

Laboratory and Clinical Validation of RoG Anchors.

William Rhode, PhD

Rhode Orthopedic research Institute

Disclosure: The author did not receive payments or services, either directly or indirectly, from a third party in support of any aspects of this work. The author has not had any financial; relationship, in the thirty six months prior to submission of this work, with any entity in the biomedical arena that could be perceived or have the potential to influence what is written in this work.

Laboratory Validation.

Purpose. FDA510(k) approved shoulder anchors were tested for performance by an independent laboratory to ensure that they performed equivalent to Arthrex and Biomet anchors that are considered to be orthopedic standards. The goal of RoG Sports Medicine is to streamline the supply chain in order to substantially reduce anchor costs while maintaining a level of performance equal to the best in the orthopedic supply business. A case series of 90 consecutive patients that were implanted with these anchors showed no known defect of the anchor/suture combination.

Background. The anchors are made of Zeniva® polyetheretherketone (PEEK) resin from Solvay Advanced Polymers, LLC. Zeniva PEEK is manufactured in compliance with the relevant aspects of ISO 13485 and under the relevant aspects of current Good Manufacturing Practices. Solvay's biomaterial manufacturing processes are carefully validated and enhanced controls provide product traceability. In addition, all materials are tested in an accredited lab that is ISO 17025 compliant (Orchid Design¹).

Zeniva PEEK offers numerous advantages over metals such as titanium for these implantable devices. The material offers many important benefits including biocompatibility, chemical inertness, and a modulus of elasticity that is close to that of bone. It boasts high strength and stiffness and is totally radiolucent enabling the surgeon to clearly see the bone/soft tissue interface on x-rays without the shadows and opacity of titanium.

Methods. Orchid Design performed the laboratory pullout testing on the RoG anchor line that consisted of a 5.5mm rotator cuff anchor, a 2.9mm labral anchor, and a 5.5mm knotless anchor². An MTS Q/Test10 Test Frame with a load cell was used to test pullout strength. The knotless anchors were tested in porcine femur while all other anchors were tested in 5, 10, and 20 pounds per cubic foot (pcf) foam. Only results from the 10 pcf foam are shown here. The 5 and 20 pcf test results were consistent with those of the 10 pcf foam tests. All forces are given in Newtons (N).

Results. Average pullout force for the knotless anchors was consistently higher for the RoG anchors relative to The Biomet Allthread knotless anchor as shown in Figure 1. The initial pullout force was 55N \pm 4.1 for the Biomet anchor versus 67 \pm 7.4N for the RoG anchor where the results are given as the mean \pm σ (standard deviation). The pullout forces were relatively unchanged after cycling the anchors for 1000 cycles (fatigue)

considering the range of values. The force after fatigue was $60.5 \pm 5.6\text{N}$ for the Biomet anchor and $65 \pm 7.4\text{N}$ for the RoG anchor with the error bars indicating there is no statistically significant difference between the two.

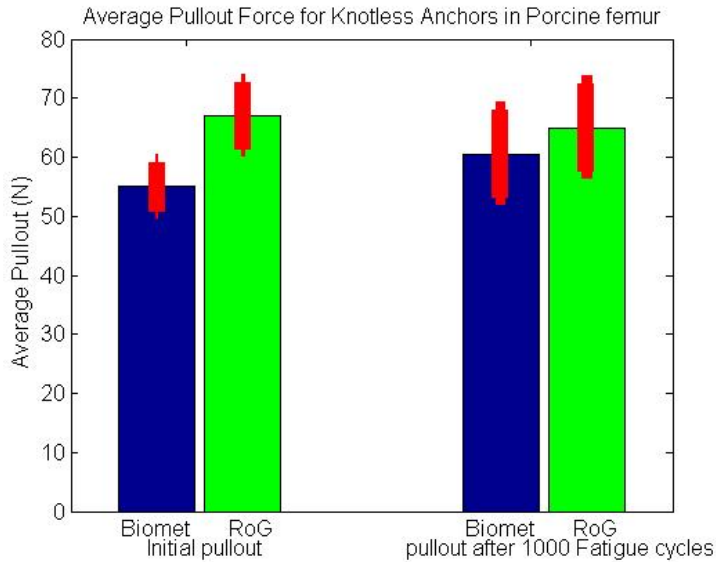


Figure 1. Average pullout force for knotless anchors in porcine femur in Newtons (N). Comparison of Biomet Allrhead Knotless to RoG Knotless Anchors. Both initial pullout force and pullout force after 1000 fatigue cycles are compared. Error bars (red) indicate $\text{mean} \pm \sigma$ (SD=standard deviation).

