In Vivo Calibration of a Femoral Fixation Device Transducer for Measuring Anterior Cruciate Ligament Graft Tension: A Study in an Ovine Model

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Toward developing a transducer for measuring in vivo tension in anterior cruciate ligament grafts in humans, the objectives of this study were to determine the following: (1) whether the calibration of a previously reported femoral fixation device transducer (FDT) (Ventura et al., 1998) is affected by the presence of the graft when implanted in the tibial metaphysis of an ovine model, (2) whether the FDT remains calibrated at 4 weeks postoperatively, and (3) whether the biological incorporation of the graft occurs prior to a change in the FDT calibration. The FDT was implanted in the hind limb of five sheep using an extra-articular procedure. Both the proximal common digital extensor tendon (i.e., graft) and a Teflon-coated wire were looped around the FDT inside a tunnel in the tibial metaphysis. The FDT was calibrated on three occasions using the loop of wire: once intraoperatively before graft insertion, once intraoperatively after graft insertion, and once postoperatively after the animals had been sacrificed at 4 weeks. Following sacrifice, the load transmitted to the FDT by the graft was also determined. The FDT exhibited linear calibration intraoperatively both before and after graft insertion with an average error relative to the calibration before insertion of the graft of −4.6 percent of full-scale load (150 N) and this average relative error was not significantly different from zero ($p = 0.183$). After 4 weeks of implantation, the average relative percent error was −5.0 percent and was not significantly different from zero ($p = 0.434$) indicating that the FDT remained calibrated in the in vivo environment. Because only 15 percent of the graft tension was transmitted to the FDT after 4 weeks, biological incorporation of the graft preceded the loss of calibration. In light of these findings, the FDT offers the capability of measuring the intra-articular ACL graft tension in vivo in animal models and possibly humans before the biological bond develops and also of monitoring the formation and maturation of the biological bond between a graft and bone tunnel.
[DOI: 10.1115/1.1385842]

Introduction

It would be useful to know the loads generated in an anterior cruciate ligament (ACL) graft during rehabilitation to design a rehabilitation program that allows a safe, early return to daily activities (i.e., walking, stair climbing) and exercise (i.e., weight lifting, bicycling, running, or jumping). Since the fixation method is generally the weakest link in the graft-fixation complex, activities of daily living and strenuous exercise may cause fixation failure if the tensile loads transmitted by the graft to the fixation are greater than the strength of the fixation [1–4]. An implantable transducer that directly measures the ACL graft loads transmitted to the fixation would determine the activities that place the graft-fixation complex at risk for failure.

A fixation device transducer (FDT) that accurately measures tension transmitted to the device by an ACL graft in-vitro [5] and accompanying telemetry to transmit and record the transducer signal external to the body [6,7] have been developed in our laboratory. The FDT is a modification of an existing femoral fixation device (bone mulch screw, Arthrotek, Inc., Warsaw, IN) that secures a double-looped semitendinosus and gracilis (DLSTG) hamstring graft. The graft is looped around a beam that extends from the threaded body of the FDT inside the femoral tunnel. The FDT is instrumented with two foil-backed strain gages so that shear strain in the beam can be detected. Because the beam is cantilevered, the shear strain measured by the two strain gages is affected only by the magnitude of the total load applied by the graft and not by the position the load is applied along the beam [1]. A microcircuit contained within the body of the FDT converts strain into a frequency-modulated signal. The telemetry system housed in the body of the FDT permits signal transmission via skin-dwelling electrodes without the use of transcutaneous wires [6,7] By recording the voltage output of the FDT, the total tensile loads transmitted to the FDT by the graft can be measured if the calibration of the FDT is known and does not change after implantation.

Although the FDT has been proven to measure intra-articular graft tension accurately in cadaveric knees, the transducer requires in vivo testing in an animal model before its use can be justified in humans. This is because several factors that might affect measurement accuracy are unique to the in vivo environment. One factor is the graft, whose insertion in the bone tunnel could change the intra-operative calibration. To ensure that the FDT is properly positioned and functioning, the FDT must be calibrated intraoperatively before the graft is inserted. Calibration prior to graft insertion may be performed by passing a wire loop (i.e., cable) around the beam and measuring the voltage output produced from the application of known tensile loads to the cable. However, the graft could cause a change in this calibration if the presence of the graft changes the boundary conditions of the beam. If insertion of

Contributed by the Bioengineering Division for publication in the JOURNAL OF BIOMECHANICAL ENGINEERING. Manuscript received by the Bioengineering Division March 7, 2000; revised manuscript received February 27, 2001. Associate Editor: R. Vanderby, Jr.

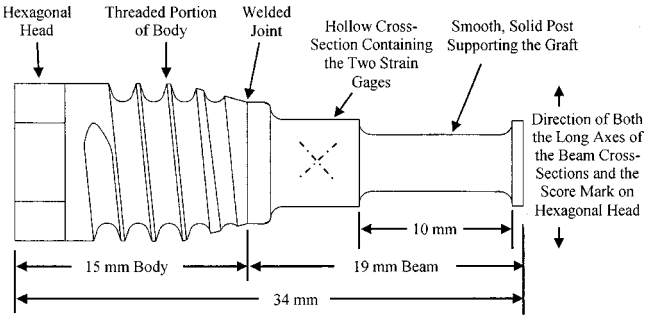

Fig. 1 Diagram showing the threaded body and hexagonal head welded to the instrumented beam of the FDT. The strain gages were applied to the larger rectangular section and oriented at ±45 deg relative to the long axis of the beam. The threaded body and hexagonal head were hollow to accommodate the three-pronged socket for data transmission.

the graft changes the initial calibration, then a second calibration would be required thus increasing the time and complexity of the surgery. To determine whether the FDT can be calibrated only once intra-operatively before insertion of the graft, the first objective was to test the hypothesis that the intra-operative calibrations before and after graft insertion were similar in an ovine model.

