An Implantable Transducer for Measuring Tension in an Anterior Cruciate Ligament Graft

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The goal of this study was to develop a new implantable transducer for measuring anterior cruciate ligament (ACL) graft tension postoperatively in patients who have undergone ACL reconstructive surgery. A unique approach was taken of integrating the transducer into a femoral fixation device. To devise a practical in vivo calibration protocol for the fixation device transducer (FDT), several hypotheses were investigated: (1) The use of a cable versus the actual graft as the means for applying load to the FDT during calibration has no significant effect on the accuracy of the FDT tension measurements; (2) the number of flexion angles at which the device is calibrated has no significant effect on the accuracy of the FDT measurements; (3) the friction between the graft and femoral tunnel has no significant effect on measurement accuracy. To provide data for testing these hypotheses, the FDT was first calibrated with both a cable and a graft over the full range of flexion. Then graft tension was measured simultaneously with both the FDT on the femoral side and load cells, which were connected to the graft on the tibial side, as five cadaver knees were loaded externally. Measurements were made with both standard and overdrilled tunnels. The error in the FDT tension measurements was the difference between the graft tension measured by the FDT and the load cells. Results of the statistical analyses showed that neither the means of applying the calibration load, the number of flexion angles used for calibration, nor the tunnel size had a significant effect on the accuracy of the FDT. Thus a cable may be used instead of the graft to transmit loads to the FDT during calibration, thus simplifying the procedure. Accurate calibration requires data from just three flexion angles of 0, 45, and 90 deg and a curve fit to obtain a calibration curve over a continuous range of flexion within the limits of this angle group. Since friction did not adversely affect the measurement accuracy of the FDT, the femoral tunnel can be drilled to match the diameter of the graft and does not need to be overdrilled. Following these procedures, the error in measuring graft tension with the FDT averages less than 10 percent relative to a full-scale load of 257 N.

Introduction

Postoperative rehabilitation following ACL reconstruction plays a major role in the functional outcome of the reconstructed knee. Both the strength and stiffness of the healing graft benefit from stress (Anderson and Lipscomb, 1989). Although the goal of a more aggressive protocol is to minimize the adverse effects of immobilization, the rehabilitative exercises should not develop levels of graft tension that either threaten the structural integrity of the graft complex (i.e., graft and fixations) or interfere with the biological healing. The graft tension required to stress the graft optimally during the healing has not been determined. The loads imposed on the graft during rehabilitation exercises and activities of daily living are not known. If graft tension could be measured during rehabilitation and the degree of tension that is excessive could be determined *in vivo*, then more optimal rehabilitation programs could be recommended and the graft tension could be monitored.

Transducers that are currently available are unsuitable for measuring graft tension during rehabilitation activities *in vivo*. Buckle transducers, which sense tension in fiber bundles passing through the buckle, cannot remain implanted and deform the fiber bundles measured (Barry and Ahmed, 1986; Lewis et al., 1982). Devices inserted within the tissue substance, such as an implantable force transducer (Xu et al., 1992; Ray et al., 1993; Glos et al., 1993; Herzog et al., 1996), arthroscopically implantable force probe (Tohyama et al., 1994), and miniature pressure transducer (Holden et al., 1994, 1995), measure force only in a portion of the tissue. A common limitation to all these transducers is that they are difficult to calibrate *in vivo*.

To overcome the limitations of previous transducers, the goal of this study was to develop a new implantable transducer by taking a unique approach of integrating the transducer into a femoral fixation device. The transducer was designed to measure total tension in a four-bundle, double-looped semitendinosus and gracilis (DLSTG) graft, a commonly used graft construct in humans. To devise an *in vivo* calibration protocol for the fixation device transducer (FDT), one hypothesis investigated was that calibration of the FDT with a cable was just as accurate as using the DLSTG graft. If this hypothesis was accepted, then the intraoperative calibration procedure would be simplified since it is more difficult to apply calibration loads to a multibundle DLSTG graft rather that a cable. A second hypothesis tested was that the number of flexion angles at which the device is calibrated has no significant effect on the accuracy of the FDT measurements. Again, to simplify the calibration procedure, the smallest number of flexion angles needed to maintain accuracy was of interest. Finally the graft tension measured by the FDT within the femoral tunnel could be less than the graft tension within the intercondylar notch if friction between the graft and femoral tunnel is substantial. To evaluate the effect of friction, the hypothesis was tested that the accuracy

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of the FDT was the same for tunnels that either were overdrilled or were drilled to match the diameter of the DLSTG graft. If this hypothesis was accepted, then snug-fitting tunnels, which encourage biologic bonding in vivo, could be drilled without compromising the measurement accuracy of the FDT.

Design

An implantable transducer to measure *in vivo* graft forces in the human knee must satisfy stringent requirements. The transducer: (1) must be easy to install during reconstructive surgery, (2) must remain implanted throughout the remaining lifetime of the patient, (3) must be biocompatible and have no adverse effect on the surrounding tissue, (4) must be able to house the electronics for telemetry, (5) must accurately indicate the graft tension, and (6) must provide secure fixation. To fulfill these requirements, a commercially available femoral fixation device (Bone Mulch Screw, Arthrotek Inc., Ontario, CA) was modified to function both as a tension transducer and fixation device.

