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**Sidney Kimmel  
Medical College**  
at Thomas Jefferson University

## Pro: Balloon



**Joseph A. Abboud, M.D.**  
**Professor of Shoulder and Elbow Surgery**  
**Thomas Jefferson University**



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- I am **not Financially Conflicted**. Receive no consulting or Royalties on this product
- Was a IDE sight



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# Formidable Opponent

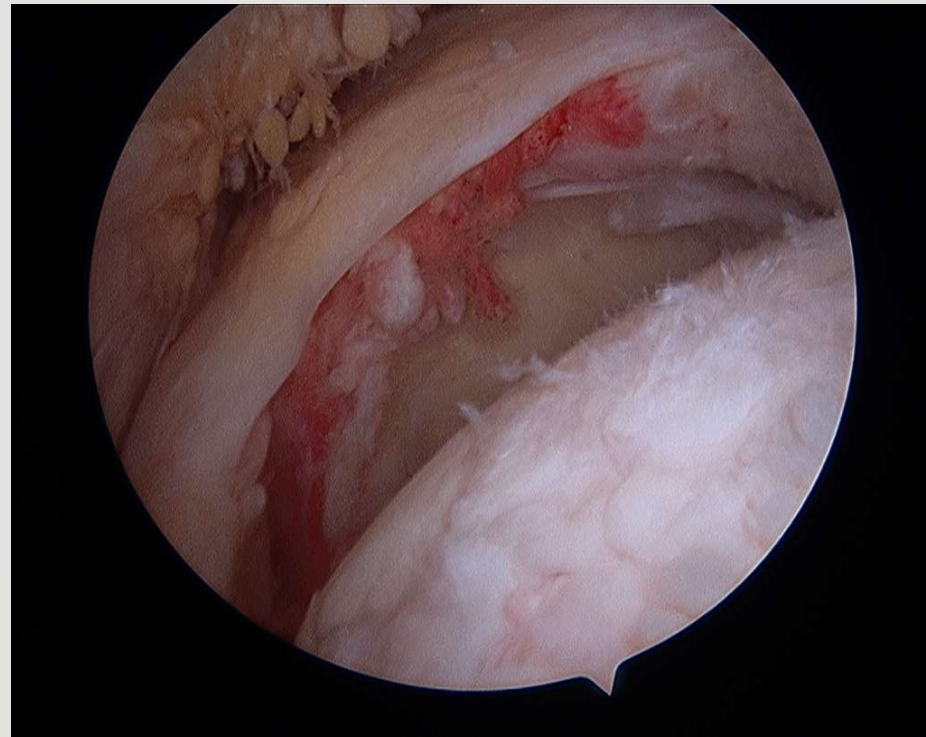


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# Problem?



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Let's go Head to Head!!!!

**SCR**

**Balloon Arthroplasty**



# Goal with Procedures

- Permanent Solution

SCR	TT	Partial repair	Balloon
NO	NO	NO	NO



- Can Be Converted to Another Solution Easily



SCR	TT	Partial repair	Balloon
Yes	Maybe	Yes	Yes

- Easy to Implant

SCR	TT	Partial repair	Balloon
NO	NO	NO	YES



- Easy to Remove



SCR	TT	Partial repair	Balloon
NO	NO	NO	YES



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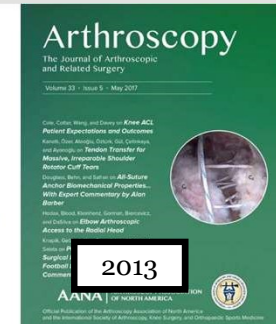
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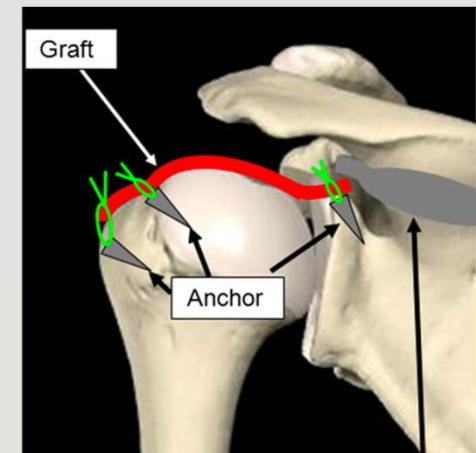
# Superior Capsular Reconstruction w/Fascia Lata

