

Static and Fatigue Strength of a Fixation Device Transducer for Measuring Anterior Cruciate Ligament Graft Tension

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To determine which exercises do not overload the graft-fixation complex during intensive rehabilitation from reconstructive surgery of the anterior cruciate ligament (ACL), it would be useful to measure ACL graft loads during rehabilitative activities in vivo in humans. A previous paper by Ventura et al. (1998) reported on the design of an implantable transducer integrated into a femoral fixation device and demonstrated that the transducer could be calibrated to measure graft loads to better than 10 percent full-scale error in cadaveric knees. By measuring both the static and fatigue strengths of the transducer, the purpose of the present study was to determine whether the transducer could be safely implanted in humans without risk of structural failure. Eight devices were loaded to failure statically. Additionally, seven devices were tested using the up-and-down method to estimate the median fatigue strength at a life of 225,000 cycles. The average ultimate strength was 1856 ± 74 N and the median fatigue strength was 441 N at a life of 225,000 cycles. The maximum graft load during normal daily activities is estimated to be 500 N and the 225,000 cycle life corresponds to that of the average healthy individual during a 12-week period. Considering that patients who have had an ACL reconstruction are less ambulatory than normal immediately following surgery and that biologic incorporation of the graft should be well developed by 12 weeks thus decreasing the load transmitted to the fixation device, the FDT can be safely implanted in humans without undue risk of structural failure. [S0148-0731(00)00606-3]

Introduction

To achieve a successful reconstruction of the anterior cruciate ligament (ACL), the fixation devices must be able to support the graft loads generated during both aggressive rehabilitation and activities of daily living. Initially following reconstruction, the fixation devices bear all of the loads generated in the ACL graft. So, to be used with confidence, both the static and fatigue strengths of the fixation devices must be sufficient to support these loads.

The fixation device transducer (FDT) has been developed to measure the in-vivo tensions generated in the human ACL graft. Recent papers have focused on both the measurement accuracy [1] and telemetry electronics [2,3] of the transducer. While the calibration, accuracy, and telemetry transmission for the FDT all appear promising for human use, the structural performance of the transducer has not been tested.

For the FDT to be used with confidence in humans, its static strength should be comparable to the strongest femoral fixation device commonly used in ACL reconstructions. The 1125 N failure load of the bone mulch screw (Arthrotek, Inc., Warsaw, IN) in human bone is much higher than the failure loads of other femoral fixations such as either the button (430 N) or the anchor (312 N) [4]. The first purpose of this study was to determine if the static strength of the FDT is higher than the static strength of the bone mulch screw.

The FDT also must be able to withstand the repetitive daily loads during the first 12 weeks following ACL reconstruction. It is estimated that the maximum daily load in the intact ACL is at most 20 percent of the 2500 N tissue failure strength of the ACL

[5–8], which would correspond to 500 N. A recent case study demonstrated that ossification of a hamstrings graft was complete 12 to 15 weeks following reconstruction [9]. Because aggressive rehabilitation programs recommend restricted activities for 2 to 4 weeks following surgery [10,11], a fixation device will experience loads from normal daily activities for at most 12 weeks following surgery. For normally active people, 12 weeks of activity corresponds to 225,000 ACL loading cycles [12]. The second purpose of this study was to determine whether the FDT could withstand a maximum repetitive load of 500 N for 225,000 cycles by estimating the median fatigue strength of the device.

Methods and Materials

Experiments. The FDTs for testing were manufactured from two pieces of titanium (Fig. 1). One piece was the body consisting of the hexagonal head integral with the hollow threaded portion and the other piece was the beam consisting of a rectangular hollow cross section integral with the smooth solid post. To form the transducer, normally two strain gages would be mounted inside of the hollow rectangular cross section before the beam and body are welded together. For purposes of strength testing, the strain gages were omitted. The two pieces were joined using a yttrium–aluminum–garnet (YAG) laser weld that gave full penetration through the annular cross section of the interface to a depth of 0.8 mm. The autogenous (i.e., no filler material) weld was performed using a pulsed laser in an argon-shielded environment.

