Technical Information
Research and Development
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Competitive Testing of Fully Threaded Anchors

Objective:

The objective of the testing was to determine the fixation strength and performance during cyclic loading of the following Fully Threaded Suture Anchor configurations:

Anchor	Company	Size	Material	Sutures
CrossFT	ConMed Linvatec	4.5mm	PEEK	3, #2 HiFi
CrossFT	ConMed Linvatec	5.5mm	PEEK	3, #2 HiFi
ThRevo-FT	ConMed Linvatec	5.0mm	Titanium	3, #2 HiFi
BioCorkScrew-FT	Arthrex	5.5mm	PLA	2, Hi-Strength Suture*
Healix	DePuy Mitek	4.5mm	PEEK	2, #2 Orthocord
Healix BR	DePuy Mitek	5.5mm	Composite	2, #2 Orthocord

CrossFT™
ConMed Linvatec
4.5, 5.5 and 6.5mm
PEEK

ThRevo-FT®
ConMed Linvatec
5.0mm
Titanium

Materials and Methods:

The identified Fully Threaded Suture Anchors were used to fixate the manufacturer's suture in a 40/12.5lb/ft³ composite cellular rigid foam bone model. The foam bone model best represents the compressive properties of human bone.[1] The density of the 12.5lb/ft³ cancellous foam base is within the range for weak to average human bone density according to a literature search done by Truman.[2] The density of the 2mm thick 40lb/ft³ cortical foam bone layer exceeds that measured from the lesser and greater tuberosities of the humerus according to Tingart et al.[3]

The Suture Anchors were implanted in the foam bone, following manufacturer's instructions, and the constructs placed in an Instron servo-hydraulic testing machine (Instron Corporation, Canton MA) with a 1 kN load cell. The sutures in each anchor were fixed with a suture bar and the angle of load set to 45º to reproduce the direction of load produced by the rotator cuff

upon implantation. Each construct was then subjected to 5000 cycles of cyclic loading with a load of 10 to 60N at 1Hz. This cyclic load is representative of a 12-week healing cycle under normal rehabilitative stresses, as described in multiple published studies.[4]
* Specific suture loaded on BioCorkscrew included fiberchain, Fiberwire and Tigerwire

A study published by Brown et al. defined anchor failure as displacement of 5mm-10mm from the initial fixation site.[5] The more conservative criteria, 5mm, was utilized as the pass-fail criteria for this test. The anchor (with suture) construct's displacement was measured and recorded during and at the completion of the initial 5000 cycles of the cyclic loading to determine displacement.

Once cyclic loading was completed, the ultimate fixation strength of the anchor was determined by increasing the maximum cyclic load (60N) by 1N every subsequent cycle until failure. The mode of failure and failure load was recorded.

