Editorial Commentary: Rotator Cuff Repairs Fail at an Alarmingly High Rate During Long-Term Follow-Up: Graft Augmentation and Biologics May Improve Future Outcomes

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Abstract: Rotator cuff repairs (RCR) frequently fail to heal, particularly those with advanced fatty infiltration, supraspinatus and infraspinatus atrophy, narrowed acromiohumeral distance, and large-to-massive tear size. Unfortunately, the longer the follow up, the more sobering the statistics, with some reported retear rates ranging up to 94%. Importantly, recent long-term radiographic assessments after primary RCR reveal direct correlations between failure and patient-reported outcomes, functional deterioration, and ultimately, progression of glenohumeral arthritis and/or frank cuff tear arthropathy. As shoulder surgeons, we must continue to seek out novel approaches to improve tendon to bone healing and recapitulate the native rotator cuff enthesis. In doing so, we hope to engender more sustained subjective and objective results for our patients over time. Investigations are ongoing into several biomechanical and biological or structural adjuncts, from platelet-rich plasma and bone marrow aspirate concentrate to autograft or allograft structural augments. We must continue to push the envelope and refuse to settle for the current reality and alarmingly high failure rates following RCR.

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Despite our best efforts, rotator cuff repairs fail at an alarming rate, particularly those with advanced fatty infiltration, supraspinatus and infraspinatus atrophy, narrowed acromiohumeral distance, and large to massive tear size. Whether the mechanism is traumatic reinjury, attritional compromise, nonhealing, or "failure in continuity,"[1] we cannot hide from the data. While we can all agree that many rotator cuff repairs fail, these retears can present in an asymptomatic or minimally symptomatic fashion. As a result, this has often led to controversy and confusion among surgeons.

There are a few noteworthy studies that have fueled this debate over the past 20 years. While a comprehensive summary or review is outside the scope of this commentary, selected landmark studies are important to highlight. Firstly, Galatz et al. performed a retrospective study of 18 cases of arthroscopic rotator cuff repair (RCR) for tears greater than 2 cm in the transverse direction.[2] Ultrasound was used at 12 months to assess repair integrity, and patient-reported outcomes (PROs) were collected, including the American Shoulder and Elbow Surgeons score (ASES). Even though 17 of 18 repairs had failed at 1 year, 16 patients had significantly improved ASES scores, with 13 of those patients reporting ASES scores $\geq$90. However, by 24 months, only 9 patients still reported ASES scores $\geq$90, and the overall cohort had decreasing mean ASES scores and forward elevation, suggesting a decline in shoulder function over time.

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The authors report the following potential conflicts of interest or sources of funding: N.A.T. is a paid presenter for DJO. B.R.W. reports he is a board or committee member of AAOS, the American Orthopaedic Society for Sports Medicine, the American Shoulder and Elbow Surgeons, the Arthroscopy Association of North America and is an editorial or governing board member of Arthroscopy *and* Video Journal of Sports Medicine. *He is a paid presenter or speaker for Arthrex, Sparta, and Vericel; has received publishing royalties from Elsevier and* Arthroscopy*; has received stock or stock options from Kaliber AI, Sparta, and Vivorte; has received financial and material support from Arthroscopy, the Musculoskeletal Transplant Foundation, and Smith and Nephew; is a paid consultant for DePuy and FH Ortho; and is an unpaid consultant for Kaliber AI and Sparta. Full ICMJE author disclosure forms are available for this article online, as supplementary material.*

0749-8063/22466/$36.00
https://doi.org/10.1016/j.arthro.2022.04.002

In a separate meta-analysis of 14 RCR studies, Russell et al. assessed both PROs and radiographic repair integrity with minimum 1-year follow up.[3] The authors did not find clinically significant differences in postoperative patient-reported outcomes between patients with and without intact repairs at mean 30-month follow-up. However, just 3 years later, a similar meta-analysis was performed on 29 publications with 2,611 rotator cuff repairs at minimum 1-year follow up.[4] In that analysis, Yang Jr. and colleagues found that patients with full-thickness retears had significantly lower ASES scores, Constant scores, UCLA scores, *and* abduction strength, thereby refuting these prior results. So, as they say, "what gives"?

