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a randomised crossover trial

Riel, Henrik; Vicenzino, Bill; Jensen, Martin Bach; Olesen, Jens Lykkegaard; Holden, Sinead; Rathleff, Michael Skovdal

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MR HENRIK RIEL (Orcid ID : 0000-0003-4575-6293)

PROFESSOR BILL VICENZINO (Orcid ID : 0000-0003-0253-5933)

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The Effect of Isometric Exercise on Pain in Individuals with Plantar Fasciopathy: a randomised crossover trial

Running head: Isometric exercise in plantar fasciopathy

Authors: Henrik Riel[1]: hriel@dcm.aau.dk; Bill Vicenzino[2]: b.vicenzino@uq.edu.au; Martin Bach Jensen[1]: mbj@dcm.aau.dk; Jens Lykkegaard Olesen[1,3]: jlo@dcm.aau.dk; Sinead Holden[1,4]: siho@hst.aau.dk; Michael Skovdal Rathleff[1,4,5]: misr@hst.aau.dk

[1]Research Unit for General Practice in Aalborg, Department of Clinical Medicine, Aalborg University, Fyrkildevej 7, 9220 Aalborg East, Denmark

[2]The University of Queensland, School of Health and Rehabilitation Sciences: Physiotherapy: Sports Injury Rehabilitation and Prevention for Health, St. Lucia QLD 4072, Australia

[3] Institute of Sports Medicine, Bispebjerg Hospital, Bispebjerg Bakke 23, 2400 Copenhagen NV, Denmark

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[4]Center for Sensory-Motor Interaction (SMI), Department of Health Science and Technology, Faculty of Medicine, Aalborg University, Fredrik Bajers Vej 7D, 9220 Aalborg East, Denmark

[5]Department of occupational therapy and physiotherapy, Aalborg University Hospital, Hobrovej 18-22, 9100 Aalborg, Denmark

Correspondence: Henrik Riel, hriel@dcm.aau.dk, Research Unit for General Practice in Aalborg, Fyrkildevej 7, 9220 Aalborg East, Denmark. Telephone no.: +45 30201570

ABSTRACT

Isometric exercise is commonly recommended for immediate pain relief in individuals suffering from lower limb tendinopathies, despite the limited evidence supporting its analgesic effect. Due to the similarities between plantar fasciopathy and tendinopathies, the aim of this trial was to investigate the acute effect of isometric exercise on pain, compared to isotonic exercise, or walking, in individuals with plantar fasciopathy. We recruited 20 individuals with plantar fasciopathy for this prospectively-registered, participant-blinded, randomised, superiority crossover trial (ClinicalTrials.gov: NCT03264729). Participants attended three exercise sessions (isometric, isotonic or walking) in a randomised order, within a two-week period. Both isometric and isotonic exercises were performed standing with the forefoot on a step bench, while walking was performed barefoot. The primary outcome was pain (measured on a 0-100mm VAS) during a pain-aggravating activity. Secondary outcomes included pressure pain threshold (PPT) under the heel, and plantar fascia thickness (PFT). All outcomes were measured before and after each exercise session. There were no significant differences between the three exercises on pain (P=0.753), PPTs (P=0.837) or PFT (P=0.718). Further, there was no change in pain from before to after any of the exercises (isometric exercise 2.7mm (95%CI: -12.2; 6.8), isotonic exercise -3.4mm (95%CI: -5.0; 11.8) or walking 1.6mm (95%CI: -16.1; 12.9)). Contrary to expectations, isometric exercise was no better than isotonic exercise or

walking at reducing pain in individuals with plantar fasciopathy. None of the exercises induced any systematic analgesic effect.

