Microelectronic telemetry implant for myo-electric control of a powered prosthesis

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An induction micro powered synchronous telemetry implant for myoelectric control of a powered prosthesis is described in technical detail. Surgical implantation in a human, subsequent control of a powered prosthesis and future implications are discussed.

Description technique détaillée d'une implantation de télémétrie synchrone à micro-induction pour la commande myoélectrique d'une prothèse. On examine l'implantation chirurgicale chez l'homme, la commande subséquente d'une prothèse et les implications pour l'avenir.

Introduction

The electromyographic (EMG) signals from skeletal muscles are under the voluntary control of the individual. The use of EMG as a means of controlling an externally powered prosthesis was established as early as 1955[1], and it has now become routine in many applications[2,3,4,5]. These "myoelectric" control systems use electrodes on the surface of the skin to pick up the EMG signal. Dry electrodes are prone to surface perspiration problems. Wet electrodes require electrode paste and are subject to smearing of paste. Both often cause allergic dermatitis from repeated application and they are a nuisance to apply and keep clean. In addition, they are susceptible to electrical interference and "crosstalk" and hence their sensitivity and selectivity are limited. Electronic implants overcome all of these problems and hold great potential for improving the control of powered prostheses and orthoses. In addition, it has been shown that regional groups of "motor units" within one muscle can be voluntarily and independently controlled[6]. To obtain the EMG from regional groups of motor units, and to avoid all the disadvantages of surface electrodes mentioned above, it is necessary to use an implanted transmitter which will broadcast the EMG for control of the external prosthesis. As an alternative to surface electrodes, the use of an implanted radio transmitter has been demonstrated to be feasible by work done at this institution.

Research on multiple-function powered limb prostheses has pointed to the need to obtain a considerable number of channels of myoelectric control signals from the amputee. Implants have been proposed for such applications, since surface electrodes would not be sufficiently stable nor selective in their pick-up of the EMG signals[7,8]. Another area of research where implants will find application is in the feedback of sensory information to the amputee from his prosthesis. This feedback in the form of electrical stimulation, will possibly be combined with EMG pick-up electrodes[9], or it will go directly to a sensory nerve trunk in the amputee's stump[10].

Radio frequency induction has been used as the means of powering the myo-telemetry implants in order to eliminate any dependence on implanted batteries, to impart a potentially unlimited life to the implanted telemeter, and to reduce size[11,12,13,14,15].

The use of radiotelemetry from within the body presents unique problems in addition to those present in any RF link. The choice of transmission scheme, operating frequency, modulation, receiver and operating environment must all be considered in the optimization of a system.

The use of low frequency in a portable telemetry system is advantageous in that the body is not a lossy medium at low frequencies[16]. Schuder and Stephenson[16,17] who used a frequency of about 400 kHz

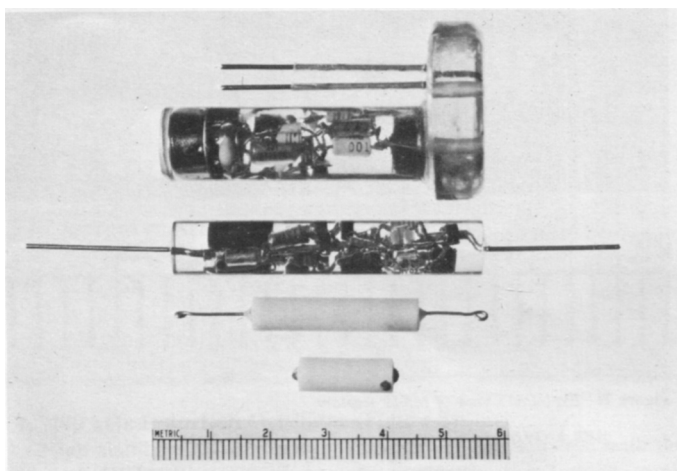

Figure 1: *Myo-telemetry implant units MKI-MKIV*

obtained high efficiencies by thorough theoretical analysis and attention to practical details. Very low standby power consumption can be attained using CMOS (complementary symmetry metal-oxide semiconductor) integrated circuits. As a result a smaller and much lighter power supply is required thus keeping the prosthesis weight minimal. Low frequency systems are relatively immune to "capacitance detuning" and proximity of metal; signal radiation efficiency is low[18] thus minimizing interference to other telemetry systems.

