ELECTRONIC ASPECTS OF SPINAL CORD STIMULATION

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Summary

In addition to the detailed study of the medical effects of Spinal Cord Stimulation carried out at Southampton, consideration has been given to the electronic aspects of stimulation. We feel that the type of equipment commonly used in S.C.S. has several limitations and are able to suggest ways in which it may be improved. The amplitude and shape of the stimulating pulse waveforms used have been analysed, and the electronic 'equivalent circuit' of a patient as seen by the stimulator, has been derived. Our results indicate that there may be an important correlation between the pulse amplitude chosen by a patient and the degree of benefit which that patient obtains from Spinal Cord Stimulation. Finally, we present our justification for believing that the methods and equipment used are safe.

Introduction

The use of Spinal Cord Stimulation (S.C.S.) in the rehabilitation of patients suffering from Multiple Sclerosis requires an item of electronic equipment (a stimulator), to provide an output which may be specified by doctor or patient (the stimulating pulses), into a complicated 'load' (the tissues in the vicinity of the stimulating electrodes). The reaction of the 'load' to the stimulator output, i.e. the sensations experienced by the patient during stimulation, the efficacy of the treatment - and, indeed, its safety - are all dependent upon the electrical characteristics of that output.

Furthermore, the stimulators used during our early research into S.C.S. are, in electronic terms, fairly simple, and were not specifically designed for use with Multiple Sclerosis patients. As the medical aspects of S.C.S. become clearer, the requirements which are placed upon the stimulators will change. The present situation is analogous to that of cardiac stimulation two decades ago. During that time, cardiac stimulators have developed from simple circuits to sophisticated and reliable stimulators of which, following implantation, users are almost unaware. Now that S.C.S. has been shown to be of real value to some Multiple Sclerosis patients, it is certain that similar refinements will greatly improve the stimulators available, which will, in turn, increase the use of S.C.S. with Multiple Sclerosis and, possibly, other neurological problems.

In view of the above considerations, it is important to study S.C.S. from the point of view of an electronic engineer, as well as that of the medical practitioner. Four aspects of such a study are presented in this contribution:

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i) A brief explanation is given of the operation and limitations of the stimulators commonly used at present in S.C.S.

ii) The electronic specification which any new stimulators should meet is described.

iii) It is suggested that measurement of some of the electronic 'requirements' of a patient may yield important information about the mechanism of action of S.C.S., and about the way in which a particular patient is likely to respond to the treatment.

iv) The electronic and electrochemical aspects of the safety of the methods used at Southampton are discussed.

The Equipment Used for Spinal Cord Stimulation

The stimulator used for most of the work carried out so far at Southampton is the Avery Laboratories Inc. 'Dorsal Column Stimulator'. This stimulator employs inductive coupling between an implanted receiver whose circuit is encapsulated in an epoxy resin, and an external transmitter, and is similar to inductively coupled stimulators made by other manufacturers. It was, in fact, originally intended to be used by patients requiring S.C.S. for pain relief.

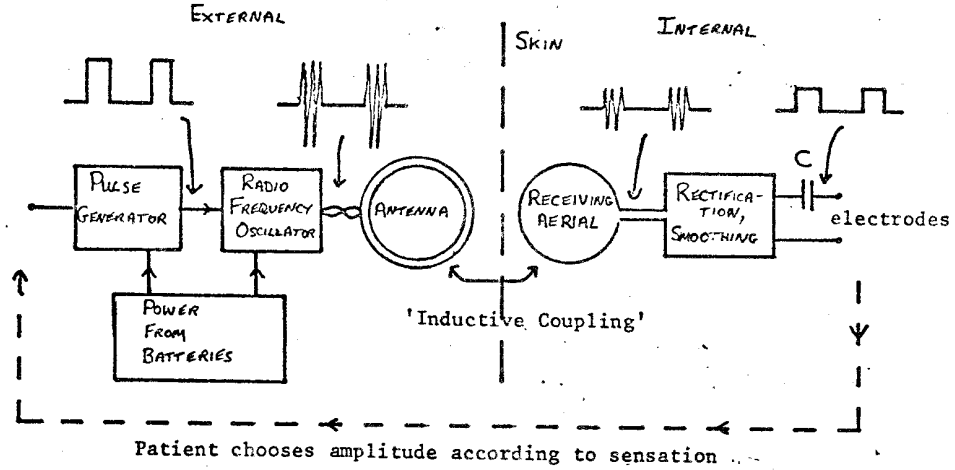

Figure 1: The Inductively Coupled Stimulator

Figure 1 shows a block diagram of an inductively coupled stimulator. The pulse generator output is used to determine the amplitude of oscillation of the r.f. oscillator. The electrical energy required for stimulation is transferred to the implanted circuitry by means of the antenna and receiver coils, which form a loosely coupled tuned transformer (hence the term 'inductive coupling'). After rectification and smoothing of the signal picked up by the receiver coil, the receiver output, which is connected to the electrodes, is (ideally) identical in shape to that of the pulse generator. The capacitor C ensures that no net current passes between the electrodes, minimizing the

risk that electrolysis will occur in the body tissues near the electrodes.

