

## Original Article

# Treatment Alternative for Irreparable Rotator Cuff Ruptures: Arthroscopic Biodegradable Balloon

HÇ Basat, C Kirçil, M Armangil<sup>1</sup>, M Demirtaş<sup>2</sup>

Koru Hospital, Department of Orthopaedic Surgery, <sup>1</sup>Faculty of Medicine, Department of Orthopaedic Surgery, Ankara University, <sup>2</sup>Memorial Hospital, Department of Orthopaedic Surgery, Ankara, Turkey

ABSTRACT

**Background:** The treatment of massive irreparable rotator cuff rupture has still no consensus among shoulder surgeons. It is assumed that symptomatic rotator cuff tendon rupture is accepted as irreparable if retraction amount of tendon is Patte stage 3 on MRI; degree of fatty atrophy is Goutallier stage 3 or 4; narrowing of acromiohumeral distance is lesser than 7 mm and excursion of tendon to repair has decreased and patient has severe pain. Biodegradable balloon is one of the newest methods for the treatment of irreparable massive rotator cuff ruptures. **Objective:** The aim of this study was to assess shoulder function in the patients who underwent biodegradable balloon procedure for irreparable massive rotator cuff ruptures. **Materials and Methods:** Arthroscopic biodegradable balloon method was carried out on the 12 patients, who presented with symptomatic irreparable massive rotator cuff rupture, from October 2010 to November 2013. **Results:** Preoperative and postoperative mean constant score of patients were 25.8 and 75.4 respectively. The mean Oxford shoulder score of the patients were 21.3 and 42.9 respectively, and mean shoulder abduction degree of the patients were 73.5 and 165 respectively. All the patients stated that they were satisfied with the treatment and there was significant regression in their complaints. **Conclusion:** If conservative treatment is insufficient for patients with irreparable rotator cuff tears, biodegradable balloon method has yielded favorable outcomes in terms of pain and functionality in comparison with other surgical methods. Moreover, lesser morbidity, short procedure time and absence of postoperative rehabilitation requirement can be considered as advantages of this method.

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**KEYWORDS:** *Biodegradable balloon, rotator cuff rupture, shoulder function*

## INTRODUCTION

Massive irreparable rotator cuff ruptures characterized with retracted rotator cuff up to glenoid level, advanced stage fatty atrophy, narrowed acromiohumeral distance, and decreased excursion of tendon despite adequate releasing of muscle during shoulder arthroscopy result in movement restrictions, especially in elderly patients, due to pain and weakness, and such ruptures also lead to a pseudo-paralysis.<sup>[1,2]</sup> Pain during daily activities and altered sleep quality are usually observed in patients with rotator cuff rupture. Generally, subacromial joint space appears narrow on plain radiograph, and muscular atrophy and fatty

degeneration are observed on MRI.<sup>[2]</sup> If this condition is left untreated, these patients can be the candidate for cuff tear arthroplasty.<sup>[3]</sup>

There are numerous treatment choices for symptomatic massive irreparable rotator cuff rupture. Firstly, conservative treatment, such as non-steroidal anti-inflammatory drugs (NSAID), corticosteroid injections, physiotherapy (aims to strengthen intact components of the rotator cuff and deltoid muscle),

**Address for correspondence:** Dr. HÇ Basat, Koru Hospital, Department of Orthopaedic Surgery, Ankara, Turkey.  
E-mail: [cagdasbasat@gmail.com](mailto:cagdasbasat@gmail.com)

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sick leave and modifying patient's activity level, should be preferred to alleviate pain and disability.<sup>[4-6]</sup> If conservative treatment fails, surgical options can be considered. Simple arthroscopic debridement, acromioplasty, tendon transfer, biceps tenotomy or tenodesis, and reverse shoulder arthroplasty are common surgical options for symptomatic massive irreparable rotator cuff rupture. There is no consensus or absolute algorithm about proper surgical treatment; however, there has been renewed interest among shoulder surgeons in alleviating pain and restricted movement in symptomatic massive irreparable rotator cuff rupture.<sup>[1,2,7-11]</sup> The arthroscopic biodegradable balloon spacer is one of the newest methods for symptomatic massive irreparable rotator cuff rupture. In this technique, the balloon is placed in subacromial space between humeral head and acromion after edge of the cuff is debrided during shoulder arthroscopy. Thus, humeral head moves downward, resulting with lengthening of deltoid lever arm to work. Also, humeral head is centralized anterior to the glenoid and slides easily under the acromion.<sup>[12,13]</sup>

This study demonstrates short-term functional results for patients who were treated with arthroscopic Inspace™ (produced in Ortho Space Ltd., Israel) balloon method, which is a copolymer of polylactide and  $\epsilon$ -caprolactone. It is a biodegradable and widely used material that biodegrades over a period of 12 months.<sup>[12,13]</sup> The hypothesis of this study is that arthroscopic Inspace™ method would alleviate pain and improve movement in patients who did not benefit from conservative therapy.

