BIOMEDICAL ENGINEERING SPECIFICATIONS FOR EPIDURAL SPINAL CORD STIMULATION TO AUGMENT MOTOR PERFORMANCE

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ABSTRACT

A pair of electrodes were placed in the posterior portion of the epidural space in the upper thoracic spinal region in 15 patients with upper motor neurone disorders. Parameters of stimulation commonly used for chronic stimulation were a 200 microsecond pulse width, 33 Hz repetition rate, and 5 ma amplitude. Using a 16 gauge thin-walled Touhy needle, platinum electrodes were passed between the vertebrae, into and up the spinal canal to appropriate stimulating locations. Passive, implanted receivers, powered and controlled by external RF transmitter/pulse generator devices were employed to provide the stimulus current to the electrodes. A description of available systems, problems and future directions is presented.

INTRODUCTION

Stimulation of spinal cord structures can have a beneficial effect in patients with motor disorders due to certain upper motor neurone disorders (1,2). Specifically, it has been found that such stimulation could suppress hypertonia and modify the activity of segmental reflexes such as clonus and withdrawal reflexes, and could thereby augment preserved volitional control of movement as well as endurance.

This paper will describe the systems used for Spinal Cord Stimulation (SCS). The elements to be discussed include the electrode, the electrode leads, the receiver and connecting devices, the external antenna, and the pulse generator/transmitter. Commercially available systems for this purpose will be compared. Our results concerning characteristic system parameters and impedance values measured in vivo will also be presented. Finally, desirable characteristics for the next generation systems will be discussed, along with the mechanical and electrochemical safety aspects of chronic SCS.

STIMULATION SYSTEMS

The stimulation systems available for use employ a passive, implanted receiver as the stimulus source. The receiver is energized by an antenna placed on the skin just above it, inductively coupling the necessary power and control information to the buried unit. The receiver circuit is in essence a half-wave rectifier with filtering, producing a monophasic pulse during the time the RF energy is received, with no attempt to regulate either voltage or current. The stimulating current is capacitively coupled, to provide no-net-DC stimulation and to thereby attempt to minimize the deleterious tissue reactions to the stimulation. The output does have some droop due to the capacitive coupling, but it is not significant due to the relatively short duration pulses normally employed.

The electrodes are connected via leads tunneled subcutaneously from the receiver site to the point where the electrodes exit the spinal canal. Except for the older Davis-Geck electrodes, the leads are made of platinum-irridium, and are formed into a helical coil covered with insulation, but with a hollow core to allow maximum flexibility. The Davis-Geck electrode leads are of twisted, stainless steel wire, with a teflon coating.

To use the system, the patient or physician operates the controls on the external pulse generator/transmitter unit which are provided to adjust pulse width, repetition rate, and amplitude. Systems with which we have had experience are produced by Avery Laboratories and Medtronic Inc., Neurological Division.

AVERY SYSTEMS: The Avery S 205 transmitter unit, shown in Figure 1 along with its antenna and implantable receiver, utilizes two 9-volt alkaline batteries to achieve a typical life expectancy of

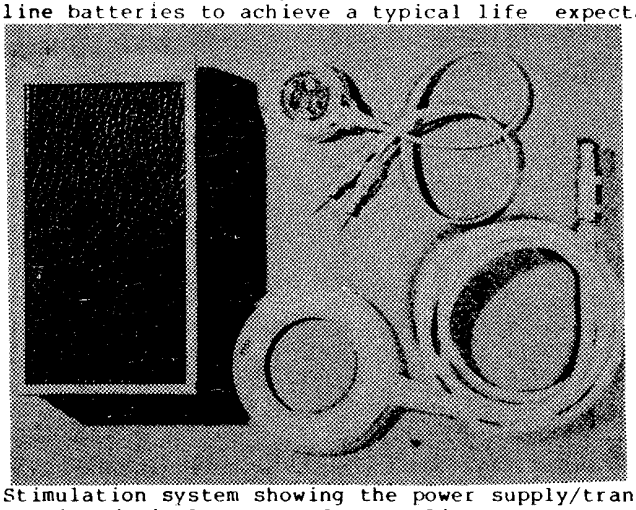

Figure 1. Stimulation system showing the power supply/transmitter, implanted receiver/stimulator, and coupling antenna. These particular units are made by Avery Laboratories.

