DEVELOPMENT OF A SURGICALLY IMPLANTED MYO-TELEMETRY CONTROL SYSTEM

F. R. TUCKER, WINNIPEG, CANADA

Department of Orthopaedic Surgery, the University of Manitoba

and

R. N. SCOTT, FREDERICTON, CANADA

Executive Director, Bio-Engineering Institute, University of New Brunswick

The efforts of surgeons and limb fitters to satisfy the needs of patients with amputations of the upper and lower limbs have not met with equal success. The functional requirements of prostheses for the upper and the lower extremities are as different as the functions of the normal extremities. The aim should be to incorporate the desired functions in the artificial limb.

Artificial legs are generally adequate because the prime requirement is a mechanical system for weight transmission. Conversely, the ideal artificial arm should provide all or most of the movements which have been lost, and all movements should be separately controlled and performed with precision and coordination. The objective for upper extremity prostheses is obviously high, but it is commensurate with the needs of the patients. To this end we must strive, and in this age of science and technology it is within our grasp.

The use of shoulder harness and mechanical cable to operate one or two joints is unsatisfactory. It is simple, inexpensive and reliable but the prosthesis and harness are uncomfortable and movements of the shoulder girdle and stump are unnatural and often grotesque. Furthermore, the movements in the limb are limited in number and often in range. The patient rightly desires a limb that looks normal, moves naturally and does not require extraneous movements for its operation.

Sources of external energy in the form of cylinders of carbon dioxide and electrical batteries have introduced new possibilities into the field of prosthetics. Even now, the sources of energy are quite compact, light and easily recharged. Motors used to convert stored energy into useful motion are reasonably small and efficient, and miniaturisation of mechanical and electronic equipment offers hope of providing smaller and more efficient powered systems.

Irrespective of the nature of the source of energy and the mechanism for conversion of energy into motion, the patient must have delicate control over the system. Our efforts have been directed to the establishment of an efficient control system which we consider to be mandatory in achieving improved function in upper extremity prostheses. Further, we have restricted our efforts to improvement of means of transmitting control signals from the central nervous system to the prosthesis, without reference to the design of the prosthesis or provision of feedback from it to the central nervous system.

Electrical impulses, released by contraction of muscle fibres, were used initially by Battye, Nightingale and Whillis (1955) to control the movement of prosthetic components. By 1960 Kobrinski had established the practicability of myo-electric systems to control an electric hand in forearm amputees (Kobrinski et al. 1961). In this system, and in most of its successors, the functions of the muscles controlling the prosthetic movements are natural; the flexors of the forearm produce flexion of the digits, the extensors produce extension. Also, one muscle or muscle group produces one function.

There are limitations to the application of this system to more proximal amputations, where muscles must be trained to perform unnatural functions to control the terminal device. Although many patients can achieve reasonable voluntary control of the stump muscle, which
is used as the control site, they are unable to divorce completely the control site muscle from its natural function.

The biceps and triceps are inseparably related to shoulder function and sudden or resisted shoulder movement inevitably results in activity of these muscles. This will cause activation of the prosthetic component unless the sensitivity of the control system is undesirably low. The criticism of one muscle action for one prosthetic function still pertains. This is an extravagance which patients with above-elbow amputations or shoulder disarticulations cannot afford.

CAPABILITIES OF MYO-ELECTRIC CONTROL

It is well known that the brain exerts fine control over striated muscles. Since Sherrington defined the "motor unit" in 1929, it has been appreciated that the motor unit is the functional unit of striated muscle.

The motor unit consists of the anterior horn cell, the motor axon and a number of muscle fibres. The number of muscle fibres served by an axon varies widely, from less than ten to more than 1,000. Muscles producing fine movements, such as the ocular muscles, have the smallest number of muscle fibres per motor unit. The larger muscles in the limbs have larger units. The motor unit is the functional unit of the muscle, because an impulse passing along an axon causes all the fibres to contract almost simultaneously. The units may contract up to a highest rate of fifty per second and are absolutely quiescent at rest.

Of particular interest are the publications of Harrison and Mortensen (1962), Basmajian, Baeza and Fabrigar (1965) and Basmajian (1967). They have demonstrated the ability of most individuals to control motor units and produce isolated contractions of at least one motor unit. The subject learns to turn it on and off with a short period of training, using the oscilloscope or loudspeaker as a feedback mechanism. Further, many subjects after such training are able to control up to three favourite motor units without visual or aural feedback. The exquisite control is demonstrated by the subject's ability to alter the tempo of firing of the motor units. Percutaneous wire electrodes were used in these studies.

