

# ULTRASONIC ENERGY AS A TREATMENT FOR CHRONIC REFRACTORY TENDINOPATHY AND FASCIITIS OF THE FOOT AND ANKLE

*Bernard F. Morrey, MD*

*David J. Caldarella, DPM*

*Todd B. Haddon, DPM*

## PATHOPHYSIOLOGY

The burden of healthcare has been estimated to consume approximately 13% of the gross domestic product. Of this staggering figure approximately half of the healthcare expense is directed towards managing musculoskeletal disorders (1). In 2013, there were over 30,000,000 ICD-9 codes recorded for tendinitis or fasciitis. Hence, the burden to society of musculoskeletal disorders in general and tendinopathy and plantar fasciitis, are dramatic.

It comes therefore as no surprise that the pathophysiology of these various conditions has been aggressively studied particularly in recent years. The process has in general been defined as occurring in three stages, the first is the insult or the injury usually due to chronic repetitive activity. The second is an effort at a healing response secondary to a signaling mechanism, and the third is resolution or a development of a chronic residual symptomatology (2) (Figure 1). Analysis of the numerous studies investigating the pathological alterations associated with these processes provides insight into the complexity of the problem. As many as 30 changes in various matrix components, cytokine and signaling factors and enzymes involved in tendon metabolism have been implicated from several sources (2).

## NATURAL HISTORY

In spite of the prevalence and the impact to society, relatively little is known of the natural history of chronic tendinopathy. At the elbow, the only population-based study to date has documented that symptoms persist for at least six months in approximately 20% of patients (3). For this group, final resolution takes almost an additional two years. Furthermore, this study documented a 15% recurrence rate after apparent resolution of the epicondylitis. There are no population based studies assessing Achilles tendinopathy or plantar fasciitis. Nonetheless, the frequency with which these problems are seen in the office is well known to all podiatrists. It is therefore understandable that ongoing efforts to better understand and treat these various conditions would be of great value not just to the patient but to society in general.

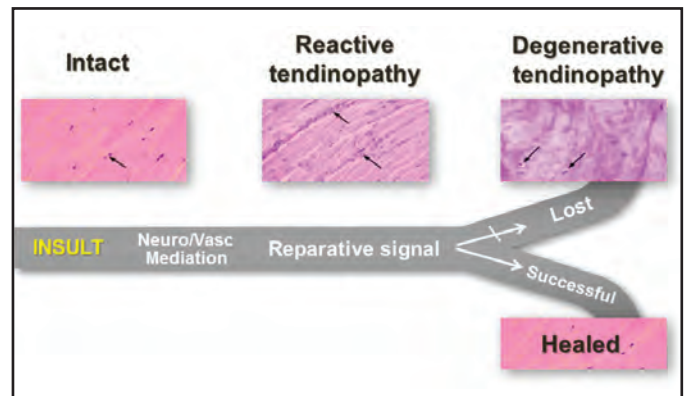


Figure 1. The phases of tendinopathy. A single event or more commonly a repetitive trauma results in tendon damage. This induces a neurovascular-mediated response that generates a reparative signal, which in most instances successful results in a spontaneous physiologic healing process. In some instances the reparative signal is not successful and a degenerative tendinopathy ensues.

## TRENDS IN MANAGEMENT

Overall there are several accepted goals and trends in managing these conditions (4). Patient-centric considerations include earlier definitive intervention to avoid the effects of the chronic expression of the disease. As is the trend for most treatments today, a minimally invasive yet definitive alternative is preferred. In an ideal setting a rapid recovery rather than one that takes months to see the full benefit of the procedure is desirable both from the patient and from the employer perspective.

In addition to these patient-centric features there are additional trends within the profession. In an ideal setting, the intervention could take place in a less expensive environment such as in an office or a cast room as opposed to an ambulatory surgical center. The value of ultrasound guidance to first identify the pathology and then to direct the treatment has been well documented (5). An increased emphasis on documentation of effectiveness from carefully constructed studies will be required to validate the performance of a given treatment. Consistent with this is the absolute need to have an awareness of the cost of the procedure, which when coupled with the effectiveness allows a physician and patient to judge the overall cost/

benefit of the procedure. Finally, as with any intervention, the most compelling variable to judge a new technology is the safety factor. Very successful procedures that had a significant complication rate will not and should not be adopted. Of interest, even those procedures that are known to be unpredictable are still accepted in refractory conditions if the safety factor is near absolute. An example of this is platelet-rich plasma treatment.