Suffice to say, studies with longer-term postoperative surveillance have consistently found declining clinical outcomes in the presence of repair failure. Unfortunately, these studies are often painstaking and difficult to perform, particularly with delayed radiographic analysis. In one such study, Plachel et al. assessed repair integrity and Constant score in 40 patients at a mean of 12.1 years after either single or double-row RCR.[5] Failure rate was reported as 27% at 2 years and an astounding **45%** at 12 years. Furthermore, patients with intact repairs had a mean Constant score of 92, while patients with a failed repair had a mean Constant score of 73 ($P < .05$). Interestingly, patients with repair failure had greater prevalence of osteoarthritis (OA) on final radiographs ($P < .05$), but no significant difference in Hamada grade ($P = .748$).

In a current study, "Retear After Arthroscopic Rotator Cuff Repair Results in Functional Outcome Deterioration Over Time,"[6] Jeong, Nam, Yeo, Rhee, and Oh shed more light on the long-term failure rates after RCR, as well as the clinically significant consequences of these failures. The authors present a series of 201 rotator cuff repairs with a mean of 8.6-year follow-up. The failure rate was 21.4%, defined by either MRI or ultrasound evidence of retear. Importantly, the authors also analyzed the implications of failure, both in terms of outcomes and the progression of OA. For patient-reported outcomes, the authors should be commended for performing their analysis in the context of minimal clinically important differences (MCID). Patients with retears demonstrated significantly lower rates of meeting MCID for both pain and ASES scores. For pain scores, a striking 97.5% (154/158) of healed patients met MCID at final follow-up, whereas patients with retears only met this threshold in 60% (26/43) of cases. Similarly, for ASES scores, 91.8% (145/158) of patients met MCID at final follow-up; patients with retears only met MCID in 34.9% (15/43) of cases. Finally, when analyzing for OA, 69 patients showed progression of radiographic glenohumeral OA at final follow up (as defined by increased Samilson—Prieto grade), with patients experiencing retear accounting for 39.1% (27/69) of this subset. By comparison, the retear rate was only 12.1% ($n = 16$) in the 132 patients who did not demonstrate OA progression. While this does not delineate causation, the difference in retear percentage between OA progression and nonprogression groups was statistically significant ($P < .001$). Unfortunately, there was no mention of Hamada grade or differentiation between glenohumeral OA and cuff tear arthropathy.

The present study further highlights what has really been evident all along—for sustained results after RCR, radiographic healing and biologic remodeling are preferred, if not required. Nevertheless, we in the shoulder community have struggled to make progress in this area. Decades of research have earnestly sought to improve on the failure rates after RCR. Much of this research has focused on technical aspects of the repair. How can we improve the mechanical stability of our repair? How can we achieve "footprint compression" at the tuberosity? How can we reduce tension at the repair site? What we have found is that even with appropriate soft tissue releases, double row (or even triple row![7]) repairs to compress tendon tissue at the insertion site, and carefully designed rehabilitation protocols, we continue to have high rates of healing failure or retear.

No matter how technical the repair, failure rates climb with longer-term follow-up. A recent systematic review of rotator cuff repairs with minimum 9-year follow-up found retear rates between 27 and 50% after arthroscopic rotator cuff repair, with a pooled rate of 43% over 178 cases.[8] We cannot be satisfied with 2 out of 5 repairs failing by a minimum of 9 years, especially as we see the consequences of those failures manifest in increased rates of osteoarthritis and declining patient-reported outcomes. But what are we as surgeons left to do?

The answers must be rooted in the biology and, ultimately, recapitulation of native tendon to bone healing. We can create a favorable mechanical environment with surgical techniques, but we have yet to optimize the biologic environment for healing. Investigations are ongoing into the role of bone marrow aspirate concentrate,[9] marrow stimulation,[10,11] platelet-rich plasma,[12,13] autologous microfragmented adipose tissue,[14] bursal tissue,[15-18] meshed biceps tendon autograft,[19] pulsed electromagnetic field therapy,[20] xenograft,[21] growth factors,[22] allograft,[23] or a combination of these augments.[24-27] Although many of these studies have reported early feasibility, few have investigated long-term outcomes. We truly need further studies of structural or biologic adjuncts with 5- and 10-year follow-up to determine whether we can improve upon the sobering 43% failure rate over the long term. Thankfully, there are plenty of reasons for hope and enthusiasm in forthcoming research. A search of ongoing clinical trials in the U.S. National Library of Medicine database reveals 144 rotator cuff studies, at least 28 of which investigate structural or biological adjuncts to rotator cuff repairs.