## 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.



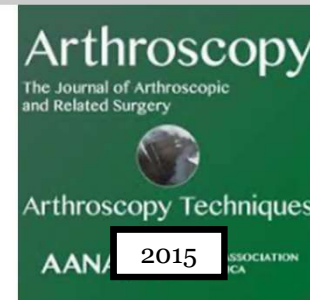
- Retrospective 24 shoulders w/irreparable cuff tears
  - Included: irreparable tears
  - Excluded: Hamada V, severe superior migration, deltoid dysfunction
- Harvested 6-8 mm fascia lata
- Results: **83.3% had no graft tears @** mean 34 months
- **ROM & ASES improved significantly**



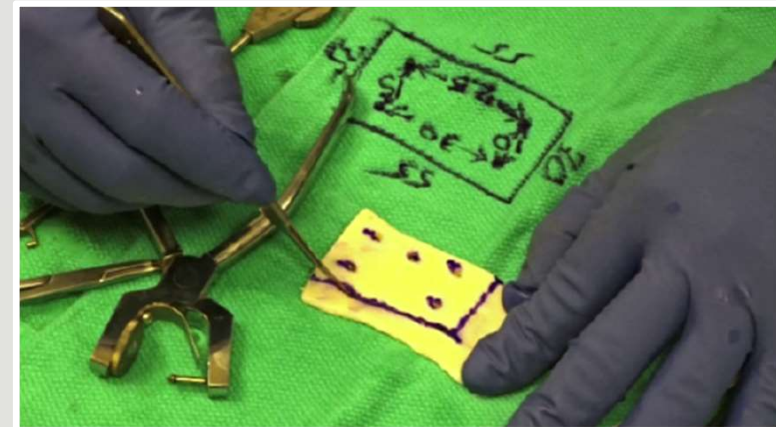
# SCR w/Dermal Allograft

## Arthroscopic Superior Capsular Reconstruction for Treatment of Massive Irreparable Rotator Cuff Tears

Alan M. Hirahara, M.D., F.R.C.S.C., and Christopher R. Adams, M.D.



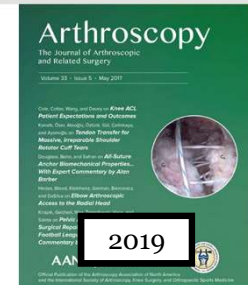
- Described dermal allograft technique
  - **3.5m thick (1/2 thickness Fascia lata)**
- Advantages described:
  - Avoid harvesting autograft
  - Allows faster mobilization
  - More accurate measurement & graft placement



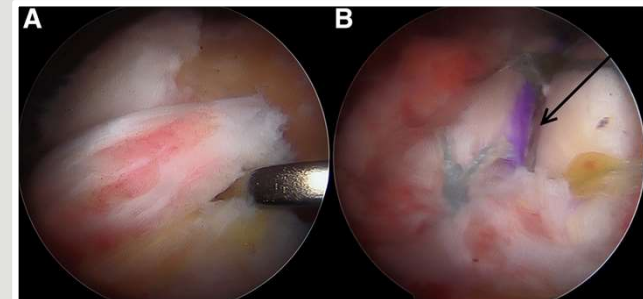
# Good Outcomes Preserved for Some

## Superior Capsular Reconstruction for the Operatively Irreparable Rotator Cuff Tear: Clinical Outcomes Are Maintained 2 Years After Surgery

Stephen S. Burkhart, M.D., Joel J. Prankun, D.O., and Robert U. Hartzler, M.D., M.S.



- Retrospective review 41 patients @ mean 34 months
- Conservative rehab protocol
  - 6 wks sling, Active Overhead motion @ 4 months
- Results: improved ASES scores
- 85% grafts healed for 26 patients who obtained MRI
- 5% revisions, 14% failures



