Research Article

Structural and Clinical Outcomes after Tenex Debridement for Rotator Cuff Tendinopathy

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https://doi.org/10.60118/001c.88229

Journal of Orthopaedic Experience & Innovation

Vol. 5, Issue 1, 2024

Background

Rotator cuff tendinopathy (RCT) is a frequently encountered condition by the orthopedic surgeon. Patients presenting with tendinopathy or partial thickness tear present a difficult challenge to treat. Treatments for rotator cuff tendinopathy include nonsurgical and surgical intervention. While surgical management can be effective in the treatment of RCT, patients must be willing to accept risks of anesthesia and surgery and be willing to potentially undergo a lengthy post-operative rehabilitation course. Our study evaluates the use of percutaneous ultrasonic debridement (percutaneous ultrasonic tenotomy (PUT)) of tendinopathy lesions for rotator cuff tendinopathy.

Methods

This study consisted of 15 patients with symptomatic rotator cuff pathology diagnosed by physical exam and magnetic resonance imaging (MRI). Operative and non-operative treatment options for RCT were discussed with the patients, including the Tenex procedure. The 15 patients who underwent the Tenex procedure were followed post-procedure for clinical improvement with Shoulder Pain and Distability Index (SPADI) scores and for structural improvement with MRI.

Results

The present study included 15 patients (16 shoulders) consisting of 8 women and 7 men. The average age of our cohort was 59.9. 14 of the patients achieved improvements in their SPADI (Shoulder Pain and Disability Index) scores and had similar or improved structural appearance on MRI after undergoing percutaneous ultrasonic debridement.

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Conclusion

The results from this study show that patients with RCT who have tried conservative treatment but are not interested in surgical intervention can consider the Tenex procedure. The procedure carried a high safety profile with significant improvement in outcomes in the majority of patients.

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INTRODUCTION

Rotator cuff tendinopathy (RCT) is a frequently encountered condition by the orthopedic surgeon. It affects patients of all ages but is more common in older patients with a prevalence greater than 60% in patients over 80 (Quinlan et al. 2022). Patients presenting with tendinopathy or partial thickness tear are a difficult challenge to treat. Clinically, these patients present with severe shoulder pain in variable locations in the shoulder. Imaging work up includes x-rays with possible ultrasound or MRI to further evaluate the extent of tendon degeneration and/or tear.

Treatment options for symptomatic RCT include nonoperative and operative treatments. Non-operative treatment options include physical therapy, oral medications, and injections among others. Injection options include corticosteroid and platelet rich plasma (PRP) injections. Steroid injections can be performed in clinic and are relatively inexpensive, however, there are concerns of damaging tendon quality after repeated use of steroid injections. PRP, obtained by centrifuging whole blood, has been shown to contain growth factors including transforming growth factor b1, platelet-derived growth factor, vascular endothelial growth factor, hepatocyte growth factor, and insulinlike growth factor-1 which could facilitate healing of degenerative tissue (Lin, Wei, and Wu 2020). While there are limited studies on the use of PRP for RCT, current evidence indicates efficacy of PRP in the short term but not necessarily in the long term (Kwong et al. 2021). Operative treatment options include shoulder arthroscopy with subacromial decompression and rotator cuff debridement versus repair depending on the appearance of the rotator cuff intra-operatively. While this option may help improve pain and function, patients will also have the risks of anesthesia and surgery and potentially a long recovery period post-operatively.