Most subjects soon acquire the ability to isolate and master one or two units. Furthermore, if electrodes are inserted in other regions of the same muscle with a separation of at least one centimetre, subjects can control individual motor units at each site (Scott and Tucker, in press). If this degree of accuracy of isolation is possible in most patients, muscles appear to be the ideal site of contact between the body tissues and the electronic equipment.

The advantages of obtaining myo-electric signals from single motor units or regional groups of motor units seem clear. Surface electrodes are not adequate for this purpose. Percutaneous electrodes or implanted wireless telemetry systems are needed to utilise the independent function of the motor units. Percutaneous electrodes are excellent for relatively brief studies of motor units but the breaking of fine wire electrodes, or the complications of sepsis, makes them impractical for prolonged use. In order to determine the feasibility of a myo-telemetry control system, it was decided to undertake the development of such a system for above-elbow amputees.

SITE OF IMPLANTATION

Four requirements must be considered in determining the best site for an implanted control system. First, it is essential that movement between the electronic equipment and the control muscle be as little as possible. Movement of the muscle over the electrode may cause electrical noise and movement of the electrode relative to the electronic equipment involves flexion of the electrode assembly, a common cause of failure of implanted systems.

Secondly, close proximity to the control muscle is desirable. Thirdly, the implanted equipment must not obstruct the normal movement of a joint or protrude excessively beyond the normal bone contours. Finally the surgical procedure should be simple.
The first two requirements are met by fixing the control equipment to bone close to a point of attachment of the muscle. In the above-elbow stump, placing the implant in the medullary cavity of the humerus is convenient and meets all requirements.

**ENCAPSULATION**

Electronic components implanted in the body must be protected from contact with body fluids in order to maintain satisfactory performance. A barrier must be provided to protect the body from contact with these components, some of which might cause tissue reaction. Encapsulation of the electronic equipment in a protective material serves these two functions, and if the encapsulant is rigid it also provides structural support for the assembly.

At present the authors are employing an epoxy encapsulant of a type which has been found satisfactory for encapsulation of cardiac pacemakers. Centrifugal moulding is used to eliminate the entrapment of air.

**ELECTRODES**

At present it seems satisfactory to make electrodes of surgically acceptable stainless steel; they do not carry enough current for polarisation to be a problem. The spontaneous potentials reported by Flasterstein (1966) have not been observed, probably because of the low input impedance of the telemetry system.

Sitting of the electrodes is important. It is desirable that they should be in intimate contact with the muscle fibres. But relative movement between the electrode and contracting fibres may produce electrical noise, and embedding the electrode among these fibres is apt to cause breakage of the electrode. Faced with these conflicting factors, the authors proposed fixation of electrodes to bone, adjacent to a point of attachment of the muscle. Proximity to the point of attachment would tend to reduce the relative movement between electrode and muscle. It was proposed at first that the electrodes should not penetrate the muscle but rather that they should lie in contact with its surface. However, the electrical potentials measured in animal experiments with the proposed electrode system were disappointingly small. This matter is being studied further. Until it is resolved it is considered preferable that the electrodes should penetrate the muscle. Bending forces are reduced by placing the electrodes parallel to muscle fibres.

Spatial selectivity of the electrode system is a third consideration. It is important that electrodes measure the electrical activity in a specific muscle or in a very small part of a muscle. The resulting signal should be free of contamination from activity of nearby muscles. This indicates that the electrodes should be small, and designed for greatest selectivity. The coaxial needle electrodes, widely used for clinical electromyography, are examples.

Two problems may be expected with an extremely selective electrode system. If the prosthesis is to respond to the gross myo-electric activity of a muscle, electrodes responsive only to the output of a few motor units will yield an excessively erratic signal, making signal processing more difficult than if the electrodes perform spatial averaging of the outputs of many motor units. Also, to avoid injury to muscles, the electrodes must be inserted without complete visual control. It is conceivable that they may not be placed in contractile tissue. Since the ability to contract fibres voluntarily at a specific site can be determined only some time after operation, this circumstance could prove very serious. Consequently, the authors now feel that electrodes for implanted myo-telemetry systems should be rigid structures, made of stainless steel, located within the control muscle, close to a point of attachment to bone, oriented parallel to the muscle fibres, with the minimum spatial selectivity which is acceptable for the specific application.

