Foot Orthoses Enhance the Effectiveness of Exercise, Shockwave, and Ice Therapy in the Management of Medial Tibial Stress Syndrome

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Abstract

Objective: Our aim was to assess the effects of adding arch-support foot-orthoses (ASFO) to a multimodal therapeutic intervention on the perception of pain and improvement of recovery from medial tibial stress syndrome (MTSS) in recreational runners. **Design:** A prospective randomized controlled trial. **Setting:** Sport training and medical centers. **Participants:** Fifty female recreational runners with MTSS were randomized into 2 groups. **Interventions:** Runners either received ASFO or sham flat noncontoured orthoses. Both groups received a multimodal therapeutic intervention, including ice massage, ankle muscle exercises, and extracorporeal shockwave therapy. **Main Outcome Measures:** Pain during bone pressure using a numerical Likert scale (0-10), MTSS severity using an MTSS scale, perceived treatment effect using the global rating of change scale, and quality of life using the short Form-36 questionnaire were determined at week 6, 12, and 18. **Results:** Pain intensity and MTSS severity were lower, and the perceived treatment effect and physical function were better in the ASFO than in the sham flat noncontoured orthoses group at week 6 and week 12. Cohen's d_z effect size for between-group differences showed a medium difference. However, arch-support foot-orthoses did not add to the benefits of multimodal therapeutic intervention on pain, MTSS severity and perceived treatment effect at week 18. **Conclusions:** Adding ASFO to a therapeutic intervention leads to an earlier diminishment of pain and MTSS severity, and improved PF and perceived therapeutic effects.

Key Words: shin splints, exercise-related leg pain, overuse injury, insole, running

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INTRODUCTION

Running is associated with high rates of medial tibial stress syndrome (MTSS),[1] defined as exercise-induced pain along the posteromedial border of the distal two-thirds of the tibia that is provoked by palpation of this area.[2,3] Up to 82% of runners experience MTSS over a running season and of these, approximately 75% reported that it had interfered with their subsequent participation, training, or competition.[4] The 4-week to 18-month recovery time and high recurrence rate (20-32 times higher in individuals with than without MTSS history) add to the costs and inconvenience of MTSS.[5,6] There is thus an urgent need to treat, reduce reoccurrence rates, and prevent MTSS.

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The authors report no conflicts of interest.

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Treatment of MTSS includes avoiding the offending activity and cross-training, cryotherapy,[3,7] shockwave therapy, massage, and a pneumatic leg brace.[5,6] However, there is no evidence that any of these interventions have a beneficial effect in treating MTSS,[6,8] and most of these interventions only address pain in MTSS[9,10] with only a few addressing the main causes of MTSS.[6] Therefore, interventions that address modifiable risk factors, such as normalizing lower-limb biomechanics, arch taping, foot orthoses, and ankle strengthening and stretching exercises, are expected to be more effective than pain relief interventions.

A history of a previous injury, high body mass index, and higher navicular drop or foot pronation are consistently linked with MTSS.[11–13] For example, prospective studies have shown that runners who developed MTSS demonstrated more pressure under the medial aspect of their foot at initial foot contact and foot flat, and greater peak amounts and durations of rear-foot eversion during the stance phase than those who did not develop MTSS.[13,14] Therefore, targeting excessive dynamic foot pronation could be an effective therapeutic option to treat and/or prevent MTSS.

Foot orthoses have been recommended for the treatment of MTSS.[14–16] It has been reported that approximately 54% of those using orthotics for exercise-induced leg pain (EILP) experienced a decrease in EILP symptoms.[15] It should be noted, however, that EILP may include other causes than MTSS, such as tibial stress fracture and chronic compartment syndrome. Nevertheless, these observations suggest that foot orthoses effectively reduce pain experienced by athletes with MTSS. Foot orthoses may be effective through (1) improvement of foot and

ankle joint biomechanics that reduces foot pronation during running,[17] (2) altering muscle activity pattern and lever arm,[17,18] and (3) normalizing dynamic foot pressure distribution in runners with MTSS during running.[14,17] Yet, to the best our knowledge, no data have been published so far on the effectiveness of arch-support foot-orthoses for the treatment of MTSS.

The aim of this study was to determine whether adding arch-support foot-orthoses to an 18-week multimodal therapeutic intervention accelerates the recovery from MTSS in female recreational runners. We hypothesized that foot orthoses diminish pain and improve recovery of MTSS more effectively than multimodal therapeutic interventions on their own.

METHODS

Study Design

This was an 18-week, prospective, double-blind parallel-group randomized controlled trial using an attentional control group with repeated measures at 6, 12, and 18 weeks follow-up. All procedures were in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of the University of Nahavand. Written informed consent was obtained from participants. The trial was registered with the Iranian Clinical Trials Registry (IRCT20170114031942N8; www.irct.ir).

Participants

Female 18- to 25-year-old recreational runners with MTSS were recruited using flyers and pamphlets posted in the physiotherapy clinics and in public places in Hamadan, Iran, from June 2018 to August 2018. Medial tibial stress syndrome can be reliably diagnosed using history and physical examination.[19] Participants were diagnosed with MTSS from a clinical assessment using the following criteria: (1) pain was induced by exercise and lasted for hours or days after exercise, (2) pain was located in the distal half of the posteromedial tibia and had to cover an area of more than 5 cm long,[20] and (3) palpation of the tibial posteromedial border induced recognizable discomfort that was restricted to this area,[21] that were confirmed by a healthcare sports physiotherapist. Of the 180 recreational runners suspected to suffer from MTSS, 50 women met the MTSS inclusion criteria (Figure 1). Runners either received bilateral arch-support foot-orthoses (ASFO) or sham flat noncontoured orthoses (SFO). Both groups received a

