

# Peer-Reviewed Clinical Publications

## Published/Accepted

- ☐ Koh et al – Am. Journal of Sports Medicine, 2013 (elbow)
- ☐ Hackel – Orthopedics Today 2013 (procedure overview / mixed tendons)
- ☐ Morrey – Techniques in Elbow and Hand Surgery 2013 (elbow)
- ☐ ElAttrache – Operative Techniques in Sports Medicine 2013 (knee)
- ☐ Barnes – Operative Techniques in Sports Medicine 2013 (procedure overview/mixed tendons)
- ☐ Khanna et al – Am Academy of Physical Med & Rehab Poster 2013 (mixed tendons)
- ☐ Traister et al – Am Med Society for Sports Medicine Presentation 2014 (mixed tendons)
- ☐ Barnes et al – accepted, Journal of Shoulder and Elbow Surgery 2014 (elbow)
- ☐ Patel – accepted, American Journal of Orthopedics 2014 (plantar fascia)
- ☐ Mayo Clinic Epidemiology study – accepted, American Journal of Sports Medicine 2014 (elbow)

**Studies revealed at least 90% patients pain-free within 6 weeks of treatment**

**No additional treatment – single minimally invasive procedure / well-tolerated**

**Strong safety profile**

## Submitted/In Preparation

- ☐ Kamineni (Univ. of KY) – Controlled animal model study
- ☐ Koh et al (Singapore/Mayo) – Two year clinical efficacy and safety follow-up in elbow tendinosis
- ☐ Yanish (Des Moines, IA) – Cost effectiveness study: Tenex vs Surgery (elbow)
- ☐ Vanderwoude (Lincoln, NE) – Plantar fascia study
- ☐ Ellis et al (Phoenix, AZ) – Achilles tendon study
- ☐ Patel (Indianapolis) – Plantar fibroma study
- ☐ Stowers (Florida State) – Patellar tendon study

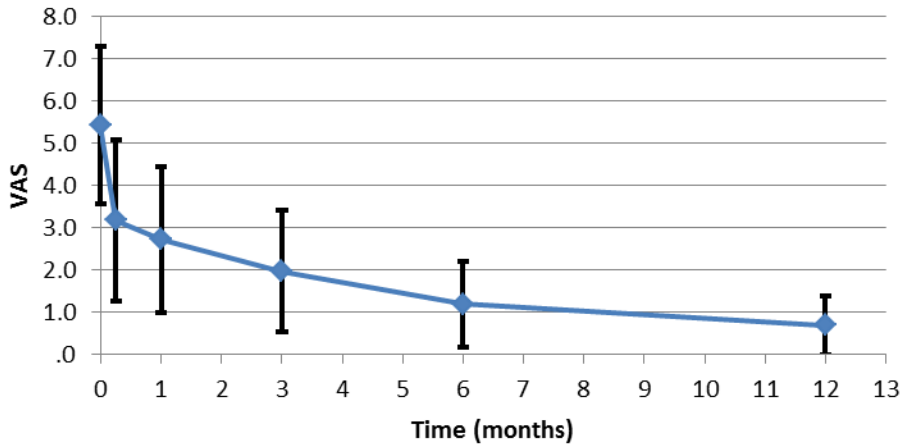


# Koh et al (Singapore/Mayo) - Elbow

- ❑ Prospective IRB-approved study of 20 pts with chronic epicondylitis who failed non-surgical treatment (medical, PT, cortisone)
- ❑ Single treatment with TX1
- ❑ Post-procedure care - no PT, OTC pain control, activity modification for 2 weeks
- ❑ Patient follow-up: 2 weeks, 1, 3 , 6 and 12 months
  - Adverse events
  - Pain score (VAS)\*
  - Quality of life (DASH/Disability of the Arm, Shoulder and Hand)
  - Diagnostic ultrasound at baseline and 6 months

