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Evaluation of eyelet failure in generic PEEK rotator cuff anchors.

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Abstract

Purpose. This study was performed to compare the durability of molded-generic polyetheretherketone (PEEK) anchors designed for rotator cuff repair with commercially available PEEK anchors that have been recently characterized.

Methods. 5.5 mm anchors double loaded with #2 ultrahigh molecular weight polyethylene (UHMWPE) sutures were inserted at approximately a 45° angle into porcine humerus cortical bone. Bones were secured in a vise and the sutures were tied across a metal bar.15 anchors were cycled between 10 and 100 N for 200 cycles at 4 Hz followed by a destructive test at 635mm/min to determine the ultimate failure load. Durability of 23 anchors was tested by cycling the force from 20 to 180 N 10,500 times followed by a destructive test at 635mm/min. Several anchors were further tested for durability with up to 100,000 cycles. Failure was recorded as eyelet breakage, suture breakage, knot slippage, or anchor pullout.

Results. No generic PEEK anchor eyelet ever failed when the force was cycled from 20 to 180 N regardless of the number of cycles. The ultimate failure force averaged 451 N for eyelet breakage was comparable to several recently characterized PEEK anchors. When sutures failed it was at the knot, never at the eyelet.

Conclusions. Neither anchor or eyelet failed with usage. There was no suture wear at the location of the eyelet even for an extremely high number of test cycles. It is likely that rotator cuff tendon repair failure will be in the traditional manner, i.e., the quality of the tissue and/or bone is the limiting rotator cuff property.

Clinical relevance. The durability of generic PEEK anchors ensures that they will not compromise rotator cuff repair in patients and result in reduced cost that increases with the use of increasing numbers of anchors.

Introduction.

Rotator cuff (RC) disease is one of the most frequently treated clinical problems in the U.S. It increases with age resulting in repairs more than doubling from 1996 to 2006 (1). While there is a long history of treatment with a variety of approaches, arthroscopy has become the preferred surgical technique as it is the least invasive and results in faster patient recovery times (2). Rotator cuff tears repaired arthroscopically use anchors loaded with sutures and as such the biomechanical properties of these elements are of great importance. There are currently numerous suture anchor designs varying in composition and suture materials.

Anchors have been shown to break at the eyelet. In a recent study of anchors inserted in fresh porcine humeri, it appeared that the frequency of eyelet breakage is design dependent (3).Various suture/anchor combinations demonstrated that the frequency of eyelet failure is dependent on anchor type but not on whether the insertion is in cancellous or cortical bone (4). Anchor designs have been getting increasingly complex and expensive. To address performance/cost aspects of RC 5.5mm polyetheretherketone (PEEK) anchors a study of molded- generic PEEK anchors that are made of a chemically resistant crystalline thermoplastic material that is not biodegradable, radiolucent and drillable if revision surgery is required. Mechanical testing was performed in porcine cortical bone to focus exclusively on the durability of the anchor eyelets that have been shown to be a frequent site of failure either due to breakage or suture failure due to wear.

Hypothesis.

H0: There is no difference between current branded rotator cuff anchors and molded-generic 5.5mm PEEK anchors as measured by number of cycles to failure, ultimate failure load (UFL) or eyelet failure.

Methods.

10 porcine shoulders were obtained from a wholesale meat market. The humeri were isolated and frozen until use. Parameters employed in prior studies of rotator cuff repair were based on estimates of the maximum force on human supraspinatus tendons to be approximately 300N (5). 180N has been estimated to be 2/3 of the maximum load of a maximum contraction of the rotator cuff (6, 7, 8, 9). The number of times the force was cycled and the rate was chosen to be 3500 cycles at 635mm/min based on the number of cycles that the human shoulder would normally undergo and the rate of motion. Biomechanical studies use measurement/test instruments to perform cyclic tests of the anchors with the force cycled between 10 and 180-N (Newtons) 3500 times or until failure (10). Tests and measurements of the generic anchors were performed with a TestResources 225LB Actuator (Shakopee, MN).

