A novel Approach to Treatment of Partial and Full Thickness Rotator Cuff Tears

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The Problem:
- Partial-thickness rotator cuff tears represent a significant challenge to the orthopaedic surgeon.

The Problem:
- Studies have demonstrated that small, full-thickness tears and partial-thickness rotator cuff tears have an active cellular response and thus, do possess some intrinsic healing ability.

The Problem:
- Partial-thickness rotator cuff tears represent a significant challenge to the orthopaedic surgeon.
- Unfortunately, there is no consensus on a single algorithmic treatment approach for a patient with a symptomatic, partial-thickness rotator cuff tear.

The Problem:
- Studies have documented spontaneous healing in a limited number of partial-thickness cuff tears as manifested by a reduction in size or disappearance of the defects.

Balancing Biomechanics and Biology

Healing of Rotator Cuff Lesions
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  Yamanaka and Matsumoto, CORR 1994

  Maman et al, JBJS 2009

  40 patients with partial-thickness joint tears @ 2 year follow-up
  - 4 lesions decreased in size (healing?)
  - 4 lesions disappeared (healed?)
  - 32 lesions enlarged or progressed to full-thickness lesions

  Yamanaka and Matsumoto, CORR 1994

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A Proposed Solution:

“Just add a patch.”

Current Patches

- Goal: To augment the biomaterial properties of mechanically compromised rotator cuff tendons.

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- Variety of tissue types (dermis, fetal dermis, small intestine submucosa [SIS], pericardium), donor species (allograft, xenograft), and processing techniques.

Human dermis

Human fascia lata
Current Patches

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- Variety of tissue types (dermis, fetal dermis, small intestine submucosa [SIS], pericardium), donor species (allograft, xenograft), and processing techniques.

- Considerable variation in mechanical properties

  Derwin et al 2006; Chaudhury et al 2011; and biological incorporation. Adams et al 2006; Dejardin et al 2001

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A New Concept

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  - Provide a matrix scaffold to support the ingrowth of host tissues.
  - Provide an inductive and conductive stimuli for cell and vessel migration.
  - Allow for normal tissue remodeling.
A New Concept
Balancing Biology and Biomechanics

Create an IDEAL Scaffold:

• Provide a matrix scaffold to support the ingrowth of host tissues.
• Provide an inductive and conductive stimuli for cell and vessel migration.
• Allow for normal tissue remodeling.
• Eventually be removed by the host.

Implant Design:

• Highly-purified, bovine type I collagen (<50 ng/mg of DNA)
• Highly-oriented and highly-porous (85-90%)
• Minimally cross-linked and freeze-dried


Pre-clinical Study:
When placed on the superior surface of a rotator cuff tendon (T), the implant consistently induced a layer of highly-aligned, connective tissue (*), which continued to remodel over time without evidence of an inflammatory response. The implant was completely resorbed by 6 months and replaced by new host tissue.


Pre-clinical Study:
At 26 weeks, the new tissue (NT) was well-integrated with the native bone (NB). The bony insertion of the new tissue demonstrated evidence of a fibrocartilagenous (FC) component that suggests a normal, direct insertion.

Key findings
• Rapid incorporation of the bio-inductive implant by host tissues


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• Rapid incorporation of the bio-inductive implant by host tissues
• Implant stimulated both an inductive and conductive response
• Consistent production of a dense, regularly-oriented, connective tissue layer suggests functional adaptation, remodeling and maturation
• Excellent integration into bone with a fibrocartilaginous transition zone reminiscent of a normal direct insertion


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Early Clinical Results with use of a Bovine Bioinductive Implant

Rotator Cuff Disease

- A large number of partial-thickness tears progress to become full-thickness tears
- Literature indicates repair for partials >50%
- Significant debate among physicians on most effective treatment for symptomatic, partial-thickness rotator cuff tears
- Significant incidence of re-tears and impaired function after repair of full-thickness tears (25% - Fleurin et. al.)
- Patient rehab can be very long, painful and disruptive causing many to 'opt out' or delay surgery

