Sub-acromial spacer for Massive Rotator Cuff Tears- Biomechanical rationale and Review of Literature

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Abstract

Massive rotator cuff tears are a common cause of shoulder pain and functional disability in the elderly population. No consensus exists regarding management of massive irreparable tears of the shoulder. Conventional surgical modalities include acromioplasty, debridement, biceps tenotomy, tendon transfers or reverse shoulder replacement. Debridement and tenotomy have a short-term effect on pain and functional scores, while reverse shoulder replacement is an invasive and radical surgery to offer to a patient who might have several co-morbidities. Subacromial spacer implantation is a novel, minimally invasive and safe procedure which can produce good functional outcomes in selective patient population.

Introduction

Rotator cuff tears are a common cause of functional disability and pain, accounting for as many as 4.5 million physician visits in the United States annually(13).Massive rotator cuff tears account for up to 40% of all tears(1). There is no consensus on the definition of a massive rotator cuff tear. Cofield et al. described them as tears with antero-posterior diameter more than 5 cm(5). Gerber et al. suggested that a massive cuff tear can be defined as a tear with complete detachment of at least two tendons(7). Management of rotator cuff tears depends upon the severity of injury and the functional expectations of the patients. Massive tears are regarded irreparable when it is not possible to mobilise the retracted tendon to achieve a bone tendon repair. The treatment of a massive rotator cuff tear is often challenging due to patient related variables and biology of tendon healing(20). Surgical intervention is usually reserved for patients who are symptomatic after a trial of conservative treatment. Conventionally massive cuff tear is treated by arthroscopic debridement, biceps tenotomy and partial repair whenever possible. Arthroplasty is reserved for patients with gleno-humeral arthritis or pseudoparalysis of the shoulder(9). In 2008, a novel technique which uses a biodegradable subacromial balloon, the Inspace device (Orhospace, Saba, Israel) was introduced. The purpose of this study is to discuss patho-mechanical implications of a massive rotator cuff tear, the proposed effects of a subacromial spacer device and critically evaluate evidence for the use of such a technique.

Biomechanics of massive rotator cuff tear

The shoulder joint has evolved to allow a great degree of freedom in positioning of the hand in space. For the gleno-humeral articulation to function, a delicate balance between stability and mobility has to be maintained. Unlike the hip joint, shoulder is minimally constrained by the glenoid and passive stability comes from the capsule. Dynamic stability is provided by contraction of rotator cuff muscles which counteract the shearing forces of powerful abductors like the deltoid and keep the humeral head in the glenoid by a mechanism described as "concavity -compression"(21). Probably of less importance is the barrier effect of supraspinatus which prevents the superior migration of humeral head(12). Small and isolated tears of supraspinatus have minimal effect on the stability of the shoulder joint in cadaveric models where pain is not an issue. However, in the setting of a large tear, the stabilizing effect of the rotator cuff is lost. Tears are usually initiated in the anterior portion of supraspinatus and then propagate posteriorly(14). It has been noted that normal function is possible even if tear involves supraspinatus and superior infraspinatus as the force couple is balanced by subscapularis anteriorly and inferior infraspinatus(15). But if the tear involves the inferior infraspinatus, functional impairment is seen due to loss of balanced force couples and destabilising effects of deltoid pull(3). Using a rat rotator cuff tendon model, Hsu et al. demonstrated that restoration of anterior-posterior force balance is sufficient to restore shoulder function even in setting of a massive two tendon tear(11). Several authors have recommended a partial repair of massive rotator cuff tear to improve kinematics. Burkhart et al. popularised the concept of "suspension bridge" and introduced the rationale of partial repair to restore the rotator 'cables' and force couples(3). As long as the coronal and transverse force couples are balanced, patients would have a normal shoulder function. However, cadaveric studies have several limitations. They do not account for the face that even patients with small tears experience significant pain. This results in reflex inhibition of cuff musculature which can change shoulder biomechanics in vivo. Similarly, other factors which can potentially affect the prognosis is the level of tendon retraction and fatty infiltration. First used in 2008, the subacromial balloon

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Figure 1: The InSpace system consists of the subacromial spacer with the insertion device and the inflation syringe. (Courtesy: Ortho-space Ltd. Caesarea, Israel.)

