

Can the Bio-Transfix Pin Fail During Initial ACL Graft Insertion?

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Abstract

Background: The Bio-Transfix pin is a biodegradable device used for femoral tunnel anterior cruciate ligament (ACL) graft fixation. Recent clinical studies have suggested the possibility of the pin's postoperative failure.

Methods: This investigation evaluates the initial strength of several Bio-Transfix pin ACL fixations in a simulated femoral tunnel model. The forces generated by five surgeons during simulated ACL graft tensioning were also measured.

Results: Average strengths of the pins ranged from 1075 to 2160 N for 10 and 8 mm tunnels, respectively, whereas the maximum surgeon-generated forces were 535 N.

Conclusions: These results imply that initial fracture of the pin itself is unlikely; however, failure of the supporting bone or a decrease in pin strength due to biodegradation could account for early loss of the fixation.

The anterior cruciate ligament (ACL) is the most commonly disrupted and reconstructed ligament in the knee, with an annual incidence of roughly 200,000 new injuries and approximately 100,000 graft reconstructions.^{1,2} On the femoral side, fixation of a soft tissue graft

can be performed by a variety of techniques, including interference screw fixation, EndoButton fixation, and transfixation.^{3,4} One of the common methods of transfixation utilizes the Bio-Transfix pin (Arthrex, Naples, Florida), which is composed of biodegradable PLLA (poly-L-lactic acid).

In a recent retrospective case series by Cossey and colleagues,⁵ of the 49 patients who underwent ACL reconstruction with hamstring autograft using Bio-Transfix femoral fixation, 16% had implant deformation or fracture on MRI evaluation, at an average of 20 weeks after surgery. Although the investigators reported no clinical evidence of instability, it seems intuitive that the loss of femoral-sided fixation may eventually lead to graft loosening and instability. Proposed mechanisms of implant failure included fracture at the time of intraoperative graft tensioning, fracture at the time of rehabilitation, and resorption and weakening of implants, followed by failure due to cyclic loading or a combination of these factors.

The purpose of the current study was to evaluate whether excessive tensioning could cause initial fracture of the Bio-Transfix implant. We examined the size of the femoral tunnel and evaluated whether off-center insertion of the implant would affect its load to failure. We also used this model to determine the maximum tensioning forces by surgeons.

Materials and Methods

A model was created to test the Bio-Transfix femoral fixation pin, using 8 and 10 mm holes created in a metal plate holder, in order to simulate typical-sized femoral tunnels used in ACL reconstruction. The use of a metal testing device removed the variable of bone, or Sawbones (Vashon, Washington), strength and allowed determination of the strength of the pin itself. A Bio-Transfix pin was placed over the simulated femoral tunnel and a polypropylene rope, to simulate a graft, was looped around the pin. The

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Figure 1 Experimental set-up using a looped polypropylene rope to tension the Bio-Transfix pin.

diameter of the looped, polypropylene rope was just under 8 mm, to allow placement through the simulated 8 mm tunnel (Fig. 1).

The rope was then attached to the load cell of an Instron 2000 universal material testing machine (Instron, Canton, Massachusetts) and the metal holder to the actuator. The specimens were loaded to catastrophic failure at a rate of 1 mm/sec. Failure was defined as the onset of plastic deformation and failure strength was that load at which the load-displacement curve became nonlinear. Thirty-six specimens were tested for six different scenarios (six specimens each). Each pin was placed over the hole (8 mm or 10 mm) in one of three positions: either centered over the hole or offset 7 mm towards its tip or head, in order to simulate under-insertion and over-insertion, respectively (Fig. 2).

The normal and maximal tensile loads exerted by five orthopedic surgeons on the simulated ACL graft were measured. The surgeons were asked to initially pull on the rope as if they were tensioning an ACL graft intraoperatively and then to exert a maximal force.

Data was analyzed using analysis of variance (ANOVA) and multiple comparison Tukey tests.

Results

Average load to failure with an 8 mm tunnel was significantly greater ($p < 0.0001$) than the average load to failure with a

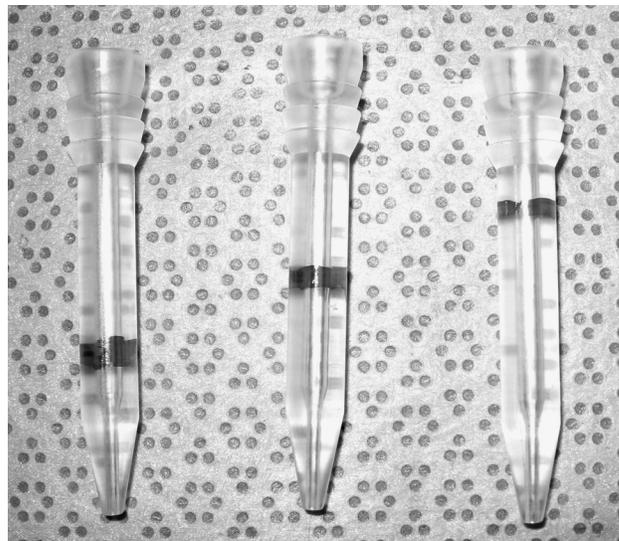


Figure 2 Bio-Transfix pins showing central and off-center loading points.

