SAS Journal of Medicine
Abbreviated Key Title: SAS J Med
ISSN 2454-5112
Journal homepage: https://saspublishers.com

OPEN ACCESS

Orthopaedics

Subacromial Balloon Spacer in Massive Irreparable Rotator Cuff Tears – What Does the Evidence Say?

Mestre, Pedro Guimarães[1*], Brazão, Carla[2], Climent-Peris, Vicente[3]

[1]MD, Department of Orthopaedics, Hospital Espírito Santo de Évora, Portugal
[2]MD, Department of Orthopaedics, Hospital Espírito Santo de Évora, Portugal
[3]MD, Traumatology and Orthopaedics Unit, Hospital Públic Lluis Alcanyis de Xàtiva, Valencia, Spain

DOI: 10.36347/sasjm.2023.v09i12.004 | **Received:** 01.11.2023 | **Accepted:** 05.12.2023 | **Published:** 11.12.2023

***Corresponding author:** Pedro Guimarães Mestre
MD, Department of Orthopaedics, Hospital Espírito Santo de Évora, Portugal

Abstract **Original Research Article**

The rupture of the rotator cuff is a common condition in Orthopedics, with massive and irreparable tears posing a challenge for Orthopedic surgeons. There are multiple techniques described for its treatment, with one of the most recent being the implantation of a subacromial balloon. This technically simple technique has shown good biomechanical results in the literature but controversial clinical outcomes. Most of the existing literature is of low scientific evidence. Studies with higher evidence are starting to emerge, but there is still no clear definition of the role of subacromial balloons.

Keywords: Subacromial balloon, rotator cuff tear, massive irreparable rotator cuff tear, shoulder, shoulder pain.

INTRODUCTION

Rotator cuff rupture is a common cause of shoulder pain and disability that can progress to significant limitations in daily activities and work [1, 3-5]. The pain can be so intense that it wakes patients up at night [2]. Most of these tears are surgically repairable, with scientifically proven benefits and positive outcomes recognized by patients [1]. However, approximately 30% of tears are non-repairable, usually due to their chronic progression, which leads to tendon healing and retraction, muscular atrophy with fatty infiltration, making reattachment to its original anchor site impossible [13]. Typically, these tears are large, can involve more than one tendon, and are common in older patients [2]. With these characteristics, these tears are referred to as massive (>5 cm in diameter and involving 2 or more tendons [11, 12]) and irreparable.

Massive irreparable rotator cuff tears in a significant percentage of patients can improve with conservative treatment, including physiotherapy and corticosteroid injections [6, 7]. However, there is a subset of patients who do not respond to these conservative measures, requiring surgical intervention, which, according to the literature, typically yields poorer results and a narrower range of surgical options than in patients where repair was possible [1, 2, 47]. In older patients, a reverse total shoulder arthroplasty is a good solution, with predictable improvement in symptoms and a return to daily activities [1, 9]. But in younger and more active patients, arthroplasty, with its associated risks, is not the ideal treatment, leaving options such as isolated debridement and bursectomy, partial tendon repair, repair with grafts or augmentation, tendon transfer, superior capsule reconstruction, and finally, subacromial spacer balloon [1, 8, 10, 21, 28, 47].

This review aims to gather and synthesize the current evidence regarding the use of the subacromial balloon in patients with massive irreparable rotator cuff tears, potentially serving as an auxiliary decision-making tool.

METHODS

A literature search was conducted using SciELO, MEDLINE, and the Cochrane Library to analyze studies containing relevant information about the use of subacromial balloons in patients with massive irreparable rotator cuff tears. With the exception of some initial studies to provide context and conceptual review, the analyzed and included studies were published within the last 5 years.

This article encompasses the most recent studies that have assessed functional outcomes and

complications of subacromial balloon use in patients with massive irreparable rotator cuff tears, or studies that have compared these outcomes with the use of other techniques for treating these tears. Additionally, articles referring to the cost-effectiveness of surgical interventions were included. Only relevant articles written in English were considered.