The static strength and the median fatigue strength of the FDT were determined using a materials testing machine (Model 458.10 MicroConsole, MTS, Minneapolis, MN). The static and fatigue testing protocols were the same as those used by a manufacturer of orthopedic devices to test a similar commercially available fixation (Bone Mulch Screw, Arthrotek, Inc.) to obtain FDA approval. The FDTs were cantilevered in custom-designed Delrin

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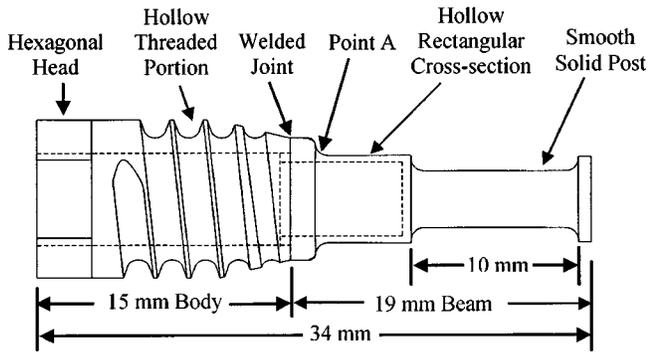


Fig. 1 Diagram of the two-piece FDT. The fillet designated "Point A" marks the failure location for all specimens loaded statically. The welded joint was the region of failure for the two median fatigue strength specimens that failed before 225,000 cycles.

pieces that were mounted between two aluminum blocks attached to the testing machine (Fig. 2). Delrin was used to support the FDT because its tensile modulus (3.0 GPa) is comparable to that of human cortical bone [13]. Devices were aligned in the materials testing machine using a procedure that insured that the long axis of the beam was perpendicular to the axis of motion and that the long dimension of the hollow rectangular cross section was parallel to the axis of motion. Following alignment, loads were applied to the center of the post and measured using a load cell (Model 1010AF-1K-B, Interface, Inc., Scottsdale, AZ). A hydraulically controlled actuator moved the load applicator. The dynamic loading error generated by movement of the load cell during the fatigue tests (described below) was less than 2.0 N at 10 Hz for the largest load amplitudes.

To determine the static strength of the FDT, eight specimens were loaded to failure at a constant displacement rate of 1.27 mm/s. Both load and displacement data were collected at 500 Hz using a personal computer equipped with a data acquisition card.

To estimate the median fatigue strength of the FDT at 225,000 cycles, seven devices were tested using the up-and-down method [14]. This method uses results from a series of fatigue tests to determine the median fatigue strength of a specimen. The load

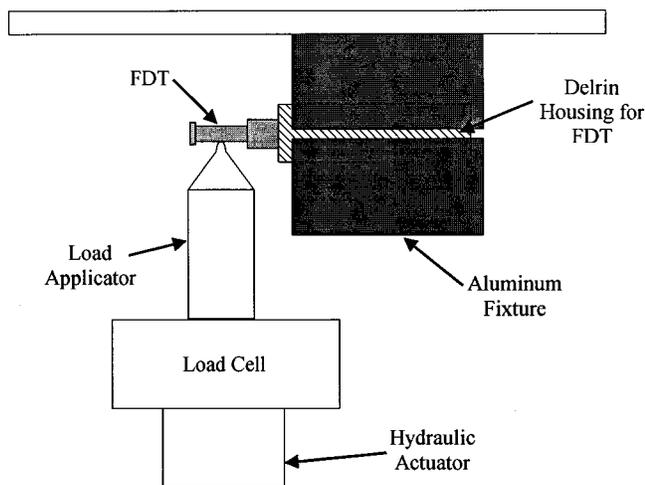


Fig. 2 Testing setup for the static and median fatigue strength tests. The FDT was threaded into the Delrin piece that was clamped in the aluminum fixture. The load applicator was attached to the load cell and moved by the hydraulic actuator. Loads were applied at the midpoint of the 10 mm FDT post.

