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A biomechanical analysis of flowable injectable calcium bone void filler on acromial tensile stresses: a method to reduce acromial stress fractures

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ABSTRACT

Introduction: Acromial fracture after reverse shoulder arthroplasty (RSA) is a known complication. These fractures are difficult to treat and negatively impact outcomes in patients who experience them. As the rate of RSA increases worldwide, it will be valuable to identify ways to decrease the risk of postoperative acromion fractures. The goal of this study was to evaluate if injecting an acromion with a synthetic bone graft substitute can strengthen the acromion and theoretically provide a means to reduce the incidence of acromial fractures after reverse shoulder arthroplasty.

Methods: Eight cadaveric scapulae matched pairs (n = 16) were randomly allocated to two groups with the contralateral side in the different group. The experimental group (n = 8) had synthetic bone graft filler (CERAMENT) injected while the control group (n = 8) did not. The experimental group had the injection both through an anterolateral and posterolateral corners of the acromion for filling of the acromion. Each scapulae was fixed to the base of a MTS Bionix test frame. Cantilever bending testing to failure was performed on each scapulae with a loading rate of 0.1 mm/s. Failure load (N), force (N/mm), and displacement (mm) were recorded and compared for each specimen. CT scans and fluoroscopy imaging was performed for each specimen before and after testing.

Results: All 16 specimens were available for analysis. The experimental group was injected with 4 cc +/- 0.5 showed material-to-area ratio fill of 39% mid-acromial area and 38% of the acromial area at the Levy I-II junction. The load to failure was 396 N +/- 89 in the control group and 521 N +/-147 in the experimental group ($P = .017$). Displacement at failure was less for the control group at 8 mm +/- 2 mm compared to the experimental group at 12 mm +/- 4 mm ($P = .051$). All samples failed with Levy Type II acromion fractures.

Conclusion: This biomechanical study showed that injection of 4 cc of flowable synthetic bone graft filler into the acromion increased load to failure 32% compared to control scapu-

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

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lae. The stiffness was greater and the displacement before failure was greater in the control group compared to the experimental group, although not statistically significant. The ability for the acromion to plastically deform a greater distance prior to failure allow for greater resistance to fracture under higher tensile loads when flowable bone graft filler is injected.
Level of evidence: Basic Science Study.

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Introduction

Acromial and scapular stress fractures are a known complication following reverse total shoulder arthroplasty (rTSA) with a reported incidence as high as 10% in the literature [2,6,14,15,17,18,19,22,23,25,28-30,34]. When the fracture occurs, patients generally have worse functional outcomes and no consistent treatment has yet been identified [2,17,19,22,23,25,28-32]. In a recent study by Zmistowski, nearly two thirds of those patients identified had a stress reaction and tenderness to the bone without an overt fracture seen on imaging [34]. The exact mechanism is still not fully understood and likely multifactorial with both patient and implant related factors implicated. Patient related factors noted in several recent multicenter studies have included female sex, rheumatoid arthritis, osteoporosis, massive rotator cuff tear, treatment for fracture sequelae and postoperative falls/trauma [3,18,21,25]. Implant related issues are debatable and predicated on the opinion of whether the acromion fails under tension or compression. Several biomechanical studies have demonstrated that glenosphere lateralization results in higher tensile stress in the acromion imparted by the deltoid either thru resting tension or muscle activation [8,16,26,33]. This increased stress and tension imparted to the acromion has presumptively been felt to be responsible for the higher incidence of fractures seen in several retrospective series comparing Grammont style implants with more lateralized designs [2,3,6,14-17,18,19,22-24,28-34]. Recently, Moverman postulated that another potential mechanism of failure could be the result of compression of the acromion [18]. As noted by Laderman, onlay humeral stems have a higher incidence of impingement between the acromion and tuberosity as compared to inlay humeral implants [11]. This abutment between the two bony surfaces, therefore, could result in repetitive compression and ultimate failure of the acromion and may be another explanation for the higher incidence of fractures seen in several clinical series comparing onlay versus inlay humeral components [2,7,12,18]. Although these design implications and preoperative factors have been frequently discussed, the primary consistent factor amongst most series to date has been the preoperative presence of low bone density and conditions or situations with a higher predilection for osteoporotic bone such as female sex and rheumatoid arthritis [2,5,13,18,22,25,31,34]. Given the poor outcomes associated with attempts at fixation after the fracture occurs, methods that could treat the problem before it happens could prove extremely useful [2,23].

