

Myofascial Release for the Management of Plantar Fasciitis: A Randomized Controlled Trial

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Statement of Original Authorship

The work contained in this thesis has not been previously submitted for a degree or diploma at any other higher education institutions to the best of my knowledge and belief. This thesis is structured based on the regulations and procedures governing the award of the degree of 'Doctor of Osteopathy' by National University of Medical Sciences, Madrid, Spain

Signed: Dr. Ajimsha M S

19/01/2015

(Ajimsha Mohammed Sharafudeen)

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INTRODUCTION

Plantar fasciitis (PF) is the most commonly reported cause of inferior heel pain.¹ It has been estimated that PF affects as much as 10% of the general population over the course of a lifetime.² In fact, some authors have reported that PF accounts for between 8% and 15% of foot complaints in nonathletic and athletic populations.^{3,4} The incidence of PF peaks in people between the ages of 40 to 60 years with no bias towards either sex.⁴ To date, there is evidence that this condition may not be characterized by inflammation but, rather, by noninflammatory degenerative changes in the plantar fascia.⁵ Both surgical and nonsurgical approaches have been proposed for the management of plantar heel pain.⁶ There has been limited evidence for the effectiveness of corticosteroid therapy, conflicting evidence for low-energy extracorporeal shockwave therapy, and no evidence for therapeutic ultrasound or low-intensity laser, in reducing pain in individuals with plantar heel pain.^{7, 8} Stretching of the Gastrocnemii muscle and the plantar fascia have shown moderate evidence of effectiveness in the short term management of plantar heel pain.^{7, 8} Simons et al⁹ have suggested that myofascial restrictions /muscle trigger points (TrPs) in the Gastrocnemii muscles may be involved in the development of plantar heel pain. TrPs are defined as hyperirritable areas associated within a myofascial restriction that are painful on compression, contraction, or stretching of the muscles/fascia, and elicit a referred pain distant to the TrP.⁹ Chen et al in their study have concluded that the stiffness of TrP myofascial restrictions were 50% greater than that of the surrounding muscle tissues.¹⁰ It is probable that the increased stiffness

induced by myofascial restrictions with TrPs may interfere with the extensibility of the muscles or the fascia.

Myofascial release (MFR) is the application of a low load, long duration stretch to the myofascial complex, intended to restore optimal length, decrease pain, and improve function.¹¹

It has been hypothesized that fascial restrictions in one part of the body cause undue tension in other parts of the body due to fascial continuity. This may result in stress on any structures that are enveloped, divided, or supported by fascia.¹² Myofascial practitioners believe that by restoring the length and health of restricted connective tissue, pressure can be relieved on pain sensitive structures such as nerves and blood vessels. MFR generally involves slow, sustained pressure (120 –300s) applied to restricted fascial layers either directly (direct technique MFR) or indirectly (indirect technique MFR). The rationale for these techniques can be traced to various studies that investigated plastic, viscoelastic, and piezoelectric properties of connective tissue.¹²⁻¹⁴ The primary objective of the present study was to evaluate the efficacy of MFR on pain, disability and pressure pain threshold for the management of PF in comparison with a control group receiving Sham Ultra Sound Therapy (SUST), treating fascia of the Gastrocnemii, Soleus and Plantar fascia in accordance with the fascial meridians proposed by Myers.¹⁶

METHODS

This study was carried out in the clinical wing of Myofascial Therapy and Research Foundation, Kerala, India. Patients with a primary complaint of unilateral plantar heel pain were screened for possible inclusion in this study. Inclusion criteria for the study was male and female patients aged 20 - 50 years, with a primary complaint of unilateral plantar heel pain with the following clinical features^{17,18,19}: (1) insidious onset of sharp pain under the

plantar heel surface upon weight bearing after a period of non-weight bearing; (2) plantar heel pain that increases in the morning with the first steps after waking up; and (3) symptoms decreasing with slight levels of activity, such as walking. Clinical history intake of the participants included questions related to the onset of pain and duration of the symptoms, and previous medication and treatments. Patients were excluded if they exhibited any of the following: (1) red flags to manual therapies (ie, tumor, fracture, rheumatoid arthritis, osteoporosis, severe vascular disease, etc), (2) Bilateral plantar heel pain, (3) prior surgery in the lower extremity, (4) diagnosis of fibromyalgia syndrome,⁴² or (5) previous manual therapy interventions for the foot region.