## TREATMENT OPTIONS

The treatment options for chronic tendinopathy and plantar fasciitis are almost too numerous to document. The gold standard of nonoperative management is eccentric exercises (6). The effectiveness of this treatment has been well documented. However it is known that the effectiveness of eccentric exercises is variable and it is also somewhat site-specific with certain anatomic sites responding better than others. Specifically, substance Achilles tendinopathy is known to respond much better to eccentric exercises than is insertional tendinopathy (7). Nonetheless, this is safe. One commonly cited issue is the time period for improvement is weeks or months.

Cortisone has been the standard of treatment particularly for the very acute or “hot” cases of tendinopathy. This is still probably the most common form of treatment, but the emerging evidence clearly reveals the benefits of cortisone injection tend to be short lived. More importantly, more recent data has suggested that cortisone in fact may be harmful long-term with a higher incidence in patients still having symptoms at one year compared to the control of eccentric exercises (8).

Platelet-Rich Plasma, the use of a person’s own blood that has been specially prepared to concentrate the elements to promote or accelerate healing has been widely publicized and used. However, this is a complex area that involves significant variation in the manner of preparing the active

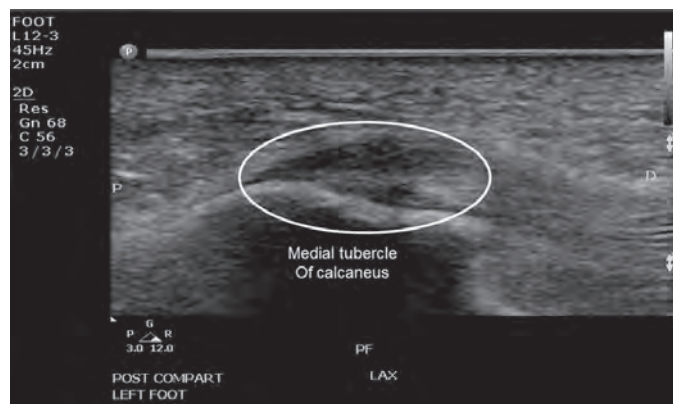


Figure 2. Ultrasound image of plantar fasciitis showing thickening and a hypoechoic area at the insertion of the plantar fascia at the site of the medial tubercle of the calcaneus.

ingredients (9). The timing of the injection as it relates to the spectrum of tendinopathy all contribute to the well-recognized unpredictable nature of the outcome of this treatment (10). While there is no consensus on the proper preparation, indication or anatomic application it continues to be used because it is safe. It should be emphasized, however, that this is not a treatment that is reimbursed by insurance companies and thus is an out-of-pocket expense.

## “WAVE THERAPY”

It is known that cells and cellular elements are sensitive to external energy. It is for this reason that various efforts at external “wave therapy” or energy applied to the involved part have been aggressively pursued in recent years. Extracorporeal shock wave therapy has been extensively studied with various outcomes (11). It is attractive because it is noninvasive and safe. However, because it is felt that this cannot be effective unless there is a significant painful sensation, patient tolerance is somewhat limited. In addition the prospective randomized studies have failed to demonstrate that this consistently outperforms the alternative controls.

## PERCUTANEOUS ULTRASOUND TENOTOMY AND FASCIOTOMY

The ultrasound image provides precise localization of the pathology, which for the plantar fascia occurs at the attachment of the plantar fascia at the medial tubercle of the calcaneus (Figure 2). The probe emits an ultrasonic energy level that cuts through the diseased tendon or fascia and has relatively little effect on normal tissue (12). The probe is hollow thus the degenerative tendon is both cut and then removed from the field by aspiration through the hollow probe. Continuous irrigation cools the instrument and prevents normal tissue injury (Figure 3).



Figure 3. The TX1 hand piece has a hollow tip that emits ultrasonic energy. Concurrently the field is bathed in saline irrigation (white arrow) and after the tendon is cut it is removed through the hollow ultrasonic tip (solid black arrow).

