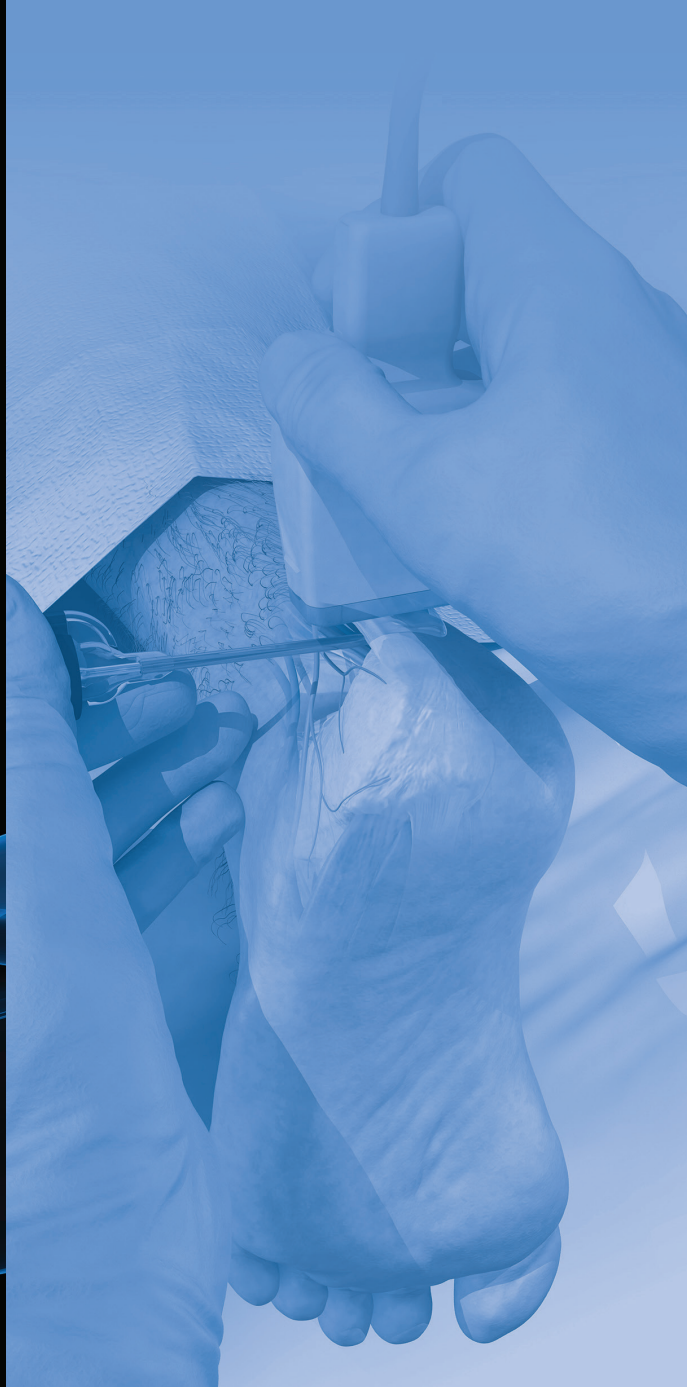
Tenex Health TX® System

Procedure Reference Guide for the Achilles Tendon and Haglund Deformity



TENEX HEALTH

Disclaimer: The information in this document is based on physician counsel and is intended for reference purposes only. A physician must always rely on his or her professional clinical judgment when deciding whether to use a particular product or procedure to treat a particular patient. Tenex Health does not dispense medical advice and recommends that the physician is familiar with the use of any particular product before using it in a procedure. Physicians should refer to the Intended Use and Instructions for Use before using any Tenex Health product. See the back page of this document for more details on indications for use, warnings and cautions.

Introduction

Tendinopathy can occur at the Achilles midportion or insertion. Insertional Achilles tendinopathy may have additional contributions from calcaneal enthesophytes, a prominent posterior superior calcaneus (referred to as a Haglund deformity), and associated retrocalcaneal and superficial bursitis. When symptoms fail to respond to conservative treatment and persist beyond 3-4 months, the clinical diagnosis becomes chronic refractory tendinopathy. Diagnostic imaging (X-ray, ultrasound, and MRI) can provide valuable information beyond the clinical history and physical examination and can help identify structural pathology amenable to treatment with the Tenex Health TX® System. Imaging is of particular importance when considering treatment of bone pathology in addition to the Achilles tendon.

