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Ultrasound-guided tenotomy for lateral epicondylitis with TenJet improves physical functional and decreased pain outcomes at 1 year: a case series review

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Background: Common extensor tendinopathy is a common cause of lateral elbow pain. Ultrasound-guided minimally invasive tenotomy (MIT) has been utilized successfully as a treatment for several years, but the use of TenJet device has not been well described.
Purpose: To evaluate the effectiveness and safety of MIT with TenJet who failed nonsurgical management of common extensor tendinopathy in an outpatient setting.
Methods: A total of 100 patients with common extensor tendinopathy who failed conservative treatment underwent ultrasound-guided MIT with TenJet device in the outpatient setting at a single institution. All 100 patients prior to MIT underwent diagnostic musculoskeletal ultrasound showing common extensor tendinosis. The findings were interpreted by a fellowship-trained and board-certified musculoskeletal radiologist. Patients were evaluated with the Oxford Elbow Score prior to the procedure and at 1-year follow-up. Exclusion criteria included prior corticosteroid injection within the past 6 weeks of the MIT intervention, active local or systemic infection, complete full thickness tear of the common extensor tendon, and pregnancy.
Results: Oxford Elbow Score had a statistically significant difference in baseline to 1 year ($P < .001$). No complications were reported and zero patients went on to require open surgical intervention.
Conclusion: MIT with TenJet is a safe, effective, and well-tolerated treatment for common extensor tendinopathy.

Lateral elbow tendinopathy is a common cause of elbow pain, affecting anywhere between 1% and 3% of adults.[12] Most patients are initially treated with nonoperative interventions such as rest, lifestyle modifications, wrist bracing, and physical therapy.[2] However, despite the current research literature published to date, there is a lack of consensus for the next best step in management when conservative treatment fails. Second-line treatment modalities include corticosteroid injections, platelet-rich plasma injections, extracorporeal shockwave therapy, minimally invasive percutaneous needle tenotomy, and open surgery.[11]

Ultrasound-guided percutaneous needle tenotomy is a minimally invasive procedure used in the treatment of refractory chronic tendinosis.[1] This procedure involves needle fenestrations that typically include multiple passes through the abnormal tendon. This results in a release of local angiogenic factors leading to increased vascular permeability and a controlled inflammatory response yielding new vessel formation and collagen deposition while removing degenerative areas of tendon.[6,12] Current literature has many studies showing the effectiveness of percutaneous needle tenotomy.[1-4,6,8,12-15,17,18]

Seng et al examined 20 patients who underwent percutaneous tenotomy with a follow-up ultrasound at 3 years showing a decrease in tendon hypervascularity by 94% and tendon thickness reduction in 100% of patients.[14] Median visual analog scale scores decreased from 5.5 to 0.5 at 1 year with 19 of 20 patients being satisfied with the procedure.[10] Another study involved 30 patients with both medial and lateral epicondylitis with average symptom duration of 25 months, showing no statistical difference in Tenex (Tenex Health Inc., Lake Forest, CA, USA) vs. platelet-rich plasma.[5] Seven patients who underwent percutaneous tenotomy with American Shoulder and Elbow Surgeons score of 55.6 initially and

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93.4 at 1 year; only one patient went on to need open tendon débridement.[4] Another study involved 19 patients with medial or lateral epicondylitis and a median duration of symptoms for at least 6 months, who underwent ultrasonic needle tenotomy observed the preprocedure and postprocedure Quick Disabilities of Arm, Shoulder, and Hand and Mayo Elbow Performance Index scores. Respectively, the Quick Disabilities of Arm, Shoulder, and Hand improved from 44.1 to 8.6 at 1 year and Mayo Elbow Performance Index from 59.1 to 90.5 at 1 year.[3] Ang et al showed that 19 patients were either very satisfied or satisfied at a median follow-up time of 90 months post-Tenex procedure demonstrated long-term durability of pain relief and functional recovery.[2]

Most existing literature only describes methodologies that utilize Tenex, and only one study to date has been completed for common extensor tendinopathy utilizing TenJet (HydroCision Inc., North Billerica, MA, USA). This study showed statistical significance in improvement in Patient-Rated Elbow Evaluation scores up to 1 year.[16] The primary objective of this case series is to analyze the efficacy of TenJet utilizing the Oxford Elbow Scores (OES) at 1-year follow-up. The secondary objective is to see if the degree of tendinosis (mild, moderate, or severe), fascial thickening, hypervascularity, and enthesophyte presence are associated with better or worse functional outcomes. The third objective is to determine the safety of TenJet as a minimally invasive technique for common extensor tendinopathy.

