Effectiveness of Hallux Valgus Strap: A Prospective, Randomized Single-Blinded Controlled Trial

Navaporn Chadchavalpanichaya, M.D., Chuenchom Chueluecha, M.D.

Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

ABSTRACT

Objective: To study the effect of night-time hallux valgus strap usage on decreasing the progression of hallux valgus angle.
Methods: Patients, who were older than eighteen years old with moderate to severe degree of hallux valgus, were randomized into 2 groups: the study group (prescribed to use night-time hallux valgus strap for 8 hours per night for 12 months), and the control group. Patients in both groups were advised to have proper foot care with proper shoes.
Results: There were 25 patients in the study group and 22 patients in the control group. No statistical difference was found in demographic data between both groups. The hallux valgus angle, which was obtained through radiographic measurement, was decreased in both groups. However, there were no statistically significant differences in the decrease of hallux valgus angle between the two groups ($p>0.05$).
Conclusion: Prescribing to use night-time hallux valgus strap for 12 months cannot decrease the progression of the hallux valgus angle more than the control group.

Keywords: Hallux valgus, hallux valgus strap

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Hallux valgus is a common disorder of the forefoot and the most common pathologic condition involving the great toe. This may be defined as a progressive deformity affecting the forefoot in which lateral deviation of the great toe and medial deviation of the first metatarsal with or without medial soft-tissue enlargement of the first metatarsal head (bunion) is seen.[1] In addition, the pathology may involve the following conditions: rotation of the great toe, overriding of the great toe and the second toe, metatarsalgia, claw toe and hammer toe and bunionette of the fifth metatarsal, as well. Undoubtedly, the cause of hallux valgus is multifactorial.[1] There are both extrinsic and intrinsic causes. Moreover, improper shoes-wearing appears to be the major extrinsic cause.[2] Furthermore, the intrinsic cause such as heredity, pes planus, and metatarsus primus varus also play a role.[3-6]

Hallux valgus can be diagnosed and graded in its severity by physical examination and radiographic evaluation. By radiographic evaluation, hallux valgus will be diagnosed if the hallux valgus angle, the angle determined by a line that bisects the proximal phalanx and the shaft of the first metatarsal, is more than 15 degrees.[7,8] The progression of this deformity can also be detected by clinical evaluation and an increased hallux valgus angle.

One of the leading problems that brought the patients to the physicians was the need to correct their hallux valgus deformity. To solve this problem, surgical correction has become the best choice.[9] For ones who did not want to have surgery and expected only to stop or to decrease the progression of their hallux valgus deformity, a conservative treatment, such as using proper shoes with wide-and-depth toe box or shoes that were modified for the deformity, and avoiding pointed and high-heel shoes or using orthotic devices, were suggested.[10] Many types of orthotic devices, such as toe separators, total-contact insoles, and hallux valgus straps, had been used.[11-14] The commercial night-time commercial hallux valgus strap was one of the orthotic devices which has commonly been prescribed. Many literatures reported good results of orthotic devices in preventing recurrent hallux valgus deformity after surgical corrections.[12-14] However, no one reported the effectiveness of the commercial night-time

Correspondence to: Navaporn Chadchavalpanichaya
E-mail: drnavaporn@gmail.com

hallux valgus strap in decreasing the progression of the hallux valgus deformity.

The purpose of the present study was to reveal the effectiveness in application of the night-time hallux valgus strap in decreasing the progression of the hallux valgus angle.

MATERIALS AND METHODS

Patients

From January 14, 2008 to February 20, 2008, 47 patients who had hallux valgus were enrolled in the present study by announcement at the Out-Patient-Rehabilitation Clinic, Siriraj Hospital.

The inclusion criteria were the ones who were older than eighteen years old with a moderate to severe degree of hallux valgus (Hallux valgus angle 20^{o}-45^{o}).[7] They were not admitted to the study if any of the following criteria were present: (1) having previous foot surgery, (2) having hallux rigidus, (3) having rheumatoid arthritis diagnosed, or (4) continuously using any types of hallux valgus strap. A physiatrist who specialized in foot disorders conducted a physical examination and provided the clinical diagnosis of hallux valgus. If the patients had bilateral hallux valgus, the more severe one which was considered by physical examination and radiographic measurement would have been chosen.

Sample size calculation

Based on the literature and past clinical records, the mean of hallux valgus angle in patients who had moderate to severe degree deformity was 30^{o}.[7] A sample size calculation was based on the ability to detect a clinically important difference in hallux valgus angle. In addition, the change of hallux valgus angle that would have been clinically significant was 5^{o}. Based on a 0.80 power to detect a significant difference (5% type I error and 20% type II error, p=0.05, two-sided), 17 patients were required for each study group. To compensate for any non-evaluable patients, the authors planned to enroll 25 patients in the study group and 22 patients in the control group.