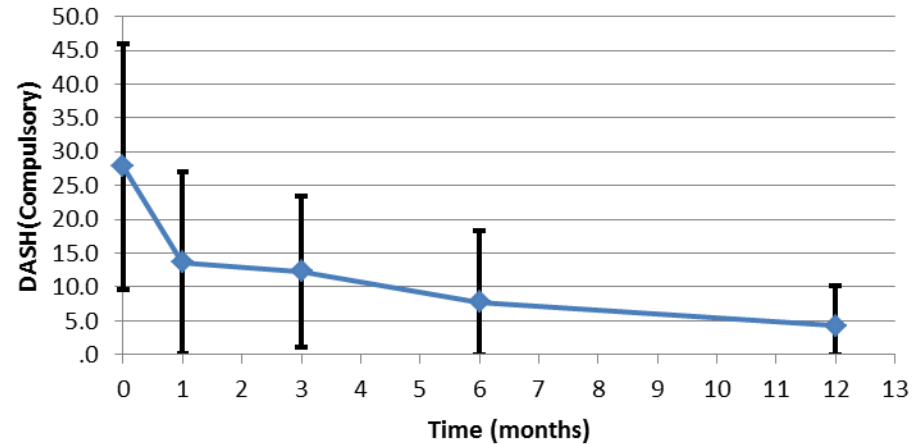
# Koh et al (Singapore/Mayo) - Elbow

VAS over time



$p < 0.001$

DASH(Compulsory) over time



$p < 0.001$

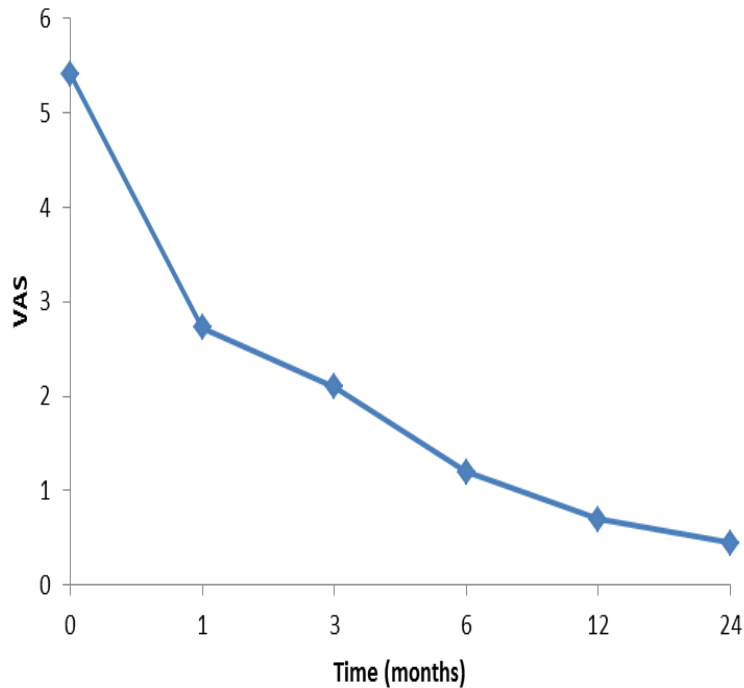
95% (19/20) patients pain free

No device-related complications

No patient-related complications

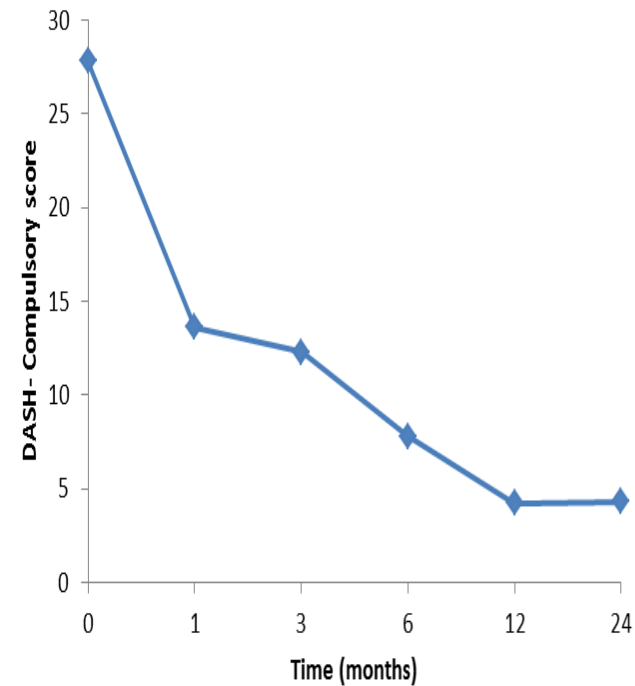
# Koh et al (Singapore/Mayo) – Elbow (2 yr results)

