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BASIC SCIENCE

The effect of the subacromial balloon spacer on humeral head translation in the treatment of massive, irreparable rotator cuff tears: a biomechanical assessment



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Background: The current management of massive, irreparable rotator cuff tears is challenging, and no individual surgical technique has demonstrated clinical superiority. This study evaluated the role of a subacromial balloon spacer and its ability to depress the humeral head in the setting of a massive, irreparable rotator cuff tear.

Methods: Eight cadaveric shoulders were tested. The specimens were mounted onto a shoulder simulator that applied muscle loading. Five shoulder states were tested: intact; irreparable rotator cuff tear; and inflation of the subacromial balloon spacer with 10, 25, and 40 mL of saline solution on the irreparable rotator cuff tear. Humeral head migration was measured at 0°, 30°, 60°, and 90° of shoulder abduction.

Results: After creation of a massive, irreparable rotator cuff tear, in 0° of abduction, the humeral head migrated superiorly by a mean of 3.5 ± 0.7 mm compared with the intact shoulder state ($P = .002$). The subacromial balloon spacer inflated to 25 mL translated the humeral head inferiorly relative to the torn state by an average of 3.2 ± 0.6 mm ($P = .001$) for all abduction angles. The balloon inflated to 10 mL was ineffective at restoring humeral head position as it was still significantly superior than intact ($P = .017$). The balloon inflated to 40 mL was successful in depressing the humeral head; however, it over-translated the humeral head anteroinferiorly, such that it was significantly different from the intact condition ($P < .001$). Overall, the 25-mL balloon best restored the humeral head position.

Conclusion: The results of this study demonstrate that the subacromial balloon spacer is most effective in depressing the humeral head and restoring the glenohumeral joint position when inflated to 25 mL.

Level of evidence: Basic Science Study; Biomechanics

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Institutional review board approval was not required for this basic science study.

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Massive, irreparable rotator cuff tears are common and have been estimated to account for approximately 40% of all rotator cuff tears.⁸ The definition of what constitutes such a tear, however, is varied and includes tears greater than 5 cm in size, involvement of 2 or more tendons, severe tendon retraction, and chronic changes such as

muscle atrophy and fatty infiltration, as well as tears that cannot be attached back to the greater tuberosity of the humerus.⁵ The current management of these tears is challenging, and no individual surgical procedure has demonstrated clinical superiority in the literature.² A surgical dilemma exists in the management of a patient with a massive, irreparable rotator cuff tear and no evidence of glenohumeral joint arthritis. Various treatment options exist including subacromial decompression and a biceps procedure, partial tendon repairs, interposition of synthetic grafts, tendon transfers, superior capsular reconstruction, and reverse arthroplasty; however, no definitive guidelines for optimal surgical treatment have been accepted.^{2,5,8}

The biodegradable subacromial balloon spacer was described first by Savarese and Romeo¹⁴ in 2012 and then by Gervasi et al⁶ in 2014 as a new arthroscopic treatment option in the management of massive, irreparable rotator cuff tears.⁷ The surgical procedure involves the insertion of a biodegradable subacromial balloon spacer between the humeral head and acromion.^{6,7,14-16} The goal of treatment is to restore normal shoulder biomechanics by depressing the humeral head, as a decreased acromiohumeral distance has been associated with poorer outcomes.⁴ Senekovic et al^{15,16} published the first prospective clinical trial after inserting 20 subacromial balloon spacers in patients with massive, irreparable rotator cuff tears. Clinically, significant improvement in patient symptoms was noted as early as 1 week. At 3 years postoperatively, sustained improvement in subjective pain, shoulder function, and strength was reported. In contrast, Ruiz Ibán et al¹³ reported a higher rate of patient dissatisfaction with the subacromial balloon spacer, quoting only a 40% patient satisfaction rate at 2 years' follow-up.

Although several clinical studies have been published on the insertion of the subacromial balloon spacer, few biomechanical studies have been conducted to test the device's ability to depress the humeral head. A recent biomechanical study comparing the subacromial balloon spacer with superior capsular reconstruction showed that both techniques restored the humeral head to its intact position after massive, irreparable rotator cuff tear creation.¹⁷ This mechanism of depressing the humeral head is likely the reason the balloon is clinically effective.^{3,17} Presently, little literature exists on how the subacromial balloon translates the humeral head, the direction of translation, and the influence of inflation volume. Thus, the objective of this study was to evaluate the balloon's ability to translate the humeral head and compare its performance with the intact shoulder, as well as after creation of a massive, irreparable rotator cuff tear. In addition, humeral head depression and translation by the subacromial balloon were assessed at varying inflation volumes.