Study Protocol, Data collection, and Outcome measurement

Patients who met the inclusion criteria for the study completed a self- administered questionnaire that provided (1) the background information, (2) the foot-problem information, and (3) the impact of deformity to patients function information.

The background information included ages, genders, BMI, educational levels, working hours which they needed to stand or walk, shoes-wearing durations, and types of shoes. The foot-problem information included side and duration of deformity, family history, history of foot pain, the previous treatments and their results. The impacts of the hallux valgus deformity which included walking problem, shoes-fitting problem, working problem, and daily activities problem, were recorded by using a numeric rating scale. The questions were scored from 0 (no problem) to 10 (worst problem). After completion of the questionnaire, a foot size was evaluated by a Brannok Device. Moreover, the hallux valgus angle was obtained through the radiographic measurement.

By a coordinator, the patients were then randomized into one of two groups. The randomization code was developed using a computer random number generator to select random permuted blocks. The details of the series were unknown to any of the investigators and a coordinator; and were contained in a set of sealed and pre-addressed-by-only-numbers envelopes. The patients had an equal probability of assignment to each of the groups.

Patients in both groups were given a conventional treatment including proper foot care (removing callus at the plantar surface or medial side of the foot) and proper shoes ((1) low heel shoes with wide-and-deep toe box or (2) shoes which were modified for the deformity such as stretching the upper part of the shoes at the bunion site or adding medial arch support), and patients who were randomized to the study group were given a night-time hallux valgus strap. They were instructed to use the strap at night time at least 8 hours per night. The patients were asked to record the real duration (hours per night) of using the strap in a log book daily including complication records.

The hallux valgus angle was obtained through the radiographic measurement. Each radiographic imaging was evaluated in month 6, 9, and 12 by three physiatrists who did not know which group the patients were from. The hallux valgus angle then was recorded by mean of the three values. For the study group, the satisfaction of using night-time hallux valgus strap was evaluated by using a numeric rating scale at the end of the study. The question was scored from 0 (very unsatisfied) to 10 (very satisfied).

The present study protocol was approved by the Siriraj Institutional Review Board (Si 418/2007), and was supported by the Siriraj Routine to Research Management Fund.

Statistical analysis

Statistical analysis was done by using SPSS version 11.5.

The outcome was reported in intention to treat analysis. The qualitative data such as genders, educational levels, hallux valgus side, family history, history of foot pain and previous treatment were reported in number and percentage. Continuous variables, such as age, BMI, shoe-wearing duration, duration of deformity and degree of hallux valgus angle, were calculated in mean and standard deviation. The impact of the hallux valgus deformity and the satisfaction were calculated in median (range). Paired t-test, unpaired t-test; and repeated ANOVA was used to explore the difference of quantitative data that had normal distribution and Mann-Whitney test and Wilcoxin signed-rank test were used to explore the difference of quantitative data that has non-normal distribution. Chi-Square test and Fishers Exact test was used to explore the relationship of qualitative data. The p-value of less than 0.05 was considered a statistically significant difference.

The results of the present study were reviewed in month 6 to enable the study to be stopped if, as in deed occurred, a clear result emerged.

RESULTS

Forty-seven patients were randomized in the present study. There were 25 patients in the study group and 22 patients in the control group. All of them returned for a follow-up evaluation in month 3. In addition, forty patients returned for a follow-up evaluation in month 6, and remained to the end of the study. (Fig 1)

Table 1 summarizes the baseline characteristics and

TABLE 1. Demographic data.

Characteristics	Study group (n=25)	Control group (n=22)	p-value
Age (year), mean ± SD	44.3 ± 14.2	43.8 ± 16.8	0.91
Gender n (%)			
Female	23 (92.0)	21 (95.5)	1.00
Body mass index (kg/m.^{2}), mean ± SD	23.8 ± 3.1	23.4 ± 2.7	0.63
Educational level n (%)			
Tertiary school	5 (20)	4 (18.2)	
Certification	1 (4)	2 (9)	0.63
Bachelor, Master and Ph.D.	19 (76)	16 (72.7)	
Working hours that need to stand or walk (hours per week), mean ± SD	28.0 ± 15.2	32.2 ± 22.2	0.45
Duration of shoes wearing (hours per day), mean ± SD	7.3 ± 3.1	7.0 ± 3.0	0.65
Hallux valgus problems			
Side n (%)			0.79
Right	5 (20)	5 (22.7)	
Left	1 (4)	2 (9)	
Bilateral	19 (76)	15 (68.1)	
Duration (year), mean ± SD	16.3 ± 12.77	13.2 ± 10.1	0.37
Family history n (%)			
Yes	18 (72)	12 (54.5)	0.35
Problems from hallux valgus*			
Median [min-max]			
Walking problem	5 [0,10]	4 [0,10]	0.60
Shoes-fitting problem	7 [0,10]	8 [0,10]	0.20
Working problem	5 [0,10]	4.5 [0,10]	0.98
Daily activities problem	4 [0,10]	3 [0,10]	0.83
History of foot pain n (%)			
Yes	24 (96)	15 (68.2)	0.02
Previous treatment n (%)			
Yes	9 (36)	8 (36.4)	1.0
Conventional treatment n (%)			
Removing callus	25 (100)	22 (100)	
Shoes	0.72		0.72
Without modification	20 (80)	17 (77.3)	
With modification	5 (20)	3 (13.6)	

