TENEX HEALTH TX® SYSTEM CLINICAL PUBLICATIONS

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ELBOW

Barnes DE. Ultrasonic energy in tendon treatment. Operative Techniques in Orthopaedics 2013;23(2):78-83. [Elbow]

Tenotomy and debridement of diseased tendon can resolve symptoms due to chronic degenerative tendinopathic lesions (i.e. tennis elbow). Recent improvements musculoskeletal ultrasound imaging and the development of a minimally invasive ultrasound-guided ultrasonic energy debridement tool, the TX1 MicroTip from Tenex Health, have created a viable less-invasive alternative to open tenotomy and debridement procedures. The rationale behind this novel and minimally invasive procedure is to first ultrasonographically visualize the diseased portion of the tendon. Next, a small ultrasonic cutting and debridement tool is percutaneously inserted and guided under dynamic sonographic imaging into the tendinopathic region to complete a percutaneous tenotomy or fasciotomy. The TX1 MicroTip is safe and has demonstrated similar or better outcomes to open tenotomy and fasciotomy.

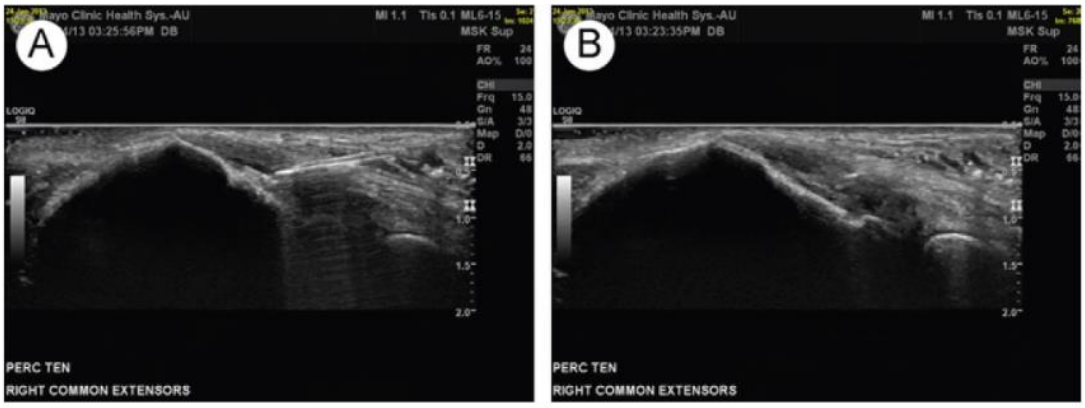


Figure 12 (A) US appearance of tendinopathic area prior to treatment. (B) US appearance of tendinopathic area after treatment.

Koh JSB, et al. Fasciotomy and surgical tenotomy for recalcitrant lateral elbow tendinopathy: early clinical experience with a novel device for minimally invasive percutaneous microresection. American Journal of Sports Medicine 2013;41(3):636-644. [Elbow]

Purpose: To explore the safety and efficacy of a new minimally invasive mode of treatment that delivers focused, calibrated ultrasonic energy, effectively microresecting and removing the pathological tendon tissue with the Tenex Health TX1 device. This prospective study explores the safety, tolerability and early efficacy of this technique in patients suffering from lateral epicondylitis.

Results: Twenty (20) patients between the ages of 33-65 years of age underwent the ultrasonic microresection procedure in an outpatient clinic setting using the TX1 device. The patients had failed non-operative therapy and were symptomatic for an average 12.5 months. Patient's baseline pain (VAS), quality of life/QOL (DASH Score) and ultrasound evidence of tendonosis were documented and at 2 weeks, and 1, 3, 6, and 12 months post-procedure. There were no device or patient related complications. All patients were treated under local anesthesia with an average ultrasonic energy application of 33 seconds required to complete the percutaneous tenotomy. No additional treatments or physical therapy were provided to the patients. Improvement in pain and QOL measurements were observed in 2 weeks and reached statistical significance by 1 month, which was sustained at 12 months. 19 of the 20 patients (95%) expressed satisfaction with the procedure.

Conclusion: Ultrasonic microresection of diseased tissue with the Tenex Health TX1 device provides a focally directed, safe, specific, minimally invasive and well-tolerated treatment for recalcitrant elbow tendinopathy in an office based or ambulatory setting with good evidence of some level of efficacy in 19 of 20 and is sustained for at least one year.

Morrey BF. Ultrasound percutaneous tenotomy for epicondylitis. Techniques in Shoulder and Elbow Surgery 2013;14(2):51-58. [Elbow]

The use of therapeutic ultrasound is well recognized in the medical field. Successful medical treatment of cataracts with phasoemulsification is now treated quickly and effectively as an outpatient surgery. The same concept has been applied for the management of chronic tendinopathy. This treatment employs an ultrasonic probe – surgical instrument that uses ultrasonic energy to effectively tenotomize the diseased tendon. Ultrasound imaging is used to diagnose and identify the pathology of diseased tissue and the treatment can be performed in a clinical or ambulatory surgical center. The patient is placed supine on an operating or clinical exam table and positioned based on surgeon preference and anatomical location. The site of maximum tenderness is identified by the patient, confirmed by the physician and diagnostic ultrasound identifies the hypoechoic area that appears darkened under ultrasound imaging. The area is prepped and a fast-acting local anesthetic is used to create a skin wheal approximately 1.5 cm. The needle is then advanced through the skin wheal to the area of precise tenderness and 3 to 4 ml of a fast-acting anesthetic is injected in the region. To facilitate the percutaneous insertion of the Tenex Health TX1 ultrasonic probe, a size 11 scalpel blade is used to create a puncture site through the skin wheal. The TX1 MicroTip is then introduced through the puncture site, identified with the sensor and under ultrasound guidance is introduced to the hypoechoic region. During the procedure, the TX1 MicroTip surgical instrument is moved in a linear manner in and out of the lesion and the hypoechoic region is visually altered, indicating the lesion has been effectively treated. <u>The procedure is extremely well tolerated and has a low complication rate. The effectiveness appears to improve up to one year after the initial procedure and is emerging as a viable and attractive alternative for the treatment of chronic epicondylitis.</u>

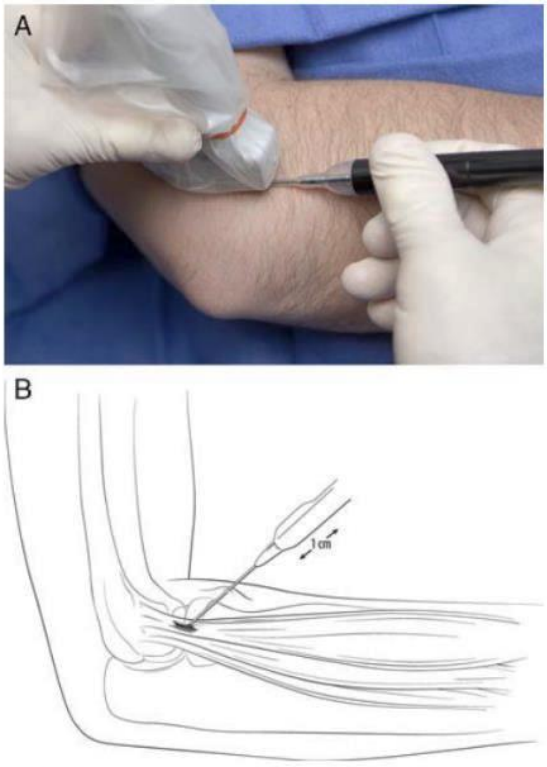


FIGURE 14. In a patient with lateral epicondylitis, the probe has been directed into the hyperechoic area (A). The lesion is treated with a back and forth motion (B).

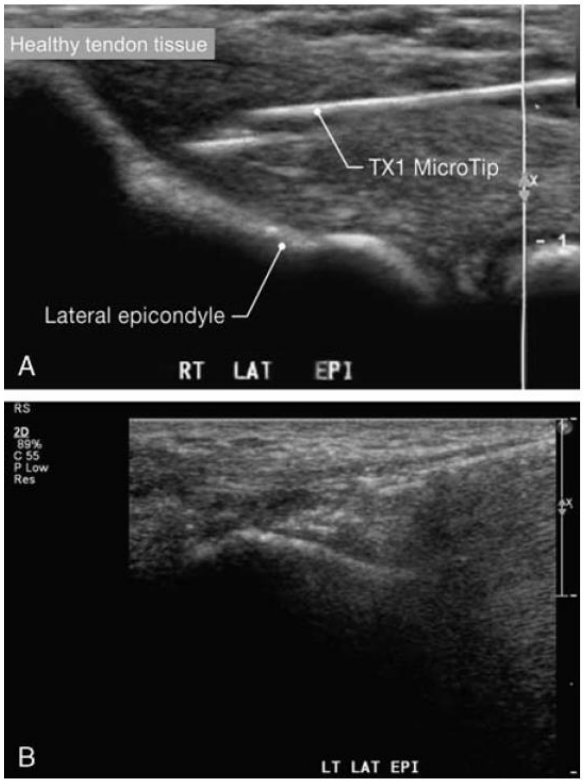


FIGURE 15. After approximately 30 seconds of treatment, the hyperechoic area has assumed a more normal echoic appearance. This is the visual indication of adequate treatment.

Barnes DE, Beckley JM, Smith J. Percutaneous ultrasonic tenotomy for chronic elbow tendinosis: a prospective study. Journal of Shoulder and Elbow Surgery 2015;24(1):67-73. [Elbow]

Clinical "lateral epicondylitis" or "tennis elbow" is the most common cause of elbow pain, affecting 2-3% of the population and resulting in significant activity restriction and economic burden. Although historically considered to be an inflammatory condition of the common extensor tendon, it is now well established that chronic symptoms are typically associated with tendon degeneration resulting from repetitive microtrauma. Although most patients respond to conservative medical treatment, the balance are refractory and considered candidates for surgical intervention with the goal of cutting and removing the "tendonotic" tissue and stimulating a healing response. The objective of this study was to test the hypothesis that ultrasound guided percutaneous tenotomy using the Tenex Health TX System would produce comparable outcomes to open surgical intervention at one year. Nineteen consecutive patients ages 38-67 years failing conservative management for > 6 months with either medial (7) or lateral (12) tendinopathy were prospectively studied. Patient assessment included: visual analog pain scale (VAS), the Disabilities of the Arm, Shoulder and Hand index (DASH), and the Mayo Elbow Performance Score (MEPS) by an independent observer pre-treatment and 6 weeks, 3 months, 6 months and 12 months post-procedure. Results revealed no procedural complications and a significant improvement in pain VAS scores from 6.4 pre-treatment to 2.6 at 6 weeks and sustained at 12 months post-procedure ($p < 0.0001$), pre-treatment DASH of 44.1 to 8.6 at 12 months ($p < 0.0001$), and MEPS pre-treatment score of 59.1 while at 12 months 83.4 ($p < 0.0001$). By localizing, tenotomizing and removing diseased tissue, ultrasonic percutaneous tenotomy appears to be a safe and definitive, treatment option for chronic, refractory lateral or medial elbow tendinopathy.

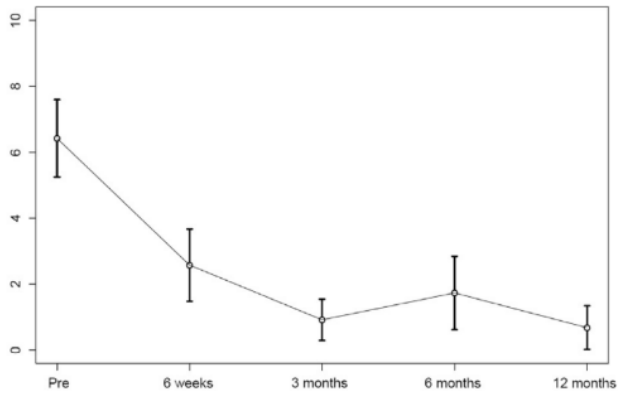


Figure 3 Visual analog scale (VAS) pain scores (range, 0-10)

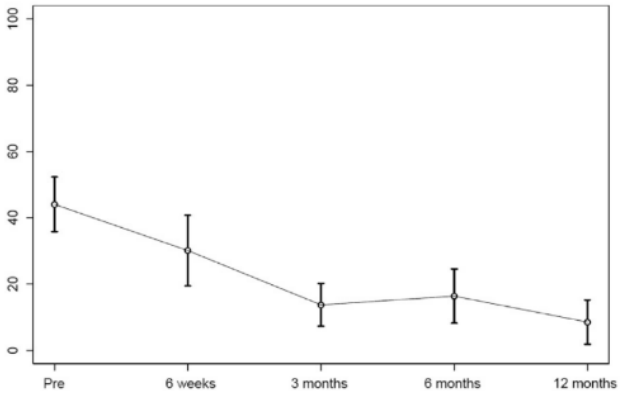


Figure 4 Scores for the Quick (11-item versio iti

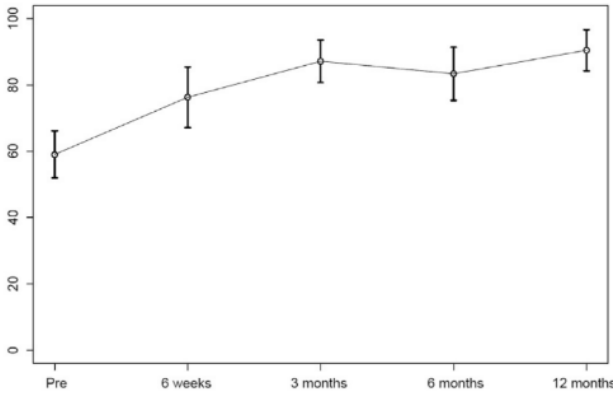


Figure 5 Mayo Elbow Performance Scores (MEP ıo

Sanders TL, Maradit Kremers H, Bryan AJ, Ransom JE, Smith J, Morrey BF. The epidemiology and health care burden of tennis elbow: a population-based study. American Journal of Sports Medicine 2015;43(5):1066-1071 [Elbow]

Lateral epicondylitis is a common condition both in primary care and specialty clinics. The purpose of this study was to evaluate the natural history (i.e., incidence, recurrence and progression to surgery) of lateral epicondylitis in a large population

Study Design and Methods: This was a retrospective population-based analysis with a cohort consisting of all residents in Olmsted County, MN over a 12-year span using the Rochester Epidemiology Project to ascertain medical information. The study population was comprised of patients with new-onset lateral epicondylitis between 1/1/2000 and 12/31/2012. The medical records of a 10% random sample (n=576) were reviewed to ascertain information on patient and disease characteristics, treatment modalities, recurrence and progression to surgery. Age- and sex-specific incidence rates were calculated and adjusted to the 2010 United States population.

Results and Conclusion: Results from the study estimate that in absolute numbers there are approximately 1 million individuals with new onset lateral epicondylitis each year in the United States. This population-based study indicates that lateral epicondylitis is relatively common, particularly among individuals aged 40-59 years during their most productive years. 18% patients required care for more than 6 months. 12% of these patients required surgery. About 3% of the 1168 lateral elbow tendinosis cases between 2009 and 2011 had surgery within 2 years of their diagnosis (compared with about 1% in earlier years). 8.5% patients had recurrence, with a median time to recurrence of 20 months.

