Human Acellular Dermal Allograft for Massive Rotator Cuff Tears

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AOAO SPRING MEETING
SALT LAKE CITY UTAH
Purpose

- Use of human dermal allograft in massive rotator cuff repairs
- Review literature
- Review techniques

CONFLICTS

- Sequoia Surgery Center
- Bellevue Physician Owner Distributorship
- Visalia Co-management Group
Anatomy

- ‘Normal’ cuff footprint includes attachments to capsule
  - Superior capsule (Clark et al 1990)
    - Joint stability
    - Attachment onto 30-61% GT
- Capsular thickness varies
  - 0.4 - 4.47mm
- Reverse trampoline effects
  - Separates acromion from head
  - Serial resection superior migration
- Biceps tendon invagination

Multiquadrant digital analysis of shoulder capsular thickness

The Rotator Cuff and the Superior Capsule: Why We Need Both
Adams, DeMartino, Rego, Denard, Burkhart
Anatomy

- SC tear the ‘essential lesion’
- The cable concepts
- Mechanical studies supports concept that forces at coupled to intact superior capsule
  - Superior stability/Suspension bridge
  - SSN palsy or RCTa still functional if intact SC
- The ‘cable’ is a droop of the superior capsule
- Restoration of the cable after double row cuff repairs
- PASTAR should be repaired to restore mechanical advantages of SC

The Rotator Cuff and the Superior Capsule Why We Need Both. Adams, Burkhart, et al. Arthroscopy JARS 32:12, 2016, pg 2628-2637
Massive Cuff Tears

- Multiple tendons
  - 2 or greater
- Tears greater then 5cm
- SA less than 7mm
- Atrophy-Goutallier
- Patients younger than 65
  - Active
  - Physical demands
- Patients older than 65
  - RTSA
- RTSA 4x complications TSA
  - 39% in younger ptx
  - Infections in 5% of RTSA

Ernstbrunner L, Suter A, Catanzaro S, Rahm S, Gerber C. Reverse total shoulder arthroplasty for massive, irreparable rotator cuff tears before the age of 60 years: Long term results. JBJS 2017;99:1721-1729
Massive Rotator Cuff Tears Repair

- Repairs failure 20-90%
  - 85% failures < 6m PO to 94% @36m.
  - Poor healing
  - Still satisfactory results are reported by patients

- Causes
  - Tension at repair site
  - Tendon quality
  - Gap formation > 5mm
  - Fatty infiltration
    - Atrophy
  - Inflammation- <7 days
    - Fibrin-cytokines
  - Proliferative- 48hrs - 6 wks
    - Vascularize scar tissue
  - Remodeling- several months post-op
    - Col3-Col1
    - Scar persists

Rotator Cuff Healing: Improving Biology
David Savin, MD, Molly Meadows, MD, Nikhil Verma, MD, and Brian Cole, MD/M.B.A
Oper Tech Sports Med 25:34-40
Massive Rotator Cuff Tears

- Direct repair
  - SR vs DR vs TransOsseousEquivalent
- Tendon transfers
  - Pectoralis major
  - Latissimis dorsi- ER weakness
- Interpositional
  - Cuff allograft (Nevasier)
  - Fascia lata autograft (Mihata)
  - Balloon Arthroplasty
- Interpositional grafting of residual defects
- Augmentation
  - Repair in tension
  - Residual defects
  - Retear rates <9%
  - HDA
  - Xenograft
    - Porcine
    - Equine
  - Synthetics

Retear rates <9%
Biomechanical Analysis of Rotator Cuff Repairs With Extracellular Matrix Graft Augmentation
Erin E. Ely, MD; Nathania M. Figueroa, MD; Gregory J. Gilot, MD
Orthopedics. 2014; 37(9):608-614

Abstract: Despite advances in surgical techniques, 20% to 90% of rotator cuff (RTC) repairs fail. They tend to fail at the suture-tendon junction due to tension at the repair and gap formation prior to healing. This study evaluated the gap formation and ultimate tensile failure loads of a RTC repair with a decellularized human dermal allograft. Augmentation of a RTC repair with an extracellular matrix graft decreased gap formation and increased load to failure in a human RTC repair model.
Biomechanical Analysis of Rotator Cuff Repairs With Extracellular Matrix Graft Augmentation

