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Abstract

Background: The value of strengthening and stretching exercises combined with orthosis treatment in a home-based program has not been evaluated. The purpose of this study was to compare the effects of augmenting orthosis treatment with either stretching or a combination of stretching and strengthening in participants with stage II tibialis posterior tendon dysfunction (TPTD).

Methods: Participants included 39 patients with stage II TPTD who were recruited from a medical center and then randomly assigned to a strengthening or stretching treatment group. Excluding 3 dropouts, there were 19 participants in the strengthening group and 17 in the stretching group. The stretching treatment consisted of a prefabricated orthosis used in conjunction with stretching exercises. The strengthening treatment consisted of a prefabricated orthosis used in conjunction with the stretching and strengthening exercises. The main outcome measures were self-report (ie, Foot Function Index and Short Musculoskeletal Function Assessment) and isometric deep posterior compartment strength. Two-way analysis of variance was used to test for differences between groups at 6 and 12 weeks after starting the exercise programs.

Results: Both groups significantly improved in pain and function over the 12-week trial period. The self-report measures showed minimal differences between the treatment groups. There were no differences in isometric deep posterior compartment strength.

Conclusions: A moderate-intensity, home-based exercise program was minimally effective in augmenting orthosis wear alone in participants with stage II TPTD.

Level of Evidence: Level I, prospective randomized study.

Keywords: rehabilitation, tendinopathy, foot

Tibialis posterior tendon dysfunction (TPTD) is a common tendinopathy that is associated with adult acquired flatfoot deformity.[6,11,13,22] Therapeutic options for stage II TPTD entail nonoperative care with bracing and exercise or operative management.[7,20,21,30,31] The severity of TPTD may affect the choice of nonoperative or operative treatment. Stage II TPTD is characterized by signs of tendinopathy (ie, pain and swelling along the tendon) in the presence of a passively correctable foot deformity or loss of the medial longitudinal arch.[13] Stage II TPTD is associated with a wide range of weakness, foot deformity, and functional problems.[17,33,34] Ultimately, relatively few participants with TPTD, 12.5% to 27% in recent studies, elect operative management.[28,30] The low use of operative management of TPTD emphasizes the need to optimize nonoperative treatments.

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Orthosis prescription, including above-ankle and below-ankle orthoses, are the most commonly recommended nonoperative treatment.[28] Uncontrolled studies note that participants experience a decrease in pain and improved function when using orthoses.[1,2,14,17,20] Further, long-term (4- to 8-year) follow-up of orthoses suggested that 60.6% of participants were "satisfied." However, the average initial length of orthosis wear was 14.9 months, and 36% of the participants returned to wearing their orthosis at some time during the follow-up period. Intermittent continuing use of an orthosis suggests unresolved symptoms over prolonged periods. Two unaddressed issues are (1) whether some orthosis strategies are more effective than others and (2) whether other treatments, such as exercise, augment orthosis use.

A prefabricated clamshell orthosis may be cost-effective and adequate for foot support in patients with TPTD. A kinematic study showed that a prefabricated clamshell orthosis limited hindfoot eversion and raised the medial longitudinal arch.[27] These same movements in a cadaver study demonstrated unloading of the tibialis posterior tendon.[23,26] These positive kinematic findings are coupled with positive outcomes in studies that use the prefabricated clamshell orthoses.[14] Considering the markedly lower cost of the prefabricated clamshell orthosis and the demonstrated clinical benefits,[14] this type of orthosis was considered a good choice for clinical management.

The conflicting evidence regarding whether exercise augments orthosis wear in patients with stage II TPTD stems from varying study design (uncontrolled vs controlled trials), orthosis use (wide range), and exercise dosage. First, uncontrolled trials demonstrate the potential benefit of combining an orthosis and exercise programs for stage II TPTD.[1,16] However, only 1 of 2 controlled trials demonstrated a similar benefit.[17] Second, orthotic designs that restrict ankle and foot motion may induce muscle disuse.[25] Whether combining exercise with less restrictive orthoses maintains muscle function and similar clinical benefits is unclear. Third, the optimal intensity of training is undetermined. One uncontrolled trial suggested marked improvements as a result of high-intensity training.[1] Two randomized controlled trials[3,17] included lower dosage training and did not replicate the positive results of a high-intensity dosage.[1] Untested is the effect of a program that may be easily used in the clinic with moderate-intensity exercise to improve muscle weakness and improve pain-free function.

The purpose of this study was to examine the effects of strengthening treatment combined with orthosis and stretching compared with the effects of orthosis and stretching alone in participants with stage II TPTD. The dosage for the strengthening treatment group was as high as possible with the limit being that the exercises would need to primarily be performed in the home and within patient tolerance.

