Structural Integrity of Rotator Cuff Repair Affects Shoulder Strength but Not Range of Motion or Patient-Reported Outcomes at One Year: A Prospective Causal Inference Study

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Introduction: Over 250,000 RCRs are performed annually in the US[1], 20-30% of which experience structural failure (re-tear), usually within a year of surgery.[2] Clinical outcomes after RCR are frequently assessed using patient-reported outcome measures (PROMs) as well as by objective measures such as shoulder strength and range of motion (ROM). However, the *causal role* of repair integrity on such outcomes has not been studied. We hypothesized that patients with failed RCR would have lower shoulder strength and ROM, but not PROMs at 1 year postoperatively.

Materials and Methods: Patients undergoing primary, arthroscopic double-row repair of the supraspinatus and/or infraspinatus tendons by 7 shoulder surgeons in 2016-2018 were prospectively enrolled [IRB-16-089, NCT02716441]. During RCR, 1-4 radiopaque markers (FibermarX, Viscus Biologics) were tied on the repaired tendon surface just medial to the repair site. Various demographic, preoperative and intraoperative measures were collected. Shoulders were imaged preoperatively (MRI), immediately following surgery (CT), and after 3, 6, and 12 months (both). Isometric abduction strength, active and passive scapular plane ROM (aROM, pROM), and Penn Shoulder Score (PSS) were assessed at each visit. Repair integrity was defined by both Sugaya grading of MRI images[4] (grade 1/2/3–intact vs. 4/5–failed) and by tendon retraction (longitudinal positional changes of the radiopaque markers) on CT images[5,6]. Directed acyclic graphs (DAGs, i.e., causal graphs) were used to select covariate adjustment sets allowing asymptotically unbiased estimation of causal effects of repair integrity (Sugaya grade, tendon retraction) on 12 month strength, aROM, and PSS. We then fit multivariable linear (strength, aROM) or logit-link beta (PSS) regression models using such adjustment sets, chosen based on confidence in covariate measurement validity/reliability and on covariate explanatory power (**Table 1**).

Table 1. DAG-derived covariate sets for total causal effect of RCR integrity (Sugaya grade/ tendon retraction) on 1y clinical outcomes

Outcome	Covariates (values are reported in Table 2a)
1y Strength	Age, BMI, Sex, Supra Occupation Ratio (OR), RC tear size-AP, RC tear size-ML, Dominant arm affected
1y aROM	Age, BMI, Sex, Supra OR , RC tear size-AP, RC tear size-ML, Dominant arm affected, pROM (6mo)
1y PSS-total	Age, BMI, Sex, Supra OR, RC tear size-AP, RC tear size-ML, CCI, Smoking, Synovitis, Acromioplasty, Shoulder Activity Level (6mo), pROM (6mo)

Results: 113 of 117 (97%) enrolled patients completed follow-up. At 1y, PSS-total was 95 (90, 98), tendon retraction was 13.9 ±8.7 mm, and 18% had a Sugaya 4/5 failed RCR (**Table 2**). A significant causal relationship was observed between 1y RCR integrity and strength **(Table 3)**: Sugaya 4/5 failed repairs resulted in 3.4 lb lower abduction strength compared to Sugaya 1/2/3 intact repairs ($p<0.001$), and a 1 cm increase in tendon retraction caused a 1 lb lower strength ($p=0.05$), although this borderline statistical significance was highly sensitive to choice of covariate adjustment set. No statistically significant causal relationships were observed between RCR integrity and aROM or PSS at 1y.

Table 2a. Baseline/6 month Covariates	
PSS-total (0-100)	55 (42, 63)
Age (years)	58.5 ±8.5
Sex (F)	43%
BMI	30 ±6
Smoking (no, quit, yes; %)	55, 36, 9
CCI	0 (0, 1)
Dominant arm affected (yes)	66%
RC tear size-AP (cm)	2.2±0.9
RC tear size-ML (cm)	1.2±0.5
Supra OR (grade 0-3) (%)	34, 16, 49, 1
Synovitis (yes)	65%
Acromioplasty (yes)	65%
Shoulder Activity Level (6mo)	10.1±4.4
pROM (deg) (6mo)	150 ± 23
Table 2b. 1y Predictors & Outcomes	
PSS-total (0-100)	95 (90, 98)
RCR tendon retraction (mm)	13.9 ± 8.7
Sugaya grade (1/2/3, 4/5) (%)	82, 18
Isometric abduction strength (lb)	10.5 ± 5.0
aROM (deg)	154 ± 19

Discussion: While the consequences of failed RCR on clinical outcomes have been explored for decades, existing literature consists primarily of small, retrospective studies with mixed findings, so this important clinical question remains a subject of debate. This first-in-kind prospective study of 117 patients with 97% 1y follow-up used causal inference methods to more comprehensively and rigorously investigate possible relationships. We found that patients with failed RCR (Sugaya grade 4-5), and possibly those with higher tendon retraction, have less strength but aROM and PSS that were indistinguishable from patients with intact repairs at 1y. Future research will explore both the direct and indirect effects (through plausible mediators) of RCR integrity on strength. Long-term follow-up of these patients will investigate whether successful RCR healing interrupts, whereas failed healing predisposes to, progression of degenerative tendon and shoulder joint pathologies and clinical decline.

Table 3. Causal effect estimates (* statistically significant effect, p≤0.05)

OUTCOME	EXPOSURE [Exposure level]	1y Sugaya grade [4/5 vs. 1/2/3]	1y Tendon Retraction [per 10mm increase]
1y Strength	Difference in Means (lb)	-3.4 (-5.3, -1.5)*	-1.0 (-2.0, 0.0)*
1y aROM	Difference in Means (deg)	-3.7 (-11.0, 3.6)	1.3 (-2.5, 5.0)
1y PSS-total	Odds ratio	0.84 (0.55, 1.27)	0.94 (0.74, 1.18)

References: [1] Colvin AC, et al. J Bone Joint Surg Am, 2012. [2] Iannotti JP, et al. J Bone Joint Surg Am, 2013. [3] Byeon S, et al. J Minim Invasive Surg, 2023. [4] Sugaya, H et al. Arthroscopy, 2005. [5] Sahoo, S et al. PLoS One, 2019. [6] Jun, BJ et al. JSES Int, 2020.

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