To appreciate the modifications, it is first useful to understand how the device is used clinically in ACL reconstructive surgery. Two tunnels, through which the graft is placed, are drilled through the tibia and into the femur in the location of the origin and insertion of the torn ACL (Fig. 1). The fixation device, which consists of a threaded, hollow body with a protruding beam, is screwed through the lateral femoral condyle so that the beam bisects the femoral tunnel. Composed of two tendons, the semitendinosus and gracilis, the DLSTG graft is looped around the beam to fix the graft in the femur. The four free ends of the two tendons are then secured to the tibia using a screw and studded washer.

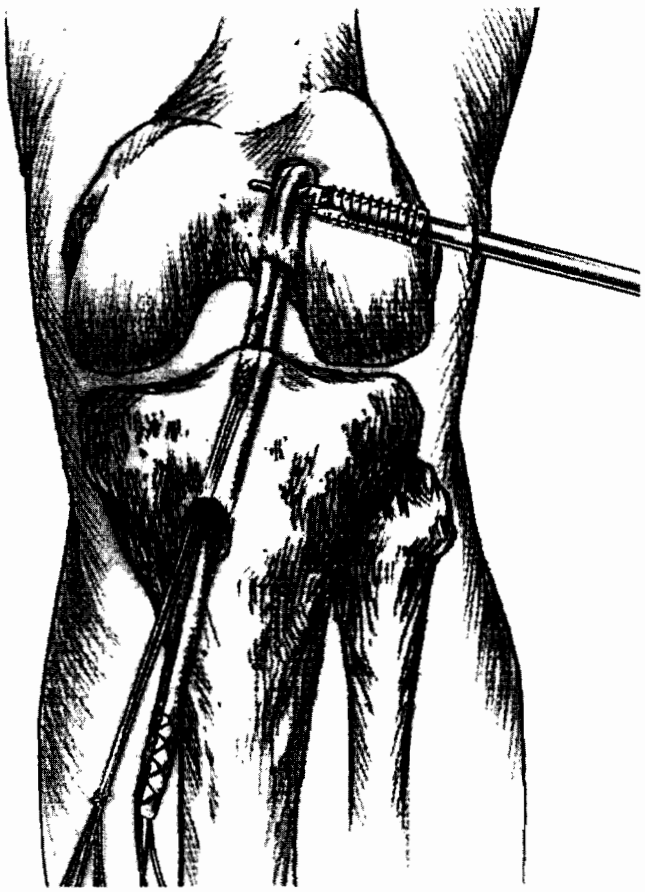

Fig. 1 Method of ACL reconstruction with femoral fixation device. The femoral fixation device is inserted through the lateral femoral condyle and is advanced until the beam portion bisects and spans the femoral tunnel. The semitendinosus and gracilis tendons are threaded up through the tibial and femoral tunnels, looped around the beam portion of the femoral fixation device, threaded down through the tunnels, and fixed to the tibia.

With several modifications, the femoral fixation device was converted into a transducer (Fig. 2). The FDT consists of two titanium (Ti 6Al 4V) parts for ease of sensor installation. One part of the FDT is the threaded body. The other part is the beam, which consists of a hollow rectangular cross section joined to a solid rectangular in cross section 10-mm-long beam. At the tip of the beam is a flat disk, which prevents the graft from slipping around the tip of the beam.

Because the graft loops around the beam, which is cantilevered, the transducer design was based on cantilever beam principles. Equal to the total tension in the graft, the applied force is measured by two foil strain gages mounted on the center of opposite sides of the inside of the hollow rectangular section of the FDT beam. The two strain gages are oriented along the axes of principle strain due to shear at opposite 45 deg angles and are interconnected in a half-bridge circuit. In this circuit the outputs of both strain gages are summed together to yield a signal proportional to the direct shear stress but insensitive to shear stress due to torsion and temperature variations. Because the applied force governs the direct shear stress in the hollow rectangular section, the transducer output is theoretically independent of the center of pressure, which may shift due to the movement of the graft bundles along the beam and/or redistribution of the load carried by the bundles. Once the sensors are installed, the beam is laser-welded to the threaded body to create an integral fixation device.

Performance Evaluation

Pre-implantation Calibration. FDT pre-implantation calibration included the evaluation of two factors: the point-of-load application along the beam and the angle of load application. The point-of-load application was of interest to confirm that the FDT was insensitive to shifts in the center of pressure while the angle was of interest to determine how precisely the FDT must be oriented when implanted. The FDT was secured in a vise through a fixture that allowed the FDT to be rotated from 0 (vertical), ±5, ±10, ±15 deg. For each angle of load application (or FDT orientation angle), loads were applied at three different equally spaced points along the span of the solid portion of the beam (closest to the threaded body, at the center of the beam, and at the tip of the beam). For each combination of angle and point of load application, the FDT output was recorded as load was applied incrementally up to a maximum of 290 N by hanging weights from a cable looped over the beam.

In Vitro Testing

Specimen Preparation. *In vitro* tests were conducted to test the three hypotheses. Five fresh-frozen cadaver knees from individuals who ranged in age from 48 to 77 years were used. The femur, tibia, and fibula were sectioned approximately 30 cm from the knee articulation. The bone ends were cleaned to remove soft tissue and the medullary canal was reamed for insertion of intramedullary rods. These rods served to interface the specimen with the test apparatus during alignment.

