Percutaneous Ultrasonic Tenotomy Reduces Insertional Achilles Tendinopathy Pain With High Patient Satisfaction and a Low Complication Rate

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Abbreviations

AOFAS, American Orthopedic Foot and Ankle Score; IAT, insertional Achilles tendinopathy; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, Short-Form 12-Item Survey

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Due to the novelty of percutaneous ultrasonic tenotomy, the risks and benefits of this minimally invasive procedure for insertional Achilles tendinopathy pain have only been examined in case studies and retrospective chart reviews for other diagnoses. This retrospective chart review over a 3.5-year period identified 34 patients with insertional Achilles tendinopathy who had percutaneous ultrasonic tenotomy (mean age ± SD, 52.2 ± 11.6 years; mean body mass index, 32.9 ± 7.5 kg/m^2; 62% female). This procedure reduced the rate of moderate/severe pain from 68% at baseline to 15% at the long-term follow-up and had a satisfaction rate of 70%. There was 1 minor complication out of 40 procedures in 34 patients.

Key Words—Achilles tendon; enthesopathy; minimally invasive procedure; musculoskeletal; percutaneous ultrasonic tenotomy; tendinopathy; tendonitis

Insertional Achilles tendinopathy (IAT) is a painful condition that limits mobility, reduces work capacity, and impedes exercise participation.[1] There are many nonsurgical treatment options for IAT; however, the level of evidence guiding care remains low. Percutaneous ultrasonic tenotomy allows patients to undergo a minimally invasive procedure and return to activity in a shorter time than an open surgical procedure. However, due to the novelty of this treatment option, the effectiveness and safety of this procedure for IAT is unknown.

Most data supporting the use of percutaneous ultrasonic tenotomy for IAT are based on literature reporting positive outcomes for tendinopathy at the elbow. There are a number of studies supporting the use of percutaneous ultrasonic tenotomy to reduce elbow tendinopathy pain, with no complications reported.[2–7] Rates of patient satisfaction were high and ranged from 79% to 100%, yet the sample sizes for each of these studies were small (≤20 patients).[2–7] To date, there is only a single published study (n = 6) on outcomes of percutaneous ultrasonic tenotomy for chronic Achilles tendinopathy.[8] That case series reported complications related to percutaneous ultrasonic tenotomy, including deep venous thrombosis (n = 1) and lack of pain relief or increased pain (n = 6, 5 midportion Achilles tendons and

1 insertional Achilles tendon).[8] Larger studies are needed to estimate the complication rate for percutaneous ultrasonic tenotomy as a treatment option for IAT.

This retrospective chart review of a relatively larger sample is a needed first step toward advancing the level of evidence examining this minimally invasive procedure for tendinopathy. The risks of percutaneous ultrasonic tenotomy for IAT need to be interpreted within the context of the potential benefits for pain relief, improved quality of life, and patient satisfaction. The primary aims of this series were to examine the following: (1) changes in self-reported pain, quality of life, and function; (2) patient satisfaction; and (3) complications with the procedure.

Materials and Methods

A retrospective review of charts dated between September 2013 and May 2017 of all patients who had a percutaneous ultrasonic tenotomy procedure for IAT identified 34 patients. The median duration of symptoms was 1.5 years (interquartile range, 1–2.3 years). Most patients had tried other treatment options before percutaneous ultrasonic tenotomy, including physical therapy (22 of 34) and cortisone injection (5 of 34). Six patients had the tenotomy procedure performed on both sides; therefore, a total of 40 procedures were performed during the chart review period.

Outcomes were assessed before the tenotomy procedure, at a short-term follow-up (6 or 12 weeks), and at a long-term follow-up (median, 1.7 years; interquartile range, 11–36 months). Most outcomes were measured in the clinic as part of routine care. To maximize the number of long-term follow-up responses, an online and phone survey was approved by our institution's Human Subjects Review Board. Of the 34 patients, 18 completed the long-term follow-up survey.