ADDRESS THE TENDON WHEN THE TEAR IS SMALL

AUGMENT THE FULL THICKNESS TEAR TO IMPROVE HEALING

Traditional Approach to Partial Thickness Tears

- Acromioplasty
- Debridement with or without Acromioplasty
- Transtendon Repair
- Conversion to Full-Thickness with Repair

Traditional Treatment of Partial Rotator Cuff Tears

Transtendon

- Can be difficult with bursal-sided lesions
- Technically difficult
- Damage to remaining tendon
- Poor results in high demand shoulders (throwers)
- Stiffness

Convert to Full Thickness

- Morbidity of cuff repair surgery
- Potential failure to heal
- Proper tensioning??

Treatment of Partial Thickness Cuff tears

Traditional Rehabilitation

- 4 weeks in sling
- PROM for 6 weeks
- 4-6 months to become satisfied with procedure

The concept: Balancing Biology and Biomechanics

Hypothesis

Inducing a layer of new tendinous tissue on the bursal side of the supraspinatus tendon will reduce the micro-strains within the tendon, which theoretically could provide:
- Pain relief through reduced micro-motion and associated inflammation
- An inhibition or arrest of tear propagation
- An optimized, mechanical environment for tendon healing

Unique Implant Design Induces Biological Response

Unique Characteristics:
- Reconstituted, bovine collagen with 90% porosity
- High purity to avoid inflammatory response
- Low strength material not intended for mechanical augmentation
- Permanent strength comes from patient’s induced, remodeled tissue
- Bioabsorbable
- Ability to implant arthroscopically as well as mini-open

Induces a layer of new, tendon-like tissue on the surface and fills in defects
The Rotation Medical Rotator Cuff System™

The Rotation Medical Rotator Cuff solution is a procedural approach that combines:

- A highly oriented, highly porous collagen bio-inductive implant
- Novel arthroscopic instrumentation

The first regenerative pathway to stimulate angiogenesis and be restorative, not reparative. If you believe in biology, this is a big step.”

- Buddy Savoie

Clinical Trial in Australia

- Conducted at five hospitals in Sydney
- Drs. David Sonnabend, Des Bokor, Ben Cass and Allen Young
- 24 treatment patients and 6 comparison patients

Treated patients:

15 partial-thickness tears (14 ASD only, 1 ASD plus repair)
- Ellman scale: 1 small, 5 medium, 4 large; 5 intra-substance (2 large)
- Cofield scale: 1 small, 8 medium

Comparison patients

- Partial-thickness tears, acromioplasty only

Implant attached to bursal surface of supraspinatus
- NPL, ASES, Constant, and SF-36 Scores
- Pre-operative, 3 months, 6 months, 12 months, 24 months

- All MRIs read by one independent radiologist, blinded to clinical outcomes
- Mean follow-up time = 27 months
- Median implantation time = 15 minutes
- 14 arthroscopic, 10 mini-open

Partial-Thickness Patients Showed a Significant Increase in Tendon Thickness, Defects Filled-In

- 64% average increase in tendon thickness
- Continued tissue maturation and integration at 24 months
- All defects filled in

Controls

- Tendons generally look worse than pre-op
- Increase in tendon thickness due to edema
- No evidence of defect filling in

Partial-Thickness Tears Treated Post-Operatively Similar to ASD

Partial-Thickness tears with bioinductive implant, without cuff repair

- Sling discarded when comfortable (max 1 week)
- Graduated progression of motion as tolerated from
  - PASSIVE ➔ ACTIVE ASSISTED ➔ ACTIVE
- Active ROM allowed with:
  - Forward flexion 0 – 160° for first 4 weeks
  - External rotation allowed with arm by side (No ABER for 6 weeks)
  - No resistance exercises for 6 weeks
- No restriction of motion or use of arm after 6 weeks

Demonstrated Healing: Articular-Sided, Partial-Thickness Tear (No Repair)