Keywords

Plantar fasciopathy; tendinopathy; exercise; pain

INTRODUCTION

Patients with plantar fasciopathy (PF), a condition affecting one in 10 (1–4), often report a sharp heel pain. The pain is usually intense during the first steps in the morning or after periods of inactivity, and improves with ambulation but can worsen during the day.(5)

Resistance exercise is commonly prescribed for patients with musculoskeletal pain,(6) and is effective in long-term pain reduction in patients with tendon pain.(7) As such, there is strong evidence (systematic reviews) supporting loaded exercise programs as treatment for both Achilles and patellar tendinopathy.(8,9) Preliminary evidence suggests that PF also responds favourably to a loading program.(10)

Rio and colleagues(11) found that isometric exercise reduced pain during an aggravating task, compared to isotonic (or dynamic) resistance exercise, in six male volleyball players with patellar tendinopathy. This is the only available published study evaluating the acute analgesic effect of different resistance exercises in patients with lower limb tendinopathy. Despite the limited evidence, isometric exercise is now recommended for lower limb tendinopathies.(12) The immediate effect of

similar exercises on pain has not been examined in PF. As they require minimal equipment or time, these simple exercises could be valuable to help patients manage their pain, if effective.

The aim of this trial was to compare the acute analgesic effect of isometric resistance exercise, isotonic resistance exercise, and walking, in participants with plantar fasciopathy. We hypothesised that isometric exercise would induce more analgesia than isotonic exercise or walking.

MATERIALS AND METHODS

Study design

This trial was a randomised cross-over, participant-blinded, superiority trial, prospectively registered on clinicaltrials.gov (ID: NCT03264729), conducted in Aalborg, Denmark. Participants were blinded to the hypotheses and, thus, did not know which exercise was hypothesised to reduce pain the most. Reporting of this trial follows CONSORT guidelines for reporting non-pharmacologic treatments(13) and TIDieR for intervention description(14,15). The trial was approved by the Ethics Committee of the North Denmark Region (Project ID: N-20170021) prior to recruitment.

Participants

Participants were recruited through advertisement on Facebook. Potentially eligible participants were screened by telephone, and subsequently invited to a clinical examination to ensure they met the inclusion criteria (outlined below). The assessor, who was responsible for inclusion, exercise instructions and data collection, was a registered physiotherapist with six years of experience in treating patients with musculoskeletal disorders. Written informed consent was obtained prior to the physical examination. The inclusion and exclusion criteria were applied as follows (in line with

previously published criteria in plantar fasciopathy)(16)): history of inferior heel pain for at least three months before enrolment; pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia; thickness of the plantar fascia of 4.0 mm or greater; pain during at least one of three pain aggravating activities (static stance, half squat and heel raise); and mean heel pain of ≥ 20 mm on a 100-mm Visual Analogue Scale (VAS) [0mm=no pain, 100mm=worst pain imaginable] during the past week. The exclusion criteria were: below 18 years of age; history of inflammatory systemic diseases; pain or stiffness in the 1st metatarsophalangeal joint to an extent where the exercises cannot be performed; prior heel surgery; pregnancy; pain medication; and corticosteroid injection for PF within the past six months. The procedure for the three single-leg pain-aggravating activities is described in detail below.

1. The static stance was performed for 30 seconds. Participants were allowed to stabilise themselves by placing a hand on the wall.
2. The half squat was performed with the participant flexing the knee of the stance leg to 45-degree knee flexion. The test was performed for 10 repetitions with a 1-second eccentric phase and a 1-second concentric phase.
3. The heel raise was performed with participants performing a maximal plantar flexion of the ankle joint with the knee in full extension. The test included 10 repetitions with a 1-second eccentric phase and a 1-second concentric phase. Based on a previous study(17) we expected that 88% of participants would experience pain aggravation from at least one of these tests.

Participants provided a pain rating by marking a 100-mm line anchored left with “No pain” and right with “Worst pain imaginable” immediately after termination of each of the tests. In cases where bilateral pain was present, the most affected side was used for investigation.

Intervention

Participants attended three sessions (isometric, isotonic, and walking) over the course of two weeks. The order of the exercises was randomised for all participants, using a Williams Design, with six different potential exercise sequences (e.g. A-B-C, B-C-A, C-A-B).(18) The allocation sequence was generated using a random number generator on www.random.org by an independent researcher not involved in the study, who placed them into sequentially numbered opaque sealed envelopes. The assessor was blinded to the allocation sequence, and assigned each participant to the next envelope upon inclusion. There was a minimum 48-hour interval between sessions, with all three being completed within a two week period. Participants performed the sessions at approximately the same time (within ±1 hour) to account for any variations according to time of day.

