INNOVATIONS IN SPORTS MEDICINE

To infinity and beyond…

Eric Gifford MD

DISCLOSURE

- This presentation highlights two current, evidence-based procedures available as treatment modalities and they will be referred to by their commercial names. Both of these procedures are one-of-a-kind, without direct competitors. All effort will be taken to present modalities without bias.
- Dr. Eric Gifford has no financial relationships with any commercial interests.

CHRONIC TENDINOPATHIES

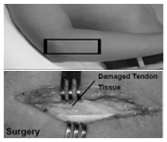
- Make up a large percentage of chronic pain and disability
- Similar to degeneration of cartilage of a joint – instead it is degeneration of muscle tendons around joints
- Difficult to treat
  - Physical therapy-soft tissue work, eccentric exercises, stretching, scraping, etc…
  - Rest, bracing, splinting
  - NSAIDS, injections-steroid, prolotherapy
  - PRP
  - Surgery

CHRONIC TENDINOPATHIES
WHAT ELSE CAN BE DONE?

TENEX PERCUTANEOUS TENOTOMY

ULTRASOUND GUIDED TENDON TREATMENT

Problem

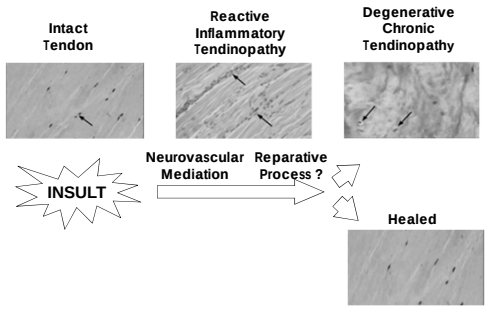


1. Conservative measures are often ineffective
2. Surgery is fairly invasive and often still results in prolonged recovery and down time as well as continued pain

Solution

Replicate surgical approach <u>but</u> through a **minimally invasive manner** using an ultrasound guided Ultra-sonic needle tip.

DISEASE PROCESS



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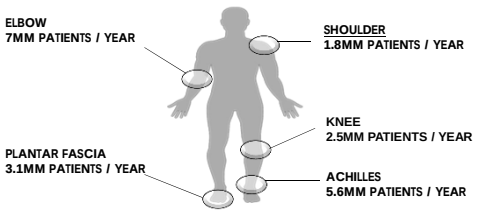
BURDEN OF DISEASE – CHRONIC TENDONOSIS

20 Million Patients per Year in US



* Based on 2013 ICD - 9 diagnosis code

UNMET CLINICAL NEED

Conservative	Minimally Invasive	Fully Invasive
• Rest / Ice • OTC Medication • Physical Therapy • Use of cortisone injection declining due to published reports of damaging effects on tendon	**TENEX System** • to cut and remove pain generating tissue • Local Anesthesia only • Single Treatment • Relatively quick recovery and return to activity	**Open/Arthroscopic Surgery** • Goal is to cut & remove damaged tissue – pain generator • General anesthesia • Prolonged recovery with rehab protocol/PT

When patients fail conservative treatment and experience chronic pain

The TENEX system provides the goals of surgery but with the invasiveness of an injection

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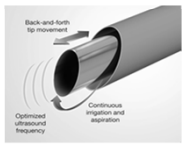
"MICRO-JACKHAMMER"



TENEX delivers optimized ultrasonic energy to tip of the instrument that precisely **cuts** diseased **tendon tissue** while sparing healthy tissue – harmonic resonance of diseased tissue (necrotic) is different from healthy tissue (elastic)

Cutting of targeted tissue is achieved through longitudinal movement of needle at the speed of sound (ultrasonic) – tissue is cut via "jack-hammer effect"

Continuous saline **irrigation cools** the Microtip to control unwanted heat and also simultaneously **removes target tissue**

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TENEX TX™ SYSTEM

TX1 Console

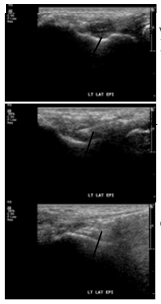
- User interface with circuitry for precise & targeted tissue cutting and removal
- Targeted diseased tissue is removed while sparing healthy tissue with built in safety features

TX1 Microtip

- Percutaneous (18 gauge) pen-like function
- Pre-assembled w/foot pedal activation
- Single use – entirely disposable

