Irreparable Cuff Tear - new treatment modality

Eran Maman MD

Director of the Shoulder Unit
Tel-Aviv Sourasky Medical Center
Sackler Faculty of Medicine,
Tel-Aviv University
Tel-Aviv Israel
disclosure

- Orthospace: consultant stock Options
Definition of Irreperable Tear

Size?
Definition of Irreperable Tear

Size?

Patient’s age/condition?
Definition of Irreperable Tear

Size?

Patient’s age/condition?

Muscle condition (fatty degeneration/atrophy)?
Definition of Irreperable Tear

Size?

Patient’s age/condition?

Muscle condition (fatty degeneration/atrophy)?

Bone condition?
Definition of Irreperable Tear

Size?

Patient’s age/condition?

Muscle condition (fatty degeneration/atrophy)?

Bone condition?

Duration?
Definition of Irreperable Tear

Surgeon’s skills? / technique?
In theory

- Nearly all cuff tear can be repaired
- Not all should be repaired
Conclusion:
- Nearly all tear can be repaired with proper techniques
  - Gotelier?? - 100% atrophy should be the only reason not to attempt repair

Conclusion: Irreparable
Arsenal

- **Non Surgical:**
  - Physiotherapy
  - NSAID
  - Steroids
  - Analgesics
  - Skillful neglect
Arsenal

- **Surgical:**
  - Debridement (LHB Tenotomy, Tuberoplasty)
  - Partial Repair
  - Patches
  - Deltoid flap
  - Tendon transfer
  - Superior Capsule Reconstruction
  - Reversed TSR
  - Inspace
• **Surgical:**

  - **Debridement** (LHB Tenotomy, Tuberoablasty)
  - Partial Repair
  - Patches
  - Deltoid flap
  - Tendon transfer
  - Superior Capsule Reconstruction
  - Reversed TSR/Hemiarthroplasty
  - **Inspace**
Debridement

• Verhelst L. et al:

39 irreparable cuff tears
32 shoulders (age 69.9 +/- 7.3 years) (male/female ratio: 11/22)
mean follow-up of 38 months (21 - 52) Constant-Murley score (CMS) improved from 34.9% +/- 11.6 to 84.0% +/- 11.6 (p < 0.0001).

Debridement

Liem D et al.:

31 patients (mean age, 70.6 years)
mean 47 months (24 - 69 months)
mean ASES score was significantly improved from 24.0 to 69.8 points
Scores for pain 7.8 to 2.9 Points

Liem D. Arthroscopic debridement of massive irreparable rotator cuff tears Arthroscopy. 2008 Jul;24(7):743-8
Debridement

Boileau, JBJS 2007:

- 68 patients – 78% satisfied
- Healthy T. minor better results
- Pseudoparalysis and DJD – Contra Indication
Arsenal

- Surgical:
  - Debridement (LHB Tenotomy, Tuberoplasty)
  - Partial Repair
  - Patches
  - Deltoid flap
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  - Reversed TSR/Hemiarthroplasty
  - Inspace
Partial Repair


• Iagulli, Field, Hobgood, Ramsey, Savoie
  Comparison of partial versus complete arthroscopic repair of massive rotator cuff tears. AJSM 2012.
  - significant improvement in both groups
  - no differences in postop. Between the 2

• Porcellini JSES 2011 CS 44-73
Surgical:

- Debridement (LHB Tenotomy, Tuberoplasty)
- Partial Repair
- Patches
- Deltoid flap
- Tendon transfer

Superior Capsule Reconstruction
- Reversed TSR/Hemiarthroplasty
- Inspace
Patches

- Augmentations

1. Autograft
2. Allograft
3. Xenograft
4. Synthetic materials
Tendon Augmentation / substitute background

• tendon substitutes are limited in availability and holds high complication rate (Comley 1999, Wang 2007)

• several RC repair patches (tensile strength: 11.9 – 32.7 MPa) (Chaudhury 2011), have a reported graft failure rate of 20% to 60% (Walton 2007, Badhe 2008, Chaudhury 2011, Downie 2012)
Tendon Augmentation / substitute background