Synthetic bone-graft substitutes have been increasingly used in clinical applications to help augment fracture fixation, fill bone defects and help strengthen the repair construct [1,4,9,10]. In a recent study by Hoffman, bioresorbable hydroxyapatite and calcium sulfate cement was compared to iliac bone graft for treatment of tibial plateau fractures and found to have comparable outcomes regarding fracture healing and bone remodeling [10] CERAMENT® bone void filler (Cbvf; Bonesupport) is a bioresorbable synthetic bone graft substitute made up of a combination of 60% calcium sulfate and 40% hydroxyapatite. It has been previously validated in preclinical and clinical studies [1,10,20]. The current authors postulate that if the acromion fails under tension overload caused by osteoporotic defects in the bone, then filling those defects with bone void filler could improve the strength and potentially avoid failure. The purpose of the current paper, therefore, is to biomechanically evaluate if pre-injecting the acromion with bone void filler affords improved strength under tensile loads.

Materials and methods

Cadaveric testing

A total of 8 matched pairs (n = 16) cadaveric scapulae were used for this study. There were 4 female specimens and 4 male specimens with an average age of 69 years (range 45-79 years old). Upon receipt, the specimens were randomly allocated into the following groups, assuring to maintain the contralateral sides in different groups:

1) Control Group (n = 8): This group will not be injected with bone graft substitute.
2) Experimental Group (n = 8): This group will be injected with bone graft substitute.

All cadaveric samples were stripped of soft and connective tissue—the clavicle was not included in testing, therefore the coracoclavicular ligament and acromioclavicular ligament were removed, as well as the coracoacromial ligament. The samples were then wrapped in 0.9% saline soaked gauze pads and stored at -20°C until instrumentation and testing. In preparation for instrumentation and testing, the specimens began the thawing process the night before and were all at room temperature the day of testing. On instrumentation day, the samples were evaluated radiographically using a C-arm. Every specimen was screened for underlying pathology or fracture prior to injection using fluoroscopy in three views (true AP, axillary lateral, and scapular Y).

Figure 1 – Multiple views illustrating the cannula insertion over 2.5 mm K-wires into the lateral and medial aspect of the acromion.

The samples in the experimental group were then injected with approximately 4cc +/- 0.5 of bone void filler by a fellowship trained shoulder surgeon. The material (CERAMENT) used in this study was donated and supplied by Bone Support, Inc. A lateral and medial entry approach was followed to inject the acromion, where a 2.5 mm K-wire was inserted into the Meso-acromion and Meta-acromion. The injection cannula was first inserted into the Meta-acromion using the K-wire as a guide (Fig. 1). Once the K-wire was removed, 2cc of bone void filler was injected into the Meta-Acromion using a 1cc syringe. Thereafter, the same process was followed where 2cc of bone void filler was injected into the Meso-acromion. Following injection, the amount and distribution of the bone void filler was confirmed with fluoroscopy imaging (Fig. 2) in the same three views. The samples were wrapped in 0.9% saline soaked gauze and stored at room temperature following injection.

CT images of all samples post-injection were taken in the supine position (Toshiba Aquilion Lightning; 120 kV; 350 mA; 20-cm field of view; and 512 × 512 matrix; pixel size ~0.535 mm) with 0.6mm slice thickness with images stored in DICOM format and transferred to computers for analysis. Based on the CT images (Fig. 3), 3D-CT reconstruction was performed on all samples (Fig. 4) in Mimics (Materialise, Leuven, Belgium). To assess material-to-area ratios, acromion and bone void filler measurements were obtained using a mid-acromial axial reslice and a reslice along the Levy I-II junction as shown in Table I [14]. Semi-automatic tools from Mimics own toolbox for measurements were utilized to capture the areas of bone cross-section and area of cement (tools captured the area of the bone based on the signal intensity). The same threshold for bone graft substitute injection signal was set for all studies specimens. All measurements were performed by research scientist (PS) with 15+ years in image analysis and processing. Bone graft substitute volumes based on 3-D reconstructed scapulae, were compared to injected volumes for each specimen (Table II).