Three other factors that may cause the intra-operative calibration to change are bone formation, cancellous bone failure, and rotation of the FDT. The calibration may change either because of bone formation that limits deflection of the beam, because of cancellous bone failure around the body of the transducer resulting in angulation of the beam in the graft tunnel, or because of FDT rotation about the axis of the transverse tunnel. Because the FDT will not accurately measure transmitted graft tension during either activities of daily living or intensive exercise unless the calibration remains unchanged for several weeks after implantation, the second objective of this study was to test the hypothesis that the FDT calibration following 4 weeks of implantation in an ovine model remains similar to the intra-operative FDT calibration.

A final factor that may affect the measurement accuracy of the FDT is the biological bond that forms between the graft and the bone tunnel. After implantation, the force transmitted to the FDT is expected to decrease below the intra-articular graft load. The decrease may be caused either by a calibration change due to one of the factors noted above or by load sharing between the biological bond of the graft in the bone tunnel and the beam. Depending on the cause of this decrease, it may be possible to use the FDT to monitor the development of the biological bond. If the biological bond develops before the calibration of the FDT changes, then the growth of the biological bond can be tracked by measuring the difference between the FDT output for a given activity over time. To justify using the FDT as a tool to detect the formation and measure the development of the biological bond, the third objective was to test the hypothesis that the biological bond forms before the FDT loses calibration.

Methods and Materials

Experiments. To accommodate the bond structure of the ovine model, the FDT was designed 5 mm shorter than the transducer used in vitro in human cadaveric knees [5,7]. Each transducer was comprised of two titanium pieces; one was a 19 mm long beam with a hollow rectangular cross section merged with a smaller solid rectangular cross section measuring 3.8 mm × 2.5 mm and the other was a hollow cylindrical body that measured 15 mm in length and 8 mm in outside diameter. Twelve millimeters of the body were threaded to purchase in the bone (Fig. 1). The remaining 3 mm length of the body was machined to a hexagonal head that fit a 9 mm socket to facilitate insertion into the bone. Two foil-backed strain gages (PA05-062RB-350 LEN, JP Technologies, Inc., San Bernadino, CA) oriented at ±45 deg relative to the long axis of the beam were mounted on two of the internal surfaces of the hollow rectangular cross section of the beam. A score mark was etched on the hexagonal head of the threaded body and the beam and body were welded together such that the long axis of the beam's rectangular cross section (i.e., the gaged surface) was parallel to the score mark on the threaded body. A 12 mm (O.D.) cap of ultra-high-molecular-weight polyethylene (UHMWPE) was constructed to fit over the hexagonal head of the FDT after implantation. Telemetry was not installed in the transducer because continuous in-vivo measurements were not needed for the data collection in this study. A three-pronged miniature connector (DR-3S-3, Microtech. Inc., Boothwyn, PA) was installed in the threaded body to allow for signal transmission to a strain amplifier (SG71 Strain Gage Amplifier, Validyne, Northridge, CA). Medical grade silicon (MED-6015, Nusil Technology, Carpenteria, CA) was used to create a hermetic seal between the socket and the threaded body.

Under general anesthesia, the FDT was implanted into the right hind limb of five skeletally mature black-faced Suffolk sheep. An extra-articular procedure was used so that the biological bond could be measured without the graft failing during post mortem tensile tests to be described shortly [8]. The origin of the common digital extensor tendon was detached from the lateral femoral condyle through an 8 cm vertical incision placed lateral to the patellar tendon (Fig. 2). Four centimeters of the free end of the tendon were sutured with #1 Ethibond (Ethicon, Inc., Somerville, NJ). The graft was formed by folding the tendon in half to double its thickness and trimming the width until it could be passed through a cylinder 10 mm in diameter (sizing sleeve, Arthrotek, Inc).

The location of the tunnel to house the FDT was selected by drilling a guide wire 2.4 mm in diameter from anteromedial to

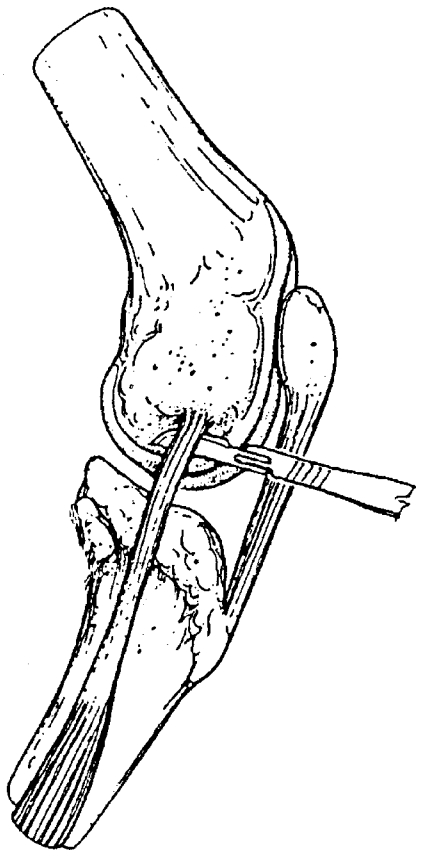

Fig. 2 Diagram showing the detachment of the common digital extensor tendon from its origin on the lateral femoral condyle

posterolateral across the proximal tibial metaphysis 10 mm distal and parallel to the tibial articular surface. A tunnel 12 mm in diameter was drilled through the anteromedial cortex to a depth of 5 mm using a cannulated reamer. The 12 mm tunnel was needed to allow the FDT to be fully seated using a hex screwdriver and to allow the UHMWPE cap to be countersunk. The tunnel for the FDT was completed by drilling a 37 mm in length $\times$ 8 mm in diameter closed-end tunnel using a cannulated reamer from the anteromedial surface of the tibia over the same 2.4 mm guide wire. The tunnel was drilled 3 mm longer than the transducer to ensure that the tip of the beam would not contact bone when the FDT was inserted. A modified guide (U-guide, Arthrotek) was used to drill a graft tunnel 10 mm in diameter from the anterolateral surface of the tibia that intersected the FDT tunnel 8 mm from the lateral end. This created a 3 mm in length $\times$ 8 mm in diameter recess in the lateral wall of the graft tunnel to ensure that the tip of the FDT did not contact bone when fully inserted.

