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Research Article

Comparison of the ThermaWedge® Device versus Calf-Stretching for the Treatment of Plantar Fasciitis: A Randomized Cross-Over Study

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ABSTRACT

Objective: To compare the effectiveness of a novel, patented device which combines calf muscle and intrinsic foot stretching with deep plantar massage and hot/cold therapy against a clinical standard calf stretching therapy for chronic plantar fasciitis.

Design: A 6-week cross-over design with 1-week washout period.

Setting: An outpatient sports medicine facility in Vancouver, Canada.

Participants: 29adult men and women diagnosed with plantar fasciitis.

Main Outcome Measures: The Foot and Ankle Disability Index (FADI) and Numerical Rating Scale of Worst Pain scores assessed weekly over a 13-week period.

Results: Over the 13-week protocol there was a significant ($p < 0.05$) difference in both the reported worst pain and FADI values between the treatment phases, with the ThermaWedge® phase reporting lower plantar pain and improved foot and ankle function.

Conclusion: Individuals with plantar fasciitis appeared to experience greater improvement in pain, as well as foot and ankle function, when they use a device and exercise protocol that addressed multiple aspects of soft-tissue management (ThermaWedge®) versus calf-stretching alone. Further study on the ThermaWedge® is, however, merited as the reported clinical improvements may not be clinically significant given the sample size.

INTRODUCTION

Chronic plantar fasciopathy is a painful condition secondary to repeated tissue insult, typically with a focal point of tenderness at the medial plantar heel and medial longitudinal arch of the foot. It is a very common condition contributing to a significant number of visits to first line care providers. Approximately 1 million patient visits annually were made to physicians in the United States nation-wide over a 6-year period, from 1995-2000, for diagnosis and treatment of plantar fasciopathy [1]. Up to 10% of the general population reportedly develops plantar fasciopathy over their lifetimes [2].

Plantar fasciopathy is common amongst individuals required to spend prolonged periods of time on their feet [3]. In a study of over 500 supermarket workers, the highest incidence of foot injuries corresponded with workers who had the highest

frequency of standing at work; individuals who report standing for the majority of the day are over 300% more likely to develop heel pain than their counterparts [4,5]. Similar findings are reported in the automobile industry; for every 10% increase in the time spent walking or standing on a hard surface there is a respective 50% and 390% increase in the likelihood of developing plantar fasciopathy [6].

The etiology of plantar fasciopathy is multifactorial secondary to both modifiable and non-modifiable risk factors with dependence on individual history. The role that prolonged standing has on the onset of injury is speculative; however, it is reasonable that tissue overload and overuse plays a role. The plantar fascia ligament is a thick band of dense connective tissue that provides support for the longitudinal arch of the foot during weight-bearing by forming a truss that spans the calcaneus to the metatarsophalangeal joints with divisions attaching at the distal phalanges. This broad, thick ligament therefore undergoes tensile loading when body weight is applied to the foot. Prolonged standing fatigues lower limb musculature that is shown to alterpostural control and muscle activation patterns that may lead to inappropriate loading of the plantar soft tissue [7]. An additional component may be fatigue of plantar intrinsic muscles including flexor hallucis brevis and abductor hallucis, which are known to provide dynamic support for the medial longitudinal arch, thoughthis association has not been specifically studied in relation to a prolonged standing task [8].

Treatment options for workers with plantar fasciopathy are varied and there is little consensus on a validated clinical approach when rest is not an option. Steroid injections are a common treatment for plantar fasciopathy as a short-term symptom management treatment [9-12]. By nature, corticosteroids are not regenerative, but are primarily utilized to provide pain relief. There is limited evidence supporting long-term treatment effectiveness with corticosteroid therapy [2,9]. Surprisingly, exercise has only received sparse attention in the medical literature despite the fact, commonly employed as the treatment approach for chronic heel pain plantar fasciitis. Exercise-based treatment options for plantar fasciopathy offer promise given that the focus is on restoring tissue function and limiting further mechanistic damage, rather than simply symptom reduction. Histological reports from surgical biopsies of the plantar fascia do not demonstrate inflammatory infiltrates, but rather mycoid or fibrocartilaginous tissue suggesting an aberrant remodeling process [13]. Accordingly, treatment efforts aimed at restoring ligament function and improving lower extremity coordination, to offload stress from the plantar fascia, should be a priority. The objective of the present study is to conduct a preliminary investigation on the effect of a device that offers multi-element treatment for plantar fasciitis, including stretching, massage, and temperature therapy versus traditional calf stretching exercise therapy.

