Original Article

The Efficacy of Modified Total Contact Orthosis in Decreasing Pain While Walking Indoors in Patients with Posterior Tibial Tendon Dysfunction: A Prospective, Randomized, Double-Blind Controlled Trial

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ABSTRACT

Objectives: To evaluate the effectiveness of a modified total contact orthosis (modified TCO) in reducing pain during indoor walking among patients with posterior tibial tendon dysfunction (PTTD). Patient satisfaction, complications, Foot Function Index (Thai version), and device compliance were also evaluated

Study design: A prospective, randomized, double-blind controlled trial

Setting: The Foot Clinic at Siriraj Hospital, a tertiary care academic medical center in Bangkok, Thailand

Participants: Forty-two patients aged 45–65 years with stage I–III PTTD lasting more than 6 weeks.

Methods: Participants were enrolled between November 2023 and June 2024 and randomized into two groups. The study group received a modified TCO, whereas the control group received a sham orthosis. Both groups used the orthoses indoors for 2 weeks. Pain scores, Foot Function Index (Thai version), satisfaction, and compliance were assessed at baseline and after 2 weeks.

Results: The participants, with a mean age of 62.2 (SD = 8.9) years in the study group and 63.2 (SD = 9.5) years in the control group, were predominantly female (90.5%) and had stage II PTTD. All participants completed the study. After 2 weeks, the study group reported significantly less pain at the posterior tibial tendon and demonstrated better total foot functionality compared to the control group ($p < 0.001$ and $p = 0.03$, respectively). Both groups expressed high satisfaction with the devices, using them for more than 80.0% of the time spent indoors.

Conclusions: A modified total contact orthosis can reduce pain at the posterior tibial tendon in PTTD patients during indoor walking and can improve the Foot Functional Index without serious adverse effects.

Keywords: acquired adult flatfoot deformity, foot orthosis, flatfoot, orthotic Insoles, posterior tibial tendon dysfunction

ASEAN J Rehabil Med. 2026; 36(3): 107-114.
doi: 10.67880/ajrm.2026.36.01

Introduction

Posterior tibial tendon dysfunction (PTTD) is a common condition of adult-acquired flatfoot deformity which is common in women aged 45-65 years.[1,2] Patients typically present with medial foot and ankle pain due to abnormal weight-bearing resulting from the dysfunctional foot arch. Over time, the condition can lead to foot deformities.

PTTD is classified into four stages. In stage I, symptoms may include mild pain and swelling along the posterior tibial tendon, but no deformity or sign of "too many toes" is present. The patient can perform the double heel-rise test as well as the single heel-rise test. In stage II, the posterior tibial tendon is degenerating, and foot deformities, such as forefoot abduction and hindfoot valgus, are beginning to develop but the foot remains flexible. The arch of the foot may collapse. The patient may not be able to perform the single heel-rise test, but may be able to perform the double heel-rise test. The too many toes sign is present, with no heel valgus and no foot inflammation. In stage III, the deformities become rigid and the hindfoot valgus cannot be corrected. In stage IV, the symptoms are similar to stage III, but with additional degeneration of the ankle joints, such as a tear of the deltoid ligament, leading to eversion of the ankle and degeneration of the tibiotalar joint.

Treatment options include non-pharmacological approaches, pharmacotherapy, and surgery. One non-pharmacological intervention involves shoes with total contact orthosis (TCO), which aims to reduce strain on the posterior tibial tendon and support the foot arch. These devices are recommended for continuous wear, both indoors and outdoors. Many studies[3-8] confirm that TCOs or proper foot orthoses can decrease foot pain, improve patient comfort, and help increase compliance, as demonstrated in the following research studies.

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Received: January 29, 2026 Revised: April 2, 2026 Accepted: April 3, 2026

The research by Kido M. and colleagues[3] studied the effects of foot orthotics in 8 patients with an average age of 32.1 years who had symptoms of PTTD. The patients were asked to wear sneakers with TCOs, including a 10-millimeter arch support and a 5-millimeter medial wedge. Computed tomography (CT) scans were taken to compare the weight-bearing and non-weight-bearing positions of the foot. The CT images indicated that the arch support significantly reduced the degree of foot deformity. All patients reported increased comfort while wearing the insoles.