Surgical Technique

The surgical technique of the subacromial spacer balloon is based on the use of a biodegradable implant placed between the acromion and the humeral head. This technique was initially described by Savarese and Romeo in 2012 [14, 17] and subsequently by Gervasi *et al*., [15, 17] and Senekovic *et al*., [16, 17]. Its purpose is to restore the normal biomechanics of the shoulder by lowering the humeral head and recentering it in relation to the glenoid [43, 46]. This alteration is supposed to provide relief from painful complaints and improve shoulder function, increasing the range of motion and reducing subacromial impingement [43]. There is also described a protective effect of the balloon in patients who have undergone concomitant rotator cuff repair [17, 18, 43, 46, 47].

Biomechanics

In patients with irreparable rotator cuff tears, there is described superior migration of the humeral head as a result of an imbalance of forces since there is no opposing force to the elevation caused by the deltoid muscle. The consequence is contact between the humeral head and the underside of the acromion, leading to pain and limited shoulder mobility [20]. The purpose of the subacromial balloon is to counteract the force exerted by the deltoid by lowering and recentering the humeral head with the glenoid. This reduces subacromial impingement, allows for more physiologic shoulder mobility, and decreases pain [14, 20, 34, 35, 44], as well as reducing tension on the rotator cuff tendons, protecting against the development of cuff arthropathy [37].

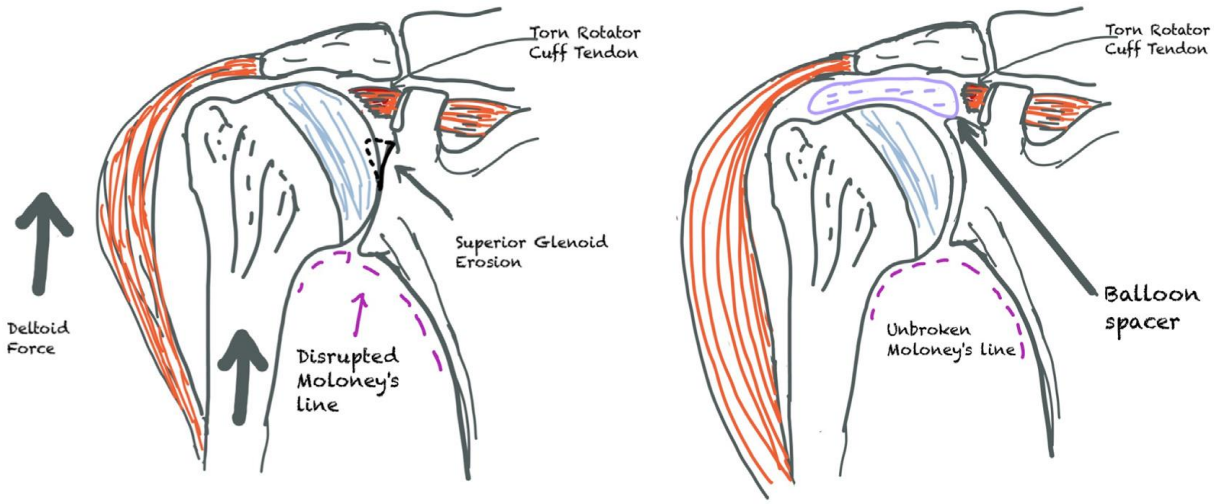

Figure 1: Effect of the massive rotator cuff tear and of the subacromial balloon [1]

Recent cadaver studies have demonstrated this descent of the humeral head. Singh *et al*., were able to show this effect with various different volumes (10 mL, 25 mL, and 40 mL) and concluded that the subacromial balloon inflated with 25 mL was the volume that most closely approximated normal shoulder anatomy and kinematics in all angles of shoulder abduction, with the other volumes being insufficient or causing deleterious effects [34, 35, 36].

In one of these studies, Singh also compared the effect of the balloon with superior capsule reconstruction, raising the hypothesis that the humeral head depression effect of the subacromial balloon would be superior. He ultimately concluded that both techniques restore abduction function equally [35, 36].

Functional Results

Since its approval for use in patients in 2010, several studies have been conducted to assess the outcomes of the subacromial balloon, most of them with small sample sizes and highly variable results. More recently, systematic reviews have emerged, summarizing the results of various studies, but with varying study designs, inclusion criteria, and outcome measurements, indicating a high likelihood of bias.