The Research Ethics Committee of the Myofascial Therapy and Research Foundation reviewed the study and raised no objections from an ethical point of view. Between March 2011 and June 2013, 87 patients with a primary complaint of unilateral plantar heel pain were referred to the Myofascial Therapy and Research Foundation. Of these, 66 individuals who met the inclusion criteria and provided written informed consent were randomized to the MFR or to the control arm of the study. Participants were asked to maintain a pain and medication diary in which any medication or change in pain pattern during the treatment period was to be recorded with date and time. Two evaluators blinded to the group to which the participants belonged analyzed scores from the FFI and PPT.

OUTCOME MEASURE

Foot Function Index (FFI)

FFI was developed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction. The FFI is a self-administered index consisting of 23 items that measure pain, disability, and activity restriction. Scoring is based on a visual analog

scale.^{20,21} The Foot Function Index has been reported to be reliable, valid, and sensitive to change in subjects with foot pathologies.^{20,21}

STUDY PROTOCOL

The 2 interventions were provided 3 times weekly for 4 weeks (weeks 1–4), with a minimum of a 1 day gap between the 2 sessions; the duration of each treatment session was 30 minutes. Both groups were treated by clinicians blinded to the group and the outcome of the study. Both the treatments were only applied to the affected side. Outcome measures were captured at Week 1 (pretest score), Week 4 (posttest score), and follow-up at Week 12 after randomization. Patients were unaware of the true objective of the study in that they were aware of the ethical implications without revealing the details of the intervention that was being evaluated. All subjects were informed of the true nature of the study at the end of the study.

MFR technique. We used the following treatment protocol for all the patients in the MFR group.^{15,16} The techniques were administered by Physiotherapists certified in MFR who had been trained in the techniques for at least 100 h and with a median experience of 12 months with the technique.

The protocol was as follows.

MFR for Gastrocnemius

Client's position: Prone, with feet off the end of the table to allow for easy dorsiflexion.

Therapist's position: facing towards head while standing at the foot end of the table for technique number 1 & 3, facing toward the feet while standing at the client's side, at around mid-thigh level for technique number 2. (5mts x 1 repetition). (Fig 1,2 & 3)



Figure 1: MFR of the Gastrocnemii using elbow



Figure 2: Finger placements for release of the Gastrocnemii tendons in the posterior aspect of the knee.



Figure 3: Initial finger placements for the release of the fascia at the Calcaneus.

MFR for Soleus

Client's position: Prone with feet over a bolster to induce 10–15° of knee flexion and put the Gastrocnemii off stretch.

Therapist's position: facing towards the head while standing at the foot end of the table.

(5mts x 1 repetition). (Fig 4)



Figure 4: Soleus Release with 10–15° of knee flexion

MFR for Plantar Myofasciae

Client's position: Prone with feet off the end of the table to allow for easy dorsiflexion.

Therapist's position: Sitting on a stool at the end of the table. (5mts x 2 repetitions) (fig 5)



Figure 5: Release of the plantar myofasciae using a soft fist.

Control intervention. Patients in the control group received sham ultrasound therapy (SUST) over the Gastrocnemii, Soleus and Plantar fascia in the same areas of the application of MFR (in the other group) for 30 minutes per treatment session, three times a week for 4 weeks. SUST units were prepared by removing the ultrasound producing quartz crystal from the treatment transducer head of the ultrasound therapy units without the knowledge of the attending therapist. After the completion of the study, patients in the control arm were provided MFR therapy, as advised by the ethics committee.

STATISTICS

Participants in both groups (MFR group, n=34; control group, n=32) were comparable at baseline, as shown in Table 1. The primary outcome measure was the difference in FFI scale scores between baseline (pretest score), Week 4 (posttest score), and follow-up at Week 12 after randomization. Statistical analysis of the data was done by using a 2x3 (group x time) analysis of variance (ANOVA) and repeated-measures of 2x3 ANOVAs. In accordance with the primary objective of the study, we compared the FFI scores of the MFR and control groups at different time intervals. A $P < .05$ was accepted as statistically significant.

Table 1: Summary of Baseline Characteristics

Characteristics	MFR Group (n=33)	Control Group (n=32)
Men:woman	7:26	10:22
Age (y)	42.4±4.6	40.8±7.1
Duration of condition (mo)	4.0±0.6	4.1±0.5
Body mass index (kg/m ²)	26.3±3.5	27.9±5.0

NOTE. Data are mean ±SD or as otherwise noted

RESULTS

Of the 66 individuals recruited into this study, 65 participants (MFR group, n=33; control group, n=32) completed the study protocol. One participant from the control group dropped out of the study without providing any specific reason and the data was excluded from the results presented below. Within the study period, no serious adverse events occurred in either of the groups as recorded in the patient diary. All the participants (n=65) attained 100% engagement rate to their allotted sessions. Five patients from the MFR group reported an increase of pain in the first week after initiation of treatment, and this was reported to have subsided within a week without any medications.

