Bearing Area: A New Indication for Suture Anchor Pullout Strength?

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ABSTRACT: Studies performed to quantify the pullout strength of suture anchors have not adequately defined the basic device parameters that control monotonic pullout. The bearing area of a suture anchor can be used to understand and predict anchor pullout strength in a soft-bone model. First, conical-shaped test samples were varied in size and shape and tested for pullout in 5, 8, and 10 pcf sawbone models. Next, bearing area and pullout strength relationships developed from the test samples were validated against nine commercially available suture anchors, including the Mitek QuickAnchor and SpiraLok, Opus Magnum, ArthroCare ParaSorb, and Arthrex BioCorkscrew. The samples showed a direct correlation between bearing area and pullout strength. Increased insertion depth was a secondary condition that also increased pullout strength. The pullout strength for the suture anchors followed the predicted trends of conical devices based on their individual bearing areas. For the 5 and 8 pcf models, only two and three devices, respectively, fell outside the predicted pullout strength range by more than a standard deviation. The use of a synthetic sawbone model was validated against the pullout strength of an Arthrex Corkscrew in five fresh-frozen cadaver humeral heads. The bearing area of a suture anchor can be used to predict the pullout strength independent of design in a soft-bone model. This work helps provide a foundation to understand the principles that affect the pullout strength of suture anchors. © 2009 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

Keywords: suture anchors; pullout strength; soft bone; osteoporosis; bearing area

Suture anchors are devices used to reattach a torn tendon to bone and are commonly used at active muscles sites.1 These devices must possess good pullout strength so that rehabilitation can begin shortly after surgery. The pullout strengths of different types of anchors have been compared in a variety of bone models.2–8 These studies have had significant clinical impact, but have not laid a foundation to understand basic design parameters controlling monotonic pullout. In some instances, studies were performed in healthy or hard-bone models in which pullout is not the dominant mode of failure compared to suture breakage, device breakage, or tendon tearing.9 Even when device pullout is the dominant failure mode, no fundamental understanding has emerged as to why some anchors perform better than others.

In recent studies by Barber et al.,4,10 monotonic pull tests were performed on a range of suture anchors in a porcine model. Smaller sized suture anchors like the BioRaptor 2.9 and AxyaLoop/Parafix 3 mm devices mostly failed due to anchor pullout, while larger 5 to 6.5 mm devices like the SpiraLok, BioCorkscrews, and the AxyaLoop/ParaFix failed due to eyelet or suture breakage. Eyelet breakage was associated with polymer-based anchors; suture breakage was associated with titanium anchors. The study did not comprehensively assess pull-out strength, as three modes of failure occurred due to the high bone density of the porcine model.

Other cyclic or time-dependent studies have been performed to gain insight over monotonic pullout tests.11–17 with many focused on pullout strength after a limited number of cyclic loads or on tendon gap formation. Several authors have created unique experi-

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MATERIALS AND METHODS

Materials
An acrylic-based polymer was used to manufacture conical-shaped samples to measure the effects of geometrical design on pullout strength. Size #2 CP Fiber sutures (CP Medical, Portland, OR) were used for the conical samples and the Opus Magnum anchors. Bone blocks (5, 8, and 10 pcf) were chosen as our bone model (Pacific Research Labs, Vashon, WA). Sawbone models provide a consistent test medium and comparable results between specimens. The 5 pcf model simulated cancellous bone with poor bone mass; the 8 and 10 pcf sawbones represented stronger, healthier cancellous bone. The compressive and tensile strengths of the 5 pcf sawbone range between 0.8 and 1.0 MPa, and the compressive and tensile moduli range between 21 and 32 MPa. These values are within the low range of mechanical properties of the glenoid, as measured in eight cadavers with a mean age of 81, and cancellous bone in the distal humerus. These densities were chosen to represent a broad range of cancellous bone properties and to ensure pullout as the primary failure mode during testing. Five fresh-frozen humeral heads (80.8 ± 3.5 years; Science Care, Phoenix, AZ) were used to verify that the sawbones would represent cancellous bone.