Participants were instructed in the first of the three exercises after being diagnosed, randomised, having baseline outcomes assessed, and having performed the aggravating activity. The isometric and isotonic exercises were a heel-raise, performed standing with the forefoot on a step (full details are outlined in Table 1).(19) The load used for either the isometric or isotonic session was determined on the same day as the respective type of exercise was performed. The load for the isometric exercise was determined by instructing participants to find a load they would be able to endure for no more than one minute. Participants were able to try different exercise variations such as standing on one leg or by adding a backpack. They were allowed to use the different exercise variations for a self-selected period of time, until they felt confident that the correct load was found. The load for the isotonic exercise was 8-repetition maximum (RM), determined by instructing participants to find a load with which they would only be able to perform 8 repetitions (i.e. 8-RM). If the participant's bodyweight was inadequate to reach sufficient loading, the participant was fitted with a backpack with books or weights. The walking session was performed barefoot, participants were instructed in walking at a pace they would use when walking at home. The duration was four minutes, to match the contraction time of the exercises.

To promote retention, participants were offered to be instructed in performing exercises with the purpose of long-term recovery after they had completed the trial.(10) If a participant would withdraw from the trial prematurely (e.g. if they were unable to perform the activities, or withdrew consent) they would be excluded from the data analysis.

All intense activities that were unusual to the participant in duration and load were prohibited for the 48 hours prior to each session. Participants were not allowed to receive treatment for PF during the course of participation in the trial.

Outcomes

The primary outcome was pain experienced during the most pain-aggravating activity found during screening, measured on a 100-mm VAS [0mm=no pain, 100mm=worst pain imaginable].

Secondary outcomes included (i) thickness of the plantar fascia measured by ultrasound, (ii) pressure pain threshold (PPT) on the most painful spot under the heel, and (iii) pain (measured on a 100-mm VAS) during the exercise sessions (isometric, isotonic and walking sessions). After completion of each session, participants rated their average pain experienced during the session.

Outcomes were evaluated in the same order before and after each session, as shown in Figure 1.

First, the plantar fascia thickness was measured using ultrasound (SonoSite M-Turbo® (FUJIFILM SonoSite, Inc., Washington, USA)), with a 6-13 MHz transducer frequency (see web-appendix 2 for a sample image of the ultrasound measurement). The participant was lying in prone, with the toes dorsiflexed against the examination table while a longitudinal scan was performed. The average of three consecutive measurements was used for analysis. This method has established reliability (ICC=0.67-0.77).(20) This was chosen as an outcome to investigate if there were changes in plantar fascia thickness in response to the exercises. To investigate if the aggravating activity and PPT

measurement influenced plantar fascia thickness, an ultrasound measurement was performed both before and after aggravating activity and PPTs (Figure 1).

PPTs were measured using a hand-held mechanical pressure algometer (Somedic, Hörby, Sweden) with a 1-cm^2 probe on the most painful spot under the heel (found by palpation). This was conducted with the participant lying in prone on the examination table, with the feet hanging freely over the end of the table. The probe was placed perpendicular to the skin and pressure was increased gradually at a rate of 30 kPa/s. Participants were instructed to press a handheld switch when the sensation changed from pressure, to the first onset of pain. This was repeated three times, with a 30-second break between tests, and the average being used for the analysis. This was chosen as an outcome to provide a reliable measure of pain sensitivity.(21) Pressure pain threshold testing under the heel in patients with PF has been found to have a good intrarater reliability (ICC=0.75-0.92).(22)

Figure 1: Flow chart of measurements.

Sample size estimation

We expected a 19-mm greater reduction on VAS in the isometric exercise compared to the isotonic exercise (with 19 mm being considered the the minimally important difference in this patient population).(23) Based on a standard deviation of 19 mm (similar to the overall standard deviation found in the study by Rio et al. 2015(11)), a two-sided 5 % significance level and a power of 80 %, a sample size of 16 participants would be necessary. Despite an effect size of 4.64 in the study by Rio et al., we aimed to include 20 participants to account for a potentially greater variability due to a more heterogenous patient population compared to Rio et al.