Recent studies suggest that percutaneous ultrasonic debridement (percutaneous ultrasonic tenotomy (PUT)) of tendinopathy lesions can adequately remove the pathologic tissue and stimulate healing with restoration of tendon structure and improved pain with fewer complications than a surgical procedure. Tenex is a minimally invasive procedure that has been in use since its FDA approval in 2013 and has been implemented in the use of many degenerative musculoskeletal conditions including Achilles tendonitis, lateral epicondylitis, and patellar tendonitis. A recent systematic review of the use of percutaneous ultrasound tenotomy for tendinopathy of the elbow, Achilles tendonitis and plantar fasciitis was performed and found decreased pain and improved function (Vajapey et al. 2020). Another recently performed case series evaluated the role of Tenex in the treatment of calcific tendinopathy in 8 patients and found significantly improved pain scores at 3 months after the procedure (Erickson and Jagim 2020). While previous studies have shown beneficial effects of Tenex in tendinopathies throughout the body, none have assessed its utility in the shoulder with rotator cuff pathology. The purpose of this study is to provide objective data on the outcomes of the Tenex Health Tx system (Tenex Health, Lake Forest, CA.) with the TXP tissue removal system in patients with symptomatic rotator cuff tendinopathy. Specifically, the goals of this study were to: 1. To assess the ease of use and possible complications of the TXP MicroTip in the shoulder for rotator cuff tendinopathy. 2. To identify the clinical effectiveness of treatment and healing rates of treatment.

PATIENTS AND METHODS

This study was approved by the Institutional Review Board at our institution (IRB# 13606). The study group consisted of 15 patients (16 shoulders) with ages ranging from 20-80 and gender self-identified by the patient. We included all patients with rotator cuff tendinosis with or without low grade (<50% thickness) partial thickness bursal sided tear. We excluded patients who had a traumatic onset of their pain, full thickness rotator cuff tear, symptomatic gleno-humeral or acromio-clavicular arthritis, clinically suspected labral tear, infection, prior ipsilateral shoulder surgery, and cervical spine pathology.

Patients were diagnosed with rotator cuff pathology based on several factors including a history of lateral shoulder pain with overhead activities and physical exam maneuvers including mid arc impingement pain. Patients underwent x-rays of the shoulder and a magnetic resonance imaging to evaluate the rotator cuff tendons. All patients pre-treatment underwent MRI of the shoulder and tendinosis was graded based on the system proposed by Sein et al.8 Patients underwent a treatment course consisting of activity modifications, over-the-counter (OTC) medications, 6 weeks of physical therapy, and at least one subacromial steroid injection.

Patients were offered the Tenex treatment as an alternative to the standard non-operative and operative treatment options. After a discussion of risks and benefits, each patient agreed to proceed with the Tenex procedure which was performed by a fellowship-trained sports medicine family medicine physician. On the day of the procedure, written consent was obtained by the patient.

Patients were positioned supine on the procedure table. The skin was prepped and draped in sterile fashion with 2 ml of 1% of lidocaine with epinephrine injected subcutaneously for local anesthetic and then 0.5 ml of 1% lidocaine within the supraspinatus tendon. An 11 blade was used to make a small incision of the skin over the lateral deltoid. The Phillips HD11Xe ultrasound was utilized for imaging guidance. Under ultrasound guidance the Tenex probe was advanced with a lateral approach into the heterogenous signal consistent with tendinosis and a debridement was performed of the area of heterogenous signal. An 18 gauge needle was then used to trephinate the bone for crimson duvet bone marrow release. The probe was then removed and steri-strips were placed. A pressure dressing with a Tegaderm was placed over the debridement site.

All patients were given standard post-injection instructions. Patients were recommended to avoid submersion of the joint in water for 24-48 hours and to avoid overhead lifting for the first 2 weeks. After this, patients were allowed to lift overhead (no more than 10lbs) for 4 more weeks after which they did not have any restrictions.

A retrospective review of 15 patients (16 shoulders) undergoing ultrasound guided Tenex procedure for rotator cuff (supraspinatus) tendinosis or low grade partial thickness supraspinatus tear was performed. Pre and post procedure Shoulder Pain and Disability Index (SPADI) scores were compared at 6 months post-procedure, and rotator cuff healing was evaluated based on magnetic resonance imaging (MRI) studies pre procedure and 1 year after procedure. Tendinosis was graded on the post-procedure MRI by a fellowship trained musculoskeletal radiologist based on the system proposed by Sein et al (Sein et al. 2007).

