Bioabsorbable Tricalcium Phosphate Bone Cement Strengthens Fixation of Suture Anchors

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Abstract

Background Failure of suture anchor fixation in rotator cuff repair can occur at different interfaces. Prior studies show fixation at the bone-anchor interface can be augmented using polymethylmethacrylate (PMMA) cement, and screw fixation into bone can be strengthened using bioabsorbable tricalcium phosphate cement.

Questions/purposes We wished to determine whether augmentation of suture anchor fixation using bioabsorbable tricalcium phosphate cement would increase pullout strength of suture anchors from bone and the number of cycles to failure, to determine the mode of failure after cement augmentation, and to compare strength and mode of failure with those after augmentation with PMMA.

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

This work was performed at VA Bone and Joint Rehabilitation Research and Development Center, Palo Alto, CA.

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Methods We used 10 matched pairs of cadaveric proximal humeri and implanted a metal screw-type suture anchor in one side and on the other side injected tricalcium phosphate cement into the anchor holes before anchor placement. We tested all specimens to failure using a ramped cyclic loading protocol.

Results Tricalcium phosphate cement augmentation increased the final load to failure by 29% and the number of cycles to failure by 20%. Visual inspection confirmed that failure occurred at the cement-bone interface.

Conclusions Tricalcium phosphate cement appears to augment suture anchor fixation into bone, reducing the risk of anchor pullout and failure.

Clinical Relevance When relying on suture anchor fixation in bone of questionable quality, we suggest considering augmentation of suture anchor fixation with bioabsorbable cement. This method also provides potential for bioabsorbability and may be more amenable to arthroscopic application.

Introduction

Rotator cuff tears are a common cause of shoulder pain and dysfunction. Orthopaedic surgeons often repair rotator cuff tears using arthroscopic techniques. Suture anchors are commonly used during arthroscopic rotator cuff repairs. The strength of the rotator cuff repair is a function of many factors, including soft tissue quality, suture strength, anchor design, and bone quality. These factors all represent potential sites of failure.

Retear rates reportedly range from 15% to 90% [1, 2, 11, 20], with approximately 4% of failures being attributed to metal anchor pullout from bone at the time of revision surgery [5, 6]. The pullout rates for bioabsorbable anchors

reportedly are much higher, with as much as 30% of painful shoulders showing anchor pullout on MRI after cuff repair [12]. Pullout rates may be influenced by poor bone quality in the region of the proximal humerus, particularly in the case of chronic tears, which may cause more focal osteopenia [13]. Chronic impingement can lead to the development of subchondral bone cysts located where an anchor would need to be placed, and in the revision situation, prior surgery and anchor placement may compromise bone quality in the region of the greater tuberosity.

PMMA bone cement has been used to augment screw fixation in spine [4, 10, 16, 18, 19, 22] and trauma [3, 7, 15, 17] applications. These studies all showed increases in failure strength of constructs augmented with PMMA. PMMA alone also has been used to anchor suture to bone without use of a traditional suture anchor [14]. That study showed that PMMA alone can be used to anchor a suture directly into a hole in bone without the use of a suture anchor while providing fixation similar or superior to traditional suture anchor fixation. Suture anchors provide a particular advantage over transosseous sutures and sutures embedded directly into PMMA as they have an eyelet allowing the suture to slide. The potential for dislodging the anchor during knot tying theoretically is reduced if augmented with cement. In one study injecting PMMA into a suture anchor hole before placement of the anchor increased pullout strength and number of cycles to failure when a suture anchor was placed into an intact or a stripped anchor hole (representing primary augmentation or a revision scenario, respectively) [9]. Pullout strength was increased by 71% in intact specimens and 111% in stripped specimens by augmenting with PMMA. Cycles to failure increased by 34% and 31%, respectively, after augmentation with PMMA. But PMMA has inherent limitations. It is not bioabsorbable, which may inhibit tendon-to-bone healing and may complicate revision surgery.