Semitendinosus and gracilis tendons were harvested with a tendon stripper and the attached muscle tissue was removed. The body of each tendon was sutured into a compact tube and a #2 polyester braided, inelastic suture (Ti-cron, Davis and Geck, Danbury CN) was stitched into the end of each tendon. The midpoint of both tendons was looped over a suture to form a double-looped graft. The graft was drawn through a series of sizing sleeves. The diameter of the sleeve that allowed free passage of the graft was considered to be the "true" or standard diameter of the graft (Howell and Gottlieb, 1996).

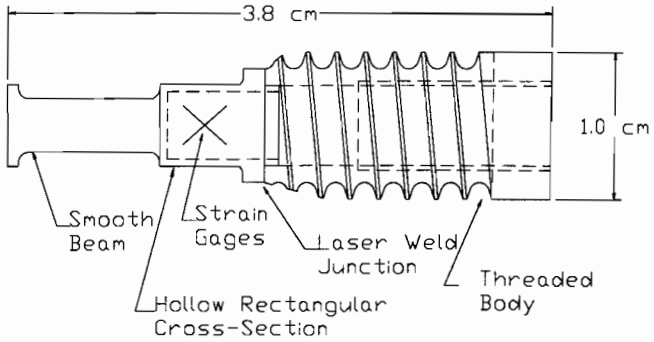

Fig. 2 Diagram of assembled fixation device transducer. Strain gages mounted along principle axes of shear strain within the hollow rectangular cross section and interconnected into a half bridge provided an output that indicated the graft tension independent of the location of the center of pressure.

To perform ACL reconstruction, the ACL was excised and the reconstructive surgery was performed using a drill guide system (Arthrotek, Ontario, CA) and surgical technique (Howell and Gottlieb, 1996). The location of the tibial tunnel was customized for variability in roof angle and knee extension by using an impingement-free tibial guide system (Arthrotek, Ontario, CA). The tibial tunnel was overdrilled 1 mm from the true graft size to insert a Teflon bushing with a 0.5 mm wall thickness. This Teflon bushing was used to eliminate friction between the graft bundle and the tibial tunnel. Next, a femoral tunnel was reamed to the true graft diameter.

For installation of the FDT, a 12 mm transverse tunnel was drilled through the lateral femoral condyle so that it entered perpendicular and 18 mm inside the femoral tunnel. To improve the purchase of the FDT in osteopenic bone, the transverse tunnel was then packed with polymethylmethacrylate (PMMA), and re-drilled to an 8-mm-dia tunnel. The tunnel was tapped to accept the nonstandard thread of the FDT. The FDT was screwed into the tunnel until the tip of the beam was flush against the medial wall of the femoral tunnel.

A method for orienting the FDT in the femur was necessary to maximize the sensitivity of the sensor. The knee was secured in a custom-built positioning jig that allowed the flexion angle to be adjusted. The knee was positioned between 45 and 60 deg of flexion where the femoral and tibial tunnels were collinear. A 0.8-mm-dia cable was looped around the beam and allowed to exit the knee through the tibial tunnel. A 125 N weight was attached to the cable outside the tibial tunnel using a system of pulleys. The voltage output from the FDT was recorded with the cable at two different locations along the span of the beam, closest to the lateral tunnel wall and closest to the medial tunnel wall near the tip of the beam. The FDT was rotated with a screw driver until the voltage output was the same at both points of load application.

In Vitro Calibration. After the FDT was oriented, it was calibrated *in vitro* using both a cable and a graft with the knee still mounted in the customized positioning jig. A cable was used because it is easier to load than a four-bundle graft during intra-operative calibration. The cable was positioned along the center of the solid portion of the beam and the FDT output was recorded as weights were applied incrementally up to 245 N for 0, 30, 45, 60, 75, 90, and 120 deg flexion angles. A 15 deg flexion angle was omitted because of difficulty in positioning the knee at that angle due to certain restrictions with the experimental setup.

Leaving the FDT at the same orientation, the cable was removed and the graft was inserted. A graft was used because it might produce more accurate results than a cable. Using the sutures sewn to the ends of each tendon, the four-bundle graft was inserted by pulling the two tendons up through the tunnels, looping the tendons around the beam, and pulling them back through the tunnels so that the midpoint of each tendon was located over the beam (Howell and Gottlieb, 1996). The suture ends were attached to the weights, which were applied incrementally up to 245 N distributed equally between the four graft bundles for 0, 30, 45, 60, 75, 90, and 120 deg flexion angles. The voltage output was recorded.

In Vitro Tension Measurement. The accuracy of the FDT was determined by deriving a calibration curve to convert voltage output from the FDT to graft tension, loading the specimens, and comparing the tension indicated by the FDT to the summed tension in each of the four ends of the two tendons measured by load cells at the exit of the tibial tunnel. The reference standard for measuring graft tension was the external load cells (Wallace et al., 1997). To perform these measurements under a variety of loads, the knee preparation was transferred to a computer-controlled load application system (LAS).

