Controversies in the management of Biceps/SLAP

The Painful Biceps: How I Fix it and Why = SUBPECTORAL

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Head, Section of Shoulder and Elbow Surgery
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Chief Medical Editor, Orthopaedics Today

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6. Publisher Support: Elsevier, Orthopedics Today

Treatment: Biceps Tenotomy

Is anything else indicated?

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Tenotomy versus Tenodesis?

Frost, Zafar, Maffulli: AJSM 2008
– Systematic Review of Literature
– Low Quality of Evidence
– 1 RCT, 7 Prospective Cohort Studies,
  11 Retrospective Cohort Studies
– Coleman Methodology Score 58 ± 14

Lack of strong scientific evidence to advocate one technique over the other…

Slenker, et al (Rothman)
Systematic Review
Arthroscopy April 2012

Biceps Tenotomy versus Tenodesis: Clinical Outcomes
16 Studies (Pubmed): 15 Level 4, 1 level 2

Table 3. Averaged Results Comparing All Studies

<table>
<thead>
<tr>
<th></th>
<th>Tenotomy</th>
<th>Tenodesis</th>
<th>Tenotomy</th>
<th>Tenodesis</th>
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<tbody>
<tr>
<td>No. of patients</td>
<td>699</td>
<td>433</td>
<td>420</td>
<td>156</td>
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<tr>
<td>Excellent/good</td>
<td>77%</td>
<td>71%</td>
<td>74%</td>
<td>81%</td>
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<tr>
<td>Good/Popeye</td>
<td>24%</td>
<td>5%</td>
<td>49%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Conclusions:
– Only major difference is cosmetic deformity with tenotomy alone
– No evidence that one is clinically superior
– “Patient factors should guide the surgeon”

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Arthroscopic release of the long head of the biceps tendon: functional outcome and clinical results.

Kelly, Drakos, Fealy, Taylor, O’Brien
Arthroscopy. 2005 Feb;21(2):182-5

- 54 patients
- Scoring Scales: “70’s”
- 70% “popeye” sign
  - > 80% of men
  - 36% of women
- 38% - fatigue discomfort

Tenodesis vs Tenotomy:
Discuss with your patient PRE-OP

Do you care if you have a lump (deformity) in your arm?
Do you care if you get cramping discomfort with repetitive activities or resistance?
Do you care if there is an extra incision on your arm?

PERSONALLY, I can not recommend Tenotomy for:
- Athletic population
- Workers compensation or legal patient
- Anyone concerned about cosmesis

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Proximal Biceps Tenodesis: Where?

Right Shoulder

Subscapularis

New Suprascapular Technique

"Original" Intergitial Space Arthroscopic Technique

Romeo AA, Mazzocca AD, Tauro JC

SubPectoral Technique

Mazzocca AD, Rios CG, Romeo AA, Arciero RA.

New SupraPectoral Technique


Is there clinical support for this explosion?

Fixation

Strength of Fixation:
Interference Screw → Suture Anchor → Suture
Controversies in the management of Biceps/SLAP

Load To Failure

(P<0.05)

Interference Screw  Suture Anchor

Arthroscopic Biceps Tenodesis
Romeo AA, Mazzocca AD, Tauro JC.

Intrarticular Biceps Distance
Biceps origin to biceps sheath:

= 3.45 cm ± 4.24 mm
Controversies in the management of Biceps/SLAP

Problems with Proximal Fixation?

ISSUES:
- Tendon Quality
- Bone Quality
- Pain Generator

Proximal biceps tendon: injuries and management.
Friedman, Dunn, Higgins, Warner.
188 Patients
Revision Rate:
- 12% (Proximal)
- 2.7% (Distal)

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-40% chronic pain in proximal tenodesis versus 0% in distal tenodesis

Proximal Bicep Tendon Pathology

Bicep Groove Pathology

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Clinical and radiologic results of arthroscopic biceps tenodesis with suture anchor in the setting of rotator cuff tear
Lee HI, Shin MS, Koh KH, Lim TK, Han J, Yoo JC
J Shoulder Elbow Surg. 2013 Sep 7. pii: S1058-2746(13)00281-4

- 25% distal migration of tenodesed tendon on MRI
- 12.9% pop-eye deformity
- 7.1% cramping pain
- 86 patients with suture anchor fixation of biceps in setting of arthroscopic cuff repair and 33.2 months mean f/u

Subpectoral Tenodesis

Subpectoral Biceps Tenodesis

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Mini-open Subpectoral Biceps Tenodesis

Subpectoral Biceps Tenodesis with Interference Screw Fixation.
Mazzocca AD, Rios CG, Romeo AA, Arciero RA.

Clinical Outcomes After Subpectoral Biceps Tenodesis With an Interference Screw
Mazzocca AD, Cote MP, Arciero CL, Romeo AA, Arciero RA

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Controversies in the management of Biceps/SLAP

2.0% Complication Rate (7 / 353)
Mean age of patient: 45 years old
57% Male / 43 % Female
Complications:
- 2 patients: persistent pain
- 2 patients: Failure of fixation
- 1 patient: infection
- 1 patient: Musculocutaneous neuropathy
- 1 patient: RSD

The Proximal Biceps Tendon...

- Biceps pathology common
- Tenodesis over tenotomy
- Strong fixation = Interference Screw
- Subpectoral Bicep Tenodesis
- Arthroscopic

Where is the evidence?

Use dermabond...

Thank You

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Why Bicep Tenotomy is Preferred to Tenodesis

Ken Yamaguchi, MD, MBA
Sam & Marilyn Fox Distinguished Professor
Chief, Shoulder & Elbow Service

Disclosure

- Tornier Latitude design team
  - Royalties
- Zimmer Shoulder design team
  - no income at this time
- No consulting agreements

- Disclosures made in accordance to Washington University Orthopedics Departmental Policy

Treatment

Tenotomy vs Tenodesis

?
Tenotomy vs Tenodesis

- Not one correct answer for everyone
- 40 yo thin male ≠ 70 yo + sized Female

Tenotomy vs Tenodesis

Cosmesis?