Another area of interest has been the muscle tissue itself.[28] Preventing or reversing fatty change and fibrosis within the musculature could have long-term implications, either by improving tissue compliance (and thereby reducing repair tension) or by supporting the health and vascularity of the associated tendon. Research in this area remains mostly in the basic science phases with limited clinical data available thus far. However, specific interventions are being actively studied to prevent or reverse fatty degeneration of the rotator cuff musculature, including minced muscle injections (NCT03752034) and oxandrolone (NCT03091075).

In conclusion, the study "Retear After Arthroscopic Rotator Cuff Repair Results in Functional Outcome Deterioration Over Time" by Jeong and colleagues[6] is an important reminder of the high rate of rotator cuff repair failure long term and the consequences of those failures. These results should dually frustrate us *and* motivate us to find better solutions for our patients. We can, and we will!

References

1. Akelman MR, Howard MC, Waterman BR. Editorial commentary: Repairing retracted rotator cuff tears: Histologically different, but success still achievable with "failure in continuity". *Arthroscopy* 2021;37:3432-3433.
2. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *JBJS* 2004;86.
3. Russell RD, Knight JR, Mulligan E, Khazzam MS. Structural integrity after rotator cuff repair does not correlate with patient function and pain: a meta-analysis. *J Bone Joint Surg Am* 2014;96:265-271.
4. Yang J, Robbins M, Reilly J, Maerz T, Anderson K. The clinical effect of a rotator cuff retear: A meta-analysis of arthroscopic single-row and double-row repairs. *Am J Sports Med* 2017;45:733-741.
5. Plachel F, Siegert P, Rüttershoff K, et al. Long-term results of arthroscopic rotator cuff repair: A follow-up study comparing single-row versus double-row fixation techniques. *Am J Sports Med* 2020;48:1568-1574.
6. Jeong Hj, Nam KP, Yeo JH, Rhee S-M, Oh JH. Retear after arthroscopic rotator cuff repair results in functional outcome deterioration over time. *Arthroscopy* 2022;38:2399-2412.
7. Tanaka M, Hanai H, Kotani Y, Kuratani K, Koizumi K, Hayashida K. Triple-row technique confers a lower retear rate than standard suture bridge technique in arthroscopic rotator cuff repairs. *Arthroscopy* 2021;37:3053-3061.
8. Plachel F, Jo OI, Rüttershoff K, Andronic O, Ernstbrunner L. A Systematic review of long-term clinical and radiological outcomes of arthroscopic and open/mini-open rotator cuff repairs. *Am J Sports Med* 2022:3635465211073332.
9. Mazzocca AD, McCarthy MB, Chowaniec DM, Cote MP, Arciero RA, Drissi H. Rapid isolation of human stem cells (connective tissue progenitor cells) from the proximal humerus during arthroscopic rotator cuff surgery. *Am J Sports Med* 2010;38:1438-1447.
10. Ajrawat P, Dwyer T, Almasri M, et al. Bone marrow stimulation decreases retear rates after primary arthroscopic rotator cuff repair: A systematic review and meta-analysis. *J Shoulder Elbow Surg* 2019;28:782-791.
11. Dierckman BD, Ni JJ, Karzel RP, Getelman MH. Excellent healing rates and patient satisfaction after arthroscopic repair of medium to large rotator cuff tears with a single-row technique augmented with bone marrow vents. *Knee Surg Sports Traumatol Arthrosc* 2018;26:136-145.
12. Villarreal-Villarreal GA, Simental-Mendía M, Garza-Borjón AE, et al. Double-row rotator cuff repair enhanced with platelet-rich therapy reduces retear rate: A systematic review and meta-analysis of randomized controlled trials. *Arthroscopy* 2021;37:1937-1947.e1931.
13. Zhang C, Cai YZ, Wang Y. Injection of leukocyte-poor platelet-rich plasma for moderate-to-large rotator cuff tears does not improve clinical outcomes but reduces retear rates and fatty infiltration: A prospective, single-blinded randomized study. *Arthroscopy* 2022;38:2381-2388.
14. Randelli PS, Cucchi D, Fossati C, et al. Arthroscopic rotator cuff repair augmentation with autologous microfragmented lipoaspirate tissue is safe and effectively improves short-term clinical and functional results: A prospective randomized controlled trial with 24-month follow-up. *Am J Sports Med* 2022:3635465221083324.
15. Morikawa D, Johnson JD, Kia C, et al. Examining the potency of subacromial bursal cells as a potential augmentation for rotator cuff healing: An in vitro study. *Arthroscopy* 2019;35:2978-2988.
16. Baldino JB, Muench LN, Kia C, et al. Intraoperative and in vitro classification of subacromial bursal tissue. *Arthroscopy* 2020;36:2057-2068.
17. Tamburini LM, Levy BJ, McCarthy MB, et al. The interaction between human rotator cuff tendon and subacromial bursal tissue in co-culture. *J Shoulder Elbow Surg* 2021;30:1494-1502.
18. Levy BJ, McCarthy MB, Lebaschi A, Sanders MM, Cote MP, Mazzocca AD. Analysis of the cellular and matrix composition of subacromial bursal tissue. *Arthroscopy* 2022;38:1115-1123.
19. Colbath G, Murray A, Siatkowski S, et al. Autograft long head biceps tendon can be used as a scaffold for biologically augmenting rotator cuff repairs. *Arthroscopy* 2022;38:38-48.
20. Tucker JJ, Cirone JM, Morris TR, et al. Pulsed electromagnetic field therapy improves tendon-to-bone healing in a rat rotator cuff repair model. *J Orthop Res* 2017;35:902-909.
21. Avanzi P, Giudici LD, Capone A, et al. Prospective randomized controlled trial for patch augmentation in rotator cuff repair: 24-month outcomes. *J Shoulder Elbow Surg* 2019;28:1918-1927.
22. Kovacevic D, Suriani RJ Jr, Levine WN, Thomopoulos S. Augmentation of rotator cuff healing with orthobiologics. *J Am Acad Orthop Surg* 2022;30:e508-e516.
23. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. A prospective, randomized evaluation of acellular human