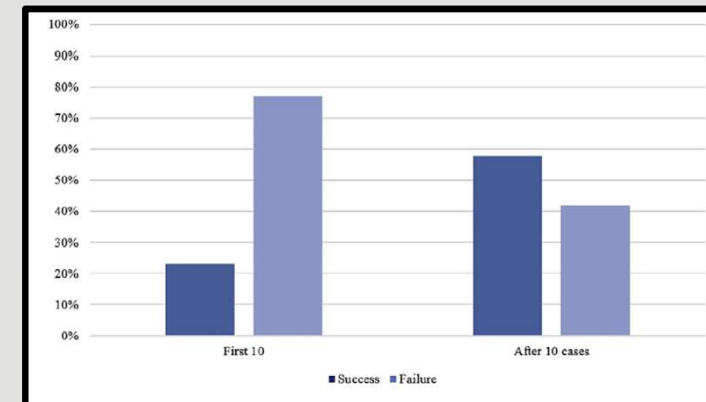
# SCR: Not All Good Outcomes

## Superior capsule reconstruction using dermal allograft: early outcomes and survival

Jarret M. Woodmass, MD, FRCSC<sup>a,1</sup>, Eric R. Wagner, MD<sup>b,1</sup>, Kyle A. Borque, MD<sup>c</sup>,  
Michelle J. Chang, BS<sup>c</sup>, Kathryn M. Welp, MS<sup>c</sup>, Jon J.P. Warner, MD<sup>c,\*</sup>



- 34 pts w/SCR
- Minimum 6 month FU
- Results: 22 patients identified as failures (65%)
  - 8 reoperations
  - 14 clinical failures (pain & lack of function)
- Risk Factors for Failure:
  - Revision cases, Female gender, increased fatty infiltration, **low surgeon volume (n<10)**



# Balloon Arthroplasty

- Device currently available in Europe for patients with massive irreparable rotator cuff tears, without arthritis and with preserved passive ROM.
- Material: biodegradable polymer of (PLA and epsilon-caprolactone)
- FDA IDE in USA Underway; Enrollment completed



Subacromial Biodegradable Spacer



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# Expanding Indications in OVS

- Massive irreparable tear with Subscap involvement
- Double balloon insertion
- Repairable cuff repair, with balloon augment
- Dare I say some may be doing it for repairable tears that they do not feel like fixing.....Oooops. Probably not PC to say
  - But hey if you become a hammer every cuff repair may become a nail



# Commercial Experience: Europe



>20,000 COMMERCIAL  
CASES SINCE DEVICE  
LAUNCH IN 2010 (~7000  
CASES IN 2018)



INCREASING FOLLOW UP  
DATA BEING COLLECTED  
PATIENTS WITH VARIOUS  
FU DATA BETWEEN 6  
MONTHS AND 5 YEARS



Expanding  
Number of  
Publications  
on European  
Experience

## Peer-reviewed publications



**“The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: a prospective study with 5-year follow-up”,**  
V. [Senekovich](#), Arthroscopy and Sports Medicine



**“Sub acromial spacer implantation for massive rotator cuff tears, Clinical outcome of arthroscopically treated patients”,**  
Jens D. [Agneskirchner](#)’s, [Obere Extremitat](#)



**“Fluoroscopy-guided biodegradable spacer implantation using local anesthesia: safety and efficacy study in patients with massive rotator cuff tears”,**  
E. [Gervasi](#), Musculoskeletal Surgery



**“Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears”,**  
V. [Senekovich](#), [Eur J Orthop Surg Traumatology](#)