The TX MicroTip allows the physician to perform a tenotomy and debridement quickly and safely in the outpatient setting through a small 5 mm incision. By using diagnostic ultrasound imaging technology, the diseased tissue is precisely localized and treated. This significantly reduces damage to surrounding tissues, reduces post-procedure pain, and accelerates recovery and return to activity. With the introduction of the TX-Bone MicroTip, the bone related contributions to the chronic tendinopathy can now be addressed, allowing for comprehensive treatment of Haglund's syndrome.

Pre-procedure Ultrasound

The pre-procedural ultrasound is required to confirm pathology amenable to treatment with the Tenex Health TX® System and to identify "at-risk" structures.

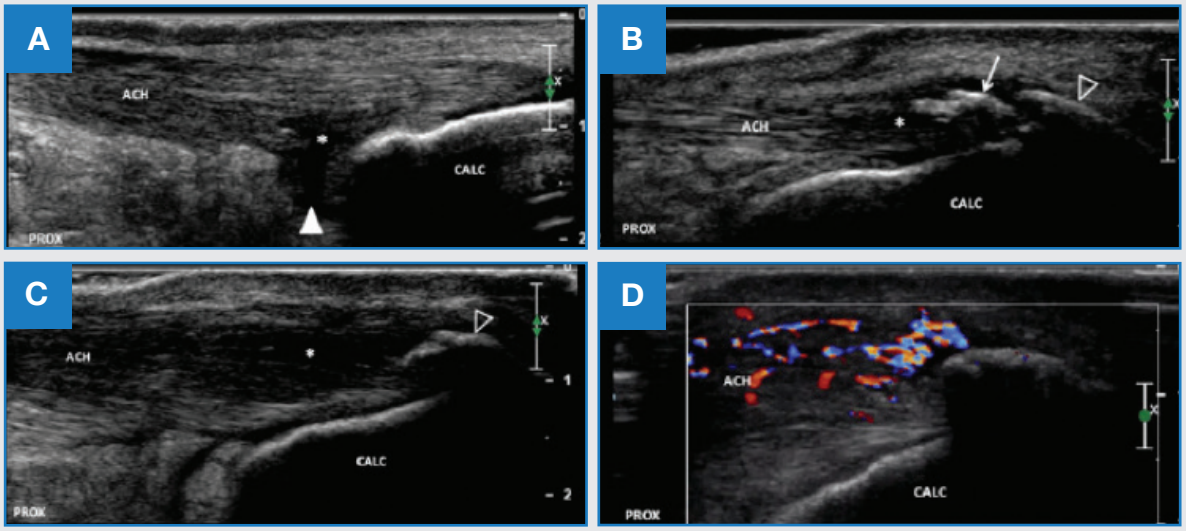
- **Confirm pathology**

  Chronic Refractory Tendinopathy (degenerative tendon tissue) appears hypoechoic, or dark, relative to surrounding healthy tissue (Figure 1). Calcifications within the region of degenerative tissue are also common which are hyperechoic, or bright. Regions of partial tearing will appear anechoic, or black, and may be fluid-filled. Doppler imaging will typically demonstrate neovessels within and surrounding the region of tendinosis (Figure 1). The abnormal region of tendon should correlate with the location of pain.

  In cases where a prominent Haglund deformity results in tendon impingement, resection with the TX-Bone MicroTip may be considered. Helpful findings in making this determination include partial tearing of the deep undersurface of the Achilles, cortical irregularities/prominence of the posterior superior calcaneus, retrocalcaneal bursitis, pain with palpation deep to the Achilles tendon, and deep pain with ankle dorsiflexion.

  Posterior calcaneal enthesophytes are often asymptomatic. However, they may be associated with superficial bursitis, localized swelling, and pain. If deemed symptomatic and resection is performed, the same considerations discussed with Haglund resection should be applied.

Figure 1.



Long-axis images of Achilles tendon insertion showing variability in the location and extent of pathologic findings. **(A)** Hypechoic changes (asterisk) are shown adjacent to the posterosuperior calcaneus. The boundary with the retrocalcaneal bursa (arrowhead) is poorly defined. Note the relatively normal appearance of the superficial/posterior portion of the tendon. **(B)** The deep/anterior portion of the tendon is relatively normal; however, changes of tendinosis (asterisk) are shown adjacent to an intratendinous calcification (arrow). There is minimal posterior acoustic shadowing suggesting a"soft" calcification, which is amendable to percutaneous debridement. An enthesophyte (arrowhead) shows dense posterior acoustic shadowing consistent with cortical bone. **(C)** Hypoechoic changes of tendinosis (asterisks) are more extensive and pronounced. An enthesophyste is present (arrowhead), but no intratendinous calcification is shown. **(D)** Color Doppler image corresponding to C. There is hyperemia within the superficial/posterior tendon as well as paratenon. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.

