A novel, resorbable suture anchor: Pullout strength from the human cadaver greater tuberosity

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The pullout strength of a collagen bone anchor that creates interference fixation as the result of radial swelling on hydration was compared with a Mitek rotator cuff anchor after insertion into the greater tuberosity of human cadaver humeri. Bones were fully hydrated at 37°C. Stiffness, peak load, and the mode of failure were recorded. Real and apparent bone densities were measured. Peak load for the collagen anchor at 15 minutes (121.0N ± 81.3N) was greater than at 2 minutes (60.5N ± 38.5N) after insertion (P < .05). At between 5 and 60 minutes after insertion, peak loads for the Mitek and the collagen anchors did not differ. After 30 minutes from insertion, the mode of failure of the collagen anchor changed from pullout with minor body damage to pullout with major body damage. Peak load at pullout correlated with bone density for the Mitek (P < .05, r = 0.516) but for the collagen bone anchor appeared unaffected by bone density. (J Shoulder Elbow Surg 2001;10:286-91.)

INTRODUCTION

Available techniques of fixing soft tissue to bone include staples, sutures through bone tunnels, and bone anchors for suture. 14,26 Anchors are currently available in metallic or polymeric materials, the latter being either biodegradable or inert. The potential advantages of resorbable bone anchors are lack of interference with imaging investigations, easier revision surgery, 2 and the avoidance of complications associated with metal implants. 30

The collagen bone anchor (CBA) is a new anchor

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composed of high-density type I collagen. The use of resorbable anchors (collagen or polymeric) may have a potential advantage over metallic devices related to imaging artifacts. Its fixation in bone is proposed to occur by hydration and swelling within a bone tunnel. The time elapsed for hydration of the collagen is thought to affect its strength of fixation. This study examined the initial pullout strengths of the CBA and the Mitek rotator cuff anchor and how these varied with bone density (both anchors) and time elapsed after insertion (CBA only). Bone anchors were inserted into the greater tuberosity of the humerus in a human cadaver model that simulated the fixation of sutures in a rotator cuff repair in a saline water bath at 37°C.

MATERIALS AND METHODS

Eighteen fresh-frozen human cadaver humeri (mean age, 73 years; range, 53 to 90) were used. Each consisted of the proximal one third of the humerus. The rotator cuff was removed by sharp dissection, and the cortex of the superior surface of the greater tuberosity was debrided with a high-speed burr. Care was taken to avoid penetration of the cortex. The bone was kept hydrated with a saline drip. Four sites for later placement of the bone anchors were marked on the superior surface of the greater tuberosity with the tip of the high-speed burr. The points were made in a curved line, parallel to and 4 mm from the edge of the humeral head articular surface. The most anterior point was 4 mm posterior to the bicipital groove, and subsequent points were separated from each other by 8 mm. The sites were numbered 1 to 4 in sequence. The specimens were individually wrapped in a cloth soaked in saline and stored at -18°C until use.

The CBA consisted of (1) a hollow, cylindrical collagen body, (2) a polymethylmethacrylate (PMMA) washer, and (3) suture material. The suture passes through the collagen body and loops around the PMMA washer (Figure 1). The collagen bodies used in this study were made of highly purified, fibrillar collagen derived from bovine skin (>95% type I collagen). During manufacture of the anchors, collagen was cross-linked with glutaraldehyde and dried. The collagen body was nominally 3.5 mm in diameter and 10 mm in length. All anchors were sterilized by gamma radiation (2.5 Mrad).

The metal anchors used were standard Mitek Rotator Cuff Anchors, with titanium bodies and two nickel-titanium arcs. CBA devices were loaded with monofilament nylon fishing line of nominal breaking load 18 kg (Berkley Tri-

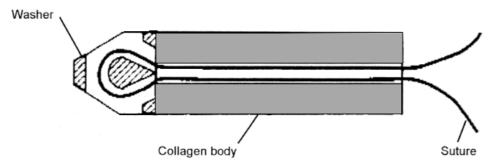


Figure 1 Longitudinal section of collagen bone anchor.

