

Modes of Failure of Knotted and Knotless Suture Anchors in an Arthroscopic Bankart Repair Model With the Capsulolabral Tissues Intact

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Abstract

The purpose of this study was to assess failure modes of knotless and knotted anchors in a Bankart repair model with the capsulolabral soft tissues intact. Previous reports used a model stripped of soft tissues.

In 8 matched pairs of cadaver shoulders, a Bankart lesion was repaired arthroscopically using either 2 Bio-SutureTak anchors (Arthrex, Naples, Florida) or 2 Bioknotless anchors (Mitek, Westwood, Massachusetts).

The shoulders were mounted with the repaired capsulolabral tissues attached to a custom sinusoidal clamp, and were tested in cyclic loading (20–80 N, 100 cycles, 0.5 mm/s) and then load to failure (1.25 mm/s).

Cut-through at the suture–tissue interface (23/32 anchors) was more common than pullout at the anchor–bone interface (9/32) as a mode of failure ($P = .02$). Failure at the suture–tissue interface occurred in 10/16

knotted and 13/16 knotless anchors. Mean (SD) ultimate load of knotted vs knotless anchors was 125.3 (67.4) N and 96.9 (95.1) N, respectively. Mean (SD) stiffness of knotted vs knotless anchors was 20.9 (6.4) N/mm and 19.8 (8.6) N/mm, respectively.

We concluded that both knotted and knotless anchors fail most often at the suture–tissue interface. The tested model with the capsulolabral tissues intact is distinct from previous models, which tested the anchor–bone interface only.

Arthroscopic repair with suture anchors is a standard technique for management of Bankart capsulolabral lesions associated with shoulder instability.¹ Bioabsorbable anchors are common and show good results in comparison with nonabsorbable anchors.² Use of knotless bioabsorbable anchors has become increasingly common since their introduction,³ which was intended to address the time-consuming and technically challenging task of tying knots arthroscopically.⁴ Several case series have shown good outcomes for knotless repairs with respect to dislocation and revision rates^{5,6}; however, some case–control studies have indicated unacceptably high dislocation and revision rates for knotless repairs compared with knotted repairs.⁷

The modes of failure and biomechanical properties of bioabsorbable knotless and knotted anchors may influence clinical outcomes. However, previous reports used a model stripped of soft tissues, testing failure only at the bone–anchor interface or within the anchor itself, and not testing the suture–tissue interface. Zumstein and colleagues⁸ presented cadaveric data in 7 specimens showing more displacement in cyclic loading for knotless vs knotted metal anchors. Leedle and Miller,⁹ comparing a knotless anchor and 2 knotted anchors in 15 cadaveric glenoids, found that the knotless device had the highest load to failure. Barber and colleagues¹⁰ performed a comprehensive cadaveric comparison in 8 specimens of 7 anchors from different vendors with various types of suture (these anchors included both knotless and knotted devices) and concluded that there were no consistent differences in knotless knotted performance in cyclic loading and load to failure that

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Figure. Jig for biomechanical testing loaded with scapula containing Bankart lesion repaired with knotted suture anchors. Custom sinusoidal clamp attaches directly to capsulolabral complex, allowing simultaneous testing of entire bony and soft-tissue repair.

would account for the differential clinical outcomes reported by Cho and colleagues.⁷

The purpose of this study was to assess the modes of failure, ultimate load, and stiffness of knotted suture anchors (Bio-SutureTak; Arthrex, Naples, Florida) and knotless suture anchors (Bioknotless; Mitek, Westwood, Massachusetts) for fixation of simulated Bankart capsulolabral lesions in 8 matched cadaver shoulders. Lesions were created and repaired arthroscopically, and the specimens were tested with the repaired capsulolabrum attached to a custom jig. We hypothesized that both the knotted and knotless anchors would fail at both the suture–tissue and bone–anchor interfaces and would have similar ultimate load and stiffness.