METHODS

We carried out a randomized cross-over designed trial to investigate the effectiveness of the patented ThermaWedge® device versus traditional calf-stretching exercise therapy. All procedures within this study were approved by the Clinical Research Ethics Board at the University of British Columbia (approval number H14-01870).

Setting and eligibility criteria

The study was carried out at the Allan McGavin Sports Medicine Centre and surrounding community in Vancouver, Canada between May 2015 and March 2017. Recruitment was diversely performed through newspaper advertisements, information sheet dissemination at various work places, and word-of-mouth. Participants were required to have a history of inferior heel pain for at least 12 months and to report a minimum heel pain of 20mm on a 100mm visual analog scale and have pain through direct palpation of either the medial calcaneal tubercle or proximal plantar fascia.

We excluded potential recruits if they had received a corticosteroid injection for plantar heel pain within the previous six months, current skin or soft tissue infection near the plantar fascia, inflammatory disease, diabetes mellitus, previous local surgery, or a history of local trauma or other musculoskeletal condition that might impair function of the foot or ankle. We excluded individuals who are involved in litigation for their heel pain or on worker's compensation benefits.

Procedures

Participants were invited to a workshop information session where they underwent informed consent, which was approved by the local university clinical ethics review board, and they had an opportunity to ask any questions about their

participation in the study. Randomization was performed by having participants randomly choose a paper slip with aunique participant code that corresponded to one of two groups randomly assigning were the order of treatment interventions. The two group treatment schedules were opposite with either initial ThermaWedge® treatment protocol followed by conventional calfstretch therapy or vice versa. Treatment interventions were employed daily for a 6-week period, followed by a 1-week wash-out period, before they switched to the other therapy regimen. Both the ThermaWedge® treatment and the calf stretch exercises were reviewed with participants prior to commencing the 13-week study phase.

Participants will be were clinically screened for plantar fasciopathy by senior medical

students (Sunjit Parmar, Naima Kotadia and/or Harpreet Singh). Weight and height were measured and instruction was provided for the respective exercises or use of the ThermaWedge® device. Participants then received a device at the workshop to use during the appropriate 6-week period of the study phase.

Interventions

ThermaWedge® Device: The ThermaWedge® device consists of following therapeutic elements (Figure 1):

1. A hard foam ramp that is positioned to facilitate stretching of the triceps-surae muscle group;
2. A round cork doweling tool for both deep massage to the plantar intrinsic muscles, as well as the plantar fascia itself;
3. A hot/cold pack for symptom relief and tissue relaxation.

Participants were given detailed instructions on how to use the ThermaWedge® device and had to demonstrate the technique prior to involvement in the study. Mastery was considered achieved when participants demonstrated smooth, controlled motions that progressed through the appropriate range for that exercise.

The 5 exercises performed using the ThermaWedge® device included:

1. Everyday Calf Stretch: Participants placed their foot on the ThermaWedge®

device and stretched their calf. The first exercise set was done with the knee straight,

while the second was done with the knee bent. This alternation allows both soleus and gastrocnemius muscle groups to be stretched.

2. Cooling / Warming Calf Stretch: Participants inserted the frozen gel pack into the

ThermaWedge® device pocket and repeated the same calf stretches in step 1.

3. Targeted plantar fascia stretch with toe dorsiflexion: Participants put their foot on the ThermaWedge® device and positioned the roller under their toes to stretch the plantar fascia and the calf simultaneously.

4. Foot intrinsic muscle massage: Participants placed the cork roller on a flat surface and rolled their foot forward and back over the roller to stretch the plantar fascia. They applied as much pressure as was comfortable for myofascial release of the plantar fascia.

5. Plantar fascia massage: Participants sat and positioned their foot so they could reach the bottom of their foot with the cork tool in their hand. They pulled their toes back, held the tool firmly and pressed the rounded end of the cork tool into the sole of the foot. They moved the tool side to side slowly across the plantar fascia.

Participants performed two repetitions of the 5 exercises on each foot twice daily, once in the morning and once in the evening. The duration of each exercise was sustained for 30seconds and each exercise was done twice, therefore totaling 1 minute per exercise and a total of 10 minutes to complete the exercise regime on both feet.

Calf stretching: The control intervention in this study was a calf-stretching protocol with their back knee first kept straight (extended) and in the second exercise set, their back knee bent (flexed). Participants stood in front of a wall or table and they split their legs forward and back with their feet approximately shoulder width apart. The front knee was bent, and back knee was initially straight for first set of two and bent for second set of two stretches for a total of four stretches. A wall ortable was used to steady themselves and provide counter traction if needed. The four sets of stretches were done on each leg and each stretch was held for 30 seconds. The stretches were completed twice daily, once in the morning and once in the evening as was consistent with the ThermaWedge® device.