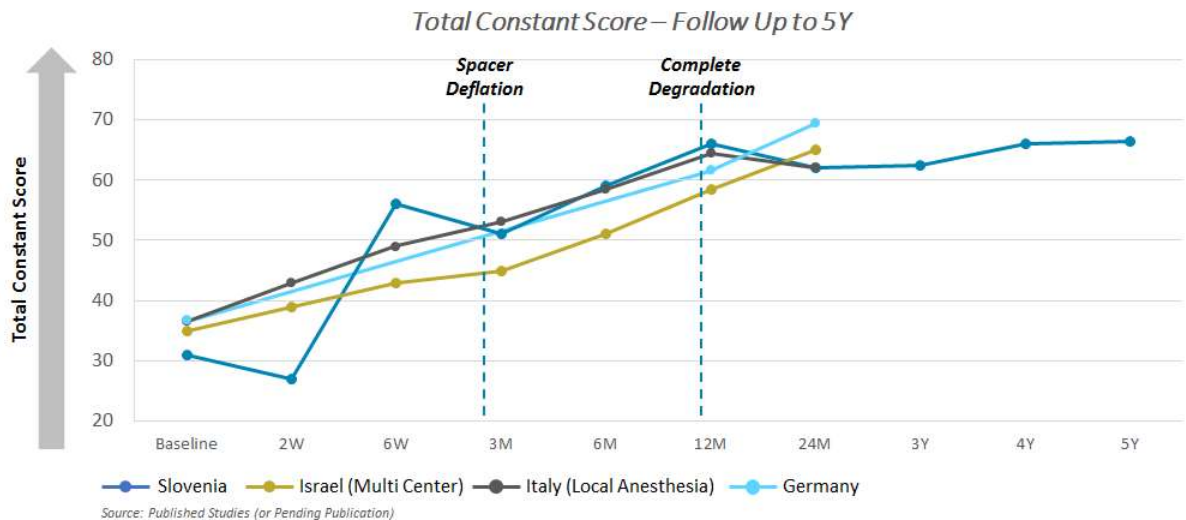
# European Clinical Studies

## Summary of Clinical Studies Scope

- 124 patients studied in 8 centers through 4 studies
- 3 studies have been published
- Study endpoints were safety and efficacy as measured by Total Constant Score (TCS) which considers pain, functional assessment, range of motion, and strength parameters

## Results Highlight High Efficacy of InSpace

- >80% of patients in clinical study saw an improvement in their TCS
- Studies followed patients for up to 5 years
- Patients experienced long term improvement in all parameters



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# Cadaveric Biomechanical Data Increasing

[J Bone Joint Surg Am.](#) 2019 Jun 5;101(11):e49. doi: 10.2106/JBJS.18.00850.

## **Biomechanics of Biodegradable Subacromial Balloon Spacer for Irreparable Superior Rotator Cuff Tears: Study of a Cadaveric Model.**

[Lobao MH](#)<sup>1</sup>, [Canham RB](#)<sup>1</sup>, [Melvani RT](#)<sup>1</sup>, [Abboud JA](#)<sup>2</sup>, [Parks BG](#)<sup>1</sup>, [Murthi AM](#)<sup>1</sup>.

### **Author information**

- 1 Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, Baltimore, Maryland.
- 2 Rothman Institute, Philadelphia, Pennsylvania.

[J Shoulder Elbow Surg.](#) 2019 Oct;28(10):1841-1847. doi: 10.1016/j.jse.2019.03.036. Epub 2019 Jul 2.

## **The effect of the subacromial balloon spacer on humeral head translation in the treatment of massive, irreparable rotator cuff tears: a biomechanical assessment.**

[Singh S](#)<sup>1</sup>, [Reeves J](#)<sup>1</sup>, [Langohr GDG](#)<sup>1</sup>, [Johnson JA](#)<sup>1</sup>, [Athwal GS](#)<sup>2</sup>.

### **Author information**

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- 2 Roth McFarlane Hand and Upper Limb Centre, St. Joseph's Health Care London, London, ON, Canada. Electronic address: [gathwal@uwo.ca](mailto:gathwal@uwo.ca).

[Arthroscopy.](#) 2019 Feb;35(2):382-389. doi: 10.1016/j.arthro.2018.09.016. Epub 2018 Dec 4.

## **The Subacromial Balloon Spacer Versus Superior Capsular Reconstruction in the Treatment of Irreparable Rotator Cuff Tears: A Biomechanical Assessment.**

[Singh S](#)<sup>1</sup>, [Reeves J](#)<sup>1</sup>, [Langohr GDG](#)<sup>1</sup>, [Johnson JA](#)<sup>1</sup>, [Athwal GS](#)<sup>2</sup>.

### **Author information**

- 1 Hand and Upper Limb Centre, University of Western Ontario, London, Ontario, Canada.
- 2 Hand and Upper Limb Centre, University of Western Ontario, London, Ontario, Canada. Electronic address: [gathwal@uwo.ca](mailto:gathwal@uwo.ca).

# Cost Analysis

- Expected-value decision analytic model to compare estimated 24-month outcomes associated with management of IRCT in terms of cost per quality-adjusted life years (QALYs) gained

## Comparative cost-effectiveness analysis of the subacromial spacer for irreparable and massive rotator cuff tears

Alessandro Castagna<sup>1</sup> · Raffaele Garofalo<sup>2</sup> · Eran Maman<sup>3</sup> · Alisha C. Gray<sup>4</sup> · Elizabeth A. Brooks<sup>4</sup>