Erin E. Ely, MD; Nathania M. Figueroa, MD; Gregory J. Gilot, MD
Orthopedics. 2014; 37(9):608-614

- Barber et al-16 GraftJacket SR Load sharing
  - 273 vs 325 N (19%)
  - Stiffness NR
- Shea et al-14 Conexa DR Load sharing (Lateral row)
  - 335 vs 429 N (28%)
  - 2.1 vs 1.3 mm (38%)
- Beitzel et al-39 ArthroFlex DR TOE 349 vs 470 N (35%) 349 vs 576 N (65%)
  - 2.4 vs 1.8 mm (25%), 2.4 vs 1.5 mm (37.5%)
- Current- ArthroFlex Modified DR TOE Load sharing (Medial row)
  - 551 vs 643 N (17%)
  - 2.8 vs 2.2 mm (21%)
  - {Not significant}
Biomechanical Effects of Fiber Patch Augmentation on Rotator Cuff Repairs

Vishal Mahul Mehta, MD; Cassie L. Mandala, PA-C; Ryan J. Shriver, BS; Melanie Benson, PA-C
Orthopedics. 2020;43 (1): 42-45

- Six human cadaveric supraspinatus
- BioFiber Patch (Tornier)
  - P4HB (poly-4-hydroxybutyrate)
- 1-cm wide strips repaired to the rotator cuff footprint using a titanium anchor
  - single mattress suture
- Shoulder repaired with and without a fiber patch.
- Cyclic loading (100 cycles) and load-to-failure (LTF)
  - Suture only-1.07 mm gap vs Fiber patch-augmented- 0.50 mm gap (P=.002)
  - Suture only- Load-to-failure 54.26 N vs Fiber patch-augmented- LTF 109.53 N (P<.001)
- Purely biomechanical study
- Measurement faulty- visual/tactile
- Small volume
A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair.


- Twenty two GJA
- Twenty DR
- GJA 85% intact cuff
- DR 40% intact cuff
- Improved ASES (P=0.035)
  - 48.5 to 98.9
  - 46.0 to 94.8
- Improved Constant (P=0.008)
Relatively high failure rates have been reported after treatment of large and massive cuff tears. The suboptimal results ... have stimulated the development of various tissue augmentation scaffolds to potentially enhance repair constructs...In this chapter, we describe the surgical technique for human dermal allograft rotator cuff augmentation, and early results of the technique are also discussed.
Superior Capsular Reconstruction

- Mihata et al 2012
- Human dermal allograft
- Fascia Lata autograft
  - Thicker graft
  - Improve HAD
- Goals
  - Restore the suspension balance to the superior shoulder
  - Lower the moment arm in elevation
  - Suture graft from superior glenoid to greater tuberosity
- Interpositional spacer
- Dampens SA forces
- Trampoline Effects
- Force Couple
Superior Capsular Reconstruction

Arthroscopic Superior Capsular Reconstruction With Acellular Dermal Allograft for the Treatment of Massive Irreparable Rotator Cuff Tears: Short-Term Clinical Outcomes and the Radiographic Parameter of Superior Capsular Distance

WT Pennington, M.D., BA Bartz, P.A.-C., JM Pauli, P.A.-C., CW, B.A., W Schmidt, B.S.

- 88 consecutive shoulders IRCT
- Arthroscopic superior capsular reconstruction (SCR) using an acellular dermal allograft.
- Review arthroscopic SCR with a minimum 12-month follow-up.
- Eighty-six patients with an average age of 59.4 years presented with massive rotator cuff tears (Cofield >5 cm).
  - Improvement in VAS (4.0-1.5)
  - ASES (52-82) at 1 year (P ¼ .005)
  - Xray with increase acromiohumeral interval (mean 7.1 mm preoperatively to mean 9.7 mm at 1 year) (P ¼ .049)
  - Superior capsular distance (mean 52.9 mm preoperatively to mean 46.2 mm at 1 year) (P ¼ .011)
  - FF/ABD/ER 4.8/4.1/7.7 lb preoperatively to 9.8/9.2/12.3 lb at 1 year, ROM (FF 120/103 preoperatively to 160/159 at 1 year) (P ¼ .044/P ¼ .007/P ¼ .02)
- 90% of patients were satisfied.
  - Level of Evidence: Level IV, retrospective case series.

