Original Article

The Effectiveness of Indoor Socks with Medial Arch Support in Decreasing Pain in Patients with Posterior Tibial Tendon Dysfunction: a Prospective, Double-blinded, Randomized Controlled Trial

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ABSTRACT

Objectives: To study the effectiveness of application of indoor socks with medial arch support in decreasing pain in patients with posterior tibial tendon dysfunction (PTTD).

Study design: Prospective, double-blinded, randomized controlled trial

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

Subjects: Patients with PTTD and foot pain at the out-patient clinic, during August 2017 – August 2018

Methods: Forty–two patients were randomized into two groups, the study group (using socks with medial arch support, Rehband®) and the control group (using socks with flat foam). All were advised to wear them while walking and standing indoors for 2 weeks. Complication and duration of using the socks were recorded in a logbook. Foot pain was assessed with numeric rating scale (NRS) before and after 2 weeks of using them. Pre-post differences in pain and success rates of pain reduction (at least two points) were compared between the two groups.

Results: After using the socks for 2 weeks, there were statistically significant decreases in foot pain in both groups (the study group, $p < 0.001$ and the control group, $p = 0.004$). However, the pre-post intervention differences in foot pain between two groups was not statistically significant ($p = 0.07$). The success rates of pain reduction were statistically significant difference between the two groups (the study group 80.9% and the control group 42.9%, $p = 0.025$). No serious complication was reported.

Conclusion: In patients with posterior tibial tendon dysfunction, using indoor socks with medial arch support showed no statistically significant difference in decreasing foot pain when comparing with the control group using socks with flat foam. However, the former had higher success rate in pain reduction than the latter.

Keywords: posterior tibial tendon dysfunction, flat foot, medial arch support, foot pain

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Introduction

Posterior tibial tendon dysfunction (PTTD) is a common cause of adult-acquired flatfoot. This condition typically occurs in women aged 45 to 65 years old.[1-2] It is caused by increasing age, chronic overuse due to long periods of standing or walking, and obesity. Another cause that leads the tendon to be prone to degeneration is the anatomy of this tendon. The area 4 cm proximal to its insertion is the hypovascular region and the direction that the tendon passes through the medial malleolus is sharply flexed. Degeneration of this tendon results in the collapse of the medial longitudinal arch. When the medial structures of the foot are subjected to abnormal alignment, it leads to the development of inflammation and deformity in the structures such as foot flattening, forefoot abduction and hindfoot valgus.[3] Clinical presentation includes frequent pain at the medial aspect of the foot or ankle. In chronic cases, there is foot deformity. Further, pain may shift to the lateral side of the foot.[2]

PTTD can be divided into four stages.[2] In stage I, there may be pain and swelling along the posterior tibial tendon. No deformity is presented. Patients are able to perform the double heel-rise test and also the single heel-rise test. In stage II, there are more degenerative changes in the tendon. The foot deformity includes forefoot abduction and hindfoot valgus. However, all deformities remain flexible. The medial arch begins to collapse. They are unable to perform the single heel-rise test but may be able to perform the double heel-rise test. There is usually pain along the posterior tibial tendon and/or pain at the lateral side of the foot or lateral malleolus. The forefoot becomes splayed out, leading to more than 2 toes being seen from the back view. This is called the “too many toes” sign. In stage III, the deformities become rigid. The valgus of the hindfoot cannot be corrected while performing a double heel-rise. In stage IV, the ankle joint is involved. The deltoid ligament tear results in ankle eversion and degeneration of the tibiotalar joint.[3]

At present, the treatment of PTTD is based on each patient’s symptoms and the stage of the disease. There are

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non-pharmacological, pharmacological and operative treatments.[4] The primary goals of treatment include pain relief and foot deformity prevention. There are many kinds of non-pharmacological treatments, such as weight control, lifestyle modification, orthotic management, shoe modification, exercise, and physical therapy. Medial arch support is an orthosis generally used in the shoes to reduce foot pain and inflammation from PTTD. It showed reduction of hindfoot valgus deformity.[5] With shoe modification, it is recommended for patients with PTTD to rest the tendon leading to pain relief[6] and improve walking performance.[7]