Table 1 The ultimate loads and failure locations for the eight FDTs tested for static strength. All eight devices failed at the fillet labeled "Point A" in Fig. 1.

Specimen	Failure Location	Peak Load [N]
100	Point A	1806.3
101	Point A	1773.8
102	Point A	1902.4
103	Point A	1756.0
104	Point A	1852.1
105	Point A	1880.6
106	Point A	1900.2
107	Point A	1974.5
Average		1855.7
Standard Deviation		73.7

amplitude for the first test was set at 266 N based on data from pilot tests. Non-reversed loads were applied to the FDT from 44 N to 310 N at a rate of 10 Hz. The test was stopped if the number of cycles exceeded the runout value that was set at 225,000 cycles. Subsequent tests were performed at amplitudes determined by the results of the previous test. If the device from the previous test did not fail before the runout was reached, then the load amplitude for the following test was increased by a pre-defined load increment. If the device in the previous test failed, then the load amplitude for the following test was decreased by the same pre-defined load increment. A load increment of 89 N was used based on fatigue testing of the bone mulch screw (Arthrotek, Inc.). Specimens were tested until a nominal sample size of 6 was reached [14]. The median fatigue strength was estimated under the assumptions that the fatigue strength followed a normal distribution and that the load increment was equal to the standard deviation of the fatigue strength.

Data Analysis. To determine the ultimate load that the FDT can withstand, the ultimate loads from the eight devices were averaged. The location of failure was also noted.

To estimate the median fatigue strength for 225,000 cycles, outcomes of the seven devices were analyzed. The median fatigue strength for the test series was estimated using the initial load amplitude, the load increment, and two factors based on the test series that are listed in published tables [14]. The calculations are shown in the appendix.

Results

The average static failure load for the eight devices was $1856 \text{ N} \pm 74 \text{ N}$ (Table 1). All devices failed at the fillet shown in Fig. 1.

Analysis of the results of the fatigue tests (Table 2) revealed a biased estimate for the median fatigue strength of 447 N for 225,000 cycles. Correcting for the bias by assuming that the stan-

Table 2 Load amplitudes and outcomes for the seven FDTs tested to determine the median fatigue strength. Runout signifies a specimen that did not fail before 225,000 cycles. The test series used to calculate the median fatigue strength was OOX-OOO where O denotes a runout and X denotes a failure. The nominal sample size (n) was six (disregarding specimen 110).

Specimen	Load Amplitude [N]	Test Outcome
110	267	Runout (O)
111	356	Runout (O)
112	445	Failure (X)
113	356	Runout (O)
114	445	Failure (X)
115	356	Runout (O)
116	445	Runout (O)

standard deviation of the fatigue strength is less than 89 N, which is the worst-case scenario, yielded a median fatigue strength of 441 N.

Discussion

Methodological Issues. Because this study was conducted to determine if the FDT will support the graft loads generated following ACL reconstruction in humans, any differences between the FDT design that was tested and the FDT design to be used in future human studies could potentially affect the results. The only major modification that will be made to the FDT used in a human will be the addition of a ceramic hexagonal head that will be brazed to the titanium body to enable inductive powering of the telemetry electronics. The addition of the ceramic-titanium brazed joint will not decrease the static strength of the FDT if the strength of the brazed joint can support the shear stresses at the interface. For a 500 N applied load to the center of the beam, a simple worst-case analysis [15] showed that the shear stress at the brazed joint will be less than 4.0 MPa, which is smaller than published strength values for a ceramic-titanium brazed joint by more than an order of magnitude [16]. So, the addition of the ceramic hexagonal head to the longer titanium threaded body will not change the critical failure point of the implanted FDT as determined by this study.