### Table 3. Dynamometric Strength Measurements (lb)

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<th>FF</th>
<th>ABD</th>
<th>EXT</th>
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<tr>
<td></td>
<td>Surgical</td>
<td>Nonsurgical</td>
<td>Surgical</td>
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<tr>
<td>Preop</td>
<td>4.8 (0-11.5)</td>
<td>14.1</td>
<td>4.1 (0-11.9)</td>
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<td>6 months</td>
<td>6.2 (0-15.0)</td>
<td>13.0</td>
<td>5.8 (0-17.0)</td>
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<td>1 year</td>
<td>9.8 (3.0-18.1)</td>
<td>11.5</td>
<td>9.2 (0.5-16.1)</td>
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<tr>
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<td>P = .016</td>
<td>P = .0022</td>
<td>P = .018</td>
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The Role of SCR in Irreparable Rotator Cuff Tear-A Systemic Review

- Systematical review the literature on SCR for functional outcome scores and failure rates.
  - Review of the online databases Medline and EMBASE 28th January 2019.
- All nine studies reported significant improvement in functional scores after SCR.
  - Rates of secondary surgery were only provided in the dermal allograft studies at short-term follow-up (mean 10.9 to 32.4 months) and ranged from 0 to 18.6%.
  - Radiological assessment revealed graft failure in 5.5 to 55% of dermal allografts and 4.2 to 36.1% of fascia lata autografts.
- Conclusion: SCR is useful for patients with irreparable rotator cuff tears. SCR associated with significantly improved functional outcome scores in all studies.
  - Preserved/increased mean AHD.
  - Radiological graft failure rate ranged from 4.2-55%
  - Short follow-up in most studies—an important concern that requires longer-term evaluation.

Pennington et al. [3] n = 88 Age 59.4 (27-79) Male 69%
- Dermal allograft 3 mm PA margin convergence LHB tenotomy 100%, limited acromioplasty 100%, distal clavicle excision 26%
- FU 16-28 mos ASES 52 to 82 VAS pain 4 to 1.5 AFE 121 to 160, abduction 103 to 159
- AHI 7.1 to 9.7 mm MRI 4.5% failure rate Revision rate 1.2%

Mihata et al. [12] n = 88 Age 66.2 (43-80)
- Fascia lata autograft (6-8 mm thickness) LHB tenodesis 8%, LHB tenotomy 1%, acromioplasty 100%, subscapularis 39% Anterior and posterior margin convergence
- FU 60 (35-110) Overall improved ASES, VAS
- 4.5% graft failure rate Complication rate 9% 3.4% stiffness 3.4% anchor pull out 2.3% infection

Denard et al. [19] n = 59 Age 62 ± 8.7 Male 66.1%
- Dermal allograft (1 to 3 mm) LHB tenodesis 42%, LHB tenotomy 15%, Limited acromioplasty 81%, Distal clavicle excision 5% Subscapularis repaired
- FU 17.7 months ASES 43.6 to 77.5 SSV 35 to 76.3 VAS pain 6.8 to 1.7 AFE 130 to 158, ER 36 to 45, IR L3 to L1 Complication 6.8-3.4% falls, 1.7% LHB pain and 1.7% infection Revision 18.6-11.9% RSA, 3.4% SCR revision, 1.7% infection, 1.7% biceps tenodesis AHI 6.6 to 6.7 mm

Burkhart et al. [18] n = 10 Age 69 ± 1.5 90% male
- Dermal allograft (3 mm thickness) Subscapularis or infraspinatus repair in all LHB tenodesis 40%, LHB tenotomy 20%
- FU 10.9 months AFE 27.1 VAS pain 4.6 to 0.5 Graft in tact 70%, 30% partially intact AHI 7 [5-9] to 6 (4-8)
Clinical Outcomes of Superior Capsular Reconstruction for Massive, Irreparable Rotator Cuff Tears: A Systematic Review Comparing Acellular Dermal Allograft and Autograft Fascia Lata

