

Research Article

Patient-Reported Outcomes of Ultrasound-Guided Partial Percutaneous Tenotomy and Fasciotomy using The Tenex Device: A Long-Term Study

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- MSK Ultrasound
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Abstract

Purpose: Partial percutaneous tenotomy and fasciotomy are emerging minimally invasive treatment options for chronic, refractory tendinopathies and fasciopathies. Our aim is to investigate the effectiveness of ultrasound-guided partial percutaneous tenotomy and fasciotomy.

Methods: We conducted a retrospective satisfaction review via telephone call of 316 patients who had completed partial percutaneous tenotomy or fasciotomy with the Tenex device approximately 1 to 1.5 years earlier. A survey asked patients to rate overall satisfaction, recent pain levels, and willingness to undergo the procedure again. We performed a global analysis as well as subgroup analyses based on associated procedure diagnoses, including insertional Achilles tendinosis, plantar fasciitis, and medial epicondylitis or lateral epicondylitis.

Results: Of all 189 patients who completed the follow-up interview, 92.5% reported that they were “very satisfied” or “satisfied” with the procedure, 91% reported their pain in the past week was “none” or “mild pain”, and 95% reported they were “willing to undergo procedure again”. Within subgroup analyses, 90% of patients with medial or lateral epicondylitis, 96% with insertional Achilles tendinopathy, and 94% of those with plantar fasciopathy reported satisfaction with their procedure at >1 year follow-up.

Conclusion: High rates (>90%) of satisfaction, reduced levels of pain, and willingness to repeat partial percutaneous tenotomy and fasciotomy with the Tenex device at >1 year post-procedure highlight the clinical value of this procedure. The results showed no correlation with age, and there was no significant difference between men and women relating to outcome or satisfaction with the procedure.

INTRODUCTION

Chronic tendinopathy and fasciopathy are problems with increasing prevalence in both athletic and general populations [1]. Prevalence of tendinopathies vary by body site, gender, age, level of sport intensity, and other intrinsic and extrinsic risk factors. In the general population, prevalence is reported to range from 4% for Achilles tendinopathy, 0.85% for painful plantar fasciitis, and 1-2% for lateral epicondylitis [2-3]. A limited number of therapeutic options, including trials of rest, modification of activity, bracing, analgesic and nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, acupuncture, corticosteroid injections, and noninvasive or invasive surgical treatments, are available for chronic, refractory tendinopathies and fasciopathies. In addition, long-term longitudinal studies that have shown 10% of patients with elbow tendinopathy and 24 to 45.5% of patients with Achilles tendinopathy failed nonoperative

therapies and required surgical intervention [4-7]. Given the increased cost, longer recovery periods, and risks of invasive surgical intervention, a minimally invasive treatment modality would be of high value in the treatment of chronic, refractory tendinopathies and fasciopathies.

Partial percutaneous tenotomy and fasciotomy are emerging minimally invasive treatment options for chronic, refractory tendinopathies and fasciopathies. The company Tenex developed a device that was approved for use by the United States Food and Drug Administration in 2013. This device uses focused, high frequency ultrasonic vibrations to break up and remove disorganized myxoid tissue that is found in chronic degenerative tendon and fascia. Partial percutaneous tenotomy and fasciotomy procedures using the Tenex device are typically performed under ultrasound guidance and require only a 3mm microincision. Procedure times range from 1 to 5 minutes of active ultrasonic

device cutting time and 10-20 minutes in total treatment time. These procedures typically only require local anesthesia and often allow for reduced immobilization and recovery time as compared to the more invasive surgical procedures. There exists a limited number of primarily case series in the literature that characterize tenotomy and fasciotomy using the Tenex device. Several published case-series revealed clinically and statistically significant improvements in short-term and long-term patient-oriented outcome measures. These include patient satisfaction ratings, visual analog scale pain scores, and validated joint specific questionnaires (e.g., Disability of Arm, Shoulder, and Hand, American Shoulder and Elbow Surgeon, American Orthopedic Foot and Ankle Society scores, etc.) in the treatment of recalcitrant medial elbow tendinopathy, lateral elbow tendinopathy, insertional Achilles tendinopathy, chronic patellar tendinopathy, and plantar fasciopathy [8-13].

There remains a need to determine the effectiveness of partial percutaneous tenotomy and fasciotomy for chronic tendinopathies and fasciopathies. Our aim is to investigate the effectiveness of ultrasound-guided partial percutaneous tenotomy and fasciotomy through use of a long-term follow-up phone survey that evaluated patient-reported outcomes of post-procedure satisfaction, recent pain levels, and willingness to undergo procedure again.

