J Shoulder Elbow Surg (2020) 29, e313–e316

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Symptomatic foreign body reaction secondary to subacromial balloon spacer placement: a case report

Emilio Calvo, MD, PhD, MBA[a], Maria Valencia, MD, PhD[a], Jose Angel Merino-Garcia, MD[b], Gonzalo Luengo-Alonso, MD[a,*]

[a]*Shoulder and Elbow Reconstructive Surgery Unit, Department of Orthopaedic Surgery and Traumatology, IIS-Fundación Jiménez Díaz, Universidad Autónoma, Madrid, Spain*
[b]*Department of Pathology, HU Fundación Jiménez Díaz, Universidad Autónoma, Madrid, Spain*

Keywords: Subacromial balloon spacer; shoulder arthroscopy; failed rotator cuff surgery; rotator cuff retear

Rotator cuff tears (RCTs) can be detrimental to patient quality of life and are one of the most common causes of shoulder pain. According to reports appearing in various case series, up to 40% of all tears are massive (greater than 5 cm in size or complete tear of 2 or more tendons).[2] Massive tears can be irreparable because surgical repair may pose a substantial risk of postoperative retear.[11,16]

One treatment option available to patients with irreparable RCTs that are unresponsive to conservative treatment is reverse shoulder arthroplasty, an approach with proven satisfactory long-term outcomes. However, in some patients presenting irreparable rotator cuffs, prosthetic shoulder surgery may not be recommended because of comorbidities, contraindications to arthroplasty, or patient preference. An alternative for these patients is less invasive arthroscopic surgery, which includes débridement and biceps tenotomy, partial repair or margin convergence, superior capsular reconstruction, and tendon transfer.

Recently, a new device consisting of a biodegradable subacromial spacer, the InSpace balloon (OrthoSpace, Kfar Saba, Israel),[7] has been proposed as an option in this clinical setting. Made of a biodegradable copolymer (poly-L-lactide-*co*-ε-caprolactone), the spacer is filled with a physiological solution (NaCl), deflates within 3 months of placement, fully degrading approximately 12 months after surgery.[13] The goal of this device is to improve gliding between the humeral head and the undersurface of the acromion. Additionally, the balloon may also improve shoulder kinematics by helping to keep the humeral head centered during dynamic movements.[3,14]

The subacromial balloon spacer has been adopted by the orthopedic community based on encouraging clinical and imaging results, including increased acromiohumeral distance at short and medium-term follow-ups.[4,8,10,13] An additional advantage of this technique is that it can be placed easily and with minimal invasiveness as part of a conventional arthroscopic procedure or percutaneously under fluoroscopic or ultrasound guidance.[2,5,12,15] Furthermore, because the subacromial balloon spacer degrades, it does not trigger a symptomatic foreign body reaction, and existing reports of complications are rare.[4,13]

We present a case of failed degradation of an implanted subacromial balloon spacer causing a symptomatic foreign body reaction, the first of its kind to appear in the literature.

Institutional review board approval was not required for this case report.

*Reprint requests: Gonzalo Luengo-Alonso, MD, Department of Pathology, HU Fundación Jiménez Díaz, Universidad Autónoma, Av. Reyes Católicos, 2. 28040, Madrid, Spain.

E-mail address: ecalvo@fjd.es (G. Luengo-Alonso).

https://doi.org/10.1016/j.jse.2020.02.029

Case report

A 47-year-old woman visited our hospital to address the pain she was having in her dominant (right) shoulder. Her history was not remarkable except for a right rotator cuff tear for which she had undergone 2 previous surgeries in another facility. The initial surgery took place 2 years before the patient came to our hospital and consisted of arthroscopic cuff tear repair with anchors. Ten months after surgery, the pain persisted, and the shoulder showed severe weakness. A magnetic resonance imaging scan of the shoulder showed a retear of the rotator cuff. She was scheduled for revision surgery, and 1 year after the first procedure, arthroscopic revision rotator cuff repair was carried out. For this procedure, a subacromial balloon spacer was implanted to protect the suture.

