

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

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- There are no relevant disclosures to report

- 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

- 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 (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
- Trepination
  - 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

- 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?

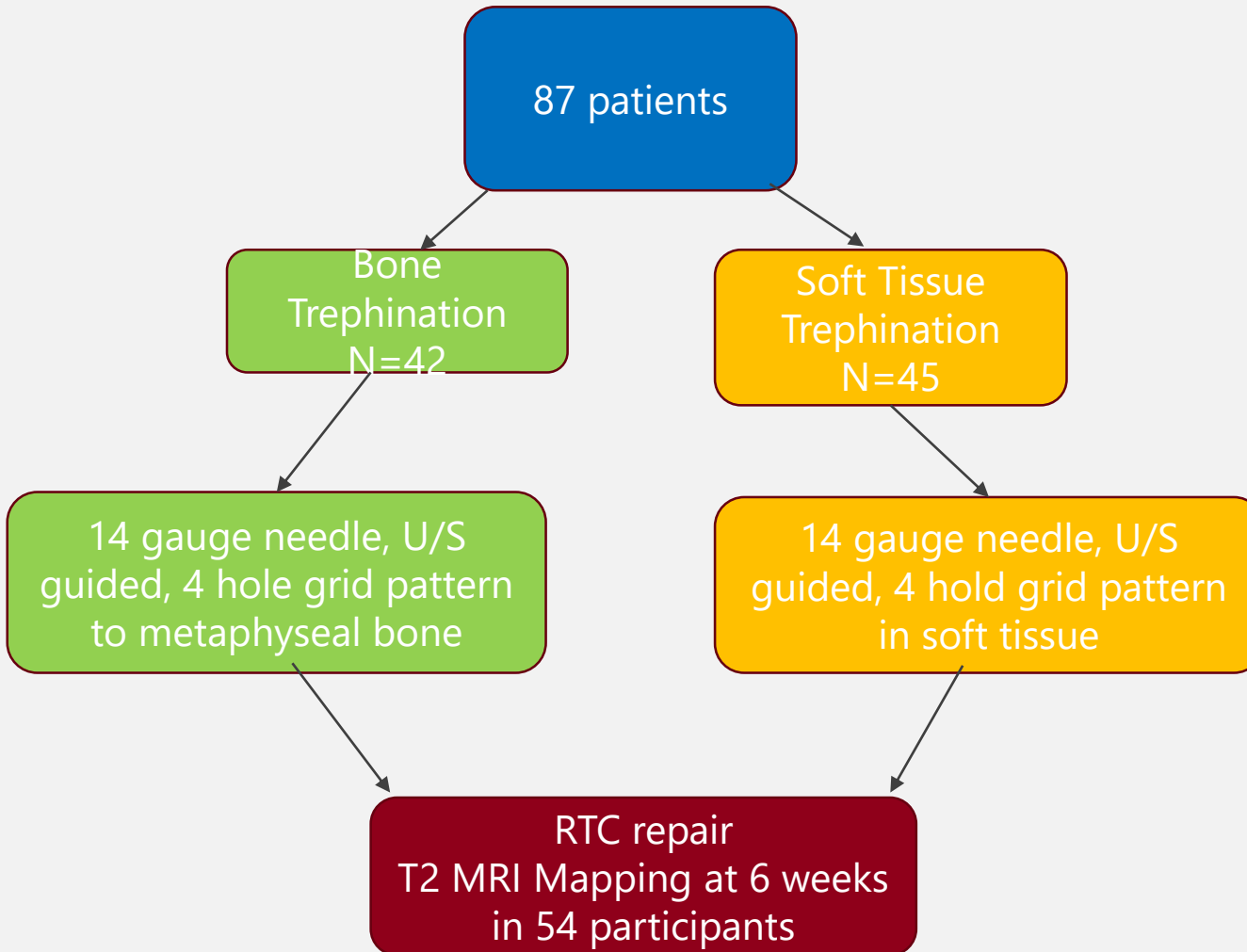
*HYPOTHESIS: Pre-operative bone trephination will allow for an increased early healing reaction on T2 MRI mapping within the supraspinatus enthesis*

