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. 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, and the avoidance of complications associated with metal implants.

The collagen bone anchor (CBA) is a new anchor 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 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 (Berkeley Tri...
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-

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).
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

Statistical analysis was performed with Statistica (StatSoft, 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 g × cm–3 (SD, 0.19) and 0.44 g × 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 1: Study design: Distribution of 72 anchors (54 CBA and 18 Mitek) over 18 humeri each with 4 insertion sites

<table>
<thead>
<tr>
<th>Humerus</th>
<th>Site 1</th>
<th>Site 2</th>
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<td>CBA 30</td>
<td>CBA 2</td>
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Numbers after CBA indicate minutes from insertion to pullout testing. 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 92lb 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 groups. 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 g × 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 translate in the cancellous bone bed and capture 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. 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, that experience has not been universal. Other researchers have reported either a nonspecific synovitis or cystic change around the anchor. In other applications of the above polymers, similar nonspecific adverse reactions have been noted.

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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REFERENCES


