RECRUITMENT CHARACTERISTICS OF NERVE CUFF ELECTRODES AND THEIR IMPLICATIONS FOR STIMULATOR DESIGN

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ABSTRACT

Recruitment characteristics of nerve cuff electrodes implanted in four cats for five months have been measured. Monopolar, bipolar and tripolar configurations were considered. Approximately twice the current was required to achieve a given response using the tripolar configuration as compared with monopolar stimulation. Bipolar stimulation was generally intermediate to the other two configurations. Muscle tension can be modulated by using pulse amplitude modulation (PAM) or pulse duration modulation (PDM). For PAM it is desirable to operate at a low pulse duration and in the high end of the allowable range for pulse amplitude. For PDM, one should operate at a low pulse amplitude and in the high end of the allowable range for pulse duration. KEYWORDS: nerve cuff electrodes, recruitment, pulse amplitude modulation, pulse duration modulation.

INTRODUCTION

Cuff electrodes have been used to stimulate peripheral nerves in a number of clinical applications, incuding diaphragm pacing [4], correction of footdrop [13], pain control [6], and voiding the bladder [Tanagho (personal communication)]. Complications have included injuries to the nerve and late infection, however, mechanical failures of cuff electrodes have been rare [3,7,12]. In recent reviews it was found that 7 electrodes used to stimulate the peroneal nerve were still functioning 10-12 years after implantation [12] and diaphragm pacers with cuff electrodes were still functioning in 15 patients after 10-16 years [2]. Based on this experience it is anticipated that cuff electrodes will be used in future systems being developed to enable persons with neurological impairments to stand and walk [9,11].

Despite the use of nerve cuff electrodes in clinical applications for the past 20 years, there is a scarcity of published data on the recruitment characteristics of cuff electrodes that can be used by design engineers to establish specifications for implanted stimulators. Recruitment data (muscle tension versus stimulus pulse amplitude or duration) for an experimental electrode used in dogs was published by Rabischong et al in 1974 [10]. More recently, Gorman and Mortimer presented recruitment data for a monopolar cuff electrode placed on the nerve branch to the medial gastrocnemius muscle in cats [5]. Both of these studies were acute experiments in which the electrodes were placed on the nerve just prior to the collection of data.

The objectives of the present study were to record recruitment data on chronically implanted nerve cuff electrodes and to develop preliminary specifications for the design of implantable stimulators. Data are presented for monopolar, bipolar and tripolar electrode configurations.

METHODS

The nerve cuff electrodes used in this study consisted of three 1x2 mm platinum discs inside a 3 mm diameter silicone-rubber cuff (Avery Laboratories, Farmingdale NY). The platinum discs were separated by 3 mm in the axial direction and were oriented every 120° around the nerve. Electrodes were placed on the posterior tibial nerve of four cats.

Adult cats were anesthetized with 45 mg/kg pentabarbital given intraperitoneally. Throughout the surgery the animal's body temperature was maintained with a heating pad, and heart rate was monitored with an audio signal. The left popliteal fossa was exposed, and the cuff electrode was carefully placed around the tibial nerve just below the bifurcation of the sciatic nerve. Lead wires were passed subcutaneously to the lateral proximal thigh and coiled beneath the skin. Postoperatively the animals were placed in a restricted area with body temperature maintained by a heating pad during recovery from the anesthesia. Antibiotics were administered for three days prior to surgery and maintained for at least five days following the surgery.

Four months after implantation, the animals were again anesthesized with pentabarbital and placed in a supportive frame with a strain-gage transducer to measure the plantarflexion moment at the ankle. The frame and transducer were constructed in our laboratory. The transducer was calibrated prior to each test session.

The electrode leads were explanted without disturbing the region near the electrodes. For monopolar stimulation, the anode was a 2 cm diameter, stainless-steel disc placed in the leg opposite to that being tested. When using the bipolar configuration, the two outer electrodes were used (6 mm separation), with the distal electrode cathodic. For the tripolar configuration, the center electrode was the cathode with the two outer electrodes shorted together to form the anode.

Recruitment data were collected for each configuration using a Grass S8 Stimulator with a constant-current output stage. The pulse duration of a monophasic pulse was fixed at 10, 20, 50, 100, 200 and 350 µs, and the pulse amplitude was varied to generate isometric twitch moments between threshold and maximal values. To prevent fatigue, twitches were produced, and the peak value of the resulting twitch was recorded.