Methods

Participants

From spring 2007 to summer 2009, a total of 88 participants were screened for participation in this study. Of the 88 participants who were screened, a total of 39 were admitted to the study. A power analysis, based on pilot data on strength and self-reported outcomes, suggested that a sample size of 20 per group would provide greater than 80% power to detect differences between the groups at an effect size equal to 0.75 the standard deviation of the measures used. Recruitment was conducted at a university medical clinic by a foot and ankle fellowship–trained physician. To qualify for the study, participants met the following criteria to be diagnosed with stage II TPTD: (1) presence of either pain or swelling along the course of the tibialis posterior tendon and (2) presence of correctable flatfoot deformity. Participants also had to be able to walk 15 m and were required to be older than 40 years. Participants were excluded if (1) they were unable to walk 15 m, (2) a test using Semmes-Weinstein 5.06 monofilament showed decreased sensation, (3) participants had an arch height index of less than 0.255 (2 SD below arch height index of controls),[5] (4) participants were unable to assume subtalar neutral posture, or (5) they had bilateral TPTD. Participants with inflammatory arthropathies (rheumatoid arthritis, psoriasis) and comorbidities for foot conditions (hallux rigidus, plantar fasciitis) were also excluded. Participants signed a consent form approved by the institutional review board at the University of Rochester and Ithaca College. This clinical trial was registered at ClinicalTrials.gov in 2008.

Randomization and Blinding

A stratified block randomization protocol was used to assign participants to the stretching or strengthening group. Participants were stratified, according to their Foot Function Index (FFI) Total score, into moderate/severe (FFI-Total 20 or more) and minimal (FFI-Total less than 20) categories. Participants in the moderate/severe and minimal groups were randomized separately into the stretching (orthosis and stretching) and strengthening (orthosis, stretching, and strengthening) groups to ensure equal distribution on severity of the FFI-Total score. Allocation was not concealed. However, to ensure randomization, an independent investigator tracked the assignment to groups throughout the experiment. Once participants were admitted to a particular study protocol, all participants were told they were in the intervention group. However, the treating therapist administered both interventions.

Interventions

Stretching Group (Orthosis and Stretching). All participants were provided and fit with an orthosis (AirLift TPTD,

Aircast, DJO Global Inc, Vista, CA) that includes an ankle stirrup support and medial longitudinal arch support, commonly used for TPTD. The prefabricated orthosis has demonstrated validity for improving foot kinematics during walking.[25] In addition to wearing the orthosis during all weight-bearing activities, participants were provided with written descriptions and pictures demonstrating exercises that included a wall calf stretch and a supine ankle active range of motion exercise. The wall calf stretch included a knee-extended gastrocnemius stretch and a knee-flexed soleus stretch. For the foot and ankle active range of motion stretch, instructions were to point the big toe down (ie, plantar flexion) while moving it toward the other foot (ie, inversion) and then point the toe up (ie, dorsiflexion) and away from the other foot (ie, eversion). This movement is known to stretch the tibialis posterior muscle.[9] It is also anecdotally associated with pain relief. Participants were instructed to perform 3 sets of the stretching exercises, 2 times a day. Each stretching exercise was performed twice and held for 30 seconds. The effects of these 2 exercises were not expected to cause muscle hypertrophy.

Strengthening Group (Strengthening Combined With Orthosis and Stretching). The strengthening exercises included a progression of 3 exercises that were meant to restore the ability of participants with TPTD to perform a single-leg heel raise (see the Appendix in the online Supplemental Materials).

1. Bilateral heel raises (standing)
2. Ankle plantar flexion with foot adduction and hindfoot inversion (side-lying or seated) with elastic bands (Thera-Band, Hygenic Corporation, Akron, OH).
3. Unilateral heel raises (standing)

The focus for each of the strengthening exercises was to progressively load the tibialis posterior tendon and ankle plantar flexors. This included both eccentric and concentric contractions during the elastic band exercise and a deliberate focus on raising the arch and inverting the hindfoot during the heel-raise exercises. A recent study noted moderate contribution of the tibialis posterior muscle during a heel raise.[15] The seated elastic band exercise for the subtalar inverters complied with published recommendations.[10] Participants sat cross-legged with the ankle plantar flexed. An elastic band was wrapped around the forefoot and anchored with the opposite leg on the floor. Participants were then asked to invert and adduct their foot against the resistance of the band, effectively raising their foot toward the ceiling. They were taught not to substitute with their tibialis anterior muscle. Participants were encouraged to exercise to exhaustion against the heaviest resistance bands that could be provided and perform the heel-raise exercises to the target number and height. Participants were progressed at each visit they attended throughout the program so long as they (1) could execute the exercise and (2) did not experience significant pain in the tibialis posterior tendon. The goal was for participants to progress to 3 sets of 30 repetitions, 2 times per day for each exercise. Participants were told that muscle soreness in the leg was a normal response to the exercise. The participants in the strengthening group (orthosis and strengthening) performed the same exercises as the stretching group as well as the strengthening exercises.