four days. Stimulus parameters are adjustable over the ranges 50 to 400 microseconds, 6 to 200 Hz, and 0 to 45 volts with the specially modified units we use, and with the maximum mutual inductance, i.e., with the antenna directly on receiver, driving a 1000 ohm load. It is housed in an aluminum case, with the battery compartment in the bottom. The method of installation leads to some difficulty for the patients when changing batteries, and hence to frequently broken battery leads. The controls for rate and amplitude are on the top of the unit and, although slightly recessed, are easy to move accidentally, unless they are secured with a piece of tape or other means.

The Avery electrodes utilize a stylet inserted into the hollow core to provide some control of stiffness and direction

during implantation. If temporary connections are required, they must be made via a disposable lead extension set. The connectors used with the permanently implanted system resemble a tiny drill chuck with a center guide wire which slips into the core of the electrode connector, then tightens over it.

Avery Laboratories also supplies a system with a biphasic output, in which each successive pulse is of the opposite polarity. While the system is capacitively coupled, our observation that cathodal current is by far the most effective in producing the desired results cause us to question whether this type of biphasic system would allow duplication of the physiological effects we have seen.

MEDTRONIC SYSTEMS: The Medtronic PISCES (TM) transmitter, Model 3522, utilizes one 9-volt alkaline battery, which provides about 5 days service. The PISCES unit is specified to produce stimulating pulses with adjustments over the ranges 100 to 1000 microseconds, 1 to 120 Hz, and 0 to 10 mA current. It uses a different energy coupling design, which requires a larger antenna, but produces an optimum coupling with a vertical coil separation of 1 cm, producing near specification performance when implanted. The case is plastic, with shielded knobs which are quite resistant to accidental movement, but perhaps are more difficult for the motor-impaired patient to operate. The battery compartment is easily accessible, with a snap-in connection, eliminating the problem of broken battery leads. The test features of this unit, however, are not completely self-contained.

The Medtronic electrode leads are constructed with a fine wire leading from the tip through the core, extending for approximately 30 cm beyond the end of the electrode lead, for use as a temporary test extension.

ELECTRICAL STIMULATION REQUIREMENTS

In order to achieve adequate stimulation, there must be adequate current density in the vicinity of the nerve fiber to cause it to depolarize. For a given current level, this is best accomplished by placing an electrode with a relatively small active area in the immediate vicinity of the structure being stimulated. It has been shown that cathodal current is more efficient, because of the nature of the interaction with the nerve membrane. For maximmum stimulation then, the electrode should be placed as close as possible to the nerve fiber which one wishes to depolarize. In the currently used epidural systems, a compromise is made with the desire to produce the minimum surgical trauma. The electrodes are placed in the spinal canal, while monitoring both visually and by checking the effects of the stimulation. In this approach, the electrodes is passed through the shank of a thin-wall 16 gauge Touhy, Hustead, or other spinal tap needle. A large electrode area is contra-indicated, both for ease of placement and to achieve the high current density required for effective stimulation. The electrode active elements are 0.5 mm in diameter and approximately 5 mm long.

Biocompatibility: The electrode must be non-reactive with the tissue, with and without the presence of the stimulating current. Thus, the material must approximate, to the maximum possible extent, the characteristics of an ideal, non-polarizable electrode. Platinum is the material of choice at the present time. Long periods of use with both this type of application and in pacemaker applications suggest that these materials are biocompatible.

