

A New Technique for Transmission of Signals from Implantable Transducers

Derek P. Lindsey, Eric L. McKee, *Member, IEEE*, Maury L. Hull,* and Stephen M. Howell

Abstract—To reduce space requirements for implant electronics in *in vivo* telemetry applications, the purpose of this project was to develop and test a new data transmission method that utilizes the ionic properties of bodily fluids as the transmission medium. Motivated by an interest in using the new method to transmit information from a sensor which measures tension in anterior cruciate ligament (ACL) grafts, a sine wave was injected into a cadaver leg using platinum electrodes implanted into the lateral femoral epicondyle. The signal was detected by electromyogram (EMG) surface electrodes. The effect of transmission frequency, the current injected, interelectrode separation, distance of the electrodes from the joint line, and the surface of electrode placement on the signal attenuation was studied. The logarithmic relation between attenuation and frequency was constant from 2 kHz until 10 kHz. For frequencies above 10 kHz, the attenuation increased linearly at the rate of 1 dB/octave. Attenuation was inversely sensitive to both current and interelectrode separation with larger separations and currents giving less attenuation. Attenuation was significantly less for the lateral thigh surface than for the anterior surface and increased with increasing distance from the joint line for both surfaces. For the application of interest here, suitable values of transmission variables to avoid the possible negative consequences of injecting current into living tissue are a current of 3 mA injected at a frequency of 37 kHz. The values of reception variables for minimum attenuation are wide interelectrode separation (5 cm) with the electrodes placed 5 cm proximal of the joint line on the lateral surface of the thigh. With the exception of the surface which is application dependent, these values of the reception variables should also be appropriate for other applications.

Index Terms—Anterior cruciate ligament, electrode, graft, implantable transducer, telemetry, volume conduction.

I. INTRODUCTION

B IOMEDICAL telemetry has contributed to our understanding of the human body by providing the ability to monitor various parameters within the functioning body. However, for a telemetry device to be useful, transmission of data to an external data acquisition system is required. For any device which is to be implanted for any length of time, protrusion through the skin by wires, needles, or other connectors for data transmission is unacceptable because of the risk of infection and rejection by the body. Therefore,

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D. P. Lindsey and E. L. McKee are with the Biomedical Engineering Graduate Group, University of California, Davis, CA 95616 USA.

*M. L. Hull is with the Department of Mechanical Engineering and the Biomedical Engineering Program, Room 1050F, EU II, University of California, Davis, CA 95616 USA (e-mail: mlhull@ucdavis.edu).

S. M. Howell is with the Department of Mechanical Engineering, University of California, Davis, CA 95616 USA.

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transmission methods which do not pose harm to the body are required.

Different transmission methods which are compatible with the body have been developed. Because the majority of telemetry devices have used batteries as the power source, the most prevalent method has been radio frequency (RF) transmission [6]. The transcutaneous inductive power link has also been used to either passively or actively send the data to and from the implant (e.g., [3]). Recently, transcutaneous optical data links have been used to transmit information to and from both artificial hearts [12] and ventricular heart assist devices [11].

Drawbacks exist for each of the data transmission methods just described. A coil is needed in RF transmission for generating the output signal. Some applications are extremely space limited and do not have the physical space for this coil. Other applications, which use a transcutaneous inductive power link, have such a poor coupling coefficient that it does not allow the power link to be used as the data link. Likewise, a transcutaneous optical data link cannot be employed either when no optical path is available or when the separation of the transmitter and the receiver is too great for successful operation. Because of these drawbacks, the goal of this project was to develop an alternative data transmission method to overcome these limitations.

II. METHODS

A novel scheme utilizing the ionic and volume conduction properties of body fluids was used to transmit data from an implanted telemetry device. Current injected into the tissue from an implanted device was utilized to produce voltage differences between different locations throughout the body, which were then detected by surface electrodes.

