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Research Article

Subacromial Balloon Spacer is an Acceptable Therapeutic Option for Massive and Irreparable Rotator Cuff Tears

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Abstract

Introduction: Rotator cuff tear is a frequent pathology, which is present in approximately 50% of patients between 40 and 70 years of age. The concept of irreparability is rather surgical, which is defined according to Rockwood as the inability to carry out a primary repair of the tendon to its original insertion site, so other options must be chosen. Among these, the use of a biodegradable subacromial spacer is a recent technique that has shown good and comparable results with other techniques, with no literature reported in our country to date. The objective of this study is to present the clinical and functional parameters of a series of patients with a diagnosis of massive rupture (≥5 cm or with involvement of 2 or more tendons) and irreparable rotator cuff, treated with a biodegradable subacromial spacer since 2018 at clínica Dávila.

Method: The present study corresponds to a cross-sectional study of patients operated with a subacromial spacer from 2018 to 2022 at the Dávila Clinic. A current evaluation was carried out where the QuickDASH and Constant tests were applied.

Results: we obtained 15 of 21 shoulders for evaluation. 66% of patients were men, average age of 59 years and a range from 43 to 70 years at the time of surgery. QuickDASH score for patients evaluated at 6 months post-surgery was 48, 39 at 6 to 12 months post-surgery and 28 in patients evaluated with more than 12 months from surgery. The average Constant score was 52 at patients evaluated at 6 months post-surgery, 51 at 6 to 12 months post-surgery and 78 in patients evaluated with more than 12 months from surgery. Patients were partial repair was performed, higher scores where obtained, bit without statistical analysis made.

Conclusion: Management of massive and irreparable rotator cuff tears remains a challenge, there are multiple treatment options but no consensus about a gold standard for optimal management. The subacromial balloon spacer shows good results in patients with massive and irreparable rotator cuff tears.

Keywords: Subacromial Balloon Spacer; Massive; Irreparable; Rotator Cuff Tears

Abbreviations

ASES: American Shoulder and Elbow Surgeons; CMS: Constant-Murley Shoulder; OSS: Oxford Shoulder Score; PRO: Patient Related Outcomes; ROM: Range of Movement; TCS: Total Constant Score

Introduction

Rotator cuff tears are one of the most prevalent conditions in patients over 50 years, with an overall incidence of 5-40% [1]. The prevalence of rotator cuff pathology grows with age, compromising 54% of people of 60 years old and up to 62% of 80 years old individuals [2,3]. Massive tears are up to 20% of rotator cuff tears and must be addressed specially because of high rates of retear (18-94%), healing failure after repair and irreparability potential [4].

Massive tears have many definitions in the literature. Cofield define them as a tear diameter of 5 cm or greater, Gerber as a detachment of two or more tendons from the greater tuberosity, and Davidson and Burkhart as a contracted tear greater than 2x2 cm (sagittal and coronal plane) [5-7]. In the other hand, an irreparable rotator cuff tear is defined by Rockwood as the incapacity to bring the rotator cuff tendon to its original insertion site [8] and it depends of many factors, such as tendon retraction, fatty infiltration, muscle atrophy, tear size, pseudoparalysis, comorbidities, tear time, tobacco use, among others [9,10]. Not all massive tears are irreparable tears, but larger tears are associated with worse outcomes and higher retear rates [1,10]. It's recommended to attempt primary repair in massive tears, considering all these "predictors of irreparability" before and during the surgical procedure. If the

tendon can't be re-attached to the original foot print, it would be considered as a massive and irreparable rotator cuff tear [4].

In this scenario, there are multiple treatment alternatives, from nonsurgical treatments such as pain management, injections, and physiotherapy; to surgical options like partial repair with and with out augmentation, superior capsule reconstruction, subacromial balloon spacer, tendon transfers and reverse total shoulder arthroplasty. None of these surgical treatment options has demonstrated clear superiority, so studies evaluating the results of them may contribute to a better comprehension of the pathology and better treatment for massive and irreparable rotator cuff tears. The present study shows an updated evaluation of patients operated with subacromial balloon spacer in a single center.

