Bio-INTRAFIX™ vs. the Delta™ Screw

A Cyclic Load Study in Cadaver Bone

Background – The pullout strength of devices at time equals zero provides a base line for the product performance but cyclic load data provides an understanding of how the product will perform during rehabilitation. Cyclic loading was used to evaluate the new Bio-INTRAFIX implant from DePuy Mitek (Raynham, MA). The results were compared to the Delta™ screw. **Method –** Bio-INTRAFIX and the Delta screw were implanted into six paired human cadaver knees and cyclically loaded between limits of 50 N and 200 N at a rate of 1/2 Hz for a total of 1000 cycles (33 min., 20 sec). **Results –** The results are based on the data collected from the specimens that survived cyclic loading. Five out of six of the Bio-INTRAFIX devices and three out of six of the Delta screw devices survived cyclic loading (see appendix for details and side by side comparisons). The average migration after 1000 cycles for the DePuy Mitek Bio-Intrafix was 2.28 ± 1.19 mm (n=5) and 2.36 ± 1.29 mm (n=3) for the Arthrex Delta screw. The average ultimate load and stiffness for the DePuy Mitek Bio-Intrafix were 643 ± 152 N and 325 ± 111 N/mm, respectively. The average ultimate load and stiffness for the Arthrex Delta screw were 567 ± 117 N and 169 ± 35.9 N/mm, respectively. **Discussion -** The DePuy Mitek Bio-INTRAFIX when used for hamstring grafted tibial fixation has proven to be stable under cyclic loading, as well as, being strong and stiff. Based on these results, the Bio-Intrafix appears to be less dependent upon bone quality than the Delta screw.

I. OBJECTIVE

The objective of this study was to test the cyclic stability of hamstring grafted anterior cruciate ligament (ACL) reconstructions in the tibial tunnel using the DePuy Mitek Bio-INTRAFIX. The test articles were compared to the Delta Screw. The migration of the ligament complex relative to the tunnel was measured to compare the relative stability of the fixation systems.

II. TEST SYSTEM

A. Test System Specifications

Six matched pairs of human cadaver knees were used in this study. The specimens were screened for gross anatomical defects and degenerative joint disease, and none were found. The knees were obtained from five male and one female donor with an average age of 63 ± 10 years at the time of death.

Six matched pair of knees were used in this study. A tibia and hamstring graft were harvested from each knee. The right or left knee was chosen at random and reconstructed with the DePuy Mitek Bio-INTRAFIX. The contralateral knee was reconstructed with the Delta Screw. Both devices were inserted as per the manufacturer's recommended procedure.

To avoid errors in graft migration measurement due to potential slippage between the graft tissue and the clamp, a video motion analysis system (DMAS, Spica Technology Corp, Maui, HI) was used to assess relative motion of the graft with respect to the tunnel lip. Contrast markers were attached to the bone at the exit of the graft tunnel, and to the soft tissue portion of the graft near its exit from the graft tunnel before placing the graft-anchor-bone complex into the materials test machine for testing. These markers formed a gage length for video measurement of displacement during the cyclic tensile testing.

B. Mechanical Testing

Specimens were mounted in custom fixtures to the materials test machine such that the applied force to the specimen was along the long axis of the graft. Using a high-magnification lens, a video camera (Pulnix TM-1040, 1024x1024x30 fps, Sunnyvale, CA) was focused on the contrast markers attached to the soft tissue graft and bone. The size of the markers in the video window was maximized to achieve the best accuracy and resolution for the video-based length measurements. A reference length was filmed in the same focal plane as the graft and bone markers to allow determination of physical lengths between the markers using the video motion analysis system. The graft-anchor-bone complex was cyclically loaded between limits of 50 N and 200 N at a rate of 1/2 Hz for a total of 1000 cycles (33 min., 20 sec). Load-elongation data was collected continuously until the graft-anchor-bone complex failed or 1000 cycles was reached. Analog load and displacement signals from the materials test machine were acquired on a personal computer using a National Instruments A/D board and LabView software at 25 Hz.

If the graft-anchor-bone complex did not fail during cyclic testing, tensile testing to failure was performed. A 10 N preload was put on the graft along the axis of the tunnel followed by continuous displacement at a rate of 8.5 mm/sec (20 in/min) until the complete failure of the graft occurred. Experimental notes and details including ultimate load and failure mode were recorded manually on a data sheet. During all testing, the graft and bone were kept moist with saline.

C. Data Analysis

The DMAS motion analysis software was used to determine the distance between the bone and soft tissue markers at the peak (200 N) of load application at the thousandth cycle. From this measurement and the initial measurement of distance between the markers at the start of the test, the migration of the graft with respect to the bone (in millimeters) was determined. The average migration after 1000 cycles, load to failure, and stiffness were calculated for both devices.