Custom designed and built in our research laboratory, the LAS allows six degrees of freedom with flexion-extension being fixed, though adjustable over the complete physiologic range (Bach and Hull, 1995). Forces and torques corresponding to each of the remaining five degrees of freedom can be applied both independently and in combination using pneumatic actuators. Translations and rotations corresponding to each degree of freedom are also measured according to the coordinate system of Grood and Suntay (1983).

Using the intramedullary rods as an interface with the LAS alignment fixtures, specimens were aligned using the functional axes approach (Berns et al., 1990; Bach and Hull, 1995). The functional axes approach aligns the natural axes of the joint motion with those of the LAS. Once aligned, both the femur and tibia were potted in rectangular aluminum tubes with PMMA, enabling removal of the alignment fixtures. Also the fixation within the aluminum tubes enabled specimen removal from the LAS and reinstallation without the loss of alignment.

The external load cells used to measure graft tension in each bundle were custom made (Precision Measurement, Ann Arbor, MI) to the smallest possible size to fit between the distal exit of the tibial tunnel and the test apparatus. Each load cell had the capability of measuring tension from zero to 150 N. The suture attached to each graft bundle was tied in a slip knot around the pin of a clevis, which was in turn attached to a turnbuckle. The load cell was attached to the other end of each turnbuckle and the opposite end of the load cells was fixed to the tibial unit of the test apparatus through spherical bearings (Fig. 3). The spherical bearings insured that the axis of each load cell was aligned with the axis of the graft bundle to which it was attached. The load cells were slightly staggered to fit the available space and pull on the sutures at a minimal angle from the tibial tunnel axis.

Prior to preconditioning, the graft pretension was set to 10 N for each of the four bundles with the knee flexed at 30 deg. Then the graft was preconditioned by applying two cycles each of 200 N anterior force, 30 Nm varus and valgus moment, and 10 Nm internal axial moment at 0, 30, 60, 90, and 120 deg of flexion. If necessary, then the graft pretension was reset to 6–10 N after preconditioning.

Graft tension was measured with both the FDT and external load cells during passive flexion from 0 to 120 deg and during the application of the following loads at 0, 30, 60, 90, and 120 deg of flexion: 200 N anterior force, 15 Nm single varus/valgus moment stepped up to 30 Nm, 5 Nm single internal moment stepped up to 10 Nm and 5 Nm and 10 Nm internal axial moment combined with 10 Nm and 15 Nm varus moment. An external moment was not applied because only the loads that produced the highest graft tension during pilot studies were used. Both loads and flexion angles were randomized. Prior to each load application, the knee was taken to 30 deg of flexion and the pretension was adjusted to 10 N if necessary. Load

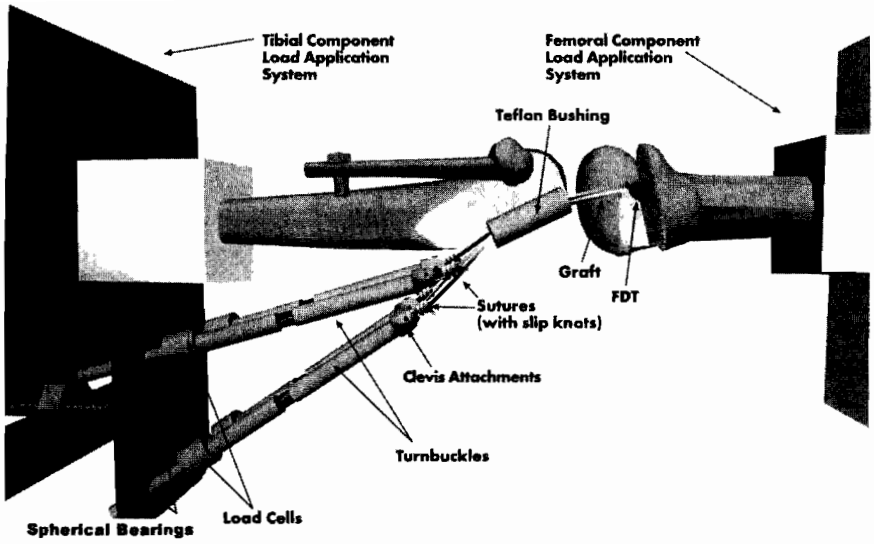

Fig. 3 Experimental setup for the accuracy evaluation. Knee specimens were mounted in a custom load application system, which applied the load components of interest while allowing unconstrained movement of the joint. Graft bundles were passed through a Teflon bushing in the tibia to minimize graft-tunnel friction, which was a possible source of error in the four external load cells used to measure the standard tension for error analysis. The load cells were connected at their base through spherical bearings. Only two of the four load cells and two of the spherical bearings are indicated for clarity.

transducer outputs were sampled at 2.5 Hz as the LAS increased the load from zero up to the maximum levels given above.

The effect of friction in both the tibial and femoral tunnels on the tension measurements was evaluated by enlarging the tunnel diameters by 1 mm and repeating the *in vitro* calibration and load application. Two additional evaluations were performed including one with the tibial tunnel overdrilled 1 mm and the femoral tunnel having a true diameter, and the other with both the tibial and femoral tunnel overdrilled by 1 mm. When the tibial tunnel was overdrilled, a new Teflon bushing with 0.5 mm wall thickness and outside diameter matched to the overdrilled size was inserted.