Research by Han K. and colleagues[4] investigated biomechanical effects on rear-foot and ankle movement in 28 male patients with flat feet, with an average age of 20 years. Each patient wore three types of insoles: standard insoles, arch-supported insoles, and both arch-supported and cushioned insoles. Video recordings of the patients walking were made, with each patient walking at the same pace and speed. The analysis revealed that using insoles with arch support or insoles with both arch support and cushioning significantly reduced the degree of foot deformity compared to standard insoles.

Research by Yurt, Y. and colleagues[5] investigated the effects of different types of insoles on foot pain and the quality of life in patients with flat feet aged 18-45 years. The study found that patients using custom-made insoles, whether produced by computer-aided design (CAD-CAM) or traditional methods, experienced greater pain relief than those using standard insoles. No significant difference was observed between the insoles made using CAD-CAM and those made using conventional methods.

Research by Açak[6] studied the effects of custom-made insoles in 34 patients aged 18-28 years with flat feet. The insoles were made of 1-millimeter-thick stainless chrome steel covered with 3 millimeters of leather which included specific arch support tailored for each patient. Patients wore the insoles daily for one year, both at home and outside, although they switched to sandals for indoor use. The study found that patients experienced weight loss due to increased physical activity, reduced arch pain, improved quality of life, and enhanced physical performance, allowing them to run faster and jump higher.

Research by Karimi and colleagues[7] investigated the effect of insoles on the energy expenditure index during walking in patients with flat feet. The study involved two groups of 25 participants each. The first group consisted of patients with flat feet, while the second group comprised individuals with normal feet. The findings revealed that patients with flat feet used more energy during walking than those with normal feet due to abnormal foot alignment. Additionally, wearing insoles improved foot alignment, leading to better, faster walking and significantly reducing the energy expenditure index.

A systematic review by Gómez-Jurado, I. and colleagues[8] examined the use of supportive devices in treating patients with stage I and stage II PTTD. They reviewed four randomized control trials involving 186 participants and evaluated treatments including supportive devices, footwear, and exercise. The findings indicated that combining supportive devices with exercise yielded better outcomes than using supportive devices alone. Additionally, customized insoles with arch supports were more effective at reducing arch pain than non-customized insoles.

Other studies have found that adjusting footwear and using medial arch supports, recommended treatments for patients with PTTD, can reduce the workload on the tendon, leading to decreased pain for patients.[9,10]

The Foot Clinic at the Department of Rehabilitation, Siriraj Hospital has been in operation since 2004, serving approximately 1,000 patients annually. Many patients seek consultation for foot health issues, with adult flatfoot being a common problem that leads to foot deformities and pain, and is a significant reason for patients to visit the doctor. Surveys indicate that a large number of patients at the Foot Clinic have flatfoot due to PTTD. Once diagnosed with this condition, patients receive treatment that includes medication together with other non-pharmacological methods such as weight management, lifestyle modifications, exercise, footwear adjustments, arch supports, and custom-made TCOs. Most patients who were provided with either sports shoes or supportive footwear with custom-made TCOs experienced reduced pain while wearing them. However, nearly all patients refused to wear sports shoes or supportive footwear indoors, opting to wear them only outside the house. This resulted in alleviated pain while outside but continued pain while walking indoors, leading to suboptimal treatment outcomes. Despite recommendations to wear sports shoes or supportive footwear indoors, many patients compromised by choosing easy-to-wear sandals instead as they did not require bending over to adjust laces or straps.