Arthroscopy, Sports Medicine, and Rehabilitation, Vol 3, No 1 (February), 2021: pp e257-e268

- Preferred Reporting Items for Systematic Reviews and Meta-Analyses-PRISMA guidelines systematic review.
- Clinical studies assessed for patient-reported outcomes and ROM, comparing dermal allografts to fascia lata autografts, minimum FU of 12 m
- 16 clinical studies involving 598 patients (606 shoulders)
- Mean FU 36.9 months (range 12 to 60)
- VAS decreased from 4.0 - 6.9 to 0 - 2.5 mm
- ASES score increased 20.3 -54.5 to 73.7 -97.0
- FF increased from 27.0 -142.7 to 134.5 - 167.0
- External rotation increased from 13.2 -41.0 to 30.0 -59.0
- AHD increased from 3.4 -7.1 mm to 6.0 -9.7 mm
- Total rates of complications 5.6%
- Graft failure 13.9%
- Revision surgery 6.9%
- Irrespective of tissue source, SCR serves as a reasonable joint-preserving option for massive, irreparable rotator cuff tears, with favorable short- to midterm improvements in patient-reported outcomes and range of motion.

Level of Evidence: IV, systematic review of level III and IV studies.
Superior Capsular Reconstruction With the Addition of an Acromial Acellular Dermal Allograft Spacer
Justin L. Makovicka, M.D., Karan A. Patel, M.D., and John M. Tokish, M.D.

- Graft thickness and its role as a spacer
- The original description of the autograft was tensor fascia lata
  - folded achieve thickness 8 mm
  - 8-mm graft is superior biomechanically to a 4-mm graft (standard human dermal allograft)
- Remainder of the graft used to resurface the undersurface of the acromion
- Arthroscopic acromial resurfacing
- Effectively doubling the thickness of the spacer function of the graft
- Standard approach to massive irreparable rotator cuff tear Hamada stages 2 and 3.
Massive Rotator Cuff Tears

- MRCT
  - >2 tendons
  - Retraction to glenoid
  - Avascular tears
- Mobilized the cuff
  - AMPLI
- Rip Stop Stitches vs Margin Convergence
- Most MRCR can pulled down to articular edge
- Lateral row to protect the knot
- Minimize gap formation
- PRCR with <1cm gap
- Minimal goal repair ISP SSC
HDAA Technique

- Arthroscopic assessment of MRCT
- Most tears are “L” or “T” shaped
- Pulling the flaps
- Standard cuff mobilization
  - AMPLI
- Most shoulders graft size 2x4cmx3mm thickness
- Passing sutures
- PM passing sutures
  - Horizontal PM to spine
- Middle passing sutures
  - Nevassier
- AM sutures
  - Base of coracoid process
HDAA Technique

- SA decompression
- Acromioplasty
  - Mesenchymal precursor cells in acromial aspirate
- Standard scar and soft tissues releases
- Bursectomy
- Scarify articular edge 5mm medial
- End zone portal
- Marrow vents
- Get biceps out of the way
HDAA Technique

- HAD soaked in saline bath
  - Bacitracin
- General size
  - >2mm thickness
  - 2x3cm
- Lateral stabilizing sutures
- Arthrex #2 Fiberwires
- Arthrex bio/Ti Corkscrews
- Arthrex bio Swivel lock
- Fluffy side down
- Mark medial and lateral edges
HDAA Technique

- Passport or large cannula
  - Currently use 2cm percutaneous portal
- Medial passing sutures passed at corners
- 5mm from graft edge
- Strip sutures
  - Suture saver tubes
- Grip medial edge with grasper and push into the SA space
- Medial sutures are reduced
- Medial sutures tied, post on graft
An OrthoRadiological review of superior capsular reconstruction in the shoulder

Z Al-Ani, P Monga, M Walton, L Funk, S Basu
Skeletal Radiol (2021) 50:267–280

This article will ... review the biomechanical concepts of SCR in improving glenohumeral joint stability and restoring the force couples around the joint. The radiological appearances of the intact graft and the various patterns of graft failure will be illustrated, along with various radiological examples.
Failed Dermal Allograft Procedures for Irreparable Rotator Cuff Tears Can Still Improve Pain and Function: The “Biologic Tuberooplasty Effect”

