CHAPTER **47**

PERCUTANEOUS ULTRASONIC DEBRIDEMENT FOR TREATMENT OF RECALCITRANT FOOT ULCERS

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INTRODUCTION

Chronic neuropathic ulcerations of the feet are common and costly complications of diabetes mellitus, with elevated morbidity and mortality. Population studies project that one-third of the US population will have diabetes by the year 2050 (1), and 15-20% of diabetic patients run the risk of pedal ulcerations during their lifetime (2). Successful offloading and wound care may be thwarted with recurrence if underlying pathology or patient noncompliance are not addressed, and consensus panels and the International Diabetes Foundation cite recurrence rates of 40-50% (3, 4). Pioneering work on a novel application of existing percutaneous ultrasonic technology offers a unique treatment option that has met with initial favorable success.

Ultrasonic energy is oscillating sound pressure waves with a frequency above human hearing (20,000 hertz) (5). A generator produces electrical energy that is converted to acoustic energy through mechanical deformation of a piezoelectric crystal located within the transducer. The waves produced are transmitted by propagation through molecular collision and vibration, with a progressive loss of the intensity of the energy during passage through the tissue (attenuation), due to absorption, dispersion or scattering of the wave (5). Ultrasonic energy is commonly used in the food processing industry to sterilize food (6). Medical applications have been researched over the past 70 years and are currently employed for lithotripsy, thrombolysis, enhancement of drug delivery, ablation, and for topical wound debridement systems.

The TX1 microtip device (Tenex Health, Lake Forest, California) delivers ultrasonic energy and simultaneously irrigates the tissue to avoid thermal injury to healthy tissue and aspirates the treated tissue through a 16 gauge needle (Figure 1). The technological rationale for the TX1 handpiece is rooted in ophthalmologic phacoemulsification. This device received Food and Drug Administration (FDA) approval to treat soft tissue conditions in September, 2011, and therefore is FDA approved to be used to treat ulcers. Importantly, it has been shown to be extremely safe and effective when treating approximately 15,000 cases of degenerative tendinopathy. To date only one complication, local infection, has been encountered.

We present a technique and rationale for this novel, percutaneous, subvulnic (latin: sub = under, vulnus = wound) treatment for chronic neuropathic wounds. While other wound care treatments address topical colonization, biofilm, or coverage, and surgical intervention may address realignment of osseous deformity, potentially destabilizing exostectomy of plantar prominences, or additional superficial debridement, the approach we present addresses the problem from the inside out and offers multiple potential advantages.

SURGICAL TECHNIQUE

Following application of local anesthetic, the foot is prepped and draped. Access portals are made via small stab incisions at cardinal points and the TX1 percutaneous ultrasonic needle is advanced into the pathologic target region. On high setting, ultrasonic energy is imparted at a proprietary frequency designed to debride and aspirate the targeted abnormal tissue. Simultaneous irrigation and aspiration allow for removal of treated abnormal detritus. The single-use hand piece is maneuvered to position the echogenic needle tip subvulnically to access bursa, cicatrix, or osseous prominence and delivery of energy is controlled using a foot plate control.

The physician should target the outer cortex of osseous prominences to "pepper" the cortex from all access portals. Simultaneous visual ultrasound can be employed in the non-dominant hand to visualize precise position of the TX1 tip and vital anatomical structures per physician preference. Upon completion of treatment, a sterile dressing is applied to the wound and access portals. Post-procedural follow-up

Figure 1. TX1 probe and unit (photo courtesy of Tenex Health, Lake Forest, California).

is performed weekly until wounds heal, then monthly to monitor for recurrence. Persistent wounds are treated with continued wound care and offloading.

RESULTS

An initial retrospective pilot study of 12 patients treated between August 2013 and March 2014 was performed to gauge early results and found 83% successful healing in an average of 1.94 weeks and without recurrence in all 10 wounds that healed at mean follow-up time of 24.75 weeks. These were all neuropathic wounds that had failed conservative therapy for a minimum of 5 months. The average duration of the ulcer prior to treatment was 109.2 weeks. The percutaneous debridement was thoroughly discussed with patients prior to treatment, which was performed under local anesthesia in either an ambulatory surgery center or in the office setting.

Patient clinical and operative notes were reviewed for collection of patient age, sex, body mass index, anatomic location of ulceration, size of wound, age of ulcer, prior treatments, past medical history, date of percutaneous ultrasonic procedure, elapsed treatment time, time to healing if applicable, length of follow-up and presence of recurrence if applicable. Healing was defined as complete epithelializaion of the wound. Patients were contacted via telephone and submitted information regarding any other prior treatments not recorded in their chart. Current status of the ulcer including photographic confirmation was solicited.

