Percutaneous ultrasonic tenotomy for chronic elbow tendinosis: a prospective study

Darryl E. Barnes, MD\textsuperscript{a}, James M. Beckley, MD\textsuperscript{b}, Jay Smith, MD\textsuperscript{c,}\textsuperscript{*}

\textsuperscript{a}Department of Orthopedics and Sports Medicine, Mayo Clinic Health System, Austin, MN, USA
\textsuperscript{b}Department of Orthopedic Surgery, Mayo Clinic and Mayo School of Medicine, Rochester, MN, USA
\textsuperscript{c}Departments of Physical Medicine & Rehabilitation, Radiology, and Anatomy, Mayo Clinic and Mayo School of Medicine, Rochester, MN, USA

\textbf{Background:} Elbow tendinopathy is the most common cause of elbow pain affecting active populations. Surgical excision is reserved for patients with refractory symptoms. Percutaneous ultrasonic tenotomy performed under local anesthesia also removes degenerated tissue and therefore provides an alternative treatment option to surgical excision. This investigation prospectively documented the safety and 1-year efficacy of ultrasonic percutaneous tenotomy performed by a single operator.

\textbf{Methods:} Nineteen patients, aged 38 to 67 years, in whom >6 months of conservative management for medial (7) or lateral (12) elbow tendinopathy had failed were prospectively studied. All patients were treated with percutaneous ultrasonic tenotomy of the elbow by a single operator. Visual analog scale (VAS) for pain, the 11-item version of the Disabilities of the Arm, Shoulder, and Hand (Quick DASH) index, and the Mayo Elbow Performance Score (MEPS) were assessed by an independent observer before treatment and at 6 weeks, 3 months, 6 months, and 12 months after treatment.

\textbf{Results:} No procedural complications occurred. Total treatment time was <15 minutes, and ultrasonic energy time averaged 38.6 ± 8.8 seconds per procedure. Average VAS scores were significantly improved from 6.4 to 2.6 at 6 weeks and were 0.7 at 12 months (\(P < .0001\)). Similar improvement occurred with the Quick DASH (pretreatment, 44.1; 12 months, 8.6, \(P < .0001\)) and MEPS (pretreatment, 59.1; 12 months, 83.4; \(P < .0001\)).

\textbf{Conclusion:} Percutaneous ultrasonic tenotomy performed under local anesthesia appears to be a safe and effective treatment option for chronic, refractory lateral or medial elbow tendinopathy up to 1 year after the procedure.

\textbf{Level of evidence:} Level IV, Case Series, Treatment Study.

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\textbf{Keywords:} Tennis elbow; golfer’s elbow; ultrasound; tendinopathy; ultrasonic; tenotomy

Clinical “lateral epicondylitis,” or “tennis elbow,” is the most common cause of elbow pain, affecting 2% to 3% of the population and resulting in significant activity restriction and economic burden.\textsuperscript{1,15,27,28} 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, cellular apoptosis, and autophagic...
cell death. More specifically, patients with chronic symptoms demonstrate a histologic pattern of angiofibroblastic hyperplasia, characterized by fibroblast proliferation, increased ground substance, disorganized collagen, and poorly functional neovascularity. Consequently, the terms “tendinopathy” or “tendinitis” are now preferred when referring to “epicondylitis” or “tennis elbow.”

Although most patients respond to activity modification, nonsteroidal anti-inflammatory drugs, bracing, physical therapy, modalities (e.g., ice, electrical stimulation), and various injections, approximately 10% to 15% will be refractory and therefore considered surgical candidates. Multiple open, arthroscopic, and percutaneous surgical procedures have been described to treat elbow tendinopathy, all sharing the fundamental goals of removing the pathologic tendinotic tissue and stimulating a healing response. These procedures have been effective in 75% to 90% of patients but expose patients to operative risks and a recovery that is often prolonged.