Participants in both the stretching and strengthening treatment groups were seen a total of 7 sessions (initial, week 1, week 2, week 3, week 4, week 5, and week 6). The initial visit was used to complete tests and orient participants to the exercises, and the week 1 to week 3 sessions were used to teach correct technique and progress resistance as indicated. The week 4 through week 6 sessions were used to answer questions and encourage compliance and progression. From week 6 until the follow-up at 12 weeks, participants were encouraged to continue with their exercises independently. All sessions, for both the stretching and strengthening groups, lasted approximately 30 minutes, ensuring that both groups received approximately the same amount of attention.

A compliance log was used to encourage follow-through and record orthosis wear and exercise sets. At the end of study participation, the compliance log was collected, and the hours of orthosis wear and sets completed were tallied. The number of wear hours and number of sets performed by each participant were divided by the total possible orthosis wear hours (8 hours per day × total days [12 weeks × 7 days per week]) and total sets possible (2 sets per day × total days [12 weeks × 7 days per week]). Each participant's total brace wear time and sets completed were then expressed as a percentage of total possible to document compliance.

Outcome Variables

Foot Function Index. The FFI is a validated questionnaire previously used to document outcomes in TPTD.[2-4] The test-retest reliability, internal consistency, and factor analysis of the original scale support the construct validity for patients with TPTD.[4,8,19,29] The 3 domains of the FFI include pain (FFI-Pain), disability (FFI-Disability), and activity limitations (FFI-Activity Limitations). Each category asks participants to rate items relative to pain. The average of the 3 scales is the FFI-Total. The reported minimal clinically important difference is 12.3 mm for FFI-Pain, 6.7 mm for FFI-Disability, undetermined for FFI-Activity Limitations, and 6.5 mm for FFI-Total.[18]

Short Musculoskeletal Function Assessment. The Short Musculoskeletal Function Assessment (SMFA) is a self-report

questionnaire consisting of the Mobility Index, Dysfunction Index, and Bother Index. The Dysfunction Index is used to assess patients' perceptions of their functional performance, while the Bother Index is used to assess participants' perceptions of how much they are bothered by problems. The Mobility Index is a subset of questions specific to community ambulation. Note that pain is not mentioned in the questionnaire, making this outcome distinct from the FFI. The scale was originally validated in participants who had acute fracture or soft tissue injury.[32] The responsiveness to change of the SMFA is 10 points out 100 for each scale (function, Mobility, and Bother Indexes).[32]

Isometric Deep Posterior Compartment Strength

Maximal efforts of isometric deep posterior compartment were used to document strength. A custom-made isometric strength testing system that isolated the deep posterior compartment by resisting foot adduction was used.[12] A force transducer (Model SML-200, Interface, Scottsdale, AZ), connected in series with a resistance plate and oscilloscope (TDS 410A, Tektronix, Beaverton, OR) was used to display force readings. Participants were seated with their leg in an air stirrup brace (Aircast Inc) mounted on uprights. The air stirrup brace was adjusted so the heel was approximately 10 cm above the resistance plate, resulting in 30 to 45 degrees of ankle plantar flexion depending on foot length. The resistance plate was mounted on ball-bearing tracks in the medial-lateral direction, and moleskin was used to fit to the general shape of the medial forefoot. The result was that participants could exert maximum effort against the resistance plate (medial direction) with little discomfort.

Visual feedback of the amount of force exerted and electromyography of the tibialis anterior muscle for each effort was used to encourage participants to exert maximal efforts and minimize contribution of the tibialis anterior. A surface electrode (DE-2.1, Delsys Inc, Boston, MA) placed over the tibialis anterior was tracked using electromyography (Bangoli-2 EMG System, Delsys Inc) and displayed on the oscilloscope. The force and muscle activity results were used to provide feedback to the examiner and participants.

Participants were instructed to "press down and in" to reproduce a maximum plantar flexion, subtalar inversion, and forefoot adduction effort. To track substitution by the tibialis anterior muscle, electromyography was used. Maximal ankle dorsiflexion efforts were recorded and used to calculate 10% of the maximum peak to peak electromyographic signal. During 5 submaximal efforts, if tibialis anterior muscle activity was high (exceeded 10% of maximum voluntary contraction), participants were given verbal cues to reduce tibialis anterior muscle activity (push down harder and/or push medially with their forefoot), diminishing the contribution of the tibialis anterior muscle. After the practice trials, visual feedback of the force and verbal encouragement were used to motivate participants to exert 3 maximal efforts. The average of the peak force was used to document the peak isometric deep posterior compartment strength. A previous study demonstrated adequate reliability with intraclass correlation coefficients above 0.87 and a standard error of measurement of 0.14 N/kg.[12]