The data suggest that those without resolution of symptoms within 6 months of onset and conservative treatment will tend to have a more prolonged course possibly requiring definitive procedural intervention.

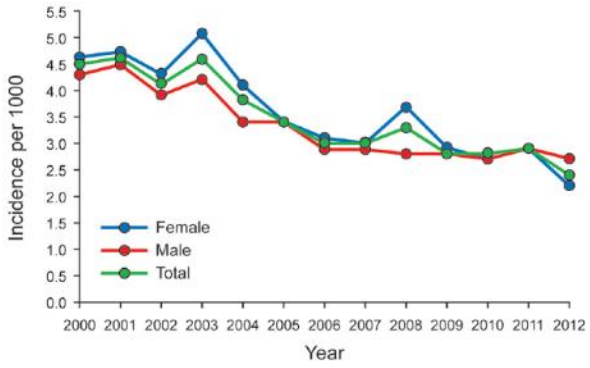


Figure 1. Trends in incidence of lateral elbow tendinosis (Olmsted County, Minnesota; 2000-2012).

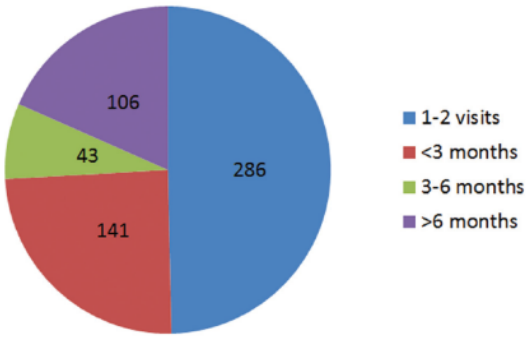


Figure 2. Duration of care for 10% random sample of lateral elbow tendinosis patients (Olmsted County, Minnesota; 2000-2012).

Seng C, et al. Ultrasonic percutaneous tenotomy for recalcitrant lateral elbow tendinopathy: sustainability and sonographic progression at 3 years. American Journal of Sports Medicine 2016;44(2):504-510. Epub 2015 Nov. [Elbow]

Minimally invasive surgical techniques for recalcitrant lateral elbow tendinopathy have gained popularity in recent years. Ultrasound guided percutaneous microresection using ultrasonic energy of the diseased tendon is a novel procedure that can be performed safely in the office or ambulatory surgery setting and is well tolerated. Good clinical outcomes at 1 year have been documented previously. We aim to assess the efficacy and clinical outcomes of our patients who have undergone minimally invasive ultrasound guided percutaneous microresection for recalcitrant lateral elbow tendinopathy with the Tenex Health TX System at 3 years post procedure. As a follow up on the original study group reporting the 1 year clinical, we assessed outcomes of 7 male and 13 female patients with a mean age of 47 years who failed non-operative therapy. We interviewed all 20 original patients at a minimum of 3 years post procedure and documented outcomes of patient satisfaction; visual analog scale (VAS) pain scores; and Disabilities of the Arm, Shoulder and Hand (DASH) scores. All of these patients reported no or minimal pain at 3 years, with median VAS score of 0.7 at 3 years (range 0-2.5, p<0.001). Functional outcomes of patients also improved, with median DASH-Compulsory score of 0.4 at 3 years (range 0-10.8, p<0.001). There were no cases of adverse complications and no recurrences. In conclusion, ultrasonic microresection of the diseased tissue using the Tenex Health TX System for recalcitrant lateral elbow tendinopathy is safe, well tolerated, minimally invasive, and can be conveniently performed in the outpatient or ambulatory setting. This novel treatment can be considered for early and definitive intervention of elbow tendinopathy.

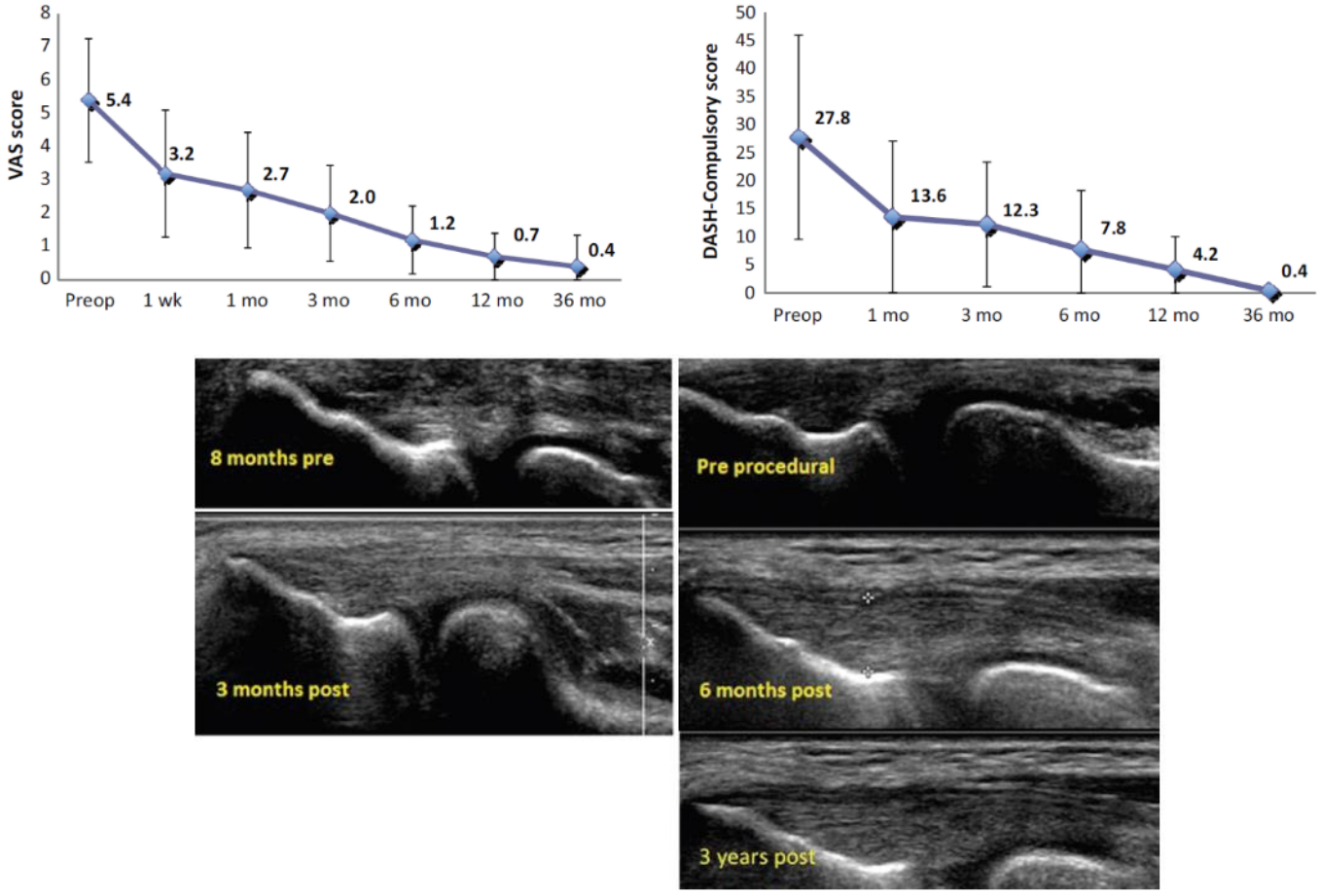


Figure 4. Persistence of lesion documented within an 8-month interval before the index procedure. Subsequent reduction in hypoechoic lesion at 3-month follow-up, which was sustained at 36 months postprocedure.

Morrey BF. Chapter 60: Percutaneous ultrasound tenotomy treatment of epicondylitis. In: Morrey BF, Sanchez-Sotelo J, Morrey ME, eds. Morrey's The Elbow and its Disorders. 5th ed. Elsevier; 2017:582-587. [Elbow]

One of the most significant, recent changes in the management of epicondylar tendinopathy has been the introduction of ultrasound (US) guided treatment. Percutaneous ultrasonic treatment of the pathology with the TX1 MicroTip has the simplicity of a cortisone injection but the effectiveness of a surgical procedure without the cost or morbidity. Ultrasonic energy was first utilized to cut or ablate and remove pathologic tissue in the treatment of cataracts (phacoemulsification) in the early 1980's. It is now standard of care for most cataracts. The same technology has been applied by Tenex Health to the management of chronic refractory tendinopathy.

If symptoms persist for 6 months, which occurs in 20% of epicondylitis cases, mean time for non-surgical resolution is 24 additional months, with recurrence in 15% patients. Patients with symptoms for 6 months and failed non-operative management, are candidates for the procedure. Patients who are not improving and whose pain interferes with daily activities, sleep or employment are candidates for earlier intervention.

Ultrasound imaging is a simple and effective means for identifying tendon pathology. Tendinopathic tissue appears as a hypoechoic signal, or black defect in the tendon, often with an element of edema. Normal tendon appears more hyperechoic, as a white image, and more homogenous. A blinded study reported that ultrasound examination provides 90% sensitivity, 89% specificity and 94% diagnostic accuracy.

The TX1 MicroTip provides ultrasonic energy for debriding tissue with continuous irrigation. It also provides suction through the hollow bore of the device. Ultrasound guided percutaneous tenotomy with TX1 may be performed in a clinical or ambulatory surgical center. The authors perform the procedure in a cast room. The text details the technique.

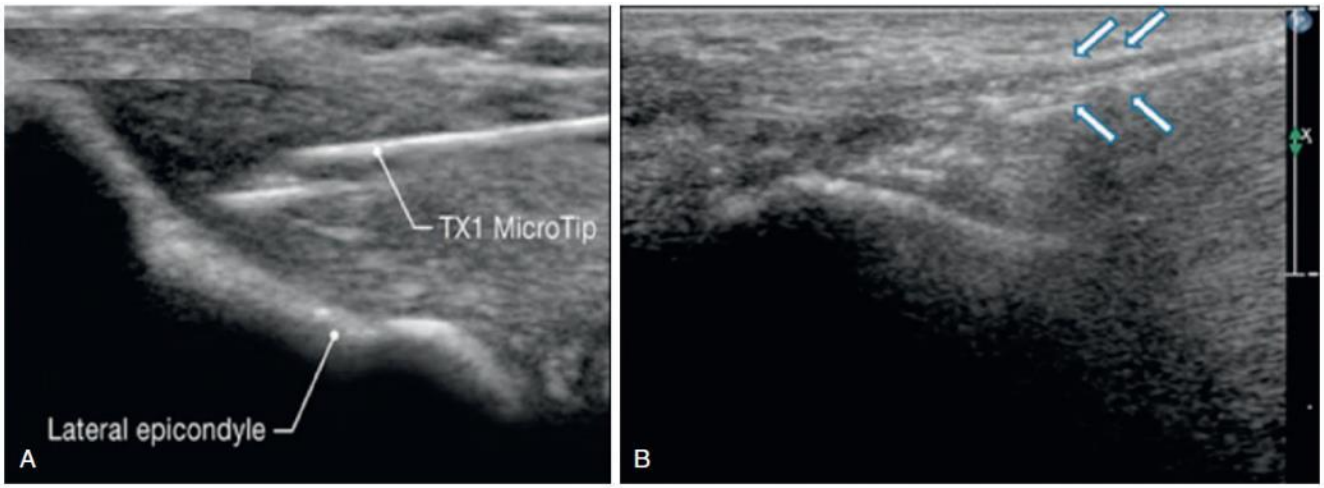


FIG 60.8 (A) The ultrasound image demonstrates the TX1 microtip being inserted into the hypoechoic region at the lateral epicondyle. (B) Following the procedure the track of the probe is identified with the *arrows*. Notice the blackened hypoechoic area has changed its appearance indicating the area has been treated with the ultrasonic energy.

Battista CT, Dorweiler MA, Fisher ML, Morrey BF, Noyes MP. Ultrasonic percutaneous tenotomy of common extensor tendons for recalcitrant lateral epicondylitis. Techniques in Hand & Upper Extremity Surgery 2018;22(1):15-18. [Elbow]

Tennis elbow is a common musculoskeletal condition affecting middle-aged patients. The symptoms usually last from 6 months to 2 years. The majority of individuals will respond to conservative therapy; however, some will require surgical intervention. A new treatment system uses ultrasound guidance in the ultrasonic microresection of tendinopathic tissue. The TX1 System is used to treat various tendinopathies by debridement with targeted ultrasonic energy. We describe the surgical technique for the TX1 system as well as provide pain and functional outcome scores for a series of seven patients with recalcitrant lateral epicondylitis treated with the device for percutaneous tenotomy.

For the seven patients, mean ASES scores improved significantly from a mean of 55.6 pre-operatively to 94.1 at 2 years. Significant statistical improvement was also shown at 6 weeks. Mean VAS scores improved from 7.9 ±0.9 pre-operatively to 1.1 ±1.2 at last follow-up. 6 out of 7 patients reported satisfaction with the procedure. 1 of the satisfied patients who had an open surgery 5 years prior, returned to work 6 weeks after the percutaneous tenotomy.

Ultrasound-guided percutaneous ultrasonic tenotomy of the common extensor tendons with the TX1 device seems to be a safe, effective, and well-tolerated procedure with significant improvements in pain and clinical function at 2-year follow-up. The lack of complications in the patient population supports the previously documented safety profile.

TABLE 1. Improvement in ASES Scores

Improvement in ASES scores for 7 patients			
ASES timeframe	**Mean**	**SD**	***P***
Preoperative	55.6	7.7	—
Postop 6 wk	91.1	8.2	< 0.001
Postop 3 mo	91.0	10.5	0.001
Postop 6 mo	91.4	14.0	0.002
Postop 12 mo	93.4	8.1	< 0.001
Postop 24 mo	94.1	7.9	< 0.001

ASES indicates American Shoulder Elbow Surgeons; postop, postoperative.

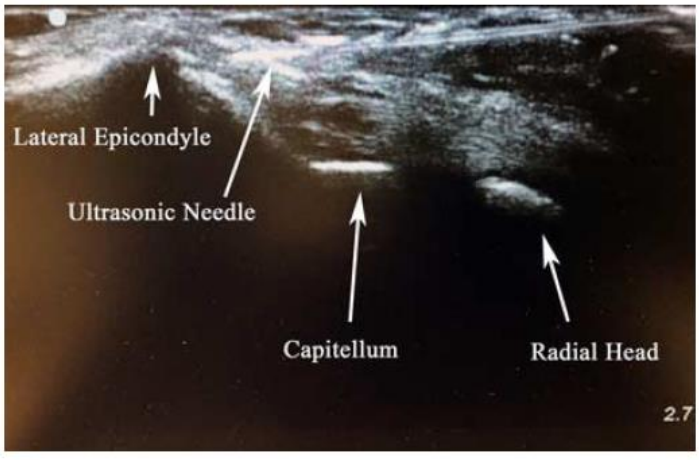


FIGURE 5. Ultrasonic image of the TX1 probe directed toward the lateral epicondyle, a common site for tendinosis and interstitial tears. full color online

Williams RC, Pourcho AM. Percutaneous ultrasonic tenotomy for refractory common extensor tendinopathy after failed open surgical release: a report of two cases. PM &R: the Journal of Injury, Function, and Rehabilitation 2018;10(3):313-316. [Elbow]

Common extensor tendinopathy (CET) is painful overuse and degenerative condition of the lateral elbow that affects an estimated 2 million patients per year. Although many cases resolve with conservative treatment, recalcitrant cases may lead to open surgical intervention. For patients who do not improve with surgical management, treatment options are extremely limited. In this article, we present 2 cases of recalcitrant surgically treated CET successfully treated with percutaneous ultrasonic tenotomy with 1-year follow-up. To our knowledge, this is the first publication of successful treatment of recalcitrant CET with the use of ultrasonic tenotomy after open surgical repair.