Biomechanical testing

The potted scapulae were then rigidly coupled to a lockable vise-clamp, capable of rotation in two planes, which was fixed to the base of the MTS Bionix test frame (Fig. 5) equipped with a 5kN load cell. The scapulae were oriented with the adjustable vise, such that the load frame's vertical axis coincides with the loading vector (downward and outward direction). The vise was then locked in place and cantilever bending (ramp to failure) testing was performed. The point load was applied with a cylindrical loading tip through the acromion at a loading rate of 0.1 mm/s.

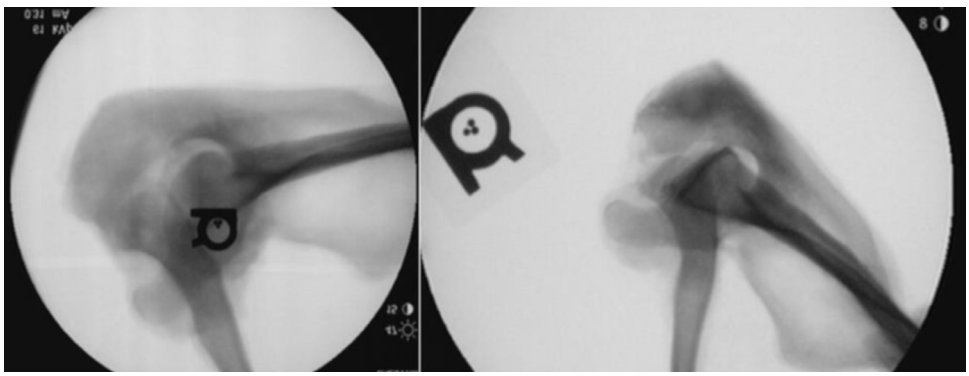

Figure 2 – Cerament distribution confirmed with fluoroscopy. The circle indicates injection site.

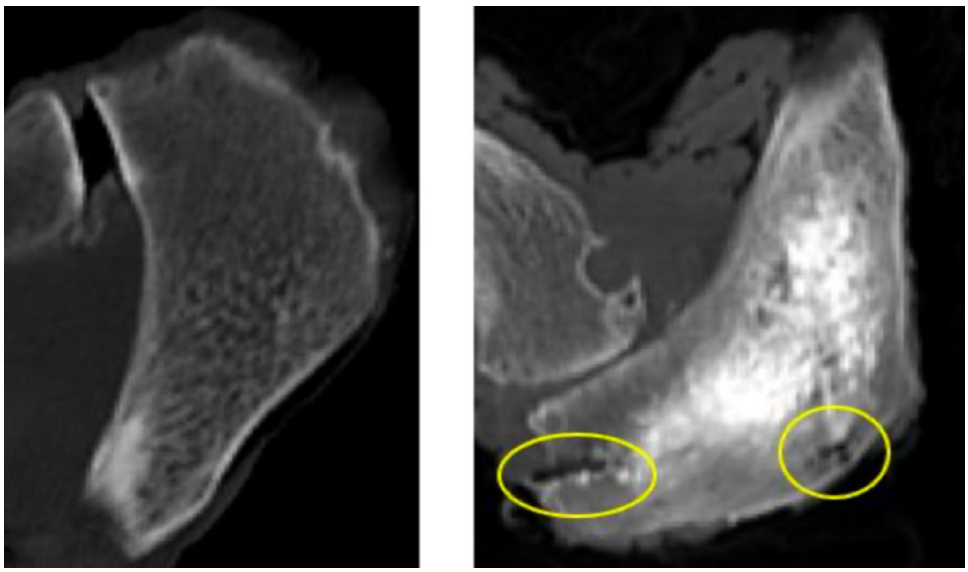

Figure 3 – Post injection CT images of 0.6 mm slice thickness were obtained for all samples.