Pain was assessed by the 4-point scale from the American Orthopedic Foot and Ankle Score (AOFAS) questionnaire as follows: 40, none; 30, mild/occasional; 20, moderate/daily; and 0, severe/almost always present. Quality of life was assessed by the Physical Component Summary (PCS) and the Mental Component Summary (MCS) subscales of the Short-Form 12-Item Survey (SF-12). The *t* scores of the PCS and MCS summary scales reference the general population, with a mean *t* score of 50 and an SD of 10.[9] For function, patients were asked whether they had resumed their normal level of activity and whether they had returned to work. Patient satisfaction was assessed by asking the patient "Are you satisfied with the procedure and outcome?" and was graded on a 5-point scale: 1, very satisfied; 2, somewhat satisfied; 3, neutral; 4, somewhat dissatisfied; and 5, very dissatisfied. Complications were evaluated on the basis of the clinic evaluation and patient report. As opioids were not routinely prescribed for postprocedure pain control, any prescription of an opioid for excessive procedure-related pain was also noted from the chart review.

Procedure Description

All procedures were performed by the senior author (M.H.), who is a fellowship-trained sports medicine physician with greater than 7 years of experience performing ultrasound-guided musculoskeletal interventions. The procedures were performed in an outpatient setting (clinical procedure suite) under sterile conditions with local anesthesia only (ie, no sedation). Patients were placed in the prone position with feet hanging free off the edge of the table. A preprocedural ultrasound scan was performed with a high-frequency linear array transducer (12–5 MHz; Philips Healthcare, Bothell, WA) to identify the location and extent of the disorder, which were used to individualize the technique for each case (Figure 1). The patient was then prepared and draped in the usual sterile fashion; a sterile ultrasound transducer cover and sterile acoustic coupling gel were used for all procedures. Local anesthesia was obtained with 1% lidocaine without epinephrine infiltrated via a 25-gauge, 50-mm needle under live ultrasound guidance first into the subcutaneous tissues and then proceeding into the Achilles tendon and down to the retrocalcaneal bursa when a deep/anterior abnormality was to be addressed. Approximately 5 to 10 mL of 1% lidocaine was used for each procedure without undue patient discomfort or the need for additional anesthesia such as conscious sedation.

A number 11 blade was then used to make an approximately 5-mm incision down to the tendon to allow introduction of the cutting device. All incisions were made longitudinal (in line) with the Achilles tendon fibers to limit iatrogenic tissue damage

(Figure 2). A TX ultrasonic cutting device (Tenex Health, Lake Forest, CA) was then introduced and first used to debride the more superficial/posterior retro-Achilles bursal tissue and thickened paratenon from the Achilles tendon until the device was free to move within this tissue plane unobstructed (Figure 2), after which the intratendinous abnormality identified during the preprocedural scan was addressed. Intratendinous calcifications were debrided, as well as any regions of tendinopathic tissue represented by heterogeneous hypoechoic tissue. If a compressive disorder was appreciated at the deep/anterior surface (often in association with a Haglund deformity), the device was advanced to this location and further debridement performed. Examples of this subtype of compressive disorder are shown in Figures 1A, 2C, and 3C. A limited retrocalcaneal bursectomy was performed when bursal hypertrophy or hyperemia associated with the bursa was noted on Doppler imaging (suggesting active bursitis). In rare cases, if the Haglund deformity was thought to be amenable to limited debridement, the TX device was used off label to perform bony debridement (Figure 3). Any off-label use of the device was explicitly discussed with the patient before any procedure. The average energy time for all procedures was 7 minutes 18 seconds with an SD of 4 minutes (range, 2 minutes 30 seconds–19 minutes 12 seconds). Once debridement was complete, the skin incision was closed with an adhesive bandage (Nexcare Steri-Strips; 3M, Minneapolis, MN), an occlusive film (Tegaderm; 3M), and a compressive sleeve.

