ENERGY CONSIDERATION IN THE DESIGN OF IMPLANTABLE ELECTRODES FOR PERIPHERAL NERVE STIMULATION - A PRELIMINARY REPORT

H. Friedman

Summary

Implantable electrodes are currently used in a number of clinical programs to achieve motor or sensory nerve stimulation. Many of the design charateristics of these electrodes were a result of limited subjective investigations; some were based on classical parameters successful under ideal laboratory conditions.

The primary objective of this study has been to evaluate various electrode configurations in regard to the stimulation energy required to achieve desired levels of muscle contraction. Four electrode configurations (unipolar, "guarded" bipolar, narrow-spaced bipolar, and wide-spaced bipolar) were evaluated in this study.

A total of ten leads were placed on the sciatic nerves of each of five dogs (two leads in each dog). The leads were allowed to stabilizes for a 12 week period. When data was to be collected, the connector end of the leads system was exposed without disturbing the rest of the lead.

For each electrode configuration, stimulation energy versus strength of muscle contraction (as measured with a strain gauge attached to the Achiles tendon) data were taken. Energy values were directly recorded as the product of voltage and current pulses integrated with time.

Preliminary data show that the unipolar configuration is optimal in terms of energy required to elicit a response.

Objectives

Implantable electrodes are currently used in a number of clinical programs to achieve motor or sensory nerve stimulation /1, 3, 9, 10, 16, 23/. Many of the design characteristics of these electrodes were a result of limited subjective investigations; some were based on clinical parameters successful under ideal laboratory conditions /12, 16/.

The objective of this study was to demonstrate that there is a significant difference in the amount of energy required to stimulate a nerve depending on the design configuration of the electrodes used. Further, it was an objective to show that the testing system used could be used to quantitatively evaluate electrode designs.

Classically, literature describes nerve stimulation with an isolated nerve bundle laying across bipolar electrodes /2, 7, 20, 21/. Perhaps it is only natural, then, that a bipolar electrode was the most common means adopted for implantable nerve stimulation with little regard to design and dimensions /1, 5, 19/. Hagfors /8/ and Testerman /22/ appear to be the only authors to attempt an exact justification of the design characteristics used (such as electrode spacing and surface area exposed). Further, most efforts to quantitatively evaluate the physiological effectiveness of electrode designs have been more qualitative in nature /4, 8, 22/. A major area of exception to this has been in the electrode design for implantable cardiac pacemakers where "threshold" (heart capture) can be precisely and repeatedly measured /6, 17/.

The physiology of the nerve bundle and its fibers, along with the characteristics of the electrical stimulation used for nerve excitation, are as important /2, 5, 11, 15/ for effective stimulation but were not dealt with in this work.

Discussion of Electrodes

In this discussion an "electrode" refers to that end of a "lead" whose exposed conductors interface directly with a nerve, while the other end of the lead is referred to as the "connector" end. The electrodes used in this study are of a "wraparound" type. When the two tab portions of an electrode (Gray in Figure 1) are brought together and sutured, a cuff is formed. The bare portion of the conductors are then exposed only to the nerve wrapped within the cuff. The conductors are made of a woven platinum wire and supported by a silicone rubber, dacron filled structure.