**TELEMETRY SYSTEM**

Certain general aspects of the design of the telemetry system may be of interest. The electrical properties of the amplifier input circuit (Figs. 1 and 2) are important. Since myo-
electric potentials have zero average value and relatively little energy in the frequency range below 20 Hertz (Hz), capacitive coupling may be employed. Direct current is thus prevented from passing through the electrodes, except for the very small leakage current of the coupling capacitor. The input impedance over the frequency range of interest, approximately 20–300 Hz, should be high relative to the impedance of the signal source. However, it is not necessary that the ratio of input to source impedance exceed five or ten, and there is merit in avoiding excessively high impedances. For a totally implanted system, a differential input is not necessary and the circuit is simplified by using a single-ended input.

The choice of modulation system is an interesting topic. Frequency modulation has been adopted almost universally for bio-telemetry systems, but the authors prefer amplitude modulation for this myo-electric system. The preference for frequency modulation is based upon the independence of the received bio-electric signal on distance between the transmitter and receiver (Ko and Neuman 1967). However, in the myo-telemetry system being considered...
here, the distance between the implanted transmitter and the signal receiver located in the prosthesis will be fixed. Also, small variations in the total gain of the control system will probably not be perceived by the patient, nor will they affect his performance. Another reason for the use of frequency modulation systems has been the choice of a tunnel diode as the active element in the oscillator, which precludes amplitude modulation. If a transistor is used, either an amplitude modulation or frequency modulation system may be designed with equivalent complexity. At present it is considered preferable, in terms of energy consumption and stability, to use a transistor rather than a tunnel diode. The receiver circuit for an amplitude modulation system is much simpler, and frequency stability in such a system may be achieved by using a crystal oscillator, a technique which is not practical in a frequency modulation system.

Transistor frequency should be reasonably low, to minimise energy absorption in body tissue and consequent loss of signal. At the same time, if the energy source for the implanted transmitter involves transmission of radio-frequency signals into the body, a substantial separation between the ''power'' and ''signal'' frequencies must be maintained in order to reduce interaction between the two.

One of the most important considerations in design is that the reliability of the implanted system be high. This implies a simple circuit with the fewest components. Reliability of components is important, and this requirement conflicts to some extent with the desire for miniaturisation. Energy consumption must be very low.

ENERGY SOURCE

The use of electromagnetic coupling of radio frequency energy from an external source is based upon consideration of several possibilities. Implanted primary cells are widely used, particularly to operate implanted cardiac pacemakers. These cells wear out and must be replaced when discharged. The necessity of repeated surgical procedures for this purpose make them unattractive for long-term use, a fact which is evident from the attention now being directed to the development of externally powered pacemakers. Also, the reliability of primary cells is lower than that of any other component in the electronic system.

Implanted secondary cells could be used, avoiding the necessity for replacement of discharged cells. However, these cells deteriorate after a number of charge-discharge cycles and must then be replaced. Also, secondary cells are less reliable than primary cells. Finally, it may be difficult to provide means of recharging implanted secondary cells.

If electromagnetic coupling is used to transmit electrical energy through the intact skin, the energy source is external to the body and problems of size, weight, reliability, replacement or recharge are much less stringent. Such a system has the advantage of simplicity. An external energy source, probably a rechargeable battery, is used to operate an oscillator. The output of this oscillator, an alternating current in the low radio-frequency range, is fed to an induction coil. This external coil is electromagnetically coupled to a second coil located within the body. The pair of coils acts as a transformer, and energy transmission from one to the other is relatively efficient.

As an energy source for a myo-telemetry system, electromagnetic coupling from an external source is clearly preferable. Such a system involves implanted components which are smaller, lighter and more reliable than electro-chemical cells. Replacement due to predictable deterioration is not required. Further, by adjusting the external oscillator, the electrical operating conditions of the implanted equipment may be altered should this be desired, a feature which is unique to this system.

PRESENT SYSTEM

A block diagram of the present myo-telemetry system is shown in Figure 1 and a schematic circuit diagram of the implanted portion of the system in Figure 2. The power oscillator
frequency is 150 kHz, with an output of 10 milliwatts to the external coupling coil. With a coupling coil having dimensions such that it may encircle the stump of an adult above-elbow amputee, this power level is adequate to provide the desired 2 milliwatts direct current operating power for the implanted equipment. While the efficiency of the coupling system could be improved, even at this low power level, significant improvement would necessitate increasing the size of the inductor L1 (Fig. 2). This is not considered necessary or desirable.