* measured by numeric rating scale 0- no problem, 10-worst problem

the foot-problem information of the subjects. The analysis of baseline measurement of the two groups revealed that they were very similar with regard to age, gender, BMI, educational levels, hours of work time which they needed to stand or walk and shoes-wearing duration. The analysis showed that there were no significant differences between the two groups ($p>0.05$). The result of foot sizes recorded by the Brannok Device was returned in shoe sizes. Most of the subjects had a total length of foot size 7, arch length size 6 and foot width size D. Most of them used low-heel height moccasin shoes either before or after having hallux valgus deformity. With the exception of number of patients who had a history of foot pain ($p<0.05$), covariates for baseline measures demonstrated no significant differences between the two groups. The percent of patients who had a history of foot pain in the study group was higher than of the control group. Most of the patients had never received any treatment (63.8%). For the ones who had received treatments, the treatment done the most was warm foot bath with a fair result.

All of the patients in both groups were given conventional treatment. All of them had callus removal done by the doctors. Most of the patients (78.7%) used low heel shoes with wide-and-deep toe box and the rest of them used shoes with some modifications to make them fit properly (stretching the upper part of the shoes at the bunion site or adding medial arch support). (Table 1)

The hallux valgus angles in month 0 (start), 6, 9 and 12 are presented in Table 2 and the means of the difference of hallux valgus angle between month 0 (start) and month 6, month 0 and month 9, and month 0 and month 12 (means of the pre and post intervention difference)

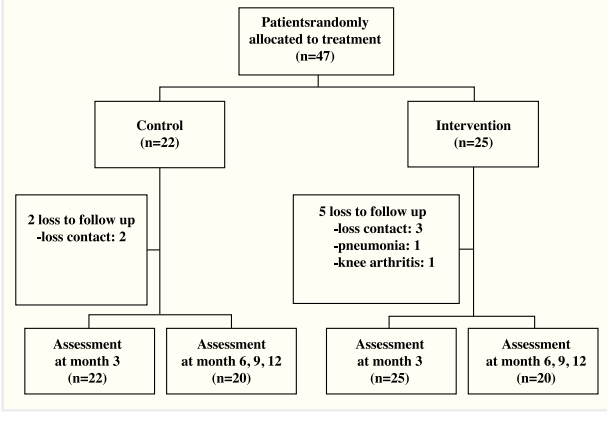

Fig 1. Flow of participant.

TABLE 2. Hallux valgus angle at month 0 (start), 6, 9 and 12.

	Mean ± SD (degree)		
	Study group (n=25)	**Control group (n=22)**	**p-value†**
Month 0 (start)	33.4 ± 7.8	32.3 ± 7.6	0.62
Month 6	32.3 ± 7.2	32.4 ± 7.5	0.97
p- value*(month 6-0)	0.04	0.94	
Month 9	32.0 ± 7.3	30.9 ± 6.9	0.58
p- value*(month 9-0)	**0.09**	**0.01**	
Month 12	32.6 ± 7.3	31.0 ± 76.9	0.45
p- value*(month 12-0)	0.27	0.01	
Mean adjusted from baseline using regression analysis			
Month 12	32.15 ± 0.66	31.24 ± 0.62	0.32

p-value*- analyzed between pre and post intervention in the same group
p-value†- analyzed between the study group and the control group

are presented in Table 3. The analysis revealed that the pre intervention hallux valgus angle of the subjects in both groups were similar (p>0.05). The result showed the decrease of the hallux valgus angle in month 6, 9 and 12 in the study group and in month 9 and 12 in the control group. (Table 3) The analysis by repeated ANOVA revealed that there were no significant differences of the decrease of hallux valgus angle between the two groups (p=0.65). (Fig 2) The analysis of hallux valgus angle between pre and post intervention in the same group revealed that there were significant differences of hallux valgus angle between pre intervention and in month 6 in the study group and pre intervention and in month 9 and 12 in the control group (p<0.05). (Table 2)

A summary of compliance with using the hallux valgus strap is presented in Table 4. The data from the patients logbook showed the highest compliance was in the first 3 months and the lowest compliance was in the last 3 months. For the complications from using the hallux valgus strap, there were nine patients who had the complications (36%). The complication reported the most was feeling too much stretching at the lateral side of the big toe when the patients put the strap too tight. There was no serious complication from using the strap.