## MATERIALS AND METHODS

### Inclusion/Exclusion Criteria

All the study patients were diagnosed with massive irreparable rotator cuff rupture from October 2010 to November 2013. The inclusion criteria were as follows: 1) persistent pain despite 6 months of conservative treatment; 2) massive irreparable rotator cuff rupture with complete disruption of at least supraspinatus and infraspinatus tendons; 3) presence of functional deltoid muscles; and 4) patient age of above sixty years. The exclusion criteria were as follows: 1) arthropathy due to rotator cuff rupture, as determined on X-ray or MRI, 2) repairable rotator cuff rupture, as determined on MRI and during arthroscopy, 3) infection of the shoulder joint, 4) neurologic deficit in muscles around the shoulder (except pseudoparalysis).

Irreparable rotator cuff tendon rupture was assessed according to following criteria: 1) tendon retracted up to glenoid level (patte classification stage 3 on MRI);

2) advanced stage fatty atrophy of rotator cuff on MRI (goutallier stage 3 or 4); 3) proximal humeral migration accompanied by narrowed acromiohumeral distance as lesser than 7 mm on true anteroposterior radiography scanned in neutral rotation or MRI; 4) the diagnosis of irreparable rotator cuff rupture confirmed during shoulder arthroscopy and evidenced with presence of tendon retraction, poor quality of tendon margin, and decreased excursion of tendon despite adequate releasing of muscle.

Twelve patients met those criteria and were enrolled to the study. Demographics of patients are seen in [Table 1]. A single senior surgeon had carried out those surgeries. Morphology of the rupture, quality of the rotator cuff and retraction of the tendon were evaluated before applying the arthroscopic biodegradable balloon method, and diagnosis of irreparable massive rotator cuff rupture was confirmed in each patient. Based on the patients' medical history, pain during sleeping and basic daily activities was noted prior to surgery.

### Physical examination

Range of motion (ROM) [Table 2] (passive and active) of shoulder joint and strength of muscles around the shoulder were evaluated and neurologic examinations and instability tests (apprehension test, relocation test) were also done and recorded in physical examination.

### Imaging

Shoulder anteroposterior (AP) X-ray and MRI of shoulder were preoperatively scanned. Degenerative changes in glenohumeral joint and amount of superiorhumeral migration were investigated on AP X-ray. The following determinations were made on MRI scans: 1) anterior-posterior size of the rupture as evaluated using the Ellman and Gartsman classification, 2) identification of muscles that were affected by the rupture, 3) the presence of fatty degeneration, as evaluated with Goutallier classification, 4) degree of retraction according to Patte classification, and 5) presence of glenohumeral degeneration and degeneration of the long head of the biceps muscle [Table 1].

### Surgical technique

All the patients were operated under general anesthesia in beach chair position by the same senior surgeon. Arthroscopy was carried out through conventional posterior, lateral and anterior portals. Ruptured edges were debrided with arthroscopic method subsequent to make diagnosis of massive irreparable cuff rupture verified by evaluating retraction of the rotator cuff, poor quality of the tendon edges and atrophy of the muscle,

based on intra-articular exploration. Biceps tendons were tenotomised if partial rupture was observed on the exploration [Table 1, Figure 1a], joint was verified as in normal range following inflation of balloon [Figure 1d]. The distance from 1 cm medial of the glenoid margin to the lateral margin of the acromion was measured before the application using a measurement probe through the lateral portal [Figure 1b]. After the measurement, the appropriate size of balloon was selected (small 40x50, medium 50x60, or large 60x70), and the operation was carried out through the lateral portal. If measurement value was just between two sizes, the larger size was preferred to avoid displacement of the balloon. 0.9% normal saline solution was injected into the balloon until it became swollen as much as the balloon could not become loosen and move freely inside subacromial space and shoulder joint to cause restriction of physiologic movements. [Figure 1c]; the balloon was placed 1 cm medial to the glenoid superior side [Figure 1c]. The operation terminated when mobility of glenohumeral joint was verified as in normal range following inflation of balloon. Then portals were closed. Finally, a velpau bandage was used. A scheme of the procedure is shown in [Figure 2a-b-c-d].