Materials and Methods

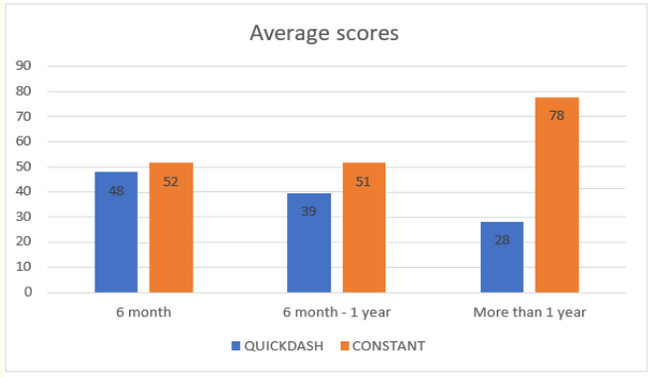
We considered all patients operated with subacromial balloon spacer in a single center (Clínica Dávila, Santiago of Chile) from January 2018 to June 2022. We included in the study patients with massive tears according to Gerber's criteria and irreparable tears considered with preoperative factors and the decision was made intraoperatively. We excluded patients with less than 6 months since the surgery and unreachable patients. We obtained patients demographic, surgical protocol information and reinterventions from clinical records and we evaluated them with the CONSTANT and Quick DASH questionaries. This study was approved by the scientific and ethical committee of Clinica Dávila.

Results and Discussion

Since 2018, 20 patients and 21 shoulders meet our inclusion criteria. 6 patients were excluded because of impossibility to evaluate them in this period, obtaining 15 shoulders for evaluation. 66% of patients were men, average age of 59 years and a range from 43 to 70 years at the time of surgery. The average length of stay was 0.8 nights, with 4 ambulatory patients and 11 with 1 night of hospital stay, without readmissions related to the surgery.

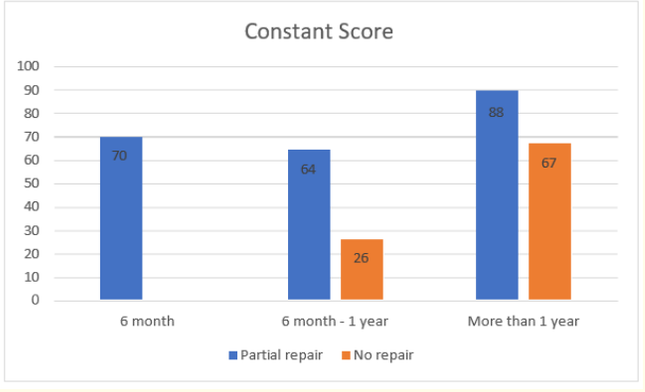
According to the questionaries applied, we obtained that the average QuickDASH score for patients evaluated at 6 months post-surgery was 48, 39 at 6 to 12 months post-surgery and 28 in patients evaluated with more than 12 months from surgery. The average Constant score was 52 at patients evaluated at 6 months post-surgery, 51 at 6 to 12 months post-surgery and 78 in patients evaluated with more than 12 months from surgery. These results are summarized in graph 1.

We did a second analysis considering partial repair or not of the remaining rotator cuff. We obtained that 10 of 15 patients underwent partial repair with 1 or 2 anchors. Patients with partial repair at the moment evaluation shows better results than patients without it, but no statistical analysis were made (Graph 2 and 3).

