Subcutaneous Ultrasonic Needle Treatment of Chronic Refractory Foot Ulcers

Rationale, Technique, and Pearls

Christopher K. Bromley, DPM, Lewis Freed, DPM, Devon N. Glazer, DPM

Introduction

Scope of the Problem

Diabetes is recognized as one of the leading causes of disability and death worldwide.[1] In the United States, an estimated 34.2 million people aged 18 years or older are currently diagnosed with diabetes, with the highest prevalence observed among racial and ethnic minority populations.[2] The complications caused by uncontrolled diabetes include cardiovascular disease, diabetic kidney disease, diabetic retinopathy, neuropathy, and foot ulcerations, which may lead to lower extremity amputations.[3-7]

Lower-extremity amputations resulting from poorly controlled diabetes, significantly decreases patient function and quality of life. An early European study found that up to 5% of patients with diabetes with a diabetic foot ulcer (DFU) will require a major amputation in 1 year.[8] More than 25% of patients with a DFU will require amputation in their lifetime.[9] Importantly, DFU patients have a greater than two-fold increase in mortality compared with nonulcerated patients with diabetes.[10]

There are also major economic implications associated with DFUs. Hospital admissions involving DFU can average more than $100 000 per admission if an amputation or revascularization is required.[11] As recently reported by de Smet, et al., treatment of DFUs accounts for approximately one-third the total cost of diabetic care, which, in the US, was estimated to be $176 billion in direct healthcare expenditures in 2012.[12]

Despite advances in DFU treatment approaches, approximately 20% of patients have unhealed DFUs at 1 year. Recurrence of DFUs following treatment are also common, with a recurrence rate of approximately 40% within 1 year.[13] Even intense treatment with multiple efforts and strategies is often inadequate.

In 2019, the Tenex Health TX® System (Tenex Health, Lake Forest, California), which utilizes the TX-Bone MicroTip, was cleared by the US Food and Drug Administration (FDA) for the specific purpose of treating the DFU and other conditions requiring removal of bone. In this article we describe the system features, present a summary of the debridement procedure, and discuss our collective experiences and best practices using the system in over 400 patient cases.

Tenex Health TX® System

The Tenex Health TX® System imparts ultrasonic energy by way of the hollow MicroTip that is activated by a foot peddle, irrigates and cools the TX-Bone MicroTip though an outer sheath and aspirates the debris through the lumen of the hollow MicroTip removing it from the field of treatment. (**Figure 1**) The beveled end of the tip cuts by direct tissue contact. Ultrasonic energy drives the needle and propagates an energy wave in the tissue. Cavitation facilitates rapid pressure changes from ultrasonic vibrations cause small bubbles to form and collapse. Continuous irrigation and aspiration emulsifies the fragmented tissue, flushes the treatment area and is evacuated by the Console pump. All these functions are performed in the 'medium' energy setting, while the irrigation and aspiration are performed under the 'high' setting.

Figure 1. Tenex Health TX® System

The MicroTip comes in a sterile package and includes attachments to the energy console and irrigation source. An aspiration collection bag is included along with a cassette that delivers the irrigation stream. One assistant, ideally a medical professional but not essential, is helpful to facilitate preparation of the system, but no other personnel resources are required for the procedure.

The Debridement Procedure

Outpatient Selection

Using the Tenex system, the goal is to restart the phases of wound healing to prompt new tissue regeneration. The ideal patient has a Meggitt-Wagner Grade 2 or Grade 3 ulcer, ≤3 cm in diameter that has failed 3 months or more of good wound management. For outpatient selection, we are looking for patients who are stagnant in their ulcer care despite previous approaches using more conservative methods (e.g., macro-debridement, wound dressing). Normally, patients will get stuck in the inflammatory stage and healing does not progress forward.

The procedure can also be used in patients who are just beginning to ulcerate. In patients with a Grade 0 ulcer, the Tenex system is used as a pre-emptive approach to prevent the patient from experiencing pain and/or further ulceration. It is beneficial to catch these patients early because they still have some protective sensation. When they cross the threshold to no sensation due to neuropathy, they are at significantly increased risk for infection and further progression of the ulcer.