Materials and methods

Specimen preparation and experimental setup

Eight previously frozen, male, right cadaveric shoulders were used for this study (mean age, 68 years; range, 60-76 years). Pre-screening with computed tomography scans was conducted to ensure no rotator cuff or glenohumeral joint pathology was present. Specimens were thawed at least 12 hours prior to testing. The overlying skin, soft tissues, muscles, capsule, and joint were preserved. The 4 rotator cuff tendons were identified and tagged with No. 5 nonabsorbable braided suture (Ethibond; Ethicon [Johnson & Johnson], Somerville, NJ, USA). The 3 heads of the deltoid muscle were exposed distally at the lateral aspect of the humeral shaft. The anterior, middle, and posterior heads of the deltoid were tagged through transosseous holes made in the humeral shaft with a 2.0-mm drill.

A load cell assembly unit (ATI; Apex, NC, USA) was inserted in the humeral shaft using cement to permit the measurement of abduction force, and the scapula was attached using a clamp and bolts to a shoulder simulator (Fig. 1). A distal humerus restraining jig that was secured to a hemispherical arc around the simulator permitted constraint of the shoulder abduction angle in the scapular plane (scaption) from 0° to 90° while permitting translation of the proximal aspect of the humerus in 3 dimensions. The tagged rotator cuff muscles were attached to cables and routed to computer-controlled pneumatic actuators. These actuators controlled the loads placed on each muscle-tendon unit. The deltoid was loaded at 80 N during testing, and each individual rotator cuff muscle had a 10-N load applied (per the protocol used by Mihata et al¹⁰⁻¹²). Optical tracking sensors (Northern Digital, Waterloo, ON, Canada) were fixed to the scapula and humeral shaft to allow for the determination of bone and joint position.

Testing variables and protocol

For each testing condition, superior-inferior and anterior-posterior humeral head migration was measured after the loads were applied at 0°, 30°, 60°, and 90° of static abduction in the scapular plane. Five shoulder conditions were tested as follows: intact, rotator cuff tear, and subacromial balloon at 3 fill volumes.

Intact

The intact shoulder was tested for humeral head migration at 0°, 30°, 60°, and 90° of static shoulder abduction. This was achieved by locking the distal humerus restraining jig at the set angles and then applying the pneumatic loads as mentioned earlier. The optical tracking system measurements were taken 10 seconds after load application.

Rotator cuff tear

The second shoulder state tested was the simulated massive, irreparable rotator cuff tear. Through a mini-open lateral deltoid split, the rotator cuff footprint (insertion of the supraspinatus and infraspinatus tendons) was visualized. A large, posterosuperior full-thickness tear involving the supraspinatus and infraspinatus

