BIOMECHANICAL PULLOUT STRENGTH & CYCLIC TESTING OF THE SURELOCK™ ALL-SUTURE ANCHORS

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OBJECTIVE:

The purpose of this study is to compare the ultimate pullout strength and cyclic displacement of the SureLock All-Suture Anchors to competitive all-suture anchors in a consistent and acceptable bone block model. We specifically used cyclic testing parameters from Barber et al[1]. Both soft and hard bone blocks were used to simulate a range of surgical indications. The SureLock Anchors and the competitive anchors were all tested within the same parameters to provide a direct comparison.

CLINICAL BACKGROUND:

Traditional soft tissue fixation techniques involve solid anchor fixation loaded with non-absorbable suture. While traditional anchors have provided desired clinical results, they do have their downfalls. Concerns over bone loss, the ability to utilize magnetic resonance imaging post-operatively, and articular damage if pullout occurs have led to the development of "all-suture" anchors. New, all-suture anchors minimize these concerns by providing a smaller, soft construct that reduces bone loss, virtually eliminates articular damage, and allows for multiple anchor fixation with a smaller diameter.

Competitive all-suture anchors on the market rely on a manual "tugging" on the sutures to deploy and engage the anchor in or below the subchondral bone. This has led to concerns about reliability and consistency of deployment, with the threat of occasional pullout of the entire anchor during or after deployment. The Cayenne SureLock inserter design addresses these concerns with a reliable technique that relies on the inserter knob to tension and consistently deploy the anchor. As such, the sutures do not need to be manually "tugged" to deploy the suture anchor.

METHODS & MATERIALS:

The parameters in this protocol were modeled after those found in Barber et al[1,2]. This was done to facilitate comparisons of the Cayenne Medical all-suture anchors to other all-suture anchors using the same testing method.

The SureLock All-Suture anchor is entirely composed of Ultra High Molecular Weight Polyethylene Suture (UHMWPE). There are two sizes of SureLock All-Suture Anchors; the first is size 1.4mm and is pre-loaded with one #2 high strength UHMWPE suture. The second is size 2.2mm and is pre-loaded with two #2 high strength UHMWPE sutures.

Sawbones® biomechanical test blocks from Pacific Research were chosen for testing[2]. Ultimate load testing was performed in 20 pound per cubic foot (pcf) cellular rigid polyurethane foam with a 3mm 50 pcf "cortical" shell to represent glenoid or other hard bone. Cyclic testing was performed in 15 pcf cellular rigid polyurethane foam with a 3mm 20 pcf "cortical" shell to represent soft humeral head bone.

Materials:

- TCD-500 force tester and operator console (Chatillon P/N TCD500-0500E)
- E-DFE-500 2500N limit force gauge (Chatillon P/N E-DFE-500)
- Force gauge to test stand interface cable (Chatillon P/N NC000647)
- PC with NEXYGEN™ TCD Series software installed

Anchors were deployed 1cm apart in alternating locations in bone block. The free suture ends were tied around a hook on the force gauge. Using the testing apparatus, the suture strands were cycled in-line with the anchor insertion axis at a rate of 5mm per second, followed by a constant-speed pull to failure. The anchors were preloaded to 10N and cycled from 10 to 60N for 500 cycles, then pulled to failure at 200mm/min.

RESULTS:
The 1.4mm SureLock All-Suture Anchor has an ultimate repair strength of 322N and the 2.2mm SureLock All-Suture Anchor has 472N (Table 1). Cyclic test results showed 1.1mm displacement for the 1.4mm anchor and 0.6mm displacement for the 2.2mm anchor (Table 2).

