Telemetry system for monitoring anterior cruciate ligament graft forces in vivo

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Abstract—Quantifying changes in the tension of an anterior cruciate ligament (ACL) graft in vivo during rehabilitative exercises is useful for developing the optimum rehabilitation for patients who have had reconstructive surgery. The purpose of the work reported is to design, build and test a telemetric system that can measure the in vivo ACL graft tension postoperatively. A commercially available telemetric device is modified to sense the graft tension, house electronic components, transmit an output signal and pass the power generating signal. A transcutaneous inductive link is used to power the implanted telemetric electronics. The current difference technique is used to measure changes in two resistance strain gauges that monitor shear strain developed on the femoral fixation device by the ACL graft. This current regulates a frequency-modulated output signal that is transmitted using a new technique. Harnessing the ionic and volume conductive properties of the body fluids, the new technique involves injecting current subcutaneously into the tissue and then sensing the potential developed on the skin by surface electrodes. The waveform shape, amount of charge injected, charge density and current density are regulated to avoid tissue damage, pain and unwanted muscular stimulation. A signal conditioning board detects and converts the output to an analogue voltage for collection by a computer data-acquisition system. A performance evaluation demonstrates that the telemetric system either meets or exceeds all of the criteria necessary for the application.

Keywords—Implantable, Telemetry, Anterior Cruciate Ligament, Graft, Tension, Transducer


1 Introduction

Rehabilitation is important to the success of an anterior cruciate ligament (ACL) reconstruction. The goal of rehabilitation is to restore full functionality to the reconstituted knee as quickly as possible, without either stressing the graft or losing fixation, both of which can cause recurrent instability.

In recent years, an aggressive rehabilitation approach emphasizing early motion and weight bearing has been pursued to avoid the complications stemming from a more conservative approach that immobilizes the knee and avoids weight bearing (Sheehan and Nit, 1990; Posnisky, 1992). However, a potential complication of aggressive rehabilitation is that the graft may be exposed to excessive tension. Excessive tension could cause failure of the graft or the initial fixation and compromise the remodeling and maturation process (Marckolf et al., 1994). Consequently, to avoid this complication, the graft tension must be determined for various rehabilitation activities.

Although there are several approaches for determining graft tension, such as mathematical models (Harrington, 1970) and in vitro measurements (Marckolf et al., 1993), in vivo measurement offers the advantage of monitoring and modifying the rehabilitation programme if necessary. In vivo tension measurements have been obtained using the goat model (Holden et al., 1994; Lewis et al., 1994). However, the results of the goat study are useful only in the design and interpretation of other animal studies and cannot be extrapolated to humans (Holden et al., 1994).

In human studies, suture attached to an ACL graft were secured to load cells mounted externally on the fibula (Shino et al., 1994; Wallace et al., 1997). Data could be collected only in the operating room and during simple knee extension exercises against gravity (Shino et al., 1994). Such exercises do not encompass the full spectrum of activities in an aggressive rehabilitation programme.

Because of the limitations inherent in the previous studies that have measured ACL graft tension in vivo, there is a need for instrumentation that can be implanted into ACL reconstructive patients, so that the graft tensions can be measured during the rehabilitation process. The purpose of this project was to design, build and test a prototype telemetric system that can directly measure the in vivo ACL graft tension for several weeks post-operatively. The remainder of this paper describes the design of the telemetric system, presents an evaluation of performance and discusses how well the design meets the established criteria.

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2 Design description

Several criteria were established for developing the instrumentation to measure the ACL graft forces in vivo.

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Fig. 1 System design

(a) The device must be entirely integrated within a present fixation device and fit into its geometric constraints, so that modification of the surgical procedure is not needed.
(b) As the device requires a power source and will be implantable, the device must be inherently safe to protect the patient from any possible harmful side-effects.
(c) The device must minimise power drain.
(d) The device must be capable of operating for up to 12 weeks, the maximum expected time for the graft to become fixed biologically, so that the device no longer senses load.
(e) So that it does not contribute significantly to the error in measuring graft tension, the device must have a resolution of at least 1% of full-scale output and a non-linearity of less than 1%. Also, the output signal rise time must be less than 10 ms, so that relatively fast changes in the ACL graft tension that are developed by dynamic rehabilitation activities can be monitored.
(f) If possible, then the device should incorporate diagnostic capabilities, so that the functionality of the device while implanted can be determined.

