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The role of biodegradable spacer implantation under local anesthesia for patients with massive rotator cuff tears and significant medical comorbidities

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Background: Massive rotator cuff tears are common, and the incidence increases with age. They are a challenging problem to deal with as many are irreparable. While there are a host of surgical options available, these can be prolonged procedures requiring general anesthesia and thus not suitable for elderly patients or those with significant medical comorbidities. In this study, we evaluate the role of a biodegradable balloon inserted under local anesthetic for a series of patients with massive cuff tears and significant medical comorbidities.

Methods: A prospective pilot study was performed on a series of patients between June 2018 and April 2019. Demographic data, as well as preoperative and postoperative clinical data including Subjective Shoulder Value and Oxford Shoulder Scores, were obtained.

Results: Four patients with magnetic resonance imaging-proven massive rotator cuff tears involving the supraspinatus were treated with an InSpace balloon under local anesthesia. All were of American Society of Anesthesiologists grade 4 and had exhausted nonoperative treatment. The mean Oxford Shoulder Score improved from a preoperative baseline of 17.25 (range 6-25) to a peak of 25.75 (range 15-34) at the 6-week postoperative mark before declining to 13.67 (range 6-23) at the final follow-up of 6 months. Subjective Shoulder Values also improved initially from a mean of 31.25 (range of 20-40) to a peak of 58.75 (range of 50-70) before reducing to 36.67 (range of 30-50) at the final follow-up of 6 months.

Conclusion: We have described the safety and early benefit from the use of a biodegradable balloon spacer inserted under local anesthetic as a management option for patients with massive rotator cuff tears, who may be unfit for other extensive reconstruction options, particularly for short-term pain relief as significant long-term gains were not demonstrated.

Rotator cuff tears are among the most common tendon injuries seen in orthopedic patients, resulting in significant pain and disability. The incidence of rotator cuff tears increases in frequency with age (prevalence of 54% in those older than 60 years compared to 34% in the general population)[21] and is often associated with tendon degeneration.

A massive rotator cuff tear (MRCT) was historically described as a rotator cuff tear with a diameter of 5 cm or more (usually an intraoperative classification)[7]; a complete tear of 2 or more tendons[10]; or a tear with a coronal length and sagittal width greater than or equal to 2 cm.[8] Other factors such as retraction of 1 of the 2 torn tendons beyond the glenoid (eg, Patte 3 in the coronal plane for supraspinatus) are also important for the classification.[13]

MRCTs comprise approximately 20% of all rotator cuff tears and 80% of recurrent tears.[4,16] MRCTs can result in altered glenohumeral kinematics, resulting in superior migration of the humeral head, cuff arthropathy, and pseudoparalysis of the shoulder.[22]

Managing MRCTs can present a very challenging problem for both orthopedic surgeons and patients as a significant proportion of these tears are determined to be irreparable on assessment[17]; have high rerupture rates, reported in the literature between 11%[14] and 94%[9]; long periods of rehabilitation after

