



## The use of a subacromial spacer-inspace balloon in managing patients with irreparable rotator cuff tears



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### ABSTRACT

**Aim:** The objective of this prospective non-randomized study was to establish the role of biodegradable subacromial spacer (InSpace™) insertion in the management of patients with massive irreparable rotator cuff tear by reporting beneficial effects on the pain relief and functional outcomes in these patients.

**Methods:** This is a prospective non-randomized study of patients treated for irreparable cuff tears during a period between January 2014 and November 2016. 14 patients with symptomatic massive irreparable rotator cuff tears were managed with arthroscopic debridement and implantation of a biodegradable subacromial spacer and were followed up for at least one year (8–16 m). Inclusion criteria were patients with irreparable rotator cuff tears that failed the conservative management, with muscle retraction (Patte > stage 2), muscle atrophy, and fatty infiltration (Goutalier type 3). Patients with osteoarthritis grade 3 in the Hamada classification and/or without preserved passive motion were excluded from our study. Outcome measures included pre and postoperative, the range of motion, Constant and Oxford shoulder scores. The decision to perform surgery was made after failure of nonoperative treatment and rehabilitation (massive rotator cuff tear protocol, reading shoulder unit) for at least six months.

**Results:** Fourteen shoulders (14 patients, ten male four female) met the inclusion criteria. The mean age of patients was 76.2 (70–85) years. During the last follow-up (8–16 months mean 12.6 months), the range of motion was significantly increased in all patients with anterior elevation (from 80 to 105°), abduction (from 70 to 110°), and external rotation (from 25 to 35°). The mean Constant score was also significantly ( $P < 0.001$ ) improved from 22.5 (13–33) preoperatively to 51.4 (30–64) at the last follow-up. The Oxford shoulder score improved from 26 preoperatively (21–28) to 48.2 postoperatively (34–56). No night pain following surgery and ADL increased by 40%, which is significant in these patients. No significant perioperative complications were found except for one patient who had a spacer migration. However, no action was required in that case.

**Conclusions:** Arthroscopic implantation of a subacromial spacer for irreparable rotator cuff tear resulted in a noticeable improvement in pain relief and shoulder function at a mean 12.6 months follow up. It is a quick, safe and a minimally invasive procedure that is suitable for elderly patients with irreparable cuff tears and medical co-morbidities.

### 1. Introduction

Therapeutic options for the treatment of irreparable rotator cuff tears are dependent on the patients' symptoms, demands and on the grade of the ongoing cuff tear arthropathy. Massive tears [Figs. 5 and 6] have been described as  $> 5 \text{ cm}^{1,2}$  and tears involving two or more tendons.<sup>3</sup> An IRCT (irreparable rotator cuff tear) is any cuff tear which cannot be repaired back to the footprint, despite intra and extra-articular release of the remaining tissue or any repair that is successful but will almost certainly be associated with structural failure.<sup>4</sup> The incidence may vary from 6.5% to 30%.<sup>5–8</sup> Static anterosuperior

subluxation with AHD (acromiohumeral distance) [Fig. 4] less than 6 mm<sup>46</sup> and pseudoparalysis on anterior elevation and dynamic anterosuperior subluxation of the humerus upon resisted abduction<sup>4</sup> also suggests that the repair is not going to be successful. Other poor prognostic signs include a lag sign and a positive Horn blowers sign [9,10] for infraspinatus and teres minor function respectively. Grade 3 and 4 fatty infiltration commonly considered irreparable,<sup>4,11</sup> although Burkhart has disputed this.<sup>12</sup> The cuff tears are generally categorised into posterosuperior (supraspinatus, infraspinatus and teres minor), anterosuperior (supraspinatus and subscapularis) and global tears that include both anterosuperior and posterosuperior tears. Mulieri et al.<sup>13</sup>

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reported reverse shoulder arthroplasty in patients with at least two-tendon tear without glenohumeral arthritis who failed to respond to conservative management for at least six months. In his study with a minimum of two years of follow-up, 58 patients out of 60 shoulders had shown improvement in pain and shoulder joint range of movement. Nevertheless, this procedure is associated with a high complication rate (~20%) and considered as a salvage option.