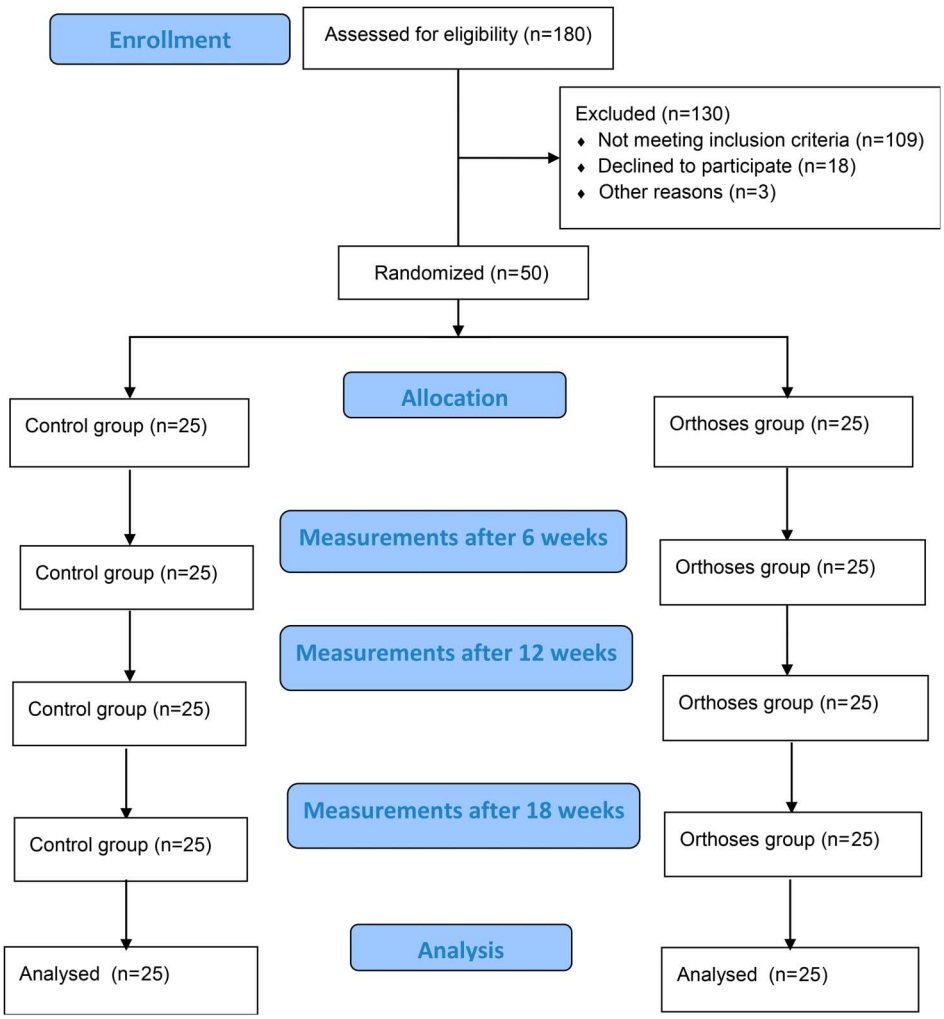

Figure 1. Flow of participants during the course of the study.

multimodal therapeutic intervention, including ice massage, ankle muscle exercises, and extracorporeal shockwave therapy.

The inclusion criteria were: run ≥2 times per week for >45 minutes and/or >10 km per week; 18- to 25-year-old women; present symptoms for ≥3 weeks; dynamic arch index (DAI) ≥26%[22]; using foot orthoses in 90% of training sessions during the study; being able to provide informed written consent; and willing to receive our recommended treatment for MTSS.

Exclusion criteria were a history of paresthesia; symptoms indicative of other causes of EILP (such as tibial stress fracture and chronic compartment syndrome)[20]; used arch-support orthoses or received physiotherapy in the previous 6 months; and a history of lower-limb traumatic injury or surgery within the last year.

The DAI was calculated as the ratio of the area of the middle third of the footprint relative to the total footprint area excluding the toes[23]: DAI = $\frac{\text{Midfoot}}{\text{Forefoot + Midfoot + Rearfoot}}$ (Figure 2). A higher ratio indicates higher foot pronation: ≤21% high arch, 21%−26% normal arch, and ≥26% low arch.[22,23] The dynamic pressure distribution during self-selected walking speed trials was assessed using a force plate (PT 3D Scan, Payafnavaran Ferdowsi Company, Tehran, Iran, 50 × 60 cm) in the middle of a 12-m-long runway. The foot scan system was calibrated according to the guidelines of the manufacturer before each session. To eliminate interrater bias, the same sport therapist measured DAI for all participants.

Procedures

Based on an effect size f = 0.26 of a previous study,[24] we anticipated that for a 2-tailed significance level (α) of 0.05 and a desired power (1 − β) of 0.85, each group needed 20 participants. With an expected 20% dropout rate, we enrolled 25 participants per group.

Potential participants contacted the research coordinator for an interview to ensure they fulfilled the criteria. Then, the sport therapist evaluated whether they met the inclusion criteria. Participants were enrolled by an independent physiotherapist who was not involved in data collection and was blinded to the allocation of participants to experimental conditions. An independent, blinded person made a random allocation sequence using a computer-generated sequence (Random Allocation Software 2.0) to block-randomize participants to the ASFO or SFO group (block size of 2, 4, 6 allocation ratio 1:1). Group allocations were concealed from the researcher enrolling and assessing participants in sequentially numbered, opaque, sealed envelopes. The envelope number was noted on a form by an independent researcher. Corresponding envelopes were opened by a research assistant (S.B.) after enrolled participants completed all baseline assessments to then allocate the intervention. A laboratory specialist, not directly involved in the study and blinded to the interventions, performed the clinical assessments. The data analysts were blinded to group allocation. Participants were unaware of the intervention provided to other participants. Participants were instructed not to reveal or discuss treatment with the evaluator.