Materials and methods

Study design

This study was approved by the institutional review board. Patients were considered a candidate for minimally invasive tenotomy (MIT) to the common extensor tendon if they (1) were at least 18 years of age; (2) had experienced symptoms of common extensor tendinopathy for a minimum of 3 months; (3) failed nonsurgical management including a previous history of corticosteroid injection; and (4) underwent diagnostic musculoskeletal ultrasound by a board-certified fellowship-trained musculoskeletal radiologist confirming the diagnosis of common extensor tendinosis. As part of the standardized departmental methodology of reporting, several ultrasound characteristics such as mild, moderate, or severe tendinosis, hypervascularity present or not, partial tearing present or not, and fascial thickening present or not.

Patients were excluded if they had a complete tear of the common extensor tendon, received a corticosteroid injection within the last 6 weeks, pregnancy, or had active local or systemic infection.

Our case series includes 100 patients in which outcomes were evaluated with the OES score at baseline and 1 year postprocedure. The OES score has been validated to evaluate patient-reported outcomes after elbow surgery.[7] Procedures were performed during January 2018 to December 2019. Outcomes were obtained before the procedure in the outpatient setting by either an in-office visit or by telephone interview at 1-year follow-up. Our treatment group consisted of 46 males and 54 females, with an average age of 51 years. Table I depicts our cohort population demographics along with reported findings on the musculoskeletal ultrasound.

Table I
Baseline patient characteristics and 1-year OES data for the analysis cohort and also classified by lateral epicondylitis.

Variable	Level	Lateral epicondylitis (N = 100)
Age, median [25th; 75th]		51.0 [45.0; 59.2]
Gender, N (%)	M	46 (46.0)
	F	54 (54.0)
Hyperemia, N (%)	No	11 (11.0)
	Yes	89 (89.0)
Enthesophyte, N (%)	No	45 (45.0)
	Yes	55 (55.0)
Fascial thickening, N (%)	No	26 (26.5)
	Yes	72 (73.5)
Degree of tendinosis, N (%)	Severe	23 (23.0)
	Mild	16 (16.0)
	Moderate	61 (61.0)
Body side, N (%)	Left	29 (29.0)
	Right	71 (71.0)
Baseline OES, median [25th; 75th]		23.5 [18.0; 29.8]
1-y OES, median [25th; 75th]		45.0 [39.5; 48.0]
OES delta, median [25th; 75th]		18.0 [12.0; 23.0]

OES, Oxford Elbow Score.
The age range, 31-74 years old, for the lateral epicondylitis cohort (N = 100).

Procedural technique

All procedures were performed in a hospital outpatient environment under local anesthesia by three primary care sports medicine physicians at a single institution. An ultrasound was performed to locate the region of tendinosis within the common extensor tendon. The area was prepared and draped in a sterile fashion. A total volume ranging from 5 to 10cc of 0.5% ropivacaine was used to anesthetize the subcutaneous tissue and tendon. Using a No. 11 blade, a small incision was made through which the TenJet device was placed and advanced into the area of tendinosis. Under ultrasound guidance, the TenJet device was utilized to deliver a high-velocity sterile saline with a Venturi suction effect at the needle tip creating a cutting window to hydroresect diseased tendon tissue. The procedure was completed when visual changes of less hypoechoic tendon were observed on ultrasound. The incision was closed with Steri-Strips (3M, St. Paul, MN, USA) and then covered with a Tegaderm (3M, St. Paul, MN, USA) dressing. Patients were then placed in a wrist brace for the following 7-10 days.

