HEALIX ADVANCE™ KNOTLESS Anchor
Fixation Strength vs. Arthrex® SwiveLock® & PushLock®

Introduction
The HEALIX ADVANCE KNOTLESS Anchors are the latest addition to the already successful 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 maximize 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 maximize torque strength and prevent anchor breakage

In addition to the design features listed above, the HEALIX ADVANCE KNOTLESS Anchors also include a novel 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 slippage.

The formation of a gap between the soft tissue and bone caused by suture slippage, may inhibit healing and result in a clinical failure. Therefore, the performance of these anchors was evaluated by measuring the suture fixation strength to 3mm suture slippage (3mm 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 10pcf, laminated with a 3mm-thick 20pcf 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 30mm suture loop (15mm, 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 (10N) of preload on the suture loop. The loops were then pulled at 10 in/min until the first failure (3mm 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 0.0-3.0mm of suture slide, as well as the ultimate failure load.
• Repeat for a total of 10 of each anchor.
Results:

PEEK Anchors

4.5mm & 4.75mm PEEK Knotless Anchor Fixation Strength

- **Mitek Sports Medicine HEALIX ADVANCE KNOTLESS, 4.75mm**
  - Ultimate Failure Load (lbs): 68
  - 3mm of Suture Slide (lbs): 23

- **Arthrex SwiveLock C, Vented, 4.75mm**
  - Ultimate Failure Load (lbs): 49
  - 3mm of Suture Slide (lbs): 19

- **Arthrex PushLock, 4.5mm**
  - Ultimate Failure Load (lbs): 26
  - 3mm of Suture Slide (lbs): 15

5.5mm PEEK Knotless Anchor Fixation Strength

- **Mitek Sports Medicine HEALIX ADVANCE KNOTLESS, 5.5mm**
  - Ultimate Failure Load (lbs): 73
  - 3mm of Suture Slide (lbs): 23

- **Arthrex SwiveLock C, Vented, 5.5mm**
  - Ultimate Failure Load (lbs): 56
  - 3mm of Suture Slide (lbs): 22

- **Arthrex PushLock, 5.5mm**
  - Ultimate Failure Load (lbs): 36
  - 3mm of Suture Slide (lbs): 12
BIOCRYL® RAPIDE™ Biocomposite Material and Biocomposite Anchors

Results: BIOCRYL® RAPIDE™ Biocomposite Material and Biocomposite anchors

4.5mm & 4.75mm BR/Biocomposite Knotless Anchor Fixation Strength

<table>
<thead>
<tr>
<th>Device/Anchor Type</th>
<th>Ultimate Failure Load (lbs)</th>
<th>3mm of Suture Slide (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitek Sports Medicine HEALIX ADVANCE KNOTLESS, 4.75mm</td>
<td>69</td>
<td>26</td>
</tr>
<tr>
<td>Arthrex SwiveLock C, Vented 4.75mm</td>
<td>54</td>
<td>20</td>
</tr>
<tr>
<td>Arthrex PushLock, 4.5mm</td>
<td>47</td>
<td>20</td>
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</table>

5.5mm BR/Biocomposite Knotless Anchor Fixation Strength

<table>
<thead>
<tr>
<th>Device/Anchor Type</th>
<th>Ultimate Failure Load (lbs)</th>
<th>3mm of Suture Slide (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitek Sports Medicine HEALIX ADVANCE KNOTLESS, 5.5mm</td>
<td>70</td>
<td>24</td>
</tr>
<tr>
<td>Arthrex SwiveLock C, Vented, 5.5mm</td>
<td>71</td>
<td>24</td>
</tr>
</tbody>
</table>
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 3mm 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 do 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 0.25mm. For example, the diameter of the 4.75mm HEALIX ADVANCE KNOTLESS Anchor increases from 4.75mm to 5.0mm 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.
2. The HEALIX ADVANCE KNOTLESS Anchors are 1-piece devices comprised of a threaded anchor body which lock suture between the anchor and bone on one side of the anchor.

The SwiveLock and PushLock anchors utilize a 2-piece design comprised of a threaded [SwiveLock] or ribbed [PushLock] proximal anchor body and a distal eyelet. After insertion, suture is routed along one side of the proximal anchor body, through the distal eyelet, and back along the other side of the anchor body.

Reference *figure 2* for images of fully inserted HEALIX ADVANCE KNOTLESS Anchor, SwiveLock, and PushLock anchors. Reference *figure 3* for images of the distal tip of the three anchors and how suture is interacts with each system.

The SwiveLock and PushLock distal eyelets are not locked or constrained axially against the proximal anchor body when the devices are inserted per the Arthrex directions for use (DFU-0087), in fact there is actually a 2-3mm gap between the anchor body and distal eyelet. Therefore these anchors provide “1-sided fixation” during initial suture slippage, “2-sided fixation” of the suture only occurs after the distal eyelet moves proximally and contacts the anchor body. Once the distal tip comes into contact with the anchor body, only then must the suture slide past both sides of the anchor body in two-sided fixation.

The difference in the suture slippage 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 0-3mm 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 3mm displacement (see *Figure 4*).
In addition, there is a risk that the distal eyelet on SwiveLock and PushLock may migrate away from the anchor body after insertion. This is especially a concern for the self-punching anchor options for PushLock, as it includes a distal eyelet tip made from titanium in order to penetrate bone without the use of an awl. If suture slippage occurs and the distal tip travels up to meet the anchor body, the PushLock-SP titanium tip could be free to migrate around the anchor body and out of the bone, if the bone quality is poor enough to allow this (see Figure 5).
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 3mm 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 mode where there is no risk of device components pulling out of bone or detaching from the system and becoming free-floating bodies as is the case with the 2-piece Arthrex SwiveLock and PushLock anchors.

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References
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All raw data can be found on file at DePuy Synthes Mitek Sports Medicine, Raynham MA.

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