• Identify "at-risk" structures

The usual approach to the Achilles tendon in long axis does not encounter any significant at-risk structures. However, be familiar with the anatomic location of the sural nerve and consider documentation of location during the procedural planning.

If a lateral short axis approach is used, then documentation of the sural nerve position (and lateral calcaneal branches) becomes critical. Likewise, if a medial short axis approach is utilized, the medial calcaneal nerve (sensory branch from tibial nerve) should be carefully identified as well as any potential variant anatomy within the proximal tarsal tunnel.

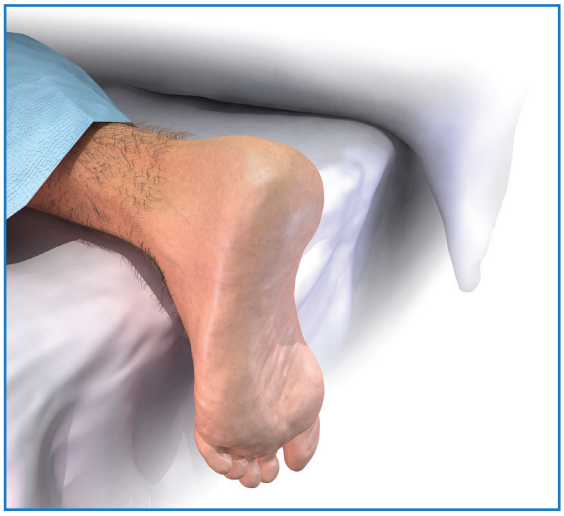
• Plan approach and entry site

A distal to proximal approach in the long axis of the Achilles tendon is preferred. Occasionally, a short axis approach may allow for treatment of a Haglund deformity and associated tendinopathy of the deep compressive side of the Achilles tendon. A lateral to medial approach is more ergonomic and typically allows for adequate resection. A medial approach may be considered in select cases. More than one incision may be required to fully address the pathology.

Appropriate entry site is critical when navigating posterior calcaneal enthesophytes. In cases of large enthesophytes, a proximal to distal approach may need to be considered.

Patient Positioning

• The patient should be positioned prone with feet hanging free off the edge of the table.



Preparation

• Clean the region with skin cleanser (e.g. Chlorhexidine).

• The surgical field should be squared off with sterile towels or drapes.

• A sterile ultrasound transducer cover and sterile ultrasound acoustic coupling gel should be used.

Anesthesia

• Local anesthetic should be used to create a skin wheal at the incision site and then infiltrated into the subcutaneous tissues, superficial bursa, and tendon down to the bone. Additional anesthetic into the retrocalcaneal bursa is recommended if the deep side of the tendon, the bursa, or the calcaneus will be debrided/resected.

• A short acting anesthetic should be used alone or in combination with a long acting anesthetic.

• Between 5-10mL of local anesthetic provides adequate anesthesia in most cases. Significant bone resection may require additional anesthetic in certain cases. Anesthesia should be titrated to patient comfort using the lowest effective dose.

• The flow pattern of the anesthetic within the tendon can be helpful to observe as regions of tendinosis or tear will often become more hypoechoic as the anesthetic fluid fills the region.

• A nerve block may be considered when bone resection is planned. The medial calcaneal branch of the tibial nerve and lateral calcaneal branch of the sural nerve should both be addressed. Additional training in regional anesthesia is recommended if not familiar with principles of ultrasound-guided nerve blocks.