DISCUSSION

The initial pilot study showed very favorable results and has been expanded and is being submitted for peer-reviewed publication. Ongoing data continue to be promising. One advantage to this treatment is that it simultaneously addresses the 3 essential elements of the diabetic foot ulcer: ischemia, subdermal prominence, and secondary infection. Long-term chronic wounds are encompassed by thickened bursa or cicatrix, which may decrease the potential vascularity to the wound which are addressed with the presented technique. Proximal intra-vessel stenosis or occlusion is not addressed with this technique. Osseous prominence can be obvious, as in the case of a Charcot rocker-bottom midfoot, or more subtle as with hallux interphalangeal ulcerations. Traditional plantar exostectomy involves a more extensive dissection and potentially destabilizes the foot, leading to further collapse, worsening global deformity, and possible Charcot reactivation.

The technique can address osseous prominence to a certain degree, with minimal damage from soft tissue dissection and it avoids major destabilizing exostectomies. Precise technique is crucial, favoring a controlled pistoning motion along the long axis of the hand piece to minimize soft tissue trauma/dissection. Concern over secondary infection is assuaged by the potential 1-2 mm zone of sterility produced by the ultrasonic energy itself, and by accessing the target tissue through periwound portals that avoid introducing colonizing bacteria from the wound bed into deeper tissues. One of the most promising aspects of the pilot study was that nothing was changed in the treatment of the recurrent and recalcitrant wounds other than addition of the ultrasonic procedure. Topical wound care and offloading prescribed by the patients' referring physicians were continued, with the addition of our procedure and its immediate post-procedural care. In the absence of a formal control cohort, the patient history of recurrence or recalcitrance served as informal controls, and the subsequent absence of recurrence during a mean follow-up of 24.75 weeks is significant, despite some documented cases of individual patient non-compliance. In all cases, post-procedural offloading must not be ignored as the etiological increased plantar pressure must be addressed for long term success. Ongoing research is underway to further characterize the ideal inclusion and exclusion criteria, patient selection, and long term benefits from this procedure.

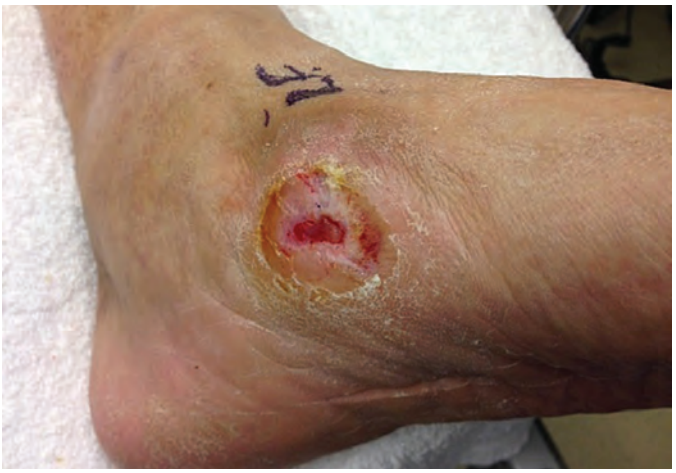

Figure 2. Left foot peri-navicular ulcer prior to ultrasonic procedure. Hyperkeratotic tissue has been debrided. A total of 4 access portals will be created in cardinal orientation around the wound.

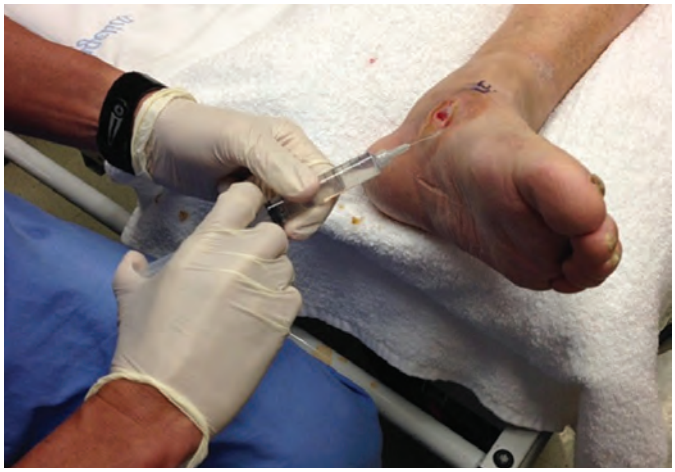

Figure 3. Administration of local anesthetic.