Following at least 14 days postprocedure, patients began a physical therapy protocol for 1-2 sessions per week. Physical therapy protocol consisted of utilizing a 2:1 eccentric to concentric program with the elbow flexed arm for weeks 3 and 4, and a longer lever elbow extended arm for weeks 5 and 6. During the first 6 weeks after the procedure, patients were strongly encouraged to adhere to a limit of no greater than 10 pounds lifting. At 6 weeks, postprocedure patients followed up with the physician, were discharged from physical therapy, and cleared by one of the sports medicine physicians to progress toward activities as tolerated.

Statistical methods

Descriptive statistics were generative for the entire sample population. Continuous variables were summarized with median and interquartile ranges. Categorical variables were displayed using frequency and percentages (%). Wilcoxon signed-rank test was performed to compare the change of OES scores from baseline to postoperative follow-up for the two-analysis cohort. Wilcoxon signed-rank test was implemented because the distribution of the 1-year OES scores in these two cohorts was not normally distributed. Multivariable linear regression model was used to identify which covariates associated with 1-year OES scores. For continuous variables, age estimates were rescaled to reflect interquartile range increase (from Q1 to Q3) of the variables. Adjusted R^2 is used to measure how well the outcomes are explained by their respective models. R^2 usually ranges from 0 to 1, with a score closer to 1 as optimal. *P* values less than .05 were considered statistically significant; and analysis was done in R (v4; R Foundation for Statistical Computing, Vienna, Austria).

Table II
The Wilcoxon signed-rank test results.

Variable	*P* value
OES (lateral)	<.001

OES, Oxford Elbow Score.
The change in OES scores from baseline to 1-year follow-up is statistically significant in both lateral epicondylitis cohorts.

Results

Our case series included 100 patients who underwent MIT with the TenJet device. Of the 100 patients, our final cohort consisted of 95 patients with both OES scores at baseline and 1 year in addition to all musculoskeletal ultrasound variables of interest. Study population ranged from ages 31 to 74 with a median age of 51 years. The population consisted of 46 males and 54 females (Table I). Zero patients went on to require open common extensor tendon release.

Oxford Elbow Score

The initial baseline OES median for the cohort was 23.5. The descriptive analysis utilized the Wilcoxon signed-rank test whose results demonstrated a statistically significant ($P < .001$) change in OES scores from baseline to 1-year follow-up after undergoing MIT (Table II). The final median 1-year OES was 45. The median average change in OES was 18. A linear regression model was performed resulting in a statistically meaningful conclusion the baseline OES is a significant predictor of the OES score at 1 year follow-up (Fig. 1). For every additional point, higher in baseline OES score, the 1-year OES score increased by 0.36 (95% confidence interval: 0.19-0.53-point increase) after adjusting for other covariates. Therefore, the results demonstrate that the higher the baseline OES score, the higher the 1-year OES score (Table III).

Degree of tendinosis

We then looked at the cohorts' severity of tendinosis documented on the initial diagnostic ultrasound. Our population exhibited 16% of patients with mild tendinosis, 61% moderate tendinosis, and 23% tendinosis (Table I). Utilizing a linear regression model to predict if the degree of tendinosis had any correlation to the 1-year outcome in OES, there was a low level of correlation between the variables with a *P* value of .793 mild vs. moderate and a *P* value of .770 for comparing moderate vs. severe tendinosis (Table III).

Hypervascularity

On the initial diagnostic ultrasound, 89% of the population studied exhibited hypervascularity within the tendon and 11% had hypervascularity absent. Utilizing a linear regression model to predict if the hypervascularity had any correlation to the 1-year outcome in OES, there was a low level of correlation between the variables with a *P* value of .829 (Table III).

