Commentary & Perspective

The InSpace Balloon: Useful Augmentation or First-Line Therapy?

Commentary on an article by Nikhil Verma, MD, et al.: "InSpace Implant Compared with Partial Repair for the Treatment of Full-Thickness Massive Rotator Cuff Tears. A Multicenter, Single-Blinded, Randomized Controlled Trial"

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Massive rotator cuff tears account for 10% to 40% of all rotator cuff tears[1]. With current demographic characteristics and the age-related decrease in tissue quality for repair, there is a growing need for additional treatment options. The goal is to find technically simple, reproducible, and affordable surgical management for all patients with massive rotator cuff tears. Recently, the U.S. Food and Drug Administration (FDA) approved the InSpace balloon, a subacromial spacer that has been used in Europe since 2012. First described by Savarese and Romeo, the balloon is a pre-shaped spacer made of poly-L-lactide-co-ε-caprolactone that is inflated with saline solution, deflates 3 months after implantation, and is biodegradable within 12 months[2]. Similar to its competitive surgical solutions for massive rotator cuff tears, the principle behind the InSpace balloon is to recenter the humeral head, allowing for normal shoulder kinematics[2]. After promising cohort outcomes studies from Europe, the literature has lacked a Level-I randomized comparative study[3].

We applaud the efforts of Verma et al., who performed a prospective, randomized study that included 24-month follow-up from 20 sites where 184 patients were randomized to 93 InSpace balloons and 91 partial repairs. With the exception of superior forward elevation in the InSpace cohort, the study group reported equivocal clinical results after 24 months for the InSpace balloon and partial repairs for the treatment of massive rotator cuff tears. Inclusion criteria were a massive rotator cuff tear, International Cartilage Repair Society (ICRS) Grade <3, the rotator cuff defect being amenable to partial repair, and an intact subscapularis tendon. No decrease in range of motion was observed after the balloon's degradation. The InSpace group also experienced earlier functional recovery and shorter operative times. These findings were similar to prior observational clinical studies performed by Familiari et al.[3].

So should we all forget what we have learned in the last 2 decades and just inflate subacromial balloons? We think not! Verma et al. speculate that the efficacy of the balloon is caused by the recentering of the humeral head and reeducation of the deltoid. However, given knowledge from prior experiences following muscle transfer (latissimus dorsi transfer, trapezius transfer, pectoralis major transfer), the balloon provides a relatively short muscular retraining window prior to balloon deflation after just 3 months.

Although imaging was not performed in the present study by Verma et al., Familiari et al. reported no correlation of the acromiohumeral distance with the clinical outcome at a 3-year follow-up[3]. In his editorial commentary on the article by Familiari et al., Guevara speculated that the InSpace balloon serves more as an acromiohumeral cushion rather than producing a complex biomechanical change[4]. This may support the faster recovery and reduced pain after implantation of an InSpace balloon as reported by Verma et al., as the balloon prevents contact between the humeral head and the undersurface of the acromion. In addition to improved pain control and recovery time, Verma et al. reported an overall similar range of motion in both groups, which raises the question: are partial repairs the correct comparison group for the InSpace balloon? Why not perform a partial repair if amenable and then implant the balloon as a second-line therapy if the repair fails? Furthermore, if a full repair is not feasible, should a partial repair and a balloon be used in combination? Assuming that pain control leads to early rehabilitation and better functional outcomes, perhaps nonoperative treatment should be considered a more ideal comparison group. In 2008, Levy et al. reported that applying a strict 9-month physiotherapy regimen for massive rotator cuff tears in elderly patients resulted in an improvement in forward flexion from 40° to 160°[5]. In addition to improved clinical function, the rotator cuff prevents superior humeral head migration and therefore averts cuff tear arthropathy. The clinical outcomes after 24 months reported by Verma et al. should be followed with long-term radiographic outcomes to verify and further investigate the effects of the balloon. An additional concern of the balloon raised by Guevera was the demand for more scientific evidence on the potential increase in periprosthetic joint infections that the biodegradable balloon could produce[4]. We commend Verma et al. because their article illustrates a well-designed, multicenter Level-I study with the largest InSpace balloon group in the current literature.

However, considering the excellent 24-month clinical results of the superior capsular reconstruction from Lacheta et al.[6] and others, perhaps there should be a 3-way therapy algorithm for irreparable rotator cuff tears. We believe that, in young, active

patients with an irreparable massive rotator cuff tear, the more surgically demanding superior capsular reconstruction provides the best salvage option. With regard to the clinical results reported by Verma et al., one could consider augmenting partial repairs with a balloon to secure the construct and provide the possibility of early mobilization. In elderly patients, it is our opinion that the balloon should be considered alongside nonoperative treatment and reverse shoulder arthroplasty. Further long-term studies with radiographic imaging, histologically analyzed intraoperative biopsies, and comparative randomized clinical studies of competing treatment options are necessary to answer these questions.

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