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# Measuring the effect of hyaluronic acid on tendon healing after arthroscopic rotator cuff repair: A prospective randomized clinical trial


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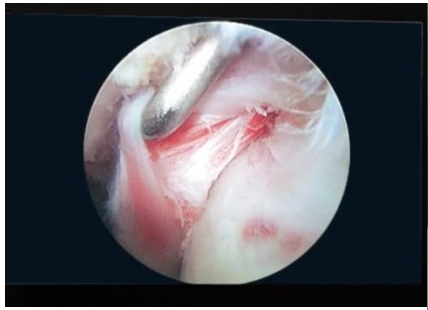
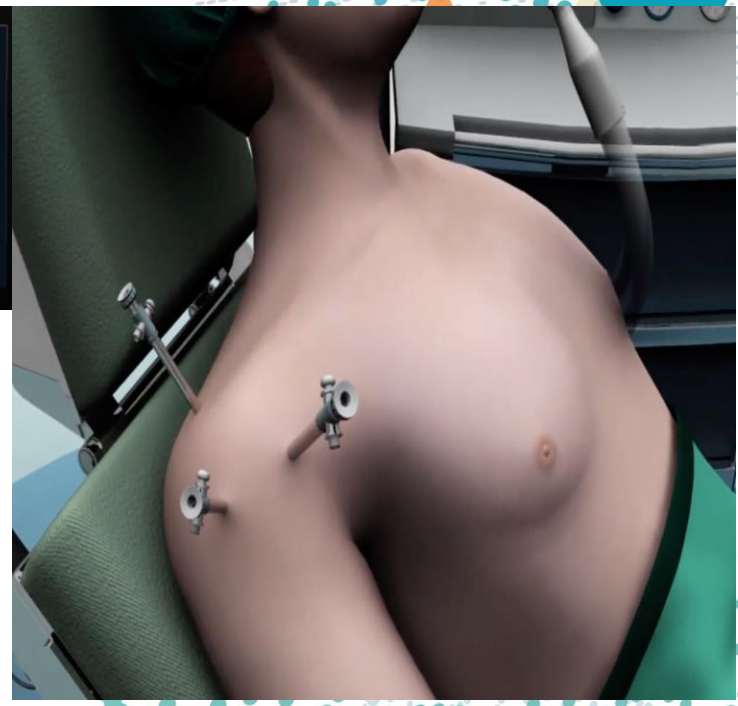
# Faculty Disclosure Information

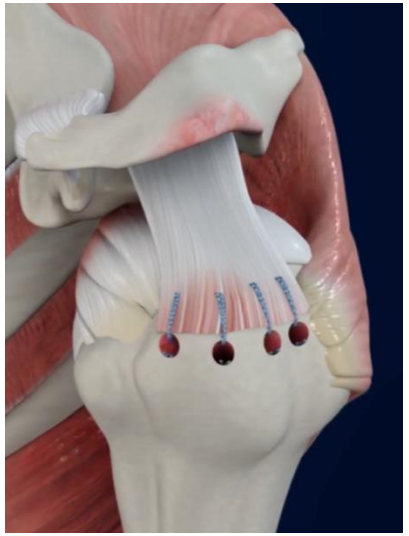
- No financial disclosures

# Rotator cuff repair (RCR)





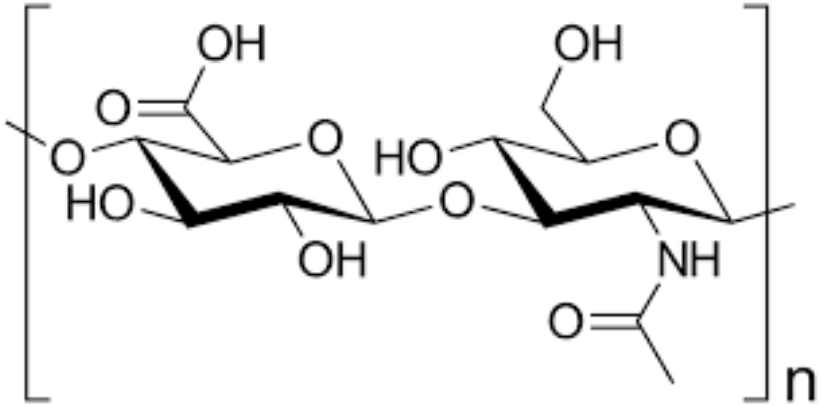
Arthroscopic RCR is widely accepted as a reliable treatment for patients with cuff injuries, with favourable outcomes in terms of pain relief and range of motion afforded[1,2]



