Early Healing Following Pre-operative Trephination: Results from a Randomized Controlled Trial

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• There are no relevant disclosures to report
Rotator Cuff Tears

• Most common cause of shoulder pain
  • 30% incidence > 60 years of age, 50% incidence > 80 years

• Failure of the repair is the most common reported complication
  • 20% - 40% re-tear rate reported

• Biologic approaches to improve healing rates
  • Expensive
  • Labour intensive
  • No clear benefit
Healing

- Rotator cuff repair healing results in “scar” fibrocartilage formation rather than cell regeneration. Causes may include:
  - Insufficient gene expression
  - Insufficient numbers of undifferentiated cells
  - Excessive tendon loads
  - Inadequate cell differentiation

- Literature suggests that improved structural integrity of the rotator cuff lowers the re-tear rate
Mesenchymal Cells

- Mesenchymal cells (MSCs)
  - Shown to have regenerative potential
  - Important role in re-establishment of tendon-bone healing and restoration of the enthesis of the rotator cuff tendon

- Trephination
  - Jo et al (2010, 2013) showed that creating small channels under the supraspinatus footprint to access the red bone marrow improves the structural integrity and lowered the re-tear rate
MRI mapping slide

• Tendon structure
  • Consists of cross-linked triple helices of type I collagen/elastin, water/proteoglycans and extracellular matrix
  • Degenerative tendons have more disordered collagen with an increase in water content

• T2 mapping
  • MRI imaging that assesses collagen content as a surrogate for tendon enthesis healing
Do patients who undergo a repair of the rotator cuff with adjunctive, pre-operative bone trephination have a difference in early healing as measured by T2 quantitative MRI at 6 weeks postoperatively?

**HYPOTHESIS:** Pre-operative bone trephination will allow for an increased early healing reaction on T2 MRI mapping within the supraspinatus enthesis
Secondary Objectives

• Secondary Objective
  • Collagen and water content via 3-T T2 MRI mapping in 6 other regions including
    • Proximal tendon
    • Sub-enthesial bone
    • Humeral head (lateral and medial)
    • Supraspinatus muscle
    • Infraspinatus enthesis
Inclusion Criteria

• Age 18 and older
• Full thickness supraspinatus tears
• Failed 6 months of conservative treatment
Exclusion Criteria

- Irreparable rotator cuff
- Partial thickness tears
- Significant shoulder co-morbidities
- Previous rotator cuff repair
- Active worker’s compensation claims
- Active infection
- Significant paralysis
Methods

87 patients

Bone Trephination
N=42

14 gauge needle, U/S guided, 4 hole grid pattern to metaphyseal bone

Soft Tissue Trephination
N=45

14 gauge needle, U/S guided, 4 hold grid pattern in soft tissue

RTC repair
T2 MRI Mapping at 6 weeks in 54 participants
Trephination Technique

- Skin entry point
- Trephination pins
- Cuff insertion area

- Rotator Cuff
- Cuff tear
- Cuff insertion site with Trephination holes 5 mm apart

- Needle, placed percutaneously
- Rotator cuff tear
- Cuff insertion area
- Humeral head
Double row rotator cuff repair
T2 Mapping
## Results

There were no statistical differences between demographic data

<table>
<thead>
<tr>
<th></th>
<th>Bone N=26 (48%)</th>
<th>Tissue N=28 (52%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) (min-max: range)</td>
<td>59.9 (6.7) (44.5-67.7: 23.2)</td>
<td>60.1 (9.0) (40.9-73.9: 33.0)</td>
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<tr>
<td><strong>Sex</strong></td>
<td></td>
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<tr>
<td>Male</td>
<td>16 (62%)</td>
<td>18 (64%)</td>
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<tr>
<td>Female</td>
<td>10 (38%)</td>
<td>10 (36%)</td>
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<tr>
<td><strong>Side</strong></td>
<td></td>
<td></td>
<td>0.0904</td>
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<tr>
<td>L</td>
<td>8 (31%)</td>
<td>15 (54%)</td>
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<tr>
<td>R</td>
<td>18 (69%)</td>
<td>13 (46%)</td>
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</tbody>
</table>
Results

There were no statistical differences in the results of the T2 mapping within the enthesis or the other regions of interest.

Re-tear rate (P=0.68)
- 2 (6%) in bone group
- 4 (11%) in tissue group
Conclusions

• Comparison of T2 maps between groups did not reveal a statistical difference within the enthesis of the supraspinatus tendon (p=0.58)

• Secondary outcomes revealed no significant differences between the T2 maps across the other regions of interest

• Re-tear rate was lower in the bone trephination group
  • not statistically significant, P=0.68
Strengths/Weaknesses

• Strengths
  • Randomized controlled trial
  • Simple technique
  • Autologous technique

• Limitations:
  • Complexity of signaling cascade
    • MSC’s converting to other cell lineage?
    • Timing of intervention?
    • MSC source in RTC healing not from bone marrow?
    • Aging MSC’s?
Future Directions

• Subgroup analysis comparing the enthesis over anchors compared to enthesis over bone is pending
  • Does the presence on an anchor decrease the healing response?

• Clinical outcomes of this RCT are in the final stages

• Subsequent RCT of intra-operative trephination is currently underway
• THANK YOU
• THANK YOU