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# Decision Algorithm

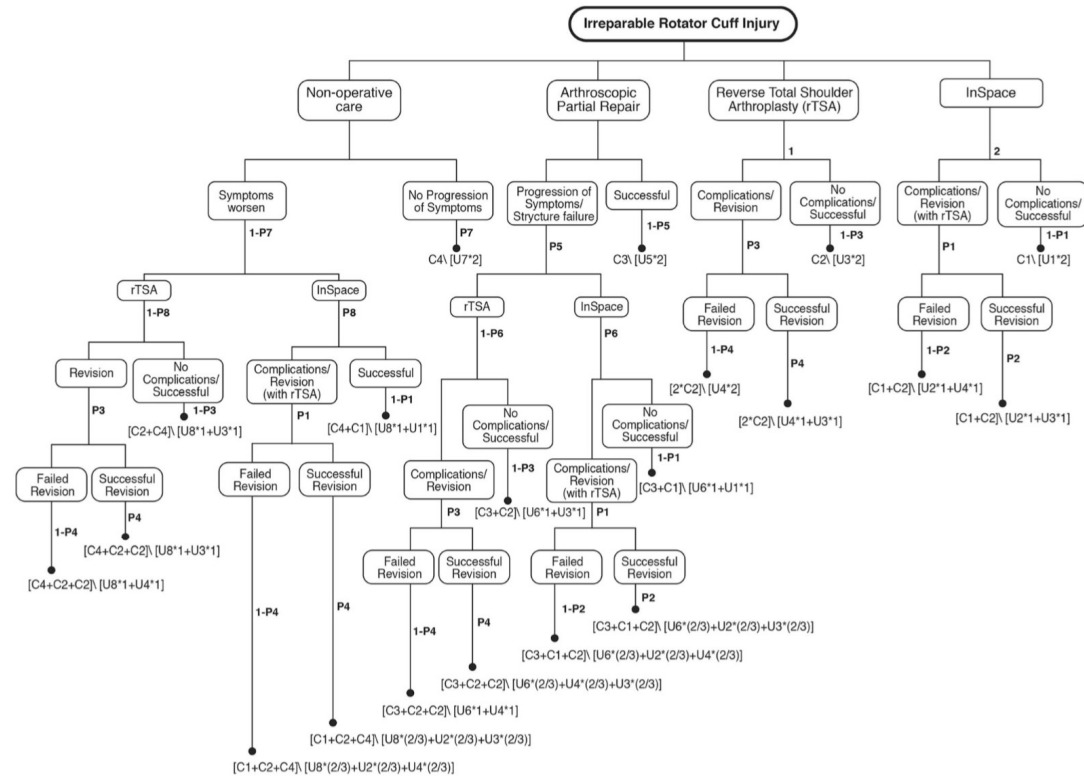
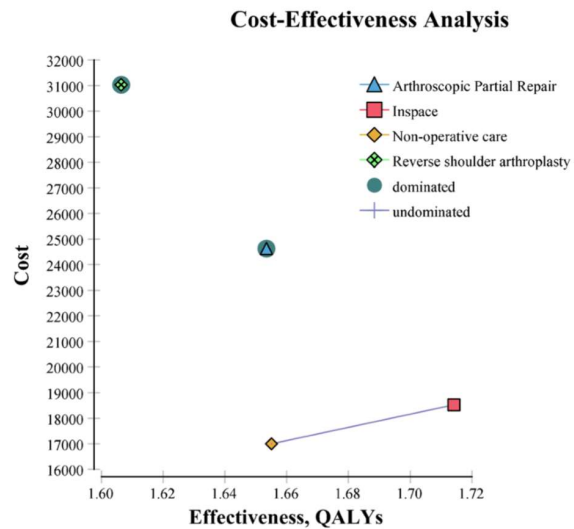


Fig. 2 Model structure—treatment alternatives for irreparable rotator cuff tear



**Fig. 3** Graph of base case cost-effectiveness analysis. The four competing treatment strategies with model parameters set at the base case scenario (QALYs, quality-adjusted life years)

**Table 2** Base case cost-effectiveness analysis

Management strategy	Total expected per patient cost (€)	Total expected QALYs
Non-operative care	16,805	1.33
InSpace™	17,327	1.38
Arthroscopic partial rotator cuff repair	24,312	1.32
Reverse shoulder arthroplasty	31,031	1.28

# Cost Effectiveness

# Results

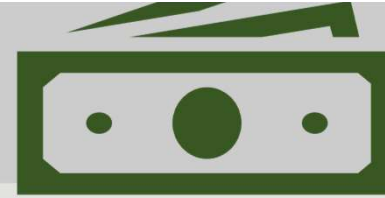
- Deranlot et al. published series on **37 patients** who underwent subacromial balloon spacer placement with minimum of 1 year of follow up (average, 33 months)
- Findings:
  - Both ROM and Constant scores demonstrated **significant improvement**.
    - Mean Constant scores improved from 44.8 to 76.0
- Radiographic examination demonstrated an average decrease of acromiohumeral interval from 8.2mm to 6.2mm, but no apparent functional impact on patient outcomes.
- **86%** of patients showed **no progression of their arthritis** on Hamada classification scale .
  - Deranlot J, Herisson O, Nourissat G, et al: Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: clinical and radiographic results in 39 retrospective cases. Arthroscopy 33(9): 1639-44, 2017.