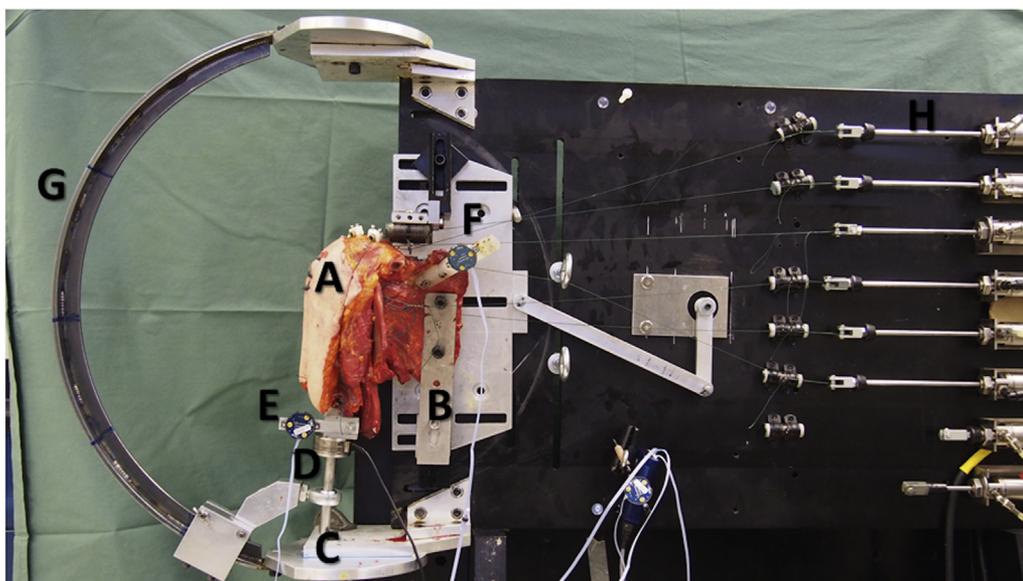


Figure 1 The cadaveric specimens were mounted onto a shoulder simulator, which permitted static shoulder abduction in the scapular plane (scaption) from 0° to 90°. The tagged rotator cuff muscles were attached to cables and routed to computer-controlled pneumatic actuators. These actuators controlled the loads placed on each muscle-tendon unit. (A) Shoulder specimen. (B) Scapular clamp. (C) Cylindrical rod-load cell assembly. (D) Load cell sensor. (E) Humeral optical tracker. (F) Scapular optical tracker. (G) Abduction arc. (H) Pneumatic actuators.

tendons and the underlying joint capsule was created. The subscapularis and teres minor tendons were left intact. After the torn shoulder state was created, the mini-deltoid split incision was closed with No. 5 Ethibond sutures.

Subacromial balloon at 3 fill volumes

The third shoulder state tested was the subacromial balloon spacer, which was inserted as recommended by the manufacturer's technical guide. The mini-deltoid split was reopened, and through the incision, the distance from the greater tuberosity to 1 cm medial to the superior glenoid rim was measured with a graded probe. All cadaveric specimens had a subacromial space larger than 5 cm, and as such, a large balloon was used per the manufacturer's guidelines. The balloon was inserted using an introducing tube through the lateral deltoid split. The insertion tube loaded with the balloon was placed 1 cm medial to the glenoid rim. The insertion tube was then pulled back, exposing the rolled up uninflated balloon. A graduated saline solution-filled syringe was then attached to the introducing apparatus, and the balloon was inflated with saline solution. Once the balloon was filled to the appropriate recommended volume, it was sealed and the insertion device was removed. The deltoid split was closed using No. 5 Ethibond suture. Three balloon inflation states were tested randomly: 10 mL (underinflation), 25 mL (manufacturer-recommended inflation), and 40 mL (overinflation).

Outcome variables

Superior-inferior and anterior-posterior humeral head translation was monitored using the optical tracking system. The relative position of the humeral head was measured and compared with the center of the glenoid. A reference coordinate system was developed on the glenoid of each specimen where the vertical and

horizontal axes were formed by the lines connecting the superior and inferior points and anterior and posterior points of the glenoid, respectively, with the origin at their intersection. Migration of the center of the humeral head was then determined relative to the initial resting position of the humeral head center with respect to the reference coordinate system attached to the glenoid and was measured at various degrees (0°, 30°, 60°, and 90°) of abduction in the scapular plane (scaption).

Statistical analyses

A repeated-measures analysis of variance was used for statistical analysis. Statistical significance was defined as $P < .05$. The abduction angle, deltoid load, and shoulder state were the independent variables, with humeral head migration being the dependent variable.

Results

Superior humeral head translation

A 5-cm tear in the superior rotator cuff was created and was identical for all specimens. After creation of the massive, irreparable rotator cuff tear, the humeral head migrated superiorly by a mean of 3.5 ± 0.7 mm ($P = .002$) in the adducted position (Figs. 2 and 3). In mid abduction, the humeral head maintained the superiorly migrated position at 2.9 ± 0.6 mm ($P = .001$) at 30° and 1.0 ± 0.4 mm ($P = .048$) at 60°. However, at 90° of glenohumeral