The satisfaction of using night-time hallux valgus strap was reported by numeric rating scale 0-10. Median of the scale was 8.

TABLE 3. Mean of pre and post intervention difference* of Hallux valgus angle.

	Mean ± SD (degree)		
	Study group (n=25)	**Control group** (n=22)	**p-value**
6-0 month	-1.16 ± 2.6	0.05 ± 2.7	0.13
9-0 month	-1.40 ± 4.0	-1.45 ± 2.5	0.96
12-0 month	-0.80 ± 3.7	-1.32 ± 1.9	0.59

*Calculated by post-intervention angle minus pre-intervention angle (Minus value means post-intervention score is less than pre intervention score.)

TABLE 4. Compliance with using Hallux valgus strap.

	Mean ± SD			
	Month 0-3 (n=25)	**Month 3-6 (n=20)**	**Month 6-9 (n=20)**	**Month 9-12 (n=20)**
Hours/day	6.0 ± 2.4	5.6 ± 2.5	5.6 ± 2.4	5.5 ± 2.6
Days/week	5.9 ± 2.0	5.5 ± 2.3	5.25 ± 2.2	5.0 ± 2.5
Hours/week	39.0 ± 17.0	34.8 ± 18.7	33.6 ± 17.9	32.6 ± 19.4

DISCUSSION

The present study was performed because a commercial night-time hallux valgus strap was one of the orthotic devices that had been commonly prescribed. Many literatures reported good results of orthotic devices in preventing a recurrent hallux valgus deformity after surgical corrections.[12-14] However, no one reported the effectiveness of the night-time commercial hallux valgus strap. The authors thought that the night-time commercial hallux valgus strap could decrease the progression of hallux valgus angle because the strap forced the hallux to move in medial way. The hallux was splinted in neutral position.

The authors chose the night-time strap because it was easier to apply than the day-time strap. Furthermore, it did not interrupt the shoe usage. There was no literature which reported the proper usage duration of this strap. The authors chose the duration of 8 hours per night because it was the duration that most of the clinicians recommended to their patients.

From the present study, the result showed the decrease of the hallux valgus angle in month 6, 9 and 12 in the study group and in month 9 and 12 in the control group. However, the analysis by repeated ANOVA revealed that there were no significant differences of the decrease of the hallux valgus angle between the two groups (p>0.05). The reasons for this result may be as follows. (1) The real compliance with the duration of using the strap was less than the duration by the protocol. Maybe it was not enough duration for the effective treatment. However,

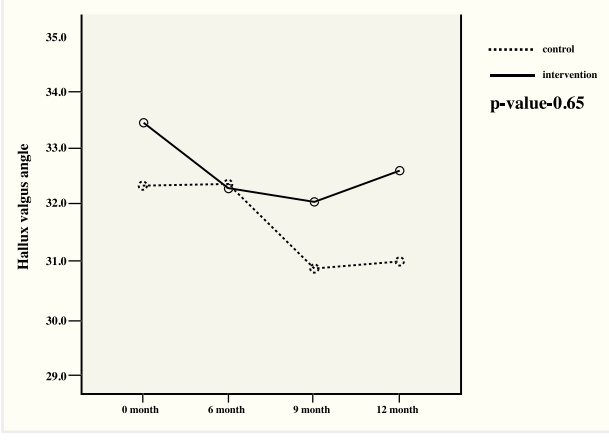

Fig 2. Hallux valgus angle in month 0 (the start), 6, 9, and 12.

it showed the authors the real situation if the strap was prescribed to the patients. Also, (2) patients in both groups were given a conventional treatment including proper shoes with wide-and-deep toe box or shoes which were modified for the deformity. Maybe a conventional treatment only was enough to decrease the hallux valgus angle.

There was no serious complication from using the night-time hallux valgus strap and the satisfaction of using the strap was good (8). The result from the present study which prescribed the patients to use this type of strap for 8 hours per night for a year could not decrease the hallux valgus angle more than giving the patients only a conventional treatment. Furthermore, the cost of the night-time commercial hallux valgus strap was rather high (34 USD). Prescribing the commercial night-time hallux valgus strap to decrease the hallux valgus angle has to be reconsidered. However, using the commercial night-time hallux valgus strap may provide a good result if the doctors can force their patients to use this strap according to the protocol. Furthermore, there may be other appropriate indications for using this type of strap which need further study in the future.

CONCLUSION

Prescribing to use the night-time hallux valgus strap for twelve months in patients who had a moderate to severe degree of hallux valgus could not decrease the hallux valgus angle more than the control group.

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