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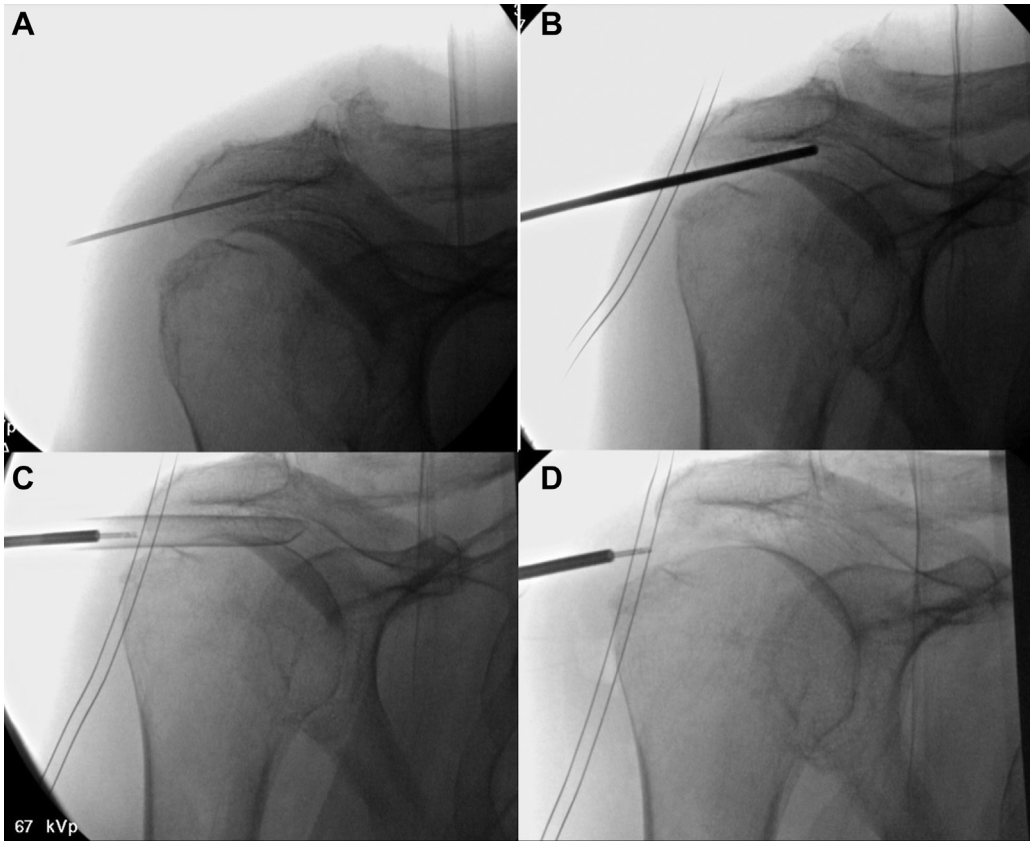

Figure 1 Image showing, under image intensifier guidance, (**A**) needle insertion, (**B**) balloon trochar insertion, (**C**) balloon being inflated, and (**D**) instrumentation removal leaving the balloon spacer behind.

repair; and high complications with rates of 10.6% quoted in the literature.[2]

A range of surgical options including cuff repair (to restore natural shoulder kinematics); débridement, with or without partial tendon repair; tendon transfer; muscle-tendon slide procedures; the utilization of rotator cuff allografts and synthetic graft materials; arthrodesis and arthroplasty, reverse arthroplasty, or hemiarthroplasty are available; but there is no consensus on the preferred option to treat this challenging patient group. These options are also prolonged procedures, often under general anesthetic, and may not be suitable for patients with significant medical comorbidities.

The InSpace balloon device (OrthoSpace, Caesarea, Israel) is a biodegradable, balloon-shaped spacer made of a biodegradable copolymer poly-L-lectide-co-ε-caprolactone in a 70:30 ratio that is deployed arthroscopically into the subacromial space of the shoulder, acting as a spacer in patients with MRCTs. It was originally designed as an alternative to cuff repair in the treatment of MRCTs, offering shorter rehabilitation and greater cost-effectiveness. Our aim in this study was to evaluate the role of InSpace balloon insertion under local anesthetic for a series of patients with massive MRCTs with significant medical comorbidities.

Materials and methods

This was a prospective pilot study comprising a series of patients who presented to our tertiary referral upper limb unit between June 2018 and April 2019. Patients were identified as having MRCTs. This assessment was made after clinical review and confirmed on magnetic resonance imaging scan. Patients had an initial period of nonoperative management with physiotherapy, analgesia, and steroid injection/s.

Patients with irreparable tears (due to extensive fatty infiltration on their parasagittal scans with Goutallier 3 and above) and extensive retraction to the glenoid (Patte 3 on their scans) who had failed a significant period of nonoperative treatment were included. They all had a significant functional limitation and were deemed to be medically unfit for general anesthesia. All were graded as high risk (grade 4) as per the American Society of Anesthesiologists (ASA) classification.[18] Preoperative evaluation included a comprehensive history and physical examination. No patients had any prior surgical intervention on the affected shoulder. Temporary improvement in clinical symptoms and active motion following an injection of local anesthetic was a prerequisite to inclusion. Preoperative and postoperative assessment included Subjective Shoulder Value (SSV) and Oxford Shoulder Score (OSS).

