Massive Rotator Cuff Tears: Patch it w/ Dermal Matrix Allograft

Mark H. Getelman, MD

Co-Director
SCOI Sports Medicine Fellowship
Southern California Orthopedic Institute
Van Nuys, CA

Southern California Orthopedic INSTITUTE

Disclosures

- Consultant
  - Depuy Synthes Mitek Sports Medicine
- Director
  - So. California Orthopedic Research and Education
- Fellowship Support
  - Depuy Synthes Mitek Sports Medicine
  - Smith Nephew
  - Ossur Medical
  - DJO
- AANA, Executive BOD, Secretary

Additional Disclosures

The use of Acellular Human Dermal Matrix is considered "on-label" by the US FDA for augmentation and bridging of rotator cuff defects < 1cm.

- The portions of this presentation that describe the use of AHDM to bridge defects > 1cm are *off label*. If a surgeon chooses to use AHDM in this manner the patients should be informed of the FDA status.

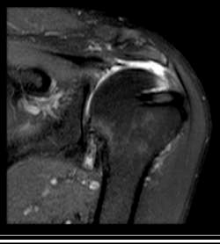
•Special Thanks to Steven J. Snyder, MD for pioneering the concept and sharing his insight

Demonstrative Case

Literature Background

Authors	Re-tear (%)
Liu 1994	70%
Galatz 2004	94%
Boileau 2005	29%
Bishop 2006	47%
Lichtenberg 2006	24%
Cole 2007	22%
Charousset 2007	35%
Ko 2009	21%
Shane 2009	36%

Failed Rotator Cuff Repair!



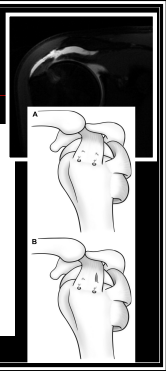
5

What about Medial Failures?

Retear Patterns After Arthroscopic Rotator Cuff Repair

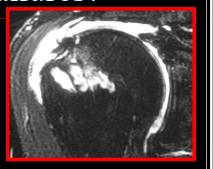
Single-Row Versus Suture Bridge Technique

Nam Su Cho,* MD, Jin Woong Yi,† MD, Bong Gun Lee,* MD, and Yong Girl Rhee,*† MD
*From the *Shoulder & Elbow Clinic, Department of Orthopaedic Surgery, Kyung Hee University School of Medicine, Seoul, Korea, and †Department of Orthopaedic Surgery, Konyang University School of Medicine, Daejeon, Korea*



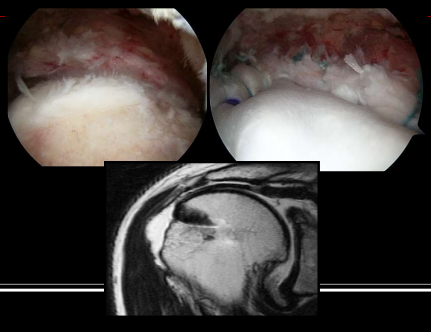
What about Medial Failures?

- Suture Bridge—27 failures
  - 26% Type I 74% Type II
- Single Row—19 Failures
  - 74% Type I 26% Type II



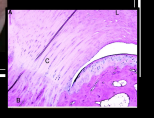
- TYPE II is possibly catastrophic MT failure
- How Do You Revise the Musculotendinous Retear?
  - Debridement and side-to-side or partial repair
  - Allograft patch?

Our Choice: Acellular Human Dermal Matrix

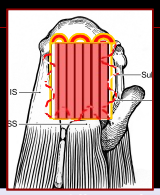


In the US, Allografts have a well accepted, safe and successful history in orthopedics!

ACL Tear



Challenges for a Rotator Cuff Augmentation/Replacement Graft

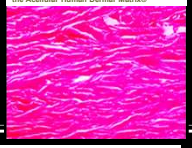


1. The scaffold must rapidly attach to the stump of the native rotator cuff and surrounding tissues
2. Attach firmly to bone
3. Attract and support appropriate cells

Mayo Canine Study

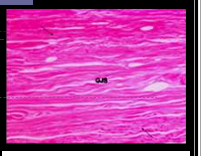
Acellular human dermal matrix

6 Month explant d Huemal Matrix® Scaffold with neotendon formation above and below the Acellular Human Dermal Matrix®

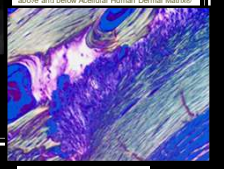


Cellular repopulation

Scott Steinmann



Dense, regularly oriented new tendon formation above and below Acellular Human Dermal Matrix®



Membrane/bone interface

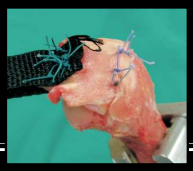
Strength of Human RCR augmented with AHDM

Ultimate Tensile Failure Loads of a Human Dermal Allograft Rotator Cuff Augmentation

Arthroscopy: Vol 24, No 1 (January), 2008: pp 20-24

F. Alan Barber, M.D., Morley A. Herbert, Ph.D., and Michael H. Boothby, M.D.

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)



Systematic Review

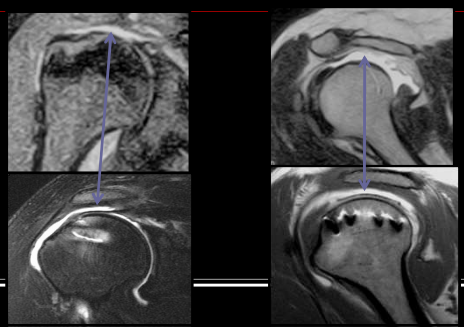
Am J Sports Med. 2016 Nov;44(11):2984-2992. Epub 2016 Feb 4.

