Original article

The treatment of irreparable massive rotator cuff tears with inspace balloon: rational and medium-term results

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Abstract. *Background and aim of the work:* The treatment of irreparable massive rotator cuff tears (MIRCTs) represents a challenge for the orthopedic surgeon both for the affected population and for the intrinsic characteristics of the injury. There are different types of treatment ranging from bursectomy to reverse shoulder prosthesis and subacromial spacers. The aim of the work is to establish the clinical and functional improvement of patients treated with subacromial spacer. *Methods:* we conducted 2 studies: the first analyzing a sample of 24 patients (14 females and 10 male, mean age 65.7 years) operated between 2015 and 2017 whose last follow up dates back to October 2021 and a second one analyzing 55 patients (including patients of the first sample) (30 females and 25 males, mean age 64 years) over a period of time from 2015 to 2021. The mean follow up was 56 months. All patients were diagnosed with irreparable massive rotator cuff tears and treated with subacromial spacer. *Results:* the result in both studies was an increase of Constant score, tripled from the pre-operative values, in ROM, doubled, and a reduction of VAS. *Conclusions:* the clinical results are encouraging and the use of the subacromial spacer could be a valid surgical alternative for patients with MIRCTs. However, we needed randomized trials with long-term follow-up. (www.actabiomedica.it)

Key words: Massive irreparable rotator cuff tears, Inspace balloon, shoulder arthroscopy

Introduction

The pathology of the rotator cuff is the most common cause of shoulder pain, functional deficit and represents, in orthopedic practice, the third cause of musculoskeletal pain after lumbar and cervical pain. This pathology can present itself in different forms and severities, ranging from tendinosis to rotator cuff tears. Rotator cuff tears are found in nearly 50% of patients between 70 and 90 years (1) and can lead to disability, job loss, and limitation of daily activities untill pseudoparalysis (2).

However, not all rotator cuff tears are the same and dependently on the type of lesion, the surgeon's therapeutic choice changes.

Among the types of rotator cuff tears, those that present the greatest challenge for the orthopedic surgeon, especially for the correct therapeutic procedure, are massive irreparable rotator cuff tears. Massive lesions are lesions greater than 5cm in size or involving two or more tendons. In an acute phase these could benefit from suturing (3).

MIRCTs constitute 10-40% of cases of rotator cuff tears and correspond to lesions which, once repaired, almost certainly lead to structural failure (4).

The reason is to be found in two peculiar characteristics: size and chronicity of the lesion (5) (6).

The first characteristic introduces the "quantity" parameter: the extent of the lesion. The second consider the quality of the tendon such as tendon retraction, the degree of muscle atrophy and fat infiltration (Goutallier grade 3 or 4). In almost all cases, the first therapeutic approach to these patients is a conservative treatment such as corticosteroid infiltrations and

physiokinesitherapy. However, there are many patients who do not respond to this type of treatment and require surgical treatment (7) for older patients, unresponsive to conservative treatment, reverse shoulder prosthesis could be resolutive. It may provide symptom relief and allow for a return to activities of daily living, but not the ideal choice for younger and more active patients. The surgical options range from simple debridement and / or bursectomy, partial sutures of the tendon, patches or allografts, tendon transfers, superior capsular reconstruction (SCR) and finally the use of the subacromial spacer (3) (8) (9). Among all these choices there are many considerations for choosing the best option.

It is necessary to consider the characteristics of the patient, the functional requirements, the severity of the tissue damage and finally the surgeon's experience. The hypothesis of this study is that the InspaceTM would relieve pain and improve movement in patients who have not benefited from conservative therapy.

In MIRCTs the acromiohumeral space (AHI) is radiographically measurable with a mean index <7mm (negative prognostic index).

The positioning of the spacer determines an elongation of the lever arm of the deltoid, in a shoulder with intact and / or suturable subscapularis, with restoration of forces. The humeral head is centralized anterior to the glenoid and slides easily under the acromion. (10)

The use of InSpace Balloon (OrthoSpace, Kfar Saba, Israel), is a rapid procedure in which this device is inserted through an arthroscopic portal and positioned in the subacromial space and whose purpose is to oppose the natural upper migration of the humeral head.