Partial-Thickness Tear – Pre-Op

Tendon Thickness = 2.9 mm

Healed Tear – 12 Months

Tendon Thickness = 4.0 mm

Repairs Heal with Increased Thickness and Fully Restored Footprint

Pre-Operative Full-Thickness Tear

24 Months Thickness = 4.0 mm
MRI Results for Partial-Thickness and Full-Thickness Tears

- 100% induction of new tendinous tissue in all patients
  - Increase in thickness in both partial and full-thickness tears
  - Mean increase in thickness of 2.4 mm (64%)
  - No increase in thickness in controls
- Filling in of defect observed in 13 partial-thickness tears
  - Observed in all patients in which pre-op MRI showed a clear defect
- Cuff repairs are all intact at two year post-operative MRI evaluation
- No foreign body/inflammatory reaction
- No implant related complications

Clinical Scores Show Improvements in Partial-Thickness and Full-Thickness

The differences in all scores compared to pre-op (except Constant overall at 3 months) are statistically significant (p < 0.05)

US STUDY

- Multicenter prospective clinical study
  - 30 partial thickness
  - 30 full thickness
  - Functional data and MRI eval
    - Ted Schlegel, M.D. – Steadman Hawkins
    - Jeff Abrams, M.D. – Princeton Orthopaedics
    - Timothy Codd, M.D. – Towsend Orthopaedics, U. of M.
    - Christopher Chuinard, M.D. – Great Lakes Orthopaedic Center
    - Rick Angelo, M.D. – PoOrtho Orthopedic Clinic
    - Gregory Leverick, M.D. – Twin Cities Orthopedics
    - Me
    - Drs. Charles Abboud, Charles Getz, Surena Namdari
    - Brad Bushnell, M.D. – Harbin Clinic
    - Mark Getleman, M.D. – SCOI
    - Jonathan Levy, M.D. – Holy Cross

Bio-Inductive Patch Arthroscopic Technique

PEARLS

- Make lateral portal parallel to supraspinatus in both coronal and axial planes or use accessory anterolateral portal
- Tendency is to place graft too far posterior and medial. Make sure graft comes out lateral enough for proper bone staple insertion
- Make sure staple gun insertion angle is not more than 45 degrees, separate portals for staples near edge of acromion
- Pay close attention to maintaining position of bone stapler while switching from punch to staple

Clinical Cases

- 38 y.o. female
- 6 mo. h/o of right after injury shoulder pain
  - On PE, pain and weakness with cuff testing
  - Failed injection and PT
Clinical Cases

- 48 yo. s/p fall
  - Smoker
  - Dominant arm
  - Previous Failed RCR
  - Workers Comp

- Supra. and anterior infra. tear with biceps subluxation
Clinical Cases

• 55 year old woman
• Right hand dominant
• Failed Index RCR
• Revision 10 months later Rotation Graft denied
• Continued Pain 7 months s/p revision. MRI 75% healing with persistent pain
• Revision Surgery with implantation of Rotation graft with no additional repair

Target Applications For The Rotation Medical Rotator Cuff System

• There are two primary target applications for the Rotation Medical (RM) Rotator Cuff System
  – Repair of partial-thickness tears
  – Augment full-thickness tears
• Clinical results have demonstrated there are benefits for both Partial-Thickness Tears Full-Thickness Tears
  
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<thead>
<tr>
<th>Partial-Thickness Tears</th>
<th>Full-Thickness Tears</th>
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<tbody>
<tr>
<td>Stimulates and enhances healing response</td>
<td>Improves tissue quality of tendon</td>
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<td>Reduced tension at repair site</td>
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<tr>
<td>Prevents tear progression</td>
<td>Reduced likelihood of re-tears</td>
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<tr>
<td>Detects fill in</td>
<td>Improved healing of repair to bone</td>
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<td>Eliminates need to cut good tissue</td>
<td>New induced tissue creates new footprint area resulting in reduced stress on tendon</td>
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<td>Patient rehab is significantly shorter (similar to ASAD)</td>
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3 Months Postop