

Plantar fasciitis

Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial

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Technological change in general orthopaedics and its multiple specialisations is continual. These changes are regulated, to varying degrees, by delegated authorities within appropriately mandated concepts. One relatively recent technology, since approximately 1990, has been the revision of treating relatively deep seated urolithiasis, whether in the renal parenchyma or the ureter, to more superficial musculoskeletal indications. Although originally conceived to dissipate calcifications in rotator cuff tendinopathy and to alter osseous biology, the technology rapidly spread to other common disorders that affect the musculoskeletal system. Unfortunately many of these applications were not tested through appropriate randomised clinical trials or practical clinical trials, which could adequately assess clinical efficacy and significant modification of the natural history of a given musculoskeletal disorder. Such studies are obviously in demand by clinicians and healthcare provider organisations to justify the application of both a given treatment modality and the efficiency of a new drug or device to accomplish an end result that is personally satisfactory to the patient and doctor and economically justifiable to the healthcare insurer/provider.

Musculoskeletal conditions are an underrepresented major affliction of most patients, especially in the active, otherwise medically healthy patient population. Many of these conditions limit the enjoyment of participation in recreational activities. Many musculoskeletal disorders also affect productivity (overuse, a controversial concept). Efforts to restore tissue tensesgrity to alleviate pain and restore function in these situations deserve careful, well conceived evaluations.

In 1995 the Food and Drug Administration (FDA) in the United States approved the initial studies to evaluate the application of a device specifically redesigned to apply extracorporeal (transcutaneous) shock waves

to chronic plantar fasciopathy (fasciitis). This study approval process led to subsequent studies of other indications (lateral epicondylitis, fracture non-union) and other devices.

Shock waves for clinical use, whether in urology or orthopaedics, are generally generated by three methods: electrohydraulic, electromagnetic, and piezoelectric. Other technologies will undoubtedly emerge as physics merges with medicine. The different medical methods vary considerably in the total amount of shock wave energy delivered to the target issue, the size of f_2 (which is the maximal energy), the size and volume of the energy, ellipsoid, and the depth of penetration of f_2 into the tissue involved. Physician training and familiarity with the physics of the treatment is integral to the appropriate application of the technology to accomplish a satisfactory treatment outcome, as it is for a radiologist to understand the risks and benefits of diagnostic technologies.

Recent publications have both supported and questioned the applicability of extracorporeal shock waves to musculoskeletal conditions. Some studies have led to "global" interpretations that extracorporeal shock wave treatment (ESWT) is not effective. Such concepts are not appropriate. The three shock wave generation methods differ significantly in the overall size and volume of the applied shock waves. Even with a specific device, these variables may change. Speed and coworkers¹ recently stated that "efficacy may be highly dependent upon machine types and treatment protocols", and that "further research is needed to develop evidence based recommendation for the use of ESWT in musculoskeletal complaints."

The recent study by Haake *et al*² was negative about the potential efficacy of ESWT in plantar fasciitis. This study, which was obviously well conceived, applied low energy shock waves (0.08 mJ/mm^2) to the plantar fascia in a transverse direction (medial to lateral) relying on ultrasound to focus a relatively narrow ellipsoid and f_2 into the

fascia. There were no descriptions of efforts by the treater (presumably a doctor) to specifically demarcate the primary focus of pain and to relate such to the ultrasound targeting. Low energy was applied in this study three times at two week intervals. The study concluded that this specific protocol was no more effective than a placebo. The conclusion that this protocol "is ineffective" was appropriate. However, the application of "ineffectiveness of ESWT" is equally inappropriate. The FDA data from Ossatron approval and Dornier Epos approval for treatment of plantar fasciitis were statistically significant. Haake *et al*² used the Dornier device, but under completely different circumstances from their FDA study. Such differences lead to confusion for doctors and healthcare providers. The FDA studies, carried out using appropriate, well conceived treatment protocols, show that the technology with high energy (which requires anaesthesia) is usually effective. The recent studies by Buchbinder *et al*,³ Speed *et al*,¹ and Haake *et al*² strongly suggest that multiple dosed, low energy, non-anaesthetically based treatments cannot accomplish the same clinical outcomes and patient satisfaction.

Evaluations need to be continued, comparing the efficacy of different generational methods and variations in the applied energy of a specific generational method. Increasing numbers of basic science publications support positive responses in the target musculoskeletal tissues (fascia, tendon, bone). Our responsibility as doctors, in an age of increasing emphasis on minimally (or even non-) invasive surgery, is to continue to evaluate, through effective and well designed clinical trials, the potential application of a procedure that is widely accepted in urology to a variety of musculoskeletal problems.

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REFERENCES

- 1 Speed CA, Nichols D, Wiles J, *et al*. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomized controlled trial. *J Orthop Res* 2003;**21**:937-40.
- 2 Haake M, Buch M, Schoellner C, *et al*. Extracorporeal shock wave therapy for plantar fasciitis: randomized controlled multicentre trial. *BMJ* 2003;**327**:75-9.
- 3 Buchbinder R, Ptasznik R, Gordon J, *et al*. Ultrasound-guided extracorporeal shock wave therapy (ESWT) for plantar fasciitis (painful heel): a randomized controlled trial. *JAMA* 2002;**288**:1364-72.