VAS with time



$p < 0.001$

DASH- Compulsory scores with time



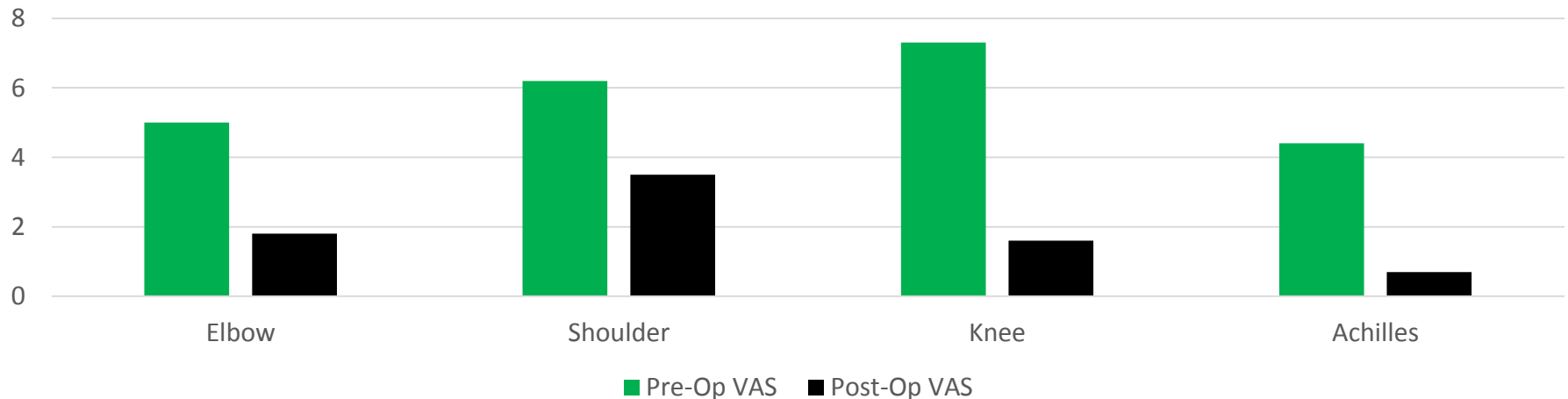
$p < 0.001$

# Elattrache (Kerlan Jobe) - Knee

- Prospective study involving 16 patients – symptomatic for atleast 6 mo
  - 10 collegiate-level athletes
- Failed conservative treatment
- Single treatment with TX1 & no additional intervention
- No complications
- Clinical outcomes
  - 15/16 (93%) revealed resolution of symptoms at 3 months with full activity at 6 months
  - All 10 athletes returned to their prior level of competition

## Khanna et al / AAPMR Abstract (Oct 2013)

- Prospective study involving 18 patients suffering from chronic tendonosis (avg symptoms 6 mo) who failed conservative treatment
- Single treatment with TX1 & no additional intervention
- No complications
- Pre-op and 2 weeks post-op assessment revealed significant improvement in VAS ( $p < 0.05$ ) and QOL ( $p = 0.0004$ )
- 16/18 patients were “pain-free” at 2 weeks post-op