Fascial thickening

Seventy-two percent of the patients were diagnosed with fascial thickening on the initial diagnostic ultrasound, while 28% of the patients were found not to have a presence of fascial thickening on diagnostic ultrasound. Utilizing a linear regression model to predict if fascial thickening had any correlation to the 1-year outcome in OES, there was not a statistically significant difference with the presence of fascial thickening nor of the baseline ultrasound *P* value of .172 (Table III).

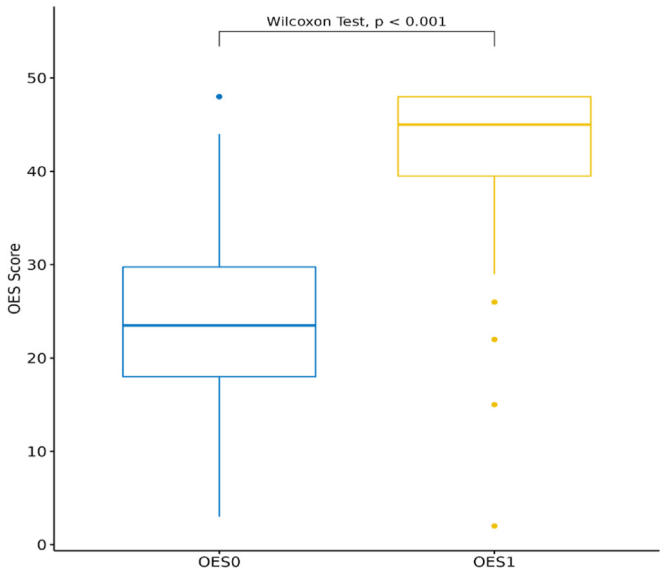

Figure 1 Boxplot for OES score change in lateral epicondylitis patient. *OES*, Oxford Elbow Score.

Enthesopathy

Fifty-five percent of the patients were diagnosed with an enthesophyte on diagnostic ultrasound. Forty-five percent were not found with the presence of enthesophyte on diagnostic ultrasound (Table I). There was no statistically significant difference with the presence of an ethesophyte on baseline ultrasound *P* value of .831 (Table III).

Discussion

Chronic elbow extensor tendinopathy results from a degenerative condition rather than inflammation. Oftentimes, treatment modalities at minimizing inflammation do not address the underlying cause of tendinosis leading to a suboptimal response.[9] The utility of TenJet offers a technique consisting of removal of tendinopathic tissue.[16] Recent literature describes the outcomes in 26 lateral elbows utilizing TenJet with statistical significance in the Patient-Rated Elbow Evaluation and visual analog scale scores at 1 year compared to baseline, with two patients requiring open surgery after failing MIT, with no reported complications.[16]

The principal finding of this study is that MIT with TenJet improves functional outcomes in lateral elbow tendinopathy at a 1-year follow-up period utilizing OES ($P < .001$). There was also a statistically meaningful significance that higher OES at baseline corresponded to higher OES at 1 year. Furthermore, it demonstrates the safety of the procedure without any reported tendon ruptures, postprocedural infections, neurovascular injuries, or other adverse events noted within the 100 patients that underwent the procedure in both short-term and long-term.[3,4,10,13,15] There have been few large prospective trials with MIT, but these findings support previous studies to show MIT can be viewed as benefits outweighing potential risks when counseling patients about the procedure.[3,4,10,13,15] Meanwhile, 0 out of the 100 patients went on to require surgical intervention. This conclusion is consistent with other studies showing the safety and effectiveness of MIT.[1-4,6,8,12-15,17,18]

Table III
Linear regression results for the model predicting the 1-year OES in lateral epicondylitis cohort.