According to a study by Sukthomya, S. and colleagues,[11] 46.8% of diabetic patients in Thailand walked barefoot at home, 38.5% wore sandals, 5.4% wore closed-toe shoes, and only 9.3% used other types of footwear despite receiving advice to wear shoes at all times, both indoors and outdoors, to prevent foot ulcers. Patients preferred to wear shoes only when going outside. It is the custom in Thailand to remove shoes before entering a house. The study also investigated factors influencing the choice of indoor footwear among diabetic patients. It found that 78.0% of patients preferred easy-to-wear shoes such as sandals, 76.7% wore shoes costing less than 30 USD, 71.0% preferred black shoes, 53.7% chose well-ventilated and comfortable shoes, 31.8% opted for flexible materials, and 18.9% preferred shoes with easily adjustable straps.

In response, researchers have developed a modified TCO for indoor use. These supports attach snugly to the upper foot, with extended leather sides that cover the arch and have a non-slip sole resembling a sandal which enhances comfort during indoor activities. The research team hypothesized that

the modified TCO would alleviate foot pain caused by PTTD during indoor use. In addition, the use of a sham orthosis was considered essential to compare the study and control groups, minimize the placebo effect, and ensure a more reliable evaluation of treatment efficacy.

The objectives of this study were to evaluate the effectiveness of the modified TCO in reducing posterior tibial tendon pain during indoor walking among patients with PTTD and to assess patient satisfaction, complications, Foot Function Index (Thai version), and compliance with device use.

Methods

Study design

The study was a prospective, randomized, double-blind, parallel-group, controlled trial with a 1:1 allocation ratio and a superiority framework. The trial was conducted at the Foot Clinic, Department of Rehabilitation Medicine, Siriraj Hospital, Bangkok, Thailand, between November 2023 and June 2024. The study protocol was approved by the Institutional Review Board (IRB No. 345/2566; Certification No. 464/2023, approve on June 13, 2023). The trial was registered with the Thai Clinical Trials Registry (TCTR20231026005) on October 26, 2023. The study was conducted in accordance with the CONSORT 2022 guidelines.

Participants

Patients aged over 40 years with stage I–III PTTD and intermittent pain persisting for at least 6 weeks were recruited. Eligible participants had a numeric rating scale pain score of ≥5 when not wearing shoes or while standing or walking indoors, specifically around the medial arch or along the posterior tibial tendon. All participants regularly wore appropriate shoes outdoors (TCO with a rigid heel counter, such as sneakers). Exclusion criteria included communication or cognitive impairments, use of non-steroidal anti-inflammatory drugs or discontinuation of such medications for less than two weeks within two weeks of the start of the study, regular use of proper shoes with TCO at home, foot numbness or ulceration, postural control disorders (e.g., Parkinson's disease), or planned extensive travel during the study period. A physiatrist specializing in foot disorders confirmed the diagnosis and classified the disease stage based on the clinical presentation. In participants with bilateral PTTD, the more symptomatic side, based on a numeric rating scale, was selected for analysis.

To determine the required sample size, we utilized data from Thammawijaya, A.[12] which indicated that medial arch supports in patients with plantar fasciitis reduced pain scores from 4.9 (SD = 1.66) to 2.7 (SD = 1.93). Assuming a power of 0.90, a two-sided α of 0.05, and an effect size of 1.036, a minimum of 21 participants per group was required.

Materials

The modified modified TCO (Figure 1) and the sham orthosis (Figure 2) were fabricated using an identical dual-layer construction of two 1-cm-thick ethyl vinyl acetate (EVA) soft rubber foam layers. Both devices had a similar external appearance, including a soft leather upper and a non-slip outsole, to maintain participant blinding. The modified TCO included a customized medial arch support and a medial wedge, whereas the sham orthosis lacked arch support and functioned as a flat insole.

Study protocol

Prior to enrollment, all qualifying patients underwent a recruitment and briefing process, culminating in the acquisition of their signed informed consent. Participants then completed a questionnaire assessing (1) background information, (2) the Foot Functional Index Thai Version (FFI-TH),[13] and (3) foot pain during the week prior to enrollment.