- Not one correct answer for everyone
- 50 yo massive/muscular male
- 53 yo small/scrawny male

Tenotomy vs Tenodesis

- Not one correct answer for everyone
- There is a correct answer for most!

Tenotomy!
**Clinical Significance**

*Surgical Morbidity  Cosmesis/Spasms*

---

**Clinical Studies**

*Effect of Bicep Tenodesis*

- Becker & Cofield, JBJS ’89
  - 54 Shoulders – bicep tenodesis
  - 22 residual pain
  - Warned against isolated tenodesis

---

**Tenotomy**

*Better Alternative?*

- No healing necessary
- Quicker, more reliable pain relief
- Minimal cosmetic deformity in older pt.

Walch, et al – JSES ’04
107 pt. w/ 87% good results
Tenotomy vs. Tenodesis

**Advantage of Tenotomy**

- Gill, Hawkins, JSES '01
  - 29/30 shoulders off pain meds (2 mild pain)
  - One complaint of deformity
  - Avg age 50

**Tenotomy**

**Advantages vs Disadvantages**

- **Pro’s**
  - Simple
  - Arthroscopic
  - Reliable pain relief!!
- **Con’s**
  - Cosmetic deformity?

**Tenodesis**

**Advantages vs Disadvantages**

- **Pro’s**
  - Less Cosmetic deform?
- **Con’s**
  - May require open
  - May cause site pain
  - Extended rehab
  - Costs
Tenotomy vs. Tenodesis

The Cosmetic Appearance of the Biceps Muscle After Long-Head Tenotomy Versus Tenodesis

Daryl C. Osthrin, R.S., Alex B. Diamond, B.A., and Kevin P. Speer, M.D.

- 80 pt with tenotomy vs 80 with tenodesis
  - Avg age, 54
  - No difference:
    - Pain
    - Muscle spasm
    - Cosmetic appearance

Tenotomy vs. Tenodesis

- Zhang et al, 151 pt - prosp/randomized ’13
  - No dif
- Koh et al, 90 pt. - No dif outcome
  - Cosmetic def 10% in tenodesis; 25% in tenotomy
- Hsu – review No dif in outcome ’11
  - Higher level of cosmetic deformity
    - Tenotomy
  - Higher level of biceps pain
    - Tenodesis
- Maffulli – no difference, rec tenotomy ’09

Common Sense Considerations

- All studies show no dif in shoulder outcome
- Multitude of studies and no consensus on pain/cosmesis
  - Difference is very small!
- Biceps tenotomy has high level of satisfaction!
  - Hard to improve
- Tenodesis adds surgical morbidity/costs
- Acute longhead rupture almost never tx’d
  - Even in young athlete

Arthroscopy ’02
Biceps Tendon
“Saving Rupture”

- 1997 - spontaneous rupture
- Immediate pain relief
- “I wish this happened 5 yrs ago”

Tony,
How does my biceps look now??

Thank You!
Instability: What about Open Repair?

Michael J. Pagnani, MD
Nashville Knee & Shoulder Center
Nashville, Tennessee

VuMedi Webinar Debates in Shoulder Surgery
Monday, December 16, 2013

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American Shoulder and Elbow Surgeons
American Orthopaedic Society for Sports Medicine
AAOS

Industry/Technical Support of Arthroscopic Techniques

• Arthroscopic Surgeon
• Open Surgeon
**Likely Failures after Arthroscopic Stabilization:**

- Contact athlete.
- Bony defect in humeral head or glenoid.
- Atraumatic instability.

**Likely Failures after Arthroscopic Stabilization:**

- Capsular deficiency (e.g., s/p thermal capsulorrhaphy)
- HAGL lesion.
- Rupture of subscapularis in association with primary dislocation.

**Causes of Open Failure:**

  - Primary reason for failure in each series:
    - *Excess capsular laxity, NOT bony defect.*
Causes of Arthroscopic Failure:

- Engaging or large Hill-Sachs.
- Glenoid defect.
- Contact athletics.
- Capsular laxity.
- Enlarged rotator interval.
- Lack of inferior anchor (Nothing below 4- or 8 o'clock).
- Inadequate post-op immobilization.

Why Revise Open?

- Arthroscopic cuff repair = Open cuff repair.
- Arthroscopic stabilization =/= Open stabilization

Advantages of Open Techniques:

- Can free capsule from subscapularis to precisely tension capsule without adherence.
- Can better visualize and tension rotator interval.
- Open RI closure is NOT the same as arthroscopic.
Advantages of Open Techniques:
- Can double thickness of repair by overlapping capsule.
- Can optimally position arm for repair.
- Can address bony lesions.

Surgical Outcomes of Primary Open Stabilization:
- Wirth & Rockwood (JBJS, 1996)
  - 3% failure
- Gill (JBJS, 1997)
  - 3/60 failed (5%)
- West Point (Uhorchak, AJSM, 2000)
  - High failure rate in cadets (22%)
  - Why?

Concerns: Subscapularis Function after Open Stabilization
- Sachs et al, AJSM, 2005:
  - 23% had an “incompetent subscapularis” with clinical testing. (Positive lift-off test)
  - Only one case documented by MRI.
Concerns: Subscapularis Function after Open Stabilization

- Scheibel et al, AJSM, 2006:
  - No complete ruptures noted on MRI.
  - Instead, a degree of atrophy was noted in superior portion of tendon that was largely compensated by hypertrophy of inferior portion.

- Reportable case prior to these 2 papers.
  - Greis et al, JSES, 1996.
  - Rowe et al, JBJS, 1984

Concerns: Shoulder Strength After Open Versus Arthroscopic Stabilization

- Hiemstra et al, AJSM, 2008:
  - No side-to-side isokinetic strength deficits between open and arthroscopic stabilization at 1 year after surgery.
- Rhee et al, AJSM, 2007:
  - Muscle strength equal between open and scope groups at 12 months.
  - Open group recovered more slowly than scope group.
**Open vs Scope**

**EBM: Meta-Analyses**

- Freedman, *AJSM*, 2004:
  - Recurrence: Open 10%, Scope 20%
- Mohtadi, *Arthroscopy*, 2005:
  - “Open repair has a more favorable outcome with respect to recurrence and return to activity.”
- Lenters, Matsen, *JBJS*, 2007:
  - “Arthroscopic not as effective as open in preventing recurrent instability or enabling patients to return to work.”