Predictors	1-year OES (lateral)	
	Estimates [95% CI]	*P* value
Intercept	29.69 (17.44 to 41.95)	<.001
Age (IQR increase)	1.20 (−1.18 to 3.58)	.319
Gender (female vs. male)	0.54 (−2.70 to 3.78)	.741
Hyperemia (yes vs. no)	0.54 (−4.43 to 5.51)	.829
Enthesophyte (yes vs. no)	0.33 (−2.73 to 3.39)	.831
Fascial thickening (yes vs. no)	−2.41 (−5.90 to 1.07)	.172
Degree of tendinosis (mild vs. severe)	−0.68 (−5.82 to 4.46)	.793
Degree of tendinosis (moderate vs. severe)	0.56 (−3.26 to 4.39)	.770
Baseline OES	0.36 (0.19 to 0.53)	<.001
Observations	95	
R^2	0.228	

OES, Oxford Elbow Score; *IQR*, interquartile range; *CI*, confidence interval.
The results indicating baseline OES score is a significant predictor of OES score at 1-year postop. For every additional point, higher in baseline OES score, the 1-year OES score increase by 0.36 (95% CI: 0.19-0.53 increase) point after adjusting for other covariates, that is to say, the higher baseline OES score, the higher the 1-year OES score.
R^2 (R-square) demonstrates the percent of variability explained by the model. R^2 of 0.228 means that the model explains 22.8% of the variability of depend variable − 1-year OES score. R^2 usually range from 0 to 1, the higher the better.

Our study population demonstrated 84% with moderate or severe tendinosis, 89% with hypervascularity, 72% fascial thickening, and 55% enthesopathy on the initial diagnostic ultrasound imaging. Our secondary aim was to see if there was any correlation with findings on preprocedural diagnostic ultrasound which correlated to patient outcomes postprocedure using the OES. Despite these findings, there was no statistical significance on whether these sonographic findings impacted the OES at 1 year. However, further studies are warranted to see if the level of tendinosis, hypervascularity, and fascial thickening have any implications on functional outcome. Ang et al study showed 16 patients at 90 months after undergoing percutaneous needle tenotomy with Tenex had 100% resolution of hypoechic tissue and 79% had resolution of hypervascularity on ultrasound.[2] While our study did not include postprocedure ultrasound, it would be a consideration for future studies to evaluate whether on postprocedure similar tendon characteristics such as resolution of hypervascularity and tendinosis are achievable with TenJet.

Limitations

There were several limitations to our study. The first limitation was the inherent nature of lacking a control group in a case series. Despite our sample size of 100 patients, it was still a relatively a small number to formulate generalizable conclusions on if ultrasound findings preprocedure has any implications on long-term outcomes. Another consideration regarding the interpretation of diagnostic ultrasound is there can be a level variance with the radiologist discerning between mild vs. moderate vs. severe tendinosis, as there are not universal criteria in delineating between the degrees of tendinosis. Another limitation was the inconsistency in the program protocol implemented by physical therapist as part of postprocedure rehabilitation. Our investigators gave the physical therapist general guidelines and principals to follow; however, there was no follow-up on how many patients actually went to physical therapy, how many sessions they attended, and if they abided to the suggest weight restrictions suggested by the physician. Furthermore, being at a single-center institution has its limitations as all procedures were performed by three different physicians, but future studies should consider multicenter sites. Finally, having additional functional outcome scores and a longer-term timeframe for follow-up would further support the sustained results from the intervention.

Conclusion

To date, our study is the largest case series of utilizing TenJet in the setting of treating common extensor tendinopathy using a validated patient-reported outcome score with long-term follow-up. This new technology appears to be a safe, effective, and well-tolerated option for patients in the treatment of common extensor tendinopathy who desire less invasive treatment without the increased risks of general anesthesia and open or arthroscopic surgery.

