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Radial shock wave treatment alone is less efficient than radial shock wave treatment combined with tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain

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HIGHLIGHTS

- ESWT for chronic heel pain is an effective and evidence-based treatment modality.
- Stretching specific to the plantar fascia is highly effective as well.
- Combining ESWT and stretching lead to better results than ESWT alone.

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ABSTRACT

Background: Whether shock wave therapy or shock wave therapy combined with plantar fascia-specific stretching is more efficient in treating chronic plantar heel pain remains unclear. The aim of the study was to test the null hypothesis of no difference of these two forms of management for patients who had unilateral plantar fasciopathy for a minimum duration of twelve months and which had failed at least three other forms of treatment.

Methods: One hundred and fifty-two patients with chronic plantar fasciopathy were assigned to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for three weeks (Group 1, n = 73) or to receive the identical shock wave treatment and to perform an eight-week plantar fascia-specific stretching program (Group 2, n = 79). All patients completed the nine-item pain subscale of the validated Foot Function Index and a subject-relevant outcome questionnaire. Patients were evaluated at baseline, and at two, four, and twenty-four months after baseline. The primary outcome measures were a mean change in the Foot Function Index sum score at two months after baseline, a mean change in item 2 (pain during the first steps of walking in the morning) on this Index, and satisfaction with treatment.

Results: No difference in mean age, sex, weight or duration of symptoms was found between the groups at baseline. At two months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with shock-wave therapy plus plantar fascia-specific stretching than those managed with shock-wave therapy alone ($p < 0.001$), as well as individually for item 2 ($p < 0.001$). Twenty-four patients in Group 1 (32%) versus forty-seven patients in Group 2 (59%) were satisfied with the treatment ($p < 0.001$). Significant differences persisted at four months, but not at twenty-four months.

Conclusions: A program of manual stretching exercises specific to the plantar fascia in combination with repetitive low-energy radial shock-wave therapy is more efficient than repetitive low-energy radial shock-wave therapy alone for the treatment of chronic symptoms of proximal plantar fasciopathy.

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1. Introduction

Plantar heel pain, commonly referred to as insertional plantar fasciitis, is a common condition among orthopedic patients [1]. The characteristic complaints are knife-like pain at the calcaneal insertion of the medial part of the plantar fascia, typically worse on first arising in the morning, and often lasting months to years [2]. Typically, diagnosis can be made based on a detailed history and physical examination that allow the clinician to pinpoint the location of maximal tenderness. Weight-bearing plain radiographs should be obtained to assess alignment and degenerative changes and to exclude fracture and other skeletal abnormalities. Advanced imaging studies and electromyography (EMG) can be used to confirm or rule out certain diagnoses and to provide additional information when the diagnosis is uncertain [1].

Recommended treatment regimens consist of one or more nonsurgical modalities, including rest, shoe wear modification, NSAIDs, home stretching exercises, physical therapy, prefabricated shoe inserts, and custom orthoses [1,3]. Such measures are effective in most patients, especially when both the patient and physician allow adequate time for them to work.

Corticoid injection around the insertion of the plantar fascia show only short-term benefit and may be associated with severe side effects as rupture of the plantar fascia, and infection [4–7].

With surgery considered only for carefully selected patients with recalcitrant pain whose symptoms have persisted despite an appropriate course of nonsurgical measures, a new treatment modality came into focus, extracorporeal shock wave therapy (ESWT) [8–10].

There is still uncertainty around the use of ESWT and its clinical effectiveness remains controversial. Moreover, use of this modality is often limited by its low insurance coverage and resultant high patient cost. In a recent survey among U.S. foot and ankle surgeons, the number of physicians who chose ESWT as their preferred intervention for long-standing plantar fasciitis (10 months) increased from 33% to 42% in the absence of patient cost or insurance considerations [11].