To meet the criteria outlined above, the system shown in Fig. 1 was designed and constructed. The ACL telemetry system incorporates a power transmission system, a telemetry device and a data-acquisition system. Power is inductively coupled into the telemetry implant by external and internal coils. The ACL graft tension is monitored by the telemetry fixation device, and a data signal is transmitted via the body’s ionic fluids and detected by surface electrodes. The signal is amplified, converted into an analogue voltage signal, and captured by the computer data-acquisition system for analysis and storage. The following paragraphs describe in detail the modifications to the present fixation device, the implantable telemetry electronics, the power-transmission system and the data-acquisition system.

2.1 Fixation device transducer

The commercially available bone-mold screw fixation device* was modified for sensing graft tension, housing electronic components, transmitting an output signal and receiving the inductive power generating signal. Because the design and accuracy evolution of the fixation device transducer (FDT) has been fully described elsewhere (VENUTA et al., 1997, 1998), only a summary sufficient for understanding how the telemetry interfaces with the transducer is presented here. To appreciate the modifications, an understanding of how the device is used for ACL graft fixation is useful. A tibial tunnel, through which the graft bundles pass, is drilled from the anterior-medial side of the tibia up through the tibial plateaus (Fig. 2). Another tunnel is drilled into the femur by inserting a drill through the tibial tunnel. The fixation device is screwed into a second closed-ended femoral tunnel, so that the graft bundles can be looped over the beam that protrudes from the threaded body of the device. The bundles are then securely fastened to the tibia with a screw and stranded washer.

With slight modifications, the femoral fixation device was converted into a transducer. Originally monolithic, the FDT was divided into two main parts for ease of sensor installation. One main part is the threaded body. The other main part is the beam, which consists of a hollow rectangular cross-section joined to a solid rectangular cross-sectioned smooth beam 10 mm long (Fig. 3). Because the beam loops around the beam, which is shortened from the original bone-mold screw (Fig. 2) such that it is cantilevered within the femoral tunnel through which the graft is routed, the transducer is based on cantilever beam principles. Equal to the total tension in the graft, the applied force is measured by two full-scale gauges mounted at the centre of opposite sides of the inside of the hollow rectangular section of the FDT beam. Their axes are oriented at opposite 45° angles with respect to the direction of the graft tension. With the two strain gauges connected in a half-bridge circuit powered by a constant voltage source, the potentials across each gauge are subtracted to yield a signal proportional to the direct shear stress but insensitive to temperature variations and torsion loads acting about the axis of the beam. Because the applied force governs the shear stress in the hollow rectangular section, the transducer signal is independent, theoretically, of the centre of pressure, which may shift owing to the motion of the graft bundles. Because the beam is cantilevered, the tip was enlarged so that the graft does not slide off of the end when the centre of pressure shifts medially (Fig. 3).

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To achieve a hermetically sealed enclosure while providing a high coupling coefficient for the inductive power link, the screw is manufactured from different materials joined by various methods. The threaded portion of the screw is manufactured out of aluminum ceramic, facilitating passage of the inductive power magnetic field. A titanium collar is brazed to the aluminum, so that the titanium beam can be laser-welded to the threaded portion of the screw. Two platinum wires, cut flush to the exterior surface on the hex head end of the fixation device, serve as the electrodes for injecting current into the tissue to transmit the transducer signal. The use of platinum wire is necessary to limit the dissolution of the electrodes (McHARDY et al., 1980). A glass seal around the wires completes the hermetic seal.

