5 (13.2)
2nd-5th metatarsal head	1 (2.6)
Callus at	
The medial side of big toe	22 (57.9)
First metatarsal head	28 (73.7)
Tip of 2nd-5th toes	1 (2.6)
2nd-5th metatarsal heads	0 (0.0)

[*]Some patients had more than one problem.
[1]Mean (SD), [2]number (%), [3]median (interquartile range)

Primary outcome

The results demonstrated the decrease of hallux valgus angle at baseline, 6-month, and 12-month follow-up and were reported in both per protocol (PP) and intention-to-treat (ITT) analysis, as shown in Table 2. From the PP analysis, the means (SD) of the hallux valgus angle were 36.77 (6.03) at baseline, 35.87 (6.37) at a 6-month and 34.94 (6.39) at a 12-month follow-up with statistically significant difference ($p < 0.001$). From the ITT analysis, means (SD) of the hallux valgus angle were 36.55 (5.60) at baseline, 35.71 (6.03) at a 6-month and 34.95 (6.04) at a 12-month follow-up with statistically significant difference ($p < 0.001$), as well.

Secondary outcomes

Regarding pain and friction, based on the PP and the ITT analyses, the result showed a statistically significant decrease in pain at the first metatarsophalangeal joint, friction between bunion and shoes, and friction between the first web space at 6-month and 12-month follow-up when compared with the baseline ($p = 0.001$) as shown in table 3.

Regarding compliance with the usage of the adjustable splint, the data from the participants' logbook showed that the compliance was higher than being recommended, with a mean (SD) of 6.60 (1.50) hours per day and 6.5 (0.70) days per week (43.9 (11.7) hours per week).

Table 4 indicates that 15 (45.5%) participants had minor complications while using the device. They did not register them as serious complications. The most reported complication was quickly slipping a device from the first toe.

The satisfaction scores with the adjustable splint were high in every domain. The median (IQR) overall satisfac-

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

	Per protocol		*p*-value	Intention to treat		*p*-value
Hallux valgus angle (degrees) Mean (SD)	Baseline (n=38)	36.77 (6.03)	< 0.001[a]	Baseline (n=38)	36.55 (5.60)	< 0.001[a]
	Month 6 (n=33)	35.87 (6.37)		Month 6 (n=38)	35.71 (6.03)	
	Month 12 (n=31)	34.94 (6.39)		Month 12 (n=38)	34.95 (6.04)	

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

Table 3. Pain at the first metatarsophalangeal joint, friction between bunion and shoe, friction between 1st webspace measured by numeric rating scale (0 as lowest symptoms, 10 as the most severe symptoms) at month 0, month 6 and month 12 follow-up

	Per protocol			*p*-value	Intention to treat			*p*-value
	Baseline (N=38)	Month 6 (N=33)	Month 12 (N=32)		Baseline (N=38)	Month 6 (N=38)	Month 12 (N=38)	
Hallux valgus pain	3 (0-3)	0 (0-1)	0 (0-1)	< 0.001	2.5 (0-3)	0 (0-1.3)	0 (0-1)	< 0.001
Friction between bunion and shoe	3 (2-5)	2 (1-3)	2 (1-2)	< 0.001	3 (2-5)	2 (1-3)	2 (1-2.3)	< 0.001
Friction between 1st webspace	2.5 (0.3-5)	2 (0.3-3)	2 (0.3-3)	< 0.001	2.5 (0-5)	2 (0-3)	1.5 (0-3)	< 0.001

Median (interquartile range); *p*-value analyzed by Friedman test, statistically significant at $p < 0.05$

Table 4. Complications and problems of using the hallux valgus adjustable splint

Complications	N (%)
No	18 (54.5)
Yes	
Easily to slip	11 (33.3)
Discomfort or mild pain at the bunion	3 (9.0)
Rash	1 (2.6)

N (%): number of participants = 33

Table 5. Satisfaction with an adjustable splint (n = 33)

Type median (interquartile range)	Satisfaction score
Pain reduction	7 (6-8)
Convenience in wearing/ easy to use	9 (7.5-9)
Cosmesis appearance	8 (7-9)
Maintenance	9 (8-9)
Durability	7 (7-8)
Overall	8 (7-8)

Measured by a numeric rating scale (0 as dissatisfied, 10 as the most satisfied)

tion score was 8 (7-8). The two subdomains with the highest scores were easy to use and maintain, as shown in Table 5.

