The Efficacy of Adjustable Toe Splint on Decreasing Metatarsalgia in Patients with Lesser Toe Deformity: A Prospective, Randomized Single-Blinded Controlled Trial

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Objective: *To study the effectiveness in application of adjustable toe splint in decreasing metatarsalgia in patients with lesser toe deformity and the complication of adjustable toe splint usage.*
Material and Method: *Thirty-six patients who had claw toes or hammer toes with metatarsalgia were enrolled in a prospective, randomized single-blinded controlled trial at the Out Patient Rehabilitation Medicine Clinic, Siriraj Hospital, Bangkok, Thailand between March and September 2011. Patients were randomized into two groups, the study group (using adjustable toe splint for 2 weeks) and the control group. Patients in both groups were advised as well to use proper shoes.*
Results: *All patients in each group completed the study. The baseline characteristics of the patients in both groups were similar. The present study group reported more decrease pain at metatarsal heads and dorsum of toes than the control group ($p < 0.05$). Two patients reported complications from toe splint usage as toe abrasions.*
Conclusion: *Using adjustable toe splint can decrease the metatarsalgia in patient with lesser toe deformity.*

Keywords: *Toe splint, Metatarsalgia, Claw toe, Hammer toe*

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Lesser toe deformities are common problems. Claw toe and hammer toe are the most common lesser toe deformities. In as much as the terms claw toe and hammer toe have been used interchangeably by various authors in describing deformities of the toes, their definitions have been confused[1]. For the present study, the authors chose the definitions from the "Introduction to Pedorthics" textbook. A claw toe is a deformity defined by hyperextension of metatarsophalangeal (MTP) joint and flexion of proximal interphalangeal (PIP) and distal interphalangeal (DIP) joint. A hammer toe is a deformity defined by hyperextension of MTP joint, flexion of PIP joint and extension of DIP joint[2]. Both claw toe and hammer toe deformities may occur with varying frequency among different populations. The incidence of these deformities ranged from 2% to 20%[3]. They may occur as an isolated entity or associated with hallux deformities. The major cause of the deformities is prolonged wearing of ill-fitting shoes, which over the number of years causes progressive buckling of the toes. Other causes could be from muscle imbalance in associated with neuromuscular diseases, rheumatoid arthritis, or traumatic joint[4,5].

Both claw toe and hammer toe deformities can cause many foot problems. As the hyperextension of MTP joint is established, the metatarsal head becomes more prominent on the plantar aspect of the foot. This can cause high pressure beneath the metatarsal head, especially when standing or walking. The high pressure results in development of pain beneath the metatarsal head (metatarsalgia) or painful plantar callosities. Furthermore, the patients who wear inadequate toe box shoes can suffer from high pressure at dorsum of toe and painful bursa over PIP joint[3]. To correct the deformities, surgical correction became the treatment of choice[4]. For those who were not

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candidates for surgery but suffering with pain, conservative treatments, such as using wide and high toe box with soft insole shoes or using an orthotic device, were suggested[3,4,6,7]. Many types of orthotic device, such as doughnut-shaped cushion, foamed toe cap, viscoelastic toe sleeves or toe splint have been used[3,7]. Custom-made toe splint was one of the orthotic devices that had been prescribed for the flexible lesser toe deformities (the toe deformity that can be passively corrected to the neutral position). The mechanism of toe splint was decreasing the MTP joint hyperextension and PIP joint flexion resulting in decreasing pressure at plantar surface of metatarsal head and dorsum of toe. Through continuous use, it can relieve pain at both areas. To accomplish the benefit of the splint, the material used for making the toe splint has to be firm enough in order to control the deformities and the patient needs to fit the splint snugly. However, past clinical records showed that using the toe splint caused many toe problems such as pain, numbness, skin abrasion, and inflammation. Especially during toe-off of the gait cycle where toes moved and rubbed with the tight strap. These were the main reasons for poor patient compliance and treatment failure.

"Adjustable toe splint" was designed by the foot care team of the Department of Rehabilitation Medicine and the staff of the Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand (Fig. 1). It was a custom-made splint. A toe strap of the splint was made of firm cow skin with 1 cm in width. Base of the splint that would be placed under the forefoot was made of 3 mm-thick Pelite, a soft and durable material, to increase the cushion. The toe strap was fixed to the Pelite by a Velcro® so the length of the strap can be easily adjusted. When using the toe splint, the toe strap would be fit on the deformed toe tightly to pull the PIP joint from flexion to neutral position. This caused the MTP joint to move into neutral position. Because the patients could adjust the strap of their splint by themselves, they could loosen the strap when they felt discomfort.