As an alternative, tricalcium phosphate cement is bioabsorbable and will be replaced by normal bone with time, eliminating the problems associated with PMMA mentioned above. Several studies have examined the use of tricalcium phosphate cement to increase fixation of pedicle screws [16, 18, 19], hip screws [7, 15], and 4.5 mm cortical screws [3]. These studies all show increases in failure strength of tricalcium phosphate augmented constructs over controls where screws were placed without the addition of cement. These increases tended not to be as great as those achieved with PMMA, however.

The purposes of this study were to determine (1) whether augmentation of suture anchor fixation using bioabsorbable tricalcium phosphate cement would increase pullout strength of suture anchors from bone in similar proportion to other applications previously studied; (2) whether said augmentation would increase the number of

cycles to failure of suture anchors placed in bone and compare to data from a previous study using PMMA; and (3) the failure mode after said augmentation and again compare to results of a previous study using PMMA [9].

Materials and Methods

Ten matched pairs of preserved cadaveric proximal humeri were obtained (average age at death, 83 years; range, 56–99 years; 50% male, 50% female) (Table 1), defrosted and cleared of all soft tissue attachments. Metal screw-type suture anchors then were placed at the articular margin using the standard technique of screwing them into virgin bone (control) or into a hole injected with tricalcium phosphate cement (experimental). These anchors then were subjected to loads according to a ramped cyclic loading protocol until failure. The primary outcome variable, load to failure, was recorded, as was the secondary outcome variable, number of cycles to failure. Visual inspection was performed to determine the failure mode.

Power analysis was performed based on estimates from prior studies [3, 7, 9, 15, 16, 18, 19]. An effect size of a 30% increase in load to failure was estimated based on these studies. A difference of this magnitude would be sufficient, in our judgment, to justify the added expense and added operative time and effort to augment the fixation of the suture anchor, particularly if the bone is of poor quality. Standard deviations of 30% and 20% of failure loads were chosen for control and experimental groups, respectively, as these prior studies showed lower standard deviations after augmentation with tricalcium phosphate as a percentage of failure loads. We chose $\alpha = 0.05$ and

Table 1. Demographic data of matched pair specimens

Specimen	Age (years)	Gender	Control side BMD (g/cm ²)	Experimental side BMD (g/cm ²)
1	99	F	0.271	0.315
2	87	M	0.370	0.328
3	89	M	0.443	0.454
4	92	M	0.487	0.546
5	76	F	0.313	0.362
6	56	M	0.656	0.655
7	81	M	0.601	0.601
8	70	F	0.328	0.326
9	88	F	0.259	0.246
10	95	F	0.307	0.329
Average	83.3		0.404	0.416
SD	12.6		0.135	0.136

Average BMD of all specimens was 0.410 ± 0.134 g/cm². Maximum side-to-side difference in BMD was 5.9% ($p = 0.26$); SD = standard deviation.

$\beta = 0.2$ to calculate a sample size providing statistical power equal to 80%. Sample size thus was calculated as 11 samples for each group. Ten matched pairs of humeri yields 20 samples in each group, as two suture anchors were placed in each humerus.

We obtained dual-energy xray absorptiometry (DEXA) scans on each humeral head to investigate side-to-side variability in bone mineral density (Discovery™ A; Hologic Inc, Waltham, MA). Any pair with greater than 20% variability between sides was discarded, as these were assumed to be mismatched during harvest or handling. No assessment could be made regarding the presence of osteoporosis as no data are available correlating bone mineral density of the proximal humerus to osteoporosis. Thus DEXA scanning was performed only to confirm that pairs were matched. Each humeral shaft was transected 10 cm distal to the inferior edge of the articular cartilage and potted in PMMA. The assignment of right or left side to each of the testing protocols, described below, was randomized by drawing folded pieces of paper labeled with an equal number of 'Ls' and 'Rs' out of a bowl. This technique ensured an equal number of right and left humeri to each group. For the 10 pairs of matched cadaveric humeri, bone mineral density measured by DEXA averaged 0.410 g/cm^2 (SD = 0.134 g/cm^2) (Table 1). We observed no difference ($p = 0.26$) between groups and the maximum difference from side-to-side in any one pair was 5.9%. As a comparison, the normal bone density in the proximal femur and spine of a 30-year-old are known to be 0.939 g/cm^2 and 1.047 g/cm^2 for females and 1.023 g/cm^2 and 1.091 g/cm^2 for males, respectively [8]. Our measurements of the proximal humerus are 31% and 28% of these values for the female specimens and 31% and 29% for the male specimens.