Patient A had an initial Quick DASH score of 52.5 and a score of 3.33 at 1-year. Patient B's scores were 80.8 initially and 9.7 at one year. Patient A returned to light-duty work at 6 weeks and unrestricted work at 12 weeks. Patient B returned to light duty at 8 weeks and unrestricted work at 12 weeks.

Both patients were successfully treated with the TX1 device for ultrasound-guided percutaneous ultrasonic tenotomy. This suggests the treatment should be considered an option for chronic refractory common extensor tendinopathy, including cases that have failed previous operative intervention.

Figure 3. DASH Scores. Graph representing postoperative DASH scores with 1-year follow-up on both cases. Case 1 (dashed line) demonstrated an improvement on DASH scores of 49.17 points (52.5-3.33) from initial presentation to final follow-up at 1 year. Case 2 (solid line) demonstrated an improvement on DASH scores of 67.5 points (70.83-3.33) from initial presentation to final follow-up at 1 year. DASH = Disability of the Arm, Shoulder, and Hand.

Boden AL, Scott MT, Dalwadi PP, Mautner K, Mason RA, Gottschalk MB. Platelet-rich plasma versus Tenex in the treatment of medial and lateral epicondylitis. Journal of Shoulder and Elbow Surgery 2019;28(1):112–119. [Elbow]

Purpose: The purpose of this study was to compare effectiveness of platelet-rich plasma (PRP) injections and ultrasound-guided percutaneous tenotomy (with the Tenex Health TX System) for the treatment of medial or lateral epicondylitis.

Methods: In this retrospective review, 62 patients (32 PRP and 30 Tenex) completed post-procedure outcome surveys. Subjective assessment of pain and function included VAS for pain; the QDASH questionnaire; and the EQ5D questionnaire. The inclusion criteria included age of 18 years or older and previous failure of nonoperative treatment.

Results: The PRP and Tenex groups both demonstrated clinical and statistical improvement in VAS pain scores; QDASH scores; and EQ5D scores. No statistically significant difference was found between the 2 treatment modalities.

Conclusion: The PRP and ultrasound-guided percutaneous tenotomy procedures were both successful in producing clinically and statistically significant improvements in pain, function, and quality of life.

Characteristics	Tenex (n = 30)
Age, yr	51 ± 8 (39-69), n = 30
Length of pain, mo	25 ± 21 (2-75), n = 29
Follow-up, mo	10 ± 6 (2-27), n = 30
Satisfaction	3.6 ± 1.4 (0.0-5.0), n = 30
Sex	
Female	12/30 (40.0%)
Male	18/30 (60.0%)
Satisfaction	
0	1/30 (3.3%)
1	2/30 (6.7%)
2	3/30 (10.0%)
3	6/30 (20.0%)
4	8/30 (26.7%)
5	10/30 (33.3%)
Elbow	
Right	17/30 (56.7%)
Left	13/30 (43.3%)
Lateral	25/30 (83.3%)
Medial	5/30 (16.7%)

Stover D, Fick B, Chimenti RL, Hall MM. Ultrasound-guided tenotomy improves physical function and decreases pain for tendinopathies of the elbow: a retrospective review. Journal of Shoulder and Elbow Surgery 2019;28(12):2386-2393. [Elbow]

Background: Tendinopathy is a very common cause of elbow pain in the active population. Ultrasound guided percutaneous tenotomy (USGT) is a minimally invasive option for cases recalcitrant to conservative management. Several case studies have shown promising preliminary results of USGT for common extensor tendinopathy and common flexor tendinopathy, but none have included USGT for triceps tendinopathy. This larger retrospective study evaluates the effectiveness and safety of USGT for all elbow tendinopathy sites at short- and long-term follow-up.

Methods: A retrospective chart review was conducted of 131 patients (144 procedures; mean age: 48.1 ± 9.8 years; mean body mass index: 32.2 ± 7.7; 59% male) with elbow tendinopathy (104 common extensor tendinopathy, 19 common flexor tendinopathy, 8 triceps tendinopathy) treated with USGT over a 6-year period by a single physician. Pain and quality-of-life measures were collected at baseline. Pain, quality-of-life, satisfaction with outcome, and complications were collected at short-term (2, 6, and 12 week) and long-term (median 2.7 years, interquartile range: 2.0-4.0 years) follow-up.

Results: USGT for elbow tendinopathy decreased overall pain from moderate/severe at baseline to mild/occasional at short- and long-term follow-up (P <.01). Quality-of-life assessments yielded significant improvement in physical function at short- and long-term follow-up (P <.01). The majority of patients (70%) were satisfied with the procedure. The complication rate was 0%.

Conclusion: USGT yields the benefits of pain relief, improved physical function, and high patient satisfaction. USGT is a safe, minimally invasive treatment for refractory elbow tendinopathy.

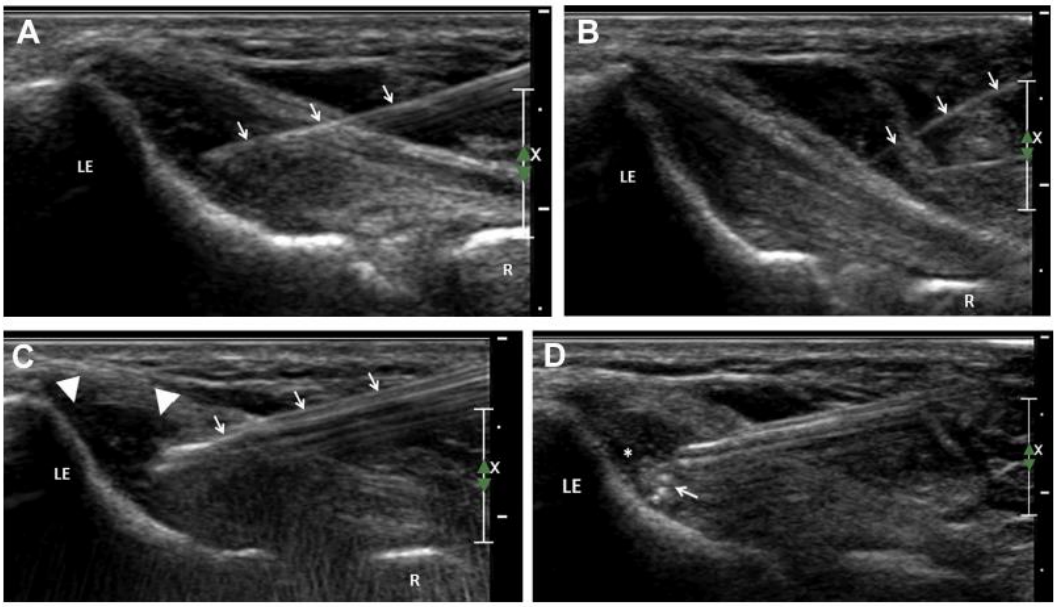


Figure 2 Ultrasound-guided tenotomy of the common extensor tendon. (**A**) Local anesthesia is delivered with a 27- or 25-gauge needle (→) into the subcutaneous tissues and down to the region of tendinosis. (**B**) A No. 11 scalpel blade (→) is used to make a 5-mm incision down to the tendon to allow introduction of the cutting device. (**C**) The TX 2 device (→) 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.

Yanish GJ, Moore CT, Pinegar C. Percutaneous ultrasonic tenotomy with ultrasound guidance vs open lateral epicondylectomy: a prospective cost comparative analysis. (Submitted to Journal of Shoulder and Elbow Surgery, April 2019). [Elbow]

This randomized, prospective study compares ultrasound-guided percutaneous ultrasonic tenotomy (with the Tenex Health TX1 MicroTip) to standard open lateral epicondylectomy. A total of 45 patients with lateral epicondylitis were treated, 18 with percutaneous ultrasonic tenotomy and 27 with open lateral epicondylectomy. The study directly compares efficacy, patient satisfaction, and cost of treatment

All data were prospectively gathered but retrospectively studied. There were no complications with either procedure. Pain relief and patient satisfaction were documented at 1 week, 1 month, 3 months and 6 months following the procedure. VAS scores were used to document residual pain. Percutaneous treatment showed less pain at all periods except 6 months, where a non-statistically significant difference favored the open procedure. For percutaneous treatment with the Tenex device, VAS scores reported a mean reduction of 84% in pain (from 8.35 initially to 1.30 6-months post-procedure).

Patient satisfaction improved at each assessment period, with essentially no difference between the 2 procedures at 3 months and 6 months post-procedure. Percutaneous ultrasonic tenotomy yielded higher early satisfaction scores, indicative of more rapid recovery vs. the open procedure. All 18 patients (100%) who had the percutaneous tenotomy felt the surgery was beneficial overall, would repeat the procedure and would recommend it to others. 24/28 patients (86%) who had the open surgery felt the same way.

The rapid recovery with percutaneous tenotomy resulted in fewer post-operative visits and a faster return to work than with the open epicondylectomy group. Average time for return to work, based on worker's compensation data, was 1.1 weeks for Tenex group and 8.2 weeks for the open surgery group ($p<0.0001$).

Total cost included office visits, surgery facility, anesthesia, and physical therapy reimbursement amounts, as well as the cost of missed work. The total average cost was $7,837 for the percutaneous ultrasonic tenotomy procedure, and $17,590 for the open epicondylectomy. There was a difference of $9,753: epicondylectomy is 120% more expensive than the percutaneous procedure; or percutaneous ultrasonic tenotomy is 45% the cost of open surgery.

All hypotheses are supported by the data: percutaneous ultrasonic tenotomy is as effective as the traditional open surgical procedure, relieves pain with equal or slightly better patient satisfaction, and incurs significantly less cost than an open procedure. Further, percutaneous ultrasonic tenotomy results in a much more rapid recovery time than the open procedure. Our experience with this technology has changed our practice and this is now our treatment of choice for this condition.

	Initial	**1 week**	**1 month**	**3 months**	**6 months**
TENEX	8.35	5.55	2.70	1.75	1.30
Open Epicondylectomy	8.64	6.01	3.32	2.07	0.50

Table 1: Average values of pain levels on a scale of 1-10 indicated by patients at initial consultation for pain, as well as at various post-operative time intervals.

	1 week	**1 month**	**3 months**	**6 months**
TENEX	8.15	8.75	8.91	9.20
Open Epicondylectomy	7.46	8.21	8.92	9.30

Table 2: Average values of post-operative overall patient satisfaction on a scale of 1-10; 10 being completely satisfied

Altahawi F, Li X, Demarest B, Forney MC. Percutaneous ultrasonic tenotomy with the TX-1 device versus surgical tenotomy for the treatment of common extensor tendinosis. Skeletal Radiology 2020 Jul. [Elbow]

Objective: Compare outcomes in patients treated for chronic common extensor tendinosis with percutaneous ultrasonic tenotomy (TX-1 device) versus open surgical tenotomy.

Methods: Outcomes from consecutive patients who underwent percutaneous tenotomy with TX-1 were compared with those from consecutive patients who underwent surgical tenotomy. Patients were contacted to retrospectively assess their outcomes at 4 time points: before treatment, and 2 weeks, 3 to 6 months, and 12 months after treatment. Outcomes were assessed with QuickDASH and Oxford elbow score (OES).

Results: Responses were 23 of 43 and 10 of 47 for surveyed percutaneous and surgical tenotomy patients, respectively. There were significant improvements from pre-procedure in all primary measures at 3-to-6-month and 12-month time points for both procedures. There were no significant changes from pre-procedure for either procedure at 2 weeks after treatment. There were no significant changes between percutaneous and surgical tenotomy in preprocedural or postprocedural scores for any measure. At 2 weeks, improved percutaneous tenotomy scores approached significance compared with pre-procedure QuickDASH ($p = 0.060$) and surgical 2-week OES function domain ($p = 0.074$).

It was noted that average TX-1 cutting time was 105 seconds, vs. 26 minutes operating time for surgical tenotomy. Also, all open surgeries involved bone treatment in addition to tendon treatment. There were no complications with TX-1. There was one severe complication in surgical tenotomy, a case of septic arthritis requiring surgical intervention. Surgical tenotomy was on average more than twice as expensive as percutaneous ultrasonic tenotomy with TX-1.

Conclusion: Ultrasonic percutaneous tenotomy with TX-1 and surgical tenotomy have similar outcomes for chronic common extensor tendinosis, with significant symptomatic improvement occurring with both procedures after 3 to 6 months.

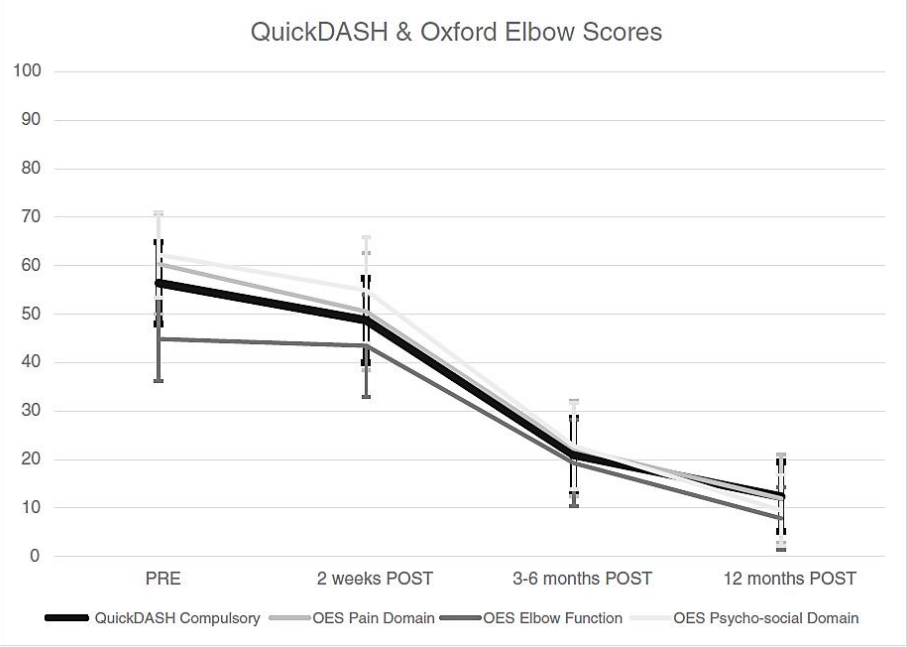


Figure 1. Ultrasound-guided percutaneous tenotomy results

FOOT AND ANKLE

Langer PR. Two emerging technologies for achilles tendinopathy and plantar fasciopathy. Clinics in Podiatric Medicine and Surgery 2015;32(2):183-193. [Achilles/Plantar Fascia]

10% to 25% of individuals affected by Achilles tendinopathy and plantar fasciitis fail conservative treatment. For those individuals who fail non-operative modalities, operative intervention is often the next option. Recently, two other treatment options have shown potential as viable options before or in lieu of surgery. Shock wave therapy (SWT) is a relatively new technology that has become increasingly popular. The mechanism of action for SWT remain poorly understood. The primary mechanisms most often cited are initial inflammatory response followed by neo- vascularization. The frequency and therapeutic dose depend on the tissue treated, depth of penetration required, clinical judgment, research, and manufacturer recommendations. The number of treatments and interval between treatments has not been standardized. 3 to 5 weekly treatments are common for Achilles tendinopathy and plantar fasciitis. Despite mixed results in the literature, SWT may be a viable treatment.