All procedures were performed by the senior author using a standardized technique. Patients were positioned in a beach-chair form in the operating theatre with antibiotics administered intravenously prior to the procedure. Ten milliliters of 1% xylocaine with adrenaline was administered to the skin at sites of standard posterior and lateral portals. A further 20 ml of 0.5% bupivacaine was injected into the subacromial space under image intensifier guidance. A 1.5-cm longitudinal incision was made in the skin just inferior to the midpoint between the anterior and posterior edges of the acromion (standard arthroscopic lateral portal). This incision was then opened using blunt dissection with an artery clip in the direction of the supraspinatus. A guide pin was then passed under fluoroscopic control, such that the tip of the pin was to lie 1 cm medial to the superior glenoid margin (proposed location of the

Table I
Patient demographics and comorbidities.

Patient	Age	Sex	Comorbidities	ASA grade
1	81	F	Aortic stenosis, AF, COPD, pulmonary hypertension	4
2	76	F	AF, aortic valve replacement, congestive cardiac failure, IDDM	4
3	71	M	CABG, IHD, COPD, lung cancer, hypertension, IDDM, peripheral vascular disease	4
4	79	M	Chronic kidney disease, IHD, IDDM, lymphoedema	4

ASA, American Society of Anesthesiologists; *AF*, atrial fibrillation; *COPD*, chronic obstructive pulmonary disease; *IDDM*, insulin-dependent diabetes mellitus; *CABG*, coronary artery bypass graft; *IHD*, ischemic heart disease.

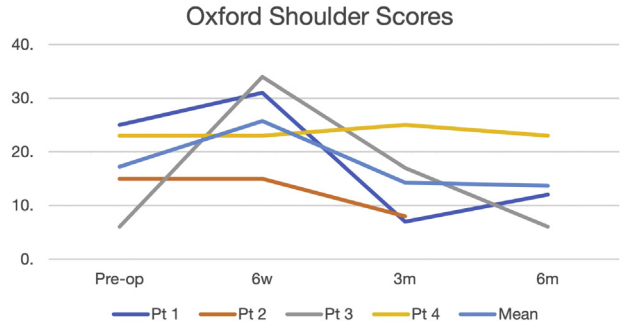

Figure 2 Change in the mean Oxford Shoulder Score at different time intervals. *Pt*, patient.

medial margin of the balloon). A second identical guide pin was inserted parallel to the initial pin to reach the lateral margin of the greater tuberosity (proposed location of the lateral margin of the balloon). A sterile measure was used to calculate the difference between the external tips of the 2 pins, thereby guiding the balloon size. A straight long hemostat was inserted in the proposed line of insertion of the balloon to ensure an adequate space was available for the next set of instruments. The introducer was then inserted via a lateral portal which contained the appropriately sized balloon (Fig. 1). The tip of the protective sheath was positioned at least 1 cm medial to the glenoid rim. After final positioning, the protective sheath of the introducer was pulled back while maintaining the position of the balloon itself. The balloon was subsequently inflated with saline as per the manufacturer's recommendations. This entire procedure was performed under fluoroscopic guidance, and the final check was to ensure the balloon was dislocated. Fixed proximal humeral migration would preclude this procedure although we did not encounter this challenge. Occasionally, a gentle downward traction by an assistant was necessary during implantation. Following the insertion of the device, the arm was then moved to allow positioning of the balloon into a natural place. The skin incision was closed with an absorbable subcutaneous suture. Postoperatively the arm was placed into a polysling for comfort only, and patients were commenced on a standardized deltoid rehabilitation program immediately. There was no restriction on their movement postoperatively. All care was supervised by a specialist shoulder physiotherapist at our unit. Patients were followed up at time intervals of 6 weeks, 3 months, and 6 months postoperatively in the clinic using validated scores including the SSV and OSS.

Results

The mean age of the patients was 76.8 years (range, 71-81). There were 2 male and 2 female patients. All patients had MRCTs involving the supraspinatus, confirmed on magnetic resonance imaging scan, and clinically had pain and weakness on assessment of supraspinatus. All patients had previously undergone

Table II
Patient-reported outcomes scores, preoperatively and at 6 weeks, 3 months, and 6 months postoperatively.

Patient	Preop		6 Weeks		3 Mo		6 Mo	
	OSS	SSV	OSS	SSV	OSS	SSV	OSS	SSV
1	25	40	31	70	7	80	12	50
2	15	40	15	60	8	40	-	-
3	6	20	34	50	17	50	6	30
4	23	25	23	55	25	45	23	30
Mean	17.25	31.25	25.75	58.75	14.25	53.75	13.67	36.67

OSS, Oxford Shoulder Score; *SSV*, Subjective Shoulder Value.