PERCUTANEOUS TENOTOMY / FASCIOTOMY

Ultrasound Imaging used to identify diseased tissue and guide Tenex TX™ Microtip during procedure



VISUALIZE DAMAGED TENDON (DARK REGION) VIA ULTRASOUND

GUIDE TENEX MICROTIP TO DAMAGED TISSUE WITH ULTRASOUND GUIDANCE

CUTS & REMOVES TARGET DAMAGED TISSUE

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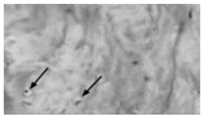
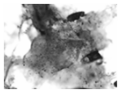
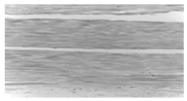
TARGETED TISSUE CUTTING AND REMOVAL

Harmonic resonance – ultrasonic energy only cuts pathology based on density of degenerated tissue

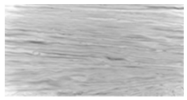




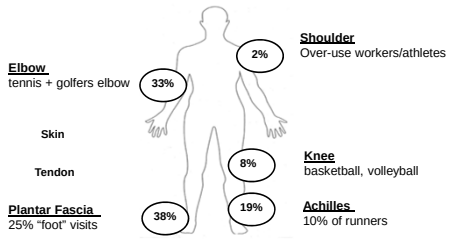
Ultrasonic energy optimized for dense degenerated tissue does not affect healthy elastic tissue



Healthy Tendon + Ultrasonic Energy



CHRONIC TENDONOSIS TREATMENTS



WHO'S A CANDIDATE?

CHRONIC PAIN (> 3 MONTHS) AT THE AFFECTED JOINT AND NOT RESPONSIVE TO CONSERVATIVE MEDICAL TREATMENT (REST, ICE, BRACE, PHYSICAL THERAPY, ETC.)

POINT TENDERNESS – POINT OF MAXIMUM PAIN TYPICALLY CORRESPONDS TO THE LOCATION OF THE DAMAGED TISSUE

ULTRASOUND CONFIRMATION – PLACEMENT OF ULTRASOUND TRANSDUCER ON THE SITE OF MAXIMUM TENDERNESS SHOULD IDENTIFY A REGION OF DEGENERATED TENDON TISSUE VISUALIZED AS A **HYPOECHOIC REGION** DUE TO IRREGULAR/DISORGANIZED FIBERS AND THICKENED TENDON TISSUE.

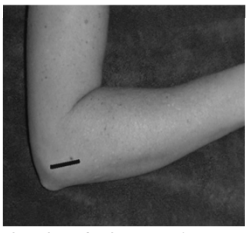
HOWS IT DONE?

- No restrictions before procedure
- Prep area with simple antiseptic
- Local anesthetic applied under ultrasound guidance
- 4-5mm incision made down to the target tissue
- Tenex needle is advanced to the target tissue and ultrasound guided tenotomy is performed
- Total cutting time usually less than 5 minutes

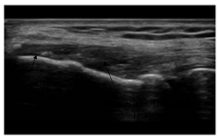
POST OP PROTOCOL

- Allowed to go home immediately following procedure
- Light activity with minimal walking, lifting, pushing, pulling for 2 weeks
- Foot and ankle usually in a boot for 2 weeks
- Gradual progression back to normal activity over next 4-6 weeks
- Physical Therapy to augment healing process in certain cases

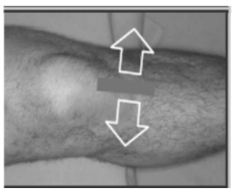
EPICONDYL / ELBOW TENDONOSIS

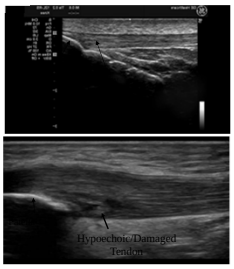


Blue strip marks placement of ultrasound transducer



PATELLAR TENDONOSIS





Orange strip marks placement of ultrasound transducer on inferior pole of patella

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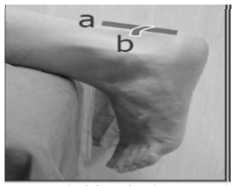
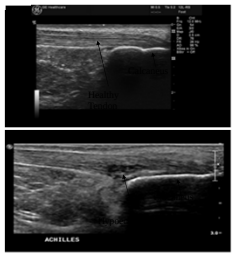
ACHILLES TENDONOSIS





Orange strip (a) marks placement of ultrasound transducer on Achilles and (b) shows cross section view to identify mid-substance tendonosis

PLANTAR FASCIITIS/FASCIOSIS

Orange strip marks the placement of ultrasound transducer on plantar fascia – typically on medial aspect.