The static strength of the FDT was defined as the ultimate load rather than the yield load based on a clinical criterion for static failure. Clinically, permanent deformation of the fixation following reconstruction will result in increased laxity and an unsuccessful reconstruction. Because side-to-side laxity differences between 3 and 5 mm have been considered acceptable for defining a successful reconstruction [10,17], a permanent displacement of 0.5 mm is a reasonable criterion of static failure clinically. However, in applying this criterion to calculate the yield load for the static specimens using a 0.5 mm offset on the load-displacement curves, six of the eight devices did not yield before the ultimate load. The two devices that did yield before the ultimate load did so at only a slightly lower load. So, based on this clinical definition of yielding, there was no difference between the yield load and ultimate load for the eight FDTs tested.

Interpretation of Results. The 1856 N ultimate load of the FDT is higher than the 1125 N ultimate load of the bone mulch screw because of the differences in the post designs between the two fixations. Unlike the FDT, the post of the bone mulch screw is not cantilevered, but is driven into the cancellous bone in the medial wall of the graft tunnel. During testing in human bone, the bone mulch screw failed because the tip of the post pulled out of the cancellous bone and bent at its base. Therefore, the bone-device interface around the threaded portion of the bone mulch screw was stronger than the device itself. Because the post of the FDT is cantilevered in the bone and not simply supported on the medial end like the post of the bone mulch screw, the cross-sectional area of the FDT post was increased to reduce the stresses generated by the applied loads. While the FDT failed by the same mechanism as the bone mulch screw (i.e., bending of the post at the base), the increased cross-sectional area of the post resulted in a higher ultimate load compared to the bone mulch screw.

Because the ultimate strength of the FDT in Delrin is higher than the ultimate strength of the bone mulch screw in human bone and because the bone-device interface was stronger than the bone mulch screw, the FDT-bone complex should support loads at least comparable to the bone mulch screw. Although the Delrin bushing supported the FDT to loads of at least 1856 N, the bone in the human femur may fail below these loads. However, because the FDT has an identical thread profile to the bone mulch screw, the FDT should be similarly fixed in human femoral bone and the post will not fail below 1125 N. Considering that the bone mulch screw has reliably supported the graft loads in human ACL reconstructions [10,18], it is unlikely that loads greater than 1125 N are

generated in the graft. So, the FDT should provide adequate static strength to support the loads generated in human ACL grafts.

Although the 441 N median fatigue strength of the FDT is somewhat lower than the maximum estimated load generated in the native ACL during daily activities, nevertheless it should be adequate to support the graft loads during recovery from an ACL reconstruction for two reasons. One reason is that 500 N is the *maximum* estimated graft load during normal daily activities and is not necessarily the typical graft load. It is expected that the majority of the loading cycles would be from walking, an activity that would develop graft loads below this maximum in all likelihood. How far below remains an open question until the graft loads can be accurately determined during walking in humans, which has not yet been done, to the knowledge of the authors. Nevertheless, a decrease in the typical graft load would decrease the fatigue strength requirement of the FDT.

A second reason is that the number of cycles where the FDT supports normal graft loads will be substantially less than 225,000 cycles. Immediately following reconstruction, patient discomfort will limit activities with the result that graft loads will be lower than loads in the native ACL [19]. As the discomfort decreases, the patient will engage in more active normal activities (i.e., walking, stair climbing) and rehabilitative exercises (i.e., weightlifting, bicycling, running, or jumping) that will generate higher graft loads. Although the graft loads may increase in the weeks following reconstruction, the developing biological bond between the graft and bone tunnel will shoulder a greater proportion of these loads and decrease the loads transmitted to the fixation devices. As demonstrated in an in vivo FDT study [15] and in other animal studies [19], the development of the biological bond between the graft and bone tunnel is well advanced within 4 weeks following reconstruction, indicating that very little load will be transmitted to the fixation devices. While bone growth in animals is faster than in adult humans [13], the bond in humans is still well developed by 12 weeks following surgery [9]. Therefore it is unlikely that the FDT will be required to support normal graft loads for more than a few weeks, and by the twelfth week, the transmitted loads should be very small if not zero. Since there is an inverse relation between fatigue strength and fatigue life, decreasing the number of loading cycles below 225,000 would increase the fatigue strength accordingly. Both of these reasons will work in concert to decrease any risk of fatigue failure.