A prior study reported that some polyetheretherketone (PEEK) anchor eyelets were prone to failure while other PEEK anchors had few failures (3). This study focused on the performance of generic 5.5 mm molded PEEK anchors double loaded with ultrahigh molecular weight polyethylene (UHMWPE) #2 sutures. The humerus was held securely in a vise. Anchors were inserted at an approximately 45° angle into cortical bone where anchor pullout is less likely and along with the use of high strength sutures focused the study on potential eyelet failure. Anchor eyelets were oriented perpendicular to the line of suture pull. Sutures were passed over a metal rod that is part of the upper grip of the test instrument and tied with eight square knots. Both sutures of the double loaded anchors were employed in these tests. Failure was recorded as eyelet breakage, knot slippage, suture breakage, or anchor pullout.

The first group of 15 anchors was cycled 200 times from 20 to 180 N at a pull rate of 635mm/min while recording load and position for every cycle similar to the anchor test used by Barber (3). The actual force range was typically 0 to 215 N due to the limited stretch of the

suture and the high pull rate which resulted in overshoot of the set limits. No overshoot occurred if the pull rate was reduced to 100mm/min which was used only as a check.

A second group of 14 anchors was used to study the durability of generic PEEK anchors, a 10 to 180 N force was cycled 3500 times at a rate of 3cycles/s three times (10,500 total cycles) while recording load/position of every twenty-fifth cycle. When the anchor survived the full regimen, an ultimate failure load (UFL) test using a pull rate of 635mm/s was performed. It was initially expected that the UFL after cycling would yield lower values than those obtained without prior cycling resulting from anchor fatigue.

The importance of fatigue testing of anchors has been previously addressed with tests of as many as 50,000 cycles (11, 12). In this study, nine anchors were cycled 20,000 or more times with two anchors cycled 100,000 times without eyelet failure. The UFL test was executed in each instance after fatigue testing.

Results.

UFL test.

The first group average UFL for 15 anchors was 451N, 355 to 556N range with a standard deviation (SD) of 57.5N. Three of the tests ended with suture breakage or the knots slipping. The statistics for the 12 anchors in which the eyelets broke were: UFL = 442N, 355 to 541N range and an SD of 51N.

Durability test (10,600 cycles).

In the second group, fourteen anchors passed the durability test, 10 -180N for 10,500 cycles. Including the initial test of 100 cycles each anchor sustained 10,600 cycles. After the durability test the UFL for eyelet breakage of 14 anchors was 479 N, with a range of 377 to 557N and a SD of 62.7 N. There were five instances of suture breakage at an average UFL of 420 N with a range of 395 to 464 N and a SD of 26.3 N. In two of those instances one suture broke and one knot slipped. All suture breaks occurred at the knot.

Ultimate durability test (18,000 to 100,000 cycles).

Nine of the 23 anchors were further tested with high cycle counts to further demonstrate the durability of the generic PEEK anchors. Four anchors were cycled 20,000 times before UFL tested. Another anchor was cycled at a high rate of > 4 cycles/sec for over 18,000 cycles without stopping before the Test Instruments stepper motor burnt out. After the instrument was repaired, the cycles per test were limited to 5000 cycles and the test repeated until the total desired count was achieved.

Four anchors were cycled for 40000, 50,000, 99,750, and 100,000 respectively. The sutures frayed and then broke at the 99,750th cycle for the one anchor. The sutures were replaced three times to determine the force for eyelet breakage. Sutures broke at 301 and 340N before the eyelet broke at 416N of the UFL test on the third try. Overall the anchor eyelets broke on average at 464 N with a range of 383 to 550 N and a SD of 67.9 N.

Anchor Eyelet Durability Summary

The results shown in Table 1 can be interpreted to mean that there is no degradation of the anchor eyelet with use. With exposure up to 100,000 force cycles, the average UFL is 452.6 N versus 451.4 N for the 200/UFL test. These high cycle counts are beyond those that rotator cuff would be exposed to during healing. If there is a repair failure it would likely result from tendon/bone failure.

Table 1.