Failure load was defined as a sharp decrease in the monotonically increasing force profile. Force (N) and displacement (mm) data were captured from the load frame at a frequency of 100 Hz with test software. Stiffness was calculated from the force vs. displacement curves and defined as the linear portion of the curve. Failure load (N), stiffness (N/mm) and displacement (mm) will be compared between the matched specimens. Digital images of the failure pattern were taken to document failure mechanism.

Statistical analysis

Due to the non-normality of data, non-parametric statistics were performed, where a Wilcoxon Signed Ranks Test was used to identify differences in failure load, stiffness and displacement between the control group and experimental group. Data are presented as mean ± standard deviation (SD). All statistical comparisons were performed at a significance level of 0.05 using SPSS v. 22 (IBM, Armonk, NY, USA).

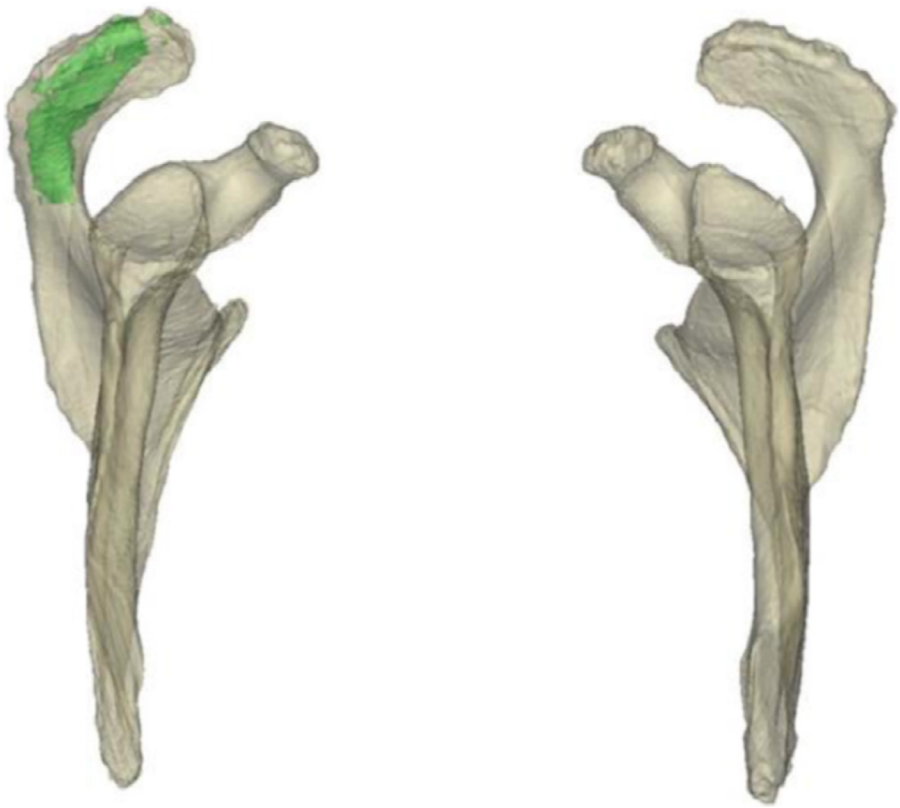

Figure 4 – 3D-CT reconstruction demonstrates volume and pattern of Cerament injection.

Table I – Acromion and bone void filler area measurements for all specimens.

Study group	Acromion area (mm^2)	Cerament area (mm^2)	Levy I-II junction acromion area (mm^2)	Levy I-II junction cerament area (mm^2)
Cerament	1680.8	688.0	244.8	96.1
Control	1768.4	N/A	280.8	N/A
Cerament	2001.6	614.0	386.3	138.0
Control	1888.5	N/A	432.1	N/A
Cerament	1700.1	756.3	228.8	91.4
Control	1735.4	N/A	274.7	N/A
Cerament	2072.2	693.6	301.1	83.3
Control	2009.9	N/A	329.8	N/A
Cerament	1633.4	504.1	299.5	87.9
Control	1669.4	N/A	322.8	N/A
Cerament	1858.1	594.0	325.4	107.5
Control	1894.4	N/A	281.6	N/A
Cerament	1456.1	976.1	251.9	130.6
Control	1417.0	N/A	262.3	N/A
Cerament	1440.2	515.9	209.8	92.8
Control	1334.4	N/A	244.2	N/A

Measurements were obtained using a mid-acromial axial reslice and reslice along the Levy I-II junction.