Mechanical properties: Since the electrode lead must pass from the electrode location (typically at the second or third thoracic vertebra, centered over the spinal cord) down the spinal canal and out through the intraspinous ligament, it is very important that a strong, durable, and flexible lead be used. In addition, the electrode should be very easy to place wherever desired. We have experienced problems with the mechanical characteristics of the Davis-Geck electrode system. The relative brittleness of the wire and the crimp connectors used have caused 3 breakages and 3 insulation problems in the 15 patients implanted to date. The insulation problems have been largely solved by improving our techniques, but some problems persist with this type of electrode. None of the electrodes exhibit ideal characteristics for placement, although the Avery and Medtronic leads are an improvement over the Davis-Geck.

Once the proper stimulation has been achieved, the electrodes must be fixed in place. Since the active electrode area is not accessible after implantation, the fixation is of the electrode lead, leaving the electrode itself free to move slightly within the spinal canal. Such movement may cause some problems for the patient. We have seen some suggestion of transitory movement of the electrodes, causing an apparent change in intensity of stimulation for the patient. However, no permanent dislocations of the electrodes have been verified to date.

Stimulation parameters: The range of stimulus parameters used in 15 patients with implanted systems has been clinically determined. In all cases, the pulse width was set at 200 microseconds, unless it was necessary to increase it to produce adequate strength of stimulation, in which case it was increased to as much as 400 microseconds. The frequencies used ranged from 20 to 75 Hz, with 2 patients at 75 Hz, one at 20 Hz, and the rest with frequencies between 30 and 50 Hz. Frequencies outside this range, either higher or lower, were not used because they resulted in discomfort, spasticity or other undesirable effects.

The amplitudes used for chronic stimulation are not readily measured, since the system is implanted, and the coupling is not exact. The transmitter dial settings indicated a range of values from about 15% to almost 100% of the unit capacity. However, according to the measurements of threshold and discomfort levels obtained while the electrode lead extensions were connected to an external stimulation system, values of 2 to 8 mA were used for routine stimulation. The very low levels were usually indicative of placement very close to a nerve root, and the very high values, of some problem with the system, in placement, poor connection, etc. There was considerable variability in the patient's upper

tolerance limits, however.

Electro-chemical safety: The maximum level of stimulation normally employed, a 200 microsecond pulse of 10 mA current delivered through an electrode area of 0.08 sq. cm, results in a current density of approximately 25 microcoulombs per square centimeter applied outside the dura, i.e, not in contact with the spinal cord itself. This is well within the allowable limit according to the assumed damage mechanisms discussed by Brummer and Turner (3). However, the resultant 2 microcoulombs per phase is greater than the 0.45 microcoulombs per phase reported to cause damage when directly applied to brain tissue (4). Of course, for epidural SCS, the electrodes are not in direct contact with nervous tissue at all, thus greatly lessening the probability of damage.

Impedance measures: During the period of time while the electrode leads are externalized, it is important to measure the current and voltage levels required to produce physiological effects, such as the threshold of sensation, and motor effects (if any), and the electrode impedance should be calculated. These values aid in assessing the nature of tissue in which the electrodes lie, the adequacy of stimulation, and the power levels required from the permanent system. In our experience, the system impedances have ranged from about 400 to 2000 ohms, with no observable dependence on the polarity of stimulation. The impedance usually lies in the 500 to 750 ohm range. Since the electrodes are both the same size in our system, it is anticipated that each contributes equally to the observed impedance. This is borne out by the experience with monopolar stimulation systems, in which approximately half this range of impedances was observed (5), and by intraoperative measurements using a large indifferent electrode as the anode.

DESIRABLE FEATURES FOR FUTURE SYSTEMS

The requirements for the next generation stimulation systems presented here are based on physiological, psychological, and technical experience with the present systems. Developments to date in techniques for SCS to improve motor control have been made using equipment designed for relief of pain, which is a more specific and perhaps simpler requirement, at least as originally hypothesized. While the human factors requirements are similar to those for many other types of systems, the physiological factors in motor control are somewhat unique.