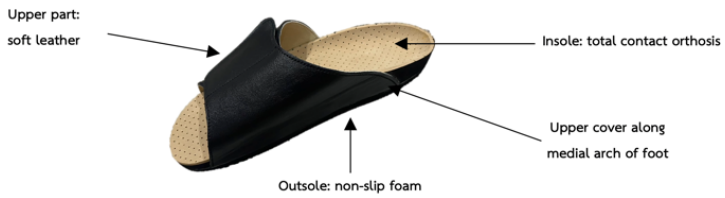

Figure 1. Modified total contact orthosis

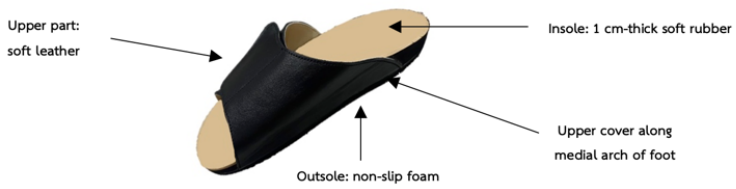

Figure 2. Sham orthosis

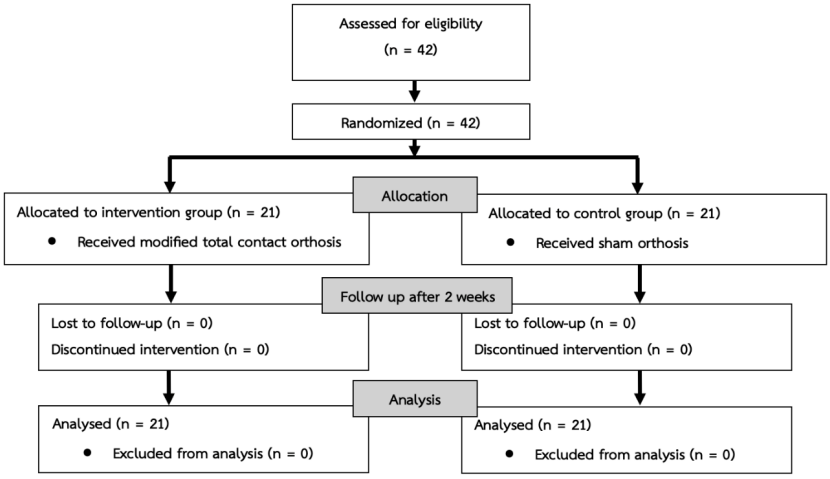

Figure 3. Flow diagram of the study

Background information included age, gender, BMI, the number of hours spent standing or walking (hours/day), and the daily duration of shoe-wearing. The duration of pain and the level of foot pain were recorded using a numeric rating scale. Questions were scored from 0 (no problem/no pain) to 10 (worst problem/worst pain). The current treatment record included activities such as taking pain-relieving medications like NSAIDs or undergoing physical therapy. After completing the questionnaire, a physiatrist conducted a physical examination to determine the stage and select the most severely affected foot.

The first investigator randomly assigned patients to two separate groups. Random permuted blocks were created using a computer-based random number generator, and allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes. To ensure objectivity, this sequence was generated by an external researcher who took no part in recruiting or evaluating the participants. To prevent bias, all participants, investigators, orthotists, and outcome assessors remained blinded to the group allocations for the entirety of the study. An equal likelihood of assignment to either group was maintained for all patients.

Patients in both groups were sent to the orthotist, who made a modified TCO (study group) or a sham orthosis (control group). Both groups underwent the same foot printing procedure. After a fortnight, the patients were fitted with their devices by the orthotist. The orthotist assessed the patient to ensure the devices fit properly. In the first week after receiving the devices, patients were instructed to gradually increase the duration of wearing them. For days 1-7, they were advised to wear them for 15 minutes on the first day, 30 minutes on the second day, 1 hour on the third day, 2 hours on the fourth day, and for the entire day on days 5, 6, and 7. Afterward, patients were instructed that after day 7, they should wear the devices whenever standing or walking at home, and to wear their own sports shoes and a TCO at all times when standing and walking outside. Patients were instructed to start recording their device usage the second week after receiving the devices. For compliance measurement, patients were instructed to document the precise amount of daily usage time within a logbook. Additionally, patients were instructed to document any device-related complications in their logbooks.