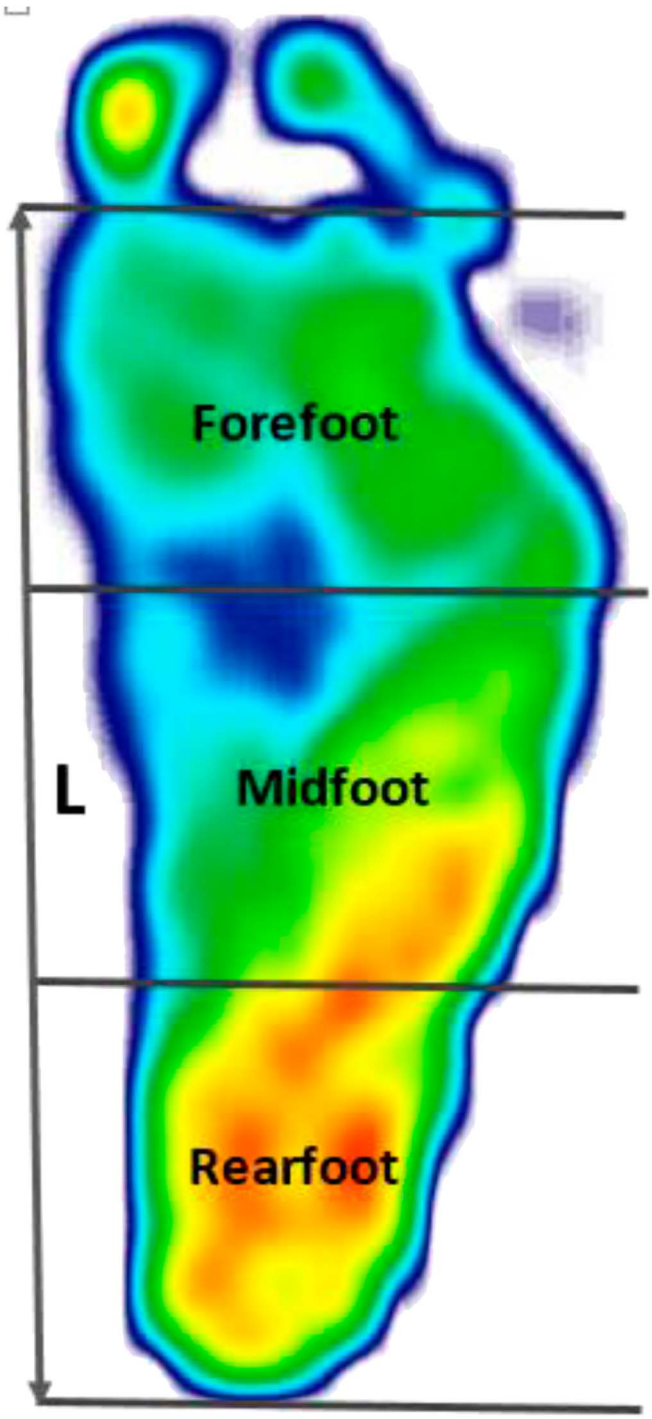

Figure 2. Calculation of the arch index (AI). (AI = Midfoot/[Rearfoot + Midfoot + Forefoot]).

Outcome Measures

Pain Level

The tenderest area of the leg (5 cm) was highlighted with a marker. The pain intensity, caused by applying a 3-kg pressure with an algometer [Baselinemodel 12-0304] over the tenderest point of posteromedial shin surface, was evaluated using a numerical rating scale.

Perceived Treatment Effect

Participants reported their perceived recovery by placing a mark on an 11-point global rating of change.[25] The "same" in

the middle of the scale represents the unchanged condition (0 point), "a very great deal better" (+5 point) at the end of the right represents a complete recovery, and "a very great deal worse" (−5 point) at the left end represents the ultimate exacerbation of the condition.

Intensity of Medial Tibial Stress Symptoms

The MTSS scale[26] was used to measure MTSS severity. This scale includes 4 items to assess limitations in sporting activities, pain while performing sporting activities, pain while walking, and pain at rest. All items have 4 response options. The total score varies between 0 and 10, where higher scores indicate more severe MTSS symptoms. The MTSS scale shows good test–retest reliability (intraclass correlation coefficient = 0.81) and internal consistency ($\alpha = 0.58$), and has a moderate to large validity (r = 0.34-0.52).[26]

Quality of Life

The 36-item Short-Form Health Survey (SF-36) was used to assess quality of life (QOL)[27] https://www.sciencedirect.com/science/article/pii/S106345840800068X.[12] The SF-36 consists of 36 items covering physical function (PF), physical role (PR), bodily pain (BP), general health, vitality (VT), social function (SF), emotional role and mental health. These 8 subscales are scored from 0 to 100 with higher scores indicating better health status. Evidence indicates that SF-36 is a suitable outcome measure in lower-limb dysfunctions.[28]

Interventions

All participants received a multimodal therapeutic intervention, including ice for approximately 10 to 15 minutes applied to the affected area directly after each run, ankle stretching and strengthening exercises, and extracorporeal shockwave therapy.[5,6,9,10] We asked participants to follow a gradual walk-to-run protocol intended to return them to a level of function consistent with their operational requirements.[2,29] Walk-to-run programs theoretically impart stress to remodeling bone and soft tissue, ensuring optimal strength and tissue integrity in accordance with the dictates of Wolff's law.[30] As all our study participants had some pain and disability, including a multimodal therapeutic intervention in both study groups overcame any ethical concerns of not treating participants.