Stewart *et al*., [38] and Johns *et al*., [36] reported significant improvements in the Constant Score (from 18.5 to 49.6) and postoperative Oxford Shoulder Score (from 21.3-26 to 34.39-48.2), respectively, in their reviews. These improvements were also associated with significant reductions in pain, improvements in daily activities, range of motion, and strength [20, 26, 32, 36, 38]. However, both reviews have important limitations

due to the low quality of evidence from the included studies, potential conflicts of interest disclosed by the study authors, heterogeneity in inclusion criteria, and the association of different surgical procedures with subacromial balloon implantation in different studies [20].

The longevity of these results and the benefits of subacromial balloon use have been reported by Familiari *et al*., [30] and by Piekaar *et al*., in their retrospective study [25, 45]. Piekaar *et al*., demonstrated that three years after subacromial balloon implantation in 39 patients with massive irreparable rotator cuff tears, the patients maintained similar Oxford Shoulder Scores and Numeric Pain Rating Scale values as those obtained one year after implantation, with a statistically significant difference compared to baseline values, even after balloon degradation [20, 25, 45]. Familiari *et al*., in their level IV retrospective study, also concluded that at the 3-year follow-up after subacromial balloon implantation, shoulder function significantly improved, there was an increase in the acromiohumeral interval, the revision surgery rate was low, and patients reported high satisfaction [30]. Previous studies with follow-up periods of up to 5 years also reported significant and sustained improvements, although with a small sample size and some patients lost to follow-up, increasing the risk of bias [19].

There is also some literature reporting poor outcomes [27, 39], but these studies often have a high risk of bias. This can happen because they include patients without massive irreparable rotator cuff tears in the same group [27] or because other procedures, such as partial cuff repair (e.g., infraspinatus), are performed in conjunction with subacromial balloon implantation [39].

In 2021, a systematic review [41] compared superior capsule reconstruction with the subacromial balloon. The results favored superior capsule reconstruction in parameters such as abduction, American Shoulder and Elbow Surgeons Score, visual analog pain scale, Oxford Shoulder Score, and University of California, Los Angeles Score, while the subacromial balloon showed more significant improvements in forward flexion, external rotation, and the Constant Score [41]. Patient satisfaction was very similar in both procedures, indicating that both approaches were satisfactory.

The most current and impactful scientific evidence on this topic was published in 2022 by Metcalfe *et al*., [2]. It was a double-blind randomized clinical trial involving 117 patients with massive irreparable rotator cuff tears. Patients included in the study were those who were symptomatic (experiencing pain and loss of function) and had failed conservative treatment, and whose cuff tear was considered technically irreparable. Exclusion criteria included advanced shoulder osteoarthritis, subscapularis insufficiency, pseudoparalysis, neuromuscular diseases, unrelated shoulder pathology, prior proximal humeral fractures, among other criteria.

The trial compared the outcomes of treatment with arthroscopic subacromial debridement and biceps tenotomy with the same procedures combined with subacromial balloon implantation. At the 12-month follow-up, a significant improvement was reported in the Oxford Shoulder Score (debridement: from 21.7 to 34.3; debridement with balloon: from 23.1 to 30.3), Constant Score (debridement: from 33.6 to 63.6; debridement with balloon: from 29.9 to 47.5), abduction angle (debridement: from 76.3° to 124.1°; debridement with balloon: from 63.9° to 87.1°), and abduction strength (debridement: from 1.9 kg to 3.8 kg; debridement with balloon: from 1.5 kg to 1.5 kg) in patients treated without the subacromial balloon.

As the trial had previously defined stopping rules for futility and efficacy, and the results clearly showed the superiority of debridement over the balloon at the 12-month mark, it was concluded that there was no advantage in using the subacromial balloon in patients with massive irreparable rotator cuff tears. Therefore, the use of the balloon in such cases was discouraged [2, 33].