To test this innovative data transmission scheme, a system was developed to generate the signal, inject the signal into a human cadaver leg specimen, and monitor the output signal (Fig. 1). This system consists of a function generator, current-limiting resistor, injection electrodes, surface electrodes, EMG amplifier, and oscilloscope. The function generator signal was injected into the cadaver tissue using two platinum electrodes 0.38 mm in diameter, which were potted into a ceramic body (Fig. 2) and separated by 2.5 mm. The ceramic body was implanted into the lateral femoral epicondyle of a human knee specimen which was frozen within 72 h postmortem and then thawed at room temperature. The hole for the ceramic body was prepared with a drill guide system (Arthrotek, Ontario, CA) used for anterior cruciate ligament (ACL) reconstructive

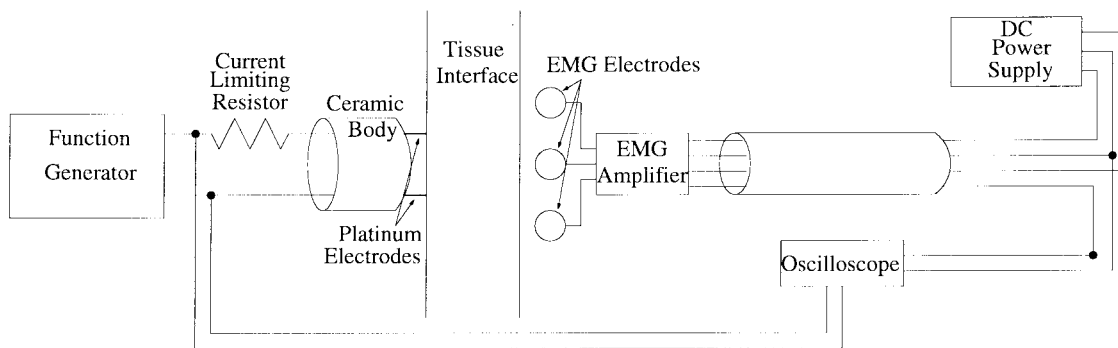


Fig. 1. System for testing the signal transmission method.

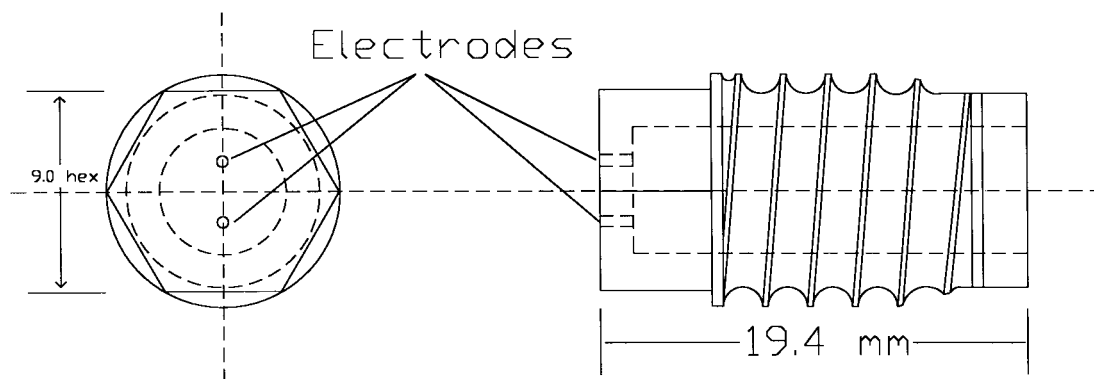


Fig. 2. Ceramic body with transmission electrodes.

surgery (Fig. 3). First, an 8-mm-diameter hole was drilled up through the tibia into the intercondylar notch and continued 25-mm deep into the femur. The tunnel for the ceramic body was drilled through the lateral femoral condyle such that it intersected the femoral tunnel and was then drilled all the way through to the medial side of the knee to allow for passage of the transmission wires. After the ceramic body was screwed into the bone so that it was flush with the surface of the bone, saline solution was injected around the platinum electrodes to provide a supply of ions for signal conduction.