Figure 2: Standard posterior portal is employed for introduction of the scope. Balloon is inserted through the lateral portal.

Figure 3: After debridement and subacromial bursectomy, tear is evaluated.

(Orthospace, Kfar, Saba, Israel) is a novel device for the treatment of irreparable and massive rotator cuff tears. The Inspace system (Orthospace, Caesarea, Israel) consists of a folded inflatable balloon made of polymer of poly-lactic acid and epsilon-caprolactone which is a completely bio-degradable material and an introducer. The polymer is widely used in medical devices and has proven record of minimal tissue reaction. Similar to an intact supraspinatus tendon, the subacromial spacer device would act as a barrier preventing superior migration of humeral head.It is proposed that the spacer would stabilise the humeral head, assisting the muscle force couple and improve biomechanics by increasing the acromio-humeral distance. Other potential mechanisms include decreasing the contact pressures between repaired tendons and under surface of acromion thereby decreasing pain and protecting the repair site. Chevalier et al. demonstrated that the device decreases mean and peak pressures over the repaired supraspinatus tendon and distributes them evenly during passive motion(4).

Technique:

The operating room setup and techniques are similar to regular arthroscopic shoulder procedures. The portals used include standard dorsal, lateral and anterolateral portals. Using a shaver, thorough debridement and bursectomy is performed. The rotator cuff is adequately visualised and the edge of supraspinatus is grasped and pulled towards the foot-print region. A decision is made at this point if the cuff tear should be partially repaired before insertion of the balloon. No consensus exists whether partial repair should be attempted or the tear left alone before balloon implantation.If found intact, the biceps tenotomy is performed. Using a probe, the subacromial space is measured from a point 2.5 cm medial to the glenoid rim to the tip of the greater tuberosity. Appropriate size of spacer is then selected and in cases where measurement is between two sizes, larger spacer is used. Using the lateral postal, the system is introduced and advanced. A probe can be inserted from the anterolateral portal to assist in the proper placement of the spacer. Positioning is confirmed by visualising the laser marking which should be in line with the lateral border of acromion.The outside sheath is withdrawn to reveal the folded balloon. Normal saline is then injected to inflate the balloon to a desired volume. After inflation and with the scope still in place, the shoulder is moved in full range of movement to confirm that the spacer is stable and does not interfere with mobility. An alternate technique has also been described which used fluoroscopy and local anaesthesia. However, no data is available on outcomes of patients implanted with the spacer under fluoroscopic guidance(8)

Discussion:

A comparative assessment of various relevant studies are presented in table 1. Holschen et al [10]. did a retrospective case- control study and compared results of arthroscopic debridement with partial repair of cuff with sub-acromial balloon implantation after debridement or partial repair. The study revealed that balloon implantation improved both function and pain scores in patients with massive cuff tears. The authors noted that improvement in shoulder function continued even after 1 year when the balloon was supposed to be degraded. This could be due to favourable effect of re-centred humeral head on muscle force couples.

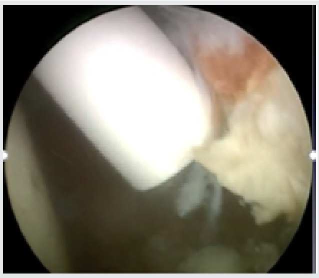

Figure 4: The spacer is advanced 2.5 cm medial to the glenoid rim. A probe can be inserted to aid in proper positioning of the sheath.

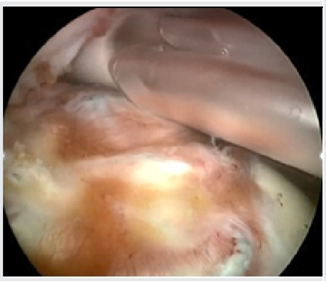

Figure 5: Sheath is now withdrawn to reveal the folded balloon

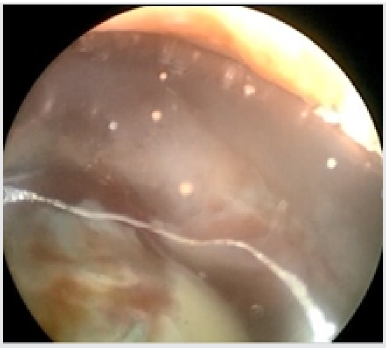

Figure 6: Saline is slowly injected into the balloon through the extension tubing and shoulder passively moved to confirm proper placement.

