PERMISSION TO MICROFILM — AUTORISATION DE MICROFILMER

• Please print or type — Écrire en lettres moulées ou dactylographier

Full Name of Author — Nom complet de l'auteur

CHARLES, DEAN
2nd name 1st name

Date of Birth — Date de naissance

March 8 1937

Country of Birth — Lieu de naissance

CANADA.

Permanent Address — Résidence fixe

11583 80th AVE EDMONTON T6G 0R7

Title of Thesis — Titre de la thèse

ADVANCES IN NEURAL NEURAL AND ELECTROMYOGRAPHIC RECORDING TECHNIQUES AND APPLICATIONS TO POWERED PROSTHESES

University — Université

U. of A.

Degree for which thesis was presented — Grade pour lequel cette thèse fut présentée

MSc

Year this degree conferred — Année d'obtention de ce grade

1981

Name of Supervisor — Nom du directeur de thèse

Dr R.B. Stein

Date

March 27 1981

Signature

Dean Charles

NOTICE

The quality of this microfiche is heavily dependent upon the quality of the original thesis submitted for microfilming. Every effort has been made to ensure the highest quality of reproduction possible.

If pages are missing, contact the university which granted the degree.

Some pages may have indistinct print especially if the original pages were typed with a poor typewriter ribbon or if the university sent us a poor photocopy.

Previously copyrighted materials (journal articles, published tests, etc.) are not filmed.

Reproduction in full or in part of this film is governed by the Canadian Copyright Act, R.S.C. 1970, c. C-30. Please read the authorization forms which accompany this thesis.

THIS DISSERTATION HAS BEEN MICROFILMED EXACTLY AS RECEIVED

AVIS

La qualité de cette microfiche dépend grandement de la qualité de la thèse soumise au microfilmage. Nous avons tout fait pour assurer une qualité supérieure de reproduction.

S'il manque des pages, veuillez communiquer avec l'université qui a conféré le grade.

La qualité d'impression de certaines pages peut laisser à désirer, surtout si les pages originales ont été dactylographiées à l'aide d'un ruban usé ou si l'université nous a fait parvenir une photocopie de mauvaise qualité.

Les documents qui font déjà l'objet d'un droit d'auteur (articles de revue, examens publiés, etc.) ne sont pas microfilmés.

La reproduction, même partielle, de ce microfilm est soumise à la Loi canadienne sur le droit d'auteur, SRC 1970, c. C-30. Veuillez prendre connaissance des formules d'autorisation qui accompagnent cette thèse.

LA THÈSE A ÉTÉ MICROFILMÉE TELLE QUE NOUS L'AVONS REÇUE

THE UNIVERSITY OF ALBERTA

ADVANCES IN NEURAL AND ELECTROMYOGRAPHIC RECORDING TECHNIQUES AND APPLICATIONS TO POWERED PROSTHESES

by

© Dean Charles

A THESIS

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES AND RESEARCH

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE

OF Master of Science

Physiology

EDMONTON, ALBERTA

Spring, 1981

THE UNIVERSITY OF ALBERTA

RELEASE FORM

NAME OF AUTHOR Dean Charles

TITLE OF THESIS ADVANCES IN NEURAL AND ELECTROMYOGRAPHIC RECORDING TECHNIQUES AND APPLICATIONS TO POWERED PROSTHESES

DEGREE FOR WHICH THESIS WAS PRESENTED Master of Science

YEAR THIS DEGREE GRANTED Spring, 1981

Permission is hereby granted to THE UNIVERSITY OF ALBERTA LIBRARY to reproduce single copies of this thesis and to lend or sell such copies for private, scholarly or scientific research purposes only.

The author reserves other publication rights, and neither the thesis nor extensive extracts from it may be printed or otherwise reproduced without the author's written permission.

(SIGNED) Dean Charles

PERMANENT ADDRESS:

11583 80th Ave

Edmonton, Alberta

Canada

DATED March 27 1981

THE UNIVERSITY OF ALBERTA

FACULTY OF GRADUATE STUDIES AND RESEARCH

The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research, for acceptance, a thesis entitled .....

..ADVANCES IN NEURAL AND ELECTROMYOGRAPHIC RECORDING TECHNIQUES AND APPLICATIONS TO POWERED PROSTHESES.

submitted by ....DEAN CHARLES.....

in partial fulfilment of the requirements for the degree of Master of Science.

.....R B Stein.....

Supervisor

.....M. S. French.....

.....

.....

.....J. J. Kobes.....

External Examiner

Date..MARCH 25, 1981.....

ABSTRACT

New types of implantable electrode arrays are described which may be allowed to remain in living animal tissue over an extended period of time and which provide useful clinical and experimental information without causing inflammation, infection or rejection. The devices and methods described differ from classical electrophysiological recording techniques in that they provide long term stable behavioural recordings in freely moving unanaesthetized subjects. Besides providing an opportunity to obtain data useful for basic research, these devices provide a potential interface for obtaining signals for the control of powered artificial limbs and a means for transmitting sensory or positional feedback to the person wearing the artificial limb.

Different types of electrode arrays are described both in construction and in implementation, including the earlier *regeneration electrode unit*, and the more recent cuff electrode units. The results of testing these cuff electrodes in mammals and eventually testing a single unit in a human amputee are described. The author's primary contributions to this area of the research have been in a technical capacity, and the contributions made by individual members of the group will be described in the body of the thesis.

The applicability of different recording techniques and different types and configurations of electrode arrays are compared and evaluated with respect to basic research data

collection as well as potential and realized *prosthetic use*. More than one cuff electrode assembly may be used at the same time in a single human or laboratory subject, and more than one type of electrode assembly may be used as well. Individual or collective elements of any given electrode array may be used for either recording or stimulating, or stimulating may be done via one electrode array while recording is done from another. Thus one system may be used to apply stimulation in one selected area of the nervous system, while yet another device is used to monitor patterns of activity in a different or related area of the nervous system. The usefulness of the devices and techniques described is thus documented with respect to setting up controlled situations of stimulating and recording the activity of the peripheral nervous system, particularly with respect to investigating posture and locomotion.

The devices and procedures are described as developed in more or less chronological order with the earlier devices developed discussed first, and with the more recent cuff electrodes discussed later. Reasons for the earlier methods are given, as well as reasons why mammalian research has focussed more recently on the cuff electrode assembly. Experience has been gained with the clinical requirements of amputees, and with problems that may be encountered in future implantation procedures when applying the devices and methods described to the control of artificial limbs on a larger number of amputees. Since the primary thrust of the

research is directed towards exploring improved methods for the control of artificial limbs rather than the design or construction of such limbs, a brief review of the most practical components commercially available for the construction of powered prostheses is given. Successful fittings and unsuccessful fittings are described, and some of the reasons influencing the outcome when using powered prostheses are given. Clinical implementation of successful modular techniques are discussed in some detail.

