Mechanical Testing of Absorbable Suture Anchors

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Purpose: Absorbable suture anchors offer great advantages but are made of mechanically weak material. The weakest link in the fixation of soft tissue to bone may therefore be the anchor itself. In this study, several commercially available anchors were mechanically tested in vitro. Type of study: Biomechanical bench study. Methods: Twelve absorbable suture anchor models were implanted into an artificial test bone according to the recommended technique. Testing temperature was $37^\circ$C ± $1^\circ$C. The anchors were loaded with an Instron testing machine with the suture material (USP No. 2, Ethibond, Ethicon, Somerville, NJ) in line with the anchor axis, with and without previous abrasion of the suture at the eyelet. Tensile load at failure and failure mode were recorded. To test creep behavior, a permanent load of 100 N was applied to the anchors, and time to failure was recorded. Suture anchor weight and crystallinity were analyzed. Results: Mean failure load on tensile testing using a cross-head speed of 60 mm/min ranged from 124 to 244 N. Failure modes were eyelet failure in 5 cases, suture failure in 6 cases, and anchor pullout in 1 case. In creep testing, eyelet failure occurred in 8 anchor models after a mean duration of 0.5 to 99 hours; 3 anchor models remained intact after 300 hours, and 1 anchor model failed by pullout of the test sample. Crystallinity ranged from 0% (amorphous) to 57.2%; anchor weight ranged from 0.036 to 0.161 g. Mechanical properties did not correlate with crystallinity but with anchor weight. Abrasion of the suture material at the eyelet had little effect on failure load. Conclusions: At $37^\circ$C, structural failure (breaking) of absorbable suture anchors may occur if loaded to the mechanical limit. Absorbable anchors are particularly sensitive to static, long-term loading. Key Words: Absorbable suture anchor—Eyelet—Failure load—Crystallinity.

Suture anchors are usually applied for the fixation of soft tissue to bone. The advantage of absorbable over metallic anchors is that they are absorbed over time; however, this strength is at the expense of mechanical strength of the material. Efforts to improve their performance have focused on the fixation of the anchors in bone.\textsuperscript{1-3} However, when suture anchors are used, the weakest link may be the anchor itself, which may fail structurally by breaking. Also, the suture material may fail at the anchor eyelet, at a bone edge, or at the suture knot.\textsuperscript{4} Possible adverse reactions to absorbable polymer implants,\textsuperscript{5-7} particularly to those with high crystallinity,\textsuperscript{5} suggest that using implants with as little absorbable material as possible, that is small and lightweight anchors are preferable. High crystallinity of the absorbable polymers may be, among other features, a mechanically favorable factor,\textsuperscript{8,9} but crystals may cause inflammatory foreign-body reactions when remaining in the body for a longer period of time. Therefore, the purpose of this study was to assess the structural strength of absorbable suture anchors at different loading conditions at body temperature ($37^\circ$CP, taking into consideration the size (weight) of the implanted suture anchor and its crystal content. Special attention was paid to possible creeping, tested by static loading.

METHODS

We assessed 8 specimens of each of 12 different absorbable anchor models (Table 1, Fig 1). Anchors

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TABLE 1. Specifications of Anchor Models

<table>
<thead>
<tr>
<th>No.</th>
<th>Anchor Model</th>
<th>Manufacturer</th>
<th>Material</th>
<th>Suture (USP No. 2)</th>
<th>Crystallinity (%)</th>
<th>Weight (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Panalok 3.5 mm</td>
<td>Mitek</td>
<td>PLA</td>
<td>1 × Polyester</td>
<td>20.0</td>
<td>0.036</td>
</tr>
<tr>
<td>2</td>
<td>Bio Roc EZ 2.8 mm</td>
<td>Innovative</td>
<td>PLA</td>
<td>1 × Polyester</td>
<td>16.0</td>
<td>0.045</td>
</tr>
<tr>
<td>3</td>
<td>Rotorloc</td>
<td>Acufex</td>
<td>PLLA</td>
<td>2 × Polyester</td>
<td>6.6</td>
<td>0.047</td>
</tr>
<tr>
<td>4</td>
<td>Panalok RC</td>
<td>Arthrex</td>
<td>PLA</td>
<td>1 × Panacryl</td>
<td>20.8</td>
<td>0.05</td>
</tr>
<tr>
<td>5</td>
<td>Bio-FASTak</td>
<td>Linvatec</td>
<td>PLLA</td>
<td>1 × Polyester</td>
<td>44.7</td>
<td>0.06</td>
</tr>
<tr>
<td>6</td>
<td>Bio-Anchor</td>
<td>Biomet Merck</td>
<td>PLDLA</td>
<td>1 × Polyester</td>
<td>1.5</td>
<td>0.065</td>
</tr>
<tr>
<td>7</td>
<td>Bio-Phase</td>
<td>Acufex</td>
<td>PGA</td>
<td>1 × Polyester</td>
<td>51.6</td>
<td>0.072</td>
</tr>
<tr>
<td>8</td>
<td>Tag Wedge 3.7 mm</td>
<td>Innovative</td>
<td>PLA</td>
<td>1 × Polyester</td>
<td>23.7</td>
<td>0.08</td>
</tr>
<tr>
<td>9</td>
<td>BioROC EZ 3.5 mm</td>
<td>Innovasive</td>
<td>PGA</td>
<td>1 × Polyester</td>
<td>57.2</td>
<td>0.108</td>
</tr>
<tr>
<td>10</td>
<td>Tag Rod II 3.7 mm</td>
<td>Acufex</td>
<td>PLLA</td>
<td>1 × Polyester</td>
<td>17.8</td>
<td>0.16</td>
</tr>
<tr>
<td>11</td>
<td>BioStatak</td>
<td>Zimmer</td>
<td>PLA</td>
<td>2 × Polyester</td>
<td>0.0</td>
<td>0.161</td>
</tr>
<tr>
<td>12</td>
<td>BioCorkscrew 5.0 mm</td>
<td>Arthrex</td>
<td>PLDLA</td>
<td>1 × Polyester</td>
<td>1.5</td>
<td>0.065</td>
</tr>
</tbody>
</table>