![Image of implant unit](image)

**FIG. 3**
The implant unit.

![Image of medullary cavity](image)

**FIG. 4**
Figure 4—The medullary cavity of a dog's femur. It has been reamed to take the implant unit.

![Image of implant in position](image)

**FIG. 5**
Figure 5—The implant in position. The electrodes are in the quadriceps.

The signal oscillator is crystal-controlled at SMHz, and is amplitude modulated as indicated in Figure 2. In order to avoid over-modulation with very strong muscle contractions, the system is designed to reach 100 per cent modulation with 2 millivolts peak-to-peak myoelectric input potentials. Received signal level is high, permitting the use of a relatively insensitive receiver. No interference from external radio-frequency sources has been observed.
A photograph of the implant unit is shown in Figure 3. Commercially available components assembled by hand have been used to expedite the investigation. Consequently the unit is rather large, the cylindrical portion being 1.27 centimetres in diameter and 6.1 centimetres long. The enlarged end supports the electrode structure and is perforated to facilitate the myodesis. Figure 4 shows the reamed medullary cavity of a dog's femur ready for insertion of the implant and Figure 5 shows the implant in place. Figure 6 shows the intended site of the implant for an above-elbow amputee. The two electrodes are formed from Kirschner wires 8 millimetres thick and are trimmed to the desired length during the operation. As shown, they are inserted into the distal end of the muscle at the point of myodesis, approximately parallel to the muscle fibres. The photograph shown in Figure 5, taken during animal surgery, illustrates this procedure. If, as in this case, it is desirable to insulate a portion of the electrode...
structure which will not be in contact with contractile tissue, a length of polyethylene tubing may be used.

Figure 7 shows a radiograph of an implant in a dog's femur taken eight weeks after operation, with electrodes extending into the quadriceps. The performance of this system has been checked at intervals during ten weeks; performance has been excellent and no change has been observed.

DISCUSSION

The authors wish to emphasise that their research on myo-telemetry systems is at a very early stage. It is recorded now in order to describe an approach that differs significantly in many aspects from that taken by other groups (Hirsch, Kaiser and Petersén 1966; Ko and Neuman 1967). In particular the concept of attaching the implant to bone and the achievement of a high efficiency in the electromagnetic coupling of energy into the body are noteworthy.

The application of this system to patients must be deferred until its reliability and safety are established and the surgical technique refined. However, it is apparent that the full potential of the system cannot be determined until it is applied to patients in whom the voluntary control of motor units can be fully employed.

From the biological aspect, we are dependent upon the ability of patients to control the contraction of groups of motor units in a muscle and of one muscle to provide many control sites. The presence of the electrodes in contracting muscle tissue naturally raises the question of their continued function. Trauma to tissues about the electrodes from movement is inevitable. The degree of damage and its effect on the function of contracting muscle fibres within the area of effective "reception" is unknown. It is expected that a sheath of fibrous tissue will envelop the electrode and protect the more distant muscle fibres, without affecting the electrical performance of the system significantly.

To improve the function and independence of control muscles, such as biceps and triceps in an above-elbow amputee, it is suggested that converting them into non-articular muscles should be helpful. Shifting the scapular attachments of biceps and the long head of triceps to the upper end of the humerus combined with a distal myodesis should enhance the effects of training and permit the muscles to be used solely for the purpose of controlling the prosthesis. Similar procedures may be applicable to the scapular muscles in amputees with shoulder disarticulation.

This myo-telemetry implant was designed specifically for application at one anatomical site. Further miniaturisation of the equipment, alterations of shapes and modification of technique of electromagnetic coupling will make it possible to extend the application of the system to the more proximal amputations, where the need for prosthetic function is greater.

At present, the system is designed to use signals from one muscle site. This is a justifiable first step. Obviously, a multi-channel system is necessary to control the many functions which are desirable for high-level amputees. In the opinion of the authors, such a system is quite feasible. It is important that advances in this area be continued and be matched by improvements in design of powered prostheses if a truly satisfactory restoration of upper extremity function is to be achieved.

SUMMARY

1. The difficulties of obtaining myo-electric signals from the muscles in amputation stumps are discussed.
2. The requirements of a myo-telemetry system which could be implanted are discussed.
3. A description is given of a new approach to the problem in which the electrical unit is contained in an inert plastic and fitted into the bone in the amputation stump, using an external power source.
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