**Open vs Scope**

**Randomized Trials**

- Fabbriciani et al (*Arthroscopy*, 2004):
- Bottoni et al, *AJSM*, 2006:
  - Arthroscopic cases carefully selected to optimize outcome.
Open vs Scope Randomized Trials

- Patel, JBJS(B) 2008: 90% without instability if no Hill-Sachs present.
- Arce CORR., 2012: 81% with no recurrence if no contact sports, no MDI, no large glenoid defect or Hill-Sachs.
- Boileau, Arthroscopy 2009: 84% success in “selected” population.
- Bartl, AJSM 2009: 89% without instability. 76% return to sport. No MDI, large glenoid defect, or engaging Hill-Sachs.
At Risk: Contact Athletes

Arthroscopic Outcomes in Contact Athletes: Disappointing
- Burkhart & DeBeer, (Arthroscopy, 2000)
  - 101 Contact Athletes
  - 14/101 failed (14%)
    - 89% with “bony defects” (8/9)
    - 7% without bony defect (6/92)

Arthroscopic Outcomes in Contact Athletes: Disappointing
- Survey of NFL & NHL (Montgomery)
  - NFL: 12% failure (3/26)
  - NHL: 45% failure (6/11)
- Mazzocca & Romeo (AOSSM, 2002)
  - 15% failure in collision athletes
  - 26% recurrence in contact athletes.
Open Outcomes in Contact Athletes:

- **Our Experience** (Pagnani & Dome, JBJS, 2002):
  - 58 American Football Players:
  - 3% recurrence rate (2 post-op subluxations, no dislocations).
  - 52/58 returned to sport. (Only 1 discontinued due to recurrence.)
  - Minimal ROM loss.

At Risk: Bony Defects of Humeral Head/Glenoid

- High recurrence rates after **arthroscopic** Bankart repair in patients with bony defects.
  - Burkhart & De Beer (*Arthroscopy*, 2000)
  - Boileau et al (*JBJS*, 2006)
Bony Defects of Humeral Head/Glenoid

- Recent recommendations of Latarjet procedure for all bony defects.
- Going from point A to point C.
  - What about point B???
- Why were bone-block procedures abandoned in the 70s-80s in North America?

Latarjet Complications
Latarjet Complications

Results of Open Stabilization WITHOUT Bone Block:

- **Rowe et al (JBJS, 1978):**
  - Glenoid lesions: 2% recurrence rate
  - 5% recurrence with moderate or large H-S.
- **Bigliani et al (AJSM, 1998):**
  - 12% recurrence with glenoid lesions.
- **Gill et al (JBJS, 1997):**
  - Large H-S doubled recurrence: 3% → 6%.
Results of Open Stabilization WITHOUT Bone Block:

- Pagnani, AJSM, 2008
  - 119 consecutive patients with recurrent instability.
  - 87 had Hill-Sachs lesions. (84%)
    - 28 “engaging.”
    - 9 “large.”
  - 14 patients had glenoid rim deficiency
    - 4 were >20% defects.

Results of Open Stabilization WITHOUT Bone Block:

- Pagnani, AJSM, 2008: Recurrence Rates:
  - Hill-Sachs lesions: 2% (2/87)
    - Large Hill-Sachs: 11% (1/9)
  - “Engaging” Hills-Sachs: 4% (1/28)
  - Glenoid deficiency: None

Results of Open Stabilization WITHOUT Bone Block:

- Pagnani, AJSM, 2008: ROM Loss
  - Large (>20%) defects of the glenoid
    - Mean loss of 7 degrees of ER.
  - Large Defects of Humeral Head
    - Mean ER loss of 4 degrees
Results of Open Stabilization WITHOUT Bone Block:

- Our results suggest that bone-block or grafting procedures do not appear to be necessary in the majority of patients with bone loss.
- Our findings also suggest an inherent difference between open and arthroscopic capsular repair.
- There is a French term for the inability to admit this...
**Special Situations:**

**Glenoid Bony Defect**
- Consider bone graft/bone block if more than 1/3 of glenoid is deficient—**only in revision situation** in our practice.

**Bristow/Latarjet Procedures**
- Up to 50% coracoid non-union rate. (Hovelius, AOS, 1983)
- Low recurrence (0-14%).
- Motion loss, high re-operation rate (15%), arthritis.
- Screw problems, revision difficult.
Summary:

• “Less invasive” not always better.
• Despite advances in technology, some inherent advantages of open techniques.
  • Rotator interval closure.
  • Free capsule from subscapularis.
  • Double capsular thickness.
  • Optimally position arm and tension repair.
  • Address bony lesions.

Summary:

• Avoid bony procedures if at all possible:
  • “Up to 50% coracoid non-union rate.
  • Motion loss, high re-operation rate (15%),
  • Arthritis.
  • Screw problems, revision difficult.
Instability – what about open repair?
Open without bone – Mike Pagnani
Arthroscopic – Mike you don’t need a 10 blade

Christopher S. Ahmad, MD
Professor
Chief, Sports Medicine
Head Team Physician NY Yankees

Disclosure
1. Basic Science Support
   a. Arthrex
   b. Arthrotek
   c. Smith-Nephew
2. Consultant
   a. Arthrex
   b. Acumed
3. Royalties – None

Arthroscopic Shoulder Instability
Ideal Surgical Technique
• Identify all pathology
• Treat all pathology
• Promote biologic healing
• Anatomic repair
• Secure fixation
• Min complications (subscap, neurovasc, stiffness)
Scope better than open
Arthroscopic Shoulder Instability
Ideal Surgical Technique