FOREWORD

In the field of implantable electrodes, connections to the human nervous system, electromyographic control systems and prosthetic applications in general, theories abound. Practical, down-to-earth proof of performance, however, is much harder to find. The literature is full of "good ideas," but a closer examination of the concepts presented often discloses that despite the elegance or supposed sophistication of the systems that are presented, no patients have actually been fitted with complete, functioning artificial arms and powered hands that could provide valid benefits in daily living. Unfortunately, the publicity and financial support these developments receive is frequently related more to the prestige and status of their developers than to the prosthetic usefulness to the patient. For example, the highly regarded journal "Electronics," (Marion, L. 1979.) devotes an entire page to an artificial arm developed at the Illinois Institute of Technology in Chicago which has not been fitted on any patients in the field at the time of writing. Similiarly, the "Boston Arm," developed by Liberty Mutual Insurance company is actually famous throughout the literature (Mann, R.W., and Reimers, S.D., 1970) . Yet the number of patients actually wearing it and who are obtaining long-term benefits from it remains a very different question to answer. Similiarly, although the University of Utah has spent more than 8.4 million dollars on its total bioengineering program

(Teresi, D., 1978), and has been active in the field for more than 14 years, its arm has never been used outside the laboratory.

As of December, 1980, 40 patients have been fitted with multifunctional powered prostheses at the University of Alberta. Various control methods and control sites have been used and the powered prosthetic appliances range in complexity from simple single-hand opening and closing functions all the way to bilateral high level fittings incorporating three degrees of freedom on each side. Follow-up studies have been done to assess the level of functional and cosmetic value to the patients and to determine if the prostheses are providing any real benefits. The powered prosthetics program has been implemented with the assistance of prosthetists working in an already-existing conventional prosthetic facility. The degree of success in the fittings ranges from total patient rejection of the prostheses, through situations of moderate to heavy use, with a number of patients expressing an enthusiastic appreciation of the devices despite their limitations. The level of funding which was necessary to achieve these results was not as high as that which has been required by many other institutions investigating these fittings, and the myoelectric rehabilitation program may represent an economic benefit if factors such as the restoration of work forces are taken into account.

The many complex factors which are being learned about practical fittings in a myoelectric situation are directly applicable to the control of more sophisticated prostheses by future neural implant controls, and this thesis deals with the many evolving approaches to this subject that we have undertaken over the years. When we began this program there were insufficient control sites available for the potential degrees of freedom a powered prosthesis could practically implement. At the present stage of our program, we can control the opening and closing of a hand, pronation and supination of a wrist, and flexion and extension of a powered or body-operated elbow on many patients who were previously considered unsuitable candidates for prosthetic fitting. Our present signal processing techniques are more successful in rejecting interference than those used by Dr. H. Schmidl of Budrio Italy, who has probably fitted the highest number of successful powered prostheses in the world. (Schmidl, H. 1977.) Our choice of control sites and our reliability of signal processing from them have reached a degree of sophistication that in many respects surpasses those available elsewhere. We have achieved an interchangeability amongst components that would have been thought impossible a few years ago, and we can demonstrate a more reliable control over the Boston Elbow using only one muscle site than the original Boston circuitry could provide with two. Some of the developments have been made independently, some are presently available to all

prosthetists on a commercial basis. If the proof of success really is in the practical application, then it is my belief that these results should bring credit to the University of Alberta, the Department of Physiology, and the team under the direction of Dr. R. B. Stein who have shown the clinical feasibility of powered prostheses for myoelectric and neural control.

The earlier regeneration electrode unit developed jointly by Dr. R.B. Stein, Dean Charles, and Allan Mannard, was awarded United States Patent number 3955560. The author's responsibilities included the selection of materials and procedures for construction of these devices and the actual fabrication of more than fifty of these units. The author was also primarily responsible for the design and construction, selection of commercially available biocompatible materials and ordering thereof, and implementation of these materials into the initial series of cuff electrodes which are still in use in our laboratory.

The author acknowledges that much of the material which is presented here has been previously published jointly with Dr. R.B. Stein and other authors. The author was mainly responsible for technical aspects of the developments, and these technical aspects are therefore emphasized in this thesis. However, they are placed in the context of the results relating to basic research and clinical applications which have been carried out in collaboration with other members of the group.

ACKNOWLEDGEMENTS

I am especially thankful to:

1. Dr. R.B. Stein, my supervisor, for valuable leadership, advice and support during a complex and difficult project.
2. Dr. Allan C. Mannard, friend and co-developer of the First Regeneration Electrode units, for encouragement and an inquiring challenging attitude.
3. Dr. Lyle Davis, for surgical expertise and excellent viewpoints on clinical and practical implementation.
4. Dr. T. Gordon, for many hours of careful construction of cuff electrodes and for unflagging cheerfulness in long experimental sessions.
5. Mr. John Arseneault, and, earlier, Mr. Tony Van der Waarde, prosthetists.
6. Dr. Andrew French who has provided valuable computer programming for the analysis and reduction of data.
7. Dr. Esmond Saunders and associates in the electron microscopy division for fine histological preparations and examinations.
8. Mr. Ron Lentz, President of Leaf Electronics Ltd., for directing the business and production aspects of the commercial modules used.
9. Dr. J.A. Hoffer, for valuable suggestions and co-authorship of many articles published with Dr. Stein during the developments described.
10. Mr. Robert Rolf, who has contributed recent computer

programming and interconnections in data processing.

11. Ms. Masako Walley, for conducting the first comprehensive follow-up evaluation of performance and use patterns in a large myoelectric user population.
12. Mr. Bert Sankey, first human volunteer for implanted cuff electrodes and E.M.G. probes assembly constructed by Dr. J.A. Hoffer.
13. Ms. Barbara Moss, O.T., for initiating valuable patient occupational therapy sessions.
14. Ms. Sharon Moorman, O.T., for recent occupational therapy sessions and patient interviews.
15. Amputees and phocomelic patients who have worn various versions of the many developments chronicled herein, including both successful and unsuccessful fittings, with our heartfelt thanks for the information obtained in both cases.

This work was supported by grants to Dr. Stein from M.R.C., (The Medical Research Council of Canada), and from M.D.A., (The Muscular Dystrophy Association of Canada)., as well as local support which was received from the Medical Research Fund of the University of Alberta and the Special Services and Research Committee of the University of Alberta Hospital.

LIST OF TABLES

LIST OF ILLUSTRATIONS

Table of Contents

I. INTRODUCTION

A. Objective:

Interface for behavioural and sensory information.