The patient later visited our department because of a poor outcome of the revision surgery. Her pain had increased, and her shoulder function was worse than before the intervention. She did not have fever or any symptoms that could suggest a potential infection. A physical examination revealed no swelling, increase in local temperature, or signs of systemic involvement. The shoulder range of motion was severely limited, and movements were painful. Active range of motion was as follows: 45° forward flexion, 45° abduction, and 40° external rotation with the arm at the side; the patient reached L3 on internal rotation. Passive range of movement was also restricted: 80° forward flexion, 80° abduction, 60° external rotation, and no changes in internal rotation.

As for the imaging studies, conventional radiographs revealed no abnormalities. The acromiohumeral distance and the space between the humeral head and the glenoid were preserved. A magnetic resonance imaging scan showed a partial-thickness supraspinatus tear and presence of a foreign body in the subacromial space (Fig. 1). The biceps tendon and the remaining joint structures appeared healthy.

On consultation with the patient, we decided to perform revision shoulder arthroscopy again to carry out a subacromial bursectomy to clear the space of any potential adhesions, check the status of the rotator cuff, and to remove the foreign body if present. Samples for culture were also to be obtained to rule out the presence of infection. The procedure was scheduled 8 months after the previous surgery.

Conventional shoulder arthroscopy was performed in the beach chair position under a combined single-shot brachial plexus blockade and general anesthesia. Arthroscopic visualization showed no abnormalities in the glenohumeral joint, including the long head of the biceps tendon. The subacromial space was then examined from the vantage point of regular posterior and lateral portals after bursectomy, revealing mild scar tissue that was resected with an arthroscopic shaver. The supraspinatus tendon was examined from both sides and appeared thin, but it healed without recurrent tears. Interestingly, a whitish oval fibrous tissue resembling a foreign body was clearly seen lodged immediately posterior to the spine of the scapula in the supraspinatus fossae over the muscle fibers of the supraspinatus. The surface of this body was smooth, consistency was soft but resistant on palpation, and it was loosely attached to the surrounding structures by some scar tissue (Fig. 2). The tissue was carefully dissected, and finally retrieved through an accessory lateral portal using a grasping forceps (Fig. 3). This portal required enlargement to allow for the passage of the foreign body. The material was sent for microbiologic culture and histopathologic analysis. Additional samples of bursae and soft tissue samples were also obtained for culture. All microbial cultures were negative, and histopathologic analysis revealed a nodular oval fragment measuring 2.2 × 1.6 × 0.7 cm showing a clear giant cell reaction associated with synovial hyperplasia (Figs. 4 and 5). The final histopathologic diagnosis was a foreign body reaction.

The patient began active range of motion and physical therapy the day after surgery. Her pain had disappeared completely after surgery, and active and passive range of

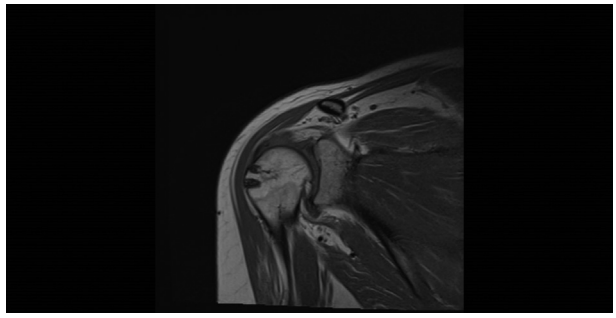

Figure 1 Fat suppression T2 coronal-view magnetic resonance imaging showing foreign body located at the subacromial space medial to the joint line.