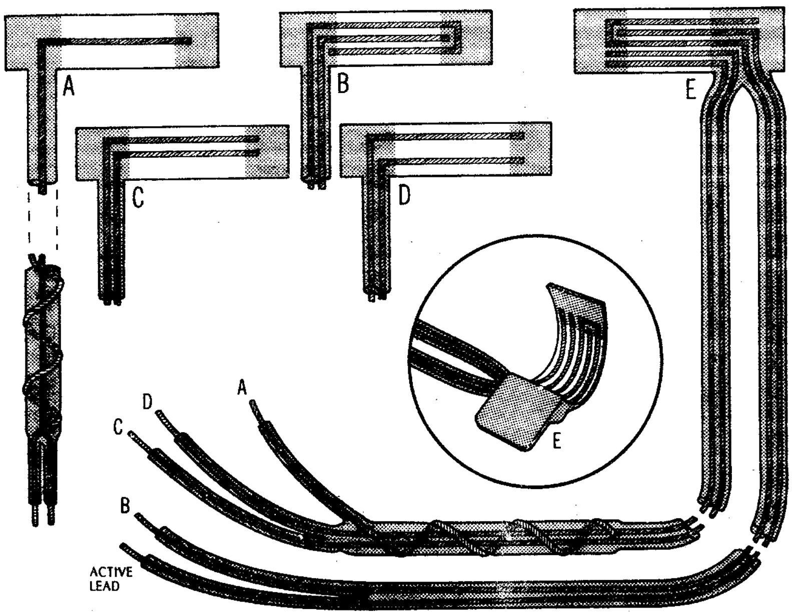

Fig. 1.

The author and his associates have used bipolar electrodes for stimulating the carotid sinus nerve (CSN) for the clinical treatment of hypertension /18/ and the relief of intractable angina pectoris /2/ and the stimulation of the peroneal nerve for the clinical treatment of "foot drop" /14, 24, 25/. Because of its common use, the bipolar electrode is used as the standard of comparison in this study, Figure 1 (D).

One of the configurations evaluated in this study is called a guarded, bipolar electrode, Figure 1 (B). Hagfors and Testerman /22/ described and examined the use of the guarded electrode to minimize current spread to surrounding tissue. They demonstrated by electrical field maps on Teledeltose* conducting paper and in animal experiments that the guarded bipolar electrode could be "just as effective as the bipolar electrode in stimulating the CSN" /8/.

The unipolar electrode configuration used in this study introduces a new concept for an indifferent electrode. As illustrated in Figure 1 (A and E) the indifferent electrode consists of a conductor wrapped in a helical fashion and partially embedded in the outer silicone rubber surface of the load. Its exposed length and spacing prevent local stimulation.

Finally, two simple bipolar electrode configurations were compared: one with widely spaced electrodes and one with the electrodes closely spaced about the nerve, Figure 1 (C and D). In general, this study uses a bipolar electrode configuration as the basis for comparisons. In this case, however, some indication was being sought to show the importance of electrode spacing.

In order to best quantify the data taken, a lead, E, (Fig. 1) was designed that encompassed all four configurations in one cuff with the same active electrode common to all. The use of this lead insures accurate comparison of each configuration while minimizing handling of the nerve.

Experimental Procedure

Electrode Implants

- Ten leads of the design described above, Figure 1 (E), were implanted on the sciatic nerves of five dogs (two leads in each dog). The connector ends of the leads were passed subcutaneously to points along the sides of the dog. This was done so the connector end could later be exposed through a

---

*Western Union Trademark

small incision without disturbing the electrode end of the lead.

- All leads were left implanted undisturbed, for a minimum of twelve weeks. Previous research has shown that any period over ten weeks is sufficient for nerve/electrode stabilization /13/.
- At the time of data collection only the connector ends of the leads were exposed and attached to the stimulating and monitoring equipment through a distributor box to facilitate switching lead pairs.

Tendon Preparation

- At the time of data collection the Achilles tendon was exposed and released from its insertion on the dog´s calcaneus (heel bone) along with a piece of the bone.
- The hind limb being used was constrained in a special holding apparatus that allows the distal end of the femur to be pinned, thus maintaining the triceps surae (gastrocnemius and soleus muscles) in a fixed position.
- The Achilles tendon is now in such a position that when it is wired to the strain gauge force transducer the muscle and tendon are isometrically pulling in natural position parallel to the two bones of the lower leg.
- Through all data taking the tendon was maintained at a preset tension of 5% maximum force contraction.