There are many features of inductively coupled stimulators which make them attractive for use at a time when our understanding of S.C.S. is developing. For example, the electronic circuits employed are fairly straightforward, which should keep their cost low; two of the parameters of the stimulating pulses, their duration and repetition rate, can be controlled externally with accuracy; and the implanted receiver is a passive network containing no batteries and, as such, is unlikely to prove harmful even in the event of it failing.

The system does, however, have some limitations. The amplitude of the stimulating pulses is not controlled because it is dependent upon the impedance seen by the output of the receiver, which is the sum of the tissue impedance and the two electrode/tissue interfaces, and upon the relative positions of the antenna and receiving aerial. Figure 2, for example, shows an example of variation of a receiver output with the value of a resistive load connected to it.

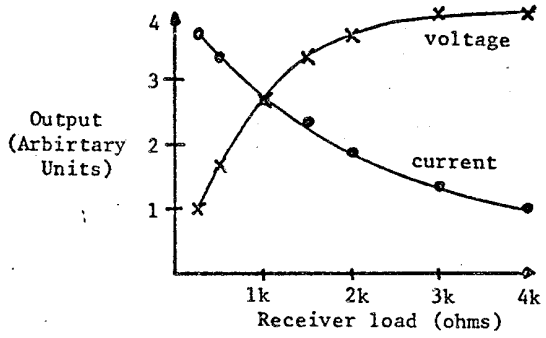

Figure 2: Receiver Output Varies With Load

It is therefore not possible to know what stimulus is applied to a patient, which, as is suggested later, may deprive us of valuable information. The patient must reset the transmitter output every time the antenna moves, using a subjective criterion to choose the desired amplitude. If required, the receiver output can be calibrated as a function of transmitter setting, the relative antenna and receiver positions and the load on the receiver. Once the receiver has been implanted, however, it is of course impossible to know with accuracy the receiver's position or electrical load, and so only an approximate estimate of the stimulation amplitude can be made.

Despite the fact that the amplitude control on the Avery transmitter is calibrated in terms of voltage, we consider the receiver output current to be of more fundamental interest. The approximate equivalent circuit of the load on the receiver is shown in figure 3. The value of the impedance presented by each component may be a non-linear function of frequency or the voltage across it. In addition, the values of the electrode impedances will change if fibrous tissues build up around them.(1) Because the way in which the receiver load is distributed between the electrodes and the tissue is not known, that component of the output voltage which is dropped across the electrode/tissue interfaces cannot be evaluated. All of the current generated by the receiver must, however, pass between the electrodes.

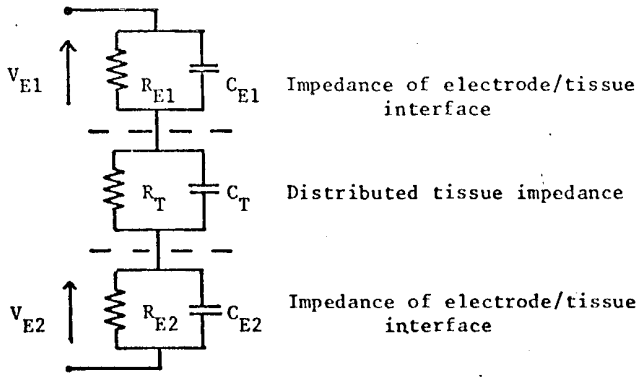

Figure 3: The Approximate Equivalent Circuit of the Load on the Receiver

The design of a prototype receiver which supplies accurate information about the current which it is delivering to the electrodes has been carried out - see figure 4. The voltage across the output capacitor of the stimu-

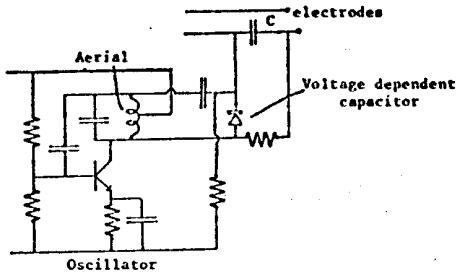

Figure 4: Prototype Receiver with Current Information

lator (which is proportional to the time integral of the output current) is used to modulate the frequency of an implantable oscillator which derives power from the external transmitter in the same way as the stimulator. An external receiver can decode the signal and the receiver current can be determined. If necessary, this information could be used to control the power of the stimulator transmitter so that the current output of the receiver could be maintained independently of the antenna-receiver separation and the receiver load.

