

# Muscle Recruitment with Intrafascicular Electrodes

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**Abstract**—We have studied muscle recruitment with Teflon-insulated, 25  $\mu\text{m}$  diameter, Pt-Ir intrafascicular electrodes implanted in nerves innervating the gastrocnemius and soleus muscles of cats. The purpose of this study was to measure the performance of these bipolar electrodes, which had been designed to optimize their ability to record unit activity from peripheral nerves, as stimulating electrodes.

Recruitment curves identified the optimal stimulus configuration as a biphasic rectangular pulse, with an interphase separation of about 500  $\mu\text{s}$  and a duration of about 50  $\mu\text{s}$ . The current required for a half-maximal twitch contraction was on the order of 50  $\mu\text{A}$ . Current and charge densities needed for stimulation were well below levels believed to be safe for the tissue and electrode materials involved.

When the spinal reflex pathway was interrupted by crushing the nerve, the force produced by a given stimulus changed in some cases, but not in others, implying that the spinal reflex contribution was not the same in all the implants.

We conclude that intrafascicular recording electrodes are also a potentially valuable technology for functional neuromuscular stimulation, and warrant further development.

## INTRODUCTION

**P**ARALYSIS caused by spinal cord injury, head trauma, or stroke leaves the peripheral nerves and muscles intact, but interrupts communication between brain and peripheral nervous system. In theory, mobility can be restored to paraplegic and quadriplegic patients by artificially stimulating motor nerves; the technique for doing so is called functional neuromuscular stimulation (FNS). The goal of the present project was to ascertain whether our new type of intrafascicular electrode [19] is effective for FNS.

The two types of electrodes commonly used for FNS are intramuscular electrodes and nerve cuff electrodes. An intramuscular electrode is a metal wire inserted into the muscle which is used to stimulate the motor end plate [6], [8], [11], [26]. A nerve cuff electrode is wrapped around the nerve and consists of an isolating cuff inside of which are two or more exposed metal areas which deliver current to trigger action potentials [13], [23], [25], [28]. Both types of electrodes elicit motoneuron activity with consequent muscle contraction and have been successfully used in clinical applications, but both have deficiencies.

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Intramuscular electrodes are subject to mechanical failure when implanted in contracting muscles, require high current pulses, and the recruitment curve is strongly dependent on the placement of the electrode relative to the motor point of the muscle [11]. Cuff electrodes are placed around the motor nerve, require custom fitting to the nerve diameter, and may damage the nerve if the fit is not optimal. To stimulate only one muscle, or muscle group, the electrode must be placed in the vicinity of the target muscle, which can cause damaging stress on the electrode due to movement of the muscle.

We have developed a new type of bipolar, intrafascicular electrode for recording activity from peripheral nerves [19]. An intrafascicular electrode is a form of intraneural electrode which penetrates the perineurium and resides within an individual fascicle of a nerve. The present study was undertaken to test our expectation that the threshold currents required to elicit muscle contractions with our intrafascicular electrodes would be low.

In FNS applications one needs to be able to predict the force produced by a given stimulus amplitude, which requires characterizing the stimulus-force relationship of the electrode. But even with this information, we would not be able to accurately predict the output force, for the recruitment curve varies substantially with time and muscle fatigue [12]. In addition, reflexes originating in the spinal cord are present in patients with high spinal injuries or stroke. These reflexes are important because with electrical stimulation we activate nerve fibers independently of the direction in which they carry information: electrical stimulation of motor nerves will activate both motoneurons and sensory afferent fibers, particularly muscle spindle and Golgi tendon organ fibers, which elicit spinal reflexes. The level of activation of the afferent fibers will influence the force produced by the muscle, Golgi tendon organs producing a negative force feedback, and muscle spindle afferents providing a negative length feedback. It is difficult to accurately predict the muscle response to electrical stimulation because of the complexity of these interdependent effects and because it has been shown that the length of individual muscle spindle fibers depends on muscle length, load, level of activation, and location of the spindle within the muscle itself [17].