Why is scope better
- Can work on all aspects of GHJ
  - Ant, Post, Sup (SLAP), Inf
- Glenoid or Humeral pathology
- Subacromial space (Rotator cuff)

Arthroscopic Instability
Technical Goals

Correct Stretch
- Posterior-inferior plication
- Anterior capsular

Arthroscopic Instability
Posterior Plication
Arthroscopic Instability
Posterior Plication

Scope is Better
Additional Pathology
SLAP

Double Row Labral Repair
CASE
RR
• 20 yo collegiate outfielder
• Dislocated left shoulder diving for a catch
• Spontaneous reduction
• Multiple subluxation episodes
Double Row Labral Repair

Technique

Anterior Inferior Labral Tear

Lateral position

Double Row Labral Repair

Technique

Diagnostic Scope – type IV SLAP
Double Row Labral Repair
Technique
SLAP Repair

Scope is Better
Standard anterior inferior labral repair

Scope is Better
Additional Pathology
360 labral tear
Shoulder Instability Pearls

• 19 RHD collegiate soccer player
• Fell with subluxation to left shoulder
• No frank dislocations
• Weekly episodes of instability

Shoulder Instability Pearls

Pearl 1 Percutaneous Technique
Shoulder Instability Pearls
Percutaneous Technique

Shoulder Instability
360 Degree Labral Tear

- 41 shoulders in 39 patients
- Ave age of 25.1 years
- 360 degree labral tear
- Ave 7.1 suture anchors
- F/u of 31.8 months
- ASES score improved 55.5 to 89.6
- SF-12 score improved 75.7 to 90.0
- 6 required revision

Tokish et al JBJS 2009

Scope is Better
Avoid missed pathology
Reverse HAGL
Shoulder Instability Pearls
Pearl 2 Avoid Missed Pathology
Comprehensive diagnostic exam - Posterior HAGL

Scope is Better
Scope can avoid missed pathology
Linear Capsular Tears
Shoulder Instability Pearls

Pearl 2 Avoid Missed Pathology

Comprehensive diagnostic exam – Linear Capsule Tear

Scope is Better

Additional pathology

Bony Bankart
Shoulder Instability
Bony Bankart

Double row repair

Shoulder Instability
Bony Bankart and Remplissage
Shoulder Instability
Bony Bankart

Scope is Better
Additional pathology
Hill Sachs

Shoulder Instability
Hill Sachs
Remplissage
Shoulder Instability
Hill Sachs
Remplissage

Scope is Better
Additional pathology
Rotator Cuff Tear

Arthroscopic Shoulder Instability Cases
- 80 yo female RHD
- Lives alone
- Fell
- ER 1 week later
- My office 2 weeks after injury
Arthroscopic Shoulder Instability Cases

MRI

Gentle closed reduction with regional anesthesia

Rotator cuff
Arthroscopic Shoulder Instability Cases

Anterior Labrum

Arthroscopic Shoulder Instability Open Repair Results

Pagnani et al, JBJS 2002
- OPEN stabilization
- 52 / 58 (89%) return to football
- 3% recurrent subluxation

Arthroscopic Shoulder Instability Open Repair Problems

Technique often requires takedown of subscapularis

Rupture of subscap after open ant stabilization
11 / 165 (7%)  Miller, et al, AOSSM 2002
Arthroscopic Shoulder Instability
Open Repair Problems
30 patients with open Bankart repair
• 23% with incompetent subscapularis
  – strength 27% of opposite
  – 57% good and excellent results
  – 57% would have the surgery again
• 77% with normal subscapularis
  – strength 80% of opposite
  – 91% good and excellent results
  – 100% would have the surgery again
Sach et al, AJSM 2005

Arthroscopic Shoulder Instability
Open Repair Problems
25 patients with open shoulder stabilization
• 53.8% with incompetent subscapularis
• Associated atrophy and fatty infiltration
Schneibel et al, AJSM 2006

Prior open stabilization
New York Presbyterian Hospital - Columbia
Operative Report
NAME: 
MSN:
Procedure Date: 07/19/2013
SURGEON: CHRISTOPHER AHMAD, M.D.
PREOPERATIVE DIAGNOSIS:
RIGHT SHOULDER CHRONIC SUBSCAPULARIS TEAR AND INSUFFICIENCY.
POSTOPERATIVE DIAGNOSIS:
RIGHT SHOULDER CHRONIC SUBSCAPULARIS TEAR AND INSUFFICIENCY.
OPERATION:
RIGHT PECTORALIS MAJOR TRANSFER.
Arthroscopic Shoulder Instability Cases

What about

• Young patient
• Laxity
• ALPSA
• Collision athlete

Arthroscopic Shoulder Instability Cases

Case

• JD 25 yo RHD starting corner back in NFL
• Dislocates left shoulder requires assisted reduction
• Elects in season surgery
Arthroscopic Shoulder Instability
Ideal Surgical Technique

- Identify all pathology
- Treat all pathology
- Promote biologic healing
- Anatomic repair
- Secure fixation
- Min complications (subscap, neurovasc, stiffness)

Scope better than open
Arthroscopic Reconstruction/Augmentation of Severely Damaged Rotator Cuff Tendon Using Acellular Human Dermal Allograft

Stephen J. Snyder

Southern California Orthopedic INSTITUTE

Potential Conflict of Interest

Consultant:
dj Ortho Global, Mitek, Wright Medical Technology

Royalties:
Linvatec, dj Ortho Global, Pacific Research, Wright Medical, Arthrex, Lippincott William and Wilkins

Research support:
Smith and Nephew, Ossur Medical, dj Ortho Global, Linvatec, Pacific Research, Mitek, Biomet, Stryker

The PROBLEM:
The PROBLEM: “Apoptosis” - Programmed Cell Death

- Degenerative, Scarred, Old, Avascular, Traumatized Tissue
- Bad Biology
- Bad Surgery

= POOR HEALING

Open Surgical treatment options for massive rotator cuff tear:

- Debridement & Decompression
- Interval Slide Mobilization - Repair
- Muscle Transfer
- Reverse Shoulder Prostheses
- Grafts
  - Autografts (Fascia lata)
  - Allografts (Achilles)
  - Xenografts (porcine, bovine)
  - Fabrics (Dacron, Polyurea)

Any other options??
How to best “fill the hole”?