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

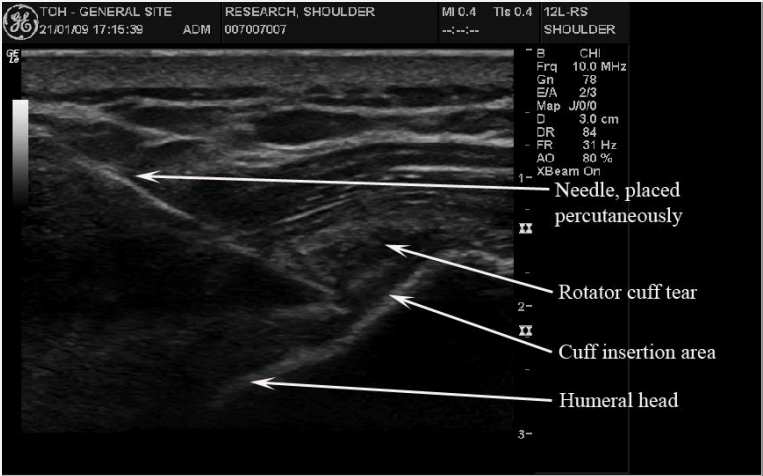
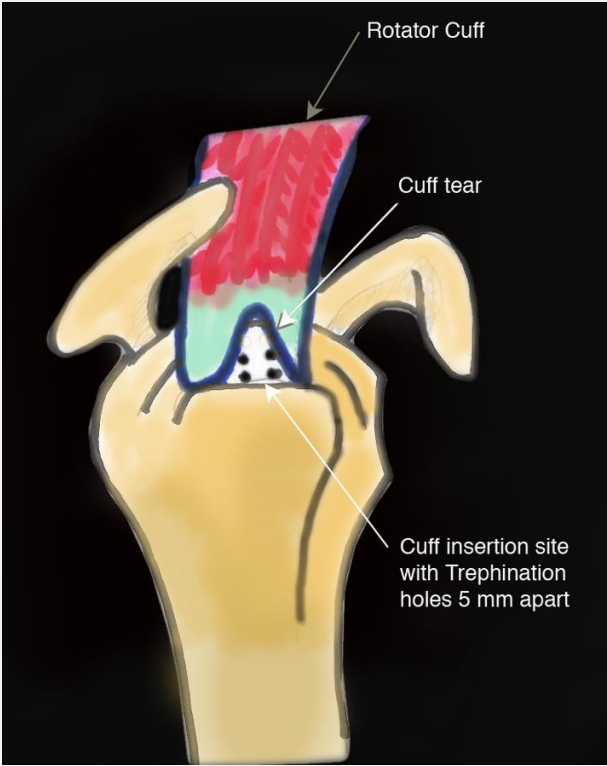
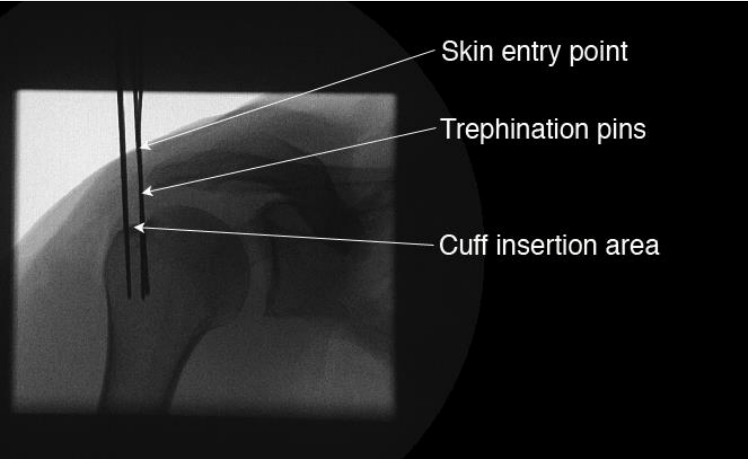