Percutaneous ultrasonic tenotomy and fasciotomy have also recently become available to treat chronic tendon disease and plantar fasciosis. The Tenex Health TX1 MicroTip is a percutaneous instrument that utilizes ultrasonic energy to precisely cut and remove pathologic tissue. The percutaneous tenotomy or fasciotomy using the TX1 instrument is ultrasound image guided. It involves a single out-patient procedure, typically completed under local anesthesia, after which the patient is protected in a walking boot for 2-3 weeks. Percutaneous ultrasonic tenotomy and fasciotomy are well-tolerated procedures that are safe and effective when applied to a variety of tendons throughout the body, as well as the plantar fascia.

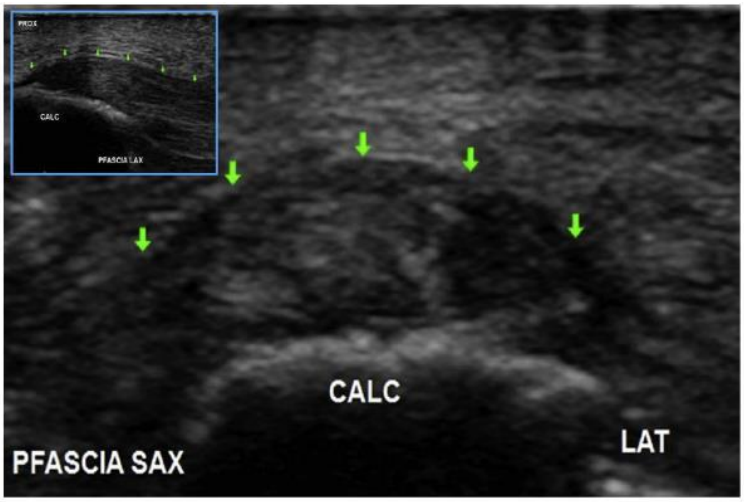


Fig. 3. Correlative short axis ultrasound view of a thickened, heterogenous, hypoechoic plantar fascia (PFASCIA) typical of chronic plantar fasciosis. *Top*, Plantar/superficial; *bottom*, dorsal/deep; *left*, medial; *right*, lateral (LAT). Arrows identify superficial portion of plantar fascia. Inset shows correlative long axis (LAX) view, proximal to the left. CALC, calcaneus.

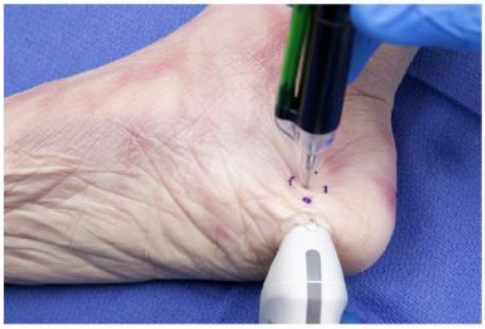


Fig. 4. After delivery of local anesthesia as described in the text, a small stab incision is created with a #11 scalpel blade to create a passage to advance the TX1 working tip to the plantar fascia under direct ultrasound guidance. *Left*, distal (toes); *right*, proximal (heel).

Patel MM. A novel treatment method for refractory plantar fasciitis. The American Journal of Orthopedics 2015;44(3):107-110. [Plantar Fascia]

Plantar fasciitis can be a disabling condition for patients. The numerous treatment modalities offered for plantar fasciitis attest to the lack of effectiveness or at least lack of consensus regarding treatment. As a consequence, an emerging set of goals for this condition are those of a minimally invasive percutaneous intervention that is safe and effective, and at the same time is well tolerated with minimal morbidity. We report herein the use of an image guided intervention together with the TX1 instrument which employs ultrasonic energy to fasciotomize the targeted plantar fascia. A prospective study of 12 patients with refractory plantar fasciitis with a minimum of 6 months of symptoms and failed treatments including but not inclusive of physical therapy, orthotics, shock wave therapy and corticosteroid injections. Four of the 12 patients had had open or endoscopic partial releases at other institutions without any improvement in their symptoms prior to presentation. All patients were treated once with the TX1 instrument and followed up for 12 months after the procedure. The mean pre-operative AOFAS score was 30.1 which improved significantly to 88.1 by 6 months and was sustained at 12 months. Resolution of pain occurred in 11 of the 12 patients by 3 months and was sustained at 12 months. There were no procedural or treatment complications. An ultrasound image-guided plantar fasciotomy using a percutaneous instrument that delivers ultrasonic energy appears to be a safe, well tolerated and effective treatment option for a condition characterized by being refractory to current treatment programs. Its safety profile and the fact that it is well tolerated make it an attractive option to definitively treat this vexing condition.

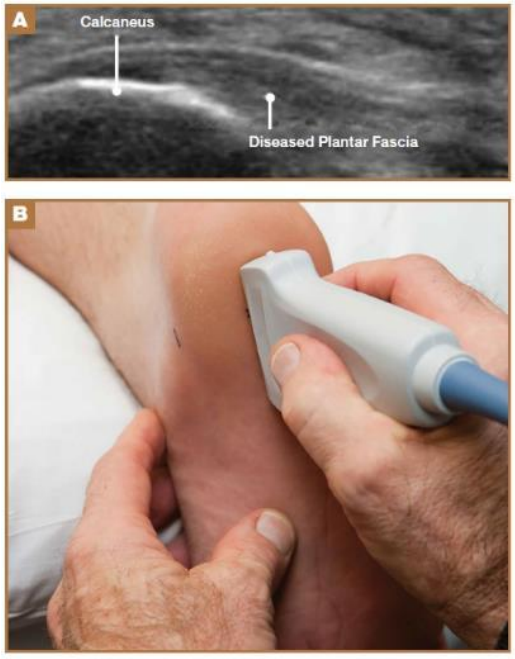


Figure 3. (A) Ultrasonic image of plantar fascia reveals its attachment to medial tubercle of calcaneus. (B) Pathologic process has multiple appearances, most commonly those of fascial edema, calcification, and hypoechoicity.

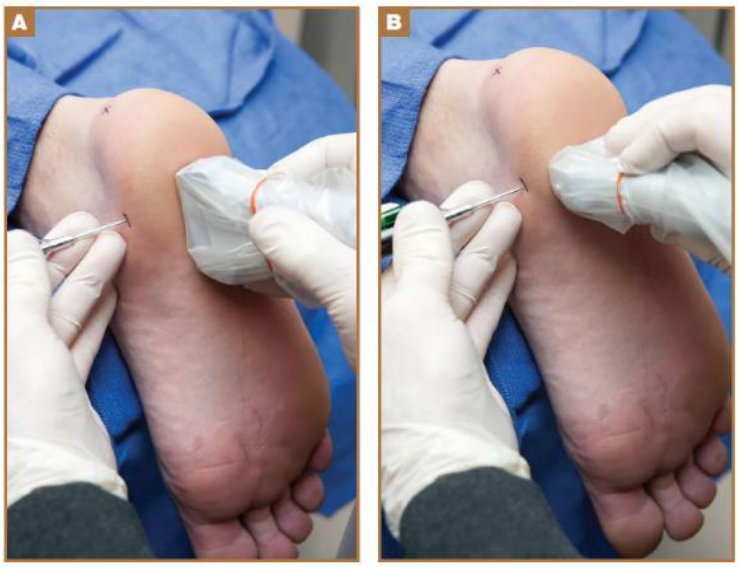


Figure 5. (A) Longitudinal image provides information on length of involvement for adequate characterization of plantar fascia insertion into calcaneus. (B) Transverse image provides information about medial/lateral extent of lesion.

Patel MM, Patel SM, Patel SS, Daynes J. A pilot study of a novel treatment method for refractory painful plantar fibromas. Austin Journal of Orthopedics & Rheumatology 2015;2(2):1014. [Plantar Fibroma]

Objective: Painful plantar fibromas may make ambulation difficult for patients. Treatment modalities may include conservative care, modified shoe wear and orthotics. Surgical treatment may include open excision. In this study, the Tenex Health TX System is a surgical instrument designed to deliver ultrasonic energy for soft tissue cutting was evaluated as a treatment modality for these painful lesions.

Methods: Eight consecutive patients who had painful plantar fibromas elected to undergo treatment for the fibromas using the Tenex Health TX System. They all had had conservative care including modifications of shoes and either over the counter orthotics or custom orthotics. They all had advanced imaging tests (MRI or CT) preoperatively to help delineate the lesions. Treatment with the Tenex Health TX System was delivered in a percutaneous fashion in an outpatient setting. Excised tissue specimens were sent to pathology to confirm fibrotic tissue and no malignancy. Preoperative and postoperative AOFAS scores were obtained for quality of life assessment. Physical therapy was offered to patients postoperatively.

Results: Average age of patient was 51.3 years (17-71). Average time of painful symptoms was 15.1 months (3-36). All patients had modified footwear or orthotics and no appearance of malignancy by tissue imaging. Preoperative AOFAS score improved from 30.8 (20-36) to 90.1 (85-92). Average time of resolution of symptoms was 63.5 days (30-112). One patient had a recurrence, but it was in a different location than the index operation. No others have had a recurrence to date. Pathology specimens were all negative for malignancy. All patients were discharged from care and no infections were recorded. Three of eight patients underwent physical therapy and were discharged from physical therapy successfully.

Conclusion: The Tenex Health TX System appears to be effective for removing painful plantar fibromas in patients who have failed all conservative measures.

Chimenti RL, Stover DW, Fick BS, Hall MM. Percutaneous ultrasonic tenotomy reduces insertional achilles tendinopathy pain with high patient satisfaction and a low complication rate. Journal of Ultrasound in Medicine 2019;39(6):1629-1635. Epub 2018 Oct. [Achilles]

This retrospective chart review over a 3.5-year period identified 34 patients with insertional Achilles tendinopathy who had percutaneous ultrasonic tenotomy (mean age ± SD, 52.2 ± 11.6 years; mean body mass index, 32.9 ± 7.5 kg/m^2; 62% female). There were statistically significant decreases in pain at short- and long-term follow-ups. This procedure reduced the rate of moderate/severe pain from 68% at baseline to 15% at the long-term follow-up. 85% patients reported no pain or mild pain at long term follow-up. The procedure's short-term satisfaction rate was 70% (although this factored in patients for which there was no data). Amongst the patients reporting, there was a 77% short-term satisfaction rate. There was 1 minor complication out of 40 procedures in the 34 patients.

Additional benefits of this procedure include reduced cost and time on behalf of the provider and patient compared to an open or endoscopic operation. The identified risk in this series was low, supporting the safety of percutaneous ultrasonic tenotomy performed in a clinical setting.

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 of 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.

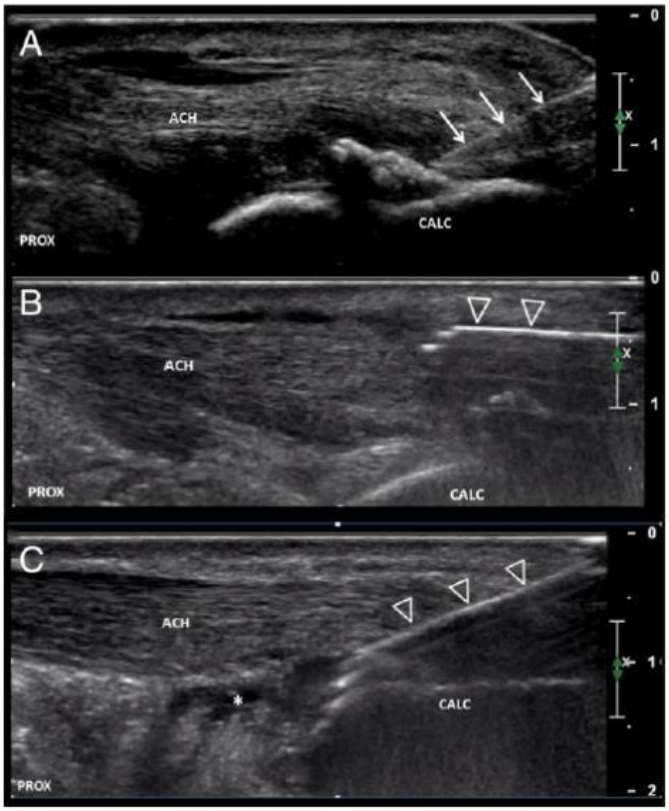


Table 1. Pain Level Reported on the AOFAS Pain Scale (N = 34)

Pain Level	Baseline	Short-term Follow-up[a]	Long-term Follow-up[b]
None	0 (0)	3 (9)	4 (12)
Mild/occasional	5 (15)	13 (39)	13 (39)
Moderate/daily	18 (55)	8 (24)	2 (6)
Severe/almost always present	4 (12)	2 (6)	1 (3)
Missing	6 (18)	7 (21)	13 (39)

Values are presented as number (percent). Short-term: 6-week follow-up, n = 13; 12-week follow-up, n = 14; long-term: n = 22; median, 1.7 years (interquartile range, 11–36 months).
[a]Wilcoxon signed rank test, n = 23, short-term follow-up compared to baseline: $P < .01$.
[b]Wilcoxon signed rank test, n = 17, long-term follow-up compared to baseline: $P = .01$.

Razdan R, Vander Woude E, Braun A, Morrey BF. Percutaneous ultrasonic fasciotomy: a novel approach to treat chronic plantar fasciitis. Journal of Surgical Procedures and Techniques 2018;3(102):1-6. [Plantar Fascia]

The purpose of this study was to assess safety, efficacy and durability of percutaneous ultrasonic fasciotomy, as a definitive treatment for chronic plantar fasciitis in a relatively large patient cohort.

This prospective study evaluated treating chronic plantar fasciitis with an ultrasound guided instrument (from Tenex Health) delivering a percutaneous fasciotomy. A total of 100 patients with a minimum of 4 months of symptoms and failure of at least one conservative treatment were treated in an out-patient setting. Pain and functional disability were assessed with the validated Foot and Ankle Disability Index (FADI). Data was collected before procedure and 2 weeks, 6 weeks and 6 months following treatment. At 6 months, 96% of patients were satisfied with the procedure and indicated they would recommend it to a friend. FADI scores showed significant improvement at all time periods compared to baseline. Ultrasound guided percutaneous fasciotomy is a safe and highly effective treatment for chronic refractory plantar fasciopathy.