METHODS

Surgical procedures were performed at Orthopaedic Research of Virginia, Richmond, Virginia and biomechanical testing was performed in the Department of Orthopaedic Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania.

Sixteen cadaver shoulders (8 matched pairs) were tested. One shoulder from each pair was assigned randomly to repair by knotted suture anchor, and the contralateral shoulder from the pair was assigned to repair by knotless suture anchor. Shoulders were thawed and mounted on a frame for arthroscopy. On each shoulder, a simulated Bankart capsulolabral lesion was created arthroscopically with a chisel blade in the anteroinferior

quadrant of the labrum. The lesion was then repaired arthroscopically with either 2 Bio-SutureTak anchors or 2 Bioknotless anchors for a total of 32 anchors (16 knotted, 16 knotless). Anchors were placed at the 4-o'clock and 5-o'clock positions in drill holes on the glenoid face adjacent to the rim. For the Bio-SutureTak anchors, the Fiberwire No. 2 (Arthrex, Naples, Florida) sutures were passed through the capsulolabrum and tied with a sliding-locking arthroscopic knot (Weston) with 3 alternating half-hitches on an alternating post.¹¹ For the Bioknotless anchors, the double-loop of suture was passed through the capsulolabrum, captured with the bifid anchor, and driven into drill holes to achieve adequate tension. Once the repair was completed, the shoulders were dissected free of tissues except the capsulolabral structures anchored to the glenoid. Each specimen then was wrapped in subcutaneous fat and skin and frozen. The shoulders subsequently were thawed to room temperature for at least 24 hours before testing.

For testing, the scapula was rigidly fixed with a metal clamp. The free end of the anchored capsulolabral tissue then was grasped in a custom sinusoidal jig, which then was attached to the distracting arm of a material testing machine (Adelaide Testing Machine model TTS-25, Toronto, Canada). The angle of pull was at a 30° angle off a plane parallel to the glenoid face. This angle was chosen to reproduce the angles of forces seen in vivo. The Figure shows the testing jig loaded with a repaired cadaver specimen.

The construct was preloaded to 5 N and underwent cyclic loading from 20 to 80 N for 100 cycles at 0.5 mm/s with a 100-lb load cell. Any specimens that did not fail during the cyclic loading protocol underwent the load-to-failure protocol. Before load to failure, specimens were rested for 30 minutes in the unloaded state. A preload of 5 N was applied, the constructs were loaded to failure at 1.25 mm/s, and a 100-lb load cell was used to monitor the process. Failure was defined as catastrophic failure or formation of a gap of more than 10 mm. Modes of failure, ultimate load, and stiffness were recorded.

Data were analyzed using SPSS Version 14 (SPSS, Inc., Chicago, Illinois). The experiment was designed by power analysis. For the 32 total anchors, the power of the exact binomial test for proportions with an α of 0.05 is 80% for an effect size of 0.25 (50% difference from null-hypothesis failure rate of 0.5). For the 16 matched anchor-pairs (32 anchors, 2 per shoulder pair), the power of the McNemar test (distributed as χ^2) for

Table I. Modes of Failure of Knotless and Knotted Suture Anchors Used to Arthroscopically Repair a Bankart-Type Capsulolabral Lesion in Cadavers With the Soft Tissues Intact

Mode of Failure	Knotted Anchor	Knotless Anchor	Total
Suture–tissue interface	10	13	23
Anchor–bone interface	6	3	9
Total	16	16	32

matched proportions with an α of 0.05 is 82% for an odds ratio (OR) of 7 and a discordant pair rate of 75%. For the 8 matched shoulder pairs, the power of paired t tests with an α of 0.05 is 80% for a large effect size (Cohen $d = 1.2$).