To calibrate the transducer, a 0.5 m long loop of Teflon-coated stainless steel cable 0.91 mm in diameter was inserted up the graft tunnel and the FDT was advanced so that the beam passed through the loop of cable. The transducer was advanced until the hexagonal head of the threaded body was level with the medial tibial cortex and the tip was not touching any surrounding bond. The FDT was aligned rotationally using an alignment tool with a hollow cylindrical portion 10 mm in outer diameter and a forked end that was wider than the beam of the FDT (Fig. 3). The two free ends of the cable were threaded through the hollow center of the alignment tool and the forked end of the tool was advanced into the graft tunnel such that the fork fit around, but did not touch the FDT. An **L**-shaped wrench was fit over the head of the FDT such that the wrench handle was parallel to the score mark on the hexagonal head. The FDT was rotated using the wrench until the wrench handle was parallel to the cylindrical tool protruding from the graft tunnel. This ensured that the gaged surfaces were aligned parallel to the long axis of the graft tunnel, which minimized the calibration error of the FDT [5]. The UHMWPE cap was fit over the hexagonal head of the FDT to allow the cortical bone to provide additional support to the transducer.

The initial intra-operative calibration (i.e., before insertion of the graft) was performed by crimping the two ends of the cable with an aluminum cable sleeve and hooking the cable to a sterile hand-held load cell (SSM-AJ-100, Interface, Inc., Scottsdale, AZ) that was connected to a strain gage amplifier. A sterile wire was used to connect the three-pronged connector in the FDT to the strain amplifier. Manual tension was applied to the FDT through the load cell and cable in line with the alignment tool and tunnel to a load of 150 N at an approximate rate of 25 N/s, and data were collected using a data acquisition card (AT-MIO-16E-2, National Instruments, Austin, TX) and a personal computer. Eight calibration curves were obtained.

A second intra-operative calibration was performed using the same loop of cable after the graft was inserted. The graft was passed up the tunnel, looped around the post of the FDT, passed back out the tunnel and sewn to itself with #1 Ethibond (Ethicon, Inc., Somerville, NJ) (Fig. 4). Using the cable, the calibration procedure was performed a second time with the graft in place. Since the alignment tool was not used with the graft in the tunnel, the direction of pull was approximated to be along the axis of the graft tunnel. The cable was left in place around the beam with the free ends protruding from the tunnel and the wound was closed in layers.

Following surgery, the animals were cared for up until the time that they were sacrificed. The operated leg was placed in a modified Robert–Jones pressure bandage for 24 hours postoperatively. To prevent infection, peri/post-operative broad-spectrum antibiotic (Naxcel, 2 mg/kg, SmithKlein Beecham, Philadelphia, PA) was administered every 24 hours 1 day prior to and 7 days postsurgery. Each animal received oral analgesics (Buprenex, Reckitt & Coleman Pharmaceuticals, Richmond, VA, 0.0075 mg/kg) every 12 hours for at least 48 hours postoperatively. Each animal was confined to its own cage that measured 3.66 m$\times$1.22 m and they were allowed to ambulate ad libitum. Because a study in a canine model showed that biological bonding begins as early as 2 weeks and is fairly well developed by 4 weeks postoperatively

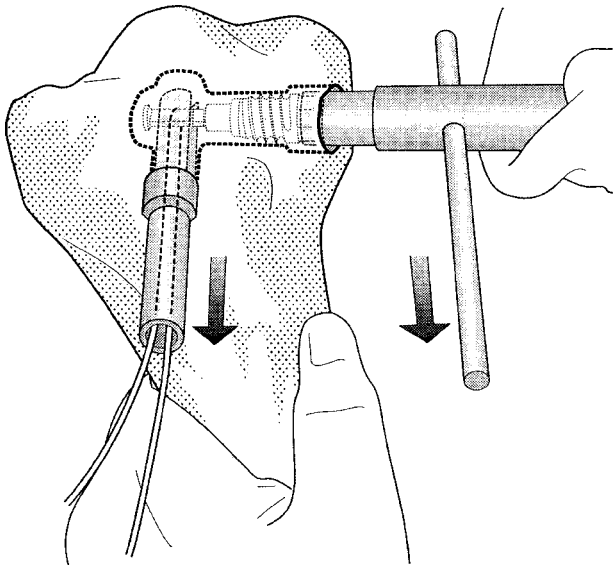

Fig. 3 Diagram showing alignment of the L-shaped wrench to the hollow cylindrical alignment tool. The alignment tool was inserted into the graft tunnel with the cable passing through the center. The L-shaped wrench fit over the hexagonal head of the FDT such that the rod pointed in the direction of the long-axis of the cross section of the FDT beam. When the rod of the L-shaped wrench was parallel to the hollow alignment tool, the FDT was oriented correctly.

