

Surgical evaluation science comes of age. Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS RCT)

Rotator cuff tears are common and painful injuries involving the muscles and tendons forming a “cuff” around the glenohumeral joint of the shoulder. They can be treated by surgery, in the form of repair, or sometimes respond to exercise therapy and rehabilitation.¹ The recent paper by Metcalfe and colleagues,² reporting on the benefit of an innovative surgical device in orthopaedics (a balloon spacer for rotator cuff tears in the shoulder) serves three very important purposes. Firstly, it provides rigorous evidence for the efficacy of a potentially new treatment for rotator cuff tear patients. Secondly, it showcases a new adaptive design which may well prove useful for future surgical trials. And thirdly, because of the negative findings and by fortuitously showing this before the treatment becomes embedded in widespread practice, (at least outside of Europe), it highlights the development of scientific evaluation in surgery and device assessment. Surgical science may at last have come of age.

The blinded adaptive randomised trial conducted in 24 centres compared the outcome, using a common shoulder score, in patients undergoing arthroscopic subacromial debridement, with and without an innovative new spacer device, randomised 117 patients with rotator cuff tears requiring surgery. The mean age of the patients was 67 years (SD 8.3) of which 50 (43%) were women. The primary outcome was the Oxford Shoulder Score at 12 months. The trial was stopped at the first interim analysis as pre-defined stopping boundary (for futility) was reached. The new device was found to be inferior to the control treatment at an early stage in the evaluation process. The mean Oxford Shoulder Score at 12 months was 34.3 in the debridement-only group (n=59) and 30.3 in the debridement with balloon group (n=55) [primary analysis difference -4.2, favouring control; 95% confidence interval -8.2 to -0.26; P=0.037]. Notably, there was no difference in safety events. The study showed that a new device aiming to provide a superior healing environment and biomechanics of the shoulder, simply did not work and should not be used. In fact, the outcome was worse than non-effectiveness, the balloon device appears to be detrimental.

The study utilised a well-considered innovative design itself. The adaptive approach, that allowed early data to inform key decision making, was new.³ This has significant implications for the cost and longevity of future surgical trials. It is also commendable that the study was done on an externally

valid population that was more likely to benefit from the new technology, should the spacer be effective. The “fair subject” selection factor is an important one, with some trials testing new medical interventions in low resource settings. Such trials, exposing participants to potential risks, may show benefits of medications/devices that are out of reach of the population studied. Whilst these are strong positive features, one limitation perhaps (and which the authors allude to) was the inability to cast light on the mechanism for the findings, especially as the new device was found to be detrimental.

The trial also has a wider influence and message for the world of surgical evaluation in orthopaedics and other specialties. This timing of this trial is so very important. It was conducted before the device reached mainstream use. So often in surgery and surgical devices, and particularly in orthopaedics, innovation uptake has been rapid and with minimal governance. The result has been a trail of poorly evaluated flawed and failed devices and procedures which sadly have had negative effects on patients.⁴⁻⁶ Remarkably, surgical evaluation, in terms of optimum sequencing has lagged behind the tightly controlled pharmaceutical world for too long. The START:REACTS trial is a perfect example of an efficacy study conducted at just the right time. It may have prevented much misery and disappointment in a patient population and prevented ill gained profits in the commercial healthcare world. Note, any negative trial of medical innovation has consequences for the designers and sponsors but their positive involvement in this work alongside the Warwick researchers should be acknowledged, supported and applauded.

The trial is a good exemplar of how well the surgical evaluation world has responded to the disparaging (but ultimately catalytic and very helpful) words of the editor of this very journal.⁷ Back in 1996 Professor Horton called for major improvements in the quality of clinical trials in surgery. Driven by the likes of Alderson, Morton, Hutchinson and co. at the Royal College of Surgeons (Eng), and the inception of dedicated surgical trials units both in the UK and globally over the past fifteen years, surgical science is almost unrecognisable from the past. The research team and surgical community should be very proud that a surgical trial on a new and unproven device that was stopped early for potential harm finds itself reported here. It may well become a landmark for progression in orthopaedic surgery, perhaps as much the practice changing placebo trial of Moseley et al twenty years ago.⁸

However, there is still work to do; on the lack of diversity in the research professions, on the acceptance that ALL new innovations should be tested properly before full introduction (in line with IDEAL principles⁹), on finding the most appropriate and efficient trial designs, on not stifling innovation or always looking to the negative, on implementing the findings and changing practice,

and ultimately on conducting research on questions that will provide most benefit to patients. This trial has shown that this specific innovation for shoulder pain patients may not be beneficial, but the next modification or different approach may well be different. We shouldn't stop at one trial, nor should we stop trying to find the best treatment for patients in any surgical discipline.

We declare no competing interests.

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1. Carr A, Cooper C, Campbell MK, et al. Effectiveness of open and arthroscopic rotator cuff repair (UKUFF): a randomised controlled trial. *Bone Joint J* 2017;99-B(1):107-15. doi: 10.1302/0301-620X.99B1.BJJ-2016-0424.R1
2. Metcalfe A, Parsons H, Parsons N, et al. . Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS): a group-sequential, double blind, multicentre randomised controlled trial. *Lancet* 2022
3. Parsons N, Stallard N, Parsons H, et al. An adaptive two-arm clinical trial using early endpoints to inform decision making: design for a study of sub-acromial spacers for repair of rotator cuff tendon tears. *Trials* 2019;20(1):694. doi: 10.1186/s13063-019-3708-6 [published Online First: 20191209]
4. Grammatopoulos G, Pandit H, Kwon YM, et al. Hip resurfacings revised for inflammatory pseudotumour have a poor outcome. *J Bone Joint Surg Br* 2009;91(8):1019-24. doi: 10.1302/0301-620X.91B8.22562
5. de Steiger RN, Hang JR, Miller LN, et al. Five-year results of the ASR XL Acetabular System and the ASR Hip Resurfacing System: an analysis from the Australian Orthopaedic Association National Joint Replacement Registry. *J Bone Joint Surg Am* 2011;93(24):2287-93. doi: 10.2106/JBJS.J.01727
6. Handel N, Garcia ME, Wixtrom R. Breast implant rupture: causes, incidence, clinical impact, and management. *Plast Reconstr Surg* 2013;132(5):1128-37. doi: 10.1097/PRS.0b013e3182a4c243

7. Horton R. Surgical research or comic opera: questions, but few answers. *Lancet* 1996;347(9007):984-5. doi: 10.1016/s0140-6736(96)90137-3
8. Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med* 2002;347(2):81-8. doi: 10.1056/NEJMoa013259
9. McCulloch P, Altman DG, Campbell WB, et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009;374(9695):1105-12. doi: 10.1016/S0140-6736(09)61116-8