2.2. Telemetry device design

For ease of description and understanding, the design can be conceptually separated into three sections: power supply, signal transduction and signal transmission (Fig. 4). In the power supply section, a custom-designed inductive pick-up coil L1 receives the transmitted magnetic field. The coil consists of 100 turns of 24 AWG wire wrapped around a ferrite core (length = 6.4 mm, diameter = 4.6 mm). Capacitor C0 develops a resonant circuit at the power transmission frequency significantly increasing the coupling efficiency of the power coupling link. Diode D2 and capacitor C2 provide rectification and filtering of the incoming AC voltage, supplying a stable DC voltage to voltage regulator U1. Resistors R1 and R2, along with U1, establish the circuit power supply voltage at 3.25 V. Capacitors C3 and C4 provide additional filtering, removing any spurious noise that may have been transmitted from the power generating portion of the circuit. Signal transduction is achieved using two current sources, U2 and U3, connected in series using the current difference technique (BERGMANN et al., 1988). The output of the current sources is regulated by the resistive value of each of the strain gauges, SG1 and SG2. The interconnection between the two current sources provides the current difference that is used in the signal transmission scheme. Resistor R2 maintains a permanent offset, so that current always flows out of the interconnection point, providing charging current to capacitor C4. If resistor R4 is infinite, then U5 might require more current than could be provided by U2, making the circuit inoperable. The output frequency can be adjusted by slightly altering the value of Ra, which changes the charging current available.

An innovative approach, exploiting the ionic and volume conduction properties of body fluid, is used for data transmission (LINDGREN et al., 1998). The frequency-modulated output signal is transmitted through the tissue medium and received by external surface electrodes. The transmitted signal is at a higher frequency, nominally 5 kHz, than normal muscle activation frequencies, so that the signal both can be distinguished from them and does not cause serious muscle contractions. Also, this reduces the amount of noise introduced into the data signal at the transmission frequency.

The general-purpose timer U4 is connected as an astable multivibrator for generating the frequency-modulated output. The current from the signal transduction section charges capacitor C4 until it triggers U4, causing the output to go low and the capacitor to be discharged through resistor R4. At the end of the discharge cycle, the output returns to a high state, and charging of the capacitor proceeds as previously. The time for charging capacitor C4 is regulated by the current difference between the two current sources and, thereby, modulates the output frequency of the timer, which is nominally set at about 5 kHz.

In the use of this telemetry technique, it is a requirement that the waveform shape, total charge injected, charge density and current density be regulated to prevent tissue damage, pain and/or muscular stimulation (LINDGREN et al., 1998). The guidelines that must be adhered to are as follows:

(i) Use a balanced biologic waveform to reduce tissue damage (LILLY et al., 1955).

(ii) Limit the amount of injected current to avoid pain (HAWKES and NAKAM, 1960).

(iii) Use a combination of current density and charge density to prevent platinum dissolution (BREMMER et al., 1977).

(iv) Use a charge density below 350 μC/cm² to limit the development of potentially harmful gases (BREMMER and TURNER, 1977).

(v) Use a total charge per phase below 0.45 μC per phase to reduce tissue damage (PEIDING et al., 1975).

(vi) Use an appropriate inductive charge that does not result in musculoskeletal stimulation (DURAND, 1991).

An RC circuit was designed to meet all of these guidelines. In the design procedure, R is determined first such that the peak current is limited to a value that satisfies the second guideline, and then a value for C is found such that the combination of current density and charge density meets the
third guideline. Once values for $R$ and $C$ are found that satisfy the second and third guidelines, the charge density and the total charge per phase are checked for conformance with the fourth–sixth guidelines. Additional circuit parameters are then adjusted to meet the final guideline. The details of this procedure are described in the following paragraphs.

