

WHITE PAPER

Fixation Strength and Failure Mechanism of PUNCHTac[™] vPEEK 5.5mm Anchor System

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OBJECTIVE

The purpose of this study was to compare the fixation strength and failure mechanism of Dunamis Medical's PUNCHTac™ vPEEK 5.5mm Anchor System to a Smith & Nephew's 5.5mm TWINFIX PK FT Anchor with two #2 sutures.

MATERIALS

The Study was performed using 9 PUNCHTac™ vPEEK 5.5mm Anchor System including five of these with two #2 Sutures and four with two 2mm tapes (Dunamis Medical, Greenville, AL). These were compared to 10 5.5mm TWINFIX PK FT with two #2 sutures (Smith & Nephew, Andover, MA). The samples used for testing were provided in their final design configuration and sterilized form.

A synthetic bone material of consistent density, Polyurethane foam synthetic bone (Sawbones Pacific Research Laboratories, Inc., Vashon WA), was used for testing. This material conforms to the specifications described in ASTM – for testing Orthopedic Devices and Instruments. Axial pullout strength was performed according to the guidelines established by the FDA's Guidance Document. Pullout testing was performed using a MTS Criterion 43 with a 30KN load cell (MTS, Eden Prairie, MN).

The implantation holes were spaced 25mm apart. Pilot holes were created using manufacturers' techniques for implantation of anchors. Each device was implanted into the polyurethane foam per the manufacturers' instructions for use. The sutures/tapes were then tied around a dowel pin and pulled at the normal rate of 12.5mm/min until the failure occurred followed by measuring the peak force at the time of failure. The failure modes were categorized as one of the following: Suture Failure, Tape Failure, Surrogate Bone Failure - anchor loosened from polyurethane foam block with suture intact, and Anchor Failure - a portion of the anchor failed.

Statistical Analysis was performed using a SPSS Statistics 22.0. One-way ANOVA with post-hoc Tukey test was performed and $p < 0.05$ was considered significant.

RESULTS

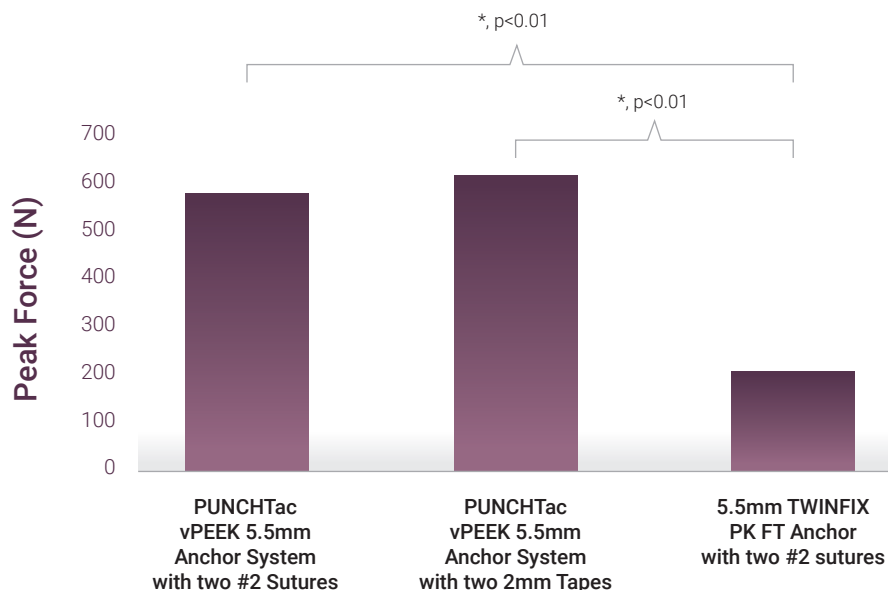


Figure 1: Peak Force (N) comparison of PUNCHTac™ vPEEK 5.5mm Anchor System with two #2 sutures, PUNCHTac™ vPEEK 5.5mm Anchor System with two 2mm tapes and 5.5mm TWINFIX PK FT with two #2 sutures. (* shows significant difference i.e. $p < 0.05$).

The peak force (N) at the time of failure for both PUNCHTac™ vPEEK 5.5mm Anchor System with two #2 sutures as well as with two 2mm tapes was significantly ($p < 0.01$) higher compared to 5.5mm TWINFIX PK FT with two #2 sutures (Figure 1). The failure mechanism for PUNCHTac™ vPEEK 5.5mm Anchor System with two #2 sutures, PUNCHTac™ vPEEK 5.5mm Anchor System with two 2mm tapes and 5.5mm TWINFIX PK FT with two #2 sutures were suture failure, anchor bridge failure and anchor pullout respectively.

CONCLUSION

In conclusion, the Dunamis Medical's PUNCHTac™ vPEEK 5.5mm Anchor System with two #2 sutures and PUNCHTac™ vPEEK 5.5mm Anchor System with two 2mm tape has a significantly higher Peak Force to failure than Smith & Nephew's 5.5mm TWINFIX PK FT with two #2 sutures. We believe that Dunamis Medical products may be better suited for fixation in locations expecting higher load and poor bone architecture.