For all patients, active infections in the soft tissue and/or bone should be managed and resolved using prophylactic antibiotics before performing this procedure. Use of the Tenex system should be avoided in patients with varus foot or severe ulcers that are not likely to heal.

Pre-Procedure

Bacterial colonization of diabetic ulcers is often polymicrobial and may require multiple agents for most effective prophylaxis. It is important to verify that any antibiotic agents metabolized by the kidneys are compatible with the renal function of the diabetic patient. (**Table 1**)

Table 1. Considerations for Anti-bacterial Medication Use

No allergies and normal renal function	Penicillin allergy and/or renal compromise
• Augmentin 875mg/ BID, plus Bactrim 1 dose BID • Doxycycline 100mg BID	• Doxycycline 100mg BID • Clindamycin 300 mg TID • Moxifloxacin 400 mg QD

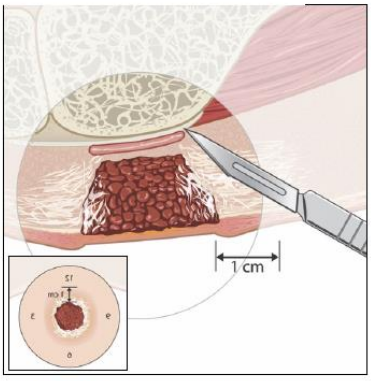
If there is excessive scarring around the margin of the ulcer, limited sharp debridement may be necessary prior to use of the Tenex system. Unless sensation is totally absent, a fast acting local anesthetic is administered, as for any ulcer debridement. For visualizing the ulcer, our preferred method is to use ultrasound. However, physicians who are not comfortable with ultrasound can use computed radiography (CR).

Debridement

1. Patient Placement

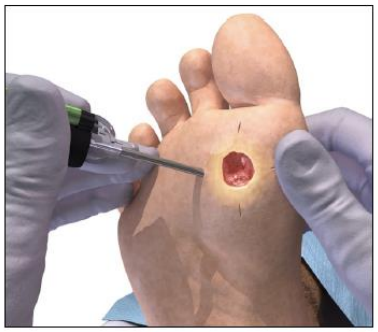
The patient is usually placed supine on the cart or treatment table and positioned to be clear of the table to facilitate irrigation fluid drainage.

2. Establish Portals

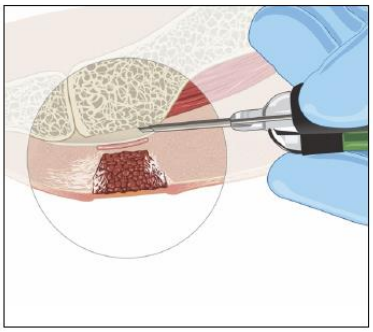


A minimum of two 5 – 7 mm stab incisions are placed at least 1 cm from the ulcer edge or in a position to facilitate removal of both the scar tissue and osseous prominence. Think about the wound as a clock, with portals made at 12, 3, 6, and 9.

3. Tissue Removal/Debridement



The TX-Bone MicroTip is introduced into the first portal at a 45-degree angle and the firm indurated avascular subdermal scar tissue surrounding the ulcer orifice is removed. The ischemic margin of the ulcer is removed with ultrasonic debridement. The osseous prominence removed using the MicroTip.



Each portal allows removal of the diseased tissue using a back and forth motion. Using successive portals, the entire ulcer is treated. Bone removal is achieved with a planning maneuver across the osseous prominence.

Post-Operative Care

Post-operative care following the procedure is no different than with other approaches. Oral antibiotics should be used for two weeks post-surgery or until the wound is completely healed. In 90% of our cases, the wound is totally closed within two weeks.

Wound management following the procedure is no different than what is used with other approaches. In our experience, physicians need to treat post-operative care as they would any other wound case with risk of infection where the patient is immune suppressed. We generally prefer to use a CAM boot for off-loading.

