

Isolating Suture Slippage During Cadaveric Testing of Knotless Anchors

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Abstract

We evaluated a testing method designed to isolate and analyze the effectiveness of different suture-retention mechanisms in knotless suture anchors used for rotator cuff repairs.

Six knotless PushLock implants (Arthrex) with a suture-retention mechanism dependent on a press-fit of suture between the anchor's outer diameter and surrounding bone were compared with 6 ReelX STT devices (Stryker) reliant on an intrinsic suture-locking mechanism. Suture slippage beyond minimal clinical failure thresholds, as well as ultimate failure load, were determined with a novel testing fixture that isolated suture slippage.

Suture slippage was isolated from anchor–bone disengagement. Each PushLock exhibited suture slippage of more than 3 mm, and each ReelX exhibited slippage of less than 3 mm. The PushLock implants also exhibited significantly ($P < .05$) more interval and maximum slippage; 5 of these 6 implants failed via complete suture slippage before dynamic testing could be completed. All ReelX devices survived dynamic testing and ultimately failed via suture breakage.

This novel axial load biomechanical testing technique isolated suture slippage in 2 uniquely designed knotless anchors. The press-fit PushLock implant was prone to slippage failure, whereas the ReelX device with its internal suture-locking mechanism exhibited minimal slippage.

Knotless suture anchor fixation techniques continue to evolve as efficient, low-profile options for arthroscopic rotator cuff repair (RCR).^{1,2} Excellent outcomes have been reported for constructs that use knotless fixation laterally, typically in suture bridge-type configurations.²⁻⁴ Early comparative biomechanical and clinical studies have also demonstrated equivalent results for all-knotless versus conventional constructs for arthroscopic RCR.⁵⁻¹⁰ Given the increased use and availability of multiple implant designs, it is important

to supplement our clinical knowledge of these devices with laboratory studies delineating the biomechanical properties of the anchors that are used to help guide appropriate clinical use of the implants in specific patient populations.

Several biomechanical studies have shown suture slippage to be the weak but crucial link in the design of knotless anchors and the most likely mode of in vivo failure.^{11,12} Other studies have demonstrated frequent anchor dislodgement from bone, but these analyses involved use of elderly cadaveric specimens and relatively high-force testing protocols.^{12,13} Because suture-retention force may have exceeded anchor resistance to pullout (imparted by weak cadaveric bone in such biomechanical settings), the focus on suture-retention properties was limited.¹¹ It is thought that, in clinical practice, the majority of patients who undergo RCR tend not to generate the high forces (relative to resistance to bone pullout) used to cause the anchor pullouts observed in biomechanical studies, particularly in the early postoperative setting.¹¹⁻¹⁵ Cadaveric testing, however, often involves use of specimens with diminished bone mineral density (BMD), relative to age, because of the illness and other factors leading to death and donation.

Using a novel testing apparatus, we isolated, analyzed, and compared suture slippage in 2 anchor designs, one with entirely press-fit suture clamping and the other reliant on an intrinsic suture-locking mechanism.

Materials and Methods

Six human cadaveric proximal humeri specimens were used for this biomechanical study. Mean (SD) age was 53.3 (5.7) years (range, 46-59 years). Middle-aged specimens were used in order to best represent the quality of bone typically encountered in RCR surgery. To approximate tissue in clinical use, we used fresh-frozen cadaver tissue. Specimens were maintained at -20°C until about 24 hours before use and then were thawed to room temperature for testing. Specimens were included only if they had a completely intact humeral head and no prior surgery or hardware placement. Before instrumentation, dual-energy x-ray absorptiometry with a QDR-1000 scanner (Hologic) was used to determine BMD of all proximal humeri.

Two knotless suture anchors were compared: PushLock

Authors' Disclosure Statement: Stryker Research Division donated devices and specimens used in this study.

(4.5×18.5 mm; Arthrex) and ReelX STT (5.5×19.4 mm; Stryker). These anchors have multiple surgical indications (including RCR), allow patient-specific tissue tensioning, and use polyetheretherketone eyelets. The clamping force for PushLock depends entirely on the interference fit achieved for the suture between the outside of the anchor and the surrounding trabecular/cortical bone after device insertion, whereas the suture in ReelX is secured within the anchor shaft entirely by an internal ratchet-locking mechanism.