Compliance with study protocols was confirmed with an online training log that participants submitted on a weekly basis using their unique ID. Each participant was contacted by emailon a weekly basis to ensure clarity, execution of the exercise regimen and survey completion.

Outcome measures

The primary clinical outcome measures used in this study include the Foot and Ankle Disability Index (FADI) which was designed to assess functional limitations related to foot and ankle conditions [14]. The clinimetric properties of the FADI have been reported previously and have performed well in comparison to other subscales for assessing foot and ankle disability [15,16]. Secondary clinical measures include a numerical rating scale of worst pain over the preceding 7-days [17]. Outcome measures were assessed weekly through the Qualtrics survey tool provided by the University of British Columbia.

Data analysis

Our a-priori power analysis was based on preliminary data conducted on a previous investigation using a multi-element exercise program using a population with plantar fasciopathy, that reported an average baseline pain score of 52.8 with a standard deviation of 24.6 [18].The Minimum Clinically Significant Difference (MCID) has not been reported for the FADI; therefore, a 30% change in pain scores between groups is (difference in VAS scores of 15.84) will be considered a clinically significant difference. Based on these a-priori data, and considering the cross-over design approach, 13participants were needed with a 95% probability of avoiding a type I error and a power level of 0.80. Descriptive statistics were carried out for initial group characterization to examine and confirmed through independent t-tests and chi-square analyses, where appropriate for categorical variables, group homogeneity in participant age, gender distribution, height and weight (Table 1). Group variances were examined and confirmed to be homogeneous for worst pain (p=0.208) and FADI (p=0.170). An univariate general linear model was used to examine main effects for Group and Time, and their corresponding interaction effect across the 13-week trial period. The alpha for this study set at 0.05 for significance.

Table 1: Overview of independent and dependent outcome measure variables at baseline.

Independent Measure	Group A (ThermaWedge™ – Calf Stretch)	Group B (Calf Stretch - ThermaWedge™)	Group Difference
Number of subjects	15	14	-
# Female (% group)	8 (53%)	9 (64%)	1.0,p=0.84
Bilateral # (% group)	6 (40%)	5 (36%)	1.0, p=0.75
Age (years) ± SD	52.4 ± 7.5	46.2 ± 8.5	6.2,p=0.36
Weight (kg)	67.7 ± 13.0	65.8 ± 16.7	1.9,p=0.71
BMI (kg/m^2)	24.3 ± 3.6	26.2 ± 4.7	1.9, p=0.65
Symptom duration (months)	69.4 ± 86.2	71.4 ± 100.3	2.0, p=0.52
Exercise compliance	83 ± 16%	87 ± 17%	4.0, p=0.43

RESULTS

In total, 29 patients with plantar fasciopathy were included in the final analysis (Figure 2). In cases where patients presented with bilateral symptoms, the foot with greater symptom severity (based on numerical pain rating scale for worst pain) was reported. There were no significant differences in any of the clinical or demographic measures at baseline across groups.

Participants using the ThermaWedge® device reported a significant main effect on group with a 0.96 point (95%CI -1.6 – -0.37; p=0.018) reduction in their worst pain and a 7.6 point (95%CI -11.3 – -3.8; p=0.034) improvement in their foot and ankle function (FADI) compared to calf-stretching alone (Figure 3).

DISCUSSION

The objective of this study was to compare the effectiveness of a device designed to assist in administering stretching, self-massage and temperature therapy compared to a standard-of-care protocol of calf stretching. Limited formal investigations on the effectiveness of exercise-based interventions have been reported for plantar fasciopathy, despite it being a mainstay of therapy for this condition. Therefore, there is a need for

formal documentation of exercise and physiotherapy protocols for treating plantar fasciitis and evidence supporting their effectiveness, both in the broader scope of this condition and in the specific cases of workers spending prolonged periods of time on their feet. Despite the significant improvement in both worst pain and foot/ankle function, the mean differences do not surpass the Minimum Clinically Important Difference (MCID) previously reported for these measures [18,19]. Results from this study suggest that using a multi-element device to assist rehabilitation exercises for plantar fasciitis provides a measurable improvement in symptoms over a calf stretching program; however, these differences may not be clinically meaningful.