In addition to multimodal therapeutic intervention, runners in the ASFO group received arch-support foot-orthoses for both feet. Arch-support foot-orthoses (Model; LX-0701-1, Longxin, Industrial Co., Ltd, Guangdong, China) were fit in the shoes using double-sided tape and were made from 4-mm thick polypropylene of medium density (Durometer Shore 50A) with an approximately 15-mm high heel cup and a 25-mm peak height arch support (Figure 3). Runners in the SFO group received SFO for both feet. Flat orthoses were made from polypropylene with the same hardness to the arch-support foot-orthoses, but they did not provide any mechanical support at the arch. This form of device has been used previously as a sham condition.[31] The orthoses were reusable. Participants were informed of the insert condition and that the objective of the study was to evaluate the efficacy of shoe inserts to treat MTSS.

Cointerventions

Participants were asked to refrain from cointerventions during the study period starting 72 hours before participation in the study. Analgesic use was registered at baseline and at all follow-ups.

Adverse Events and Adherence

Adverse events were recorded by someone not involved in the study using a questionnaire completed by participants each month. Adverse events were defined as short-to-long-term consequences, manifested in serious, distressing, uncomfortable, and unacceptable symptoms with a known or plausible association with the treatment.[32] Participants were asked to report frequency, types and severity of the symptoms. An open-response type format was used.

Adherence with the foot orthoses was assessed daily in a preprinted activity diary. Runners reported the number of days they had not worn their foot orthoses during running sessions and physical activities beyond the recreational running. We used a Likert scale with a score from 0 (not comfortable) to 10 (very comfortable). The items scored were (1) quality of heel cup fit, (2) longitudinal arch support, (3) flexibility, (4) the combination of orthoses and shoes, and (5) running with orthoses relative to running without orthoses to evaluate orthoses comfort.[33]

Statistical Analysis

Using an intention-to-treat principle, all participant data were included in the analysis, with zero change being recorded for missing data. Descriptive statistics (frequencies, mean, and SD) were calculated and the 95% confidence interval (CI) reported as a measure of uncertainty. Continuous data were tested for normality using the Shapiro–Wilk test. Differences between groups at baseline were analyzed by the independent *t* test for continuous variables and χ^2 test for categorical variables. The generalized estimation equation (GEE) method with an autoregressive correlation matrix was used to compare intervention effectiveness between groups. We used the GEE to model the association between the outcomes and the predictors group (ASFO vs SFO), time (baseline, 6, 12, and 18 weeks), and their interaction. Different effectiveness between groups was considered

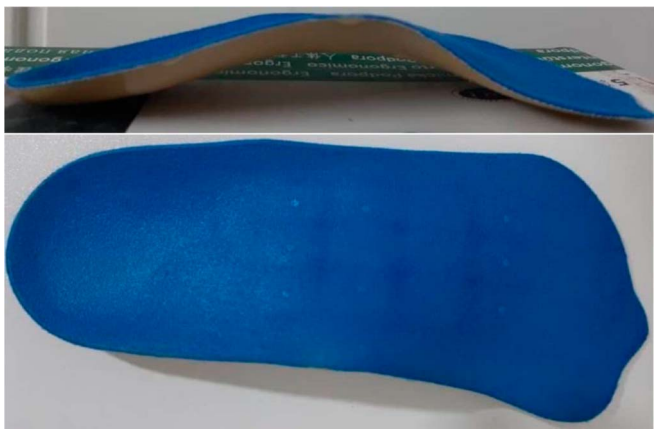

Figure 3. Foot orthoses.

TABLE 1. Participant Demographics and Clinical Characteristics of Women With MTSS.

Variables	ASO Group (n = 25)	SFO Group (n = 25)
Age, y	27.1 ± 6.2	25.5 ± 5.5
Body mass, kg	69.3 ± 7.9	71.6 ± 8.2
Height, m	1.66 ± 0.1	1.68 ± 0.1
Body mass index, $kg \cdot m^{-2}$	25.1 ± 2.3	25.5 ± 3.2
Affected side, n (left/right/bilateral)	3/14/8	1/16/8
Target side, (n) (dom/nondom)	17/8	17/8
Pain history, wk	6.80 ± 1.8	7.9 ± 2.7
Run history, wk	18.8 ± 4.8	20.6 ± 4.5
No. of running sessions per week	3.5 ± 0.7	3.3 ± 0.6
Minutes run per week	109 ± 19	107 ± 18
Distance run per week, km	14.3 ± 3.2	13.6 ± 3.5
Supplements intakes, (n) (yes/No)	11/14	8/17
Analgesic using, (n) (yes/No)		
Baseline	13/12	12/13
6 week	9/16	12/13
12 week	7/18	9/16
18 week	4/21	7/18

Mean values with SDs (mean ± SD) or frequencies presented.

present in case of significant group × time interaction. Follow-up Bonferroni-corrected *t*-tests for multiple comparisons were conducted where appropriate. To better understand the magnitude of gains, the Cohen's d effect size for a paired-samples *t* test was calculated. For Cohen's d effect size, values of ≤0.19, 0.2 to 0.49, 0.50 to 0.80, and ≥0.81 represented trivial, small, medium and large effects, respectively. All statistical analyses were conducted using SPSS statistical software (Version 18.0, SPSS Inc., Chicago, IL), where $P < 0.05$ was considered statistically significant.

RESULTS

There were no significant differences in baseline characteristics between groups (Table 1).

No adverse effects were reported. The adherence rate to the insole use for the SFO group and ASFO group was 96.7% (range 93.5%-100%) and 97.3% (range 95.2%-100%), respectively. Five runners of the SFO group and 4 of the ASFO group did not use foot orthoses during some runs. "Forgetting" was the main reason for nonadherence.

