Bio-INTRAFIX Cadaver Testing
White Paper
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SUMMARY

Tibial fixation of soft tissue grafts has presented a challenge to orthopedic surgeons. The INTRAFIX system has provided surgeons with a strong fixation system for this indication however the trend is toward absorbable fixation system. DePuy Mitek developed an absorbable version of INTRAFIX made with PLA (polylactic acid) and TCP (Tricalcium Phosphate) an osteoconductive material. BioINTRAFIX was tested in cadaver tissue to determine the strength and characteristics of the system. The average pullout strength of the system is 1274N when the recommended sizing scheme is used (DePuy Mitek recommends using a 6-8mm screw in an 8mm tunnel).

INTRODUCTION

Bio-INTRAFIX is a patented, absorbable, tibial fixation system, designed to maximize the strength and stiffness of an ACL reconstruction using soft tissue grafts. The system consists of two TCP/PLA components: the expansion sheath, and the tapered screw. Fixation of the graft inside the tibial tunnel is achieved by first placing the expansion sheath into the tibial tunnel between the soft tissue graft strands and then inserting the screw into the sheath. The implant system compresses the graft against the tunnel and due to the design of the expansion screw, engages the cortical wall at the distal end of the tunnel creating strong, rigid fixation.

The INTRAFIX system has been used clinically since 1999. The non-absorbable system consists of an expansion sheath, molded from High Density Polyethylene and a tapered expansion screw molded from Delrin. The concept of Bio-INTRAFIX has been around for a number of years but the technology has only recently been developed to allow an expandable sheath to be molded out of an absorbable material.

MATERIALS and METHODS

The strength and stiffness of the non-absorbable INTRAFIX system is documented in the literature[1]. Two cadaver studies were performed with Bio-INTRAFIX. The purpose of the first study was to determine if Bio-INTRAFIX is comparable to INTRAFIX in terms of strength. The second study was designed to evaluate two different sizing protocols for the absorbable system.

INTRAFIX vs BioINTRAFIX

Eight paired cadaver tibia were used to perform the testing. The average cadaver age was 67. The bone quality was relatively soft. The semitendinosus and gracilis tendons were harvested, stripped of muscle, whip stitched and sized. The tunnel was drilled to match the graft diameter. The graft was pulled into place, the Trial was used to separate and compress the graft, the sheath was inserted, a guidewire was placed in the center of the sheath and the screw was inserted flush with the cortex. The screw diameter was determined by referring to the standard INTRAFIX sizing recommendations.

The tibia was secured in an Instron mechanical testing machine. The looped portion of the graft was placed over a hook on the Instron machine and pull tested. The peak load to failure for INTRAFIX and BioINTRAFIX was 640N (n=7) and 622N (n=9) respectively. The 622N Bio-INTRAFIX mean strength was not statistically different than the 640N INTRAFIX strength at a 95% confidence interval.

TWO SIZING SCHEMES

Seven paired cadaver knees were used to compare the pullout strength of the BioINTRAFIX implant system utilizing two different sizing schemes. In one group the maximum screw diameter equaled the tunnel diameter (ex, 6-8mm screw in an 8mm tunnel). In the second group, the maximum screw diameter was 1mm larger than the tunnel diameter (ex, 6-8mm screw in a 7mm tunnel). The average cadaver age was 60. The bone quality was considered good. The surgeon was asked to comment on the ease of insertion of each screw.

The mean pullout strength when the maximum screw diameter equaled the tunnel diameter was 1275N (n=7) and the mean pullout strength when the maximum screw diameter was 1mm larger than the tunnel diameter was 856N (n=5). The average pullout strength for the BioINTRAFIX implant when both sizing schemes are pooled is 1067N.

Four out of seven Bio-INTRAFIX screws inserted with a diameter 1mm larger than the tunnel were considered difficult to insert. One screw could not be inserted using this sizing scheme, a smaller diameter screw (using the screw=tunnel sizing scheme) was used to complete the fixation. One set of cadaver knees was removed from the study for very poor bone quality.

DISCUSSION

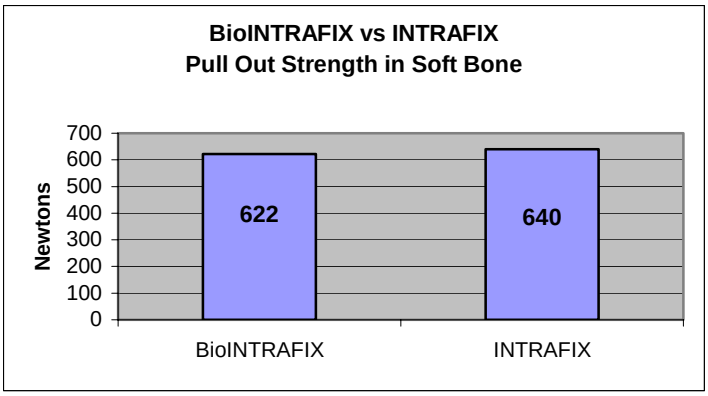
The first test demonstrated that there is no statistical difference in the pullout strength of BioINTRAFIX vs INTRAFIX. The results of the second test demonstrate that using a screw with the maximum diameter equal to the tunnel diameter will reduce the difficulty of inserting a larger screw and provide excellent fixation in a cadaver model.

It is common practice in tibial fixation of soft tissue grafts to use an interference screw diameter that is 1mm larger than the tunnel diameter. But the INTRAFIX and BioINTRAFIX systems use a sheath as well as a screw so a 6-8mm screw has a max diameter of 8mm at the cortical bone plus 1mm of sheath material totaling 9mm. The study performed demonstrated that this construct and sizing scheme provided sufficient fixation in a cadaver model.

The screw diameter is ultimately determined by the surgeon and will vary based on the quality of the patient's bone. This study supports the *maximum screw diameter=tunnel diameter* sizing scheme.

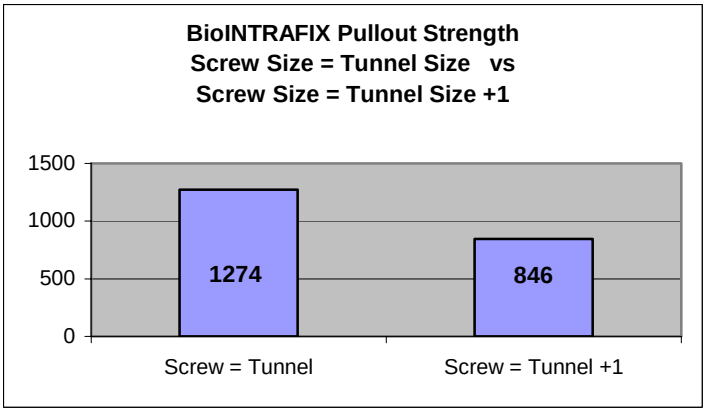
SIZING PROTOCOL

Tunnel	Screw Diameter
7mm	6-8mm screw
8mm	7-9mm screw
9mm	8-10mm screw



SIZING PROTOCOL

Tunnel	Screw Diameter	
	Screw = Tunnel	Screw = Tunnel +1
8mm	6-8mm screw	7-9mm screw
9mm	7-9mm screw	8-10mm screw



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[1.] Kousa P, Jarvinen TLN, Vihavained M, Kannus P, Jarvinen M: The Fixation Strength of Six Hamstring Tendon Graft Fixation Devices in Anterior Cruciate Ligament Reconstruction Part II: Tibial Site. *Am J Sports Med 31: 182-188, 2003*