

Biomechanical Evaluation of PressFT™ 2.1mm Anchor

Purpose: To evaluate the biomechanical and design characteristics of the 2.1 PressFT anchor (ConMed Linvatec, Largo, FL), in comparison to commercially available alternatives. **Methods:** 20 suture anchors were tested in the distal metaphysis of porcine femurs using an MTS Synergie 810 Materials Test System. The anchors were pulled-to-failure with the peak load recorded. Defining characteristics, such as anchor diameter, anchor length, and pilot hole dimensions were noted for comparison. **Results:** The PressFT anchor exhibited average pull-out strength of $207\text{N} \pm 92\text{N}$ in cortical bone and $180\text{N} \pm 82\text{N}$ in cancellous specimens. The PressFT exhibited other favorable characteristics, as well, including a small outer diameter (2.5mm) and short length (<10mm). **Conclusions:** The PressFT anchor exhibited mean pull-out strength 20% higher than previously reported for competing anchors with 3.0mm outer diameters. This is despite its 35% reduction in anchor volume compared to these conventional 3.0mm anchors. Among the glenoid anchors reviewed, it is the only press-in style labral anchor not to exhibit a failure at a load of less than 50N (the lowest load resulting in a PressFT failure was 75N).

In recent years, press-in style suture anchors have become more prevalent as a means for performing labral and capsular-based repairs in the glenohumeral and femoroacetabular joints. Such anchors are malleted into a pre-drilled pilot hole in the bone that is smaller than the major diameter of the anchor. This results in an interference fit between the bone and the anchor with sufficient force to maintain tissue-to-bone contact throughout the healing period. The suture that is secured by the anchor is then passed through soft tissue and secured by tying knots or utilizing a knotless fixation mechanism, depending upon the anchor.

Real estate is at a premium on the glenoid, and as such, efforts are made to minimize the size of the anchor while maintaining the holding power required for healing to occur.

ConMed Linvatec (Largo, FL) has released an anchor, which, at the time of its release, is the smallest available PEEK anchor for instability repair procedures. This study seeks to benchmark the design and biomechanical characteristics of this anchor against available alternatives, including the SutureTak (Arthrex, Naples, FL), Bioraptor (Smith & Nephew, Andover, MA), and Gryphon (Mitek, Raynam, MA) anchors.

To achieve a head-to-head comparison, pull-out testing was conducted in the distal metaphysis of porcine femurs in similar manner to testing conducted by Dr. Alan Barber at the Plano Orthopedic and Sports Medicine Center.^{1,2,3}

Methods

Anchor Description

The PressFT™ 2.1 anchor tested in this study is comprised of Polyetheretherketone (PEEK), a non-absorbable radiolucent polymer with a modulus similar to that of cortical bone. It has a "headless" design and is loaded with a single strand of number two (#2) Hi-Fi® suture through a distal eyelet.

Table 1 outlines key attributes of the PressFT 2.1 anchor in comparison to the anchors to which it is being compared in this paper. The comparative anchors were chosen based on their common use by surgeons and the availability of published biomechanical test results.

Figures 1 and 2 show photographs of the four press-in style anchors being compared in this paper.



Figure 1: PressFT Anchor

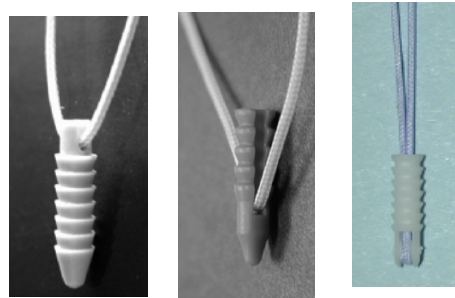


Figure 2: SutureTak PEEK (left), Bioraptor PK (middle), and Gryphon BC (right)

Anchor	Company	Material	Suture	Minor (mm)	Major (mm)	Length (mm)	Approximate Volume [†] (mm ³)
PressFT 2.1	ConMed Linvatec	PEEK	No. 2 Hi-Fi®	2.1	2.5	9.7	48.1
SutureTak 3.0	Arthrex	PEEK	No. 2 FiberWire	2.3	3.0	12.0	84.8
Gryphon 3.0	Depuy-Mitek	BR	No. 2 Orthocord	2.5	3.0	10.7	75.6
Bioraptor 2.3	Smith & Nephew	PEEK	No. 2 Ultrabraid	2.3	3.0	11.6	82.0

Table 1: Suture Anchor Properties for PressFT⁵, SutureTak², Gryphon¹, and Bioraptor² anchors

Test Procedure

Twenty (20) single-loaded PressFT 2.1 PEEK anchors were tested in the distal metaphysis 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. In ten (10) of the samples, a decorticated anchor site was prepared via removal of the cortical bone layer with a bur.

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 suture was 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 10 samples in porcine distal metaphysis with the cortex in place, and 10 decorticated samples.