Sonographically guided percutaneous tenotomy using ultrasonic energy to remove diseased tissue has recently become available with the release of the TX1 device (Tenex Health Inc, Lake Forest, CA, USA). The U.S. Food and Drug Administration-approved TX1 procedure uses standard ultrasound guidance to place a proprietary needle-like device into the pathologic tendon region. Ultrasonic energy rapidly oscillates the hollow 18-gauge tip of the TX1 to emulsify tissue, which is subsequently removed by an inflow-outflow fluid circuit (Fig. 1). The TX1 technology is based on the widely used process of phaco-emulsification that is used to treat cataracts.

Recently, Koh et al. published the initial experience from Singapore in 20 patients with refractory lateral tendinosis treated with the TX1. These authors reported improvements in pain and function as early as 1 week postprocedure, which were maintained at the 1-year follow-up. Importantly, no complications occurred, and 19 of 20 patients (95%) were subjectively “very” or “somewhat satisfied” with their treatment. However, this investigation was limited to lateral elbow tendinosis, and 3 different orthopedic surgeons had performed the TX1 procedure. Although less common than lateral elbow tendinosis, medial elbow tendinosis (“golfer’s elbow”, or medial epicondylitis) is nonetheless common in clinical practice, shares similar histopathology to lateral elbow tendinosis, and should be amenable to treatment with the TX1 tenotomy and debridement procedure.

The primary purpose of this investigation was to prospectively document the safety and 1-year efficacy of sonographically guided percutaneous tenotomy using the TX1 device. All procedures were performed by a single physician (D.E.B.) experienced with ultrasound diagnosis and guided injections. We hypothesized that the procedure would be well tolerated, safe, and would produce statistically significant improvements in pain and function over a 1-year follow-up period.

Materials and methods

Study design

This study represents the prospective clinical experience of a single physician (D.E.B.), board-certified in Primary Care Sports Medicine, who offered the TX1 procedure as a treatment option to patients presenting with chronic, refractory lateral or medial elbow symptoms between October 6, 2011, and December 3, 2012. The treating physician had implemented the TX1 procedure into his practice on September 30, 2011. At the time of introduction, he had more than 6 years of experience in diagnostic and interventional musculoskeletal ultrasound and had been specifically trained in the TX1 procedure.

Inclusion criteria included: (a) age >18 years, (b) chronic lateral or medial elbow pain >6 months’ duration, (c) history and clinical examination consistent with lateral or medial epicondylitis, (d) sonographic evidence of medial or lateral elbow tendinosis, (e) >6 months of formal nonoperative treatment that included nonsteroidal anti-inflammatory drugs, activity modification, physical therapy, elbow straps, and steroid injections. Exclusion criteria included a documented ipsilateral upper extremity musculoskeletal condition (other than elbow tendinosis in the same arm on the opposite side) and patient choice not to participate.

Patients who satisfied the inclusion and exclusion criteria were offered several treatment options, including but not limited to ultrasound-guided percutaneous needle tenotomy, ultrasound-guided corticosteroid injection, surgery, and ultrasound-guided percutaneous tenotomy and debridement with the TX1 device.
Those patients opting for the TX1 procedure were prospectively entered into the clinical investigation.

On the day of treatment, demographic information, visual analog scale (VAS) pain score (range, 0-10; lower score is better), the Quick (11-item version) Disabilities of the Arm, Shoulder and Hand (Q-DASH) score (range, 0-100; lower score is better), and Mayo Elbow Performance Score (MEPS; range, 0-100; higher is better) were recorded for each patient. VAS scores, Q-DASH, and MEPS were also recorded at 6 weeks, 3 months, 6 months, and 12 months after treatment. All assessments were performed by a trained clinical nurse and reflected the patient’s status on the day of the assessment.

Procedural time was recorded in seconds as the total time that the TX1 was activated during the procedure using the on/off pedal. Complications were recorded on the day of treatment and during each follow-up point.

