Biomechanical Evaluation of Y-Knot® Flex 1.8mm Double-Loaded All-Suture Anchor

Purpose: To evaluate the biomechanical characteristics of the 1.8mm Y-Knot® Flex anchor (ConMed Linvatec, Largo, FL), in comparison to commercially available alternatives. **Methods:** 10 suture anchors were tested in porcine femurs using an MTS Synergie 400 Materials Test System. The anchors were pulled-to-failure with the peak load recorded. Defining characteristics, such as anchor diameter and pilot hole dimensions were noted for comparison. **Results:** The Y-Knot Flex 1.8mm anchor exhibited average pull-out strength of 380N ± 91N. It requires less than $54mm^3$ of bone to be displaced by the drill. **Conclusions:** The Y-Knot® Flex 1.8mm anchor exhibited mean pull-out strength over 31% higher than those reported in peer-reviewed literature for other all-suture anchors < 2.0mm in size. Perhaps more importantly, it requires 61% and 39% less bone removal compared to the double-loaded 2.9mm Juggerknot and 2.3mm Iconix anchors, respectively.

All-suture anchors, also called soft anchors, are becoming a more prevalent means for reaffixing soft tissue to bone in orthopedic procedures. These anchors are most often utilized for labral and capsular-based repairs in the glenohumeral and femoroacetabular joints, where their small size is particularly advantageous due to limited bone stock. All-suture anchors therefore enable more points of fixation per unit area of soft tissue, which has been shown to increase the strength of a soft tissue repair.[1] With minimal bone removal, revision surgery becomes less complicated as well.

While the first all-suture anchors were equipped with a single high strength suture to minimize required bone removal, subsequent versions have been released that contain multiple sutures to expand their surgical utility. To achieve this, manufacturers have either had to increase the size of the anchors above 2mm (E.g. Biomet's 2.9mm Juggerknot and Stryker's 2.3mm Iconix Anchors) or reduce the size of the suture (Smith & Nephew's 1.9mm SutureFix Ultra is available double-loaded with #1 sutures). This is significant because press-in style double-loaded anchors for labral repair already exist in diameters as small as 2.4mm, and #2 suture is the suture most commonly used in shoulder anchors. The 2.9mm Juggerknot and 2.3mm Iconix anchors are largely geared for rotator cuff repair.

ConMed Linvatec has released an all-suture anchor which, at the time of its release, is the only one to be loaded with two #2 strands of high strength suture with a diameter of less than 2mm. This study seeks to benchmark the biomechanical characteristics of the Y-Knot® Flex 1.8mm Anchor with two #2 HiFi® sutures against available all-suture anchor alternatives.

To achieve a head-to-head comparison, pull-out testing was conducted in porcine femurs in a similar manner to testing conducted by Dr. Alan Barber at the Plano Orthopedic and Sports Medicine Center.[2,3,4]

Methods

Figure 1: *Y-Knot Flex 1.8mm All-Suture Anchor with two strands of #2 HiFi® Suture*

Anchor Description

The anchor evaluated in this biomechanical comparison is pictured in *Figure 1*. The Y-Knot® Flex 1.8mm All-Suture Anchor body is made of a 3mm by 25mm flat braid of Ultra High Molecular Weight Polyethelene (UHMWPE) suture. Two strands of number two (#2) HiFi® suture are threaded through six equally spaced piercings in the anchor body. The anchor body is then folded back on itself, and inserted between two tines of an anchor inserter.

The anchor is inserted into a 1.8mm pilot hole drilled into bone stock, then deployed within the pilot hole by drawing back on the ends of the suture strands. When deployed, the anchor contracts vertically and expands laterally to create circumferential contact within the pilot hole, referred to as 360° FormFit™ fixation. See *Figure 2* for a depiction of the deployment.

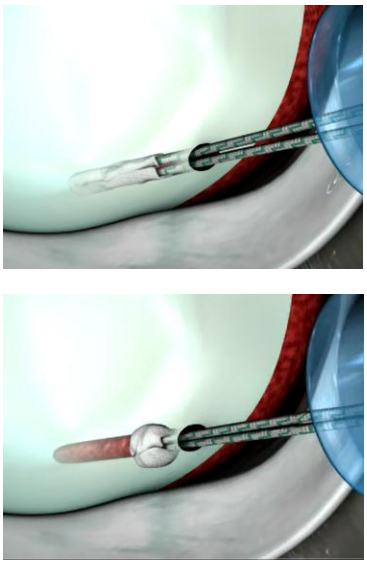

Figure 2: *Y-Knot All-Suture Anchor pre-deployment (top) and post-deployment (bottom) illustrating 360° FormFit™ Fixation.*

Table 1 outlines key attributes of all-suture anchors available for labral repair at the time of this paper.