In the ASFO group, orthoses comfort in terms of quality of heel cup fit was 8.44 ± 1.36 (range 6-10), longitudinal arch support was 8.84 ± 1.28 (range 6-10), flexibility was 7.88 ± 1.30 (range 5-10), and the combination of orthoses and shoes was 8.36 ± 1.41 (range 6-10). In addition, 83% of ASFO participants reported that running with orthoses relative to running without orthoses is much better and the other 17% reported somewhat better.

Generalized estimating equation was used to assess between-group differences that are presented in Table 2. There were significant group × time interactions for pain intensity, MTSS severity, perceived treatment effect, and PF

TABLE 2. Results of Generalized Estimated Equations Analyses

	Group Effects		Time Effects		Group × Time Effects	
Variables	Wald $\chi 2$	*P*	Wald $\chi 2$	*P*	Wald $\chi 2$	*P*
Pain intensity (mm)	1.63	0.2	384	0.001	14.41	0.002
MTSS severity (0-10)	2.1	0.15	349	0.001	18.1	0.001
Perceived treatment effects (−10-+10)	3.1	0.08	563	0.001	8.4	0.03
Quality of life (0-100)						
Physical function	1.8	0.2	190	0.001	11.0	0.01
Physical role	1.0	0.4	390	0.001	6.1	0.1
Bodily pain	4.2	0.04	380	0.001	13.1	0.01
General health	0.1	0.8	180	0.001	3.1	0.4
Vitality	0.7	0.4	89	0.001	1.0	0.8
Social function	0.1	0.9	23	0.001	1.4	0.7
Emotional role	0.3	0.6	58	0.001	0.6	0.9
Mental health	0.4	0.5	61	0.001	6.7	0.07

TABLE 3. Within-Group Differences and Effect Sizes (Cohens *d*) With 95% CI

Variables	Baseline	Week 6	Week 12	Week 18	ES (Baseline to week 6)	ES (Baseline to week 12)	ES (Baseline to week 18)
Pain intensity, mm							
ASO group	62.9 ± 6.5	43.8 ± 6.7	25.4 ± 5.9	16.1 ± 8.4	1.3 (0.7 to 1.9)*	4.3 (3.2-5.2)*	5.8 (4.5-6.9)*
SFO group	60.6 ± 6.8	49.6 ± 10.0	29.4 ± 7.8	16.8 ± 9.2	2.9 (2.1 to 3.6)*	5.9 (4.7 to 7.2)*	5.8 (4.4 to 6.9)*
Between-group ES	0.7 (0.1 to 1.2)†	0.6 (0.0 to 1.1)†	0.1 (−0.4 to 0.6)				
MTSS severity (0-10)							
ASO group	4.8 ± 1.5	3.2 ± 1.1	2.2 ± 0.6	1.0 ± 0.9	1.2 (0.6 to 1.8)*	2.3 (1.5 to 2.9)*	3.1 (2.2 to 3.8)*
SFO group	4.7 ± 1.3	3.9 ± 1.1	2.7 ± 0.7	1.2 ± 0.8	0.7 (0.1 to 1.2)*	1.9 (1.2 to 2.6)*	3.2 (2.4 to 4.0)*
Between-group ES	0.6 (0.2 to 1.3)	0.8 (0.1 to 1.2)†	0.2 (−0.3 to 0.8)				
Perceived treatment effect (−5 to +5)							
ASO group		2.1 ± 0.8	2.6 ± 0.8	3.4 ± 0.9	—	—	—
SFO group		1.5 ± 0.9	2.2 ± 0.8	3.1 ± 1.1	—	—	—
Between-group ES	0.7 (0.12 to 1.3)†	0.5 (−0.1 to 1.1)	0.3 (−0.3 to 0.9)				
Quality of life (0-100) physical function							
ASO Group	56.6 ± 16.7	65.3 ± 18.9	70.5 ± 19.9	73.0 ± 17.3	0.5 (−0.1 to 1.1)*	0.8 (0.2 to 1.3)*	1.0 (0.4 to 1.5)*
SFO Group	52.9 ± 17.8	56.3 ± 18.7	62.6 ± 19.4	67.4 ± 18.7	0.2 (−0.1 to 0.8)	0.5 (−0.1 to 1.1)*	0.8 (0.2 to 1.4)*
Between-group ES	0.5 (−0.1 to 1.1)†	0.4 (−0.2 to 1.0)†	0.3 (−0.2 to 0.9)				
Physical role							
ASO group	52.3 ± 12.7	59.3 ± 13.2	60.9 ± 14.4	62.8 ± 13.6	0.5 (0.0 to 1.1)*	0.6 (0.1 to 1.1)*	0.8 (0.2 to 1.4)*
SFO group	51.6 ± 11.2	55.4 ± 13.2	57.0 ± 12.8	59.2 ± 13.1	0.3 (−0.2 to 0.8)	0.4 (−0.1 to 1.0)*	0.6 (0.1 to 1.2)*
Between-group ES	0.3 (−0.3 to 0.9)	0.3 (−0.3 to 0.9)	0.2 (−0.3 to 0.8)				
Bodily pain							
ASO group	41.9 ± 12.9	55.5 ± 14.6	63.0 ± 14.3	76.9 ± 16.4	1.0 (0.4 to 1.6)*	1.6 (0.9 to 2.2)*	2.4 (1.6 to 3.1)*
SFO group	38.6 ± 9.5	45.7 ± 15.0	53.5 ± 15.7	71.6 ± 17.6	0.6 (−0.1 to 1.2)*	1.2 (0.5 to 1.7)*	2.3 (1.6 to 3.0)*
Between-group ES	0.7 (0.1 to 1.2)†	0.6 (0.0 to 1.2)†	0.3 (−0.3 to 0.9)				
General health							
ASO group	71.9 ± 20.9	75.0 ± 22.7	78.5 ± 20.5	85.4 ± 18.7	0.2 (−0.4 to 0.7)	0.3 (−0.2 to 0.9)*	0.7 (0.1 to 1.2)*
SFO group	73.1 ± 19.6	74.2 ± 19.8	77.7 ± 18.9	85.3 ± 16.5	0.1 (−0.5 to 0.6)	0.2 (−0.3 to 0.8)	0.7 (0.1 to 1.2)*
Between-group ES	0.04 (−0.5 to 0.6)†	0.04 (−0.5 to 0.6)†	0.01 (−0.5 to 0.5)				
Vitality							
ASO group	68.9 ± 25.8	71.9 ± 23.6	74.9 ± 24.2	78.0 ± 22.0	0.1 (−0.4 to 0.7)	0.2 (−0.3 to 0.8)	0.4 (−0.2 to 1.0)*
SFO group	63.0 ± 22.3	65.9 ± 22.3	69.3 ± 22.1	74.1 ± 22.1	0.1 (−0.4 to 0.7)	0.3 (−0.3 to 0.9)*	0.5 (−0.1 to 1.1)*
Between-group ES	0.3 (−0.3 to 0.8)	0.3 (−0.3 to 0.8)	0.2 (−0.4 to 0.7)				
Social function							
ASO group	62.8 ± 28.5	65.5 ± 27.3	67.8 ± 27.1	68.2 ± 27.8	0.1 (−0.5 to 0.7)	0.2 (−0.4 to 0.7)	0.2 (−0.4 to 0.7)
SFO group	63.0 ± 22.3	66.2 ± 27.3	67.5 ± 25.3	68.6 ± 25.9	0.1 (−0.4 to 0.7)	0.2 (−0.4 to 0.7)	0.2 (−0.3 to 0.8)
Between-group ES	0.03 (−0.5 to 0.6)	0.01 (−0.5 to 0.6)	0.01 (−0.5 to 0.6)				
Emotional role							
ASO group	58.3 ± 23.9	61.2 ± 23.5	64.2 ± 25.3	63.6 ± 25.2	0.2 (−0.4 to 0.8)	0.2 (−0.3 to 0.8)	0.2 (−0.3 to 0.8)
SFO group	62.2 ± 25.9	65.2 ± 26.3	68.1 ± 25.9	68.1 ± 25.8	0.1 (−0.4 to 0.7)	0.2 (−0.3 to 0.8)	0.2 (−0.3 to 0.8)
Between-group ES	0.2 (−0.4 to 0.7)†	0.2 (−0.4 to 0.7)†	0.2 (−0.4 to 0.7)				