EXPERIMENTAL RESULTS

Normalized moments for a monopolar cuff electrode in one animal were plotted in Fig. 1 as a function of pulse amplitude (PA) at various pulse durations (PD). Lower PA were required as PD was increased from 10 to 350 µs, with little change seen in the recruitment curves for PD greater than 200 µs. The gain, represented by the slopes of the curves, decreased significantly as PD was decreased.

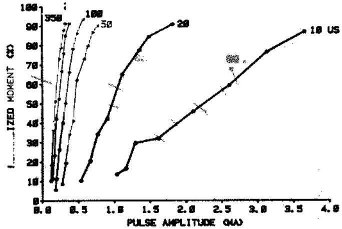

Figure 1. Recruitment characteristics (normalized moment vs. pulse amplitude) for a monopolar cuff electrode implanted on the posterior tibial nerve of a cat for five months.

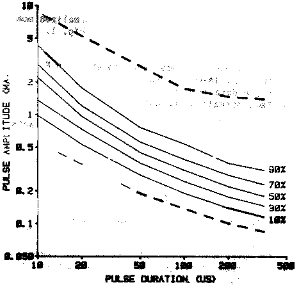

Figure 2. Amplitude-duration curves for the electrode used in Fig. 1 (solid lines). Upper and lower boundaries for all electrodes (dashed lines)

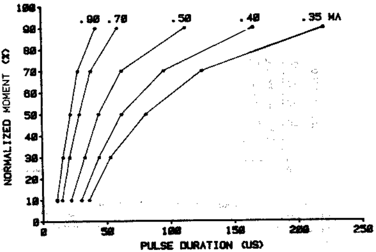

Figure 3. Recruitment characteristics (normalized moment vs. pulse duration) for the electrode used in Fig. 1.

A useful representation of these data are shown in Fig. 2. A family of pulse amplitude-duration (A-D) curves at constant moments (solid lines) were plotted from the data in Fig. 1 by reading the PA required at each PD to generate constant normalized moments of 10, 30, 50, 70 and 90%. The dashed lines shown in Fig. 2 represent the upper and lower boundaries of the families of A-D curves for all 12 sets of data (4 animals and 3 electrode configurations).

Normalized moments as a function of PD for the same monopolar electrode used in Fig. 1 and 2 were plotted in Fig. 3 for various PA. As PA was increased, the slopes of the curves increased and lower PD were required to generate the same normalized moment.

Recruitment characteristics for the bipolar and tripolar configurations were similar to data obtained with monopolar stimulation except that more charge per pulse was required at comparable output levels. This can be seen in Fig. 4 in which A-D curves at a normalized moment of 50% were plotted for each electrode configuration. The monopolar curves fell below the bipolar and tripolar curves in each animal tested. For any given PD, the tripolar configuration required about twice the PA needed for monopolar stimulation. The A-D curves for the bipolar configuration were close to the tripolar curves in two animals and closer to the monopolar curves in the other two animals.

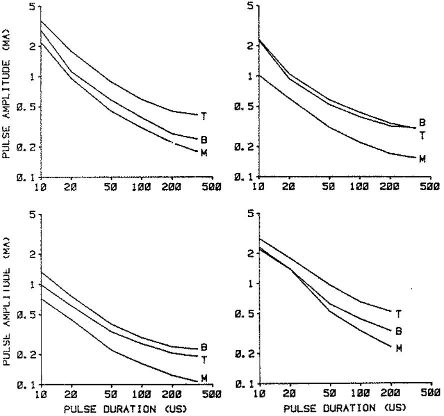

Figure 4. Amplitude-duration curves at a normalized moment of 50% for all four cats and for the monopolar (M), bipolar (B) and tripolar (T) electrode configurations.

DESIGN CONSIDERATIONS

Muscle tension can be controlled by fixing PD and varying PA (pulse amplitude modulation, PAM) or by fixing PA and varying PD (pulse duration modulation, PDM). Both methods are considered below. In the analyses it has been assumed that both PA and PD can be varied only in discrete steps (digital control), but the results will be of value to designers using an analog approach. It has also been assumed in these analyses that the implant stimulator is to be designed to accommodate monopolar, bipolar and tripolar cuff electrodes. The 12 sets of recruitment data are therefore assumed to be a representative subset of all cuff electrodes.