There are many patients with PTTD who visit the foot clinic at the Department of Rehabilitation Medicine, Siriraj Hospital. After being diagnosed with PTTD, they receive treatments such as shoe modification and medial arch support. These can be effective for relieving pain after being used all the time while walking and standing. However, many patients in Thailand refuse to wear shoes in the house due to cultural traditions. They only wear shoes that are modified for outdoors. Although the pain is reduced while walking outdoors, they still feel pain while walking indoor barefoot. Even though they are suggested to wear shoes in the house, many patients do not comply with the advice. For this reason, the treatments do not relieve the pain effectively. Some of them ask to wear socks instead, but this may not be effective due to lack of support at the medial arch.

In this study, we created innovation: indoor socks with medial arch support. We chose to use an over-the-counter medial arch support, Rehband® which has been often prescribed at a foot clinic but inserted in the shoe. It is made from a material called Technogel®, which has high elasticity, provides good support, does not irritate the skin and is self-adhesive. There are 3 different sizes to fit foot size measured while sitting with non-weight bearing. We attached the medial arch supports to the non-slip socks with Velcro®, so these socks could be taken off for washing. We determined a proper position on the socks before attaching the Velcro®. We expected that this innovation could replace wearing modified shoes indoor. (Figures 1-2)

Since there had been no prior study that reported the effectiveness of indoor socks with medial arch support in decreasing pain, we carried out this study under the hypotheses that these socks with medial arch support could decrease foot pain while standing and walking indoors. The primary objective was to study the effectiveness of indoor socks with medial arch support in decreasing pain in patients with PTTD. The secondary objectives were to study the effectiveness in decreasing limitation of activities of daily living (ADLs), household activities, indoor walking, and foot instability, as well as complications, and patients' satisfaction and adherence to using these socks.

Methods

This study was approved by the Siriraj Institutional Review Board (SIRB), reference number 356/2560 (EC1) certification number Si 494/2017. This study was supported by the Siriraj Research Development Fund.

Participants

Patients who were diagnosed with posterior tibial tendon dysfunction by physiatrists at the foot clinic, Department of Rehabilitation Medicine, Siriraj Hospital from August 2017 – August 2018 were invited to participate in the study, and 42 patients gave informed consent were recruited in total.

Inclusion criteria

- Age not less than 40 years old
- Stage I or II PTTD with intermittent foot pain at least 6 weeks
- Barefoot pain at the medial aspect or along the posterior tibial tendon, with a numeric rating scale (NRS) of pain at least 5. If there was foot pain on more than one side, the most severe side was chosen, as considered with NRS and further physical examination.
- Wearing modified shoes outdoors regularly

Exclusion criteria

- Not being able to answer the questionnaire due to cognitive impairment or communication limitation
- Stage III or IV PTTD
- Taking NSAIDs or not taking NSAIDs less than 2 weeks prior to the screening
- Previous foot surgery
- Having an indoor shoe modification
- Foot numbness or foot ulcer
- Balance problem
- Having a traveling plan that might affect regular walking time during the study period

Sample size calculation

After reviewing previous studies, there was a study that might be relevant. Thammawijaya et al. reported that after using a custom-molded medial arch support in patients with plantar fasciitis, foot pain was significantly decreased from

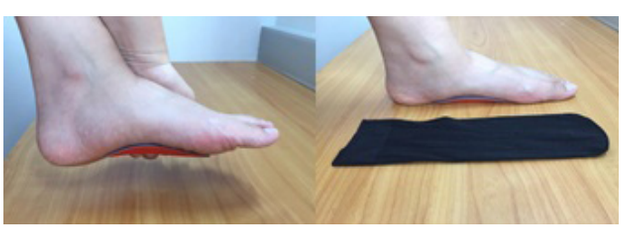

Figure 1. Measurement of proper size and position of the medial arch support

Figure 2. Attachment of the medial arch support to non-slip socks with Velcro®; left, top view; right, lateral view

4.87 (SD = 1.66) to 2.70 (SD = 1.93).[8] In this study, we expected that indoor socks with medial arch support could reduce the pain score by at least 2 points. Based on a power of 0.90 to detect a significant difference (5% type I error and 10% type II error, p = 0.05, two-sided), 21 patients were required for both the study group and the control group. The recruited sample size was 48 subjects in total (24 subjects per group with an estimated 10% drop-out).