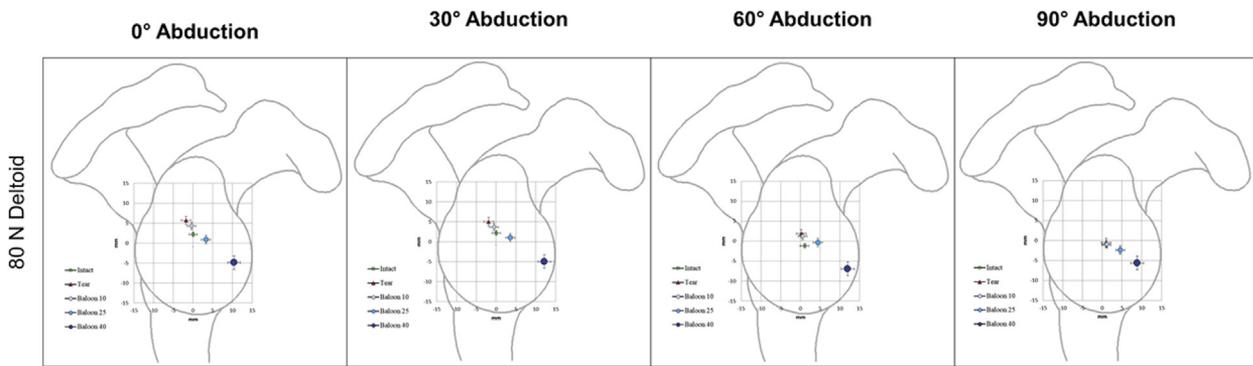


Figure 2 Mean values (± 1 standard deviation) of superior-inferior and anterior-posterior humeral head position for various shoulder states (intact; torn; and balloon inflated to 10, 25, and 40 mL) and shoulder abduction angles (0° , 30° , 60° , and 90°). These results are shown with the deltoid activated at 80 N.

abduction, the tear state was not significantly different from the intact state ($P = .09$).

The insertion of the subacromial spacer balloon inflated to 10 mL resulted in the humeral head translating inferiorly relative to the torn state by an average of 1.0 ± 0.3 mm ($P = .008$) for all abduction angles. Although the subacromial balloon at 10 mL was successful in translating the humeral head inferiorly, it was not fully able to restore its position as

it was still significantly superior compared with the intact state ($P = .017$).

When the balloon was inflated to 25 mL, the humeral head translated inferiorly relative to the torn state by an average of 3.2 ± 0.6 mm ($P = .001$) for all abduction angles investigated. The 25-mL balloon was effective at depressing the humeral head from its superiorly migrated position to a position that was a mean of 1.2 ± 0.5 mm

