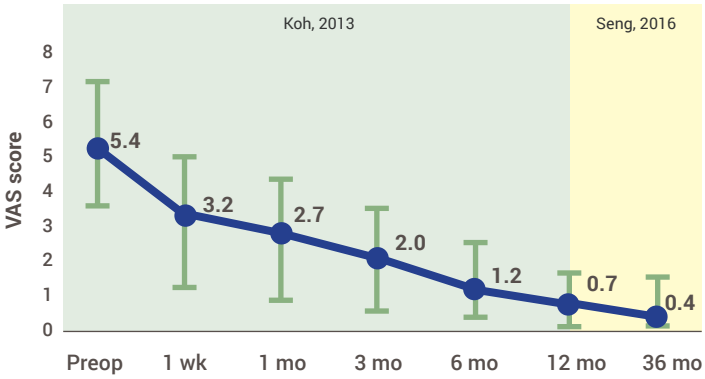
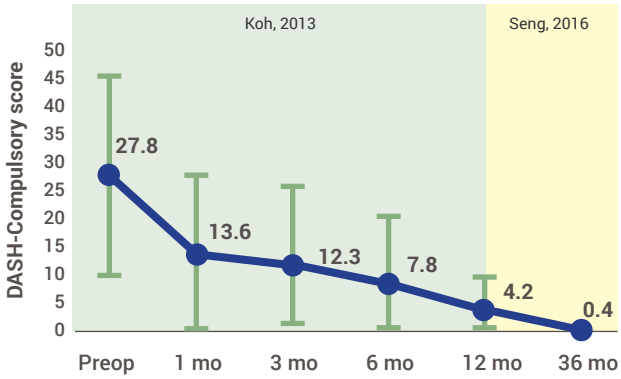
Tenex Health TX® Clinical Study Highlights

ELBOW

100% Lateral Epicondylitis Patients Pain-Free and Satisfied No Further Treatments Required - Sustained Over 3 Years

A Prospective Study Published in Two Papers in the American Journal for Sports Medicine (Koh et al., 2013) (Seng et al., 2016)





Study Methods

- A case series; prospective study.
- 20 patients averaging 12.5 months of failed non-operative therapy for recalcitrant lateral elbow tendinopathy were treated with percutaneous ultrasonic tenotomy using the TX System.
- Patient outcomes were assessed via patient satisfaction, VAS pain scores, DASH scores and ultrasound imaging.
- Results were assessed at 1, 3, 6 and 12 months (Koh, 2013) and at 36 months (Seng, 2016).

Key Takeaways

- 100% long-term success (sustained > 3 yrs).
- Rapid pain relief (some in 1 week).
- Safe and well tolerated.
- No further treatment required; no recurrence.
- Authors termed the treatment a “definitive intervention”.
- Suitable for early intervention and in an out-patient setting.
- No complications.

Results and Conclusions

- 19/20 patients were essentially pain-free and satisfied at 6 months. 20/20 patients were essentially pain-free and satisfied at 36 months.
- Complications = 0.
- Mean VAS score improved at 3, 6 and 12 months (from 5.5 to 2.0, 1.0 and 0.5). Mean DASH-Compulsory score improved significantly at 3, 6 and 12 months (from 21.7 to 8.6, 4.6 and 2.5).
- At 36 months, Mean VAS score = 0.4 (±0.9); DASH-Compulsory score = 0.4 (± 0.6).
- Mean procedure time: 10 mins.
  Mean energy time: 33 secs.
- Percutaneous ultrasonic tenotomy demonstrates sustained results with positive sonographic evidence of tissue-healing response and is an attractive alternative to surgical intervention.
- Ultrasound imaging showed reduced tendon thickness, resolved or reduced hypervascularity, and reduced hypoechoic area by 6 months (further reductions and resolved hypoechoic area were seen at 36 months).

100% PATIENT SATISFACTION, PAIN RELIEF SUSTAINED AT 3 YEARS - 20 PATIENTS

Clinical Study Summary

Fasciotomy and Surgical Tenotomy for Recalcitrant Lateral Elbow Tendinopathy: Early Clinical Experience With a Novel Device for Minimally Invasive Percutaneous Microresection

Koh JSB, Mohan PC, Howe TS, Lee BP, Yang Z, Morrey BF. American Journal of Sports Medicine. 2013;41(3):636-644.

Purpose: To explore the safety and efficacy of a new minimally invasive mode of treatment that delivers focused, calibrated ultrasonic energy, effectively microresecting and removing the pathological tendon tissue with the Tenex Health TX1 device. This prospective study explores the safety, tolerability and early efficacy of this technique in patients suffering from lateral epicondylitis. Results: Twenty (20) patients between the ages of 33-65 years of age underwent the ultrasonic microresection procedure in an outpatient clinic setting using the TX1 device. The patients had failed non-operative therapy and were symptomatic for an average 12.5 months. Patient's baseline pain (VAS), quality of life/QOL (DASH Score) and ultrasound evidence of tendonosis were documented and at 2 weeks, and 1, 3, 6 and 12 months post-procedure. There were no device or patient related complications. All patients were treated under local anesthesia with an average ultrasonic energy application of 33 seconds required to complete the percutaneous tenotomy. No additional treatments or physical therapy were provided to the patients. Improvement in pain and QOL measurements were observed in 2 weeks and reached statistical significance by 1 month, which was sustained at 12 months. 19 of the 20 patients (95%) expressed satisfaction with the procedure. Conclusion: Ultrasonic microresection of diseased tissue with the Tenex Health TX1 device provides a focally directed, safe, specific, minimally invasive and well-tolerated treatment for recalcitrant elbow tendinopathy in an office based or ambulatory setting with good evidence of some level of efficacy in 19 of 20 and is sustained for at least one year.

Ultrasonic Percutaneous Tenotomy for Recalcitrant Lateral Elbow Tendinopathy: Sustainability and Sonographic Progression at 3 Years

Seng C, Mohan PC, Koh JSB, Howe TS, Lim YG, Morrey BF. American Journal of Sports Medicine. 2016;44(2):504-510. Epub 2015 Nov.

Minimally invasive surgical techniques for recalcitrant lateral elbow tendinopathy have gained popularity in recent years. Ultrasound guided percutaneous microresection using ultrasonic energy of the diseased tendon is a novel procedure that can be performed safely in the office or ambulatory surgery setting and is well tolerated. Good clinical outcomes at 1 year have been documented previously. We aim to assess the efficacy and clinical outcomes of our patients who have undergone minimally invasive ultrasound guided percutaneous microresection for recalcitrant lateral elbow tendinopathy with the Tenex Health TX System at 3 years post procedure. As a follow up on the original study group reporting the 1 year clinical, we assessed outcomes of 7 male and 13 female patients with a mean age of 47 years who failed non-operative therapy. We interviewed all 20 original patients at a minimum of 2 years post procedure and documented outcomes of patient satisfaction; visual analog scale (VAS) pain scores; and Disabilities of the Arm, Shoulder and Hand (DASH) scores. All of these patients reported no or minimal pain at 3 years, with median VAS score of 0.7 at 3 years (range 0-2.5, $p<0.001$). Functional outcomes of patients also improved, with median DASH-Compulsory score of 0.4 at 3 years (range 0-10.8, $p<0.001$). There were no cases of adverse complications and no recurrences. In conclusion, ultrasonic microresection of the diseased tissue using the Tenex Health TX System for recalcitrant lateral elbow tendinopathy is safe, well tolerated, minimally invasive, and can be conveniently performed in the outpatient or ambulatory setting. This novel treatment can be considered for early and definitive intervention of elbow tendinopathy.

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