



Subacromial Balloon Spacer Implantation

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Abstract

Purpose of Review Massive irreparable rotator cuff tears present a treatment challenge for the orthopedic surgeon. There is no gold standard among numerous treatment options including nonoperative management, partial repair, debridement, superior capsular reconstruction, and reverse shoulder arthroplasty. In recent years, yet another option, an implantable biodegradable subacromial balloon spacer has become available with promising early results.

Recent Findings Biomechanical studies have demonstrated that the balloon spacer effectively restores the normal humeral head position and glenohumeral joint mechanics. This device has been used in Europe since 2012 with promising clinical results. Most of the studies on this implantable balloon represent single surgeon uncontrolled case series with small numbers of patients, but they report improvements in pain and function following spacer placement, with the longest term studies reporting maintenance of improvements for up to 5 years. Certain studies have shown a benefit when the procedure is done in isolation as well as in combination with other arthroscopic procedures, such as partial rotator cuff repair.

Summary The balloon subacromial spacer is a promising new device that can be used in the treatment of patients with massive, irreparable rotator cuff tears. In our experience, patients without arthritis who have active forward elevation over 90 degrees and an intact subscapularis have the best chance of a good outcome. We recommend performing the procedure arthroscopically along with any other indicated procedures including debridement, partial repair, and biceps tenotomy or tenodesis. High-quality long-term studies are needed to better define the indications and outcomes of the implantable balloon spacer in the management of irreparable cuff tears.

Keywords Balloon implantable spacer · Subacromial spacer · Irreparable rotator cuff tear · Chronic rotator cuff tear · Nonoperative treatment of rotator cuff tears

Introduction

Massive rotator cuff tears represent approximately 10 to 40% of all rotator cuff tears [1, 2] and many of these are deemed irreparable due to host, tissue, and biomechanical factors. Nonoperative modalities, such as anti-inflammatories and

physical therapy, are used initially in the treatment algorithm of these tears, but a challenging problem remains when such treatments fail. There is no consensus or well-defined algorithm to direct the surgeon who proceeds with the operative management of functionally irreparable rotator cuff tears [3]. Depending on the patient's goals and tear characteristics, treatment may include arthroscopic debridement, biceps tenotomy or tenodesis, partial rotator cuff repair, cuff augmentation, tendon transfers, superior capsular reconstruction, and ultimately reverse shoulder arthroplasty [4–10]. An implantable biodegradable subacromial balloon (InSpace, OrthoSpace, Inc., Caesarea, Israel) for the treatment of massive irreparable rotator cuff tears, first described in 2012 [11] represents another treatment alternative to consider. The goal of balloon implantation is to offer a relatively quick, lower risk procedure to relieve pain, and restore the biomechanics of the glenohumeral joint through the depression of the humeral

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head and reduction of subacromial friction during shoulder abduction [11]. This technique has shown promising early results, but better quality long-term data are needed.

How Does the Subacromial Spacer Balloon Work?

The InSpace subacromial spacer is inserted between the acromion and the humeral head (Fig. 1). It is made of a copolymer poly-L-lactide-co-ε-capro-lactone that degrades over 12 months and is insufflated with normal saline. The balloon is contraindicated only in patients with allergy to the material or in the presence of active infection or tissue necrosis at the implantation site. Ideal indications have not yet been defined. Implantation of the balloon is typically done arthroscopically, either in a beach chair or lateral decubitus position, which allows the surgeon to address any other pathology found in the shoulder at the time of implantation [12]. When the balloon is inserted as an isolated procedure, it is generally best done with minimal to no debridement of the subacromial bursae to prevent the balloon from escaping from the subacromial space to other areas, such as the supraspinatus fossa. If rotator cuff repair or other procedures are being performed at the same time, then visualization of the field should be performed per surgeon preference. The balloon comes in three sizes: small, medium, and large. The medial border of the spacer should be 1 cm medial to the superior glenoid rim and the lateral border of the spacer should be at the lateral acromial border. In order to minimize implant migration, a larger balloon is recommended if the measurement falls between two sizes [12•]. In the setting of partial rotator cuff repair, one study has recommended using the smaller of the two sizes to limit restriction of blood flow and any potential stress on the repair [13].