• complete healing is rarely achieved

(Rodeo 2007).
R.C Patch Augmentation

• Define the problem:
  - A hole we need to “fill”
  - Bad tissue we need to augment
Commercial ECM (extra cellular Matrix) scaffolds:

- Most influence properties of delivered product:
  - Source (dermis/small intestine submucosa)
  - Species (human, porcine, or bovine)
  - Donors age (fetal or adult)
  - Processing

Derwin KA, Baker AR, Spragg RK, Leigh DR, Iannotti JP. JBJS. 2006
Human Tendon Cell Response to 7 ECM (extracellular Matrix): in vivo study

- GraftJacket
- Conexa
- Collagen Repair Patch
- Fascia Lata
- OrthADAPT
- Restore
- SportMesh

Shea et al  Arthroscopy 2010
Human Tendon Cell Response to 7 ECM: in vivo study

• Human Tenocytes react most favorably to dermal ECM–GraftJacket & Conexa (tenocytes actually attached)

Shea et al  Arthroscopy 2010
Synthetic Augmentation:

- 10 SSP tears - RCR augmented with a polycarbonate polyurethane patch
- significant improvements in VAS, SST (Simple Shoulder Test), ASES, UCLA - 6 & 12 months PO
- MRI at 12 months - healing in 90%
- no adverse events associated with the patch

Encalada-Diaz I, Cole BJ, Macgillivray JD, Ruiz-Suarez M, Kercher JS, Friel NA, Valero-Gonzalez F JSEJ 2011
Arsenal

• Surgical:
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The InSpace
The InSpace

- biodegradable spacer ((Poly L-lactide-co-ε-caprolactone - widely used biodegradable material/polymer)
- >6,000 patients all over
- >5 years follow-up
Science
## Users and Publications

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<th>User/s (Surgeon/s)</th>
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<th>Publication</th>
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<tr>
<td>Laurent Lafosse</td>
<td>France</td>
<td>Subacromial Spacer Placement for Protection of Rotator Cuff Repair</td>
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<tr>
<td>Martyn Snow</td>
<td>UK</td>
<td>Arthroscopic treatment options for irreparable rotator cuff tears of the shoulder</td>
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<tr>
<td>Donato Rosa</td>
<td>Italy</td>
<td>Treatment of massive irreparable rotator cuff tears through biodegradable subacromial InSpace Balloon</td>
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<td>Vladimir Senekovic; Boris Poberaj</td>
<td>Slovenia</td>
<td>Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears</td>
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<td>Eugenio Savarese; Rocco Romeo</td>
<td>Italy</td>
<td>New Solution for Massive, Irreparable Rotator Cuff Tears: The Subacromial “Biodegradable Spacer”</td>
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<td>Enrico Gervasi</td>
<td>Italy</td>
<td>Fluoroscopy-Guided Implantation of Subacromial “Biodegradable Spacer” Using Local Anesthesia in Patients With Irreparable Rotator Cuff Tear</td>
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<tr>
<td>Leslie Naggar</td>
<td>Switzerland</td>
<td>ESSKA, 2014</td>
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<td>Bijayendra Singh</td>
<td>UK</td>
<td>Bess, 2014</td>
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<td>Jens Agneskirchner</td>
<td>Germany</td>
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<td>Annecy, 2015</td>
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Spacer in treatment of massive irreparable rotator cuff tears

• objective: safety & performance of the InSpace

• Inclusion criteria:
  ◦ Massive Irreperable RCT
  ◦ pain and functional disability > 6 months
  ◦ Failed conservative treatment

Vladimir Senekovic · Boris Poberaj · Ladislav Kovacic Martin Mikek · Eliyahu Adar · Assaf Dekel
* Single-center: University Medical Center, Ljubljana
Clinical Data

- A prospective study to assess safety and performance
- 2008 on- 5Y follow-up
- 24 subjects, mean age 69Y
- 20 irreparable RCT, 2 PTT (not repaired), 2 Massive RCT (underwent partial repair)
Safety results

