Clinical Biomechanics 54 (2018) 132–136

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Pullout strength of standard vs. cement-augmented rotator cuff repair anchors in cadaveric bone

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ARTICLE INFO

Keywords:
Augmented rotator cuff anchor technique
Bone cement
Pullout strength
Rotator cuff repair
Standard anchor fixation
Suture anchors

ABSTRACT

Background: We evaluate a novel method of rotator cuff repair that uses arthroscopic equipment to inject bone cement into placed suture anchors. A cadaver model was used to assess the pullout strength of this technique versus anchors without augmentation.

Methods: Six fresh-frozen matched pairs of upper extremities were screened to exclude those with prior operative procedures, fractures, or neoplasms. One side from each pair was randomized to undergo standard anchor fixation with the contralateral side to undergo anchor fixation augmented with bone cement. After anchor fixation, specimens were mounted on a servohydraulic testing system and suture anchors were pulled at 90° to the insertion to simulate the anatomic pull of the rotator cuff. Sutures were pulled at 1 mm/s until failure.

Findings: The mean pullout strength was 540 N (95% confidence interval, 389 to 690 N) for augmented anchors and 202 N (95% confidence interval, 100 to 305 N) for standard anchors. The difference in pullout strength was statistically significant ($P < 0.05$).

Interpretation: This study shows superior pullout strength of a novel augmented rotator cuff anchor technique. The described technique, which is achieved by extruding polymethylmethacrylate cement through a cannulated in situ suture anchor with fenestrations, significantly increased the ultimate failure load in cadaveric human humeri. This novel augmented fixation technique was simple and can be implemented with existing instrumentation. In osteoporotic bone, it may substantially reduce the rate of anchor failure.

1. Introduction

Rotator cuff tears cause pain, disability, and financial burden (Mather et al., 2013; Mitchell et al., 2005). The number of patients presenting with shoulder pain and the number of rotator cuff repairs increased dramatically from 1996 to 2006 (Colvin et al., 2012; Harryman et al., 2003; Jones and Savoie, 2003; Vitale et al., 2007). These increases likely relate to the aging of the United States population because full-thickness tears are more common with increasing age (U. S. Department of Health and Human Services, n.d.; Tashjian, 2012). Treatment of rotator cuff tears in the elderly is challenging because of the decreased rate of soft-tissue healing and the higher prevalence of osteopenia and osteoporosis (Chung et al., 2011).

Obtaining good fixation in osteoporotic and osteopenic bone is important and challenging in arthroscopic repair of rotator cuff tears. Arthroscopic repair has become the most common treatment for rotator cuff tears (Colvin et al., 2012; Yadav et al., 2009). Whereas arthroscopic suture anchor repairs commonly fail at the suture-tendon interface (Cummins and Murrell, 2003), bone-anchor integrity is compromised in osteoporotic bone, weakening the suture anchor fixation strength (Chung et al., 2011; Tingart et al., 2004; Yakacki et al., 2010). Researchers have studied several techniques for improving fixation of implants in osteoporotic bone by using cement (Braunstein et al., 2015; Klos et al., 2010; Sermon et al., 2012a, 2012b; Stoffel et al., 2008), but only Braunstein et al. showed that cement augmentation can improve fixation strength in rotator cuff repairs specifically. Braunstein et al. used an augmentation technique in which the anchor hole was predrilled and injected with polymethylmethacrylate cement before the anchor was “potted” into the injected cement. Although the “potting” method was adequate to show that cement augmentation can improve fixation strength, this would not be feasible in an arthroscopic setting because of the risk of cement extrusion. Therefore, in our study, the cement was injected into and through an open-architecture type anchor after its initial placement and with equipment compatible with an

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https://doi.org/10.1016/j.clinbiomech.2018.03.016
Received 10 July 2017; Accepted 19 March 2018

arthroscopic setting.

In this study, we introduced a novel method of suture anchor cement augmentation that allows for direct cement augmentation of an anchor in situ. We aimed to assess whether this new method increases the purchase into cadaveric bone as measured by pullout strength. We assessed specimens that included osteoporotic, osteopenic, and normal bone. We hypothesized that when controlling for bone quality, cement augmented anchors would increase anchor pullout strength compared with the standard anchor technique.

2. Methods

2.1. Testing protocol

Six cadaveric fresh-frozen matched pairs of upper extremities were screened. Exclusion criteria were history of neoplasm, proximal humerus fracture, or evidence of shoulder surgery. A T-score for each sample was measured using dual-energy X-ray absorptiometry (Discovery QDR system, Hologic Inc., Bedford, MA, USA). One side from each pair was randomized to undergo standard anchor fixation, with the contralateral side to undergo augmented anchor fixation. All fixations were performed with fenestrated HEALICOIL PEEK suture anchors (Smith & Nephew, Andover, MA, USA). The paired humeri were stored at −20 °C after being harvested fresh. The specimens were thawed at room temperature for 24 h before testing. After thawing, shoulders were dissected free of all soft tissue.