Table II – Comparison of bone void filler volumes measured from 3-D reconstructed scapulae to injected volumes.

Donor ID	Scapula (Side)	CERAMENT volumes (cc)	Volume injected (cc)
4691	R	4.3	4.0
4678	L	3.9	4.0
4028	L	3.6	4.0
3966	L	6.9	5.0
4187	L	3.5	3.5
4674	R	4.0	4.0
4560	R	4.0	3.5
4470	R	4.4	4.0

*Standard was to inject x4, 1cc syringes: 2 cc from Ant. Direction & 2 cc from Post. Direction.

Results

In the current biomechanical analysis, all fractures failed in the region of the mid-acromion defined as a Levy Type II fracture [14]. Bone graft substitute occupied an average of 39% of the mid acromial area and 38% of the acromial area at the Levy 1-II junction. (Fig. 6) Acromion injected with bone graft substitute on average had a 32% increase load to failure as compared to the control ($P = .017$). The control group load to failure on average was 396 N ± 89, whereas the experimental group load to failure was 521 N ± 147. There was a large difference in strength in between the two groups in younger cadavers, and no significant difference between cadavers

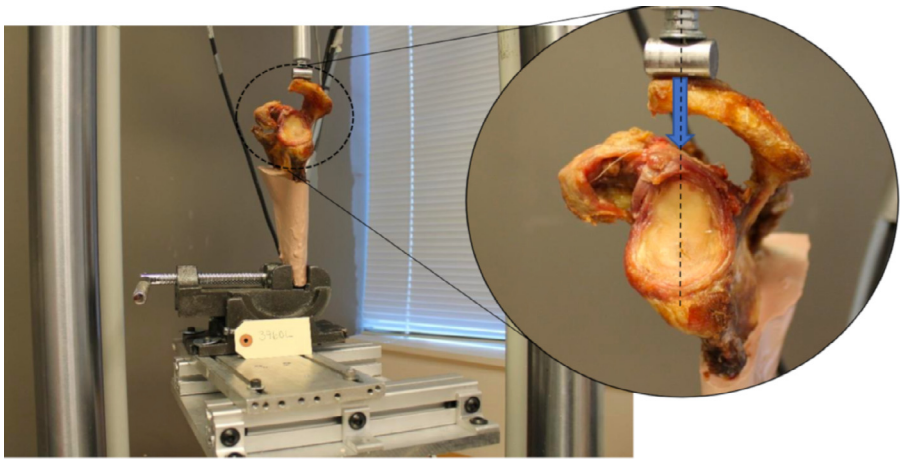

Figure 5 – Biomechanical test setup with potted scapulae coupled with lockable vise-clamp.

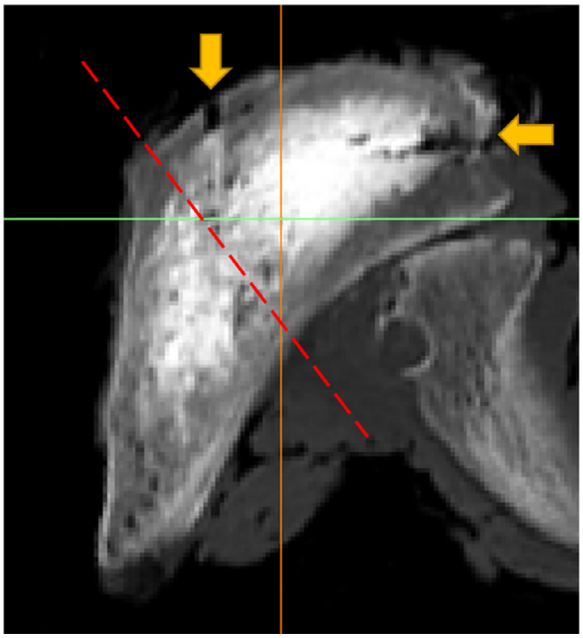

Figure 6 – Post-injection CT scan with the injection tracts indicated with yellow arrows and estimated fracture location indicated with red dashed line.