Graft Utilization in the Augmentation of Large-to-Massive Rotator Cuff Repairs: A Systematic Review.

Ferguson DP[1], Lewington MR[2], Smith TD[2], Wong IH[3].

CONCLUSION: Augmentation of large-to-massive rotator cuff repairs with human dermal allografts is associated with superior functional and structural outcome when compared with conventional primary repair. Xenograft augmentation failed to demonstrate a statistically significant difference and may be associated with worse rerupture rates and occasional severe inflammatory reactions. Polypropylene patches have initial promising results. Research in this field is limited; future researchers should continue to develop prospective, randomized controlled trials to establish clear recommendations.

SCOI Experience with Bridging of Defects In Massive Non-Repairable Cuff Tears



SCOI Human Acellular Dermal Allograft 7 Year Experience

SST improved
preoperative 6.2 post-op score 11.25 ($p<0.001$)

UCLA improved 14.56 pre-operatively to 29.45 ($p<0.001$).

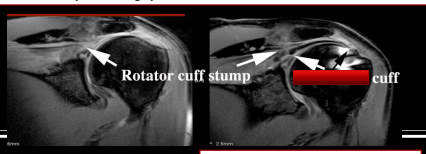
VAS improved 3.3 pre-operatively to 1.02 ($p<0.001$)

Constant scores averaged 76 for patients at the final follow-up.
minimum 2yr and most greater than 3 years follow up

15

SCOI Human Acellular Dermal Allograft
7 Year Experience

These results demonstrate AHDM allograft is a safe reliable option for rotator cuff reconstruction with the vast majority of the reconstructions intact at longer than 2 years and significant improvements in shoulder outcome scores especially pain relief.



16

Systematic Review Bridging!

Graft Utilization in the Bridging Reconstruction of Irreparable Rotator Cuff Tears: A Systematic Review

Matthew R. Lewington, MD, FRCS(C), Devin P. Ferguson, MD, T. Duncan Smith, MD, Robert Burks, MD, Catherine Coady, MD, FRCS(C), Ivan Ho-Bun Wong, MACMMA, MD, FRCS(C), Dip Sports Medicine‡ Show les

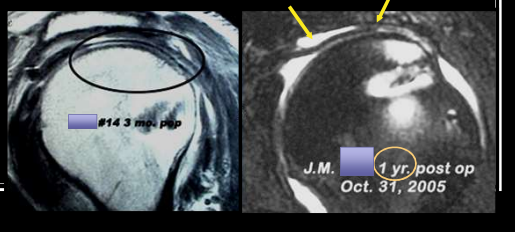
Conclusion:

Using a graft for an anatomic bridging rotator cuff repair results in improved function on objective testing and may be functionally better than nonanatomic or partial repair of large to massive rotator cuff tears. Allograft or xenograft techniques appear to be favorable options, given demonstrated functional improvement, imaging-supported graft survival, and lack of harvest complication risk. More high-quality randomized controlled studies are needed to further assess this technique.

How does the ECM rotator cuff replacement work?

Perhaps

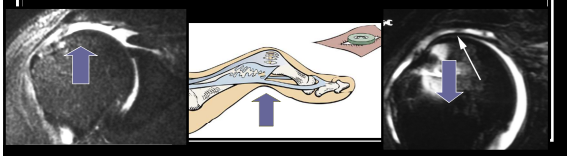
1. It create a smooth *living* interposition membrane between the humeral head and the acromion?



Why does the AHDM rotator cuff replacement work?

Perhaps

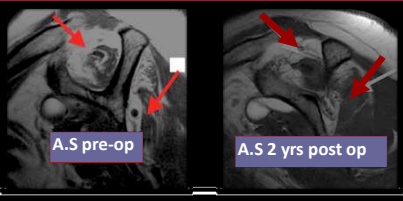
Establish a *force couple* between any remaining anterior and posterior cuff elements giving the *deltoid* better biomechanical advantage? (reduce the boutonnière deformity)



Why does the DMA rotator cuff replacement work?

Perhaps

Connecting any remaining viable supraspinatus and infraspinatus muscle fibers back to the humerus- ***may*** salvage them and prevent more atrophy



20

Conclusion

-We (Barber, Steinman, Deutsch and Toth) have proven that this allograft is safe and appears effective for use as an augmentation or cuff replacement with high patient satisfaction, ***without the morbidity*** of tendon transfer or arthroplasty.

-The procedure does not "*burn any bridges* "for those cases where additional surgery may be required.