RESULTS

Our study included 15 patients (16 shoulders) consisting of 8 women and 7 men. (Table 1). The average age of our cohort was 59.9 years. SPADI scores on average prior to Tenex were P: 75.4, D: 58.1, T: 64.7. We obtained 6-month postprocedure SPADI scores for 14 of the patients (15 shoulders). We did not obtain 6-month post-procedure SPADI scores on one patient who did not adhere to the recommended post procedure restrictions and re-injured her shoulder after a fall. The remaining 14 patients (15 shoulders) had average 6-month post-procedure SPADI scores P: 29.9, D: 24.1, T: 26.4. After undergoing Tenex procedure, patients noted a significant improvement in their SPADI scores with an average improvement difference of 38.9 points.(Table 2) Of the 15 patients in the study, 3 patients did not obtain post-procedure MRIs. Two patients left the healthcare system and one patient elected not to have a post-procedure MRI due to severe claustrophobia. Of note, this patient was not seeking further treatment for her shoulder and had significant improvement in her SPADI scores. Of the remaining 12 patients, one did not adhere to post-procedure activity restrictions and re-injured her shoulder. She was found to have a partial thickness articular sided rotator cuff tear. Two patients had progression of their rotator cuff pathology but the remaining patients either had improved or similar grading on MRI. Of the 15 patients, 1 patient, at last follow-up, had subsequent rotator cuff repair surgery due to continued pain symptoms. There were no reports of any complications after the procedure (including infection, drainage, bleeding, or unusual redness or swelling).

DISCUSSION

Patients with rotator cuff pathology remain a difficult problem to treat but still comprise a significant percent of the patients seen in an orthopedic sports practice. While many operative and non-operative treatment options exist, no single treatment has been proven to be superior. The Tenex procedure, previously implemented in other chronic tendinopathies with some success, represents a less invasive treatment option for patients with rotator cuff pathology.

In this study, we retrospectively reviewed 15 patients (16 shoulders) undergoing the Tenex procedure for RCT. 14 of the patients in our study had significant improvements in the SPADI scores after Tenex. We report a mean improvement of 38.9 points total SPADI score which was significantly improved compared to pre-procedural scores. Prior studies have reported a minimum clinically important difference threshold of 8 to 13 SPADI points for rotator cuff pathology (Dabija and Jain 2019). One of the patients in our cohort did not adhere to post-procedure guidelines for activity restriction and sustained an injury to the shoulder after the Tenex procedure. Two of the 15 patients in our cohort did not obtain MRI after the Tenex as they left the medical system and could not be contacted for further follow up. Of the remaining 12 patients who did have a post-

Table 1. (Patient Results Pre and Post Treatment)

Patient	Age	Gender	Pre-Tenex SPADI	Post-Tenex SPADI	Pre-Tenex Sein Grade	Post-Tenex Sein Grade
1	63	F	P: 74% D: 46.25% T: 56.92%		Partial thickness supraspinatus tear	Reinjury
2	49	м	P: 72% D: 40.0% T:52.31%	P: 6% D: 0 T: 2.31%	2	2
3	56	F	P: 100% D: 100% T: 100%	P: 40% D: 46.25% T: 43.85	2	1
4	45	F	P: 84% D 63.7% T: 71.5%	P: 20% D: 12.5% T: 15.4%	Partial thickness supraspinatus tear	1
5	80	м	P: 66% D: 68.75% T: 67.69%	P: 12% D: 13.75% T: 13.08%	2	2
6	52	F	P: 66% D: 62.5% T: 63.8%	P: 54% D: 33.8% T:41.5%	2	Cancelled further appts
7	64	F	P: 62% D: 46.25% T 52.31%	P: 20% D: 12.5% T: 15.38%	3	3
8	42	м	P: 80% D: 31.25% T: 50.0%	P: 14% D: 8.8 % T: 10.8%	3	3
9	67	м	P: 84% DL 72.5% T: 76.92%	P: 14% D: 6.3 % T: 9.2%	3	3
10 (Right)	62	F	P: 62% D: 46.25% T 52.31%	P: 12% D: 4% T: 7.69%	3	3
11 (Left)	62	F	P: 54% D: 50% T: 51.54%	P: 10% D: 1.3% T: 4.6%	3	Partial thickness bursal sided supraspinatus tear
12	62	F	P: 58% D: 71.25% T: 66.15%	P: 22% D:13.75% T: 16.92%	Partial thickness supraspinatus tear	Patient declined MRI due to claustrophobia
13	63	F	P: 100% D: 37.5% T: 61.5%	P: 74% D: 70% T: 71.54%	3	Full thickness tear, underwent arthroscopic Rotator cuff repair.
14	60	М	P: 76% D: 42.5% T: 55.38%	P:4% D: 1.25% T: 2.31%	2	Left medical system
15	47	М	P: 88% D: 71.25% T 77.69%	P: 66% D: 57.50% T: 60.77%	3	Bursal sided partial thickness tear
16	85	М	P: 80% D: 80% T: 80%	P: 80% D: 80% T: 80%	3	Bursal sided partial thickness tear