MATERIALS AND METHODS

This research study was approved by the UNC Office of Human Research Ethics (IRB Study number/Approval ID# 16-1465). We conducted a retrospective satisfaction review of all patients >18 years old who presented with chronic tendinopathy or fasciopathy (i.e., insertional Achilles tendinosis, patellar tendinosis, gluteus medius tendinosis, plantar fasciitis, medial epicondylitis, or lateral epicondylitis) and underwent partial percutaneous tenotomy or fasciopathy using the Tenex device between April 2014 and January 2017. All procedures were performed by the corresponding author, who is a non-surgical sports medicine physician with training in MSK ultrasound. Procedures were completed using the Philips Affiniti 50 ultrasound machine with an L12-4 linear transducer at frequency ranges 4–12 MHz; both machine and transducer were manufactured by Philips Healthcare (Seattle, WA). Prior to undergoing the procedure, all patients had failed at least 6 months of conservative therapy with rest, ice, compression, NSAIDs (if no contraindication present), home stretching/strengthening rehab exercises, formal physical therapy, or, in the setting of plantar fasciitis and lateral epicondylitis, a peri-tendon corticosteroid injection. From March to June 2018, all patients who underwent the procedure during the specified time frame were called and asked to complete a simple three-question survey by our research personnel. The survey provided long-term follow-up as data was collected at an average of 1 to 1.5 years after the date of the procedure. The survey asked patients to “Rate your overall satisfaction with the procedure” (answered on a scale of “very satisfied”, “satisfied”, “neutral”, or “not satisfied”), “Rate your pain in the past 1 week” (answered on a scale of “none”, “mild”, “moderate”, or “severe”), and “Would you undergo partial percutaneous tenotomy with the Tenex device again?” (answered “yes” or “no”).

Analysis of the data was performed to determine both the

overall and subgroup satisfaction rates, commonalities of pain reduction, and willingness to repeat procedure. Subgroups were constructed by grouping similar CPT codes (CPT 28008 for procedure of plantar fascia, CPT 24357 for procedure of elbow, etc.) in order to evaluate any trends in satisfaction, pain relief, or willingness to repeat procedure based on the procedure’s anatomic location. We further evaluated each CPT subgroup by gender and age to evaluate any trends in satisfaction, pain relief, or willingness to repeat procedure.

RESULTS

Of 314 patients contacted for follow-up, 189 patients (61%) were available to complete the survey. The age range of respondents was 20 to 81 years old and had a mean age of 50.49 years. Of the 125 patients that were unreachable by telephone at the time of our survey, three patients were deceased due to unrelated causes, four patients refused an interview, and 118 patients did not answer phone call or had an expired phone number at the time of follow-up.

Global analysis: Of all 189 patients who completed the follow-up interview, 92.5% (175 patients) reported that they were “very satisfied” or “satisfied” with procedure results versus 13 patients (6.9%) reported being “neutral” or “not satisfied” (see Figure A). Of these patients, 94% of men (65 out of 69 total) and 92% of women (110 out of 120 total) reported satisfaction (i.e., “very satisfied” or “satisfied”) with procedure (see Figure B). One patient was unable to rate satisfaction level due to cognitive effects of an interval concussion. Regarding pain levels, 91% (172 patients) reported their pain in the past week was “none” or “mild pain”, 7% (14 patients) reported “moderate pain”, and only 1% (three patients) reported “severe pain” (see Figure C). Lastly, 95% (180 patients) reported they were “willing to undergo procedure again” (see Figure D).

Subgroup analyses: Of the 79 patients who underwent partial percutaneous tenotomy of the medial or lateral elbow, 90% (71 patients) were “very satisfied” or “satisfied” with their procedure results (see Figure A), 96% (76 patients) said they would undergo the procedure again (see Figure D), and 90% (71 patients) reported “no pain” or “mild pain” in the past 1 week (see Figure C). Of those patients who underwent elbow partial tenotomy, a slightly higher percentage of men, 91% (32 out of 35), reported satisfaction compared to women, 87% (39 out of 44); see Figure B. There was no association between age and satisfaction in this group.

Of 46 patients who underwent partial percutaneous tenotomy of the insertional Achilles tendon, 96% (44 patients) were “very satisfied” or “satisfied” with their results (see Figure A), 96% (44 patients) said they would undergo the procedure again (see Figure D), and 94% (43 patients) reported “no pain” or “mild pain” in the past week (see Figure C). Of those patients who completed Achilles partial tenotomy, 100% of men (18 patients) and 93% of women (26 out of 28) reported satisfaction with procedure (see Figure B). There was no association between age and satisfaction in this group.