Another randomized clinical trial conducted by Verma *et al*., [31], involving 184 patients, aimed to compare subacromial balloon implantation with partial rotator cuff repair in patients with massive and irreparable rotator cuff tears. The results showed a significant clinical improvement in the American Shoulder and Elbow Surgeons Score in a similar percentage in both groups. Additionally, patients who underwent subacromial balloon implantation experienced a more rapid and sustained improvement in range of motion [31]. In contrast to the previous clinical trial, Verma *et al*., [20, 31] concluded that the use of the balloon is a therapeutic alternative to consider in this patient population, with the advantage of being a quicker surgical intervention, an idea supported by other studies [49].

Complications

Complications described in the literature following subacromial balloon implantation, as reported in the systematic review by Johns *et al*., [36], were documented in 8 out of the 350 patients included in the evaluated studies. Four of these complications were reported in the study by Prat *et al*., [17], which involved 24 operated shoulders. These complications included: one patient experienced transient postoperative paresthesia in the territory of the lateral antebrachial cutaneous nerve for 6 months; one patient developed a superficial surgical site infection, which resolved with oral antibiotics; one patient had a deep surgical site infection requiring one week of intravenous antibiotics followed by two weeks of oral antibiotics and subsequent surgical removal of the balloon; one patient had balloon

migration at 4 weeks postoperative, necessitating surgical removal. In addition to the Prat *et al*., study, four patients from other studies included in Johns *et al*., 's review experienced balloon migration and required surgical reintervention. Six patients did not experience improvement or worsened in their symptoms and underwent conversion to arthroplasty.

Another systematic review based on studies of low scientific evidence (7 studies with 200 patients) [29] reported complications, including three cases of conversion to arthroplasty, one case of balloon migration requiring revision surgery, and two patients who did not experience any clinical improvement. Despite the low quality of the scientific evidence available on the topic, all of these reviews and studies are consistent regarding complications and safety profiles, reporting a low rate of complications [49].

The study by Metcalfe *et al*., [2], despite discouraging the use of the subacromial balloon, did not demonstrate a significant difference in the complication rate between isolated debridement and tenotomy versus debridement and tenotomy combined with the subacromial balloon. Among the 20 patients with intervention-related complications, only three were considered severe, including one in each group with persistent pain or functional impairment at 12 months and requiring care, and one patient requiring surgical reintervention (reverse total shoulder arthroplasty) in the debridement with device group [2].

Cost-effectiveness

Regarding cost-effectiveness, a study published by Castagna *et al*., [42], based on the Italian healthcare system, estimated costs over a 24-month period and concluded that, for patients with massive irreparable rotator cuff tears, the subacromial balloon compared to other surgical techniques considered (reverse shoulder arthroplasty, partial cuff repair/debridement) was the least expensive procedure, more effective, and associated with an increase in Quality-Adjusted Life Years (QALYs). Only conservative treatment was calculated to be cheaper, with the subacromial balloon considered the most cost-effective treatment for massive irreparable rotator cuff tears [42].

However, it's important to note that the study mentioned has a significant potential for bias due to the fact that the authors of the study have conflicts of interest, as they are consultants for OrthoSpace, the company that owns the InSpace subacromial balloon and is responsible for its development.

CONCLUSIONS

The available scientific evidence on the use of the subacromial balloon in massive rotator cuff tears is inconsistent. Despite numerous systematic reviews published, most of the studies conducted are of low-level evidence, mainly corresponding to Level III or IV. According to the majority of these studies, the subacromial balloon appears to have a role in the treatment of this condition either alone or in combination with other procedures. It is not possible to distinguish from which surgical step the benefit for the patient arises, and in which patients this benefit is significant, as these studies often include patients with repairable tears [24], for example.

Cadaveric studies have demonstrated biomechanical advantages and improvements in shoulder function after device implantation. However, clinical results do not consistently show such good outcomes, particularly after the publication of the multicenter, randomized, double-blind trial by Metcalfe *et al*., [2], which states that debridement and tenotomy are superior to the same surgical steps when combined with the device. Verma *et al*., [31] refute this conclusion, and despite being a randomized clinical trial, the trial's design and the comparison of tears that end up being reparable with irreparable tears may introduce some bias into the results.

From a financial perspective, the fact that it is a quick and relatively simple procedure, cheaper than other surgical options for this condition, with a low rate of complications and cost-effective in terms of improving Quality-Adjusted Life Years (QALYs), makes it a procedure still worth considering and possibly beneficial in selected cases [48].