Table 1: Assessment of relevant studies

Study	Type/Sample size	Procedures	Improvement in Constant scores
Deranlot,2017	Retrospective/39	Acromioplasty and tenotomy	48.8 to 76.0
Pieekar, 2017	Prospective/46	Bursectomy,tenotomy ± partial repair	37.06 to 60.15
Holschen, 2017	Retrospective case-control /23	Group 1- conventional procedures, group 2- + balloon	Gp.1- 60.7 to 77.6, Gp.2-36.8 to 69.5
Ricci, 2017	Retrospective /30	Bursectomy, acromioplasty and tenotomy	39.89 to 65.38
Senekovic, 2012	Retrospective /20	Bursectomy and tenotomy	33.41 to 65.42 at 3 years

The study reports a single case of a possible foreign body reaction which was managed conservatively. A considerable heterogeneity in sample population rules out comparison, and further studies with larger sample size and longer follow-upare needed to assess safety and cost effectiveness of the procedure[10]. In a prospective study, Senekovic et al [19] followed 17 patients implanted with the spacer balloon for a period of 36 months. 68.8% of patients had improvement of total Constant score of minimum 25 points. The patients had significant improvement in their activities of daily living, beginning 3 weeks post-surgery, with continuous improvement throughout the follow-up period. The continued beneficial effect of the spacer even after it degrades might be explained by replacement of subacromial space by fibrous tissue which prevents migration of the humeral head(Senekovic et al., 2013). Deranlot et al [6] followed up 37 patients for a mean period of 32.8 months and found significant improvement in both range of motion and mean Constant score. The patients were also evaluated radiologically to study the progression of osteoarthritis. 81% of the shoulders did not show any progression of arthritis at the end of follow-up(Deranlot et al., 2017). Piekaar et al. reported overall satisfaction rate of 80 % in a prospective cohort study. Similar to previous study, significant improvement in pain scores and functional outcome was seen at end of follow-up period(16). Ricci et al. reported similar improvements in pain and function scores(17). The results of subacromial balloon implantationare comparable to that of other conventional techniques like bursectomy, acromioplasty, tenotomy and capsular repair. Rockwood and colleagues found satisfactory clinical results in 83% of patients treated with debridement(18). The implantation of the spacer device requires debridement of the subacromial space and biceps tenotomy is frequently carried out in addition to spacer implantation. It is difficult to quantify the exact effect of the balloon in early post-operative pain reduction. However, as an isolated procedure, debridement is associated with progressive arthropathy and hence its role limited. Similarly, though good short-term pain control is achieved with biceps tenotomy it has not proven long term benefit(7). Further studies with long term follow-up and randomised control trials are needed to conclusively demonstrate the benefits of subacromial spacer implantation.

Conclusion:

Though the evidence is limited in quality and quantity, the subacromial spacer appears to be an effective modality for management of massive rotator cuff tears. It reduces the contact pressures and friction in subacromial space by providing a gliding surface which might have a role in reducing shoulder pain. Evidence suggests that it significantly improves shoulder functions and range of motion. Though the balloon degrades over a period of one year, improvement in functional scores continued to progress even beyond this period. Studies with longer follow-up periods are required to prove whether spacer implantation has any utility in preventing or delaying tear related arthropathy. Though currently it adds to the expenditure for treatment of massive rotator cuff tears, a reduction in the conversion rate to reverse shoulder arthroplastywill have a wider implication on cost-effectiveness. Elderly patients with comorbid conditions are not always ideal candidates for more invasive procedures like reverse arthroplasty. Considering the low complication rate, minimally invasive nature and short procedure time, spacer implantation is an attractive alternative to arthroplasty where simple conventional procedures have failed.

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