Materials

- Three different sizes of Rehband®, an over-the-counter medial arch support (Figure 3)
- Flat foam with 2 mm thickness (Figure 3)
- Free adult size of non-slip socks
- Velcro®
- Glue

Study protocol

Patients who met the criteria were recruited for this study. An information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained. Subsequently, they went to see the first investigator which was blinded in the study, to get a complete foot examination; and completed a questionnaire consisting of demographic data, foot problem, baseline foot pain while walking barefoot indoor in the past week, limitations in ADLs, household activities and indoor walking, and foot stability. Pain and limitations were assessed with NRS ranged from 0, no pain/limitation to 10, worst pain/complete limitation. Foot instability was also assessed with NRS ranged from 0, completely unstable to 10, completely stable.

The patients were then randomly allocated to either a study or a control group by a research coordinator who used a computer program to set sequential numbers and put each number in a sealed envelope. This made all patients had an equal probability of assignment to each of the groups. There were 21 patients in each group. Each patient got one envelope and went to see the second investigator who opened it and chose socks and medial arch support/flat form according to allocation numbers.

All received the same measurement, two pairs of socks and an instruction on how to use the socks by the second investigator. In the study group, the patients got indoor socks with medial arch support (Rehband®). In the control group, the patients got indoor socks with a sham made of flat foam with 2 mm thickness (Figure 3). It was permanently attached to the socks with glue and had the same size as the medial arch support in the study group.

In the first week, the patients in both groups had to increase duration of wearing the socks 5 minutes per day, for foot accommodation.

In the second and the third weeks, they were informed to wear socks as long as possible while walking and standing indoors as well as to continue using outdoor modified shoes; and to record patient's adherence to wearing the socks, complications and other treatments (if had) in a logbook for two weeks, from the second week to the third week.

At the end of the study, they came back to see the first investigator, who did not know which group they were in, to complete the questionnaire. In addition, patient's satisfaction in using the socks was assessed with NRS, from 0 (dissatisfaction) to 10 (most satisfaction). Any complication from using the socks was also recorded in the logbook.

Each patient returned the logbook to the first assessor on the follow-up day when the study ended.

Success rate of pain reduction was defined as decreasing in pain score at least 2 points.

Statistical analysis

For demographic data, an unpaired t-test and Mann–Whitney test was used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Additionally, Fisher's exact test and chi-squared test were performed to analyze the differences in categorical data. Multiple logistic regression was used to analyze the association between duration of disease and the success rate.

To explore the primary outcome of foot pain and secondary outcomes, the Mann-Whitney U was used to analyze the comparison between the two groups at baseline (pre-) and post-intervention. Pre-post intervention differences in foot pain, activity limitations and foot instability between the two groups were also analyzed by the Mann-Whitney U test. Wilcoxon signed-rank test was used to analyze the pre-post intervention differences within the group.

Chi-squared test was performed to compare the success rates between the two groups.

Unpaired t-test was used to compare the duration of using indoor socks with medial arch support, duration of walking indoors, and percent of usage from the duration of standing and walking between two groups.

To explore satisfaction, the Mann-Whitney U test was used to compare between the two groups.

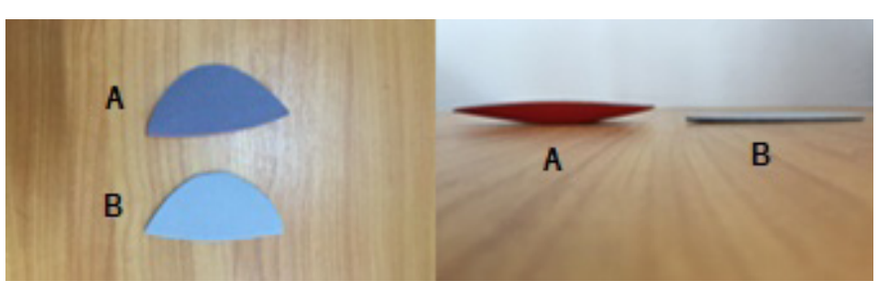

Figure 3. A: Rehband®, a commercial medial arch support; B: Sham, flat foam; left, top view; right, lateral view

All statistical analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS Inc, Chicago, IL, USA). A *p*-value of less than 0.05 was considered a statistically significant difference.

