

TRUESPAN™ Meniscal Repair System: System Strength Compared to Alternative All-Inside Meniscal Repair Devices

Objective

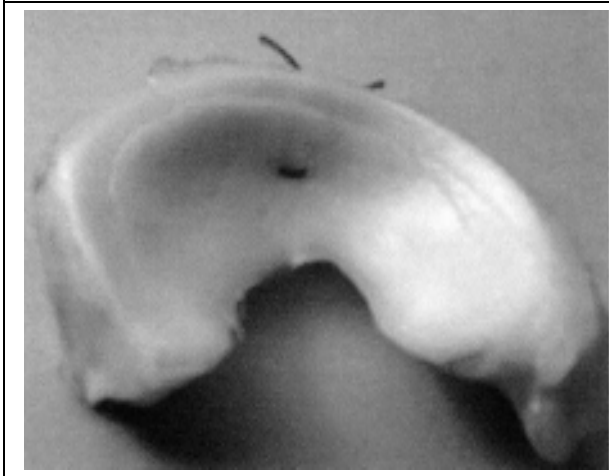
This study was conducted to characterize the system strength of the TRUESPAN™ Meniscal Repair System as well as that of several other commonly used all-inside meniscal repair devices: the OMNISPAN™ Meniscal Repair System, Fast-Fix 360™, and Ultra Fast-Fix™.

Methods

A minimum of 5 samples of each all-inside meniscal repair system were used to repair meniscal tears in young adult porcine menisci. Porcine meniscal tissue was selected as the standardized test medium as it has been established to have similar characteristics as human menisci in external studies^{1,2,3,4,5,6}. Vertical longitudinal meniscal tears were created in the tissue samples with a scalpel, roughly 2-3mm from the periphery.

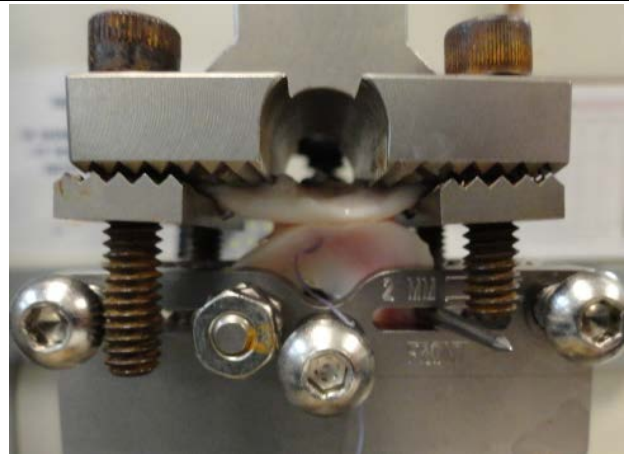
Devices were implanted according to each device manufacturer's instructions / directions for use, with implants placed in a horizontal mattress configuration. The systems were tensioned until the gap in the torn meniscal tissue was held closed by the implant system as shown in Figure 1.

Figure 1, Tissue Sample w/Completed Repair



Tissue samples were securely clamped in a custom test fixture as shown in Figure 2 and attached to a servo-hydraulic tensile test machine for mechanical testing.

Figure 2, Mechanical Test Setup



The mechanical test methods used in this research were based on several previously conducted peer-reviewed studies which investigated meniscal repair devices and techniques^{7,8}.

For this study, a tensile pre-load of 5N was applied to each construct and then the samples were cyclically loaded from 5N to 20N for 1,000 cycles, at a rate of 1 Hz (1 cycle per second). Upon completion of the 1,000 cycles, constructs were pulled in tension until failure at a rate of 12.5 millimeters per second. The peak load observed during the pull to failure portion of the test was recorded as the device's "system strength".

Results

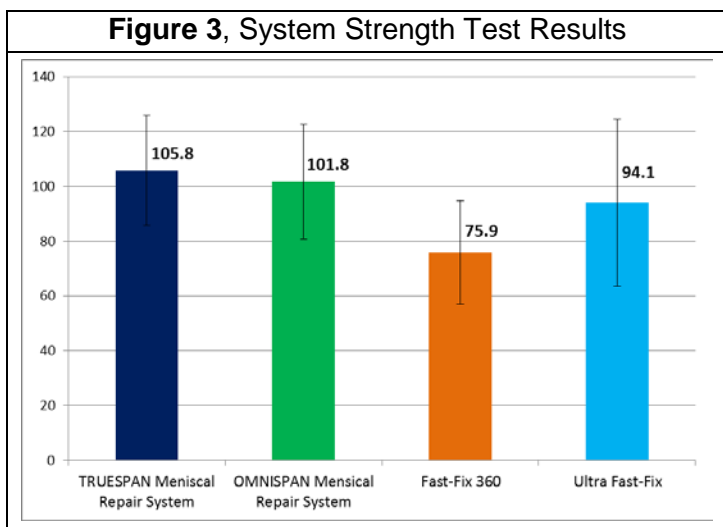
The average system strength results and standard deviations are shown in Table 1, as well as graphically in Figure 3 (the error bars in Figure 3 represent ± 1 standard deviation).

The TRUESPAN Meniscal Repair System was found to have the highest average system strength of the four devices evaluated in this study at 105.7N, while the OMNISPAN Meniscal Repair System was 101.7N, Fast-Fix 360 was 75.9N, and Ultra Fast-Fix was 94.1N.

References:

- 1 - Seil et al, "Cyclic Testing of Meniscal Sutures". Arthroscopy: The Journal of Arthroscopic and Related Surgery. Volume 16, Issue 5 (July-August), 2000: pages 505-510
- 2 - Durselen et al, "Cyclic Joint Loading Can Affect the Initial Stability of Meniscal Fixation Implants". Clinical Biomechanics. Volume 18, Issue 1 (January) 2003: pages 44-49.
- 3 - Barber, F.A. & Herbert, M., "Meniscal Repair Devices". Arthroscopy: The Journal of Arthroscopic and Related Surgery. Volume 16, Issue 6 (September) 2000: pages 613-618.
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- 5 - Chang, H.C., et al, "Biomechanical Evaluation of Meniscal Repair Systems". American Journal of Sports Medicine (AJSM). Volume 33, Issue 12 (December) 2005: pages 1846-1852.
- 6 - Rosso, C., et al, "All-Inside Meniscal Repair Devices Compared with Their Matched Inside-Out Vertical Mattress Suture Repair". AJSM. Volume 42, Issue 9 (September) 2014: pages 2226-2233.
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- 8 - Barber, F.A., et al, "Biomechanical Testing of New Meniscal Repair Techniques Containing Ultra-High Molecular Weight Polyethylene Suture". Arthroscopy: The Journal of Arthroscopic and Related Surgery. Volume 25, Issue 9 (September) 2009: pages 959-967.
- 9 - Internal Data: Test Report 103248458
- 10 - Internal Data: Notebook 2014-10, Pages 5-9
- 11 - Internal Data: Notebook 2014-10, Pages 15-21

Table 1 – System Strength Evaluation Results		
Device	System Strength	
	Average (N)	STDEV (N)
TRUESPAN Meniscal Repair System ⁹	105.8	20.1
OMNISPAN Meniscal Repair System ⁹	101.8	20.9
Fast-Fix 360 ¹⁰	75.9	18.9
Ultra Fast-Fix ¹¹	94.1	30.5



Medos International SÀRL
 Chemin-Blanc 38
 2400 Le Locle
 Switzerland

Distributed in the USA by:
DePuy Mitek, Inc.
 325 Paramount Drive
 Raynham, MA 02767 USA
 Tel: +1 (800) 382-4682