It is desired to record from identified fibers in the peripheral nervous system during the free movement of the subject. The direct information which may thereby be obtained on the roles of the sensory and motor neurons associated with mammalian muscles requires implantable arrays of electrodes which are stable in position even during movement. It is important that the means used for obtaining these recordings be reliable over a long term and that the implant may continue giving reliable recordings without interfering with the normal motion of the animal or causing undesirable problems in biocompatibility with tissues. It is also important that a means be provided for two-way electrical access to the electrode array, both for stimulation and recording specific channel signals, and that this electrical access to the interior of the animal past the skin barrier not cause problems with infection. It is desirable to record from as large a number of sites as possible in order to identify temporal and spatial differences in the neural signals, and to maximize the chances of obtaining correlations between neural signals and

the stimulus under observation.

Possible solutions:

(A) Regeneration Electrode Unit - cross-sectional (transverse) data

(B) Cuff Electrode Unit - longitudinal data

A brief description of what these devices consist of is as follows.

1. Regeneration electrode. The Regeneration electrode consists of a thin wafer which has been provided with a number of holes. A nerve is sectioned, and the regeneration electrode is placed between the two cut ends of the nerve so that fibres may grow through it. The channels are equipped with electrodes for recording any signals the nerves may propagate.

2. Cuff Electrode unit. The cuff electrode consists of a flexible silicone rubber cuff a few cm in length. The inside of this cuff is equipped with at least three semicircular wire electrodes which pass down an insulated cable to the underside of an insulated socket mounted in the skin of an animal.

Comparative Applications of Electrode Types.

Regeneration electrode:

The main advantage of the regeneration electrode is that the data which is obtained is representative of the cross-sectional activity in a bundle of fibres, and as such, may be used to explore the questions related to the anatomical organization of fibres within a bundle and the spatial coding with respect to function and destination. Longitudinal recording, such as that represented by cuff recording cannot give this type of data, and hence cannot provide information about the organization of fibres within a given bundle. A second advantage of the regeneration electrode unit is that the small size may permit it to be used in auditory, visual, or higher central nervous system applications.

The main disadvantage of the regeneration electrode is that the signals obtained from mammalian regeneration experiments using the preamplification techniques that were available at that time, (Mannard, A., Stein, R.B., and Charles, D. 1974.), were of insufficient amplitude for clinical applications which were accorded highest priority .

A second, and very important disadvantage of the regeneration electrode, is that it requires transsection of the nerve, and by its presence in the path of the regenerating nerve bundle, blocks the majority of the fibres from reaching their destination. Thus the normal activity of

the animal may be interfered with over long periods of time, and it cannot be shown even in the amphibian experimental series that the fibres which remain are giving recordings which are representative of those which would be obtained if the entire bundle were intact.

A third disadvantage of the regeneration electrode is the requirement which it imposes that the experimenter allow sufficient time to elapse for the nerves to regenerate at least as far as the electrode before recordings can be made. Even then the recording situation cannot be expected to remain stable as reinnervation takes place and the nerves eventually make contact with their end organ. It cannot be shown that the activity of the central nervous system and its connections to the nerve which had been severed were not affected by the operative procedure and hence it is questionable as to whether the signals being recorded are representative of a normal situation.

Cuff electrode unit:

The cuff electrode unit which is currently being used in a number of experiments in our laboratory has several advantages over the regeneration electrode for prosthetic applications. It is easier than the regeneration electrode to manufacture, and hence can be made available more readily for a larger variety of experimental situations. It does not require the severing of a nerve for installation. The

signals obtained from the present development of the cuff electrode are satisfactory for many measurement and recording uses, and show promise of being useful in the control of prosthetic devices.

This is not to say, however, that the cuff electrode is the ultimate development in recording devices, or that its function and application are as remote from those of the regeneration electrode as its current intensive use would seem to indicate. In fact, the cuff electrode itself has limitations which can be seen by comparison with the regeneration electrode and the proposed scanning electrode.

The cuff electrode is constructed with a series of "C"-shaped conductive rings surrounding the nerve bundle on the outside of the bundle. As such, it is capable of recording with a good signal-to-noise ratio the averaged sum activity of a population of fibres and therefore it presents its highest recording sensitivity in synchronous firing situations. While a synchronous volley of impulses in an entire bundle of fibres is easy to accomplish in an experimental situation using a stimulator, the normal situation in posture and locomotion, and volitional efferent activity in particular, rarely presents a high degree of synchronicity in impulses. Neural signals representing fine details of movement or sensory feedback would be largely swamped by a near-synchronous burst in the same bundle, and no degree of sophistication in filtering would be practical in resolving such a signal. If a low-level nonsynchronous

signal represented the individual finger movements, for example, a great deal of valuable information could be lost with respect to the control of a powered prosthesis.

B. Implantable Electrodes.

Applications:

1. Physiological experiments on motor control.

   a. Exploration of the roles of sensory fibres from mammalian muscles.
   b. Investigation of the anatomical organization and activity patterns of motor nerve fibres to mammalian muscles.
   c. Investigation of the interplay of different patterns of neural activity in neurons supplying different muscle groups that interrelate in the positioning of the extremities in posture and locomotion.
   d. Direct quantitative measurements of the synaptic delays and propagation time latencies in gamma fibre activity with respect to alpha motoneurone activity, in order to answer questions still outstanding on load compensation and tremor in motor control.

2. Clinical applications.

The clinical application which has been selected to test the usefulness of the implantable electrodes is the provision of control signals for artificial prosthetic appliances powered by rechargeable battery packs. In this

application, the improved selectivity of control sites offered by the implant as compared to traditional surface E.M.G. electrodes is important. It can be shown that the implanted electrodes offer improved rejection of unwanted signals compared to surface electrodes and by providing more independent channels of information, have the potential to offer the amputee more degrees of freedom in the operation of his powered prosthesis. The implanted devices can be made to be less subject to external mechanical shock and amplitude instability due to positioning than surface E.M.G. electrodes, and since their recording site is chosen at the time of implant, they provide a signal of improved reproducibility and stability.

Although the initial application of these devices is in the field of prosthetics, they are by no means limited to that application clinically. A whole spectrum of clinical information gathering and data processing applications have been suggested. (Mann, R.W., 1973.) For instance, the electrodes may be used to gather information on neural activity in chronic illnesses and rehabilitation medicine, denervated muscles and prevention of muscular hypotrophy. Electrical stimulation through implantable devices has been used to alleviate the drop foot condition in stroke. Urinary bladder control, sphincter control, blood pressure control, visual and auditory prostheses, stimulation for pain suppression, electroanesthesia, relief from contractive and possible sensory feedback in upper extremity prostheses are

all potential applications for implantable devices. (Reswick, J.B., 1973.)