In light of the current evidence, more studies of Level I or II (controlled randomized clinical trials or comparative studies) are needed, including cost-effectiveness analyses, to clearly define the role and which patients truly benefit from subacromial balloon implantation alone compared to other surgical procedures. To date, the best evidence does not recommend its use and even suggests it may be detrimental.

REFERENCES

1. Viswanath, A., & Drew, S. (2021). Subacromial balloon spacer - Where are we now? *Journal of Clinical Orthopaedics and Trauma*, 17, 223-232.
2. Metcalfe, A., Parsons, H., Parsons, N., Brown, J., Fox, J., Mannion, E. G., ... & Higgs, D. (2022). Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START: REACTS): a group-sequential, double-blind, multicentre randomised controlled trial. *The Lancet*, *399*(10339), 1954-1963.
3. Yamaguchi, K., Ditsios, K., Middleton, W. D., Hildebolt, C. F., Galatz, L. M., & Teefey, S. A. (2006). The demographic and morphological features of rotator cuff disease. A comparison of asymptomatic and symptomatic shoulders. *J Bone Joint Surg Am*, 88, 1699-1704.

4. Burkhart, S. S., & Lo, I. K. (2006). Arthroscopic rotator cuff repair. *J Am Acad Ortho Surg*, 14, 333-346.
5. Gerber, C., Fuchs, B., & Hodler, J. (2000). The results of repair of massive tears of the rotator cuff. *JBJS*, 82, 505.
6. Koubaa, S., FZ, B. S., Lebib, S., Miri, I., Ghorbel, S., & Dziri, C. (2005, October). Conservative management of full-thickness rotator cuff tears. A prospective study of 24 patients. In *Annales de readaptation et de medecine physique: revue scientifique de la Societe francaise de reeducation fonctionnelle de readaptation et de medecine physique*, 49(2), 62-67.
7. Bokor, D. J., Hawkins, R. J., Huckell, G. H., Angelo, R. L., & Schickendantz, M. S. (1993). Results of nonoperative management of full-thickness tears of the rotator cuff. *Clinical Orthopaedics and Related Research (1976-2007)*, *294*, 103-110.
8. Kovacevic, D., Suriani Jr, R. J., Grawe, B. M., Yian, E. H., Gilotra, M. N., Hasan, S. A., ... & Research Initiative. (2020). Management of irreparable massive rotator cuff tears: a systematic review and meta-analysis of patient-reported outcomes, reoperation rates, and treatment response. *Journal of shoulder and elbow surgery*, *29*(12), 2459-2475.
9. Mulieri, P., Dunning, P., Klein, S., Pupello, D., & Frankle, M. (2010). Reverse shoulder arthroplasty for the treatment of irreparable rotator cuff tear without glenohumeral arthritis. *JBJS*, *92*(15), 2544-2556.
10. Malahias, M. A., Brilakis, E., Avramidis, G., & Antonogiannakis, E. (2019). Satisfactory mid-term outcome of subacromial balloon spacer for the treatment of irreparable rotator cuff tears. *Knee Surgery, Sports Traumatology, Arthroscopy*, *27*, 3890-3896. https://doi.org/10.1007/s00167-019-05485-4
11. Cofield, R. H., Parvizi, J., Hoffmeyer, P. J., Lanzer, W. L., Ilstrup, D. M., & Rowland, C. M. (2001). Surgical repair of chronic rotator cuff tears: a prospective long-term study. *JBJS*, *83*(1), 71-77.
12. Gerber, C., Fuchs, B., & Hodler, J. (2000). The results of repair of massive tears of the rotator cuff. *JBJS*, *82*(4), 505.