### Postoperative care

The patients who had undergone balloon procedure were discharged in the first postoperative day. They were instructed to use a basic arm sling for a period of 2-3 weeks. Each patient was placed on pendulum exercises in the first postoperative day. After a week, the patients were allowed to use their shoulders actively for daily activities, such as reading and eating. Stitches were removed on the end of the second week of surgery. Physiotherapy was started in postoperative week 3 to strengthen shoulder joint and adjacent muscles.

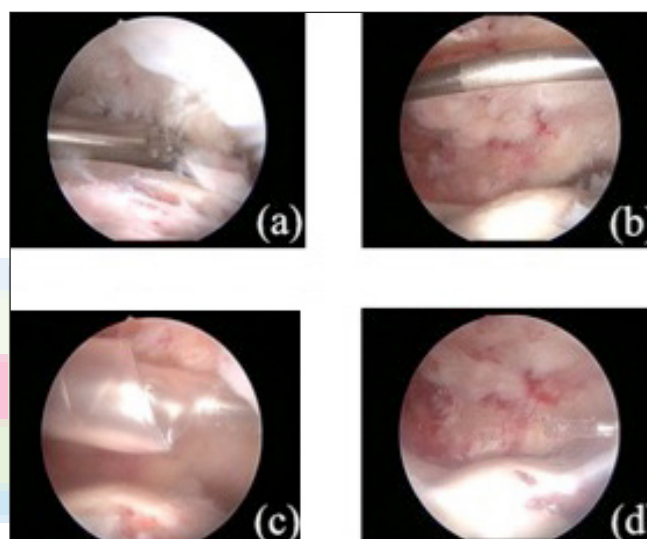
### Evaluation Protocol

All the patients were re-evaluated in postoperative Week 3, Week 6, Month 3, Month 6 and Month 12; patients attended follow-up visits annually thereafter. ROM of shoulder joint and instability tests were reviewed in physical examination. The patients were assessed on Constant and Oxford scales prior to and following the operation. Assessment outcomes were categorized as perfect (100-90 points), good (89-75 points), medium (74-51 points) or poor ( $\leq 50$  points) on the Constant scale. Regarding the Oxford scale, outcomes were divided to following categories: perfect (40-48 points), good (30-39 points), medium (20-29 points), or poor ( $\leq 19$  points). The patients' pain scores were assessed using visual analog scale (VAS) scores.

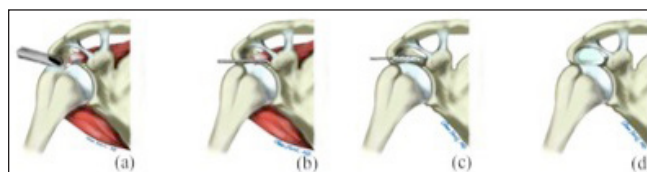
The statistical analysis of two groups was performed using the paired sample t test. The parameters suitability for normal distribution was assessed by Shapiro Wilks test. Significance was set at  $p < 0.05$ . Analyses were performed using SPSS v. 22 for Windows (SPSS Inc., Chicago, IL, USA) software.

### RESULTS

The patients who underwent arthroscopic biodegradable balloon surgery for massive irreparable rotator cuff ruptures were followed up for minimum 2 years. Average follow-up time was 38.3 months and average operation period was 33 minutes. During the operation, patient findings were summarized in [Table 2].



**Figure 1:** The arthroscopic procedure. (a) Arthroscopic debridement; (b) measurement progress using the probe after the debridement; (c) location of the balloon; (d) inflation of the balloon



**Figure 2:** Schematic diagram of the method. (a) Debridement of the right shoulder; (b) measurement of the distance between 1 cm medial to the glenoid side and the lateral side of the acromion; (c) placing of the balloon on the glenoid superior side; (d) the joint after the balloon's inflation



**Figure 3:** Range of shoulder abduction in patients in the second year following the operation using the arthroscopic biodegradable balloon

**Table 1: Demographic features and findings during preoperative and intraoperative period**

Patient	Gender	Age (yr)	Side	Size (cm)	RCR	BR	TT	DoS(min)	FD(stage)
1	m	64	R	>5	GL	+		36	4
2	m	67	R	>5	GL	+		27	4
3	m	69	L	>5	GL	-	+	42	4
4	f	62	R	>5	GL	-	+	36	4
5	f	60	R	>5	GL	+		34	4
6	m	68	R	>5	GL	+		32	4
7	m	70	R	>5	GL	-	+	28	4
8	f	64	L	>5	GL	-	+	35	4
9	m	65	L	>5	GL	+		36	4
10	m	63	R	>5	GL	+		34	4
11	m	60	L	>5	GL	+		27	4
12	f	60	L	>5	GL	-	+	29	4
Mean±SDs		64.3±3.55						33±4.55	