A further list of clinical applications includes the following:
The control of self-feeding apparatus for the handicapped.
The control of powered wheelchairs.
The control of other tools and communication devices to improve the independence and overall lifestyle of the handicapped. e.g. Telephone dialers, entertainment channel selection, book page turners, hospital bed angle adjustment motor controls, typewriters, etc.

Concept of a multiple-channel implantable electrode unit.

Differences from Classical Electrophysiological Recording Techniques.

Those who have been exposed to the classical techniques of neural recording, either intracellular or extracellular, have often expressed difficulty in fully understanding that the new techniques described yield a qualitatively different kind of information than the older techniques. Whereas a single microelectrode imbedded in a cell may yield information concerning the membrane potentials of the cell, and hence give valuable theoretical information regarding the electrochemical functioning of that cell, it cannot give

information useful for reliably directing the control of a prosthesis. There are several explanations why this is so.

1. Firstly, the single cell pickup does not represent a large enough statistical sampling of the neural events relating to muscle tension or velocity.
2. Secondly, it is subject to physical trauma and movement, and since its position is critical, it cannot be used during the free movement of the subject for reliable data output.
3. Thirdly, a single pickup gives no temporal or phase information concerning the activity of other neural locations that may also be involved in the movement or other parameter being monitored.

Understanding the importance and potential implications of these new developments requires that full consideration be given to the differences between this approach to neural recording and the classical approaches. The traditional approach gives a train of impulses from a single site, related only unto themselves with respect to frequency, amplitude, and interspike interval patterns. These signals contain little or no information as to the anatomical distribution and spatial-temporal patterning of other signals which may be equally important. It is the interrelationship between neural signals and their allocation to different destinations which determines the overall coordinated movement and posture of an animal, and

single-unit recordings do not give information concerning these interrelationships. While too little is known about the exact neural coding mechanisms at the present time to draw an exact analogy between the processing of digital data in a computer and the organization of neural signals, nevertheless certain similiarities and differences are obvious. The presence of large numbers of motor fibres all involved in the accomplishment of a single smooth co-ordinated movement, for example, indicates that the neural organization in nature favors reliability. The failure of any single neuromuscular unit will not disturb the functioning of the entire system. Similiarly, the accidental false firing of the smallest neuromuscular units will have little effect on the overall motor output of the system. However, the same averaging effect which increases the overall reliability of the natural system also increases the difficulty of obtaining valid meaningful and representational outputs from single units, with respect to their being an accurate and reproducible analogue of real motor activity. Cuff electrodes preserve average signal components of a nerve. It is too early yet to make firm distinctions about the degree to which electrode assemblies should be designed for discreteness and to what degree they should be designed to average the summed activity of entire bundles, but it seems reasonable at this time to assume that it will depend upon the application. For instance, the monitoring of neural data in which a high degree of fine

detail is transmitted, such as the areas of vision and audition, may require electrode assemblies which only average the output of small numbers of neurons, and the Regeneration Electrode Unit falls into this category. Investigation of the degree of synchronicity of fibres firing within a bundle may also be amenable to exploration with the Regeneration Electrode.

On the other hand, recording situations where a high degree of parallel innervation is found, and in which the averaging effect an be used to advantage, such as the derivation of prosthetics control from the main muscle groups of the upper extremities may well profit from the use of an averaging-type electrode. The larger ring electrodes of the implantable cuff assembly provide this type of output, and although they may not transmit information on the cross-sectional activity of the nerve bundle, or information on the phase components of all fibre sizes within the bundle, the overall output may be satisfactory for prosthetic controls.

Information obtained by single-channel classical techniques.

Intracellular recording can give information appropriate to the studies of membrane potential and neural electrochemistry, in the form of D.C. resting potentials and

D.C. level and polarity shifts during depolarization and repolarization. But this is like attempting to obtain meaningful arithmetic outputs from the output of only one gate in a logic system. Not until the information present at the other gates is made available with their time and amplitude relationship to the gate under question does the information have meaning. A single neuron may provide information on pulse repetition rate, number of pulses per burst of activity, temporal patterning within the burst, burst repetition rate, and changes in patterning with respect to time such as adaptation and accomodation. It may even provide data that can be correlated with physical motion elsewhere in the body, or with other neural events.

Information obtained by multiple-channel techniques.

The addition of each extra recording channel beyond the first channel of information has implications far beyond the duplication of the measurements possible in classical electrophysiology.. Not only can all of these parameters be measured independently or simultaneously on the new neural source, but more importantly, an entire set of comparisons can be made between the various aspects of patterning within the first neural signal and *each* of the pattern components of the new one. But an even more important piece of data is also obtained, of paramount significance, and this is the difference in spatial distribution of the neural signals

coded as to differences in their topgraphical destinations or muscle groups, and this may be correlated with behavioural activity , as well as with each of the parameters obtained from the first recording site.

The amount of new information obtained in such matrix correlations is much more than would be expected by simply adding the recording of one new channel, and it may be seen that as more and more channels of recorded information are added, the total data picture presented becomes closer to an analog of the patterning within the subjects central nervous system. That these patterns may be obtained selectively, analyzed, and acted upon outside the body of the fully-conscious, freely-moving unrestrained normal human being or test animal constitutes an entirely new type of behavioural neural recording, in which the data collected is of a fundamentally different kind than is usually obtained in peripheral recordings.

Previous work leading up to the Regeneration Electrode Unit:

The concept of interfacing electronic apparatus and signal processing equipment with the human nervous system is not new, and the possibility of modifying or controlling the mechanical output of muscles via electrical stimulation must trace its origin back to the earliest work of Galvani and Volta. (Davies, 1968).

W.B. Marks proposed the concept of the regeneration electrode in the proceedings of the Symposium of Information Processing in Sight Sensory Systems.(P.W.Nye, 1965.)

The possibility of the regeneration electrode discussed here arose in discussions between R. Llinas and Dr. R.B. Stein at Boulder in 1969.

Brindley (1972), captured intact spinal root fibers in narrow channels bearing electrodes.

Hugo Gernsback wrote extensively in his editorials in the radio and electronics magazines of the 1940-1950 period of his firm belief that an area of great importance would evolve at the interface between Medicine and Electronics, and as a man of penetrating insight and brilliant imagination, foretold in surprising detail many of the exciting advances of today's Biomedical Engineering. Some of Gernsback's ideas were expanded upon by the author and discussed with Dr. R.B. Stein in October of 1968, and a plan was made at that time to proceed towards the goal of a multiple-channel implantable neural interface. The author suggested a series of metal wires with only the tips bared inserted at various depths into a nerve bundle within an insulating tube, and that a prosthetics control application would be useful for evaluating the practicability of the multiple channel information theory. It was agreed to use prosthetic control as an evaluation, but Dr. Stein felt that the better approach for that stage of development was to investigate the regeneration of nerves through enclosed

pores, and if that approach proved feasible, to equip those pores with recording electrodes and attempt to document the presence of valid neural signals. Several different approaches to this end goal were begun simultaneously which included various methods of achieving very narrow diameter holes in a variety of insulating, conducting, and multi-layered materials.