Two recent meta-analyses [12,13] described ESWT as a safe and effective treatment of chronic plantar fasciitis refractory to non-operative treatments. And stretching specific to the plantar fascia has recently been shown to provide superior pain relief when compared with Achilles tendon stretching at 8 weeks; however, no significant difference was seen at 2-year follow-up [14,15].

So far, to the best of our knowledge, there was no controlled testing of the usefulness of combining both modalities in chronic plantar fasciitis. The aim of the study was to test the null hypothesis of no difference of these two forms of management for patients who had unilateral plantar fasciopathy for a minimum duration of twelve months and which had failed at least three other forms of treatment.

2. Materials and methods

The study was designed as a randomized, parallel treatment study with a blinded independent observer to evaluate the effectiveness of repetitive low-energy radial shock wave therapy without local anesthesia, administered weekly for three weeks or this exact shock wave treatment in combination with an eight-week plantar fascia-specific stretching program.

2.1. Inclusion criteria

Patients had to report start-up pain, that is, plantar medial heel pain that culminates either with their first steps in the morning or subsequent to prolonged periods of rest for at least twelve months. Physical examination revealed tenderness at the site of the plantar fascial insertion on the medial calcaneal tuberosity. Tenderness extended along the plantar fascia, and it increased with maneuvers that stretch the plantar fascia, including passive toe dorsiflexion [1,2]. All patients were referred for orthopedic diagnosis and treatment. All of the patients enrolled had at least three of the previous non-operative treatments: nonsteroidal anti-inflammatory medications, orthoses, heel cups, calf stretching exercises, massages, night splints, injections, and/or activity modifications. None had undergone surgery of the plantar fascia.

2.2. Exclusion criteria

Patients were excluded if they were <18 years of age; if they had bilateral plantar fasciitis; if there was a history and/or physical findings of lower-extremity dysfunction, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, or local arthrosis; if there were signs of neurologic abnormality (changes of deep tendon reflexes, or motor or sensory deficit); if there was arthrosis of the foot or ankle, as confirmed by radiographic diagnosis (anteroposterior and lateral views); if it patients participated in a Workers' Compensation program or planned to apply for the program; if there was thrombopathy, infection, tumor, diabetes mellitus, systemic lupus erythematosus, severe cardiac disease, or other severe systemic diseases; if patients were pregnant; if there was restricted ankle dorsiflexion due to contracture of the Achilles tendon or the gastrocnemius muscle itself: the Silfverskjöld test was performed to differentiate between primary contracture of the gastrocnemius muscle itself and of the gastrocnemius–soleus complex [16]; if they had prior heel surgery; if heel pain was not consistent with proximal plantar fasciitis; if patients were unwilling to accept either of the interventions in this study.

2.3. Enrollment

The prospective, randomized controlled study was conducted in a single center. The study design and the information documents were approved by the Internal Study Board of the author's institution, and the study is registered at Current Controlled Trials (http://www.controlled-trials.com/ISRCTN11644582). Patients received oral and written information about the two treatments and gave informed consent to participate in the study.

Patients were informed that they were free to leave the study, without explanation and without any negative consequences on their future treatment. Every precaution was taken to protect the privacy of research subjects and the confidentiality of their personal information. All personal patient details were rendered anonymous before data entry, by referring to all patient records and data only by their assigned research number. There are no known additional risks associated with patient participation in the study, other than the normal risks associated with these common treatments.

Recruitment strategies included: informational brochures at the office, information articles about our study in publications, and informational lectures given at community centers of the Rhein-Main area.

Following the suggestions from DiGiovanni et al. [14], the patients initially completed a self-administered questionnaire that provided background information and a history profile of the heel pain. The background information included age, sex, height, weight, hours spent standing during the day, duration of symptoms, and types of prior treatments.

One hundred and ninety-five patients were checked for selection criteria; six patients did not meet the inclusion criteria and thirty-three refused consent (Fig. 1). Thus, a total of one-hundred

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