Rompe JD, Furia J, Maffulli N. Eccentric Loading Compared with Shock Wave Treatment for Chronic Insertional Achilles Tendinopathy A Randomized, Controlled Trial. JBJS Am 2008;90:52-61.

Design: Randomized clinical trial

Purpose of study: to compare the effectiveness of an eccentric loading exercise program with that of extracorporeal shock wave therapy (ESWT) for patients with insertional Achilles tendinopathy

Population/sample size/setting:
- 50 patients (30 women, 20 men, mean age 40) treated for insertional Achilles tendinopathy at an orthopedic trauma clinic in Germany
- Eligibility criteria defined Achilles tendinopathy as localized pain over the distal part of the Achilles tendon at its insertion onto the calcaneus, with local tenderness and a reduced level of activity
  - A sonogram was required in order to rule out midportion tendinopathy, identified by thickening of the tendon and/or a hypoechoic area in the midportion of the tendon; the sonogram also excluded patients with retrocalcaneal fluid as a sign of bursitis
  - A plain x-ray film was also used to exclude patients with tendon calcification or a Haglund deformity (a bony enlargement on the back of the heel)
  - The condition had to be present for at least six months with failure of nonoperative management, which included at least one injection with anesthetic or steroid, NSAIDS, physiotherapy and/or an orthotic device
- Exclusion criteria were a peritendinous injection in the past four weeks and other conditions which sound contribute to posterior ankle pain such as midportion tendinopathy, ankle arthritis, prior surgery of the ankle, a prior Achilles tendon rupture, or a dislocation or fracture in the area in the past 12 months

Interventions:
- Randomization was to eccentric loading exercise (n=25) or to ESWT (n=25)
- The eccentric loading exercise group was instructed by the senior author on a sequence of exercises in which the affected foot was placed on a step and the foot was slowly dorsiflexed by lowering the limb until the heel was well below the level of the step in maximum dorsiflexion
  - No concentric loading was performed, as the patients were to use the unaffected limb to return to the start position
  - Three sets of 15 repetitions were to be done twice daily for 12 weeks, and the patients were told to progress by use of a backpack with 5 kg of books in order to add to the load on the foot
- ESWT was done by the senior author using an energy flux density of 0.12 mJ/mm², three times spaced one week apart, without local anesthetic

Outcomes:

- Followup was done 16 weeks after baseline (4 weeks after the completion of eccentric loading exercise and 12 weeks after the completion of ESWT); an additional followup was done 15 months from baseline
- Outcomes were the VISA-A (Victorian Institute of Sport Assessment-Achilles) score, a general assessment (success defined as patient report of complete recovery or much improved), pain assessment on a 10 point self-reported VAS, and pain threshold using an algometer by a blinded examiner
- Four months after baseline, the ESWT group fared better than the eccentric loading group on all measured outcomes
  - On VISA-A, the baseline scores for ESWT and for eccentric loading were 53.2 and 52.7 respectively; the followup scores were 79.4 and 63.4 respectively
  - 64% of the ESWT patients reported complete recovery or much improvement; 28% of the eccentric loading group reported the same successes
  - The VAS had improved for both groups form their baseline scores, but the mean VAS for ESWT was 3.0 and for the eccentric loading was 5.0
  - Pain thresholds were similar at baseline, but at followup the mean threshold for ESWT was higher (3.5 kg) than for the eccentric loading group (2.2 kg)
- At the 15 month followup, all 18 patients in the eccentric loading group who had a poor outcome chose to cross over to ESWT, and 8 of the 9 patients in the ESWT group with a poor outcome chose to cross over to eccentric loading
- No complications of treatment were reported
  - The ESWT patients had transient reddening of the skin, but no bruising
  - The eccentric loading patients often reported aching of the calf after exercises were performed
  - No patient had a rupture of the tendon during followup

Authors’ conclusions:

- In this patient population, the group which received ESWT had greater success of treatment than the group randomized to eccentric loading
- The fact that the study was unblinded could be a source of bias, and given the small sample size and lack of blinding, the study could be categorized as “hypothesis-generating” rather than hypothesis confirming
- ESWT should be considered as an alternative to surgery in patients with insertional Achilles tendinopathy
Comments:

- The patients randomized to eccentric loading were not asked to complete exercise logs or otherwise to keep track of adherence to the treatment program
  - However, if there are problems with adherence to a daily exercise program, or if there are factors such as calf aching associated with the program, those factors would be relevant to its likelihood of success in daily practice, and the lack of a compliance log would not necessarily bias the results
  - The degree to which lack of blinding is a source of bias versus being a source of information is uncertain; if the exercises hurt, that would constitute relevant information regarding its likelihood of success

- The study excluded patients with calcification of the tendon, which is probably more common with insertional than with midportion tendinopathy
  - This also is not a likely source of bias in the study, if the exclusions would tend to remove patients not likely to benefit from exercise

- Although further research could easily change the estimate of the difference between ESWT and eccentric loading exercise, the study does qualify for a statement of “some evidence” of better outcomes with the former than with the latter

- The dose of ESWT with a flux density of 0.12 mJ/mm² is considered a low to moderate dose in studies of its use in plantar fasciitis, and may explain why no local anesthetic was required

Assessment: adequate for some evidence that in patients with insertional Achilles tendinopathy who have no calcification of the tendon at the calcaneus and have not improved with six months of conservative treatment, three sessions of a moderate dose (flux density of 0.12 mJ/mm²) is likely to be more successful than a 12 week program of eccentric loading exercise