13. Rockwood Jr, C. A., Williams Jr, G. R., & Burkhead Jr, W. Z. (1995). Débridement of degenerative, irreparable lesions of the rotator cuff. *JBJS*, *77*(6), 857-866.
14. Savarese, E., & Romeo, R. (2012). New solution for massive, irreparable rotator cuff tears: the subacromial "biodegradable spacer". *Arthroscopy Techniques*, *1*(1), e69-e74. DOI:10.1016/j.eats.2012.02.002.
15. Gervasi, E., Cautero, E., & Dekel, A. (2014). Fluoroscopy-guided implantation of subacromial "biodegradable spacer" using local anesthesia in patients with irreparable rotator cuff tear. *Arthroscopy techniques*, *3*(4), e455-e458. doi:10.1016/j.eats. 2014.05.010
16. Senekovic, V., Poberaj, B., Kovacic, L., Mikek, M., Adar, E., & Dekel, A. (2013). Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears. *European Journal of Orthopaedic Surgery & Traumatology*, *23*, 311-316. doi:10.1007/s00590-012-0981-4.
17. Prat, D., Tenenbaum, S., Pritsch, M., Oran, A., & Vogel, G. (2018). Sub-acromial balloon spacer for irreparable rotator cuff tears: Is it an appropriate salvage procedure?. *Journal of Orthopaedic Surgery*, *26*(2), 2309499018770887. doi:10.1177/2309499018770887
18. Szöllösy, G., Rosso, C., Fogerty, S., Petkin, K., & Lafosse, L. (2014). Subacromial spacer placement for protection of rotator cuff repair. *Arthroscopy Techniques*, *3*(5), e605-e609. doi:10.1016/j.eats.2014.06.017.
19. Senekovic, V., Poberaj, B., Kovacic, L., Mikek, M., Adar, E., Markovitz, E., ... & Dekel, A. (2017). The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: a prospective study with 5-year follow-up. *Archives of orthopaedic and trauma surgery*, *137*, 95-103.
20. McNamara III, J. K., Sudah, S. Y., Manzi, J. E., Constantinescu, D. S., Nicholson, A. D., & Menendez, M. E. (2023). Subacromial Balloon Spacers for the Treatment of Irreparable Rotator Cuff Tears: A Review. *JSES Reviews, Reports, and Techniques*, 3(3), 331-335. doi:10.1016/j.xrrt.2023.01.010
21. Basat, H. C., Kirçil, C., Armangil, M., & Demirtş, M. (2017). Treatment alternative for irreparable rotator cuff ruptures: arthroscopic biodegradable balloon. *Nigerian Journal of Clinical Practice*, *20*(8), 952-957.
22. Deranlot, J., Herisson, O., Nourissat, G., Zbili, D., Werthel, J. D., Vigan, M., & Bruchou, F. (2017). Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: clinical and radiographic results of 39 retrospectives cases. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, *33*(9), 1639-1644.
23. Gervasi, E., Maman, E., Dekel, A., & Cautero, E. (2016). Fluoroscopy-guided biodegradable spacer implantation using local anesthesia: safety and efficacy study in patients with massive rotator cuff tears. *Musculoskeletal Surgery*, *100*, 19-24.
24. Naggar, L. (2016, December). Massive irreparable rotator cuff tears without arthropathy: the role of the balloon (biodegradable spacer) and comparison with other operative treatments. In *Orthopaedic Proceedings* (Vol. 98, No. SUPP_21, pp. 13-13). Bone & Joint.
25. Piekaar, R. S. M., Bouman, I. C. E., Van Kampen, P. M., van Eijk, F., & Huijsmans, P. E. (2020). The subacromial balloon spacer for massive irreparable rotator cuff tears: approximately 3 years of prospective follow-up. *Musculoskeletal Surgery*, *104*, 207-214.