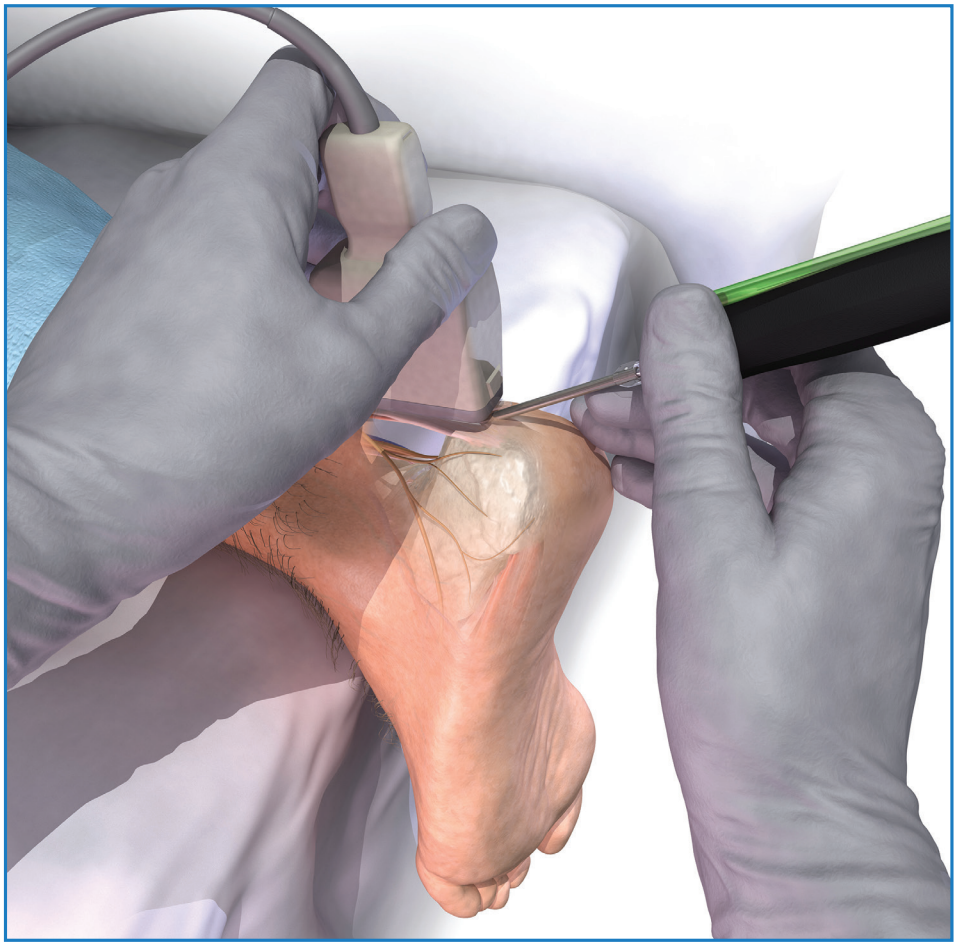
Technique

• Incision

A #11 blade should be used to make a stab incision at the skin and create a tract into the tendon. The incision should be performed in-line with the tendon fibers to avoid horizontal fiber laceration. If possible, the incision should be performed under live ultrasound guidance (Figure 2). More than one incision may occasionally be required to adequately address all pathologic tissue.

• Tendon and Bursa Debridement

When using a distal to proximal long axis approach, the TX MicroTip is first used to debride the superficial/posterior bursal tissue and thickened paratenon from the Achilles tendon until the device can move freely and unobstructed within this tissue plane. Then the regions of intra-tendinous pathology identified during the pre-procedural scan are addressed. This may include regions of degenerative tendon tissue as well as calcifications. If retrocalcaneal bursitis is present, the debridement may be extended into the bursal tissue as well.



Once the TX MicroTip has entered the tendon, try to avoid completely withdrawing from the tendon while the foot pedal is activated. This will reduce the amount of irrigation fluid that leaks into the surrounding tissues. The TX MicroTip should be moved in a “pistoning”

action with forward and back motion at all times. Never sweep the TX MicroTip left to right. The energy should be cycled with the foot pedal to ensure adequate aspiration and cooling of the device. The recommended duty cycle is 15 seconds on, 45 seconds off. The console will provide an audible signal if aspiration slows or stops. If this happens, the device should be slightly withdrawn a few millimeters. If this does not restore adequate aspiration, the foot pedal should be deactivated to allow the aspiration system to clear. Energy times will vary based on the extent and composition of the pathology. Energy times should not exceed 10 minutes when using the TX1 or TX2 MicroTips. Cumulative energy time (both hard and soft tissue) may be extended to 15 minutes when using the TX-Bone, but hard tissue applications should not exceed 10 minutes.