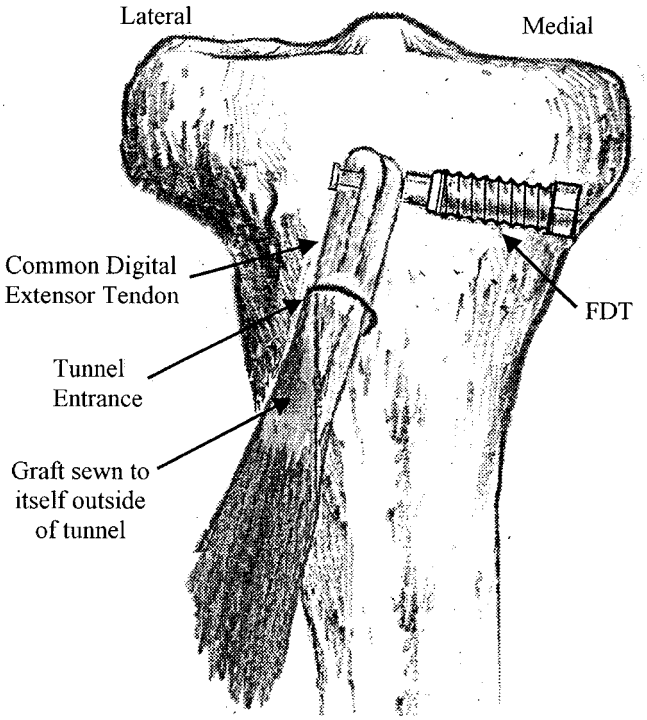

Fig. 4 Diagram of the completed FDT surgery. The common digital extensor graft was looped around the post of the FDT and passed back out of the graft tunnel where it was sewn to itself.

[8], euthanasia was performed by intravenous injection (B. Euthanasia, Chering-Tlough Animal Health Organization, Kenilworth, NJ, 20–30 cc) 4 weeks postoperatively. The operated limb was removed from each animal and anteroposterior and lateral roentgenograms of the proximal tibia were obtained to determine the cable's position relative to the beam.

The limb was prepared for testing in a materials testing machine (Instron 5566 Materials Testing Machine, Instron Corp., Canton, MA) by disarticulating the tibia from the knee, and removing all soft tissue except the graft and the common digital extensor muscle. To ensure that all of the loads applied to the graft would be transmitted either to the FDT or to the biological bond between the graft and bone tunnel, the graft (i.e., tendon) and common digital extensor muscle were freed from the cortical surface of the tibia. The cable was also freed from any surrounding tissue by gently sliding it over the beam. The diaphysis of the tibia was potted into an aluminum cylinder using polymethylmethacrylate (PMMA) so that it could be mounted in a custom-designed four-degree-of-freedom fixture that was attached to the materials testing machine. To ensure that all applied loads were along the axis of the graft tunnel, the potted tibia and fixture were adjusted until the long axis of the graft tunnel was concentric with the axis of the materials testing machine (Fig. 5). The cable was closed into a continuous loop and hooked to the crosshead of the materials testing machine. Because the roentgenograms of several specimens showed that the cable was not fully resting on the beam, a 150 N load was applied to ensure that the cable contacted the beam and was then removed. To determine whether the FDT remained calibrated in the ovine, eight calibrations were performed by moving the crosshead of the materials testing machine at a rate of 20 mm/min until a total of 150 N had been applied to the cable. The rate of movement of the crosshead applied the load to the cable at a rate similar to that when the load was applied manually to the cable intraoperatively.

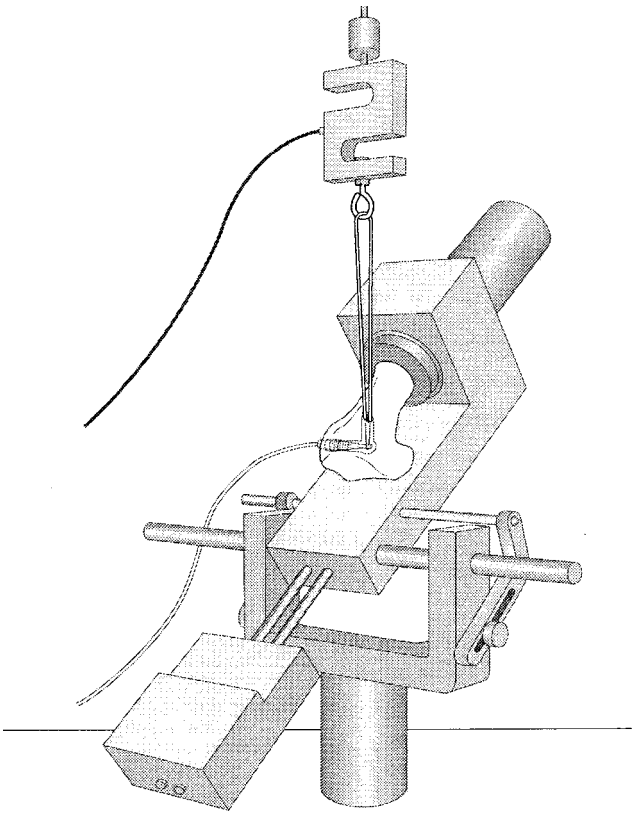

Fig. 5 Diagram of the testing setup showing the alignment of the bone tunnel with the axis of the materials testing machine

To determine the percentage of graft load transmitted to the FDT, a load was applied to the graft and the FDT output was recorded. A custom-designed freeze clamp was attached to the crosshead of the materials testing machine and the tendon was gripped with the clamp approximately 10 mm from the tunnel entrance. The crosshead displaced the tendon at 20 mm/min until either 150 N had been applied to the graft or the graft ruptured. Following this test, the FDT was removed from the tibia and recalibrated on the bench to insure that the in vivo environment did not alter calibration. The recalibrations confirmed that the in vivo environment did not affect the calibration of the FDTs.

Data Analysis. To determine the FDT calibration before the graft was inserted, all the voltage versus load values for the eight calibration trials for each specimen were combined (approximately 800 data points) and a least-squares linear regression was performed. The calibration factor (Newtons/Volt) was defined as the reciprocal of the sensitivity (i.e., slope) of the voltage-load curve. The voltage output multiplied by the calibration factor yielded the force registered by the FDT.