Materials and Methods

Aim of the study is analyze the medium-long term clinical results of InSpace Balloon in a group of 30 patients (17 females, 13 males, mean age 65.7 years) operated between 2014 and 2015 whose last follow up dates back to October 2021.Of these patients, 24 (14 females and 10 males) are eligible for the study because four underwent surgery and two were lost during FU. All participants provided written informed consent to participate in this study. This study was conducted under the principles of Declaration of Helsinki.

At the same time we wanted to evaluate the functional results for patients who were treated with the balloon over a period of time ranging from 2014 to 2021.This group includes 67 patients (39 females and 28 males). Of these, 12 were lost during follow-up (6 belonging to the previous study group), leading to a sample of 55 patients (30 females) whose mean age is 64 years (range between 50 and 82 years). The average duration of surgery is 42 minutes.

The mean duration of follow up is 56 months (range between 12 and 72).

All patients were diagnosed with MIRCTs in order to meet the inclusion criteria for the study: persistent pain unresponsive to conservative treatment; irreparable massive rotator cuff tears with complete rupture of at least two tendons (usually supraspinatus and infraspinatus); presence of functional deltoid.

The exclusion criteria are: arthropathy due to rupture of the rotator cuff determined on x-ray or MRI; repairable rotator cuff tear determined on MRI and during arthroscopy; shoulder joint infection; neurological deficit in the shoulder muscles (except pseudoparalysis). A preoperative clinical evaluation was performed including: clinical examination, radiological study including radiographs in the anteroposterior and axillary projections and the Grashey projection and an MRI. During the visit, the Constant Score, ADL, ROM and VAS score were collected. Clinical checks were performed at one, three, six and twelve months and then annually. During the periodic checks the patient was subjected to a clinical examination and re-evaluated using Constant score, ROM, VAS and ADL.

Clinical examination

Patients underwent a clinical examination before surgery and at the last follow-up; the results were documented using a standardized data sheet.

Active shoulder ROM was recorded for degrees of flexion and abduction, external rotation with the arms adducted laterally and elbows at 90, and internal rotation with the patient's arm behind the back.

Imaging

MIRCTs was diagnosed according to the following criteria: tendon retracted up to the glenoid level (Patte classification stage 3 on MRI); advanced stage adipose infiltration of the rotator cuff on magnetic resonance imaging (stage 3 or 4 Sec. Goutallier); migration of the proximal humerus with an acromio-humeral distance less than 7 mm on the anteroposterior radiograph; the diagnosis was confirmed during shoulder arthroscopy with the presence of tendon retraction, poor quality of the tendon margin and reduced excursion of the tendon despite adequate debridement.

Surgical technique

All patients were operated in general anesthesia and in lateral decubitus.

Arthroscopy was performed through the conventional portals: posterior, lateral and anterior.

Arthroscopic debridement was performed after diagnosing of MIRCTs. The integrity of the subscapularis and the posterior cuff (infraspinatus and teres minor) was evaluated to allow the correct positioning of the spacer and to recreate the right anterior and posterior tendon tension for a correct centering of the humeral head respect to the glena and allow the desired rotations.

The long head of biceps was always subjected to tenotomy.

We measured the subacromial space with an arthroscopic meter (provided in the InSpace kit); then we selected the suitable size (choosing from three sizes: small, medium and large). We prepared the insufflation system and filled a syringe with saline solution (0.9% NaCl) pre-heated to about 40. After inflating the balloon, we checked its stability during the range of motion (figure. 1)

Postoperative instructions

Patients were discharged on the first postoperative day with an arm sling prescription for one week. From the first postoperative day, pendulum exercises of the shoulder and physiotherapy with complete passive ROM and low-level active ROM were granted; the overhead activities were granted starting from the sixth week.

Statistic analysis

The results were analyzed by the SPSS program (version 20.0 Macintosh) and the differences in the obtained means were evaluated with the Wilcoxon T test. P values <0.05 were considered to be statistically significant.