Suture Configuration	Anchor	Manufacturer	Anchor Material	Suture Size	Pilot Hole Size (mm)	Also marketed for Rotator Cuff Repair
Single-loaded	**Y-Knot Flex 1.3**	**ConMed Linvatec**	**Polyethylene**	**#2**	**1.3**	**No**
	JuggerKnot 1.4mm	Biomet	Polyester	#1	1.4	No
	Iconix 1	Stryker	Polyester	#2	1.4	No
	JuggerKnot 1.5mm	Biomet	Polyester	#2	1.5	No
	SutureFix Ultra	Smith & Nephew	Polyester	#2	1.7	No
Double-loaded	**Y-Knot Flex 1.8**	**ConMed Linvatec**	**Polyethylene**	**#2**	**1.8**	**No**
	SutureFix Ultra 1.9	Smith & Nephew	Polyester	#1	1.9	No
	Iconix 2	Stryker	Polyester	#2	2.3	Yes
	JuggerKnot 2.9mm	Biomet	Polyester	#2	2.9	Yes

Table 1: *Suture Anchor Properties for Select All-Suture Anchors in Ascending Size. The Y-Knot® Flex Anchors are the smallest available in both the single and double-loaded categories.*

Test Procedure

Ten (10) double-loaded Y-Knot® Flex 1.8mm All-Suture Anchors were tested in the proximal diaphysis of porcine femur specimens using an MTS Synergie 400 Materials Test System. First, excess soft tissue was removed from the porcine femur specimens by dissecting or utilizing a shaver to expose the bone surface.

A lower test fixture (custom angled block holder) and an upper test fixture (custom block with dowel pin) were loaded onto the MTS Synergie 400 Materials Test System as depicted in *Figure 3*.

The anchor's sutures were attached to the upper hook/dowel pin by tying a square knot followed by three alternating half hitches. Spacing between the upper and lower fixtures was adjusted to achieve a gauge length of 2-4 inches.

The construct was pre-loaded to 1.0 lb. and the displacement measurement channel was zeroed. The anchor was subsequently pulled at a rate of 2.0 inches per minute and the peak load was recorded. This test was repeated for each of the 10 double-loaded samples.

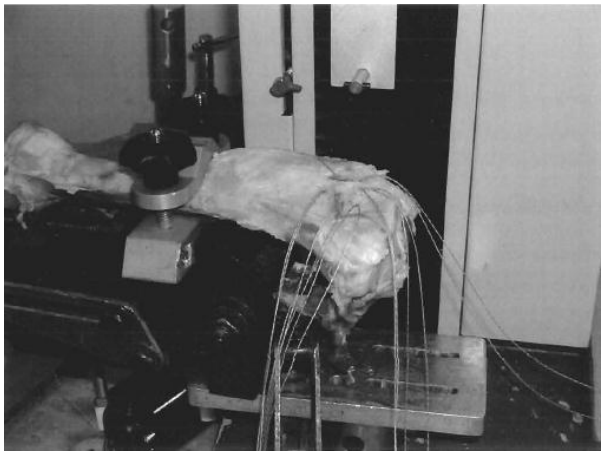

Figure 3: *Anchors inserted in porcine femur*

Results[5]

Test results in cortical bone are summarized in *Table 2*. Test results for the Y-Knot Flex 1.3mm, Juggerknot 1.4mm and 1.5mm, and Iconix 1.4mm anchors were obtained from studies conducted by Dr. Alan Barber.[1,2] SutureFix Ultra data was not available at the time of this study.

Mean Loads-to-failure

The Y-Knot Flex 1.8mm All-Suture anchor exhibited pull-out strength of 380 ± 91N. This was over 31% higher than all other all-suture anchors < 2.0mm in size, which are geared specifically for labral repair.[6] Double-loaded anchors are able to achieve pull-out strengths higher than the strength of a single suture.