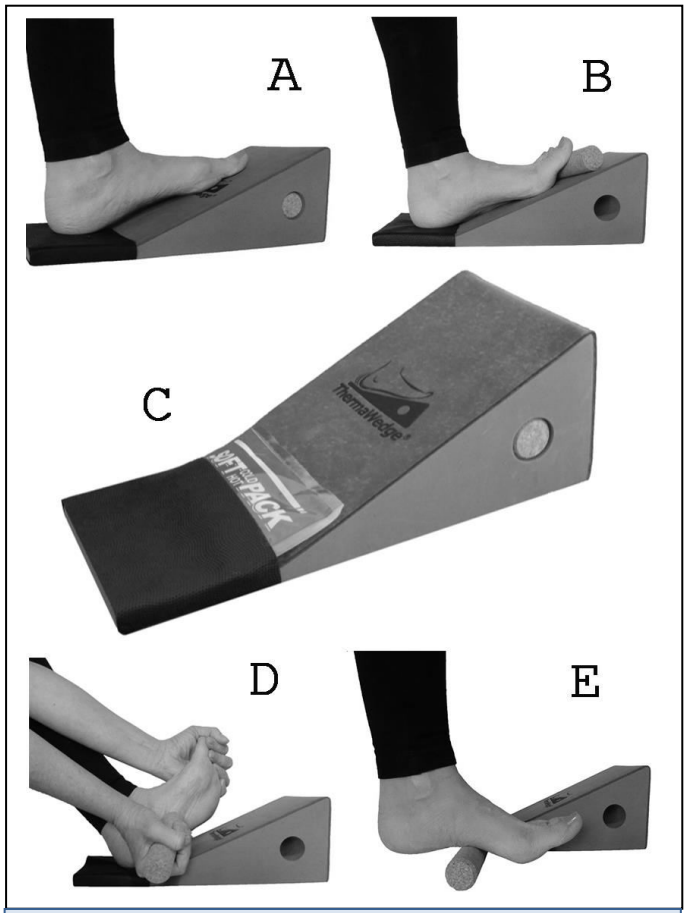

Figure 1: Composite illustration of the 5 exercise components included in the ThermaWedge device® treatment protocol: A) Calf stretch; B) Targeted plantar fascia stretch with toe dorsiflexion; C) Cooling/warming calf stretch; D) Plantar fascia massage; E) Foot intrinsic muscle massage.

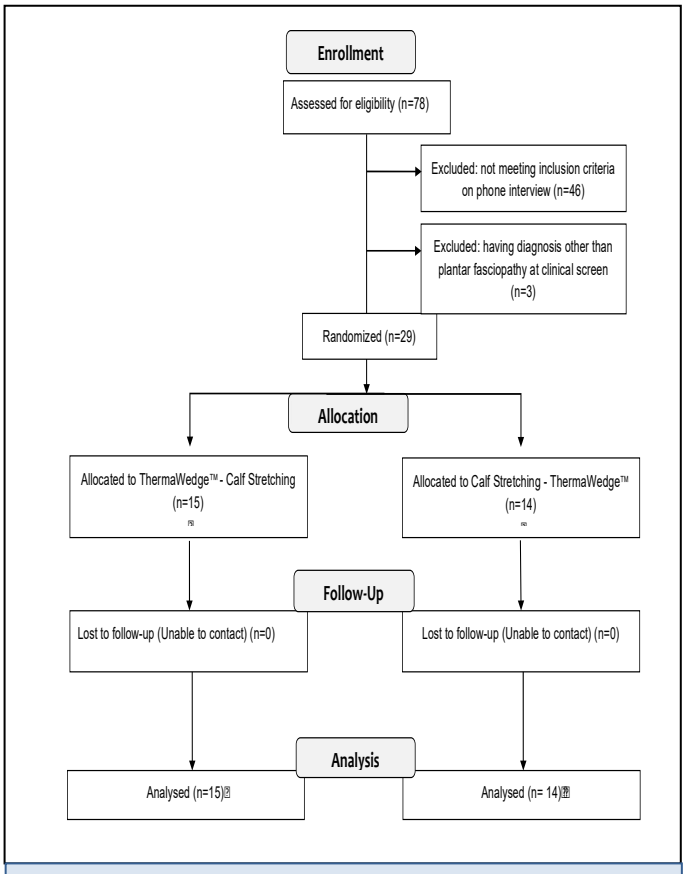

Figure 2: CONSORT flow diagram of participant recruitment and group allocation.