Despite modern improvements in techniques, implants, and rehabilitation, incidence of repair failure and post-operative stiffness still ranges between 20% and 95% - hence the impetus to find further ways to improve cuff healing[3,4]

# Hyaluronic acid (HA) and RCR

HA is a *high–molecular weight glycosaminoglycan* of repeating disaccharide units of glucuronic acid and N-acetyl-glucosamine; naturally present in synovial fluid, it exhibits viscoelastic properties that may facilitate normal joint fluid mechanics, and is reported to be highly safe when given as an injection [5-7]





Multiple studies in animals and humans point to trends on the *positive effects of HA following RCR* in terms of ultimate load-to-failure, collagen maturation, mesenchymal stem cell count, and re-tear incidence reduction when compared to placebo[8-10]

# Objectives

Determine if hyaluronic acid supplementation will improve outcomes of arthroscopic repair of complete rotator cuff tears compared to placebo, in terms of the following parameters:

1. Post-operative pain (VAS)
2. Clinical outcome scores (ASES, Constant)
3. Range of motion (ROM) recovery
4. Re-tear or repair failure (Sugaya)

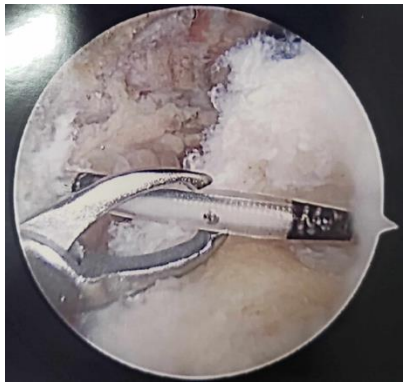
# Methodology

## ***Double-blind prospective RCT***

Patient selection at clinics
Patient inventory [VAS, ROM, ASES, Constant scores] obtained

*Exclusion criteria*
<18y/o, >75 y/o
Advanced shoulder arthritis
Rheumatoid/inflammatory arthritis
Primary shoulder instability
Revision cuff surgery
Irreparable tears
Smokers
Chronic pain syndromes
HA allergy

**N=90**
Arthroscopic RCR surgery
On-Q catheter inserted



**n=45**
Given 4 ml saline injection at recovery room

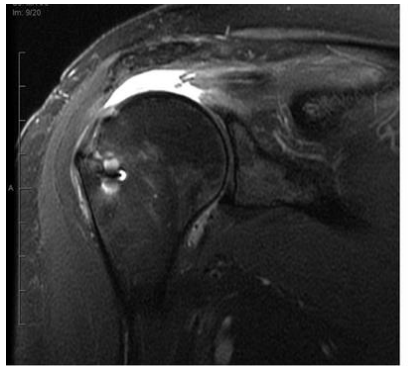
**n=45**
Given 4 ml HA (MONOVISC™) injection at recovery room

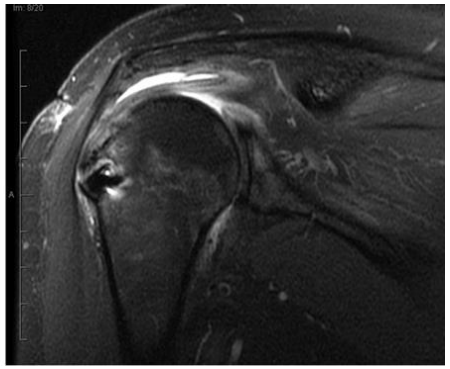
<u>2 weeks</u>:
VAS check

<u>3 mos</u>:
Patient inventory

<u>6 mos</u>:
Patient inventory

<u>12 mos</u>:
Post-op MRI
Sugaya scores
Patient inventory





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# Results: Patient characteristics

| | | HA (n=45) | Placebo (n=45) | Total (N=90) | P (<0.05) |
|---|---|---|---|---|---|
| Age | | 60.11 ± 9.95 | 61.42 ± 9.08 | 60.44 ± 9.90 | 0.75 |
| Sex | Male<br>Female | 26<br>19 | 28<br>17 | 54<br>36 | 0.66 |
| Handedness | Right<br>Left | 39<br>6 | 41<br>4 | 80<br>10 | 0.50 |
| Operative side | Right<br>Left | 29<br>16 | 24<br>21 | 53<br>37 | 0.28 |
| Tear width (cm) | | 1.70 ± 0.74 | 1.85 ± 1.07 | 1.85 ± 0.93 | 0.12 |
| Repair type | Single-row<br>Double-row | 40<br>5 | 35<br>10 | 75<br>15 | 0.16 |
| Subscapularis tear | Yes<br>No | 3<br>42 | 7<br>38 | 10<br>80 | 0.18 |
| Biceps procedure | Tenodesis<br>Tenotomy<br>None | 24<br>13<br>8 | 27<br>14<br>4 | 51<br>27<br>12 | 0.46 |
| VAS (initial) | | 6.16 ± 1.94 | 5.49 ± 2.41 | 5.82 ± 2.21 | 0.15 |
| ASES (initial) | | 43.20 ± 17.33 | 49.97 ± 19.36 | 46.59 ± 18.58 | 0.08 |
| CONSTANT (initial) | | 59.09 ± 18.97 | 63.98 ± 17.17 | 61.53 ± 18.16 | 0.20 |
| Strength (lbs) | | 32.62 ± 23.38 | 37.96 ± 23.63 | 35.29 ± 23.53 | 0.29 |