Methods
The test anchors were machined to the shape of a conical frustum with a through-hole that allowed a suture to run the length of the anchor and fasten to a button (Fig. 1A). The button (3 mm diameter with four notches machined in the sides to hold up to two sutures) was placed flush against the bottom of the anchor to help distribute pullout forces to the anchor. The through-hole diameter was 1.25 mm, the minimum diameter required to pass four suture strands. The minor diameter matched the common diameters of current anchors: 3.0, 5.0, 6.5 mm. The half apex angle (α) was varied from 5 to 35° in 5° increments. The device length was comparable with those of commercially available devices. The length-diameter ratios for screw-type suture anchors are typically between 2 and 2.5. This yielded lengths of 7.2, 12, and 13 mm for 3, 5, and 6.5 mm devices, respectively. However, due to machining limitations, the 5 and 6.5 mm devices were restricted to 10 mm in length. The major diameter was dependent on the length, minor diameter, and conical angle. Figure 1B shows a projected view of the top surface with the bearing area labeled. Bearing area was the surface area of the device in contact with the bone from a projected view.

Pullout strength was assessed by an Instron testing machine (Fig. 2). First, the anchor was threaded with the suture and securely attached to the button. For tests requiring <100 N of force, only one suture was used; for tests requiring >100 N, two sutures were used. Next, the suture anchor assembly was back-loaded into a 38.1 mm bone cube. The cube was drilled to match the profile of the anchor and to allow the anchor to be flush with the cube’s top surface. For a second set of tests, the anchors were inserted 3.6 mm deeper into the sawbone. The bone blocks were placed in a custom fixture for testing. The suture was then tied using a double half-hitch knot around a dowel pin attached to the machine crosshead. Before testing, the suture was tensioned to 1 N. Testing was performed at 50 mm/min, and all tests were performed in triplicate.

Predicate devices were also tested for pullout strength: Mitek QuickAnchor and 5 mm SpiraLok, Opus Magnum, ArthroCare 3 mm and 5.5 mm ParaSorb, and Arthrex 3.7 mm, 5 mm, 6.5 mm, and 6.5 mm FT BioCorkscrew (Fig. 3). The devices were inserted to match their instructions for use. For all devices, holes were punched in the sawbone blocks. Mitek SpiraLok and Arthrex BioCorkscrew punches were available in their 5 mm sizes and used to ready the tunnel. The 5 mm Arthrex punch was used for the remaining screw devices ≥5 mm. Custom punches were made for the other devices. A 2.7 mm diameter × 20.0 mm long punch was made to ready the 3.7 mm BioCorkscrew, 3 mm ParaSorb, and Magnum tunnel, while a 1.6 mm diameter × 9.5 mm long punch was made to ready the QuickAnchor tunnel. Both punches were cylindrical with a 45° end taper. Attention was paid to attaching the sutures of the screw devices in close proximity to the crosshead to prevent the devices from unscrewing during testing.

The bearing areas were estimated by direct measurement or computer-aided analysis. The bearing area of the QuickAnchor was calculated as the length × width of the barbs, while the bearing area of the Magnum was taken from a CAD model. The bearing areas of the screw devices were estimated from:

\[ \text{Bearing Area} = \text{Revolutions} \times \text{Circum} \times \text{Thread Width} \]  
(1)

\[ \text{Circum} = \pi \times \text{Mean Diameter} \]  
(2)

For example, the 5 mm BioCorkscrew had approximately 2.5 revolutions, a mean diameter of 4 mm, and a thread width of 0.96 mm, thus a bearing area of 30.2 mm². Without CAD models of the screw-type anchors, exact bearing areas cannot be calculated, but only closely approximated.