An appropriate value for resistor $R_3$ is chosen to meet the second guideline and set the bias for meeting additional guidelines. For our application with $V_{dc}=2.5$ V, resistor $R_3$ is set at 768 $\Omega$, thus allowing a current of 3.25 mA (peak) at 5 kHz, which is safely below the pain threshold of 5.5 mA (IBM). (HAWKES and WARD, 1960) yet still develops a strong signal at the receive electrodes on the skin surface (LINDSEY et al., 1998). This current and the given area of the electrodes (1.13 x $10^{-2}$ cm$^2$), the corresponding current density is 2.86 A/cm$^2$. This current density allows a charge density of no greater than 60.4 $\mu$C/cm$^2$ to prevent rapid platinum dissolution, which is necessary to meet the third guideline (HAWKES et al., 1977).

To limit the charge density to one-half of the value above, the value of capacitor $C_7$ must be specified. Capacitor $C_7$ is chosen to hold twice the charge that is injected into the tissue. ($C_7=2C_9$). With the electrode area and the charge density of 30.2 $\mu$C/cm$^2$, $Q_{max}=34.2$ $\mu$C, which is conservative relative to the upper limit given in the third guideline. Solving for $C_7$ gives $C_7=27.4$ $\mu$F. With this value, not only is the third guideline met, but the fourth and fifth guidelines are satisfied as well.

For our application, the nearest muscle stimulation site to our transmission electrodes is the peroneal nerve, approximately 38 mm away. For distances above 1 mm, doubling the distance requires four times the current amplitude to produce stimulation (DURHAM, 1995). Owing to the separation of 30 mm, the injected charge seen at the peroneal nerve will be approximately 1/900 of the charge injected. For the 34.2 $\mu$C injected, approximately 38 $\mu$C will be seen at the peroneal nerve, which is well below the 158 $\mu$C used by WATKINS et al. (1975) to correct footdrop, therefore meeting the fifth guideline.

To create a balanced bipolar waveform necessary to meet the first guideline, the value of resistor $R_5$ is set such that the pulse width is the time required for half of the charge on $C_7$ to be injected into the tissue. The pulse width is equal to $T/2$ to $T$. Substituting the $R$ and $C$ values determined above into $I=Q/C$ gives a pulse width of 6.4 $\mu$s. Resistor $R_5$ is set to the value that will drain the voltage on capacitor $C_9$. $C_9=320$ pF, from 3/4 $V_{dc}$ down to 1/3 $V_{dc}$. Taking into account the constant current input from the current difference, the value of $R_5$ is 40.2 M$\Omega$. At the end of the pulse, the output of $U_6$ returns high, and the charge previously injected is extracted back into $C_9$ from the tissue. The signal conditioning board receives the amplified EMG signal and converts the frequency to an analogue voltage for input into a computer data-acquisition board (Fig. 4). A computer algorithm whose output goes high when the signal exceeds the threshold set by resistor $R_4$ detects the incoming frequency and converts it to a TTL compatible signal. Flip-flop $U_2$ gates the $50\%$ duty cycle signal to the buffer, which halves the input frequency, which is then used to drive the frequency-to-voltage converter (FVC) $U_2$. The operational amplifier $U_3$, along with $R_{11}$ and $R_{10}$, provides a DC offset and variable gain factor to the FVC output to make maximum use of the input dynamic range of the data acquisition system. Resistor $R_2$, and capacitor $C_4$ yield a low pass filter with a 370 Hz frequency cutoff to reduce output noise. The output, which is as a 0–5 V signal, is connected to a data-acquisition board.

The power transmission system consists of 10ums of 175/40 lite wire wrapped around a plastic bobbin form (length = 71.1 mm, outside diameter = 60.2 mm). The chosen diameter allows for the expected movement of the external coil, relative to the internal coil, without appreciably decreasing the coupling coefficient and thereby lowering power transfer (KO et al., 1977). However, the external coil diameter has been minimized so that coupling with the internal coil can be maximized (SOMA et al., 1987).