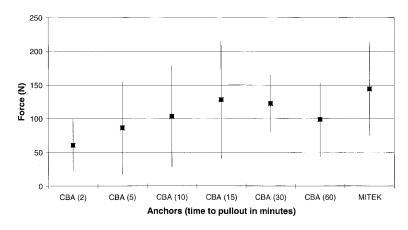


Figure 2 Peak load for each anchor (mean and SD).

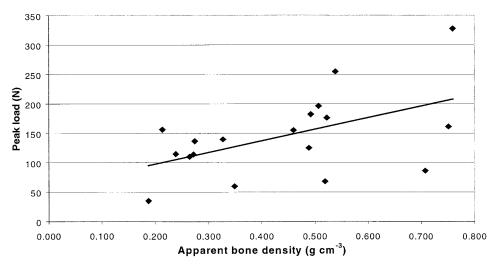


Figure 3 Scatterplot of peak load versus apparent bone density for Mitek anchor (P < .05, r = 0.516, n = 18).

lene; diameter, 0.60 mm) because the narrow aperture of the PMMA washer precluded use of wire. Mitek anchors were loaded with 1×7 strand, braided stainless steel wire of nominal breaking load 27 kg (Mason Tackle Co,

Otisville, Mich; diameter, 0.56 mm). The study design (Table I) allocated 1 Mitek anchor and 3 CBA anchors to each humerus. Groups of 9 CBA devices were assigned different hydration times of 2, 5, 10, 15, 30, or 60 min-

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Table I Study design: Distribution of 72 anchors (54 CBA and 18 Mitek) over 18 humeri each with 4 insertion sites

Humerus	Site 1	Site 2	Site 3	Site 4
1	Mitek	CBA 60	CBA 30	CBA 2
2	CBA 60	CBA 30	CBA 2	Mitek
3	CBA 30	CBA 60	Mitek	CBA 2
4	CBA 2	CBA 5	CBA 60	Mitek
5	Mitek	CBA 2	CBA 5	CBA 60
6	CBA 60	Mitek	CBA 2	CBA 5
7	CBA 5	CBA 10	Mitek	CBA 2
8	CBA 2	CBA 5	CBA 10	Mitek
9	Mitek	CBA 2	CBA 5	CBA 10
10	CBA 10	Mitek	CBA 15	CBA 5
11	CBA 5	CBA 10	Mitek	CBA 15
12	CBA 15	CBA 5	CBA 10	Mitek
13	Mitek	CBA 15	CBA 30	CBA 10
14	CBA 10	Mitek	CBA 15	CBA 30
15	CBA 30	CBA 10	Mitek	CBA 15
16	CBA 15	CBA 30	CBA 60	Mitek
1 <i>7</i>	Mitek	CBA 15	CBA 30	CBA 60
18	CBA 60	Mitek	CBA 15	CBA 30

Numbers after CBA indicate minutes from insertion to pullout testing.

CBA, Collagen bone anchor.

utes between insertion and pullout testing. Eighteen Mitek anchors were tested immediately after insertion.

Humeral samples were thawed overnight and placed in a saline bath at 37°C for 1 hour before anchor implantation. The anchors were inserted into the greater tuberosity at the designated points and the humerus replaced in the saline bath at 37°C for the designated length of time before pullout testing of the anchor. For insertion of the CBA, the cortex was first perforated with a 2.9-mm drill bit and then a 3.2-mm diameter round hole punched with a custom awl. The hole was irrigated with 20 mL of warm saline and the anchor pushed into it by means of a custom insertion device, which buried the top of the anchor 3 mm below the surface of the cortex. The technique of insertion of a Mitek anchor was as described by the manufacturer, with the use of a 2.9-mm drill bit to create a hole of fixed depth, into which a Mitek anchor was inserted with the use of a custom holder. Both types of anchor were inserted as shown in Figure 2.