**TX1 technique**

The TX1 technique is a novel sonographically guided percutaneous tenotomy and debridement technique that uses ultrasonic energy to produce low-amplitude, high-frequency longitudinal oscillations of an 18-gauge hollow-tip needle. The rapid needle movement cuts through tendon and emulsifies tenodisitic tissue along an approximately 1-mm pathway distal to the needle tip. The oscillating tip is cooled by fluid that flows into the tip region from the outer hollow shaft of the double-lumen tip, whereas outflow occurs through the inner lumen, removing heated fluid and emulsified tissue and debris (Fig. 1). The TX1 technique is performed percutaneously under local anesthesia with the use of standard ultrasound guidance, as previously described in detail.

In short, for the lateral elbow procedure, the patient was placed semirecumbent with the shoulder slightly abducted and resting comfortably on an arm board with the elbow flexed between 60° and 90° (Fig. 2, A). For the medial elbow procedure, the patient was placed supine with the shoulder externally rotated and the arm resting on an arm board with the elbow flexed at 90° (Fig. 2, B).

The tendinotic region was identified by ultrasound and the skin marked accordingly. For medial elbow procedures, the position of the ulnar nerve was determined to ensure that it had not subluxated or dislocated volarly into the working field. If so, the procedure was done with the elbow in a more extended position. The arm was prepared using a ChloraPrep scrub (CareFusion Corp, San Diego, CA, USA), and sterile ultrasound transducer covers and sterile gel were used to ensure sterile technique. Local anesthesia was obtained with 1% lidocaine (3 mL) delivered into the skin, subcutaneous tissue, and tendinotic region using a 25-gauge, 50-mm needle and direct ultrasound guidance with a 12-3-MHz linear transducer and Philips CX50 ultrasound machine (Philips Healthcare, Andover, MA, USA). Thereafter, using ultrasound guidance, a number 11 scalpel blade was used to make a 4-mm stab incision through the skin, subcutaneous tissue, and into the tendon, in plane with the forearm and just distal (1-2 cm) to the epicondyle. The tip of the TX1 device was then introduced into the incision and advanced into the lesion using direct ultrasound guidance (Fig 2, C). Thereafter, the tip was activated using the on/off foot pedal attached to the TX1 console, and the tip moved through the lesion in a “to-and-fro” manner for 3- to 5-second intervals. During treatment, the working tip was observed using direct sonographic guidance in 2 orthogonal planes (long axis and short axis to the tendon) to ensure that the entire lesion was treated. As the tip was activated and tissue emulsified, microbubbles were produced secondary to device-induced cavitation. These microbubbles manifested as hyperechoic speckling, which were conspicuous on ultrasound and therefore served as a marker for treatment of a specific region. The procedure was continued until the pathologic area was completely treated, as identified by ultrasound.

**Rehabilitation**

After treatment, the stab incision was pressurized for approximately 2 minutes to achieve hemostasis, after which the wound was covered, compressive wraps were placed around the elbow, and the patient was given verbal and written postoperative care.

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**Figure 2** (A) Patient positioning for TX1 (Tenex Health Inc, Lake Forest, CA, USA) percutaneous tenotomy and debridement procedure on the common extensor tendon (lateral elbow). The box marks the transducer position over the lateral epicondyle and parallel to the forearm. The arrow denotes the approach for the procedure (distal to proximal). (B) Patient positioning for the TX1 percutaneous tenotomy and debridement procedure on the common flexor pronator tendon (medial elbow). The box marks the transducer position over medial epicondyle and parallel to the forearm. The arrow denotes approach for procedure (distal to proximal). As discussed in the text, the ulnar nerve should be evaluated before the procedure. If ulnar nerve instability is present, the elbow should be positioned in lesser degrees of flexion to keep the ulnar nerve posterior to the medial epicondyle. (C) Correlative sonographic image of the lateral elbow (compare panel A) during TX1 percutaneous tenotomy and debridement. Outer sheath (white arrows) is clearly visualized, with the metallic tip producing from the sheath and located within the common extensor tendon (CET, *). The yellow arrows demonstrate the reverberation artifact from the metal tip. Bottom, deep/medial; LE, lateral epicondyle; left, distal; LG, longitudinal; right, proximal; top, superficial/lateral.
Table 1  Elbow percutaneous tenotomy aftercare instructions