The postprocedure protocol included 2 weeks of protected weight bearing in a walking boot, after which patients were allowed to wean out of the boot and transition to a self-selected shoe as tolerated. Patients were allowed to come out of the boot to perform pain-free active range of motion starting on postprocedure day 1 and were not required to sleep in the boot. Strengthening exercises were started at 2 weeks after the procedure, and patients were allowed to return to daily activities as tolerated. No heavy use (eg, prolonged walking, running, jumping, or change of direction) was allowed until a minimum of 6 weeks.

Analysis

For the 6 patients who had percutaneous ultrasonic tenotomy on both sides, only a single side per patient

Figure 1. Long-axis images of Achilles tendon insertion showing variability in the location and extent of pathologic findings. **A**, Hypoechoic changes (asterisk) are shown adjacent to the posterosuperior calcaneus. The boundary with the retrocalcaneal bursa (arrowhead) is poorly defined. Note the relatively normal appearance of the superficial/posterior portion of the tendon. **B**, The deep/anterior portion of the tendon is relatively normal; however, changes of tendinosis (asterisk) are shown adjacent to an intratendinous calcification (arrow). There is minimal posterior acoustic shadowing suggesting a "soft" calcification, which is amendable to percutaneous debridement. An enthesophyte (arrowhead) shows dense posterior acoustic shadowing consistent with cortical bone. **C**, Hypoechoic changes of tendinosis (asterisks) are more extensive and pronounced. An enthesophyte is present (arrowhead), but no intratendinous calcification is shown. **D**, Color Doppler image corresponding to **C**. There is hyperemia within the superficial/posterior tendon as well as paratenon. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.

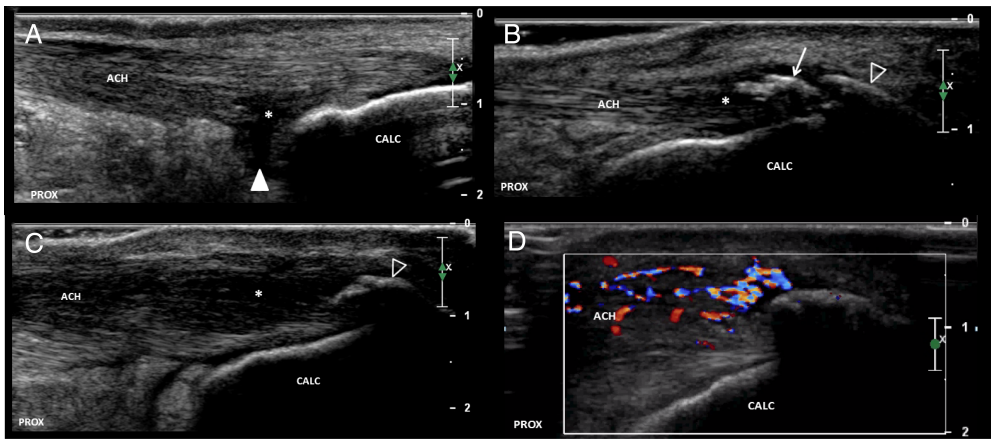


Figure 2. Long-axis images of the Achilles tendon showing the procedural technique. **A**, After administration of local anesthesia, a number 11 blade (arrows) is used to make an incision down to the tendon. **B**, The TX device (arrowheads) is then introduced superficial/posterior to the tendon, and the hypertrophied paratenon and connective tissue are debrided from the tendon. **C**, The device is then guided into the tendon, and the regions of tendinosis are debrided. In this example, there was concomitant retrocalcaneal bursitis (asterisk), and a limited bursectomy was performed. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.

