

1 **Abstract**

2

3 Patch augmentation for rotator cuff repair is attractive but needs to be robustly evaluated
4 before widespread adoption. In this commentary, a plea is made for further evidence
5 (including a large randomised trial and a registry) to move the field on and ensure patient
6 safety, and avoid wasting precious resources.

7

8 Article text

9 Rotator cuff repair (RCR) has a substantial failure rate despite various attempts to improve
10 outcome and prevent a re-tear. Patch augmentation is an intuitively appealing approach to
11 seek to reduce failure rate and improve outcomes for patients. Two main augmentation
12 approaches are used “on-lay” and “bridging” to improve outcome. Orozco and colleagues¹
13 conducted a review of randomised trials looking at patch augmentation versus conventional
14 surgery rotator cuff repair for RCR tears. The review identified just 6 randomised trials
15 evaluating 5 different patches, and concluded there may be improved re-tear rate but no
16 clear evidence of a difference for other outcomes like shoulder function.

17 There are a number of features of the review by Orozco that merit comment. They seem to
18 only have searched for studies that used the terminology of “patch augmentation” despite
19 other terms like “graft” being in used – this is reflected in the small number of studies
20 undergoing initial screening. Additionally prior systematic reviews do not seem to have been
21 consulted such as the one we conducted.² Only one of the six studies in this new review has
22 been published since an earlier review³ but two others Lamas⁴ and Leuzinger⁵ were not
23 included. There is some inconsistency in presentation with the focus on “large tears” yet
24 studies with tears of varying sizes were included – differences in diagnostic imaging and no
25 universally accepted classification system makes restriction to specific ‘tears types’
26 notoriously difficult. Together these features limit the value of this new review. Lastly no
27 meta-analysis was carried out, perhaps fairly, reflecting a view that each of the studies differ
28 in important ways such as variations in surgical approach, the patch used, or the lack of
29 consistent outcome reporting. Where such disparity exists for the randomised evidence,
30 consideration of high-quality comparative observational studies is worthwhile, and can allow
31 tentative exploration of effects in more homogenous groupings.²

32 It is hard not to view the evidence on patch augmentation for rotator cuff repair as disparate
33 and weak. The largest study in the review contained only 112 patients with 381 in total. Of
34 these 72 patients were involved in two studies which evaluated a patch (RESTORE™) which

was withdrawn from the market. Orozco and colleagues' review does give an overview of the evidence, and highlights in general, that the evidence on patch augmentation has regrettably not substantively moved on since earlier reviews.² Perhaps with the impact of the COVID pandemic this is not surprising, and more generally, it is known that trials evaluating surgical procedures and devices are difficult to do.

So where do we go from here? There is still a need for randomised trials of patch augmentation for RCR; ideally one or two large multicentre studies that can move this field forward. Additionally, a comprehensive registry of use of patch-augmentation and related adverse events would help detect any issues with specific patches or pick up rarer events. It is not a happy situation to have implants used, somewhat arbitrarily based on weak evidence, potentially leads to use in 100s perhaps 1000s of operations in a haphazard way. Surgery, orthopaedics in particular, has seen this before, and patients have paid the price of surgical innovation and enthusiasm without the corresponding rigour in evaluation. Our hope is that this can still be rectified before patients come to avoidable harm and precious surgical and financial resources are wasted. Is the orthopaedic community up to the challenge of evaluating patch augmentation in a rigorous manner? We certainly hope so.

References

1. Orozco E, Dhillon J, Keeter C, Brown TD, Kraeutler MJ. Rotator Cuff Repair with Patch Augmentation is Associated with Lower Retear Rates for Large Tears: A

61 Systematic Review of Randomized Controlled Trials. Arthroscopy in press. available
62 online 19 September, 2023. doi:10.1016/j.arthro.2023.08.072

- 63 2. Baldwin M, Nagra NS, Greenall G, et al. Use of patch augmentation for rotator cuff
64 repair - a systematic review and meta-analysis. BMJ Open 2020, 10:12. doi:[10.1136/
65 bmjopen-2020-039552](https://doi.org/10.1136/bmjopen-2020-039552).

- 66 3. Lee G.W, Kim JY, Lee HW, Yoon JH, Noh KC. Clinical and Anatomical Outcomes of
67 Arthroscopic Repair of Large Rotator Cuff Tears with Allograft Patch Augmentation: A
68 Prospective, Single-Blinded, Randomized Controlled Trial with a Long-term Follow-
69 up. *Clin Orthop Surg*. 2022; 14: 263-271. doi:10.4055/cios21135

- 70 4. Lamas JR, García-Fernández C, Tornero-Esteban P, et al. Adverse effects of
71 xenogenic scaffolding in the context of a randomized double-blind placebo-controlled
72 study for repairing full-thickness rotator cuff tears. *Trials* 2019;20:1–9.
73 doi:[10.1186/s13063-019-3504-3](https://doi.org/10.1186/s13063-019-3504-3)

- 74 5. Leuzinger J, Sternberg C, Smolen D, et al. [Patch Augmentation in Rotator Cuff
75 Repair Surgery with Elder Patients]. *Z Orthop Unfall*. 2016;154:504–12. doi:10.1055/
76 s-0042-106475.

77

78