Figure 3: Anchors inserted in porcine femur

Results⁵

Test results in cortical and cancellous bone can be seen below in *Tables 2 and 3*. Test results for the SutureTak, Gryphon, and BioRaptor were obtained from studies conducted by Dr. Alan Barber.^{1,2}

The PressFT™ 2.1 anchor was the only anchor to achieve mean pull-out strength of over 200 N, which was the mean peak force seen in cortical bone. The absence of the cortical layer reduced mean pull-out strength to 180 N. This is the smallest percentage drop (12.9%) from cortical to cancellous amongst the anchors reviewed in this study.

The PressFT anchor was also the only anchor to hold until the #2 suture broke as the failure mechanism. Further, no failures were attributed to the suture cutting through the eyelet (see *Table 4*). Bimodal failure modes (suture break and pull-out) led to a standard deviation (92N in cortical bone and 82N in cancellous bone).

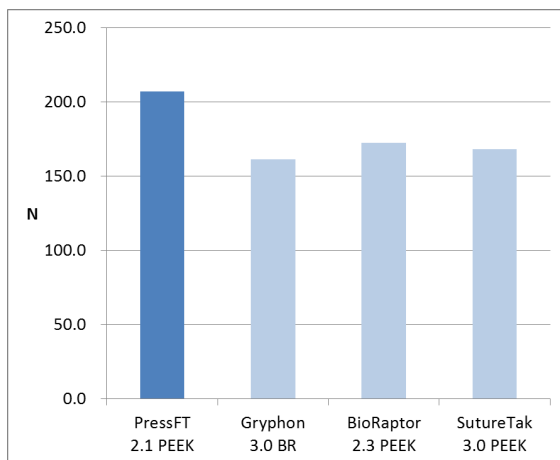


Figure 4: Cortical loads to failure in porcine

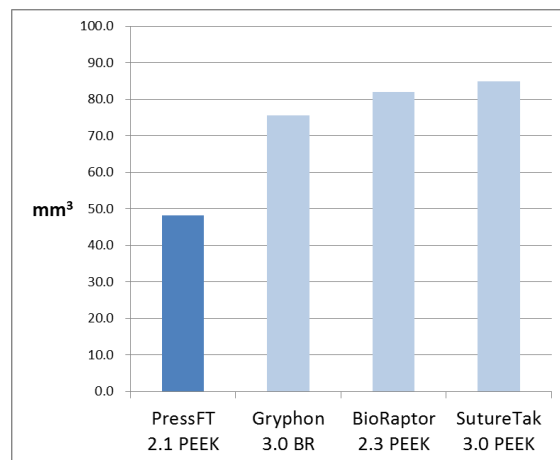


Figure 5: Approximate anchor volume

Anchor	No. of Tests	Mean Force (N)	Standard Deviation (N)	Range (N)
PressFT 2.1	10	207.1	92.2*	75-307
SutureTak 3.0	10	168.1	14.9	145-189
Gryphon 3.0	10	161.1	22.5	128-194
Bioraptor 2.3	10	172.2	91.7	58-302

Table 2: Cortical Loads to Failure

Anchor	No. of Tests	Mean Force (N)	Standard Deviation (N)	Range (N)
PressFT 2.1	10	180.4	81.7*	86-258
SutureTak 3.0	11	144.8	51.8	38-193
Gryphon 3.0	10	116.8	50.8	44-193
Bioraptor 2.3	10	76.0	27.5	29-116

Table 3: Cancellous Loads to Failure

Anchor	No. of Tests	Anchor Pullout	Eyelet Break	Suture Break
PressFT 2.1	20	11	0	9
SutureTak 3.0	21	5	16	0
Gryphon 3.0	20	8	12	0
Bioraptor 2.3	20	20	0	0

Table 4: Modes of Failure

Conclusions

The PressFT 2.1 anchor's mean load to failure of 207N ± 92N in cortical porcine femur is over 20% higher than the mean strength reported for conventional 3.0mm anchors. This is remarkable as, by volume, the PressFT 2.1 anchor is over 35% smaller than conventional 3.0mm press-in style anchors. The high standard deviation evident in the data relates to the existence of two distinct failure modes (suture breakage and pull-out). When tested to suture breakage (n=9) the load to failure was 273.6N ± 9.8N. The small size and strong fixation of the PressFT 2.1 anchor make it ideally suited for labral and capsular-based procedures in the shoulder and hip.

References

¹ Barber, FA. et al. Biomechanical Analysis of Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2011 Update. *Arthroscopy*. 2011; 27:895-905.

² Barber, FA. et al. Suture Anchor Materials, Eyelets, and Designs: 2008 Update. *Arthroscopy*. 2008; 24:895-867.

³ Pull-to-failure conducted at slower rate in PressFT study compared to Barber studies (2" per minute vs. 29.5" per minute)

⁴ Based on the formula of volume = $h\pi r^2$ where h = anchor length and r = $\frac{1}{2}$ anchor major diameter. This formula thus assumes anchor has a cylindrical shape, and does not take into account ribs and tapering.

⁵ Data on File: TR12-182: PressFT Suture Anchor Porcine Femur Testing