- Rest arm and hand today.
  - May resume nonrepetitive use of arm and hand in
    2 days. Gentle range of motion is encouraged
    immediately after the procedure.
  - No lifting objects with arm/hand greater than 5 pounds
    for 6 weeks.
  - May resume normal use of arm in 6 weeks.
- Replace bandage at least once per day for first 7 days.
  - Keep compression sleeve on arm for 4 days.
  - Keep bandages and procedure area clean and dry.
  - Do not bathe (submerge arm in water) arm for 1 week,
    showering is ok.
- If you experience discomfort in the first few days after
  the procedure, you may use application of an ice pack over the
  elbow. Keep in place for 20 minutes and then remove for at
  least 20 minute before reapplying if necessary. You may
  also use acetaminophen (Tylenol) as directed on
  container.
- If you notice increasing redness, warmth, pain, fever
  or drainage from the wound, contact our office at 507-
  XXX-XXXX.
- Return to this clinic for your follow-up visit in 2 and
  6 weeks.

instructions (Table 1). All patients were given postprocedural activity restrictions for 6 weeks and scheduled for 2-week and 6-week clinic follow-up appointments. At the 2-week and 6-week follow-up assessments, the wound was inspected for complications, and patients were specifically asked about complications or significant discomfort. At the 6-week follow-up, formal VAS, Q-DASH, and MEPS scores were also obtained, as previously noted. Thereafter, VAS, Q-DASH, and MEPS scores were obtained by mail at 3, 6, and 12 months. All data were obtained and entered into a data set by the trained clinical nurse without direct knowledge of the treating physician.

Statistical analysis

The statistical analysis was done by a trained statistician. All data are reported as means with the range or standard deviation for continuous variables and as count and percentage for categoric variables, unless otherwise specified. The analysis focused on the outcomes of pain (VAS scale), the Q-DASH score, and the MEPS. These outcomes were evaluated across the 5 time points (preprocedure and at 6 weeks, 3 months, 6 months, and 12 months postprocedure) using repeated-measures analysis of variance. When the overall analysis of variance F test for time was observed to be significant, pairwise comparisons were performed between each time point using the Ryan-Einot-Gabriel-Welsch multiple comparisons test to maintain the overall type I error rate. For each outcome, secondary analyses were performed to compare the change from baseline to the 6-week, 3-month, 6-month, and 12-month time points by gender, arm dominance (ie, involvement of dominant vs nondominant arm), and medial vs lateral elbow using nonparametric rank sum tests. The association of change from baseline to the 6-week, 3-month, 6-month, and 12-month time points with treatment duration and with patient age was evaluated by calculating Spearman correlation coefficients. Owing to sample size constraints, statistical power was limited for the secondary analyses. All statistical tests were 2-sided, and P values of <.05 were considered significant.

Results

The treatment group consisted of 10 men and 9 women, who were a mean age of 55.3 years (range, 38-67 years), presenting with >6 months of refractory elbow symptoms. All patients were right-hand dominant. Ten dominant (52.6%) and 9 nondominant (47.4%) elbows were treated, including 12 lateral (63.2%) and 7 medial (36.8%) elbows.

Preprocedure, mean pain VAS scores were 6.4 ± 2.4 (range 2-10), mean Q-DASH scores were 44.1 ± 17.1 (range 20.5-79.5), and mean MEPS were 59.1 ± 14.6 (range 30-85). The VAS of 2 was reported by a patient on the day of the procedure. This patient had several years of chronic, refractory, activity-related elbow symptoms averaging 7 of 10 in severity, with a relative paucity of resting symptoms. He had been scheduled for open surgery but chose to pursue percutaneous ultrasonic tenotomy instead. He had not been active on the day of the procedure, and thus his VAS score was artifactually low.