The procedure can also be done under local anesthetic with fluoroscopic guidance [14]. The subacromial space is infiltrated with lidocaine and marcaine under sterile conditions. A



Fig. 1 Schematic of the subacromial balloon spacer in position between the rotator cuff and the acromion. Illustration courtesy of OrthoSpace

lateral portal incision is then made, and the spacer is inserted under fluoroscopic guidance instead of direct arthroscopic visualization to measure the space and select the appropriate size implant. The adequate position of the balloon is confirmed with fluoroscopic images (Fig. 2). More recently, ultrasound-guided implantation under local anesthesia has also been reported [15]. Such minimally invasive techniques have the advantage of not requiring any general anesthesia, a potential benefit in an elderly or medically debilitated population [14, 15]. However, an important drawback of this technique is the inability to directly visualize the joint for evaluation of associated pathology and the inability to perform any concomitant procedures for pain reduction or functional improvement, such as subacromial decompression or biceps tenotomy. The majority of clinical reports to date are based on arthroscopic implantation, which allows for full visualization and adjuvant treatment.

Biomechanical Data

Since the first description of balloon implantation for irreparable rotator cuff tears in 2012, biomechanical studies have contributed to further understanding of the direct effects of the spacer on the glenohumeral joint and the potential reasons for clinical benefit. Using a static cadaver model to study the impact of balloon implantation in massive rotator cuff tears, Chevalier et al. found reductions in peak pressures across the glenohumeral joint and increased distribution of the load in the subacromial space [16•]. The authors speculated that due to these changes, strain in the rotator cuff could also decrease with this procedure, making balloon implantation theoretically beneficial not only in correcting shoulder biomechanics but also in protecting against further development of cuff tear arthropathy.

Lobao et al. used a dynamic cadaveric shoulder model to assess the biomechanics of the balloon spacer in the setting of a massive multi-tendon irreparable tear [17••]. The implantable balloon restored glenohumeral contact pressures, lowered the humeral head, and increased the deltoid load, all of which may contribute to normalizing the biomechanics of the shoulder and counteract the derangements seen in rotator cuff arthropathy.

A recent study assessed the impact of various fill volumes of the balloon spacer on humeral head translation, concluding that 25 mL was best to appropriately depress the humeral head and restore its position to that of the intact glenohumeral joint [18]. Additionally, these authors found that the insertion of the balloon spacer caused anterior translation of the humeral head beyond the normal head position at all fill levels studied. Although the anterior translation was small and unlikely to be clinically significant, this translation raises concerns about using balloon implantation in the setting of a torn

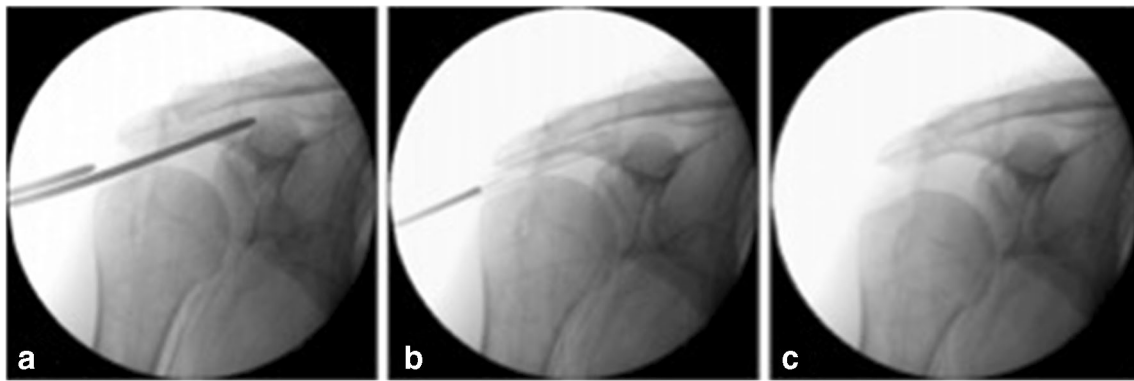


Fig. 2 These images demonstrate implantation of the balloon spacer under fluoroscopic guidance. Reprinted from Gervasi et al. [14]

subscapularis, where the anterior translation of the humeral head could become more pronounced and pathologic or could excessively stress a repaired subscapularis.