Initial average pullout force for the 5.5mm anchors in pcf foam was $185.7 \pm 4.2\text{N}$ for the Arthrex Corkscrew FT anchor versus $279.2 \pm 20.8\text{N}$ for the RoG anchors (Figure 2). The

average pullout force after 1000 fatigue cycles was $186.1 \pm 9.1\text{N}$ for the Arthrex anchor and $232.6 \pm 8.1\text{N}$ for the RoG anchor. A significant increase in the pullout strength for the RoG anchor versus the Arthrex anchor was demonstrated.

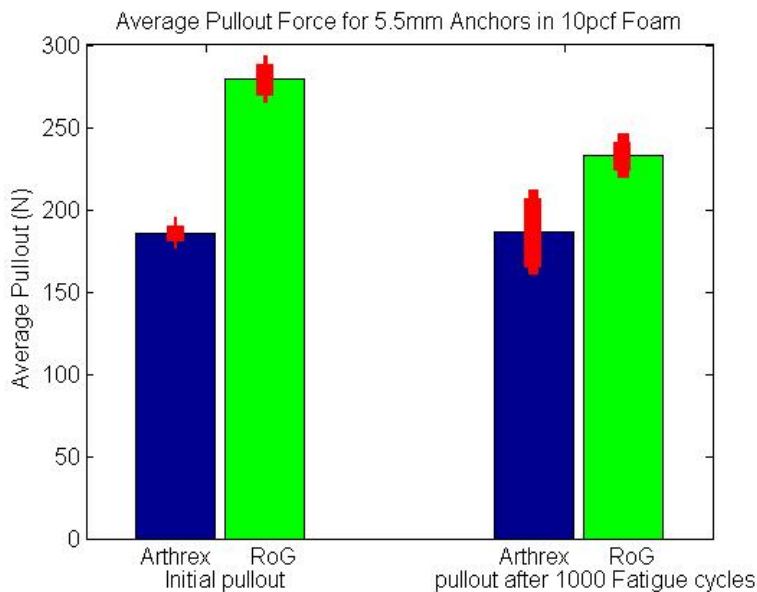


Figure 2. Average pullout force for 5.5mm anchors in pcf foam. Comparison of Arthrex 5.5mm corkscrew FT to RoG 5.5mm Anchors in 10pcf foam. Both initial pullout force and pullout force after 1000 fatigue cycles are compared.

The third anchor is the 2.9mm labral anchor. Again both the initial pullout force and the pullout force after 1000 fatigue cycles was greater for the RoG anchor than the Arthrex 3.0mm SutureTak anchor (Figure 3). The initial pullout forces for the Artrex/RoG anchors were $44.2 \pm 3.8\text{N}$ and $63.4 \pm 4.8\text{N}$ respectively. The pullout forces after the 1000 Fatigue cycles were $50.5 \pm 3.1\text{N}$ and $56.9 \pm 5.4\text{N}$ respectively. Significantly higher pullout forces for the RoG anchors relative to the Arthrex anchors were found.

