Radwan YA, Mansour AM, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. Int Orthop. 2012 ;36(10):2147-56.

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of extracorporeal shock wave (ESWT) with endoscopic plantar fascia release (EPFR) for the treatment of recalcitrant heel pain

Population/sample size/setting:

- 65 patients (40 men, 25 women, mean age 39) treated for plantar fasciopathy at an orthopedic surgery department at Cairo University in Giza, Egypt
- Inclusion criteria were pain after the first five minutes of walking in the morning that was more than 40 mm on a 100 mm VAS pain scale, the failure of at least three lines of conservative therapy during the past six months, including NSAIDS, steroid injections, physical therapy with an exercise program (Achilles tendon and plantar fascia stretching exercises), and orthotic devices (heel cup, shoe insert, night splint, or cast)
- Exclusion criteria were age under 18, local infection, systemic medical conditions such as diabetes and arthritis, recent trauma of the foot or ankle, foot/ankle deformities, steroid injection in the past six weeks, pregnancy, and contralateral heel pain of 40 or more mm on the 100 mm VAS

Interventions:

- Patients were randomized to tither ESWT (n=34) or to EPFR (n=31)
- ESWT was done under conscious sedation anesthesia with a device which focused the treatment wave into the plantar fascia for a total of 1500 shocks applied at a rate of 4 shocks/second at 0.22 mJ/mm^2 for a total of 324 J
- EPFR was done under general or spinal anesthesia with the patient in a supine position, exposing the plantar fascia and dividing it with a standard #11 scalpel blade into two leaflets, debriding the posterior leaflet with a motorized incisor blade, irrigating the region, and closing the wound
    - Early ankle and foot mobilization with toe touch weight-bearing was done in the first week, progressing to full weight bearing after 2 to 4 weeks, depending on tolerance

Outcomes:

- Morning pain was measured at baseline, 3 weeks, 12 weeks, and 12 months after the intervention was done

- American Orthopedic Foot and Ankle-Hindfoot Scale (AOFAS) baseline, 3 weeks, 12 weeks, and 12 months, which allocates 40 points for pain, 50 points for function, and 10 points for alignment assessment
    - AOFAS was dichotomized so that a 50% improvement was a measure of success at 12 weeks and an 80% improvement was a measure of success at 12 months
- Patient subjective assessment based on the four-point Roles and Maudsley scale:
    - Excellent: no pain, full movement, full activity
    - Good: occasional discomfort, full movement, full activity
    - Acceptable: some discomfort after prolonged activity
    - Poor: pain-limiting activity
    - "Success" was defined as excellent or good; acceptable and poor were defined as failure
- AOFAS success was equal in ESWT and EPFR groups at 12 weeks and 12 months
    - At 12 weeks, AOFAS success (at least 50% improvement) was reported in 25/34 ESWT and in 21/31 EPFR patients
    - At 12 months, AOFAS success (at least 80% improvement) was reported in 22/34 ESWT and in 18/31 EPFR patients
- Success by the Roles/Maudsley criteria was also comparable between the treatment groups at 3 weeks, 12 weeks, and 12 months; at the 12 month followup, success was reported in 24/34 ESWT patients and in 24/31 ESWT patients
- A telephone followup was done at 2 years post-intervention, when 13/26 (50%) ESWT patients who were contacted reported that they felt they had had a successful outcome, compared to 20/25 (80%) of EPFR patients, and the numbers remained similar at a 3 year telephone followup
    - Although the p values for the 2 and 3 year followup comparisons were 0.026 and 0.021, they were not statistically significant because the Bonferroni adjusted p value for multiple comparisons required a p value of 0.01 for statistical significance to be declared

Authors' conclusions:

- In patients with a failure of conventional treatment for plantar fasciotomy, high dose shock wave treatment is comparable to plantar fascia release at 3 months and at one year; later comparisons appear to be more favorable for fascia release than for shock wave, but not in a statistically significant way
- Shock wave may represent a cost-effective alternative to surgery and reduce the need for fascia release

Comments:

- Methodological criteria such as randomization and allocation concealment, as well as adequate followup, are satisfactorily met
- A study protocol is not available, and it is not clear whether the analyses which were done in the group comparisons were preplanned or were done after the data were available, since a primary outcome is not declared
    - For example, the AOFAS criterion for success at 12 weeks was a 50% improvement and at 12 months was an 80% improvement; the reasons for the change in definition is not clear
    - Similarly, the method of adjustment for multiple comparisons, which rendered the later advantage of surgery statistically non-significant, was the Bonferroni adjustment, which is one of the most conservative (making it more difficult to have a statistically significant result) methods of adjusting for multiple comparisons; other methods are available which could have changed the adjusted p value requirement from 0.01 to some higher value
    - Although there is some uncertainty about the way that the data were analyzed, a clinically large difference in effectiveness of surgery over shock wave treatment is not likely in this population
- The ESWT group was treated under conscious sedation because of the high dose of energy, which could present some practical considerations if its use is being contemplated

Assessment: adequate for some evidence that high dose shock wave produces successful outcomes similar to those for endoscopic plantar fascia release in patients with persistent plantar fasciopathy which has not responded to more conservative treatment