Current, frequency, interelectrode separation, distance from the joint line, and surface were the five independent variables that were investigated with respect to attenuation. The sine wave from the function generator was fixed at 3.25-V rms and the current limiting resistor was varied to allow currents of 1-, 2-, and 3-mA rms. Three silver/silver chloride surface electrodes (7.25 mm in diameter) (*In Vivo* Metric, Healdsburg, CA) filled with conduction gel were separated in varying interelectrode separations (± 1.5 cm, ± 2.5 cm, and ± 5 cm with the ground electrode in the middle), placed at different distances from the implanted electrodes to the ground electrode along the long axis of the femur (0, 10, and 20 cm), and placed on different surfaces (anterior and lateral sides of the thigh). For all combinations the frequency of the sine wave was started at 2 kHz, increased to 5 kHz, and then increased by octaves up to 160 kHz. Four other combinations ($+5$ cm and $+15$ cm on both the anterior and lateral surfaces at 5 kHz,

3 mA, with an interelectrode spacing of ± 2.5 cm) were also included to help determine the relationship between distance and attenuation. The total number of combinations was 382 (three currents times three interelectrode separations times three distances times two surfaces times seven frequencies plus four others).

The output signal from the electrodes was amplified differentially with a fast instrumentation amplifier (INA111, Burr-Brown, Tuscon, AZ) whose frequency response was flat (within 1%) to 640 kHz. To determine the effect of the variables on the attenuation, the amplitudes of both the function generator and the amplified EMG signal were measured from an oscillographic trace. The phase portion of the frequency response of the signal transmission was determined using a Lissajous figure which was corrected for the phase of the instrumentation amplifier.

III. RESULTS

The logarithmic relationship between attenuation and frequency was piece-wise linear with the region from 2 kHz to the transition being constant, and increasing linearly from the transition to 160 kHz (Fig. 4). The transition frequency was directly related to current; as the current increased the transition frequency increased. Beyond the transition frequency, the increase in attenuation was independent of current; the attenuation increased by approximately 3 dB from the transi-

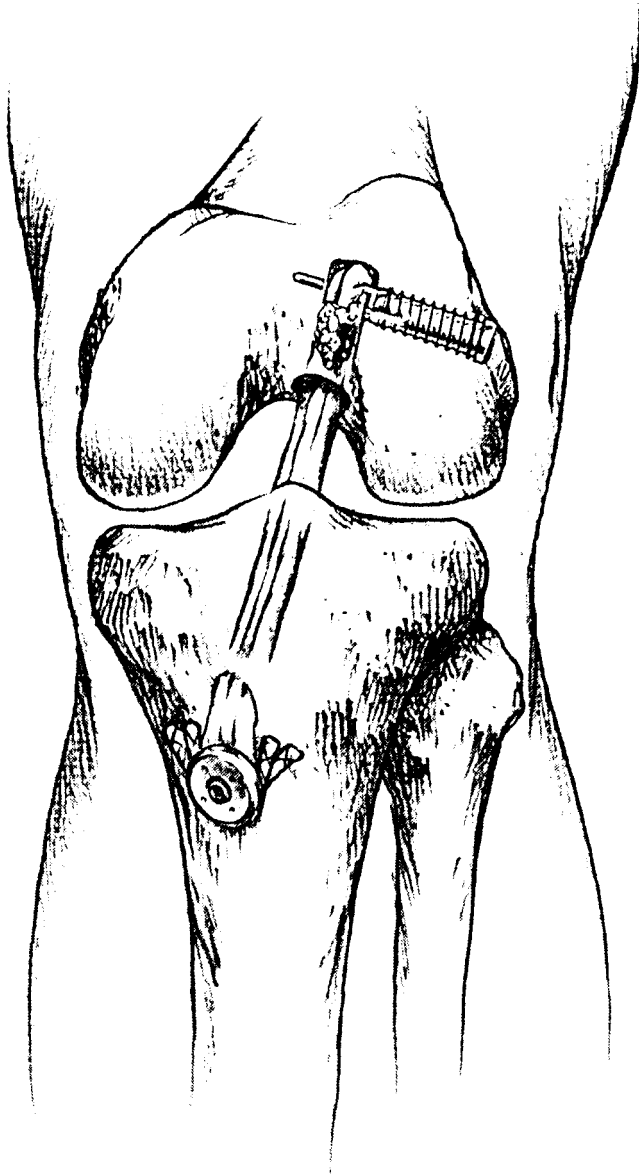


Fig. 3. Method of ACL reconstruction.

tion frequency to 160 kHz for each current (1, 2, and 3 mA). Minimum attenuation was for the highest current (3 mA) at the lowest frequency (2 kHz) with a value of 46.8 dB. Note that all attenuation values given are normalized to unity gain.