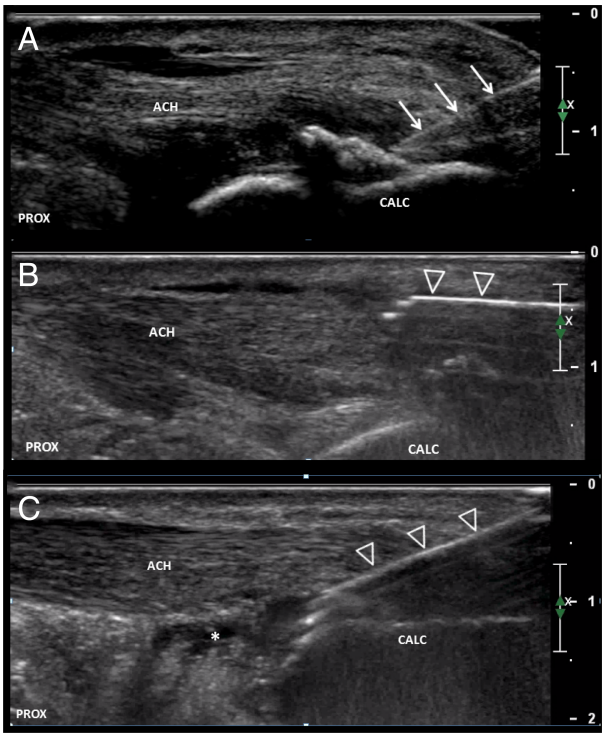


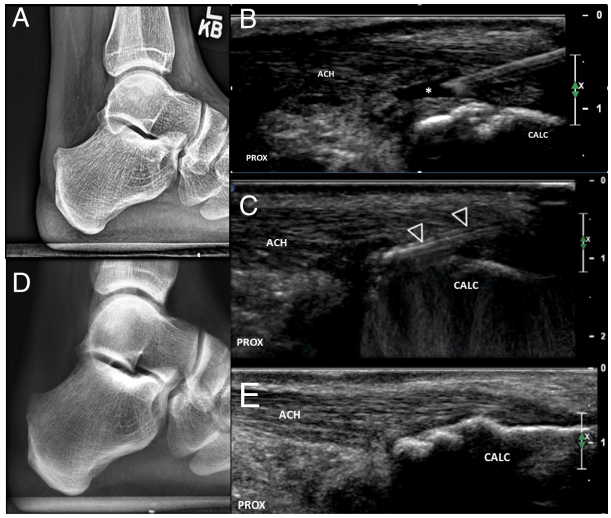
Table 1. Pain Level Reported on the AOFAS Pain Scale (N = 34)

Pain Level	Baseline	Short-term Follow-up[a]	Long-term Follow-up[b]
None	0 (0)	3 (9)	4 (12)
Mild/occasional	5 (15)	13 (39)	13 (39)
Moderate/daily	18 (55)	8 (24)	2 (6)
Severe/almost always present	4 (12)	2 (6)	1 (3)
Missing	6 (18)	7 (21)	13 (39)

Values are presented as number (percent). Short-term: 6-week follow-up, n = 13; 12-week follow-up, n = 14; long-term: n = 22; median, 1.7 years (interquartile range, 11–36 months).
[a]Wilcoxon signed rank test, n = 23, short-term follow-up compared to baseline: $P < .01$.
[b]Wilcoxon signed rank test, n = 17, long-term follow-up compared to baseline: $P = .01$.

was used in the statistical analysis to maintain independence of observations. Data corresponding to the second time a patient had a procedure (on the opposite side) was analyzed when available (4 of 6); otherwise, data for the first side were used (2 of 6). The Wilcoxon signed rank test was used to compare baseline to short- and long-term follow-up time points. Pair-wise deletion was used, so that participants with baseline data yet missing short-term data could be included in the analysis of the long-term follow-up compared to baseline (and vice versa with missing long-term data). Therefore, the sample size for the statistical analyses was smaller than the sample size with data at any single time point. Although most people with missing baseline data were also missing subsequent follow-up data (n = 4; AOFAS pain scale), there were a couple of people with missing baseline data yet available follow-up data who were

Figure 3. Haglund bony debridement. **A**, Preprocedural radiograph showing a posteriorly projecting bony protuberance at the posterosuperior calcaneus, which correlated with the location of the patient's maximal pain. **B**, Procedural long-axis sonogram during local anesthesia showing a partial-thickness tear (asterisk) adjacent to the region of cortical irregularity at the posterosuperior calcaneus. **C**, The TX device (arrowheads) is used to shave down the posteriorly projecting bony protuberance using a layer-by-layer technique working from superficial to deep. **D**, Follow-up radiograph at 6 weeks showing decreased prominence of the previously noted bony protuberance. **E**, Follow-up sonogram at 3 years is consistent with bony remodeling and complete healing of the debrided partial-tendon tear. The patient reported no pain or functional limitation at the 3-year follow-up. ACH indicates Achilles tendon; CALC, calcaneus; and PROX, proximal.