Electronic Equipment

- Constant voltage pulses were used to stimulate the nerve. The output of the pulse generator was variable from 0 to 10 volts at pulse width of 50, 100, 200 and 400 μ sec. The pulse rate was fixed at 50 pulses per second.
- The test system monitors the force of contraction as measured by the strain gauge transducer.
- Voltage and current per pulse are monitored, electronically multiplied, and integrated with time. This provides the energy per pulse.
- The pulse generator was designed to deliver a one second burst of pulses every ten seconds (a precaution to minimize fatigue).
- At the end of the last pulse of the stimulating burst a voltage that is proportional to the energy in that pulse

and a voltage that is proportional to the force measured by the transducer are delivered to an X-Y recorder. A trigger pulse is also delivered to the recorder. It drops the recording pen when the pen is in the proper position to indicate force and energy.

Data Taking

- The maximum force of contraction for that limb is measured.
- Up to six points between 10 and 70% of maximum force of contraction are recorded versus energy for each of four pulse widths, Figure 2.
- The above two steps are repeated again for each electrode configuration and for each of the ten leads.

Along with the automatically recorded data, data sheets as shown in Figure 5 are filled out and used as follows:

- From these sheets curves such as shown in Figure 2 are constructed with maximum force now normalized to 100%.

Typical data recorded for wide bipolar electrode configuration at constant pulse widths (PW): 50, 100, 200, 400 μ seconds

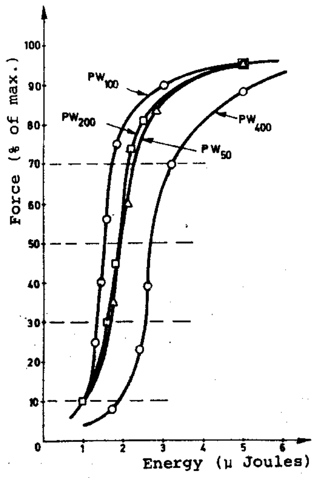

Fig. 2. Force of contraction vs. stimulation energy.

From Figure 2 the curves of Figure 3 are constructed for values of constant force. The horizontal line represents the optimum pulse width for that electrode configuration.

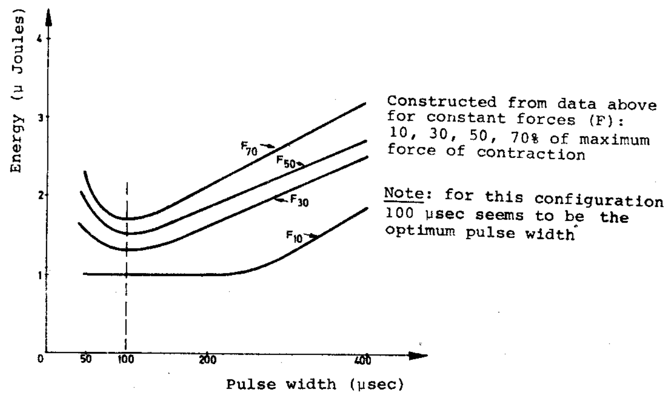

Fig. 3. Stimulation energy vs. pulse width.

- Finally, when the optimum pulse width for all of the electrode configurations is recorded, a family of curves (Fig. 4) is constructed. Each curve represnts a different electrode configuration and the data for that individual curve was compiled at the optimum pulse width for that configuration. By "optimum" the author refers to the pulse width at which an electrode can operate over a functional range of stimulation and require the least amount of energy. In Figure 2 this is represented by a theoretical curve that is furthest to the right. In Figure 3 the optimum pulse width is determined by the low point on these curves.

Finally, after several hours had elapsed, much of the data was again retaken in order to test the system for repeatability.

Discussion of Experimental Technique

Referring back to the work of Hagforts /8/ and Testerman /22/, three aspects made it difficult for them to quantitate their data. First, their use of the uniform conductive paper assumes a model