As the frequency increased from 2 kHz to 5 kHz, the phase angle between the input and output waveforms decreased for current values of 2 and 3 mA, but remained constant for 1 mA (Fig. 5). However, for all three current values, the phase increased approximately linearly in the region from 10 kHz to 160 kHz. The minimum phase difference occurred at a frequency of 5 kHz with a current of 2 mA giving a value of 0° .

As the distance from the implanted electrodes increased, the ratio of V_{out}/V_{in} dropped off approximately in proportion to the inverse of distance squared for both surfaces (Fig. 6). In general, the attenuation was less for the lateral surface than the anterior surface at the same distance from the joint line. For the

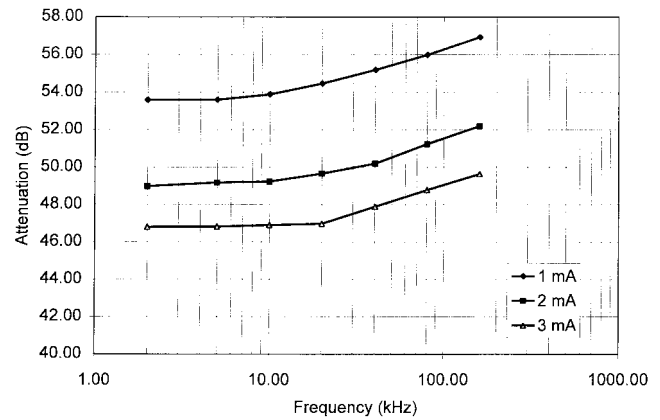


Fig. 4. Frequency versus attenuation for three levels of current (inter-electrode separation = ± 2.5 cm, lateral surface, distance = 10 cm from the joint line).

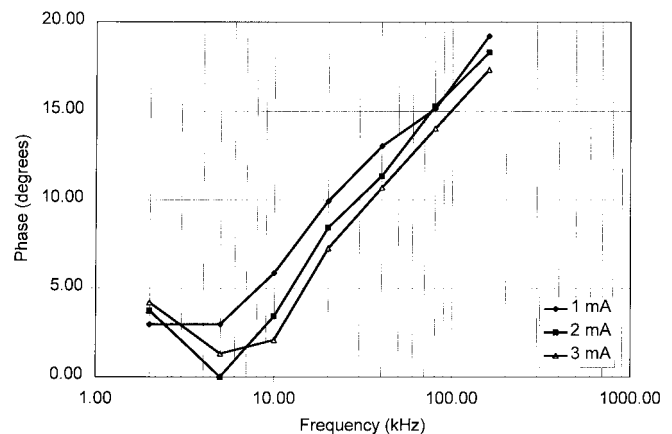


Fig. 5. Frequency versus phase for three levels of current (inter-electrode separation = ± 2.5 cm, lateral surface, distance = 10 cm from the joint line).

lateral surface, the minimum attenuation of 13.8×10^{-3} (37.2 dB) was achieved at a distance of 5 cm from the joint. Also, as the distance from the joint line increased the difference in V_{out}/V_{in} between the two surfaces decreased.

As the interelectrode separation increased V_{out}/V_{in} increased linearly (Fig. 7). The increase in attenuation was independent of frequency and was approximately 12.5 dB for all separations. The minimum attenuation of 10.2×10^{-3} (39.8 dB) was recorded with an interelectrode separation of 5 cm at 2 kHz.

Finally, as the injected current was increased, V_{out}/V_{in} increased, but not linearly (Fig. 8). As with the electrode separation, the increase in attenuation was independent of frequency with the increase being approximately 3.5 dB for all currents. At an injected current of 3 mA and a frequency of 2 kHz the minimum attenuation of 4.6×10^{-3} (46.8 dB) was recorded.