Two weeks post-treatment, participants from both groups returned to complete a follow-up assessment. This survey evaluated their foot pain over the preceding week, utilizing the Foot Functional Index Thai Version [FFI-TH],[13] alongside a numeric rating scale to gauge treatment satisfaction. To maintain blinding, a physiatrist unaware of the group assignments administered this portion of the questionnaire. Afterward, individuals in the intervention group met with the orthotist to submit their logbooks. They were also interviewed to assess their willingness to use the modified TCO moving forward and to gather feedback on optimizing the device's design.

Statistical analysis

Statistical analysis was performed using SPSS version 29.0 (IBM Corp, Armonk, NY, USA). Qualitative data, including gender, current treatment, stage of disease, and side of disease involvement, are reported as numbers and percentages. Continuous variables, including age and body mass index (BMI), are expressed as mean and standard deviation (SD) or median and interquartile range (IQR), as appropriate, and compared between groups using the independent t-test or the Mann–Whitney U test, depending on data distribution. The duration of posterior tibial tendon pain and the working hours during which the patient needed to stand or walk indoors and outdoors were calculated as median (IQR). Baseline pain status during the week before the study, post-study pain, and satisfaction with the treatment, which were recorded using a numeric rating scale, are reported as median (IQR). The complications associated with the use of a modified TCO were calculated as numbers and percentages. The foot functional index was calculated as median (IQR). Compliance with the use of a modified TCO was calculated as the mean and standard deviation. An unpaired t-test was used to

explore differences in quantitative data with normal distributions, and a Mann-Whitney U test was used to explore differences in quantitative data with non-normal distributions. The Chi-Square test and Fisher's exact test were used to explore differences in qualitative data. A *p*-value of less than 0.05 was considered statistically significant.

Results

In this study, 42 patients were randomly assigned to one of two groups and all successfully completed the follow-up evaluation after a 2-week period, concluding their involvement in the research. The baseline characteristics of the subjects included in the study are presented in Table 1.

Upon analyzing the baseline measures for both groups, a similarity emerged in key factors, including age, gender, body mass index (BMI), working hours involving standing or walking indoors and outdoors, baseline pain, duration of PTTD, current treatment, side of involvement, and stage of disease. Analysis of baseline characteristics revealed no significant differences between the two groups ($p > 0.05$).

Table 2 presents the median of baseline pain status at the posterior tibial tendon, recorded on a numeric rating scale for the 2 weeks preceding the current study. Analysis of these baseline measures indicated no significant differences between the two groups ($p = 0.08$).

Primary outcome

NRS pain score at 2 weeks

As shown in Table 2, both groups had comparable baseline pain scores at the posterior tibial tendon ($p = 0.08$) prior to the intervention. After the 2-week intervention, the study group demonstrated a significantly lower pain score than the control group ($p = 0.01$). Within-group analysis revealed significant pain reduction in both groups after treatment (study group: $p < 0.001$; control group: $p = 0.03$). The reduction in

Table 1. Demographic data

Characteristics	Study group n = 21	Control group n = 21	*p*-value
Age (years)[1]	62.2 (8.9)	63.2 (9.5)	0.74[b]
Gender[2]			
Male	0.0 (0.0)	4.0 (19.0)	0.11[c]
Female	21.0 (100.0)	17.0 (81.0)	
Body mass index (kg/m^2)[1]	25.4 (3.9)	26.5 (3.9)	0.38[b]
Hours the patient needed to stand or walk in-doors (hours/day)[3]	2.0 (1.0-3.3)	1.9 (0.9-2.5)	0.55[d]
Hours for which the patient needed to stand or walk outdoors (hours/day)[3]	1.1 (0.6-2.4)	1.0 (0.4-2.0)	0.70[d]
Duration of foot problems (years)[3]	7.0 (3.0-10.0)	7.0 (3.0-17.0)	0.70[d]
Level of pain[3]	7.0 (7.0- 8.0)[a]	7.0 (6.0-7.5)[a]	0.08[d]
Current treatment[2]			
Paracetamol	1.0 (4.8)	5.0 (23.8)	0.18[c]
NSIADs	0.0 (0.0)	0.0 (0.0)	
Physical therapy	1.0 (4.8)	0.0 (0.0)	1.00[c]
Others (Norgesic®, Duocetz®)	2.0 (9.5)	6.0 (28.6)	0.24[c]
Side[2]			
Right	1.0 (4.8)	2.0 (9.5)	1.00[f]
Left	2.0 (9.5)	1.0 (4.8)	
Bilateral	18.0 (85.7)	18.0 (85.7)	
Stage[2]			
Stage I	1.0 (4.8)	0.0 (0.0)	1[f]
Stage II	17.0 (81.0)	18.0 (85.7)	
Stage III	3.0 (14.3)	3.0 (14.3)	

