Tenex Health TX® System

Ultrasound Guided Tenotomy Procedure Reference Guide for the Elbow

TENEX HEALTH

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Introduction

Tendinopathy can occur at multiple locations about the elbow including the common extensor tendon (often referred to as lateral epicondylitis or “tennis elbow”), the common flexor/pronator tendon (often referred to as medial epicondylitis or “golfer’s elbow”), and the triceps tendon. When symptoms fail to respond to conservative treatment and persist beyond 3-4 months, the clinical diagnosis becomes chronic refractory tendinopathy. Diagnostic imaging with ultrasound or MRI, can provide valuable information beyond the clinical history and physical examination and identify structural pathology amenable to treatment with the Tenex Health TX® System.

The TX MicroTip allows the physician to perform a tenotomy and debridement quickly and safely in the outpatient setting through a small 3 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.

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

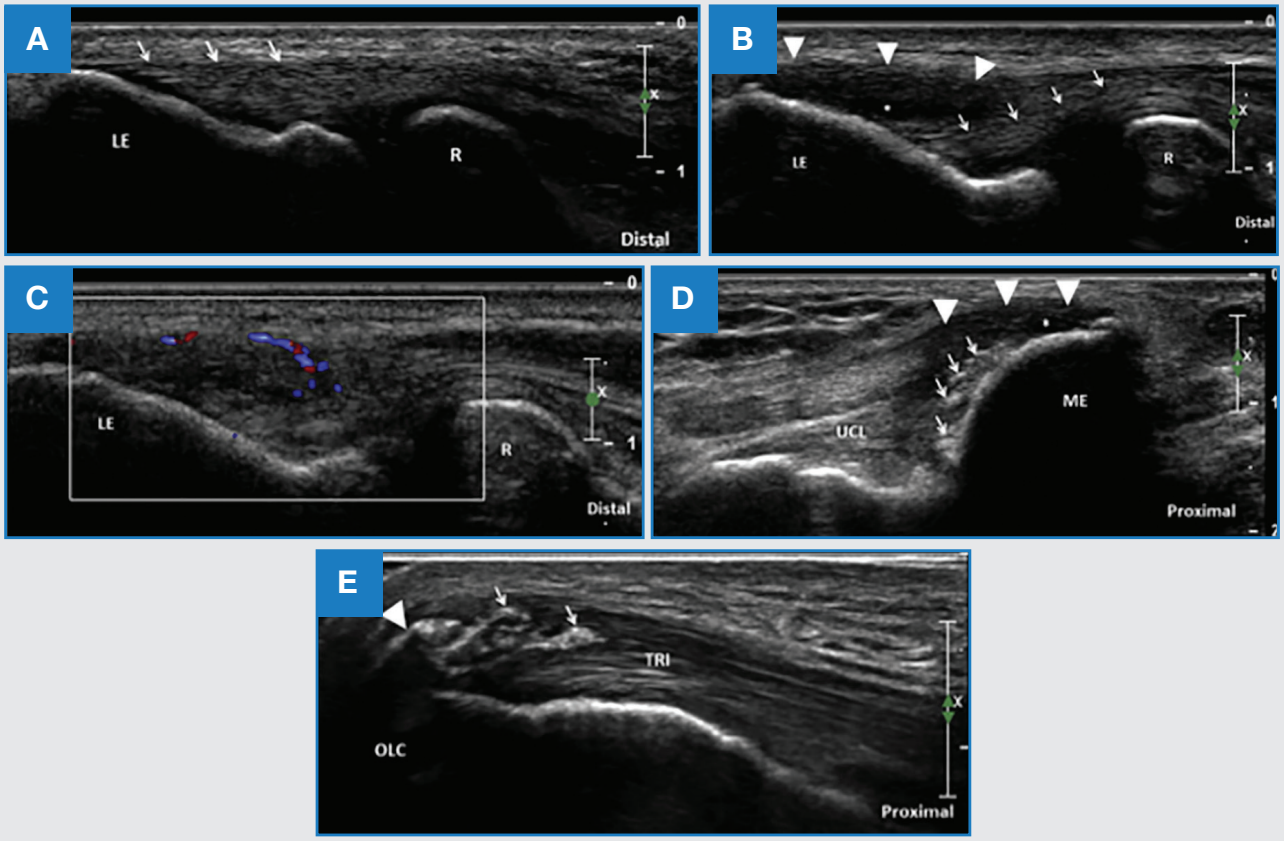
Chronic Refractory Tendinopathy (degenerative tendon tissue) appears hypoechoic, or dark, relative to surrounding healthy tissue (Figure 1). Calcifications within the region of degenerative tissue are also common which are hyperechoic, or bright. Regions of partial tearing will appear anechoic, or black, 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.