Inductive coupling is rather inefficient in terms of energy consumption. The overall efficiency, defined as

$$\text{Efficiency} = \frac{\text{Electrical Energy Delivered to Electrodes}}{\text{Energy Drawn From Batteries}}$$

is typically about 1% under the conditions in which the stimulators are used.

Fully implantable stimulators which, like most cardiac pacemakers, contain their own energy source, are much more efficient than inductively coupled stimulators. There are, however, two important differences between spinal cord and cardiac stimulation:

i) Largely as a result of the pulse repetition rate being much higher in S.C.S., it has an energy requirement which is higher by a ratio of 20 - 50 times than cardiac stimulation. Implanted batteries would either need to have a correspondingly larger capacity or would have to be rechargeable.

ii) It would often be necessary to communicate with a fully implantable stimulator to alter the amplitude of the stimulus provided. As some circuits external of the patient would therefore still be required, the need to always carry external circuitry, as with the inductively coupled system, is not a great disadvantage.

The Electronic Requirements of Spinal Cord Stimulation

There are two reasons why an electronic engineer should measure the electronic requirements of a patient receiving S.C.S. The first is that the information so obtained enables the specifications of any new designs of stimulator to be described. Secondly, it may be possible to reduce the energy requirements of S.C.S. by choosing a particularly suitable pulse width in a way similar to that in which it was found that a minimum in the energy required to initiate cardiac activity was present when pulse widths of between 0.2ms and 1.0ms were used.(2)

During a two-week assessment period which each patient undergoes, direct electrical access to the electrodes is available by percutaneous wires. Each of eleven patients has been asked to select the pulse amplitude which gives the most satisfactory sensation for a variety of pulse widths between 50μs and 5ms. In this limited study, only one pulse frequency (33Hz) has been used. Although the results for repeated tests with one patient during each session are reproducible to an accuracy of about 10%, the intensities chosen by different patients vary over a large range. The maximum, minimum and mean values encountered so far of the pulse current and energy are shown in figure 5.

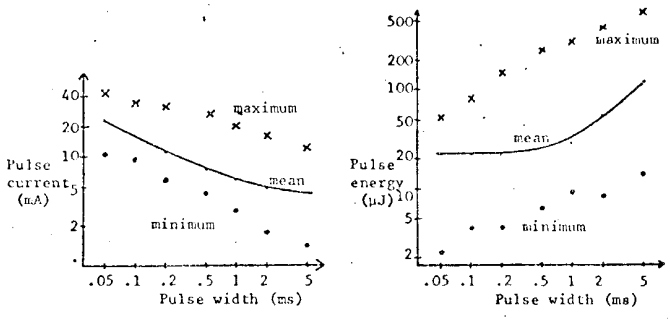

Figure 5: Pulse Current and Energy as Functions of Pulse Width. The Maximum, Minimum and Geometric Means are Shown.

Our results show that the energy required for S.C.S. is at its minimum value for pulse widths of 0.2ms, although shorter pulses do not increase the energy requirement. Pulse widths of 0.2ms usually give a satisfactory sensation and most patients have, in fact, been stimulated with pulses of this duration.

Approximate component values can be assigned to the circuit shown in figure 3. The electrodes used were platinum cylinders, 1mm in diameter and 3mm long. The component values which are found with any one patient depend upon the electrode positions and the particular electrodes used. Figure 6 shows the equivalent circuit of the electronic load upon the receiver, reduced to its simplest form, with the range of component values encountered. The capacitor C_T in figure 3 is small and has not been included.

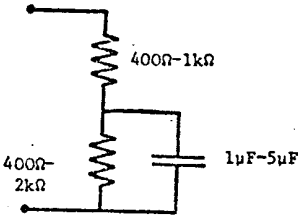

Figure 7: Approximate Electrical Load on the Receiver; Range of Component Values Encountered.