procedure MRI, one sustained a re-injury to the shoulder and was found to have a partial articular supraspinatus tendon avulsion (PASTA) lesion. Two patients had progression to a rotator cuff tear but the remaining ones had similar or improved tendinosis on post-procedure MRI.

To our knowledge, this is the first study to evaluate the utility of the Tenex procedure for partial thickness rotator cuff pathology and obtain follow up imaging to evaluate healing. While a recent study indicated that the Tenex procedure is beneficial in calcific tendinopathy of the shoulder, our study evaluated its utility in rotator cuff tendinopathy and followed these patients to evaluate symptomatic and radiographic healing (Erickson and Jagim 2020). Previous studies have evaluated the efficacy and utility of Tenex in epicondylitis, plantar fasciitis, patellar tendonitis and other tendons in the body. Published studies have indicated that the most significant improvement in function and pain was noted within 3 months of the procedure (Shomal Zadeh et al. 2023). A study published in 2019 on use of Tenex vs platelet rich plasma in medial and lateral epicondylitis

Table 2. Statistical Analysis of Outcomes

	Total (N=15)	p-value
Tendon Imaging Grade difference, n (%)		
Decrease	2 (16.7%)	
No Change	6 (50.0%)	
Increase	4 (33.3%)	
Missing	3	
SPADI score pain difference		
Ν	15	
Mean (Standard deviation)	-45.6 (22.39)	<0.0001
Median	-50	
Range	-72.0, 0.0	
SPADI score disability difference		
Ν	15	
Mean (Standard deviation)	-34.8 (25.68)	0.0001
Median	-41.3	
Range	-66.2, 32.5	
SPADI score total difference		
Ν	15	
Mean (Standard deviation)	-38.9 (22.15)	<0.0001
Median	-46.9	
Range	-67.7, 10.0	

showed that patients in both treatment groups experienced significant improvements in their pain and function (Boden et al. 2019).

The results of our study indicate that the Tenex procedure can be considered in patients with rotator cuff tendinopathy who have tried conservative treatments but are not interested in surgery. Our study showed a high safety profile with no apparent significant complications after the procedure. Patients can reliably achieve clinical outcome improvements of their symptoms with some achieving imaging signal improvement. Two of the patients in this cohort experienced imaging progression of their RCT, highlighting the importance of discussing the natural history of rotator cuff tendinosis and possible RCT with patients prior to considering the Tenex procedure. There seems to be some potential for healing based on imaging after the procedure, however. In one patient with a partial thickness supraspinatus tear, there was improved signal grade with healing seen on post-procedure imaging.

The limitations of this study include its retrospective nature, the sample size, and the lack of long term follow up. Lastly, our protocol included microfracture of the footprint to encourage more healing response at the tendinosis area. This may be a confounding factor in isolating the effects of the Tenex procedure. However, recent randomized controlled studies have reported no differences in patient reported outcomes measures and imaging healing rates after use of trephination in the setting of arthroscopic rotator cuff repair (Toro et al. 2022; Lapner et al. 2022).

In conclusion, the results from this study are promising and could facilitate a larger, longitudinal study. Tenex can be a safe and effective treatment option for clinically symptomatic rotator cuff tendinosis patients who have failed other conservative treatments.

ACKNOWLEDGEMENTS

The authors would like to thank Dr. Tadashi Funahashi, M.D. and Dr. Jiaxiao Shi, Ph.D., for their guidance and assistance toward the completion of this project.

Submitted: August 06, 2023 EDT, Accepted: September 24, 2023 EDT

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