Results

As regards the first part of the study (Table 1) (Figure. 4), relating to the group of 24 patients surgically

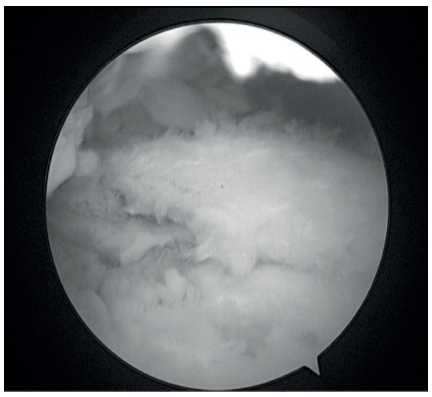

Figure 1. MIRCTs.

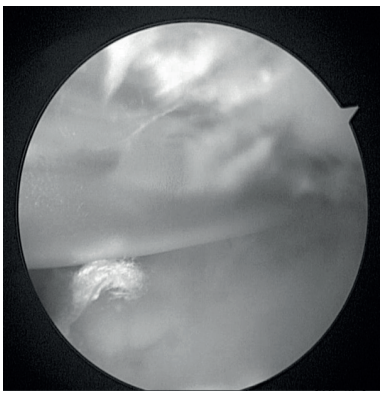

Figure 2. Insert spacer.

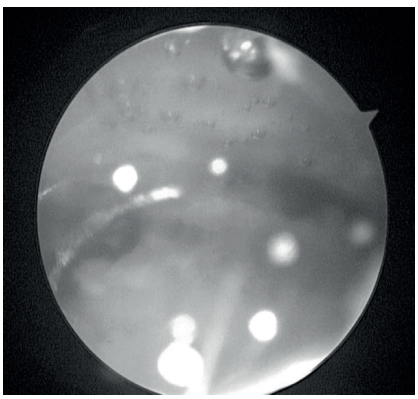

Figure 3. Spacer inflaction.

Table 1. (Scores of CS, ROM, VAS and ADL in the preoperative, at 24 months and last FU).

Score	Preoperative	24 months	70 months	p-value
Constant score	39.89	66,8	69.57	<0.0001
ROM FLEX	65°	130°	140°	<0.0001
ROM ABD	75°	150°	155°	0.0001
VAS	6,6	2,8	2,4	<0.0001
ADL	1,1	3,6	4,1	0.0001