Before preparation and testing, the specimens were defrosted in a 37°C water bath for 24 hours. Two sites in each humerus were chosen for anchor insertion located 1 cm and 3 cm posterior to the bicipital groove in the trough between the articular surface and the greater tuberosity. Metal screwlike suture anchors (5-mm Fastin® RC; Mitek, Norwood, MA) were used in this study. The sutures were removed from the eyelets and replaced with 0.64-mm-diameter stainless steel wire to eliminate suture breakage as a mode of failure, as this study is designed to assess fixation at the anchor-bone interface. This wire was tested to a failure load exceeding 1000 N, well above any of the values obtained in a previous study for anchor pullout [9]. The wire then was clamped to a materials testing machine (858 Bionix®; MTS, Eden Prairie, MN). The clamp was placed at a distance of 4 cm from the bone surface. Both sites on each humerus received the same experimental treatment. These sites were spaced sufficiently far apart such that there was no influence of one site

on the other based on results from a previous study [9] and the regions defined by Tingart et al. [21]. Additionally, Tingart et al. [21] showed there is no difference in the bone mineral density between the anterior, middle, and posterior portions of the proximal region of the greater tuberosity.

To create the control group, suture anchors were inserted into a randomly assigned humerus in the standard fashion (without placement of any cement) at the two sites mentioned above. To create the augmented experimental group, tricalcium phosphate cement (Callos® Inject; Acumed LLC, Hillsboro, OR) was mixed at room temperature according to manufacturer's instructions. A Jamshidi needle (supplied by the manufacturer) was used to make a pilot hole at each anchor insertion site on the contralateral matched humerus. The cement then was injected until substantial back pressure was encountered, usually resulting in the cement hardening at the tip of the Jamshidi needle. This technique resulted in a volume of approximately 0.5 to 1.5 cm^3 of liquid cement being injected at each site. A new suture anchor then was inserted into each hole (Fig. 1) and the cement was allowed to fully cure for 24 hours at 37°C , per manufacturer's instructions and according to prior studies using tricalcium phosphate cement [3, 7, 15, 16, 18].

Suture anchors then were loaded along their axis of insertion as described previously [9] (Fig. 2). Mechanical testing of the suture anchor fixation was performed according to a ramped cyclic loading protocol described by Tingart et al. [21]. Load was applied in line with the axis of insertion of the suture anchors, representing a worst-case

Fig. 1 A cross-sectional radiograph shows penetration of tricalcium phosphate cement into bone trabeculae around a suture anchor.

Fig. 2 A photograph shows a prepared specimen with suture anchors implanted 1 cm and 3 cm posterior to the bicipital groove at the articular margin. Anchors were tested in line with the axis of insertion, representing a worst-case scenario for pullout.

scenario for pullout. The suture anchors were cyclically loaded with a preload of 4 N and a load rate of 25 N per second. A 50-N maximum load was chosen for the first 10 cycles. This maximum load increased in 50-N increments after each 10 cycles for a total of 40 cycles. After 40 cycles (maximum load of 200 N), the suture anchor was loaded at a linear rate of 1 mm per second until failure. For each test, cycles to failure and the maximum tensile load during the test were recorded. Thus, 20 tests were performed in each experimental group.

Specimens were examined visually to determine mode of failure. If the wire broke, and the suture anchor remained in bone, failure mode was at the wire-anchor interface. If the anchor pulled out but the cement remained in the bone, then the failure mode was at the anchor-cement interface. If the anchor pulled out with cement attached to it with no cement remaining in the bone, then the failure mode was at the cement-bone interface.