Discussion: The Different Current Requirements of Patients Receiving Spinal Cord Stimulation

The clinical response of the patients to treatment during the two-week assessment has varied from spectacular improvement to little change.(3) For the purposes of this discussion, patients whose response has been sufficiently encouraging for them to be offered a receiver implant, and therefore, permanent stimulation, shall be referred to as 'successful', and vice-versa.

Successful patients are usually able to choose a stimulus amplitude which gives a satisfactory sensation in both legs; most unsuccessful patients experience less pleasant sensations - for example, a tightening feeling around the chest.(3)

We have also observed that the current amplitude chosen by the successful patients tends to be less than that chosen by unsuccessful patients. Table 1 shows the currents chosen by each patient when a pulse duration of 0.2ms was used. Where a patient appears more than once in the table, this indicates that measurements were made on more than one occasion; extra measurements were usually made after an attempt to reposition the patient's electrodes.

Before attaching any significance to the results, it is necessary to show that there is a statistically meaningful difference between the current requirements of the two groups. In the following analysis, the current requirement of each patient is used only once, so that the results are not weighted by those upon whom more than one set of measurements were made. The average current chosen by each such patient is used.

The mean current chosen by successful patients is 8.75mA; that of the unsuccessful patients is 20.70mA. The combined standard error of the two groups is 4.27mA. Assuming that the results are approximately normally distributed, the difference between the mean currents of each group, and the 95% confidence interval, is given by:

Difference between mean currents = 11.9 ± 9.7mA

As this result is derived from measurements on only eleven patients, it must be handled with caution. It does, however, indicate that it is possible to state, with 95% confidence, that there is a real difference between the currents chosen by 'successful' and 'unsuccessful' patients. Two interpretations may be placed upon this result. One is that patients who choose a high pulse intensity and experience unsatisfactory stimulation sensations are unlikely to benefit from S.C.S. for reasons associated with the pathology of the disease in that particular patient. For example, lesions may be preventing the stimulation of regions of the nervous system which must be stimulated for S.C.S. to be successful.

Table 1: CURRENT REQUIREMENTS OF 'SUCCESSFUL' AND 'UNSUCCESSFUL PATIENTS

Patient	Current (mA)	S = Succ. U = Unsucc.
Ed:	9	S
Po:	6	S
Sa:	7	S
Ba:	9	S
Ba:	10	S
Ri:	9	S
Ri:	12	S
Fl:	9	S
Fl:	8	S
Fl:	12	S
Fl:	13	S
Em:	19	U
Mo:	20	U
Me:	18	U
Bi:	10	U
Bi:	11	U
Pu:	32	U
Pu:	40	U

Table 2: ELECTRODE POSITIONS OF 'SUCCESSFUL' AND 'UNSUCCESSFUL' PATIENTS

Upper Electrode (On midline (m-1) except where indicated)	Lower Electrode	Separation mm
T5	T7	65
No information available		
T3	T5(off m-1)	52
T4/5	T6(off m-1)	62
T4/5(off m-1)	T6/7	60
T2/3	T3(off m-1)	21
T4/5	T6/7	60
T4/5	T6/7	63
T6(off m-1)	T8/9	65
T8	T9	31
T4/5	T5/6	33
No information available		
No information available		
T8	T8/9	18
T5(off m-1)	T7	57
T8(off m-1)	T9/10	60
T4(off m-1)	T4/5	27
T4(off m-1)	T5/6	36

Alternatively, it may be suggested that the stimulating electrodes have been positioned in such a way that the wrong tracts of the spinal cord were stimulated. Our evidence indicates that this latter suggestion is not correct. Table 2 shows the positions of the electrodes used in each patient at the time at which each current measurement was made. There is no consistent difference between the levels, distances from the midline or vertical separations of the electrodes used on each group. The fact that the use of more than one electrode position in a particular patient does not greatly alter that patient's current requirement also indicates that the difference between the groups arises because of differences between the patients, not differences between the electrode positions used. Indeed, several patients have achieved successful clinical results and low current requirements when there has been a considerable deviation of the electrodes from the midline.

Table 2 does not contain information about the separation between electrodes and nervous tissue in the anterior-posterior direction, because the separation is too small and too strongly dependent upon the posture of the patient to measure accurately. However, if the current requirement or success of treatment were strongly dependent upon this separation, patients would be able to change their stimulation by altering their posture. We have observed that by changing his posture, a patient rarely alters his current requirement by more than 10%.