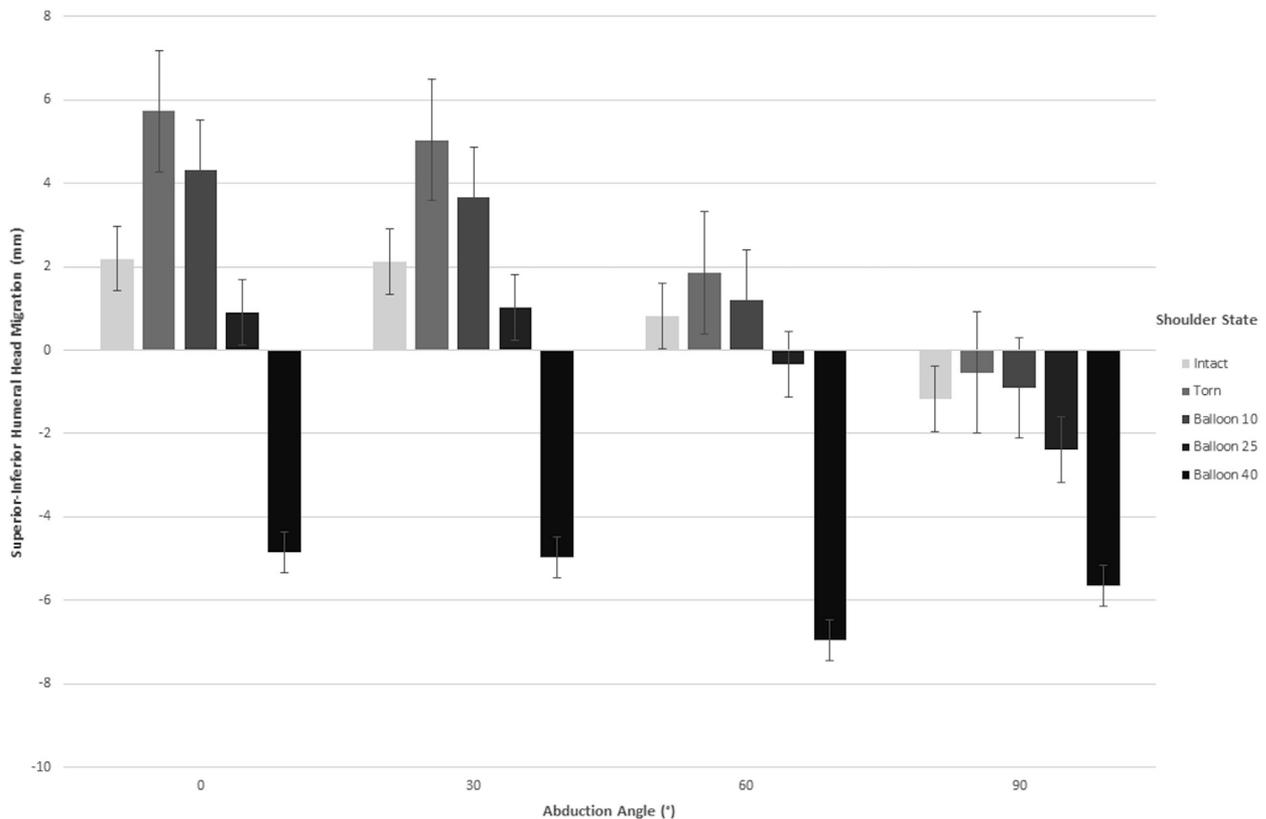


Figure 3 Bar graph showing mean values (± 1 standard deviation) of superior-inferior humeral head migration for various shoulder states (intact; torn; and balloon inflated to 10, 25, and 40 mL) and shoulder abduction angles (0° , 30° , 60° , and 90°). A positive value on the y-axis represents superior displacement, and a negative value on the y-axis represents inferior displacement.

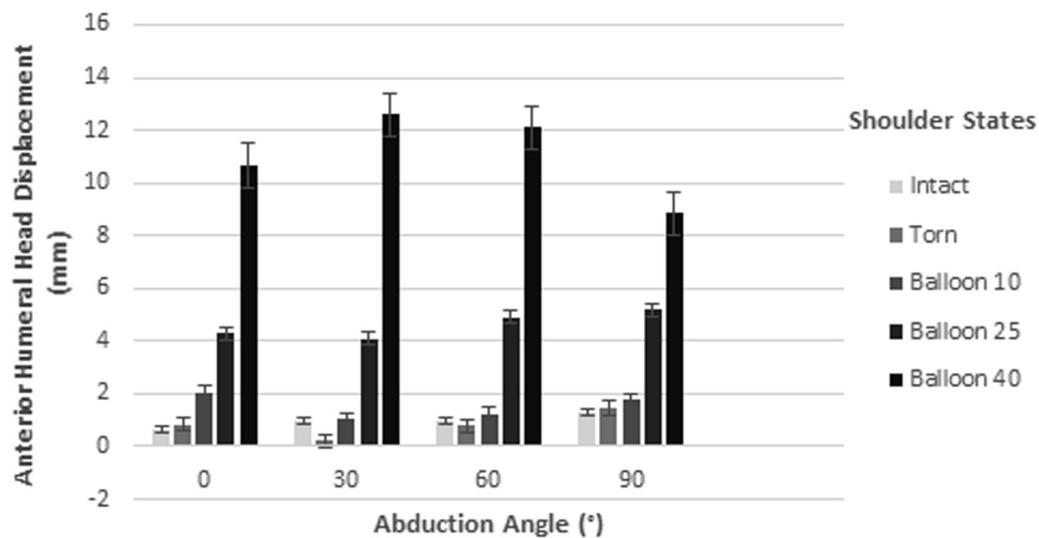


Figure 4 Bar graph showing mean values (± 1 standard deviation) of anterior-posterior humeral head migration for various shoulder states (intact; torn; and balloon inflated to 10, 25, and 40 mL) and shoulder abduction angles (0° , 30° , 60° , and 90°).

($P = .041$) more inferior than the intact state. These trends continued through all angles of abduction, with the 25-mL balloon consistently translating the humeral head inferiorly by an average of 1.7 ± 0.5 mm ($P = .012$) compared with the intact state.