Data Analysis. The accuracy of the FDT was evaluated by comparing the tension measured by the FDT to that measured by the external load cells. The voltage output of the FDT was converted to a tension using the calibration values appropriate for each flexion angle. The error in the FDT tension measurements was defined as the difference between the graft tension measured by the FDT and the summed tension measured by the four load cells. For each of the three tunnel size combinations for each specimen, error values were normalized to the maximum output of the sum of the load cells when applying an anterior force with the knee flexed at 30 deg. In most cases, an applied anterior force at 30 deg flexion angle produced the largest output measured by the load cells. The corresponding graft tension was 257 N on average with a range of 235 N to 297 N. The root mean squared error (RMSE) for each treatment (i.e., specific combination of calibration material, tunnel size, load, and flexion angle) applied to each specimen was calculated by averaging the squared normalized error values over the total number of samples taken at the 2.5 Hz rate during the period to reach a particular maximum load level.

A repeated measures analysis of variance (ANOVA) was used to determine whether the material used for calibration (i.e., cable or graft) was a significant factor affecting the accuracy of the FDT. The factors included in the analysis were flexion angle at five levels (0, 30, 60, 90, 120 deg), load type at five levels (200 N anterior force, 10 Nm internal axial moment, 30 Nm varus moment, 30 Nm valgus moment, and 15 Nm varus moment combined with 10 Nm internal axial moment) and calibration material at two levels (cable or graft). The dependent variable was the average of the RMSE's over the three tunnel sizes for every combination of calibration material (i.e., cable or graft), load type, and flexion angle. The RMSE's were computed using the non-curve-fit flexion angle group.

To determine the minimum number of flexion angles needed for accurate FDT calibration, calibration values were plotted for the first tunnel size combination (standard tibial and femoral tunnel size) for each of the five specimens (Fig. 5). Calibration curves were then fitted using four different flexion angle groups: (1) 0-30-45-60-75-90-120 deg; (2) 0-30-45-60-75-90 deg; (3) 0-60-120 deg; (4) 0-45-90 deg. In most cases the curves were fit to a second-order polynomial, except for two specimens where flexion angle groups 1 and 2 were fit to a third-order polynomial. The minimum R^2 value was 0.9551. New calibration values computed with the polynomial equations obtained from the four curve-fit groups were obtained for 0, 30, 60, 90, 120 deg (flexion angles used for active load testing). For the two groups that were curve fit excluding the 120 deg angle (groups 2 and 4), the calibration values at 120 deg were extrapolated. RMSE values were recomputed for each curve fit group with the new calibration values.

A three-factor ANOVA was performed using RMSE values for graft calibration only as the dependent variable. The factors were curve fit with five levels (the four curve-fitting groups and the gold standard non-curve-fit group), flexion angle with five levels (0, 30, 60, 90, 120 deg), and load type with five levels (200 N anterior force, 10 Nm internal axial moment, 30 Nm varus moment, 30 Nm valgus moment, and 15 Nm varus combined with 10 Nm internal axial moment).

A four-factor ANOVA was used to determine whether the tunnel size was a significant factor affecting the FDT accuracy. The factors and levels were the same as the first ANOVA except that tunnel size at three levels (T1F1: standard tibial and femoral, T2F1: over-drilled tibial-standard femoral, T2F2: over-drilled tibial and over-drilled femoral) was included. The data from four specimens were used since data were missing for the second tunnel size combination for one specimen. The RMSE for the non-curve-fit flexion angle group was the dependent variable.

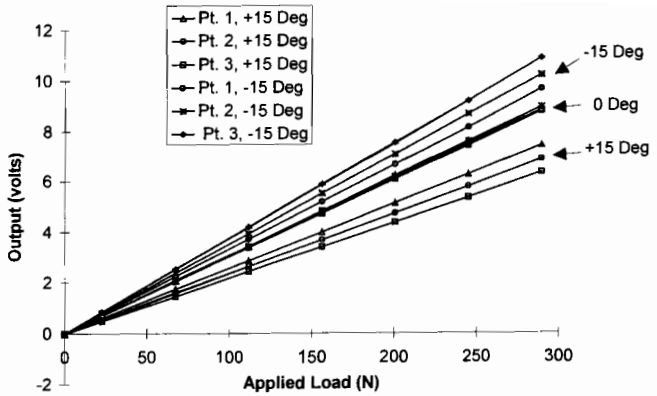

Fig. 4 Pre-implantation calibration plot. Pt. 1 is on the beam closest to the threaded body of the FDT, Pt. 2 is at the center of the beam, and Pt. 3 is at the tip of the beam. Results are shown for three angles of orientation, 0 deg where the direction of load application was in the plane of the strain gages mounted inside the FDT, and 15 deg rotations in the either direction away from the 0 deg direction. Because the calibration changes depending on the orientation, the results emphasize the importance of properly orienting the FDT in the femoral tunnel when it is inserted.