CLINICAL PUBLICATION SUMMARY

In Print/Accepted

- Koh – American Journal Of Sports Medicine (Elbow)
- Hackel – Orthopaedics Today (Procedure Overview / Mixed Tendons)
- Morrey – Techniques In Elbow And Hand Surgery (Elbow)
- Elattrache – Operative Techniques In Sports Medicine (Knee)
- Barnes – Operative Techniques In Sports Medicine (Procedure Overview)
- Khanna – Am Academy Of Physical Med & Rehab Poster (Mixed Tendons)
- Traistor – Am Medical Society Of Sports Medicine (Mixed Tendons)
- Barnes – Journal Of Shoulder And Elbow Surgery (Elbow)
- Patel – Journal Of Orthopedics (Plantar Fascia)
- Sanders – American Journal Of Sports Medicine (Epidemiology Study)
- Stuhlman – Journal of Sports Medicine (Patellar Tendon)
- Kamineni – Journal of Orthopedic Research (Basic Science)
- Patel – Austin Journal of Orthopedics and Rheumatology (Plantar Fibroma)
- Koh – Three Year Clinical Follow-up/American Journal of Sports Medicine (Elbow)
- Ellis – American Journal of American Podiatric Medical Association (Achilles)

Submitted/In Preparation

- Razdan – Plantar Fascia Study
- Moore – Tenex Vs Open Surgery (Elbow)
- Noyes – Elbow Study
- Hackel – Tenex vs Endoscopic Surgery (Plantar Fascia)

Study revealed 90% 0f patients pain free within weeks of treatment

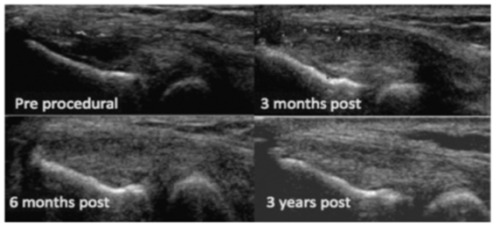
- Cost Effective Intervention – Less expensive (>$11,000) and quicker recovery time vs surgery
- Sustained Pain Relief With Long Term Follow-up (6 – 36 Months)
- Strong Safety Profile

KOH ET AL (SINGAPORE/MAYO) - ELBOW

- Prospective 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 ,12, 24* and 36* months
  - Adverse events
  - Pain score (VAS)
  - Quality of life (DASH/Disability of the Arm, Shoulder and Hand)
  - Diagnostic ultrasound at baseline, 3, 6 and 36 months

American Journal of Sports Medicine Vol 41, 636-644, 2013
* In print, Am Journal of Sports Medicine, 2015

SENG ET AL (3 YR) – ELBOW TENDONOSIS & US EXAM



	3 mo	6 mo	36 mo
Resolution of Tendon Thickness & Hypoechogenicity	**13/20**	**18/20**	**20/20**

Seng, et al; Am Journal of Sports Med, 2015

BARNES, BECKLEY, AND SMITH (MAYO) - ELBOW

- Prospective study involving 19 patients – symptomatic for at least 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 et al, Journal of Shoulder & Elbow Surgery, 2014

MOORE ET AL (IA) – TENEX VS SURGERY (ELBOW)

- Prospective study randomizing Tenex vs Open Surgery for elbow
- 45 patients with chronic epicodylosis not responsive to conservative care
  - 23 treated with TX1
  - 22 treated with open surgical repair
- Outcomes measured at 1 week, 1 month and 6 months post-treatment

	Tenex Vs. Surgery		
• Efficacy/Pain Relief	91%	77%	(p<0.01)
• Post-treatment Visits	2.5	4.25	(p<0.001)
• Avg Work Weeks Missed	1.1	8.2	(p<0.001)
• Total Cost/Savings Per Pt	Tenex was $11,753 less than surgery		

Manuscript submitted for publication

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
  - Sustained effect at 12 months
  - All 10 athletes returned to their prior level of competition