To verify the appropriateness of sawbones for pullout testing, an Arthrex self-tapping 5 mm Corkscrew was tested for strength in both sawbone and cadaver specimens. In cadaver specimens, the cortical layer of the humeral heads was removed with a burring tool. Strength was measured at seven locations in the head (Fig. 4). The anchors were inserted normal to the surface. A custom fixture was created to ensure pullout was performed along the insertion axis.
RESULTS
The pullout strengths of the conical-based test samples scaled with the size and apex angle of the devices (Fig. 5A). The 3 mm size devices had the lowest strength of 10.1 N at a 5° apex angle and increased as high as 95.3 N at 35°. The 5 and 6.5 mm sample strengths were 23.2 and 30 N at 5° and increased to 174.9 and 185.7 N at 35°, respectively. The strengths for the 5 and 6.5 mm devices at 30° were the same. By comparing the pullout strengths of the devices with respect to bearing area, the three curves of the different sized devices converged to one trend (Fig. 5B) that could be represented by a 2nd order polynomial with coefficients (±SD) of \( K_1 = 1.0283 \pm 0.0314, K_2 = -0.0013682 \pm 0.000139 \).

Pullout strength increased nonlinearly for the 3 mm conical samples as sawbone density increased (Fig. 6). By comparison, a 25° angled device with 67 mm² of bearing area had strengths of 57, 115, and 203 N for the 5, 8, and 10 pcf sawbones. The strengths of the conical devices inserted 3.6 mm deeper into the sawbones are represented by the dotted lines in the figure. The 5, 15, 25, and 35° devices showed consistently higher strengths. With regard to increased sawbone density and increased insertion depth, the increased pullout strength is attributed to an enhanced efficiency to distribute stresses throughout the porous bone microstructure. All of the performance curves were well characterized by 2nd order polynomials. Values are not presented for devices >25° in the 10 pcf model because suture breakage was the primary failure mode.

Figure 7A compares the pullout strength of the commercial suture anchors to the predicted performance curves of Figure 6 in the 5 pcf sawbone model, while Figure 7B compares the devices in the 8 pcf sawbone. The predictions were based on the relationships developed from the conical device data. The lower limit was derived from conical devices flush with the sawbone surface, while the upper limit was derived from conical devices.
and 6.5 mm BioCorkscrew FT. The predicted performances of the 5 mm BioCorkscrew and 5.5 mm BioCorkscrew were within a standard deviation of the experimental pullout strength. The 3.7 mm BioCorkscrew and 3 mm ParaSorb anchors performed slightly better than predicted. A summary of the pullout strengths and bearing areas for the commercial devices is presented in Table 1.

The performance of the Magnum and BioCorkscrew fell within the predicted ranges for the 5 and 8 pcf tests (Fig. 8). However, the predictions underestimated the strength of the BioCorkscrew and slightly overestimated the strength of the Magnum in the 10 pcf model, because secondary effects had a higher role in pullout strength in harder bone models. For instance, the BioCorkscrew threads were inserted deeper than the base of the conical samples. At low densities, insertion depth had less of an effect on strength, and our model predicts the strength of the BioCorkscrew. In the 10 pcf model, the deeply inserted threads likely increased the pullout force past the predicted range based on a smaller nominal insertion depth. The BioCorkscrew strength was consistently higher than the Opus Magnum, but this was simply due to the larger device size (5 vs. 3 mm) and larger corresponding bearing area.

The pullout strength of an anchor in the sawbones was within the range of those in cadaveric bone (Fig. 9). An Arthrex 5 mm Corkscrew showed increasing strength and minimal variation when tested across the three sawbone densities. The average strength in cadaveric bone was divided between the areas of insertion in the humeral head (HH). The distal portion of the greater tuberosity (GTd) had the lowest average strength; however, it was not appreciably different from the lesser (LT) or proximal greater (GTp) tuberosities. The anchors pulled from the HH showed significantly higher strengths than those in the other locations (Table 2). The average strength of the anchor in the 5 pcf model fell within the strengths in the greater and lesser tuberosities, while the strength of the 10 pcf bone was slightly under the variation in the HH.

