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smith&nephew
FAST-FIX◇ 360
Meniscal Repair System

The Biomechanical Performance of the FAST-FIX◇ 360 Meniscal Repair System

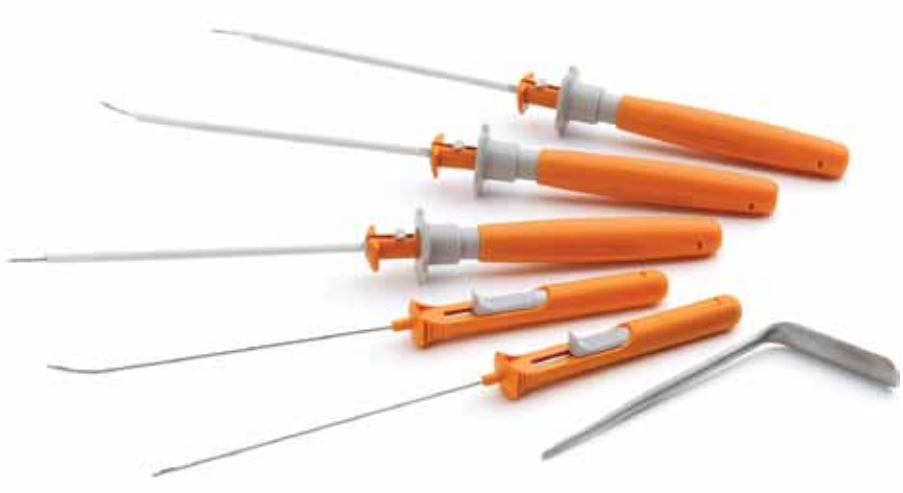
Abstract

The objective of this study was to evaluate the mechanical performance of the new FAST-FIX 360 System compared to other currently available meniscal repair systems. Porcine menisci were repaired using a single vertical stitch from various devices, and meniscal repairs using the inside-out vertical mattress suture were also evaluated. Repaired menisci were cyclically loaded simulating everyday activities and were subsequently pulled to failure. The FAST-FIX 360 System maintained the closest tissue proximity following cyclic loading with a significantly lower displacement than Cayenne™ CrossFix™, Arthrex™ Meniscal Cinch™ and Mitek™ RapidLoc™ Meniscal Repair Systems. When pulled to failure, the FAST-FIX 360 system delivered superior strength with a significantly higher peak load than Cayenne CrossFix, Arthrex MeniscalCinch, Mitek RapidLoc, and Biomet™ MaxFire™ Meniscal Repair Systems. No difference was detected between the performance of the FAST-FIX 360 System and the vertical mattress suture. The superior mechanical performance of the FAST-FIX 360 System could lead to better meniscal repair outcomes in the clinical environment.

Introduction

The FAST-FIX 360 Repair System builds upon the strong mechanical performance of the FAST-FIX System while improving the procedure and reducing the amount of material needed to repair a meniscal tear. Procedural improvements include audible confirmation of push-out implant deployment, the ability to adjust the depth limiter within the joint, and a stiffer needle to allow precise control of repair placement. Improvements include overall smaller repairs with smaller implants, suture and knot size, reducing the amount of material left in the patient's meniscus.

With the improvement of the FAST-FIX 360 System, we hypothesize the mechanical performance of FAST-FIX 360 System will remain strong in comparison to the FAST-FIX System due to the use of high-strength ULTRABRAID◇ Suture, the patented, one-way, self-locking, sliding knot and the optimized implant geometry. The purpose of this study was to assess the mechanical performance of the FAST-FIX 360 System in comparison to the industry standard vertical mattress stitch and other current all-inside meniscal repair devices.



Method

Forty-two fresh-frozen medial porcine menisci were used in this study since porcine menisci have been shown to have similar mechanical properties to human menisci[1], and provide a more mechanically consistent tissue than menisci harvested from humans. Meniscal tears were created using a scalpel blade and a template was used to assure the tear was placed at a consistent distance from the peripheral edge of the meniscus (Figure 1).

Tears were repaired with a single vertical stitch. The following all-inside meniscal repair devices were evaluated and compared with the standard inside-out vertical mattress stitch:

- Smith & Nephew FAST-FIX® 360 Meniscal Repair System
- Smith & Nephew FAST-FIX Meniscal Repair System
- Cayenne™ CrossFix™ Meniscal Repair System
- Arthrex™ MeniscalCinch™ Meniscal Repair System
- Mitek™ RapidLoc™ Meniscal Repair System
- Biomet™ MaxFire™ Meniscal Repair System

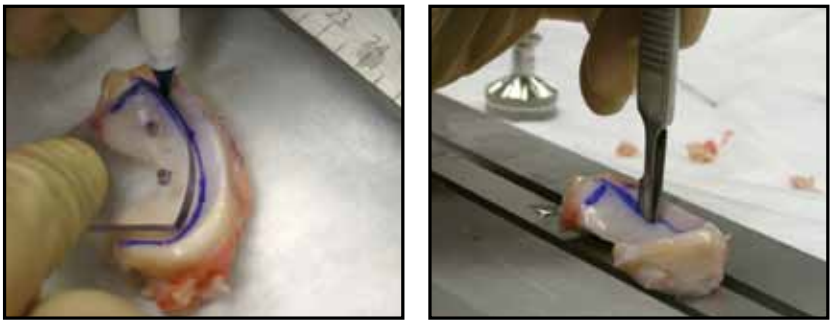


Figure 1. Using a template, porcine menisci were torn using a scalpel blade at a consistent distance from the peripheral edge. Menisci were repaired using various devices providing a single vertical stitch.