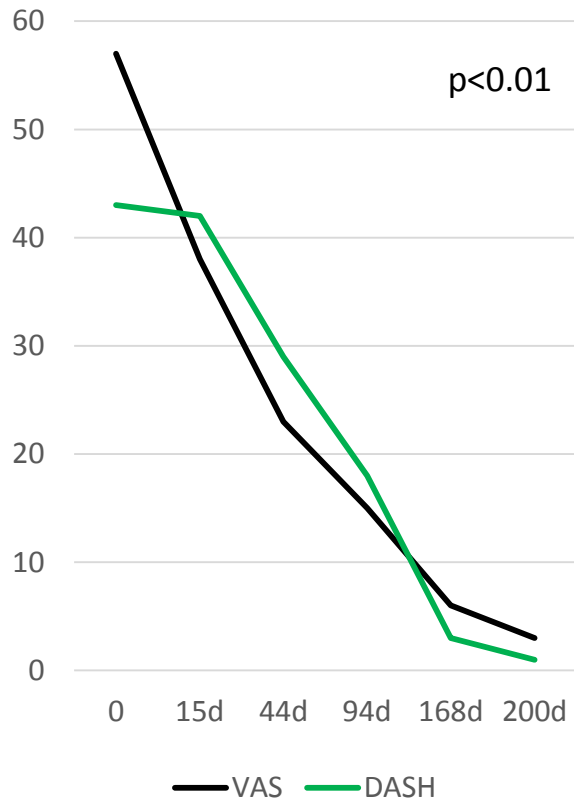


# Traister, Lingor, Simons (Notre Dame) – Mixed Tendon

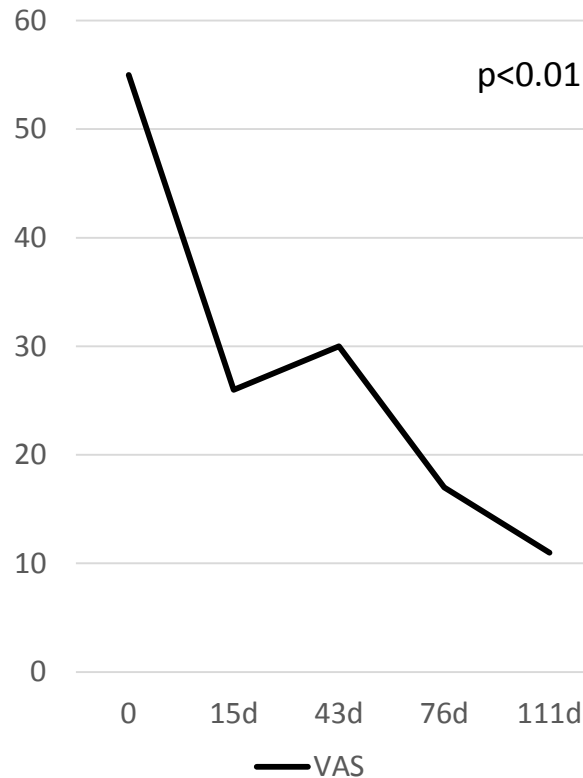
- Clinical evaluation of 43 patients with tendonosis not responsive to conservative treatment for at least 3 months
  - 24 lateral epicondylitis (elbow)
  - 8 patellar tendonosis
  - 11 plantar fasciosis
- Measured clinical outcomes of pain (VAS/100 point scale) and DASH (elbow only) at baseline, 2, 6, 12, and 24 weeks post-treatment with TX1
- No complications or adverse events