[1]Mean (SD), [2]Number (%), [3]Median (IQR); [a]Numeric rating scale (0: no pain, 10: worst pain), [b]Unpaired t-test, [c]Fisher's exact test, [d]Mann–Whitney U test, [f]Chi-square test with exact test, NSAIDs: non-steroidal anti-inflammatory drugs

Table 2. Comparison of pain Scores between pre-intervention and post-intervention

Pain (NRS) Median (IQR)	Study group (n = 21)	Control group (n = 21)	*p*-value between groups
Pre-intervention pain	7.0 (7.0-8.0)	7.0 (6.0-7.5)	0.08[a]
Post-intervention pain	3.0 (2.0-4.5)	5.0 (3.0-7.5)	0.01[a]
p-value within group	< 0.001[b]	0.03[b]	
Pre-post intervention difference	4.0 (4.0,5.0)	2.0 (0.0-3.0)	< 0.001[a]

NRS, numeric rating scale (0: no pain, 10: worst pain); [a]Mann–Whitney U test, [b]Wilcoxon signed-rank test

pain scores was significantly greater in the study group (p < 0.001).

Secondary outcome

Patient satisfaction

Satisfaction with the treatment was recorded using a numeric rating scale, as shown in Table 3. The questions were scored from 0 (dissatisfied) to 10 (highest satisfied). Satisfaction scores were high across all aspects in both groups. The medians (IQR) of the pain reduction satisfaction score in the study group and the control group were 9 (8.5, 10) and 7 (4.5, 9), respectively. The overall satisfaction scores in the study and control groups were 9 (8,10) and 8 (6.5,9), respectively. There were statistically significant differences in satisfaction scores for pain reduction and overall satisfaction between the two groups (p = 0.001 and 0.002, respectively).

Complications

Complications related to device use were observed in both groups. One patient (4.8%) in the study group reported pain, compared with six patients (28.6%) in the control group. Foot abrasions or blisters were reported by two patients (9.5%) in each group. Foot eczema was reported by only one patient (4.8%) in the control group.

Foot Function Index (FFI-TH)

Table 4 shows no statistically significant differences between the two groups in total scores for the FFI-Thai version[13], pain, disability, and activity limitation at baseline (p = 0.70, 0.21, 0.72, and 1.00, respectively). However, at the 2-week follow-up, significant differences were observed in total score, pain, and disability (p = 0.001, < 0.001, and 0.01, respectively). When comparing the pre- and post- intervention differences in total score of FFI-Thai version[13], pain and disability, and activities between the two groups, there was a significant difference (p = 0.001, < 0.001, and 0.004, respectively)

Compliance with device use

Table 5 presents patients' adherence to device compliance, where the percent of usage was calculated by dividing the duration of indoor device use by the duration of standing