The repaired meniscus was secured in a fixture (Figure 2) and subjected to cyclic loading from 5–20 N for 1,000 cycles[2,4], simulating clinically relevant loads hypothesized to occur during daily activities[3]. The displacement after 1,000 cycles of loading was measured, where a low displacement after 1,000 cycles represents a strong system that maintains the proximity of the torn tissue, enhancing the healing process. The repair was pulled to failure at a rate of 12.5 mm/s[2,4] and the peak load and stiffness were measured using MultiPurpose TestWare™ software (MTS Systems, Eden Prairie, Minnesota). A high peak load and high stiffness represents an optimal repair with increased likelihood of surviving a traumatic tissue loading incident. All specimens were kept hydrated throughout all stages of preparation and testing. Statistical analysis was completed using Analysis of Variance (ANOVA) with a Tukey's post-hoc test.

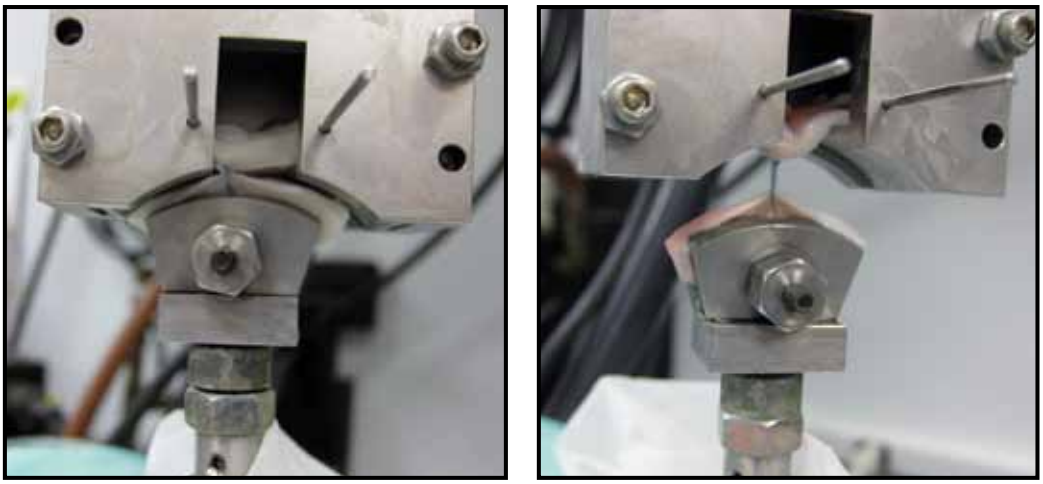


Figure 2. (Left) Pre-test image of repaired porcine meniscus, clamped in a fixture to isolate the repaired site. (Right) Image acquired during the pull-to-failure testing where the upper fixture moves away from the stationary lower fixture, causing the repair to fail.

System/Technique	Displacement after 1,000 cycles, mm (± Std. Dev)	Mean failure load, N (± Std. Dev)	Stiffness, N/mm (± Std. Dev)
Smith & Nephew FAST-FIX 360 Meniscal Repair System	1.99 (0.70)	74.6 (11.3))	23.4 (2.20)
Smith & Nephew FAST-FIX® Meniscal Repair System	2.32 (0.51)	66.6 (5.69)	20.1 (2.02)
Vertical matress stitch (Ticron 2-0)	2.78 (0.47)	74.8 (5.54)	20.5 (1.16)
Arthrex™ MeniscalCinch™ Meniscal Repair System	**4.48 (0.95)***	**51.6 (11.8)****	20.7 (4.81)
Biomet™ MaxFire™ Meniscal Repair System	**N/A***	**15.9 (2.92)****	N/A
Mitek™ RapidLoc™ Meniscal Repair System	**3.59 (0.68)***	**36.9 (1.86)****	**17.1 (1.84)+**
Cayenne™ CrossFix™ Meniscal Repair System	**3.64 (0.73)***	**35.0 (9.85)****	20.2 (1.63)

Table 1. Summary of the mechanical performance of various meniscal repair devices. (*) indicates significantly higher displacement after 1000 cycles than FAST-FIX 360 System. (**) indicates significantly lower peak load than FAST-FIX 360 System, (+) indicates significantly lower stiffness than FAST-FIX 360 System.