# Benefits

- Ease and safety of surgical technique –
- Shortened operative time – studies found that that placement of device required only 2 to 30 minutes with two of the studies stating an average of **10 minutes**.
  - Senekovic V, Poberaj B, Kovacic L, et al: Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears. Eur J Orthop Surg Traumatol 23(3): 311-316, 2013.
- As the learning curve improves, required operative time becomes less
- My experience has been very similar

# COST ??????





## • Implant Cost

- SCR ~ Beaucoup Bucks 
- Balloon – Unknown 



## • Learning Curve

- SCR..... Long 
- Balloon .....Short 

## • OR Time

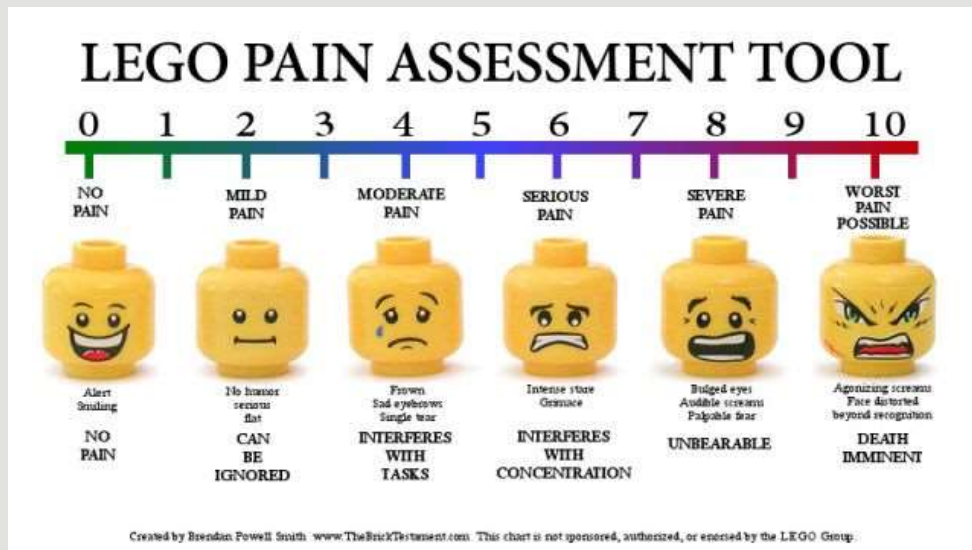
- SCR.....Long 
- Balloon.....Short 

## • Post op immobilization, Duration of PT, RTW

- SCR..... Long 
- Balloon.....Short 



# Pain and Risk to Patient ????



"The patient in the next bed is highly infectious. Thank God for these curtains."

# Representative Case Presentation

- 63 yo RHD mason with history of right rotator cuff tear treated operatively 3 years previously.
- Increasing pain over past 6 months.
- Pain with overhead activity, fatigability, disruption of sleep.
- Short-term improvement with cortisone injections (x 3).



# Examination

- Ht: 5'9" Wt: 175 lbs. BMI: 25.5
- Atrophy of supraspinatus fossa
- ROM:
  - FE: 90 active, 160 passive
  - Abd: 80 active, 110 passive
  - ER: 20 active, 40 passive
  - IR: L5
- + Jobe, + impingement signs