The mean ultrasonic energy time was 38.6 seconds (range 25-63 seconds), and total procedure time was generally completed in <15 minutes, including tendon localization, delivery of local anesthesia, and TX1 treatment. No procedural complications requiring specific management occurred in any patient during the 12-month follow-up period.

As demonstrated in Figure 3, mean pain VAS scores significantly improved by 6 weeks, and this improvement compared with the baseline was maintained at 3, 6, and 12 months after treatment (pretreatment VAS, 6.4; 6 weeks, 2.6; 3 months, 0.9; 6 months, 1.7; 12 months, 0.7; P < .0001). For most patients, the majority of the improvement in VAS occurred during the first 3 months postprocedure, with VAS scores improving significantly between pretreatment and 6 weeks post-treatment and also between 6 and 12 weeks post-treatment. VAS scores remained statistically unchanged thereafter (ie, between 3 months and 12 months post-treatment). As demonstrated in Figure 4, the improvement in Q-DASH scores paralleled that for VAS scores. Q-DASH scores significantly improved by 6 weeks after treatment, statistically improved further by 3 months, and remained stable thereafter (pretreatment Q-DASH, 44.1: 6 weeks, 30.1; 3 months, 13.8; 6 months, 16.4; 12 months, 8.6; P < .0001). MEPS values improved with the same pattern (pretreatment, 59.1; 6 weeks, 76.3; 3 months, 87.2; 6 months, 83.4; 12 months, 90.5; P < .0001; Fig. 5).

At the end of the 12-month follow-up period, 15 of 19 patients (78.9%) reported a >75% reduction in their VAS pain scores. Within the statistical limits of this investigation (see Statistical analysis), there was no significant effect of
gender, arm dominance (ie, whether dominant or non-dominant arm was treated), or side of elbow (lateral vs medial) treated on VAS, Q-DASH, or MEPS throughout the follow-up period.

**Discussion**

Chronic elbow tendinopathy represents a degenerative condition accompanied by the lack of an appropriate healing response rather than true inflammation. Consequently, contemporary treatments focus on the promotion of normal healing through therapeutic exercise, injection of prorregenerative agents, percutaneous needling, or surgical removal of the affected tissues. The TX1 technique offers the benefit of precisely guided percutaneous removal of tendinopathic tissue and can be performed in a variety of practice settings. Recently published data indicate that the TX1 procedure is well tolerated and significantly improved pain and function in 20 patients with lateral elbow tendinopathy treated by 3 surgeons during a 1-year follow-up period. The current investigation extends these previously published results by demonstrating that percutaneous tenotomy with the TX1 produces significant and sustained improvements in pain and function in medial and in lateral elbow tendinopathy during a 1-year follow-up period (Figs. 3-5). Furthermore, no complications occurred in our 19 patients, confirming the previously documented safety of the TX1 treatment.

Several aspects of the current investigation warrant further discussion. First, despite methodologic differences, our results parallel those of Koh et al, documenting statistically significant and sustained improvements in pain and function during a 1-year follow-up period. Second, similar to Koh et al, the most dramatic clinical results typically occurred within the first 6 to 12 weeks after TX1 treatment (Figs. 3-5). The explanation for this early improvement remains indeterminate and was not the primary focus of the current investigation. However, the early improvement may be due to removal of the tendinotic...
tissue, a potential analgesic effect of the TX1 treatment itself, or some other factor. Although it is unlikely that an analgesic response to TX1 treatment could result in sustained clinical improvements at 1 year, further investigation is warranted to clarify the mechanism(s) producing the early clinical improvement after TX1 treatment.