The biomechanics of balloon implantation have been compared with superior capsule reconstruction for irreparable rotator cuff tear, with no differences between the two in terms of depression of the humeral head or restoration of humeral head position in reference to the intact state [19]. By restoring the humeral head to its native position against the glenoid, these techniques restore the concavity compression of the glenohumeral joint and allow for compensated functional shoulder motion with minimal pain. Current biomechanical data show that balloon implantation functions well in this regard, giving a sound biomechanical foundation for the functional improvements seen in clinical studies.

Clinical Results

In the USA, balloon implantation remains under clinical investigation. A single-blind randomized multicenter clinical trial comparing balloon implantation to partial rotator cuff repair of massive rotator cuff tear was conducted at 18 sites with preliminary results submitted to the FDA in 2019. However, in Europe, balloon implantation has been approved for use since 2010 and since the original report of the technique, multiple authors have published their indications and results with the procedure [14, 20, 21, 22•, 23, 24].

In the first prospective study of 20 patients undergoing the procedure, improved Constant scores were observed for up to 3 years [20]. These investigators also found improvements in pain scores as early as 1 week post-procedure and improvements in strength 18 months post-procedure. Similar results were found in 15 patients who had the spacer placed under fluoroscopic guidance, with sustained improvements in Constant score from 31.9 preoperatively to 69.8 at 1-year follow-up and improvements in pain VAS and ASES score as well [14].

Other small studies have examined objective findings including a range of motion and radiographic data. One study of

14 patients who underwent balloon implantation for irreparable rotator cuff tears found an improved range of motion and improved Constant and Oxford shoulder scores in all patients at an average of 35 months with no complications [21]. A study of 37 patients with an average follow-up of 33 months found improvements in range of motion and Constant scores despite decreased acromial humeral index at final follow-up [22•]; in this study, one revision was performed to remove a spacer that had migrated. A study of patients who underwent balloon implantation with and without biceps tenotomy found no differences in outcomes, with over 85% of patients demonstrating an improvement in Constant score of at least 10 points at 12 months post-procedure [23]. Similarly, another study of 31 patients undergoing balloon implantation found 80% patient satisfaction at final follow-up with no differences in outcome when comparing those who had debridement of their tears and those who had partial non-anatomic repair of their tears with balloon implantation [25•].

These studies reported improvements for the majority of patients, but they were small and lacked controls or comparison to alternative accepted procedures. Holschen et al. attempted to address this gap with a retrospective case-control study of 23 patients with rotator cuff arthropathy but no osteoarthritis [26••]. They compared 11 patients who underwent debridement, synovectomy, bursectomy, biceps procedure, and partial rotator cuff repair with 12 patients who underwent the same procedures in addition to balloon implantation. Patients in the balloon group had lower preoperative Constant scores (36.8 versus 60.7). At a mean follow-up time of 23 months, there were statistically significant improvements in Constant scores in both groups, to 69.5 in the balloon group ($p < 0.001$) and to 77.6 in the control group ($p < 0.001$), with a larger absolute improvement in the balloon group ($p < 0.001$). This study is limited by its retrospective nature and lack of randomization with preoperative differences between the groups undergoing the two procedures [26••].

Long-term data on balloon implantation are needed. According to the manufacturer, balloon degradation occurs after 12 months, although published reports note degradation

as early as 3 to 6 months. However, studies have shown clinical improvements beyond 12 months, for reasons that are not yet clear. Sustained improvements in Oxford Shoulder score and pain were reported for 44 patients with balloon implantation between 1- and 3-year follow-up [27]. In another study, 5-year follow-up data showed maintenance of Constant score improvements at 3 years and 5 years [28••]. These results are promising, but more controlled and longer-term follow-up studies are still needed, as well as studies to elucidate the mechanism of these sustained improvements, given the anticipated earlier degradation of the spacer.