Statistical Analysis

Two-way mixed-effect analysis of variance (ANOVA) models were used to analyze differences between groups on the dependent variables (ie, self-report scores and isometric deep posterior compartment strength). The 2 factors of each model were time and group. Time included 3 time points (initial, 6 weeks, and 12 weeks). The second factor, group, included 2 levels designated the strengthening and stretching groups. Differences between interventions at either time point (6 weeks or 12 weeks) were consistent with significant interaction effects (group × time). In the presence of a significant main effect for time, pairwise comparisons between time points were completed (initial, 6 weeks, and 12 weeks). To further investigate comparisons between the groups, changes between each of the time points (initial to 6 weeks, initial to 12 weeks, and 6 weeks to 12 weeks) were calculated. Further, the percentage of participants who made improvements on the FFI above a minimal clinically important difference, and on the SMFA equal to or above responsiveness (10 points), were identified and compared using a nonparametric chi-square analysis. For deep posterior compartment strength, the standard error of the measurement (0.14 N/kg) was used to determine improvements in strength. An alpha level of .05 was used for each analysis. The dependent variables analyzed included the subscales of the FFI (Activity Limitations, Disability, Pain, and Total), subscales of the SMFA (Mobility, Function, and Bother Indexes), and isometric deep posterior compartment strength.

Results

Recruitment and Retention

Eighty-eight participants were screened for the study, with 39 meeting the study criteria (Figure 1). Of the 39 participants, 20 were randomized to the strengthening treatment group while 19 were randomized to the stretching treatment group. There were no significant differences between any of the subjects' initial characteristics (Table 1). One participant in the strengthening treatment group decided to have surgery after the 2-week follow-up (Figure 1). In the stretching group, 2 participants were lost between the 6- and 12-week follow-ups. Data for these 3 participants were not included in the final analysis. Compliance for completing 2 sets of exercise per day for the 12 weeks of the study for both of the groups ranged from 29% to 126% (average