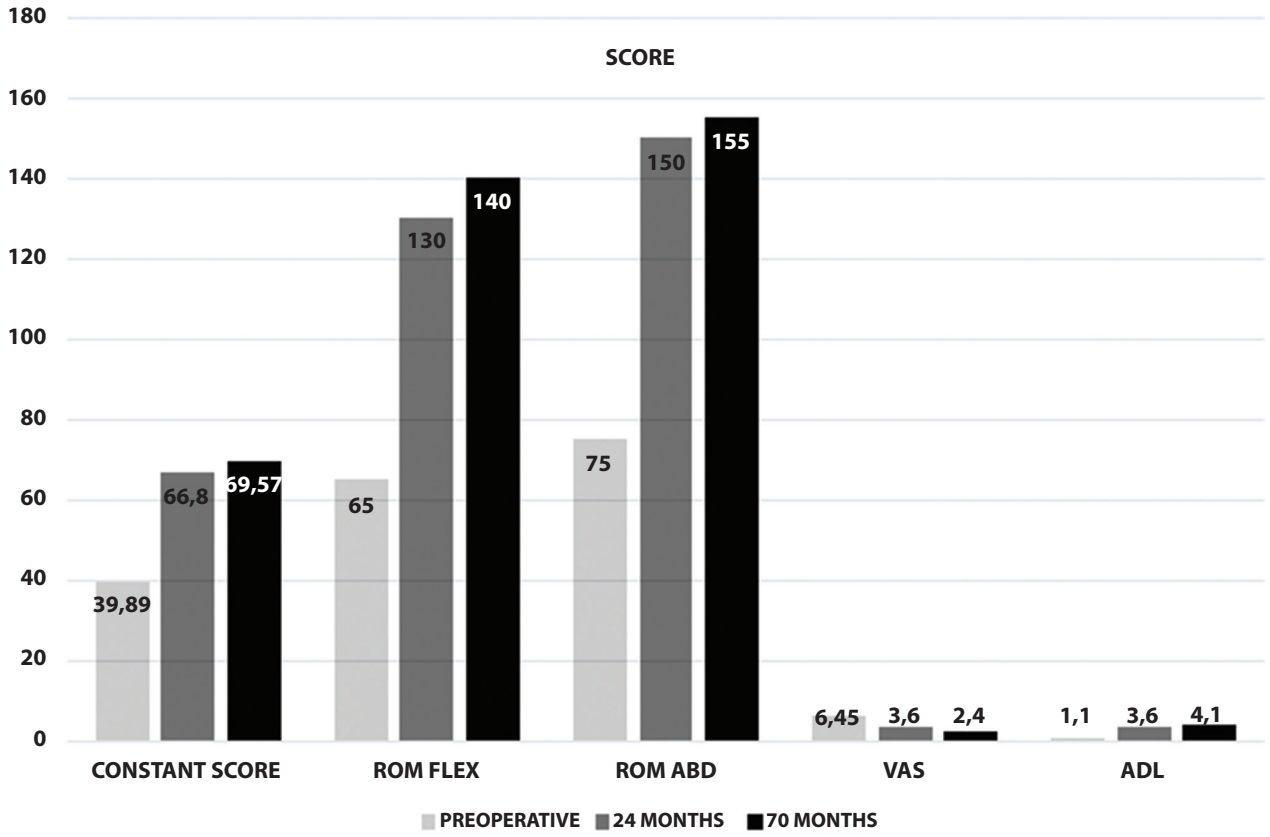

Figure 4. Clinical-functional results at 70 months.

treated from 2014 to 2015 and followed up to October 2021, we saw an increase in the mean Constant score from 39.89 (+/- 7.15) to an mean value of 69.57 (+/- 3.18).

Of the patients examined, only four had a worsening of the clinical trend compared to controls at 24 months.

For the ROM, it can be seen that the degrees of anterior elevation and abduction are significantly increased, with average values of 140 and 155 respectively during the last control, compared to the average preoperative values of 65 and 75 beyond which he witnessed a clear scapular compensation by disrupting normal daily activities.

The VAS for this group of patients started from a mean value of 6.6 to a mean value at follow up of 2.4.

The average of the ADL is 4.1 at follow up, higher than in the preoperative period (equal to 1.1)

Considering the second study group (Table 2) (Figure. 5), relating to the total of 55 surgically treated patients in the period 2014-2021, it can be noted that the mean preoperative Constant score

value is 27.54 (+/- 6.22) and in the last follow-up was 73.57 (+/- 4.22). The mean preoperative ROM values in anterior elevation and abduction were 60 and 70, respectively, significantly lower than the follow-up of 150 and 165. The VAS decreased from a mean preoperative value of 7.8 to a mean value of 2.2.

The mean value of the preoperative ADL is 1.3, during FU is 4.7

Table 2. (Scores of CS, ROM, VAS and ADL in the preoperative and last FU).

Score	Preoperative	56 months	p-value
Constant score	27,54	73,57	<0.0001
ROM FLEX	60	150	<0.0001
ROM ABD	70	165	<0.0001
VAS	7,8	2,2	<0.0001
ADL	1,3	4,7	<0.0001

Discussion

Rotator cuff pathology is a subject of discussion among shoulder surgeons as there is no unanimous consensus on the correct treatment process (3,4,8,11).

In addition to the type of injury, the age group of the population most frequently affected must be considered: patients over 60 years characterized by various comorbidities such as diabetes, osteoporosis and poor quality of the tissues that are important for proper healing (12,13).

For this reason, the first therapeutic approach is based on conservative treatment (4) (14) which, if ineffective, justifies surgical treatment.

Among these we report the simple debridement with or without tenotomy of long head of biceps (LHB) with good results in terms of pain and