dermal matrix augmentation for arthroscopic rotator cuff repair. *Arthroscopy* 2012;28:8-15.
24. Berthold DP, Garvin P, Mancini MR, et al. Arthroscopic rotator cuff repair with biologically enhanced patch augmentation. *Oper Orthop Traumatol* 2022;34:4-12.
25. Voss A, McCarthy MB, Bellas N, et al. Significant improvement in shoulder function and pain in patients following biologic augmentation of revision arthroscopic rotator cuff repair using an autologous fibrin scaffold and bone marrow aspirate derived from the proximal humerus. *Arthrosc Sports Med Rehabil* 2021;3:e1819-e1825.
26. Muench LN, Uyeki CL, Mancini MR, Berthold DP, McCarthy MB, Mazzocca AD. Arthroscopic rotator cuff repair augmented with autologous subacromial bursa tissue, concentrated bone marrow aspirate, platelet-rich plasma, platelet-poor plasma, and bovine thrombin. *Arthrosc Tech* 2021;10:e2053-e2059.
27. Muench LN, Kia C, Berthold DP, et al. Preliminary clinical outcomes following biologic augmentation of arthroscopic rotator cuff repair using subacromial bursa, concentrated bone marrow aspirate, and platelet-rich plasma. *Arthrosc Sports Med Rehabil* 2020;2:e803-e813.
28. Murray IR, LaPrade RF, Musahl V, et al. Biologic treatments for sports injuries. II Think tank-current concepts, future research, and barriers to advancement, Part 2: Rotator cuff. *Orthop J Sports Med* 2016;4:2325967116636586.