Of 53 patients who underwent partial percutaneous fasciotomy of the plantar fascia, 94% (50 patients) were “very satisfied” or “satisfied” with their results (see Figure A), 96%

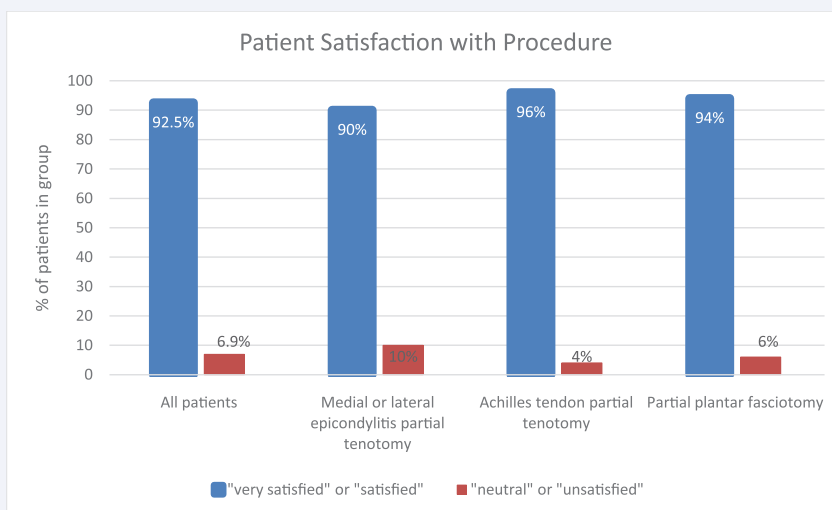


Figure A Patient Satisfaction with Procedure. Patients who reported “very satisfied” or “satisfied” (noted in blue) vs those who reported “neutral” or “unsatisfied” (noted in orange).

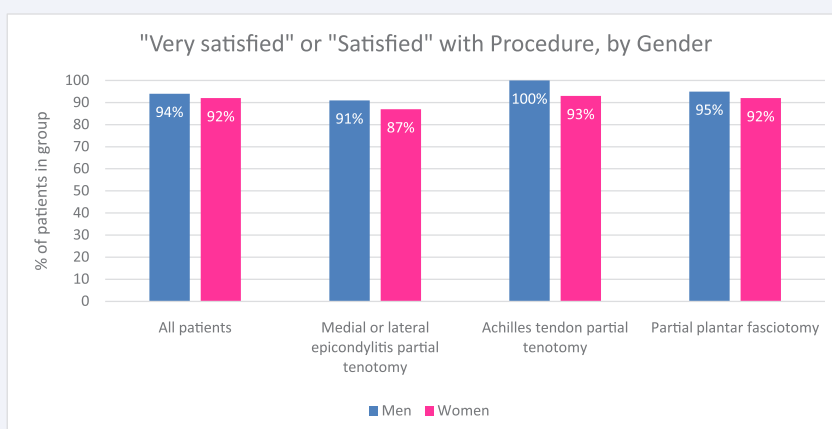


Figure B “Very satisfied” or “Satisfied” with Procedure, by Gender. Percentage of patients, men (in blue) vs women (in pink), who reported “very satisfied” or “satisfied” with procedure.

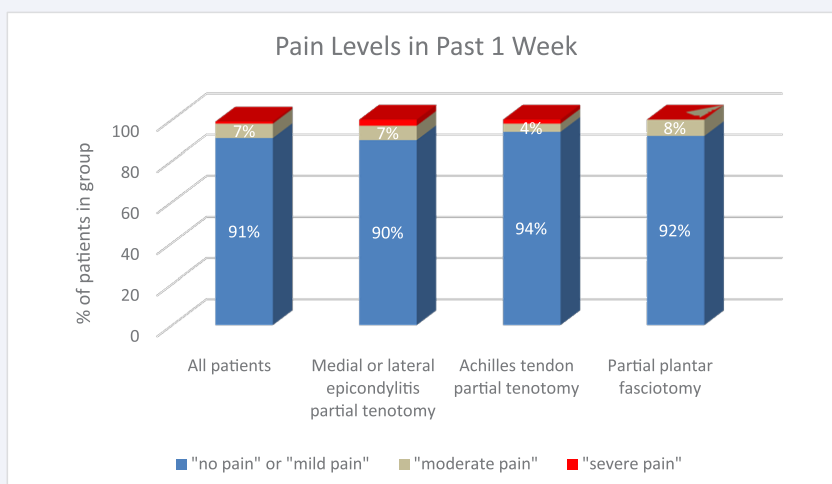


Figure C Pain Levels in Past 1 Week. Percentage of patients who reported “no pain” or “mild pain” (noted in blue) vs those who reported “moderate pain” (noted in gray) and those who reported “severe pain” (noted in red) in the prior week.