BR: Biceps rupture; TT: Tenotomy; GL: Glenoid level; RCR: Rotator cuff retraction; DoS: Duration of surgery; FD: Fatty degeneration

**Table 2: Demographic features and findings in the preoperative period and last follow up**

Patient	Follow up (mo)	PreOpAbd (active) (°)	PsOpAbd (active) (°)	PreOpCS	PsOpCS	PreOpOS	PsOpOS
1	50	76	163	22	87	19	47
2	48	75	164	21	76	18	46
3	42	79	170	25	76	23	43
4	38	78	165	24	68	20	39
5	35	72	172	22	78	18	43
6	43	70	167	24	85	21	46
7	46	67	165	26	76	22	44
8	40	75	165	22	74	18	42
9	24	68	166	24	72	20	43
10	30	70	164	26	75	24	44
11	29	77	157	35	66	26	37
12	35	75	162	38	72	26	41
Mean ± SDs	38,3 ± 8,03	73,5 ± 3,99	165 ± 3,79	25,8 ± 5,31	75,4 ± 6,05	21,3 ± 2,95	42,9 ± 2,91

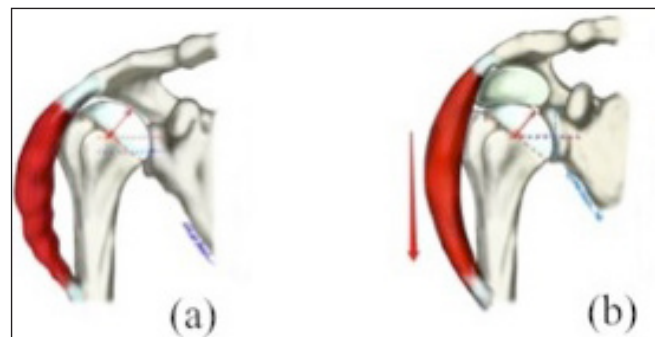
PreOpCS: Pre-operative constant score; PsOpCS: Post-operative constant score; PreOpOS: Pre-operative Oxford score; PsOpOS: Post-operative Oxford score; PreOpAbd: Preoperative shoulder abduction; PsOpAbd: Postoperative shoulder abduction

**Table 3: Biostatistics findings**

	<b>p</b>
PreOpAbd-PsOpAbd	0.001*
PreOpCS-PsOpCS	0.001*
PreOpOS-PsOpOS	0.001*

\*Paired Sample t Test  $p < 0.01$ . Statistically significant p values are written in bold. PreOpCS: Preoperative constant score; PsOpCS: Postoperative constant score; PreOpOS: Preoperative Oxford score; PsOpOS: Postoperative Oxford score; PreOpAbd: Preoperative shoulder abduction; PsOpAbd: Postoperative shoulder abduction.

minor muscles were intact in all patients, whereas fraying and tendinosis were observed in subscapularis muscle in 7 and 5 patients, respectively, and there was no evidence of labral pathology. The mean Oxford shoulder score, Constant score, and shoulder abduction degree were 42.9, 75.4, and 165 respectively at the most recent follow up, and is significantly higher from



**Figure 4:** Schematic diagram of balloon biomechanics (a) Changing location of the humerus head towards the acromion after a rotator cuff rupture and the shortening of the lever arm of the deltoid muscle; (b) lengthening of the lever arm of the deltoid muscle by adjusting the normal level of the humerus head downward against the glenoid after balloon application

the mean preoperative Oxford shoulder score, Constant score, and shoulder abduction degree, which were 21.3,

25.8, and 73.5 respectively [Table-3]. All the patients especially specified regression in night time pain [Figure 3]. We couldn't evaluate strength of the muscles surrounding the shoulder, and degree of internal and external rotation in preoperatively because of the painful shoulder.

## DISCUSSION

The treatment of massive irreparable rotator cuff rupture is still a challenging situation for shoulder surgeons, since there is no consensus on preferring a particular treatment modality.<sup>[1,2,4,5,7,8]</sup> Massive irreparable rotator cuff rupture is more common after 60 years of age and those patients are characterized with poor compliance and motivation for postoperative rehabilitation. Tissue quality is usually not enough for healing due to age, smoking and other comorbidities such as diabetes mellitus and osteoporosis.<sup>[14-18]</sup> To avoid complications of surgical intervention for massive irreparable rotator cuff rupture, the first attempt should be conservative therapy.<sup>[4-6]</sup> If functioning is compromised and pain persists despite sufficient conservative therapy, surgical treatment should be considered.<sup>[8,10-13]</sup>