Given that the observations are independent in paired specimens and possibly nonparametric, a Wilcoxon signed rank test was used to compare experimental groups. Statistical analysis was performed using Excel (Microsoft Corp, Redmond, WA).

Results

The maximum load to failure increased from an average of 202.5 N for the control group to 261.2 N for the experimental group, representing a 29% increase ($p = 0.027$) in load to failure after tricalcium phosphate cement augmentation (Table 2).

The control group failed after an average of 27.6 cycles which increased to 33.1 cycles for the experimental group, representing a 20% increase ($p = 0.050$) in cycles to failure after augmentation with tricalcium phosphate cement (Table 3).

Table 2. Maximum load to failure of matched-pair specimens

Specimen	Location	Control (N)	Experimental (N)
1	Anterior	208.0	152.7
1	Posterior	137.6	199.5
2	Anterior	141.3	175.8
2	Posterior	102.8	229.8
3	Anterior	202.6	145.5
3	Posterior	151.0	158.0
4	Anterior	136.3	252.9
4	Posterior	113.6	299.1
5	Anterior	*	177.2
5	Posterior	200.5	302.7
6	Anterior	443.9	722.3
6	Posterior	227.7	418.9
7	Anterior	231.1	380.7
7	Posterior	366.7	337.9
8	Anterior	265.3	213.4
8	Posterior	137.7	199.5
9	Anterior	150.3	147.0
9	Posterior	133.8	119.2
10	Anterior	349.3	249.4
10	Posterior	148.9	342.9
Average		202.5	261.2
SD		94.2	138.0
% increase	29%		
p value	0.027		

* Data set omitted from analysis secondary to malfunction of the MTS machine during testing of this specimen; SD = standard deviation.

Visual examination of the suture anchors and specimens from the cement-augmented experimental group revealed varying amounts of tricalcium phosphate cement attached to the suture anchors, with no cement remaining in the insertion site on the specimens (Fig. 3).

Discussion

Techniques for augmenting suture anchor fixation into bone can be of value. Osteoporosis, disuse, fracture, poor bone preparation, cysts in the bone, or prior surgery can leave a bony bed of questionable quality. Previous studies show suture anchors can fail at the anchor-bone interface [5, 6, 12]. Giori et al. showed that anchor fixation can be augmented using PMMA [9]. We therefore determined whether load to failure and fatigue strength could be increased by augmenting suture anchor fixation with bioabsorbable tricalcium phosphate cement and explored the limitations of PMMA and potential advantages of using tricalcium phosphate.

Table 3. Cycles to failure of matched-pair specimens

Specimen	Location	Control	Experimental
1	Anterior	30	20
1	Posterior	20	30
2	Anterior	20	30
2	Posterior	11	40
3	Anterior	32	20
3	Posterior	21	20
4	Anterior	20	40
4	Posterior	20	40
5	Anterior	*	30
5	Posterior	31	40
6	Anterior	40	40
6	Posterior	40	40
7	Anterior	40	40
7	Posterior	40	40
8	Anterior	40	40
8	Posterior	20	31
9	Anterior	20	20
9	Posterior	20	20
10	Anterior	40	40
10	Posterior	20	40
Average		27.6	33.1
SD		9.9	8.6
% increase	20%		
p value	0.050		

* Data set omitted from analysis secondary to malfunction of the MTS machine during testing of this specimen; SD = standard deviation.

Fig. 3 A photograph shows anchors after the pullout test. Varying amounts of tricalcium phosphate cement can be seen attached to the anchors, indicating failure at the cement-bone interface.