To determine whether the graft changed the calibration, the comparison between the two calibration curves required that one be chosen as the standard. The calibration before the graft was inserted was used as the standard because this calibration must always be performed to verify that the FDT is functioning. For each specimen, the relative percent error from inserting the graft was calculated by multiplying the voltage difference between the standard calibration (i.e., before graft insertion) and the calibration after the graft was inserted at 150 N by the calibration factor of the standard calibration. This yielded a load difference that was divided by 150 N and multiplied by 100 to obtain a relative percent error. The relative percent error was then tested statistically using a *t*-test to determine whether the average relative percent error was significantly different from zero.

To determine whether the FDT remained calibrated after implantation, the post-mortem calibration data were reduced as previously described to determine the regression coefficient and calibration factor. Preliminary analysis was done on specimens to determine whether they had *R*-squared values greater than 0.990 for both the post-mortem calibration and the intra-operative calibration before graft insertion, and whether they had less than a 20 percent difference in voltage output between the standard and post-mortem calibration at 150 N. For these specimens, the relative percent error of the post-mortem calibration compared to the standard calibration (i.e., before graft insertion) was calculated by multiplying the voltage difference between the standard calibration and the post-mortem calibration at 150 N by the calibration factor of the standard calibration. This yielded a load difference that was divided by 150 N and multiplied by 100 to obtain a relative percent error. The relative percent error was then tested statistically using a *t*-test to determine whether the average relative percent error was significantly different from zero.

To determine whether the FDT remained calibrated after formation of the biological bond, the development of the biological bond at 4 weeks was quantified. For each specimen that maintained an unchanged post-mortem calibration, the percentage of graft load transmitted to the FDT was computed. The voltage output of the transducer for a 150 N load applied to the graft was multiplied by the calibration factor of the post-mortem calibration, divided by 150 N, and multiplied by 100 to report the value as a percent. Because some tendons ruptured before 150 N was reached, the development of the biological bond for these specimens was measured at the highest load applied to the tendon before rupture. The relative percent change in load was then tested statistically using a *t*-test to determine whether the average relative percent change was significantly different from zero.

Results

The intra-operative calibrations both before and after the graft was inserted compared favorably. The average *R*-squared values

Table 1 Calibration factors in Newtons/Volts (R^2-values) and the relative errors. The calibration factors are the inverse of the sensitivity coefficients determined by linear regression. Both errors are relative to the before-graft insertion case.

Sheep Number	Before graft insertion	After graft insertion	After graft insertion relative error	Post-mortem	Post-mortem relative error
S198	37.4 (0.998)	40.6 (0.996)	- 7.9 %	44.6 (0.999)	- 16.7 %
S199	35.5 (0.995)	40.1 (0.995)	- 11.3 %	40.6 (0.999)	- 12.6 %
S202	40.7 (0.997)	43.1 (0.990)	- 5.4 %	39.2 (0.999)	+ 4.3 %
S218	44.2 (0.991)	41.9 (0.997)	+ 5.6 %	591 (0.703)*	N/A
S219	39.0 (0.995)	40.5 (0.995)	- 3.8 %	37.2 (0.999)	+ 4.8 %
	Avg = 39.4 SD = 3.3	Avg = 41.2 SD = 1.2	Avg = - 4.6 % SD = 6.4 %	Avg = 40.4 SD = 3.1	Avg = - 5.0 % SD = 11.2 %

*Indicates device did not recalibrate and hence the corresponding value was not included in the mean and standard deviation.

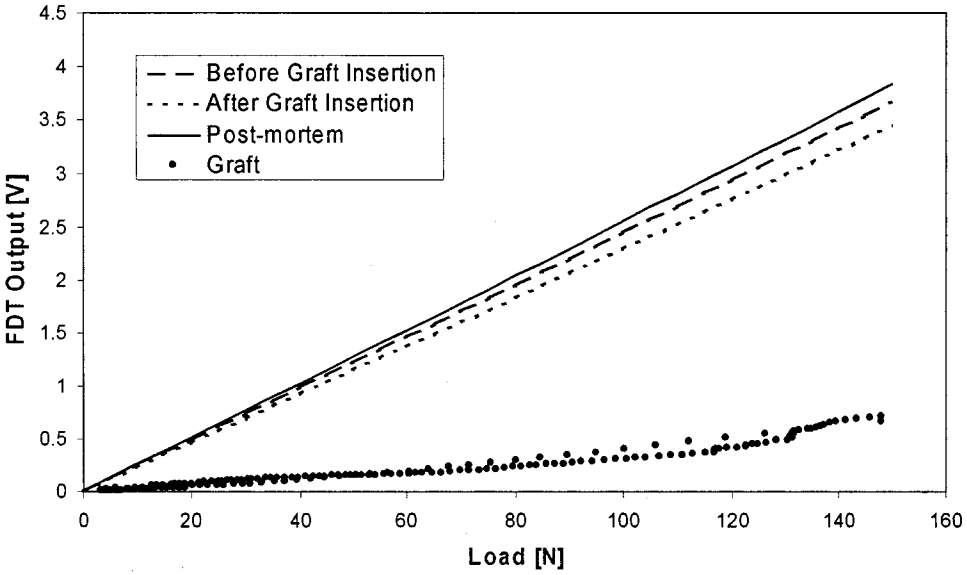

Fig. 6 Calibration regressions and graft loads for animal S202. The after-graft insertion calibration was nearly identical to the before-graft insertion calibration. The post-mortem calibration matched the before-graft insertion calibration well with a relative percent error of only 4.3 percent using before-graft insertion calibration as the standard. The voltages caused by loading of the graft were very low compared to those in the post-mortem calibration indicating that only a small fraction of the load applied to the graft was actually transmitted to the FDT. The majority of the load was supported by the biological bond between the graft and bone tunnel.

for the five specimens was 0.995 both before and after the graft was inserted (Table 1). The average relative percent error of the intra-operative calibration after the graft was passed compared to the standard was −4.6 percent (Table 1, Fig. 6) and this average relative percent error was not significantly different from zero ($p=0.183$). Because the two intra-operative calibrations compared favorably, the only calibration necessary is the one before the graft is inserted.