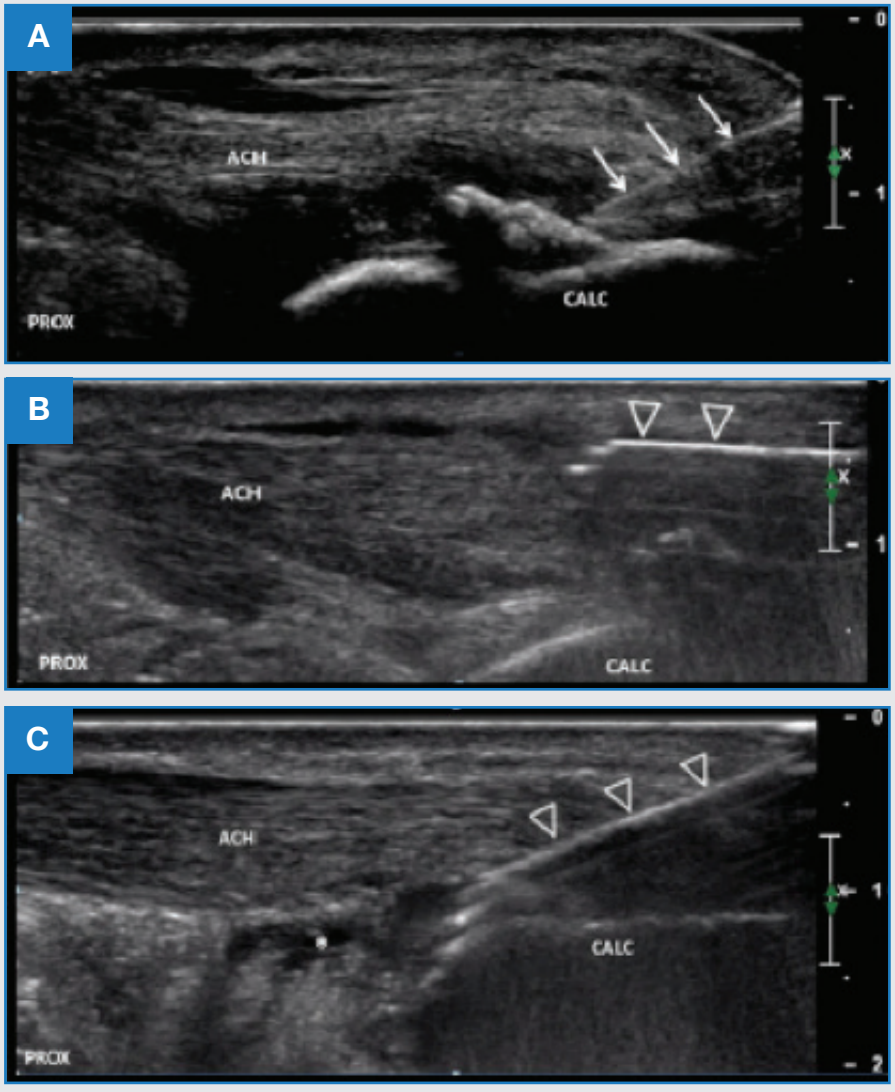
• Bone Resection

When using the TX-Bone MicroTip to treat a Haglund deformity or posterior calcaneal enthesophyte, the same general principles mentioned above apply. Bone is best resected using a “shaving” technique in which the TX-Bone MicroTip is introduced at the most superficial aspect of the targeted bone with subsequent passes moving to deeper layers as the resection is performed. The TX-Bone MicroTip should always be moved in a forward and back motion and never swept side to side. Care should be taken to avoid aggressive placement of the TX-Bone MicroTip into the bone which may result in obstruction of the aspiration lumen or potential damage to the device.

• Confirmation

Effective treatment of the targeted tissue is appreciated when there is a tactile change in resistance at the tip of the device and a change in the local tissue appearance on ultrasound. The region of tendinosis which was hypoechoic will often demonstrate hyperechoic microbubbles from the irrigation fluid after debridement. Any calcifications should decrease in size and lose posterior acoustic shadowing (meaning tissue deep to the calcification should become visible). Regions of targeted bone should visibly change in contour. Fluoroscopy may be considered as needed to further confirm bony resection.

Figure 2.