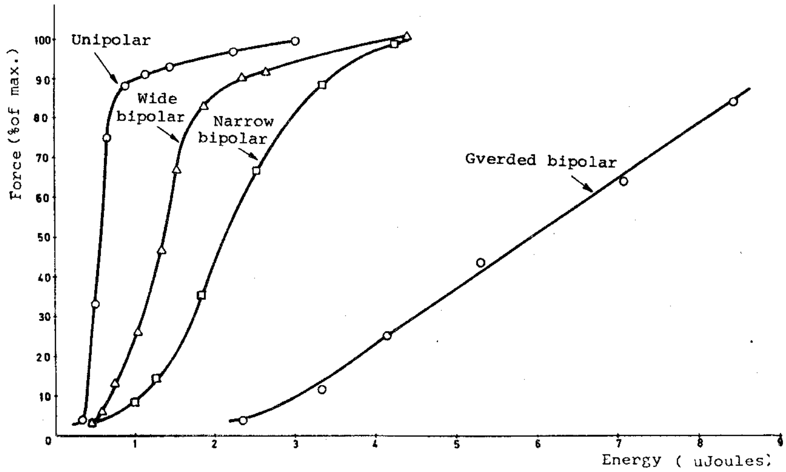

Fig. 4. Force of contraction vs. stimulation energy for four nerve electrode configurations.

for the nerve bundle and its surrounding tissue as homogeneous and with passive constant impedance. This author feels that these simplifications severely limit the use of this technique as a valid representation of the nerve and electrode.

A second problem they encountered in their work was in their animal studies. Blood pressure reduction was measured versus amplitude of the stimulating voltage as their means of indicating the relative merit of various electrode configurations. Here the investigators were contending with the problem that most of their pressure responses were somewhat transitory because the body was trying to correct the drop in blood pressure with its various autonomic mechanisms.

Third, Testerman /22/ notes that the CSN was a difficult nerve to use in this study because electrode placement was extremely crucial and quite unrepeatable. Even when the need to exchange electrodes on a single nerve bundle was eliminated, the fact that positioning was a major source of variability in data collecting made it difficult to correlate quantitative data.

There are several features of this study that help to produce

Date ___/___/___ Page ___/___

ELECTRODE STUDY ____________________

Researcher __________ Assisted by __________

Dog Identification __________ Limb __________

Type Lead __________ Pulse rate __________ pps.

Electrode Configuration __________ Run ___/___

Comments ____________________

Measured: 100% force of contraction F_{100} __________ lb

Calculated: F_{70} _____ lb. F_{50} _____ lb. F_{30} _____ lb. F_{10} _____ lb.

Pulse Width (u sec.)	Voltage (Volts)	Energy (u Joules)	Force (lb)	Force (% of F_{100})	
400					
200					
100					
50					

Fig. 5.

quantitative data. They are the following:

The four in one electrode design, which uses a common active electrode, insures identical placement for each configuration. It also minimize nerve handling trauma.

The choice of the sciatic nerve, gastrocnemius-soleus muscles, and Achilles tendon as the physiological link in this study was a good one. The nerve was easily located and the electrode easily attached. The gastroc-soleus muscles provided strong contractions thereby minimizing the percent error in the recording force. The Achilles tendon was large and easily affixed to the force transducer. The way that the tendon was used did not let the neural reflex system interfere with the data collection. This was most important.

All electrodes remained chronically implanted in the dogs for a minimum of twelve weeks for impedance stabilization.

Force of contraction versus stimulation energy per pulse were basic parameters measured for this study. Force proved to be a repeatable parameter that could easily be measured. Energy was chosen as the stimulating parameter because it was felt to be the most "all-encompassing" taking voltage, current, and time into account. With the electronic equipment used, energy was simply and accurately recorded.

Care was taken to minimize neuromuscular fatigue. All force data was normalized to the percent of maximum force of muscle contraction to enable the correlation of the data from all the dogs.

The optimum pulse width determined for each electrode configuration. This enabled all comparisons to be made for each configuration at its "best".

Results

At the time of this writing for early publication, only one of the five dogs (two of the ten leads) has been evaluated. The data compiled in Figures 2, 3, and 4 are quite representative for the first dog.

Keeping in mind the limited sample at this time, from an energy viewpoint, it can be concluded from Figure 4 that the unipolar electrode configuration was the most effective, while the guarded bipolar electrode configuration was the least effective. Also, the spacing of bipolar electrodes can make a significant difference in the energy required for stimulation.