For these reasons, a clinical orthosis could benefit from closed-loop control. In this respect our electrode design is of interest since it can be used both for stimulation and for recording of feedback signals from muscle, joint, and cutaneous sensory receptors.

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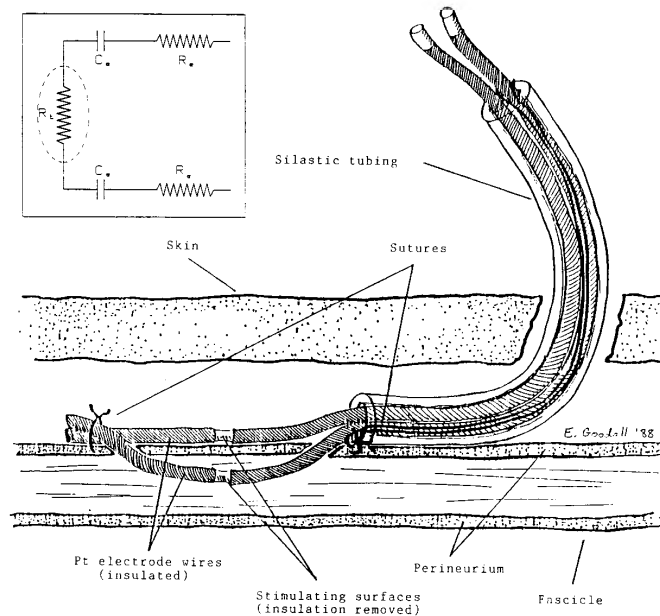


Fig. 1. Implanted intrafascicular bipolar electrode. The drawing is not to scale, but illustrates the salient features. The inset shows an equivalent circuit of the implanted electrode pair.  $R_e$  and  $C_e$  are the series resistance and capacitance of each electrode;  $R_i$  depends on the resistivity of the tissue surrounding the implant. In our implants,  $R_i \gg R_e$ .

## METHODS

### Electrode Fabrication

A bipolar electrode pair consisted of two Pt-Ir wires, 25  $\mu\text{m}$  in diameter, insulated with Teflon (the insulated diameter was 27.5  $\mu\text{m}$ ). The insulation was removed for approximately 1 mm about 20 mm from the distal end of each wire by inserting it in a Pt loop which was heated by a current flow. By varying the current level and duration we were able to adjust the length of insulation removed.

The distal end of one wire was attached with cyanoacrylate to a 50  $\mu\text{m}$  diameter, 3 cm long electrochemically sharpened tungsten needle. A second wire with similar impedance was aligned with the first wire, and the two wires were threaded into a 600  $\mu\text{m}$  diameter silastic tube together with a 6-0 silk thread. A small suture loop was left emerging from the distal end of the tubing to allow anchoring of the implant to the nerve. Silastic adhesive was then injected into the tubing and allowed to cure for 24 h.

A drawing of the implanted electrode is shown in Fig. 1; the illustration is not to scale and is intended only to show the general design.

### Animal Preparation

Adult cats were anesthetized with sodium pentobarbital given intraperitoneally (40 mg/kg). A catheter was inserted in the saphenous vein and the anaesthesia level was maintained with a 1:10 solution of pentobarbital admin-

istered intravenously as needed. Body temperature was monitored and maintained near 37°.

In one leg the superficial part of the lateral head of the gastrocnemius muscle was exposed for its full length, and the Achilles' tendon was attached to a suture thread and dissected distally. The tibia was fixed with bone pins and clamps. The fat pad in the popliteal fossa was removed and the sciatic nerve was exposed approximately where it divides into tibial and peroneal branches. Under microscopic viewing, the tibial branch that innervates the gastrocnemius was isolated and the largest fascicle innervating the muscle was identified and separated from the others using fine forceps.