Statistical analyses

All statistical analyses were pre-specified. We assessed normality using Q-Q plots. The assumption of negligible carryover effects was investigated with preliminary unpaired t-tests.(24) The primary

analysis (investigating the effect of isometric *versus* isotonic exercise *versus* walking on pain during aggravating activity) was undertaken with a 3 X 2 repeated measures ANOVA. Independent factors were exercise type (isometric *vs*. isotonic *vs*. walking) and time (pre *vs*. post). Dependent variable was pain.

Additionally, the proportion of participants achieving a clinically relevant pain reduction was calculated for each exercise. It was defined a-priori that no conclusions would be made favouring any of the exercises, unless pain was reduced more than the clinically important difference (19 mm VAS).(23)

Analysis of secondary outcomes (plantar fascia thickness, and PPTs) was done using 3×2 repeated measures ANOVA (factors as above). Pain during exercises was examined using a one-way repeated measures ANOVA, with exercise (isometric, isotonic, or walking) as the independent factor, and pain (VAS) as the dependent variable.

As plantar fascia thickness was measured after the other measurements, paired t-tests of plantar fascia thickness measurements were used to determine if the aggravating activity and PPT impacted plantar fascia thickness. Pearson's correlation coefficient was used to test the association between change in plantar fascia thickness, and the pain reduction during exercise. All statistical analyses were performed according to a pre-established analysis plan (clinicaltrials.gov: NCT03264729) using STATA ver. 14.

RESULTS

Participants were recruited between August and September 2017, with the final follow-up conducted in October 2017. Twenty-eight potential participants responded to the advertisement, with 26 eligible for clinical examination. Of these, two declined, one had no pain during any of the aggravating activities, one had a mean heel pain during the past week <20 mm VAS, and one had a plantar fascia thickness <4.0 mm. One participant was withdrawn after inclusion due to illness. Baseline characteristics of the included 20 participants are presented in Table 2.

Fifteen participants had sought medical care for their pain, all of whom had been in contact with their general practitioner. Ten participants had been treated by a physiotherapist, which was the second most common healthcare personnel that had been contacted. Other treatment providers were medical specialists (n=3), acupuncturists (n=3), chiropractors (n=2), cranio-sacral therapist (n=1), massage therapist (n=1), and reflexologist (n=1). Three of the 15 participants who were in the work force had taken time (5 to 548 days) off work because of heel pain. For the aggravating activity, 15 participants felt most pain during heel raise, three during half squat, and two during static stance.

Primary analysis

There was no significant exercise type×time interaction for pain during the pain-aggravating activity ($F(1,95)=0.28$, P=0.753) (Figure 2). Despite all participants reporting pain during at least one of the aggravating activities during eligibility screening, two participants felt no pain during the aggravating activity before either of the exercises. In three participants the isometric and isotonic exercises led to clinically relevant pain reductions (reduction≥19 mm) while the walking sessions led to clinically relevant pain reductions in two participants. Two participants experienced clinically relevant pain reductions after both the isometric and isotonic exercises. To test the robustness of our findings, we

also used a non-parametric statistical analysis which supported our pre-determined primary analyses (full non-parametric analyses can be seen in web-appendix 1).

Secondary analyses

There were no significant interactions for pain during exercises ($F(2,38)=1.45$, P=0.248), for PPT ($F(1,95)=0.18$, P=0.837) or for plantar fascia thickness ($F(1,95)=0.33$, P=0.718) (Table 3). There was no association between change in pain and change in plantar fascia thickness ($r=0.15$, P=0.266). Performing the aggravating activity and the PPT test had no effect on the plantar fascia thickness during either session (mean difference= 0.1 mm, 95%CI: -0.1 to 0.2, P=0.482; mean difference= 0.0 mm, 95%CI: -0.2 to 0.2, P=0.763; and mean difference= -0.1 mm, 95%CI: -0.3 to 0.0, P=0.124).

Figure 2: Individual participant data on pain during the aggravating activity before and after the exercises. The stars depict mean pain. Dotted lines show clinically relevant pain reductions.

DISCUSSION

This was the first trial comparing the acute analgesic effect of different types of resistance exercise and walking, in participants with PF. Contrary to expectations, isometric exercise was not better than isotonic exercise or walking at reducing pain with none of the exercises inducing any systematic analgesic effect.

