

Ultrasound Percutaneous Tenotomy: An Intervention for Managing Lateral Epicondylitis: A Narrative Review

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ABSTRACT

A growing emphasis is being focused on percutaneous ultrasonic tenotomy for expedited recovery from lateral epicondylitis (LE) and enhanced functionality. The TX1 tissue removal system, also known as the Tenex device from Tenex device (Tenex Health Inc., Lake Forest, CA, USA), notably excels in the management of chronic LE. Utilizing ultrasonic energy, this device offers three tips, namely, TX1, TX2, and TXBone-introducing novel avenues, for determining the previously inaccessible tendon pathology. The procedure disrupts degenerated segments, which creates fenestrations that induce local hemorrhage and the release of vasoactive substances. The overarching goal of Tenex is to boost vascularity through the initiation of tendon repair via the deposition of new collagen and elimination of necrotic tissues. This review assesses Tenex's effectiveness through gathering information, aiming to understand how it helps doctors and other healthcare professionals in their work.

KEYWORDS:

lateral epicondylitis, percutaneous ultrasonic tenotomy, Tenex device, treatment results

INTRODUCTION

Lateral epicondylitis (LE) refers to a prevalent musculoskeletal condition identified by its effect on the lateral epicondyle of the elbow; it features an annual incidence rate of 2.4–4.5 per 1,000 individuals¹. A standard therapeutic approach for the treatment of lateral elbow tendinosis has yet to be established. Traditionally, conservative management constitutes the primary strategy for initial intervention, encompassing measures, such as activity modification, physiotherapeutic interventions, administration of anti-inflammatory agents, and implementation of counterforce bracing, acupuncture, and corticosteroid

administration²⁻⁴. Surgical intervention may be warranted in cases with persistent symptoms despite these conservative measures.

Research focus is being increasingly centered on the use of percutaneous ultrasonic tenotomy (PUT) as a surgical procedure to alleviate symptoms of LE and improve functionality within a reduced recovery timeframe. Notably, PUT using the TX1 tissue removal system, also known as the Tenex device (Tenex Health Inc., Lake Forest, CA, USA), has been proven effective in the management of chronic refractory LE. The Tenex device (Tenex Health Inc., Lake Forest, CA, USA). uses ultrasonic energy to debride

and aspirate pathological tendon tissue. This device is equipped with three distinct tips (TX1, TX2, and TXBone). The introduction of the longer TX2 tip and the more powerful TXBone tip has opened up new possibilities for the treatment of tendon pathology, which was previously inaccessible via a percutaneous approach⁵. The procedure involves the disruption of degenerated segments through the creation of fenestrations, which elicit local hemorrhage and subsequently induces the release of vasoactive substances, such as calcitonin gene-related peptide and substance P⁶. The overarching objective of this procedure is the augmentation of vascularity, thereby prompting the initiation of tendon repair through the deposition of new collagen and concomitantly eliminating degenerated and necrotic tendon tissue.

This review assessed the efficacy of Tenex and obtained the latest empirical findings on PUT in the context of LE. This narrative review aimed to aid healthcare professionals in conducting comprehensive evaluations and rendering informed treatment choices rooted in optimal clinical practices.

PATHOGENESIS OF LATERAL EPICONDYLITIS

The definitive etiological factors of LE remain controversial. This condition is frequently associated with repetitive microtrauma linked to daily activities, such as gripping overload and wrist motion in various positions, particularly the extension position⁷⁻⁸. The extensor muscle group, particularly the extensor carpi radialis brevis muscle, is often impacted⁹. Initially characterized as an inflammatory process, especially in its early stages, LE is currently assumed to result from prolonged exposure to repetitive microtraumatic stressors, leading to the rupture of collagen fibril and triggering the innate immune response¹⁰⁻¹¹. Nonetheless, histopathological examination of this condition through biopsies has yielded unexpected results, including the lack of inflammatory cells in individuals with chronic LE¹²⁻¹³. To date, based on

cumulative pieces of empirical evidence, an increased presence of fibroblasts, heightened vascular hyperplasia, and disorganized collagen within the affected tendon tissue are speculated to be causes of a symptomatic degenerative process¹⁴.