Several data collecting practice runs were taken. During this time the physiological system appeared to stabilize (tendon stretching in particular). After this period of time - regardless of the electrode, pulse width, or elapsed time - most of the data was repeatable within 5% of maximum force of contraction. Further, when normalized to 100% maximum force of contraction as in the curves of Figure 2, the data points between 10 and 70% of maximum were within 2% of each point.

Discussion

Despite the limited data, it is felt that the results are a positive indication of fulfilling the objectives of this study. A few points might be made at this time.

The testing system does appear to be a good means of evaluating nerve electrodes. The repeatability of the data, particularly when normalized, is quite encouraging. How consistant the data will look from dog is not yet known, of course.

One hundred micro seconds appears to be an optimum pulse width, based on energy considerations for the electrodes used in this study. However, working with this narrow of pulse width has some disadvantages. Because of the nature of the classic Strength/Duration curve, the engineer must often design with longer pulse widths in order to make use of lower voltage power sources.

For this limited séries the relative effectiveness of each electrode configuration is summarized in Figure 4. Each Energy vs. Force curve represents the effectiveness of each electrode configuration at its optimum pulse width. The unipolar electrode looks promising but there could be one engineering drawback. If the slope of the Force vs. Energy curve is too steep it is difficult to obtain a graded response from the nerve. That is, it is often desireable to be able to slowly vary the stimulation amplitude and obtain a gradually increasing muscle contraction, "fine tune" the activity on an autonomic nerve, or whatever the case might be.

A final note. Even if this technique indicates the relative effectiveness of one electrode type over another, it does not mean that the parameters used for each design were optimum. This is evident by looking at the difference between the results obtained from the two simple bipolar electrodes. Spacing and exposed surface area are probably quite important and an attempt should be made to optimize these parameters for different size nerve diameters.

Acknowledgement

The author wishes to express his gratitude to Donald McNeal, Ph. D., Rancho Los Amigos Hospital, California, U.S.A., for his many helpful discussions and suggestions.

Bibliography

/1/ Anagnostopoulos, C.E., Glenn, W.W.L., "Electronic Pacemakers of the Heart, Gastrointestinal Tract, Phrenic Nerve, Bladder, and Carotid Sinus: Current Status", *Surgery 60*, No. 2: 480 - 494, August 1966.

/2/ Brazier, M.A.B., *The Electrical Activity of the Nervous System*, Third edition, Baltimore, The Williams and Wilkins Co., 1968, pp. 79-91.

/3/ Braunwald, N.S., Epstein, S.E., Braunwald, E., "Carotid Sinus Nerve Stimulation for the Treatment of Intractable Angina Pectoris: Surgical Technic", *Annals of Surgery*, 172:5, Nov. 1970.

/4/ de Villiers, R., Nosé, Y., Meier, W. and Kantrowitz, A., "Long-Term Continuous Electrostimulation of a Peripheral Nerve", *Trans. Amer. Soc. Artif. Int. Organs*, 10:357-365, 1964.

/5/ Ferris, C.D., "Metallic Electrodes", *Sixth Annual Rocky Mountain Conference on Biomedical Engineering*, 1969.

/6/ Greatbatch, W. and Chardack, W.M., "Myocardial and Endocardiac Electrodes for Chronic Implantation", *Ann. of the N.Y. Acad. of Sci.*, 148, Article 1: 234-251, February 1, 1968.

/7/ Guyton, A.C., *Textbook of Medical Physiology*, Third Edition, Philadelphia, W. B. Saunders Co., 1966, p. 72.

/8/ Hagfors, N.R., Testerman, R.L., and Schwartz, S.I., "Evaluation of Nerve Stimulating Electrode Geometrics", *31st Annual Conf. Eng. in Med. and Biol.*, Nov. 1968.

/9/ Jeglič, A., Smolnik, M., Brodnik, L., "Implantable stimulator technology. Development of Orthotic Systems Using Functional Electrical Stimulation and Myoelectric Control", Final Report, Project No. 19-P-58391-F-01, Univ of Ljubljana, Dec. 1971.