Allografts have a long and successful history in orthopedics!

Why not use an Allograft for Rotator Cuff?
Goals of Rotator Cuff Augmentation

• Supplement rotator cuff repair at weakest point, the **tissue**

• Improve biomechanics of cuff repair:
  - Reduce tension at cuff insertion to avoid suture cut out.
  - Reattach and restore tension to muscle tendon units.
• Supplement rotator cuff repair at weakest point, the tissue

• Improve biomechanics of cuff repair:
  - Reduce tension at cuff insertion to avoid suture cut out.
  - Reattach and restore tension to muscle tendon units.
  - Restore the biomechanical “force couple” of the cuff.

Goals of Rotator Cuff Augmentation

• Improve biologic environment for cuff healing with an appropriate biologic matrix
  - Ideal Collagen Scaffold

- Absorbed and Replaced with Host Tissue
Goals of Rotator Cuff Augmentation

- Improve biologic environment for cuff healing with an appropriate biologic matrix:
  - Ideal Collagen Scaffold
  - Absorbed and Replaced with Host Tissue
  - Attracts Platelets with Growth Factors &
  - Pluripotent Bone Marrow Stem Cells

Challenges for a Rotator Cuff Augmentation or Replacement Graft

1. The scaffold must rapidly attach to the stump of the native rotator cuff and surrounding tissues
2. Attach firmly to bone
3. Attract and support appropriate cells
Challenges for a Rotator Cuff Augmentation or Replacement Graft

1. The scaffold must rapidly attach to the stump of the native rotator cuff and surrounding tissues
2. Attach firmly to bone
3. Attract and support appropriate cells

Extracellular Matrix Landscape

<table>
<thead>
<tr>
<th>Material Source</th>
<th>Tissue Type</th>
<th>Cross-Link</th>
<th>Approved Use</th>
<th>Sterilization</th>
<th>Size(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHDM® (GraftJacket)</td>
<td>Human Dermis</td>
<td>N</td>
<td>Reinforce and augment soft tissue</td>
<td>Aseptic processing</td>
<td>Multiple</td>
</tr>
<tr>
<td>FlexHD/DermaMatrix</td>
<td>Human Dermis</td>
<td></td>
<td>Reinforce and augment soft tissue</td>
<td>Aseptic processing but USP 71(not terminal in process)</td>
<td>Multiple</td>
</tr>
<tr>
<td>Restore®</td>
<td>Porcine SIS</td>
<td>N</td>
<td>Rotator cuff</td>
<td>Sterilized</td>
<td>6cm²</td>
</tr>
<tr>
<td>TissueMend®</td>
<td>Bovine Dermis</td>
<td></td>
<td></td>
<td>Gamma irradiation</td>
<td>5x6cm</td>
</tr>
<tr>
<td>ZCR® Patch</td>
<td>Porcine Dermis</td>
<td>Y</td>
<td>Rotator cuff</td>
<td>Yes</td>
<td>5x5cm</td>
</tr>
<tr>
<td>OrthoADAPT™</td>
<td>Equine Pericardium</td>
<td>Y</td>
<td>Reinforce and augment soft tissue</td>
<td>Yes</td>
<td>3 x 3 cm, 4 x 5 cm</td>
</tr>
<tr>
<td>CuffPatch®</td>
<td>Porcine SIS</td>
<td>Y</td>
<td>Rotator cuff</td>
<td>Yes</td>
<td>6.5 x 9 cm</td>
</tr>
<tr>
<td>SportMesh™</td>
<td>Synthetic</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Extracellular Matrix Landscape (New additions)

1. “Conexa” (Tornier)- Porcine Dermis Non-crosslinked, Aseptic processing, Multiple sizes
2. Allopatch H.D. (MTF)- Human Dermis Non-crosslinked, Aseptic processing, Multiple sizes
3. Arthroflex (Arthrex)- Human Dermis, two sizes, two thicknesses, sterile, 97% DNA removal
4. Bio Fiber (g4HB) (Tornier) is a biologically derived fiber woven polymer produced through a fermentation process. Size 13x23x1mm strips
5. DermaSpan (Biomet)- Human Dermis, Non-crosslinked, sterilized with irradiation, hydrate in saline, 3 sizes available
6. X Repair— Polylactide two layer Mesh with pocket- Multiple sizes clinically tested
Before we ever accept a significant new technology we MUST HAVE:

1. Good lab data (biomechanical and surgical simulation)
2. Good animal data (in vitro and in vivo)
3. Good reproducible clinical data
4. Good reliable follow-up

Strength of Human RCR augmented with AHDM

Conclusion:
The specimens augmented with AHDM were significantly stronger to both cyclic loading and ultimate failure than the non-augmented specimens (273 +/- 116 N vs 325 +/- 74 N)

Commercial Extracellular Matrix Scaffolds for Rotator Cuff Tendon Repair

There are chemical and mechanical differences among the four ECMs tested. It is likely that the source, species, age of donor, and processing of the ECM contribute to the unique biophysical properties of delivered product.
Clinical Relevance: The results of this study suggest that dermal ECM may more favorably react with human tendon tissue than ECM of other origins. This may have great relevance as research continues in the field of augmenting surgical soft-tissue repair.

These Stem Cells can differentiate into tendon and bone for improved healing of Rotator Cuff repairs

Bone Marrow Platelets are the source of Growth Factors
Regeneration Key: “Crimson Duvet”

Why not?? *Nature* should know the best dose, concentration, timing and factors needed– who could disagree

Free…

Safe…

Good Lab Data…

Excellent Clinical Data…

Crimson Duvet

Crimson Duvet
12/16/2013

Mesenchymal Pluripotential Cells Platelets and their Growth Factors New Blood Supply

Bone Marrow “Crimson Duvet”

How do the bone marrow cells invade the dermal allograft?