INDICATIONS AND CONTRAINDICATIONS FOR PERCUTANEOUS TENOTOMY

The procedure is indicated for patients suffering from chronic lateral elbow tendinopathy with persistent symptoms for more than 3 months, regardless of attempted conservative therapies, such as anti-inflammatory treatments, physical therapy, and activity modification¹⁵. Notably, the presence of an active infection is a contraindication for this procedure.

MECHANISM OF ACTION OF TENEX

The mechanism of action of Tenex in the treatment of LE is based on the selective removal of damaged tissue and the promotion of tissue healing. With ultrasound (US) serving as a guide to target and break down the degenerated or scarred tissue in the tendon, the procedure stimulates the body's natural healing response. As a result, production of healthy collagen and other tissue components occurs, which promotes the regeneration and repair of the affected tendon.

PROCEDURAL TECHNIQUE OF TENEX

The TX2 MicroTip ultrasonic device (Tenex Health Inc., Lake Forest, CA, USA) was used in this study (figure 1). With the aid of US-guided identification, aberrant regions within the lateral part of the elbow, which are indicative of the pathological site, were located along the proximal-to-distal direction from the elbow to the forearm using a sterile technique. A surgical blade was used to create a small surgical wound to facilitate the passage of the Tenex needle system, which is an instrument with an 18-gauge caliber, through skin layers, subcutaneous adipose tissue, and the superficial fascia enveloping the tendon (figure 2).

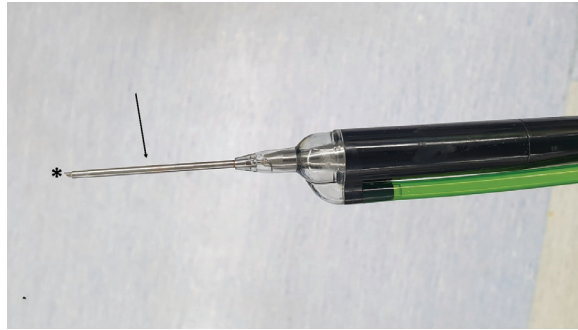


Figure 1 Operational end of the TX2 MicroTip ultrasonic device (Tenex Health Inc., Lake Forest, CA, USA). The working tip, constructed from 18-gauge hollow stainless steel (indicated by the black arrow), oscillates at elevated frequencies, facilitating the emulsification of tissues in close proximity. The tip has a cannula (denoted by asterisk), with the tip and cannula affixed to a handpiece resembling a pencil. This handpiece establishes a connection with the TX2 console, serving as the energy source that propels the tip and incorporates a motor for the management of the inflow/outflow of irrigation fluid and debris. Continuous irrigation is maintained through fluid circulation into the working site, which occurs between the canula and shaft of the working tip, with the efflux of fluid from the working site facilitated through the hollow working tip.



Figure 2 Left: Alignment of patient for percutaneous tenotomy and debridement procedure on the common extensor tendon (lateral elbow) using the TX2 device (Tenex Health Inc., Lake Forest, CA, USA). Right: Image captured after surgical intervention, featuring the incision secured with a strap.

The Tenex needle must be precisely guided to remain within the aberrant tendon region under US guidance (figure 3). A pedal mechanism was then engaged to initiate the Tenex module, which induced rapid oscillations in the 18-gauge inner needle at frequencies between 18 and 24 MHz. These oscillations created ultrasonic energy, which effectively emulsified the pathological tissue. Simultaneously, a saline irrigation procedure was performed to enhance the therapeutic process. Systematic movement of the device was made possible by a controlled, back-and-forth motion, akin to the technique employed in dry needling. Guided by real-time US

visualization, the Tenex needle can be repositioned to address any additional aberrant areas within the tendon (figure 4). Typically, the needle's high-frequency oscillations result in the progressive softening of the initially rigid tendon tissue in the region afflicted by tendinosis after a few passes, which reduces the required pressure during needle manipulation. In instances involving the detection of microcalcifications, the oscillating needle, in conjunction with saline flush, effectively facilitates their removal. The overall duration of the cutting procedure ranges from 40 to 60s, depending on the extent and severity of tendon degeneration¹⁶⁻¹⁷.