Abbreviations: PLA, polylactic acid; PLDLA, poly D,L-lactic acid; PLLA, poly L-lactic acid; PGA, polyglycolic acid.

were provided by 7 manufacturers (Acufex Microsurgical, Mansfield, MA; Arthrex, Naples, FL; Biomet Merck GmbH, Oberengstringen, Switzerland; Linvatec, Largo, FL; Mitek Products, Westwood, MA; Zimmer, Warsaw, IN). All anchors are designed for use with USP No. 2 suture material.

Testing Temperature

Because the biomechanical properties of absorbable materials vary with temperature, mechanical testing was carried out in a water-bath (tap water), thermally adjusted to body temperature (37°C ± 1°C).

Mechanical Testing

After all suture material was removed, weight measurements of the dry anchors were performed using a balance with an accuracy of less than 0.001 g. A protocol was designed to test the capability of absorbable suture anchors to hold suture material in bone when the anchors were implanted according to the manufacturer’s instructions into a mechanically favourable environment. Specifically, the anchors were implanted into polyurethane test bone (diameter, 5 cm) with a cortical thickness of 3 mm, filled with polyurethane foam (Synbone AG, Malans, Switzerland). The test bone with implanted anchor was then clamped to a holder in a water bath at 37°C ± 1°C, 5 cm below the water surface. All probes were conditioned to the temperature for 10 minutes before testing. In all tests, the suture material was pulled perpendicularly to the test bone’s surface, in line with the anchor axis.

Tensile tests with a crosshead displacement rate of 60 mm/min were performed using an Instron testing machine (Instron Limited, High Wycombe, UK) onto which the water bath was mounted. Both branches of the suture, 20-cm long each, were attached to the machine’s crosshead by winding them around a steel hook to avoid weakening due to knot tying and loaded in parallel with the same force until failure. A dynamometer with a range of 5 kN was used.

Tensile Testing Using Provided Sutures: In tensile testing, the suture material may be the weakest link. It may break or be cut by the anchor eyelet.
Therefore, 3 anchors of each type were tested with the preassembled suture material. If no sutures were delivered with the anchor, braided polyester USP No. 2 sutures (Ethibond, Ethicon, Somerville, NJ) were used (Table 1).

**Static Loading (Creep):** As absorbable polymers may creep (slow, highly viscous deformation), a static load was applied to 3 anchors of each type, again in a water bath at 37°C ± 1°C. A load of 100 N (Fig 2) was chosen, representing about 50% of the suture material's tensile strength. Time to failure was determined by a stopwatch. In all anchors, braided polyester USP No. 2 sutures were used to focus on the anchor material properties and to omit weakening of absorbable sutures due to degradation over time.

**Abrasion Test With Subsequent Tensile Testing:** Sutures may be damaged by anchor eyelets and vice versa. To assess if knot tying can weaken the anchor eyelet or the suture material, the force applied during tightening a slip knot on wet braided polyester USP No. 2 suture material around a 3mm steel bar was measured using a spring balance. The mean of ten measurements was 9.5 ± 1 N.

Applying a load of 10 N, the entire 20-cm length of sutures were drawn through the eyelets for 25 cycles at a frequency of 0.5 Hz. This high number of cycles was used to amplify possible fraying effects. After 25 cycles, the sutures were loaded with a crosshead speed of 60 mm/min, as described previously.