2.4 Data-acquisition system

The data-acquisition system consists of EMG leads with amplifier, 3.5 mm cable, signal conditioning board and computer with an installed data-acquisition board (Fig. 1). Placed near the knee on the lateral side, silver/silver chloride surface electrodes record the output of the internal telemetry device. The electrodes are placed on the lateral surface of the thigh, 5 cm proximal of the joint line, at an interelectrode separation of 5 cm to minimize the attenuation of the received signal (LINDSEY et al., 1998). An instrumentation amplifier (INA 102) amplifies the telemetry output signal and transmits the signal to the signal conditioning board. The amplifier is configured to provide a high pass filter with a cutoff frequency of 23 Hz, eliminating low-frequency noise. At the case of power transmission, a cable tethers the patient to the ACL telemetry system.

The signal conditioning board receives the amplified EMG signal and converts the frequency to an analogue voltage for input into a computer data-acquisition board (Fig. 4). A computer algorithm whose output goes high when the signal exceeds the threshold set by resistor $R_4$ detects the incoming frequency and converts it to a TTL compatible signal. Flip-flop $U_2$ gates the $50\%$ duty cycle signal to the buffer, which halves the input frequency, which is then used to drive the frequency-to-voltage converter (FVC) $U_2$. The operational amplifier $U_3$, along with $R_{11}$ and $R_{10}$, provides a DC offset and variable gain factor to the FVC output to make maximum use of the input dynamic range of the data acquisition system. Resistor $R_2$, and capacitor $C_4$ yield a low pass filter with a 370 Hz frequency cutoff to reduce output noise. The output, which is as a 0–5 V signal, is connected to a data-acquisition board.

3 Performance evaluation

Performance evaluation of the ACL telemetry system can be separated into the three system components as described above: the power transmission system, the telemetry device and the data acquisition system. Because the performance evaluation of the data transmission technique is the subject of another article (LINDSEY et al., 1998), the interested reader should consult this source information to how the strength of the received signal was affected by various transmit (e.g. carrier frequency) and receive (e.g. interelectrode separation) variables.

The purpose of the power transmission system is to provide sufficient power to the implanted electronics for them to operate properly at the required external and internal coil separation. With the class E power supply operating in feedback mode, it generates sufficient magnetic field to power the telemetry device. At the operating frequency of 200 kHz, the voltage across the output coil is 60 V peak-to-peak, so that the power required to drive the coil from the power supply is 1.6 W. At a coil separation of 20 mm, this induces the 3 mW required by the implant, giving 0.56% efficiency. Because the estimated separation for the two coils differs experimentally
The first design criterion was to minimize the power drain of the implanted electronics. Most designs utilizing synch gauges employ Wheatstone bridges and operational amplifiers for amplification of the small resistance change, but this requires a large number of components and has a high

4 Discussion

The objective of this project was to design, build, and test a telemetry system that can monitor ACL graft forces in vivo during rehabilitation. Many physiological quantities have been measured using implantable telemetry devices, especially with the aid of microcircuitry and hybrid circuit design (Butter, 1983). Telemetry devices have been used extensively in hip implants to monitor human hip cartilage surface pressures (Carlsson et al., 1974), hip joint forces (Ozmen and Bergmann, 1991; Kelvin and Goodman, 1981), and strain measurements (Barlow et al., 1984; Taylor et al., 1992). However, owing to the unique nature of the application here, no previous system built around these devices satisfied the design criteria for measuring ACL graft tension. Accordingly, the design of a new system was undertaken.

To meet the first design criterion of using a current fixation device, so that the surgical procedure did not need to be modified, the bone match screw was selected. The internal components were designed to fit into the geometric constraints of the screw, which severely limited the number of components allowed and the construction technique to be used. Some modifications to the screw were required, but the basic form and function were not altered. Accordingly, the modified screw can be used without affecting the surgical procedure.