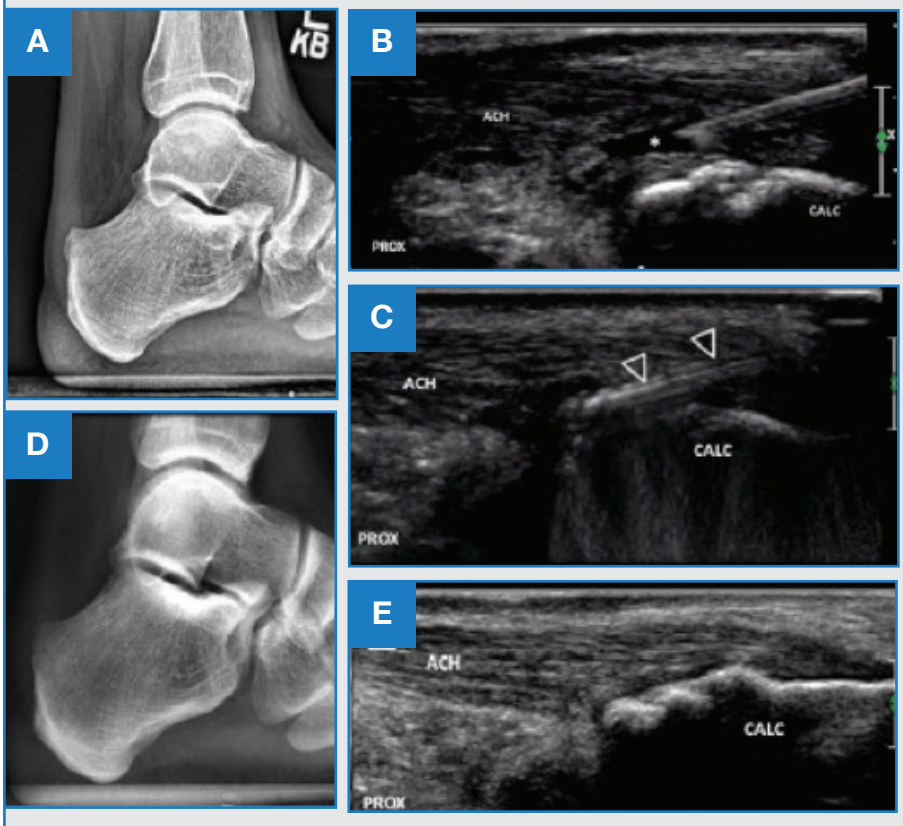


Long-axis images of the Achilles tendon showing the procedural technique. **(A)** After administration of local anesthesia, a number 11 blade (arrows) is used to make an incision down to the tendon. **(B)** The TX device (arrowheads) is then introduced superficial/posterior to the tendon, and the hypertrophied paratenon and connective tissue are debrided from the tendon. **(C)** The device is then guided into the tendon, and the regions tendinosis are debrided. In this example, there was concomitant retrocalcaneal bursitis (asterisk), and a limited bursectomy was performed. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.

Special Considerations

- Decision on treatment of soft tissue vs bone is made based on a comprehensive history, physical examination, and characteristic structural findings on imaging.
- When there is significant partial thickness tearing or concern for functional insufficiency of the Achilles tendon, repair and/or augmentation techniques may need to be considered in addition to debridement with or without bone resection. These are clinical decisions made on a case by case basis.
- Given the large variation in pathology and anatomy in this region, the physician should be comfortable with multiple approaches and familiar with all regional anatomy including the sural nerve and lateral calcaneal branches and the medial calcaneal branch of the tibial nerve.
- When using the cutting function on the console, there will be a 1 second delay between activation of the foot pedal and delivery of ultrasonic cutting power. This is to allow for sufficient supply of irrigation fluid to the TX MicroTip.
- Never sweep the TX 1, TX 2, or TX-Bone left to right. Always keep needle tip bevel facing up to help with navigation and removal of tissue.
- A user-controlled duty cycle of 15 seconds ON, 45 seconds OFF (15s/45s) is to be followed. This is equal to a ratio of 1:3 of FOOT PEDAL ON time to FOOT PEDAL OFF time with a maximum of 15 seconds of continuous FOOT PEDAL ON time.

Figure 3.



Haglund bony debridement. **(A)** Prepro–cedural radiograph showing a posteriorly projecting bony protuberance at the pos–terosuperior calcaneus, which correlated with the location of the patient's maximal pain. **(B)** Procedural long-axis sonogram during local anesthesia showing a partial-thickness tear (asterisk) adjacent to the region of cortical irregularity at the posterosuperior calcaneus. **(C)** The TX device (arrowheads) is used to shave down the posteriorly projecting bony protuberance using a layer-by-layer technique working from superficial to deep. **(D)** Follow-up radiograph at 6 weeks showing decreased prominence of the previously noted bony remodeling and complete healing of the debrided partial-tendon tear. The patient reported no pain or functional limitation at the 3-year follow-up. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.