The tungsten needle was used to thread the inside wire of the electrode through the fascicle for about 1 cm with the exposed zone centered in this region. The needle was cut off, the other wire was placed on the outside the fascicle, and the distal ends of the two wires were sutured to the fascicular endoneurium with a 9-0 suture. The proximal end was secured in place by suturing the loop emerging from the silastic tubing to the epineurium. The tubing was then led to the skin and the wound was closed, leaving the two wires accessible. After implantation, electrode integrity was confirmed by measuring its impedance with a 1 kHz controlled current source.

After a complete set of data had been collected, the nerve was crushed proximally to the implant site by repeatedly squeezing it with a pair of forceps and the experiment was repeated. The advantage of crushing versus



cutting the nerve is that crushing leaves the current pathways as unaltered as possible while still effecting a complete block of conduction [18]. Finally, this set of procedures was repeated with the soleus muscle. The data presented here are from experiments in 15 cats, although not all measurements were made in all cats.

#### Instrumentation

The suture attached to the tendon was connected to a strain gauge force transducer, the output of which was amplified, filtered, displayed on an oscilloscope, and fed to an 8-bit A/D converter on a microcomputer system. The stimulator consisted of a controlled current source driven with waveforms generated by the computer through an 8-bit D/A converter. Amplitude, duration, and interphase separation for individual biphasic pulses could be changed during the experiment, as could the frequency and duration of trains of pulses.

#### Stimulus Parameters

Several different types of waveforms were used: they all had an initial rectangular stimulating (cathodal) pulse while the charge balancing wave had different shapes. The charge balancing waveform tends to repolarize the cell membrane, counteracting the effect of the cathodal stimulus [7], [14], [20]. To lessen this effect we tried two solutions: make the anodal pulse smaller in amplitude and/or have it occur after a delay. We studied whether different anodic shapes and phase separations influenced the stimulus-force relationship. In all the waveforms studied, the stimulating and balancing phases injected equal amounts of charge.

The anodal waveforms included simple rectangular, in which the balancing pulse had the same amplitude and duration as the stimulating pulse; balancing rectangle of duration four or eight times the stimulus duration, in which case the amplitude was adjusted proportionately; and triangular balancing phase of duration three or seven times the stimulus duration. The results showed that there were no statistically significant differences between the different anodal waveforms in the force of evoked muscle contractions.

On the other hand, separation between cathodal and anodal waveforms did have an effect. There was a small (on the order of 10–15%), but statistically not significant, increase in force with a phase separation of 500  $\mu$ s compared to unseparated waveforms. Separations longer than 1000  $\mu$ s showed no further increase. One might argue that the increased force generated by separated waveforms is due not to the effects described above, but to activation of a second set of action potentials by the balancing pulse. However, we, like others [14], found that the biphasic stimuli were not more effective than simple, monophasic stimuli, ruling out this possibility.

For the results presented below, we used simple rectangular waveforms with an interphase separation of 1 ms.

In order to minimize muscle fatigue and the time re-

quired by the experiments, recruitment curves were primarily studied with single pulses. The results obtained with the single pulses were periodically tested with 50 Hz, 300 ms duration pulse trains. In the former case, peak twitch force was the measure used in determining recruitment. For pulse trains, plateau force was the measure used.

To control for muscle fatigue, we periodically tested the muscle with a standard stimulus. The standard stimulus was selected early in each experiment as that stimulus which produced approximately 50% of peak contraction force. If the contraction force remained the same, we knew that the muscle was not undergoing fatigue. If the force changed, we suspended further testing until the muscle had recovered.

Recruitment curves were obtained by varying the stimulus intensity between the threshold value and the value that gave maximal force production. This was done either by increasing the current amplitude while the stimulus duration was maintained constant or by changing the duration while the current remained constant. Advantages of one method with respect to the other were examined.

The main problem we faced was variability in contraction responses not only between animals, but within a single experiment as well. This is a common factor in this type of experiment [10], [12] and is influenced by physiological changes which are not completely understood or identified. In spite of this, the data are consistent when normalized and averaged.