Recently, several innovative studies used a biodegradable inspace balloon insertion in the subacromial space to restore shoulder biomechanics, by replicating the lowering effect of humeral head by rotator cuff tendons and reducing the subacromial friction. These studies with short follow up periods reported successful re-establishment of acromiohumeral distance (AHD) to improve the deltoid muscle lever arm to facilitate its function.

The Ortho-Space InSpace™ system is a biodegradable balloon-shaped spacer made of a copolymer Poly (L-lactide-co-ε-caprolactone) which biodegrades over 12 months, during which stage the force coupling should return and allow for long-term improvement in the glenohumeral joint movement. The spacer is available in three sizes to accommodate anatomic variation. The spacer size (small, medium or large) is selected based upon the surgeon's discretion after determining the extent of the tear and following measurement of the distance from the lateral border of the greater tuberosity to approximately 1 cm medial to the glenoid apex.

### 1.1. Surgical technique

The insertion method is reported to be simple, safe and reproducible. Standard shoulder arthroscopy for evaluation of the shoulder and tendon's condition to determine the presence of an irreparable rotator cuff tear [Fig. 1]. Perform debridement and bursectomy. We have not performed any concomitant acromioplasty or tuberosity. Selection of the correct balloon size by measuring the subacromial space using an arthroscopic probe. Three balloon sizes are available (S/M/L). After selection of appropriate size, Insert the rolled-up spacer introducer into the subacromial space through a lateral portal [Fig. 2]. Inflate the balloon by using saline to fill the subacromial space [Fig. 3]. The balloon was secured into position by circumferential hoop forces like in press-fit implantation between the acromion and humeral head. The shoulder is then taken through a full range of movement to ensure stability. After sealing Balloon, retract deployer. Inspace balloon can be used in patients with tears of Supraspinatus, Infraspinatus. It is advised in patients with intact or repaired Subscapularis for anterior stabilisation that helps in restoring biomechanics. It is contraindicated in pre-existing glenohumeral arthritis, active infection and allergies to the material of device components. Possible complications of this

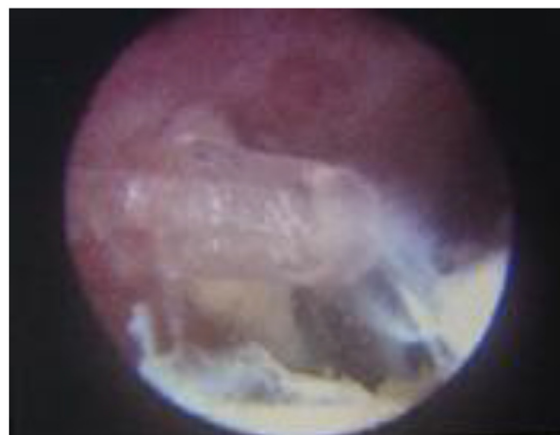


Fig. 2. Intraoperative insertion and inflation of balloon.



Fig. 3. Intraoperative finding of massive cuff tear, and full inflation of balloon.

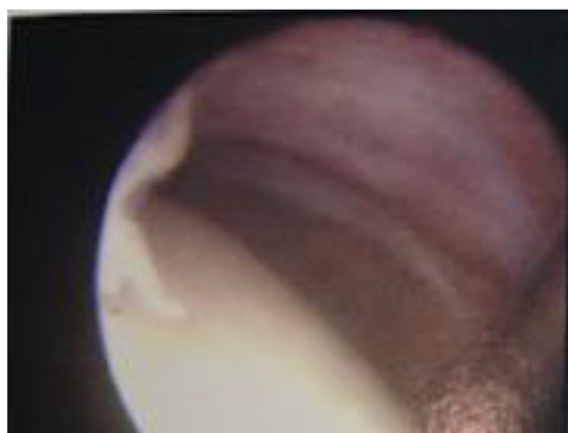


Fig. 1. Intraoperative finding of massive cuff tear, and stages of balloon insertion.



Fig. 4. X-ray AP Shoulder showing proximal migration in cuff deficient shoulder with no significant arthritis.

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