Patient Adherence

Suboptimal patient adherence to post-operative care remains a major obstacle to wound healing and preventing recurrence. Patients with larger and more severe DFUs and greater perceived foot pain tend to be more adherent to their prescribed post-operative care, particularly off-loading and wound management, compared with those with less severe DFUs and/or pain.[14] Given the visible improvements observed following treatment with the TX system in patients with less severe DFUs, these findings suggest that clinicians should place even greater focus on informing (convincing) these patients about the importance of adherence to promote faster wound healing, which lessens the opportunity for new infections to develop.

Because diabetic peripheral neuropathy may also be present in the setting of dementia and impaired cognition,[15] it is important that physicians be very clear and confident when talking to patients about their post-operative care. Patients need to understand the importance of following instructions for dressing changes and staying off their feet until the wound has fully healed. Otherwise, their chance for new infection and wound recurrence is significantly increased. Leveraging your leadership and authority as a physician is key to success in getting patients to do what they need to do to let the wound heal. In all cases, it is also ideal to have the patient's spouse or caretaker present when providing these instructions when possible.

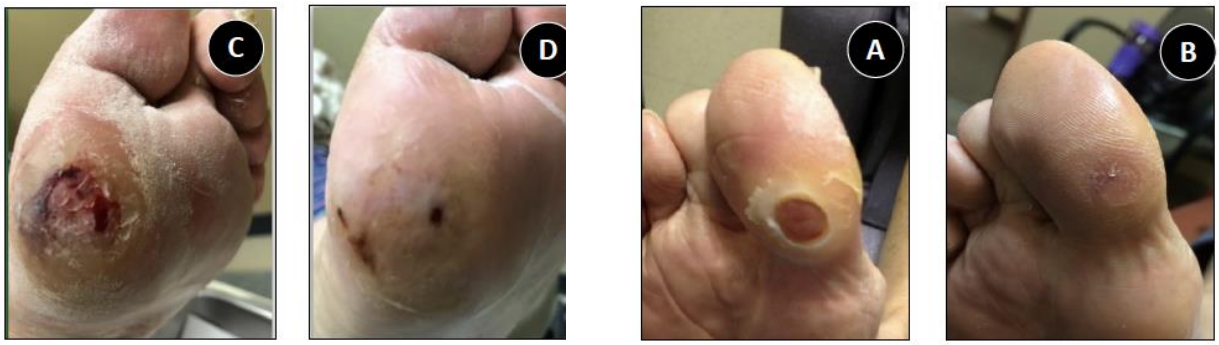
Efficacy and Safety

A key advantage of this approach is the bactericidal characteristic of the ultrasound energy.[16] Additionally, unlike standard macro-debridement, which is currently used to achieve the same goal, the size of the ulcer is not increased, so no tissue that may have recently healed is

lost. Unlike other treatment strategies, this single outpatient treatment, which is typically performed in less than 30 minutes, will effect a lasting cure in the vast majority of patients. In fact, physicians can oftentimes directly observe the cellulitis decrease in real time as they are performing the procedure in the majority of patients being treated.

It is often difficult to assess an average recurrence rate due to the large number of variables that may be at play, particularly patient non-adherence (not changing the dressing, walking too early, taking a shower). However, outcomes from a study of 102 consecutive DFU patients are currently being evaluated. The results to date are very encouraging, with complete healing occurring in >90% of these procedures, with only five recurrences over a 4-year period. Examples of pre- and post-procedure outcomes are presented in (**Figure 2**)

Figure 2. Example of Pre- and Post-Operative Outcomes



A. 2.5 x 2.5 cm ulcer of the phalanx of the great toe of 13 months duration.
B. Complete healing at 40 days with no recurrence at one year.
C. 2.5 x 1.8 sub first metatarsal ulcer of 20 months duration.
D. Complete healing 14 days after treatment with no recurrence at 3 years surveillance.

