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# Evaluation of the Mechanical Properties of the ULTRA FAST-FIX◇ Meniscal Repair System in a Bovine Meniscus Model

## Objective

The primary objective of this study was to evaluate the mechanical properties of the Smith & Nephew ULTRA FAST-FIX◆ Meniscal Repair System in a bovine meniscal model. The results were compared with the clinically successful FAST-FIX Meniscal Repair System. Compared to the FAST-FIX device, cyclic testing showed that meniscal repair using the ULTRA FAST-FIX device resulted in a significant increase in ultimate strength and a decrease in elongation of the repair complex. These improved properties could lead to better meniscal repair outcomes in the clinical environment.

## Introduction

Smith & Nephew has developed a statistically superior meniscal fixation device, the ULTRA FAST-FIX device. It utilizes the Smith & Nephew ULTRABRAID◆ suture, which is significantly stronger and stiffer than the polyester suture and has improved knot-sliding properties[1]. The ULTRA FAST-FIX device also utilizes the stronger polyetheretherketone (PEEK-OPTIMA® from Invibio®) material in the implants. It is hypothesized that material improvements in both the suture and implant will lead to improved repair properties and, subsequently, better tissue healing and outcomes in meniscal repair.

The literature was reviewed to determine the most appropriate *in vitro* mechanical evaluation of meniscal repair devices, and it was determined that cyclic and load-to-failure mechanical tests on a repaired bovine mensicus were appropriate in representing the human meniscus[2-14].

This study evaluated the ultimate elongation, ultimate strength, and stiffness of ULTRA FAST-FIX device repairs after cyclic loading, in comparison to the clinically successful FAST-FIX device in a bovine meniscal model.

## Method

Fresh frozen medial menisci were harvested from adult cows between one and two years old. Preparation, implantation, and testing were carried out in a similar method to Arnoczky et al[2]. By means of a template, lacerations were uniformly created and lesions were repaired with a standard vertical stitch, using either the FAST-FIX (polyester size 0 suture and acetal implants) or ULTRA FAST-FIX (ULTRABRAID size 0 suture and PEEK-OPTIMA implants) devices. A repaired meniscus was secured in the meniscal fixture. The universal joint was attached to the meniscal clamp and secured to the 450 N load cell (Honeywell/Sensotec, Columbus, Ohio). The meniscus was secured with pins to the actuator of a MTS 858 servohydraulic materials testing system (MTS, Eden Prairie, Minnesota; Figure 1).

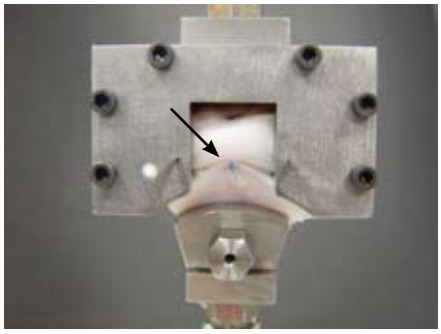

Figure 1. Test fixture with bovine medial meniscus. The arrow designates the laceration and implant location.

Cyclic testing was performed between loads of 5 N and 20 N for 1000 cycles. At completion, a load-to-failure test was performed at a rate of 12.5 mm/s. The load values and number of cycles chosen during testing reflected loading forces previously used in the literature. These parameters are within known clinical medial meniscus loads for both intact and deficient anterior cruciate ligaments[2-5, 9, 14]. Ultimate elongation, ultimate strength, and stiffness of the FAST-FIX and ULTRA FAST-FIX devices were evaluated using MultiPurpose TestWare® data acquisition (MTS, Eden Prairie, Minnesota).

An f-test and t-test were performed to determine the significance of all data. The ULTRA FAST-FIX device was analyzed with a sample size of nine, while the FAST-FIX device was analyzed with a sample size of eight.

## Results and Discussion

### Less Elongation in the ULTRA FAST-FIX® Device in Cyclic Loading

A cyclic loading test was performed to reproduce physiological loading conditions and evaluate the effects on the repair. All the meniscal repair devices tested mechanically withstood the cyclic loading evaluation. However, repair complexes using the ULTRA FAST-FIX device displaced an average of 21% less ($P<0.05$) than the traditional FAST-FIX device (3.5 mm compared to 4.5 mm), Figure 2. In addition, as previous studies have shown, the current FAST-FIX device has significantly lower repair elongation than standard suture repair (5.6 mm) and Mitek's RAPIDLOC® (6.8 mm)[3]. Therefore, the significantly lower elongation in the ULTRA FAST-FIX device repairs, as compared to the FAST-FIX device repairs, suggests a more stable repair clinically.

### Load-to-Failure Test Showed Greater Strength and Stiffness in the ULTRA FAST-FIX Device

The ULTRA FAST-FIX device also gave a stronger and stiffer repair. Repairs with the ULTRA FAST-FIX device had stiffness values 11% higher and ultimate strength values 28% higher than those with the FAST-FIX device (Figure 3 and Table 1). These improved biomechanical properties indicate a higher potential for the meniscal repair to withstand repetitive loading during exercise or daily activities, as simulated by the cyclic loading test in this study.