Table 3. Patient satisfaction scores by device attributes

Type Median (IQR)	Satisfaction score		
	Study group	Control group	*p*-value[a]
Pain reduction	9.0 (8.5-10.0)	7.0 (4.5-9.0)	0.001
Cosmesis appearance	8.0 (7.0-9.0)	8.0 (6.5-8.5)	0.14
Convenience in wearing/easy to use	10.0 (9.0-10.0)	10.0 (8.0-10.0)	0.52
Maintenance	9.0 (9.0-10.0)	9.0 (8.0-10.0)	0.33
Durability	9.0 (6.0-10.0)	9.0 (6.5-9.0)	0.66
Overall satisfaction	9.0 (8.0-10.0)	8.0 (6.5-9.0)	0.002

Satisfaction was assessed using a numeric rating scale (0: no satisfaction, 10: highest satisfaction); [a]Mann–Whitney U test

Table 4. Comparison of Foot Functional Index Scores between pre-intervention and post-intervention

Subscale Median (IQR)	Study group	Control group	*p*-value
Total			
Pre-intervention	104.0 (94.5-115.0)	99.0 (78.0-127.0)	0.70[a]
Post-intervention	45.0 (35.5-60.0)	80.0 (59.5-103.0)	0.001[a]
p-value within group	< 0.001[b]	0.005[b]	
Pre-post intervention difference	54.0 (39.0-65.0)	26.0 (-1.0-46.5)	0.001[a]
Pain			
Pre-intervention	50.0 (45.0-54.0)	44.0 (40.0-57.5)	0.21[a]
Post-intervention	24 (19-29)	38 (27-48)	< 0.001[a]
p-value within group	< 0.001[b]	0.007[b]	
Pre-post intervention difference	27.0 (20.5-32.5)	15.0 (-0.5-23.0)	< 0.001[a]
Disability			
Pre-intervention	50.0 (46.0-57.5)	47.0 (41.0-64.0)	0.72[a]
Post-intervention	23.0 (17.0-32.0)	37.0 (29.5-49.0)	0.01[a]
p-value within group	< 0.001[b]	0.003[b]	
Pre-post intervention difference	25.0 (15.0-34.0)	13.0 (0.0-23.0)	0.004[a]
Activity limitation			
Pre-intervention	3.0 (0.0,7.0)	2.0 (0.0,7.0)	1.00[a]
Post-intervention	0.0 (0.0,2.0)	2.0 (0.0,5.0)	0.16[a]
p-value within group	0.002[b]	0.01[b]	
Pre-post intervention difference	1.0 (0.0-4.5)	0.0 (0.0-2.0)	0.16[a]

[a]Mann–Whitney U test; [b]Wilcoxon signed-rank test

Table 5. Comparison of indoor mobility and device adherence between the study and the intervention groups

Composite mobility & Compliance metrics Mean (SD)	Study group	Control group	*p*-value
Duration of using indoor devices (hours per week)	26.8 (16.0)	23.1 (13.3)	0.42[a]
Duration of standing and walking indoor (hours per week)	34.6 (19.9)	30.9 (19.9)	0.56[a]
Percent of usage from duration of standing and walking	81.7 (22.4)	80.1 (24.4)	0.82[a]

[a]t-test

and walking indoors, then multiplying by 100. The mean (SD) percentage of use was high in both groups: 81.7% (22.4) in the study group and 80.1% (24.4) in the control group. There was no statistically significant difference in the duration of standing and walking indoors, the duration of using the modified TCO, or the percent of usage from the duration of standing and walking between the two groups (p = 0.51, 0.97, and 0.22, respectively).

Discussion

The use of total contact orthoses (TCO) and shoes with heel counters, such as sports shoes, for alleviating pain and optimizing physical performance among patients with posterior tibial tendon dysfunction (PTTD) is well established.[3-10] However, compliance with wearing closed heel design shoes in-house is relatively low,[11] which leads to persistent pain symptoms. Therefore, the researchers who conducted this study developed a new device, a modified TCO. This device features an open heel design, which facilitates donning. To maintain the function of the heel counter, the modified TCO was designed with an upper that covers the medial arch of the foot.

The present study was conducted specifically among patients who usually wore proper shoes outdoors and excluded those who wore proper shoes indoors, since wearing proper shoes indoors is considered the most effective treatment.