The safety of radio frequency induction systems has been previously considered at this institution (12: pp. 109-113). In the frequency range of our induction system (400 kilohertz) no *non-thermal* biological effects have been reported in the literature[19,20]. *Thermal* effects of electromagnetic fields are generally considered to be negligible if the energy absorbed by body tissues remains below 10 mW/sq.cm[21]. In the proposed frequency range, however, the proportion of electromagnetic energy absorbed from the incident field is almost negligible (usually less than 1%)[14,16]. Since the total power applied to our induction systems is less than 10 milliwatts, it is obvious then, that this application is quite safe. In fact, chronic exposure of dogs and mice to induction fields, in the same frequency range, and at a level of *50 watts* has produced no observable tissue damage[19,22].

The materials used to encapsulate the electronic circuits have been selected with biological compatibilty in mind. The electrodes are made of surgical grade stainless steel (type 316), which has been an acceptable orthopaedic implant material for many years[23]. The outer shell is of high density alumina ceramic (Figure 2). Although a much newer implant material than stainless steel, this type of ceramic has been shown to be virtually inert in the body[24,25,26]. To prevent the ingress of body fluids, the joints are sealed with a type of epoxy resin which has been used for several years to encapsulate cardiac pacemakers and known to have low reaction with interstitial fluids[27].

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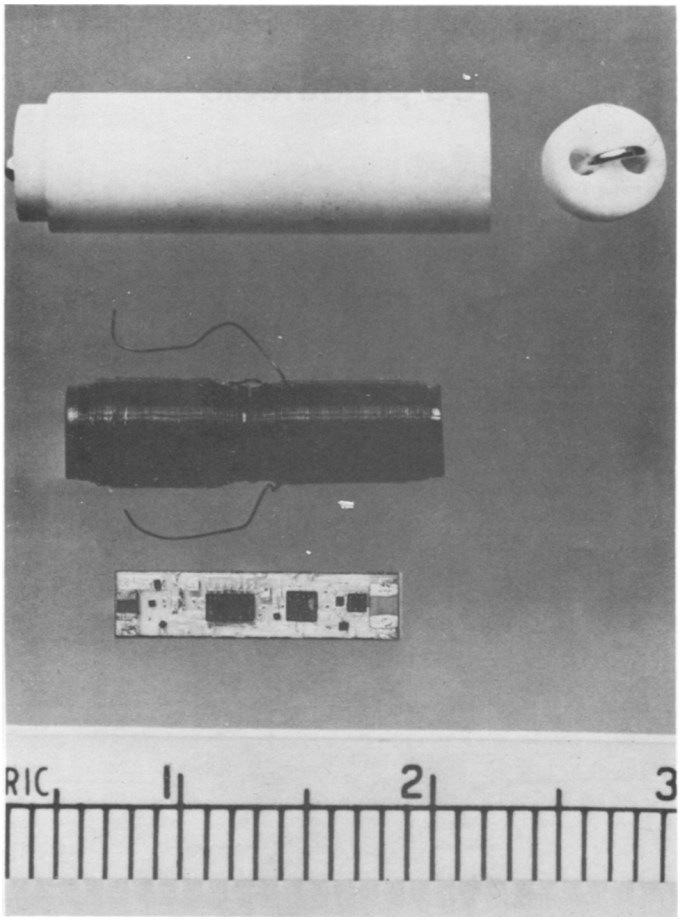