Samples were tested in a saline bath at 37°C on a servo-hydraulic, mechanical testing machine (MiniBionix 858, MTS Corp, Minneapolis, Minn). The humerus was loaded onto a jig with the long axis of the humerus inclined so that the anchor holes were in line with the axis of the testing machine (Figure 2). The nylon line or wire of the anchor was gripped in serrated pneumatic jaws (62 kPa) with an initial free length of 25 mm and the anchor pulled out at a rate of 50 mm/min. Recordings of instantaneous load and displacement were taken at a frequency of 100 Hz on a personal computer, up to peak load at failure (defined as sudden reduction of load). The mode of failure of each anchor was recorded.

Specimens were maintained in a fully hydrated state for density measurements. Slices of bone approximately 10 mm thick were taken from the greater tuberosity in a plane perpendicular to the axis of insertion of the bone anchors. From these slices, 7-mm-diameter bone cylinders were taken from areas of undamaged bone alongside the anchor holes, with the use of a diamond grit crown drill mounted in a drill press. True and apparent bone densities were estimated by methods described by Sharp et al.²⁷

were estimated by methods described by Sharp et al. 27 Statistical analysis was performed with Statistica (Stat-Soft, Tulsa, Okla) on a Pentium IBM-compatible personal computer. A 2-way analysis of variance of insertion site and time for peak load was performed. The chi-squared test (with Yates correction) was applied to a 2×2 table of body failure mode (no or minimal body damage vs major body damage) for the CBA in two groups (before 30 minutes and 30 to 60 minutes from insertion time). Pearson coefficient of correlation was calculated for peak load with bone density and with age.

An in vitro experiment was performed to determine the swelling of the CBA devices in saline in an unconfined environment. Three sterilized CBA anchors were allowed to hydrate in normal saline at 37°C, and the mass and dimension (diameter and length) were collected at 1, 2, 3, 4, and 7 days after the start of hydration.

RESULTS

The peak loads for the CBA at each time point and the Mitek Rotator Cuff anchor are summarized in Figure 2. The peak load for the 2-minute CBA was significantly lower than that for the 15-minute CBA and the Mitek (P < .05). There were no significant differences in peak loads between the CBAs at any time point after 2 minutes and the Mitek. There was no significant variation of peak load with implantation site in the greater tuberosity.

The modes of failure noted for each of the anchors were as follows: (1) CBA pullout from bone with no or slight body deformation, (2) CBA pullout from bone with major (more than 20% shortening) or complete body deformation, (3) CBA washer breakage with the body remaining within bone, (4) CBA nylon line breakage with the body and washer remaining within bone, (5) Mitek pullout from bone without deformation of its metal arcs, and (6) Mitek pullout from bone with deformation of its metal arcs. The frequencies of the modes of failure are shown in Table II. We observed that the CBAs failed by collapse of the collagen body in one of 9 anchors at 15 minutes, 3 of 9 at 30 minutes, and 5 of 9 at 60 minutes. For statistical analysis, the failure modes for the CBA were grouped into no/slight body damage [including (1), (3), and (4) from above] or major/complete body failure [including (2) only from above]. Cumulative frequencies were taken for two time zones, 15 minutes or less and 30 minutes or more. The change in failure mode to major body damage for the CBA after 30 or more minutes of insertion time was significant (P < .001, chi-squared = 12.15, 1-tailed test).

The real and apparent bone density in the present study were $1.32 \text{ g} \times \text{cm}^{-3}$ (SD, 0.19) and 0.44 g $\times \text{cm}^{-3}$ (SD, 0.18), respectively. For the Mitek Rotator Cuff Anchor, correlation of peak load with bone density was significant (P < .05, r = 0.516, n = 18) and is shown in

Table II Anchor mode of failure

	Mode of failure					
Anchor group	CBA pullout with no or slight body damage	CBA pullout with major or complete body failure	CBA washer breakage	CBA nylon line breakage	Mitek pullout without deformation of arcs	Mitek pullout with deformation of arcs
CBA 2 (n = 9) CBA 5 (n = 9) CBA 10 (n = 9) CBA 15 (n = 9) CBA 30 (n = 9) CBA 60 (n = 9) Mitek (n = 18)	9 8 8 5 3 3	1 3 5	1 1 3 2 1	1	7	11
For statistical analysis CBA 15 min or less CBA 30 min or more Total	No or slight body dam 35 10	nage Major	or complete bod 1 8	y failure		

CBA, Collagen bone anchor.