The FDT remained calibrated after 4 weeks of implantation in four out of the five specimens (Table 1). The average relative percent error of the post-mortem calibration compared to the standard (i.e., before graft insertion) for these four specimens was −5.0 percent and this average relative percent error was not significantly different from zero ($p=0.434$).

The FDT output from loads applied to the graft at 4 weeks indicated that only a small fraction of the load was transmitted to the FDT. Of the four specimens that maintained calibration at 4 weeks, only an average of 15.1 percent of the graft load was transmitted to the transducer (Table 2, Fig. 6) and this average represented a significant reduction in load ($p<0.002$). The small proportion of graft load transmitted to the transducer at 4 weeks indicated that the biological bond between the graft and bone tunnel developed before the FDT changed calibration.

Table 2 Percent of graft load transmitted to the FDT 4 weeks following surgery for the four animals whose FDTs recalibrated post-mortem

Sheep	Maximum graft load (N)	Load measured by the FDT (N)	Percent of graft load transmitted
S198	147	16.5	11.3
S199	149	34.9	23.4
S202	148	27.4	18.5
S219	89	6.4	7.1
	Avg = 133	Avg = 21.3	Avg = 15.1

Discussion

The key findings from this study were as follows: (1) The FDT can be calibrated intra-operatively using the cable to apply loads before the graft is inserted because the average relative percent error between the two intra-operative cable calibrations both without and with the graft inserted was less than 5 percent, (2) the FDT has the potential to measure graft forces transmitted to the transducer in vivo for 4 weeks after implantation because four out

of five FDTs recalibrated with an average relative percent error equal to 5 percent, and (3) the FDT can be used to track the biological incorporation of the graft in the tunnel because the graft begins to bond to the tunnel before the transducer loses calibration. Before interpreting the findings of this study several methodological issues should be discussed.

Methodological Issues. In calibrating the FDT intra-operatively to assess whether the insertion of the graft had any effect, it was assumed that the load transmitted to the FDT would be the same whether the calibration load was applied to either the cable or the graft. Since any difference in the transmitted load would be due to frictional effects, this assumption was justified because the surgical procedure either minimized or eliminated sources of friction. Specifically, the graft tunnel was overdrilled by 1 mm, thus minimizing friction between the graft and tunnel and the graft did not wrap around the corner of the tunnel as it exits from the bone (Fig. 4), thus eliminating friction. Moreover, a previous study demonstrated that calibrations performed with loads applied to a cable and with loads applied to a graft when both of the above-described frictional effects were present yielded no statistical differences in measurement error [5].

A rationale for determining an acceptable in vivo relative percent error for the FDT is required to interpret differences in calibration curves. A 10 percent relative percent error seems acceptable in light of the usefulness of graft tension measurements bounded by this relative error value. It is estimated that the maximum daily load in the intact ACL is less than 500 N [9–11], and that these loads may be lower in the first few weeks following reconstruction because of post-surgical discomfort. A 10 percent error for a measured 400 N load would give an 80 N range for the actual load, which would be useful for comparing the effectiveness of different tibial and femoral fixations. Inasmuch as the failure loads for many common tibial and femoral fixations vary by hundreds of Newtons between methods [1,12,13] knowing peak graft loads bounded by only a 10 percent error would allow clinicians to determine if some fixations are not strong enough to support graft loads generated by certain exercises.

Because the study was performed in ovine knees, the results from this study may not be directly applicable to humans. The rate of bone formation and remodeling in animals may be faster than that in the humans [14], which makes translating time period results affected by bone growth from ovine to humans difficult. However, because the rate of bone remodeling is faster in the ovine, the number of weeks that the FDT remains calibrated in the ovine is probably a lower bound in the human.

To check the validity of the statistical findings that neither the intra-operative calibration after graft insertion nor the post-mortem calibration was significantly different from the intra-operative calibration with the cable, the powers of the statistical tests were computed to determine the probability of a Type II error (i.e., accepting the null hypothesis when it should be rejected). Using Δ/σ ratios as determined from the values indicated in Table 1, where Δ is the average percent difference and σ is the corresponding standard deviation, the powers were less than 0.5 for both statistical tests. Consequently the probability of a Type II error is relatively high so that the null hypothesis (i.e., no difference in the calibrations) cannot be accepted with confidence. Nevertheless, since the approximately 5 percent difference for both calibrations is substantially lower than the acceptable percent difference of 10 percent determined above, even if the alternative hypothesis (i.e., 5 percent difference) were accepted, then this would still be an acceptable result.

Interepretation of Results. Because the average relative percent error between the intra-operative calibrations was less than 5 percent and because only one of the individual relative percent errors exceeded 10 percent by a small margin (Table 1), the FDT needs to be calibrated only once intra-operatively before the graft is inserted. Considering that overdrilling of the tibial tunnel minimized friction as a source of error as mentioned earlier, any difference between the intra-operative calibrations can be attributed primarily to changes in the direction of the applied load, which was not controlled during the intra-operative calibration after the graft was inserted. Hence, if the FDT is used in either animal models or humans, then the surgical procedure can be simplified by avoiding the second calibration and also the time that the subject is under anesthetic can be reduced accordingly.