>70 years of age. (Fig. 7) Interestingly, the displacement at failure was less for the control group than the experimental group. On average, the control group displaced 8 mm ± 2 compared to the experimental group which displaced 12 mm ± 4 but this difference was not statistically significant ($P = .051$). Stiffness between the two groups showed no statistically significant difference (Table III).

Discussion

Acromial stress fracture (ASF) is a complication distinctive to rTSA with one postulated mechanism thought to be a result of the added tensile strain created by the deltoid following surgery [2,6,14,15,17,22,23,28-32,34]. Several published series report that when fractures do occur, the majority happen within the first six months, which further lends to the theory that the acromion fails under tension before Wolf's law and bony remodeling can be completed [14,31,34]. While many authors have attempted to identify patient- and prosthetic-specific factors contributing to the development of an ASF, the only consistent finding in multiple studies has been the preoperative presence of poor bone density [22,23,31,34]. In three large retrospective series encompassing over 3700 patients collectively, osteoporosis was identified as a significant risk factor for the development of postoperative acromial fracture in each clinical series [18,31,34]. Other studies have also associated female sex and rheumatoid arthritis as other independent risk factors with both variables also associated with a higher incidence of poor bone quality and osteoporosis [5,13,18,25]. Finally, in a smaller comparative series, Otto et al noted a nearly two-fold increased risk of developing a fracture when osteoporosis was present preoperatively [22]. Unfortunately, once the fracture occurs, patients are usually met with poorer outcomes and given the complications reported with attempts at fixation, the mainstay of treatment to date has been nonoperative management [2,23,28]. Treating the osteoporosis and providing a means to strengthen the acromion could, therefore, provide a viable means to lessen the risk of this devastating complication.

The current authors postulated that injecting the acromion with a synthetic bone graft substitute could improve the