Other vertical repair techniques were evaluated by Zantop et al[3,4] in a bovine meniscus model and were shown to have higher elongation, lower ultimate strength, and lower stiffness in comparison to the FAST-FIX and ULTRA FAST-FIX devices (Table 1).

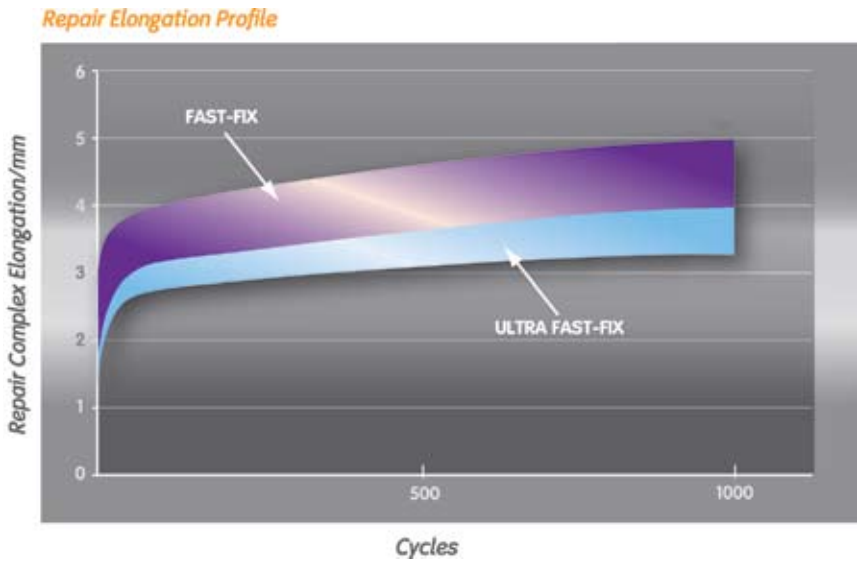


Figure 2. Repair elongation profile of FAST-FIX and ULTRA FAST-FIX devices over 1000 cycles.

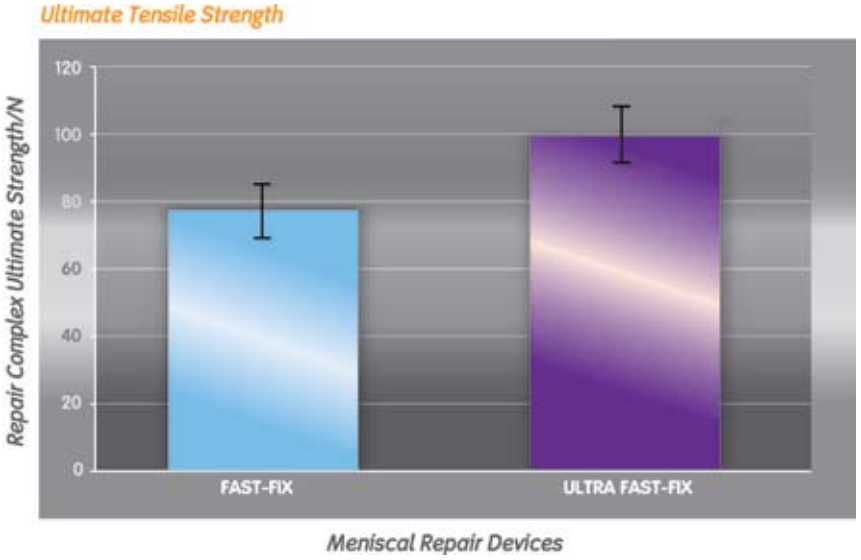


Figure 3. Ultimate strength of meniscal repair complex after 1000 loading cycles between 5 N and 20 N ($P < 0.07$).

| After 1000 cycles between 5N and 20N | Elongation, mm | Ultimate Strength, N | Stiffness, N/mm |
|---|---|---|---|
| ULTRA FAST-FIX* device | 3.53 ± 0.24 | 99.1 ± 10.2 | 18.0 ± 1.2 |
| FAST-FIX* device | 4.49 ± 0.48 | 77.2 ± 9.0 | 16.2 ± 1.0 |
| ETHIBOND® Suture** | 5.61 ± 0.57 | 71.3 ± 3.9 | 7.7 ± 0.6 |
| Mitek RAPIDLOC®** | 6.84 ± 0.89 | 30.3 ± 2.1 | 8.5 ± 0.7 |

* This study. **Zantop et al[3]. All values are means ± standard errors.

Table 1. Mechanical properties of meniscal repair devices after 1000 cycles between 5 N and 20 N.

The biomechanical properties of an ULTRA FAST-FIX◆ device repair were an improvement over conventional repair systems and were due to improvements in mechanical properties of both the suture and the implant.

## Conclusion

Improvements in suture and implant material in the new ULTRA FAST-FIX meniscal repair device have resulted in a repair system that biomechanically outperforms other meniscal repair systems. The ULTRA FAST-FIX device provides a more stabile and stronger repair, which maximizes the chance of a successful meniscus tear recovery.

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