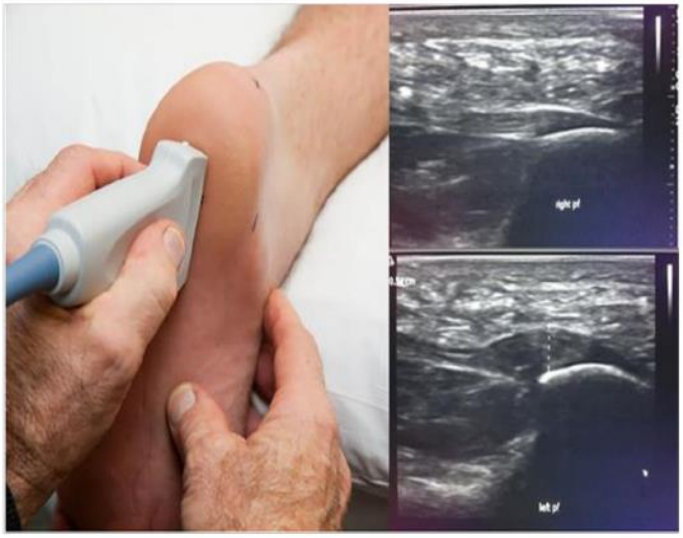


Figure 1. An ultrasound image of normal plantar fascia (left). Chronic fasciitis is associated with hypoechoic thickening of the attachment site at the medial tubercle of the calcaneus (right).

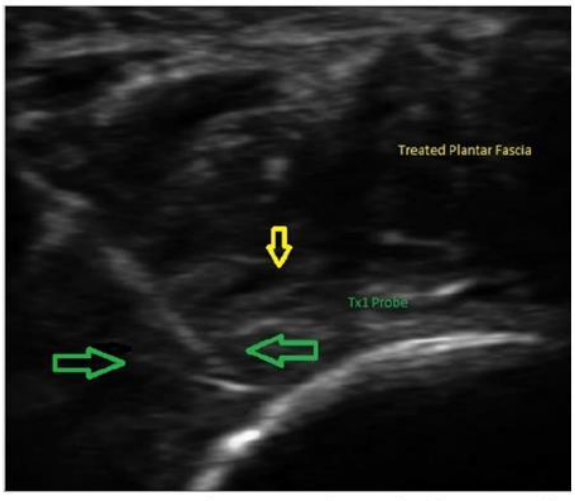


Figure 4: TX1 probe inserted into the lesion under ultrasonic visualization.

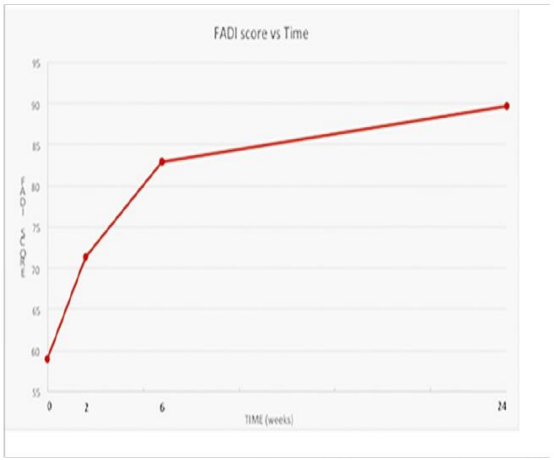


Figure 5: Average Foot and Ankle Disability Index (FADI) score across all patients immediately prior to procedure (0) and each subsequent follow-up time point (2,6, and 24 weeks) ($P<0.05$).

Freed L, Ellis MB, Johnson K, Haddon TB. Fasciotomy and surgical tenotomy for chronic achilles insertional tendinopathy: A retrospective study using ultrasound-guided percutaneous microresection. Journal of the American Podiatric Medical Association 2019;109(1):1-8. [Achilles]

Background: Achilles insertional tendon pathology is a common condition affecting a broad range of patients. When conservative treatments are unsuccessful, the traditional open surgical resection, debridement, and reattachment of the Achilles tendon is a variably reliable procedure with significant risk of morbidity. Fasciotomy and surgical tenotomy using ultrasound-guided percutaneous microresection is used on various tendons in the body. Its efficacy for treating the Achilles tendon is specifically examined in this study.

Methods: A retrospective review evaluated 26 procedures in 25 patients with chronic insertional tendinopathy who underwent percutaneous tenotomy using the Tenex Health TX System. Patients aged 18 to 85 years had documented chronic Achilles tendinopathy per persistent Achilles tendon pain for at least 3 months, with failed conservative therapy. The patients had each failed an average of 5.8 (range 4 to 8) conservative treatments. Average time from onset of symptoms to time of procedure was 19 months. Mean energy time for cutting the targeted tissue was 4 minutes and 32 seconds. The Foot Function Index (FFI) was used to quantify pain, disability, activity limitation and overall scores.

Results: Mean FFI scores were: pain, 8.5%; disability, 7.9%; activity limitation, 2.5%; and overall, 7.0%. Twenty index procedures were successful, and two patients repeated the procedure successfully for an overall 84.6% success rate. Mean surveillance time was 16 months. 88% of patients reported they were strongly likely to have the procedure again if needed or recommend it to friends or family. There were no procedure or patient related complications.

Conclusions: Ultrasound-guided percutaneous microresection with the Tenex Health TX System is a safe and minimally invasive percutaneous alternative that can be used before proceeding to an open procedure.

Sussman WI, Hofmann K. Treatment of insertional peroneal brevis tendinopathy by ultrasound-guided percutaneous ultrasonic needle tenotomy: a case report. The Journal of Foot & Ankle Surgery 2019;58:1285-1287. [Peroneal Tendon]

Treatment options for recalcitrant insertional lesions of the peroneal brevis tendon are rarely described in the literature. Ultrasound-guided percutaneous ultrasonic needle tenotomy has been described for the treatment of recalcitrant tendinopathy in the elbow, knee and plantar fascia, but not for the treatment of peroneal tendinopathy. We report a case of recalcitrant insertional peroneal brevis tendinopathy treated successfully with an ultrasound-guided percutaneous ultrasonic needle tenotomy. The treatment resulted in a rapid recovery, with sustained results, asymptomatic, at 6-months follow-up. No complications were observed, and the minimally invasive percutaneous procedure offers clear advantage over open techniques.

A 54-year-old female presented with over 2-years of right lateral midfoot pain localizing to the base of the fifth metatarsal. An MRI showed high-grade peroneal brevis tendinopathy. Ultrasonographic examination demonstrated cortical irregularity at the base of the fifth metatarsal and microcalcification of the distal peroneal brevis tendon. She had had repeated cortisone injections, resulting in short-term relief, but with subsequent return of symptoms.

Percutaneous ultrasonic needle tenotomy was performed with the Tenex Health TX System targeting the abnormal appearing footprint and adjacent peroneal brevis tendon under ultrasound guidance. At the 2-week follow-up, she reported a 70% improvement in symptoms. At 6-weeks post-treatment, she reported no significant symptoms, and at 6-month follow-up she remained asymptomatic.

GENERAL SCIENCE

Cimino WW, Bond LJ. Physics of ultrasonic surgery using tissue fragmentation: part I. Ultrasound in Medicine and Biology 1996;22(1):89-100. [Tissue Selectivity]

The ultrasonic surgical aspirator (20-50 kHz) employs a vibrating metal tip to fragment tissue and aspirate debris through the hollow center of the tip. In this study, the role of stroke, suction, frequency, tissue type and tip area are examined with regard to the tissue fragmentation rate.

Results demonstrate that fragmentation is a function of the elastic modulus and strength of the tissue. These have direct impact on acoustic velocity and impedance in the tissue. Collagen type, quantity and organization contribute to the structural quality of the tissue and also play a role in the fragmentation performance. Tissue with less structural strength, collagen or elastin fragment more efficiently. Tissue with more collagen and/or elastin has greater strength and aspirates less efficiently. Examples of such tissue that fragments poorly are vessel structures, healthy tendons, ligaments, healthy skin and organ capsules.

The study determined the relative importance of five variables in the fragmentation of tissue with an ultrasonic aspirator. These variables are operating frequency, tissue type, stroke amplitude, suction and tip area. Stroke amplitude and suction are the most important. Tissue strength, however, strongly predicts the performance effect on that tissue. Higher strength tissue fragments far less easily than lower strength tissue. It was found that fragmentation is not a direct function of the tissue's water content. Finally, it is the acceleration (frequency^2 * stroke) of the tip that is responsible for the peak pressures and forces resulting in fragmentation, not the velocity.

Table 2 shows decreasing fragmentation performance with greater modular of elasticity (E).

Table 2. Pig tissue parameters. The values shown are possible tissue descriptors. The average fragmentation rate for each tissue with stroke set at 0.1-mm peak, suction at 20 W, frequency at 23 kHz, and using the large tip is shown at the right. Water content is the average of values given in Duck (1990).

Tissue	%H_2O +2%	Density (kg/m^3)	E (MPa)	σ (MPa)	$E\sigma$	E/σ	σ^2/E	Frag. rate (mg/s)
Brain	77	1040	0.03 (est)	0.01 (est)	<.001	3.00	0.003	484
Heart	76	1050	0.86 ± 16%	0.27 ± 10%	0.23	3.18	0.085	26
Liver	75	1055	1.69 ± 13%	0.25 ± 9%	0.42	6.76	0.037	25
Kidney	77	1050	1.53 ± 4%	0.33 ± 12%	0.51	4.63	0.071	18
Aorta	70	1050	2.09 ± 3%	1.34 ± 12%	2.80	1.55	0.859	0

The Figure 3 excerpt defines the significant parameters involved in fragmentation.

```
 **     1 Area
***     3 Suction
***     4 Stroke
***    10 Frequency*Suction
 **    13 Suction*Stroke
 **    15 Stroke*Tissue
  *    17 Frequency^2
  *    32 Frequency^2*Stroke
```

Fig. 3. Statistical significance of model terms. One star indicates a p-value of less than 5%; two stars for a p-value less than 1%; and three stars for a p-value less than 0.1%.

O'Daly BJ, Morris E, Gavin GP, O'Byrne JM, McGuinness GB. High-power low-frequency ultrasound: a review of tissue dissection and ablation in medicine and surgery. Journal of Materials Processing Technology 2008;200(1-3):38-58. [Tissue Selectivity]

High power, low-frequency (20-60 kHz) ultrasound has wide application in surgical and medical instruments for biological tissue cutting, ablation, fragmentation and removal. Different mechanisms and rates of tissue removal are observed with soft and hard tissue types. Device operating parameters that affect the interaction include frequency, peak–peak tip amplitude, suction and application time. To date, there has been little analysis of the effect of these parameters on tissue removal and damage for individual tissue types. Potential damage mechanisms in tissues include alteration in global biomechanical properties, histomorphological changes, protein denaturation and tissue necrosis. This paper presents a critical review of the literature on the clinical application, mechanism of tissue interaction, removal and residual tissue damage. It describes known mechanisms for distinct tissue types.

Unique mechanical effects of ultrasonic energy are "tissue selective". This selectivity is based on tissue strength, determined primarily by the amount, type and organization of collagen in each type of tissue. Stronger tissues with higher collagen content better withstand vibratory insult from ultrasonic energy and do not fragment, whereas weaker tissues do. Experiments have correlated tissue compressive strength with resistance to fragmentation. As collagen and elastin content increase (associated with increased tissue strength), ultrasonic devices aspirate less efficiently.

Studies of ultrasonic device impact on arterial walls have demonstrated no thermal damage or injury to arterial smooth muscle, and selective disruption of rigid fibrous elements and calcium in the atherosclerotic arterial wall. Neither study reported evidence of vessel perforation."

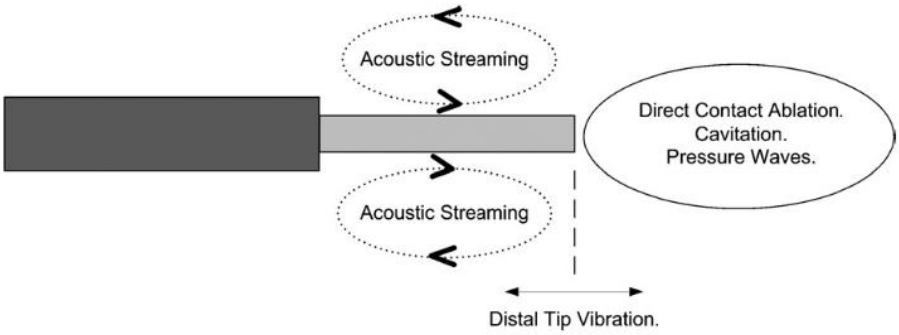


Fig. 2 – Schematic of mechanisms of fluid and tissue interaction.

Kamineni S, Butterfield T, Sinai A. Percutaneous ultrasonic debridement of tendinopathy – a pilot achilles rabbit model. Journal of Orthopaedic Surgery and Research 2015;10:70:1-8. [Stimulates Healing]

Tendonosis is a common clinical pathology, with mixed treatment results, especially when chronic. Localization and treatment of a tendinopathic lesion by a non-invasive technique affords an opportunity for precise and a well-tolerated intervention. Treatment of such lesions by focused ultrasonic energy designed to cut and remove the necrotic tendon tissue is a novel and attractive treatment modality. In this study, we report the results of an ultrasonic treatment to promote healing of Achilles tendonosis, in a rabbit model. Mature female New Zealand White rabbits (n= 12) were treated by ultrasonography-guided injection of 0.150 ml of collagenase injected into the central region of the achilles tendon. The contralateral tendons were used as non-operative controls. A subset of the rabbits with the collagenase- induced Achilles tendonosis were exposed to an ultrasound guided percutaneous tenotomy of the hypoechoic region consistent with degenerated tendon tissue using the Tenex Health TX system. The tendons were harvested at 3 weeks after treatment and subjected to biochemical (collagen content) and histological assessment. Histopathological examination revealed that tendons injected with collagenase showed focal areas of hypercellularity, loss of normal tissue architecture, and regions of tendon disorganization and degeneration, when compared to control tendons. In animals treated with the TX System, expression of collagens I, III, and X, returned to levels similar to a normal tendon. In conclusion, these results are encouraging for the use of the TX System as a definitive treatment of a chronic tendinopathic lesion, based on the cutting and removal of degraded tendon material.