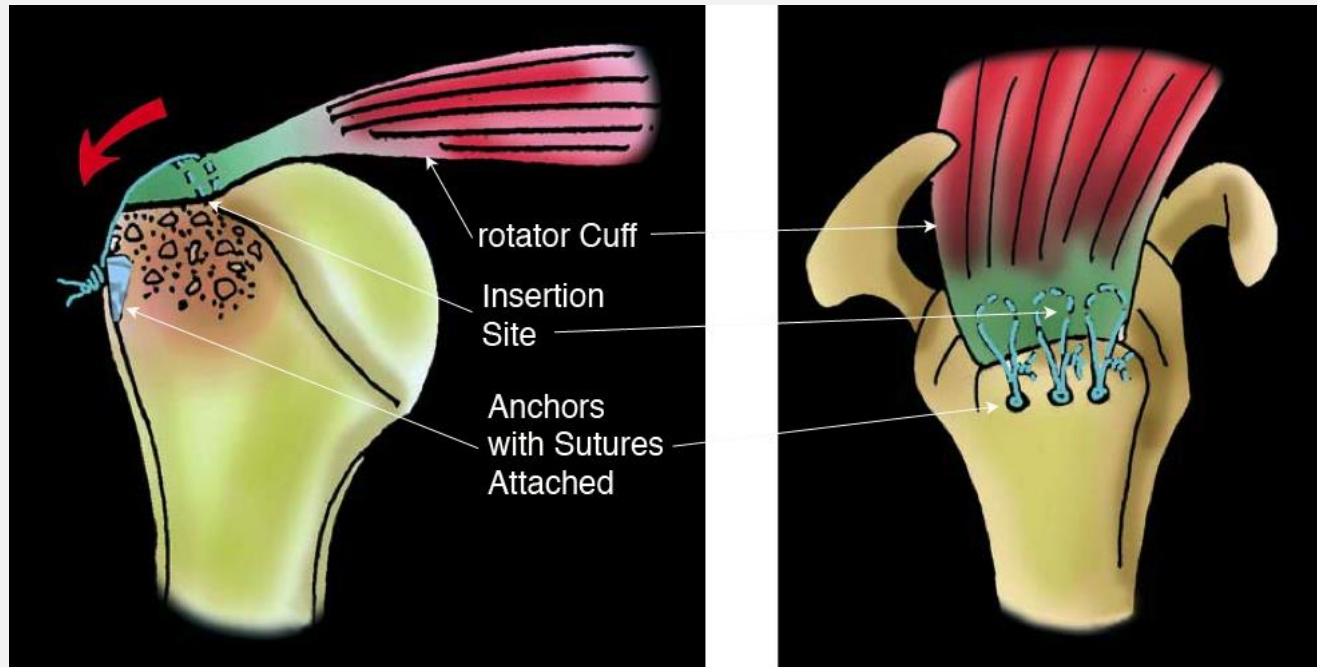
- Age 18 and older
- Full thickness supraspinatus tears
- Failed 6 months of conservative treatment

