Tenex Health TX® Clinical Study Highlights

PLANTAR FIBROMA

TX System Is Safe and Effective For Removing Plantar Fibromas With Complete Resolution of Symptoms at ~ 2 Months

A Study on Treating Painful Plantar Fibromas with the TX System Published in the Austin Journal of Orthopaedics & Rheumatology (Patel, et al., 2015)

RESOLUTION
NO RECURRENCE AT 2.5 YEARS
8 PATIENTS

Study Methods

- A case series; retrospective study.
- 8 patients who had failed conservative treatment underwent definitive treatment with the Tenex Health TX® System and arthroscopy for symptomatic plantar fibromas.

Results and Conclusions

- Mean AOFAS score improved from 30.8 (20-36) preoperatively to 90.1 (85-92) postoperatively.
- Mean time to resolution of symptoms was 64 days.
- No recurrence over a mean follow-up time of 2.5 years.
- Complications = 0.
- The TX System appears to be a safe, effective method for removing painful plantar fibromas in patients who have failed conservative measures.

Key Takeaways

- 100% pain relief.
- No recurrence over 2.5 years.
- TX System can be used with arthroscopy (or ultrasound).
- No complications.

100%

RESOLUTION - NO RECURRENCE AT 2.5 YEARS
8 PATIENTS

A Pilot Study of a Novel Treatment Method for Refractory Painful Plantar Fibromas

Patel MM, Patel SM, Patel SS, Daynes J. Austin Journal of Orthopedics & Rheumatology. 2015;2(2):1014.

Objective: Painful plantar fibromas may make ambulation difficult for patients. Treatment modalities may include conservative care, modified shoe wear and orthotics. Surgical treatment may include open excision. In this study, the Tenex Health TX System is a surgical instrument designed to deliver ultrasonic energy for soft tissue cutting was evaluated as a treatment modality for these painful lesions.

Methods: Eight consecutive patients who had painful plantar fibromas elected to undergo treatment for the fibromas using the Tenex Health TX System. They all had had conservative care including modifications of shoes and either over the counter orthotics or custom orthotics. They all had advanced imaging tests (MRI or CT) preoperatively to help delineate the lesions. Treatment with the Tenex Health TX System was delivered in a percutaneous fashion in an outpatient setting. Excised tissue specimens were sent to pathology to confirm fibrotic tissue and no malignancy. Preoperative and postoperative AOFAS scores were obtained for quality of life assessment. Physical therapy was offered to patients postoperatively.

Results: Average age of patient was 51.3 years (17-71). Average time of painful symptoms was 15.1 months (3-36). All patients had modified footwear or orthotics and no appearance of malignancy by tissue imaging. Preoperative AOFAS score improved from 30.8 (20-36) to 90.1 (85-92). Average time of resolution of symptoms was 63.5 days (30-112). One patient had a recurrence, but it was in a different location than the index operation. No others have had a recurrence to date. Pathology specimens were all negative for malignancy. All patients were discharged from care and no infections were recorded. Three of eight patients underwent physical therapy and were discharged from physical therapy successfully.

Conclusion: The Tenex Health TX System appears to be effective for removing painful plantar fibromas in patients who have failed all conservative measures.

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