After Care

• Wound closure and care

The incision is closed with a single adhesive wound closure strip followed by a transparent film dressing. A compression sleeve/sock is recommended. The wound should not be submerged under water for 2 weeks.

• Activity restrictions

Protected weight bearing is as tolerated in a walking boot for the first 7-14 days. Gentle non-weight bearing pain free range of motion should begin the day following the procedure. Light walking for daily activities may resume as tolerated, typically 2-4 weeks after the procedure. Return to heavier use (running, jumping, lifting, etc.) should be decided on an individual basis, but not sooner than 6 weeks post-procedure.

• Pain management

Ice, compression, and activity modifications are typically sufficient for adequate pain management. If no contraindications, over-the-counter analgesics such as acetaminophen may be used. Based on potential negative impact on tendon healing and growth factors, NSAIDs would be held from treatment immediately post-procedure.

• Rehab

Post-procedure rehabilitation may vary based on the degree of pathology treated and the functional demands of the patient. A sample rehabilitation protocol is included here:

Criterion Based Rehabilitation Progression Following Ultrasound Guided Tendon Debridement of the Lower Limb

Rehabilitation Phase	Estimated Timeline*	Special Considerations	Restrictions	Goals	Functional test to progress to next phase
1	0–2 weeks	Early NWB pain free ROM encouraged starting day after procedure	1. PWB on crutches x 7 days (knee/hip) 2. WBAT in walking boot x 7 days (foot/ankle) 3. May d/c crutches/boot when able to walk pain free without a limp 4. Do not walk barefoot (foot/ankle)	1. Control swelling 2. Restore ROM 3. Muscle activation	1. Normal/symmetrical gait pattern (no assistive device) 2. Pain free passive ROM (ankle dorsiflexion, hip and knee flexion)
2	2–6 weeks	Pain < 3/10 with all activities	1. No running, jumping, cutting, pivoting	1. Neuromuscular control 2. Proprioception 3. Gentle muscular strengthening	1. Foot/Ankle: at least 1 unilateral SL heel raise through full ROM 2. Knee/Hip: Single let squat through partial ROM
3	6+ weeks		1. Monitor load progression#	1. Progressive strengthening 2. Sport/region specific RTP preparation	1. Lunge walk x 10 steps 2. Pain free jogging prior to formal return to run progression 3. 10 single leg hops
4	12+ weeks	Not applicable for all patients	1. Continue to monitor load progression#	1. Full unrestricted return to sport/work 2. Transition to maintenance program (S&C, personal trainer, self–directed HEP)	1. Specific to demands of sport/position 2. Guided by AT and S&C staff

* To be used as a general guide based on biologic tissue healing. This timeline does not consider the location and extent of diseased tissue as well as other intrinsic patient factors that may impact time to clinical healing.

Basic load progression principles: Pain level <3/10 activity. Any pain associated with the activity should not persist into the following day. If pain persists than load needs to be decreased.

• Follow up recommendations

Follow up may vary. An initial wound check is recommended between 1-3 weeks and additional appointments as needed to provide guidance on functional progression and release to activity. A common follow up schedule would be 2 weeks, 6 weeks and 12 weeks.

Reference:

Chimenti, R.L., Stover, D., Fick, B., Hall, M. Percutaneous Ultrasonic Tenotomy Reduces Insertional Achilles Tendinopathy Pain With High Patient Satisfaction and a Low Complication Rate. *J Ultrasound Med.* 2018; 00: 1–7

INDICATIONS FOR USE:

The Tenex Health TX® System (with the TX1/TX2 MicroTips) is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

The Tenex Health TX® System with the TX-Bone (TXB) MicroTip is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of both soft and hard (e.g.: bone) tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

The Tenex Health TX® System with the TXB MicroTip (TXB) is also indicated for use in the debridement of wounds, such as, but not limited to, diabetic ulcers, in applications in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

Specific use. The Tenex Health TX® System's minimally invasive technology is an ultrasonic surgical tool that can be used to perform diverse procedures within the cleared intended use of the device, such as for tendinopathy or resection of Haglund bone deformity.