The initial series of epoxy wafers, however, simply contained a densely-spaced group of very fine channels, and were used primarily to test the hypothesis that nerves would grow through such channels.

A. Marks,(1969), demonstrated that cut nerve fibers would regenerate into Teflon sponge, continuous-pore Teflon, or arrays of 25 micron internal diameter gold cylinders embedded in Teflon. Successful invasion of sciatic nerve implants was obtained, and axons were found to regenerate into Teflon or gold-lined pores in implants placed in the sciatic nerves, the optic nerves, and the intertectal region of the bullfrog.

This preliminary work was valuable, in that it demonstrated that the implants seem to get penetrated by the axon, but no photographs were published actually showing nerve fibers going right through the channels and continuing on past the implant. Also, it was not shown that the fibres in question were still electrically excitable, since no electrical recordings were made. Therefore, it could not be said that the fibres in question were capable of full

amplitude action potentials of normal waveshape, or that their output would be useful in clinical prosthetic applications even if external leads had been connected to the embedded gold channels. In addition, no information on impedances, cross-talk, E.M.G. signal suppression, or signal-to-noise measurements appear in these early papers. It should also be noted that all this early work was done on non-mammalian species, and it is known that the nervous system of amphibians shows a lack of selectivity requirements in regeneration compared to mammals.

A similiar criticism applies to the paper by R. Llinas, (1973), which on casual reading might appear to pre-empt our 1974 publication in the journal *Science* (Mannard, Stein, and Charles, 1974.) Llinas' publication is entirely theoretical, and although it is useful and valuable in that it calls on the major semiconductor manufacturers to show an interest in the development of a monolithic recording electrode, it does not demonstrate actual fibres penetrating a prototype and giving useful electrical signals. Work which has been done since the publication of this paper shows that Llinas' estimates of the optimal thickness of the wafer would have to be modified to include the superior interference rejection capabilities of the three-ring electrode configuration, and the new preamplifier matching techniques which have resulted in reliable long-term recordings in our laboratory.

A. Holz (1973), reports work done on regeneration through small glass capillary tubes. When a multiple-capillary body consisting of nineteen glass tubes each having an inside diameter of 80 microns and a total length of 8 mm, was sewn between two stumps of a transsected nerve and examined seventy days after implantation with the electron microscope, evidences of neural growth through the tubes could be found. Holz observed both young myelinated and unmyelinated fibres, with most fibres being enveloped merely by a diffuse plasm edge, which he interpreted as early stages of myelination. He did not, however, publish photographs of these fibres, nor was any proof shown of the ability of the fibres to conduct an impulse. Although Holz postulates that the regeneration of axons into electrically-contacted capillaries would permit the recording of nerve signals for the trainable control of all kinds of artificial limbs and organs, he does not state how this would be done, nor has he shown awareness of the necessities of impedance matching, shielding from E.M.G. contamination, or maximization of the signal via multipolar electrode techniques. The paper is, however, valuable, in that it identifies glass capillaries of the formula he used as not being toxic to regenerating axons and this information will presumably be useful in future developments where the long-term stability of glass and its resistance to water permeability degradation may be an asset in electrode construction.

J.A. Hoffer, W.B. Marks, and W.Z. Rymer (1974), described techniques for monitoring muscle afferent and efferent fibers from normal animals during unrestrained movement. Nerve fiber bundles were captured in insulating groove electrodes containing one or two recording contacts. Multiunit activity was observed from the dorsal roots of the cat and from the tibial nerve of the rabbit, and single units were also resolved. The work was especially valuable in showing the feasibility of recording from animals in an unrestrained normal condition, and also in demonstrating the importance of a good blood supply to the neural filament when the fascicle is split. This technique may prove valuable in future work where it becomes necessary to obtain several control sites from a single nerve, or where it becomes necessary to divide a nerve for other purposes, such as the provision of position and velocity feedback from an external prosthesis. In 1971, A. F. Marks demonstrated the acceptance of implanted plastic structures by the brain of the mature rat. Clean strips of porous and solid Teflon were implanted into the midbrain and pons of mature rats. Some of these had been etched and coated with a variety of different substances, including Epoxylite, Epotek, Carbowax, and Paraffin. Bundles of fibres were found to penetrate as deep as 40 microns into a slot 6 microns high and 80 microns long, and all tested implants contained at least some axon bundles except the one coated with Carbowax.

II. REGENERATION ELECTRODE STUDIES.

A. METHODS: Regeneration Electrodes.

Experimental animals- Xenopus.

Before any animal experiments were done, it was first necessary to establish some method of manufacturing implantable electrode arrays and to determine the reaction of the tissues to the materials available. Since this would require a large number of animals to be sacrified after they had been maintained over a period of months or even a year, it was decided to do the initial experiments in the amphibian *Xenopus laevis*. This animal is relatively resistant to infection, shows good regenerative properties and requires a minimum of upkeep space.

No skin-mounted sockets were used in the amphibian experiments, therefore the access to the leads at the time of measurement was made by incision. For convenience in discussion, however, the regeneration electrode will be discussed as a member of a class of recording devices as if the recording method used did not involve a skin incision, but rather a plug-in socket similiar to those employed in cats. Many of the comments concerning optimum construction and reliability of the devices apply equally well to both types of electrodes, especially in areas of biocompatibility and cable insulation techniques.

Implantable electrodes: Design requirements.

The design of any implantable electrode assembly consists of three parts:

1. -The neural implant device proper.
2. -The implanted cable.
3. -The external interface socket. (when used).

There are a number of interacting problems to be solved in the design of a satisfactory Regeneration Electrode Unit. The implantable device must stay in place on the nerve in spite of repeated and extensive movement of the animal over a long period of time. The external plug-in device must be very effective in preventing the passage of bacteria into the body, and must also present no protrusions or ledges which could catch on objects and cause the traumatic dislocation of the device. There must be a sufficient number of channels that the device can fulfill the purpose for which it is intended even though active and useful neurons may not grow back through a majority of the channels. Yet the cable of electrical conductors which connects the Regeneration Electrode Unit termination with the neural channels to the externally-mounted socket for accessibility must not be excessively bulky.