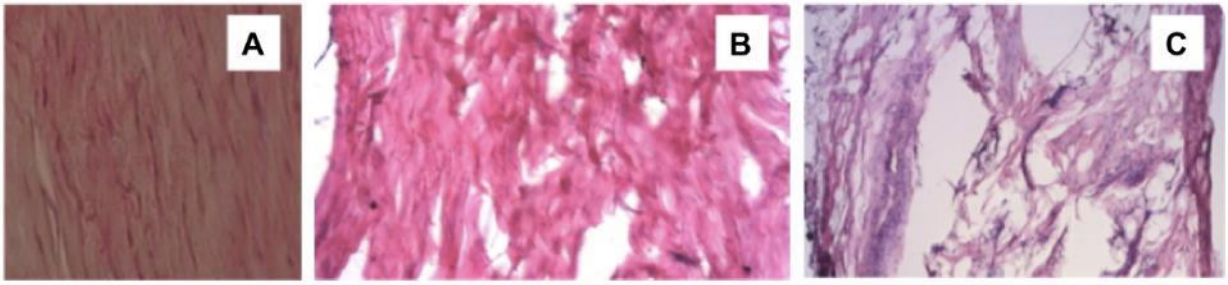


Fig. 3 Staining of Achilles tendon sections with hematoxylin-eosin. **a** Normal Achilles tendon, **b** necrosis and disorganization induced by collagenase at 6 weeks, and **c** the histological appearance after 3 weeks of collagenase and 3 weeks of treatment reveals a repopulation of the evacuated cavity and early collagen bundles

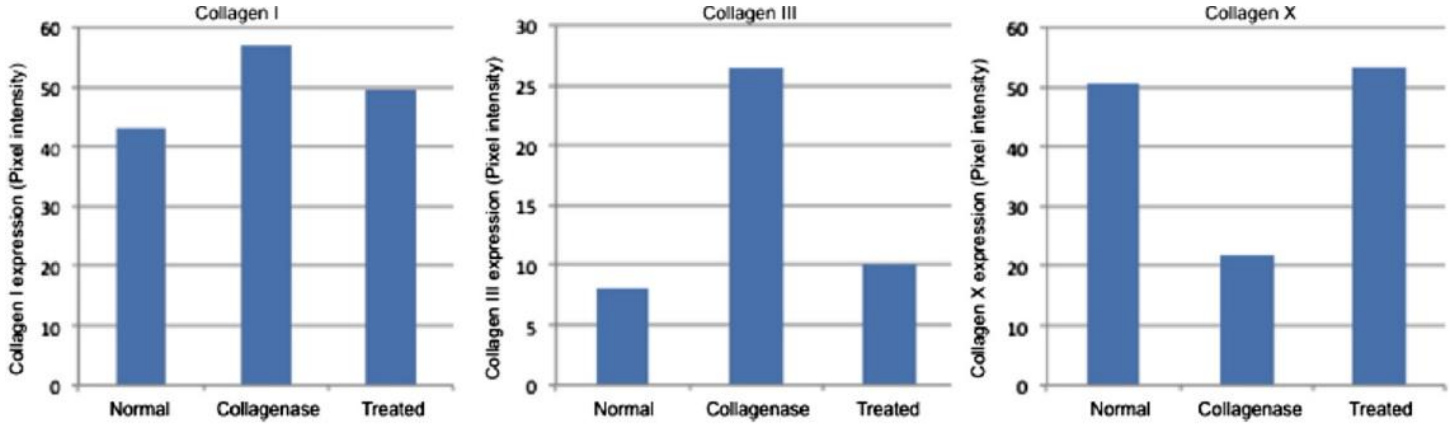


Fig. 4 **a** Semi-quantification of collagen subtypes using western blot analysis. **b** The *Y*-axis corresponds to signal intensities: (*A*) collagen I (129 kDa), (*B*) collagen III (138 kDa), and (*C*) collagen X (66 kDa)

Kamineni S, Dhawan V, Huang C. Porphyromonas gingivalis response to ultrasonication. International Journal of Clinical Microbiology 2019 Mar;1(1):25-28. [Bactericidal]

Recent data supports the use of ultrasonic debridement in the treatment of diabetic foot ulcers.

Purpose: The purpose was to investigate the antibacterial effect of a clinical grade, lower energy ultrasound probe on P gingivalis bacterial viability.

Methods: A Tenex TX1 probe with standard settings for clinical use was used. A Gram negative (Porphyromonas gingivalis) bacteria, known for its pathological activity, was investigated. The bacteria were cultured in an anaerobic broth, re-suspended to achieve a consistent bacterial count, and 5ml of the re-suspension was placed in a test tube for testing. Each tube was sonicated with the TX1 probe for varying lengths of time (10, 30, 60, 120 seconds). The sonicated suspension was diluted and plated on blood-agar plates, then incubated for 48 hours at 37°C in an anaerobic growth chamber. The number of colony forming units were counted on each plate and the anti-bacterial effect calculated.

Results: A statistically significant antibacterial effect was demonstrated with sonication. 120 seconds of sonication provided a 64% kill rate compared to the control. Although greater sonication times led to greater kill rates, 120 seconds achieved the only statistically significant time comparison.

Conclusion: The Tenex TX1 ultrasonic probe has an antibacterial effect against the gram negative anaerobic bacterial species P gingivalis. This may partially help to explain the ability of ultrasonic debridement to result in the healing of long-term diabetic ulcers that have been recalcitrant to other forms of treatment.

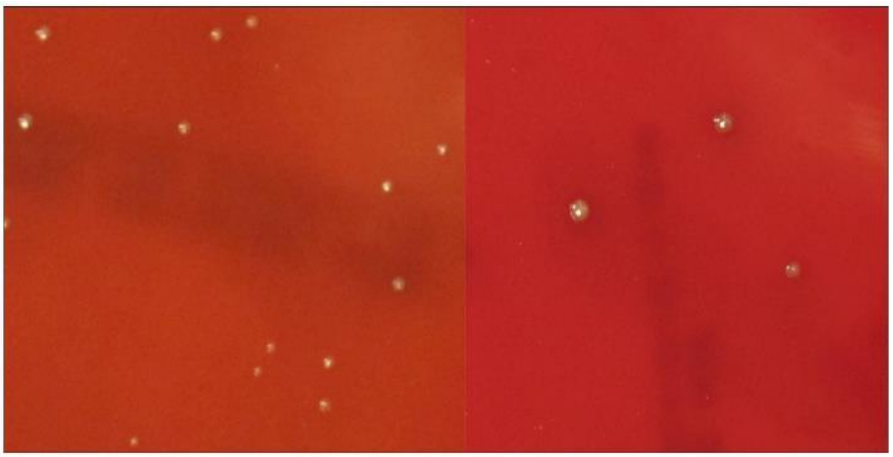


Figure 1. Porphyromonas Gingivalis; Culture plates (a) Control, (b) 120 seconds

Kamineni S, Huang C. The antibacterial effect of sonication and its potential medical application. Journal of the Société Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT J) 2019;5(19):1-4. [Bactericidal]

Introduction: Early data support the use of ultrasonic probe debridement in the effective treatment of recalcitrant diabetic foot ulcers. We investigated the effect of the Tenex Health TX1 ultrasonic debridement probe with respect to bacterial viability.

Methods: A commercially available Tenex TX1 probe was used for this study. Three bacterial strains, aerobic and anaerobic, were tested, G-negative (Porphyromonas gingivalis) and G-positive bacteria (Staphylococcus aureus and Streptococcus gordonii). Bacteria were cultured and tested with ultrasonication for different lengths of time (10, 30, 60, and 120 s). The tested bacterial samples were plated, number of colonies on each plate counted, and anti-bacterial effect calculated. Statistical analysis was conducted with a one-way analysis of variance.

Results: Sonication exhibited a significant time-dependent antibacterial effect. Statistically significant anti-bacterial effect was observed in all three species tested. Compared to the control, 120 s of sonication had a kill rate of 34% for S. gordonii, 60% for S. aureus and 64% for P. gingivalis. S. aureus kill rate was statistically significant at all times, S. gordonii was statistically significant at all times above 10 s, and P. gingivalis was only statistically significant at 120 s.

Conclusion: This study demonstrates that the Tenex Health TX1 probe has an antibacterial effect against a wide spectrum of gram-positive, gram-negative, aerobic and anaerobic bacterial species. This may partially explain the dramatic healing of long-standing recalcitrant diabetic ulcers debrided with this device and may have a place in treating pathologies with bacterial mechanisms.

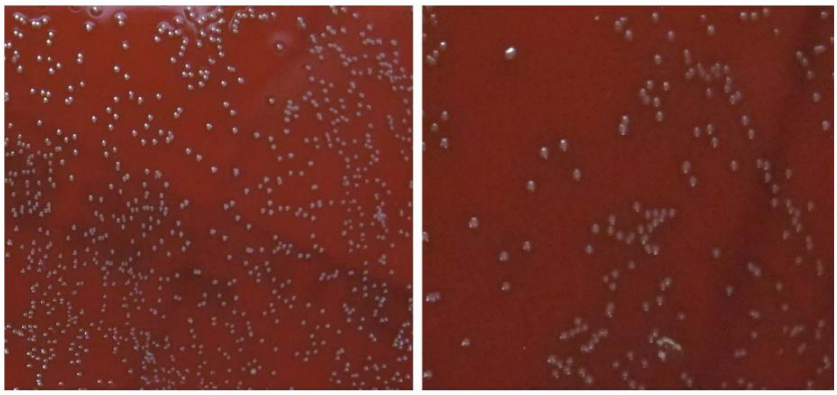


Figure 1. *Streptococcus gordonii*; Culture plates (a) Control. (b) 120 s.

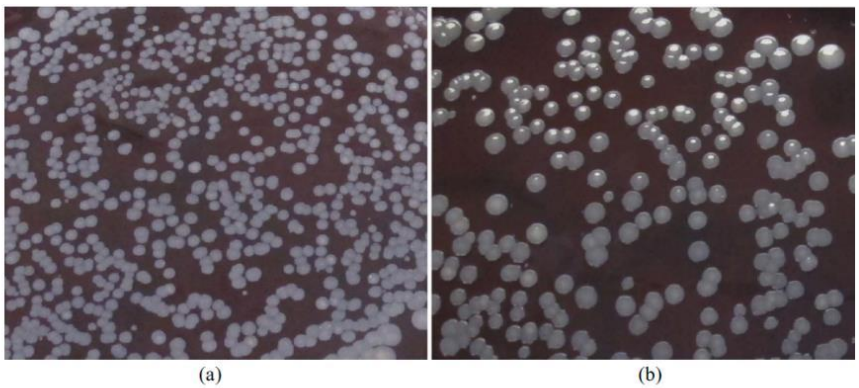


Figure 2. *Staphylococcus aureus*; Culture plates (a) Control. (b) 120 s.

Kamineni S, Kamineni E, Kamineni A, Huang C. Anti-staphylococcal effect of ultrasonication. Novel Techniques in Arthritis & Bone Research 2019;3(3):001-003. [Bactericidal]

Diabetic foot ulcers are known to have polymicrobial flora, including Staphylococcus, that is part of the reason for recalcitrant persistence. A recent application of ultrasonic debridement of diabetic foot ulcers has yielded promising clinical results.

Purpose: The purpose was to investigate the effect of ultrasonic energy on staphylococcal survival.

Methods: We investigated the effects of sonication, using a Tenex TX1 probe, for varying lengths of time (10, 30, 60, 120 seconds) on a gram-positive bacterium, Staphylococcus aureus. The tested bacterial samples were plated, the number of colonies counted, and the anti-bacterial effect was calculated.

Results: A statistically significant antibacterial effect was demonstrated with sonication. 120 seconds of sonication provided a 60% kill rate of the Staphylococcus Aureus, compared to the control. The kill rate was statistically significant at all times, compared to the control ($p=0.0001 – 0.004$).

Conclusion: The Tenex TX1 Ultrasonic Probe demonstrates an anti-bacterial effect, in a time dependent manner, on the gram-positive bacterium Staphylococcus aureus. The success of recalcitrant diabetic foot ulcers treated with ultrasonic debridement may be partially explained by this anti-staphylococcal effect of this treatment modality.

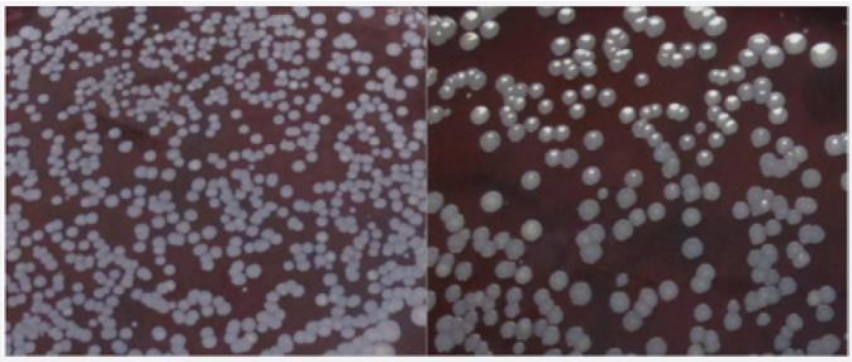


Figure 1: Staphylococcus Aureus; Culture plates (a) Control (b) 120 seconds.

HIP

Ostrom E, Joseph A. Percutaneous ultrasound tenotomy using the Tenex System on the adductor longus tendon: a pilot case series. MOJ Sports Medicine 2018;2(1):1-6. [Hip: Adductor Longus]

Groin pain caused by tendinopathy is a significant problem in athletic populations; an accurate and effective treatment is required for minimal turnaround time for athletes. Treatments focusing on removing the tendinopathic tissue and promoting the body's natural healing response are desirable to get their patients back to full activity in a relatively short amount of time. The purpose of this investigation was to describe the ultrasound guided percutaneous tenotomy procedure using the Tenex Health TX System on the adductor longus tendon, report patient NPS (Numeric Pain Scale) scores before and after the procedure, and report recovery time. Twelve patients were included in this study and ten (83%) reported improvement after the procedure. Average NPS scores before and after the procedure was as follows: Pre NPS M=7.3 ± 2.1, post NPS M=2.6 ± 2.2. Patients showed significant improvement in pain after percutaneous tenotomy (P<0.001). Patient's average time to recovery was 4.6± 2.9 weeks and this improvement was sustained out to the 6-month post-treatment evaluation period. Two of the 12 patients reported little relief at 6 months post-treatment. There were no patient reported complications associated with the procedure. Our results suggest this procedure may be effective in reducing patient's pain symptoms for adductor tendinopathy when conservative treatment fails. Furthermore, the procedure provides a quick recovery time.

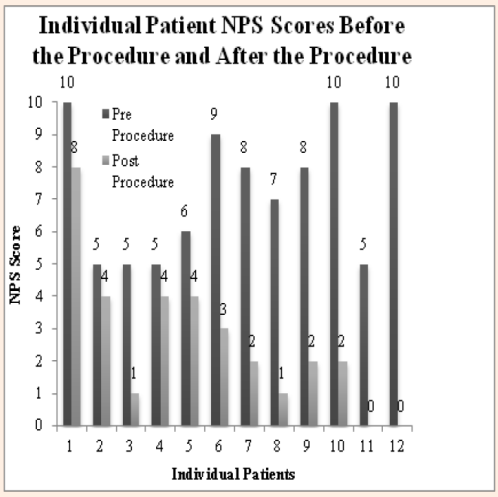


Figure 3: Individual pre and post NPS scores; dark grey is the pre procedure NPS score and light grey is the post procedure NPS score.

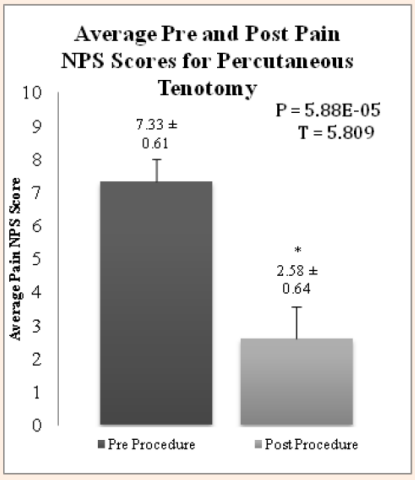


Figure 4: Average pre procedure NPS scores versus average post procedure NPS scores. Average ± standard error of the mean (SEM), T=5.875, P=7.81x10^{-5}.