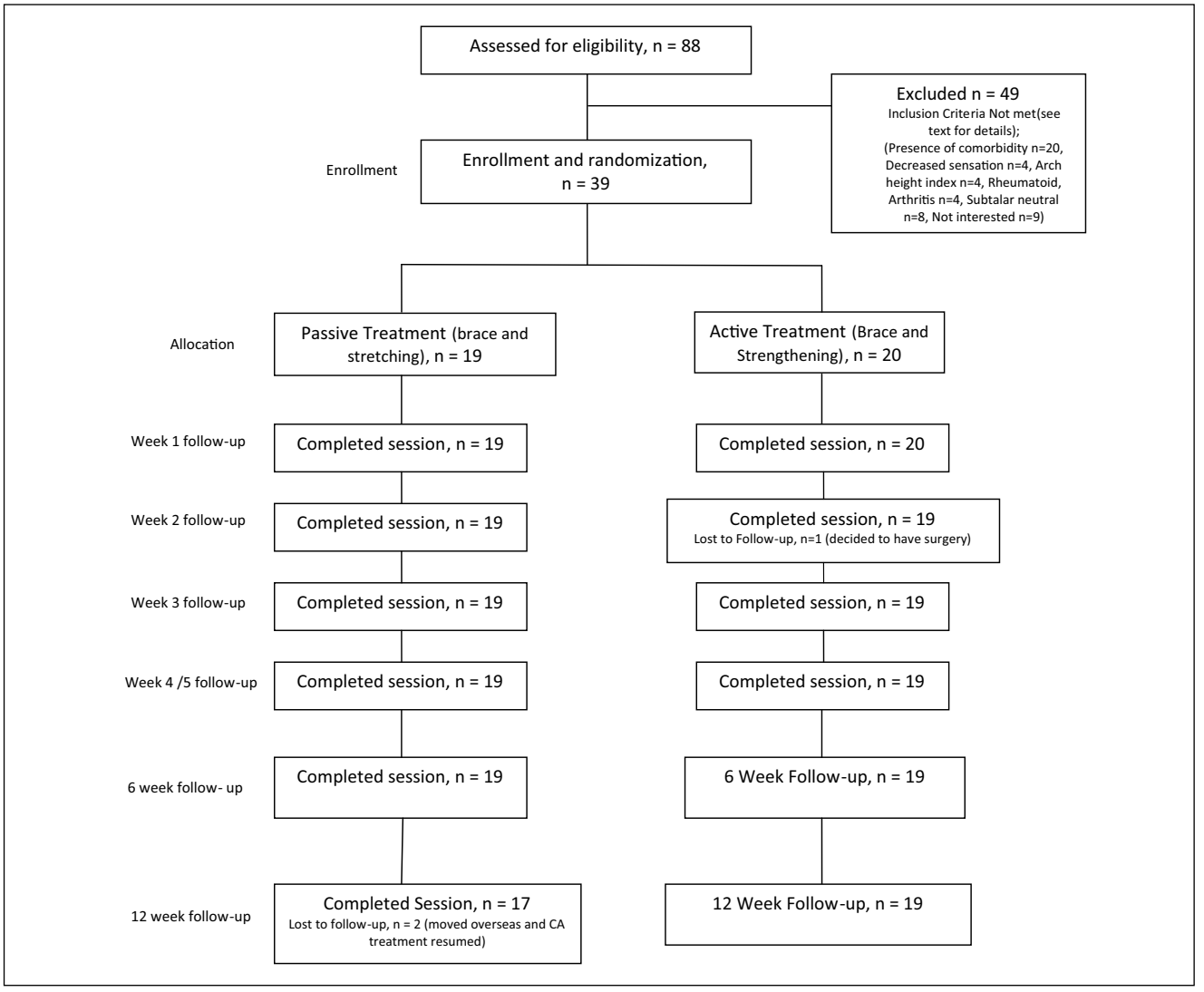

Figure 1. Consolidated Standards of Reporting Trials flow chart.

79%) for all participants completing the study. Compliance for wearing the orthosis ranged from 6 to 15 hours per day (average 9.9 hours). There were no significant differences between the groups in compliance with exercise or orthosis wear. Additionally, there were no recorded adverse events from exercise (extreme muscle soreness, increase medial ankle pain) or orthosis wear (blisters, calluses, increased pain). All participants were analyzed in the groups to which they were originally assigned, and data collection was terminated when study sample approximated the anticipated recruitment goals.

Foot Function Index

For all FFI dependent variables, there were significant main effects for time, indicating that both groups improved over time (Table 2). For all FFI dependent variables, 6- and 12-week time points were associated with significantly better scores compared with initial scores. However, there were no significant differences between the 6-week and 12-week time points for any of the FFI dependent variables. There were also no significant differences in change scores between the strengthening and stretching groups associated with the FFI from initial to 6 weeks or from initial to 12 weeks (Table 3). Change scores on the FFI were similar from 6 to 12 weeks. The proportions of participants experiencing a significant change was not significant for all intervals assessed for the FFI.

SMFA Questionnaire

For all SMFA dependent variables, there were significant main effects for time, indicating that both groups improved over time (Table 2). For all SMFA dependent variables, 6- and

Table 1. Comparison of Patient Characteristics, Foot Posture, Gait, and Self-Report of the Stretching Group (n = 17) and the Strengthening Group (n = 19) at the Initial Visit.

	Stretching Group[a]	Strengthening Group[a]	*P* Value[b]
Patient characteristics			
Age	58 ± 9	57 ± 12	.14
Height, cm	167 ± 9	166 ± 9	.99
Weight, kg	87 ± 15	82 ± 18	.43
Body mass index, kg/m^2	31 ± 5	30 ± 6	.09
Male sex, n	4	4	.62[c]
Left side involvement, n	11	13	.45[c]
Foot posture			
Arch height index	0.32 ± 0.03	0.32 ± 0.02	.20
Gait			
Walk speed, m/s	1.1 ± 0.1	1.0 ± 0.1	.45
Self-report			
Foot Function Index			
Activity Limitations	13 ± 12	16 ± 11	.60
Disability	31 ± 16	40 ± 20	.10
Pain	35 ± 11	38 ± 18	.08
Total	26 ± 10	31 ± 13	.22
Short Musculoskeletal Function Assessment			
Mobility	22 ± 12	27 ± 14	.56
Dysfunction	17 ± 9	22 ± 12	.38
Bother	23 ± 16	26 ± 20	.81

[a]Values expressed as mean ± standard deviation, except for male sex and left side involvement.
[b]*P* values are from 2-sample *t* test for all comparisons, except those noted with "c."
[c]Chi-square test was used for these comparisons.

12-week time points were associated with significantly better scores compared with initial scores. However, there were no significant differences between the 6-week and 12-week time points for any of the SMFA dependent variables. In contrast to the FFI, between initial visit and 6 weeks, the change scores of the Mobility Index and Dysfunction Index of the SMFA were significantly higher in the strengthening group (Table 3). Further, the proportion of participants experiencing a 10-point change significantly favored the strengthening group (Table 3). Significantly more participants in the strengthening group experienced an improvement above 10 points for the Mobility Index and Dysfunction Index compared with the stretching group from initial visit to 6 weeks. The significant change scores from initial visit to 6 weeks on the SMFA Mobility and Dysfunction Indexes were not accompanied by a significant change in the Bother Index. All other change scores from initial visit to 12 weeks for the SMFA were nonsignificant.