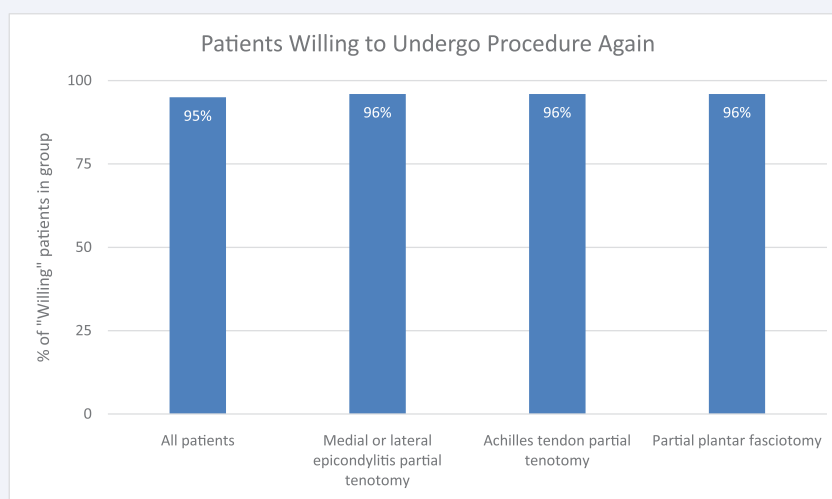


Figure D Patients Willing to Undergo Procedure Again. Percentage of patients who reported "willing to undergo procedure again" at time of survey follow-up.

(51 patients) said they would undergo the procedure again (see Figure D), and 92% (49 patients) reported "no pain" or "mild pain" in the past week (see Figure C). Of those patients who completed partial percutaneous plantar fasciotomy, a slightly higher percentage of women, 95% (39 out of 41), reported satisfaction compared to men, 92% (11 out of 12) as shown in Figure B. There was no association between age and satisfaction in this group.

Subgroups analysis of shoulder, hip, and knee partial percutaneous tenotomy was not performed as each group had four or less patients in each category.

DISCUSSION

The high rates (>90%) of satisfaction and willingness to repeat partial percutaneous tenotomy and fasciotomy in the future with the Tenex device highlight the clinical value of this procedure in the appropriate patient populations, e.g. those patients with chronic, refractory plantar fasciopathy or tendinopathies of the elbow, Achilles, shoulder, hip, or knee. Our long-term findings at >1 year since procedure confirm high rates of satisfaction with procedure, decreased levels of pain, and willingness to repeat procedure which is consistent with the current published body of literature about the Tenex device [8-13]. This study adds to the current literature by detecting similar successful outcomes with the Tenex device in a larger sample size. The results showed no correlation with age within the global analysis or subgroup analyses. Additionally, based on the responses in this study, there was no significant difference between men and women relating to outcome or satisfaction with the procedure.

Limitations of this study include non-response bias and vulnerability to response bias. Although 39% of our original patient sample was unreachable by telephone at the time of our interview, most of these patients had extenuating circumstances that prevented our ability to contact them (e.g., three patients were deceased due to unrelated causes and 118 patients did not answer phone call or had an expired phone number at the time of follow-up); only four patients refused an interview after contacted.

Response bias may have affected the accuracy of patients' survey responses since >1 year had lapsed since their procedure; however, our survey questions investigate current satisfaction ratings and recent pain levels, i.e. in past 1 week, which attempts to mitigate error inherent in recall. Additionally, low numbers of hip, shoulder, and knee partial percutaneous tenotomy limit this study's ability to characterize these procedures' performance in terms of patient satisfaction and pain reduction.

CONCLUSION

High rates (>90%) of satisfaction, reduced levels of pain, and willingness to repeat partial percutaneous tenotomy and fasciotomy with the Tenex device at >1 year post-procedure highlight the clinical value of this procedure. The results showed no correlation with age, and there was no significant difference between men and women relating to outcome or satisfaction with the procedure.

DECLARATIONS

- **Ethics approval and consent to participate:** This research study was approved by the UNC Office of Human Research Ethics (IRB Study number/Approval ID# 16-1465).
- **Availability of data and material:** Data in the form of deidentified participant data are available upon reasonable request. Please contact Julie Titter MS, ATC (Clinical Research Specialist at UNC Orthopaedics, 3160 Bioinformatics Bldg, Campus Box 7055, Chapel Hill, NC 27599, email: julie_titter@med.unc.edu) for data sharing request.

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