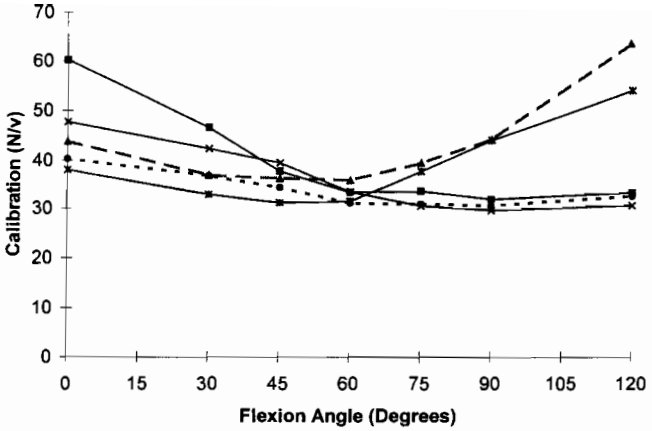

Fig. 5 Graft calibration curves for all five specimens using the standard tibial and femoral tunnel sizes. The results demonstrate the need to calibrate each specimen at different flexion angles.

To determine the probability of a Type II error, the power of the hypothesis tests was analyzed. A separate but similar analysis was performed for each hypothesis. For all three analyses the power was determined by specifying a significance level of 0.05 and a sample size equal to four. The most conservative value of one was used for the ratio of Δ/σ, where Δ is the minimum range of the dependent variable (RMSE) produced by the independent variable (cable/graft for hypothesis 1, tunnel size for hypothesis 2, and curve-fit group for hypothesis 3) and σ is the standard deviation of the model. For all three hypotheses the power was greater than 0.95. Hence, it was very unlikely that any one of the three null hypotheses would be accepted when, in actuality, it should be rejected.

Results

Results for the pre-implantation calibration showed that point of load application had a minimal effect on the sensitivity of the voltage output as long as the applied load was oriented at 0 deg. At this angle, the maximum voltage output difference between any of the three points of load application was 2 percent full scale (FS) (Fig. 4). As the orientation angle of the FDT was increased by rotating the FDT either clockwise or counterclockwise, the maximum output difference between any of the three points of load application also increased. For example, with the FDT oriented at +15 and −15 deg, the maximum output difference between any of the three points of load application was 15 percent FS and 11 percent FS, respectively. For all conditions the hysteresis (maximum percent difference between the loading and unloading points for any applied load) was less than 1 percent FS, the nonlinearity was less than 2.5 percent FS, and the R^2 values for loading and unloading curves were 0.99 or greater.

The calibration material did not have a significant effect ($p = 0.624$) on the RMSE values. Although there was no statistical difference between graft and cable, the mean RMSE values for each tunnel size tended to be lower for graft calibration than for cable calibration (Table 1). Also neither load type ($p = 0.094$) nor flexion angle significantly affected the FDT accuracy ($p = 0.231$). However, at 120 deg flexion angle, mean RMSE values for both cable and graft calibration were highest (15.6 and 9.6 percent, respectively), while at 30 and 60 deg flexion the RMSE values were lowest (5.5 and 4.6 percent for cable and 3.8 and 4.4 percent for graft) (Table 1).

For the data that were curve fitted (Fig. 5) there was no significant effect due to the curve-fitting groups ($p = 0.117$). Load type was a significant factor ($p = 0.033$), although flexion angle was not ($p = 0.298$). Significant interaction occurred between curve fit and flexion angle ($p = 0.010$). Unexpectedly, the 0-60-120 deg group RMSE mean value (6.87 percent) was slightly lower than the standard, non-curve-fit group RSME mean (7.07 percent) (Table 2). For the 0-45-90 degree group, the RMSE mean value (7.67 percent) was only slightly higher because of increased error at 120 deg of flexion (Table 2).

Overdrilling either the tibial or femoral tunnel did not affect the RMSE values ($p = 0.958$). There was a significant effect

Table 1 Mean RMSE values (with standard deviation) for each tunnel size (averaged over subject, flexion angle, and load type) and mean RMSE values for each flexion angle (averaged over subject, tunnel size, and load type)

TUNNEL SIZE	RMSE CABLE (%)	RMSE GRAFT (%)
T1, F1	9.18 ± 11.90	7.05 ± 6.13
T2, F1	9.52 ± 10.94	8.35 ± 5.83
T2, F2	9.71 ± 11.79	5.98 ± 3.65
FLEXION ANGLE		
0°	13.65 ± 9.72	7.57 ± 4.33
30°	5.54 ± 4.72	3.61 ± 2.47
60°	4.80 ± 4.68	4.41 ± 4.86
90°	7.91 ± 6.63	8.95 ± 5.06
120°	15.62 ± 19.71	9.55 ± 6.88

T1, F1 denote standard tunnel size.
T2, F2 denote overdrilled tunnel size.

Table 2 Mean RMSE values (percent) (with standard deviation) for standard tibial and femoral tunnel with three flexion angle groups