- **no** device related adverse effects, no abnormal blood findings

- **US** - no significant implant dislocation was noted at 3m

- **MRI (3Y PO)** - no significant findings, no bone or cyst formation
Total Constant Score up to 4 Y post op
TCS 5Y Post OP

TCS: Total Constant Score

Baseline
1 w 3 w 6 w 3 m 6 m 1.5Y 3Y 4Y 5Y

Spacer deflation

Complete degradation

34.36 34.77 38.46 42.86 44.64 50.85 58.45 62.14 66.19 66.39
TCS: Total Constant Score; ADL: Activity of Daily Living; ROM: Range Of Motion
SUB-ACROMIAL BIODEGRADABLE BALLOON USE IN MASSIVE ROTATOR CUFF TEAR: PRELIMINARY RESULTS OF MULTI-CENTER STUDY

Maman Eran, Aadar Eli, Dekel Assaf, Bernstein Michael, Vellex Stiven, Auton Ehud, Rak Ofer, Mozes Gavriel

Israel
The Israeli Multi-Center Study

Study Objectives:
safety & efficacy of InSpace in Massive IRCT

Study Design:
– One-arm, Non- Randomized, Multi-center Study
– Efficacy - Constant score:
  - pre-surgery
  - 2 weeks, 6 weeks, 3/6/12/24 months
The Israeli Multi-Center Study

– 58 subjects in 5 clinical sites (49 eligible for analysis, mean age 68Y)

– 48 in arthroscopic approach; 10 fluoroscopy guided under local anesthesia

– FU period: 6m (46 pts.) ; 12m (46 pts.) ; 24m (13 pts.)
Mean Change in TCS From Baseline up to 2Y
Constant variables up to 2Y Post OP

% TCS
% Pain
% ADL
% ROM
% Power

TCS: Total Constant Score; ADL: Activity of Daily Living; ROM: Range Of Motion

48/55 (87%) improved in TCS (4: no change, 3: deteriorated)
43/55 (81%) improved in ROM (6: no change, 6: deteriorated)
46/55 (83%) improved in Pain (4: no change, 5: deteriorated)
Safety Results

2 Serious AEs

Inflammatory reaction required device explanation

Pain - suspected infection (Antibiotic)

- dislocation (Diprosan inj.)

Other Events

were mild and resolved following observation or pharmaceutical treatment and included:

- Pain
- Synovitis
- Local Swelling
- 1 Deterioration in shoulder function R-TSA ~ a year post implantation
Inspace
my 5-6 years experience
How exactly does it work?
I am not sure

- Artificial Bursa?? 2 revisions-50% bursa
- Improve deltoid function
- Improve rehab by lowering pain

Bringing back the shoulder to a “non painful, deltoid functioning, massive cuff tear”
Is the debridement or LHB procedure is the issue?

- In our study some of the patients already had no LHB and still improved
Clinical Indication / patient selection

- Irreparable Rotator Cuff tear:
  - Tissue quality: Muscle fatty infiltration/poor tendon
  - Tear size
  - Biological age?

- Patients selection:
  – Inability to undergo RCR
  – Reluctant of long rehab and pain

– The Ideal- FROM painful non arthritic irreparable cuff tear
Which Patient Do Not Fit

- Evidence of OA or cartilage damage

- GH instability

- Patients who had major joint trauma, infections or necrosis of the shoulder
What to expect?

- Pain will improve already at 6 weeks and will continue to improve until 4 months when devise deflate.
- 2 weeks after deflation will improve again
- Some patients need 4-6 months to ease the pain
- Some will improve immediately

In rare case pain will be un tolerable
Conclusions

• Easy to Manage/ Straightforward Procedure (~10 min to insert and inflate)
• Relatively Quick Pain Reduction
• Significant improvement in TCS (> 15 points) in 78% of patients at 1 and 2Y post-op
• Low Risk : Mild and easy to manage AEs (<4%)
Mail: eemaman@gmail.com

Shoulder Unit
Tel-Aviv Sourasky Medical Center
Sackler Faculty of Medicine,
Tel-Aviv University
Tel-Aviv Israel