The FDT will accurately measure the transmitted graft load for 4 weeks and possibly longer in most subjects. For the four out of five animals in which the FDT remained calibrated for 4 weeks (Table 1), the average relative percent error was 5 percent for the 4-week post-mortem calibration using the intra-operative calibration before inserting the graft as the standard. Although the individual relative percent errors exceeded 10 percent for two animals, only one of these error values (16.7 percent) exceeded 10 percent by a wide margin. Again the error between the calibrations was probably due to either small differences in the direction of the applied load or to some minor support to the beam provided by any formation of a fibrin clot. In any case, since 3 out of 5 (60 percent) of the devices yielded post-mortem calibrations with relative percent errors bounded approximately by 10 percent, the FDT will measure the transmitted graft load with the desired accuracy for the majority of subjects.

Bone formation was the most likely cause for the failure of the one FDT not to recalibrate post mortem. To determine whether the FDT remained calibrated at 4 weeks, it was assumed that the Teflon-coated cable would not become biologically bonded to surrounding tissue. However, this assumption was not valid in the case where the specimen for which the FDT did not recalibrate. While the cable was free to slide around the post of the FDT in all five specimens, the cable loop was isolated from the FDT by calcified bone that had grown between the beam and cable for the one specimen that did not recalibrate. For this specimen, the loads applied to the cable were not freely transmitted to the FDT. Because the FDT was being shielded from the loads applied to the cable, it was impossible to determine if the FDT was not calibrated because of either changing boundary conditions on the beam of the transducer or the lack of transmitted load from the cable. If the change in calibration was caused by the lack of transmitted load from the cable, then all five of the FDTs remained calibrated for at least 4 weeks.

Confidence in the ability of the FDT to monitor the formation of the biological bond hinges on whether the FDT remains calibrated longer than the biological bond between the graft and femoral tunnel takes to develop. Because the FDT remained calibrated for 4 weeks following surgery and because only an average of 15 percent of the graft load was transmitted to the transducer (Table 2), the FDT remained calibrated long enough for a substantial bond to form between the graft and bone tunnel. If the same relationship between the rate of biological bond maturation and the time until the FDT loses calibration holds in humans, then initial decreases in the voltage output of the FDT can be attributed to the development of the biological bond and not to changing calibration. Since the biological bond was well developed before the calibration of the FDTs changed, the transducer may be a useful tool for tracking the growth of the biological bond in humans. Tracking this growth is important in aggressive rehabilitation because as the bond increases in strength, less graft loads will be transmitted to the mechanical fixations and the patient can increase weight bearing and exercises with confidence [8].

For the FDT to realize its potential as a tool for tracking the growth of the biological bond in humans, a means of checking the calibration in vivo is necessary. This can be accomplished via a manual maximum test using a knee arthrometer. The arthometer enables the application of a controlled anterior load to the tibia. Because the tension developed in an ACL graft equilibrates almost all of this load at 30 degrees of flexion with little contribution from other knee structures [15], the use of the arthrometer would

enable a repeatable tension to be developed in the graft provided that the joint is stable. If the joint is unstable, however, then other structures may play a role in supporting the anterior tibial load with the result that the tension transmitted to the FDT would be decreased. If the transmitted tension was decreased, then the calibration could not be checked. Because the arthromter also measures the stability of the joint, however, any decrease in stability and hence potential change in tension transmitted to the graft could be detected.

Because nonlinear intra-operative calibrations were obtained in preliminary experiments, the extra-articular procedure used to implant the FDT required some refinement so that linear calibrations could be obtained. Bone sectioning revealed that the cause of the nonlinear intra-operative calibrations was the nonhomogeneity of the metaphyseal bone in the location where the FDT was implanted. Because fat in the medullary canal extended into the metaphyseal bone of the proximal tibia and the tunnel for the FDT was positioned such that a portion of the distal surface of the transducer tunnel extended into the medullary fat, the inferior aspect of the transducer body was not supported by cancellous bone in the preliminary experiments. Accordingly, application of the load during the intra-operative calibration caused the beam of the FDT to angulate a few millimeters distally. As a result of this angulation, the end of the beam contacted the tunnel wall, hence reducing the sensitivity as load increased. Once the cause of the nonlinear calibrations was discovered, the tunnel for the FDT was moved proximally closer to the tibial plateau a few millimeters, with the result that the majority of tunnels were completely contained in cancellous bone. For all such animals (which includes all those reported herein) excellent structural support of the FDT was achieved and linear intra-operative calibration curves were obtained. These findings emphasize the importance of a solid support for the body of the FDT if the device is to provide useful measurements of graft tension.

Considering the need for solid support of the body of the FDT, precautions can be taken in humans to improve the quality of the cancellous bone near the implant site. First, young, active men should be selected as subjects because of the high density of their cancellous bone [16]. Second, by underdrilling the transducer tunnel with a 7 mm reamer and dilating the tunnel to 8 mm with expansion rods, the local bone density at the implant area will increase [17] and give the FDT better structural support. With these two precautions, it is expected that the support provided by the cancellous bone to the FDT will be sufficiently solid that linear calibrations will be obtained in humans. If this expectation is not met in specific patients, however, then the FDT can be removed and replaced with a bone mulch screw. The bone mulch screw has an identical thread profile so it can be inserted properly into the same tunnel as the FDT.

A further safeguard against structural support failure in humans can be achieved by properly adjusting the length of the beam of the FDT to the diameter of the tibial tunnel. The surgical procedure in the ovine was designed to allow the tip of the beam to recess in the lateral wall of the graft tunnel and be free from surrounding bone (Fig. 3). If excessive loads were applied to the FDT and the bone supporting the threaded body yielded causing the FDT to pitch, then the bony recess would support the tip of the beam and prevent the fixation from failing. However, because the beam of the FDT did not span the 10 mm in diameter graft tunnel, the bony recess was unable to support the device as it angulated. This will not be a problem in most humans because the average DLSTG tunnel is drilled to a diameter of only 8 mm [18]. In humans with larger graft diameters, the length of the post portion of the beam (i.e., solid cross section) should be increased to 12 mm, which will allow it to be recessed in the lateral wall of larger graft tunnels.