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References

1. 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 Radiol 2021;50:115-24. https://doi.org/10.1007/s00256-020-03540-7.
2. Ang BFH, Mohan PC, Png MA, Allen JC Jr, Howe TS, Koh JSB, et al. Ultrasonic percutaneous tenotomy for recalcitrant lateral elbow tendinopathy: clinical and sonographic results at 90 months. Am J Sports Med 2021;49:1854-60. https://doi.org/10.1177/03635465211010158.
3. Barnes DE, Beckley JM, Smith J. Percutaneous ultrasonic tenotomy for chronic elbow tendinosis: a prospective study. J Shoulder Elbow Surg 2015;24:67-73. https://doi.org/10.1016/j.jse.2014.07.017.
4. Battista CT, Dorweiler MA, Fisher ML, Morrey BF, Noyes MP. Ultrasonic percutaneous tenotomy of common extensor tendons for recalcitrant lateral epicondylitis. Tech Hand Up Extrem Surg 2018;22:15-8. https://doi.org/10.1097/BTH.0000000000000178.
5. 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. J Shoulder Elbow Surg 2019;28:112-9. https://doi.org/10.1016/j.jse.2018.08.032.
6. Chalian M, Nacey NC, Rawat U, Knight J, Lancaster T, Deal DN, et al. Ultrasound-guided percutaneous needle tenotomy using Tenex system for refractory lateral epicondylitis; short and long-term effectiveness and contributing factors. Skeletal Radiol 2021;50:2049-57. https://doi.org/10.1007/s00256-021-03778-9.
7. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. The development and validation of a patient-reported questionnaire to assess outcomes of elbow surgery. J Bone Joint Surg Br 2008;90:466-73. https://doi.org/10.1302/0301-620X.90B4.20290.
8. Hatamiya NS, Kobayashi Y, Gottschalk AW. Utility of percutaneous needle tenotomy to reduce pain and improve function in common extensor tendinosis of the lateral epicondyle. Ochsner J 2021;21:326-8. https://doi.org/10.31486/toj.21.0044.
9. Khan KM, Cook JL, Taunton JE, Bonar F. Overuse tendinosis, not tendinitis part 1: a new paradigm for a difficult clinical problem. Phys Sportsmed 2000;28:38-48.

10. Koh JSB, Mohan PC, Howe TS, Lee BP, Chia SL, Yang Z, et al. Fasciotomy and surgical tenotomy for recalcitrant lateral elbow tendinopathy: early clinical experience with a novel device for minimally invasive percutaneous microresection. Am J Sports Med 2013;41:636-44. https://doi.org/10.1177/0363546512470625.
11. Kroslak M, Murrell GAC. Surgical treatment of lateral epicondylitis: a prospective, randomized, double-blinded, placebo-controlled clinical trial. Am J Sports Med 2018;46:1106-13. https://doi.org/10.1177/0363546517753385.
12. Mattie R, Wong J, McCormick Z, Yu S, Saltychev M, Laimi K. Percutaneous needle tenotomy for the treatment of lateral epicondylitis: a systematic review of the literature. PM R 2017;9:603-11. https://doi.org/10.1016/j.pmrj.2016.10.012.
13. McShane JM, Nazarian LN, Harwood MI. Sonographically guided percutaneous needle tenotomy for treatment of common extensor tendinosis in the elbow. J Ultrasound Med 2006;25:1281-9. https://doi.org/10.7863/jum.2006.25.10.1281.
14. Seng C, Mohan PC, Koh SBJ, Howe TS, Lim YG, Lee BP, et al. Ultrasonic percutaneous tenotomy for recalcitrant lateral elbow tendinopathy: sustainability and sonographic progression at 3 years. Am J Sports Med 2016;44:504-10. https://doi.org/10.1177/0363546515612758.
15. 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. J Shoulder Elbow Surg 2019;28:2386-93. https://doi.org/10.1016/j.jse.2019.06.011.
16. Strauser-Curtis K, Varacallo CP, Voss TT, Stephens CB, Kapteyn RW. Ultrasound-guided tenotomy via a hydrosurgery resection device improves symptoms of chronic elbow tendinopathy: a multi-center prospective study. Published online June 22 J Orthop Exp Innov 2022;3:34671.
17. Vajapey S, Ghenbot S, Baria MR, Magnussen RA, Vasileff WK. Utility of percutaneous ultrasonic tenotomy for tendinopathies: a systematic review. Sports Health 2021;13:258-64. https://doi.org/10.1177/1941738120951764.
18. Williams RC, Pourcho AM. Percutaneous ultrasonic tenotomy for refractory common extensor tendinopathy after failed open surgical release: a report of two cases. PM R 2018;10:313-6. https://doi.org/10.1016/j.pmrj.2017.07.077.