Figure 2: *"Exploded" view of MKIV implant*

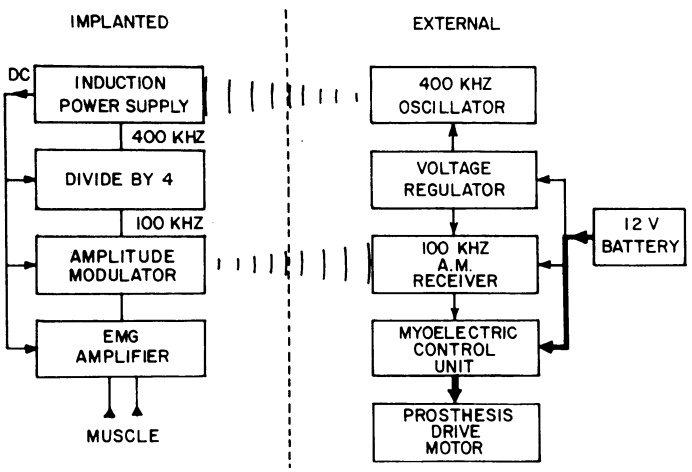

Figure 3: *Block diagram of MKIV synchronous myotelemetry system*

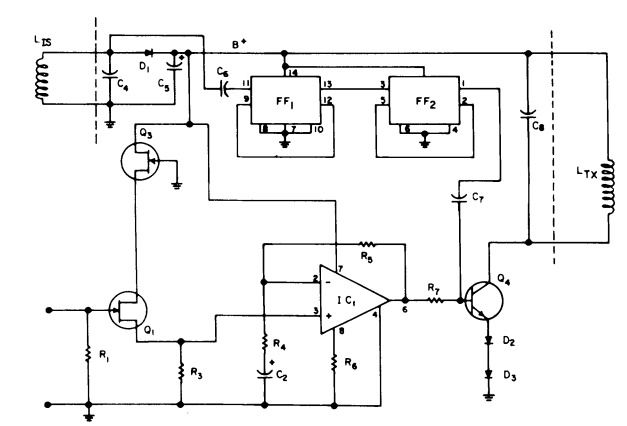

Figure 4: *Schematic diagram of MKIV implant circuitry*

Circuitry of Mark IV Implant

Figure 3 shows a complete block diagram of the synchronous myotelemetry system. A schematic diagram of the Mark IV implant circuitry is shown in Figure 4. A "COS/MOS" monolithic, integrated dual D-type flip-flop circuit (FF_1 and FF_2) is used to divide the induction power frequency of 400 kHz (induced into L_1) by a ratio of 4:1, yielding an output of 100 kHz. The 100 kHz is then used as the carrier for transmission of the EMG signals. This "synchronous" arrangement provides crystal-controlled carrier stability without the bulkiness of an implanted crystal.

The amplifier consists of field-effect transistok Q_1 coupled to a micropower operational amplifier, IC_1. The field-effect transistor provides the required high input impedance and low noise. R_4, R_5, and C_2 make up the feedback loop around the operational amplifier, providing unity feedback at zero frequency and a closed loop gain of about 30 dB in the EMG pass band. The zero frequency unity feedback ensures dc temperature stability and eliminates the need for both an offset adjustment and an input coupling capacitor.

The remaining Mark IV circuitry consists of the amplitude modulator Q_4, driving the transmitter coil L_{TX}, and the induction power supply made up of L_1, C_4, D_1, and C_5. Field-effect transistor Q_3 provides voltage regulation to the sensitive input stage Q_1.

Implant Construction

All circuit elements, other than the two coils, are in the form of hybrid microelectronic chip components mounted on either side of a thick film ceramic substrate as shown in Figures 5 and 6. The hybrid

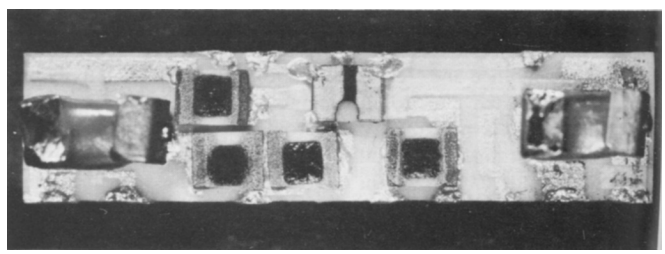

Figure 5: *MKIV hybrid microelectronic substrate containing "passive" components (scale: 12 mm)*

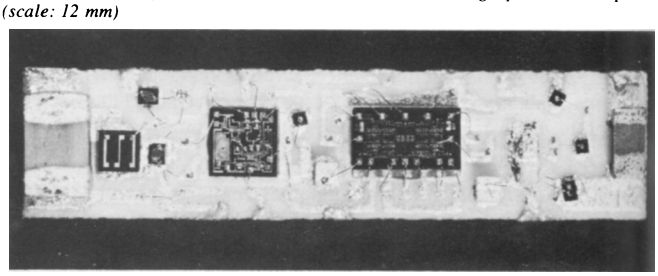

Figure 6: *MKIV hybrid microelectronic substrate containing wire-bonded "active" components (scale: 12 mm)*

microelectronic assembly technique provides a very substantial size reduction while maintaining design flexibility through the use of a wide range of "off-the-shelf" components, including monolithic integrated circuits. Further size reductions with advances in hybrid integrated circuitry and encapsulation techniques are being investigated.