Practice Pearls

When using the Tenex system, the goal is to restart the phases of wound healing to prompt new tissue regeneration. To achieve this goal, we focus on two areas of debridement. The first area of focus is the soft tissue that is located below the wound bed. The reason we focus on this area is to decrease any venous congestion and correct any arterial insufficiency that may be present by removing necrotic tissue, decreasing bacterial burden and biofilm, and reducing inflammatory cytokines. The second area of focus is any bony prominence that may be compressing the underlying tissues. In most cases of DFUs, it is helpful to address and correct the issue of a problematic bony prominence, otherwise it is likely that there will be recurrence of

the ulcer. The TX-Bone MicroTip can be used to perform cortical debridement, which serves to reduce the bony prominence and decompress the wound.

When initiating the cortical debridement, we carefully avoid poking holes into the cortex. Instead, we skive off the cortical tissue, taking a small pass in one direction, then rotate the handpiece and make a small pass in the other direction. Once the cortex is gone, we smooth out the cancellous bone. When we are done with debriding, we do not want to feel any hard bone; it should feel spongy, indicating that the wound has been decompressed.

An important piece of advice we have for physicians who choose to use the Tenex system is to let the MicroTip do the work. The mechanics of the technology are designed to perform their function with minimal pressure. Physicians who follow this tenet with practice and care are more likely to have good clinical outcomes.

Conclusions

Utilizing the Tenex system for treating DFUs provides a revolutionary approach to wound healing. In traditional approaches, we have been debriding the top of the wound, which is the wrong side of the ulcer. By debriding the underside of the ulcer, we start the cascade of healing. Removing the cortical bone beneath the ulcer not only decompresses the wound but releases intrinsic growth factors that reside in that cancellous bone. Essentially, the procedure is a way of grafting and releasing those growth factors in addition to decompressing or "off loading" the wound.

Despite the demonstrated efficacy of the Tenex system, there is some headwind against this approach because debridement of the top side of the ulcer has been the standard approach for more than a century. In our view, we have been debriding the 'wrong side' of the wound for years.

Given the significant and increasing rate of lower extremity amputations due to DFUs, it is critical that the most effective treatments are made available to the physicians who care for these patients. In the risk-benefit analysis of using the approach discussed here, there is minimal risk but a significant benefit.

Author Biographies

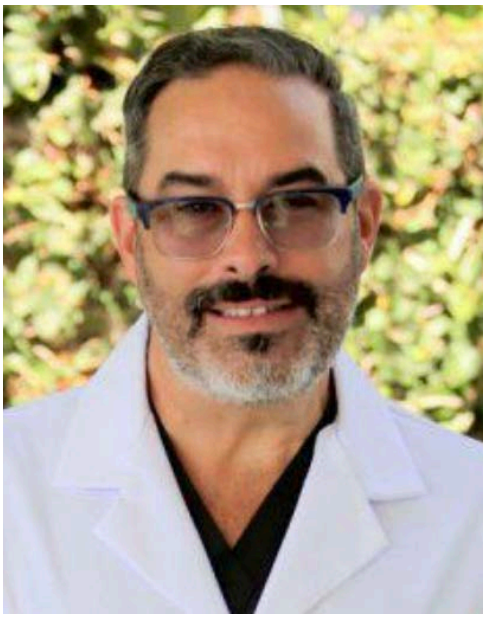
Christopher K. Bromley, DPM

Dr. Bromley obtained his Doctorate in Podiatric Medicine from the Ohio College Of Podiatric Medicine in Cleveland Ohio, graduating with honors and was a recipient of the Henry Haber Award for Clinical Excellence. He completed his residency in Podiatric Medicine and Surgery at the University of Maryland and Johns Hopkins teaching hospital system located in Baltimore, Maryland. Dr. Bromley is Board Certified in Foot Surgery by the American Board of Podiatric Surgery and is a Fellow of the American College of Foot and Ankle Surgeons. He served as the Chief of Podiatric Medicine at Vassar Brothers Hospital from 2005-2021 and is a former Director of the St. Francis Hospital Wound Care Center. He is an internationally respected expert in Wound Care and Regenerative Medicine and has authored numerous publications around this subject matter. Dr. Bromley currently practices Podiatric Medicine and Surgery in Delray Beach, FL.