## RESULTS

#### Preload Effects

Recruitment curve measurements showed that as long as the preload was high enough, the shape of the recruitment curve did not change over a wide range of preloads. This proved to be true for both muscles and allowed us to use only one preload for each experiment. Preload was applied by changing the rest length of the muscle. The chosen length was the one at which the force produced above the preload was maximal, but was always within the normal physiologic range of the muscle.

#### Voltage-Current Relationship

A series of tests was performed to study the electrical characteristics of the electrodes both *in vivo* and in saline solution after the electrode had been explanted. Both tests gave similar results, and the equivalent circuit for the range of current densities and pulse durations used in the animal experiments is presented in Fig. 1. The electrode could be modelled by a series resistor ( $R_e$ ) and capacitor ( $C_e$ ), and the tissue by a simple resistance.  $R_e$  was small, so the behavior of the system was dominated by the electrode capacitance and tissue resistance.

The relationship between stimulus duration and amplitude for activation of single nerve fibers was shown by Hill in 1936 [15], [16] to be

$$I_t = I_r / (1 - e^{-t/\tau})$$



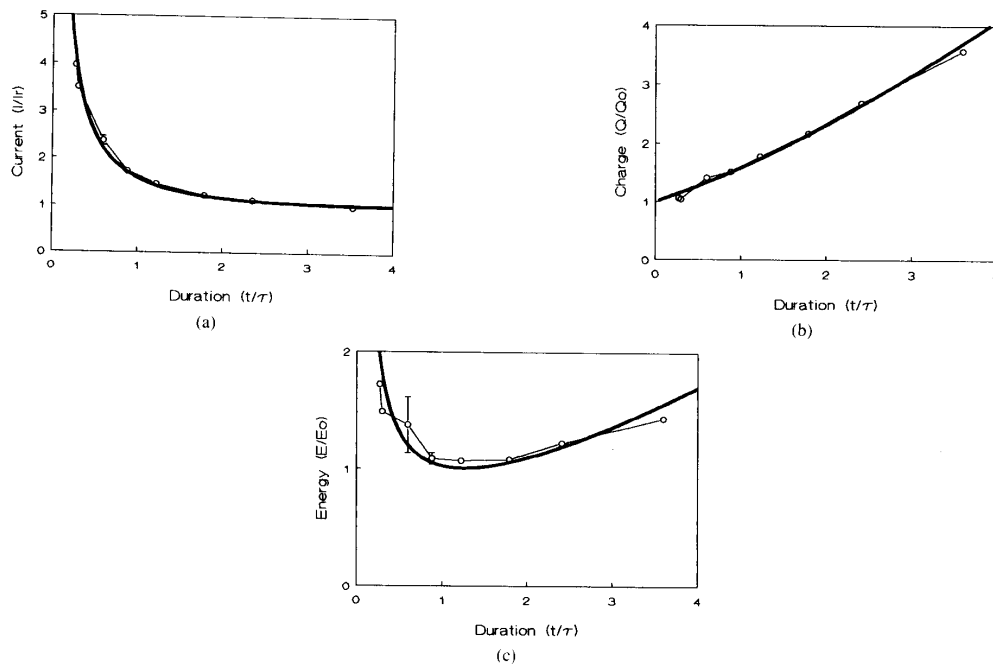


Fig. 2. Strength-duration curves (gastrocnemius muscle). (a) The current needed to obtain a midrange contraction force is plotted versus stimulus duration. The current was normalized with respect to the rheobase and the duration to the time constant  $\tau$  for each experiment; the data were then averaged. (b) The data in (a) are plotted as a function of charge. The charge has been normalized to its minimum value  $Q_0$ . (c) The data in (a) are plotted in terms of an energy index (see text). The energy index has been normalized to its minimum  $E_0$ . The error bars represent the standard deviation; when not present, the standard deviation was smaller than the size of the symbols. Superimposed on each plot is the theoretical curve from Hill's equation.

where  $I_r$  is the threshold current for production of an action potential at pulse duration  $t$ .