The device must stay in place on the nerve, yet must not be a source of trauma to the nerve. It must remain in

place with sufficient stability that the neurones can regenerate through channels having a dependable position during the extended time required for their growth, and yet the rigidity of the device must not present a pressure such that normal physiological function of the nerve is impeded. The cable of wires must have sufficient strength to withstand the repeated flexing encountered in the manufacture and surgical implantation of the system, and must withstand chemical and mechanical attack by the living system which surrounds it, and must present sufficient isolation from the interfering signals present in the body that it can be useful. Yet it must not be so bulky with cable diameter and shielding that it would transmit the torsional and longitudinal stresses inevitable in implantation procedures to the opposite end where the device is firmly secured to the nerve.

The device must be made of materials that are within the practical realization of equipment, time, energy, and funds available, yet it must withstand an extended period of time, even years, within a conductive, chemically corrosive environment, and yet exhibit overall excellent long-term electrical characteristics. It must be non-toxic, non reactive and not damaging to the nerve. In animal implants, the exposed connector must withstand mechanical abrasion as the animal rubs its body against mechanical hazards encountered over a period of time of a year or more, and must withstand grooming, licking, and scratching.

Meanwhile, the neural implant wafer of the Regeneration Electrode Unit is subject to a different set of performance and design tradeoff considerations. The individual channels through which the axons grow must have dimensions that fulfill often contradicting requirements. The channel must not be so small that normal transport of metabolites and oxygen is greatly impeded, yet it must be small in order for a satisfactory signal to be obtained. The channel length should not be so great that it interferes with the process of regenerate growth itself, yet it must be long enough for the development of sufficient signal amplitude. The individual channels must be spaced sufficiently far from each other that mechanical strength of the device is obtained, yet the device must not become bulky or exceed in width the useful pickup area of the nerve. An adequate signal isolation must be preserved between channels, yet there is no commercially-available shielding that would permit such isolation without seriously increasing mechanical bulk and stiffness. Shielding individual channel openings from each other would also add electrical capacitance which would shunt an already very small signal. The desirable qualities of a low source impedance at the site of neural generation and transmission must be weighed in consideration against the equally-important desirable quality of a high initial signal amplitude. One empirical way to determine the values for such contradictory tradeoff considerations would be to run a series of implants testing

the electrical characteristics resulting from a series of graded hole diameters and lengths. Since the time, and expense of such an extended series duplicating each set of parameters more than once to avoid error due to individual fluctuations would preclude such an in-depth practical test, another approach had to be devised. This alternative approach based the practical construction of the devices on a set of theoretical and mathematical considerations which had been obtained from earlier experiments, and the measurements of the parameters obtained with a limited series of devices made within the constraints imposed by available resources. Not all of these potential variables could conveniently be tested, and it seemed unwise to spend a great deal of time doing so, when the overlapping work which was being done developing the nerve cuff techniques seemed to hold so much promise. However, the early work on the Regeneration Electrode Unit did provide a great deal of information on finding materials that exhibit good tradeoffs between their mechanical and electrical characteristics and their biocompatibility qualities.

In the early mammalian implants, which were being designed at the same time, the type of mounting of the socket, on the head of the animal, and the heavy shielded cable under the skin down to the nerve site, were undergoing re-evaluation.

Construction of a Typical Regeneration Electrode Unit.

The conducting cable as material for channel contacts.

The basic starting material for the cables of the very earliest devices was formed by twisting together a group of insulated silver wires each of which had a core diameter of .003" (76 micrometers) It is interesting to note that the present material of choice, platinum-iridium, was actually tested first, before silver. Had these initial tests been continued, it is likely that an entire series of problems with lead breakage would have been avoided. platinum-iridium, however, is very much more expensive than silver, and the budget for obtaining this material did not permit purchase of more than the initial sample, which was unfortunately not stranded, and not of small diameter. In the soft, wet, thin delicate tissues of Xenopus, the stiff springy solid platinum-iridium wire caused troubles. Even in attempting to manufacture the units, the Teflon insulation became abraded while trying to handle the material. The torsion of attempting to form the twisted part of the cable transferred down each separate wire individually rather than as a group, and displaced the fragile Teflon at the clamping point. When these problems were finally overcome, and a successful device which had passed all its electrical tests was finally implanted in a Xenopus, the high torsion of the wires caused damage to the nerve, and eventually the springy

material even worked it way through the skin of the animal. So, although the platinum iridium material was recognized by the author as being of greater resistance to breakage by longitudinal stresses, the much higher cost, excessive springiness and difficulty in handling made the more ductile silver wire the material of choice in the early amphibian pilot series. The silver wires did not corrode as rapidly in the cooler amphibian environment as they did later in the much warmer mammalian tissues, and so useful results were obtained. On a later stage of manufacture of the Regeneration Electrode Units, a return to platinum iridium wire was used for a different reason. The additional stiffness of platinum iridium becomes an advantage when ultrasonic bonding is used. Platinum-iridium wire has proven to be the most inert in mammalian situations. Ability to accept solder is good, protection by epoxy and Silastic in combination appears to be effective for periods of at least two years, and, providing that the central fibre core concept with external spiralling is used, resistance of the leads to breakage is exceptionally good. The concept of a gradual tapering of diameter of the external Silastic coating away from any solid object, such as the Regeneration Electrode, the Nerve Cuff Units, or the percutaneous connector assembly at the skin interface helps avoid lead breakage by distributing the strains over a greater area of wire, and minimizes the sharp repeated bends at one single point along the wires which otherwise lead to wire breakage.

Signal-to-noise considerations and channel dimensions.

Regeneration electrodes were expected to satisfy the requirements for an implantable array of electrodes that remain in a fixed position relative to the nerve bundle during movement of the animal. It was postulated that these devices would give us at least initial information on the roles of sensory and motor nerve fibres during locomotion. By designing an implant perforated with a series of cylindrical channels, each channel of which is provided with an independent electrode wire, it was thought possible to stimulate and record selectively from smaller populations of fibres than was previously possible. In the extreme case, with exceptionally narrow channels, it might even be possible to record from a single unit, providing that sufficient voltage were developed in the device to permit detection. One of the constraints on this procedure is that the channel must be sufficiently long that the peak-to-peak amplitude of the signal developed can be recorded over the noise of the metal-to-tissue contacts and the preamplifier noise of the individual channel.

The calculated peak-to-peak amplitude of a triphasic spike expected from a fibre in a channel of length L and diameter D is approximately $k(L/D)^2$ for small values of L and D. (Constant k ranges from 0.3 to 3 uv.) (Stein and Wong, 1971.) A typical value for channels 100 micrometers wide and 700 micrometers long would be 15 to 150 uv.