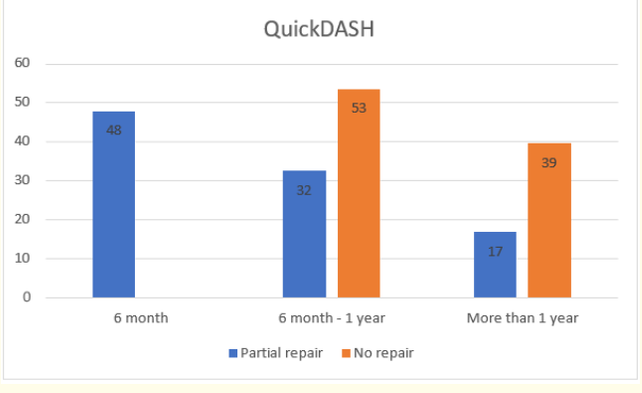


Graphic 1: Results of QuickDASH and CONSTANT scores at the moment of evaluation, correlated with the time from the surgery.

The biodegradable subascromial balloon spacer (InSpace™ balloon, then OrthoSpace, Kfar, Israel; now Stryker, Michigan, USA) was first introduced by Saverense and Romeo in 2012 for



Graphic 2: Result of constant score according to time from the surgery and partial repair.



Graphic 3: Result of QuickDASH score according to time from the surgery and partial repair.

patients with torn and irreparable supraspinatus with or without infraspinatus tendon, and an intact or reparable subscapularis tendon rupture [11]. The only contraindications were active joint infection, glenohumeral arthropathy, allergy to device material, and axillary nerve palsy, but now with more biomechanical studies, pseudoparalysis and torn teres minor or subscapularis are more factors to consider before indicating the surgery [9].

The InSpace™ balloon is made from a co-polymer poly-L-lactide-co-ε-capro-lactone that degrades in about 12 months and is insufflated with normal saline solution. It is degraded in two steps, first an ordered foreign body reaction and then a complete removal of the material, without chronic active inflammation or system toxicity [9,12,13]. The balloon should be filled with 25 ml of saline solution, which is apparently the best fill volume to achieve adequate depress of the humeral head and restoration of position compared to the intact glenohumeral joint [14].

The balloon comes in three sizes: small, medium and large and it should be measured intraoperatively. It must be 1 cm medial to the superior glenoid border and the lateral border should be at the lateral acromial border. It's used to reduce friction between the humeral head and the acromion, and also by pulling inferiorly the humeral head, it looks to restore the normal shoulder kinematics [9,13]. Some cadaveric studies have found reductions in peak pressures across the glenohumeral joint and increased distribution of the load in the subacromial space [15]. Other found that the implantation of the subacromial balloon spacer 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 [16].

Clinical studies of the subacromial balloon spacer for massive, irreparable rotator cuff tears have generally shown positive results, but the level of evidence varies greatly, limited primarily to case series and small prospective trials.

Senekovic., *et al.* [17] published clinical results of 20 patients with massive rotator cuff tears (3 lost to follow- up). Of the 17 patients analyzed, the mean Constant Score increased from 33.4 to 65.4 points at 3 years. In another later study with 24 patients, which included the above cohort, the same authors demonstrated improvement in 90% of their patients at a 5-year follow-up [18]. Deranlot., *et al.* [19] demonstrated significant improvement in shoulder function at a minimum of 1 year postoperatively in a retrospective review of 37 patients. Familiari., *et al*. [20] prospectively analyzed 51 patients at mean 3-year follow-up, resulting in improvement in shoulder function, limited need for revision surgery, and high patient satisfaction with 90%. Piekaar., *et al.* [21] in a prospective study demonstrated significant reduction in pain and improvement of functional daily activities during 3 years of follow-up and maintain over time beyond device degradation, suggesting the effects of the device persist.

There are few studies that compare the spacer with other treatments for irreparable massive tears, but they do not show superiority [22-24]. Viswanath., *et al.* [9]. published a review in 2021, analyzing 20 studies that added a total of 513 patients where most of the studies recommended the device, with only 4 suggesting it was not recommended based on their results and there were no papers providing greater than level III evidence. They conclude that there is too much heterogeneity in study design, patient inclusion and concomitant surgery to draw any conclusions.