Figure 3 Left: US probe strategically placed on the lateral epicondyle to pinpoint the origin of the common extensor tendon. Right: Introduction of TX2 device (Tenex Health Inc., Lake Forest, CA, USA) following the meticulous creation of strap incision.

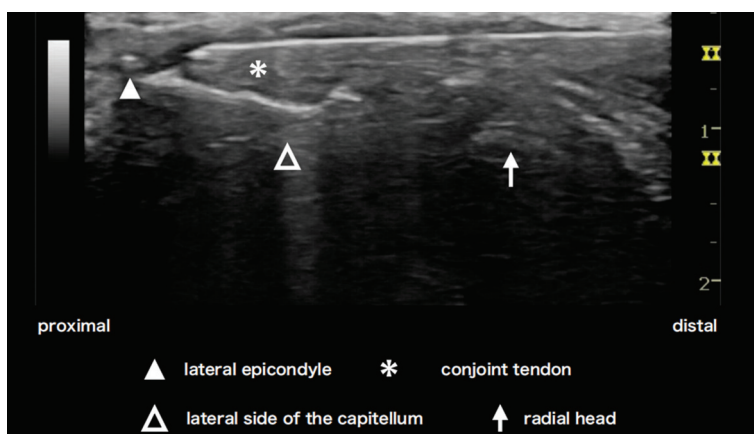


Figure 4 The outer sheath is distinctly visualized, with the metallic tip protruding from the sheath and positioned within the common extensor tendon (*).

REVIEW OF EVIDENCE OF PUT

Several studies have explored Tenex’s effectiveness and compared it with those of other procedures. In this section, we delved into the latest evidence regarding PUT (table 1).

PUT ALONE

Koh et al.¹⁸ (2013) investigated a case series of an innovative and minimally invasive approach for the treatment of persistent lateral elbow tendinopathy. This method utilizes an ultrasonic microsection procedure using a specialized device called TX1 under local anesthesia. The process

is secure and well received, with no adverse incidents ever documented. The patients treated with this method experienced notable improvements in both pain levels, as indicated by their visual analog scale (VAS) scores, and functional outcomes measured through disabilities of the arm, shoulder, and hand (DASH) scores after one month. These improvements lasted until the 12-month follow-up period. Sonographic evaluations at the 6 month revealed positive changes in tendon thickness and vascularity. A total of 19 out of 20 patients expressed their satisfaction with this procedure.

Table 1 Evidence related to PUT

Authors (year)	Patient (n)	Study Design	Comparisons	Study duration	Conclusions
Ferrero et al. ²¹ (2011)	32	Retrospective cohort study	Steroid injection (SI)	12 months	The SI group initially exhibited a significant reduction in pain levels during the 2-week assessment ($p < 0.001$), favoring this approach. However, the PUT group did not demonstrate significant improvement after 2 weeks. In longer-term evaluation (3 months to 12 months), the PUT group revealed more substantial pain relief in comparison with the steroid group ($p < 0.001$).
Koh et al. ¹⁸ (2013)	20	Case series	No comparison	12 months	Significant and rapid improvements were observed in the VAS, DASH-compulsory, and DASH-work scores following the procedure, with sustained benefits observed at 3, 6, and 12 months.
Barnes et al. ¹⁹ (2015)	19	Case series	No comparison	12 months	Procedural complications were absent. Significant improvements were noted in the average VAS scores ($p < 0.0001$). Similar positive trends were noted in Quick-DASH ($p < 0.0001$) and MEPS ($p < 0.001$).
Seng et al. ¹ (2016)	20	Case series	No comparison	36 months	The study achieved 100% clinical follow-up with US assessment, maintaining patient satisfaction. Initial improvements in pain and function scores were sustained, and further significant decrease in the DASH-compulsory scores was observed. Tendon abnormalities presented notable improvements, with progressive reduction in scar tissue over time.
Battista et al. ¹⁵ (2018)	7	Case series	No comparison	24 months	ASES scores showed significant improvements ($p < 0.001$), which were evident at 6 weeks and maintained until 24 months. Statistically significant improvements in ASES and VAS scores were noted, demonstrating sustained benefits.
Boden et al. ¹⁷ (2019)	62	Retrospective Cohort Design	PRP injections	PRP and Tenex groups (17 and 10 months, respectively) varied significantly ($p = 0.002$)	The PRP and Tenex groups exhibited clinical and statistical improvements in the VAS pain, Quick-DASH, and EuroQol-5D scores. No statistically significant difference was observed between the two treatment modalities.
Altahawi et al. ²³ (2021)	200	Retrospective Study	Surgical Tenotomy	12 months	Average VAS scores improved significantly ($p < 0.001$). This positive trend extended to Quick-DASH ($p < 0.001$) and MEPS ($p < 0.001$), indicating a sustained and significant improvement across various assessment measures.
Ang et al. ²⁰ (2021)	20	Case series	No comparison	90 months	Satisfaction remained at 100%, with sustained improvement in VAS and DASH-compulsory scores ($p < 0.001$). No symptom recurrence occurred, eliminating the need for secondary interventions. Hypervascularity remained resolved in 79% of patients at 90 months, indicating the durability of positive outcomes.