(Mannard et al, Science, (1974).)

Channels produced by etching out silver wires.

In the final version of the Regeneration Electrode Units two main methods of manufacturing the devices were used. In one system, silver wires 25 micrometers in diameter were bonded ultrasonically to specially prepared smooth flat surfaces of 77 micrometers platinum - iridium wire, supported in a section of rigidly-supported epoxy. (Epon 812, Ladd Research Industries, Burlington, Vermont.) These silver strands were then firmly captured in place by re-embedding the assembly in a fresh drop of epoxy. The two parallel side walls of the droplet were then milled down to two flat faces separated by 0.7 mm and parallel to the twisted wires. It was found to be necessary to complete the twisting of the wires prior to the encapsulation in order to prevent transmission of torsional forces into the epoxy droplet. A 25% solution of ferric nitrate in water was then used in an ultrasonic bath to penetrate into and dissolve the silver wires from their channels, leaving the channels empty and bare except for the one single platinum-iridium contact in the centre of the channel.

Micro-drilled channels.

A second technique, which gave more immediate results was to simply manufacture the unit out of the less-expensive silver wires, and, after milling down the two perpendicular faces, to drill a single hole through each wire using 100 micrometers bits. (Sphinx micro drills in a Swisso precision drill press, Swiss Instruments, Toronto Ontario.) The channels were then placed in a distilled water bath and cleaned ultrasonically to remove any debris from the drilling procedure. Each channel was then examined microscopically, and its impedance measured. Any given unit which contained more than a few leads having impedances outside the range of 20 K ohms to 300 K ohms was discarded, and the impedances of the various leads in saline was recorded for future comparisons. Leads having a impedance lower than 20 K ohms were assumed to have damaged insulation, while leads having impedance higher than 300 K ohms were assumed to have blocked channels or holes that did not contact wire leads as planned.

Surgical implantation of regeneration electrode units.

In a typical implantation, a Xenopus laevis would be anesthetized by immersion in a 0.2 g/litre solution of tricaine methanesulfonate, (Fraser, Vancouver, British Columbia.) Each unit was secured into a snug-fitting notch which had been cut into the side of a 3 mm length of Intramedic PE 160 tubing. A double-loop suture, passed

through two larger holes drilled in the outside of the device served to retain the device in place in the slit which had been made three-quarters of the way into the sciatic nerve. (See Figure 1.) A 12 to 25 week period was then allowed to elapse for possible nerve fibers to regenerate through the channels.

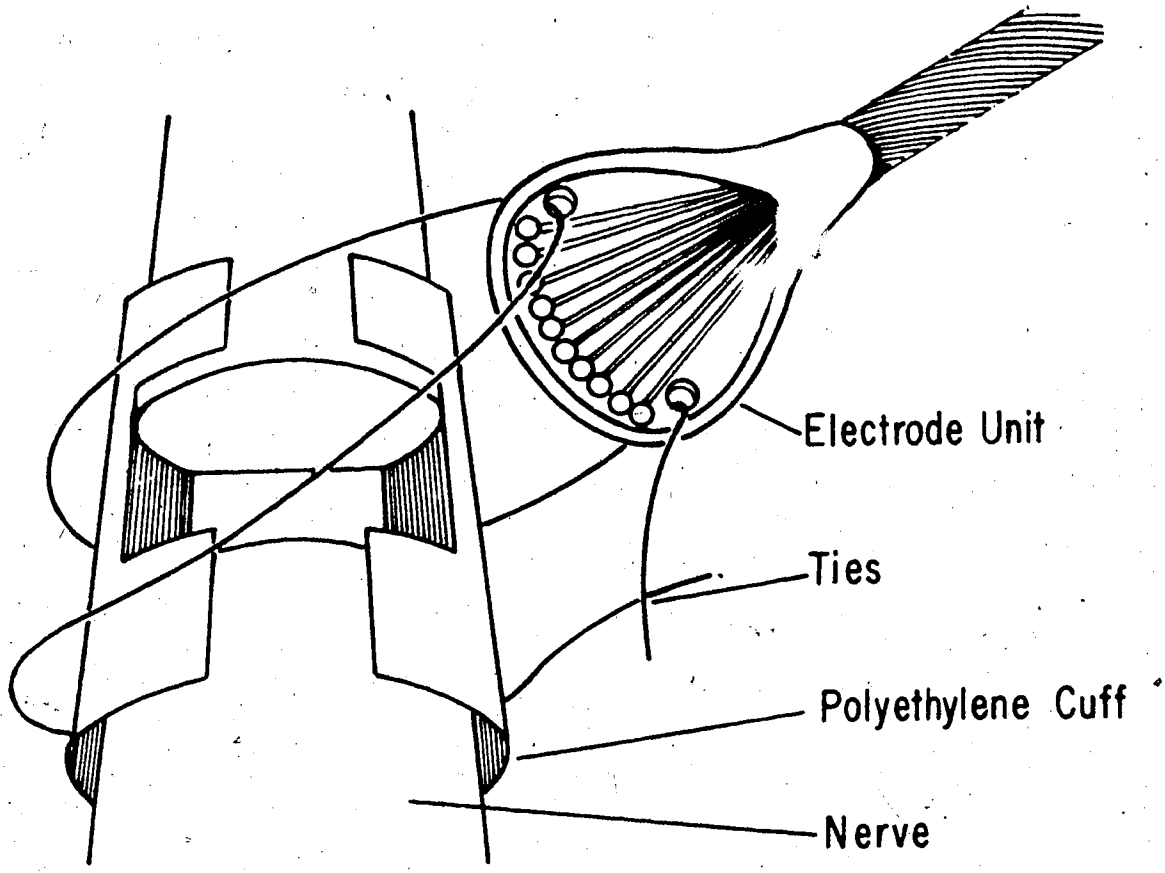


Fig. 1. Sketch of an idealized regeneration electrode showing the method of implantation. By means of a double-loop suture, the units were drawn into slits extending about three-quarters through the sciatic nerve, then tied to a 3-mm length of notched Intramedic PE 160 tubing that had been cut end-to-end and fitted around the nerve. The nerves were about 1.5 mm in diameter.

B. RESULTS: Regeneration Electrode Studies.

Histological confirmation of regeneration.