For anchor insertion, shoulders were dissected down to the greater tuberosity of the proximal humerus, and all implants were inserted (by a fellowship-trained surgeon in accordance with manufacturer guidelines) at a 25° insertion angle with manufacturer-supplied instruments. One anchor of each type (Figure 1) was inserted into the center of the rotator cuff footprint on the greater tuberosity of each specimen. Anterior and posterior positions were randomized, and an anchor from the other group was inserted into the matching location on the contralateral matched-pair specimen. In all instances, distance between the anterior and posterior anchors was 2 cm, and anchors were placed midway between the articular margin and the lateral edge of the greater tuberosity (Figure 2). Two strands of size 2 ultrahigh-molecular-weight-polyethylene Force Fiber (Stryker) were loaded into all anchors.

A custom urethane fixture was secured over the center of each anchor to allow testing to focus on suture slippage by minimizing anchor migration (Figure 3). The small aperture of this device allowed suture tails to pass freely through the center of the fixture but prevented disengagement and proximal migration of the suture anchor from the underlying bone through contact of the urethane fixture with the anchor perimeter. Any system deformation observed during testing was restricted to the suture and/or the anchor's suture-locking mechanism. Testing fixtures also oriented the suture anchor coaxial with the axis of tension, creating a worst-case loading scenario (Figure 3).

PushLock implants were inserted with 5 pounds of tension, as indicated, using a manufacturer-supplied suture tensioner, and ReelX devices were inserted and locked with 2 full rotations, as specified by the manufacturer. After one end of each suture was cut, as would be done in vivo, the 2 other suture ends, which would have been part of the RCR in vivo, were tied together to form an 8-cm circumference loop that was brought through the urethane fixture. Humeri were then mounted in a materials testing system (MTS 810; MTS Systems) servohydraulic load frame, and the suture loop was passed around a cross-bar on the actuator of the testing device. A mechanical testing protocol consisting of modest

repetitive forces was carefully chosen to simulate expected activity during rehabilitation after RCR.¹⁵ In this protocol, a 60-second preload of 10 N was followed by tensile loading between 10 N and 90 N at a frequency of 0.5 Hz for 500 cycles.¹⁵ Cycle duration at 3 mm and 5 mm of suture slippage (threshold for clinical failure) was recorded.^{12,16,17} In addition, suture slippage was measured after 1, 10, 50, 100, 200, 300, 400, and 500 cycles. The first 5 test cycles were not counted in the analysis to control for initial knot slippage. Finally, after completion of dynamic testing, samples were loaded at a displacement rate of 0.5 mm/s for tension-to-failure testing in the custom fixtures. Maximum failure load, stiffness, and failure mode were recorded. Ultimate failure was defined as suture breakage or gross suture slippage.

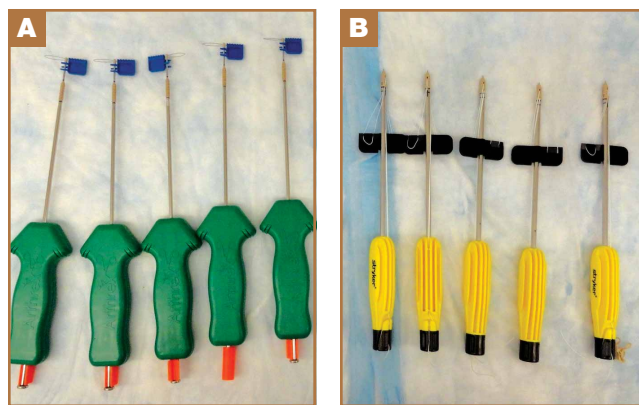


Figure 1. (A) PushLock implant (polyetheretherketone, 4.5×18.5 mm; Arthrex) and (B) ReelX STT device (polyetheretherketone, 5.5×19.4 mm; Stryker).

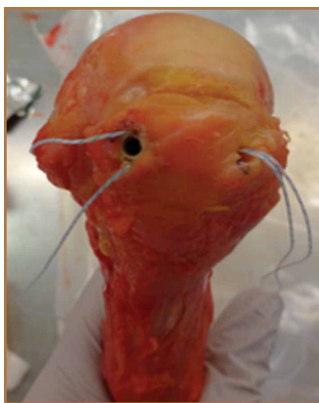


Figure 2. Anchors were inserted into rotator cuff footprint on greater tuberosity of each cadaveric specimen, per manufacturer protocol. Anterior and posterior positions were randomized, and placement was midway between articular margin and lateral edge of greater tuberosity, with 2 cm between anterior and posterior positions.

