HEALIX ADVANCE™ KNOTLESS ANCHOR FIXATION STRENGTH VS. ARTHREX® SWIVELOCK® & PUSHLOCK®

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Introduction
The HEALIX ADVANCE KNOTLESS Anchors are part of the comprehensive HEALIX ADVANCE family of anchors, and provide knotless fixation for rotator cuff and biceps tenodesis repairs.

The HEALIX ADVANCE KNOTLESS Anchor design incorporates the following proven HEALIX ADVANCE Anchor features:

- Independent cortical and cancellous threads to enhance fixation
- Multi-thread design for fast anchor insertion
- Enclosed and protective can’t-miss distal tip to aid in anchor alignment and usability
- Increased driver length to enhance torque strength and prevent anchor breakage

In addition to the design features listed above, the HEALIX ADVANCE KNOTLESS Anchors also include a sliding suture cleat management system for repair tensioning and a sliding #2 ORTHOCORD® High Strength Suture for a stay suture.

Objective
The objective of this study was to evaluate the HEALIX ADVANCE KNOTLESS Anchors in a side-by-side performance test with its major competitors: the Arthrex SwiveLock® and PushLock® anchors. These three anchors are similar in that each locks suture between anchor and bone and their primary failure mode is suture slide.

The formation of a gap between the soft tissue and bone caused by suture slide, may inhibit healing and result in a clinical failure. Therefore, the performance of these anchors was evaluated by measuring the suture fixation strength to 3 mm suture slide (3 mm of gap formation), as well as the ultimate failure load (anchor pullout strength). All anchors were loaded with high strength #2 suture and inserted into biomimetic foam blocks to carry out a repeatable and reproducible anchor performance test.

Materials & Methods

- Using the appropriate awl for each anchor, pilot holes were created in polyurethane foam blocks. The blocks were 10 pcf, laminated with a 3 mm-thick 20 pcf layer to mimic the cortical layer of humeral head bone (Sawbones P/N 1522-633, Pacific Research Labs, Vashon, WA). All pilot holes were filled with saline prior to anchor insertion.

- Anchors were loaded with both ends of one strand of #2 ORTHOCORD Suture, leaving a suture loop coming from one end of the anchor. The anchors were inserted per their respective IFUs, leaving a 30 mm suture loop (15 mm, doubled-over) on which to pull using an Instron mechanical tester.

- Samples were loaded into an Instron mechanical tester and the displacement was zeroed with 2.25 lbf (10 N) of preload on the suture loop. The loops were then pulled at 10 in/min until the first failure (3 mm suture slide in all cases) was observed, then the moving head was stopped.

- The free tails of suture were then tied around the moving head of the Instron, and the test was resumed at 10 in/min until the ultimate failure (anchor pullout in all cases) was observed.

- For each sample, the data recorded (see results section) was the peak force between 0.0-3.0 mm of suture slide, as well as the ultimate failure load.

- Repeat for a total of 10 of each anchor.
The HEALIX ADVANCE KNOTLESS Anchor design has several advantages, including high fixation strength. Comparison of Anchor Fixation Strength data showing statistically significant differences between 4.75 mm PEEK HEALIX ADVANCE KNOTLESS and 4.75 mm PEEK SwiveLock C, Vented (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.002) or 4.5 mm PEEK PushLock (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.000).

Results: BIOCRYL RAPIDE Biocomposite Material and Biocomposite Anchors

Comparison of Anchor Fixation Strength data showing statistically significant differences between 4.75 mm BR HEALIX ADVANCE KNOTLESS and 4.75 mm BioComposite SwiveLock C, Vented (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.000) or 4.5 mm BioComposite PushLock (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.000). Comparison of 5.5 mm PEEK HEALIX ADVANCE KNOTLESS with 5.5 mm Swivelock C, Vented showed that Ultimate Failure Load is significantly higher (p = 0.000) but 3 mm Suture Slide showed no statistically difference between devices (p = 0.157).

Comparison of Anchor Fixation Strength data showing statistically significant differences between 4.75 mm BR HEALIX ADVANCE KNOTLESS and 4.75 mm BioComposite SwiveLock C, Vented (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.000) or 4.5 mm BioComposite PushLock (Ultimate Failure Load, p = 0.000; 3 mm Suture Slide, p = 0.000).

Discussion

These bench testing results indicate that the HEALIX ADVANCE KNOTLESS Anchors have produced better or similar results when compared to the Arthrex SwiveLock and PushLock anchors with respect to load to 3 mm of suture slide as well as ultimate failure load (anchor pullout strength).

The HEALIX ADVANCE KNOTLESS Anchor design has several advantages relative to the Arthrex SwiveLock and PushLock anchors:

1. The proximal cortical threads unique to the HEALIX ADVANCE KNOTLESS Anchors maximize fixation of the suture in the harder and more dense cortical bone layer whereas SwiveLock and PushLock may not provide variable cortical and cancellous bone interaction.

The thread diameter of the HEALIX ADVANCE KNOTLESS Anchors also increases slightly at the proximal end of the anchor by 0.25 mm. For example, the diameter of the 4.75 mm HEALIX ADVANCE KNOTLESS Anchor increases from 4.75 mm to 5.0 mm at the proximal end of the anchor. This “cortical flare” provides additional compression of suture in cortical bone when compared to devices with constant diameters such as SwiveLock and PushLock.

In addition, the HEALIX ADVANCE KNOTLESS Anchor has the same amount of fixation points, 4, on one side of the anchor as the SwiveLock and PushLock anchors have on both sides of the anchor combined, 4.

Reference figure 1 below for images of the proximal geometry for the HEALIX ADVANCE KNOTLESS Anchor, SwiveLock, and PushLock anchors.

Figure 1. HEALIX ADVANCE KNOTLESS, SwiveLock, & PushLock Proximal Anchor Geometry
The difference in the suture slide force profile as a function of distance pulled is observed in mechanical testing. HEALIX ADVANCE KNOTLESS Anchors have a peak suture slide force within the 0-3 mm displacement zone. Conversely, the SwiveLock and PushLock anchors encounter a small peak to break free the distal tip, then a drop in slide force as the distal tip travels up to meet the distal end of the anchor body, and finally another rise in suture slide force during two-sided fixation – but this occurs after 3 mm displacement (see Figure 4).

Conclusion

In bench testing the HEALIX ADVANCE KNOTLESS Anchors showed superior or equivalent load to clinical failure, as defined by the suture slide strength of the system to 3 mm of suture displacement, when compared to the Arthrex SwiveLock and PushLock anchors. In addition, the suture slide failure mode observed during testing is a type of failure where the device component will neither pullout nor detach from the system and becoming free-floating bodies.
References