Due to the range of compliance observed in the strengthening and stretching groups, Pearson correlations between compliance and the primary outcome measures (FFI and SMFA) were explored. The relationships between compliance and FFI scales or compliance and SMFA scales were all weak and nonsignificant ($r < 0.14$).

Isometric Deep Posterior Compartment Strength

No significant interactions were detected between time and group for isometric deep posterior compartment strength, nor was there a main effect for time (Table 4). There were also no significant differences in change scores for isometric deep posterior compartment strength for any of the intervals tested (Table 5). The proportion of participants who experienced improvement above a standard error of the measurement in strength was not significantly different in the strengthening group on the involved or uninvolved sides for any of the intervals tested.

Discussion

The new findings of this study are that a moderate-intensity, home-based exercise approach minimally improves outcomes over orthosis alone in participants with stage II TPTD. There were significant differences favoring the strengthening treatment group associated with the Mobility and Dysfunction Indexes of the SMFA at 6 weeks. These improvements in mobility and function were not coupled with improvements in pain (FFI scores) or strength. Both groups improved during the initial interval of training from 0 to 6 weeks on the FFI and SMFA.

A positive effect of the strengthening treatment was observed in the Mobility and Dysfunction Indexes of the SMFA; however, this was not coupled with parallel improvements in pain. During the initial 0- to 6-week period when participants learned how to progress their exercises, 53% and 42% of the strengthening group improved their Mobility and Dysfunction Index scores, respectively, on the SMFA. This compared with only 18% and 12% for the same 2 SMFA Indexes in the stretching group (Table 2). Despite this effect on mobility, no differences between the strengthening and stretching groups were observed in the FFI scale or the Bother Index of the SMFA, which focus on the effect of pain and bother, respectively. Gains in ankle muscle strength or improved recruitment of muscles used for mobility might explain these mobility findings, while it may also be possible that increased mobility adversely affects any reduction in pain that might result from the strengthening program.

Alternatively, the strengthening treatment protocol may have lacked sufficient intensity and length to capture treatment effects associated with pain and function in participants with stage II TPTD. Three studies, 1 controlled and 2 uncontrolled, demonstrated significant benefits of exercise to augment orthosis treatment for stage II TPTD.[1,17] In these studies, the intensity of the exercise and the length of the center-based treatments were greater than this study.

Table 2. Comparison of Self-Report Scores of the Stretching Group (n = 17) and the Strengthening Group (n = 19).

			Analysis of Variance	
	Stretching Group[a]	Strengthening Group[a]	Time	Interaction
Foot Function Index[b]				
Initial visit				
Activity Limitations	13 (7-18)	16 (11-21)		
Disability	31 (23-38)	40 (31-49)		
Pain	35 (29-40)	38 (29-46)		
Total	26 (21-31)	31 (25-37)		
6 Weeks				
Activity Limitations	8 (4-12)[c]	8 (4-12)[c]		
Disability	21 (15-27)[c]	21 (15-28)[c]		
Pain	21 (15-28)[c]	21 (14-27)[c]		
Total	17 (13-21)[c]	17 (12-22)[c]		
12 Weeks				
Activity Limitations	7 (3-10)[c]	10 (4-16)[c]	.001	NS
Disability	18 (12-24)[c]	24 (15-34)[c]	<.001	NS
Pain	18 (12-25)[c]	19 (11-27)[c]	<.001	NS
Total	14 (10-19)[c]	18 (11-25)[c]	<.001	NS
Short Musculoskeletal Functional Assessment[d]				
Initial visit				
Mobility	22 (16-28)	27 (20-33)		
Dysfunction	17 (12-21)	22 (17-28)		
Bother	23 (15-31)	26 (17-35)		
6 Weeks				
Mobility	18 (13-24)[c]	15 (10-20)[c]		
Dysfunction	13 (9-16)[c]	13 (9-17)[c]		
Bother	14 (9-18)[c]	15 (9-21)[c]		
12 Weeks				
Mobility	16 (12-19)[c]	17 (12-22)[c]	>.001	NS
Dysfunction	12 (9-15)[c]	15 (10-19)[c]	>.001	NS
Bother	12 (9-15)[c]	16 (8-25)[c]	>.001	NS

Abbreviation: NS, not significant ($P > .05$).
[a]Values expressed as mean (95% confidence interval);
[b]Foot Function Index values are reported in millimeters; lower scores indicate better function and less pain.
[c]Indicates significantly different post hoc test ($P < .05$) from baseline.
[d]Short Musculoskeletal Functional Assessment scores are reported as percentages; lower scores indicate better function.