# Traister, Lingor, Simons (Notre Dame) - Mixed

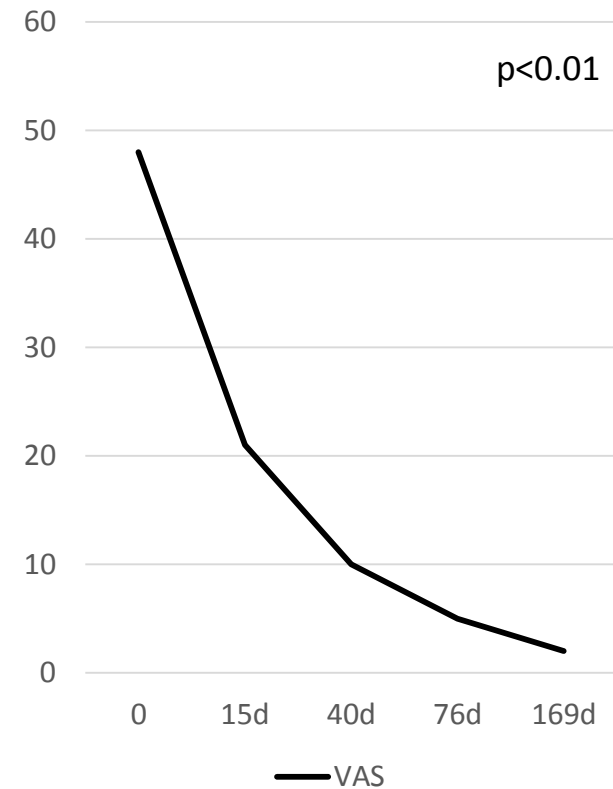
## ELBOW



## PLANTAR FASCIA



## PATELLAR TENDON





# Patel (OrthoIndy) – Plantar Fascia

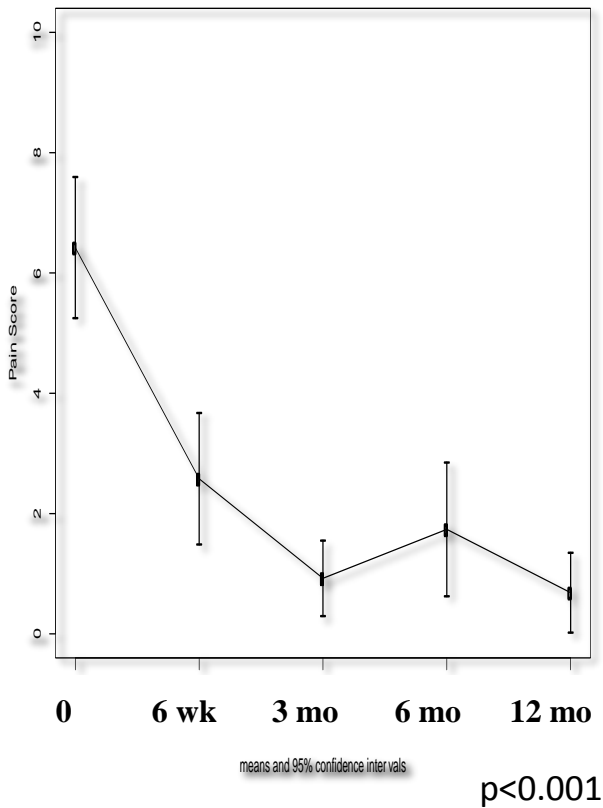
- Prospective study involving 18 patients – symptomatic for at least 6 mo
- Failed conservative treatment - 4 patients had failed open surgery
- Single treatment with TX1 & no additional intervention
- No complications
- Clinical outcomes
  - 17/18 (94%) revealed resolution of symptoms at 3 months
  - Significant statistical improvement of AOFAS score from 30.1 (pre) to 88 (post) at 6 mo
  - One patient had bilateral treatment 12 weeks apart and symptom free at 6 months
  - Two patients lost 25 and 40 pounds, respectively

# Barnes, Beckley, Smith, (Mayo) - Elbow

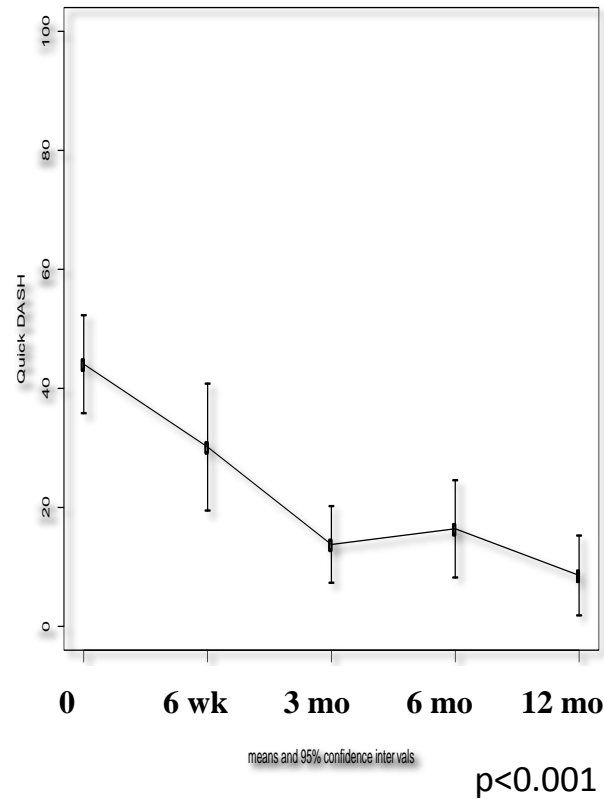
- Prospective study involving 19 patients – symptomatic for atleast 6 mo
- 7 medial and 12 lateral tendonosis patients who failed conservative treatment (rest, PT, ice, single cortisone)
- Single treatment with TX1 & no additional intervention
- Total procedure time < 15 minutes with mean energy time = 38 seconds
- No complications
- Clinical outcomes at baseline, 6 weeks, 3 mo, 6 mo and 12 mo
  - VAS (pain)
  - Mayo Elbow Performance Score / MEPS (range of motion)
  - Disability of the Arm, Shoulder and Hand/DASH (quality of life)

