Biomechanical Evaluation of the JuggerStitch™ Meniscal Repair Device

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Introduction

The JuggerStitch™ all-suture, all-inside meniscal device builds upon the heritage of the JuggerKnot® soft anchor implant and ZipLoop™ technology. The primary benefits of the JuggerStitch device are the strong, knotless, all-suture implant and the, low-profile insertion device.

This white paper investigates the effect of tissue models on the biomechanical results of meniscal fixation for soft anchors and hard polymer anchors using the JuggerStitch device and the Ultra FAST-FIX device (Smith and Nephew). This white paper summarizes the performance of each of these devices in cadaveric and porcine tissue during this study.

Materials and Methods

The JuggerStitch is a second-generation knotless, all-suture meniscal repair device that utilizes a 1.6 mm needle inserter to deploy two soft, polyester suture anchors linked by a 2-0 UHMWPE adjustable locking suture. The locking suture is tensioned in a two-step process that independently tensions the two strands tightly and equally. The Ultra FAST-FIX device consists of two 5.0 mm PEEK or PLLA hard anchors linked by a #0 UHMWPE suture with a pre-tied sliding knot that is tensioned during the repair.

17 samples of the JuggerStitch Meniscal Repair Device (Zimmer Biomet, Warsaw, IN) and 17 samples of the Ultra FAST-FIX (Smith & Nephew, London, UK) were tested. 9 of each device were tested in porcine tissue and 8 of each device were tested in cadaveric tissue.

All specimens were prepared by creating a vertical longitudinal tear 3 mm from the periphery of the meniscus. These tears were fixed with a single vertical mattress suture using either a JuggerStitch or Ultra FAST-FIX meniscal repair device. Following fixation by the meniscal implant, the tear was completed at the anterior and posterior horns, creating an independent inner and outer portion of the meniscus fixed together only by the meniscal implant. The menisci were then detached from their root insertion and mechanically tested. Prepared porcine specimens using each device are pictured in Figures 1-4.

The specimens were pre-loaded, followed by cyclic loading from 5 N to 50 N at a frequency of 1 HZ for 200 cycles using a tensile load. Specimens that did not survive 200 cycles or experienced greater than 5 mm elongation under cyclic loading were considered failures. Specimens that survived cyclical testing were tensile loaded to destructive failure at a rate of loading of 5 mm/min. The mode of failure was determined by visual inspection.

The test location was Warsaw, IN and performed using an Instron materials testing machine (Instron, Canton, MA).

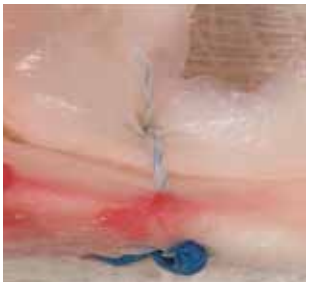


Figure 1 and 2
Vertical mattress stitch using the JuggerStitch knotless, all-suture device

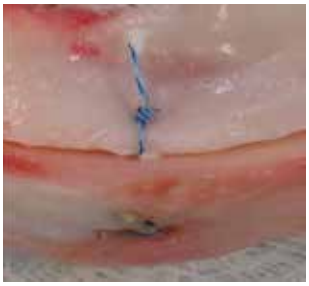


Figure 3 and 4
Vertical mattress stitch using the Ultra FAST-FIX device (Smith and Nephew)

Results

All 9 of the JuggerStitch implants passed cyclical testing with porcine menisci compared to 78% (7 of 9) of Ultra FAST-FIX implants. Two failures of Ultra FAST-FIX occurred – 1 due to the pre-tied knot slipping and 1 due to the implant suture breaking.

In human menisci, 4 of 8 JuggerStitch implants passed cyclical testing. One specimen experienced failure at the tissue-clamp interface, and 3 specimens failed due to elongation (> 5 mm). Visual inspection revealed that the failures due to elongation for both devices were primarily due to delamination of the tissue at the clamp or suture rather than elongation of the suture loop.