One parameter of interest when comparing alternate strategies for modulation of muscle tension is the Maximum Gain (MG), which is defined to be the maximum % change in normalized moment per unit step. An MG of 5 indicates that at some point on the recruitment curve a one step change in PA (with PAM) or PD (with PDM) will result in a 5% change in muscle tension, and at all other points the change will be ≤ 5%. MG is therefore an indication of the fineness of control; the lower the MG, the finer the available control.

Pulse Amplitude Modulation

One strategy for PAM is to use a single hardware-fixed value of PD and vary only PA. This was the approach used with the Neuromuscular Assist (NMA) system for correction of footdrop [13]. Using this strategy, MG values were calculated for each of the 12 sets of recruitment data in the present study, and the results are summarized in Table I for fixed pulse durations of 10, 20, 50 and 100 μs. In each case, the upper limit on the range of PA was set at a value which slightly exceeded the highest PA which generated full muscle recruitment for all 12 sets of data (top dashed line in Fig. 2). Calculations were made on the basis of 256 steps in PA, but the data in Table I can be easily converted to alternate numbers of steps.

TABLE I

PAM: HARDWARE-FIXED PD

PD (μs)	10	20	50	100
PA Range (ma)	0-10	0-6	0-3	0-2
PA Step Size (μa)	39	23	12	8
Mean MG (%Δ/step)	5.7	6.2	6.2	5.6
Range of MG (%Δ/step)	1.2-12.9	1.4-18.8	1.3-15.7	1.6-17.5

The most striking result was that the mean and range of MG are essentially independent of the selected PD. This result was quite surprising on the basis of the family of curves shown in Fig. 1. Larger step sizes in PA may be used with shorter PD, perhaps decreasing the sensitivity to system or controller variations, but this advantage is gained only at the expense of an increased maximum output.

A significant improvement in MG **can be achieved by using a** software-selectable PD which can be **individually set for each electrode.** This feature allows the designer to use a narrow range on PA and enables the user to select the lowest possible PD (thereby decreasing MG as shown in Fig. 1) to ensure full recruitment within the PA range. In the following analysis, the PA range was 0-2.55 ma and the number of steps was 256. This range was broad enough to cover all of the recruitment data, but narrow enough to provide adequate resolution for good control. **To determine an appropriate resolution for PD, four step sizes (5, 10, 20 and** 50 μs) were considered. In each case, **it has been assumed that PD can be** set to any multiple of the given step size. For each electrode and step **size,** the PD was set as low as possible above the PD at 2.55 ma on the 90% **A-D curve for that** electrode to ensure full muscle recruitment.

It is seen in Table II that both the mean MG and the largest MG decreased as the PD step size was decreased from 50 to 5 μs. For a step size of 10 μs, the mean MG was approximately one-third of that obtained with a hardware-fixed PD, and the largest computed MG of 3.3 was an even greater improvement over the largest MG obtained using a fixed PD strategy. Little improvement in MG was gained by decreasing the PD step size below 10 μs.

TABLE II

PAM: SOFTWARE-SELECTABLE PD

	PD Step Size (μs)			
	5	10	20	50
Range of PDs Selected (μs)	10-60	10-60	20-60	50-100
PA Range (ma)	0 - 2.55			
PA Step Size (μA)	10			
Mean MG (Sa/step)	1.8	2.1	2.8	3.4
Range of MG (Sa/step)	1.0-2.3	1.0-3.3	1.0-6.0	1.0-13.3

Pulse Duration Modulation

A hardware-fixed amplitude strategy for PDM was not analyzed. The PA would have to be at least 1.5 ma to accommodate all of the data (Fig. 2), and the subsequent PD for maximum recruitment for three of the data sets was less than 10 μs, too low for adequate control.

The approach taken was similar to **that used** previously **with the** software-selectable PD strategy for PAM. For PDM, it was assumed that **PA** could be selected for each electrode and set to any multiple of a given PA **step size.** Four step sizes (50, 100, 200 and 500 µa) were considered. **The** PD range was assumed to be 0-255 µs with 256 steps. For each electrode **and PA** step size, the PA was set as low as possible above the value of the PA at 255 µs on the 90% A-D curve for that electrode. This minimized MG (as **shown in Fig. 3) and** ensured full recruitment within the assumed range for **PD.**