The charge associated with these currents,  $Q_t = I_t * t$ , decreases as the duration decreases until the latter reaches the value  $t/\tau = 0.05$ , below which there is no further significant decrease in charge. The smallest value of  $Q_t$  at  $t = 0$  is given by  $Q_0 = I_r * \tau$ .

The energy content of the threshold stimulus can be expressed as charge times voltage. Although we usually did not measure the voltage drop across the electrodes, voltage was proportional to current (see Fig. 1), so we can define an energy index

$$E_t = Q_t * I_t = I_t^2 * t$$

which is directly proportional to the energy. The energy function has its minimum  $E_0$  at  $t/\tau = 1.26$ .

Fig. 2 shows plots of the three equations described above. In the plots, current, charge and energy have been normalized to their minimum values, while duration is normalized with respect to the time constant. Superimposed on these plots are data from experiments on the gastrocnemius muscle, in which the stimulus intensity required to elicit a fixed force of contraction was determined

for different stimulus durations. Although this is *not* the same as the threshold stimulus needed to elicit single action potentials, the data fit the curves very well.

For the gastrocnemius muscle, the time constant  $\tau$  for the fit to Hill's equation was found to be the same in all experiments,  $85 \mu s$ , allowing us to average the data. The current values were normalized to the rheobase, while the duration was normalized to  $\tau$ . Fig. 2(a) shows current versus duration. Fig. 2(b) and (c) show charge and energy versus duration; the normalization has been done with respect to their minimum values  $Q_0$  and  $E_0$ , respectively.

Experiments on the soleus muscle did not give a fixed value for the time constant; for this reason the data have not been averaged. Fig. 3 is a plot of current versus pulse duration; both have been normalized as previously explained. Different symbols correspond to data from different experiments and the continuous curve represents Hill's equation. In this case as well, the data show a good fit to the equation.

#### Force Modulation

Fig. 4 compares recruitment curves obtained with pulse amplitude modulation to recruitment curves obtained with



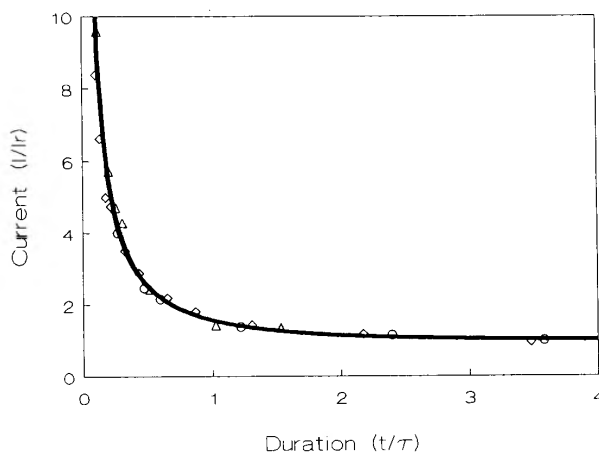


Fig. 3. Strength-duration curve (soleus muscle). The current needed to obtain a midrange force value is plotted versus duration for three different experiments. The current was normalized with respect to the rheobase and the duration to the time constant for each experiment. The theoretical curve from Hill's equation is superimposed.

pulse duration modulation. In each plot, force has been normalized to the maximum value obtained with amplitude modulation, while charge has been normalized to the amount needed to produce 50% of the maximal force in each case.

Fig. 5 shows two recruitment curves obtained with different pulse durations: 50  $\mu$ s (circles) and 20  $\mu$ s (diamonds). In Fig. 5(a) the force is normalized to the maximum value obtained with the 50  $\mu$ s duration and is plotted versus the current. With the shorter duration stimulus, the current required to obtain the same force is higher, but the slope of the curve is less steep. If the force is plotted versus charge [Fig. 5(b)], the two curves are substantially the same and the charge required is slightly lower for the curve with shorter duration stimuli.