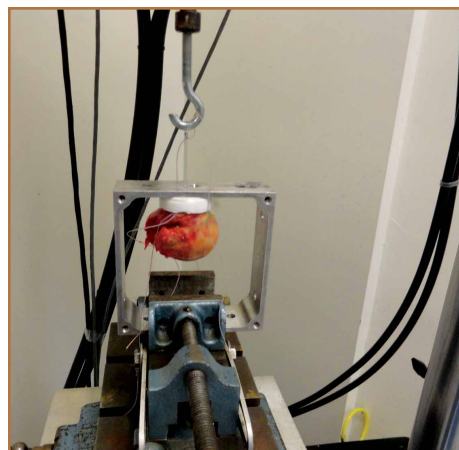


Figure 3. Custom cannulated urethane fixture was secured over center of each anchor to isolate suture slippage by preventing anchor migration. Testing fixture also oriented suture anchor coaxial with axis of tension, creating worst-case loading scenario. Two strands of size 2 ultrahigh-molecular-weight-polyethylene Force Fiber (Stryker) were loaded into all anchors.

Paired Student t test was used to determine significant differences in suture slippage distance between the 2 groups at various cycle durations. In addition, Kaplan-Meier survival test was used to determine statistical differences in sample survival during the dynamic loading test.

Results

Mean (SD) BMD of the cadaveric shoulder specimens was 0.55 (0.13) g/cm² (range, 0.29-0.68 g/cm²). The testing fixtures isolated suture slippage from anchor–bone disengagement. All 6 PushLock implants demonstrated slippage of more than 3 mm, and 5 of the 6 demonstrated slippage of more than 5 mm. All 6 ReelX devices exhibited slippage of less than 3 mm. In addition, PushLock demonstrated more suture slippage at cycles 1, 10, and 100 (*P* < .05) and more maximum slippage after 500 cycles (mean, 11.2 mm; SD, 4.7 mm) compared with ReelX (mean, 1.9 mm; SD, 0.5 mm) (*P* = .004). **Figure 4** shows mean suture slippage at each cycle.

Kaplan-Meier analysis revealed significantly ($\lambda^2 = 8.170$; *P* = .0043) decreased survival after dynamic testing for PushLock versus ReelX (**Figure 5**). Survival was defined as suture slippage of less than 5 mm after completion of dynamic testing. Only 1 of the 6 PushLock anchors completed dynamic testing; the other 5 failed via complete suture slippage from the anchor before testing could be completed. All 6 ReelX devices survived dynamic testing.

Therefore, 1 PushLock implant and all 6 ReelX devices were available for subsequent load-to-failure testing. Failure in this setting was defined as suture slippage of more than 10 mm or suture breakage. The PushLock implant failed at a maximum force of 171.8 N with a stiffness of 74.4 N/mm and eventually exhibited gross suture slippage. All 6 ReelX devices failed at a mean (SD) maximum of 273.5 (20.2) N, with a mean (SD) stiffness of 74.1 (17) N/mm. Mechanism of failure for all ReelX devices was suture breakage during the tensile load-to-failure test.

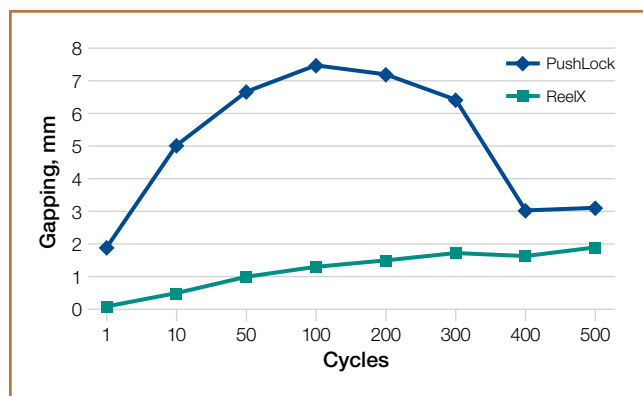


Figure 4. Mean results of suture-slippage testing. PushLock implants exhibited significantly more slippage at first recorded cycle (*P* = .031) and larger maximum slippage value (*P* = .004) compared with ReelX STT devices. Gapping was decreased for PushLock implants with increased cycles because several anchors failed before testing could be completed.