Physiologically based requirements: The choice of this list of physiological features was made in the desire to improve the control of motor functions. The achievement of selective stimulation of specific structures of the central nervous system is an important feature which may be the key to many new clinical applications. The use of electrodes which are moveable under external control via non-invasive techniques would be one step toward selective stimulation. It would be desirable to place an electrode at any desired position, moving both rostrally and caudally as well as over the ventral and dorsal surfaces of the

dura. Similar effects might be achieved through the placement of an array of electrodes over the spinal cord. Selection of the appropriate pair could substitute electrical for physical movement. In addition, stimulation through groups of electrodes would be possible, to set up specific current density patterns and the resulting patterns of depolarization in specific neural structures.

The availability of different sets of parameters of stimulation may also result in improved motor control in patients with specific disabilities. These sets might include the following: stimulation which turns on and off gradually by adjusting pulse amplitude or pulse width, similar to the patterns used in electrophrenic respirators; or specific patterns of stimulation; or stochastic stimulation; or finally, the use of continuous trains of stimuli. It has already been shown that a higher frequency range than is normally available is required in some instances, such as in the treatment of torticolis.

Finally, the incorporation of a mechanism for feedback control of the stimulation, either through turning on and off, or proportional control, would allow a more physiological approach to stimulation. It would be necessary, of course, to develop suitable transduction of the functions to be controlled, such as spasticity.

Human factor elements in stimulator designs: The requirements for system designs for ease of use by the patients are, in most respects, not significantly different from the requirements for other types of systems, such as cardiac pacemakers or other prosthetic devices. These requirements include the desire for a longer life expectancy of the unit and of its energy source, a lighter weight, more reliable and inexpensive device, and a system which is easy to replace. The requirement for a system which is easy to use may be more difficult to achieve and more critical in designing for the individual with problems of motor control, than it would be for an individual with other problems.

There is an alternate approach to the use of external power and control units with passive implanted receivers, which makes it unnecessary to wear an external unit. In this alternate approach, the power source is provided in the implanted unit, together with the control features necessary to adjust the stimulus parameters. Devices using this approach are in the clinical evaluation stage but may soon be available from Cordis Laboratories (5). They reportedly provide a life expectancy of 18 months to 3 years.

Technical aspects in stimulator designs: The technical requirements for a system are similar to those for other systems, or are dictated by the physiological requirements. Elements of the technical design which might not be obvious from these other requirements are the ability to monitor the operation of the unit, and to provide modular replaceability. It would be helpful to be able to measure the precise levels of current being delivered by the system, as a check on system performance, and to aid in neurophysiological measurements of the effects of SCS. A modular system which allows relatively simple replacement of the various elements becomes more necessary with the implantation of systems in young individuals (21 year old spinal cord injury patients, for

example) who have a life expectancy of 30 or more years. It seems unlikely that all the original components will survive this long a period without problems.

REFERENCES

1. Cook, A.W., "Electrical Stimulation in Multiple Sclerosis," Hospital Practice, 2(4):51-58, 1976.

2. Sharkey, P.C., Dimitrijevic, M.M., and Campos, R.J., "Effects of Spinal Cord Stimulation on Modification of Motor Disability in Patients with Upper Motor Neurone Disorders," Proceedings of the 5th Annual Conference on Systems and Devices for the Disabled, Houston, Tx., June 5-9, 1978, pp 205-209, publ. by Texas Institute for Rehabilitation and Research, Houston, Tx, 1978.

3. Brummer, S.B. and Turner, M.J., "Electrochemical Considerations for Safe Electrical Stimulation of the Nervous System with Platinum Electreodes," IEEE Trans. Biomed. Eng., BME-24: 59-63, 1977.

4. Pudenz, R.H., "Adverse Effects of Electrical Energy Applied to the Nervous System," Neurosurgery, 1: 190-191, 1977.

5. Personal communication with Dr. Seligman of Cordis Laboratories.