# Xrays

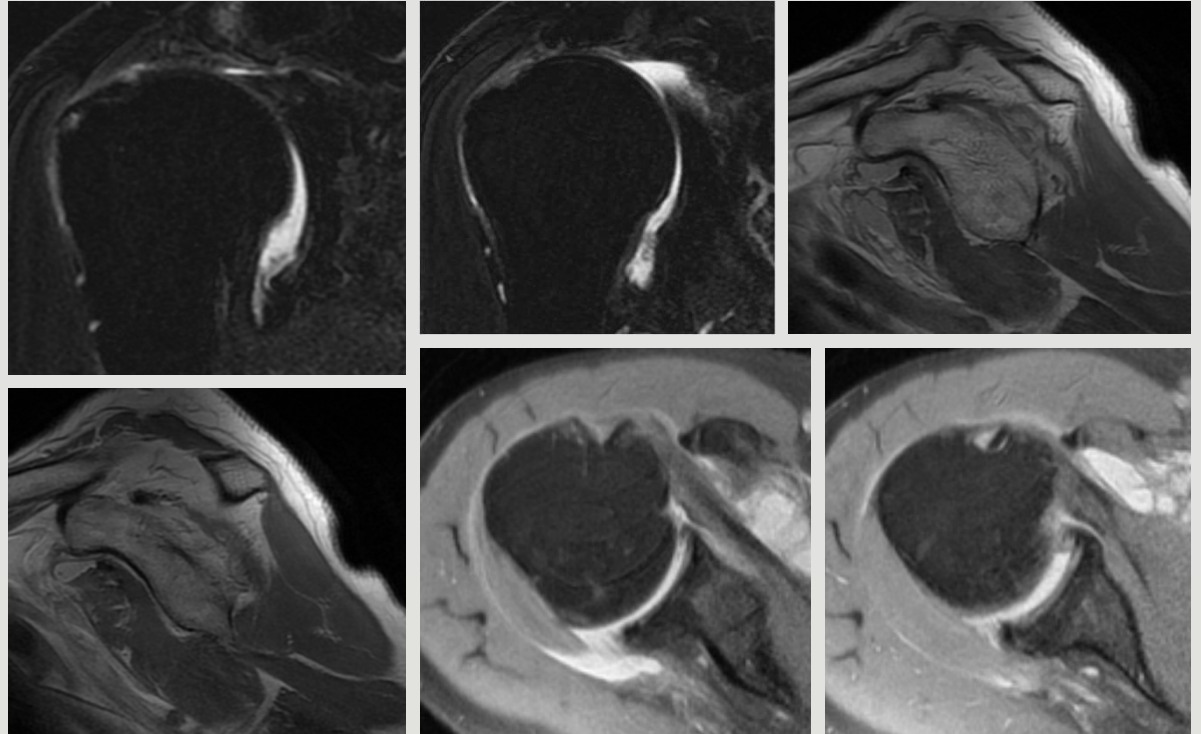


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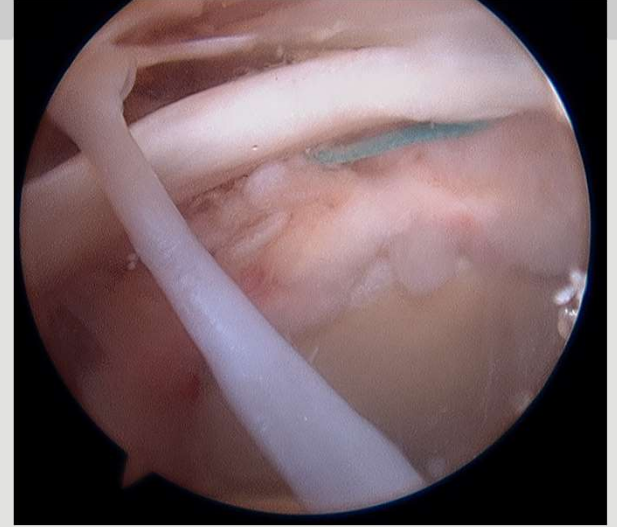
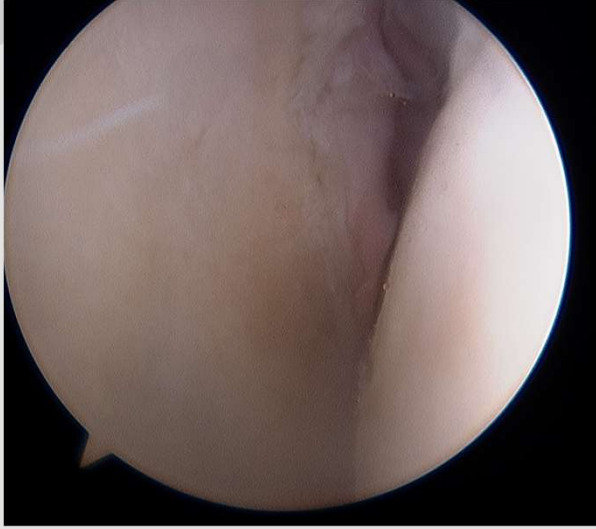
# MRI