Debridement of rotator cuff, subacromial decompression and biceps tenotomy are possible options for patients who have massive irreparable rotator cuff rupture.<sup>[5,7]</sup> Superior and anterior migration of humeral head has been shown in cases where coracoacromial ligament is restricted during subacromial decompression, resulting in more painful shoulder movements than they were prior to the operation.<sup>[19,20]</sup> Pain alleviation is reported for biceps tenotomy and tenodesis. However, these procedures can also restrict functioning and lead to cosmetic deformities.<sup>[4]</sup>

Arthroplasty is a method that is used to treat patients with irreparable massive rotator cuff rupture. Reverse shoulder arthroplasty is a surgical method, which is reserved especially for patients with arthrosis, along with irreparable massive rotator cuff rupture.<sup>[21,22]</sup> However, as long-term outcomes of reverse shoulder arthroplasty are unclear, risk of postoperative instability<sup>[21,23]</sup> or indications in the patients without arthritic changes in the glenohumeral joint is controversial.<sup>[24,25]</sup> Tendon transfers can be used alone or in combination with arthroplasty on patients who have irreparable massive rotator cuff rupture.<sup>[2,4]</sup> This method is also tried to eliminate movement restriction in those patients. Latissimusdorsi and pectoralis major tendons are more commonly used for this purpose.<sup>[9,10]</sup> Since tendon transfers can increase morbidity and pain cannot be always alleviated, this technique has not been used as a standard method of treatment.<sup>[11]</sup>

Arthroscopic biodegradable balloon method represents one of the most recent treatment methods for irreparable rotator cuff rupture. In this procedure, a balloon is placed into the subacromial gap by inflation, allowing for the humerus head to slide easily by decreasing its friction against the acromion and decreasing short-term pain.<sup>[12,13]</sup> Our study results were in line with prior investigations. In addition, the center of axis of motion is re-established by directing the humeral head downward. This provides the necessary length of lever arm for the deltoid muscle to work and significantly increases the range of motion [Figure 4a-b]. These balloons are believed to be absorbed in 10-12 months, but literature demonstrates no evidence of absorption or what occurs after absorption. One of the most important advantages of this method is that shoulder movement is allowed in early postoperative course. In a 3-year study of 20 patients who were treated with this method, Vladimir Senekovich V *et al.* reported an increase in the average Constant score from 33.4 to 65.4. Moreover, these patients' subjective pain scores were 6.4 points lower in postoperative Week 1, and this outcome was maintained for as long as 3 years.<sup>[12]</sup> In the present study, the average pre-operative Constant score was 22.8, and the score was 77 in Year 3, consistent with the above results. Wall B *et al.* reported an average preoperative Constant score of 22, which increased to 65 after the operation. In this previous study, 59 patients were undergone reverse shoulder arthroplasty for rotator cuff tear arthropathy.<sup>[25]</sup> The authors noted that their scores were consistent with the literature. Gerber *et al.* reported that the average preoperative Constant score of the patients increased from 46 to 61 on latissimusdorsi tendon transfers that were carried out for irreparable rotator cuff ruptures.<sup>[9]</sup> The results that were obtained with both the tendon and arthroplasty methods were similar to the biodegradable balloon application, which was performed arthroscopically. The arthroscopic biodegradable balloon application is minimally invasive, shorter in duration and has lower morbidity compared to arthroplasty and tendon transfers. Additionally special physical treatment programs are unnecessary following balloon application.<sup>[2,12,13,23,26]</sup>

We had no complication during application of balloon or postoperative period. In the literature, there has been no data about encountered complication of balloon method in the treatment of irreparable massive rotator cuff rupture. But the possible risks of balloon method can include foreign body response, local irritation at wound site, local infection, inflammation, implant dislocation, and tissue necrosis.<sup>[12,13]</sup> Regarding limitations of our study, the number of patients was small and follow up duration was short. We couldn't take any MRI for evaluating situation of balloon during follow up and it

is not clear what happens after absorption of the balloon. In the literature, there has been no enough information about long term results of balloon method. Randomized studies with long term follow up on more patients are needed to prove the efficiency of this new method.

## CONCLUSIONS

The momentous finding of this study indicate that arthroscopic inflatable balloon application yielded good results (i.e., pain alleviation and better functioning) in the patients who did not improve with conservative treatments for irreparable rotator cuff ruptures. Other advantages of the procedure include absence of an increase in morbidity in patients and the short duration of the procedure.

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Nil

## Conflicts of interest

There are no conflicts of interest

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