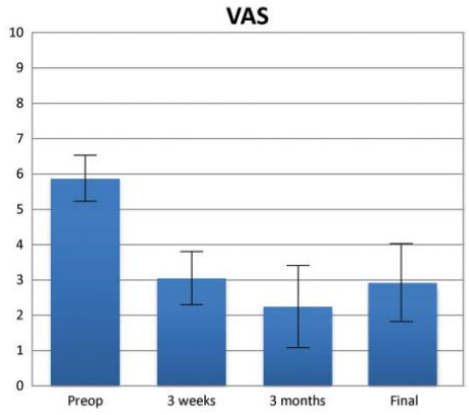
Baker CL., Mahoney JR. Ultrasound-guided percutaneous tenotomy for gluteal tendinopathy. The Orthopaedic Journal of Sports Medicine 2020 Mar 19;8(3)1-8. [Hip: Gluteal]

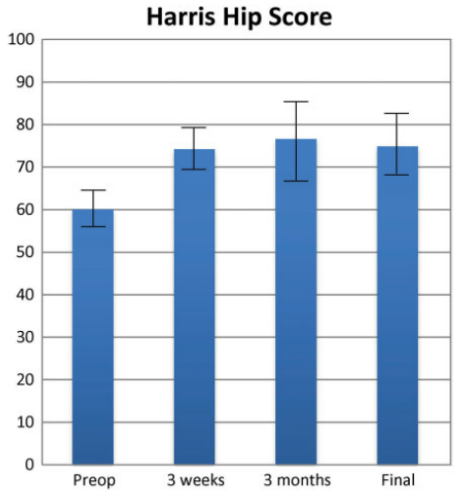
Purpose: To evaluate the efficacy of ultrasound guided percutaneous ultrasonic tenotomy for patients who have failed conservative management of gluteal tendinopathy.

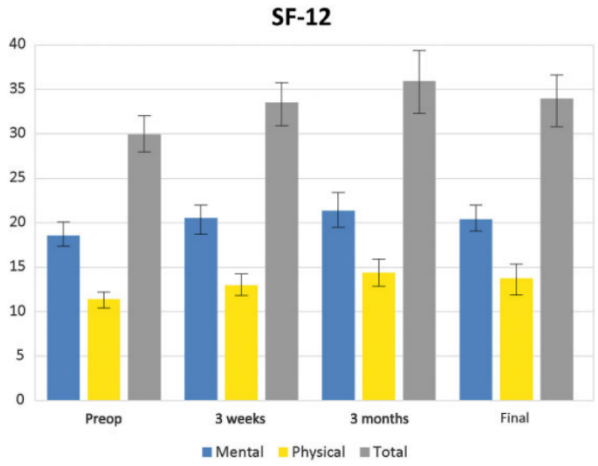
Methods: 29 patients over the age of eighteen who had failed more than 4 months of conservative treatment were enrolled in this prospective, IRB approved study to evaluate the safety and efficacy of Ultrasound Guided Percutaneous Ultrasonic Tenotomy (PUT) in an outpatient setting. All patients had an MRI demonstrating tendinopathy of the gluteus minimus/medius tendons prior to PUT. Outcomes were assessed by use of a visual analog pain scale (VAS), Harris Hip Score, 12-item Short Form Health Survey and additional specific hip function questions. Patients were followed for a minimum of 6 months. Patients were given outcome questionnaires before the procedure and at follow-up of 3 weeks, 3 months, and 6 months.

Results: The mean VAS score improved from 5.86(±1.73) preoperatively to 2.82 (±2.22) 6 months after the procedure. Harris Hip Scores improved from a mean of 60.0 (±10.86) preoperatively to 77.47 (±14.34.5) at 6 months. When asked at 6 months if they would have the procedure again, 15 replied "yes definitely", 3 replied "yes probably", 3 replied "maybe", 1 replied "likely not" and 2 replied "definitely not". Data was not available for 2 patients. 3 patients continued to have pain and went on to have additional surgical repair. 26/29 patients (90%) had pain relief. There were no complications.

Conclusion: This first prospective evaluation of ultrasound guided PUT for gluteal tendinopathy showed early improvement in pain and function with no complications. PUT appears to be an effective and safe alternative to surgical intervention, that can be done in an outpatient setting and is well tolerated.







KNEE

Elattrache NS, Morrey BF. Percutaneous ultrasonic tenotomy as a treatment for chronic patellar tendinopathy-jumper's knee. Operative Techniques in Orthopaedics 2013;23(2):98-103. [Knee]

Chronic tendinopathy of the patella or "jumper's knee" remains a major treatment challenge. Surgery has considerable morbidity and is unpredictable in effectiveness and most surgeons will try other conservative treatment for about a year prior to performing. The result is often the patient has marked dysfunction even for daily activity. Most recently the use of ultrasound to guide various treatments has been introduced and documented. Emerging as a treatment for chronic tendinopathy is to first isolate the lesion by ultrasound guidance and perform a percutaneous tenotomy using ultrasonic cutting energy. Tenex Health has developed the TX1 instrument with targeted ultrasonic cutting energy to perform a percutaneous tenotomy on areas of anatomy where tendinopathy exists. To date, the safety and efficacy of the procedure in general has been exhibited in over 5000 patients treated for chronic tendinosis or plantar fasciitis. This is the only percutaneous modality, other than open resection, that is capable of cutting and debriding the diseased tendon tissue. Percutaneous tenotomy of the patella tendon with the TX1 MicroTip was successfully performed in 16 patients of which 10 were collegiate level athletes. The patients were treated with the TX1 MicroTip once with no additional follow-on treatments. The procedure is well tolerated and has a low complication rate and is a viable alternative to treat refractory patellar tendinopathy.

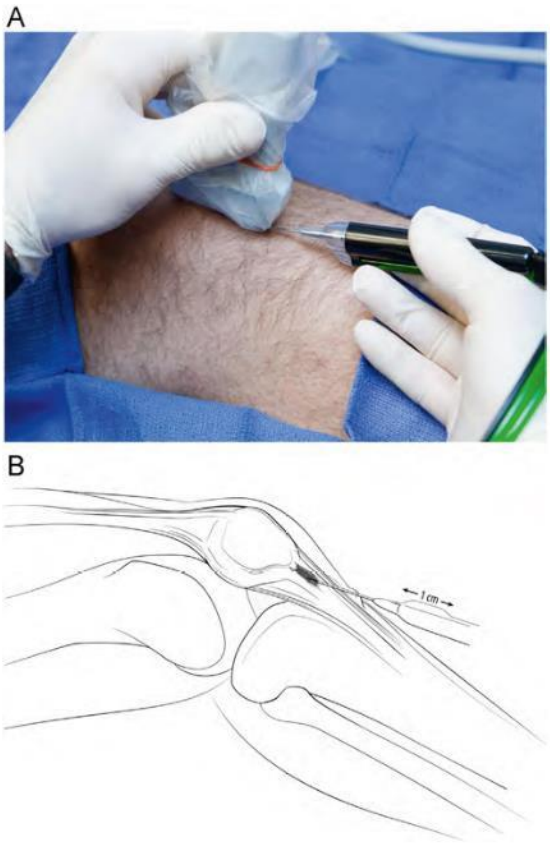


Figure 6 The probe is advanced into the lesion with ultrasound guidance. (A) The technique involves a to and fro "linear" movement of the probe as it is directed into the pathologic lesion (B). (Color version of figure is available online.)

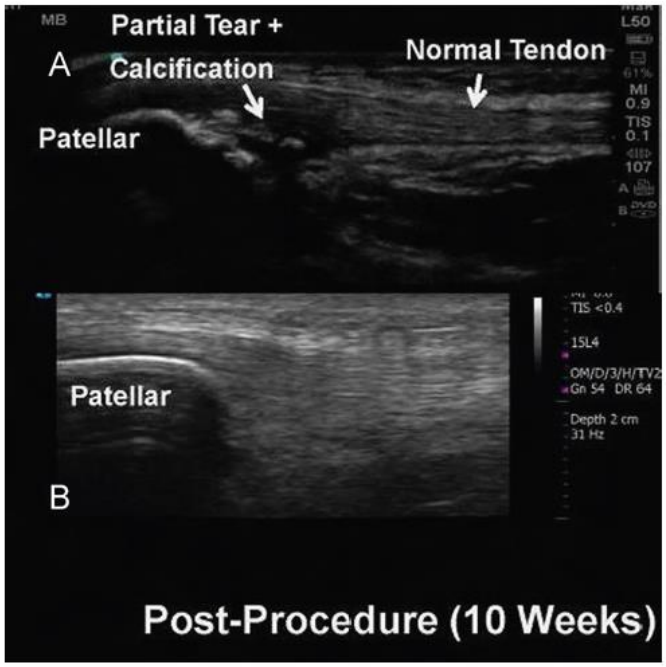


Figure 8 The pretreatment ultrasonic image (A) shown in Figure 2 demonstrates a more normoechoic appearance at 10 months. (B) The symptoms have resolved. (Color version of figure is available online.)

Nanos KN, Malanga GA. Treatment of patellar tendinopathy refractory to surgical management using percutaneous ultrasonic tenotomy and platelet-rich plasma Injection: a case presentation. PM &R 2015;7(12):1300-1305. [Knee]

Chronic proximal patellar tendinopathy is a common sports condition that may be refractory to nonoperative treatments, including activity modification, medications, and comprehensive rehabilitation. Proximal patellar tendinopathy affects up to 40% of professional athletes, particularly those involved in jumping sports. Approximately 10% of cases will become refractory. In these cases, the tendon is understood to be in a chronic, degenerative, "underhealed" histologic state. When conservative treatment fails for refractory cases, open or endoscopic surgical debridement presents a definitive treatment, albeit with success rates as low as 45%. Unfortunately, in cases where surgical intervention is unsuccessful, there are few remaining traditional therapeutic options.

This article presents a case study of a collegiate athlete with chronic, proximal patellar tendinopathy refractory to traditional interventions, regenerative interventions and surgical debridement, who was treated with percutaneous ultrasonic tenotomy (PUT) and a single PRP injection. This is the first published report of successful PUT in the setting of previous surgical failure.

The patient had a 6-year history of proximal patellar tendinopathy refractory to ice, supervised activity modification, anti-inflammatories, kenesio taping, patellar bracing, eccentric physical therapy, multiple percutaneous needle tenotomies accompanied by paratenon hydrodissection, and arthroscopic soft-tissue debridement with PRP injection. 11 months after the last surgery, his pain rated 7 of 10 on the VAS scale for daily activities and 10 of 10 with physical activity. He was unable to return to sports. PUT was performed with an accompanying PRP injection.

At 2 months follow-up, there was a 60-65% improvement in pain and function. At 5 months the patient returned to collegiate level basketball with only occasional soreness after performance. He remains asymptomatic 2 years after the procedure. Percutaneous ultrasonic tenotomy can be considered as a treatment option in patients presenting with refractory proximal patellar tendinopathy, including those who do not respond to previous operative intervention.

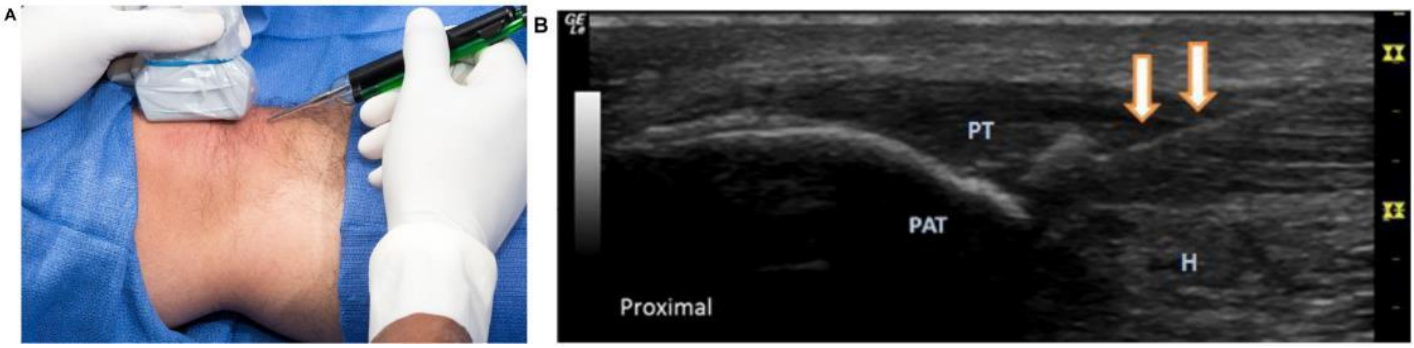


Figure 2. (A) Set-up for sonographically guided percutaneous ultrasonic tenotomy. The knee is slightly flexed to 30° to reduced tendon anisotropy. The transducer is positioned at the inferior patellar pole to provide a long axis view of the tendon as shown in Figure 1A and 2B. Following preparation as discussed in the text, the TX1 handpiece would be advanced via sonographic guidance into the tendon to complete the procedure. Left, proximal; Right, distal; Top, anterior; Bottom, posterior. (B) Long-axis view on ultrasonography of the right patellar tendon (PT) during treatment with percutaneous ultrasonic tenotomy. Orientation is the same as Figures 1A and 2A. Following local anesthesia and preparation as described in the text, the TX1 device (arrows) has been advanced using an in-plane, distal to proximal, ultrasonography-guided approach, passing into the abnormal region of the patellar tendon. At this point percutaneous ultrasonic tenotomy can be completed by activating the working tip via a foot pedal and directing the handpiece to the affected portions of the tendon using orthogonal long and short-axis imaging of the tendon. PAT, inferior patella; H, Hoffa's fat pad; Left, proximal; Right, distal; Top, superficial/anterior; Bottom, deep/posterior.

Stuhlman CR, Stowers K, Stowers L, Smith J. Current concepts and the role of surgery in the treatment of jumper's knee. Orthopedics 2016;39(6):e1028-e1035. [Knee]

Patellar tendinopathy, or "Jumper's Knee" is a common cause of anterior knee pain among athletes and active populations. Studies show the prevalence to be 8.5% for recreational athletes and 13% - 20% among elite athletes. Nearly 10% of cases will become chronic and require surgical intervention. Chronic tendinopathy results from a degenerative condition following repeated microtrauma and incomplete healing. Surgery aims to remove the pathologic tissue and provide a vacant bed to regenerate healthy tendon.

This study reviewed all articles on patellar tendinopathy, with a focus on recalcitrant cases, from 2000 to 2014. Mean duration of symptoms was 19 months for recreational athletes and 32 months for elite athletes. Approximately 33% athletes were out of their sport for 6 months or more. Recurrence following successful treatment were as high as 23%.

Numerous open and arthroscopic procedures were described with variable results. Arthroscopic surgery was theorized to offer improved results. However, these have not been demonstrated consistently in literature. Open and arthroscopic surgery offer approximately equal results with success rates of 81% (45% - 100%) for open procedures and 91% (86% - 96%) for arthroscopic procedures. Return to sport rates were 77% (16% - 91%) with open procedures and 81% (46% - 100%) with arthroscopic procedures. Average return to sport times were 5.6 months with open and 5 months with arthroscopic procedures.

The minimally invasive option of percutaneous ultrasonic tenotomy using ultrasound imaging guidance is also described. Ultrasound imaging generally provides excellent intrinsic tendon detail. It is commonly used with multiple injection treatments. Percutaneous ultrasonic tenotomy is a less invasive, highly effective treatment currently for epicondylitis. It involves the tenotomization and aspiration of pathologic tissue with an ultrasonically vibrating needle, in a process similar to phacoemulsification for cataract removal. It does not require an operating room or ambulatory surgical center, nor general or regional anesthesia. Financial implications are significantly less than with traditional surgical intervention. Current literature suggests the technique is as successful as any of the more operative interventions.