The role of isometric exercise in PF

Participants had a varied response to isometric exercise. As only 3 out of 20 participants had a clinically relevant pain reduction, isometric exercises can only be recommended on a trial and error

basis. Similar results were seen in the isotonic exercise. The effect of walking was similar to that of the resistance exercises, but less time consuming as there were no rest periods.

This trial investigated the acute pain relieving effect of exercises and walking. Loading programmes are often an important part of long-term management of tendinopathies.(7–10) The acute effect may be different to long-term treatment effects, and we still lack data on loaded exercises in PF. The type of loading may be less important than the load itself as no difference between heavy slow resistance training and eccentric training was found in patients with Achilles tendinopathy and no difference between an isometric and an isotonic program was found in patients with patellar tendinopathy.(7,25) Isotonic exercise has been found to be superior to stretching in PF(10) and other types of loading could be tested to provide clinicians with an alternative potentially based on patient preferences as there was no difference in pain during the exercises of our present trial. The effects of other types of loading need to be investigated in PF before they can be recommended in clinical practice.

Comparison with previous studies

Rio et al. (11) found a superior analgesic effect of isometric exercise. Their study included six male young athletic volleyball players, whereas the 20 participants in the current study were older and primarily female. This may partially explain differences in results between the studies. Younger people have greater exercise-induced hypoalgesia than older people, and males generally respond better to isometric exercise than females.(26,27) Additionally, participants of the current study had a median symptom duration of 8.5 (IQR: 6 to 19.5) months. This indicates a chronic state, although symptom duration was not reported in the study by Rio et al.(11) Patients with chronic pain often demonstrate lesser response to exercise than healthy individuals.(28,29) Participants responded variably to the isometric exercise similar to what has been demonstrated in patients with lateral epicondyalgia.(30) This highlights the need for research to determine which patient groups will

benefit from isometric exercise, as findings in one type of tendinopathy may not necessarily be generalisable to others.

Strengths and limitations

This trial was prospectively registered on clinicaltrials.gov. The number of repetitions, sets, and contraction time of the isometric exercise matched those used by Rio et al.(11), to replicate their methods. Nonetheless, the load magnitude could have been different as Rio et al. used isokinetic dynamometry to determine the target load while we used a more pragmatic method to achieve a load of 70-75% 1-RM. This method was chosen to make the protocol more clinically applicable. Additionally, two participants did not feel pain during the aggravating activity after inclusion. This made a pain reduction impossible and could have lead to a slight underestimation of analgesic effect. Even though the aggravating activities did not cause pain before exercise on every occasion, the lack of change in PPTs support the conclusion that neither of the exercises had an acute analgesic effect. Load determination was performed on the same day as testing which introduced a slight variation in overall training volume between participants.

PERSPECTIVE

Contrary to what was hypothesised based on previous research in patellar tendinopathy,(11) isometric exercise was no better than isotonic exercise or walking in reducing pain in individuals with plantar fasciopathy. Neither of the exercises or walking had a consistent acute analgesic effect, or change in pain sensitivity. This suggests that findings in one type of tendinopathy may not necessarily be generalisable to others and isometric exercise should not be prescribed for immediate pain relief in individuals with plantar fasciopathy. As previous research of other lower limb tendinopathies has not found superiority of one resistance type over the other,(7,25) isometric exercise could play a role in

the long-term management of PF. However, the long-term effects of different loading programmes in PF remain to be investigated.