Previous studies used either 10 weeks[17] or 120 days (median treatment period)[1] of center-based treatment combined with home exercise. This study used 6 center-based treatments followed by 6 weeks of home exercise, approximately 50% fewer center-based treatment sessions. The intensity of the exercise was also higher in previous studies. For example, a previous study[16] used a custom-built jig with loaded springs that were increased from 0.9 kg to 1.7 kg (concentric group) or to 5.6 kg (eccentric group) over the study period of 10 weeks. Another study[1] used high-repetition exercise and isokinetic training coupled with large sets of heel raises and toe walking to strengthen participants. The current study, using a moderate-intensity home-based program that included heel raises and resisted deep posterior compartment strengthening using elastic bands, did not replicate improvements in pain and function observed in these previous studies. In summary, high-exercise intensity over a longer period of time (ie, greater than 10 weeks) may show more definite benefits to participants with stage II TPTD.

The lack of increase in isometric deep posterior compartment strength (Table 4) may be associated with the intensity of training or the lack of large side-to-side deficits in strength at the initial visit. Previous studies did not document weakness specific to the tibialis posterior muscle.[1,17] The initial average side-to-side ratio of deep posterior compartment strength was 88% and 87% in the stretching and strengthening groups, respectively (Table 4). The near 90% side-to-side strength ratio in this study sample suggests that this group had less side-to-side strength deficit than documented in previous studies.[1,17,24]

Table 3. Comparison of Self-Report Change Scores of the Stretching Group (n = 17) and the Strengthening Group (n = 19).

	Mean Change (95% CI)		Participants Improved, % (n)	
	Stretching Group	Strengthening Group	Stretching Group	Strengthening Group
Foot Function Index[a]				
From initial visit to 6 weeks				
Activity Limitations	4 (2 to 7)	8 (2 to 14)		
Disability	10 (5 to 15)	19 (12 to 26)	41 (7)	37 (7)
Pain	13 (7 to 20)	17 (10 to 24)	59 (10)	53 (10)
Total	9 (5 to 14)	15 (9 to 20)	65 (11)	63 (12)
From initial visit to 12 weeks				
Activity Limitations	6 (3 to 9)	6 (0 to 13)		
Disability	13 (7 to 19)	16 (7 to 25)	29 (5)	47 (9)
Pain	16 (8 to 24)	18 (10 to 27)	47 (8)	74 (14)
Total	12 (6 to 18)	14 (7 to 20)	59 (10)	68 (13)
From 6 to 12 weeks				
Activity Limitations	2 (–1 to 4)	−2 (–5 to 2)		
Disability	3 (–1 to 7)	−3 (–10 to 4)	18 (3)	5 (1)
Pain	3 (–4 to 10)	1 (–5 to 8)	12 (2)	16 (3)
Total	3 (–1 to 6)	−1 (–6 to 3)	24 (4)	21 (4)
Short Musculoskeletal Functional Assessment[b]				
From initial visit to 6 weeks				
Mobility	4 (2 to 5)	11 (7 to 16)[c]	18 (3)	53 (10)[d]
Dysfunction	4 (2 to 5)	9 (6 to 13)[c]	12 (2)	42 (8)[d]
Bother	9 (5 to 14)	11 (6 to 16)	35 (6)	47 (9)
From initial visit to 12 weeks				
Mobility	7 (4 to 10)	10 (4 to 15)	29 (5)	53 (10)
Dysfunction	5 (3 to 7)	8 (3 to 12)	24 (4)	32 (6)
Bother	11 (6 to 16)	9 (3 to 16)	35 (6)	42 (8)
From 6 to 12 weeks				
Mobility	3.0 (–1 to 7)	−2 (–5 to 2)	24 (4)	5 (1)
Dysfunction	1 (–1 to 3)	−2 (–4 to 1)	6 (1)	5 (1)
Bother	2 (–1 to 5)	−1 (–6 to 3)	12 (2)	11 (2)

[a]Foot Function Index values are reported in millimeters (maximum 100). Minimal clinically important difference was used to calculate proportions as follows: Activity Limitations, none used; Disability, 6.7; Pain, 12.3; and Total, 6.5.
[b]Short Musculoskeletal Functional Assessment scores are reported as percentages (maximum 100). Responsiveness to change of 10 points was used to calculate proportions for the Mobility, Dysfunction, and Bother Indexes.
[c]Significantly different according to *t* test ($P < .05$).
[d]Significantly different proportion according to chi-square test ($P < .05$).

Separate from the discussion of the intensity of exercise, targeting participants with documented weakness may result in greater muscle responses and, therefore, more benefits to participants.