included in the data presented in the tables but not the statistical comparisons to baseline (n = 2; AOFAS pain scale). Paired *t* tests were used to compare the quality of life from baseline to the short-term follow-up. Descriptive statistics were used for function, patient satisfaction, and the complication rate. To minimize the sample bias and maximize the inclusion of the patients from all identified in the retrospective review, data on complications were included from any time point.

Results

The 34 patients identified had a mean age ± SD of 52.2 ± 11.6 years and a mean body mass index of 32.9 ± 7.5 kg/m^2; 62% were female. There were statistically significant decreases in pain at short- and long-term follow-ups after percutaneous ultrasonic tenotomy (Table 1; $P < .05$). The quality of life, as measured by the PCS component of the SF-12, improved at the short-term follow-up ($P = .03$; n = 23 patients), yet there was not a significant change in the MCS component (Table 2; $P = .96$). At the short-term follow-up, 11 of 21 (n = 7 at 6 weeks; n = 14 at 12 weeks) had resumed normal activity, and 14/14 had resumed work (n=11 at 6 weeks, n=3 at 12 weeks). At the short-term follow-up, 70% of patients were satisfied with their treatment (14 reported "very satisfied," and 10 reported "somewhat satisfied"). Some patients were neutral (n = 5), were somewhat dissatisfied (n = 2), or had missing data for this outcome (n = 3). For complications, 1 patient reported a superficial skin infection that resolved with oral antibiotics. No patients were prescribed opioids for pain management at any point. No other complications related to the tenotomy procedure were reported by the other 33 patients or documented in their medical records.

Table 2. Results for the PCS and MCS Components of the SF-12

Component	Baseline	Short-term Follow-up
PCS	40.8 ± 9.4	44.0 ± 7.1[a]
MCS	59.4 ± 5.2	59.8 ± 3.7

Values are presented as mean ± SD. Before percutaneous ultrasonic tenotomy: n = 24. Short-term: 6-week follow-up, n = 9; 12-week follow-up, n = 14.
[a]Paired *t* test, n = 17, short-term follow-up compared to baseline: $P = .03$.

Discussion

To our knowledge, this sample of 40 procedures in 34 patients with IAT is the largest to date that has been used to examine the efficacy and safety of percutaneous ultrasonic tenotomy. We found that percutaneous ultrasonic tenotomy can decrease pain, improve the quality of life, and have a high satisfaction rate for patients with chronic IAT. In addition, there was a low complication rate (1 of 40 had a superficial skin infection that resolved with antibiotics) over the time when complications are most likely to arise. The low severity and complication rate (3%) in this series contrast the report of severe complications and increased pain with percutaneous ultrasonic tenotomy in a case series of 6 patients with Achilles tendinopathy.[8] Larger studies are needed to resolve this current level of conflicting evidence on the severity and rate of complications of percutaneous ultrasonic tenotomy for chronic Achilles tendinopathy pain.

Although the findings of this preliminary series need to be further examined, we found that percutaneous ultrasonic tenotomy decreased chronic IAT pain ($P < .05$; Table 1). Of the 28 patients with baseline data, only 5 reported no to mild, occasional pain at baseline. By the long-term follow-up 17 patients reported no to mild pain. A limitation of this retrospective series was missing data that were not collected during routine care, which resulted in missing 18% (at baseline) to 39% (at the long-term follow-up) of the data for this key self-reported outcome measure. Despite missing follow-up data for up to 12 people, we know that at least half (n = 17) of the original sample achieved mild to no pain after the tenotomy procedure. There was only 1 patient who reported worse pain (severe/always present at the 12-week follow-up) compared to the baseline (moderate/daily) pain rating. On further chart review, it was found that the patient saw an orthopedic surgeon 7 months after percutaneous ultrasonic tenotomy, reported decreased pain, and decided not to pursue a surgical intervention at that time. Based on clinical experience, our interpretation of this finding is that it

may take up to a year to achieve maximum pain relief from the procedure.