Third, the current investigation is the first to include patients affected by both lateral and medial elbow tendinopathy. Although the current study was not necessarily powered to detect differences among patient subgroups, analysis of our data failed to reveal statistically significant differences in outcomes between lateral and medial tendinopathy patients. These observations suggest that the TX1 procedure may be equally applicable to both medial and lateral elbow tendinopathy patients. Further larger scale investigation should provide further clarification in this regard.

The TX1 procedure was easily implemented into the physician’s office-based community practice. Total treatment times were less than 15 minutes, during which the total energy time of the TX1 averaged 38.6 seconds (range, 25-63 seconds). As with most procedures, a clinical assistant was used to assist in patient positioning, machine setup, medication preparation, and postprocedural dressing and instructions. In our experience, the clinical assistant readily mastered the machine setup after a single training session, and the treatment has now been seamlessly integrated into the clinical practice. In many situations, the ease of performance allows same day evaluation and treatment.

Several study limitations warrant discussion. First, we acknowledge that this investigation included a relatively small number of patients. However, our results are consistent with those obtained by Koh et al in 20 lateral elbow tendinopathy patients, reinforcing our conclusion that the TX1 procedure provides safe and effective treatment for chronic lateral or medial tendinopathy.

Second, there was no control group. Given that our patients had refractory symptoms for >6 months, we believe that it is unlikely that many of them would have spontaneously improved during the treatment period. In fact, our requirement for >6 months of refractory symptoms was more restrictive than most previously published surgical or interventional trials, including Koh et al. Given the rapid and sustained response to the TX1 treatment in the current investigation, we are comfortable offering the TX1 treatment to patients with shorter durations of refractory symptoms (for example >3 months). Despite these observations, we recognize that the current study would have been strengthened by a control group.

Third, we are unable to comment on the relative efficacy of TX1 percutaneous tenotomy compared with other interventions for chronic elbow tendinopathy. Although our clinical results are favorable, future prospective comparative investigations are warranted. The current data and those published by Koh et al provide valuable information by which to develop appropriately designed prospective comparative studies, including direct comparisons with more traditional surgical treatments.

Fourth, the primary purpose of this investigation was to compare the safety and 1-year outcome of percutaneous ultrasonic tenotomy. Consequently, we cannot comment on the cost-effectiveness of this treatment relative to open or endoscopic surgery. Although the overall costs of percutaneous ultrasonic tenotomy are less than traditional surgical procedures, a more formal economic investigation is warranted. Along these lines, a comparative cost-analysis of TX1 vs open surgical treatment for chronic lateral elbow tendinopathy is currently in progress. In the meantime, we can state with confidence that the TX1 procedure provides a safe and attractive treatment option for patients with chronic elbow tendinopathy.

Fifth, as previously mentioned, this clinical investigation does not provide insight regarding the therapeutic mechanism of the TX1 treatment. More specifically, we did not routinely perform follow-up post-treatment ultrasound examinations. Although Koh et al documented improvements in the sonographic appearance of the common extensor tendon after TX1 treatment, the relationship between tendon structure and outcome after tenotomy is not consistent. Nonetheless, we acknowledge that the histologic effects of TX1 treatment on tendon tissue warrant further study, and this is a topic of ongoing investigation.

Finally, at the time of this study the operator had more than 6 years of experience in diagnostic and interventional musculoskeletal ultrasound, including formal training with the TX1 technique. Thus, generalization of the current results to less experienced operators should be approached with caution. Reassuringly, Koh et al published similarly good results produced by 3 orthopedic surgeons with relatively limited ultrasound experience and training in the TX1 technique before clinical implementation.

**Conclusions**

Sonographically guided percutaneous ultrasonic tenotomy and debridement using the TX1 device appears to be a safe treatment option for patients presenting with chronic, refractory lateral or medial elbow tendinopathy and provides significant and sustainable improvements in pain and function during a 1-year follow-up period. Future investigations should explore the utility of tenotomy and debridement with the TX1 on more diverse patient populations using controlled study designs.

**Disclaimer**

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References