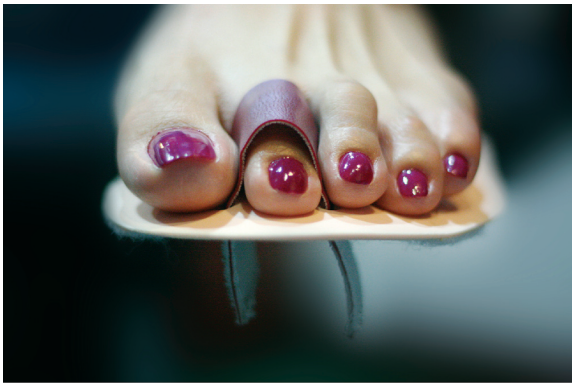

Fig. 1 Adjustable toe splint

The authors hypothesized that the adjustable toe splint may decrease the toe irritation and pain. It may thus increase the patient's compliance, resulting in decreasing metatarsalgia from continuous pressure relief.

Objective

Primary objective

To study the effectiveness in application of adjustable toe splint in decreasing metatarsalgia in patients with lesser toe deformity.

Secondary objective

To study the complication of adjustable toe splint usage.

Material and Method

Patients

Between March 17 and September 1, 2011, 36 patients who had claw toes or hammer toes with metatarsalgia were enrolled in the present study by announcement at the Out Patient Rehabilitation Medicine Clinic, Siriraj Hospital.

The inclusion criteria included being older than eighteen years old, and having flexible claw toe/hammer toe deformity with metatarsalgia evaluated by numeric rating scale as more than 4. Patients were not admitted to the study if any of the following criteria were present: (1) having foot numbness or foot ulcer, (2) having acute inflammation or arthritis of PIP, DIP or MTP joint at the present study time, (3) having a plan such as travelling that may change amount of regular walking time during the present study time, or (4) on NSAIDs for less than one week or in the duration of dosage adjustment. A physiatrist who specialized in foot disorders conducted physical examination and confirmed the clinical diagnosis. If the patients had metatarsalgia more than one site, the most severe one, considered by numeric rating scale and further physical examination, would be chosen.

Sample size calculation

Sample size calculation was based on the ability to detect a clinically important difference in pain score recorded by numeric rating scale of 3

between two groups. Based on past clinical records, the mean of the pain score was 5. Based on 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 non-evaluable patients, the authors planned to enroll 18 patients per group.

Study protocol, data collection and outcome measurement

Patients who met the inclusion criteria for the present study were interviewed with using a questionnaire that provided (1) the background information, (2) the foot-problem information, and (3) the level of foot pain during the week before the present study.

The background information included age, gender, BMI, working hours that one needed to stand or walk, shoe wearing duration, and types of daily-used shoes. The foot-problem information included causes of toe deformity, duration of deformity, and level of the shoe-fitting problem deriving from the deformity. The level of foot pain included pain at metatarsal head (metatarsalgia) and pain at the dorsum of deformed toe. The shoe-fitting problem and the foot pain were recorded by using numeric rating scale. The questions were scored from 0 (no problem/no pain) to 10 (worst problem/worst pain). After completion of the questionnaire, a physiatrist conducted a physical examination to find the co-deformity and select the toe. The deformed toe that had most severe metatarsalgia would be selected to get the splint if the patient was randomized in the study group.

The patients were then randomized into one of two groups by a coordinator. 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 the coordinator and were contained in a set of sealed envelopes, each bearing on the outside only a number. The patients had an equal probability of assignment to either of the groups.

Patients who were randomized to a study group were sent to the orthotist who would make the adjustable toe splint for them. One week later, the patients received their adjustable toe splint from the orthotist. The patients were instructed how to adjust their splint. They were instructed to tighten the strap of the splint for better joint deformity control and loosen the strap when they felt it was too tight. The patients were advised to use the splint with the proper shoes (wide and deep toe box shoes). They were asked to use the strap during daytime for two weeks. For compliance measurement of using toe splint, the patients were asked to record the real duration of their using in a log book everyday. Additionally, the patients were asked to record the complications from using the splint in the logbook every day.

Patients who were randomized to a control group were advised to use proper shoes (wide and deep toe box shoes with soft insole) by the doctor and appointed them to return for a follow-up two weeks later.