We acknowledge limitations of our study. First is the testing protocol. A ramped cyclic protocol was used in accordance with previously published data [21]. However, this method is not a true fatigue test and is not a true

pullout test. Actual in vivo load experienced by suture anchors after rotator cuff repair is not known. Therefore we chose this protocol to compare our data with data from other in vitro studies in the literature and with results of a previous study by Giori et al. [9], and to further elucidate the role of tricalcium phosphate versus PMMA in suture anchor augmentation. Second, using a Jamshidi needle works well for a primary augmentation as it creates a pilot hole for anchor insertion and seals itself preventing extrusion of cement. Given rotator cuff repairs often are performed arthroscopically, the injection technique used in this study using a Jamshidi needle easily could be adapted for arthroscopy. This method provides potential for bioabsorbability and may be more amenable to arthroscopic application. For a salvage case, however, such as augmentation of a stripped anchor hole, or in cases of revision, a method for pressurization has not been developed that would prevent extrusion of cement. Future testing theoretically could involve injecting cement directly into the void using a syringe with no pressurization, such as in a previous study using PMMA [9]. This might be difficult to perform arthroscopically, however. Alternatively, we could develop a method of sealing the margins of the void allowing the technique to be performed arthroscopically. Third, we used a linear pullout axis in line with the axis of the anchor's insertion. Typically, suture anchors are inserted at a 45° to 90° angle to the direction of loading (so-called dead man's angle). However, we believe the coaxial pullout test shows a worst-case scenario as pullout strength is likely the lowest in this direction. Fourth, this study was performed with only one sort of mechanical testing, which is linear load applied directly through the eyelet of the anchor. Our assumption was that this method most closely replicates physiologic load that would be placed on the construct in vivo. Finally, our experimental design allowed the cement to cure for 24 hours before mechanical testing. This waiting period would not likely transfer to the clinical setting as in a patient the construct would likely be loaded before a 24-hour curing period was completed. The cement, however, reaches 90% of its strength after 10 minutes. Also, the intact trabecular bone is not disrupted by cement injection (Fig. 1), so the assumption was that an augmented anchor was at least as strong as a nonaugmented anchor before completion of curing. A surgeon concerned that an anchor may have inadequate fixation before final curing of the cement could limit the patient's load-bearing by having the patient wear a shoulder immobilizer, as is commonly done. This restriction would not eliminate the load on the construct, but it potentially could reduce it to subfailure levels.

Our data suggest an increase in maximum load to failure of 29% by using bioabsorbable tricalcium phosphate cement to augment suture anchor fixation into bone. Thus,

Table 4. Review of literature analyzing cement augmentation.

Study	Application	Augmentation type	Yield strength			
			Control (N)	Experimental (N)	Percentage increase (%)	p Value
Collinge et al. [3]	4.5 mm cortical screw	PMMA	38 ± 22*	150 ± 34*	295	p < 0.001
		Ca-P	38 ± 22*	142 ± 47*	274	p < 0.001
Elder et al. [7]	Hip screw	Ca-P	1922 ± 479	2369 ± 584	23	p < 0.05
Giori et al. [9]	Suture anchors	PMMA	172 ± 56	294 ± 139	71	p = 0.02
Moore et al. [15]	Hip Screw	PMMA	1477 ± 526	1834 ± 225	27	p < 0.05
		Ca-P	1354 ± 632	1568 ± 320	16	p > 0.05
Moore et al. [16]	Pedicule screws	PMMA	823 [†]	1312 [†]	59	p < 0.02
		Ca-P	823 [†]	842 [†]	2	p < 0.04
Renner et al. [18]	Pedicule screws	PMMA entire length	910 ± 516	2797 ± 796	275	p < 0.025
		Ca-P at screw tip	1032 ± 453	1617 ± 448	78	p < 0.001
		Ca-P entire length	839 ± 514	1852 ± 574	286	p < 0.025
Rohmiller et al. [19]	Pedicule screws	PMMA	663 ± 48	1320 ± 89	99	p = 0.0001
		Ca-S	663 ± 48	1105 ± 70	67	p = 0.0003
Wittenberg et al. [22]	Pedicule screws	PMMA	709 ± 391	1860 ± 1090	162	p < 0.05
		PGF	633 ± 354	1270 ± 423	101	p < 0.05
Current study	Suture anchors	Ca-P	203 ± 94	261 ± 138	29	p = 0.018