- The early success of this procedure warrants further study with more patients, longer follow-up, and *higher levels of evidence-*
- *and also a detailed cost-effectiveness analysis to determine if it comes in under the 50,000$/QALY threshold.*

Meta-Analysis

Orthop J Sports Med. 2016 Dec; 4(12): 2325967116674191. PMCID: PMC5298461
Published online 2016 Dec 15. doi: 10.1177/2325967116674191

Can Grafts Provide Superior Tendon Healing and Clinical Outcomes After Rotator Cuff Repairs?

A Meta-analysis

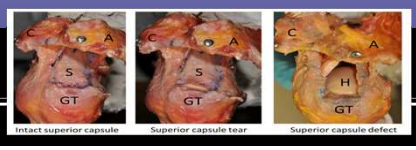
Yohei Ono, MD, PhD,*† Diego Alejandro Dávalos Herrera, MD,‡ Jarret M. Woodmass, MD,* Richard S. Boorman, MD, FRCSC,* Gail M. Thornton, PhD, PEng,*§ and Ian K. Y. Lo, MD, FRCSC*‖

Conclusion:

The use of grafts generally provides superior tendon healing and clinical outcomes compared to repairs without grafts, except for some specific graft types (eg, porcine small intestine submucosa, bovine pericardium). Further investigations are required to determine the benefits of the use of grafts.

Superior Capsular Reconstruction:

The Shoulder Capsule is known to be an important static stabilizer of the joint, esp anteriorly.
With posterior superior RC tears the Superior Capsule can be damaged as well
There is increased superior translation with SC defects Biomechanically

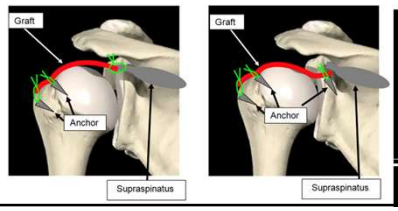


Intact superior capsule | Superior capsule tear | Superior capsule defect

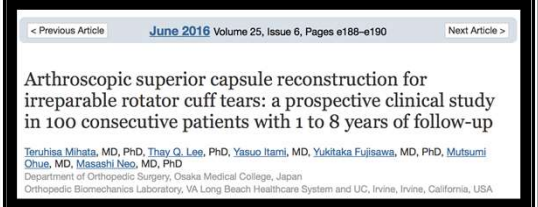
Superior Capsular Reconstruction:Mihata

Clinical Results of Arthroscopic Superior Capsule Reconstruction for Irreparable Rotator Cuff Tears

Teruhisa Mihata, M.D., Ph.D., Thay Q. Lee, Ph.D., Chisato Watanabe, M.D., Ph.D., Kunimoto Fukunishi, M.D., Mutsumi Ohue, M.D., Tomoyuki Tsujimura, M.D., and Mitsuo Kinoshita, M.D., Ph.D.



Clinical Results with the MIHATA Technique are promising



< Previous Article | June 2016 Volume 25, Issue 6, Pages e188–e190 | Next Article >

Arthroscopic superior capsule reconstruction for irreparable rotator cuff tears: a prospective clinical study in 100 consecutive patients with 1 to 8 years of follow-up

Teruhisa Mihata, MD, PhD, Thay Q. Lee, PhD, Yasuo Itami, MD, Yukitaka Fujisawa, MD, PhD, Mutsumi Ohue, MD, Masashi Neo, MD, PhD

Department of Orthopedic Surgery, Osaka Medical College, Japan

Orthopedic Biomechanics Laboratory, VA Long Beach Healthcare System and UC, Irvine, Irvine, California, USA

Time and EBM will tell if the U.S. technique with Dermal Matrix Allograft will mimic the Mihata results for SCR!

Mihata:

Collagen Graft with Fascia Lata
- 4mm graft
- 8 mm graft

4mm graft-decreases SA contact but not distance
8mm graft- decreases SA contact and Sup Translation

Mihata prefers the Autograft FL Graft and besides…Allograft use is NOT allowed in Japan

US Equivalent:

Acellular Dermal Matrix Allograft: 3mm?

4mm graft-decreases SA contact but not distance
8mm graft- decreases SA contact and Sup Translation

The native Capsule DOES NOT insert on the Glenoid Rim?

Which repair is best?

SCR

Bridge

*The **IDEAL** repair for the future…*

How do I decide to best use the DMA:

If there is good quality RC tissue to sew to:

I do an interposition and hope to get some dynamic cuff control and function

If the native RC is medial to the glenoid or poor quality:

I do an SCR and then augment anterior and posterior cuff to the graft tissue

The 3mm issue is concerning…any other option

Excellent Safe Option

It is Nice to get PAID for what you do

SCOI has the world's largest experience on interposition Dating back to 1994---approaching 850 cases!

Since the advent of SCR there have been over 15,000 in the Last 4 years!

The FDA:

Using Acellular Dermal Matrix Allograft is our best option

Off Label for bridging greater than 1cm defect and ON LABEL for Augmentation

On Label for Capsulloraphy & there is a CPT code!

Ultimately, this may become the real reason that SCR *TRUMPS* interposition in the long run…

Could be HUGE for SCR…