Use of a prefabricated orthosis and a stretching exercise program decreased self-reported pain, reduced disability, and increased activity in our sample of participants with stage II TPTD. Across the FFI scales (subscales and total), the stretching group improved between 4.4 and 18.4 mm from the initial visit to 6 weeks (Table 3). Approximately 60% of participants in both groups experienced a greater than 10-mm improvement in their FFI-Total from the initial visit to 6 weeks (Table 3). We are unaware of any previous studies that used this orthosis; however, comparisons of other orthoses suggest that moderate improvements were observed in the current study. The shorter length of the study, differences in orthoses, and severity of TPTD are important to consider when comparing this study with others that used orthosis strategies for TPTD. Interestingly, no studies, long or short term, report pain elimination using orthoses.[1,2] The lack of resolution of symptoms, even with long-term orthosis treatment (4-8 years), motivates further research.

There are several significant limitations to this study associated with study design, sample characteristics, and alternative treatments. This stratified, randomized controlled trial blinded participants but not the treating therapist. Although this clinical trial restricted inclusion to participants with stage II TPTD, there was reported variability in the degree of foot deformity, strength, and

Table 4. Comparison of Strength Measures of the Stretching Group (n = 17) and the Strengthening Group (n = 19).

	Involved Side, N/kg[a]	Uninvolved Side, N/kg[a]	Ratio of Involved to Uninvolved
Initial visit			
Stretching	0.8 (0.7-0.9)	0.9 (0.81-1.0)	0.9 ± 0.3
Strengthening	0.7 (0.6-0.8)	0.8 (0.7-0.89)	0.9 ± 0.2
6 weeks			
Stretching	0.8 (0.7-1.0)	1.0 (0.9-1.1)	0.9 ± 0.2
Strengthening	0.8 (0.7-0.9)	0.8 (0.8-0.9)	0.9 ± 0.2
12 weeks			
Stretching	0.8 (0.7-0.9)	1.0 (0.9-1.1)	0.9 ± 0.2
Strengthening	0.8 (0.7-0.9)	0.9 (0.8-0.9)	0.9 ± 0.2
Main effect—time	NS	NS	NS
Interaction effect	NS	NS	NS

Abbreviation: NS, not significant ($P > .05$).
[a]Values expressed as mean (95% CI).

Table 5. Comparison of Change in Strength of the Stretching Group (n = 17) and the Strengthening Group (n = 19).

	Mean Change, N/kg (95% CI)		Participants Improved, % (n)	
	Involved Side	Uninvolved Side	Involved Side[a]	Uninvolved Side[a]
From initial visit to 6 weeks				
Stretching	0.1 (–0.0 to 0.1)	0.0 (–0.1 to 0.1)	11 (2)	29.4 (5)
Strengthening	0.1 (–0.0 to 0.2)	0.0 (–0.1 to 0.1)	31.5 (6)	21.1 (4)
From initial visit to 12 weeks				
Stretching	0.0 (–0.0 to 0.1)	0.1(–0.1 to 0.2)	29.4 (5)	35.2 (6)
Strengthening	0.1 (–0.0 to 0.2)	0.0(0.0 to 0.1)	36.8 (7)	21.1 (4)
From 6 weeks to 12 weeks				
Stretching	0.0 (–0.1 to 0.0)	0.0 (–0.1 to 0.1)	5.9 (1)	17.6 (3)
Strengthening	0.0 (–0.1 to 0.1)	0.0 (–0.1 to 0.0)	26.3 (5)	10.5 (2)

[a]Proportions were determined by 2 standard errors of the measurement.

symptoms.[24] Differences in initial strength across various studies may also affect study results. For example, a more targeted sample of participants with documented weakness at the start of the trial may have demonstrated improvements in response to exercise. The sample size was sufficient to detect effect sizes of 6.75 mm on the FFI-Total (approximately equal to a minimal clinically important difference of 6.5 mm). However, the confidence intervals do not exclude the possibility of a significant effect. For example, the confidence interval of the change scores for FFI-Pain from the initial visit to 6 weeks ranges from 10 to 26 points for the strengthening group (Table 3). Either a larger sample or more defined sample criteria (ie, weaker participants at initial visit) may narrow the confidence intervals and subsequently avoid a type II error. Further, the length of the study was short and therefore does not take into account gradual effects of the strengthening intervention that could occur over time. Alternative interventions such as activity limitation and immobilization alone were not separated as treatment strategies in this clinical trial. In summary, study design, sample characteristics, intervention intensity, and alternative interventions are important considerations in future clinical trials.

In conclusion, a moderate-intensity, home-based exercise program was minimally effective in augmenting orthosis wear alone in participants with stage II TPTD. The improvements observed were smaller than those reported in some previous controlled and uncontrolled clinical trials, suggesting that positive effects on function and pain in response to exercise may require higher intensity than this home-based program for participants with TPTD. Irrespective of the specific exercise protocol (ie, stretching or strengthening), participants improved in pain and function in response to either a strengthening or a stretching approach over a 12-week time period.

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Note

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Supplemental Material

The online supplemental material is available at http://fai.sagepub.com/supplemental.

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