Massive meshwork of vessels throughout the allograft matrix.
Yoshikazu Kida, MDa,b, Toru Morihara, MDa, Ken-Ichi Matsuda, PhDb, Yoshiteru Kajikawa, MDa, Hisakazu Tachiiri, MDa, Yoshiio Iwata, MDa, Kazuhide Sawamura, MDa, Atsuhiko Yoshida, MDa, Yasushi Oshima, MDa, Takumi Ikeda, MDa, Hiroyoshi Fujiwara, MDa,*, Mitsuhiro Kawata, MDa, Toshikazu Kubo, MDa

Article in Press

Basic Science Information

3 month biopsy after 2nd look for catching symptoms

Graft repaired arthroscopically and biopsy taken from the graft-tendon junction

Snyder et al. Arthroscopy 2009

• New Burkhead Data- 2010

Submitted to CORR

Conclusions: Open augmented repair of large and massive cuff tears with human dermal allograft resulted in radiographic complete or partial repairs in 25/28 patients. 100% patient satisfaction, and significantly improved UCLA and SST scores. Previous surgery on the affected shoulder, acromial and/or deltoid deficiency as a result of previous surgery, and longer duration of preoperative symptoms were associated with poorer outcomes.

Rotator cuff tendon Regenerative tissue Sclerotic bone

Snyder et al. Arthroscopy 2009

Basic Science Information

3 month biopsy after 2nd look for catching symptoms

Graft repaired arthroscopically and biopsy taken from the graft-tendon junction

Snyder et al. Arthroscopy 2009

FIGURE 4. Progressive regeneration and remodeling of the graft are present with distinct areas of tendon, remodeling (GraftJacket) GJA matrix, and matrix as evidenced by the concentration of elastic fibers (Verhoeff's stain, original magnification 25X.)

Graft repaired arthroscopically and biopsy taken from the graft-tendon junction

Snyder et al. Arthroscopy 2009

Basic Science Information

3 month biopsy after 2nd look for catching symptoms

Graft repaired arthroscopically and biopsy taken from the graft-tendon junction

Snyder et al. Arthroscopy 2009

Basic Science Information
Results: Clinical
Level 2: Prospective, Randomized, Controlled, Multi-center

"Large" >3cm tears only:
Higher functional outcomes &
Significantly improved healing w/ augmentation:

Barber & Burns et al, 2012

Recent Literature
Dr. Greg J. Gilot- Cleveland Clinic, Florida

Case-control study on Large to Massive Cuff Repair – Arthroscopic Repair using AHDM – Ultra Sound eval at 12 months post op
Double Row Suture Bridge Technique n=20 – Failed 6 (32%) thickness 473 CM
Double Row Suture Bridge w/ Augmentation n=20 Failed 2 (10%) thickness 577 CM

Patient satisfaction
Control=66.7% Augmentation=93.3%

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When augmentate with AHDA

Patient satisfaction
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Orthopedic Insights (Cleveland Clinic Publication)
Fall 2013

Orthopedic Insights (Cleveland Clinic Publication)
Fall 2013
Extracellular matrix scaffold devices for rotator cuff repair
Derwin K.A., Badylak S.F., Steinmann S.P., Iannotti J.P.
Journal of Shoulder and Elbow Surgery - April 2010

SCOI Surgical Technique for Cuff Replacement

Multiple STIK Sutures
1. Fix rotator cuff using standard technique

Measure edges of cuff between anchors lateral and adjacent to the muscle medial.

Pass circumferential sutures
Shuttle STIKs
“STAY ANTERIOR”: DO NOT TANGLE!!
Push-Pull graft in
Technique
Pull graft into the shoulder by pulling on the long end of the STIK sutures.

Technique
Tie STIKs around edges of graft.
Fix laterally with push-in anchors.

So if you have a degenerative cuff and you want it to have the best chance to heal

1. STRONG LOW TENSION REPAIR
2. AUGMENT WITH A BIOLOGIC MATRIX
3. RELEASE THE BONE MARROW TO FORM A CRIMSON DUVET
Thanks for your attention
Large and Massive Rotator Cuff Tears: Fix the Tear

Stephen S. Burkhart, M.D.,
San Antonio, Texas

Disclosure

Stephen S. Burkhart is a consultant for, and receives inventor's royalties from Arthrex, Inc. (Naples, FL). He also receives book royalties from Wolters-Kluwer (Philadephia, PA).

What is a Massive Tear?

- 2 or more tendons
- > 5 cm. diameter
Results of Arthroscopic Repair of Massive Cuff Tears

Arthroscopic Massive Cuff Repair
Denard & Burkhart, Arthroscopy 2012

- 1998-2005 (341 repairs)
- 126 with f/u, 62.3 yrs old at surgery
- 62.3 yrs old at time of surgery
- Interval slides 54 cases (43%)
- 81% were completely reparable

Arthroscopic Massive Cuff Repair
- Denard & Burkhart, Arthroscopy 2012

- Mean follow-up over 8.2 years
- Forward flexion 132 -> 168
- ASES 42 -> 94
- UCLA 16 -> 31
  - Good or excellent 78%
- 91% patient satisfaction
Arthroscopic Massive Cuff Repair
Denard & Burkhart, Arthroscopy 2012

- Double-row vs. Single-row repairs
  - Patients rated shoulder 94% vs. 84% normal
  - Double-row 4.9 x more likely to lead to good or excellent functional outcome

The Ugliest Cuff Tears

- Tears with pseudoparalysis
- Irreparable cuff tears

Pseudoparalysis
Is the Tear Repairable?