The results of this analysis are shown in Table III. The mean **MG** decreased from 4.4 to 1.8 as PA step size was decreased from 500 to 50 µa. The results for step sizes of 50-200 µa are comparable with PAM using software-selectable PD **with step sizes ≤ 10 µs.**

TABLE III

PDM: SOFTWARE-SELECTABLE PA

	PA Step Size (µa)			
	50	**100**	**200**	**500**
Range of PAs Selected (ma)	**.15-1.45**	**.2-1.5**	**.2-1.6**	**.5-1.5**
PD Range (µs)	**0 - 255**			
PD Step Size (µs)	**1.0**			
Mean MG (%A/step)	**1.8**	**2.1**	**2.6**	**4.4**
Range of MG (%A/step)	**1.1-3.4**	**1.1-4.0**	**1.1-6.0**	**1.3-10.0**

DISCUSSION

Comparable results were achieved with PAM and PDM when the following step sizes were used:

PAM: **PA Step Size = 10 µa**
PD Step Size = 10 µs

PDM: **PA Step Size = 100 µa**
PD Step Size = 1 µs

In both cases, the mean MG was 2.1 and the largest MG was less than 5. When using these step sizes, the 10-90% recruitment curves for all 12 data sets fell within the blocks shown in Fig. 5. The step sizes are shown along the right and lower boundaries in each case.

The ranges and resolutions shown in Fig. 5 are not suggested as absolute specifications for implantable stimulators to be used with nerve cuff electrodes. They are intended instead to provide guidelines for designers to use in establishing their own specifications. The information shown in Fig. 5 is based on one particular electrode design, one electrode size and a limited set of data. More studies must be conducted before specifications can be established with a reasonable degree of confidence.

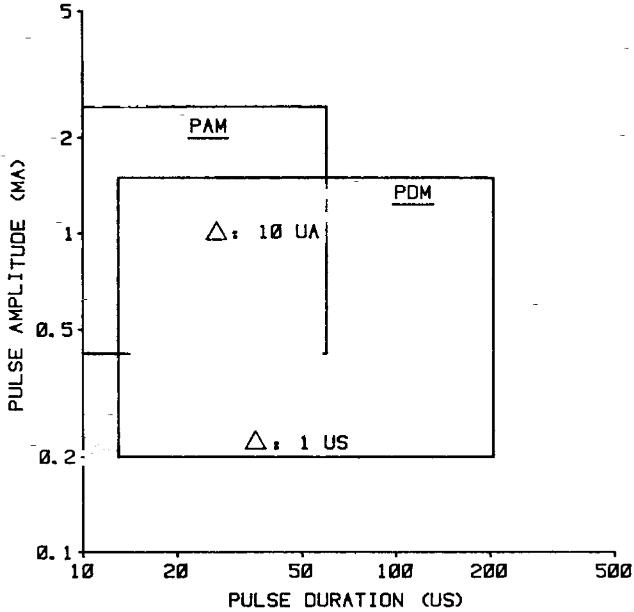

Figure 5. Ranges and resolutions required for pulse amplitude modulation (PAM) and pulse duration modulation (PDM) to insure that the maximum gains for all electrodes tested were less than a 5% change in normalized moment per control step.

It can be concluded from this study, however, that both PA and PD must be variable when using either PAM or PDM. It can also be stated that the strategies for the two methods of modulation are quite different. With PAM, controllability is improved (or alternatively MG is minimized) by setting PD as low as possible while still achieving the maximum desired muscle output within the given range of PA. With PDM, controllability is improved by setting PA as low as possible while still achieving the maximum desired output. Thus, one will generally be working at lower PD and higher PA when using PAM as compared with using PDM. Crago has shown that the charge required to produce comparable outputs decreases as PD decreases [1], therefore PAM will require less total charge than PDM when using the suggested strategies.

As shown in Fig. 4, monopolar stimulation requires less charge for stimulation than does bipolar or tripolar stimulation. This is consistent with a previous study which showed that bipolar stimulation with a 3 or 6 mm interelectrode spacing required higher currents than monopolar stimulation [8]. Monopolar electrodes also have the advantage of having only a single lead wire and requiring less dissection during implantation since the electrode can be made smaller. The primary advantage of bipolar or tripolar cuff electrodes is that there is less current spread outside the insulating cuff. It has been shown, however, that with one type of monopolar cuff electrode, maximum contractions can be achieved in muscles innervated by the motor nerves inside the cuff before excitation of any motor fibers in nerves lying just outside the cuff [8].

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