Patients in both groups returned at two weeks for completion of the follow-up questionnaire. The follow-up questionnaire included the pain during one week before the follow-up time and the satisfaction on their treatment recorded by numeric rating scale. This part of follow-up questionnaire was interviewed by the physiatrist who did not know in which group the patients were. Then, the patients in the present study group met the orthotist again to return their logbook. Furthermore, they were interviewed by using questions about their intent for using the splint in the future and suggestions for improving the toe splint quality.

The present study protocol was approved by the Siriraj Institutional Review Board (Si 540/2010) and was supported by Siriraj Research Development Fund (Managed by Routine to Research: R2R).

Statistical analysis

Statistical analysis was done with SPSS version 11.5. The qualitative data such as gender, type of daily-used shoe, shoe height, causes of toe deformity, current treatment, types of toe deformity, the deformed toe that had most severe metatarsalgia and co-deformity were reported both in number and percentage. Continuous variables, such as age, BMI, working hours for which the patient needs to stand or walk and duration of shoe wearing were calculated in mean and standard deviation. The duration of toe deformity was calculated in median (range). The shoe fitting problem from toe deformity, baseline status of pain during one week before the study, and pain after the study and satisfaction with the treatment, which were recorded by numeric rating scale, were calculated in median (range). The compliance with using adjustable toe splint was calculated in mean and standard deviation. The complications from using adjustable toe splint, suggestions to improve the quality of splint, and the continuous intense of using the splint were calculated in number and percentage. Unpaired

t-test was used to explore the difference of quantitative data that has normal distribution and Mann-Whitney test was used to explore the difference of quantitative data that has non-normal distribution. Chi-Square test and Fisher's exact test was used to explore the relationship of quantitative data. The p-value of less than 0.05 was considered to be of statistically significant difference.

Table 1. Demographic data

Characteristics	Study group number (percent) (n = 18)	Control group number (percent) (n = 18)	p-value
Age [year, mean (SD)]	62.5 (8.9)	63.1 (9.7)	0.86
Gender			
Male	0	2 (11.1)	0.49
Female	18 (100)	16 (88.9)	
BMI [year, mean (SD)]	22.7 (3.4)	24.2 (2.8)	0.18
Working hours that need to stand or walk [hours per week, mean (SD)]	45.6 (15.7)	46.7 (12.0)	0.82
Duration of shoes wearing [hours per day, mean (SD)]	6.1 (2.5)	5.8 (1.7)	0.70
Types of daily-used shoes			
Sandal	12 (66.7)	9 (50.0)	0.54
Pump	3 (16.7)	3 (16.7)	
Others	3 (16.7)	6 (33.3)	
Shoe height [inch]			
0	15 (83.3)	13 (72.2)	0.69
> 0	3 (16.7)	5 (27.8)	
Causes of toe deformity			
Hallux valgus	16 (88.9)	16 (88.9)	1.00
Trauma	1 (5.6)	2 (11.1)	
Rheumatoid arthritis	1 (5.6)	0	
Duration of toe deformity [year, median (min, max)]	10 (2, 34)	20 (3, 30)	0.29
Current treatment			
Paracetamol	1 (5.6)	0	1.00
NSAIDs	0	0	
Others	0	0	
Foot Examination			
Deformed toe that had most severe metatarsalgia			
Right 2nd toe	8 (44.4)	11 (61.1)	0.32
Left 2nd toe	10 (55.6)	7 (38.9)	
Types of toe deformity			
Claw toe	7 (38.9)	3 (16.7)	0.14
Hammer toe	11 (61.1)	15 (83.3)	
Co-deformities			
Hallux valgus without overriding toe	12 (66.7)	14 (77.8)	0.46
Hallux valgus with overriding toe	6 (33.3)	4 (22.2)	
Pes cavus	0	0	
Pes planus	0	0	
Shoe fitting problem from toe deformity [median (min, max)]	8 (5, 10)	7 (5, 10)	0.05

Age, BMI, working hours that need to stand or walk and duration of shoes wearing were recorded in mean (SD)
Duration of toe deformity and Shoe fitting problem were recorded in median (min, max)
Shoe fitting problem from toe deformity was recorded by numeric rating scale

Results

Of the 36 patients randomized into the present study, all of them returned for a follow-up evaluation after two weeks and completed the present study.

Table 1 summarizes the baseline characteristics of the subjects who completed the present study. The analysis of baseline measures for the two groups revealed that they were similar with regard to age, gender, BMI, working hours that they need to stand or walk, shoe-wearing durations, types of daily-used shoes, causes and duration of toe deformity, current treatment, types of toe deformity, the deformed toe that had most severe metatarsalgia, co-deformities and level of shoe-fitting problem from toe deformity. The analysis of the baseline characteristics revealed that there were no significant differences between the two groups ($p > 0.05$).