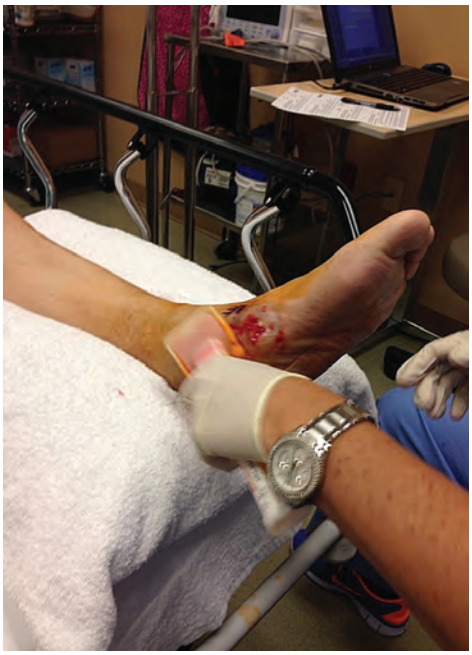

Figure 4. Preparation of the wound and surrounding skin.

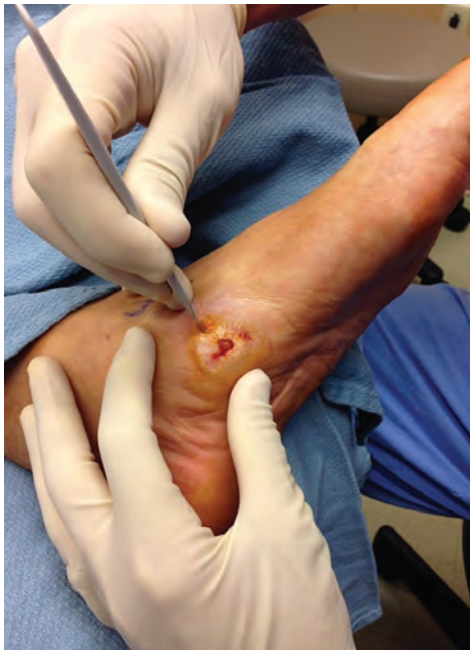

Figure 5. Creation of access portal through stab incision.

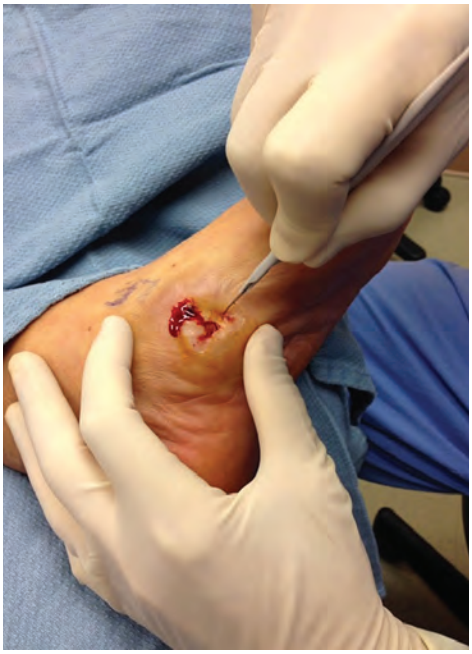

Figure 6. Creation of access portal through stab incision 2.

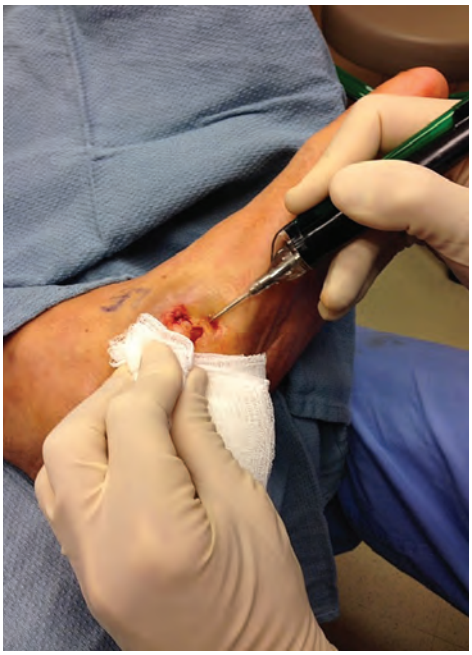

Figure 7. Ultrasonic debridement through portal 2.