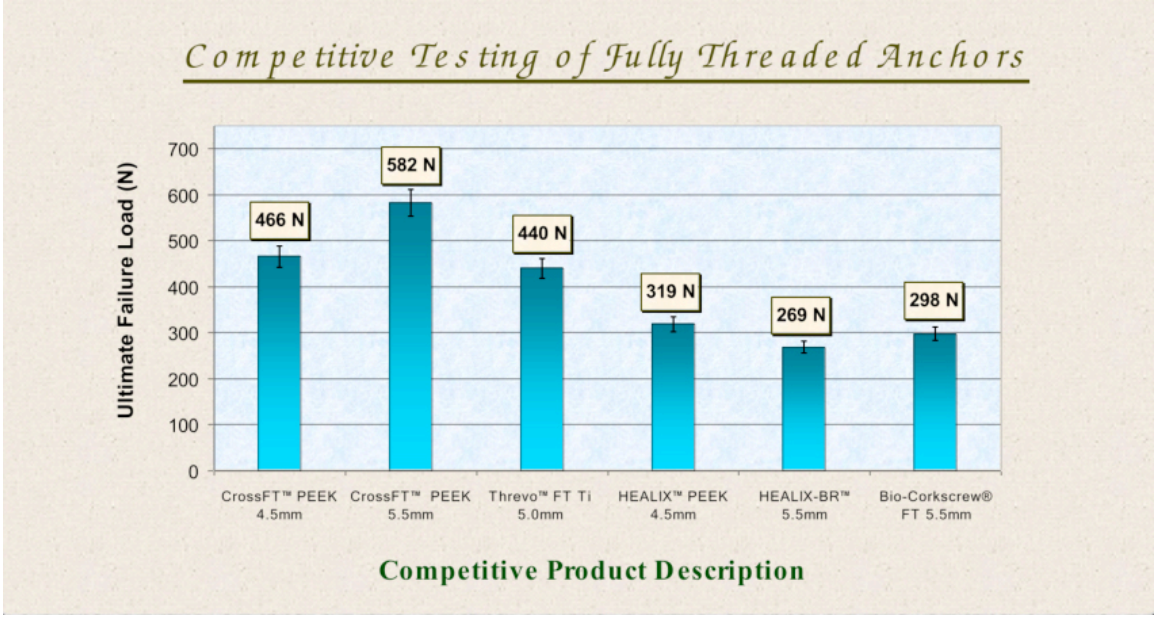
Results:

Cyclic Loading:
All suture anchors displayed less then 5mm of displacement during cyclic loading. Per Brown et al. a displacement of 5mm-10mm from the initial fixation site represents anchor failure.[5] As such all fully threaded suture anchors passed cyclic loading criteria.

Ultimate Load at Failure and Failure Mode:
The fully threaded suture anchors displayed the following failure loads and modes during ultimate fixation strength testing:

Summary:

Anchor	Average	Minimum	Maximum	Failure Modes
CrossFT, 4.5mm	466N	335N	560N	Anchor pull-out and suture breakage
CrossFT, 5.5mm	582N	387N	710N	Anchor pull-out and suture breakage
ThRevo-FT	440N	356N	540N	Suture breakage
BioCorkscrew-FT	298N	271N	335N	Eyelet failure
Healix BR, 5.5	269N	240N	285N	Broken suture and eyelet failure
Healix, 4.5	319N	242N	357N	Eyelet failure



Conclusion:

The one-way ANOVA analysis shows a statistically significant difference, at 95% confidence, for Ultimate failure load between the 4.5mm and 5.5mm CrossFT suture anchors and all competitive anchors tested.

The one-way ANOVA analysis shows a statistically significant difference, at 95% confidence, for Ultimate failure load between the ThrevoFT suture anchor and all competitive anchors tested.

The load to failure of the CrossFT PEEK (4.5 and 6.5mm) and the ThRevo-FT Suture Anchors was statistically, significantly better than the competitive Suture Anchors evaluated in this study.

References:

1. Lombardo, J. Method and Calculation of Young's Modulus of the Proximal Humerus Cancellous Bone using Physical Properties of the Femoral Head. Conmed Linvatec Technical Report TR09-192; March 2009.
2. Truman, M. Cancellous Bone and Bone Model Material Properties. Internal Zimmer Memorandum; February 10, 1993.
3. Tingart, MJ, et al. Pullout Strength of Suture Anchors used in Rotator Cuff Repair. *Journal of Bone and Joint Surgery*, 2003
4. Rodeo, S.A., Arnoczky, S.P., Torzilli, P.A., et al. (1993). Tendon healing in a bone tunnel. A biomechanical and histological study in the dog. *The Journal of Bone and Joint Surgery, 75(12),* 1795-1803.
5. Brown, Barrett S, et al. Initial Fixation and Cyclic Loading Stability of Knotless Suture Anchors for Rotator Cuff Repair. *Journal of Shoulder and Elbow Surgery* 2008.

*Additional information/Data on file at ConMed Linvatec **(Reference Document APT 389)**