The third design criterion was to minimize the power drain of the implanted electronics. Most designs utilizing synch gauges employ Wheatstone bridges and operational amplifiers for amplification of the small resistance change, but this requires a large number of components and has a high

Fig. 5 Schematic diagram of signal conditioning board. All capacitors in microfarads and all resistors in ohms

Fig. 6 Resolution as percentage of full scale against time constant.

trials is 10–15 mm, the inductive link is more than sufficient. The 0.67% efficiency is less than the optimum 3.6% calculated using the equations from Ko et al. (1977). The losses can be explained by the use of a 3.5 m cable and the fact that the inductance (i.e., number of turns) of the coil had to be increased to raise the Q, so that the closed-loop class E supply could be used. The frequency and performance of the electronic circuitry of the telemetry device were tested on the bench at ambient temperature. The telemetry electronics were powered from a DC power supply; thus the inductive power link was not used. The beam was placed in a custom-designed holder and securely held in a benchtop vice, so that weights could be hung from the beam. The output of the circuit was connected to the signal conditioning board through the 1.5 m cable and recorded using a data-acquisition computer. The output voltage was recorded under various loading conditions to quantify different performance characteristics.

To measure the hysteresis and non-linearity of the device, weights were applied incrementally during loading and unloading. The response was linear, with a full-scale voltage range of 2.5 V for a maximum load of 290 N. The maximum non-linearity for the loading condition was 0.63% of full-scale load. The hysteresis showed a maximum deviation of only 0.65%.

A drift test was conducted at four different loads: 0 N, 410 N, 200 N and 29 N. Data were collected for a 30 min time period for each of the loads. No quantifiable (i.e., <0.1% of full scale) low-frequency drift was present for any of the four tests.

The dynamic response of the system was measured by momentarily switching in a parallel resistance with one of the strain gauges. This simulated a step input in the loading. The time to reach 90% of the final output (rise time) was 9 ms, with a 5 ms time constant. Different rise times can be obtained by changing the integrating capacitor C1 for the FVC (Fig. 5). However, resolution of the system will also change, because a smaller capacitor will lead to shorter rise times, but the integrator output ripple will increase (Fig. 6).

The most important aspect of the data acquisition system is the ability of the comparator to detect signal pulse. The signal conditioning board was tested on the bench, measuring the hysteresis and threshold levels. The present circuit requires a minimum of 100 mV peak input signal for the output to change state and has a hysteresis band of 25 mV to eliminate false triggering during a state transition.
power demand. To reduce both the component count and the power demand, the current difference method was used (Bergman et al., 1988). This method was ideally suited to the application, because both current source outputs were regulated by the strain gauge resistances. As the current difference was used to modulate the frequency of a carrier signal, the insensitivities of the transducer to temperature change and tension about the axis of the FDT beam offered by a half-bridge powered by a constant voltage source were maintained.

Space limitations for the internal circuitry severely restricted the available options for data transmission. Radio-frequency transmission could not be employed, because a coil, needed for transmitting the signal, required too much space. A transparent optical data link could not be used because it required an optical path, which was unavailable (MitaMurra et al., 1990). Likewise, the transparent power link could not be used, because the coupling coefficient between the external and internal coils was so small that any change in the internal coil inductance had negligible effect on the external coil inductance (Donaldson, 1966). Therefore an innovative approach was taken, harnessing the ionic and volume conductance properties of the body fluids for data transmission.

The new data transmission technique was developed and tested (Lindsey et al., 1998). Testing demonstrated that an electrical signal, which constituted the data signal, could be transmitted into the body fluids containing ions that were used as charge carriers and then easily detected using surface electrodes. The signal’s frequency needed to be high enough so that interference with signals naturally existing in the body did not occur. To partially meet the second criterion of ensuring the patient’s safety, the amount of charge injected, charge density, and current density were regulated to prevent tissue damage, pain and unwanted stimulation.

To determine safe limits on the various electrical quantities (e.g. injected charge) associated with the data transmission technique, the approach taken was to review the literature, determine the upper limits on these variables and then design the circuit so that the variable values were below these upper limits. However, in taking this approach, some uncertainty exists, because the conditions of the tests that were used to determine some of the upper limits were not representative of the application described herein. Thus, the circuit parameters to control charge, charge density and current density must be considered tentative until they are verified. To verify that the circuit design presented herein does not cause tissue damage, the authors plan to test the circuit in an animal model before any in vivo use in a human. The results of such tests will be the subject of future article.