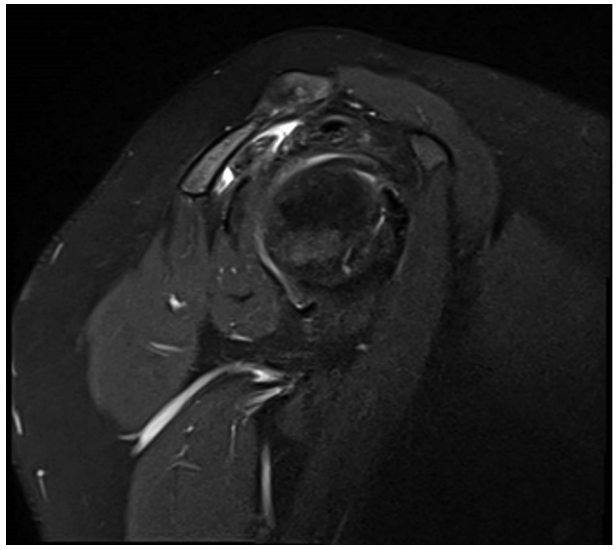

Figure 2 Shoulder arthroscopic view form a lateral portal of an oval foreign body located at the subacromial space close to the spine of the scapula.

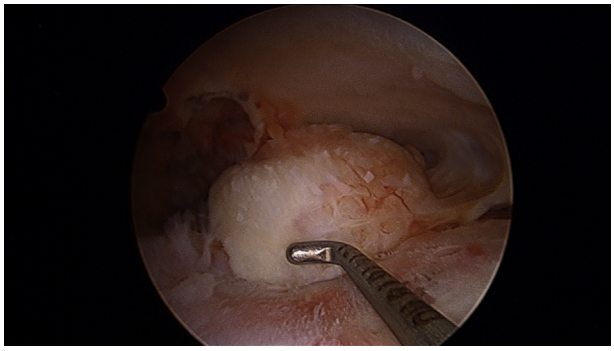

Figure 3 Foreign body removed.

Figure 4 Foreign body removed.

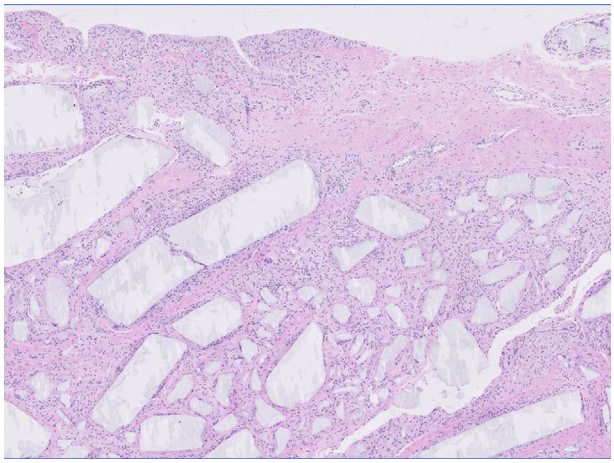

Figure 5 Low magnification shows soft tissue with synovial hyperplasia and abundant amorphous translucent material rimmed by hystiocytes and multinucleated giant cells, embedded in dense collagenous stroma with limited inflammation.

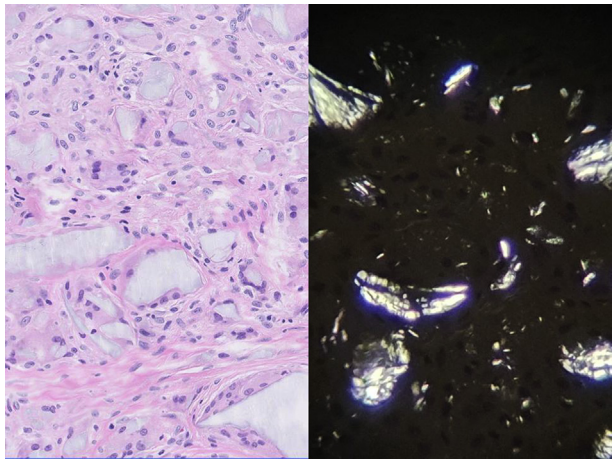

Figure 6 High magnification shows giant cell reaction to foreign body material. Under polarized light, the foreign body material was weakly birefringent.

movement were progressively resumed. Twelve months after surgery, she had no pain, had regained complete range of motion, performed daily activities, and her Constant score is 92 points.

