Rompe JD, Cacchio A, et al. Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. JBJS Am. 2010;92(15):2514-22.

Design: randomized clinical trial

Study question: In the setting of plantar fasciopathy of recent onset, are there differences in outcome between plantar fascia stretching exercises and the use of radial shock-wave therapy?

Population/sample size/setting:

- 102 patients (66 women, 36 men, mean age 51) treated for plantar heel pain attributed to the plantar fascia at an orthopedic facility in Mainz, Germany
- Inclusion criteria were history of plantar fasciitis for less than 6 weeks with a Numeric Rating Scale (NRS) pain score of at least 6 points during the first few steps in the morning, localized pain on palpation of the proximal plantar fascia, and willingness to abstain from any other treatments during the treatment and followup period
- Exclusion criteria were age under 18, receiving local plantar injections prior to the randomization visit, receiving physical therapy, NSAIDS, or self-treatment with stretching prior to the randomization visit, bilateral plantar fasciitis, history of or clinical suspicion of severe systemic diseases including connective tissue diseases, previous foot surgery, neurologic findings such as sensory/motor deficit or changes in reflexes, and participation in a Workers Compensation program

Interventions:

- Patients were randomized to plantar fascia-specific stretching (n=52) or to radial extracorporeal shock wave therapy (ESWT, n=48)
    - Stretching program involved performing stretching exercises 3 times per day for 8 weeks
        - Exercises were to be done sitting with the involved leg crossed over the other leg; the patient placed the fingers across the base of the toes and pull back so that the foot came closer to the shin
        - Each stretch was held to a count of ten and repeated ten times at each of the three daily sessions
    - ESWT was administered in three sessions scheduled a week apart
        - The energy flux density was 2000 pulses of 0.16 mJ/mm^2 for a total of 320 mJ/mm^2
        - The treatment was done without local anesthesia, starting at the point of maximal pain and proceeding in a circumferential manner

Outcomes:

- Followup was scheduled at 2 months, 4 months, and 15 months after baseline
- Main outcomes were the pain subscale of the Foot Function Index (PS-FFI) and a patient-relevant outcome measure (SROM) questionnaire which included generic items related to pain function, and satisfaction with treatment
    - Pain subscale of PS-FFI has 7 questions on dimensions of pain: pain at its worst, during the first few steps in the morning, at the end of the day, while walking barefoot, while standing barefoot, while walking with shoes, and when standing with shoes
        - The second question, which deals with pain on the first few steps in the morning, had special emphasis as a marker of improvement
    - SROM asks the patient to compare how they feel at present to how they felt before treatment overall, with respect to heel pain, with respect to daily function including work and recreation, and how satisfied they are with treatment
        - The patient satisfaction item was designated as a primary efficacy outcome for purposes of the treatment comparisons
- The primary outcome was the change in PS-FFI at two months; secondary outcomes were the changes at 4 months and at 15 months
- Both groups reported reduced pain at 2 months, but the pain reduction for the plantar stretch group was greater than for the ESWT
    - Pain during the first few steps in the morning at baseline was 7.8 for the stretch group and was 7.9 for the ESWT group; the pain reduction at 2 months was 4.5 for the stretch group and 1.8 points for the ESTW group
- At 2 months, the satisfaction item on the SROM was greater for the stretch group (65%) than in the ESWT group (35%)
- Fifteen months after baseline, the pain and satisfaction scores did not differ between groups
- During the first two months after baseline, more patients (n=38) in the ESWT group took analgesic medication such as diclofenac or ibuprofen than in the stretch group (n=15)
- For all patients in the ESWT group, transient reddening took place after the shock wave was administered, and 41 patients reported treatment-related pain of 5 or more points on a 10 point scale; for the stretch group, only 8 patients reported treatment related pain of 5 or more points

Authors' conclusions:

- A program of manual stretching exercises specific to the plantar fascia is more effective than radial shock wave therapy in reducing pain from plantar fasciitis of recent onset

- These results cannot be generalized because patients with a maximum symptom duration of 6 weeks are relatively rare in orthopedic outpatient clinics

Comments:

- Most sources of bias appear to have been controlled
    - Even though blinding of patients could not be done, the likely direction of the resulting bias would depend on the details of how the interventions were described and administered
    - That is, if patients randomized to stretching were encouraged to expect that this would be more effective than ESWT, the results would be biased in favor of stretching, but if patients randomized to ESWT were led to believe that ESWT was more effective than stretching, the results would be biased in favor of ESWT
- It is likely that in real-world clinical practice, patients given ESWT would be given a home program that would include stretching, and therefore the comparisons in this trial are not directly applicable to everyday practice
    - The question of whether ESWT adds benefit to a treatment plan based on stretching exercise therefore is not asked and cannot be answered
- Allocation concealment was probably done, because the assistant in charge of the randomization was not aware of the size of the blocks; although not crystal clear, the requirement for allocation concealment is likely to have been met
    - The randomization was done in blocks of six, and this means that there were 17 blocks for the 102 patients randomized
    - Block randomization of this kind should balance the treatment groups such that one group does not exceed another group by more than three patients; however, there were 6 more patients in the stretching than in the ESWT group
    - While this is not explained, it is unlikely to lead to a biased answer to the study question
- Workers' Compensation participants were excluded; it is a matter of judgment whether this exclusion limits its application to a population of injured workers
- At 15 months, symptom resolution had occurred in 70.4% of the stretching group and in 77.1% of the ESWT group, meaning that 25-30% of patients remain symptomatic at that time
- The discussion section seems to designate the dose of ESWT as "low-energy shock wave therapy"
    - The energy flux density was 0.16 mJ/mm^2
    - A recent study (Chow 2007) defined low energy density as less than 0.1 mJ/mm^2, and medium energy density as higher than 0.1 mJ/mm^2 but lower than 0.2 mJ/mm^2. Any ESWT delivered at higher than 0.2 mJ/mm^2 is regarded as high energy density

    - By these criteria, the dose in this study would be considered medium density
    - There may be no uniform standard for defining dose densities
- Since pain on walking in the morning is the signature symptom of plantar fasciitis, this is probably a logical choice for a primary outcome
- The overall risk of bias is probably low

Assessment: High quality study for good evidence that in the setting of plantar fasciitis of recent onset, a program of home stretching exercises directed at the plantar fascia is more effective in reducing pain than radial shock wave therapy

Reference:

Chow I, Cheing G: Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain. Clin Rehabil 2007;21:131-41