Table 2 summarizes the medians of the baseline status of pain at metatarsal head and dorsum of toe during one week before the present study as recorded by numeric rating scale. The analysis of baseline measures revealed that there were no significant differences between the two groups ($p > 0.05$).

Primary outcome

A summary of the medians of the pain at metatarsal head and dorsum of toe during one week before the follow-up time is presented in Table 2. The study group reported less pain than the control group. The analysis of the pain measures revealed that there were significant differences between the two groups. The severity of pain was also reported in the median of the pre and post intervention difference (calculated by pre-intervention score minus post-intervention score). The study group reported greater decrease of pain level than the control group. The analysis revealed that there were significant differences of decreasing pain level between the two groups.

Secondary outcome

Complications from using the adjustable toe splint are presented in Table 3. Two patients had complications from using the toe splint (11.1%). The complications found were toe abrasions. There was no serious complication.

For compliances with using the adjustable toe splint, mean (standard deviation) of using the splint was 5.1 (2.4) hours per day. Mean (standard deviation) of standing and walking hour during the present study was 6.1 (2.5) hours per day. Duration of splint usage was 91.6 percent of duration of standing and walking.

Satisfactions on the treatment were recorded by numeric rating scale. The questions were scored from 0 (dissatisfied) to 10 (most satisfied). The medians (min, max) of the satisfaction score in the study group and in the control group were 7 (5, 10) and 2.5 (1, 6), respectively. There was significant difference in the satisfaction score between the two groups ($p < 0.001$).

As for the intent of using this toe splint in the future, fifteen patients (83.3%) confirmed that they would continue using their splints. Only three patients (16.7%) reported that they might continue using their splint and no one will stop using their splint.

Table 2. Baseline status of pain during one week before study (pre-intervention) and pain after the study (post-intervention)

	Median (min, max)		p-value
	Study group (n = 18)	Control group (n = 18)	
Pre-intervention			
Metatarsalgia	6.5 (5, 10)	6 (5, 8)	0.89
Dorsal pain	7 (5, 8)	7 (8, 8)	0.86
Post-intervention			
Metatarsalgia	3 (0, 7)	7 (4, 10)	<0.001
Dorsal pain	2.5 (0, 7)	6.5 (4, 8)	<0.001
Pre and Post-intervention difference*			
Metatarsalgia	3 (1, 7)	0 (-5, 1)	<0.001
Dorsal pain	4 (1, 8)	0 (-3, 2)	<0.001

Pain was recorded by numeric rating scale

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

Table 3. Complications from using adjustable toe splint

Complications	Number (n = 18)	Percent
No	16	88.9
Yes	2	11.1
Toe abrasion	2	11.1
Increased toe pain	0	0
Toe inflammation	0	0
Toe numbness	0	0

Table 4. Suggestions to improve quality of adjustable toe splint

Suggestion	Number (n = 18)	Percent
No	6	33.3
Yes*	12	66.7
Make in total length of insole	5	27.8
Add forefoot strap	9	50.0
Make in darker color	3	16.7

* Some patients had more than one suggestion

The authors asked the patients to give suggestions to improve the quality of the splint. Twelve patients offered suggestions (66.7%). Some of them had more than one suggestion. Five patients suggested making the base of the splint as a total length insole. Nine patients suggested adding the forefoot strap so the splint can be better fixed to the foot. In addition, three patients suggested making the splint in a darker color (Table 4).

Discussion

The result of the present study revealed that after the treatment, the present study group had less pain at metatarsal head and pain at the dorsum of deformed toe than the control group. Furthermore, the study group reported more decrease of pain level than the control group. This result showed that using the adjustable toe splint with the proper shoes could decrease pain at metatarsal head and pain at the dorsum of deformed toe when compared to using proper shoes alone. The reasons of the better pain relief may be as follows. (1) The causes of metatarsalgia in claw toe and hammer toe are high pressure beneath the metatarsal head[3] and instability of MTP joint. The principle of toe splint is to control the flexible deformed toe in the neutral position, so that it can stabilized and decrease pressure beneath the metatarsal head resulting in decreasing metatarsalgia. (2) As the patients could adjust the strap of their splints by themselves, they can loosen the strap when they felt discomfort. The result from the present study showed that only two patients had toes abrasion from using the splint. However, both of them continued using their splint. For the reason that this new designed splint can decrease pain with no serious complication, it can also increase the patient's compliance. From the present study, it is reported that mean (standard deviation) of the duration of splint usage was 5.1 (2.4) hours per day. It was 91.6% of standing and walking period. This high compliance with toe splint usage resulted in the better pain relief.