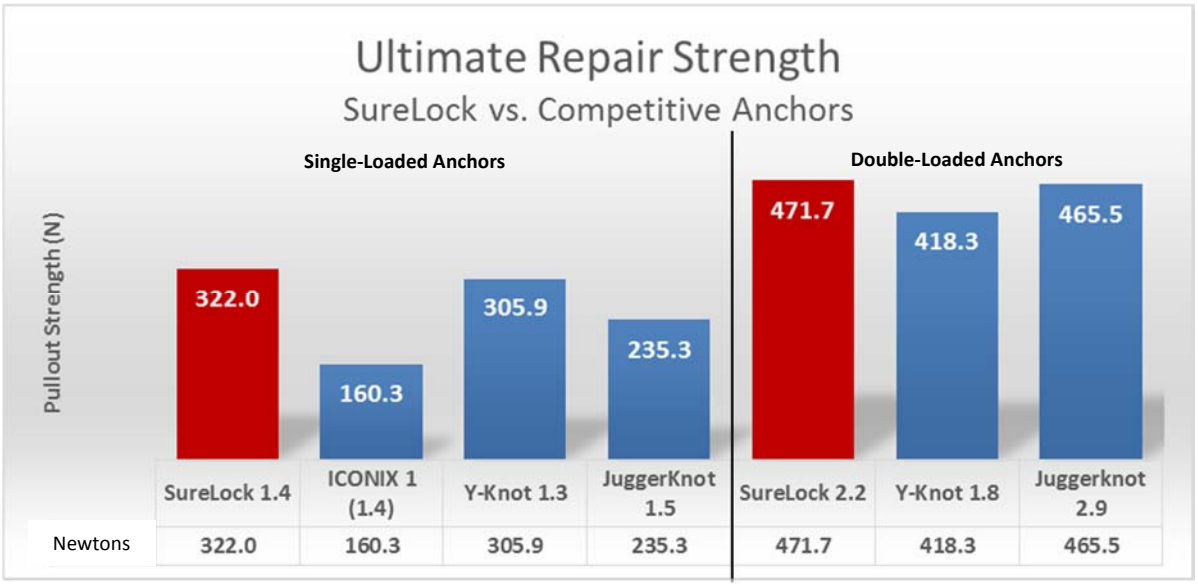

TABLE 1. *SureLock and competitive anchor mean load to failure (N).*

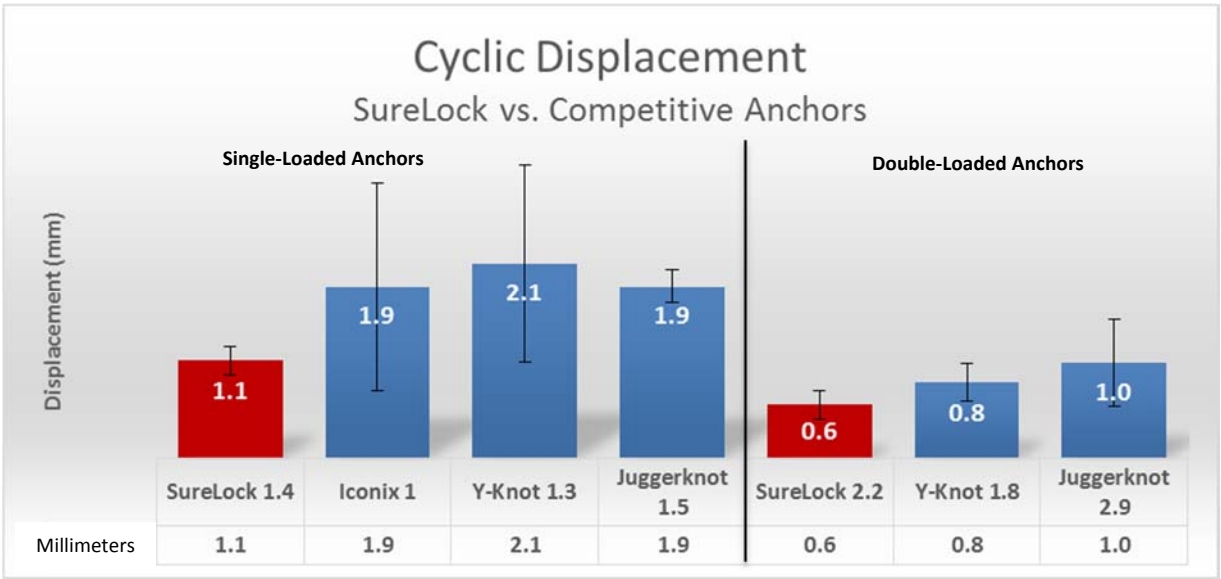

TABLE 2. *SureLock and competitive anchor cyclic displacement (mm).*

CONCLUSION: Both the 1.4mm and 2.2mm Cayenne SureLock All-Suture Anchors compare favorably to the competitors in both ultimate repair strength and cyclic displacement. As all-suture anchors become an important alternative to traditional solid anchors, variables in design and deployment may translate into favorable biomechanical properties as demonstrated in this in-vitro bone block model.

[1]Barber FA, Coons DA, et al. Cyclic Load Testing of Biodegradable Suture Anchors Containing 2 High-Strength Sutures. *Arthroscopy* 2007;4:355-360.
[2]ASTM F-1839-08 "Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments."