

# Recruitment Data for Nerve Cuff Electrodes: Implications for Design of Implantable Stimulators

DONALD R. MCNEAL, MEMBER, IEEE, LUCINDA L. BAKER, AND JEFF T. SYMONS

**Abstract**—Recruitment characteristics of nerve cuff electrodes implanted in four cats for five months were 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 also required more current than monopolar stimulation. Using the recruitment data, a number of strategies for modulating muscle tension were considered. It was shown that both pulse amplitude and pulse duration should be software-selectable to achieve adequate control of muscle tension when using either pulse amplitude modulation or pulse duration modulation. When using pulse amplitude modulation, it was found to be desirable to operate at a low pulse duration in the high end of the allowable range for pulse amplitude. For pulse duration modulation, one should operate at a low pulse amplitude in the high end of the allowable range for pulse duration. The effect of pulse amplitude and pulse duration step size on the maximum step change in muscle tension and the linearity of the recruitment curves were examined. The use of logarithmic steps in the modulation parameter was examined and was shown to result in improved controllability and linearity.

## INTRODUCTION

CUFF electrodes have been used to stimulate peripheral nerves in a number of clinical applications, including diaphragm pacing [3], correction of footdrop [18], pain control [7], and voiding the bladder [16]. Complications have included injuries to the nerve and late infection; however, mechanical failures of cuff electrodes have been rare [4], [8], [19]. In recent clinical follow ups, it was found that seven electrodes used to stimulate the peroneal nerve were still functioning 10–12 years after implantation [19] and diaphragm pacers with cuff electrodes were still functioning in 15 patients after 10–16 years [5]. Based on this experience, it can be anticipated that cuff electrodes will be used in future systems being developed to enable persons with neurological impairments to stand and walk [12], [15], [17].

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 to establish specifications for implanted stimulators

that can be used by design engineers. Recruitment data (muscle tension versus stimulus pulse amplitude or duration) for an experimental bipolar electrode placed on the motor nerve innervating the tibialis anterior muscle in dogs were published by Rabischong *et al.* in 1974 [13]. 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 [6]. Both of these studies were acute experiments in which the electrodes were placed on the nerves 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 ranges and step sizes of pulse amplitude and duration for future implantable stimulators. Data were collected for monopolar, bipolar, and tripolar electrode configurations. Some of these data were presented in extended abstract form at the IX International Symposium on External Control of Human Extremities, Dubrovnik, Yugoslavia, September 1987 [11].

## METHODS

The nerve cuff electrodes used in this paper consisted of three  $1 \times 2$  mm platinum discs placed inside a 3 mm diameter silicone-rubber cuff (Avery Laboratories, Farmingdale, NY). The platinum discs were separated by 3 mm axially and were oriented every  $120^\circ$  around the nerve. Electrodes were placed on the posterior tibial nerve of four adult cats.

The cats were anesthetized with 45 mg/kg pentobarbital given intraperitoneally. 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. Animals were housed at the Rancho Los Amigos Medical Center Vivarium in conformance with Public Health Services guidelines.

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D. R. McNeal and L. L. Baker are with Rancho Rehabilitation Engineering Center, Downey, CA 90242.

J. T. Symons is with the California Department of Rehabilitation, Sacramento, CA 94244.

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Five months after implantation, the animals were again anesthetized with pentobarbital and placed in a prone position on a supportive frame. Straps over the hip, thigh, and foot stabilized the hip and knee joints in the fully extended position. The ankle was stabilized in the neutral position by a transducer strapped to the foot proximal to the metatarsal joint. The transducer was a cantilever beam instrumented with strain gauges to measure the plantarflexion moment. The transducer was calibrated prior to each test session, and the plantarflexion moment arm was measured with a ruler and recorded.

The electrode leads were then explanted without disturbing the region near the electrodes. For monopolar stimulation, the cathode was the center electrode inside the cuff and the anode was a 2 cm diameter stainless-steel disc placed in the leg opposite to that being tested. The two outer electrodes were used for the bipolar configuration (6 mm separation) with the distal electrode cathodic. For the tripolar configuration, the center electrode was the cathode with the two other electrodes connected 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  $\mu$ s, and the pulse amplitude was varied to generate isometric twitch moments between threshold and maximal values. Twitches were elicited to prevent fatigue, and the peak value of the resulting twitch was recorded.

Histology was not performed on any of the nerves wrapped with cuff electrodes in this paper. In a preliminary study, however, cat tibial nerves that were chronically wrapped with cuff electrodes identical to those used in this paper were histologically examined. Damage to some axons was observed in each nerve. It is therefore likely that the nerves tested in the present paper did have some axonal degeneration, even though there were no clinical signs of nerve damage based on observation of the animals' movements and walking patterns.

#### EXPERIMENTAL RESULTS

Normalized moments (percentage of maximum twitch moment) for a monopolar cuff electrode in one animal were plotted in Fig. 1(a) as a function of pulse amplitude at various pulse durations. Lower pulse amplitudes were required as pulse duration was increased from 10 to 350  $\mu$ s, with little change noted in the recruitment curves for pulse durations greater than 200  $\mu$ s. The gain, represented by the slopes of the curves, increased as pulse duration was increased. These data were replotted in Fig. 1(b) using a logarithmic scale for pulse amplitude. Plotted in this way, the slopes of the curves were essentially independent of pulse duration. This was true for all electrodes and configurations tested. A similar finding was reported by Crochetiere *et al.* for cutaneous stimulation of the biceps muscle in humans [2].

Another representation of these data is shown in Fig. 2. A family of pulse amplitude-duration curves at con-

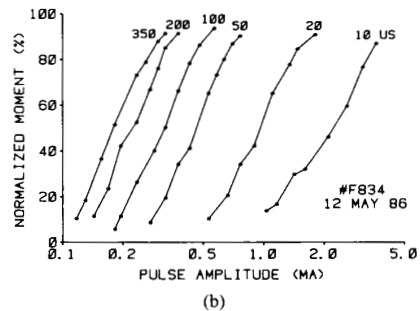
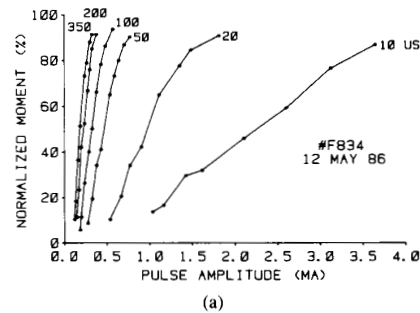


Fig. 1. Recruitment data for a 3 mm diameter monopolar cuff electrode with monophasic stimulation using a linear scale (a) and a logarithmic scale (b) for pulse amplitude.

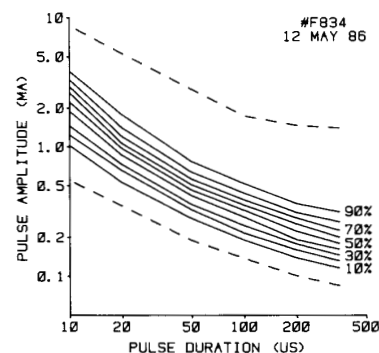


Fig. 2. Amplitude-duration curves at constant muscle tensions ranging from 10 to 90 percent of maximum for the electrode used in Fig. 1 (solid lines). The dashed lines are the upper and lower boundaries for the families of amplitude-duration curves for all 12 data sets.

stant moments were plotted from the data in Fig. 1 by reading the pulse amplitude required at each pulse duration to generate constant normalized moments from 10 to 90 percent. The dashed lines shown in Fig. 2 were the upper and lower boundaries of the families of amplitude-duration curves for all 12 sets of data (four animals and three electrode configurations).

Normalized moments as a function of pulse duration were plotted in Fig. 3(a) for various pulse amplitudes from the data in Fig. 2. It was found that the slopes of the curves increased and lower pulse durations were required to generate the same normalized moment as pulse amplitude was increased. These data were also plotted in Fig. 3(b) using

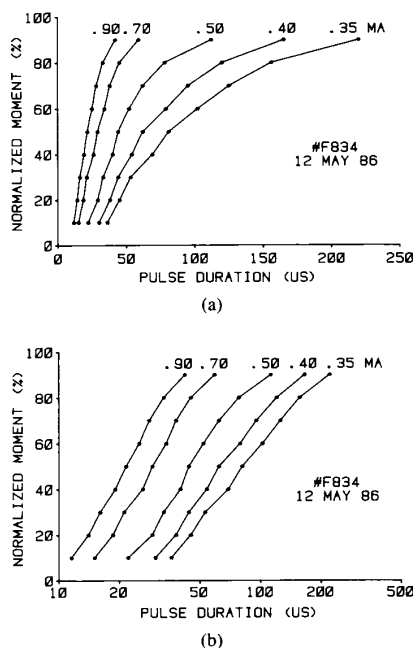


Fig. 3. Recruitment data plotted versus pulse duration for the electrode used in Figs. 1 and 2 using a linear (a) and logarithmic scale (b).

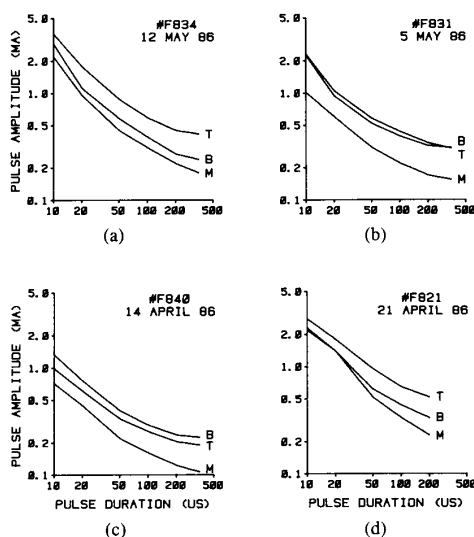


Fig. 4. Amplitude-duration curves at 50 percent of the maximum muscle tension for monopolar (*M*), bipolar (*B*), and tripolar (*T*) configurations. Curves are shown for all four animals (a)–(d).

a logarithmic scale for pulse duration. On a semilogarithmic plot, the slopes of the recruitment curves were essentially independent of pulse amplitude, and the curves were more linear.

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 levels of muscle tension. This can

be seen in Fig. 4 in which amplitude-duration curves at a normalized moment of 50 percent were plotted for each electrode configuration. The monopolar curves fell below the bipolar and tripolar curves in each animal tested. For any given pulse duration, the tripolar configuration required about twice the pulse amplitude needed for monopolar stimulation. The amplitude-duration curves for the bipolar configurations were close to the tripolar curves in two animals but fell closer to the monopolar curves in the other two animals.

#### DESIGN CONSIDERATIONS

Muscle tension can be controlled by fixing pulse duration and varying pulse amplitude (pulse amplitude modulation, PAM) or by fixing pulse amplitude and varying pulse duration (pulse duration modulation, PDM). Both methods were considered in the following analyses. It was assumed that pulse amplitude and pulse duration could 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 an implant stimulator would be designed to accommodate monopolar, bipolar, or tripolar cuff electrodes. The 12 sets of recruitment data were therefore considered to be a representative subset of all cuff electrodes.

In looking at the recruitment curves shown in Figs. 1 and 3, a control engineer would like to see curves that are linear (straight lines) and low gain (low slope). Linearity simplifies the analysis and design of the controller and low gain allows better controllability (i.e., a small change in the modulation parameter does not cause a large change in the muscle output). In the following analyses, various modulation strategies are compared to determine which strategies are best from the standpoint of controllability and linearity over the 12 sets of recruitment data that were collected.

Two parameters, maximum change and linearity ratio, are introduced as measures of controllability and linearity. Each is defined below.

Maximum change = the maximum percent change in normalized moment per step change in the modulation parameter.

For example, a maximum change of 5 percent indicates that at some point on the recruitment curve a single step change in the modulation parameter results in a 5 percent change in muscle tension, and at all other points the change is  $\leq 5$  percent. Maximum change is directly related to the maximum gain (slope) of the recruitment curve and the minimum step size of the modulation parameter. Maximum change is an indication of the fineness of control; the lower the maximum change, the finer the available control.

Linearity ratio = the minimum percent change in normalized moment per step divided by the maximum change.

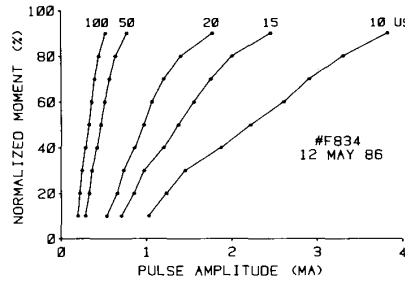


Fig. 5. Recruitment data plotted from Fig. 2 for calculation of maximum change and linearity ratio (see text for definitions).

The linearity ratio is a measure of the linearity of each recruitment curve. It is  $\leq 1$  and is equal to 1 if the recruitment curve is a straight line.

As an illustration of how maximum change and linearity ratio were calculated, consider the recruitment curves shown in Fig. 5. These curves were plotted from the data shown in Fig. 2, and they are an approximation of the recruitment curves shown in Fig. 1(a). To calculate maximum change and linearity ratio for any one of the curves, the slopes of the eight line segments approximating the curve between 10 and 90 percent of the normalized moment were calculated. Maximum change was then calculated using the maximum slope and the assumed step size for the modulation parameter (which is pulse amplitude in this case). Linearity ratio is simply the ratio of the minimum slope to the maximum slope of the eight line segments.

#### PAM: HARDWARE-FIXED PULSE DURATION

One strategy for pulse amplitude modulation (PAM) is to use a single hardware-fixed value of pulse duration and vary only pulse amplitude. This was the approach used with the neuromuscular assist (NMA) system for correction of footdrop [18] and the stimulators for diaphragm pacing [3]. Using this strategy, maximum change and linearity ratio were calculated for each of the 12 sets of recruitment data in the present paper for hardware-fixed pulse durations of 10, 20, 50, and 100  $\mu$ s. In each case, the upper limit on the range of pulse amplitudes was set at a value which slightly exceeded the highest pulse amplitude that generated full muscle recruitment for all 12 sets of data (top dashed line in Fig. 2). The ranges of pulse amplitudes used for each value of pulse duration are shown in Table I. It is seen that the larger the pulse duration, the smaller the required range for pulse amplitude.

Throughout this paper, it was assumed that the number of available steps in the modulation parameter was 256. This assumption did not affect the calculated values of linearity ratio but it did affect maximum change. The effect of changing the number of steps can be easily calculated, e.g., doubling the number of steps halves the maximum change. Given the assumption of 256 steps, the step sizes in pulse amplitude for each hardware-fixed value of pulse duration are shown in Table I.

#### PAM: HARDWARE-FIXED PULSE DURATION

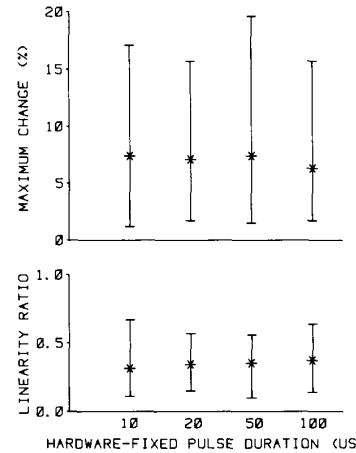


Fig. 6. Means and ranges of maximum change and linearity ratio when using pulse amplitude modulation (PAM) with a hardware-fixed pulse duration. Data are shown for four hardware-fixed values. Assumed values for range and step size of pulse amplitude are shown in Table I.

TABLE I  
PAM: HARDWARE-FIXED PULSE DURATION

| Fixed pulse duration ( $\mu$ s)      | 10   | 20   | 50   | 100 |
|--------------------------------------|------|------|------|-----|
| Pulse amplitude range (mA)           | 0-10 | 0-6  | 0-3  | 0-2 |
| Pulse amplitude step size ( $\mu$ A) | 39.2 | 23.5 | 11.8 | 7.8 |

Using the values from Table I, the calculated means and ranges of maximum change and linearity ratio are shown in Fig. 6 for each value of pulse duration. The most striking result was that the means and ranges of maximum change were essentially independent of the selected pulse duration, despite the increase in slope with increasing pulse duration (Fig. 5). This occurred because the pulse amplitude range (and therefore the pulse amplitude step size) required to ensure full recruitment for all electrodes decreased with increasing pulse duration (Table I). The decrease in step size offset the increase in slope so that maximum change was independent of the choice of a hardware-fixed pulse duration.

The values of maximum change were high for all values of pulse duration. In all cases, there was one electrode configuration in which a single step change in pulse amplitude caused a 15 percent change in muscle tension. This is undoubtedly unacceptable for most control situations, and it would mean doubling or perhaps quadrupling the number of allowable steps in pulse amplitude to reduce maximum change to reasonable values.

#### PAM: SOFTWARE-SELECTABLE PULSE DURATION

A significant improvement in maximum change was achieved by using a software-selectable pulse duration which could be individually set for each electrode. In the following analysis, the upper limit of the pulse amplitude range was selected to be 2.55 mA, a value which was high enough to ensure full recruitment for all electrodes, but

low enough to provide adequate resolution for good control. Again assuming 256 steps in pulse amplitude, the minimum step size was 10  $\mu$ A as shown in Table II. Pulse duration was assumed to be selectable. To determine an appropriate resolution for pulse duration, four step sizes (5, 10, 20, and 50  $\mu$ s) were considered. In each case, it was assumed that pulse duration could be set to any multiple of the given step size.

By referring to Fig. 5 it can be seen that the strategy that minimized the slope of the selected recruitment curve (and thereby minimized maximum change) was to set pulse duration as low as possible while ensuring full muscle recruitment within the pulse amplitude range of 0–2.55 mA. With the electrode used in Fig. 5, a pulse duration of 10  $\mu$ s could not be selected since full recruitment could not be achieved within the allowable range of 0–2.55 mA. Pulse duration had to be set at 15  $\mu$ s or greater. Following the strategy of setting pulse duration as low as possible, it was set at 15  $\mu$ s when using a pulse duration step size of 5  $\mu$ s, 20  $\mu$ s when using 10 and 20  $\mu$ s step sizes, and 50  $\mu$ s when using a step size of 50  $\mu$ s.

The fact that the slopes of the recruitment curves were essentially independent of pulse duration when normalized moment was plotted versus logarithmic pulse amplitude [Fig. 1(b)] suggests that there may be an advantage to using step sizes in pulse amplitude which vary logarithmically from the low end to the high end of the pulse amplitude range. For this reason, both linear and logarithmic steps in pulse amplitude were considered. The assumed ranges and step sizes for logarithmic steps are shown in Table II. In both the linear and logarithmic cases, 256 steps were used in the analysis. The strategy described above for selecting pulse duration for linear steps in pulse amplitude was also used for logarithmic steps. This was done not to minimize maximum change as with linear steps, but to ensure that the working range for each electrode was in the high end of the allowable range for pulse amplitude.

The means and ranges of maximum change and linearity ratio when using the above strategy are shown in Fig. 7 for linear and logarithmic steps in pulse amplitude. With linear steps it was found that the mean and the upper limit of the range of maximum change increased as pulse duration step size was increased beyond 10  $\mu$ s. With logarithmic steps, maximum change was unaffected by pulse duration step size as one would have expected since the slopes of the curves in Fig. 1(b) were essentially independent of pulse duration. Linearity ratio was not significantly affected by pulse duration step size with either linear or logarithmic steps in pulse amplitude; however, linearity ratio values were slightly higher (recruitment curves were more linear) when logarithmic steps were used.

The range of pulse durations selected and the range of pulse amplitudes required to cover the recruitment range from 10–90 percent normalized moment for all electrodes were tabulated in Table III. These values were the same for both linear and logarithmic steps.

PAM: SOFTWARE-SELECTABLE PULSE DURATION

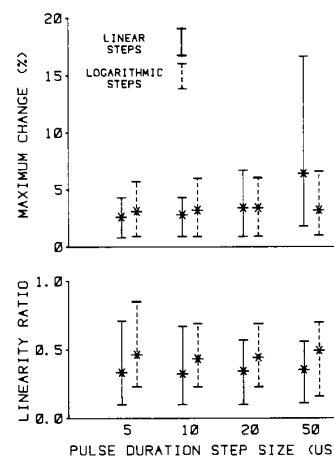


Fig. 7. Means and ranges of maximum change and linearity ratio when using pulse amplitude modulation (PAM) with a software-selectable pulse duration. Data are shown for four step sizes in pulse duration and for linear and logarithmic steps in pulse amplitude. Assumed values for range and step size of pulse amplitude are shown in Table II.

TABLE II  
PAM: SOFTWARE-SELECTABLE PULSE DURATION

|                                      | Linear Steps | Logarithmic Steps      |
|--------------------------------------|--------------|------------------------|
| Pulse amplitude range (mA)           | 0–2.55       | 0.1–2.55               |
| Pulse amplitude step size ( $\mu$ A) | 10           | Variable from 1.3–32.2 |

TABLE III  
PAM: SOFTWARE-SELECTABLE PULSE DURATION

|  | Pulse Duration Step Size ( $\mu$ s) |           |           |           |
|--|-------------------------------------|-----------|-----------|-----------|
|  | 5                                   | 10        | 20        | 50        |
| Range of pulse durations selected ( $\mu$ s)                 | 10–60                               | 10–60     | 20–60     | 50–100    |
| Range of pulse amplitudes required for full recruitment (mA) | 0.42–2.50                           | 0.42–2.50 | 0.35–2.50 | 0.19–1.75 |

#### PDM: HARDWARE-FIXED PULSE AMPLITUDE

A hardware-fixed pulse amplitude strategy for pulse duration modulation (PDM) was not analyzed. The pulse amplitude would have to be at least 1.5 mA to ensure maximum recruitment for all electrodes (see Fig. 2). At 1.5 mA, the entire range of pulse duration for full recruitment for three sets of data fell below 10  $\mu$ s. The difficulty of achieving accurate control of pulse duration below 10  $\mu$ s precludes consideration of pulse duration modulation using a hardware-fixed pulse amplitude.

#### PDM: SOFTWARE-SELECTABLE PULSE AMPLITUDE

The approach taken in this analysis was similar to that used previously for the software-selectable pulse duration strategy for PAM. For PDM, it was assumed that pulse

PDM: SOFTWARE-SELECTABLE PULSE AMPLITUDE

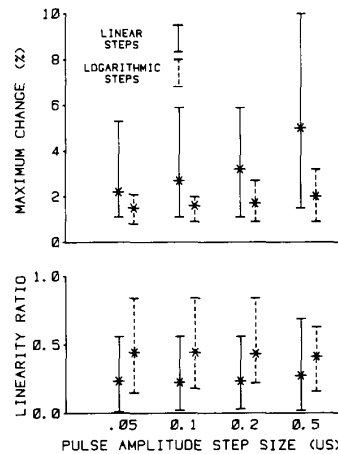


Fig. 8. Means and ranges of maximum change and linearity ratio when using pulse duration modulation (PDM) with a software-selectable pulse amplitude. Data are shown for four step sizes in pulse amplitude and for linear and logarithmic steps in pulse duration. Assumed values for range and step size of pulse duration are shown in Table IV.

TABLE IV  
PDM: SOFTWARE-SELECTABLE PULSE AMPLITUDE

|                                     | Linear Steps | Logarithmic Steps       |
|-------------------------------------|--------------|-------------------------|
| Pulse duration range ( $\mu$ s)     | 0-255        | 10-255                  |
| Pulse duration step size ( $\mu$ s) | 1            | Variable from 0.13-3.22 |

amplitude could be selected for each electrode and set to any multiple of a given pulse amplitude step size. Four step sizes (0.05, 0.1, 0.2, and 0.5 mA) were considered. The high end of the pulse duration range was assumed to be 255  $\mu$ s.

For each electrode and pulse amplitude step size, the pulse amplitude was set as low as possible above the value of pulse amplitude at 255  $\mu$ s on the 90 percent amplitude-duration curve for that electrode. For example, for the electrode used in Fig. 2 the pulse amplitude at 255  $\mu$ s on the 90 percent amplitude-duration curve was 0.34 mA; therefore, pulse amplitude was set at 0.35 mA when using a 0.05 mA step size, 0.4 mA with a 0.1 and 0.2 mA step size, and 0.5 mA with a 0.5 mA step size. This strategy minimized maximum change while ensuring full recruitment within the assumed range for pulse duration. Both linear and logarithmic steps for pulse duration were analyzed. Assuming 256 steps, the ranges and step sizes for pulse durations were as shown in Table IV.

The resulting means and ranges of maximum change and linearity ratio are shown in Fig. 8. The results are qualitatively similar to those obtained with PAM, but in this case maximum change and linearity ratio were both improved by the use of logarithmic steps. With linear steps the mean and range of maximum change increased as the minimum step size in pulse amplitude was increased beyond 0.2 mA. The range of pulse amplitudes selected and

TABLE V  
PDM: SOFTWARE-SELECTABLE PULSE AMPLITUDE

|   | Pulse Amplitude Step Size (mA) |         |         |         |
|---|--------------------------------|---------|---------|---------|
|   | 0.05                           | 0.1     | 0.2     | 0.5     |
| Range of pulse amplitudes selected (mA)                           | 0.15-1.45                      | 0.2-1.5 | 0.2-1.6 | 0.5-1.5 |
| Range of pulse durations required for full recruitment ( $\mu$ s) | 13-252                         | 13-205  | 12-186  | 12-205  |

the range of pulse durations required for full recruitment for all electrodes were tabulated in Table V.

## DISCUSSION

From the preceding analyses, it can be concluded that both pulse amplitude and pulse duration should be software variable when using either PAM or PDM. Maximum change was either too large or the working range of the modulation parameter was too restricted if either parameter was hardware-fixed. It was also shown that the strategies for the two methods of modulation are quite different. Using PAM with linear steps, controllability was improved (or alternatively maximum change was minimized) by setting pulse duration as low as possible thereby operating in the high end of the allowable range of pulse amplitudes. With PDM, controllability was improved by setting pulse amplitude as low as possible thereby operating in the high end of the allowable pulse duration range.

When using PAM with linear steps, it was shown that the selectable step size for pulse duration should be no greater than 10  $\mu$ s since larger step sizes resulted in increases in maximum change (Fig. 7). For a 10  $\mu$ s step size, the range of pulse durations required was 10-60  $\mu$ s and the range of pulse amplitudes required was 0.42-2.50 mA (Table III). This rectangular region is shown in Fig. 9 (marked PAM) with each vertical line representing a "PAM operating line" for each selectable pulse duration. As stated above, the strategy for minimizing maximum change was to select the leftmost vertical line which intersected the entire family of recruitment curves for a particular electrode. The dashed lines shown in Fig. 2 are repeated here and represent the upper and lower boundaries of the families of amplitude-duration curves for all 12 sets of data. Using step sizes of 10  $\mu$ s and 10  $\mu$ A for pulse duration and amplitude and following the proposed strategy for selecting pulse duration, the maximum change was always less than 5 percent for all electrodes and configurations (Fig. 7).

When using PDM with linear steps, the selectable step size for pulse amplitude should be no greater than 0.2 mA (Fig. 8). Using this step size, the required ranges for pulse duration and amplitude were 12-186  $\mu$ s and 0.2-1.6 mA, respectively (Table V). This region is also depicted in Fig. 9 (marked PDM), and each horizontal line represents a "PDM operating line." The prescribed strategy was to select the lowest horizontal line which intersected the en-

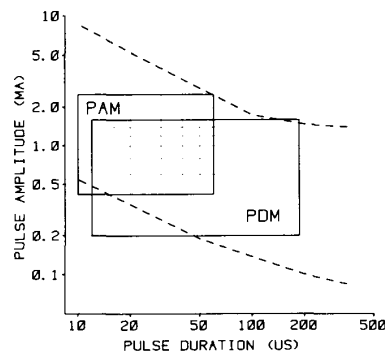


Fig. 9. When using pulse amplitude modulation (PAM), pulse duration is fixed and the operating point moves along a vertical line as pulse amplitude is modulated to control muscle tension. When the selectable pulse duration step size was  $10 \mu\text{s}$ , the range of pulse amplitudes and durations required to ensure full recruitment for all electrodes tested is indicated by the rectangle marked PAM. In like manner, the operating point moves along a horizontal line when using pulse duration modulation (PDM). For a selectable pulse amplitude step size of  $0.2 \text{ mA}$ , the range of pulse amplitudes and durations required to ensure full recruitment for all electrodes tested is indicated by the rectangle marked PDM. The dashed lines represent the upper and lower boundaries of the families of amplitude-duration curves for all sets of recruitment data.

tire family of recruitment curves for a particular electrode. Using step sizes of  $1 \mu\text{s}$  and  $0.2 \text{ mA}$  for pulse duration and amplitude and following the proposed strategy for selecting pulse amplitude, the maximum change was always less than 6 percent for all electrodes and configurations.

The ranges and resolutions specified in the previous paragraphs 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. 9 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.

Using the strategies described above, one will generally be working at lower pulse durations and higher pulse amplitudes when using PAM as compared with using PDM. Crago has shown that the charge required to produce comparable outputs decreases as pulse duration decreases [1]. PAM will therefore require less total charge than PDM when using the suggested strategies, although peak currents will be higher.

The use of logarithmic steps accomplished the following: 1) maximum change was essentially independent of the software-selectable parameter and 2) the linearity of the recruitment curves was improved (Figs. 7 and 8). These benefits would be obtained, of course, at the expense of additional complexity in stimulator design and a much smaller step size at the low end of the modulation parameter range. For a stimulator to be used only with nerve cuff electrodes, the use of logarithmic steps may not be warranted. If a stimulator is to be used with epimysial

and cuff electrodes, thereby increasing the range of charge per pulse required [14], then it may be advantageous to vary the modulation parameter logarithmically.

The recruitment data shown in Fig. 1(a) were qualitatively similar to published data from previous studies [6], [13]. In all cases, the recruitment curves were shifted to the left with an increased slope as pulse duration was increased [Fig. 1(a)]. The absolute values obtained by Gorman and Mortimer [6] were at the low end or slightly below the range of values recorded in the present study (as represented by the lower dashed line in Fig. 2). This would be expected since they used cuffs with an inner diameter of  $1.0$  or  $1.4 \text{ mm}$ , sized to fit the nerve without compressing it. Because our electrodes were chronically implanted, they were larger ( $3 \text{ mm}$  diameter) and were loosely wrapped around the nerves to avoid nerve injury from postoperative swelling. Comparison with the data of Rabischong *et al.* [13] was impossible because they used a constant-voltage stimulator and did not report the electrode impedance.