Discussion

We evaluated a new technique designed to isolate suture slippage in knotless anchors used for RCR. The impetus for developing this new method was to provide a means for better analyzing the ability of a knotless anchor to resist suture slippage in the cadaveric biomechanical testing setting. Suture slippage is an important mode of failure during such analyses.^{11,12} Significant slippage occurred in a range of implants before half the anchor–bone pullout strength was reached in a study using young bovine femoral heads.¹¹ In another study, using young, high-BMD cadaveric humeral heads, initial slippage and maximum failure loads were equivalent among numerous devices using various suture-retention mechanisms, and suture slippage was the most common failure mode.¹² Nevertheless, other biomechanical studies have demonstrated frequent failure caused by anchor pullout in elderly human cadaveric specimens with diminished BMD, often with high-force testing protocols.^{12,13} In the more modest-force, in vivo rehabilitative environment, suture slippage rather than anchor dislodgement may be the main failure mode.¹¹⁻¹⁵

We compared the PushLock implant and its entirely press-fit suture clamping design with the ReelX device, which relies on an intrinsic suture-locking mechanism. Middle-aged (mean, 53.3 years; SD, 5.7 years) cadaveric humeri were tested under physiologically relevant biomechanical conditions to begin to help identify how relatively osteopenic bone may affect suture-retention properties for a given implant. The results showed that the study methodology prevented implant failure via anchor–bone pullout. To our knowledge, this was the first study to exclusively analyze suture slippage in knotless anchors. The findings indicated that implants that rely heavily on a tight interference fit of the suture between the anchor and the surrounding bone may exhibit early slippage and failure after RCR in middle-aged patients with relative osteopenia.^{11,12} However, this study also demonstrated that devices with intrinsic clamping mechanisms that do not depend on the quality of surrounding bone may better resist suture

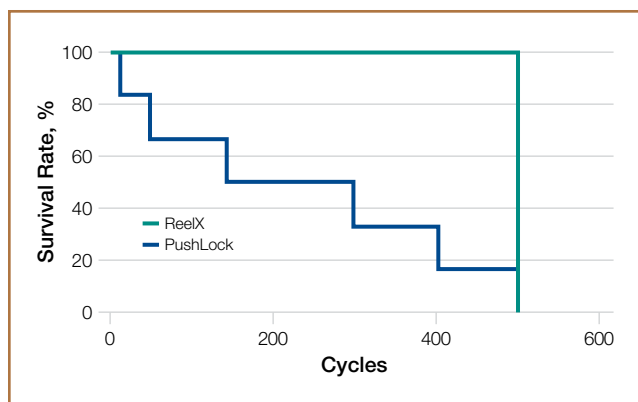


Figure 5. Kaplan-Meier analysis revealed significant difference ($\lambda^2 = 8.170$; *P* = .0043) in survival rate of dynamic testing between PushLock implants and ReelX STT devices.

slippage. It is not clear that all knotless anchors with intrinsic locking mechanisms function equivalently. For instance, Pietschmann and colleagues¹² found that 2 of 10 implants with a different internal clamping device were unable to resist failure via suture slippage, even in healthy bone. Similarly, in a study comparing ReelX devices with implants having a different internal suture-retention mechanism, ReelX failed at higher ultimate loads, and typically via anchor dislodgement, versus suture slippage in the other implants.¹⁸

It is important to note that, in the present study, the loads at which sutures broke in the intrinsic clamping anchors approached the maximum contractile force of the supraspinatus muscle (302 N).^{19,20} In addition, these loads were above the resistance of the rotator cuff tendon to cut out with modern suture material.²¹

This study's limitations include use of an in vitro human cadaveric model that precluded analysis of the effects of post-operative healing. Biomechanical testing was also performed in a single row-type suture configuration with the rotator cuff tendon removed. Fixtures used during testing oriented the load coaxially with the axis of tension, creating a worst-case loading scenario. Although this form of testing may limit its clinical applicability, its purpose was to critically isolate how well a knotless anchor could resist suture slippage. The methods we used were also limited because the stability of the bone–anchor interface was not assessed. For patients with osteopenia, anchor pullout rather than suture slippage could be the most limiting factor for knotless anchor construct failure, and therefore further testing of both failure modes is needed. Future biomechanical studies should compare various knotless anchors' suture-slippage characteristics in other constructs in physiologic testing orientations, including double-row and suture-bridge configurations, as well as with intact rotator cuff tendons. In addition, use of labral tape as a substitute for polyblend suture has been suggested to limit suture slippage, and this technique theoretically could have changed the results of this study.²²

Conclusion

An implant with an internal ratcheting mechanism for suture retention demonstrated significantly less suture slippage in an axial tension evaluation protocol than a device reliant on interference fit of the suture between the anchor and surrounding bone. In the clinical setting, this may allow for less gap formation during the healing phase following RCR with a knotless anchor. There was also increased maximum load to failure, demonstrating an increased load until catastrophic failure using a device with a ratcheting internal locking mechanism.

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