26. Ricci, M., Vecchini, E., Bonfante, E., Micheloni, G. M., Berti, M., Schenal, G., ... & Magnan, B. (2017). A clinical and radiological study of biodegradable subacromial spacer in the treatment of massive irreparable rotator cuff tears. *Acta Bio Medica: Atenei Parmensis*, *88*(Suppl 4), 75-80.
27. Ruiz Ibán, M. A., Lorente Moreno, R., Ruiz Díaz, R., Álvarez Sciamanna, R., Paniagua Gonzalez, A., Lorente Gómez, A., & Díaz Heredia, J. (2018). The absorbable subacromial spacer for irreparable posterosuperior cuff tears has inconsistent results. *Knee Surgery, Sports Traumatology, Arthroscopy*, *26*, 3848-3854.
28. Dasari, S. P., Khan, Z. A., Swindell, H. W., Mehta, N., Kerzner, B., & Verma, N. N. (2022). Subacromial Balloon Spacer: Indications, Rationale, and Technique. *JBJS Essential Surgical Techniques*, *12*(2), e21-00069. doi:10.2106/JBJS.ST.21.00069
29. Moon, A. S., Patel, H. A., Ithurburn, M. P., Brabston, E. W., Ponce, B. A., & Momaya, A. M. (2019). Subacromial spacer implantation for the treatment of massive irreparable rotator cuff tears: a systematic review. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, *35*(2), 607-614.
30. Familiari, F., Nayar, S. K., Russo, R., De Gori, M., Ranuccio, F., Mastroianni, V., ... & Srikumaran, U. (2021). Subacromial balloon spacer for massive, irreparable rotator cuff tears is associated with improved shoulder function and high patient satisfaction. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, *37*(2), 480-486. doi: 10.1016/j.arthro.2020.09.048. Epub 2020 Oct 15. PMID: 33068742.
31. Verma, N., Srikumaran, U., Roden, C. M., Rogusky, E. J., Lapner, P., Neill, H., & Abboud, J. A. (2022). InSpace implant compared with partial repair for the treatment of full-thickness massive rotator cuff tears: A multicenter, single-blinded, randomized controlled trial. *JBJS*, *104*(14), 1250-1262. doi: 10.2106/JBJS.21.00667. Epub 2022 Apr 25. PMID: 35777921.
32. Yallapragada, R. K., Apostolopoulos, A., Katsougrakis, I., & Selvan, T. P. (2018). The use of a subacromial spacer-inspace balloon in managing patients with irreparable rotator cuff tears. *Journal of Orthopaedics*, *15*(3), 862-868.
33. Frankle, M. A. (2022). In Symptomatic Irreparable Rotator Cuff Tears, Adding a Subacromial Balloon Spacer to Debridement Resulted in Worse Shoulder Pain and Function at 12 Months. *JBJS*, *104*(22), 2037. doi: 10.2106/JBJS.22.00966
34. Singh, S., Reeves, J., Langohr, G. D. G., Johnson, J. A., & Athwal, G. S. (2019). The effect of the subacromial balloon spacer on humeral head translation in the treatment of massive, irreparable rotator cuff tears: a biomechanical assessment. *Journal of Shoulder and Elbow Surgery*, *28*(10), 1841-1847. doi: 10.1016/j.jse.2019.03.036
35. Singh, S., Reeves, J., Langohr, G. D. G., Johnson, J. A., & Athwal, G. S. (2019). The subacromial balloon spacer versus superior capsular reconstruction in the treatment of irreparable rotator cuff tears: a biomechanical assessment. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, *35*(2), 382-389. https://doi.org/10.1016/j.arthro.2018.09.016.
36. Johns, W. L., Ailaney, N., Lacy, K., Golladay, G. J., Vanderbeck, J., & Kalore, N. V. (2020). Implantable subacromial balloon spacers in patients with massive irreparable rotator cuff tears: a systematic review of clinical, biomechanical, and financial implications. *Arthroscopy, sports medicine, and rehabilitation*, *2*(6), e855-e872. doi: 10.1016/j.asmr.2020.06.011. PMID: 33364617; PMCID: PMC7754516.
37. Chevalier, Y., Pietschmann, M. F., Thorwächter, C., Chechik, O., Adar, E., Dekel, A., & Müller, P. E. (2018). Biodegradable spacer reduces the subacromial pressure: a biomechanical cadaver study. *Clinical Biomechanics*, *52*, 41-48. https://doi.org/10.1016/j.clinbiomech.2017.12.008.
38. Stewart, R. K., Kaplin, L., Parada, S. A., Graves, B. R., Verma, N. N., & Waterman, B. R. (2019). Outcomes of subacromial balloon spacer implantation for massive and irreparable rotator cuff tears: a systematic review. *Orthopaedic Journal of Sports Medicine*, *7*(10), 2325967119875717. doi:10.1177/2325967119875717
39. Garríguez-Pérez, D., Lópiz, Y., García-Fernández, C., & Marco, F. (2022). Poor results after arthroscopic treatment of irreparable rotator cuff tears using a subacromial balloon spacer. *Journal of the American Academy of Orthopaedic Surgeons*, *30*(19), e1260-e1268. https://doi.org/10.5435/JAAOS-D-22-00025.
40. Holschen, M., Brand, F., & Agneskirchner, J. D. (2017). Subacromial spacer implantation for massive rotator cuff tears: clinical outcome of arthroscopically treated patients. *Obere extremitat*, *12*(1), 38-45.
41. Osti, L., Milani, L., Ferrari, S., & Maffulli, N. (2021). Subacromial spacer implantation: an alternative to arthroscopic superior capsular reconstruction. A systematic review. *British Medical Bulletin*, *139*(1), 59-72. https://doi.org/10.1093/bmb/ldab014.
42. Castagna, A., Garofalo, R., Maman, E., Gray, A. C., & Brooks, E. A. (2019). Comparative cost-effectiveness analysis of the subacromial spacer for irreparable and massive rotator cuff tears. *International Orthopaedics*, *43*, 395-403. https://doi.org/10.1007/s00264-018-4065-x
43. Horneff III, J. G., & Abboud, J. A. (2018). Balloon arthroplasty: indications, technique, and European outcomes. *Annals of Joint*, *3*, 85. https://doi.org/10.21037/aoj.2018.10.02.
44. Lobao, M. H., Canham, R. B., Melvani, R. T., Abboud, J. A., Parks, B. G., & Murthi, A. M. (2019).