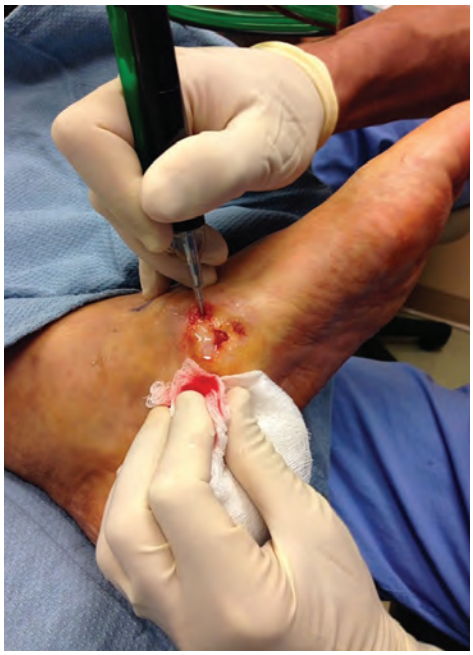

Figure 8. Ultrasonic debridement through portal 1.

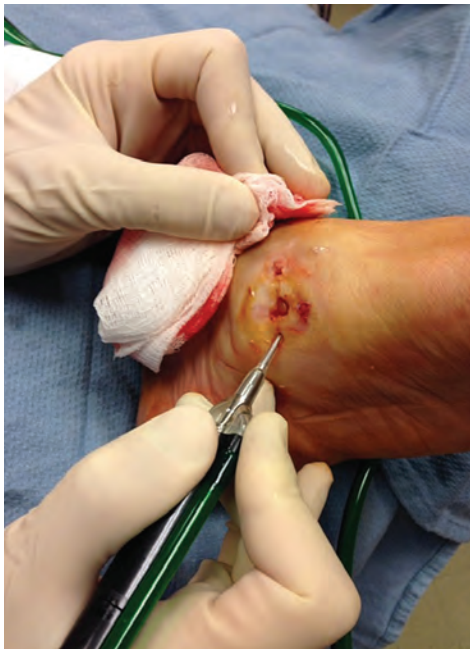

Figure 9. Ultrasonic debridement through portal 3.

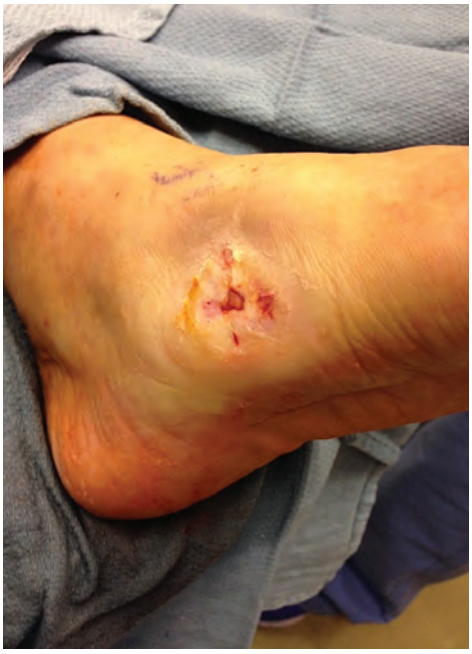

Figure 10. Post procedure showing original wound and 4 surrounding cardinal access portals. A sterile dressing was applied.

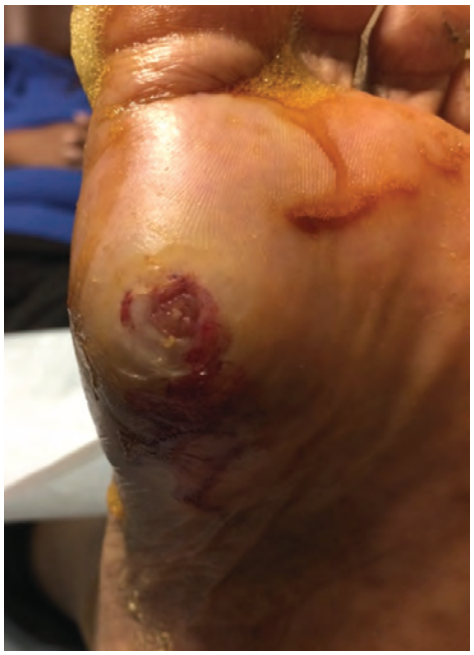

Figure 11A. Left plantar first metatarsal before treatment.

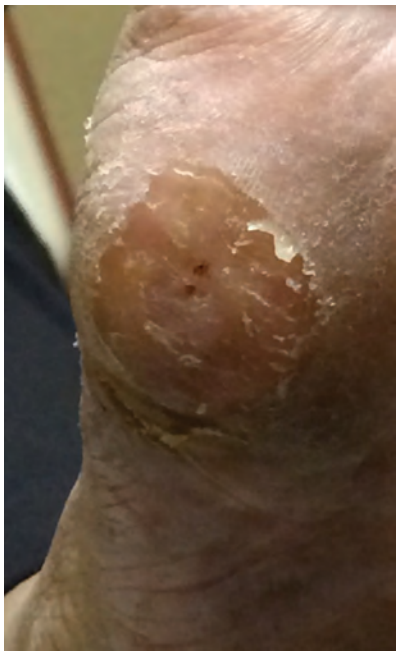

Figure 11B. After treatment.

