

Cleland JA, Abbott JH, et al. Manual physical therapy and exercise versus electrophysical agents and exercise in the management of plantar heel pain: a multicenter randomized clinical trial. J Orthop Sports Phys Ther. 2009;39(8):573-85.

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of two programs to treat plantar heel pain: manual physical therapy plus exercise versus a combination of electrophysical agents plus exercise

Population/sample size/setting:

- 60 patients (42 women, 18 men, mean age 48) treated for plantar heel pain in a multicenter international trial in the US and New Zealand
- Eligibility criteria were age 18-60, a primary report of plantar heel pain, and a Lower Extremity Functional Scale (LEFS) score ≤ 65
- Exclusion criteria were red flags to manual therapy (tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use), prior surgery to the distal tibia, fibula, ankle joint, or rearfoot region proximal to the base of the metatarsals, and inability to comply with the treatment and followup schedules

Interventions:

- Both groups were treated twice weekly for two weeks followed once weekly for two weeks, for a total of 6 sessions over 4 weeks
- Randomization was to either manual physical therapy plus exercise (MTEX, n=30) or electrophysical agents plus exercise (EPAX)
- MTEX group received 5 minutes of aggressive soft tissue mobilization followed by a set of manual therapy treatments tailored to the restrictions observed in the individual patient (talocrural joint manipulation if the patient had restricted ankle dorsiflexion, hip mobilization if restricted hip joint rotation was observed, etc)
 - o In addition, all patients in the MTEX group were instructed to perform ankle eversion self-mobilization exercise and manual mobilization of the plantar fascia at home, as well as to perform gastrocnemius and soleus stretching exercises
- EPAX group received therapeutic ultrasound (3 MHz, 1.5 W/cm² for 5 minutes) followed by iontophoresis with dexamethasone delivered with a dose of 40 milliampere-minutes), followed by ice over the medial calcaneal tubercle for 15 minutes
 - o All patients were instructed in the same soleus and gastrocnemius stretches as the MTEX group, plus strengthening exercises for the intrinsic muscles of the foot

Outcomes:

- The primary outcome was the patient's perceived level of disability due to heel pain, as measured by the Lower Extremity Functional Scale (LEFS) at 6 months followup
 - o The LEFS is a 20-item questionnaire in which each question has a score of 0 for extreme difficulty or inability to perform an activity and a score of 4 for no difficulty
 - o The items include usual work, housework, recreation, walking, putting on shoes and socks, lifting items, going up or down stairs, standing for an hour, getting into or out of a car, running, hopping, and making sharp turns while running
 - o The lowest possible score for LEFS is 0 and the highest is 80, and the scale has a minimal clinically important difference (MCID) of 9 points
 - Patients whose scores at baseline were already fairly high (65 points or greater) were excluded from the study to avoid a ceiling effect, in which an improvement in function cannot be detected because the patient is close to the maximal score at baseline
- The MTEX group had greater improvements than the EPAX group for the primary endpoint of the LEFS score at 6 months
 - o The average MTEX baseline for LEFS was 47.8 points, and the EPAX average baseline score was 51.1
 - o At the end of 6 months, the MTEX group had improved by 22.8 points and the EPAX group had improved by 12.9 points
 - o The difference between MTEX and EPAX was 9.9 points, which exceeded the MCID of 9 points for the main outcome
 - o The difference at 4 weeks (not the primary outcome) was 13.5 points in favor of MTEX over EPAX
- A few secondary analyses were done in addition to the primary outcome, and these favored MTEX over EPAX

Authors' conclusions:

- At 4 weeks and 6 months, both MTEX and EPAX patients has improved over their baseline scores on the LEFS, but the MTEX group had significantly greater benefit than the EPAX group
 - o This may be in part due to the likelihood that plantar fasciitis is not an inflammatory process, hence dexamethasone delivered by iontophoresis is not relevant to the underlying pathophysiology
- Because the MTEX group had its interventions tailored to the individual patient restrictions of movement, it is not possible to specify which specific manual therapy and exercise techniques would be most advantageous for patients with plantar heel pain

- One caution in interpreting the study results is that compliance with the home exercise program could influence the results
- Because no comparison was made with treatments such as night splints or orthoses, no information is available to compare MTEX with these interventions

Comments:

- There are two important aspects in which the interventions differed between MTEX and EPAX
 - o One difference is that between ultrasound and iontophoresis plus ice versus manual therapy during the treatment sessions
 - o The other difference is that between a standardized treatment (specified doses of ultrasound and iontophoresis current) and a treatment tailored to the joint restrictions of the individual patient
 - o This does not necessarily cast doubt on the study results, but it does provide a clear illustration of the principles of conducting what is termed a pragmatic trial, in which an intervention is designed to resemble as closely as possible what is likely to be implemented in daily clinical practice
- The comparison intervention of EPAX represents only one particular implementation of EPAX, namely ultrasound and dexamethasone plus ice, and other implementations of electrophysical interventions were not tested

Assessment: adequate for some evidence that in patients with plantar fasciitis, six sessions of individually tailored manual therapy plus exercise is more effective than six sessions of a standardized program of ultrasound and dexamethasone iontophoresis plus ice in improving foot function six months later