Spacca G, Necozione S, Cacchio A. Radial shock waver therapy [RSWT] for lateral epicondylitis: a prospective randomised controlled single-blind study. Eur Med Phys 2005;41:17-25.

Design: Randomized clinical trial

Population/sample size/setting:

- 62 patients (32 men, 30 women, mean age 47) treated for lateral epicondylitis in a university PM&R department in Italy
- Inclusion criteria were clinical diagnosis of lateral epicondylitis confirmed by imaging (ultrasound or MRI) for at least 10 months, pain on VAS of 3 or more, failed previous conservative treatments (NSAID, steroid injection, PT, functional elbow brace, exercise)
- Exclusion criteria were pregnancy, implanted pacemaker, coagulation abnormalities, shoulder/neck pathology, or steroid injection in previous 4 weeks

Main outcome measures:

- Both groups received 3 weekly sessions of RSWT with the same pressure and frequency, but the experimental group received 2000 impulses per session and the control group received 20 impulses per session
- RSWT is similar to ESWT, but with RSWT the shock wave is produced pneumatically through acceleration of a projectile inside the handpiece, while with ESWT the wave is produced electromagnetically
- Outcomes were measured at baseline, at the end of the last treatment session, and at 6 months follow-up
- Primary end points were pain VAS at rest, with palpation, and with wrist extension
- Secondary end points were DASH questionnaire, pain-free grip strength, and subjective satisfaction with treatment
- For the primary end points, the effect of RSWT was large; while both groups began the study with median VAS of 4.5 for pain at rest, the median VAS for the 2000 impulse RSWT was 0.5 at 3 weeks and at 6 months; for the 20 impulse RSWT the VAS at 3 weeks and 6 months were 5 and 6.5
- For the DASH, similar large effects were seen; baseline and follow-up scores for the 2000 impulse group were 38.5, 13, and 10; for the control group, the scores were 38, 36, and 34.5
- The effect of RSWT on grip strength was more modest; the median scores at baseline and follow-up for the 2000 impulse group were 38, 50, and 46; for the control groups, the scores were 37, 38, and 36
- At the 6 month follow-up, 26 of 31 patients who received 2000 impulses were satisfied, and only 1 of the 31 control patients was satisfied

Authors' conclusions:

- RSWT can effectively reduce pain and increase grip strength and elbow function without device-related adverse effects, and can be done without anesthesia
- The effects of RSWT are maintained over a period of 6 months

Comments:

- Sources of bias are not readily apparent for the large effect size reported
- The randomization was stated to be computer-generated, but this may or may not have meant that concealment of allocation was done
- The study was "single-blinded," which apparently means that the patients were blinded through the use of similar treatment applications
- The measurement of grip strength was not blinded, but this variable, unlike the patient-reported outcomes, was moderate in size; therefore, the measurement most susceptible to observer bias is the smallest measured effect
- The pain, DASH, and satisfaction measures would be difficult to relate to bias unless the patients were unblinded in some manner not obvious from the methodology
- The same group of investigators reported on RSWT for calcific tendonitis of the shoulder (Cacchio et al, Phys Ther 2006;678-682), and also reported a very large effect size without obvious sources of bias
- Follow-up was complete, and both pain and functional outcomes were measured with validated instruments
- The availability of the device in the US is not clear; the first Google hit for "radial shock wave" refers the user to clinics in Eastern Europe (Czech Republic and Poland)

Assessment: Adequate; may support a statement that RSWT has some evidence of functional and symptomatic benefit for lateral epicondylitis. Some caveat to the effect that study results await replication may be in order.