An "exploded" view of the assembly of the Mark IV implant is shown in Figure 2. At the centre of the photograph is the substrate on which the hybrid microcircuit is assembled. The two coils are wound on a Neosid F14 hollow ferrite core, shown at the bottom of Figure 2. The hybrid microcircuit fits inside these coils which, in turn, fit within the outer ceramic housing shown at the top of the photograph. On either side of the substrate are shown the ceramic end-pieces and EMG input electrodes. The electrodes are made of surgical grade stainless steel: only the smooth curved portion is in contact with the muscle tissue. The complete assembly is vacuum filled with a medical grade of epoxy resin, filling all interstices and sealing all joints. Figure 7 shows the cross-sectional views of the complete Mark IV implant unit.

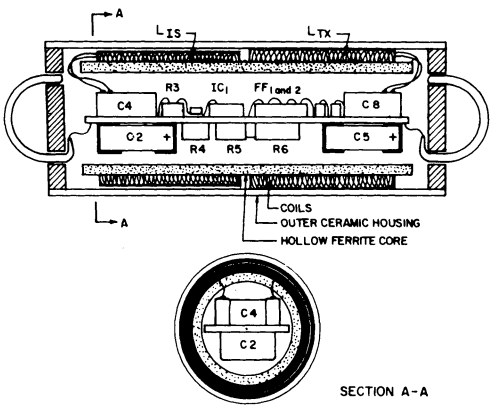

Figure 7: *Cross-sectional views of MKIV*

TABLE I
Mark IV implant specifications

Physical dimensions

Diameter: 5.71 mm
Length (excluding electrodes): 16.1 mm
Length overall: 18.4 mm
Volume (excluding electrodes): 0.413 cc
Weight: 1.55 grams

Input signal characteristics

Input impedance: 10MΩ in parallel with 7.0 pFd
Modulation sensitivity: 200μVpp for 10% modulation @ 100Hz
Maximum modulation index: 80% (before clipping)
EMG signal bandwidth: 12 to 230 Hz (−3dB)
Noise (referred to input): 40μVpp
Electrode leakage current: 5 Nano ampere

Power supply

Direct Current Drain: 125 μA @ 3.5V (nominal)
DC power required: 0.44 mW
Induction coupling efficiency*: 32% (in air)
22% (in saline)
Induction frequency (input): 400 kHz ± 1%
(for efficiency within 15% of optimum)

Transmitted signal

Carrier frequency (output): 100 kHz
Carrier frequency stability: equal to that of external induction oscillator
Carrier level @ receiver*: 200 mVpp

*4" diameter test coils

Implant Performance

Several Mark IV implants have been completely assembled and have been tested in a bath of 1% saline solution. Table 1 gives the average values of the actual measured performance specifications for these units.

Mark IV External System

Although the physical constraints of the external system are not as severe as for the implant unit, small size, temperature stability, low power consumption, immunity from electrical interference and environmental conditions are some of the design criteria. Table 2 gives the actual measured performance specifications of the Mark IV receiver system.

TABLE II
Mark IV external system specifications

100 kHz receiver

Fixed gain: 2dB
Response: 70 kHz - 120 kHz (−3dB)
DC power: 540 μw
Noise (referred to input): 135 μVpp
100 kHz input carrier level: 200 mVpp

EMG amplifier

Gain: 10dB
Response: 15-570 Hz (−3dB)
DC power: (300μw)

400 kHz induction oscillator

Frequency stability: ±0.2%
over the temperature range of −20°C to +65°C
DC power: 550μa (@ 4 VDC (2.2 mw)

Voltage regulator

DC power (standby): (192 μw)
Output: adjustable from 0-10 VDC
Power supply rejection ratio: 45 dB
Temp. stability: 0.5 mV/°C

Output control

DC power (standby): 10μw
Response to step input: 90 msec.
Release time: 45 msec.
Maximum load: 1 ampere

1. 400 kHz Induction Oscillator (Figure 8)

High stability and low power consumption are achieved with the use of "CMOS" (complementary symmetry metal-oxide semiconductor) integrated circuit and miniature ceramic resonators in a "PIERCE" configuration.