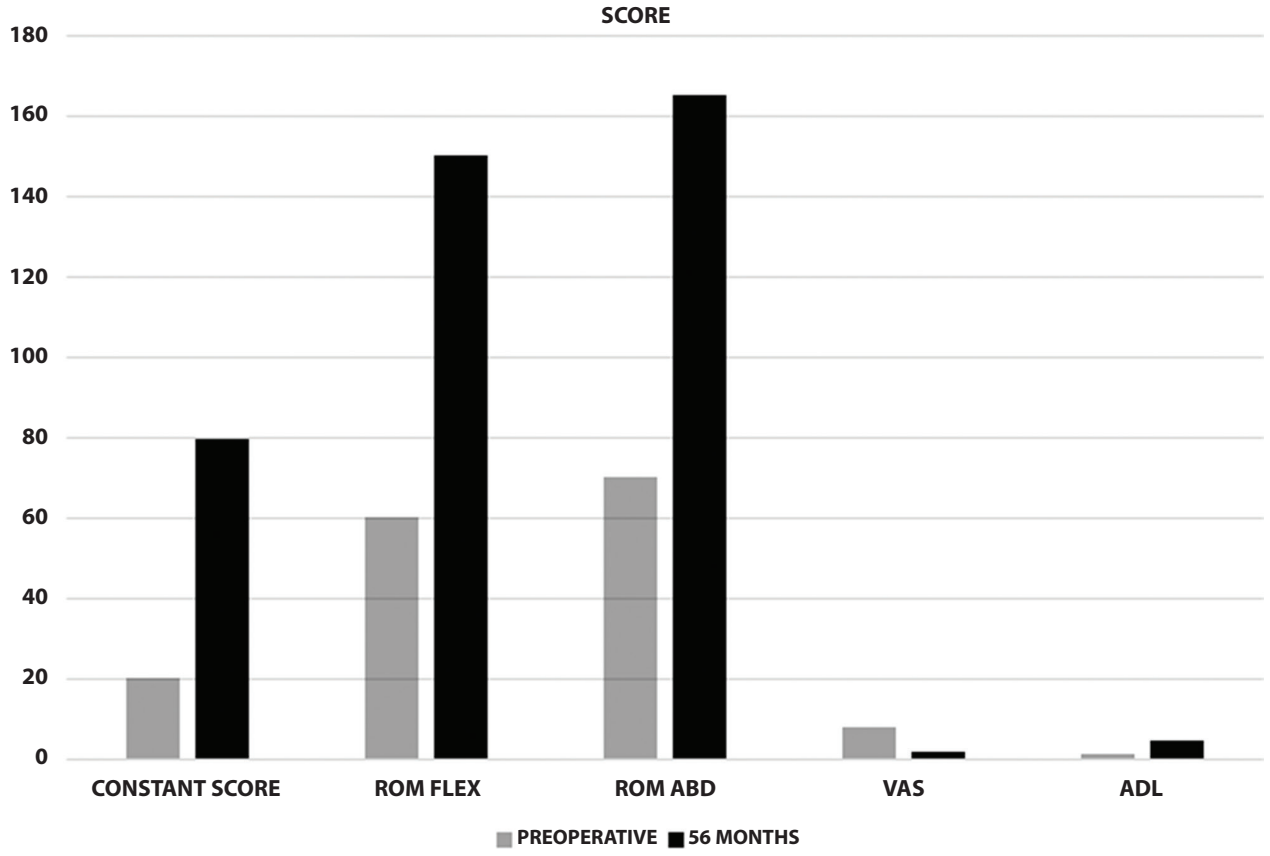

Figure. 5 Clinical-functional results with a mean follow-up of 56 months.

function, but not on stopping the progression of omarthrosis (9,11).

In addition, in cases of subacromial decompression with involvement of the coracoacromial ligament, an antero-superior migration of the humeral head has been shown with the appearance of more intense pain than preoperatively (15).

A more radical solution, mainly used in patients with MIRCTs associated with osteoarthritis, is the use of the reverse shoulder prosthesis, with or without tendon transfers (16,17).

However, in consideration of the unclear long-term outcomes of the technique, the risk of postoperative instability and the possible absence of omarthrosis in patients with MIRCTs, this procedure is reserved in selected cases (17,18).

For these reasons, the arthroscopic technique has developed new and more advanced techniques such as the functional partial suture of the rotator cuff using the concept of suspension bridge (19) whose objective is the restoration of the transverse force torque and allows a stable fulcrum for the glenohumeral articulation.

Other method is the interval slide proposed by Tauro and Lo (20) which involves a release of the supraspinatus from the rotator interval to allow easier mobilization and transport to the footprint and its subsequent repair. Recently there has been the emergence of surgical procedures such as the arthroscopic reconstruction of the superior capsule (SCR) proposed by Mihata (21) and the use of the subacromial spacer (10). Both techniques aim to address the potential superior migration of the humeral head that can occur in the presence of a massive rotator cuff tear.