Abbreviations: ASES, American shoulder elbow surgeons shoulder score; DASH, disabilities of the arm, shoulder, and hand; MEPS, Mayo elbow performance score; n, number; PRP, platelet-rich plasma; PUT, percutaneous ultrasonic tenotomy; SI, steroid injection; VAS, visual analog score

Seng et al.¹ (2016) reported a case series that investigated the long-term efficacy of PUT for this condition in all 20 participants. The study revealed the showed sustained improvements in all participants after 3 years. They reported minimal pain (0 ± 0.9) and excellent functionality (DASH-work score of 0 ± 0). Furthermore, tendon vascularity was resolved in 94% of the patients, and all of them experienced a decrease in tendon thickness. Hypoechoic scar tissue, which indicates tissue healing, decreased in all participants, with 90% experiencing positive results within 6 months. In conclusion, this minimally invasive technique provides long-lasting pain relief and functional improvement and is a favorable alternative to surgical intervention for recalcitrant tennis elbow.

Barnes et al.¹⁹ (2015) conducted a case series in which the TX1 procedure was examined as a therapeutic approach for chronic, refractory lateral, or medial elbow symptoms persisting for over 6 months. A total of 19 patients (mean age: 55.3 years) participated in this study. At the 12 months of follow-up after the procedure, 78.9% of the participants reported reduced pain, with scores reaching more than 75%.

In a 2021 case series authored by Ang et al.²⁰, the long-term clinical and sonographic outcomes of PUT applied to the extensor tendon were investigated. In previous study, 19 patients were assessed, with 16 undergoing US examination, with a follow-up period between 86 and 102 months. No adverse events were observed, and patient satisfaction consistently remained high, with 6 patients expressing satisfaction and 13 claiming very high levels of satisfaction. Notable, none of the patients experienced recurrence of symptoms or signs lateral elbow tendinitis associated with, obviating the need for any subsequent interventions. The baseline and early term improvements were sustained over time, with statistical significance ($p < 0.001$ for all). Specifically, at the 90-month mark, a significant enhancement was observed in the pain and functional scores compared with the preprocedure scores and all follow-up assessments up to the 3-month interval. Notably, no discrepancies

were observed in the pain and functional scores at the 90-month evaluation compared with the scores on other points. Functional scores were notably enhanced at the 90-month juncture compared with the preprocedure scores although no distinctions were identified when comparing DASH-work scores at the 90-month milestone with scores at any other follow-up time points. At the 90-month evaluation, 79% of the patients exhibited a continued resolution of hypervascularity, and all of them presented decreased tendon swelling, coupled with persistent resolution or reduction of the hypoechoic lesion.