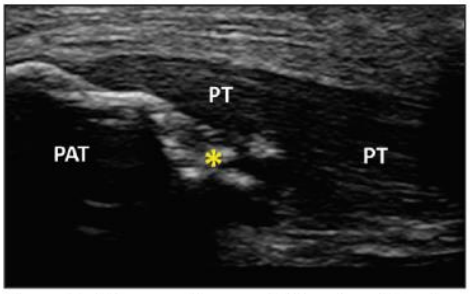


Figure 2: Ultrasound image of chronic patellar tendinopathy. Note the diffusely hypoechoic (darker than normal) patellar tendon (PT) extending from the inferior patellar pole. Intratendinous calcifications (asterisk) are seen at the enthesis, correlated with the patient's point of maximal tenderness. Left is cephalad, right is caudad, top is superficial/anterior, and bottom is deep/posterior. Abbreviation: PAT, patella.

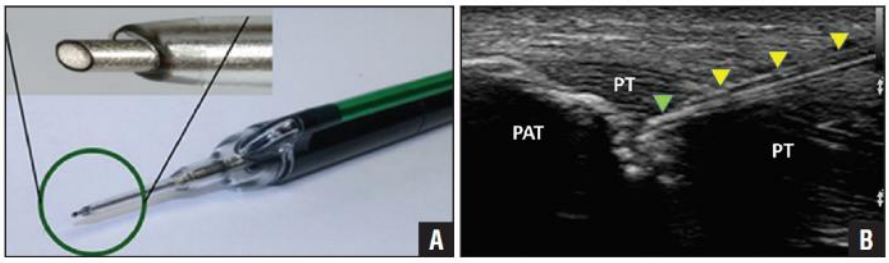
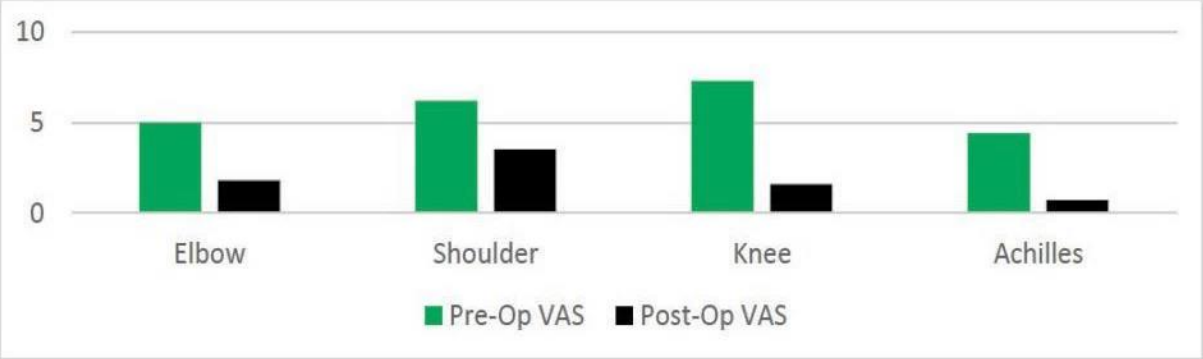


Figure 4: Handpiece to perform percutaneous ultrasonic tenotomy (TX1; Tenex Health, Lake Forest, California). The handpiece consists of a lightweight, pen-like shaft that is held in one hand. The working end (left) consists of a transparent outer sheath with a protruding hollow, stainless steel working microtip. Two plastic tubes are attached to the handpiece base (right) to provide continuous fluid inflow-outflow at the working end (A). The TX1 device is shown within the patellar tendon of the same patient demonstrated in Figure 2. Using ultrasound guidance, the active tip is precisely delivered to the desired target region to complete the tenotomy and debridement. The plastic sheath is demonstrated by the yellow arrowheads, and the exposed working microtip is identified by the green arrowhead. Although the tip is shown in the area of dystrophic calcification, using ultrasound, the operator may reposition the tip to treat all desired areas within the tendon (B). Abbreviations: PAT, patella; PT, patellar tendon. Left is cephalad, right is caudad, top is superficial/anterior, and bottom is deep/posterior.

COMBINED / OTHER ANATOMY

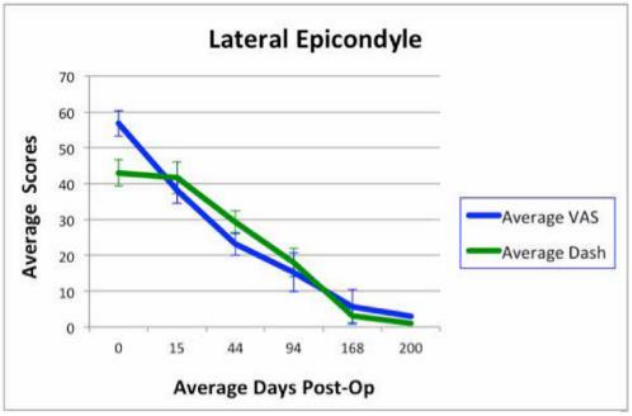
Khanna M, Wiederholz M, Rizkalla M, Jiminez J. A novel approach to the treatment of chronic tendon pathology: a pilot study. Poster presented at: Annual Meeting of American Academy of Physical Medicine and Rehabilitation 2013 Oct. [Elbow/Shoulder/Knee/Achilles]

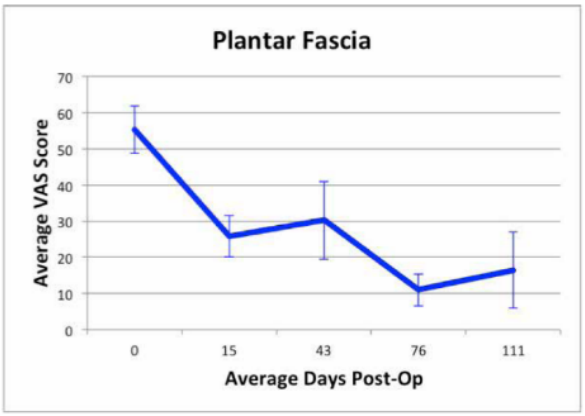
Chronic tendinopathy remains one of the most challenging orthopaedic conditions to treat. The purpose of the study is to evaluate the early efficacy of a novel percutaneous fasciotomy and surgical tenotomy technology and technique used to treat chronic patella tendonosis, rotator cuff tendonosis and lateral epicondylitis. Eighteen (18) patients with chronic tendinosis who failed conservative treatment were evaluated. These patients elected to go through a new treatment from Tenex Health which uses the TX1 MicroTip that delivers precise ultrasonic cutting energy through a percutaneous approach and ultrasound image guidance. The TX1 MicroTip is designed to cut and debride the damaged tendon tissue. The average age of the patients was 48.2 years (SD 15.2) and the average duration of symptoms was 6.4 months (SD 2.4). At two weeks after the treatment, there was a significant improvement in pain/VAS score ($p<0.05$) as well as an overall improvement in quality of life outcome measurements ($p=0.004$). Sixteen of the eighteen (89%) patients were satisfied with the procedure at the follow-up visit.

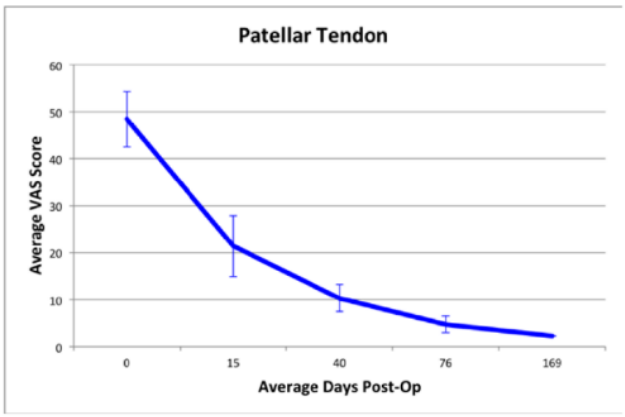


Traister E, Lingor R, Simons S. The effect of percutaneous tenotomy using Tenex on short term average pain scores in refractory tendinopathies. Poster presented at Annual Meeting of American Medical Society for Sports Medicine 2014 Apr. [Elbow/Knee/Plantar Fascia]

Patients presenting with pain due to chronic tendinopathy is common in primary care settings. Many of these patients have failed one or more conservative therapies. These therapies may include rest, physical therapy, bracing and cortisone injections. Percutaneous tenotomy via the Tenex Health TX system provides a novel technique for patients with recalcitrant tendinopathy. It combines ultrasound imaging for guidance and ultrasonic energy to precisely cut and remove degenerative tendon tissue. Given the novelty of this technology, there have been few studies looking at how patients' pain scores respond to this new procedure. The purpose of this study was to perform a review of average pain scores on a cohort of 43 patients that had recalcitrant tendinopathy and underwent percutaneous tenotomy via the Tenex Health TX system in an outpatient sports medicine clinic. Tenotomy sites included lateral epicondyle (24 patients), patellar tendon (8 patients) and plantar fascia (11 patients). These patients had failed at least one conservative measure and had a diagnostic ultrasound documenting pathology consistent with chronic tendinopathy. Pre-treatment pain scores were determined using a 100 point visual analogue scale (VAS). Patients were asked to follow-up at approximately 2, 6, 12 and 24 weeks post-treatment. A Disabilities of Arm, Shoulder and Hand (DASH) survey was also used for patients who underwent percutaneous tenotomies of the lateral epicondyle. Overall, the three tenotomy sites showed significant decline in pain scores from baseline and a similar improvement in DASH scores for the patients with elbow tendonosis. There were no adverse events reported by any patients and none of the patient's pain scores significantly worsened. The goal of this study was to look at the trends of pain scores. With the significant decline in average pain scores across all three tenotomy sites, further high powered studies are warranted to evaluate this promising technology and treatment.







Hall MM, Woodroffe L. Ultrasonic percutaneous tenotomy for recalcitrant calcific triceps tendinosis in a competitive strongman: a case report. Current Sports Medicine Reports 2017;16(3):150-152. [Triceps]

The sport of strongman has had increasing popularity in recent years. There are unique aspects of strongman training and competition which may influence injury risk. Strongman athletes are required to move near maximal loads, often of unusual size or shape, repeatedly in short durations of time. Strongman competitors appear to experience a relatively high injury rate compared with other weight training sport athletes.

A retrospective epidemiological study of strongman injuries reported 3.5% of total injuries involved tendon tears or strains of the elbow. A recent review of injuries among weightlifters and powerlifters reported elbow injuries accounted for 6% to 35% of injuries, and tendon injuries comprised 12% to 25% of injuries. While triceps tendon disorders in the general population are thought to be rare, a retrospective review of more than 800 consecutive elbow magnetic resonance imaging (MRI) demonstrated a triceps partial or complete tendon tear rate at nearly 4%. The incidence of chronic triceps tendinosis might be much higher since many of these injuries are not routinely sent for advanced imaging.

Some cases of chronic triceps tendinosis are recalcitrant, with pain and functional limitation preventing the athlete from return to sport. We present a challenging case of chronic calcific triceps tendinosis in a strongman competitor who failed traditional conservative measures and was unable to return to training/competition. Treatment with ultrasonic percutaneous tenotomy allowed for rapid pain improvement and return to full strongman competition at previous level of performance. This is the first report of this novel technique successfully treating triceps tendinosis with full return to prior level of competition and sustained benefit greater than 3 years post-procedure.

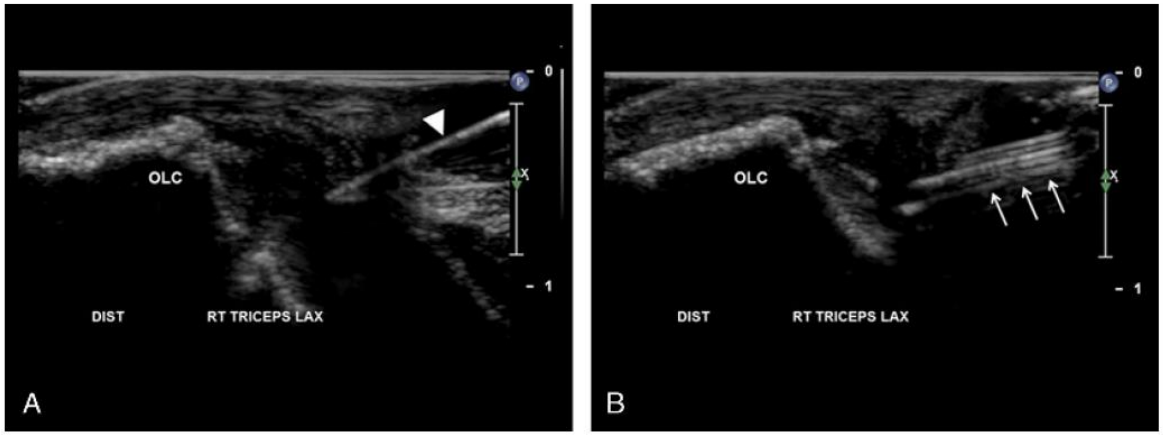


Figure 3: A companion case of triceps tendinosis treated with ultrasonic percutaneous tenotomy. (A) After obtaining local anesthesia, a no. 11 blade (arrowhead) is used to create a tract down to the tendon. (B) The TX1 device (arrows) is then directed to the pathologic regions within the tendon and ultrasonic debridement performed. DIST, distal; OLC, olecranon.

DIABETIC FOOT ULCER (DFU)

Freed L, 603-P: A Unique, Definitive, and Durable Solution for the Chronic Diabetic Foot Ulcer, Diabetes 2020 Jun; 69(Supplement 1) [DFU]

Background: In spite of significant effort and investment, definitive treatment for diabetic foot ulcers is lacking. Recurrence is common in many, if not most, instances. A novel treatment is applied which employs ultrasonic energy to address the major pathophysiologic features of this condition.

Technique: A [Tenex] ultrasonic probe effective in removing diseased tendon was applied to the management of the diabetic foot ulcer. Using 2-4 puncture sites, the ultrasonic probe removes the thickened scar tissue that surrounds the non-healing wound crater. The probe is then introduced into the osseous prominence which is also removed using the ultrasonic probe. The scar and bone are aspirated through the hollow probe and removed from the patient. The initial experience is limited to MW class 1-3 ulcers.

Methods: From Jan 2014 - Nov 2019, 105 ulcers were managed with this technique. Ulcer duration varied from a minimum of 3 months, to over 3 years (mean = 15 months). All patients had unsuccessfully undergone numerous traditional treatment modalities. The mean ulcer size was 20 mm. Mean treatment time was 4.5 minutes. Patients were followed at weekly intervals until healed and at 3-month intervals after healing.

Results: 101/105 (96%) ulcers completely healed, at a mean time of 3.5 weeks (range 7- 42 days) after treatment. 5 of the 101 (5%) healed ulcers recurred from 14 - 33 months. One patient developed a bacteremia and one a local cellulitis, both responding to antibiotics.

Conclusion: A single treatment with the [Tenex] ultrasonic probe as described has demonstrated a high rate of complete healing with low recurrence and complication rates. The procedure is relatively inexpensive and easily learned by those experienced in managing this condition.

CLI-008. Rev. G. August 2020

The publications and studies herein are the work of independent investigators.

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