• Identify “at-risk” structures

The usual approach to the common extensor tendon does not encounter any significant at-risk structures. However, be familiar with the anatomic location of the radial collateral ligament (Figure 1) and take care not to extend incision or debridement into the ligament. The radial nerve/posterior interosseous nerve should not be in the field, but confirmation of location during the pre-procedural planning is recommended.

The ulnar nerve should be identified when planning the approach to the common flexor tendon and the triceps tendon. Ulnar nerve subluxation/dislocation may occur with elbow flexion and this should be noted. A history of ulnar nerve transposition may place the nerve directly in the surgical approach to the flexor tendon and may represent a contraindication to treatment.

Figure 1.



Pre-procedure diagnostic ultrasound demonstrating the typical findings of tendinosis amendable to ultrasound-guided tenotomy. **(A)** Normal long axis appearance of the common extensor tendon with tightly packed and well-organized hyperechoic fibers (→). **(B)** The common extensor tendon origin is swollen and hypoechoic with loss of the tightly packed fibrillar structure represented as heterogeneity of the tendon (▶). A linear region of anechogenicity (*) likely represents a small partial-thickness intrasubstance tear. Note the normal appearance of the radial collateral ligament deep to the common extensor tendon (→). **(C)** Color Doppler image demonstrating neovascularity (color flow) within the region of tendinosis. **(D)** Long-axis image of the common flexor tendon with similar findings of tendinosis including hypoechoic swollen tendon origin (▶) with region of high grade tendinosis vs. partial-thickness tear (*). Small calcifications (→) are also appreciated that extend into the ulnar collateral ligament (UCL) humeral attachment. **(E)** Long-axis image of triceps tendon (TRI) insertion demonstrating amorphous intratendinous calcification (→) adjacent to an olecranon enthesophyte (▶). *LE*, lateral epiconyle; *R*, radius; *ME*, medial epicondyle; *OLC*, olecranon.

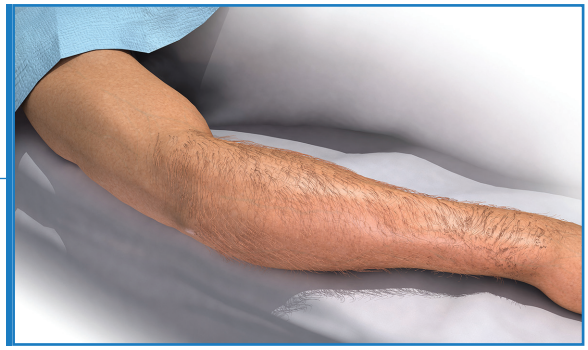
• Plan approach and entry site

A distal to proximal approach in the long axis of the common extensor tendon is preferred. Avoid an overly anteromedial approach through the musculature which may result in increased bleeding and post-procedure pain as well as potential injury to the radial nerve and/or posterior interosseous nerve.

A similar distal to proximal approach in the long axis of the common flexor tendon is also preferred. The location of the ulnar nerve is of utmost importance and the approach should be anterior to the nerve.

For the triceps tendon, a proximal to distal approach in the long axis of the tendon typically allows for optimal treatment of the involved tendon included regions associated with enthesophytes.

Patient Positioning



- **Common extensor tendon**

The patient should be positioned supine with the head of the bed elevated 30-45 degrees and the elbow resting on the procedure table in pronation and slight flexion.

- **Common flexor tendon**

The patient should be positioned supine or side-lying with the upper limb abducted and the elbow supinated and extended. Elbow flexion should only be considered if the ulnar nerve position is documented in a safe location relative to the tendon.

- **Triceps tendon**

The patient should be positioned prone with the upper limb abducted and the elbow flexed 90 degrees with the forearm and hand hanging free off the edge of the procedure table.