Operative Techniques in Orthopedics Vol 23, 2: 2013

STUHLMAN, STOWERS & STOWERS (FL STATE) - KNEE

- Prospective study involving 8 patients – symptomatic for atleast 6 mo
  - Activity limiting tendinopathy
  - 3 pts with bi-lateral pain
- Failed conservative treatment
- Single treatment with TX1 & no additional intervention
- 12 month follow-up
- No complications
- Clinical outcomes
  - 8/8 patients reported no pain (VAS = 1)
  - Improvement in symptoms between 3 days and 6 months after treatment
  - Sustained at 12 months

Manuscript accepted, Journal of Sports Medicine

RAZDAN & VANDERWOUDE (NE) – PLANTAR FASCIA

- Prospective study involving 100 patients – symptomatic for atleast 6 mo
  - All failed conservative treatment: PT, orthotics, OTC medication
- Single treatment with TX1 & no additional intervention
- 12 month follow-up
- No complications
- Clinical outcomes
  - Pain (VAS) and disability index (FADI) measured at 2 weeks, 6 weeks, 6 mo and 12 mo
  - Significant improvement in pain and disability index by 2 weeks and sustained at 12 mo
  - 91/100 (91%) patients pain free at 6 months and sustained at 12 months

Podium Presentation, Society for Interventional Radiology Annual Meeting 2015
Manuscript submitted for publication

PATEL (ORTHO INDY) – PLANTAR FASCIA

- Prospective study involving 12 patients – symptomatic for atleast 6 mo
  - All failed conservative treatment: PT, orthotics, extra-corporeal shock wave, cortisone
  - 4 pts failed open or endoscopic fasciotomy
- Single treatment with TX1 & no additional intervention
- 12 month follow-up
- No complications
- Clinical outcomes
  - 11/12 (92%) patients pain free at 3 months and sustained at 12 months
  - Significant improvement in QOL by 6 months and sustained at 12 months

    Mean baseline AOFAS 30.1

    Mean 12 mo AOFAS 88.1

American Journal of Orthopedics, 2015

ELLIS ET AL (AZ) – ACHILLES TENDON

- Prospective study of 26 patients – symptomatic for average of 18 months
- Single treatment with TX1 & no additional intervention
- Mean cutting time of 4 min 24 seconds
- Pts followed up 1 week, 1 month, 12 months and 16 months post
- No complications
- Clinical outcomes
  - 23/26 (88%) patients revealed pain relief at 1 month and sustained at 16 months
  - 24/26 (92%) patients would have the procedure done again

Manuscript accepted, Journal of APMA

PATEL ET AL (IN) – PLANTAR FIBROMA

- Prospective study of 8 patients suffering from plantar fibroma
- Patients failed conservative care inclusive of orthotics
- Average time of symptoms – 15 months
- Percutaneous cutting and removal of lesion with single treatment of TX1
- Average follow-up = 2.5 years
- Clinical Outcomes
  - 8/8 patients pain free with average time to resolution of symptoms - 63 days
  - Significant improvement of AOFAS score from pre-op of 30.8 to 90.1 at 12 mo
  - No recurrence of fibromas at 2.5 years

Austin Journal of Orthopedics and Rheumatology, Vol 2, Issue 2, 2015

COOLIEF

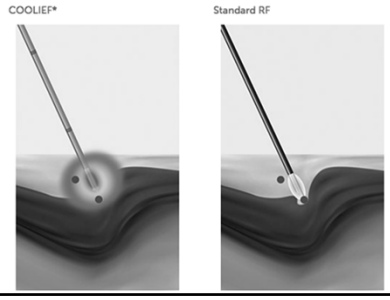
Cooled Radiofrequency Treatment

CHRONIC KNEE AND HIP PAIN DILEMMA

- Relieve pain for patients suffering with chronic joint pain
  - Utilize innovative new procedure for two challenging patient populations with hip and knee pain
    - Non-surgical candidates
      - Overweight
      - Age – too young or too old
      - Co-morbitities
    - Patients still in pain after joint replacement
    - Patients not responding to other conservative measures
      - Various injections
      - Bracing
      - Activity modification
      - Medications

COOLED RADIOFREQUENCY NEUROTOMY INTERVENTIONAL PAIN SOLUTION

- Cooled Radiofrequency Procedure
  - Provides up to 2 years in pain relief
  - Provides larger lesions than standard RF allowing for treatment of more variable peripheral sensory nerves