TABLE 3. Within-Group Differences and Effect Sizes (Cohens *d*) With 95% CI *(Continued)*

Variables	Baseline	Week 6	Week 12	Week 18	ES (Baseline to week 6)	ES (Baseline to week 12)	ES (Baseline to week 18)
Mental health							
ASO group	64.1 ± 25.7	70.2 ± 25.1	72.9 ± 23.1	75.2 ± 23.2	0.2 (−0.3 to 0.8)	0.4 (−0.2 to 0.9)*	0.5 (−0.1 to 1.0)*
SFO group	62.3 ± 25.8	64.6 ± 25.0	66.0 ± 26.1	70.4 ± 25.2	0.1 (−0.5 to 0.6)	0.2 (−0.4 to 0.7)	0.3 (−0.3 to 0.9)*
Between-group ES	0.2 (−0.3 to 0.8)	0.3 (−0.3 to 0.9)	0.3 (−0.3 to 0.8)				

** Significant within-group difference at P < 0.05.*
† Significant between-group difference at P < 0.05.
ASO; arch-support foot-orthoses group, ES; effect size.

and BP subscales of QOL, indicating a significant difference between groups (Table 2). Follow-up comparisons showed that after 6-week intervention, pain reduction ($t(48) = 3.3$, $P = 0.002$) and perceived treatment effect ($t(48) = 2.3$, $P = 0.02$) were improved more for the ASFO group than for the SFO group (Figure 4A). In addition, participants of the ASFO group showed a better score in the PF ($t(48) = 2.7$, $P = 0.01$), PR ($t(48) = 2.3$, $P = 0.03$), and BP ($t(48) = 2.8$, $P = 0.01$) subscales of the SF-36 than participants of the SFO group (Figure 5A). Some of those differences were still present after 12-week intervention, such as reduction of pain ($t(48) = 2.9$, $P = 0.01$), decrease of PAL caused by injury ($t(48) = 6.0$, $P = 0.001$), and better scores in the PR ($t(48) = 2.1$, $P = 0.03$) and BP ($t(48) = 2.4$, $P = 0.02$) subscales of the SF-36 (Figures 4B and 5B). A new finding in week 12 was a more pronounced reduction in MTSS severity ($t(48) = 2.9$, $P = 0.01$) for the ASFO group than for the SFO group (Figure 4B). However, there were no significant differences between groups at week 18 (Figures 4C and 5C). Table 3 shows within-group changes from baseline to week 6, to week 12, and to week 18 with more details.