Preparation

- Clean the region with skin cleanser.
- 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 and tendon down to the bone.
- 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. 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.

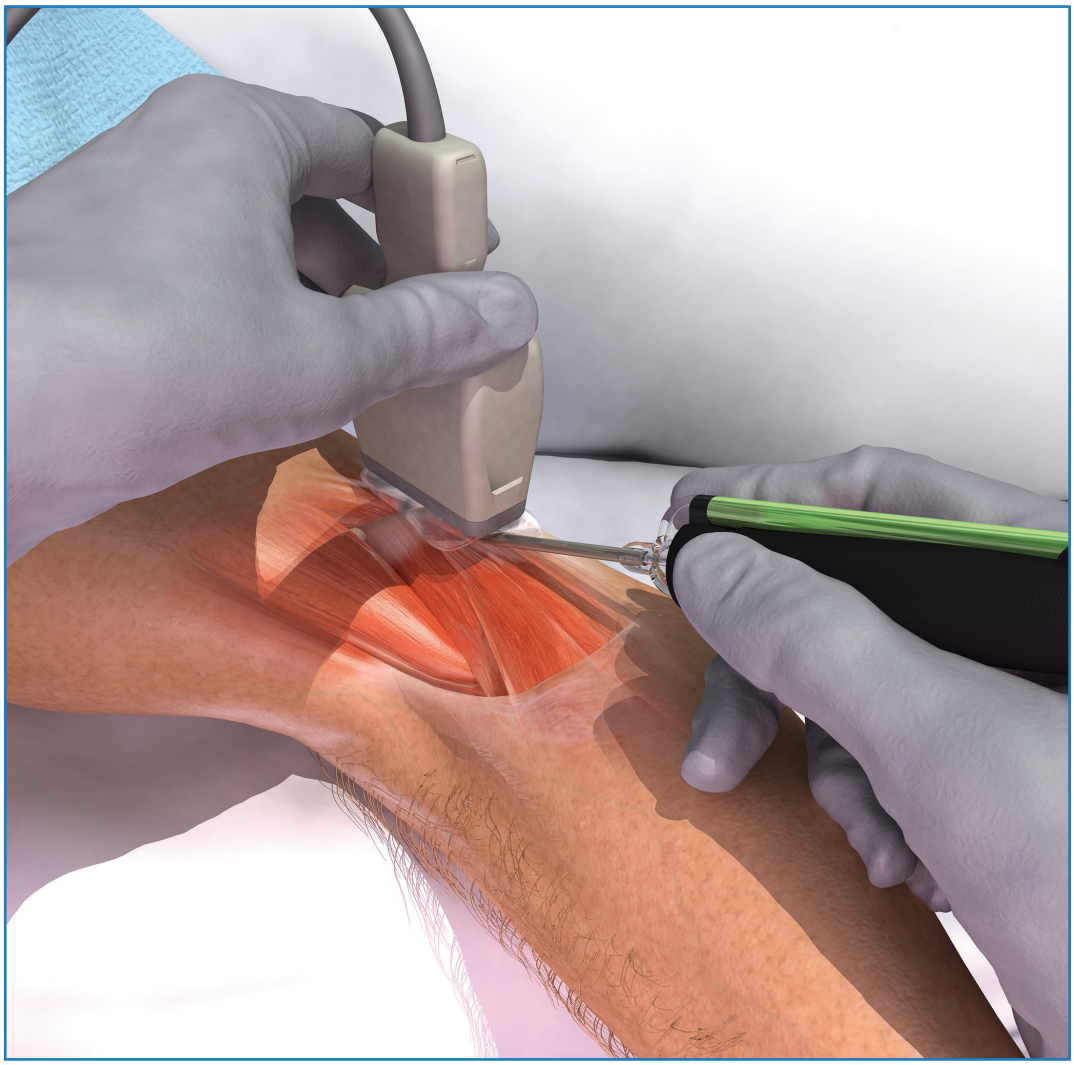
Technique