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Table 1: Exercise descriptors	**Isotonic heel raise**	**Isometric heel raise**
1. Load magnitude	8 RM	As heavy as possible for 1 minute
2. Number of repetitions	8	1
3. Number of sets	4	5
4. Rest in-between sets	2 minutes	2 minutes
5. Number of exercise interventions	1/day	1/day
6. Duration of the experimental period	1 day	1 day
7. Fractional and temporal distribution of the contraction	3s concentric 2s isometric 3s eccentric	0s concentric 45s isometric 0s eccentric
8. Rest in-between repetitions	No	No
9. Time under tension	8s/repetition 64s/set 256s/total intervention	45s/repetition 45s/set 225s/total intervention
10. Volitional muscular failure	Yes	No
11. Range of motion	65° from 20° dorsi flexion to 45° plantar flexion	Static (0°)
12. Recovery time in-between exercise sessions	≥48 hours	≥48 hours
13. Anatomical definition of the exercise (exercise form)	Participant was standing with the forefoot on a step. The toes were maximally dorsi flexed by placing a towel underneath them. The participant was instructed to perform a heel raise to maximal plantar flexion in the ankle joint and afterwards to lower the heel to maximal dorsi flexion. Supporting oneself for balance by placing the hands on a wall or a rail was allowed. The contraction time was guided by a metronome.	Participant was standing with the forefoot on a step. The participant was instructed to stand still with the ankle joint in neutral and hold this position. Supporting oneself for balance by placing the hands on a wall or a rail was allowed.

TABLE 2: BASELINE PARTICIPANT CHARACTERISTICS

WOMEN %	18 (90%)
AGE years	48.9 (12.3)
HEIGHT cm	169.7 (8.0)
WEIGHT kg	90.1 (14.3)
BMI kg/m^2	31.3 (4.8)
WEEKLY SPORTS PARTICIPATION minutes*	255.0 (90 to 360)
SYMPTOM DURATION months*	8.5 (6 to 19.5)
PAIN DURING PAST WEEK /100 mm	64 (18.2)
BILATERAL PAIN (%)	7 (35%)
PLANTAR FASCIA THICKNESS mm	5.9 (1.1)

DATA ARE PRESENTED AS MEAN (SD) OR COUNT. *INDICATES MEDIAN (INTER-QUARTILE RANGE).

TABLE 3: OUTCOMES MEASURED BEFORE, DURING AND AFTER THE EXERCISES AND COMPARISONS BETWEEN EXERCISES

	Before	During	After	Mean change from before to after
ISOMETRIC				
PAIN	29.0	32.4	31.7	2.7
0-100 mm VAS	(24.1)	(26.1)	(30.7)	(20.4)
PRESSURE PAIN THRESHOLD	384.5	N/A	383.7	-0.9
kPa	(207.2)		(229.7)	(111.6)
PLANTAR FASCIA THICKNESS	5.7	N/A	5.7	-0.1
mm	(1.1)		(1.2)	(0.3)
ISOTONIC				
PAIN	34.0	42.3	30.6	-3.4
0-100 mm VAS	(24.8)	(29.5)	(26.4)	(17.9)
PRESSURE PAIN THRESHOLD	389.2	N/A	388.4	-0.9
kPa	(205.0)		(230.0)	(145.9)
PLANTAR FASCIA THICKNESS	5.9	N/A	5.8	-0.1
mm	(1.1)		(1.1)	(0.3)
WALKING				
PAIN	35.5	33.5	37.1	1.6
0-100 mm VAS	(27.1)	(21.9)	(26.7)	(30.9)
PRESSURE PAIN THRESHOLD	435.6	N/A	413.0	-22.6
kPa	(249.9)		(252.7)	(88.1)
PLANTAR FASCIA THICKNESS	5.9	N/A	5.7	-0.2
mm	(1.3)		(1.2)	(0.4)
EXERCISE COMPARISONS				

MEAN DIFFERENCES (95%CI)

	Change in pain	Pain during exercise	Pressure pain threshold	Plantar fascia thickness
ISOMETRIC VS. ISOTONIC	6.1 (-3.9 to 16.1)	-9.9 (-23.0 to 3.2)	0.0 (-77.1 to 77.0)	0.1 (-0.2 to 0.3)
ISOMETRIC VS. WALKING	1.1 (-14.6 to 16.8)	-1.1 (-15.5 to 13.3)	21.7 (-32.7 to 76.1)	0.1 (-0.1 to 0.4)
ISOTONIC VS. WALKING	-5.0 (-21.7 to 11.7)	8.8 (-3.7 to 21.3)	21.7 (-43.8 to 87.3)	0.1 (-0.1 to 0.2)

DATA ARE PRESENTED AS MEAN (SD) UNLESS OTHERWISE STATED