# Barnes, Beckley, Smith, (Mayo) - Elbow

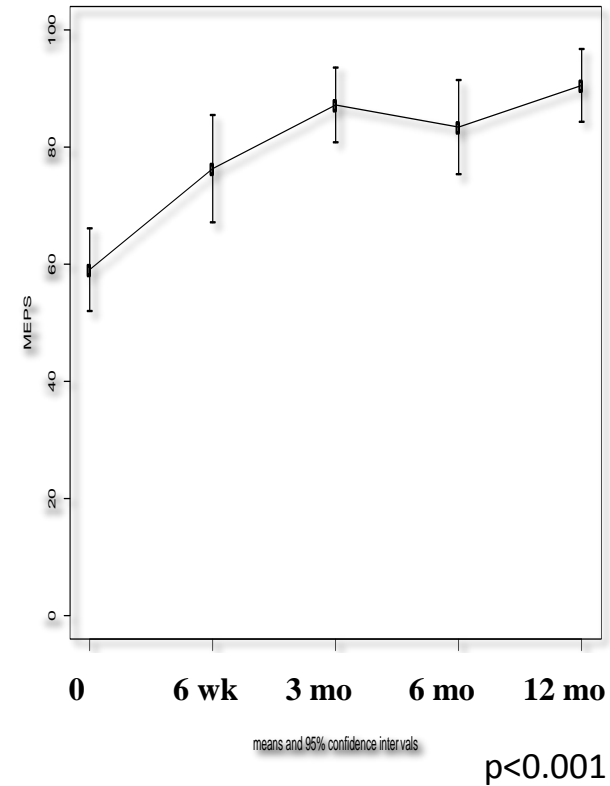
Pain/VAS



DASH



MEPS



# Razdan & Vanderwoude (Lincoln, NE) – Plantar Fascia

- Prospective study involving 53 patients – symptomatic for at least 6 mo
- Failed conservative treatment – PT and shoe support/orthotics
- Single treatment with TX1 & no additional intervention
- Clinical outcomes measured at baseline, 2 weeks, 6 weeks, 6 months
  - Highly significant improvement ( $p < 0.0001$ ) in pain (VAS) and QOL (FADI) at all time periods studied as compared to baseline/no treatment
  - No device or patient related complications