Results

A total of 42 patients with PTTD participated in this study and all completed the protocol (Figure 4). Most of them were females aged from 42 to 80 years old, with a mean age of 60.55 years old. The analysis of the baseline measurements of the two groups revealed similarities in gender, body mass index (BMI), hours needed to stand and walk indoors and outdoors, duration of disease, side and stage of the of PTTD, and site of pain, as shown in Table 1.

Primary outcome

There was no statistically significant difference in pain between the two groups at baseline (p = 0.411) or after the end of the protocol (p = 0.486).There were statistically significant decreases in foot pain in both the study group (p < 0.001) and the control group (p = 0.004) compared with the baselines. However, when comparing the pre-post intervention differences of foot pain between the two groups, there was no statistically significant difference (p = 0.07), as shown in Table 2.

The success rates of the study group and the control group were 80.9% and 42.9%, respectively, and the difference between the two groups was statistically significant (p = 0.025). The multiple logistic regression showed that the duration of disease was not statistically significant associated with the success rate (p = 0.948).

Secondary outcomes

Table 3 shows no statistically significant differences between the two groups in limitations of ADL, household activity, indoor walking, and ankle instability at baseline (p = 0.779, 0.879, 0.572 and 0.278, respectively) and after using the socks (p = 0.939, 0.647, 0.430 and 0.878, respectively). When comparing the pre-post intervention differences in limitations of the above-mentioned activities between the two groups, there were no statistically significant differences (p = 0.652, 0.472, 0.191 and 0.076 respectively. In both groups, however, there were statistically significant decreases in limitations of ADLs, household activity, and indoor walking when comparing between the pre- and the post-intervention within the group.

Regarding foot instability, there was no significant change in the study group but there was a statistically significant decrease in foot instability in the control group when comparing between the pre- and the post- intervention (the study group: 7, 8; p = 0.321; the control group: 5, 8; p = 0.004), as shown in Table 3.

Table 4 shows patients' adherence to compliance with using the socks. There was no statistically significant difference in the duration of standing and walking indoor, duration of using indoor socks with medial arch support, and percent of usage from the duration of standing and walking between two groups (p = 0.179, 0.404 and 0.483, respectively).

Table 5 shows patients' satisfaction with the socks reported as median (min, max). The satisfaction scores were high in every aspect in both groups.

Complications from using the socks were seen in both groups. No patient had serious complications. Four patients