DISCUSSION

Our results show that adding an ASFO to the multimodal therapeutic intervention to treat MTSS is safe and leads to 12.4% more shin-pain reduction, a 12.2% improvement in perceived therapeutic efficacy, and an 8.7% improved PF after 6 weeks compared to the multimodal intervention on its own. Even after 12 weeks, the benefits of ASFO were evident as an

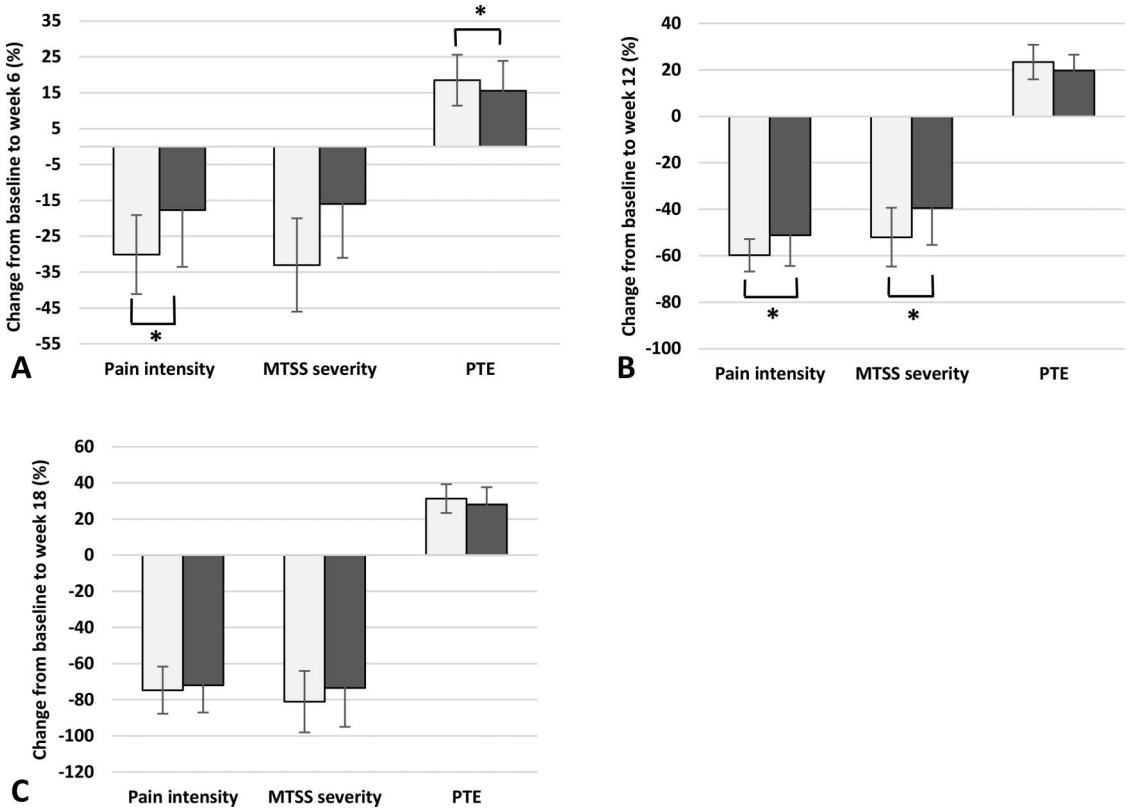

Figure 4. Relative changes (±SD) in outcomes. A, From baseline to week 6, (B) from baseline to week 12, and (C) from baseline to week 18. *Significant difference between groups at $P < 0.05$. □ASFO, arch-support foot-orthoses group; , control group; PTE, perceived treatment effects.