IV. DISCUSSION

Because of the space constraints for telemetry electronics in *in vivo* applications, particularly in humans, the goal of this study was to describe and test a new method for transmitting transducer signals without the need for either an RF coil or an optical source. The new method injected current into the

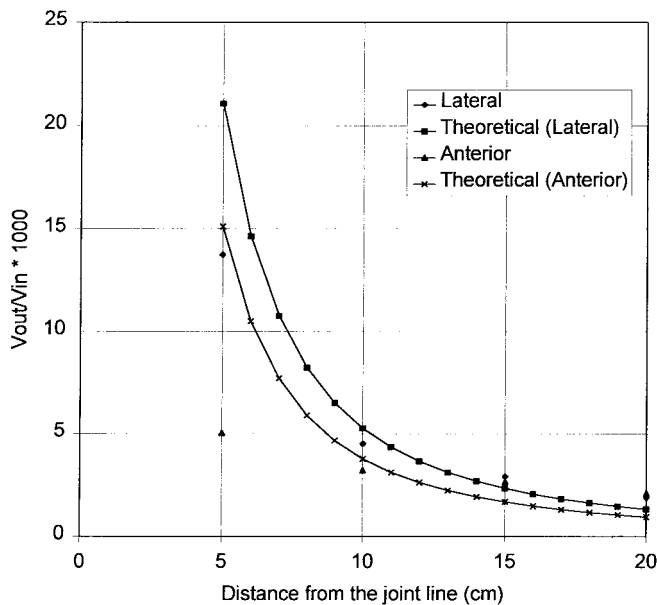


Fig. 6. Distance versus V_{out}/V_{in} for two surfaces (interelectrode separation = ± 2.5 cm, frequency = 5 kHz, current = 3 mA).

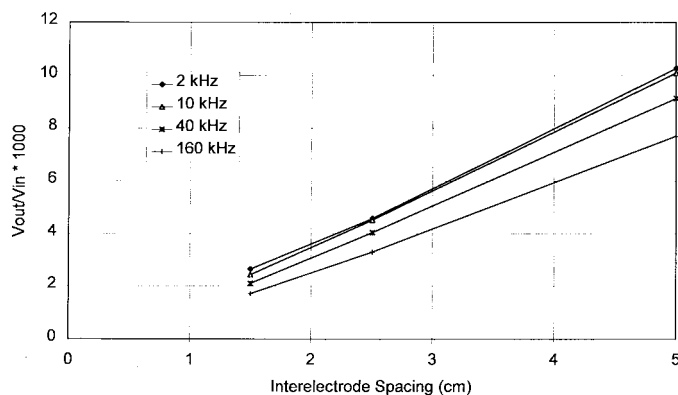


Fig. 7. Interelectrode separation versus V_{out}/V_{in} for four values of frequency (lateral surface, distance = 10 cm from the joint line, current = 3 mA).

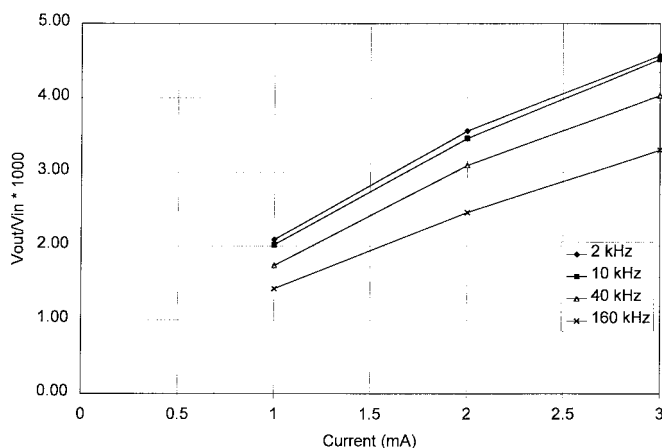


Fig. 8. Current versus V_{out}/V_{in} for four values of frequency (interelectrode separation = ± 2.5 cm, lateral surface, distance = 10 cm from the joint line).

ionic fluids of the body and then sensed potentials developed on the surface of the skin. To test the method, the current was injected by means of electrodes potted into a ceramic screw body placed in the lateral femoral condyle. To appreciate this testing procedure some background explanation is required.

The testing procedure stemmed from an interest in measuring ACL graft tension during knee-strengthening exercises and activities of daily living in a human. Following ACL reconstruction, monitoring graft tension would allow for aggressive rehabilitation and its attendant benefits [15] without the danger of overloading the graft and/or the fixation devices. Overloading can render the reconstruction ineffective in restraining abnormal knee movements.