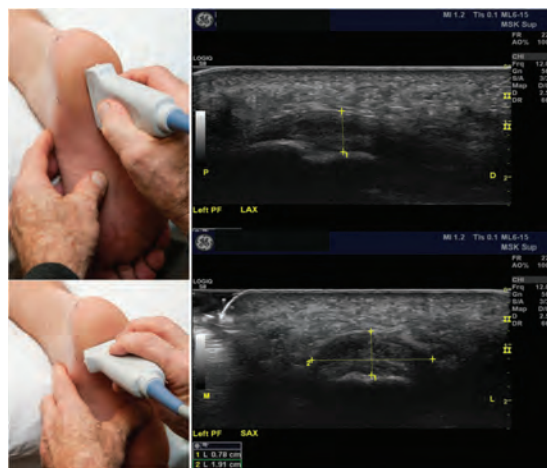


Figure 4. For plantar fasciitis, the pathology can be identified and characterized with both long axis (A) and short axis (B) diagnostic imaging.

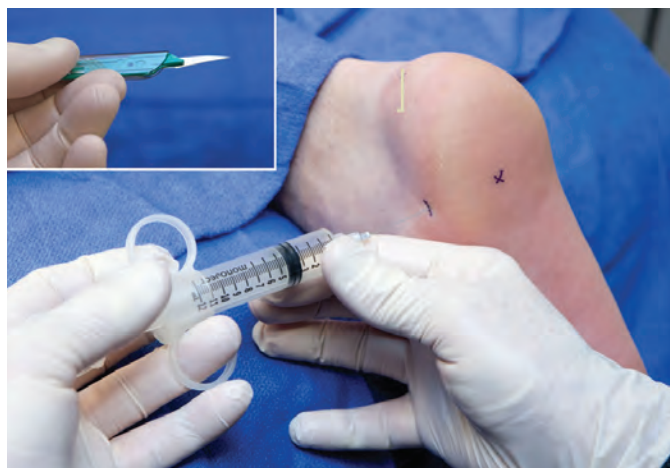


Figure 5. While several different techniques may be used, the area is anesthetized with a fast-acting local anesthetic under ultrasonic guidance. The skin is punctured with an 11-blade to facilitate the entrance of the ultrasonic probe.



Figure 6. Pathology is treated with the TX1 hand piece. Both long axis and short axis guidance is helpful in assuring accurate and complete removal of the pathologic process.



Figure 7. The puncture site is simply closed with a Steri strip and a sterile dressing is applied with gentle compression.

It is felt that this technique provides both the ability to alter the degenerative tendon but then as with an open procedure, it also allows removal of the diseased tissue. The predicate for the concept has been in use for over 30 years: phacoemulsification. The mechanism of action of this technology is not well understood. Nonetheless, it is well documented to be both safe and effective in the treatment of cataracts (13) and thus this concept has been introduced as a possible safe and effective treatment for tendinopathy and fasciitis.

## TECHNIQUE.

The procedure is performed in an office treatment room, or in a more formal treatment facility. Once the pathology is confirmed by ultrasound examination (Figure 4), the area is prepped and draped as for a cortisone injection. The site of pathology is anesthetized with a fast-acting local anesthetic,

and the skin is punctured with a #11 blade (Figure 5). The TX1 probe is introduced into the pathologic process and treated until the entire lesion has been resected (Figure 6). The format ultrasonic treatment time is usually 1.5 to 3 minutes. A Steri-strip is applied along with a sterile dressing (Figure 7).

Postoperative treatment is symptomatic protection for 2-3 weeks. Gradual progression of activity is allowed at 3 weeks. Full resolution of the symptoms usually occurs by 3 months, but in some instances may take up to 6 months.

## RESULTS

The first treatment was performed in the US in September 2012. Since this time approximately 20,000 treatments of various anatomic parts have taken place. Of these approximately 40% involve the foot and ankle tendinopathy and plantar fasciitis. The early results of the success rate are

emerging. One early report suggests that the effectiveness for plantar fasciitis may exceed 90% (14). My personal experience is such that I counsel the patient there is an 80-90% chance of success for both Achilles insertionitis and for plantar fasciitis.

## COMPLICATIONS

To date, of approximately 9,000 foot and ankle cases, there has been one infected Achilles insertionitis treatment, and one case of infection after treatment of plantar fasciitis. Both responded to debridement and medical management.

## CONCLUSION

It appears as though the application of a well-established ultrasonic treatment for cataracts, phacoemulsification, has been effectively applied to chronic refractory tendinopathy and fasciitis. Time will tell with regard to the overall effectiveness of this technology. The ultimate extent to which it is adopted by the profession will depend on the demonstration of a high rate of efficacy and safety from a broad spectrum of practices across multiple disciplines.

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