It is therefore suggested that information about the current requirements of patients may be important in assessing whether or not a patient is likely to respond to S.C.S. It may also assist our understanding of the medical effect of S.C.S. Results from a larger number of patients are needed to increase the confidence with which our results can be presented.

The major advantage of using the current requirement of a patient as a predictor of the result of using S.C.S. with that patient is that the measurements can be made and interpreted very quickly: the time taken being perhaps twenty minutes for each patient.

The Safety of the Methods Used for S.C.S. at Southampton

It is necessary to identify possible hazards associated with S.C.S. This paper is confined to the electronic and electrochemical hazards associated with S.C.S.; the neurological mechanism of S.C.S. is discussed in a separate paper.(4)

i) Thermal Effects: The passage of the stimulating current through a resistive medium, those of the patient's tissues through which current passes, causes the dissipation of energy in the form of heat. Because of the low mark : space ratio used in S.C.S., the average power dissipation between the electrodes has never exceeded 5mW, which is too low to cause any hazard to the patient. Some indication of how little power this represents can be obtained by calculating that, if the transmitter efficiency is approximately 1%, about one hundred times the power dissipated in the patient is dissipated in the transmitter. Despite this, the latter shows no perceptible temperature increase during use!

ii) Interference Effects and Stimulator Malfunction: Although some reliability problems have been encountered with the Avery stimulators we have used, the fact that S.C.S. is not, unlike cardiac pacing, a life-support mechanism, means that equipment failures cause annoyance but not danger. Even in the unlikely event of the stimulator intensity becoming jammed on maximum output, the patient has only to separate the antenna from the receiver to stop the stimulus. Radio-frequency interference from a source other than the stimulator transmitter is rejected by the receiver, which is tuned to the transmitter frequency; in any case, the output capacitor of the receiver will block the effect of any non-pulsating interference. Seepage of body fluids into the receiver encapsulant has not been encountered.

iii) Electrochemical Effects: Electrochemical reactions at the stimulating electrodes must be avoided because they could release gases (including hydrogen, oxygen and chlorine) into the patient's body; cause local changes in pH, or release kinetically active anions or metal cations into solution; corrosion of the stimulating electrodes could reduce their effective surface area and therefore increase the real density of the current at the electrodes. (5)

The use of a series capacitor at the output of the stimulator does not necessarily prevent electrochemical reactions: faradaic rectification can occur. Rather than set our own standards for the electrochemical safety of stimulation, we have compared our pulses with those which other workers have considered to represent the limit of 'safety'.

Bergveld(6), for example, considers that electrolysis will be avoided provided that, if a constant current stimulating pulse is used, the pulse is sufficiently short that the voltage does not reach a constant value. With the current intensities we have used, this would appear to limit the safe pulse width to approximately 1ms. Brummer and Turner(7) point out that, provided no solution electrolysis products are generated, any electrode reactions should be reversible. In a non-Cl^- containing solution, this would allow the injection of 750$\mu C/cm^2$/pulse with safety; although an (unspecified) lower limit applies when Cl^- ions are present. The maximum charge injection we have used with 0.2ms pulses is 60$\mu C/cm^2$/pulse; normally a value of about one-third of this is used. Both Pudenz(8) and Gilvan(9) have reported observing cell damage with charge injections of about 20$\mu C/cm^2$/pulse using parietal and cerebellar electrodes respectively. Their electrodes, however, were placed directly on nervous tissue, whereas our epidural electrodes are separated from the cord itself by the dura and immediately extradural tissue and by a layer of C.S.F. Furthermore, we are stimulating axons, rather than dendrites and there is evidence that the former are more resistant to damage than the latter.(8)

One of our patients required a second laminectomy to replace an electrode. Biopsy of the scar tissue from the region of the tip of the electrode which had been in use for five months showed no histological abnormality beyond that expected at an old laminectomy site.

At no time have we observed corrosion of electrodes that we have removed from patients. There remains, however, a need for ceaseless vigilance - especially when experimenting with unusual parameters of stimulating pulses.

Conclusion

It is of great importance that medical research carried out into the mechanism of Spinal Cord Stimulation be carried out with active collaboration between the medical team and electronic engineers. The latter are readily able to develop equipment which will enable experiments with a much greater variety of stimulating pulses than used at present to be carried out. When supplied with information about the changing requirements of patients receiving S.C.S., they will be able to develop stimulators accordingly. The safety of all work carried out must be continuously monitored. There is a need for experiments of the kind described in this paper to be carried out with a much larger number of patients so that the results which have been tentatively presented can be shown, with more confidence, to be correct and useful.

Acknowledgements

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