PUT VERSUS STEROID INJECTION (SI)

IA 2011 clinical trial conducted by Ferrero et al.²¹ examined a cohort of 46 patients with LE. The study included 16 patients subjected to PUT treatment and another 16 who received SI under US guidance. The initial findings indicate a preference for the SI group, which exhibited a notable decline in pain levels compared with the baseline during the 2-week assessment ($p < 0.001$). Conversely, the PUT group showed no notable enhancement in pain at the 2-week mark. However, in longer-term follow-up evaluations spanning from 12 weeks to 48 weeks, the PUT group exhibited more substantial pain relief than the SI group ($p < 0.001$).

PUT VERSUS PLATELET-RICH PLASMA (PRP) INJECTION

A retrospective cohort study led by Boden et al.¹⁷ (2019) conducted a comparative evaluation to assess the effectiveness of Tenex and (PRP) injection as interventions for chronic epicondylitis. The study involved 62 subjects, with 30 undergoing PUT and 32 receiving a single PRP injection. Both therapeutic treatments resulted in substantial and statistically notable alleviation of pain and improved functional outcomes and overall quality of life. No statistically significant differences were recorded ($p < 0.05$) at 10 and 17 months of follow-up.

A separate prospective study in 2013, with randomized controlled trials documented by Stenhouse et al.²², reported the PUT ($n = 13$) and

combined PUT and PRP injection (n = 15) treatments of participants afflicted with this condition. The incorporation of PRP injection with needle tenotomy increased the effectiveness on pain relief and functional outcomes during the 2- and 6-month follow-up assessments. However, none of the intergroups achieved statistical significance ($p > 0.05$).

PUT VERSUS SURGICAL THERAPY

In retrospective investigation conducted by Altafawi et al.²³ (2021), comparative analysis of tenotomy was performed using the Tenex device and surgical tenotomy. The study included 23 patients treated with the TX-1 device and 10 patients undergoing surgical tenotomy. The results reveal similar outcomes between the two treatment groups, with noteworthy improvements in pain and functional capacity at 3–6 and 12 months posttreatment intervals ($p < 0.05$). A 2-week follow-up assessment suggested a disparity in symptom progression, with the surgical cohort experiencing aggravation of symptoms and the TX-1 device-treated group showing symptom improvement. However, these distinctions did not reach statistical significance.

The investigations scrutinized in this review collectively suggest the potential efficacy of PUT as a therapeutic modality for LE. However, given the limited number of studies and participants, interpretation of these findings must be fulfilled with caution, thereby affording only a modest level of confidence in drawing definitive conclusions. Consequently, additional research is imperative to substantiate and fortify these preliminary observations. Specifically, high-quality prospective randomized controlled clinical trials in this domain are limited. The present evidence underscores the exigency for rigorous studies characterized by robust methodologies. Ideally, such trials require a meticulous design and must employ randomized, double-blind paradigms and meticulous procedures aimed at mitigating bias. Furthermore, comparative evaluation of diverse surgical interventions must be considered, with particular emphasis on various surgical modalities. Extant literature is also devoid of randomized controlled trials that systematically

assessed the spectrum of surgical treatments for LE. Methodologically sound investigation should encompass prolonged follow-up periods, that is, an interval exceeding 6 months, to determine the durability of reported therapeutic gains. Key component parameters should include pain assessment through VAS or analogous metrics, alongside evaluations of functional and impairment outcomes using instruments such as the DASH score or similar indices. Supplementary investigations should also thoroughly monitor secondary occurrences of adverse events. In summary, a call for methodologically diligent and comprehensive research endeavors is underscored to obtain robust evidence that can guide clinical decision making in the management of LE.

CONCLUSION

PUT represents a minimally invasive therapeutic approach suitable for patients with LE unresponsive to conservative interventions. However, more robust investigations are required for the precise assessment of the comparative efficacy of this treatment modality.

ACKNOWLEDGEMENT

The authors sincerely thank Department of Orthopaedic Surgery, Nara Medical University and Department of Orthopaedic, Faculty of Medicine Vajira Hospital, Navamindrathiraj University for supporting this review.

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