Recently, 2 randomized control trials were published. Verma., *et al.* [25]. reported a multicenter, randomized, single (subject)-blinded study in the United States comparing the InSpace implant with partial repair. 20 sites randomized 184 patients with massive, irreparable rotator cuff tears: 93 in the InSpace group and 91 in the partial repair group. Both groups had significant and clinically relevant improvements in the ASES score at month 12 and were maintained at month 24. There were no significant differences between groups; subacromial spacer application was not inferior to partial rotator cuff repair, which led to FDA approval in 2021.

The second randomized control study, START: REACTS trial [26], conducted a double-blind, group- sequential, adaptive randomised controlled trial in 24 hospitals in the UK, comparing arthroscopic debridement of the subacromial space with biceps tenotomy (debridement only group) with the same procedure but including insertion of the InSpace balloon (debridement with device group). A total of 317 patients were eligible but recruitment stopped with 117 patients since a significant statistical difference was obtained with greater improvement in the debridement-alone group compared with the debridement with subacromial spacer group.

These conflicting findings in studies with a high level of evidence need further analysis with more randomized studies to reach a conclusion.

As shown by some recent reviews, there is an excessive heterogeneity in study design, patient inclusion and concomitant surgery to draw any decisive conclusion. Recent systematic review by Stewart., *et al.* [27] demonstrated improvements in patient satisfaction and clinical outcomes, such as Total Constant Score (TCS) and American Shoulder and Elbow Surgeons (ASES) in patients managed with subacromial balloon spacers, also this review suggest that the beneficial effects of the subacromial

balloon system may persist beyond the time of device deflation and degradation, although the exact reason for this effect remains unclear. Main limitations are regarding the potential biomechanical and clinical advantages in addition to lack of cost-effective studies.

Systematic review by Kovacevic., *et al.* [1]. compared patient reported outcome scores across different treatment alternatives to irreparable massive rotator cuff tears. Physical therapy is promoted to be the first line of treatment when a patient is medically unfit, however, with the numbers available, 60% of the patients in this review did not respond to physical therapy or went on to have surgery. Debridement and partial repair showed improvements in VAS pain scores, functional range of motion and PRO scores with lower reoperation rates compared to physical therapy. Partial repair was the high re-tear rate (45%). Surgical reconstruction (graft interposition/tendon transfer) compared to physical therapy showed superior improvements in pain scores, forward elevation, and mean change in CMS and ASES scores. Balloon arthroplasty led to an improvement in pain scores, forward elevation, and PRO scores. The major limitation of this review is the lack of high-quality evidence available on the treatment of irreparable massive rotator cuff tears.

Other recent systematic review by Johns., *et al*. [28] demonstrated that the use of subacromial balloon spacers for the management of patients with irreparable rotator cuff tears results in a significant improvement on following scores: TCS, OSS and ROM parameters such as mean shoulder abduction, mean shoulder elevation, internal rotation, and external rotation. This improvements with subacromial balloon spacer are comparable with those seen after management with other treatments such as subacromial debridement, biceps tenotomy, partial rotator cuff repair, latissimus dorsi transfer and reverse total shoulder arthroplasty.

Figure 1: Surgical procedure of subacromial balloon spacer Implantation. (A) Arthroscopic view of massive and Irreparable rotator cuff tear. (B-C) Anchor and partial repair of the rotator cuff tear. (D) Installation and filling of the subacromial balloon spacer. (E) Implantation of subacromial balloon spacer by a lateral portal.

Conclusion

Management of massive and irreparable rotator cuff tears remains a challenge, there are multiple treatment options but no consensus about a gold standard for optimal management. Patient selection is essential to aim for better treatment algorithms and them, combined with an expert rehabilitation, can achieve good functional results. We show adequate results in patients with massive and irreparable rotator cuff tears treated with subacromial balloon spacer in a single center. Apparently, with more time from the surgery, the patients have better functional outcomes.

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No acknowledgements to declare.

Conflict of Interest

The authors have no conflicts of interest to declare relevant to the contents of this article.

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