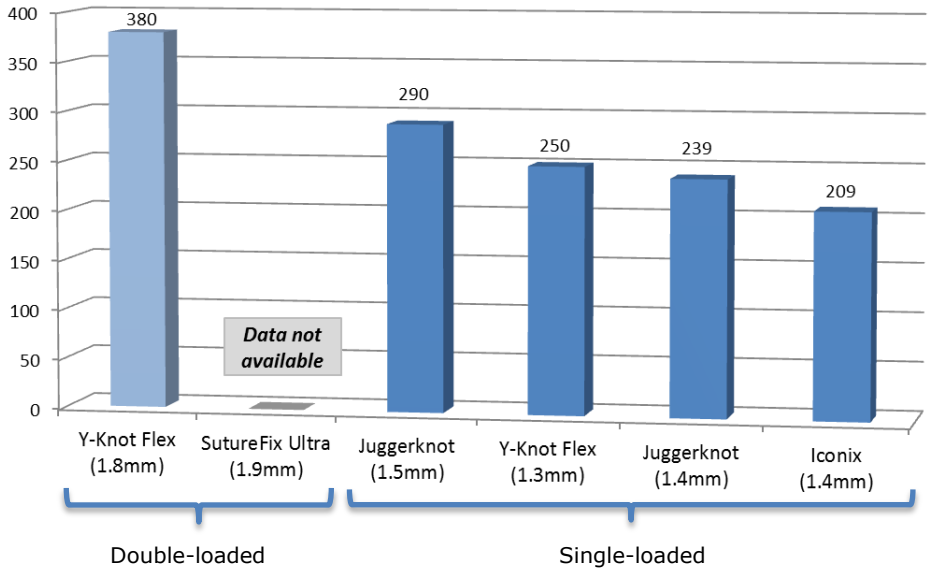

Figure 4: *Cortical loads to failure (N) in porcine for all-suture anchors < 2mm in diameter designed primarily for labral repair*

Anchor	No. of Tests	Mean Force (N)	Standard Deviation (N)	Range (N)
Y-Knot Flex® 1.8	**10**	**380.4**	**91.1**	**263-550**
Juggerknot 1.5	14	290.5	15.3	263-325
Juggerknot 1.4	10	239.1	22.5	215-263
Iconix 1.4	11	208.7	69.0	121-298
Y-Knot Flex 1.3	10	249.7	53.5	**161-302**

Table 2: *Cortical Loads to Failure in porcine for all-suture anchors < 2mm in diameter designed primarily for labral repair*

Required Bone Removal

Compared to the other double-loaded anchors with two #2 sutures, the Y-Knot Flex® 1.8mm All-Suture Anchor has a substantial size advantage. The Y-Knot Flex 1.8mm anchor requires removal of approximately 53mm^3 of bone, compared to approximately 87mm^3 of bone for the 2.3mm Iconix 2 and approximately 139mm^3 of bone for the 2.9mm Juggerknot. Therefore, the Y-Knot Flex 1.8mm anchor requires 39% less bone removal than the 2.3mm Iconix anchor and 61% less bone than the 2.9 Juggerknot anchor.[7]

Conclusions

The Y-Knot® Flex 1.8mm Double-Loaded All-Suture Anchor's mean load to failure of 380 ± 91N in porcine femur with a cortical layer is over 31% higher than the mean strengths reported for both Juggerknot and Iconix anchors geared specifically for labral repair (those that are less than 2.0mm in diameter).

Perhaps more importantly, the Y-Knot Flex 1.8mm anchor requires 61% and 39% less bone removal than the smallest double-loaded Juggerknot and Iconix anchors, respectively.

The small size and strong fixation of the Y-Knot Flex 1.8mm All-Suture anchor make it ideally suited for labral and capsular-based procedures.

References

[1] Jost PW, Khair MM, Chen DX, Wright TM, Kelly AM, Rodeo SA, Suture number determines strength of rotator cuff repair. J Bone Joint Surg Am. 2012 Jul 18; 94 (14): e1001-e1007

[2] Barber, FA. et al. Cyclic Loading Biomechanical Analysis of the Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2013 Update. Arthroscopy. 2013; 29:832-844.

[3] Barber, FA. et al. Biomechanical Analysis of Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2011 Update. Arthroscopy. 2011; 27:895-905.

[4] Pull-to-failure conducted at slower rate in Y-Knot Flex 1.8mm study compared to Barber studies (2" per minute vs. 29.5" per minute)

[5] Data on File (TR13-375-1: Y-Knot Flex 1.8mm All-Suture Anchor - Porcine Femur Testing)

[6] Y-Knot Flex 1.8mm anchor has pull-out strength of 380N, which is 31% higher than the 290N reported for the 1.5mm Juggerknot anchor: (380 – 290) / 290 = 0.31

[7] Assumes 21mm drill depth for anchors. Bone removal = $\pi r^2 h$. For Y-Knot Flex 1.8mm: $\pi(0.9mm)^2(21mm) = 53.4mm^3$. For 2.9mm Juggerknot: $\pi(1.45mm)^2(21mm) = 138.7mm^3$. For 2.3mm Iconix: $\pi(1.15mm)^2(21mm) = 87.2mm^3$. Y-Knot Flex is 61% smaller than 2.9mm Juggerknot: (138.7-53.4) / 138.7 = 0.61 and 39% smaller than 2.3mm Iconix anchor: (87.2 -53.4) / 87.2 = 0.39