#### Pulse Trains

Recruitment curves obtained with 50 Hz pulse trains showed no significant differences, other than expected increases in force amplitude, from the curves obtained with single pulses.

#### Effect of Nerve Crush

Data were also collected when the spinal reflex had been suppressed by crushing the nerve proximal to the stimulus site. With both single pulses and trains we had two classes of results: in one there was no significant difference between the curves obtained in normal and crushed situations [Fig. 6(a) and (b)], in the other the curves were shifted to the right after nerve crush [Fig. 6(c) and (d)]. As both types of behavior were seen in about the same number of cases, we could not conclude that one of the two was a result of measurement errors. The same effect was also seen in the soleus muscle.

## DISCUSSION

### Control of Force

Although different types of force modulation have been proposed [1], [24], most neuroprostheses increase muscle force by recruiting an increasing number of motor units. This is accomplished by increasing the charge injected, modulating either the current amplitude or the pulse duration. In our experiments, duration and amplitude modulation did not show any significant differences in terms of charge requirements (Fig. 4). The choice of one over the other is therefore dictated by other factors.

There are at least two important reasons for suggesting that the parameter to minimize in optimizing stimulation control may be charge. First, electrochemical studies of the behavior of materials used for stimulation show that damage is a function of the charge injected in each pulse and safe charge values for several materials have been determined [2]–[5]. Second, our long term goal is to use this electrode as a chronic implant in patients. As this will probably be associated with a battery power supply, it is important to limit the charge required in each pulse to maximize battery life.

From these considerations, we should choose short pulse durations that minimize charge. Moreover, short durations have the advantage of producing a less steep recruitment curve when current is used as the control parameter. Fig. 5(b) shows that with the shorter duration stimuli the charge requirement is slightly lower, while the two curves have almost identical shapes when force is plotted as a function of charge. But, the slope of the recruitment curve obtained with shorter duration stimuli is flatter when the force is plotted versus current [Fig. 5(a)]. This reflects the possibility of a finer force control with shorter duration stimuli, as has been noted before [10].