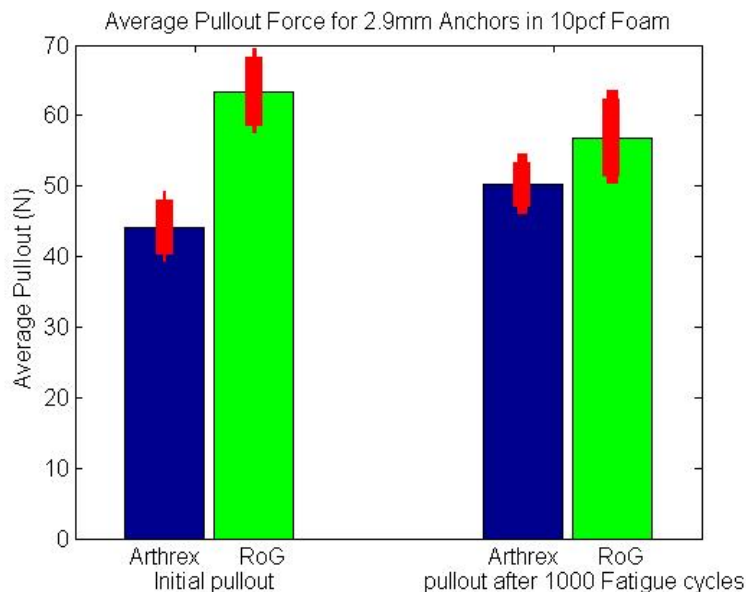


Figure 3. Average pullout force for 2.9mm anchors in pcf foam. Comparison of Arthrex 3.0mm SutureTak anchor to RoG 2.9mm Anchors in 10pcf foam. Both initial pullout force and pullout force after 1000 fatigue cycles are compared.

All tests for the Arthrex/Rog anchors were also performed in 5 and 20 pcf foam. Results were consistent with those found using the 10 pcf foam. Complete results of the tests that were performed are available via the internet³.

Clinical Validation.

Initial clinical experience was assessed with a serial case series of 90 consecutive patients (68 Males, 22 Female) undergoing shoulder arthroscopy for rotator cuff and SLAP repair were included. Average follow up was 7.2 months (0.23 months to 15.9 months). We followed patients at 1 month, 3 months, and 6 months post-operative with range of motion (forward elevation) and strength (supraspinatus isolation) assessment. Rotator cuff tear size was recorded patients were group based upon small ($\leq 3.0 \text{ cm}^2$) and large tear sizes ($>3.0 \text{ cm}^2$).

Materials and Methods.

A series of 90 consecutive patients underwent shoulder arthroscopy with rotator cuff repair (N=68) or SLAP repair (N=18). The average age of the patient was 49 years old (31 to 75 years) with 68 males and 22 females participating in this study. All patients were followed up postoperatively. Number of anchors used and rotator tear size was documented. All patients underwent monthly clinical follow up (N=7.2 months). At the patient's initial postoperative assessment, x-rays were obtained of all patients consisting of an AP and scapular Y view. Postoperative monitoring consisted of an assessment of strength and range of motion. Supraspinatus isolation strength and forward elevation strength assessment were documented at 1 month, 3 months and 6 months post-operative. If the patient's postoperative course was felt to deviate from normal, we proceeded with a postoperative MRI or ultrasound (N=12; N=5 MRI, N=7 ultrasound).

All patients underwent repair utilizing anchor fixation (RoG Sports Medicine 5.5 PEEK rotator cuff anchor (N=115), 5.5 PEEK knotless anchor (N=45), and 2.9 PEEK labral anchor (N=35). All rotator cuff repairs underwent fixation with the 5.5

PEEK rotator cuff anchor with utilization of the 5.5 PEEK knotless anchor when the tear pattern required lateral fixation. SLAP repair was performed utilizing the 2.9 PEEK anchor in standard surgical technique.

Results.

Rotator Cuff Repair Trial.

Sixty-three patients participated in the study (46 male, 17 female). The average age of the patient was 51 (33 to 75). The average follow up was 7 months (0.23 to 15.9 months). Arthroscopic rotator cuff repair was performed utilizing standard techniques. Anchor usage was dictated by tear size and pattern. 102 5.5 PEEK rotator cuff anchors and 43 5.5 PEEK knotless anchors were used in 63 rotator cuff repairs. An average of 1.6 (N=102) 5.5 PEEK rotator cuff anchors were used per repair. 0.68 5.5 PEEK knotless anchors were used per case (N=43).

The average rotator cuff tear size was 2.7 cm² (1 cm² to 10.2 cm²). Rotator cuff tears were grouped into small and large (small ≤ 3.0 cm² (N=51), large >3.0 cm² (N=12)).

Post-Operative Strength.

63 patients were evaluated for supraspinatus isolation strength at 1 month, 3 months, and 6 months post-operative. Average strength at 1 month post-operative was 4.30/5.0. Strength improved at the 3 month follow up to 4.63/5.0. At 6 months post-operative, average strength improved to 4.72/5.0. The subset of small rotator cuff tears (N=51) average strength was: 4.32/5.0 at 1 month, 4.64/5.0 at 3 months, and 4.77/5.0 at 6 months. Large rotator cuff tear (N=12) average strength was: 4.1/5.0 at 1 month, 4.5/5.0 at 3 months and 4.5/5.0 at 6 months.