APPLIED LOAD	CURVE FIT GROUPS	FLEXION ANGLE 0°	30°	60°	90°	120°
Internal	C	10.44 ±8.05	2.61 ±1.22	3.06 ±1.39	5.16 ±3.44	4.91 ±5.22
	D	10.44 ±8.05	2.18 ±1.08	3.13 ±1.35	5.22 ±3.68	8.21 ±6.02
	E	10.29 ±7.96	2.27 ±0.99	3.09 ±1.46	5.34 ±3.90	5.11 ±5.55
Anterior	C	12.25 ±10.12	6.27 ±2.83	5.89 ±2.78	4.56 ±2.96	11.48 ±6.70
	D	12.25 ±10.11	5.06 ±2.90	5.32 ±3.48	7.80 ±6.92	15.66 ±13.69
	E	12.11 ±10.02	4.78 ±3.55	5.80 ±3.01	8.12 ±6.86	11.14 ±7.85
Varus	C	8.64 ±9.54	2.99 ±1.25	3.96 ±2.68	8.13 ±5.74	9.08 ±7.19
	D	8.85 ±9.54	3.27 ±1.40	4.55 ±2.90	9.77 ±8.09	11.54 ±11.66
	E	8.59 ±9.57	3.99 ±0.89	4.25 ±2.71	9.87 ±8.63	9.08 ±7.78
Valgus	C	9.27 ±10.46	3.79 ±4.22	3.89 ±2.07	5.32 ±4.20	10.23 ±7.59
	D	9.27 ±10.48	3.44 ±2.72	3.89 ±1.96	6.83 ±6.29	14.99 ±13.80
	E	9.21 ±10.48	3.88 ±2.02	3.82 ±2.56	7.01 ±6.60	10.49 ±7.92
Internal-Varus	C	12.07 ±8.45	2.99 ±1.86	9.46 ±14.61	6.7 ±5.27	8.49 ±5.93
	D	12.08 ±8.44	2.99 ±1.24	9.02 ±15.74	8.75 ±6.11	9.44 ±6.19
	E	11.98 ±8.40	3.46 ±0.71	9.67 ±15.30	6.88 ±8.45	6.89 ±4.12

'C' represents the 0-60-120 degree group
'D' represents the 0-45-90 degree group
'E' represents the standerd, non-curve fit group

due to load type ($p = 0.029$) but not flexion angle ($p = 0.267$). The only significant interaction effect was that between flexion angle and load type ($p = 0.040$). For anterior force, the error was greater at 0 deg than 120 deg, whereas the result was opposite for varus and valgus moments.

Discussion

The purpose of this research was to develop a new implantable transducer that could be used to measure ACL graft forces postoperatively in patients undergoing ACL reconstructive surgery. Because the transducer had to meet certain design criteria, it is worth evaluating the design against these criteria to gage its promise. One criterion was that the transducer remain implanted during the rehabilitation period so that the graft tension developed during rehabilitative exercises could be monitored. To avoid inserting an extra device either within or around the tissue midsubstance of the graft, which cannot remain implanted in the knee joint, the new transducer was integrated into an existing femoral fixation device.

Incorporating the sensor into the bone mulch screw, a femoral fixation device that is in clinical use, satisfied additional criteria. Two were that it can be installed without modifying the surgical technique (Howell, 1993) and also provides secure fixation. However, this surgical technique restricts the type of graft that can be used to either single or double-looped hamstring (semitendinosus and gracilis) grafts. Once the FDT is determined to be biocompatible, which is the focus of another concurrent study, the FDT can remain implanted throughout the lifetime of the patient without requiring removal, thus satisfying another criterion. Finally, the hollow body of the bone mulch screw can be used to house the electronics for telemetry. The details for powering, and the design and evaluation of the FDT telemetry system, have already been detailed in another study (McKee et al., 1998).

The final criterion was that the FDT accurately measure total graft tension. To evaluate FDT accuracy, knee specimens were subjected to an extensive experimental protocol while the graft tension was measured by both the FDT and the four external load cells. Because the external load cells were used as the standard, possible sources of error in their measurement merit critical examination. Although the compliance of the suture used to fix each graft bundle to the clevis head of the turnbuckle-load cell assembly caused a decrease in graft tension, this decrease did not affect the evaluation of FDT accuracy. During passive and active loading, forces in an ACL graft result from changes in the intra-articular distance, which cause stretching of the stiff graft to occur. The presence of an elastic suture connection in series with the stiff bundles of this hamstring graft caused an estimated decrease in graft tension of 11 percent due to a reduction in the graft's effective stiffness (Wallace et al., 1997). However, the RMSE values were computed based on the difference between FDT and load cell outputs. Because the evaluation of accuracy did not depend on the absolute graft tension, any tension decrease due to suture compliance did not impact the results.

A second inherent source of error was the affect of friction between the graft and tibial tunnel. Significant friction inside the tibial tunnel would cause the external load cells to underestimate the tension in the intra-articular portion of the graft. The use of a Teflon bushing has been shown to be effective in reducing tibial tunnel friction (Goss et al., 1997). Furthermore, the comparison of the RMSE values for the standard and overdrilled tibial tunnels showed no significant difference.

A method for simply, practically, and accurately calibrating the FDT was of interest to avoid the calibration problems of other transducers, and to allow rapid *in vivo* calibration during a surgical procedure. A cable was used for calibration because it would allow the application of a single load, whereas the graft would necessitate the application of equal loads to each of the four bundles. However, it was speculated that usage of the graft as the calibration material instead of the cable would improve the accuracy of the FDT because it would reduce the angulation in the femoral tunnel. As indicated by the pre-implantation calibration, the angulation of the tension vector of the calibration material affects the FDT output. If this angulation varies with flexion angle as a consequence of the calibration material swinging about the beam in the femoral tunnel and the variation is not the same as that of the actual graft once the knee is reconstructed, then the calibration will introduce error into measured FDT tension. With an 8-mm-dia femoral tunnel, which is 18 mm deep to the beam, a 1-mm-dia cable can swing through an angle of ± 11 deg. The difference in voltage output with the cable oriented at $+15$ and -15 deg was 15 percent FS and 11 percent FS, respectively. Error from graft angulation should be less than cable angulation since the graft better fills the femoral tunnel and has less space to angulate.