VII. RESULTS

The average migration after 1000 cycles (n = 5) for the DePuy Mitek Bio-INTRAFIX was 2.28 ± 1.19 mm (See Table 2, below). One Bio-INTRAFIX sample failed at 645 cycles. The matched pair, fixed with the Delta Screw failed at 454 cycles. The average migration after 1000 cycles (n = 3) for the Arthrex Delta screw was 2.36 ± 1.29 mm. Three of the Arthrex Delta screw samples failed before 1000 cycles (avg. of 572 ± 173 cycles). The average ultimate load and stiffness for the DePuy Mitek Bio-INTRAFIX were 643 ± 152 N and 325 ± 111 N/mm, respectively. The average ultimate load and stiffness for the Arthrex Delta screw were 567 ± 117 N and 169 ± 35.9 N/mm, respectively. All of the DePuy Mitek and Arthrex samples, regardless of whether they failed during cyclic testing or ultimate load testing, failed due to the graft slipping past the device (See Appendix A).

Table 2. Average Migration, Ultimate Load and Stiffness for the DePuy Mitek Bio-INTRAFIX and Arthrex Delta Screw When Used For Hamstring Grafted Fixation Within the Tibia.

PROCEDURE	# of knees that survived cyclic loading	MIGRATION AFTER 1000 CYCLES (mm)	ULTIMATE LOAD (N)	STIFFNESS (N/mm)
Bio-INTRAFIX	5/6	2.28 ± 1.19	643 ± 152	325 ± 111
Delta Screw	3/6	2.36 ± 1.29	567 ± 117	169 ± 35.9

VIII. CONCLUSIONS

The DePuy Mitek Bio-INTRAFIX when used for hamstring grafted tibial fixation has proven to be stable under cyclic loading, as well as, being strong and stiff. Based on these results, Bio-INTRAFIX appears to be less dependent upon bone quality than the Delta screw. The one Bio-INTRAFIX sample that failed during cyclic testing was from a donor (04-02004) with very poor bone density. In a clinical situation this patient would have never been a candidate for ACL surgery. It is also worth noting that the Bio-INTRAFIX sample lasted 30% longer during the cyclic testing than the contralateral Delta screw sample.

The stiffness results for the DePuy Mitek Bio-INTRAFIX are the best seen by a tibial device in this lab. In general, the stiffness results are comparable to metal cross pins in the femoral tunnel. Although no actual measurements were taken, visually it appeared that there was no movement of the Bio-INTRAFIX sheath up the tibial tunnel during cyclic or ultimate load testing. This was even true for the sample that failed during the cyclic testing. In contrast, although the Delta screws were left flush with the cortex during the surgery they were usually slightly recessed after testing. The cortical fixation of the Bio-INTRAFIX is most likely a large contributor to its superior stiffness. The stiffness values for both devices are also probably somewhat elevated due to the graft drying during the course of the testing. Although all grafts were sprayed regularly with saline during testing, some drying was evident.

DEPUY MITEK Bio-INTRAFIX						
SPECIMEN	TOTAL MIGRATION	ULTIMATE LOAD	STIFFNESS	GRAFT/TUNNEL	SCREW	
04-03011L	1.48	714	289	8	6-8	*
04-02004R	FAILED after 645 cycles			9	7-9	*
04-0321R	0.70	533	410	7	6-8	*
04-04017R	3.88	459	177	8	6-8	*
04-04002R	1.92	895	490	10	8-10	*
04-02007L	3.41	613	260	9	7-9	*
AVG	2.28	643	325			
STD DEV	1.19	152	111			
ARTHREX Delta Screw						
SPECIMEN	TOTAL MIGRATION	ULTIMATE LOAD	STIFFNESS	GRAFT/TUNNEL	SCREW	
04-03011R	FAILED after 445 cycles			8	9	*
04-02004L	FAILED after 454 cycles			9	10	*
04-0321L	0.749	429	177	7	9	*
04-04017L	FAILED after 816 cycles			8	9	*
04-04002L	2.44	715	209	9	10	*
04-02007R	3.90	557	122	9	10	*
AVG	2.36	567	169			
STD DEV	1.29	117	36			

***Method of Failure = Graft pulled past device.**

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For more information, call your DePuy Mitek representative at 1-800-382-4682 or visit us at www.mitek.com.
DePuy Mitek Inc., 325 Paramount Drive, Raynham, Massachusetts 02767

Data on file at DePuy Mitek.