All of the data presented in the present paper were gathered from twitches in order to minimize the effect of muscle fatigue. The control engineer, on the other hand, must design a controller to generate tetanic contractions. It is therefore of interest to know how the recruitment curves for tetanic responses would compare with those from twitch responses. To answer this question, tetanic responses were elicited at the end of some of the data collection sessions. It was found that the recruitment curves for tetanic responses matched those for twitch responses in the upper part of the curve but were shifted slightly to the left in the lower portion of the curve. In other words, the tetanus-twitch ratio increased as the modulation parameter (pulse amplitude or duration) decreased. This would have the effect of decreasing the gain in the lower part of the recruitment curve slightly, which may decrease the maximum change in some cases. The data presented were therefore "worst-case," and the recommended specifications may be considered to be conservative.

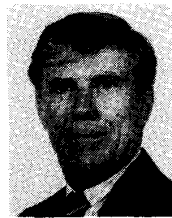
As shown in Fig. 4, monopolar stimulation required less charge for stimulation than did bipolar or tripolar stimulation. This was consistent with a previous study which showed that bipolar stimulation with a  $3$  or  $6 \text{ mm}$  inter-electrode spacing required higher currents than monopolar stimulation [10]. Lower thresholds for monopolar stimulation were also predicted by computer simulations of myelinated nerve excitation [9]. A simplified explanation is that more current was shunted between the electrodes and less current crosses the nerve membrane as the electrodes were brought closer together.

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 [10].

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**Donald R. McNeal** (S'60-M'68) was born in Lexington, KY, on March 27, 1938. He received B.S.E.E. and M.S.E.E. degrees from the University of Michigan, Ann Arbor, in 1960 and 1962, respectively, and the Ph.D. degree from Stanford University, Stanford, CA, in 1967.

From 1962 to 1968 he worked for the Advanced Flight Mechanics Group, Lockheed Missile and Space Company, Palo Alto, CA. In 1968 he joined the Professional Staff Association at Rancho Los Amigos Medical Center and was involved in the development of implantable and cutaneous electronic systems for peripheral nerve stimulation. In June 1979, he joined the staff at the National Science Foundation as Program Manager for Science and Technology to Aid the Handicapped. In October 1981, he returned to Rancho Los Amigos as Director of the Rancho Rehabilitation Engineering Center.

Dr. McNeal is a past president of the Rehabilitation Engineering Society of North America (RESNA), a member of the Scientific Review and Evaluation Board of the VA Rehabilitation R&D Service, and a member of the Ad Hoc Neural Prosthesis Program Advisory Committee for NINCDS. He was previously an Associate Editor of the IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING (1979-1985) and was co-chairman of the 6th Annual Conference on Rehabilitation Technology (1983). He also chaired the Neural Prostheses Conference on Motor Systems held in Potosi, MO, in July 1988.

**Lucinda L. Baker** was born in Pomona, CA. She received the B.S., M.S., and Ph.D. degrees in physical therapy from the University of Southern California, Los Angeles, in 1972, 1977, and 1985 respectively.

She was a Clinical Physical Therapist from 1973 to 1976. She became involved in research with the Rancho Rehabilitation Engineering Center in 1976 and is presently a Consultant with that organization. She joined the faculty of the Department of Physical Therapy, University of Southern California in 1982 and is currently Acting Chair of that Department. Her research interests in clinical applications of electrical stimulation have lead to the development and validation of guidelines for therapeutic application and identification of optimal electrode/stimulus parameters for activation of the neuromuscular system. In the basic science area, documentation of both motoneuronal and synaptic changes after spinal transection has provided a basis for further work in evaluating the mechanisms by which therapeutic intervention is effective.

Dr. Baker is involved with and presents at a variety of professional meetings including the American Physical Therapy Association, Rehabilitation Engineering Society of North America, and the Society for Neurosciences. She has served as a reviewer for the Paralyzed Veterans Association, Archives of Physical Medicine and Rehabilitation, and Physical Therapy.



**Jeff T. Symons** was born in Kingston, NY, on November 2, 1959. He received the B.S.M.E. degree from the University of California, Santa Barbara, and the M.S.M.E. degree from the University of California, Los Angeles, in 1982 and 1988, respectively.

From June 1983 to June 1988, he was employed at the Rancho Rehabilitation Engineering Center and was involved in research on neuromuscular stimulation and design of custom equipment for individuals with physical disabilities.

Also during this time he was employed by the U.C.L.A. Intervention program for disabled children as a rehabilitation engineer. Since June 1988 he has been employed by the California Department of Rehabilitation as an Associate Rehabilitation Engineering Consultant.

Mr. Symons is a member of the American Society of Mechanical Engineers (ASME) and the Rehabilitation Engineering Society of North America (RESNA).