While the SCR is a technically demanding procedure that involves anchoring a graft to both the glenoid and the humerus, the spacer is a relatively rapid procedure in which the device is inserted through an arthroscopic portal and positioned in the subacromial space. The latter represents one of the most recent treatment methods for MIRCTs not associated with advanced omarthrosis. This technique, introduced in 2012 by Savarese and Romeo, involves the use of a new biodegradable subacromial spacer, the InSpaceTM9 balloon (later OrthoSpace, Kfar, Israel; now Stryker, Michigan, USA) whose indications currently include: patients with irreparable supraspinatus tendon injured with presence of intact and functioning subscapularis and teres minor tendons to restore the force coupling of internal and external rotation and the exclusion of patients with pseudoparalysis, who are probably beyond the capacity of the balloon spacer. The InSpace kit contains an introducer and a pre-formed spacer made of poly L-lactide-co-E-caprolactone a widely used biodegradable material that degrades in approximately 12 months. To allow its introduction it is wrapped around itself and contained in a cylindrical tube, removed before inflating it. The subacromial spacer is therefore used to reduce friction between the humeral head and the inferior surface of the acromion. Moving the humeral head inferiorly and restoring shoulder kinematics and aims to reduce pain and improve function (22) (10)

The results of our study are in line with preliminary investigations

In a 3-year study Vladimir Senekovich V et al. (22) reported an increase in the mean Constant score from 33.4 to 65.4 on 20 patients treated with this method. Furthermore, the subjective pain scores of these patients were 6.4 points lower in the first postoperative week and this result was maintained for up to 3 years.

Wall B et al. reported a mean preoperative Constant score of 22, which increased to 65 after reverse shoulder replacement (23). Gerber et al. reported that the mean preoperative Constant score of patients with MIRCTs treated with trasfer of latissimus dorsi tendon increased from 46 to 61 (24).

The results obtained with both methods: tendon transfers and arthroplasty implantation, would seem at least statistically comparable to the application of the biodegradable balloon which, however, is placed under arthroscopy.

Arthroscopic placement of the biodegradable balloon is minimally invasive, short-lived, and has lower morbidity than arthroplasty and tendon transfers. Also, no special physical treatment programs are required after balloon application.

The center of the axis of motion is re-established by directing the humeral head downward.

This provides the required length of the lever arm for the deltoid muscle to function and significantly increases the range of motion.

In fact, an important aspect to consider in rotator cuff lesions, particularly in postero-superior ones, is the natural superior migration of the humeral head, with interruption of the Moloney line (25), characterized radiographically by an acromio-humeral interval (AHI) lower than 7 mm (26). Cadaver studies have shown that the subacromial spacer is capable of depressing the humeral head more than 2 mm below its anatomical position (27). However, improper positioning of the device can lead to forces in unwanted directions and reduce the contact area with the glenoid (28). Confirming this, Familiari et al. (29) described that after some distance, an increased AHI can interfere with shoulder mechanics resulting in a lower postoperative CM score at the final follow-up. In our study, all patients had AHI <6mm and Goutallier grade 3-4 preoperatively. Postoperatively, the subacromial space was always> 7mm.

A further feature of the spacer is its reabsorbance in 10-12 months, but there is no evidence in the literature, nor on what occurs after absorption. One of the most important advantages of this method is that shoulder movement is allowed immediately after surgery.

Conclusions

The clinical results obtained with this study are encouraging. Especially considering the group of 24 patients with longer FU where both function and pain values remained consistent with studies of shorter duration.

We had no complications during balloon application or in the postoperative period, however potential complications should be considered: foreign body reaction, local irritation, infection, implant dislocation and tissue necrosis (30).

It is natural to conclude that the use of the subacromial spacer could be a valid surgical alternative for patients with a massive and irreparable lesion of the rotator cuff, unresponsive to a first conservative treatment allowing to postpone or avoid more invasive procedures such as prosthetics.

However, randomized trials with long-term follow-up in more patients are needed to demonstrate the efficacy of this new method.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Ethical Approval: The ethics committee was not questioned for this type of study because our study was retrospective and not experimental.

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