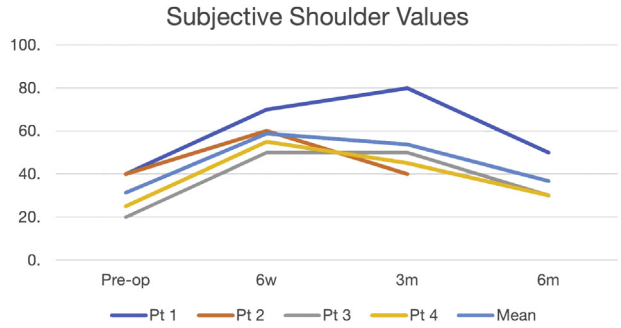

Figure 3 Change in the mean Subjective Shoulder Values at different time intervals. *Pt*, patient.

nonoperative treatment with physiotherapy, and none had had any prior surgical intervention to the affected shoulder. All patients had significant medical comorbidities and were graded ASA 4, deeming them high risk for general anesthesia (Table I). There were no complications related to the procedure.

The mean OSS improved from the preoperative baseline of 17.25 (range 6–25) to 25.75 (range 15-34) at the 6-week postoperative mark (Fig. 2). Thereafter, the benefit appeared to be lost (Table II), and the OSS were on average lower than preoperative values. The mean SSV initially improved at 6 weeks from 31.25 (range 20-40) to 58.75 (range 50-70) (Fig. 3). A clinical photograph shows some of these early improvements (Fig. 4). However, these scores then declined again at the 3-month (mean 53.75) and 6-month (mean 36.67) postoperative time periods but stayed above the preoperative score. Unfortunately, 1 patient died before the 6-month follow-up due to causes unrelated to her shoulder surgery.

Discussion

The primary function of the rotator cuff is to work synergistically with the deltoid to maintain a balanced force couple about the glenohumeral joint. Coronal and transverse plane force couples exist between the subscapularis anteriorly and infraspinatus and teres minor posteriorly. The rotator cuff force across the glenoid

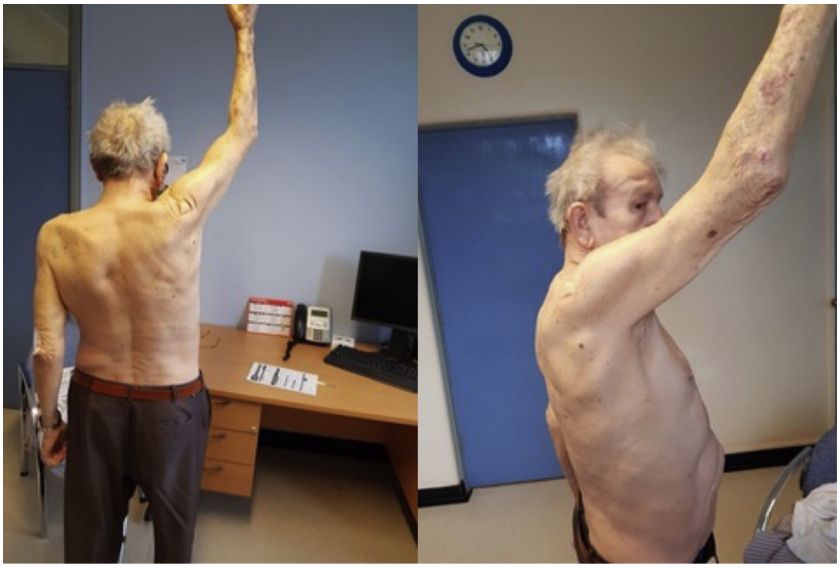

Figure 4 Early improvement of the patient at 2 months after surgery, demonstrating forward elevation.

provides concavity compression, creating a fixed fulcrum and allowing periscapular muscles to move the humerus about the glenoid. The rotator cable, a thickening of the rotator cuff, acts as a "suspension bridge"[5] and can help to maintain function even in the presence of cuff tears or a good partial rotator cuff repair. In the scenario of an uncompensated MRCT with rotator cable disruption, the moments created by the opposing muscular forces are insufficient to maintain equilibrium in the coronal plane, resulting in altered kinematics, comprising concavity compression which allows superior migration of the humeral head and ultimately may lead to pseudo paralysis.[13] MRCTs present a very challenging problem as tear size is a strong predictor of failure of cuff repair. This is independent of patient age, tissue quality, and time to surgery.[6,15] Several surgical options for MRCTs including direct repair, débridement, tendon transfer, allograft, synthetic graft materials (superior capsular reconstruction), arthrodesis, reverse arthroplasty, and hemiarthroplasty exist, but there is no consensus on the preferred option to treat this challenging patient group.