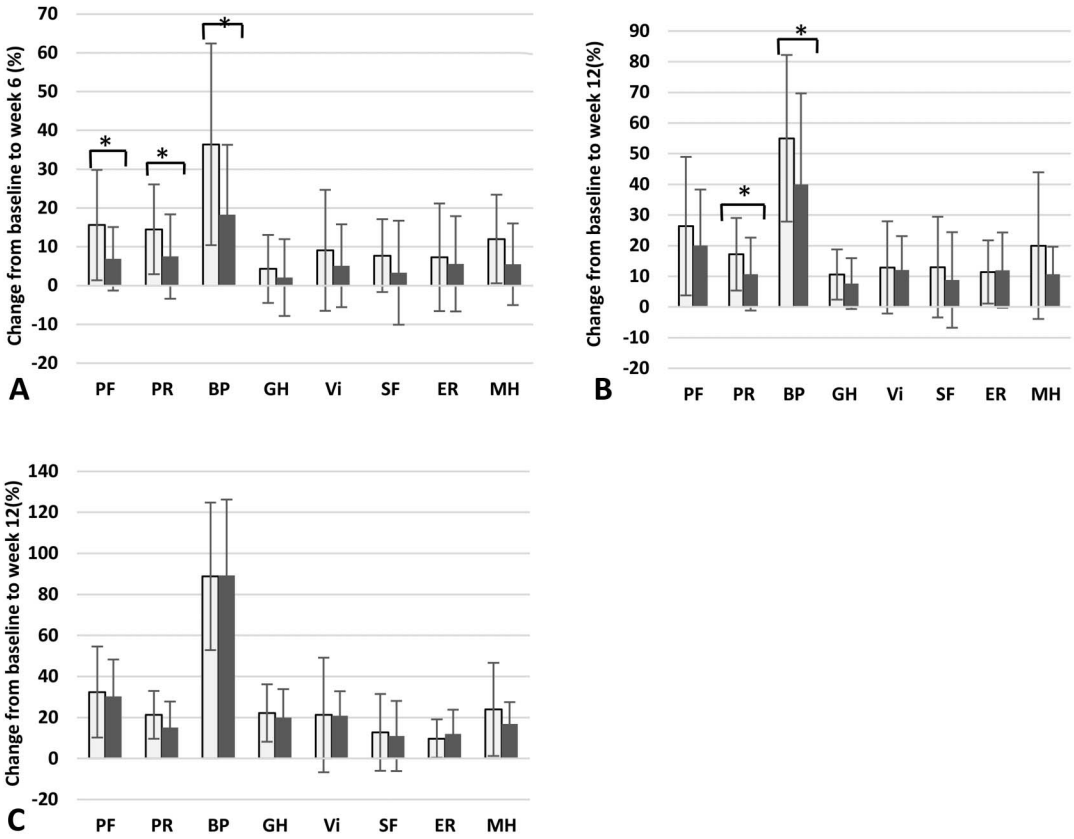

Figure 5. Relative changes (±SD) in QOL subscales. A, From baseline to week 6, (B) from baseline to week 12, and (C) from baseline to week 18. *Significant difference between groups at $P < 0.05$. □ASFO, arch-support foot-orthoses group; , sham flat noncontoured orthoses group; PF, physical function; PR, physical role; BP, bodily pain; GH, general health; Vi, vitality; ER, emotional role; MH, mental health.

8.6% larger reduction in pain, 12.5% MTSS severity and 8.7% larger improvement in PF than participants who did not use ASFO. After 18 weeks, the differences between the modal intervention with or without ASFO had disappeared. These data indicate that inclusion of ASFO in the multimodal treatment results in an accelerated recovery from MTSS.

A 15% change in pain scale is the least significant change and 33% improvement represents a "much better" outcome for musculoskeletal pain relief as a clinically important outcome.[34] Therefore, the reduction in pain during tibia palpation by a 33.5% numerical rating scale score in the ASFO group versus 18% in the SFO group after 6 weeks is a meaningful acceleration of pain reduction. The perceived therapeutic efficacy at the sixth week by the ASFO and SFO groups was 18.5% and 13.5%, respectively, which is equivalent to "somewhat better." In addition, the combination of ASFO and the multimodal therapeutic intervention led to a 2-point change on an 11-point perceived therapeutic scale, not seen in the multimodal intervention per se, which is a clinically meaningful improvement by ASFO.[25] Because a 0.35 MTSS score is the smallest significant detectable change for patients with MTSS,[26] the reduction in MTSS score by 1.6 in the ASFO group versus 0.8 in the SFO group in the sixth week indicates a significant improvement in treatment outcomes with ASFO. This indicates that adding ASFO to the multimodal therapeutic intervention achieved a greater therapeutic success, particularly at 6 weeks after start of the treatment. It was interesting that analgesic use decreased in both groups, where this decrease was slightly greater for the ASFO group than for the SFO group. In our study, analgesic use change was consistent with trends of change in the other research variables and suggests that the treatment reduces analgesic dependence to reduce MTSS-related pain.

This study also supports the observations that nearly all cross-country athletes who received foot orthoses for lower-leg pain experienced symptom reduction.[15] It also supports a prospective study[35] where a combination of off-the-shelf orthoses and calf stretching reduced pain and symptoms, and improved performance in runners with MTSS. In the latter study, however, the relative contribution of foot orthoses and stretching on pain relief could not be disentangled. In another study, 75.5% of 347 long-distance runners with lower-extremity overuse injury and 2.7% with MTSS foot orthoses use led to complete or significant pain relief, suggesting that the therapeutic outcome of foot orthoses was independent of injury type.[36]

The possible mechanisms of the successful outcomes of the use of arch-support foot-orthoses for runners with MTSS have not been investigated. However, arch-support foot-orthoses are often recommended to reduce the incidence of overuse injuries[15] through optimizing lower-extremity biomechanics, neuromuscular adaptations, reducing muscle fatigue, and improving the foot-pressure distribution.[17] Arch-support foot-orthoses are normally designed to prevent the longitudinal foot arch from collapsing. In line with this, it has been found that arch-support foot-orthoses in recreational runners

with MTSS reduce the contact time and normalize pressure distribution patterns under the foot outward during the forefoot flat and heel off.[14] Although these observations demonstrate the potential of arch-support orthoses for the treatment and prevention of MTSS, a complete kinematic analysis of the lower limb with and without the use of arch-support foot-orthoses during running can help identify the mechanisms whereby the orthoses treat and reduce the incidence of MTSS.

This is the first study to have investigated the effects of arch-support foot-orthoses for runners with MTSS in terms of pain level, MTSS severity, and perceived therapeutic effects, and it demonstrates substantial benefits. There are some limitations to this study. First, the sample size of this study is somewhat small. Second, our study is mainly based on the self-report of key variables, that is, patient's pain recall, perceived treatment effect, intensity of MTSS, and QOL. Therefore, a larger trial with objective variables such as derived from bone scanning and kinematic analysis is indicated to evaluate the effect of arch support foot orthoses in MTSS. Imaging will also help to rule out tibial stress fractures when an athlete presents with <5 cm of pain in clinical practice.[19] Third, our participants were only female recreational runners and our observations may not be applicable to other populations. Indeed, women have been reported to be at a higher risk of developing MTSS than men (Relative risk, 1.71, 95% CI 1.15-2.54).[37] Finally, we did not exactly control how much participants were running during the course of the study, but self-report running time (ASFO group = 109 ± 19 vs SFO group = 107 ± 18) and running distance (ASFO group = 14.3 ± 3.2 vs SFO group = 13.6 ± 3.5 km) at the beginning of the study were similar in both groups. In addition, the running surface type might be associated with injury[38] but both groups run in similar terrains.

Our study has shown that adding arch-support foot-orthoses to a multimodal therapeutic intervention (including ice massage, ankle muscle exercises, and standard extracorporeal shocks) led to earlier improvements in pain, MTSS severity, PF and perceived therapeutic effects than the multimodal program alone. As the orthoses are safe, these data support the use of arch-support foot-orthoses to improve the treatment of MTSS. Further research is required to understand the mechanisms whereby this earlier improvement is realized.

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