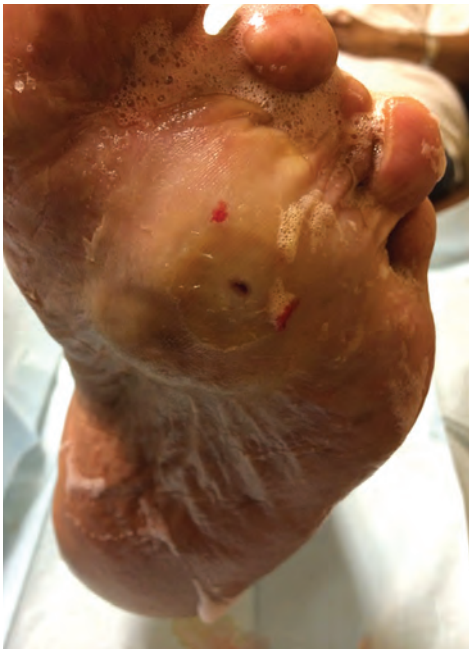

Figure 12A. Left central forefoot ulcer with significant problematic bursa before treatment.

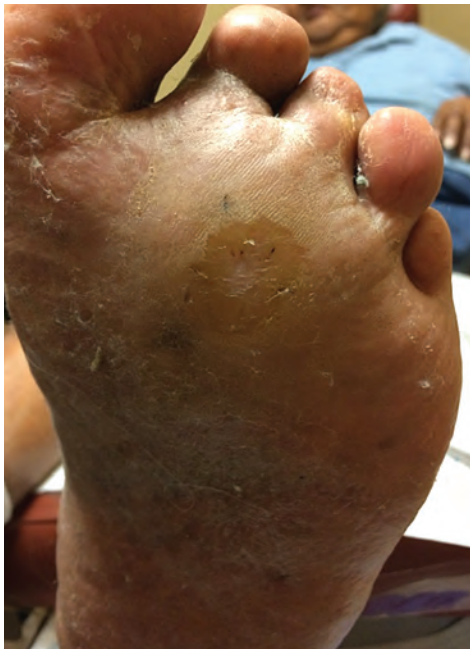

Figure 12B After treatment.

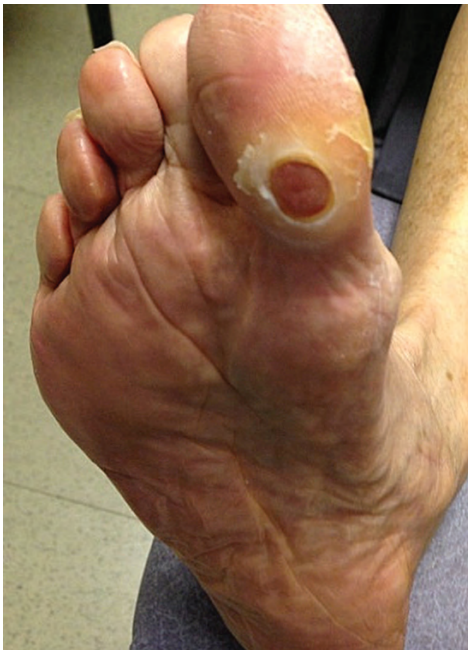

Figure 13A. Right plantar hallux before treatment.

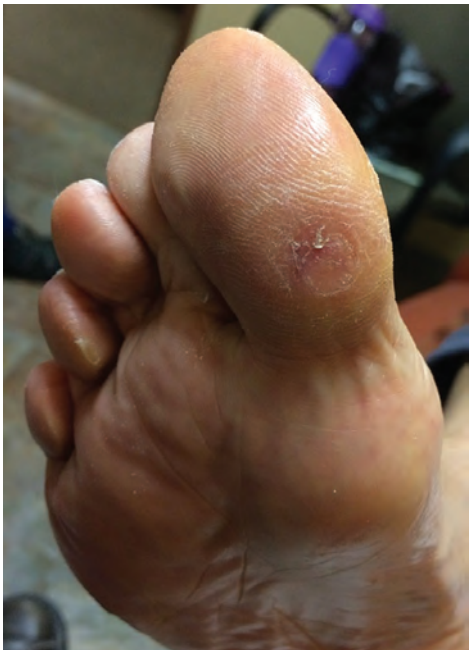

Figure 13B. After treatment.

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