**DISCUSSION**

Our results demonstrate that bearing area is a critical factor in regards to pullout strength and support our hypothesis that bearing area can predict monotonic pullout strength. A bearing area relationship to pullout strength was developed using conical-shape test samples of different shapes, sizes, and insertion depths (Figs. 5 and 6) and was tested against commercial suture anchors (Fig. 7). In a soft-bone model, the device design (i.e., winged vs. threaded) had little influence on the pullout strength, but rather strength depended primarily on bearing area. By using the fitted trend data from these conical-shaped devices, the pullout strength of devices can be predicted by bearing area, even though the device geometries differ from each other.

Other mechanical and geometrical factors (i.e., insertion depth, angle, and local stress concentrations) play
a secondary role in determining pullout strength. These
data also verify findings that state failure loads are
significantly higher for screw-type anchors with greater
insertion depth. Greater depth increases the anchor’s
ability to distribute stresses throughout the matrix.
However, our data (Fig. 6) illustrate that bearing area is
primary factor in pullout strength as compared to
insertion depth.

Table 1. Pullout Strengths and Bearing Areas of All Devices Tested in Sawbone

<table>
<thead>
<tr>
<th>Sawbone (pcf)</th>
<th>Pullout (N)</th>
<th>Bearing Area (mm²)</th>
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<tbody>
<tr>
<td></td>
<td>Average</td>
<td>SD</td>
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<tr>
<td>Opus</td>
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<tr>
<td>Magnum²</td>
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<tr>
<td>Magnum²</td>
<td>10</td>
<td>57.3</td>
</tr>
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<td>QuickAnchor</td>
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</tr>
<tr>
<td>QuickAnchor</td>
<td>8</td>
<td>6.0</td>
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<td>5 mm SpiraLoK</td>
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<td>60.7</td>
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<td>8</td>
<td>152.2</td>
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<td>ArthroCare</td>
<td>3 mm ParaSorb</td>
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<td>3 mm ParaSorb</td>
<td>8</td>
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<td>5.5 mm ParaSorb</td>
<td>8</td>
<td>155.0</td>
</tr>
<tr>
<td>Arthrex</td>
<td>3.7 mm BioCorkscrew</td>
<td>5</td>
</tr>
<tr>
<td>3.7 mm BioCorkscrew</td>
<td>8</td>
<td>70.8</td>
</tr>
<tr>
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<tr>
<td>6.5 mm BioCorkscrewPT</td>
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<td>159.4</td>
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</table>

We know of only one previous study to predict the
pullout of bone anchors in cancellous bone. Chapman
et al. predicted pullout strengths of screws using a
shear-failure relationship in similar polyurethane
foams. While their results showed good predictability,
the approach only applies to screw devices and not
winged, barbed, or conical-shaped devices, which were
used in our study. Both studies emphasize the need to
examine factors affecting pullout strength in cancellous
bone using a quantitative approach to design and
performance based on fundamental geometrical
parameters.

Figure 8. Pullout of Magnum² and 5 mm BioCorkscrew suture
anchors measured against the predicted pullout strength in 5, 8, and
10 pcf sawbone densities. [Color figure can be viewed in the online
issue, which is available at http://www.interscience.wiley.com.]

Figure 9. Pullout of a 5 mm Corkscrew suture anchor in sawbone
and cadaver bone. [Color figure can be viewed in the online issue,
which is available at http://www.interscience.wiley.com.]
In a recent article on rotator cuff repair in the presence of a loose screw, it was hypothesized that bigger devices will possess higher pullout strengths. However, the results showed that a 5.5 mm fully threaded BioCorkscrew outperformed a regular 6.5 mm BioCorkscrew. While a screw of equal proportion but greater size will possess a higher strength than its smaller counterpart, comparing screws with different thread designs and sizes is difficult. Our results also showed a 6.5 mm BioCorkscrew FT outperformed a 6.5 mm BioCorkscrew because the fully threaded version possessed a higher bearing area than the regular version.