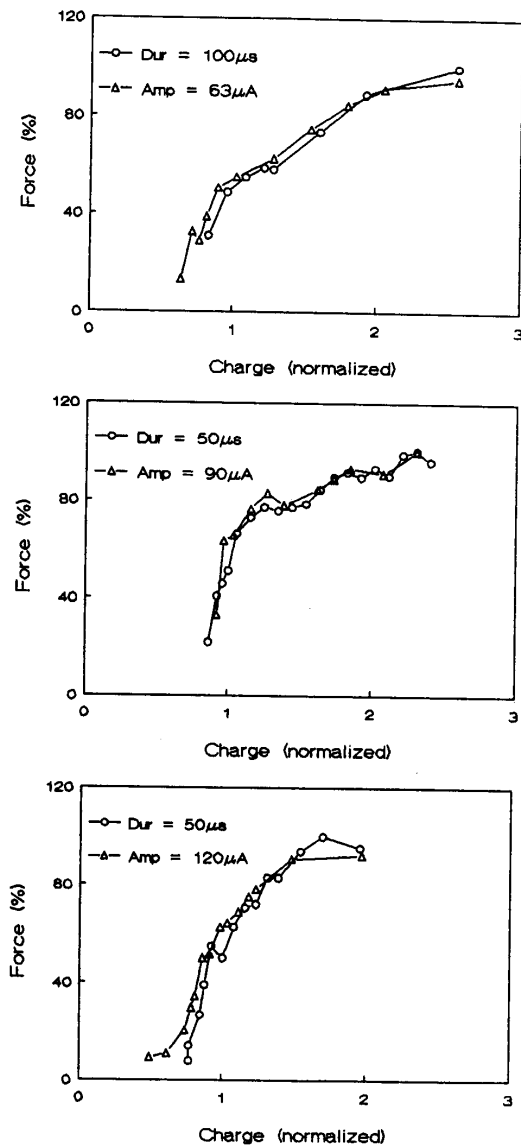


Fig. 4. Amplitude versus duration modulation. Comparison of recruitment curves obtained with amplitude modulation (circles) and duration modulation (triangles) in three different preparations of the gastrocnemius muscle. The force has been normalized to the maximum value obtained with amplitude modulation; the charge has been normalized to the quantity required to produce 50% of the maximal force for each curve.

On the other hand, the lower limit for pulse duration is dictated by the maximal current which the stimulating circuit can deliver, the minimum pulse duration which can be generated, the maximum voltage which it is safe to apply across the electrodes, and the need to limit heat dissipation that might cause nerve damage. With these considerations in mind, and examining the data presented in Fig. 2, we conclude that a stimulus duration around 50  $\mu$ s is optimal for our electrode configuration.

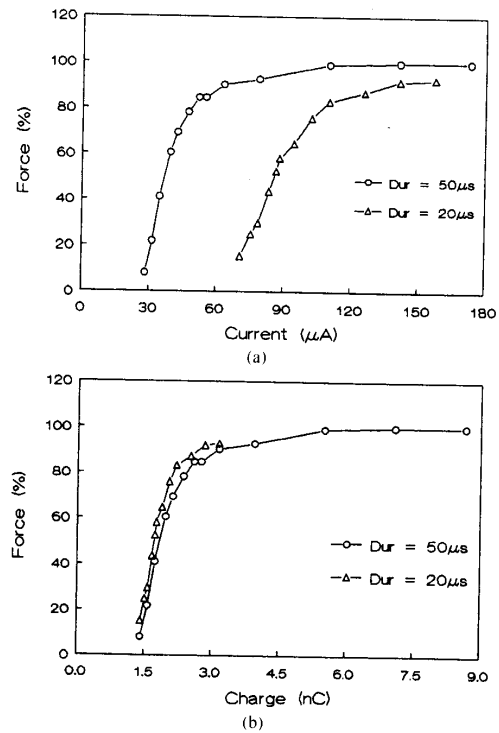


Fig. 5. Examples of recruitment curves from a gastrocnemius muscle. The curves were obtained with stimuli of two different pulse durations. The force has been normalized to the maximum value acquired with the longer pulse duration stimuli, and is plotted as a function of (a) current and (b) charge.

#### Effect of Nerve Crush

Crushing the nerve had a significant effect in some cases but not in others. If crushing the nerve proximally to the implant produces a recruitment curve different from the uncrushed situation, it means that we are stimulating both motoneurons (directly) and sensory fibers (either directly or indirectly in response to the muscle contraction). The force produced then depends on the combination of several mechanisms, including the spinal reflex, some of which may not be under our control.

We have collected preliminary data in decerebrated animals which confirm the effects seen in animals under anesthesia, implying that these results are not artifacts of the anesthesia [9], [22], [26]. While we have no good explanation, at present, as to why an effect was seen in some animals but not others, our results do indicate that the importance of the spinal reflex should not be underestimated, especially since its quantitative contribution to muscle force production is not readily predictable, and can vary with changes in the fatigue state or rest length of the muscle.

#### Electrode Design

The design and placement of these electrodes was chosen to optimize their ability to record afferent activity [19].