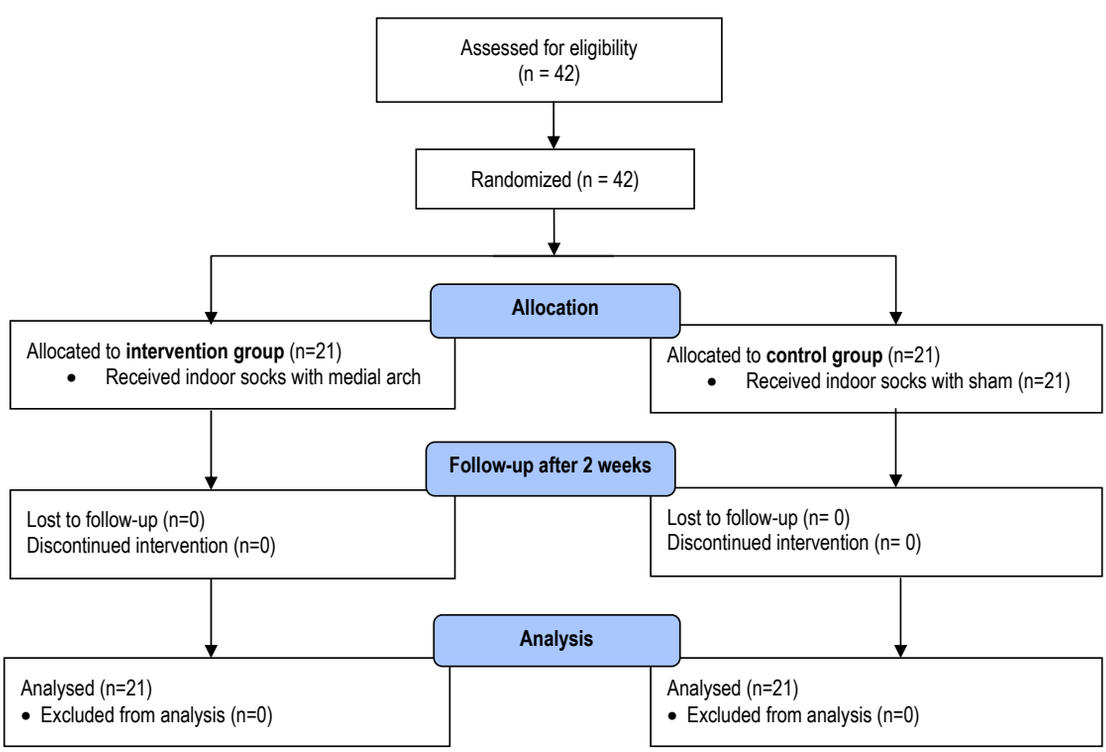

Figure 4. Flow diagram of the study

Table 1. Demographic data of participants

Characteristics	Study group (n=21)	Control group (n=21)	*p*-value
Gender[1]			
- Male	3 (14.3)	1 (4.8)	0.606[a]
- Female	18 (85.7)	20 (95.2)	0.381[b]
BMI [kg/m^2][2]	27.1 (5.4)	28.5 (4.9)	0.464[b]
Duration of stand or walk outdoors [hours per day][2]	4.0 (2.5)	3.5 (1.8)	0.551[b]
Duration of to stand or walk indoors [hours per day][2]	2.6 (1.8)	2.9 (1.3)	0.328[c]
Duration of posterior tibial tendon dysfunction [month][3]	120 (5, 240)	48 (6, 420)	
Side[1]			
- Right	2 (9.5)	4 (19.0)	0.222[d]
- Left	8 (38.1)	3 (14.3)	
- Bilateral	11 (52.4)	14 (66.7)	
Stage[1]			
- I	1 (4.8)	0 (0.0)	1[a]
- II	20 (95.2)	21 (100.0)	
Site of pain[1]			1[a]
- Navicular bone	5 (23.8)	4 (19.0)	1[d]
- Medial side of foot	10 (47.6)	10 (47.6)	1[d]
- Posterior to medial malleolus	9 (42.9)	10 (47.6)	0.606[a]
- Lateral side of foot	3 (14.3)	1 (4.8)	1[a]
- Others	0 (0)	1 (4.8)	

[1]Number (%), [2]mean (SD), [3]median (min, max)
[a]Fisher's exact test; [b]T-test; [c]Mann-Whitney U test; [d]Chi-squared test

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

Pain NRS	Study group (n=21)	Control group (n=21)	*p*-value between the groups
Pre-intervention pain	8 (5, 10)	6 (5, 10)	0.411[a]
Post-intervention pain	4 (1, 8)	4 (0, 10)	0.486[a]
p-value within the group	0.001b	0.004[b]	
Pre-post intervention difference*	3 (0, 8)	1 (-1, 7)	0.070[a]

Median (min, max); NRS, numeric rating scale
*Minus value means pre-intervention score is less than post-intervention score
[a]Mann-Whitney U test, [b]Wilcoxon signed rank test

(19%) from the study group and two patients (9.5%) reported increase in minimal pain during the first few days of using the socks. Two patients (9.5%) from the study group reported the foot sliding from medial arch support into an improper position.