Figure 3. There was no significant correlation between bone density and peak load for the CBA at any time point (P > .05, n = 9). Bone age and density were not significantly correlated (P > .05, r = 0.1, n = 18).

In vitro hydration experiments on the 3 CBA samples revealed hydration and swelling of the anchors with time. A 51% increase in original diameter was noted after 1 day in saline, which did not increase thereafter. No change in the length of the CBA samples was noted with time in saline (up to 7 days).

DISCUSSION

The CBA has been shown to be effective in securing tendon to bone healing in a sheep model. 18,19 That study used suture anchor-guided repair of the patella tendon to the tibial tuberosity, and the CBA was compared with Mitek rotator cuff anchors. New bone formation onto the surface of the metallic Mitek rotator cuff anchors as well as the CBA anchors was noted at 12 weeks. No pullouts of either anchor design were noted in this study during surgery or subsequent mechanical testing at the time that the animals were killed. Histologically, the CBA anchor remained intact with no sign of inflammatory response, cellular infiltration, or degradation at 12 weeks. Degradation of the CBA anchor in vivo up to 2 years in the sheep proximal tibia model has recently been reported. 19 The study supports the biocompatibility of the CBA device with little cellular infiltration and degradation even after 2 years in vivo.

This study is the first test of CBA performance in a human model. The aim was to describe the effect of hydration time on the axial pullout strength of this anchor. We used a commercially available and previously tested suture anchor (Mitek rotator cuff anchor)^{5,25} as a means of comparing the performance of the CBA with a recognized product. The mean axial peak load achieved by the Mitek rotator cuff anchor in our study was 144N. We found only one previous report of axial suture anchor testing in the human cadaver humerus, in which a metallic screw-type anchor was used (Ogden Anchor by Orthofix Inc, McKinney, Tex).3 This anchor had a mean axial peak load of 172N in the superior surface of the greater tuberosity, adjacent to the articular surface. Axial pullout studies of suture anchors in metaphyseal bone have also been performed on porcine femurs⁴⁻⁶ and on human cadaver tibiae. 10 In the porcine model, the Mitek rotator cuff anchor had a mean peak load of 92-lb force (405N). In the human tibial model, the Mitek G2 anchor had a mean peak load of 82.5N. The G2 and rotator cuff anchors are similar in pattern but differ in body diameter, being 2.4 mm and 2.8 mm, respectively. They have similar performances in bone.⁵ Studies of rotator cuff repair with suture anchors in human cadaver models 11,15,22,24,28 and a dog model²³ have been performed. Testing of tendon-to-bone reconstruction introduces errors caused by tendon quality and difficulty of tendon gripping. This type of model therefore introduces additional variables, and we did not seek to replicate it.

On the basis of age and sex, we were able to compare our specimens with patient groups undergoing rotator cuff surgery. The mean age of our cadaver specimens was 73 years (range, 53 to 90), and the sex ratio was 2.6 to 1 (male to female). In a clinical review of patients undergoing rotator cuff surgery, the mean age was 60 years (range, 32 to 80 years) and the sex ratio was 2.9 to 1 (men to women).20 Other clinical studies report similar parameters for their patient aroups. 13,21 This comparison implies that on the basis of age, our specimens may have had different physical properties than those of the expected candidate for rotator cuff surgery, particularly with respect to osteoporosis. However, we did not find a correlation of bone density with specimen age. Although the peak load for the Mitek anchor did vary with bone density, this variable was not directly related to age in our specimens. Also, the peak load for the CBAs did not vary with bone density. The apparent bone density of our specimens was $0.44~{\rm g}\times{\rm cm}^{-3}$ (SD, 0.18).