To measure graft tension, the senior authors have developed a strain-gage-based transducer which is a modification of the bone mulch screw, a commercially available femoral fixation device (Arthrotek, Ontario, CA). The screw consists of a beam around which the graft is looped attached to a hollow body (Fig. 3). Graft tension is sensed by measuring the shear strain developed at the base of the beam. This transducer has been used to measure total graft tension in *in vitro* studies [16].

To adapt the transducer for *in vivo* measurements, it must be integrated into a telemetry system. Although the telemetry electronics can be conveniently housed in the body of the screw, the available space precludes the possibility of including an RF coil for signal transmission. Accordingly, this application is one example where the new technique of signal transmission would be advantageous.

To determine suitable values of the independent variables which affect the signal received by the surface electrodes in the application described above, the testing procedure investigated two categories of independent variables; transmission and reception variables. The transmission variables investigated were current and frequency. Other transmission variables that could have been investigated were the separation between the transmission electrodes and the size of transmission electrodes. However, for the application described above, the interelectrode separation was limited by the dimensions of the bone mulch screw and the small size was needed to gain an hermetic seal between the electrodes and ceramic body. For receiving, the variables were interelectrode separation, surface, and distance from the joint line. Although both the type and size of EMG electrode could also have been investigated as reception variables, this was deemed unnecessary because silver/silver chloride electrodes are the most common and the received signal was not likely to be as sensitive to size as the other variables.

When choosing a transmission frequency, the frequency must be high enough to discriminate the transmitted signal from the biological activation signals for nerve conduction and muscle activation. Inasmuch as activation signals have a bandwidth of up to 3 kHz [8], the practical lower limit is approximately 5 kHz. The upper limit is restricted because the inductive and capacitive effects of the tissue substantially change the transmission characteristics [14]. As evident from the results of the present study (Fig. 4), this upper limit lies beyond 160 kHz in the region of the body where the tests were conducted.

Within the frequency range above, determining suitable values for the current and frequency is complicated because the use of platinum electrodes to inject current into living tissue presents potential problems. Control of waveform shape, charge density, total charge per phase, and current density are necessary to prevent tissue damage, pain, and/or stimulation. The guidelines to prevent these problems are as follows.

- 1) Use a balanced biphasic waveform to reduce tissue damage [7].
- 2) Use a cathodic first pulse to increase the nongassing limit [2] and decrease Pt dissolution [9].
- 3) Use an appropriate injectable charge that does not result in stimulation [4].
- 4) Use appropriate charge density for the given current density to prevent platinum dissolution [1].
- 5) Use a charge density below $350 \mu\text{C}/\text{real cm}^2$ to limit the development of potentially harmful gasses [2].
- 6) Use a total charge per phase below $0.45 \mu\text{C}/\text{phase}$ to reduce tissue damage [13].
- 7) Limit the amount of injected current to avoid pain [5].
- 8) Use an anodic first pulse to increase the threshold current for causing stimulation [10].
- 9) Use platinum electrodes to limit the dissolution of the electrodes [9].

For a sinusoidal waveform and the electrode diameter of 0.38 mm which were used in the experiments here, these criteria are satisfied by a frequency of 37 kHz and a current of 3 mA.

For applications which do not use a sinusoidal waveform, an interesting observation is that criteria 2 and 8 above cannot be achieved simultaneously. For the individual application it will be necessary to determine which is a more important issue, the threshold level for stimulation or the rate of platinum dissolution.

Using tissue as the transmission medium necessarily limits the usable modulation techniques. Simple frequency modulation (FM) seems to be the most appropriate because it does not depend on the amplitude of the detected signal and requires minimal circuitry. However, other modulation schemes such as pulse-width modulation, pulse-position modulation, pulse-code modulation, and frequency-shift keying can also be utilized.

A concern with transmitting a carrier signal through the body fluids while a person is moving is that normal fluid movement may affect the carrier. To allay this concern, the carrier signal was monitored while the cadaver leg was repeatedly flexed over the full range of motion. The frequency of the carrier was unaffected and no noise was introduced.