10 mm tunnel (Table 1). For the 8 mm tunnel specimens, the average load to failure with central insertion was significantly higher than average loads to failure for over-insertion ($p = 0.01$) and under-insertion ($p = 0.002$); there was no difference between the over-insertion and under-insertion groups ($p = 0.53$). The values for load to failure in the 10 mm tunnel specimens showed no difference between any of the insertion groups. The average force of the five surgeons pulling on the rope to simulate intraoperative graft tensioning was 114 N (range, 82 to 186 N), while the mean maximum force was 535 N (range, 450 to 658 N).

Discussion

We found that the Bio-Transfix pin should be able to resist initial loads during insertion and graft tensioning. Other laboratory studies of femoral cross-fixation of hamstring grafts have shown similar results, also in biomechanical testing.⁶⁻⁹ A study by Milano and associates¹⁰ compared the biomechanical behavior of five different femoral fixation devices for the ACL reconstruction with a doubled hamstring tendon graft and found that the Bio-Transfix had the best results in terms of graft elongation, fixation strength, and stiffness; whereas interference screw fixation showed the greatest elongation and the lowest failure load. Ahmad and coworkers⁷ similarly demonstrated that Bio-Transfix and EndoButton techniques resulted in less graft slippage and

Table 1 Average Loads (SD) to Failure for the Three Pin Test Conditions (Six Samples for Each)

Tunnel Size	Pin Position		
	Over-Inserted	Centered	Under-Inserted
8 mm	2150 N (56)	2005 N (78)	1970 N (85)
10 mm	1075 N (36)	1089 N (34)	1078 N (38)

higher ultimate load to failure, compared with Rigidfix® (DePuy Mitek, Inc., Raynham, Massachusetts) and interference screw fixation devices.

While the outcomes of ACL reconstruction with hamstring grafts and femoral transfixation have generally been excellent, several reports of complications with this technique have been described in the literature.^{5,10-12} Marx and Spock¹² noted pin protrusion in two patients (one on the medial and one on the lateral side), with both cases requiring reoperation to address the problem. Pelfort and colleagues¹¹ reported on two cases of iliotibial band friction syndrome resulting from Bio-Transfix pin extrusion and breakage of the implant tail. Neither of those two patients had any evidence of knee instability, but both required a second surgery for removal of the broken pin fragments. Cossey and associates⁵ showed in MRIs performed at 9 to 47 weeks postoperatively that 16% of Bio-Transfix implants were deformed or fractured. Although this did not translate into a detrimental clinical effect in the affected patients, one could surmise that if the loss of femoral-side fixation occurs before adequate healing of tendon to bone is completed (which may take 12 weeks or more¹³), gross motion and instability of the graft may result, potentially leading to clinical failure.

The limitations of this study include the use of a metal testing apparatus to simulate the femoral tunnel used for ACL reconstruction. Whereas this model eliminates the variability associated with cadaver bone and allowed for a reproducible testing set-up, it may not accurately represent the loading conditions experienced in vivo. It is possible that in an in vivo setting, loading of the pin “cuts through” osteoporotic bone at loads below that required for its deformation or fracture. Such a situation coupled with a cyclic loading scenario, rather than a single load to failure, may cause graft loosening at the femoral fixation site at lower loading values than those we found in the current study for failure of the Bio-Transfix device.

The cause of broken pins reported in previous literature may be due to fracture or deformation at the time of insertion (as a result of guidewire kinks leading to increased axial loading while the pin is hammered into place), in vivo resorption coupled with cyclic loading, or other factors. Degradation of PLLA-based implants has been shown to take up to several years in animal studies, with excellent retention of mechanical stability for up to 12 weeks.^{14,15} Future laboratory studies should focus on evaluation of implant failure after immersion in simulated body fluids at 37° for various times.

Disclosure Statements

None of the authors have a financial or proprietary interest in the subject matter or materials discussed, including, but not limited to, employment, consultancies, stock ownership, honoraria, and paid expert testimony.

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