The present study demonstrated the higher satisfaction level in the study group than in the control group. Even though the patients in the present study group felt satisfied, some of them had suggestions for better design one. Most suggestions were related to patients' shoe types and patients' life styles. For example, some patients who wore sandals or ones who had to walk a lot wanted to add the forefoot strap so the splint can better fix to their feet. It is the author's idea that since this adjustable toe splint was custom-made, the orthotist could make it match to patients' shoes and patients' life styles.

When comparing the effectiveness of the adjustable toe splint with other types of splint, no article showed the data of other types of toe splint on decreasing metatarsalgia in patients with lesser toes deformities directly. Two articles showed the good results of using insole with toe separator for decreasing foot pain in patients with painful Hallux valgus[8,9]. Furthermore, one article showed that gel toe props (crescent-shaped toe orthotic device that could be fitted to the toe using the elastic loop) were found to be effective for reducing pressure on the apex of the second digit in patients with claw or hammer toe deformity[10]. These data showed that there were other effective orthotic devices that decrease foot pain and toe pressure in patients with forefoot deformities. It depended on the clinicians to choose the proper one for their patients.

The limitation of the present study was the duration. The effectiveness of the toe splint was related to the compliance. In the present study, the authors recorded the compliance of using the toe splint for only two weeks. In the real situation, the patients needed to use the toe splint longer than this period. An article reported the compliance of using nighttime hallux valgus strap in 12 months. The data showed the highest compliance was in the first three months and the lowest

compliance was in the last three months[11]. This data may suggest that the long-term splint usage was uncertain. For future study, the authors recommended to study for a longer period of time.

Conclusion

Using adjustable toe splint for patients with lesser toe deformity can decrease pain at the metatarsal head and dorsum of toes with no serious complication.

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Potential conflicts of interest

None.

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ประสิทธิผลของการใช้อุปกรณ์ดามนิ้วเท้าชนิดปรับได้ในการลดอาการเจ็บฝ่าเท้าในผู้ป่วยที่มีนิ้วเท้าผิดรูป: การศึกษาไปข้างหน้าแบบสุ่ม

นวพร ชัชวาลพาณิชย์, วันรัชดา คัชมาตย์, ธนธัช จรัสรุ่งโอพาร, พาขวัญ นวลนิ่ม

วัตถุประสงค์: *เพื่อศึกษาประสิทธิผลของการใช้อุปกรณ์ดามนิ้วเท้าชนิดปรับได้ในการลดอาการเจ็บฝ่าเท้าในผู้ป่วยนิ้วเท้าผิดรูป และศึกษาผลแทรกซ้อนของการใช้อุปกรณ์ดามนิ้วเท้าชนิดปรับได้*

วัสดุและวิธีการ: *สุ่มเลือกผู้ป่วยที่มีนิ้วเท้าผิดรูปและมีอาการเจ็บฝ่าเท้าที่มารักษาที่ภาควิชาเวชศาสตร์ฟื้นฟู โรงพยาบาลศิริราช จำนวน 36 ราย เป็น 2 กลุ่ม กลุ่มละ 18 ราย กลุ่มทดลองใช้อุปกรณ์ดามนิ้วเท้าชนิดปรับได้ และให้ผู้ป่วยบันทึกการใช้อุปกรณ์และอาการแทรกซ้อนจากการใช้อุปกรณ์ในแบบบันทึกการใช้อุปกรณ์ทุกวัน โดยผู้ป่วยได้รับคำแนะนำให้ใส่รองเท้าที่เหมาะสมทั้ง 2 กลุ่ม*

ผลการศึกษา: *ผู้ป่วยเข้าร่วมการศึกษาจนจบทุกคน ผู้ป่วยทั้งสองกลุ่มมีข้อมูลพื้นฐานใกล้เคียงกัน กลุ่มทดลองมีอาการเจ็บฝ่าเท้าและหลังนิ้วเท้าที่โก่งลดลงกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ($p < 0.05$) มีผู้เข้าร่วมการศึกษา 2 ราย มีรอยถลอกที่นิ้วเท้าหลังจากใช้อุปกรณ์ดามนิ้วเท้า*

สรุป: *การใช้อุปกรณ์ดามนิ้วเท้าชนิดปรับได้สามารถลดอาการเจ็บฝ่าเท้าในผู้ป่วยที่มีนิ้วเท้าผิดรูปมากกว่ากลุ่มที่ไม่ได้ใช้*