Patients' suggestions for improvement of the socks with medial arch support in the study group were as follows: attaching the medial arch support to the sock more tightly (28.6%), reducing the medial arch support height (14.3%), increasing the medial arch support height (4.8%),using the medial arch support with their shoes (9.5%), a waterproof material (4.8%), a more beautiful design (4.8%), and a proper sock size (4.8%); and in the control group as following: increasing the foam height (38.1%), a removable foam before washing (4.8%), a waterproof material (4.8%), a full foot support (4.8%), a proper sock size (4.8%), and a more beautiful design (4.8%).

When asking about a continuation to use the socks in the study group, 52.4% confirmed, 5 patients 23.8% were not sure, and 23.8% preferred discontinuation whereas in the control group, 57.1%would continue using them, 33.3% were not sure, and 9.5% wanted to discontinue using them. However, there were no statistically significant differences in their opinions between the two groups (*p*=0.580).

Discussion

Our study showed that there was a statistically significant decrease in foot pain after using indoor socks with Rehband®, a commercial medial arch support and also showed a high success rate in pain reduction (80.9%) in patients with PTTD stage I and II. In PTTD stage I and II, apart from pharmacological treatment and physical therapy,[9] shoe modifications (such as insert heel counter, medial wedge)and foot orthoses (such as total contact orthoses or medial arch support) are commonly prescribed.[10-12] These could help maintain heel alignment and support the medial longitudinal arch to reduce forces acting on the posterior tibial tendon,[5] resulting in decreased pain.[6] For examples, therapeutic insoles for mild flatfoot deformity using subject-based three-dimensional (3D) computed tomography (CT) models significantly suppressed

Table 3. Limitations of activities and foot instability before (pre-intervention) and after (post-intervention) the study

Pain NRS		Study group (n=21)	Control group (n=21)	*p*-value between the groups
Activities of daily living limitation				
Pre-intervention		7 (3, 10)	7 (4, 10)	0.779[a]
Post-intervention		5 (0, 10)	5 (0, 9)	0.939[a]
	p-value within the group	0.001[b]	0.003[b]	
Pre-post intervention difference		2 (-2,10)	1 (0, 9)	0.652[a]
Household activities limitation				
Pre-intervention		6 (1, 10)	6 (0, 10)	0.879[a]
Post-intervention		5 (0, 8)	4 (0, 9)	0.647[a]
	p-value within the group	0.005[b]	0.011[b]	
Pre-post intervention difference*		1 (-2, 10)	1 (-2, 9)	0.472[a]
Indoor walking limitation				
Pre-intervention		8 (2, 10)	7 (2, 10)	0.572[a]
Post-intervention		4 (0, 8)	5 (0, 9)	0.430[a]
	p-value within the group	0.002[b]	0.012[b]	
Pre-post intervention difference*		2 (-5, 8)	1 (-3, 9)	0.191[a]
Foot instability				
Pre-intervention		7 (2, 10)	5 (0, 10)	0.278[a]
Post-intervention		8 (3, 10)	8 (0, 10)	0.878[a]
	p-value within the group	0.321[b]	0.004[b]	
Pre-post intervention difference**		0 (-6, 2)	0 (-10, 0)	0.076[a]

Median (min, max)
Limitations and ankle instability were assessed with numeric rating scale
Pre-post intervention difference = pre-intervention score minus post-intervention score
*Plus value means limitation was decreased (0, no limitation and 10, complete limitation)
**Minus value means instability was improved (0, completely unstable and 10, completely stable)
[a]Mann-Whitney U test; [b]Wilcoxon signed rank test

Table 4. Patients' adherence to using indoor socks with medial arch support

	Study group (n=21)	Control group (n=21)	*p*-value
Duration of using indoor socks with medial arch support (hours per week)	18.2 (10.2)	22.3 (9.4)	0.179
Duration of standing and walking indoor (hours per week)	26.6 (13.2)	29.8 (11.4)	0.404
Percent of usage from duration of standing and walking	71.4 (26.8)	76.5 (18.8)	0.483

Mean (SD); T–test

Table 5. Satisfaction with the socks with medial arch support/flat foam in different aspects