Anchor Eyelet Durability Summary

Cycles	Tests	Mean force (N)	SD (N)	Range (N)
200/UFL	15	451.4	57.5	355-556
10,600	14	479	62.7	377-557
20,000	4	423.5	95.8	353-565
40,000 – 100,000	4	484.5	57.9	410-550
Overall (>10,000)	22	452.6	66.8	353-565

Table 1. Mean force to eyelet failure as a function of tests with different number of cycles followed by a UFL test compared to the 'simple' UFL test that was preceded by 200 force cycles. In eight of the tests, the sutures failed before the eyelet implying the eyelet failure force is an underestimate of the actual failure force.

In summary, no generic PEEK anchor eyelet never failed when the force was cycled from 20 to 180 N regardless of the number of cycles. When sutures failed it was always at the knots indicating that the eyelet did not wear/weaken the suture.

Discussion.

These results demonstrate that generic-molded 5.5mm PEEK anchors for rotator cuff tendon repair have excellent properties and should survive any *in vivo* implantation in patients. Several studies of RC cuff repair have concluded that the condition of the tissue and/or the bone is the limiting reason for repair failure (13, 14, 15). The high-cycle test used here far exceeds any exposure that anchors would be exposed to in a patient. In two instances the anchors were cycled more than 50,000 times without any indication of any wear of the eyelet or anchor.

Table 2.

Load to Failure Comparison.

PEEK anchors	Tests	Mean force (N)	SD (N)	Range (N)	Ttest p-value	Ref
Stryker intraline	10	262.8	23.9	207-290	0.0001	a
Healicoil	10	298.7	37.4	244-355	0.0001	b
Quattro X	10	370.6	26.8	323-409	0.0004	b
ReelX	10	384	66	339-501	0.0126	b
Healix	10	404.3	24.4	356-451	0.0231	b
Generic	**15**	**451.4**	**57.5**	**355-556**		
Footprint Ultra	10	453.7	71.2	331-548		
TwinFix PK	10	469.4	48.7	394-563	0.9298	b
Biomet ALLthread	9	476.5	22.2	443-516	0.4240	b
Quattro Link	10	482.3	35.6	442-550	0.2259	a
					0.1443	b
MorpFix	10	605.2	214.3	171-864		
Linvatec Cross FT	10	687.7	46.2	633-786	0.0138	b
					0.0001	b

Table 2. RC 5.5mm anchors tested for force to failure in cortical bone. Force mean, SD and range in Newtons (N). Results are ordered by mean force to eyelet break. Ttest comparing the mean force for the generic anchors to branded anchors for unpaired data calculated using GraphPad Software (16). Ref: a- Table 2 (3). b- Table 2 (4).

The hypothesis that there is no difference in mean force to failure between generic and branded anchors is true for four anchors where the p-value is greater than the typical 0.05 criteria for significance (Biomet, Footprint Ultra, TwinFix PK, Quattro Link). In contrast there are five branded anchors that have significantly lower mean force to failure than the generic anchor based on highly significant p-values. Two anchors have a higher mean force to failure than the generic anchor (Linvatec Cross FT, MorpFix). Note that the MorpFix anchor had a break at 171 N, the lowest value in the table along with a SD of 214 N.

Early studies demonstrated that anchor orientation/design results in suture abrasion/failure (17, 18, 19). All generic anchors were inserted such that there was a minimal tendency to abrade due to angle of the eyelet relative to the pulling force. With the use of this orientation there were no suture failures at the eyelet.

Generic PEEK 5.5mm anchors match or outperform the currently available RC anchors. This opens up the possibility of significant cost savings which increase as the number of anchors increases for large RC tear repairs. This would be especially important as the federal healthcare requirements become enforced.

Limitations.

In the interest to assess eyelet breakage with other modes of failure removed, anchors were placed in cortical bone. This does not represent a truly physiologic situation of placing anchors into cancellous bone at the level of the tuberosity.

Conclusion.

Generic PEEK anchors perform at the highest level required for RC cuff repairs. There is no fatigue issue and it is more than likely that and repair failure will be in the traditional manner, i.e., the quality of the tissue and/or bone are the limiting properties that determine repair failure which is the motivation for those pursuing augmented tissue repairs. There may be as yet a completely new technique that will ensure increased repair success as a result of the rapid expansion of medical knowledge. In the meantime generic RC anchors appear to be more than adequate for most repairs.

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