The patients in the MFR group reported a 72.4 % reduction in their pain and functional disability as shown in the FFI score in Week 4; which persisted as 60.6% in the follow-up at Week 12 compared to the baseline. Patients in the control group reported a 7.4% and 2.0% reduction in their pain and disability in Week 4 and Week 12 respectively (fig 6). The proportion of responders, defined as participants who had at least a 50% reduction in pain and functional disability between Weeks 1 and 4, was 100% in the MFR group and 0% in the control group.

The mean differences between groups vary by time. This indicates the possible existence of their interaction effect. We have examined the effect of group and time on the FFI value by conducting, first, a 2-way ANOVA. The dependent variable, the FFI value, was normally distributed approximately for the groups, formed by the combination of the group and time because the size of the sample is more than 30 for each group. The test's between-subject effects showed that the MFR group significantly performed better than the control group in Weeks 4 and 12 ($P<.001$) (table 4), but there were no differences between the groups at Baseline ($P<.0.533$).

Table 4: FFI Pairwise comparisons of Group and Time

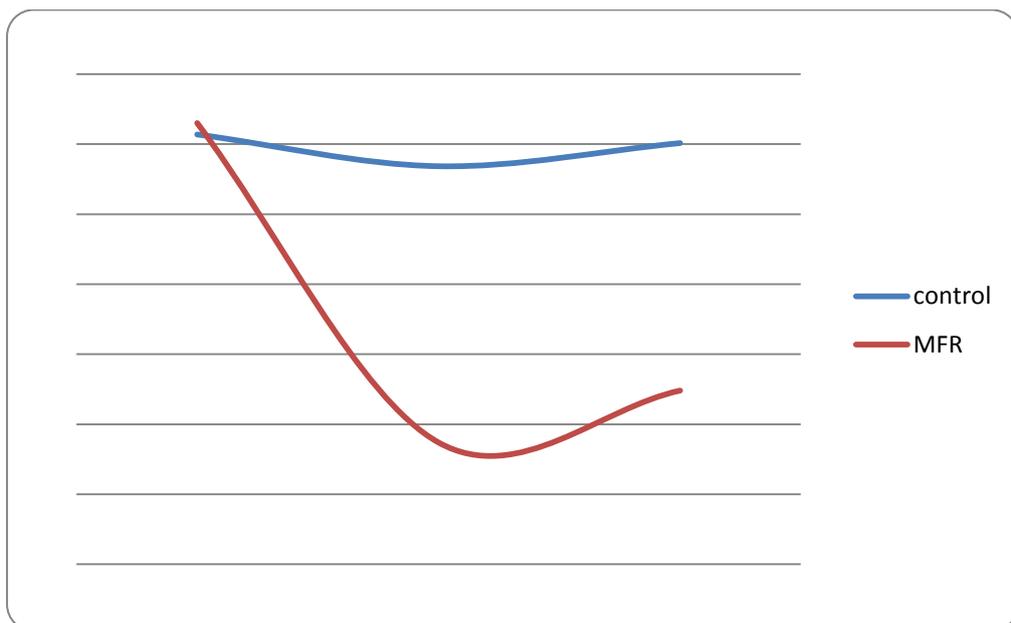
Time	Group I	Group II	Mean Difference (Group I value - Group II value)	SE	P*	95 % Confidence Interval for Difference*
Baseline	Control	MFR	0.895	0.948	0.533	0.621 to 1.321
Week 4	Control	MFR	6.813 [‡]	0.810	0.000	5.160 to 8.465
Week 12	Control	MFR	4.250 [‡]	0.844	0.000	2.529 to 5.971

NOTE: Based on estimated marginal means

*Adjustment for multiple comparisons: least significant difference (equivalent to no adjustment)

[‡]The mean difference is significant at the .05 level

Figure 6: Effects of group and time on FFI value



We observed that the interactions between time and group were significant based on univariate and multivariate methods for all 3 repeated-measures ANOVAs. Significant pairs of MFR and control groups vary at Weeks 4 and 12 due to the interaction effect between group type and time

DISCUSSION

The principal finding of the current study is that the MFR intervention tested in this trial was significantly more effective than SUST over the pain, functional disability and pressure pain threshold of PF.