Post-Operative Motion.

63 patients were evaluated for range of motion to forward elevation at 1 month, 3 months and 6 months post-operative. Average forward elevation at 1 month post-operative was 142.71°. Range of motion improved to 155.27° at 3 months post-operative. At 6 months post-operative, forward elevation range of motion was 161.67°. The subset of small rotator cuff tears (N=51) average range of motion was: 141.53° at 1 month, 153.78° at 3 months, and 161.52° at 6 months. Large rotator cuff tear (N=12) average range of motion was: 148.5° at 1 month, 162.0° at 3 months and 162.2° at 6 months.

Post-Operative Diagnostic Studies.

Diagnostic studies were ordered when they were felt indicated based upon the patient deviating from the normal post-operative course. A total of 11 diagnostic studies were ordered (5 MRI and 6 ultrasound). Of the patient sub-set that deviated from the normal post-operative course, there were 3 rotator cuff failures (27.3%). In the small rotator cuff tear sub-set, there were two rotator cuff re-tears diagnosed (20%). The large rotator cuff sub-set had one diagnostic study that revealed a re-tear. If it is accepted that all patients that did not deviate from a normal post-operative course did not re-tear, the tear recurrence rate in this trial was 6.34%. There was no evidence of anchor pull-out or failure in any patients.

SLAP Repair Trial.

Eighteen patients participated in the study (15 male, 3 female). The average age of the patient was 40 (29 to 55). The average follow up was 7.23 months (0.3 to 15.7 months). Arthroscopic SLAP repair was performed utilizing standard techniques. Anchor usage was dictated by tear. 31 2.9 PEEK labral anchors were used in 18 SLAP repairs. An average of 1.72 (N=31) 2.9 PEEK labral anchors were used per repair.

Post-Operative Strength.

18 patients were evaluated for supraspinatus isolation strength at 1 month, 3 months, and 6 months post-operative. Average strength at 1 month post-operative was 4.65/5.0. Strength improved at the 3 month follow up to 4.78/5.0. At 6 months post-operative, average strength improved to 4.83/5.0.

Post-Operative Motion.

18 patients were evaluated for range of motion to forward elevation at 1 month, 3 months and 6 months post-operative. Average forward elevation at 1 month post-operative was 140.71⁰. Range of motion improved to 158.93⁰ at 3 months post-operative. At 6 months post-operative, forward elevation range of motion was 165.71⁰.

Discussion.

The laboratory validation performed over 28 separate tests repeated 5 times with each demonstrating that RoG anchors will perform at a level that meets or exceeds existing standard anchors. This was demonstrated for the 5.5 PEEK rotator cuff anchor, 5.5 PEEK knotless and 2.9 PEEK labral anchor. Both initial pullout force and pullout force after 1000 fatigue cycles demonstrated superior characteristics of the RoG anchor design over the competitors.

The clinical case series of 90 consecutive patients demonstrated no failure of implant due to anchor pullout or implant construct failure. Out subset of 63 consecutive rotator cuff repairs demonstrated clinical improvement at 1 month, 3 months and 6 months post-operative to evaluation of strength (supraspinatus isolation) and range of motion (forward elevation). Based upon our evaluation, there was a documented re-tear rate of 6.3% (N=3). The patients with small tear sizes ($\leq 3.0 \text{ cm}^2$) performed superior to large tears ($>3.0 \text{ cm}^2$).

The subset of patient that underwent SLAP repair (N=18) also showed similar improvement in strength and range of motion at the 1 month, 3 months and 6 months follow-up. There were no documented failures in this group.

In summary, the RoG anchor design demonstrates laboratory equivalency to the existing competitors (Arthrex and Biomet) as demonstrated by laboratory pullout testing. A clinical consecutive case series of 90 patients with an average follow-up of 7.2 months demonstrated excellent outcomes with no documented failure of the implant of anchor/suture construct. There was a documented failure rate of 6.3% for the rotator cuff series with no failures of the SLAP repair series. RoG anchors offers a clinically equivalent anchor design with significant cost savings over the existing competitors for shoulder surgery.

References.

1. Orchid Design Orthopedic Solutions. 80 Shelton technology center, Shelton, CT 06484.
2. FDA 510(k) Numbers: K110229, K110230 and

Correspondence:

William Rhode, PhD
16450 S. 104th Ave
Orland Park, IL 60467