- Yes.....in > 95% of cases (Burkhart 2004)
- May need advanced techniques such as interval slides

Repair Subscap: Then Repair SS/IS

Tear Pattern Recognition

Crescent Tear
Tear Pattern Recognition
Chronic U-Shaped Tear

Tear Pattern Recognition
Chronic L-Shaped Tear

Interval Slides
• Anterior and posterior
Anterior Interval Slide
• Releases coracohumeral ligament (CHL)
• 2 ways to accomplish this:

New “Modified” Double Interval Slide
• Anterior interval slide in-continuity
• Posterior interval slide
Partial Cuff Repair

- Concept:
  - Re-establish rotator cable attachments
  - Re-establish balanced force couples
  - Re-establish stable fulcrum kinematics

Other Options for Irreparable Rotator Cuff Tears

- Debridement of cuff
- Tendon transfer
- Acellular dermal allograft
- Reverse arthroplasty
Debridement

- Good pain relief
- No improvement in strength
- Deterioration over time
- Consider debridement only for inactive elderly patients

Latissimus Dorsi Transfer
- Warner et al, 2005

Trapezius Transfer
- Omid & Lee, JAAOS 2013

REALLY???
Acellular Dermal Allografts

• FDA approved only for augmentation, and not for bridging (bridging reported by Snyder et al)
• Consider it for bridging in failed repair of massive tear in young patient, but not as a routine part of the surgery

Reverse Arthroplasty

• Results in the literature are not as good as arthroscopic repair (all age groups)
• Higher complication rate

Reverse-O-Mania
The Problem
- Trend toward reverse TSR for massive cuff tears
  - The reason: for the average surgeon, reverse TSR is easier to perform than arthroscopic repair of massive cuff tears

What is Best for the Patient?
- What would you want if it were your shoulder?

Why Repair Massive Cuff Tears?
- Because we can
- Because it works
- Because the other options suck
Thank you!
Cuff Tear Arthropathy

Michael A. Wirth, M.D.
Professor and Charles A. Rockwood, Jr.
Chair of Orthopaedic Surgery
University of Texas
San Antonio

Cuff tear arthropathy in a 63 year old patient...hemiarthroplasty is the way to go!
“25 of 26 patients were very pleased with pain relief and improved function.”

“I prefer to use a nonconstrained shoulder arthroplasty in virtually all of these patients.”  Charles Neer

Pain decreased in 14 of 18 shoulders to none or slight in 10….and 4 had pain only after unusual activity.
21 cases with an average age of 72 years
Mean follow up of 4 years (range, 2 to 6 years)
Mild or no pain in 86%

“The improvement of pain and preservation of function make hemiarthroplasty an attractive alternative to arthrodesis, resection, or constrained arthroplasty.”

* Williams and Rockwood J Shoulder Elbow Surg 1996

10 of 12 patients with good deltoid function and an adequate coracoacromial arch were successful by Neer’s limited goals criteria

Hemiarthroplasty for Cuff Tear Arthropathy
Zuckerman, Scott Gallagher J Shoulder Elbow Surg 2000

Motion and strength improved (Biodex isokinetic dynamometer)
87% of patients were satisfied
Shoulder hemiarthroplasty for glenohumeral arthritis associated with severe rotator cuff deficiency
Sanchez-Sotelo, Cofield, Rowland J Bone Joint Surg 2001

- 33 shoulders with avg f/u 5 years
- Marked pain relief in 75%

“Hemiarthroplasty is a reconstructive option that provides durable results (up to 11 years)…”

Hemiarthroplasty for the Rotator Cuff-Deficient Shoulder
Goldberg, Bell, Kim, Bak, Levine, Bigliani J Bone Joint Surg 2008

“Hemiarthroplasty is the procedure of choice for patients who can actively elevate the arm to 90° …the low prevalence of complications and the high rate of satisfaction should be weighed against other options such as RTSA that may provide greater functional benefits at the risk of a higher complication rate.”

Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff
RESULTS OF A MULTICENTRE STUDY OF 80 SHOULDERS

8 year survival was 29%
Reverse Total Shoulder Arthroplasty
5-10 year Survivorship Analysis

“Reverse total shoulder arthroplasty should be used exclusively in patients over seventy years old with low functional demands.”

60% survival at 10 years

Comparison of functional outcomes of RTSA with those of HA in the treatment of cuff-tear arthropathy

1) No difference between groups with respect to mortality and revision rates
2) For patients 65 years of age and younger there was no significant difference in functional outcome scores

Ideal Patient Criteria

1) >90 degrees elevation
2) No glenoid erosion
3) No previous surgery
4) Negative Lift-off
5) Negative Hornblower
6 months s/p hemiarthroplasty
Cuff Tear Arthropathy
Reverse TSA is the way to go

Gerald R. Williams, Jr., MD
Professor, Department of Orthopaedic
Surgery
Thomas Jefferson University
Chief, Shoulder and Elbow Service
Rothman Institute

Conflict of Interest Slide

- Royalties
  - Depuy: shoulder arthroplasty
  - Lippincott, Williams, and Wilkins: shoulder texts
  - IMDS/Cleveland Clinic
- Consultant
  - Depuy Mitek, checkpoint
- Stock Ownership: In-vivo therapeutics
- Research
  - Tornier

Results

- 20 patients, 21 shoulders
- Age 72 yrs (59-80)
- F:M 16:4
- Dominant arm 17
- Follow-up 4 yrs (2.6-6)
- Outcome measurement—Neer’s Limited Goals

Williams GR and Rockwood CA,
JSES 5, 1996
Results

Pain

- Pain, Preop, 2.9
- Pain, Postop, 0.6

Rothman Institute of Orthopaedics at Thomas Jefferson University

Results

- Neer’s Limited Goals
  - 18/21 (86%) satisfactory
  - Only 12/21 -- no pain
  - 5/21 -- <90 degrees active elevation

Rothman Institute of Orthopaedics at Thomas Jefferson University

United States
Pre 2004

Rothman Institute of Orthopaedics at Thomas Jefferson University
Reverse TSA
FDA Approved in 2004