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# Case photos

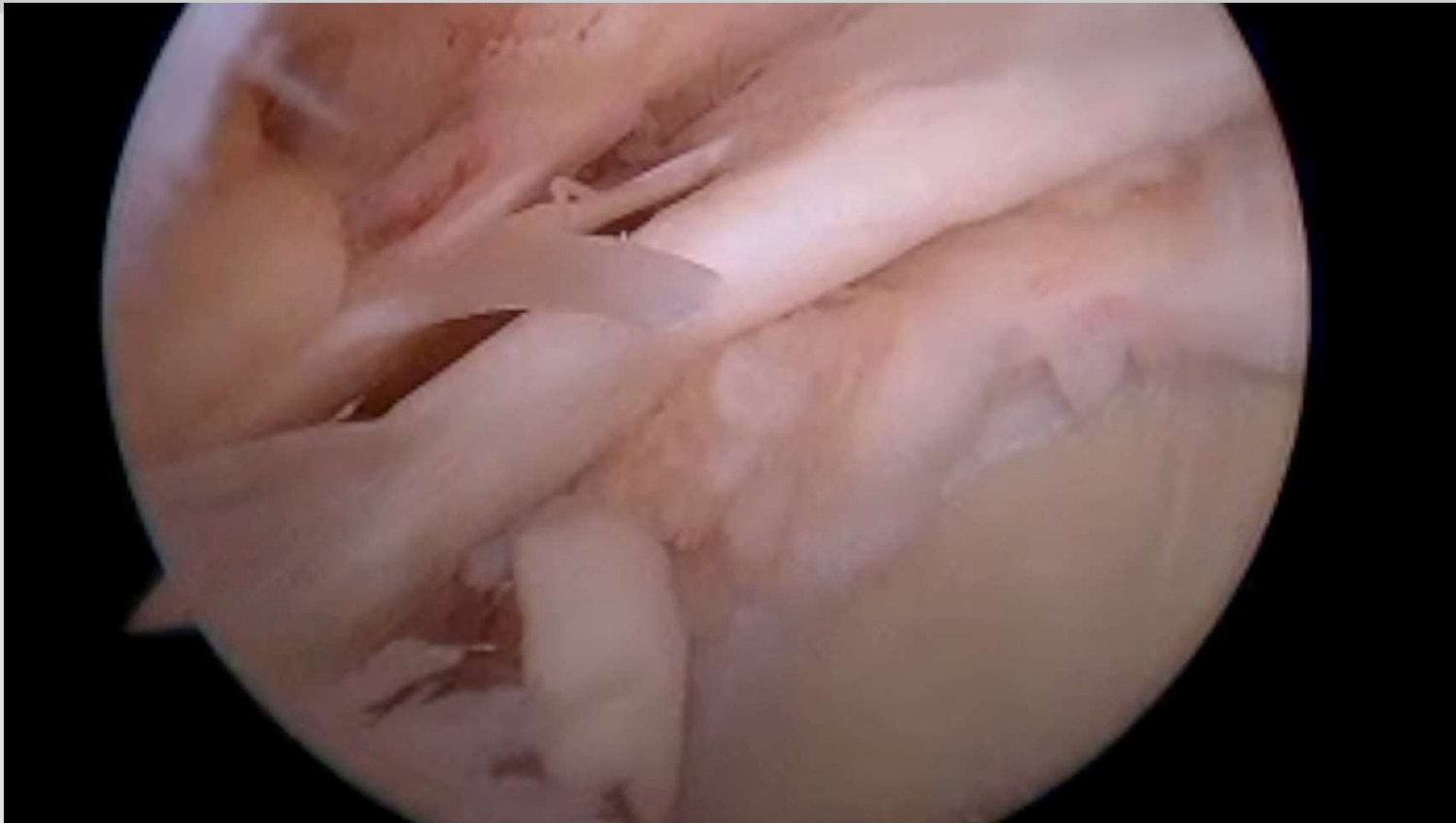


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# Case video



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# Post-Op Xray

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## Fluoro after Contrast Injected in Balloon: Dynamic Visualization



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# Patient 2 weeks Postop



Impressed???



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# So What do You Prefer?



**SIMPLE**



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Await Results of SCR  
Randomized Prospective 2  
year Outcome Study with  
MRI follow up!!!!





THANK YOU.



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