Some reports have questioned the conclusions of these single surgeon uncontrolled series. A report of a 2-year follow-up on 15 patients who underwent balloon implantation for irreparable posterior superior rotator cuff tears found that five required revision to reverse shoulder arthroplasty within 2 years for persistent symptoms [29••]. The remaining 10 patients had improvement in their median Constant score from 35 to 53, but only 4 patients had an improvement in Constant score of more than 10 points [29••]. The discrepancy between these findings and previous reports highlights the need for large, prospective trials of balloon implantation to ensure that this procedure is associated with clinical benefit beyond that of already described techniques.

A recent systematic review compiled results from seven balloon implantation studies with at least 80% of the patients in each study followed up, a follow-up time of at least 3 months, and a clear indications statement that tears were irreparable, in an effort to include only the highest quality data available [30••]. However, only one study was a level 3 case-control study, with the rest being level 4 case series. Constant scores improved from a mean of 30 to 40 to a mean of 60 to 70 in all studies at final follow-up, and the overall complication rate was 3% (three conversions to arthroplasty, one spacer migration, two patients with no improvement). This review once again highlights the need for high-quality long-term studies of the balloon spacer because limited conclusions can be drawn from this lower-level data.

Next Steps

Preliminary studies have found balloon implantation to be safe and effective at improving pain and function in patients with massive rotator cuff tears [14, 22•, 24, 26••, 28••], but a number of questions remain. Ideal indications for the procedure have not been well defined. Available studies do not provide definitive indications, and study conditions have varied widely. Some studies report balloon implantation in isolation, while others report their positive results in conjunction with extensive debridement and biceps procedures [14, 23, 26••]. Still, others report balloon implantation as an adjunct to partial repair [13]. In addition to defining the ideal indications and effect of concomitant procedures, the benefit of the balloon

itself in terms of pain relief and functional improvements must be determined to appropriately counsel patients about expectations. This will require longer-term and controlled studies.

When discussing the benefits and potential applications of a technique, we must also consider the cost. A cost-effectiveness study of balloon implantation found that balloon implantation was the most cost-effective treatment when compared with nonoperative treatment, partial repair, and reverse shoulder arthroplasty [31]. Nonoperative treatment was the least costly, but the increase in quality-adjusted life years derived from the balloon gave it a higher cost-effectiveness rating. However, that study was based on completed at the Italian health care system and results may not be generalizable to other countries. Furthermore, as with all cost-effectiveness models, this study included a number of assumptions, including equivalent length and cost of nonoperative treatment before entering the model, no inclusion of post-surgical rehabilitation costs, and that all surgical failures would go on to revision surgery. The probabilities of success and failure for the balloon spacer were extrapolated from data on partial rotator cuff repair, as there is still limited literature on the outcomes of balloon spacer implantation. Continued consideration of cost-effectiveness will be important with longer-term studies of the balloon.

Author's Indications

In our own experience with the balloon spacer, good outcomes are predicated on proper patient selection. Patients with true pseudoparalysis of the shoulder are unlikely to have a predictably good outcome with this procedure. We prefer to select the procedure for patients that demonstrate an ability to actively forward elevate to 90 degrees. Additionally, an intact or reparable anterior and posterior rotator cuff (subscapularis and part of the infraspinatus) are also important for maintaining the force couple necessary for the rotational stability of the shoulder. If preoperative MRI or CT demonstrates a torn and significantly atrophied anterior and posterior cuff, there is a concern for a less predictably outcome, and patients are counseled on these concerns and are likely better candidates for alternative procedures reviewed in this topical collection.

We believe patient selection is the biggest concern for the use of the subacromial balloon spacer. As with any surgery, patients must be thoroughly counseled on the risks, benefits, alternatives, and expectations of the surgery. The responsibility rests on the operating surgeon for determining whether a patient's condition is suitable for treatment. Based on the current literature and our own experience, the ideal patient for balloon implantation has a massive rotator cuff tear, with no evidence of arthritis, preserved passive motion, and an intact subscapularis.

Author's Technique

We have refined our operative technique based on our experience with the implant. Before taking the patient to the operating room, we offer the patient a single-shot interscalene nerve block for pain control. After the block is placed, the patient is taken to the operating room for general endotracheal intubation and balloon implantation. The patient is seated upright in the beach chair position, which allows for the gravitational distraction of the humeral head and provides a more accurate view of the *in vivo* acromiohumeral interval for the patient. This is important for the correct selection of an appropriately sized balloon.