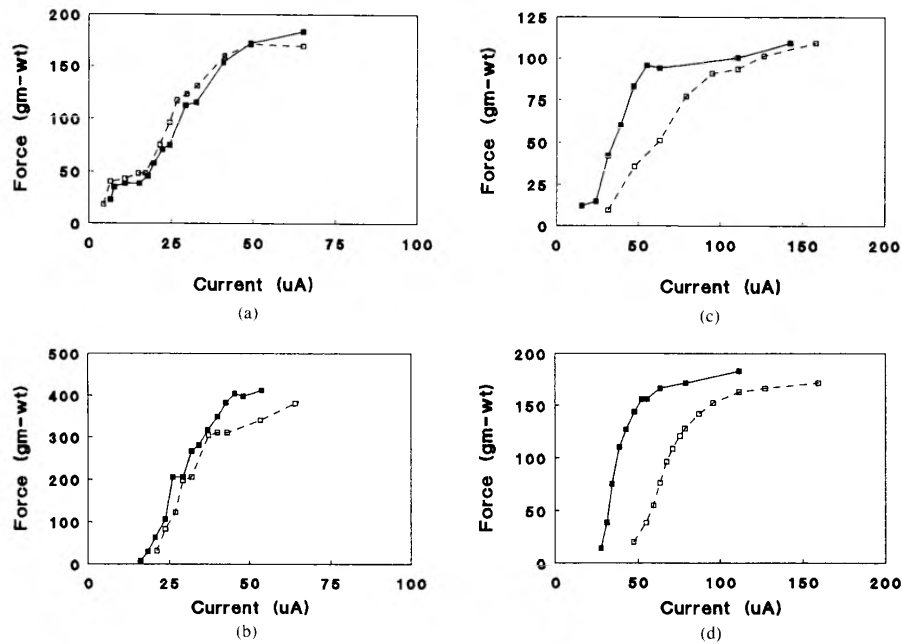


Fig. 6. Effect of nerve crush (gastrocnemius muscle). Plotted are recruitment curves from four different preparations obtained before (filled symbols, solid line) and after (open symbols, broken line) crushing the nerve proximal to the stimulation site. Parts (a) and (b) show no significant difference between the two curves, suggesting that in these experiments the spinal reflex was not an important recruitment factor. In (c) and (d), the recruitment curve after nerve crush was shifted to the right, suggesting that the spinal reflex was an important recruitment tool. The data in (a) and (c) were obtained with single pulse stimuli, while the data in (b) and (d) were collected using 50 Hz trains of pulses. The force axis is plotted in terms of gram-force ( $1 \text{ g-wt} = 9.81 \times 10^{-3} \text{ N}$ ).

The present experiments demonstrate that they are also efficient in evoking neural activity. One salient feature of our electrode design is its relatively large ( $1 \text{ mm}$ ) stimulation zone. This corresponds to an area of about  $0.8 \text{ mm}^2$  and means that small leakage paths due, for example, to breaks in the insulation will not cause significant shunting of current, which could affect the electrode performance.

The gassing limit charge density for platinum electrodes has been shown to be  $300 \mu\text{C}$  per  $\text{cm}^2$  geometric surface area [2]–[5], [21], [27]. In our electrodes, this corresponds to a pulse charge of  $2.4 \mu\text{C}$ . The median of the charge required to produce half maximal force in the present experiments was  $3.75 \times 10^{-3} \mu\text{C}$ , almost three orders of magnitude below this limit, and well below the safe limit for stimulation of neural tissue [2].

An upper limit for current density has been suggested as  $300 \text{ mA}/\text{cm}^2$  [3]–[5], [21]; for our electrode this corresponds to  $2.4 \text{ mA}$ . The maximum current needed in the present experiments was  $200 \mu\text{A}$ , over one order of magnitude below this level.

#### CONCLUSIONS

This paper shows that intrafascicular recording electrodes are also suitable for motor nerve stimulation. Ef-

ficient recruitment of muscle force can be generated with these electrodes using biphasic, charge balanced,  $50 \mu\text{s}$  duration pulses separated by about  $500 \mu\text{s}$ .

Current levels are significantly lower than those needed with either intramuscular or cuff electrodes. This reduces the amount of charge required, with a consequent possible increase in safety and decreased power supply requirements for portable clinical stimulators.

Charge density and current density requirements are well within the range considered safe for stimulation of neural tissue.

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