Why not a reverse?
Complications

<table>
<thead>
<tr>
<th>Author</th>
<th>Pts.</th>
<th>F/U</th>
<th>Comp. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Werner, Gerber</td>
<td>58</td>
<td>38 mos.</td>
<td>50</td>
</tr>
<tr>
<td>Rittmeister</td>
<td>8 (RA)</td>
<td>54 mos.</td>
<td>75</td>
</tr>
<tr>
<td>Botteau, Walch</td>
<td>457</td>
<td>43.5 mos.</td>
<td>25</td>
</tr>
<tr>
<td>Frankle</td>
<td>60 (all CTA)</td>
<td>33 mos.</td>
<td>22</td>
</tr>
<tr>
<td>Hattrup</td>
<td>53</td>
<td>?</td>
<td>19</td>
</tr>
<tr>
<td>Wiater</td>
<td>51</td>
<td>8.5 mos.</td>
<td>14</td>
</tr>
<tr>
<td>Connor</td>
<td>62</td>
<td>15 mos.</td>
<td>(no notching ?)</td>
</tr>
</tbody>
</table>

RSA Complications
2013

<table>
<thead>
<tr>
<th>Surgery Type</th>
<th>Complication rate</th>
<th>Reoperation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary (n=93)</td>
<td>4.3%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Revision (n=21)</td>
<td>9%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Table III: Comparison between baseline and follow-up values

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexion</td>
<td>120° ± 20° (90°-150°)</td>
<td>120° ± 25° (90°-180°)</td>
<td>0.03</td>
</tr>
<tr>
<td>Abduction</td>
<td>135° ± 20° (90°-180°)</td>
<td>135° ± 20° (90°-180°)</td>
<td>0.04</td>
</tr>
<tr>
<td>External rotation</td>
<td>37° ± 11° (28°-60°)</td>
<td>37° ± 11° (28°-60°)</td>
<td>0.03</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>47° ± 16° (30°-70°)</td>
<td>47° ± 16° (30°-70°)</td>
<td>0.03</td>
</tr>
<tr>
<td>OHS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>21 ± 7 (9-42)</td>
<td>21 ± 7 (9-42)</td>
<td>0.04</td>
</tr>
<tr>
<td>Pain</td>
<td>2 ± 3 (0-14)</td>
<td>2 ± 3 (0-14)</td>
<td>0.04</td>
</tr>
<tr>
<td>ADLs</td>
<td>7 ± 2 (2-25)</td>
<td>7 ± 2 (2-25)</td>
<td>0.04</td>
</tr>
<tr>
<td>ROM</td>
<td>15 ± 5 (2-30)</td>
<td>15 ± 5 (2-30)</td>
<td>0.04</td>
</tr>
<tr>
<td>Power</td>
<td>5 ± 1 (4-6)</td>
<td>6 ± 1 (5-6)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

*p = Preoperative value - Postoperative value / Postoperative value


Table IV: Mean OFA in patients and sex- and age-matched population norms

<table>
<thead>
<tr>
<th>Name</th>
<th>Patients</th>
<th>Controls</th>
<th>%</th>
<th>Patients</th>
<th>Controls</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 50-65 y</td>
<td>61.2</td>
<td>60.7</td>
<td>55.6</td>
<td>72.3</td>
<td>71.8</td>
<td>55.6</td>
</tr>
<tr>
<td>Age 25-50 y</td>
<td>73.0</td>
<td>72.5</td>
<td>52.6</td>
<td>74.1</td>
<td>73.6</td>
<td>52.6</td>
</tr>
</tbody>
</table>


Table V: OFA scores in patients and age-matched population norms

<table>
<thead>
<tr>
<th>Age group 65-74 y</th>
<th>Patients (n = 50)</th>
<th>Controls</th>
<th>P value</th>
<th>Age group 25-50 y</th>
<th>Patients (n = 50)</th>
<th>Controls</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFA</td>
<td>61.2 ± 8.0 (9-38)</td>
<td>60.7 ± 10.2</td>
<td>0.02</td>
<td>OFA</td>
<td>72.3 ± 11.3 (60-94)</td>
<td>71.8 ± 10.2</td>
<td>0.05</td>
</tr>
<tr>
<td>FF</td>
<td>61.2 ± 8.0 (9-38)</td>
<td>60.7 ± 10.2</td>
<td>0.02</td>
<td>FF</td>
<td>72.3 ± 11.3 (60-94)</td>
<td>71.8 ± 10.2</td>
<td>0.05</td>
</tr>
<tr>
<td>RF</td>
<td>52.0 ± 6.5 (9-38)</td>
<td>51.8 ± 8.0</td>
<td>0.02</td>
<td>RF</td>
<td>61.5 ± 8.0 (9-38)</td>
<td>61.2 ± 8.0</td>
<td>0.02</td>
</tr>
<tr>
<td>SL</td>
<td>52.0 ± 6.5 (9-38)</td>
<td>51.8 ± 8.0</td>
<td>0.02</td>
<td>SL</td>
<td>61.5 ± 8.0 (9-38)</td>
<td>61.2 ± 8.0</td>
<td>0.02</td>
</tr>
<tr>
<td>VT</td>
<td>52.0 ± 6.5 (9-38)</td>
<td>51.8 ± 8.0</td>
<td>0.02</td>
<td>VT</td>
<td>61.5 ± 8.0 (9-38)</td>
<td>61.2 ± 8.0</td>
<td>0.02</td>
</tr>
<tr>
<td>PC</td>
<td>52.0 ± 6.5 (9-38)</td>
<td>51.8 ± 8.0</td>
<td>0.02</td>
<td>PC</td>
<td>61.5 ± 8.0 (9-38)</td>
<td>61.2 ± 8.0</td>
<td>0.02</td>
</tr>
<tr>
<td>PCS</td>
<td>42.7 ± 8.1 (32-67.0)</td>
<td>42.7 ± 8.1</td>
<td>0.02</td>
<td>PCS</td>
<td>52.0 ± 8.1 (32-67.0)</td>
<td>52.0 ± 8.1</td>
<td>0.02</td>
</tr>
</tbody>
</table>

• Predictable outcome
  - Pain
  - Function
• Current complication rate for primary RTSA similar to anatomic
• Revision of reverse to reverse or reverse to hemiarthroplasty possible

THANK YOU.