A standard posterosuperior arthroscopic portal is created for placement of the arthroscope. A diagnostic arthroscopy is initially performed for a thorough evaluation of the intraarticular joint space. Because of the need for a functional anterior rotator cuff, the subscapularis is carefully assessed and, if necessary, repaired. After all intraarticular work is completed, the arthroscope is redirected through the posterior portal for placement into the subacromial space. Using a spinal needle for localization, a lateral portal is created in line with the posterior border of the clavicle. It is important that the spinal needle rests in parallel with the floor so that all instrumentation coming in from the lateral portal is not obscured by the acromion or humeral head upon entry into the subacromial space. Once the lateral portal is established, an arthroscopic shaver and electrocautery are used to perform a limited bursectomy and gain visualization of the humeral head and remaining portions of the rotator cuff. Extensive bursectomy should be avoided because it can facilitate balloon migration into the supraspinatus or infraspinatus fossa.

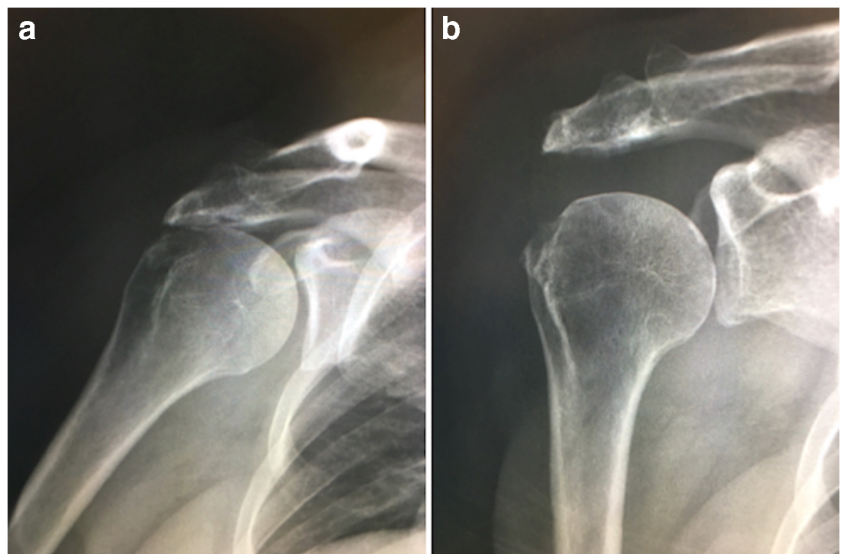
After visualization is achieved, we assess the superior and posterior rotator cuff. If the superior cuff is deemed unrepairable, the size of the deficient cuff space is measured with a graduated probe. Measurements are taken in both the

anterior to posterior direction of the acromial undersurface and the medial to lateral distance from the glenoid rim to the greater tuberosity. The available subacromial balloon sizes are small (40 × 50 mm), medium (50 × 60 mm), and large (60 × 70 mm). After measurements are obtained, the arthroscope is reintroduced into the subacromial space to view laterally. The subacromial space is then ready for balloon insertion.

Balloon insertion can proceed from the posterior or lateral portal, based on surgeon preference. The balloon insertion device is prepared on the back table. A 60-cc syringe is filled with sterile saline warmed to about 40 °C. The syringe is connected to the extension tubing of the insertional device. Any air bubbles encountered within the syringe or extension tubing are removed before balloon insertion. The insertion device is introduced into the posterior portal and positioned over the superior glenoid rim. After the balloon is positioned, the protective sheath around the balloon is withdrawn by pulling back on the handle of the inserter. With the balloon exposed, the plunger of the syringe is advanced and the balloon is visualized arthroscopically as it fills. The balloon is translucent, allowing for adequate visualization as it expands. To fully expand the balloon, it is initially overfilled by about 40 cc and then, the excess fluid is slowly evacuated, leaving behind the appropriate amount for the balloon to fill the subacromial space adequately. The balloon is then sealed and detached from the inserter.