# Ellis et al (Phoenix, AZ) – Achilles Tendon

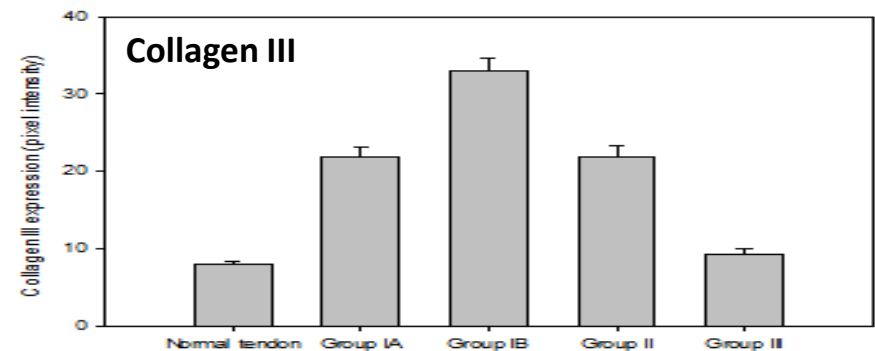
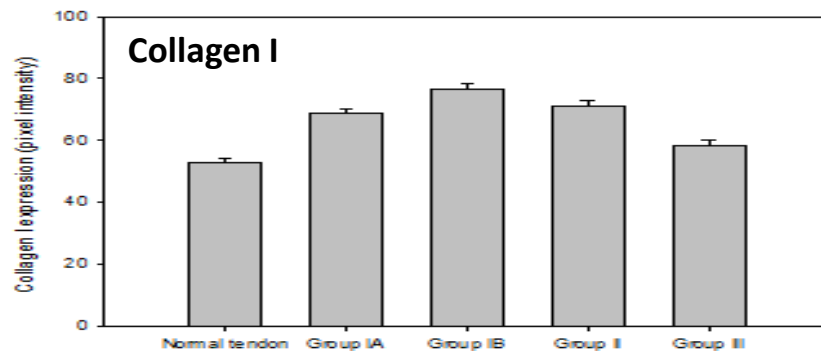
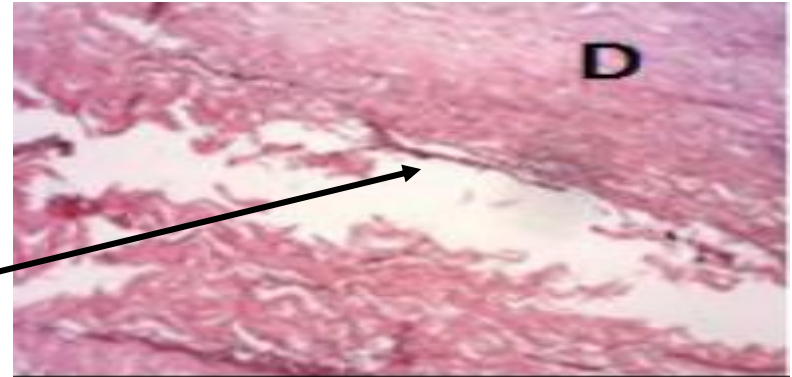
- Retrospective review of 26 consecutive patients (7 male/ 21 female)
- Failed average 5.8 conservative treatment sessions over period of 18 mos
- Single treatment with TX1 & placed in boot (1 wk) - no additional treatment
- Clinical outcomes measured at baseline, 1 week, 1 month, 16 months
  - 23 of 26 patients (88 %) were pain free at 1 month and sustained at 16 months
  - 24 of 26 patients (92 %) would recommend procedure
  - No device or patient related complications

# Yanish (Des Moines, IA) – Elbow Cost Effectiveness

- Prospective cost-comparative analysis of Tenex vs open surgery - elbow
- 45 chronic lateral epicondyle patients not responsive to conservative therapy - 23 treated with Tenex and 22 treated with open surgery
- Measure clinical, safety and economic outcomes for 6 months
- Clinical outcomes measured at baseline, 1 week, 1 month, 16 months
  - Efficacy/Pain Relief                      Tenex = 91%                      Open = 77%                      ( $p < 0.01$ )
  - Post-procedural visits                      Tenex = 2.5                      Open = 4.25                      ( $p < 0.001$ )
  - Average work weeks missed                      Tenex = 1.1                      Open = 8.2                      ( $p < 0.001$ )
  - Total cost savings/patient                      Tenex was \$11,753 less than open surgery

# Kamineni (Univ. KY) - Animal Model

- Tendonosis animal model (24 rabbits) - groups treated either with TX1 or left untreated
- Assess tissue under microscopy and collagen formation at 1 and 3 weeks post-treatment
- Microscopy revealed new fibroblasts in TX1 group
- TX1 restored collagen to normal tendon levels



Group IA      Untreated group at 1 week

Group IB      Untreated group at 3 weeks

Group II      TX1 treated group at 1 week

Group III      TX1 treated group at 3 weeks

Paper submitted for publication