Discussion

Functional improvement, pain reduction, and high satisfaction rates have been reported at short- and long-term (1-5 years) follow-up in patients with massive irreparable RCTs treated with the subacromial balloon spacer.[4,9] The subacromial balloon spacer can be placed using less invasive techniques such as arthroscopy or fluoroscopy, and is only contraindicated for use in patients with known allergy to the materials of the device and those with an active or latent infection. As in this case, the subacromial balloon has also been advocated as treatment for reparable rotator cuff tears as a method to protect the suture until healing takes place in addition to massive tears.[1,11]

Despite the encouraging results after subacromial balloon spacer implantation, many important aspects of this device have been under-researched, such as its mechanism of action, its limited duration, the exact mechanism explaining why pain and functional scores continue to improve beyond the period of spacer dissolution, and the potential adverse effects associated to its use. In a cadaveric study, Singh et al[14] demonstrated that the subacromial balloon can effectively depress the humeral head and restore glenohumeral motion when inflated with 25 mL of saline, which is higher than the volume recommended by the manufacturer. Image studies have failed to demonstrate that the subacromial balloon spacer can modify either the acromiohumeral distance or the Hamada classification of the shoulder, thus casting doubt on the

potential stabilizing effect of the balloon argued by its supporters.[10,13,14] Moreover, the subacromial balloon spacer has proven to reduce pain almost immediately after insertion,[3,5,6,12,13,15] though pain reduction may not only be attributed to the spacer but also to the débridement and bursectomy performed during the arthroscopy. This limitation has been underlined by other studies that question the potential benefit of the device.[11]

Although in vitro studies have described balloon resorption 1 year postoperatively, clinical evidence of degradation is scant,[13] and Ricci et al[10] reported longer periods of balloon degradation. In spite of this longer period, no major device-related complications have been reported: to date there has been 1 case of migration[4] and 2 of synovitis with cyst formation.[13] In the case reported here, the subacromial balloon was still present 8 months postoperatively and triggered a symptomatic foreign body reaction as proven by the histopathologic analysis of the specimen, followed by a satisfactory outcome after removal of the object.

All these data suggest that future studies including a control group and longer follow-up are needed to better understand the long-term outcomes and potential adverse effects of this procedure. There is an ongoing prospective, controlled clinical trial in the United States comparing subacromial spacer implantation and partial repair for the treatment of massive RCTs. The results of this study are expected to further elucidate the clinical safety and efficacy of the subacromial spacer.[3] Our case provides further evidence that the subacromial spacer may promote a symptomatic foreign body reaction. This is the first report demonstrating that the subacromial spacer does not necessarily degrade and can be a cause of postoperative pain and poor outcome.

Conclusions

The subacromial balloon spacer is an alternative surgical option for the treatment of massive or irreparable RCTs. Although the technique can be performed using minimally invasive methods, it is not devoid of complications, and the possibility of foreign body reaction in patients causing postoperative pain and limited range of motions should be borne in mind.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