Considering next the reception variables, the skin surface on which the electrodes are positioned is dependent on the site where the telemetry system is implanted. Because the implant was in the lateral femoral epicondyle, the two useful surfaces for the electrodes were the lateral and anterior thigh. Although the electrodes could be placed on either the medial thigh or even the calf, these surfaces were not tested because electrodes placed on the medial thigh could be easily dislodged, whereas electrodes placed on the calf would cause unnecessary motion of the umbilical connecting the subject to the external electronics.

The attenuation was less for the lateral surface than the anterior surface at equal distances from the joint line (Fig. 6). The lower attenuation for the lateral surface was likely caused by the differing paths that the signal takes to reach the electrodes. For the lateral surface, the data signal traveled a shorter path since the transmission electrodes were near the lateral surface.

When attaching the electrodes, more care should be taken to locate the electrodes closer to the site of signal injection than to separate the electrodes farther apart. Because the attenuation is proportional to the inverse of distance squared [4], the attenuation is much more sensitive to the distance from the site of signal injection than to the interelectrode separation. For our application a separation of ± 5 cm and a distance of 5 cm proximal to the joint line gave the least attenuation.

Although the test procedure was designed to determine suitable values of transmission and reception variables for the application of measuring ACL graft tension *in vivo*, the results should prove useful to other applications as well. The conclusions that the received signal is attenuated least at low frequencies, high currents, small distances of receiving electrodes from transmitting electrodes, and wide interelectrode separation can all be generalized.

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Derek P. Lindsey received the B.S. degree in electronic engineering from the California Polytechnic State University, San Luis Obispo, in 1991. Presently he is pursuing the M.S. degree in biomedical engineering at the University of California, Davis.

His main interests are bioinstrumentation, implant packaging, biotelemetry, and powering of implanted electronic devices.



Eric L. McKee (S'94–M'95) received the B.S. degree (summa cum laude) in electrical engineering from the University of Evansville, Evansville, IN, in 1989 and the M.S. in biomedical engineering and the M.B.A. from the University of California, Davis, in 1995.

From 1989 to 1992, he was on the staff of General Atomics, Fusion Group, San Diego, CA, where he developed diagnostic instrumentation and control systems for nuclear fusion research. In 1995, he joined J. Gordon Electronic Design, Inc., Minneapolis, MN, as a Design Engineer working on the development of embedded control systems for medical, industrial, and commercial applications. Presently, he is an Engineering Manager with J. Gordon, focusing on developing products for the medical field.



Maury L. Hull received the B.S. degree in mechanical engineering from Carnegie-Mellon University, Pittsburgh, PA, in 1969 and M.S. and Ph.D. degrees, also in mechanical engineering, from the University of California, Berkeley, in 1970 and 1975, respectively.

Following graduate school, he became a Faculty Member in the Mechanical Engineering Department at the University of California, Davis. In 1991 he became Professor and Chair of the Biomedical Engineering Graduate Program. His research is primarily

in the general area of musculo-skeletal system biomechanics. Because much of his research has been experimental, he has made a number of contributions in instrumentation design. Also, he was appointed to the Editorial Consultants Board of the *Journal of Biomechanics* in 1993 and as Associate Editor of the *Journal of Biomechanical Engineering* in 1998.

As a result of his contributions, Dr. Hull has received the Giovanni Borelli Award from the American Society of Biomechanics in 1989 and was elected to Fellow in the American Society of Mechanical Engineers in 1993.



Stephen M. Howell received the B.S. degree in pre-medicine/biophysics from Pennsylvania State University, University Park, in 1976, and M.D. degree from Northwestern University Medical School, Evanston, IL, in 1981, and completed a residency in orthopaedic surgery from Thomas Jefferson University, Philadelphia, PA, in 1986.

He became an Adjunct Associate Professor in the Mechanical Engineering Department at the University of California, Davis, in 1996 and is currently practicing orthopaedic surgery in Sacramento, CA.

He has maintained a strong research interest in the reconstruction of the torn anterior cruciate ligament (ACL) and the treatment of meniscal injuries in the knee. He has made a number of contributions concerning the clinical outcome and biomechanics of ACL reconstruction, the biomechanical evaluation of fixation methods used to secure an ACL graft, and meniscal repair and transplantation. As a result of these publications, he was made a member of the International ACL Study Group in 1990 and an editor for the *American Journal of Sports Medicine* in 1992.