Tenex Health TX® Clinical Study Highlights

ACHILLES

85% Patients Had Long-Term Pain Relief and No Opioids Needed

A Retrospective Review of Insertional Achilles Tendinopathy with the TX System Published in the Journal of Ultrasound in Medicine (Chimenti et al., 2019)

SIGNIFICANT LONG-TERM PAIN RELIEF
SUSTAINED AT 3.5 YEARS
34 PATIENTS

Study Methods

- Case series; retrospective review of 34 patients (40 procedures) who had a percutaneous ultrasonic tenotomy with the Tenex Health TX® System.
- Median duration for symptoms was 1.5 years. Most had failed previous conservative treatment.
- Outcomes were assessed at 6-12 weeks, 11-36 months and long term (median 1.7 years).
- Pain was assessed with the AOFAS scale; Quality of Life with the PCS and MCS subset of the SF-12.

Key Takeaways

- 85% patients had significant pain relief.
- No opioids prescribed.
- Safer than open surgery.
- A fraction of the cost of open surgery.

Results and Conclusions

- 85% patients had significant long-term pain relief.
- 70% short term patient satisfaction (not all patients reporting).
- Significant decreases in pain per AOFAS scores short and long-term.
- Significant improvement in PCS quality of life scores short-term (no significant change in MCS score).
- 1 superficial skin infection.
- Safer than surgical debridement (which has 6-30% complication rate).
- A fraction of the cost of open surgery (which is > $18k more).
- Percutaneous ultrasonic tenotomy reduces moderate/severe pain. Additional benefits include reduced cost and time compared to an open or endoscopic operation. Identified risk was low. This series supports the safety of percutaneous ultrasonic tenotomy performed in a clinical setting.

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

**Chimenti RL, Stover DW, Fick BS, Hall MM.
Journal of Ultrasound in Medicine. 2019;39(6):1629-1635.
Epub 2018 Oct.**

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/m2; 62% female). There were statistically significant decreases in pain at short- and long-term follow-ups. This procedure reduced the rate of moderate/severe pain from 68% at baseline to 15% at the long-term follow-up. 85% patients reported no pain or mild pain at long term follow-up. The procedure's short-term satisfaction rate was 70% (although this factored in patients for which there was no data). Amongst the patients reporting, there was a 77% short-term satisfaction rate. There was 1 minor complication out of 40 procedures in the 34 patients.

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, supporting the safety of percutaneous ultrasonic tenotomy performed in a clinical setting.

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/occassional	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.

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