Although there was no statistical difference between the cable and the graft, the use of the graft tended toward lower RMSE values than did the cable, particularly at the extremes of the flexion arc (Table 1). While it would appear advantageous to calibrate the device using the actual graft rather than the cable, the slight decrease in error is probably not worth the increase in complexity of applying equal loads to all four graft bundles simultaneously.

To further simplify the calibration and hence reduce the time required, the minimum number of angles that would accurately reproduce the calibration curve over a continuous range of flexion angles was of interest. With the two three-angle groups giving comparable errors to the standard non-curve-fit group (Table 2), the FDT can be calibrated at only three flexion angles. From these three angles, a curve fit can be obtained and used to determine the calibration values for a continuous range of flexion angles. Although the 0-60-120 deg group would be preferred over the 0-45-90 deg group because of the reduced error at 120 deg (Table 2), calibrating at 120 deg may not be practical if the patient's leg cannot be flexed past 90 deg due to interference with the operating table. Inspection of individual calibration curves for the specimens indicated differences in calibration values as high as 40 percent when the regression model for the 0-45-90 deg group was extrapolated to 120 deg. Thus measurements beyond about 100 deg would be prone to large error. This could limit the usefulness of the device in activities such as deep squats, which are often included in rehabilitation programs.

In addition to defining the calibration procedure, it was also of interest to determine whether tunnels, which encourage biological bonding *in vivo* by fitting the graft snugly, could be drilled without compromising the measurement accuracy of the FDT as a result of friction. Significant friction inside the femoral tunnel would cause the FDT to underestimate the tension of the intraarticular portion of the graft. Overdrilling the femoral tunnel by 1 mm to reduce friction did not reduce the error (Table 1), indicating that the frictional effect in the femoral tunnel was minimal. Wrapping of the graft as it exited the femoral tunnel, instead of friction, may explain the higher RMSE values at 0, 90, and 120 deg. The lowest RMSE values were at 30 and 60 deg (Table 1) where the orientations of the femoral and tibial tunnels were more collinear. Therefore, the diameter of the femoral tunnel can be drilled to match the diameter of the DLSTG graft, which is better for promoting biologic bonding compared to placing the graft in an overdrilled bone tunnel.

Although friction may not be a significant source of error immediately postoperatively, biological bonding of the graft to the femoral tunnel will affect the ability of the FDT to measure graft tension accurately over time. In addition, bone ingrowth around the tip of the FDT can limit the deflection of the beam. Tendons heal to the tunnel wall by 4 weeks in a dog model (Rodeo et al., 1993). If these results apply to the human, then

the FDT should provide an accurate intra-articular measurement of tension for the first few weeks of implantation.

The reduction in voltage output of the FDT over time can be used to monitor the progression of biological bonding. An experiment can be performed in which the telemeterized FDT is inserted in patients undergoing ACL reconstructions. Then a constant anterior shear load can be applied intraoperatively and daily postoperatively using a commercially available arthrometer while the FDT output is simultaneously recorded. The difference between the intraoperative and daily output of the FDT would provide a measure of the biological ingrowth, and the absence of any output would indicate when biological bonding is complete.

The ability to track the development of the biological bonding between the graft and femoral tunnel is advantageous because animal studies have shown that a weak link following ACL reconstruction with a patellar tendon autograft occurs at the femoral attachment site (Ballock et al., 1989; Butler et al., 1989). To our knowledge, no *in vivo* biomechanical studies of graft fixation within a tunnel have been done using a DLSTG graft. The determination of the time from implantation required for biologic fixation inside the femoral tunnel may be useful in predicting when it is safe to increase rehabilitation exercises to more strenuous levels.

The accuracy of the FDT is better than that of other transducers. Of the few studies that reported accuracy, Fleming et al. (1996) reported an overestimation greater than 100 percent for a 100 N graft load during *in situ* testing using an arthroscopic implantable force probe. The average relative error of the tension measured by the FDT was less than 10 percent when the cable was used as the calibration material and the calibration curve was derived from the calibration measurements made at 0-45-90 deg of flexion. This percent error is relative to a full scale load of 257 N, which was the average maximum graft tension with a 200 N anterior force applied. Because this tension value is almost identical to the maximum tension developed in the graft at 0 deg flexion during passive motion (Wallace et al., 1997), the 10 percent is a relatively small error clinically.

Conclusion

This study has presented a unique implantable transducer for measuring ACL graft tension and has defined a practical calibration protocol for use *in vivo*. The protocol that should be followed for FDT calibration is as follows:

- Drill standard size tibial and femoral tunnels.
- Orient the FDT with a cable by applying weights at two different points along the span of the beam. For optimal orientation, both of the FDT outputs should be equal.
- Calibrate with the cable at 0, 45, and 90 deg by applying weights incrementally up to 245 N.

With this protocol, the FDT error in graft tension measurement is less than 10 percent on average of the maximum tension developed in the graft at 0 deg flexion during passive motion (Wallace et al., 1997).

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