A Novel Treatment for Refractory Plantar Fasciitis

Am J Orthop. 2015 February;44(2):107-110

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Author’s Disclosure Statement: The author wishes to report that he is a member of the medical advisory board of Tenex Health, which developed the tissue removal system used in this study.

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Chronic plantar fasciitis is a major health care problem worldwide and affects nearly 10% of the US population. Plantar fasciitis presents as heel pain in the mornings and usually gets better and then gets worse. Inflammation at the plantar fascia attachment causes acute and sometimes disabling pain. Chronic pain at the site can develop as time goes on because of long-standing inflammatory changes. Fibrotic tissues may develop at the site. On a continuum, symptoms may begin in an insidious phase and progress to chronic pain. Although most cases resolve with conservative care, the numerous treatments for refractory plantar fasciitis attest to the lack of consensus regarding these cases. The condition frustrates patient and physician alike.

Treatments for refractory plantar fasciitis include conservative measures, including rest, analgesics, walking orthosis, heel cup, night splint, walking boot, and then, in a standard and logical progression, cortisone or platelet-rich plasma injections. Improved magnetic resonance imaging and ultrasonographic imaging allow accurate localization of the pathologic process,\textsuperscript{1-3} and this localization in turn provides an opportunity to deliver a more reliable and focused intervention, as in needle-guided therapy.\textsuperscript{4} Surgical procedures for plantar fasciitis have included open or endoscopically assisted plantar fasciectomies with or without gastrocnemius recession; these procedures have had varying results. The emerging goals for this condition are a minimally invasive percutaneous intervention that is safe, effective, and well-tolerated and has minimal morbidity and a low complication rate.

We conducted a prospective study in which patients were allowed either to continue with noninvasive treatment or to undergo focal aspiration and partial fasciotomy with an ultrasonic probe. Study inclusion criteria were plantar fasciitis symptoms lasting 12 months or longer. Exclusion criteria were unwillingness to participate in the study. Prior treatments, even surgeries, were not exclusionary.

Twelve patients with refractory plantar fasciitis lasting a mean of 19 months (minimum, 12 months; range, 12-24 months) chose the procedure. They all had failed conservative care, including physical therapy, casting, shockwave therapy, and invasive procedures such as injections and endoscopic partial releases. Four of the 12 had undergone an open or endoscopic partial release at a different institution but had experienced no improvement in symptoms.

Based on the study protocol, patients continued noninvasive care (night splint, stretching exercises) for 2 to 6 weeks after the initial visit. When this conservative care failed, they were offered focal partial fasciotomy with a percutaneous ultrasonic probe. American Orthopaedic Foot and Ankle Society (AOFAS) scores were obtained before and after surgery. Follow-up consisted of clinic visits 2 weeks after surgery and monthly thereafter. I saw all 12 patients 3 months after surgery (range, 11-14 weeks), and all 12 underwent postoperative physical therapy.
**Technique**

The TX1 Tissue Removal System (Tenex Health, Lake Forest, California) (Figure 1) consists of an energy module, a pump/suction cassette that provides irrigation and suction through a probe, and the probe itself, the TX1, which is the size of an 18-gauge needle and delivers ultrasonic energy. The cassette is inserted into the energy module, and the ultrasonic energy probe is primed so it will deliver the irrigation fluid, normal saline. The safety features of the energy module are such that no energy is expended unless the system is properly irrigating and aspirating the diseased tissue. Ultrasonic treatment may be performed in a clinical or ambulatory surgical center. The patient is placed supine on an operating table, on a clinical examining table, or, if in a cast room, on a cart. A pillow is placed under the distal tibia so the knees can flex slightly, and the patient is positioned so the feet are free of the edge of the bed or gurney (Figure 2).