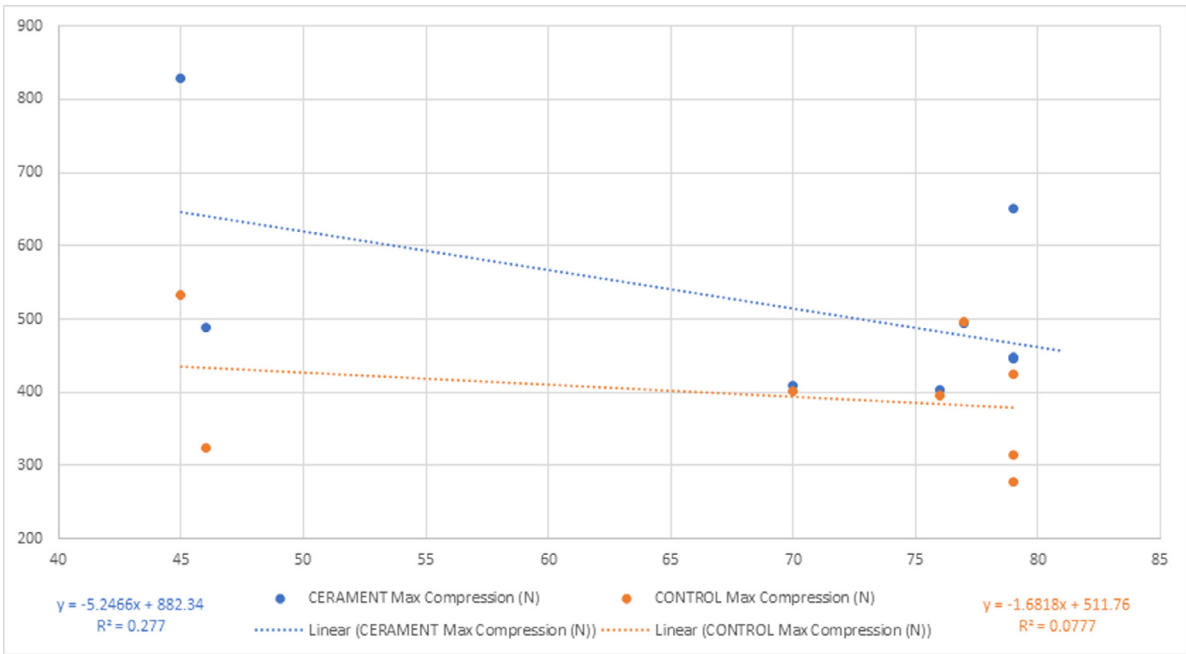

Figure 7 – Line graph with age (years) on the x-axis and load to failure (N) on the y-axis.

Table III – Biomechanical mean results of acromion samples injected with bone void filler versus controls.

	Compressive strength (N)	Stiffness (N/mm)	Displacement at failure (mm)
Bone void filler	521 N ± 147	60 N/mm ± 24	12 mm ± 4
Control	396 N ± 89	73 N/mm ± 22	8 mm ± 2
P value	.017*	.16	.051

* Indicates statistical significance.

strength of the acromion under tensile failure by making the bone stiffer. If the acromion fails under compression as postulated by Moverman thru tuberosity impingement, the current testing model would not apply nor account for this compressive mode of failure [18]. The concept of adding bone graft substitute to compromised areas of bone has been applied to other areas of the body, most notably in the tibia when addressing stress reactions associated with degenerative arthritis [4]. The current study did in fact demonstrate that the acromia injected on average had a 32% greater load to failure. Interestingly, however, the acromia did not get stiffer and actually became more flexible. The bone void filler group displaced an average of 12 mm prior to failure whereas the control displaced 8 mm. While not statistically significant, this finding may hint at the means the bone void filler is functioning within the bone to impart greater strength. Instead of stiffening the acromion, it may actually make it more flexible and pliable and able to plastically deform under greater loads prior to tensile failure.

There are several limitations to this study. First and foremost, this study has not been validated in a clinical series to determine if the added strength provided is enough to sufficiently reduce the incidence of acromial fractures following reverse shoulder surgery. Although a future clinical comparative study is now planned based on the results of this biomechanical study, the authors cannot advise on current clinical application until further analysis is obtained. Our study design also had several inherent issues with regards to the setup and testing model. The drill holes placed in the acromion and used for injection could theoretically predispose to a stress fracture in the acromion. This, however, was not seen in the current study model with all fractures occurring more posterolateral to the drill holes placed (Fig. 6). We also tested specimens that were devoid of their soft tissue attachments, specifically the coraclavicular ligament and we did not test specifically on osteoporotic specimens. As noted recently by Taylor, the strains demonstrated in the current simulation could have been greater than naturally seen when the coracoclavicular ligament is preserved [27]. In regards to age of the specimens and overall bone quality, two specimens were aged 45 and 46 with the remaining specimens over the age of 70. When analyzing only the 70 and older specimens, we found no difference in the results however bone density studies were not completed, and a more osteoporotic specimen may have demonstrated different findings. Finally, the biomechanical assumption was that the acromion fails under tension and we tested this by point loading the acromion and measuring ultimate load to failure, with all fractures occurring in the zone of Levy II [14]. We did not assess for added strength in compression and are unable to comment on this mode of failure. Furthermore, our model point loaded the anterolateral acromion which does not simulate or replicate the actual pull of the entire deltoid in vivo and our study did not account for cyclic failure that likely occurs thru repetitive loading. The design and limitations of our study model, therefore, may create inherent bias in the findings and results.

Conclusion

This study demonstrates a novel technique to help strengthen the acromion. This theoretically could help aid in the prevention of acromial stress pathology (including ASF and ASR) following rTSA however its current application cannot be advised prior to further clinical analysis.

Disclaimers

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Conflicts of interest: Miguel Diaz and Peter Simon are employed by the Foundation for Orthopaedic Research and Education (FORE). Allen Gorman II is a research fellow at FORE. The other authors, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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