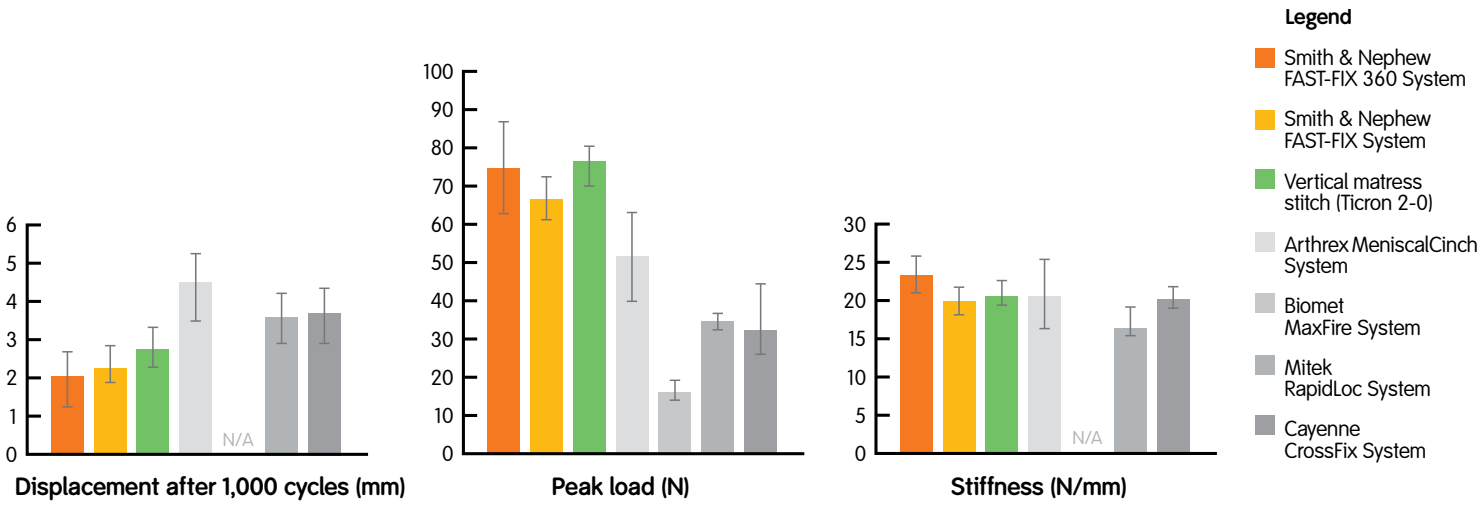


Figure 3. Displacement after 1,000 cycles of cyclic loading. The FAST-FIX 360 System showed a significantly ($p<0.05$) lower displacement than MeniscalCinch, RapidLoc and CrossFix Meniscal Systems. Menisci repaired with MaxFire failed during cyclic loading.

Figure 4. Peak load of various meniscal repair devices. FAST-FIX 360 System produced a significantly ($p<0.05$) higher peak load than menisci repaired using the MeniscalCinch, MaxFire, RapidLoc, and CrossFix Meniscal Systems.

Figure 5. Stiffness during the load-to-failure testing of various devices. FAST-FIX 360 System showed a significantly ($p<0.05$) higher stiffness than the RapidLoc Meniscal System.

Results

FAST-FIX 360 System provides reduced displacement after cyclic loading

The displacement after 1,000 cycles of loading was significantly ($p<0.05$) reduced when menisci were repaired with FAST-FIX 360 System versus CrossFix, Meniscal Cinch, RapidLoc and MaxFire systems(Figure 3). Menisci repaired with MaxFire failed during cyclic loading. There was insufficient power to detect a difference between the displacement after 1000 cycles in menisci repaired with the FAST-FIX 360 System and those repaired using the vertical mattress suture and the FAST-FIX System.

FAST-FIX 360 System delivers higher peak load

The peak load of the FAST-FIX 360 System was significantly greater than the peak load of the RapidLoc, Meniscal Cinch, MaxFire and CrossFix systems ($p<0.05$) (Figure 4). There was insufficient power to detect a difference between the peak load of the FAST-FIX 360 System, the vertical mattress suture and FAST-FIX System.

FAST-FIX 360 System delivers a high repair stiffness

The stiffness of the FAST-FIX 360 System was significantly higher than menisci repaired using RapidLoc Meniscal System (Figure 5).

Conclusion

With a significantly reduced displacement after 1,000 cycles of loading compared to the competition, the FAST-FIX° 360 System has demonstrated the ability to maintain torn tissue in close proximity which provides the optimal foundation for healing. The significantly higher peak load compared to the competition demonstrates an increased likelihood of surviving a traumatic loading incident when menisci are repaired using the FAST-FIX 360 System. The high stiffness of the repair represents a greater amount of force required to separate the torn tissue, creating an ideal repair.

The strong mechanical performance of the FAST-FIX 360 System is likely due to the high strength ULTRABRAID° Suture, patented, one-way, self locking, sliding knot and the optimized implant geometry. In conclusion, the procedural and repair improvements incorporated in the FAST-FIX 360 System maintain the high standard of mechanical performance established in the FAST-FIX product family.

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All data on file at Smith & Nephew, August, 2009; ITR 3969, *"ULTRA FAST FIX System vs Competitors,"* July (2009); ITR 4080, "*FAST FIX 360 System vs Competitors,"* January (2010).

Courtesy of Smith & Nephew, Inc., Endoscopy Division

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