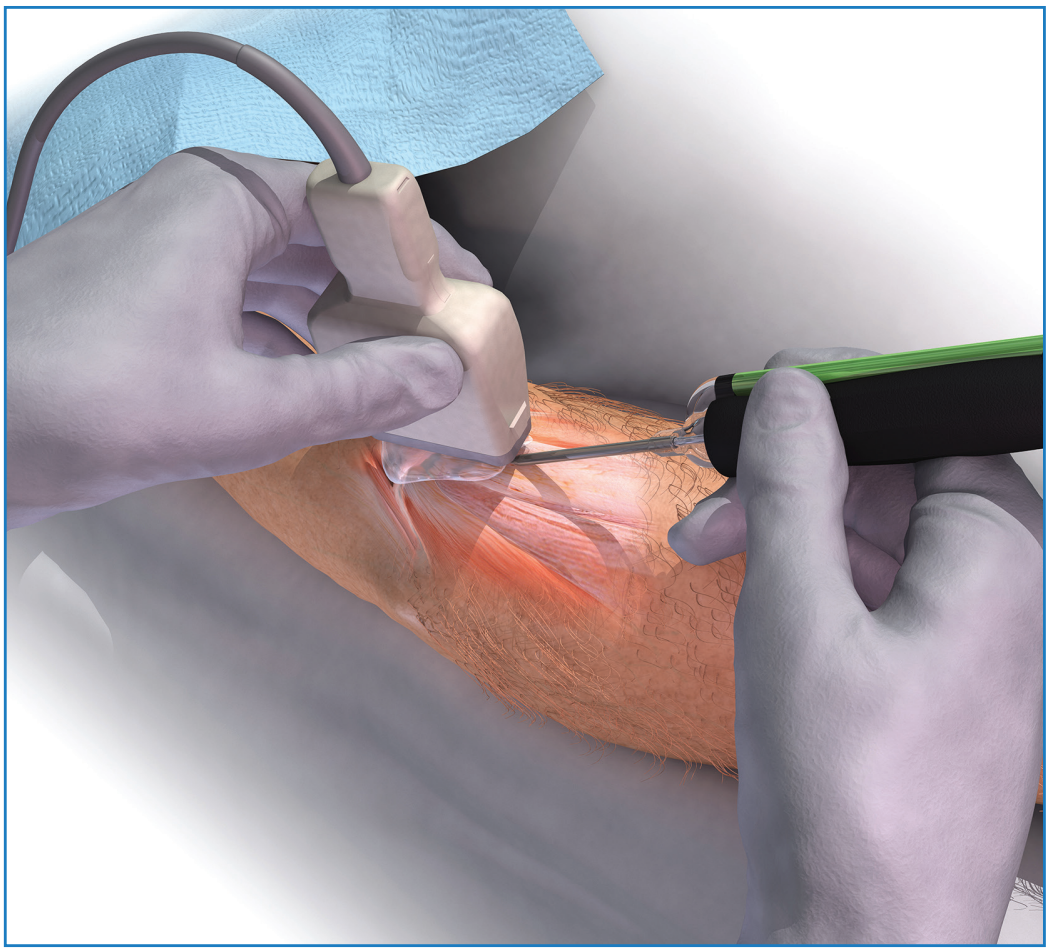
• Incision

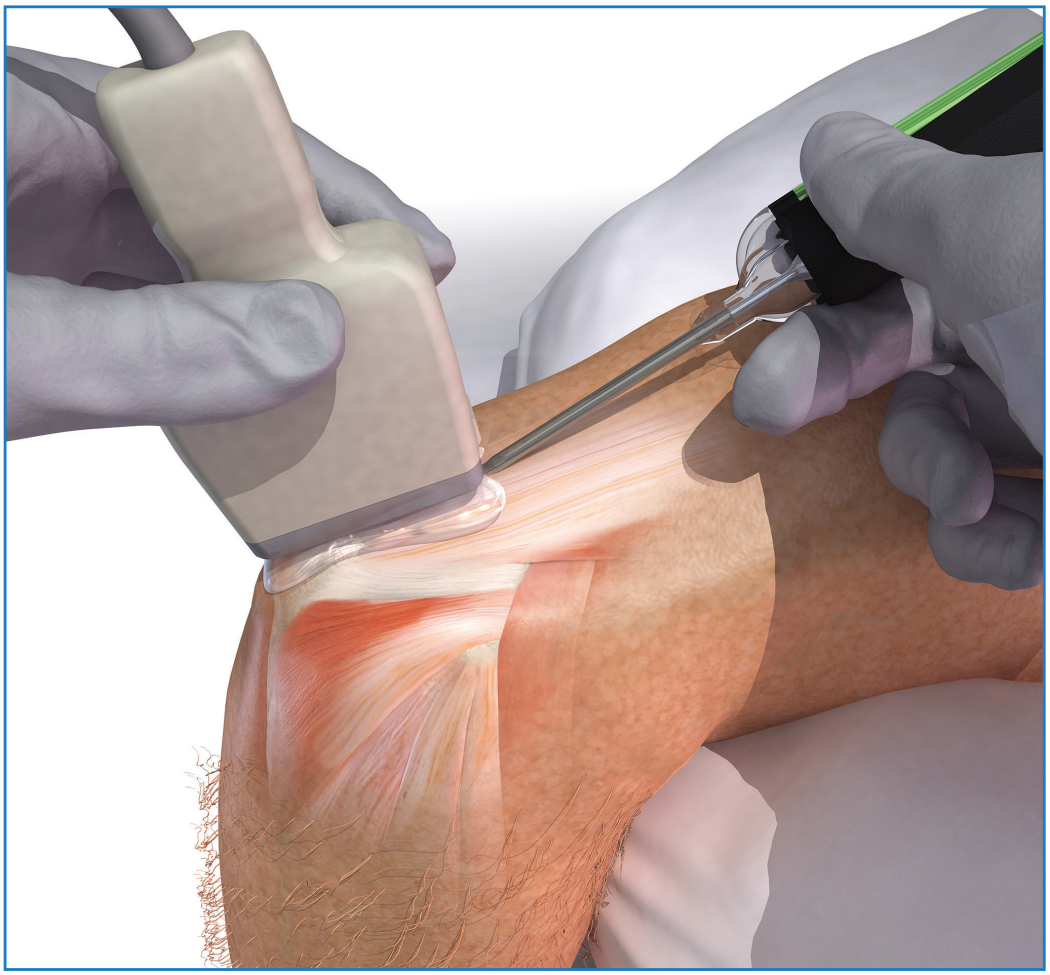
A #11 blade should be used to make a stab incision at the skin and create a tract into the tendon. If possible, the incision should be performed under live ultrasound guidance (Figure 2). The incision should be performed in-line with the tendon fibers to avoid horizontal fiber laceration.

• Debridement

The TX MicroTip is then inserted through the skin and guided into the region of tendinosis and/or calcification. Once the TX MicroTip has entered the tendon, try to avoid withdrawing completely 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.