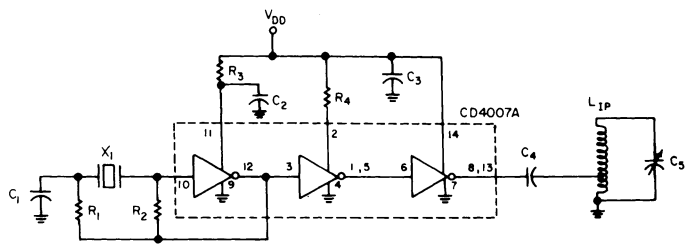

Figure 8: *400 kHz induction oscillator*

For efficient induction coupling to the implant[15], the induction coil consists of LITZ 40/44 AWG wire single layer parallel wound on the prosthesis socket. Q of the induction coil has been kept around 150 as a compromise between induction coupling efficiency and sensitivity to detuning.

2. 100 kHz Receiver (Figure 9)

A 100 kHz receiver coil is a three layer parallel wound LITZ 40/44 AWG wire on the prosthesis socket 65mm away from the induction coil.

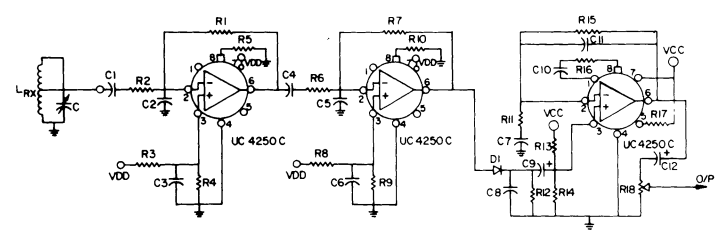

Figure 9: *100 kHz receiver*

Being in close proximity to the induction coil, the receiver coil picks up an induction power signal several times stronger than the retransmitted 100 kHz information signal. The dual low pass active filter receiver sharply attenuates the 400 kHz power signal by 40 dB while amplifying the 100 kHz signal by 2 dB. The dual active filter contains two micropower operational amplifiers while the third operational amplifier boosts the detected EMG signal by 10 dB to provide a large enough signal for the prosthesis drive motor control. Receiver automatic gain control action was deleted for the purpose of clinical evaluation.

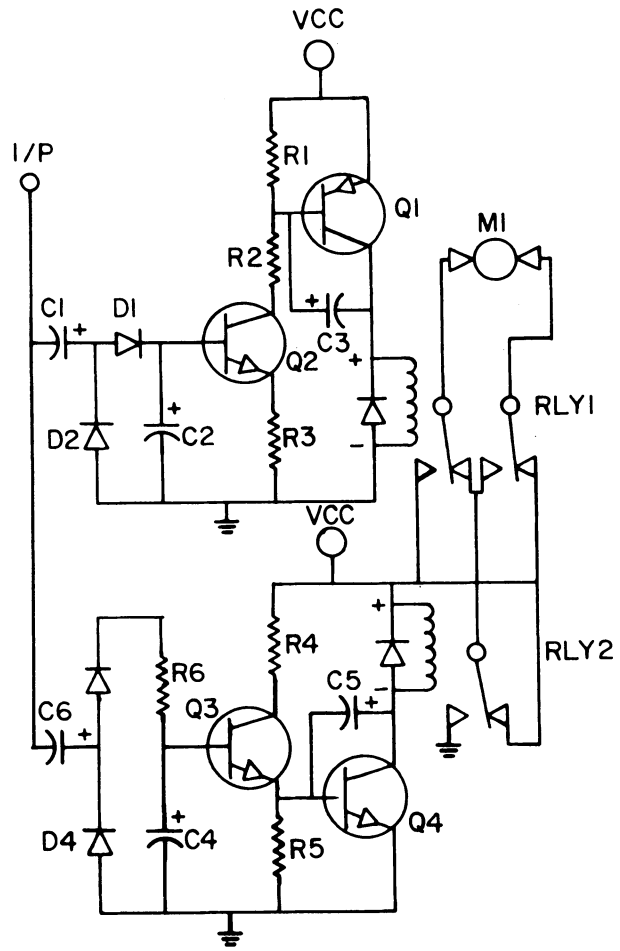

Figure 10: *Output control unit*

3. Output Control Unit (Figure 10)

The control unit is a modification of the three state control developed by the Bio-Engineering Institute of the University of New Brunswick. Modifications consisted mainly of improvements in response and release times and elimination of voltage drop to the motor.

Voltage Regulator (Figure 11)

A stable adjustable voltage is required for the induction oscillator to supply sufficient induction power to maintain telemeter operation just above its operating threshold. Total system power consumption is thus kept to a minimum.