Lewis Freed, DPM

Dr. Lewis Freed specializes in foot and ankle arthroscopy, foot & ankle reconstruction, limb salvage and minimally invasive tendon repair. He received his doctorate in podiatric medicine from the Pennsylvania College of Podiatric Medicine and completed his residency with a focus in multiple areas, including reconstructive foot and ankle surgery, foot and ankle trauma, diabetic and insensitive limbs, and pediatric foot disorders.

Dr. Freed is a published, and board-certified foot & ankle surgery Diplomate by the American Board of Podiatric Surgery, and has dedicated 30 years of practice with compassion for his patients and the well-being of the community. He has taught residents, students, and faculty at Creighton University, and has lectured nationally and internationally throughout his 30 years of practice.



Devon Glazer, DPM, FACFAS

Dr. Glazer is a respected podiatric foot & ankle surgical specialist currently practicing in Orange County, California. He completed his residency at New York Methodist Medical Center and currently sits on the Board of Directors of the American College of Foot and Ankle Surgeons. He is passionate about advancing and supporting podiatric technology that improves patient outcomes. Dr Glazer is passionate about supporting continuing education in the podiatric space, as demonstrated through his continued involvement in multiple podiatric associations and fellowship training programs.

References

1. Lin, X., Xu, Y., Pan, X. et al. Global, regional, and national burden and trend of diabetes in 195 countries and territories: an analysis from 1990 to 2025. Sci Rep 2020;10;14790. https://doi.org/10.1038/s41598-020-71908-9. Accessed April 24, 2022.
2. Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report, 2020: Estimates of diabetes and Its burden in the United States. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed February 29, 2020.
3. Gibson DM. Frequency and predictors of missed visits to primary care and eye care providers for annually recommended diabetes preventive care services over a two-year period among U.S. adults with diabetes. Prev Med. 2017;105:257–264.
4. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonlylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352(9131):837-853.
5. Holman RR, Paul SK, Bethel A, Matthews DR, Neil HAW. 10-Year Follow-up of Intensive Glucose Control in Type 2 Diabetes. N Engl J Med 2008; 359:1577-1589.
6. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications of insulin-dependent diabetes mellitus. N Engl J Med 1993;329, 977-986
7. Nathan DM; DCCT/EDIC Research Group. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study at 30 years: overview. Diabetes Care 2014;37:9–16.
8. Prompers L, Schaper N, Apelqvist J. Prediction of outcome in individuals with diabetic foot ulcers: focus on the differences between individuals with and without peripheral arterial disease. The EURODIALE Study. Diabetologia. 2008;51(5):747–755.
9. Kim SY, Kim TH, Choi J-YU, et al. Predictors for Amputation in Patients with Diabetic Foot Wound. Vasc Specialist Int. 2018; 34(4): 109–116.
10. Mauricio D, Jude E, Piaggesi A, Frykberg R. Diabetic Foot: Current Status and Future Prospects. J Diabetes Res. 2016; 2016: 5691305. doi: 10.1155/2016/5691305.
11. Skrepnek GH, Armstrong DG, Mills JL. Open bypass and endovascular procedures among diabetic foot ulcer cases in the United States from 2001 to 2010. J Vasc Surg. 2014;60(5):1255-126.
12. de Smet GHJ, Kroese LF, Menon AG, et al. Oxygen therapies and their effects on wound healing. Wound Repair Regen. 2017;25(4):591-608.
13. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017;376(24):2367-2375.
14. Crews RT, Shen B-J, Campbell L, et al. Role and Determinants of Adherence to Off-loading in Diabetic Foot Ulcer Healing: A Prospective Investigation. Diabetes Care 2016;39:1371–1377.
15. Lin Y-J, Kao T-W, Chen W-L. Relationship between peripheral neuropathy and cognitive performance in the elderly population. Medicine. 2021;100(20):e26071 doi: 10.1097/MD.0000000000026071.
16. Kamineni S, Huang C. The antibacterial effect of sonication and its potential medical application. SICOT J. 2019;5:19:1-4.