Regarding pain, the current trial found that after treatment the study group had less pain in the posterior tibial tendon than the control group. Furthermore, the study group reported a greater decrease in pain level (pre-post intervention difference). There was also an improvement in the Thai version of the Foot Functional Index in terms of pain. This result confirms that using the modified TCO can decrease pain in the posterior tibial tendon. Reasons for the better pain relief may include the following. The cause of pain in PTTD is an abnormal load on the soft tissues on the medial side of the foot, such as the posterior tibial tendon and the deltoid ligament, resulting from abnormal foot alignment (subtalar eversion) and a dysfunctional foot arch. The medial wedge and the medial arch of TCO, in conjunction with the upper part of the shoe that covers the medial arch of the foot, help maintain heel alignment and support the medial longitudinal arch.[3] As a result, these devices reduce forces acting on the posterior tibial tendon. Consequently, these devices can reduce pain.

There was a statistically significant decrease in foot pain in the control group despite the use of flat foam. This might be due to the upper part of the shoe wrapping around the medial side of the foot, acting as a medial arch support. Although the foam is unable to support the posterior tibial tendon or reduce subtalar eversion, it can act as a cushion absorbing the force causing the pain, thereby providing pain relief.

Regarding compliance and satisfaction, device usage compliance was very high. Patients in both groups rated their satisfaction high across all aspects: cosmesis, ease of use, maintenance, durability, and overall experience. Device compliance was high in both groups, with a mean (SD) of 81.7 (22.4) in the intervention group and 80.1 (24.4) in the control group, indicating that consistently wearing indoor shoes was considered beneficial. However, there was a significant difference in the satisfaction score on pain reduction between the two groups. This result establishes that using the modified TCO is the optimal solution for patients with PTTD, especially those who spend prolonged periods standing and walking indoors.

No patient had serious complications the study group had less pain. Only one patient in the study group experienced increased pain at the beginning of the study, compared with six in the control group. In the study group, the increased pain may have been due to unfamiliarity with the devices. In the control group, patients experienced progressively worsening foot pain, difficulty walking, and a sense of instability even after wearing the devices, leading them to grip the floor with their toes. In this study, the researchers instructed the patients to increase the duration of use to 15-30 minutes per day for the first week before the start of the study. However, some patients might have needed more than one week for foot accommodation. In the future, the trial period for wearing the devices should be extended beyond 1 week. Skin abrasions or blistering were found in both groups, a total of 4 patients. Only one patient from the control group developed eczema. It is recommended that patients with existing sores wear socks to help reduce the risk of complications.

The cost of the TCO was 80 USD. The labor cost for modifying the device was 10 USD, and the cost of modification materials was 5 USD per pair, a total of 95 USD per pair. The device was not difficult to fabricate. Any orthotist who could make a TCO could also easily perform the modification.

Study limitations

Several limitations affect this study. Because the research lasted only two weeks, we could not analyze the long-term outcomes. In addition, the use of subjective outcome measures may have introduced self-reporting bias. The durability of the modified TCO was also not evaluated; typically, TCO devices

last approximately 6-12 months, depending on individual use. Further studies with longer follow-up are warranted.

Conclusions

The use of an indoor modified TCO effectively reduced can effectively reduce posterior tibial tendon pain in patients with PTTD without any serious complications.

Conflicts of interest declaration

No conflicts of interest were declared by the authors concerning the research materials, authorship, or the publication of this article.

Generative AI declaration

No generative AI or large language models (LLMs) were used in the writing, editing, or data presentation of this paper. The authors only used Grammarly and QuillBot for standard copyediting and grammatical corrections.

Acknowledgements

The authors would like to express their gratitude to Miss Julaporn Pooliam from the Division of Epidemiology at Mahidol University for her valuable support with the statistical analysis.

Funding

The authors disclose that this research was conducted without any financial support or specific grants from public, commercial, or non-profit funding agencies.

Data availability

To obtain the source material supporting these findings, please reach out to the corresponding author with a valid inquiry.

Author contributions

Ploypapus Rachatacharoensap: methodology, writing - original draft,

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