**Differential Scanning Calorimetry Measurement of Polymer Crystal Content:** A representative part, 9 to 11 mg in weight, of each anchor was cut off and sealed in a sample container of aluminium. Weight was assessed to an accuracy of 0.01 mg. Calorimetric data were assessed using a differential scanning calorimetry (DSC) 220 analyzing module (Seiko Instruments, Neu Isenburg, Germany) and a DSC controller unit with software SSC5300 (Seiko Instruments). The samples were measured from 0°C to 200 to 250°C, with a heating rate of 10°C/min. The maximal temperature was always below the decaying temperature of the sample.

The measurements were performed with a flow of nitrogen (5.0, AGA) of 50 ml/min: cooling was performed using liquid nitrogen. One cycle of heating and cooling was performed for each probe, and each anchor type was analyzed twice using 2 probes.

**Statistical Evaluation**

Differences between anchor models in tensile and static tests were analyzed using analysis of variance (ANOVA) and post hoc Bonferroni comparisons. For static tests, logarithmic transformation was performed. Correlation of the anchor model performances in tensile and creep tests with crystallinity and weight were calculated using Spearman rank correlation.

**RESULTS**

**Weight Measurements**

The weight of dry absorbable suture anchors without suture ranged from 0.036 to 0.161 g. All anchor models evaluated are presented by weight in Table 1.

**Mechanical Testing**

In all but one type of anchor, the fixation of the anchors in the polyurethane test bone was stable and the anchor fixation was not the weakest link, neither in tensile testing nor in static loading. Anchor No. 8 (Tag Wedge) slipped out of the test bone hole in both tensile testing (1 time) and static loading (2 times) because 1 barb bent, even though the anchors appeared stable on insertion.

**Tensile Testing Using Provided Sutures**

Mean load to failure ranged from 124 to 244 N. The mean and lowest load to failure for each anchor model...
are displayed in Table 1. Of the 12 anchor models tested, 5 failed by eyelet cutout, and in 6 specimens, the suture material was the weakest link and broke. One anchor (No. 8) failed once from anchor slipout of the hole, once from suture failure, and once by eyelet cutout (at 120 N, 154 N, and 172 N, respectively). In anchors No. 5 and 12, in which the eyelet consists of a suture loop welded into the anchor body, the suture-eyelet broke.

In ANOVA analysis with Bonferroni post hoc comparison, 2 groups of anchors differed significantly. Anchors Nos. 1, 4, 5, 7, and 8 performed significantly worse than the other anchor models in this experiment ($P < .05$). In Spearman rank correlation, there was no correlation of tensile performance (correlation coefficient, $-0.36, P = .81$) with crystallinity, but a clear positive correlation (coefficient $0.47, P < .001$) with the weight of the anchors.

**Static Loading at 100 N:** Time to failure ranged from 0.1 hour to more than 300 hours (Table 2). Mean time to failure and lowest time to failure are shown in Table 1. Of the 12 anchor models, 8 failed from eyelet failure, 1 anchor (No. 8, Tag Wedge) failed twice from the anchor slipping out of the hole at 3.1 and 2.2 hours, and once from eyelet cutout at 23.8 hours. Of the anchor models, 3 (Nos. 9, 10, and 11) did not fail up to 300 hours, when the experiment was terminated. In anchors Nos. 5 (Bio-Fastak) and 12 (Bio-Corkscrew), the “eyelet” consists of an absorbable suture sling welded into the anchor body. These anchors failed in static loading by pulling out of the suture eyelet from the anchor body. In Fig 3, the anchors are shown after failure of anchor No. 8, the 1 specimen in which the eyelet failed.

For statistical evaluation, logarithmic transformation of the time to failure was performed. In subsequent ANOVA analysis with Bonferroni post hoc comparison, anchors Nos. 2, 3, 4, 6, 9, 10, 11, and 12 performed significantly ($P < .05$) better than No. 1. Anchors Nos. 9, 10, and 11 (all intact after 300 hours) performed significantly better ($P < .05$) than the rest of the anchor models. In Spearman rank correlation, there was no correlation of static performance (correlation coefficient, $0.29; P = .09$) with crystallinity, but a clear positive correlation (correlation coefficient $0.57; P < .0001$) with the weight of the anchors.
Fraying Test With Subsequent Tensile Testing:

In 1 anchor (No. 7), a force of 12 N is required to move the suture through the eyelet of the implanted anchor. After 5 movements, the eyelet was cut through with the suture still intact. After abrasion, anchor No. 3 failed at the eyelet at 208 N. In no other anchor was the eyelet found to be weakened after friction. In 2 anchors (Nos. 2 and 6), the suture material was slightly weakened and failed at 172 N and 167 N, respectively.