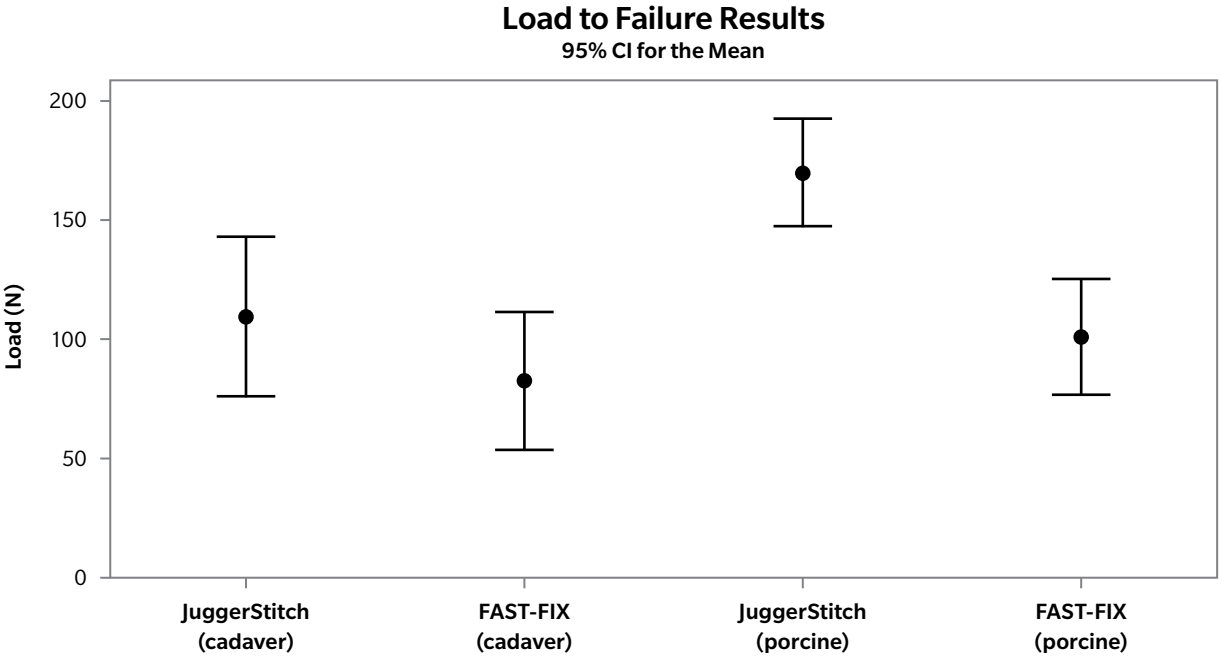
In human menisci, 4 of 8 Ultra FAST-FIX implants passed cyclical testing. Failures were due to 1 implant suture coming loose from the anchor, 2 devices failed because the implant suture cut through the tissue, and the remaining sample failed due to elongation (> 5 mm).

Cyclic displacement values for the samples that passed the cyclic load test were similar for the JuggerStitch and the Ultra FAST-FIX in porcine tissue and cadaveric tissue under the loads introduced in this study. See Table 1 for a summary of the cyclic displacement data.

Surviving samples were then tested to failure. Both implants saw similar load to failure results in cadaveric tissue. However, JuggerStitch devices experienced a statistically significantly higher load to failure in porcine tissue. In the human meniscal load-to-failure testing, one JuggerStitch specimen failed at the clamp-tissue interface and the remaining samples failed from sutures tearing through the tissue. In the porcine model, the JuggerStitch devices experienced failures at the clamp-tissue interface, the suture-tissue interface, suture breakage, and anchor pull-out. The Ultra FAST-FIX devices failed due to suture tearing through tissue or suture breakage in both tissue models.

		Completed 200 Cycles	Total Displacement (mm)	SD (mm)
Cadaver	JuggerStitch	4/8	3.70	1.07
	Ultra FAST-FIX	4/8	3.70	.88
Porcine	JuggerStitch	9/9	2.81	.66
	Ultra FAST-FIX	7/9	2.85	.74

Table 1
Cyclic Testing Result Summary



Individual standard deviations were used to calculate the intervals

Conclusion

In the human cadaveric test model, there were no statistically significant differences between the JuggerStitch device and the Ultra FAST-FIX device in either cyclic or static loading. The weaker and more variable cadaveric tissue resulted in elongation and catastrophic failures at the clamp-tissue interface and the suture/tissue interface for both devices. Testing in porcine tissue reduced the incidence of tissue failure for both devices in comparison to cadaver tissue, unveiling the statistically significant superior strength of the JuggerStitch device when compared to the Ultra FAST-FIX device during static loading ($p=.004$).* While the JuggerStitch cyclic loading results were favorable to the Ultra FAST-FIX in the porcine model, there were no statistically significant differences between the two devices. These results demonstrate that the knotless, all-suture design of the JuggerStitch implant does not compromise the strength of the device in comparison to a traditional knotted device with hard anchor fixation.

* Bench and animal testing is not necessarily indicative of clinical performance.

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