The InSpace balloon was originally intended and proposed as an alternative to repair of massive cuff tears due to the long recovery, cost, high failure rates, and complications associated with repair of these injuries. This biodegradable spacer supposedly works by reducing subacromial friction and extending the subacromial space ("subacromial spacer") and acts as a "fixed-fulcrum" keeping the humeral head centered during dynamic movement.[1] It is thought that such change in biomechanics may provide a sufficient window of opportunity for a successful deltoid rehabilitation. It may also support healing of the tendon-bone interface since studies have shown that in the presence of partial repairs of the cuff, it can improve function.[5]

Early results of the InSpace balloon for MRCTs have been promising. Senkovic et al,[20] in the first in vivo prospective cohort studies, showed that InSpace balloons offer a less invasive, simple, low-risk option with minimal morbidity and promising initial results. Holschen et al[12] also showed improved shoulder function with an InSpace balloon with an improved Constant score from 36.8 to 69.5 after 22 months. Both these studies, however, were performed under general anesthetic.

Our study shows that there is clinical improvement in both OSS (mean increase of 8.5 from 17.25 to 25.75) and SSV scores (mean increase of 27.5 from 31.25 − 58.75) in the short term (within 6 weeks). Patients subjectively felt that the procedure had improved their pain and function in the short term and would have the procedure again if offered the opportunity. There were also no specific intraoperative complications, which appears to correlate with previous studies[11,12,20] although we have exclusively performed the procedure under local anesthetic in a high-risk cohort, similar to the study by Gervasi et al,[11] suggesting that this may be a viable option in the short term for high-risk anesthetic patients (all ASA 4) with few salvage options for MRCTs as it is a low-risk, low-morbidity procedure.

Efficacy results are also comparable with previous existing techniques to treat MRCTs including arthroscopic repair by Burkhart et al[3] which demonstrated a clinical improvement in patients in the 50- to 75-year-old group with fatty infiltration >75% or arthroscopic débridement and acromioplasty described by Rockwood et al.[19] The current study also suggests that this procedure can be done under local anesthetic, achieving similar results in short term.

However, unlike previous studies,[11,12] we were unable to demonstrate long-term maintenance of this improvement with a fall in the OSS to below preoperative levels at 3 months (25.75 to 14.25) and 6 months (13.67) and a fall in the SSV from 58.75 preoperatively to 53.75 at 3 months and 36.67 at 6 months. This suggests that these improvements are not maintained in the long term; however, in the case of SSV, this still remained better than preoperative levels (31.25).

It is important to note that we have used a different outcome measure to the Constant score described in the literature[12] and also have a very small sample size with 4 patients, but only 3 analyzed up to 6 months (as 1 died during the study period from an unrelated medical condition). It is only possible therefore to draw the conclusion that the implant is safe in the short term and shows some clinical improvement although this does not appear to be maintained in the long term in our small sample size. It is also worth noting that we did not have a control group of patients, matched in terms of age and comorbidities with massive irreparable cuff tears treated with physiotherapy only (using the same deltoid rehabilitation regime). This would be useful in a subsequent follow-up study to determine if there was a difference in outcome between the two groups although our patient group had already failed nonoperative measures including standard

physiotherapy using a deltoid rehabilitation regime. This is a useful pilot study demonstrating the safety and feasibility of such a strategy in this difficult group of patients. We would recommend a further study, with a larger group of participants and perhaps longer follow-up.

Conclusion

MRCTs where nonoperative management has failed are very challenging to treat in medically unfit patients. Treatment with an InSpace balloon performed under local anesthetic provides a potential management option as it appears to be safe in this difficult patient cohort. In our series, results were not maintained after an initial improvement, and future studies are required to explore the role of this technique.

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