The relation between density and bone anchors tested may reflect the way in which the anchors are designed for fixation and the role of the bone. Failure of the Mitek devices occurs as the arcs of the device translate in the cancellous bone bed and capture the cortex. The CBA anchor, on the other hand, does not infiltrate into the cancellous bone but swells in the drill hole, thereby providing a compressive stress for fixation. The pullout of the CBA anchor represents the force required to overcome the developed shear stress caused by swelling, whereas the pullout of the Mitek anchors reflect failing of the bone tissue itself. Volumetric expansion of a material as a fixation method was suggested for a tooth-root implant in 1976¹⁶ and was demonstrated in canine femora by Greenberg and coworkers. 17 The expansion of polymeric devices on swelling during hydration produces compression and interference fixation. The axial alignment of collagen in the HDC restricted swelling to the radial direction with no change in length.

We used anchor points along the full length of the greater tuberosity of the humerus. It was possible that a difference in bone quality from anterior to posterior in the greater tuberosity might influence our results, but, based on analysis of variance, we did not find any variation in peak load with anchor site in the greater tuberosity. It has recently been reported that the pullout strength of a screw-type suture anchor was also unaffected by location (anterior or posterior) in the greater tuberosity of the human humerus.³ The large standard deviations limit the study in part because of a reduction in power that may account for no statistical differences with time in the CBA devices beyond 2 minutes. The study does, however, use human bone in the anatomic location where anchors are commonly used.

Hydration of the CBA is crucial to its proposed function. We took care to ensure that the cadaveric specimens and anchors were kept hydrated. We found that time from CBA insertion to testing affected peak load. Although the peak load values for the CBA did not change significantly from 15 to 60 minutes, the mode of failure did change. There was a significant rise in the proportion of anchors failing by major body damage at 30 minutes and longer. This suggests that the CBA undergoes a structural change after 30 minutes but retains peak load performance.

A comparison may be made between the Mitek Rota-

tor Cuff Anchor and the CBA on the basis of the peak load data. Statistically, the CBA reached the same peak load as the Mitek at 5 minutes of hydration and greater and thus matched the Mitek on peak load performance. This performance was maintained up to 60 minutes of hydration, which was the longest time interval tested in this study. Pullout strengths at longer time points beyond 60 minutes were not examined in the current study, considering that in vitro studies have shown maximum hydration of the CBA anchor occurs within 30 minutes. The pullout strengths at longer time points may be clinically relevant in the early postoperative period to avoid forces that could result in anchor failure.

In a recent study of pullout strength of biodegradable suture anchors in the porcine femur, 6 10 samples of 11 different anchors were tested axially at a pullout rate of 12.5 mm/min at 3 different bony sites, including metaphyseal bone with intact cortex, not dissimilar to the intact greater tuberosity of the humerus in our study. The range of strengths obtained at this site was 13 to 71 lb force (57N to 312N). The greatest strengths were obtained by screw-type designs. It might be expected that our study would show lower values for peak load because of the faster rate of pullout (50 mm/min compared with 12.5 mm/min) caused by the viscoelastic properties of both the bone and anchors. The bone qualities in these two models differ considerably, however, and for these reasons, a direct comparison of results is inappropriate.

Currently available biodegradable suture anchors are constructed of polyglycolic acid, polylactic acid, or a copolymer of the two. The biocompatibility of these materials in general is established. 1 One histologic study of such an anchor (expanding suture plug) in ovine femurs after 12 weeks of implantation failed to show a granulomatous adverse reaction, though resorption of the anchor was implied to be minimal. The Suretak anchor (Smith and Nephew Endoscopy, Andover, Me) has been used arthroscopically in the shoulder. Although one review of its use did not report any adverse reaction,²⁵ that experience has not been universal. Other researchers have reported either a nonspecific synovitis or cystic change around the anchor.¹² In other applications of the above polymers, similar nonspecific adverse reactions have been noted.7-9,29

The collagen bone anchor is a novel suture anchor for bone that is composed of high-density collagen. Its fixation is dependent on hydration and swelling, creating interference fixation within a bone tunnel. It underwent axial pullout testing in the greater tuberosity of human cadaver humeri under physiological conditions of hydration. It achieved a maximum peak load of 121N at 15 minutes after insertion, which was equivalent to the peak load of the Mitek rotator cuff anchor. At 30 minutes or more after insertion, the mode of failure changes significantly. This new anchor offers the

possibility of greater biocompatibility than currently available absorbable suture anchors.

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