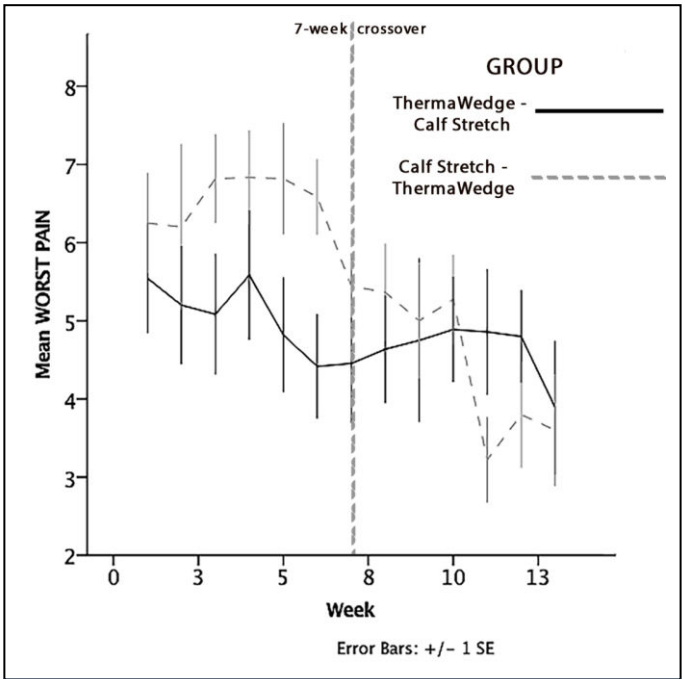

Figure 3: Mean worst pain over the preceding 7-days by group over time.

The specific mechanism behind therapeutic success with stretching remains unknown with no clear answer as to the relationship between exercise intensity, speed, or frequency and clinical outcome [20]. We speculate that the clinical success experienced by the group performing the regimen with the ThermaWedge® device in the present study is a result of one or a combination of the following 3 therapeutic effects. Firstly, the tissue-specific stretching (using the cork dowel tool under the toes during the calf stretch) and providing targeted loading to the plantar fascia. Appropriate loading of soft tissue is an important element for mechanotransduction-related maintenance of extracellular matrix tensile strength [21]. The second effect comes from improved activation and myofascial release when rolling, or applying direct pressure, with the towelling cork doweling massage tool. Extrinsic foot musculature provides important dynamic support of the longitudinal arch, and using a therapy that also benefits the direct myofascia of these extrinsic muscle groups could decrease stress on passive structures such as the plantar fascia [8]. A previous case report on a directed program of targeted exercises to increase range of motion and progressively increase sport-specific stress on the plantar fascia reported favourable clinical outcomes [22]. Lastly, the hot pack is used to assist in tissue preparation prior to loading, and the cold pack feature is used to provide pain relief [23].

The present study is the first to report on the effectiveness of the ThermaWedge® device in a clinical population, but previous authors have used components of the multi-element program in this study and reported favourable findings. Indeed, the tissue-specific stretching exercise first reported by DiGiovanni et al. [24,25] showed a strong clinical improvement after both short and long term follow-up [24,25]. A study conducted by overlapping researchers showed a positive clinical improvement following use of the same multi-element protocol in a group using minimalist footwear [18], as well as with a population who stand for prolonged periods during their workday [26].

STUDY LIMITATIONS

A cross-over design was chosen to carry out this preliminary investigation on initial response to the ThermaWedge® device in order to maximize statistical power from available participants given limited study resources. Another advantage to this cross-over design is the balancing of possible confounding factors across groups as each participant serves as their own control. Lastly, the opportunity for all participants to receive the active intervention at some point in the trial, thereby assisting recruitment, is a further advantage to this cross-over format.

There are; however, important limitations to this design that the reader should consider. Most notably, there is no true control group making it difficult to clarify whether the clinical improvements seen in either of the treatment groups are not simply a function of time. Blinding of the study personnel to treatment allocation was not performed, making our outcomes vulnerable to certain psychological effects common in clinical trial conduct, such as Hawthorne, Observer-expectancy, and Rosenthal effects [27,28]. There is large variation in the symptom duration reported in both groups in this study suggesting that there may be different levels of pathology within this sample; prolonged symptom duration can have significant negative consequences on prognosis [29]. The follow-up time frame of only 12-weeks is too short to know the medium and longer term effectiveness of either treatment arm from both a clinical and structural rehabilitation standpoint.

The findings from this study have may have implications for health-related quality of life with individuals with plantar fasciitis. The positive treatment effect from the use of the ThermaWedge® device in restoring both pain and disability suggests it may be a synthesized pragmatic option for achieving symptom improvements from plantar fasciitis. The individual exercises within the multi-element exercise protocol used in this study are relatively simple to perform, are without side-effects or adverse events, and use equipment that can be purchased at a low-cost. It is recommended that future research considers targeting specific populations with plantar fasciitis in order to more clearly delineate responders that experience a clinically meaningful difference with the use of the ThermaWedge® device.

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