All anchors were inserted by 1 fellowship-trained shoulder surgeon in a consistent manner. An awl was used to create 2 pilot holes lateral to the articular margin. The anterior anchor pilot hole was placed 10 mm posterior to the bicipital groove, and the posterior anchor pilot hole was made 15 mm posterior to the anterior hole (Fig. 1A and B). We inserted anchors at an angle of 70° relative to the horizontal greater tuberosity surface and 90° relative to the eventual direction of pull. Angles were confirmed with the built-in protractor in the MTS 858 servohydraulic testing system. The use of a 90° angle of pull has been supported by recent studies as being superior to the “deadman's angle” of 45° (Clevenger et al., 2014; Liporace et al., 2002; Strauss et al., 2009) and is consistent with typical placement in the clinical setting. No tapping was performed. After anchor placement (Fig. 2A) for the augmented anchor fixation group, 1 mL of bone cement (KyphX HV-R, Kyphon Inc., Sunnyvale, CA, USA) was loaded into a cannula, which was then seated at the top of the inserted anchor (Fig. 2B). An obturator was inserted into the cannula to discharge the cement into the anchor and surrounding bone (Fig. 2C). Cement was extruded through the cannulated obturator into the anchor, exiting the anchor through the fenestrations in the suture anchor and causing interdigitation with the bony trabeculae (Fig. 2D). After placement, cement was allowed to cure for 10 min, and fluoroscopic images were taken to confirm cement placement (Fig. 3). Humeri were mounted on a MTS 858 servohydraulic testing system (MTS Corp., Eden Prairie, MN, USA) and suture anchors were pulled perpendicular to insertion to simulate the anatomic pull of the rotator cuff (Fig. 1). The sutures were able to slide through the hybrid anchor cement construct without difficulty and did not appear to be compromised by cement curing. Sutures were pulled at a rate of 1 mm/s until failure. Force was measured using a 500-lb load cell Model 41 (Sensotec Inc., Columbus, OH, USA).

2.2. Statistical analysis

Descriptive statistics for age, sex, and T-score of the cadaveric specimens were calculated. The paired humeri from each specimen were matched and randomized to standard or augmented anchor fixation. We checked for an effect of augmentation on pullout force by using a generalized linear latent and mixed model (Skrondal and Rabe-Hesketh, 2004) with a random effects term (Stata, version 10, software, StataCorp LP, College Station, TX, USA) to account for specimen pairing. We included age and specimen T-score as covariates. Results are reported as mean values with 95% confidence intervals. Statistical significance was set at $P < 0.05$.

A

B

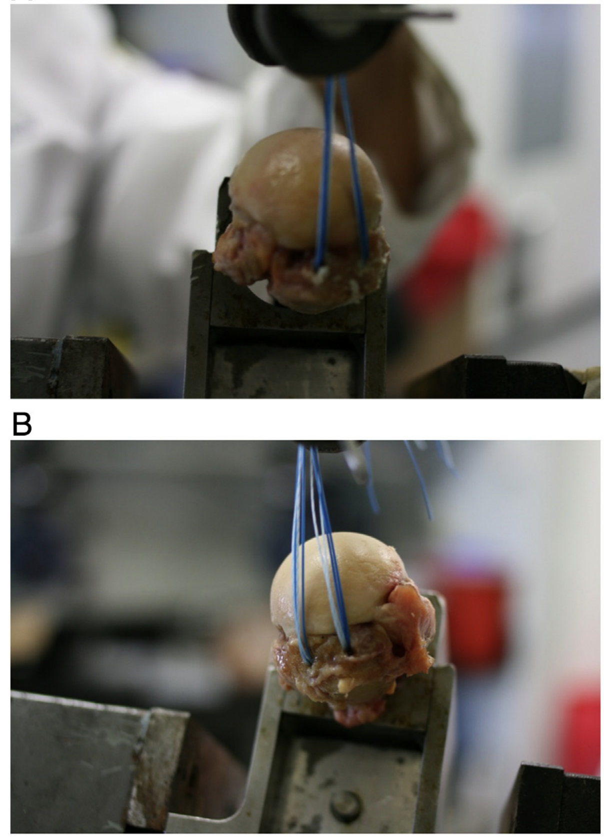

Fig. 1. Gross depiction of repair constructs with appropriately buried anchors. (A) Cemented anchor, showing that the cement injection technique prevents cement from being forced outside of any predrilled hole, which could potentially seed the joint with cement loose bodies. (B) Gross anatomical depiction of an uncemented anchor attached to the servohydraulic testing system for comparison. Note that anchors should not be visible when placed in proper position.

3. Results

The mean age of cadavers was 84 years (range, 76–94 years); 5 of 6 were male; and the median T-score was −2.6 (range, 0.55 to −4.45). In all specimens, the failure mode was either critical failure of the humerus by fracture (Fig. 4A) or pullout of the anchor (Fig. 4B), whichever occurred first. Only 1 sample, the right humerus in specimen 1, failed by humerus fracture. Augmented anchors had significantly higher mean pullout strength (540 N; 95% confidence interval, 389 to 690 N) than the standard anchor control group (202 N; 95% confidence interval, 100 to 305 N) (Table 1). Age and T-score were not significant predictors of pullout strength.

4. Discussion

The anchors augmented with cement achieved significantly greater purchase than standard anchors. Cement augmentation increased pullout strength of the construct by 167% (to 540 N from 202 N). To our knowledge, the only previous study investigating the effect of cement augmentation on pullout strength in rotator cuff repairs was performed by Braunstein et al. (2015), who reported increases of 47% (332 N from 226 N) and 45% (304 N from 209 N), depending on anatomic location. The key differences between the Braunstein study and the current study are the timing and method of augmentation. We also used an open-