Our study also helps validate the use of synthetic sawbone material as a soft-bone model. Other studies comparing pullout strengths of suture anchors in cadaveric bone showed large variations from sample to sample, where the average standard deviation in pullout strength from cancellous bone was 30.2% of the mean. However, our cadaveric testing had a 39.6% standard deviation, and synthetic material and showed a decrease in variation from 17.6 to 4%. The sawbone density can also influence monotonic pullout strength. Synthetic sawbone demonstrates pullout strengths within the range of cadaver bone and can be used as a soft-bone model for suture anchor pullout.

### Table 2. Pullout Strengths of 5 mm Corkscrew Tested in Sawbone and Cadaver Bone

<table>
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<th></th>
<th>Pullout (N)</th>
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<tbody>
<tr>
<td></td>
<td>Average</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>Sawbone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 pcf</td>
<td>46.3</td>
<td>0.9</td>
<td></td>
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<tr>
<td>8 pcf</td>
<td>113.0</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td>10 pcf</td>
<td>137.6</td>
<td>2.3</td>
<td></td>
</tr>
<tr>
<td>Cadaver</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LT</td>
<td>58.9</td>
<td>30.3</td>
<td></td>
</tr>
<tr>
<td>GTd</td>
<td>44.4</td>
<td>19.6</td>
<td></td>
</tr>
<tr>
<td>GTp</td>
<td>74.2</td>
<td>29.6</td>
<td></td>
</tr>
<tr>
<td>HH</td>
<td>205.2</td>
<td>47.3</td>
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Monotonic pullout strength is a necessary initial measure of a suture anchor’s performance. However, it does not capture the cyclic performance given the complex loading spectrum experienced by the anchor during rehabilitation and post-operative use. Resistance to cyclic pullout can scale with monotonic pullout resistance, but situations exist in which a secondary mechanism (such as screw back-out) can lead to failure modes present only under cyclic loading. In future work, it would be important to understand how bearing area would predict cyclic failure. Cyclic testing in our test setup would be difficult to interpret because neither synthetic nor cadaveric bone are biologically viable and cannot respond to cyclic loading. A further complication is that testing might have to occur over the same time period as an in vivo test.

The limitations of our study should be noted. We did not account for a cortical layer, which will have a significant impact on the pullout strength of these devices. A healthy cortex allows the bone to act as a composite structure, and because of its high density will allow for better stress distribution during pullout. However, our conditions are relevant for surgeons who burr the cortex to create a bleeding-healing response or who have patients with low bone mineral density. Our study did not assess the devices’ performance in a hard-bone model where suture breakage, device breakage, and tendon tearing are more prevalent failure modes. We also assumed uniform density with increased insertion depth, which is often not experienced in vivo and could lead to decreased pullout. This model may not work for extreme geometrical designs. For example, a screw with a very small pitch may have a very high bearing area, but will not perform well because the threads are too close together to effectively engage the trabeculae.

Our intention is not to promote one device over another. Some anchors do not perform well and are not intended for use in soft bone. The Mitek QuickAnchor is not intended for use in soft bone; the barbs of the device are designed to sit under a cortical shelf. We chose it for our study because of its small bearing area.

Lastly, our objective was not to provide clinicians with explicit data to select suture anchors for clinical use, but rather to provide an understanding of the factors that affect pullout strengths in suture anchors. This knowledge can be used by engineers to guide the design of anchors and by clinicians to interpret results in the literature for clinically relevant pullout studies in porcine or cadaveric bone. This study should promote the assessment of pullout strength in a normalized manner. Both biological and mechanical factors influence anchor performance. Many studies have examined the “bio” portion of pullout strength by investigating variables such as bone mineral density. Our study should serve as a counterpart to study mechanical factors while blocking out biological variations by using a consistent test medium.

In conclusion, the pullout strength of suture anchor devices can be predicted in a soft-bone model by using the bearing area of the device. This approach allows for the evaluation of suture anchors independent of anchor design. Other secondary factors such as insertion depth can also influence monotonic pullout strength. Synthetic sawbone demonstrates pullout strengths within the range of cadaver bone and can be used as a soft-bone model for suture anchor pullout.

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