The balloon is visualized from the lateral portal as the patient's arm is taken through a range of motion. The humeral head should be seen gliding underneath while the balloon maintains its position. If the balloon appears to sublunate or is the wrong size, it can be pierced with a spinal needle and removed for placement of another balloon. If the balloon appears to be stable, all instrumentation is removed from the shoulder and the portal sites are closed. Post-procedure radiographs typically demonstrate an increase in the distance between the humeral head and acromion (Fig. 3). Implantation

Fig. 3 X-ray images of the shoulder in one of our patients' pre- (a) and post-balloon spacer implantation (b). The depression of the humeral head and increase in the acromial humeral index are evident in these side-by-side films



of a balloon under arthroscopic visualization usually takes between 20 and 30 min. In most cases, the patient is able to begin rehabilitation relatively quickly.

From a technique perspective, there are a few tips that we now consider essential. The first is ensuring good visualization during the procedure. This is best achieved through a limited bursectomy with the maintenance of hemostasis. If bursal tissue or bleeding impedes visualization, the sizing and placement of the balloon can be jeopardized. However, avoidance of an aggressive bursectomy medial to the superior glenoid rim is also recommended to prevent medial migration of the spacer. We like to think about the preparation of the subacromial space as creating a contained pocket for the balloon. This requires a balance between making room for the device while also maintaining anterior, posterior, and medial soft tissues to help ensure proper placement of the device and minimize the possibility of migration. The second tip is taking the time to properly measure the subacromial space. The original technique described visualizing the placement of the balloon from the posterior portal. We have found that the lateral portal creates a better panoramic view of the balloon as it is inflated. If visualization is impeded from this portal, we switch between portals to proceed under the best possible visualization.

We have observed a few complications with the subacromial balloon. We had one case of migration, which was resolved by removal and replacement of the spacer in a different orientation. No other device-related complications have been observed, and the complication profile is otherwise comparable to that of an arthroscopic debridement.

Conclusions

The OrthoSpace subacromial balloon spacer may have substantial utility in the treatment armamentarium for irreparable rotator cuff tears. Balloon implantation has the potential to improve pain and function in these patients by restoring native glenohumeral biomechanics. We, as well as other authors, have seen these improvements in both function and pain relief. The ability to implant this device arthroscopically and with low morbidity may be beneficial for many patients with early to late rotator cuff disease. Our colleagues overseas have noted maintained improvements in functional outcomes over several years, without notable complications. Relative indications are increasing, as the balloon is being considered not only in the setting of irreparable tears but as a protective implant in addition to primary rotator cuff repair. Surgeons may find this device as a suitable option versus superior capsular reconstruction in the treatment of massive rotator cuff tears without pseudoparesis. However, caution is necessary as we await the minimum 2-year results on this device from the large multicenter study recently completed in the USA.

Based on the current literature and our own experience, the ideal patient for balloon implantation has a massive rotator cuff tear, with no evidence of arthritis, preserved passive motion, and an intact subscapularis. Implanting the balloon arthroscopically, in conjunction with subacromial debridement, biceps tenotomy or tenodesis as needed, and partial rotator cuff repair, is likely to give the patient the best chance at improved pain and function. Further higher-quality studies are needed to direct the best use of this implant, which has a sound biomechanical foundation.

Compliance with Ethical Standards

Conflict of Interest Melissa Wright, Joseph Abboud, and Anand Murthi declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of major importance

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 29. Ruiz-Iban MA, Moreno RL, Diaz RR, Sciamanna RA, Gonzalez AP, Gomez AL, et al. The absorbable subacromial spacer for irreparable posterosuperior cuff tears has inconsistent results. *Knee Surg Sports Traumatol Arthrosc*. 2018. <https://doi.org/10.1007/s00167-018-5083-3> **This study of 15 patients undergoing balloon spacer implantation for massive irreparable rotator cuff tear is important because of their poor results at minimum 2-year follow-up. Only 6 patients (40%) had an improvement in Constant score of at least 10 points at 2 years and 5 patients required conversion to reverse shoulder arthroplasty in that time period. These results are important to consider**

given that they are considerably different than many reports in the literature.

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mean 19 months. However, it is important to consider that none of the included studies are level one or two evidence.

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