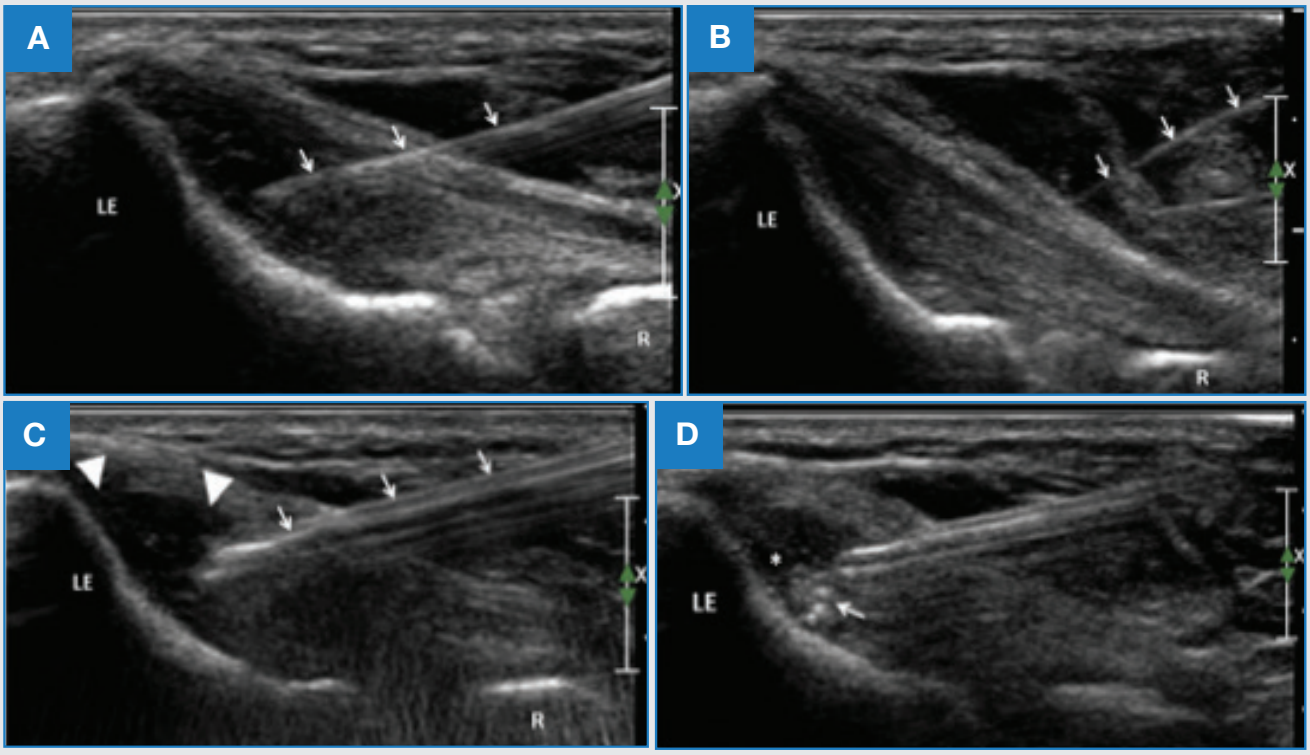


The energy should be cycled with the foot pedal to ensure adequate aspiration and cooling of the device. The recommended duty cycle is 15 seconds on, 45 seconds off. The console will provide an audible signal if aspiration slows or stops. If this happens, the device should be slightly withdrawn a few millimeters. If this does not restore adequate aspiration, then 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 with some focal regions only requiring less than 1 minute. 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.

• Confirmation

Effective treatment of the targeted degenerative 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 (Figure 2). Any calcifications should decrease in size and lose posterior acoustic shadowing (meaning tissue deep to the calcification should become visible).

Figure 2.



Ultrasound-guided tenotomy of the common extendor tendon. **(A)** Local anesthesia is delivered with a 27- or 25 gauge needle (g) into the subcutaneous tissues and down to the region of tendinosis. **(B)** A No. 11 scalpel blade (g) is used to make a 5-mm incision down to the tendon to allow introduction of the cutting device. **(C)** The TX 2 device (g) débrides the region of hypoechoic degenerative tissue (▶). **(D)** Once débridement is complete, the hypoechoic degenerative tissue is replaced with anechoic irrigation fluid (*) and hyperechoic microbubbles (→). *LE*, lateral epicondyle; *R*, radius.

Special Considerations

- Document location of ulnar nerve including any subluxation/dislocation with elbow flexion.
- Avoid overdistension of the olecranon bursa with irrigation fluid when treating the triceps tendon.
- Incision over the olecranon/point of flexion of the elbow should be avoided.
- 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 MicroTip 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.

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 Upper Limb

Rehabilitation Phase	Estimated Timeline*	Special Considerations	Restrictions	Goals	Functional test to progress to next phase
1	0–2 weeks	Early ROM encouraged starting day after procedure	1. Sling use only as needed for initial pain control 2. No lifting > 5 lbs 3. Limit repetitive use	1. Control swelling 2. Restore ROM 3. Muscle activation	1. Pain free elbow and shoulder ROM
2	2–6 weeks	Pain < 3/10 with all activities	1. No lifting > 5 lbs	1. Neuromuscular control 2. Proprioception 3. Gentle muscular strengthening	1. 5 lb lateral raise with elbow extended
3	6+ weeks		1. Monitor load progression#	1. Progressive strengthening 2. Sport/region specific RTP preparation	1. Symmetric grip strength 2. 5 push–ups (standard or knee supported)
4	12+ weeks	No applicable for all patients	1.	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:

Stover, D., Fick, B., Chimenti, R.L., Hall, M. Ultrasound-guided tenotomy improves physical function and decreases pain for tendinopathies of the elbow: a retrospective review. *J Shoulder Elbow Surg.* 2019; 28: 2386-2393. https://doi.org/10.1016/j.jse.2019.06.011

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.

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.

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