/10/ Jeglič, A., Vavken, E., Strbenk, M., Benedik, M. and Tribuson, P., "Radiofrequency Stimulation of Skeletal Muscles by Implanted Receivers", *Proc. 2nd. Eur. Symp. on Med. Elec.*, London, 1967.

/11/ Leirne, S.N., "Electrochemical Behaviour of Metals as Stimulus Electrodes", *J. Biomed. Mater. Res.*, 1:27-31, 1967.

/12/ McCarty, L.P., "A Stimulating Electrode for Nerves", *J. App-Phys.*, 20:542, 1965.

/13/ McNeal, D., Bowman, B., and Fordyce, W., "Impedance and Threshold Measurements Following Implantation of Peripheral Nerve Electrodes", *Conf. on Engineering in Med. and Biology Proc.*, 24: 203, Las Vegas, Nevada, 1971.

/14/ McNeal, D., Wilemon, W.K., Mooney, V., Boggs, R., and Tamaki, I., "The Effect of Peripheral Nerve Implanted Electrical Stimulation on Motor Control in Stroke Patients", *World Cong. of Neuro-Sci.*, New York, N.Y., Sept. 1969.

/15/ Patlak, C.S., "Potential and Current Distribution in Nerve: the Effect of the Nerve Sheath, the Number of Fibers, and the Frequency of Alternating Current Stimulation", *Bull. of Math. Biophysics*, 17: 287-306, 1955.

/16/ Pennacchietti, M., Bistagnino, C., Artom, A., and Pozzolo, V., "A New Muscle Stimulator Controlled by Myoelectric Signals", *Panminerva Medica*, 33: 312-317, 1967.

/17/ Roy, O.Z., and Wehnert, R.W., "A More Efficient Waveform for Cardiac Stimulation", *23rd Annual Conf. Eng. Med. and Biol.*, 9: 495-501. Pergamon Press, 1971.

/18/ Schwartz, S.I., Griffith, L.S.C., Neistadt, A. and Hagfors, N., "Chronic Carotid Sinus Nerve Stimulation in the Treatment of Essential Hypertension", *Amer. J. Surg.*, 114:5, 1967.

/19/ Starbuck, D.L., Shealy, C.N., Mortimer, J.I. and Reswick, J.B., "An Implantable Electrode System for Nerve Stimulation", *Proc. 19th Annual Conf. Eng. Med. and Biol.*, San Francisco, 1966.

/20/ Suckling, E.E., *Bioelectricity*, New York, N.Y., McGraw-Hill Book Co., Inc., 1961.

/21/ Tasaki, I., "Conduction of nerve impulse", *Handbook of Physiology*, Sec. I, Vol. I, pp. 75-114. Baltimore, Williams and Wilkins Co., 1959.

/22/ Testerman, R.L., Hagfors, N.R., Schwartz, S.I., "Design and Evaluation of Nerve Stimulating Electrodes", *Medical Reserach Engineering*, Jan.-Feb. 1971.

/23/ Wilemon, W.K., McNeal, D., Friedman, H., Mooney, V., Tamaki, T., "Selective Patient Control of Spastic Musculature by Means of Surgically Implanted Peripheral Nerve Stimulation Devices", In Wulfsohn, Norman L. and Sances, Anthony, Jr. eds.: *The Nervous System and Electric Currents*, Volume I, p. 18, Supplement, New York, N.Y. Plenum Press, 1970.

/24/ Wilemon, W.K., Mooney, V., McNeal, D. and Reswick, J., "Surgically Implanted Neuroelectric Stimulation - Two Years´ Experience at Rancho Los Amigos Hospital", Paper presented to Committee on Prosthetic Research and Development, Houston, Texas, June 1970.

/25/ Yergler, W.G., Wilemon, W.K. and McNeal, D., "An Implantable Peroneal Nerve Stimulator to Correct Equinovarus During Walking", *J. of Bone and Joint Surgery*, Dec. 1971.