RESULTS

Table I summarizes the modes of failure for all anchors. Cut-through at the suture–tissue interface (23/32 anchors) was more common than pullout at the anchor–bone interface (9/32 anchors) as a mode of failure, according to an exact binomial test ($P = .02$). The failure modes were also analyzed as 16 pairs of matched anchors (32 anchors total, 2 anchors per shoulder, 8 pairs of shoulders). There was no statistically significant difference in the rate of failure by cut-through vs pullout between the knotted and knotless groups, according to the McNemar test for matched proportions ($P = .37$; OR, 4; discordant pairs rate, 0.31). The results did not change with use of a Stuart-Maxwell test accounting for within-shoulder as well as within-cadaver dependency. Table II summarizes the demographic and biomechanical data for matched shoulder pairs. There was no statistically significant difference in ultimate load ($P = .41$) or stiffness ($P = .75$) by paired t tests. Data were consistent with a normal distribution by Kolmogorov-Smirnov tests ($P > .05$), and the results of the comparisons did not change with use of Wilcoxon signed rank tests.

DISCUSSION

The present study assessed the modes of failure, ultimate load, and stiffness of a knotted and knotless suture anchor for fixation of simulated Bankart capsulolabral lesions. The principle advantage of this study is that matched specimens were repaired arthroscopically and tested with the repaired capsulolabrum attached to a custom jig. Previous studies tested open repairs and stripped cadaver shoulders, neglecting the effects of soft-

tissue purchase.⁸⁻¹⁰ In these prior studies, failure at the anchor–bone interface was the primary mode of failure, of necessity due to the model. The principle finding of the present study is that failure occurs at the suture–tissue interface in addition to the anchor–bone interface for both types of devices without differences between the 2 types of anchors.

Bioabsorbable anchors are common and show good results in comparison to nonabsorbable anchors.² Use of knotless anchors for repair of capsulolabral lesions has grown rapidly since their introduction,³ in part because tying consistent knots arthroscopically is time-consuming and technically challenging.⁴ Biomechanical studies of these devices continue, and biomechanical studies may help explain variable clinical outcomes studies.⁵⁻⁷ However, a chief limitation of previous reports is that anchors were tested in glenoid bone stripped of soft tissue, resulting in anchor pullout at the anchor–bone interface as the principle mode of failure. Such a model obscures the effect of soft-tissue purchase, which may be a relevant mode of clinical failure.

Zumstein and colleagues⁸ compared a knotless metal anchor (Mitek Knotless) with a metal knotted anchor (Mitek GII) in 7 unmatched cadaveric glenoids. Modes of failure were balanced between anchor pullout and suture breakage. Specimens were stripped of soft tissue, anchors were placed, sutures were attached to the cross-head of a material testing machine, and specimens were tested in incremental cyclic loading. There was significantly more mean displacement for the knotless anchor (3.8 mm; SD, 1.4 mm) than for the knotted anchor (2.4 mm; SD, 0.5 mm) at 25 cycles at 50 N. However, there was no significant difference in mean ultimate load.

Leedle and Miller⁹ compared a knotless metal anchor (Mitek Knotless) with 2 different knotted metal anchors (Mitek GII, Mitek Panalok 3.5 mm) in 15 unmatched cadaveric glenoids. Specimens were stripped of soft tissue, anchors were placed, sutures were attached to the

Table II. Biomechanical Testing Data for Matched Pairs of Cadaver Shoulders With a Bankart Lesion Created and Repaired Arthroscopically With a Knotless Suture Anchor Construct Versus a Knotted Suture Anchor Construct