Discussion

Over time, hallux valgus angle usually progresses due to the instability of the first metatarsophalangeal joint and the weakness of soft tissue around the joint. The previous study from Chadchavalpanichaya N showed that recommending the patient to wear wide toe box shoes does not prevent such deformity as this study followed the hallux valgus angle of those who had a moderate degree of hallux valgus for 12 months and found significantly increased hallux valgus angle in the control group.[13]

Regarding the hallux valgus angle, the results of the present study showed that wearing an adjustable splint can decrease the hallux valgus angle by about 1.8°. The findings align with the research of Moulodi N et al.[17] The study presented that wearing a splint can decrease the hallux valgus angle by up to 2-3°. However, this study collected the data using a goniometer instead of a radiograph to monitor hallux valgus angle. Moreover, the average age of the population was 22 years old. This finding is not the common population in clinical practice.

Regarding the hallux valgus angle and pain at the first metatarsophalangeal joint, the previous study from Chadchavalpanichaya N revealed that wearing a custom-mold room temperature vulcanizing silicone toe separator for a year can decrease the hallux valgus angle and pain in patients who had a moderate degree of hallux valgus.[13] But this device had to be custom-made by a skilled orthotist. Furthermore, it costs about 50 USD per piece. This problem makes it difficult for patients to get this device. Therefore, our current study aimed to evaluate the effectiveness of an adjustable splint as an alternative solution. These splints are readily available at drug stores or online stores and are priced at a more affordable rate of around 10 USD. Our assumption is that both the custom-molded device and the adjustable splint have a similar effect in reducing hallux valgus angle and pain. This is achieved by allowing the soft tissues and nerves on the medial and lateral aspects of the big toe to return to a more anatomical position. As a result, the splints prevent the shortening of soft tissues on the lateral aspect of the big toe and the overstretching of soft tissues and nerves on the medial aspect, ultimately leading to a reduction in pain at the big toe and the first metatarsophalangeal joint.

Regarding complication, when compared with the custom-mold toe separator,[15] our study showed a higher rate of complications, especially in easily slipping a device from the first toe. Because of using the device for a while, the strap lost its tightness. Although this device has to be changed every six months, it still costs less than the custom-made one.

Regarding satisfaction, the subdomains with the highest scores were easy to use and maintain. An adjustable splint selected for this study was a dynamic bunion splint with a joint. This component provides the splint to move with the big toe when the patient walks. Since it is made of plastic, it is lightweight and easy to maintain. Since the splint can reduce pain at the first metatarsophalangeal joint and be easy to use, compliance with the splint was higher than recommended (6 hours). When comparing the participant's compliance with the orthosis between the custom-mold toe separator and this device,[13] the present study shows the exact compliance.

Although wearing an adjustable splint can decrease the hallux valgus angle less than the clinically significant difference angle (5°). This device is still one of the treatments of choice in clinical practice. The hallux valgus angle usually progresses overtime because of the instability of the first metatarsophalangeal joint and the weakness of soft tissue around the

joint. The devices that can decrease the progression of hallux valgus angle are still beneficial.

The present study had some limitations. By way of its design, it was a cohort analytical study that had no control group. For more substantial evidence, a randomized controlled trial study should be conducted.

Conclusions

Wearing an adjustable splint for 12 months in patients with moderate to severe degrees of hallux valgus could decrease hallux valgus angle and pain at the first metatarsophalangeal joint without serious complications.

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