The pathology is first confirmed by ultrasonography (Figures 3-5). The first step is to identify the calcaneus with the sensor along the long axis of the foot. Then the plantar fascia is visualized and followed along its long axis to the site of attachment at the medial tubercle. As the pathologic process involves the medial site of attachment, a
transverse image may also be obtained to better understand the medial/lateral extent of the disease process. The ultrasonographic image of plantar fasciitis has been well characterized.\textsuperscript{2,3} The pathology is visualized as an area of edema or of disruption of the linear appearance of the fascia as it attaches to the calcaneus. While the diagnosis is being confirmed, the optimal site for probe insertion should be considered based on the location of the pain and the localization of the pathology by the 2 orthogonal images.
The area is prepared as if for an injection and is squared off with sterile towels. Then the sensor is placed in the sterile sleeve. The area of maximum tenderness is again confirmed. Determining the location of the probe insertion site is a crucial step. We use the ultrasonic sensor in the longitudinal and transverse planes to direct the injection of a fast-acting local anesthetic to the medial aspect of the calcaneus. A skin wheal is created, and the fast-acting local anesthetic (3-4 mL) is injected into the region of the fascia pathology.

An 11-blade knife is used to create a site for the probe through the skin wheal at the medial aspect of the heel, in line with the pathology (Figure 6). The probe is then introduced through the puncture site and is identified, along with the pathology, with the sensor, which may be oriented transverse or longitudinal to the long axis of the foot.

Once the pathologic area is identified, the ultrasonic energy is delivered to the region by the probe, which is activated with a foot pedal, effectively releasing the pathologic tissue from its insertion at the medial tubercle of the calcaneus. The probe is moved in a linear fashion medially and laterally within the lesion across the site of attachment. Treatment continues until the entire soft-tissue lesion is addressed.
Postoperative Care

The wound or wounds are closed with a nylon stitch and Steri-Strip (3M, St. Paul, Minnesota) and covered with Tegaderm (3M) or similar dressing (Figure 7). A compressive dressing is applied. The dressing is removed in 2 to 3 days; the Steri-Strip and stitch are removed in 10 to 14 days. A walking boot is put on immediately after the procedure (most patients in this study already have a boot) and is worn for a few days, or until the symptoms have resolved. How long the boot is used is very much based on patient preference. Patients may continue stretching exercises at home, but there should be no high-impact activity. As-needed ice and analgesics are recommended for the first few days.

The 12 patients had a mean preoperative AOFAS score of 30 (range, 17-46) and a mean postoperative score of 88 (range, 25-92). By the 3-month postoperative visit, symptoms were resolved in 11 patients (no activity restricted by plantar fascia pain). On physical examination, 11 patients had no palpable tenderness at the site of preoperative pain. Pain relief was documented as having occurred between 5 and 13 weeks after treatment. One patient had bilateral procedures. One foot was treated, pain resolved by the 3-month postoperative visit, and the patient asked for the other foot to be treated. Three months after the second procedure, he had minimal non-activity-restricting pain. There were no postoperative infections or wound complications.

I phoned my patients during postoperative month 24. All 12 patients (13 feet) indicated they were essentially pain-free. None admitted to activity restriction or required over-the-counter pain medication. All indicated they were satisfied with the procedure and would have it again.

The refractory nature of plantar fasciitis, and the resistance to and unpredictability of current treatment options, is well known. Considerable efforts have been made to develop treatment guidelines and algorithms. A standard and logical treatment plan involves initial attempts with rest, analgesics, and a walking orthosis and then, if those fail, cortisone or platelet-rich plasma injections. Reluctance to perform surgery is well justified because of the unpredictability of the intervention. As might be expected, the utility of ultrasonography has been on the rise. The diagnostic value of ultrasonography, first recognized in the early 1970s, is of increasing importance. Subsequent use of ultrasonographic imaging as guidance for various treatments, including percutaneous release, has also been recognized and documented. The present article is the first to describe and document the outcome of using ultrasonic energy for percutaneous release of the diseased attachment of the plantar fascia.
This report is preliminary and was designed to alert the orthopedic community to a safe and promising treatment for a chronic, refractory condition. The safety and efficacy of this treatment are reflected in our experience and have been documented for tennis elbow as well.\textsuperscript{13}

This study was limited by its single-surgeon and relatively small clinical experience. Nevertheless, the benefits of this novel technique—effectiveness, safety, tolerability, and rapid recovery—are encouraging enough to share at this time. Prospective randomized controlled studies are needed.

**Conclusion**

This is the first report of a plantar fascia partial release guided by ultrasonic energy delivered by a percutaneously inserted probe under local anesthesia. The procedure appears to be a safe, effective, well-tolerated treatment for a condition that is refractory to other options. More studies are needed to further validate the safety and efficacy of this innovative treatment modality.

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