An improvement in symptoms was also shown by an increase in the PCS component of the SF-12 at the short-term follow-up ($P = .03$; n = 23). However, we failed to detect a change in the MCS component, indicating that percutaneous ultrasonic tenotomy is more effective at improving the physical component rather than the mental component of the quality of life. Despite only having short-term follow-up data at 6 or 12 weeks, the 70% rate of patient satisfaction with percutaneous ultrasonic tenotomy for IAT in this series was similar to the rates in other studies of tendinopathy at the elbow, which reported ranges from 75% to 100%.[2,4,7] In comparison, the satisfaction rate for surgical debridement of IAT is generally greater than 87%,[10–18] yet this high patient satisfaction rate also had complication rates ranging from 6% to greater than 30%, which included wound-healing issues (superficial would infection, skin necrosis, hematoma, and delayed wound healing), scar abnormalities (hypersensitivity, hypertrophy, and numbness), sural nerve injury, tendon avulsion, deep venous thrombosis, and recurrence of pain.[10,11,13–16]

There are several advantages of percutaneous ultrasonic tenotomy relative to an open or endoscopic surgical procedure. The cost associated with percutaneous ultrasonic tenotomy is a small fraction of the cost of a traditional operation. For example, at our institution, an open Achilles debridement costs greater than $18,000 more than percutaneous ultrasonic tenotomy. An additional benefit, and a partial reason for reduced cost, is that there are less resources and time required for percutaneous ultrasonic tenotomy performed in an outpatient clinical setting compared to a procedure performed in a surgical center or operating theater. There are also reduced risks associated with anesthesia. We have demonstrated that percutaneous ultrasonic tenotomy is well tolerated and safely performed using only local anesthesia. Furthermore, no patient required opioid pain medication at any point after the procedure, demonstrating a lack of excessive postprocedure pain and decreased risk of opioid abuse or future dependence. Patients are also able to return to their previous level of activity much sooner after this procedure. We found that half of the patients were able to return to their previous level of activity by 12 weeks, and all had returned to work at the 12-week follow-up.

This case series had several limitations due to the study design. Because the data were collected by chart review, there were missing baseline and follow-up data that make it more difficult to estimate the effect size of percutaneous ultrasonic tenotomy for self-reported pain, quality of life, function, and patient satisfaction. We have indicated when data were missing for particular variables to indicate the potential for a dropout bias. We also attempted to contact all participants by e-mail and phone to maximize the long-term follow-up and capture any complications that could have been overlooked in the chart review. This series also had a small sample size that included a variety of different types of tissue disorders at the tendon insertion (eg, variable involvement of the Haglund deformity, size of enthesophytes, and superficial versus deep tendon degeneration) as well as systemic factors, such as obesity, which could have affected outcomes. Due to the heterogeneity of our sample, generalization of these findings to all patients with IAT may not be appropriate. An additional limitation of this series is that it only reflects outcomes of a single physician in a single geographic area. A prospective multisite study with a large sample size is needed to more accurately evaluate the relative risk-to-benefit ratio of percutaneous ultrasonic tenotomy for IAT.

In conclusion, percutaneous ultrasonic tenotomy had the benefits of reducing the rate of moderate/severe IAT pain from 68% at baseline to 15% at the long-term follow-up and had a short-term satisfaction rate of 70%. Additional benefits of this procedure include reduced cost and time on behalf of the provider and patient compared to an open or endoscopic operation. The identified risk in this series was low, with 1 minor complication out of 40 procedures. This series supports the safety of percutaneous ultrasonic tenotomy performed in a clinical setting and the need for larger studies to further investigate its long-term efficacy.

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