At the 40-mL balloon fill volume, the humeral head translated inferiorly relative to the torn state by an average of 8.6 ± 1.1 mm ($P < .001$) for all abduction angles investigated. Comparing the humeral head position in the intact state with the 40-mL inflated balloon state, we detected a significant difference in which the humeral head was translated 6.6 ± 1.2 mm more inferior ($P = .001$) than the position of the head in the intact state. These trends continued through all angles of abduction, with the balloon inflated to 40 mL consistently translating the humeral head inferiorly by an average of 7.0 ± 1.2 mm ($P = .001$) compared with the intact state.

Anterior-posterior humeral head translation

The massive rotator cuff tear state resulted in significant posterior translation of the humeral head at the 80-N deltoid load for 0° and 30° of glenohumeral abduction by 1.8 ± 0.6 mm ($P = .02$) and 2.0 ± 0.7 mm ($P = .03$), respectively. At 60° and 90° of glenohumeral abduction, no significant anterior-posterior translation was detected between the intact and torn states (Fig. 4).

The insertion of the 10-mL subacromial spacer balloon resulted in the humeral head translating anteriorly relative to the torn state by an average of 0.8 ± 0.5 mm ($P = .06$) for all abduction angles investigated. When the intact condition was compared with the 10-mL balloon, no significant differences were detected ($P = .212$).

At 25 mL, the humeral head translated anteriorly relative to the torn state by an average of 4.6 ± 0.7 mm ($P < .001$)

for all abduction angles investigated. Comparing the humeral head anterior-posterior position in the intact and 25-mL inflated balloon states, we detected a significant difference, in which the humeral head was translated anteriorly by 3.4 ± 0.7 mm ($P = .002$) compared with the intact state.

At the maximum balloon fill volume of 40 mL, the humeral head translated anteriorly relative to the torn state by an average of 11.5 ± 1.6 mm ($P < .001$) for all abduction angles investigated. Comparing the humeral head anterior-posterior position in the intact and 40-mL inflated balloon states, we detected a significant difference: The humeral head was translated anteriorly by 10.3 ± 1.4 mm ($P < .001$) compared with the intact state.

Discussion

There is limited biomechanical literature on the subacromial balloon spacer and its ability to manage irreparable rotator cuff tears. Literature is also lacking on the appropriate inflation volumes. As this device is being used with increasing frequency, biomechanical investigations are important to determine its effects on the glenohumeral joint.

Our objective was to determine whether the subacromial balloon is an effective humeral head depressor and whether adjusting filling volumes had positive or negative effects. The results of this study demonstrated that overall, the 25-mL balloon had the ability to best restore proximal migration of the humeral head. Although our results with the 25-mL balloon did show that it displaced the humeral head more inferior than the intact condition, at a mean of 1.2 ± 0.5 mm ($P = .041$), this 1.2-mm mean difference—although statistically significant—is not likely

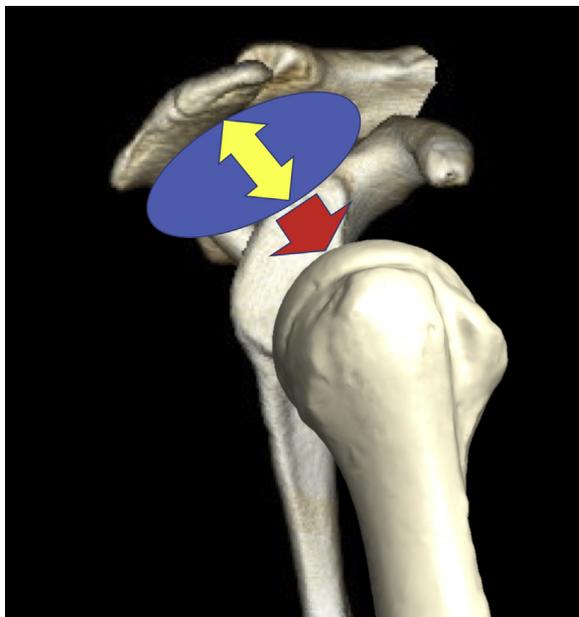


Figure 5 Schema of subacromial balloon in subacromial space (→). Overinflation of the balloon with 40 mL of saline solution resulted in anteroinferior displacement of the humeral head. This direction of displacement likely occurred because of the morphology of the subacromial space. As the balloon expands (↔), the humeral head displaces away from the balloon (↘).

clinically significant. The balloon inflated to 10 mL was able to depress the humeral head; however, its depression effect diminished at higher abduction angles, whereas the 25-mL balloon maintained its effect. The balloon inflated to 40 mL, however, had undesirable effects as it resulted in supraphysiological translation of the humeral head anteroinferiorly.