R Mirzayan, MA Stone, M Batech, DC Acevedo, A Singh,
Ortho J Sports Medicine 2019 Aug 20;7(8)

- Hypothesis: Shoulder pain MRCTs partially due to BOB contact between tuberosity and acromion. Coverage or partial coverage of the tuberosity will act as an interpositional tissue with clinical improvement.
- 2006 - 2016 25 MRCTs underwent a procedure with an ADM
- Postoperative magnetic resonance imaging (MRI) obtained 22 (88%) shoulders
- The type I, intact graft; type II, graft tear with tuberosity covered; and type III, graft tear with tuberosity uncovered (bare).
- Mean 61 yrs (range, 49-73 years); mean FU 25.6 months (range, 10-80 months)
- The graft was torn 59% (13/22 shoulders)
- Type I graft: Significant improvements VAS (7 vs 0.7) ASES scores (32.6 vs 91.2) P < .01
- Type II: VAS (8.1 vs 1.3) ASES scores (26.3 vs 84.6) P < .01
- Type III: No improvement in VAS (7.3 vs 5.7; P ¼ .2) ASES (30.6 vs 37.2) P ¼ .5
- NO Difference in postoperative VAS and ASES (0.7 vs 1.3 and 91.2 vs 84.6, respectively; P ¼ .8) between type I and type II grafts
- Patients with an intact graft or a graft tear leaving the tuberosity covered have lower pain and higher functional scores than those in whom the torn graft leaves the tuberosity uncovered.
HDA Augmentation

- Improved pain, satisfaction, function
- Residual tears
- Persistent tears DO NOT correspond with poor outcomes
- Spacer effects
- Tuberoplasty-Covers the GT
- Improves the moment arm of shoulder elevation
- Head depression
HDA Augmentation

MRI revision MRCR
HDDA with 2nd surg
Interposition HDA

Result at 18 months
VAS 1-2
Improved AFE
Strength 4+/5 ABD
ASES function 52/60
Conclusion

- MRCR repairable 90% of the cases
- SCR/HAD graft cost
  - A-flex-$3,800 3mmx4cmx7cm
- No significant differences between HAD vs FLA
  (Makovicka et al. Superior capsule reconstruction for irreparable rotator cuff tears: A systematic review of biomechanical and clinical outcomes by graft type. JBJS September 2020;29:392-401)
- Greater tuberosity anchors
- Glenoid anchors
- OR time
  - 3 anchor MRCR <45mins
  - HAD > 90mins
  - FLA harvest time
- PRCR varied results
  - > 40% retear at 2 years

Conclusion

- SCR is technically challenging though technically easier than HDAA
- Relatively limited data
  - 15,000 cases
  - <1000 cases in literature
  - Data are relatively short term, most are less than 5 years
- Techniques and graft choices are heterogeneous
  - HAD
  - FLA
  - Synthetics
  - Balloonplasty
- Data supports SCR
  - SCR graft failure (13.9%)
  - Complications (5.6%)
  - Revision surgeries (6.9%)

Conclusion

- **MRCR**
  - 3-4 anchor case, less than 1 hour work
  - Though most MRCR has high retear rates, satisfaction rates still high
  - Most MRCT are in older patients
    - Conversion RTSA
  - Most MRCT can be repaired to articular edge
    - PRCR is reasonable option
    - HDAA for residual deficits

- **SCR**
  - Active with high physical demands
  - Younger than 65’s
  - Goutallier 3-4
  - Hamada < 4
  - Failed attempted primary repair

- **RTSA**
  - Physiologically older than 65
  - Low functional demands
    - Little OHA demands
  - Hamada > 3
  - Severe pain with pseudoparalysis
Conclusion

- Grafts > 3mm lower failure rates
- Grafts > 6mm improves AHD
- Repair graft anterior and posteriorly
  - Improves trampoline effect
  - Protection of remaining cuff
- Solid Humeral Fixations
- 70% failure occurs GT side
- Tuberoplasty effect
  - Consider SCR+