To meet the second criterion fully, the packaging was also an important consideration. The packaging for an implantable telemetry device must provide protection for the electronic and mechanical components from the hazardous body environment, protection of the patient from any possible harmful effects, and compatibility with the body (ko and Spooner, 1983). An hermetically sealed enclosure is ideal, because polymers do not provide the same protection, owing to a finite permeability to moisture (ko and Spooner, 1983). An hermetically sealed enclosure was realised by using both glassy and metallic seals (Donaldson, 1988).

To ensure that the circuitry presented in Fig. 4 could be housed within the hollow of the screw (Fig. 3), a design for a thick-film hybrid circuit was completed. Although the circuitry in Fig. 4 could be accommodated, the space limitation precluded any additional circuitry for diagnostic purposes. Therefore, the sixth design criterion could not be met. However, analysis of the data transmission signal does provide information regarding the functionality of the electronics.

The fourth design criterion required that the device operate for a minimum of 12 weeks after implantation. Batteries were eliminated from consideration because current technology does not provide a battery with sufficient power, even when using switches to extend the battery life, that can be housed in the required enclosure. Thus, transcutaneous power coupling was the only possible solution and allowed for longer experimental times, more experimental trials, and repeated experiments. The poor coupling coefficient resulted both because of the 10–15 mm separation between the internal and external coils and because of the size difference between the two coils. Therefore, a closed-loop class E power supply design was chosen, because it can drive the transmitter coil with lower losses than other power supply designs (Troy and Schwan, 1992). As only limited subject movement is required during testing, the patient was tethered by a 3.5 m cable. If tracking over a larger range is required, then a rechargeable battery pack could be constructed to power the inductive link for a period of 3–4 h.

The fifth criterion concerning resolution, non-linearity, and dynamic response was satisfied. The non-linearity of the device was less than ±1% with a typical resolution of 1.1%. Thus, the inherent inaccuracy of the device is about an order of magnitude less than the inaccuracy of the actual measurement of graft tension using the FDT (Vinturuta et al., 1997; 1998), so that the device does not contribute significantly to the measurement error. The dynamic response produced a 9 s rise time and a 5 s time constant. In vivo dynamic ACL force measurements in humans have not been obtained. However, in vivo ACL force measurements in quadrupeds showed a worst case loading rate of 1572 N ms⁻¹ during normal walking (Hofsin et al., 1994). This leads to an error of 7.8 N (error = slope x time constant), which corresponds to 2.7% of full-scale load in the present system. Typically, leg movement immediately post-operation is limited owing to swelling and pain. Therefore a relatively slow loading rate is expected.

5 Conclusions Because a safe and effective rehabilitation program for ACL reconstructive patients depends upon knowing the graft tension during rehabilitative exercises, the goal of this project was to design and build a telemetry system that can monitor the ACL graft tensions in vivo. The performance evaluation demonstrated that the design satisfied all of the criteria important to the application. Accordingly, much progress toward developing an ACL telemetry device that can monitor ACL graft tension in vivo has been made. The next step for developing an implantable telemetry device is to implant a prototype and test its functionality in an animal model.

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Authors’ biographies

Eric McKee received his BS degree in Electrical Engineering from the University of Evansville in Indiana, in 1989, and both an MS in Biomedical Engineering and an MBA from the University of California, Davis, in 1995. In 1995, he joined an industrial firm as a Design Engineer and has since become Engineering Manager, focusing on the development of products for medical applications.

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Stephen Howell received a BS degree in Premedical/ Biophysics from Pennsylvania State University, in 1976, an MD degree from Northwestern University Medical School, in 1981, and completed a residency in Orthopedic Surgery at Thomas Jefferson University, in 1986. He became an Associate Professor in the Mechanical Engineering Department at the University of California, Davis, in 1996, and is currently practicing orthopedic surgery. Dr. Howell has a research interest in the reconstruction of the torn anterior cruciate ligament.