PF is thought to be caused by noninflammatory degenerative changes in the plantar fascia.⁵ Histological assessments of tissues from patients with chronically painful plantar fascia demonstrate findings more consistent with a failed healing response process, without histopathological evidence of inflammation. The tissue is characterized histologically by infiltration with macrophages, lymphocytes, and plasma cells; tissue destruction; and repair involving immature vascularization and fibrosis.⁵ The normal fascia tissue is replaced by an angiofibroblastic hyperplastic tissue which spreads itself throughout the surrounding tissue creating a self-perpetuating cycle of degeneration.⁵

The exact mechanisms of the efficacy of MFR in the management of plantar heel pain is unclear, but they may be related to a decrease in tension over the plantar fascia or decrease of risk factors, such as tightness of the Gastrocnemii and Soleus muscles and restricted ankle dorsiflexion. A study by Meltzer et al.²⁵ has shown that treatment with MFR after repetitive strain injury resulted in normalization in apoptotic rate, cell morphology changes, and reorientation of fibroblasts. It is possible that treatment with MFR in PF may result in a halt in the degenerative process of the plantar fascia by facilitating the healing process and the fascial architecture to return toward normality. According to Schleip,¹² under normative conditions, fascia and connective tissues tend to move with minimal restrictions. However,

injuries resulting from physical trauma, repetitive strain injury, and inflammation are thought to decrease fascial tissue length and elasticity, resulting in fascial restriction. It is also possible that pain relief due to MFR is secondary to returning the fascial tissue to its normative length by collagen reorganization; this is a hypothesis that merits investigation. It has also been proposed that compressing the sarcomeres by direct pressure, combined with active contraction or stretching of the involved muscle, may equalize the length of the sarcomeres and consequently decrease the pain²⁶; however, this theory has not been scientifically investigated.²⁷ As with any massotherapy techniques, the analgesics effect of MFR can also be attributable to the stimulation of afferent pathways and the excitation of afferent A delta fibers, which can cause segmental pain modulation²⁸ as well as modulation through the activation of descending pain inhibiting systems.^{29, 30} However, the follow-up at Week 12 has shown that the treatment effects were less evident compared with Week 4 after the treatment. This may be explained because, at the 12-week follow-up, the treatment effect obtained may be disguised by the continuation of the daily activities with the same causative factors or by the natural course of the disease.

STUDY LIMITATIONS

One limitation of this trial was that we only conducted a short-term follow up. We do not know if these effects would be maintained for longer periods. In this study it was impossible to interpret whether MFR to the Gastrocnemii, Soleus or the Plantar fascia brought the improvement. Future comparative analyses are advocated to find an answer to it. A slight improvement over time occurred in the control group at Week 4; this could be due to a “meaning response”.³² It will be of interest if further studies can be conducted to compare the effectiveness MFR with established treatments like arch supports, self stretching or even with surgical procedures.

CONCLUSIONS

The MFR investigated in this trial was more effective than a control intervention with SUST for the treatment of PF. MFR can be a simple and cost effective addition to the non surgical management of PF. A significant proportion of individuals with PF might benefit from the use of MFR. The mechanisms underlying these responses merit further investigation.

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ABSTRACT

Background: Previous studies have reported that stretching of the calf musculature and the plantar fascia are effective management strategies for plantar fasciitis (PF). However, it is unclear whether Myofascial Release (MFR) can improve the outcomes in this population.

Objective: To investigate whether Myofascial release (MFR) reduces the pain and functional disability associated with plantar fasciitis (PF) in comparison with a control group receiving Sham Ultrasound Therapy (SUST). **Design:** Randomized, controlled, double blinded trial.

Setting: Nonprofit research foundation clinic in India. **Method:** Sixty-six patients, 17 men and 49 women with a clinical diagnosis of PHP were randomly assigned into MFR or a control group and given 12 sessions of treatment per client over 4 weeks. The Foot Function Index (FFI) scale was used to assess pain severity and functional disability. The primary outcome measure was the difference in FFI scale scores between week 1 (pretest score), week 4 (posttest score), and follow-up at week 12 after randomization. **Results:** The simple main effects analysis showed that the MFR group performed better than the control group in weeks 4 and 12 ($P < 0.001$). Patients in the MFR and control groups reported a 72.4% and 7.4% reduction, respectively, in their pain and functional disability in week 4 compared with that in week 1, which persisted as 60.6% in the follow-up at week 12 in the MFR group compared to the baseline.

Conclusions: This study provides evidence that MFR is more effective than a control intervention for PF.

Key Words: Plantar heel pain, Myofascial restrictions, Myofascial release.

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