Mean ± standard deviation; PMMA = polymethylmethacrylate, Ca-P = calcium phosphate, Ca-S = calcium sulfate, PGF = poly(propylene glycol-fumarate); *numbers are estimations based on graphic presentation as raw data were not reported; [†]numbers are averages of multiple screw types, raw data not reported so standard deviation not calculable.

augmentation with tricalcium phosphate cement increases fixation, although not to the same extent as PMMA [9]. This trend is consistent throughout the literature (Table 4). Augmentation of fixation using tricalcium phosphate cement has been studied for spine surgery applications. Moore et al. [16] used tricalcium phosphate cement or PMMA to augment fixation of failed pedicle screws. They observed an increase in pullout strength of 147% with PMMA and 102% with tricalcium phosphate used to augment fixation. There was no difference between the PMMA and tricalcium phosphate groups statistically. Renner et al. [18] similarly tested pedicle screws augmented with PMMA or tricalcium phosphate in osteoporotic spines. Pedicle screws were tested after injecting tricalcium phosphate or PMMA along the length of a stripped screw hole representing a revision case, and in intact pedicles before screw insertion, representing a primary augmentation case. Testing showed increases in pullout strength for all methods of cement injection, revision, and augmentation. PMMA was associated with higher pullout strengths than tricalcium phosphate. Similarly, Rohmiller et al. [19] reported an increase in pullout strength of pedicle screws augmented with PMMA of 199% over native bone and an increase of 167% if augmented with tricalcium phosphate. The trauma literature also has studies regarding the use of tricalcium phosphate cement to augment screw fixation. Collinge et al. [3] studied tricalcium phosphate and PMMA

in augmentation models using 4.5-mm cortical screws inserted into synthetic osteoporotic bone models. They reported a fourfold increase in pullout strength using either cement, with no difference between the two cements. Moore et al. [15] used PMMA or tricalcium phosphate to augment fixation of standard sliding hip screws into cadaveric human femoral heads. Cutout yield strength and energy to yield increased with both types of augmentation. Elder et al. [7] created three-part unstable intertrochanteric hip fractures in matched pairs of cadaveric human femora. Sliding hip screw and side plate constructs were used to reconstruct the fractures specifically without replacement of the posteromedial (lesser trochanteric) fragment. Tricalcium phosphate cement then was used on the experimental side to augment the screw fixation and fill the posteromedial defect. Augmentation increased the construct stiffness and decreased the sliding hip screw displacement in cyclic loading but did not affect the load to failure. Our observations are similar to those published in the spine and trauma literature, and with results of the previous study by Giori et al. [9] using PMMA (Table 4).

The data presented here also show an increase in fatigue strength of bioabsorbable cement-augmented suture anchors as the number of cycles to failure increased by 20% over the control group after cement augmentation. Giori et al. [9] reported that PMMA also increases fatigue strength, and to a greater degree than tricalcium phosphate,

as the increase after PMMA augmentation was 34% over the control group.

Finally, visual inspection showed that the construct failed at the cement-bone interface, as in the study using PMMA [9]. We noticed varying amounts of tricalcium phosphate cement attached to the suture anchors in the current study. In the study by Giori et al. [9], there were varying amounts of PMMA attached to the suture anchors as well. One difference, however, was that the PMMA seemed to interdigitate into bone better than did the tricalcium phosphate, causing larger chunks of bone to be pulled out with the anchor and cement when PMMA was used. This phenomenon may explain why PMMA augmentation provides larger increases in fixation than does tricalcium phosphate.

Tricalcium phosphate cement can be used to augment suture anchor fixation into bone, reducing the risk of anchor pullout and failure. The data suggest an increase in cycles to failure and maximum load to failure when suture anchor fixation was augmented primarily with tricalcium phosphate cement and compared favorably with PMMA. When relying on suture anchor fixation in bone of questionable quality, augmentation of suture anchor fixation with bioabsorbable cement should be considered. Application of this technique for arthroscopic rotator cuff repair and salvage of stripped anchor holes using tricalcium phosphate cement warrant additional study.

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