Analysis of Polymer Crystallinity: Results from DSC and weight measurements are displayed in Table 2. Crystallinity ranged from 0% to 57.2%. The probes of anchors Nos. 5 and 12 were measured without the embedded suture material; however, some residual fibers may have been contained in the analyzed specimens and may have influenced the results. The results of the 2 measurements per anchor model did not vary more than 4.5% for any anchor model.

DISCUSSION

Little data exist on the structural strength of absorbable suture anchors at 37°C or about the influence of their crystallinity or weight on their strength. The data presented in this study show that structural failure of suture anchors, predominantly at their eyelet, may be of significant relevance in mechanically loaded anchors. Such failures may be underreported, because absorbable anchors are not radiolucent and will probably have suffered degradation up to the moment when anchor failure is clinically manifest and will probably not even be observed at reoperation.

To date, most in vitro studies investigating the pullout strength of absorbable suture anchors were performed at room temperature (20° to 23°C). It is established, however, that the properties of absorbable polymers may differ when higher test temperatures are applied. A decrease of 22% of bending strength when increasing testing temperature of absorbable plates from 22°C to 37°C has been reported. If heated to the glass transition temperature (typically 63°C), their consistency becomes comparable to chewing gum. Thus, mechanical properties of polymeric implants must be tested at application temperature.

The mechanical strength of absorbable polymers is increased by the high crystal content of the polymer. However, crystals in absorbable polymers are suspected to cause inflammatory reactions in soft tissue, in the form of foreign body reactions. This is because they may remain unabsorbed for a much longer time in the body than the amorphous part of the absorbable implant.

A large range of crystal content was found in the 12 suture anchor models, varying from 0% (in No. 12) to 57% (in No. 10), but no correlation of the mechanical performance either between tensile strength or static loading and crystallinity was apparent. It may be concluded that the inferior mechanical properties of low-crystalline materials may have been compensated for by superior anchor design and mechanically stronger polymer compositions. The weight of the anchors had a significant but not decisive influence on the mechanical performance of the anchor (correlation coefficient, 0.47 and 0.57 in tensile and static loading, respectively). It seems desirable to design absorbable implants as small as possible but with sufficient mechanical strength, to create a small drill hole, and to implant as little absorbable material as possible.

The benchmark for the mechanical strength on anchor insertion should be the ultimate failure load of the suture material, which is about 230 N for looped braided polyester suture USP No. 2. Two of the absorbable suture anchors (Nos. 3 and 12) are preloaded with 2 USP No. 2 sutures. Both anchors failed in tensile testing at only slightly higher loads than the breaking strength of a single suture loop. However, 2 other anchors (Nos. 10 and 11) could also be loaded with more than 1 USP No. 2 suture, or with thicker strands. These anchors may also withstand corresponding loading conditions, which were not tested in this study. The results of the mechanical tests show that absorbable suture anchors are particularly sensitive to permanent load, because they creep under static tension. During the first days, this failure mode is not due to degradation, but to a slow, highly viscous flowing, which is highly temperature dependent. Still, it has been reported that the tensile load to failure decreases by 75% after 3 weeks in vivo in anchor No. 8. In 6 of 12 anchors, the initial breaking strength of the suture anchor was lower than the tensile strength of the suture material. In some specimens, the structural strength at 37°C was lower than the reported pullout strength from bone. This may, in part, be due to the different testing temperatures. In further experiments, cyclic loading of absorbable suture anchors may also be of interest.

Moving the suture through the eyelet, and thus abrading the material, did not usually weaken the anchors tested. However, it did weaken anchors in Nos. 3 and 7. The suture was not weakened significantly except in anchors Nos. 2 and 6. We conclude that the soft suture anchor material adapts well to the
suture and allows suture gliding without relevant abrasion. If a suture is only tightened once, abrasion does not appear to be of relevance in any of the specimens except in anchor No. 7, in which the suture is held tight by the anchor. For this anchor, suture knotting with gliding of the suture through the hole is not recommended.

The presented study has the limitation of the small number of specimens per mechanical test investigated (n = 3), due to the variety of tests. Static loading with 100 N is not physiological, but allows us to show the mechanical response to this loading condition. Lower loads would be expected to result in linearly increased time to failure. However, differences in performance and failure mode among the anchor types showed high variations and failure modalities that were mostly unequivocal. Therefore, we believe that it is important to publish these results. In further trials, higher numbers of specimens per test, and pullout resistance from bone at body temperature would be of great interest.

Absorbable suture anchors represent attractive suture fixation implants because there is little risk of mechanical complications, no conflict in case of repeated surgery, and no interference with diagnostic imaging. This study may help surgeons select an appropriate suture anchor, providing adequate mechanical performance with as little implanted material as necessary.

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REFERENCES