A recently completed study where the FDT was used in an animal model [15] also lends confidence in the ability of the FDT to support typical graft loads without risk of fatigue failure. Devices were implanted in 15 sheep using an extra-articular procedure in which the common digital extensor tendon was detached from its origin and looped around the beam of the FDT. Following surgery, animals ambulated freely so that the contraction of the muscle supplied cyclic loading to the FDT. Although the muscle force was not measured, possibly the force applied to the FDT was greater than what would be developed in a human ACL during walking since the force was applied directly by the muscle. Animals were sacrificed up to 6 weeks, at which time the biological bond was already well advanced, and in no case was there any sign of fatigue damage.

While the fatigue strength of the FDT per se may be adequate, failure of the fixation device could still occur as a result of fatigue failure of the cancellous bone support. Assessing the potential for fatigue failure of the bone is complicated, since the bone is a living tissue formed during healing and then continuously remodeled with time. Although remodeling occurs relatively slowly so that it may not affect bone properties during the 12-week postoperative healing period [20], woven bone formation occurs at a rate exceeding 30 microns/day [21]. Thus bone formation occurs at a rate that may be sufficient to render fatigue failure of the bone support itself of no practical concern.

Since this is not known definitively, however, measures will be taken when the FDT is implanted into human patients to prevent

structural failure of the fixation device in the event of structural failure of the bone support. One measure will be to lengthen the beam portion of the FDT by several mm, and a second measure will be to counterbore the transfemoral tunnel in which the FDT is inserted on the medial wall of the femoral tunnel in which the graft is inserted. The diameter of this counterbore will be about 2–3 mm greater than the diameter of the flange at the tip of the beam (Fig. 1). When the FDT is inserted, the flange will be centered in this counterbore. The clearance will allow for deflection of the cantilevered beam to preserve the calibration of the FDT but will limit the angulation of the FDT in the event of structural failure of the bone because the flange will bottom out in the counterbore. By limiting the angulation of the FDT, the stability of the knee will be preserved.

Acknowledgments

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Appendix

Estimation of the median fatigue strength for the FDT at 225,000 cycles assuming a normal distribution of fatigue strength and using a maximum likelihood analysis.

$$\hat{S}_{50} = S_{a,1} + (\delta S_a)K - (\text{bias})\sigma \quad (A1)$$

where:

$S_{a,1}$ = estimated median fatigue limit

\hat{S}_{50} = initial load amplitude (266 N)

δS_a = load increment (89 N). This value was selected based on bone mulch screw testing.

K = K -factor based on test outcome (OOXOXOO). Assuming a normal strength distribution and a $\delta S_a/\sigma = 1.0$, the K -factor for this case is 2.0385 according to Table 2.6 [14].

bias = correction factor used when the estimated median fatigue limit differs from the initial load amplitude

σ = standard deviation of the fatigue strength distribution (assumed to be 89 N)

So,

$$\hat{S}_{50, \text{biased}} = 266 \text{ N} + 89 \text{ N} * 2.0385 = 447.4 \text{ N} \quad (A2)$$

Since this estimator is biased, the bias correction is calculated by the ratio

$$\frac{S_{a,1} - \hat{S}_{50}}{\sigma} \quad (A3)$$

which is -2.03 .

Then from Table 3.9 [14], the worst-case scenario (assuming an overestimation of σ) would yield a bias correction of 0.0757.

So,

$$\hat{S}_{50} = 447.4 \text{ N} - 0.0757 * 89 \text{ N} = 440.8 \text{ N} \quad (A4)$$

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