In summary, because the FDT remained calibrated in most subjects before the biological bond developed, the FDT can be used for the following purposes in vivo in animal models and possibly humans: (1) to measure intra-articular graft loads until the biological bond begins to develop, (2) to determine the onset of the biological bond between the graft and bone tunnel by periodically applying a calibration load using an arthromter, and (3) to track the maturation of the bond by monitoring the decrease in transducer output as the calibration load is applied over time. If the FDT can be used for these purposes in humans, then in the context of aggressive rehabilitation, these purposes will enable the following: (1) measurement of representative graft loads for specific exercises to identify exercises that might pose a risk of fixation failure, and (2) the time in an aggressive rehabilitation program at which the patient can safely tolerate exercises that load the graft beyond the strength of the fixation method(s).

Acknowledgments

This research was supported by grants from the United States Air Force and the Whitaker Foundation.

References

[1] Magen, H. E., Howell, S. M., and Hull, M. L., 1999, ''Structural Properties of Six Tibial Fixation Methods for Anterior Cruciate Ligament Soft Tissue Grafts,'' Am. J. Sports Med., **27**, pp. 35–43.
[2] Howell, S. M., and Hull, M. L., 1998, ''Aggressive Rehabilitation Using Hamstring Tendons: Graft Construct, Tibial Tunnel Placement, Fixation Properties, and Clinical Outcome,'' Am. J. Knee Surgery, **11**, pp. 120–127.
[3] Halling, A. H., Howard, M. E., and Cawley, P. W., 1993, ''Rehabilitation of Anterior Cruciate Ligament Injuries,'' Clin. Sports Med., **12**, pp. 329–348.
[4] Noyes, F. R., Mangine, R. E., and Barber, S., 1987, ''Early Knee Motion After Open and Arthroscopic Anterior Cruciate Ligament Reconstruction,'' Am. J. Sports Med., **15**, pp. 149–160.
[5] Ventura, C. P., Wolchok, J., Hull, M. L., and Howell, S. M., 1998, ''An Implantable Transducer for Measuring Tension in an Anterior Cruciate Ligament Graft,'' ASME J. Biomech. Eng., **120**, pp. 327–333.
[6] McKee, E. L., Lindsey, D. P., Hull, M. L., and Howell, S. M., 1998, ''Telemetry System for Monitoring Anterior Cruciate Ligament Graft Forces in Vivo,'' Med. Biol. Eng. Comput., **36**, pp. 330–336.
[7] Lindsey, D. P., McKee, E. L., Hull, M. L., and Howell, S. M., 1998, ''A New Technique for Transmission of Signals From Implantable Transducers,'' IEEE Trans. Biomed. Eng., **45**, pp. 614–619.
[8] Rodeo, S. A., Arnoczky, S. P., Torzilli, P. A., Hidaka, C., and Warren, R. F., 1993, ''Tendon-Healing in a Bone Tunnel. A Biomechanical and Histological Study in the Dog,'' J. Bone Jt. Surg., Am. Vol., **75**, pp. 1795–1803.
[9] Holden, J. P., Grood, E. S., Korvick, D. L., Cummings, J. F., Butler, D. L., and Bylski-Austrow, D. I., 1994, ''In Vivo Forces in the Anterior Cruciate Ligament: Direct Measurements During Walking and Trotting in a Quadruped,'' J. Biomech., **27**, pp. 517–526.
[10] Frank, C. B., and Jackson, D. W., 1997, ''The Science of Reconstruction of the Anterior Cruciate Ligament,'' J. Bone Jt. Surg., Am. Vol., **79**, pp. 1556–1576.
[11] Lundberg, W. R., Lewis, J. L., Smith, J. J., Lindquist, C., Meglitsch, T., Lew, W. D., and Poff, B. C., 1997, ''In Vivo Forces During Remodeling of a Two-Segment Anterior Cruciate Ligament Graft in a Goat Model,'' J. Orthop. Res., **15**, pp. 645–651.
[12] To, J. T., 1996, ''Biomechanical Properties of the Double Loop Hamstring Graft and Three Anterior Cruciate Ligament Graft Fixations,'' MS Thesis, Department of Mechanical Engineering, University of California at Davis.
[13] To, J. T., Howell, S. M., and Hull, M. L., 1999, ''Contributions of Femoral Fixation Methods to the Stiffness of Anterior Cruciate Ligament Replacements at Implantation,'' Arthroscopy, **15**, pp. 379–387.
[14] Martin, R. B., and Burr, D. B., 1989, *Structure, Function, and Adaptation of Compact Bone*, Raven Press, New York.
[15] Markolf, K. L., Burchfield, D. M., Shapiro, M. M., Cha, C. W., Finerman, G. A., and Slauterbeck, J. L., 1996, ''Biomechanical Consequences of Replacement of the Anterior Cruciate Ligament With a Patellar Ligament Allograft. Part II: Forces in the Graft Compared With Forces in the Intact Ligament,'' J. Bone Jt. Surg., Am. Vol., **78**, pp. 1728–1734.
[16] Ding, M., Dalstra, M., Danielsen, C. C., Kabel, J., Hvid, I., and Linde, F., 1997, ''Age Variations in the Properties of Human Tibial Trabecular Bone,'' J. Bone Joint Surg. Br., **79**, pp. 995–1002.
[17] Green, J. R., Nemzek, J. A., Arnoczky, S. P., Johnson, L. L., and Balas, M. S., 1999, ''The Effect of Bone Compaction on Early Fixation of Porous-Coated Implants,'' J. Arthroplasty, **14**, pp. 91–97.
[18] Magen, H. E., 1997, ''Structural Properties of Six Tibial Fixation Methods for Anterior Cruciate Ligament Soft Tissue Grafts,'' MS Thesis, Biomedical Engineering Program, University of California at Davis.