WARNINGS:

- DO NOT use the MicroTip after the expiration date indicated on the package.
- The MicroTip is sterile if package is unopened and undamaged. DO NOT use if the sterile package has been compromised.
- DO NOT check function of the MicroTip by placing hand or finger against the tip or unintended damage to healthy tissue may result.
- Monitor the location of the MicroTip during use. Failure to monitor the location of the tip of the device may present a hazard to the user, result in damage to unintended tissue or limit the ability to detect device malfunction or damage to the MicroTip related to use.
- DO NOT hold MicroTip static. Keep the MicroTip moving using axial motion when targeting and emulsifying tissue to prevent damage to the MicroTip and/or occlusion of the tip. Due to friction related to ultrasonic vibration, appropriate technique is necessary for thermal management at the treatment site and will minimize the potential for tissue burns.
- Verify integrity of the MicroTip needle and irrigation sheath upon completion of treatment. Failure to do so may result in device remnants left in the patient in the event of device damage.
- DO NOT recap the tip of the MicroTip.
- The MicroTip is single use. DO NOT resterilize/reuse. Reusing the device could result in compromised device performance, cross-infection, and other safety hazards.
- Surgical waste presents a biological hazard and must be handled and disposed of properly. The MicroTip must be disposed of according to local regulations.
- *{TXB}:* Use standard wound care management pre and post treatment. This should include administration of prophylactic antibiotics as appropriate. Failure to utilize standard wound care management pre and post treatment may increase the risk of infection or cross-infection.
- *{TXB}:* To prevent cross-infection, DO NOT use the device on multiple treatment sites.

CAUTIONS:

- Product uses Di (2-ethylhexyl) phthalate (DEHP) plasticized PVC. DEHP is a commonly used plasticizer in medical devices. There is no conclusive scientific evidence to date that exposure to DEHP has a harmful effect on humans. However, the risk and benefit of using medical devices with DEHP for pregnant women, breastfeeding mothers, infants and children should be evaluated prior to use.
- Only use 500cc saline irrigation bag for TX1/TX2. Only use 1000cc saline irrigation bag for TXB. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.
- Always check the saline irrigation bag for leaks prior to surgical procedures.
- DO NOT rest the saline irrigation bag on the TX Console enclosure or touchscreen.
- Gown and prepare the necessary instrumentation for STERILE procedures according to your institution's requirements.
- Failure to align the Red Dot on the MicroTip connector with the Red Dot on the console receptacle may damage the connector pins.
- Ensure successful priming cycle and presence of acoustic signal prior to incising the patient.
- Individual TX Supply Kit components (if present) are sterile if the individual package is unopened and undamaged.
- The TX1 and TX2 MicroTips should not be used on hard tissue such as bone.
- CAUTION: The Tenex Health TX® System should not be used on bone cement.
- CAUTION: Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.
- CAUTION: DO NOT activate the MicroTip with the tip in air as immediate damage may result.
- CAUTION: DO NOT use the device if the tip of the MicroTip is received bent or is bent during use.
- CAUTION: DO NOT use this device if it fails to function as described in the Operator's Manual supplied with your TX Console.
- CAUTION: Maximum tip temperature can approach 47 degrees C. This does not present a hazard to the patient if the TX System is used according to the recommended duty cycle: 15 seconds on, 45 seconds off on HIGH cutting power.
- DO NOT use the TX1 or TX2 Microtip for a total cutting time exceeding 10 minutes. Failure to limit use beyond the maximum cutting time could result in device damage or failure.
- CAUTION: DO NOT laterally load the MicroTip during use. Failure to follow appropriate technique could result in potential hazard to adjacent tissue due to excessive heating or damage to the MicroTip such as a broken needle and/or damage to irrigation sheath.
- Minimal edema associated with the TX system occurs only occasionally and is considered a routine response to treatment.
- *{TXB}:* DO NOT use the TXB for a total cutting time exceeding 10 minutes on hard tissue or 15 minutes cumulative (hard and soft tissue). Failure to limit use to the maximum cutting time could result in device damage or failure.
- *{TXB}:* Utilize Universal Precautions and Sterile Technique at all times. Failure to do so can lead to increased risk of infection or aggravation of a recent infection.
- *{TXB}:* Insufficient off-loading of the ulcer in the post-treatment period and subsequently may lead to sub-optimal outcomes, including recurrence of the ulcer (increased potential for skin breakdown and associated infection).

TENEX
HEALTH

26902 Vista Terrace - Lake Forest, CA 92630 - P 949.454.7500 - F 949.580.1270 - info@tenexhealth.com - www.TenexHealth.com