	Study group (n=21)	Control group (n=21)	*p*-value
Pain control	7 (2, 10)	7 (0, 10)	0.601
Appearance	6 (2, 10)	7 (2, 10)	0.505
Easy to use	6 (2, 10)	8 (2, 10)	0.354
Easy to clean and care	8 (2, 10)	8 (2, 10)	0.959
Durable	7 (1, 10)	8 (2, 10)	0.488
Total treatment	6 (2, 10)	8 (2, 10)	0.077

Median (min, max)
Satisfaction was assessed with numeric rating scale
Mann-Whitney U test

the eversion of the talocalcaneal joint,[5] and non-operatively with orthoses and structured exercises could effectively treated stage I and II PTTD.[13]

However, there was also a statistically significant decrease in foot pain in the control group, despite using 2 mm thickness flat foam. This might be from the foam, which was attached at the medial longitudinal arch position, acting as a cushion. All patients in the control group had stage II PTTD with collapsed medial longitudinal arch. Despite the foam that could not rest the posterior tibial tendon or decrease the subtalar eversion, it could be a cushion to absorb the force that caused the pain, resulting in pain relief.

Besides foot pain reduction, our study found that using indoor socks with medial arch support or with 2 mm thickness flat foam under the medial arch support showed statistically significant decreases in limitations of ADL, household activity, and indoor walking. These could be from the effectiveness of decreasing pain in both groups, thus leading to reduced activity limitations.

In addition, using indoor socks with medial arch support increased the foot instability in the study group. This could be from the medial arch support sliding into an improper position, in spite of attaching it with Velcro®. Foot gliding on the

medial arch support might make patients feel more unstable. The smallest size of the medial arch support (Rehband®) was still too high for some patients with very flat arch, and caused their feet tilted and not in the right position. However, wearing shoes with counter could support the foot. To be noted, in the control group there was a statistically significant decrease in foot instability which might be due to flatness of the foam not tilting the foot. Further, a decrease in foot pain after using indoor socks with flat foam might lead to reduce instability.

There were no serious complications in our study. Four patients from the study group felt more pain at the beginning of the study, perhaps caused by sliding of medial arch support led to ineffective resting of the tendons and its improper position pressed on other parts of the foot. In our study, we informed the patients to increase duration of usage 5 minutes per day for first week before starting the study. However, some might need more than one week for foot accommodation. Two patients reporting more pain after using the devices had the medial arch support sliding into an improper position. Two patients complained of the medial arch support size not fitting their arches and thus not effectively resting the tibialis posterior tendon. Longer duration of walking and standing might be a cause of foot pain as one in the study group and two in the control group complained of more foot pain.

When asking the patients to rate their satisfaction, scores were high in every aspect, especially in pain control. More than half in both groups would like to continue using the socks with medial arch support/flat foam. We expect that adjustments according to the patients' suggestions, e.g., choosing an appropriate height of the medial arch support and preventing sliding of the medial arch support while walking and standing, the indoor socks with medial arch support would be a feasible alternative for reducing foot pain in patients who do not wear shoes indoors. Nevertheless, using medial arch support and shoe modifications is still the best solution for patients with PTTD who endure foot pain from long durations of standing and walking indoors.

There were some limitations in our study. Three sizes of over-the-counter/ready-to-use medial arch support did not fit all patients' medial longitudinal arches, and thus could not beeffective in decreasing pain. A custom-molded medial arch support should be investigated in a future study. Another limitation was using free-size socks which did not tightly fit some with small-sized feet and caused the medial arch support sliding into an improper position. Moreover, using Velcro® for attachment could not prevent the medial arch support sliding into an improper position and it might increase more height causing the feet tilted and uncomfortable feeling. Therefore, preparing different sizes of socks, choosing an appropriate size for the feet, and using another material for attachment of the medial arch support to the socks, should be considered to improve effectiveness.

In conclusion, there were no statistically significant differences in decreasing foot pain and activity limitations between using indoor socks with a commercial medial arch support and with flat foam in patients with stage I or II posterior tibial tendon dysfunction. However, those using indoor socks with medial arch support had higher success rate in pain reduction than those using indoor socks with flat foam. Improper size of medial arch support, sliding of medial arch support to improper position and more increased walking and standing could be factors that made patients experience more pain.

Disclosure

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