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



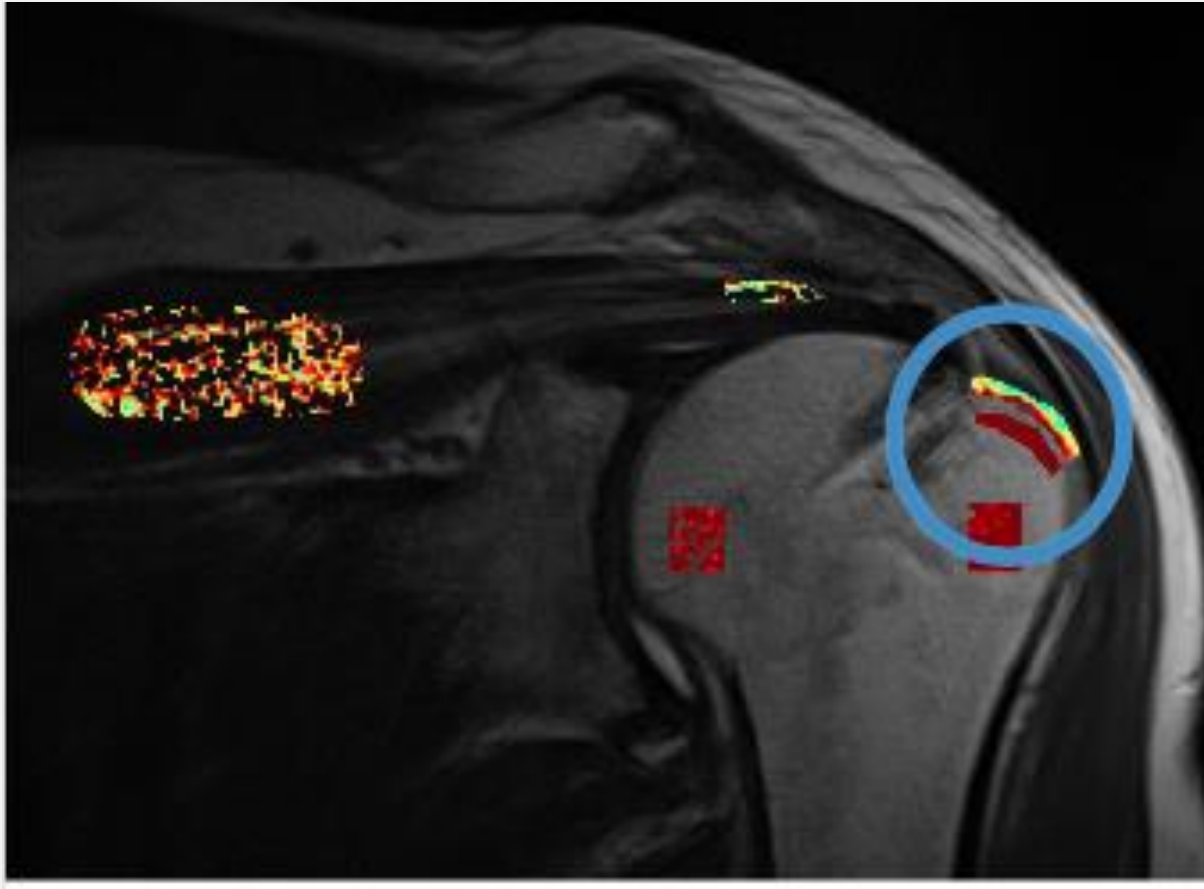
# Trephination Technique





## Double row rotator cuff repair

# T2 Mapping



	<b>Bone</b> <b>N=26 (48%)</b>	<b>Tissue</b> <b>N=28 (52%)</b>	<b>P-value</b>
<b>Age</b> <b>Mean (SD) (min-max: range)</b>	59.9 (6.7) (44.5-67.7: 23.2)	60.1 (9.0) (40.9-73.9: 33.0)	0.9054
<b>Sex</b>			0.8345
<b>Male</b>	16 (62%)	18 (64%)	
<b>Female</b>	10 (38%)	10 (36%)	
<b>Side</b>			0.0904
<b>L</b>	8 (31%)	15 (54%)	
<b>R</b>	18 (69%)	13 (46%)	

There were no statistical differences between demographic data

	Study Group												p-value
	bone						tissue						
	Number	mean	std	min	max	range	Number	mean	std	min	max	range	
<u>Enthesis</u>	24	75.9	13.2	43.4	100.9	57.5	28	73.8	12.1	49.0	100.2	51.2	0.55
<u>Enthesis Over Anchor</u>	26	79.5	10.3	60.5	93.7	33.2	28	74.5	10.8	57.4	100.4	43.0	0.09
<u>SSP Tendon</u>	26	73.4	11.9	47.9	96.5	48.6	28	70.5	10.4	51.5	90.6	39.2	0.34
<u>Subenthesis Bone</u>	26	113.6	7.5	95.4	127.8	32.4	28	114.9	7.1	99.3	129.6	30.4	0.50
<u>SSP Muscle</u>	24	83.3	15.4	54.2	110.9	56.7	27	80.1	10.5	54.1	100.0	45.9	0.39
<u>Lat Hum Head</u>	26	122	5.4	112.1	132.0	19.9	28	123.8	3.5	116.1	129.8	13.7	0.15
<u>Med Hum Head</u>	26	124.8	6.0	112.6	133.9	21.3	28	127.0	4.0	120.0	132.9	13.0	0.12
<u>Infraspinatus Enthesis</u>	22	71.7	12.3	46.1	99.2	53.1	22	79.5	19.0	51.2	118.2	66.9	0.11

- There were no statistical differences in the results of the T2 mapping within the entheses or the other regions of interest
- Re-tear rate (P=0.68)
  - 2 (6%) in bone group
  - 4 (11%) in tissue group



- 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
  - 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?

- 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



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