Matched Shoulder Pair	Age, y	Sex	Knotless/ Knotted	Ultimate Load, N			Stiffness, N/mm		
				Knotted Anchor	Knotted Anchor	Difference	Knotted Anchor	Knotted Anchor	Difference
1	86	F	L/R	26.8	146.2	-119.4	19.5	22.9	-3.4
2	86	F	R/L	72.1	89.7	-17.6	27.8	32.6	-4.8
3	87	F	L/R	42.7	26.6	16.1	12.9	12.6	0.3
4	68	M	R/L	291.7	198.4	93.3	27.2	19.5	7.7
5	88	F	L/R	84.9	73.4	11.5	27.3	13.0	14.3
6	82	F	R/L	25.7	92.1	-66.4	9.3	22.0	-12.7
7	76	M	R/L	41.7	228.9	-187.2	7.9	20.7	-12.8
8	81	M	L/R	189.8	147.1	42.7	26.1	23.6	2.5
Mean (SD)	81.8 (6.8)	—	—	96.9 (95.1)	125.3 (67.4)	-28.4 (91.4)	19.8 (8.6)	20.9 (6.4)	-1.1 (9.4)
Effect size (d)	—	—	—	—	—	small (0.31)	—	—	small (0.12)

Abbreviations: L, left; R, right.

cross-head of a material testing machine, and specimens were tested in incremental load to failure. Modes of failure were balanced between anchor pullout and suture breakage. Load to failure was significantly higher for the knotless anchor (650 N) than for either knotted anchor. The differences among the anchors also were significant when the subset that failed by anchor pullout and the subset that failed by suture breakage were analyzed separately.

Barber and colleagues¹⁰ performed a comprehensive comparison in 8 cadaveric glenoids of 7 biodegradable anchors from different vendors that included knotless and knotted devices (Bioknotless and Lupine Loop, DePuy-Mitek, Norwood, Massachusetts; BioPushLok, Bio-SutureTak, and BioFasTak, Arthrex, Naples, Florida; BioAnchor, Conmed Linvatec, Largo, Florida; BioRaptor, Smith & Nephew, Andover, Massachusetts). Specimens were stripped of soft tissue, anchors were placed, sutures were attached to the cross-head of a material testing machine, and specimens were tested in cyclic loading and load to failure. Each of the 7 anchors was placed in the rim of each of 8 glenoids, and their relative positions were rotated to control for confounding. Modes of failure were dominated by anchor pullout from bone, with a few instances of suture pullout from anchor. There were no significant differences in load to failure. There was significantly more stiffness in cyclic loading of the Bio-SutureTak than of the Lupine Loop, BioAnchor, Bioknotless, and BioRaptor. Barber and colleagues concluded that there were no consistent differences between knotted and knotless performance that would account for the differential clinical outcomes reported by Cho and colleagues.⁷

Biomechanical studies of sutures in isolation also have been reported. Barber and colleagues^{12,13} published extensive biomechanical analyses of a variety of composite and braided sutures, as well as a variety of anchors (focusing on anchors for rotator cuff repair). Biomechanical studies of anchors for rotator cuff repair with anchors placed in cadaveric humeri have appeared in parallel to the literature on anchors for labral repair in cadaveric glenoids (eg, Barber and colleagues¹⁴).

The limitations of the present study include comparison of 2 specific devices from different vendors without comparison to an open method, and a cadaveric biomechanical design with elderly specimens that shares the limitations of prior biomechanical studies in extrapolating to the clinical setting. However, the main limitation is the small effect sizes observed post hoc relative to the a priori analysis. The present study was powered to detect a large effect size (Cohen d, 1.2 for *t* tests; OR, 7 for McNemar test) with 80% probability assuming a type I error rate (*P* cutoff) of .05. For example, this corresponds to detecting a 50 N difference between knotless and knotted suture anchors, assuming an SD of 30 N for both anchors. The rationale for the a priori power analysis was based on measured standard deviations of anchors

and sutures, which are of roughly the same magnitude as strengths but are relatively wide.⁹ This methodology is also similar to that used by Barber and colleagues,¹⁰ who used *n* = 8 to compare multiple glenoid suture anchors and noted that the study was powered according to estimates obtained in an earlier study.¹⁴

However, the estimated effect sizes and powers in the post hoc analysis were much smaller than in the a priori analysis. Effect sizes were small for all statistics: OR, 4; discordant pairs rate for failure modes, 0.31; Cohen d for ultimate load, 0.31; Cohen d for stiffness, 0.12). Achieved powers were less than 20% for all statistics. As with all previous studies,⁸⁻¹⁰ it is possible to increase statistical power by increasing sample size, but the present study serves the purpose of estimating small effect sizes for all the tested biomechanical parameters. Such small effect sizes cast doubt on clinical significance as well as statistical significance—small mean differences in anchor performance, even if genuine, are unlikely to aid clinical decision-making in the context of large shoulder-to-shoulder variability.