References

1. Bozkurt M, Akkaya M, Gursoy S, Isik C. Augmented fixation with biodegradable subacromial spacer after repair of massive rotator cuff tear. Arthrosc Tech 2015;4:e471-4. https://doi.org/10.1016/j.eats.2015.04.007
2. Castagna A, Garofalo R, Maman E, Gray AC, Brooks EA. Comparative cost-effectiveness analysis of the subacromial spacer for irreparable and massive rotator cuff tears. Int Orthop 2019;43:395-403. https://doi.org/10.1007/s00264-018-4065-x
3. Chevalier Y, Pietschmann MF, Thorwächter C, Chechik O, Adar E, Dekel A, et al. Biodegradable spacer reduces the subacromial pressure: A biomechanical cadaver study. Clin Biomech (Bristol, Avon) 2018;52:41-8. https://doi.org/10.1016/j.clinbiomech.2017.12.008
4. Deranlot J, Herisson O, Nourissat G, Zbili D, Werthel JD, Vigan M, et al. Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: clinical and radiographic results of 39 retrospectives cases. Arthroscopy 2017;33:1639-44. https://doi.org/10.1016/j.arthro.2017.03.029
5. Gervasi E, Cautero E, Dekel A. Fluoroscopy-guided implantation of subacromial "biodegradable spacer" using local anesthesia in patients with irreparable rotator cuff tear. Arthrosc Tech 2014;3:e455-8. https://doi.org/10.1016/j.eats.2014.05.010
6. Holschen M, Brand F, Agneskirchner J. Subacromial spacer implantation for massive rotator cuff tears clinical outcome of arthroscopically treated patients. Obere Extremität 2017;12:38-45. https://doi.org/10.1007/s11678-016-0386-9
7. InSpace™ system in comparison to best repair of massive rotator cuff tear. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT022084402
8. Malahias M-A, Brilakis E, Avramidis G, Antonogiannakis E. Satisfactory mid-term outcome of subacromial balloon spacer for the treatment of irreparable rotator cuff tears. Knee Surg Sports Traumatol Arthrosc 2019;27:3890-6. https://doi.org/10.1007/s00167-019-05485-4
9. Piekaar RSM, Bouman ICE, van Kampen PM, van Eijk F, Huijsmans PE. The subacromial balloon spacer for massive irreparable rotator cuff tears: approximately 3 years of prospective follow-up. Musculoskelet Surg 2019. https://doi.org/10.1007/s12306-019-00614-1
10. Ricci M, Vecchini E, Bonfante E, Micheloni GM, Berti M, Schenal G, et al. A clinical and radiological study of biodegradable subacromial spacer in the treatment of massive irreparable rotator cuff tears. Acta Biomed 2017;88:75-80. 10.23750/abm.v88i4 -S.6797.
11. Ruiz Ibán MA, Lorente Moreno R, Ruiz Díaz R, Álvarez Sciamanna R, Paniagua Gonzalez A, Lorente Gómez A, et al. The absorbable subacromial spacer for irreparable posterosuperior cuff tears has inconsistent results. Knee Surg Sports Traumatol Arthrosc 2018;26:3848-54. https://doi.org/10.1007/s00167-018-5083-3
12. Savarese E, Romeo R. New solution for massive, irreparable rotator cuff tears: the subacromial "biodegradable spacer." Arthrosc Tech 2012;1:e69-74. https://doi.org/10.1016/j.eats.2012.02.002
13. Senekovic V, Poberaj B, Kovacic L, Mikek M, Adar E, Dekel A. Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears. Eur J Orthop Surg Traumatol 2013;23:311-6. https://doi.org/10.1007/s00590-012-0981-4
14. Singh S, Reeves J, Langohr GDG, Johnson JA, Athwal GS. The effect of the subacromial balloon spacer on humeral head translation in the treatment of massive, irreparable rotator cuff tears: a biomechanical assessment. J Shoulder Elbow Surg 2019;28:1841-7. https://doi.org/10.1016/j.jse.2019.03.036
15. Szollosy G, Rosso C, Fogerty S, Petkin K, Lafosse L. Subacromial spacer placement for protection of rotator cuff repair. Arthrosc Tech 2014;3:e605-9. https://doi.org/10.1016/j.eats.2014.06.017
16. Valencia Mora M, Morcillo Barrenechea D, Martín Rios MD, Foruria AM, Calvo E. Clinical outcome and prognostic factors of revision arthroscopic rotator cuff tear repair. Knee Surg Sports Traumatol Arthroscop 2017;25:2157-63. https://doi.org/10.1007/s00167-016-4392-7