RADIOFREQUENCY NEUROTOMY

- Electrode with an exposed tip, is placed onto a peripheral nerve
- High-frequency, electrical current concentrates around the tip; heats the immediately surrounding tissues; and coagulates them, including the target nerve
- Pain relieved by coagulating the afferent nerve preventing the conduction of nociceptive (pain) impulses
- Pain relief occurs by anesthetizing the source of pain

COOLED RF

- Single larger lesion compensates for variable nerve course. More efficient and more predictable than multiple passes with smaller gauge RF probe.
- Distal projection of lesion projects heat in and around difficult anatomy, scar tissue, surgical hardware etc.
- Anatomic techniques performed under fluoroscopy relies upon easily visualized landmarks.
  - May also use Ultrasound imaging for neurovascular bundle identification and needle tip placement
- Electrical stimulation can be used to verify absence of proximity to motor nerve.

IMPROVEMENT IN LONG EXISTING TECHNOLOGY, NOW WITH INTERNALLY WATER COOLED ELECTRODES

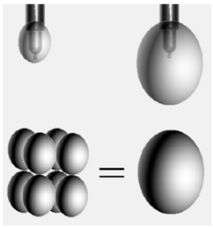
Liver Ablation

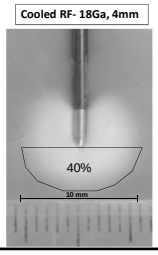
Cardiac Electrophysiology

Chronic spine and peripheral joint pain

COOLED RF LESION

- Large volume spherical lesion with distal projection





APPLICATIONS OF COOLED RF

Sacroiliac Pain

- Overlapping and forward projecting lesions are made to capture variable path of lateral branches on uneven sacral surface

Thoracic Pain

- Large spherical lesion is made to accommodate variable nerve path of medial branches especially T5-T7

Lumbar Pain

- Forward projecting and large spherical lesion allow a perpendicular approach to medial branches in one needle pass and not multiple passes. Addresses difficult anatomy or patients with hardware from previous surgeries

Cervical Pain

- Offering relief in the cervical region by delivering large volume lesions where anatomy and nerve path are variable.

PERIPHERAL NERVE PROCEDURES

Patients that are not candidates for surgery

- ***29%*** of patients over the age of 65 with chronic knee pain non responsive to conservative medical management are not candidates for surgery due to contraindications

Patients with persistent post-surgical pain

- ***53%*** of patients with TKA and ***38%*** of patients with THA with chronic pain one year out of surgery

COOLIEF COOLED RADIOFREQUENCY NEUROTOMY: A TREATMENT OPTION FOR PATIENTS WITH CHRONIC KNEE AND HIP PAIN

PATIENT SELECTION

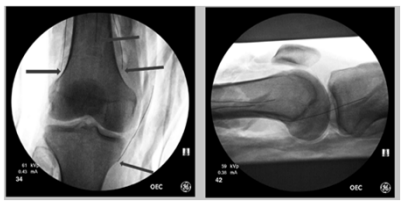
Patients that are not indicated for surgery:

- THA/TKA contraindications:
  - Age
  - BMI
  - Comorbidities
  - Patients that don't want surgery

Patients that still have significant pain following surgery

- Patients still in pain after surgery due to non-compliance
- Patients with past TKA/THA

IMAGING GUIDANCE



- Provides up to 2 years pain relief, improved physical function, and reduced drug utilization
- Larger burn areas takes into account variable nerve course

CLINICAL DATA FOR COOLED RADIOFREQUENCY

1. Patel et al. "Twelve- Month Follow-up of a Randomized Trial Assessing Cooled Radiofrequency Denervation as a Treatment for Sacroiliac Region Pain". Pain Practice. Jan 2015.
- "These 12-month results illustrate the durability of effective CRF/LBN- mediated treatment of SI region pain for selected patients

2. Liu et. Al "A Cross Sectional Survey on Prevalence and Risk Factors for Persistent Post-Surgical Pain 1 Year after Total Hip and Knee Replacement". Regional Anesthesia and Pain Management. Volume 37, Number 4, July- August 2012.
- "Persistent post-surgical pain is common after THR and TKR and is associated with reduced health related quality of life."

3. Franco et. al. "Innervation of the Anterior Capsule of the Human Knee: Implications for Radiofrequency Ablation." Reg Anesth Pain Med. 2015 Jul-Aug;40(4):363-8.

QUESTIONS?