

Pullout Strength Comparison of the MaxFire™ and MaxFire™ MarXmen™ Meniscal Repair Devices

Biomet Sports Medicine Research & Development

Methods

Ten MaxFire™ soft anchor implants were inserted into bovine meniscus, five using the MaxFire™ MarXmen™ inserter device and five using the current MaxFire™ inserter in a horizontal mattress stitch configuration. A #2 Maxbraid™ suture loop was passed under the two strands of the MaxFire™ implant connecting the two size #5 polyester anchors, as seen in Figure 1 below. The pull strand of the ZipLoop™ implant was then tensioned to remove any present slack.



Figure 1: MaxFire™ MarXmen™ Implant connected to #2 Suture Loop

The #2 suture loop was used to pull the size #5 polyester anchors through the bovine meniscus while recording the pullout strength. Testing was performed using a Sintech 1/s Screw Ball Machine in Biomet's Mechanical Testing facility. Crosshead speed was 1.18 in/min (30mm/min), a standard tension test setting for Biomet Sports Medicine.

Results

The MaxFire™ device with ZipLoop™ Technology produced average pullout strength of 28.358 lbf. The MaxFire™ MarXmen™ device trials resulted in an average of 32.271 lbf. These averages are reflected in Figure 2 below.

Final Mechanical Test Results: MaxFire™ device vs. MaxFire™ MarXmen™ device Anchor Pullout Strength

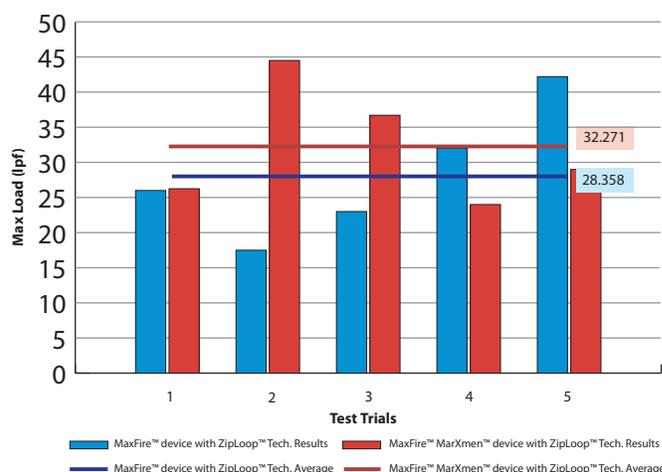


Figure 2: Maxfire™ MarXmen™ Implant connected to #2 Suture Loop

Discussion

The data demonstrates that the new MaxFire™ insertion device replacement, the MaxFire™ MarXmen™ device, has comparable average suture anchor pullout strengths. When evaluating the statistical significance, an unpaired t-test was used. By conventional criteria, the difference is considered to be not statistically significant.

Data on File at Biomet Sports Medicine. Bench testing is not necessarily indicative of clinical performance.

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