CONCLUSIONS

This study tested both knotted and knotless anchors in the setting of an arthroscopically repaired Bankart lesion with the capsulolabral tissues intact. Both types of anchors failed at the suture–tissue interface as well as at the anchor–bone interface and were not different between the tested parameters.

AUTHORS' DISCLOSURE STATEMENT

Dr. Ranawat wishes to disclose that he has no potential conflicts related to this study; he is a consultant for Mako Surgical and Smith & Nephew and is a stockholder of Conformis, Inc.

Dr. Golish wishes to disclose that he has no potential conflicts related to this study; he is a scientific advisory board member and stockholder of Cytonics Inc.

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Dr. Sekiya wishes to disclose that he is a consultant to and receives royalties from Arthrex and OrthoDynamix; he also is a stockholder of OrthoDynamix.

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REFERENCES

1. Kropf EJ, Tjoumakaris FP, Sekiya JK. Arthroscopic shoulder stabilization: is there ever a need to open? *Arthroscopy*. 2007;23(7):779-784.
2. Tan CK, Guisasaola I, Machani B, et al. Arthroscopic stabilization of the shoulder: a prospective randomized study of absorbable versus nonab-

- sorbable suture anchors. *Arthroscopy*. 2006;22(7):716-720.
3. Thal R. A knotless suture anchor. Design, function, and biomechanical testing. *Am J Sports Med*. 2001;29(5):646-649.
 4. Thal R. Knotless suture anchor: arthroscopic Bankart repair without tying knots. *Clin Orthop*. 2001;(390):42-51.
 5. Thal R, Nofziger M, Bridges M, Kim JJ. Arthroscopic Bankart repair using knotless or Bioknotless suture anchors: 2- to 7-year results. *Arthroscopy*. 2007;23(4):367-375.
 6. Garofalo R, Mocchi A, Moretti B, et al. Arthroscopic treatment of anterior shoulder instability using knotless suture anchors. *Arthroscopy*. 2005;21(11):1283-1289.
 7. Cho NS, Lubis AM, Ha JH, Rhee YG. Clinical results of arthroscopic Bankart repair with knot-tying and knotless suture anchors. *Arthroscopy*. 2006;22(12):1276-1282.
 8. Zumstein M, Jacob HA, Schneeberger AG. In vitro comparison of standard and knotless metal suture anchors. *Arthroscopy*. 2004;20(5):517-520.
 9. Leedle BP, Miller MD. Pullout strength of knotless suture anchors. *Arthroscopy*. 2005;21(1):81-85.
 10. Barber FA, Coons DA, Ruiz-Suarez M. Cyclic load testing and ultimate failure strength of biodegradable glenoid anchors. *Arthroscopy*. 2008;24(2):224-228.
 11. Elkousy HA, Sekiya JK, Stabile KJ, McMahon PJ. A biomechanical comparison of arthroscopic sliding and sliding-locking knots. *Arthroscopy*. 2005;21(2):204-210.
 12. Barber FA, Herbert MA, Coons DA, Boothby MH. Sutures and suture anchors—update 2006. *Arthroscopy*. 2006;22(10):1063.e1-e9.
 13. Barber FA, Herbert MA, Richards DP. Sutures and suture anchors: update 2003. *Arthroscopy*. 2003;19(9):985-990.
 14. Barber FA, Coons DA, Ruiz-Suarez M. Cyclic load testing of biodegradable suture anchors containing 2 high-strength sutures. *Arthroscopy*.

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