Biomechanics of biodegradable subacromial balloon spacer for irreparable superior rotator cuff tears: study of a cadaveric model. *JBJS*, *101*(11), e49. https://doi.org/10.2106/JBJS.18.00850

45. Piekaar, R. S. M., Bouman, I. C. E., van Kampen, P. M., van Eijk, F., & Huijsmans, P. E. (2018). Early promising outcome following arthroscopic implantation of the subacromial balloon spacer for treating massive rotator cuff tear. *Musculoskeletal surgery*, *102*, 247-255. https://doi.org/10.1007/s12306-017-0525-5
46. Sivasundaram, L., Hevesi, M., Berlinberg, E. J., Patel, H. H., Verma, N. N., & Forsythe, B. (2022). Combined margin convergence repair and subacromial balloon spacer for the treatment of massive rotator cuff tears. *Video Journal of Sports Medicine*, *2*(5), 26350254221114898. doi:10.1177/26350254221114898
47. Garofalo, R., De Crescenzo, A., Fontanarosa, A., Conti, M., Castagna, A., & Calbi, R. (2022). Rotator cuff repair protected with subacromial balloon spacer shows a low rate of non-healing. *Knee Surgery, Sports Traumatology, Arthroscopy*, *30*(6), 2123-2129. doi: 10.1007/s00167-021-06831-1. Epub 2022 Jan 13. PMID: 35022825.
48. Levy, K. H., White, C. A., Pujari, A., Patel, A. V., Kator, J. L., Parsons, B. O., ... & Cagle, P. J. (2023). Subacromial Balloon Spacer Implantation Is A Promising Alternative For Patients With Massive Irreparable Rotator Cuff Tears: A Systematic Review. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, S0749-8063(23)00468-1. doi: 10.1016/j.arthro.2023.05.028
49. Davey, M. S., & Kaar, K. (2022). Clinical outcomes at medium-term follow-up of sub-acromial balloon spacer insertion in the operative management of massive rotator cuff tears. *Ir J Med Sci*, *191*(4), 1687-1691. doi: 10.1007/s11845-021-02760-7. Epub 2021 Sep 3. PMID: 34480320.
50. Vecchini, E., Gulmini, M., Peluso, A., Fasoli, G., Anselmi, A., Maluta, T., ... & Ricci, M. (2021). The treatment of irreparable massive rotator cuff tears with inspace balloon: Rational and medium-term results. *Acta Bio Medica: Atenei Parmensis*, *92*(Suppl 3), e2021584. doi:10.23750/abm.v92iS3.12558.