*No significant differences between treatment arms*

Intent-to-treat analysis performed

Dropout rate at 12 mos.: **17.8%**

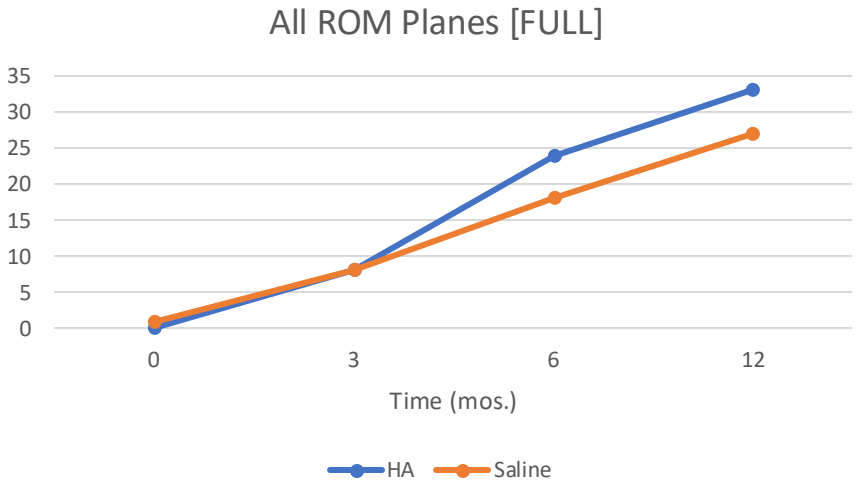
| | Pre-op | 2 weeks | 3 mos | 6 mos | 12 mos |
|---|---|---|---|---|---|
| N | 90 | 90 | 85 | 73 | 74 |

# Results: outcome measures

*No significant differences ($p<0.05$) between HA and placebo, at any time point:*

- *VAS*
- *ASES*
- *Constant score*
- *Manual strength*
- *ROM – all planes*

| | | 0 | 3 mos (%) | 6 mos (%) | 12 mos (%) |
|---|---|---|---|---|---|
| **n** | HA<br>Saline | 45<br>45 | 43<br>42 | 36<br>37 | 39<br>35 |
| **ALL** | HA<br>Saline | 0 (0)<br>1 (2.22) | 8 (18.6)<br>8 (19.05) | 24 (66.67)<br>18 (48.65) | 33 (84.62)<br>27 (77.14) |




**HA>placebo**: no. of patients with full ROM at all planes at **6** and **12 mos**

*Lubricating properties and increased rate of healing may modulate faster and safer progression of rehab for patients given HA after cuff surgery* *9-11*

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# Results: Re-tear incidence

| Sugaya MRI Score | HA (%) | Placebo (%) |
|---|---|---|
| Intact | **29** (85.3) | **22** (73.3) |
| 1 | 6 (17.6) | 5 (16.7) |
| 2 | 13 (38.2) | 10 (33.3) |
| 3 | 10 (29.4) | 7 (23.3) |
| Torn | **5 (14.7)** | **8 (26.7)** |
| 4 | 5 (14.7) | 4 (13.3) |
| 5 | 0 | 4 (13.3) |
| Total (N=64) | 34 | 30 |

Relative risk ratio (RRR): **44.5% re-tear risk lower in HA** vs. placebo

Absolute risk ratio (ARR): **12% reduction** in re-tear rates with HA

No. needed to treat (NNT): **8.33 patients** to prevent one cuff re-tear

*Sugaya scores suggest that HA may have aided in tendon healing; re-tear risk is higher in patients with T2DM, high BMI, and larger sized tears*[12]

# Conclusions

*HA administration in the immediate post-operative period showed potential improvements in arthroscopic RCR through*

- *allowing earlier improvement in functional range of motion*
- *decreasing re-tear risk rate*

*Clinical outcome scores were not significantly different for HA vs. placebo for up to 12 months*

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