Our model of a massive, irreparable posterosuperior rotator cuff tear resulted in proximal migration of the humeral head, mimicking the clinical scenario. Although the humeral head did translate superiorly, it did not significantly translate anteriorly when load was applied to the deltoid muscle load. However, the humeral head did translate posteriorly, placing it posterosuperior on the glenoid, which does match the area of bony erosion found in cuff tear arthropathy.⁹ An interesting finding was that, with the subacromial balloon spacer inflated to 25 and 40 mL, some significant anterior translation occurred. With the 25-mL balloon, the anterior translation was approximately 4 mm. With the 40-mL balloon, the anterior translation was substantially more, at a mean of 11 mm, which is concerning. Although we did not test a subscapularis deficiency model, we can only postulate that the anterior translation with the 25- and 40-mL balloons may have been greater without the intact subscapularis to provide resistance to anterior translation. On the basis of these findings,

we are apprehensive to use the subacromial balloon in patients with an irreparable subscapularis rotator cuff tear.

The reason the higher balloon fill volumes displaced the humeral head anteroinferiorly is likely the bony morphology and constraints of the subacromial space. The acromion and scapular spine are posterosuperior structures (Fig. 5); as such, with higher inflation volumes of the subacromial balloon, the unconstrained humeral head would translate in the opposite direction, anteroinferiorly. In our model and clinically, the massive rotator cuff tear results in posterosuperior humeral head translation; as such, some degree of anteroinferior displacement is desirable from the balloon to restore the position of the humeral head. However, supra-physiological anteroinferior translation, as seen with the 40-mL balloon, is likely undesirable as it may be clinically detrimental to patients with prior anterior instability or subscapularis tears.

In our unconstrained massive cuff tear model, increasing humeral abduction did not substantially impact anterior-posterior humeral head displacement. However, as abduction increased, the overall superior translation within conditions decreased (Figs. 2 and 3). In the intact, cuff tear, and 10- and 25-mL balloon states, as the arm progresses to 90° of abduction, the overall mean position of the humeral head transitions from superior to below the center point of the glenoid. This transition to inferior positioning of the humeral head is likely due to the pull of the deltoid at 90°, which is above the center of rotation of the joint.¹ As such, the superior shear force of the deltoid in adduction is converted to an inferior shear force in high abduction.

It is important to highlight some of the limitations of this cadaveric biomechanical study. Static abduction was the only plane of motion tested, and although it is representative of glenohumeral joint motion, it does not capture the complex multiaxial nature of the shoulder girdle. In addition, although anterior-posterior and superior-inferior humeral head migration was measured, the clinical relevance of the migration can only be inferred. Overall, the superior humeral head translation created with the massive tear model is likely reflective of superior migration found clinically. The clinical significance of the inferior and anterior translation encountered with higher balloon fill volumes, however, does not necessarily correlate with specific clinical findings and can only be inferred. In addition, this study only tested 10-, 25, and 40-mL balloon fill volumes; as such, it is conceivable that volumes between the tested values may be optimal. As with all cadaveric studies, the results represent the time-zero effects and do not account for soft-tissue adaptation that would occur clinically over time or the consequences of balloon biodegradation. Finally, the role of the long head of the biceps in dynamic glenohumeral joint

stabilization was not examined in this study. The long head of the biceps tendon was released during creation of the rotator cuff tear in the cadaver to mimic a clinical tenotomy.

Conclusion

This biomechanical study examined the subacromial balloon spacer for the treatment of a massive, irreparable rotator cuff tear with proximal humeral head migration. The subacromial balloon spacer was examined at 3 inflation volumes: 10, 25, and 40 mL. The results demonstrated that the balloon inflated to 25 mL restored the humeral head position such that it was not substantially different from the intact state.

Disclaimer

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