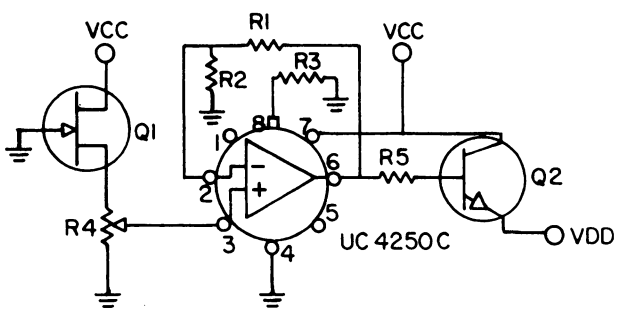

Figure 11: *Voltage regulator*

A low power regulator consisting of an adjustable low power voltage reference and a micropower operational amplifier provide a stable voltage despite fluctuations in supply voltage due to battery aging, load variations, inductive transients and charging. An adjustable low power voltage reference is provided by an enhancement mode N channel field effect transistor.

4. Power Supply

The power supply consists of ten General Electric 250 mah capacity rechargeable nickel cadmium batteries incorporated along the ulnar border of the prosthesis and as close to the distal end of the stump as possible.

5. Electric Hand

An Otto Bock Model Z6 12V Electric Hand with a gripping force of 10 kilogram and a weight of 443 grams was fitted to the prosthesis. Total prosthesis weight including batteries is 1015 grams.

Laboratory and Clinical Application

The initial surgical implantation by Scott and Tucker was performed in 1968 when a Mark I unit was planted into the marrow cavity of the distal end of the femur of a dog following amputation of the distal portion of the shaft and the femoral condyle. The wire electrodes were passed up into the quadriceps muscles which lie on the front of the femur. The muscle was fixed to the mushroom end of the implant by sutures to retain contact between the electrodes and the active muscles. The Mark I unit was constructed from available conventional components and was unduly large but it continued to function in the dog for a period of 6½ years. The dog was sacrificed at that time for removal of the implant and for examination of the surrounding tissues. Apart from a very low grade inflammatory reaction around the Teflon sleeves on the electrodes, no adverse tissue reaction was observed.

Chiefly as a result of the efforts of Nelson and the adoption of the hybrid microelectronics we were successful in progressively reducing the size of the implant (Figure 1) and improving its electronic function. The Mark IV unit was surgically implanted into a patient on the 9th of September, 1974. It had been subjected to preliminary testing on the bench, both in air and in saline at body temperature. Its performance appeared to be satisfactory.

The unit was first sterilized by gas and was implanted through a small incision into a functioning muscle in the forearm of a young woman who had had a "congenital amputation" near the junction of the proximal and middle third of the left forearm. The muscle fibres of the selected muscle were gently separated and the implant placed into this cleft in the muscle. Sutures brought the edges of the muscle together leaving the implant imbedded and surrounded by muscular tissue. The surgical procedure was done under local anaesthetic and we were therefore able immediately, with the patient's full cooperation, to have her contract the muscle and record the EMG signals. When the wound was healed, she applied the new prosthesis and was able to operate it to our fullest expectations. This allowed her to flex and extend the thumb, index and middle fingers for the grasping of objects and for their release. The patient was delighted with the performance and in particular, with the absence of surface electrodes and the electrical interference which she had previously experienced whenever in close proximity to a television set or high tension wires.

This prosthesis and implant continued to function well for exactly two months and then function ceased and the implant appeared to be "dead". Even this short period of success has proven the effectiveness of the entire system and has given us encouragement to proceed to overcome the existing problems.

Removal of the implant and subsequent drying of it was followed by full recovery of electronic function. Wetting of the electronics by tissue fluids was the obvious cause of failure and we have subse-

quently found that other implants such as cardiac pacemakers have been suffering the same defects. Investigation of ceramic to metal hermetic seals is our current research activity.

It is our aim to implant several implants into two or more muscles of the extremity so that we may obtain proportional control of a finger motion and if possible to add motion such as pronation and supination at the wrist or for the control of an elbow joint for those patients who have an amputation above elbow level. There will be natural limitations as to the number of motors which can be used in an artificial limb because of the restraints on the weight of an artificial limb. There will however be choices as to the joint motions to be performed and the muscles which will be used to control these movements.

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