Histological examination by light microscopy showed that bundles of axons had in fact penetrated the devices. In addition, electron micrographs were made of cross-sections of the channels. Even in channels as narrow as 25 micrometers, axons could be found. (Figure 2.) In 3 animals a total of 17 channels were found identifiable by microscopic examination. Of these, 9 contained clear axon profiles ranging in number from 1 to 29 per channel. When axons were measured at their greatest diameter, out of a sample of 85 penetrating fibres, their diameters were found to be from 1 to 14 micrometers, with 80 percent between 1 and 5 micrometers When examined under electron microscopy, mesaxons similiar to those believed to characterize early remyelination and patches of material of increased opaqueness to the electron beam were observed, but no clear myelination was observed. Under higher magnification, typical axoplasm could be seen with mitochondria, microtubules, and neurofilaments. The likelihood that these represented functional axons of penetrating sensory and motor fibres remained to be tested at that time by electrophysiological studies.

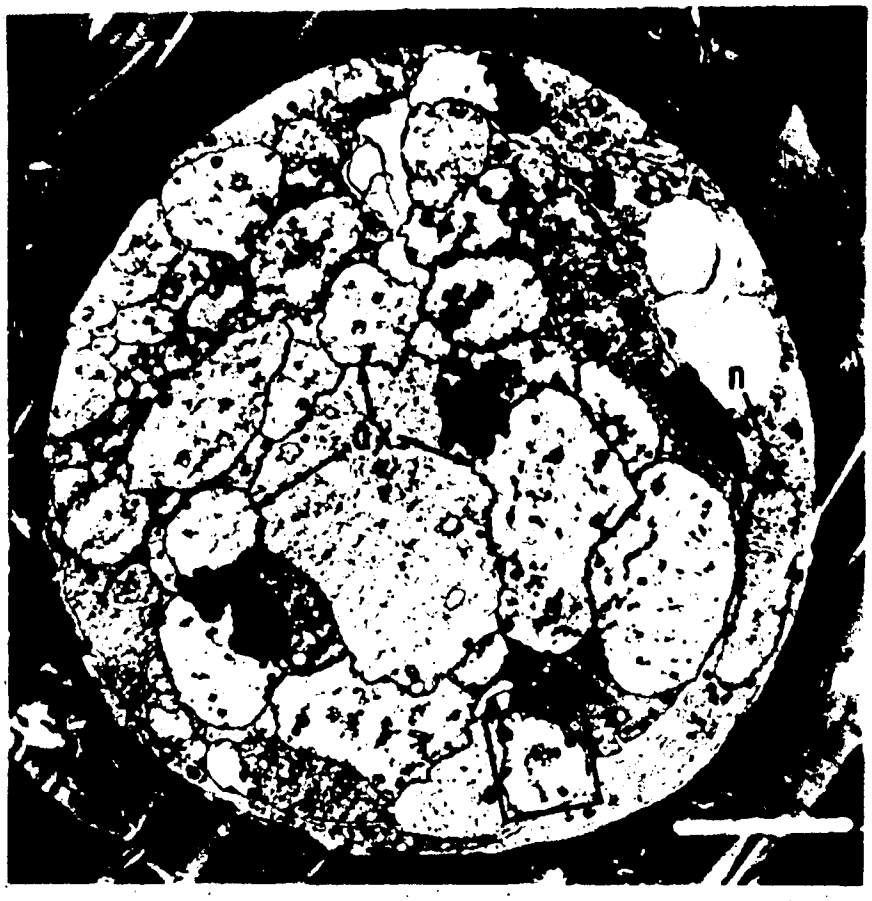


Fig. 2 Thin section through one of the channels remaining after several 25-um strands were etched out of an epoxy wafer; scale mark, 5 um. The section had been fixed in glutaraldehyde, postfixed with osmium tetroxide, and stained with uranyl acetate and lead citrate. Flakes of epoxy torn off by the ultramicrotome obscure small parts of the cross section. Note several irregularly-shaped axons, three of which are indicated by the arrows converging at the marker (ax). Note the nucleus of what appears to be a Schwann cell, marked (n).

Recording from Implanted Regeneration Electrode Units.

Immobilized animal: Impedance Measurements and solenoid stretching of muscles.

Because a skin interface socket had not yet been developed at the time of this early series, and since the animals had too fragile a skin to support a socket, it was necessary to re-anaesthetize each animal, make a small incision in the skin, and search around for the free ends of the bundle of wires connecting to the device. It was important to not tug or pull on the wires, and each lead had to be specially cleaned and affixed securely to the wires leading to the preamplifier. Differential recording was used to help eliminate hum and noise as well as other artifacts, and it was sometimes necessary to find a lead which exhibited impedance characteristics and lack of neural activity suitable to act as indifferent electrode for the reference to the lead actually being examined. After suitable leads had been selected, different types of new experimental procedure could be implemented. The response of regenerated fibres to the mechanical elongation of the gastrocnemius muscle could be electrically recorded, and the latencies of the neural action potentials with respect to the onset of solenoid-induced stretch could be determined.

Confirmation of Regenerated Fiber Activity.

Initially, 29 afferent spikes recorded from two different animals produced latencies ranging from 10 to 80 msec, with a mean value of 38 msec. Taking the onset of stretch as the time at which afferents fire, for an average conduction distance along the fibre of 50 mm, it may be seen that the range of conduction velocities found covers the rather large spectrum of from 0.6 to 6 m/ sec., or even faster. Isolated preparations of regenerated Xenopus sciatic nerve appeared to give conduction velocities of 5 to 15 m / sec, whereas normal control nerve yields the much faster velocity of 15 to 40 m/ sec. It was postulated that the reason that the implant-penetrating fibres seem to conduct with the slower range of velocities may be due to the lack of myelination of the implant penetrating fibres at the time of recording. Single spike responses were observed in six channels, bursts of two or three spikes from several channels, and a burst of eight spikes from one channel. Differences in latency and amplitude of spikes permitted separation of the activities of many of the axons, assisted by differences in the evoked threshold under stimulation, but not all of these variables may be equally accessible when recording from freely moving animals. One third of the implant channels contained functioning afferents. Motion of the animals causing shifting of the device with respect to the nerve, possible invasion by connective tissue, lead

breakage, or inadequate time for full reinnervation could account for many of the non-functional channels. If a total noise level due to Johnson noise of 10 uV is postulated for an electrode of 100 kilohm impedance at 20° C over a bandwidth of 10 Hz to 20 KHz, an amplitude in the order of 100 uV would represent 10 times the noise level. Such afferent potentials were observed. (See Figure 3.)

Triphasic in shape, the duration of the first phase measured a mean of 2.1 msec in nine cases, ranging from 1.2 to 3.0 msec. When the strength of the stimulating signal was smoothly reduced, the spikes would exhibit all-or-none behaviour, strongly indicating single unit properties. Other attributes which indicated single unit recording included intermittent complete failure under repetitive stimulation, and a jitter in latency at near-threshold stimulation. Since spike patterns recorded from one of the leads were not present on other channels, action potentials originated within the channels from fibres penetrating the implant, and not from fibres passing around the periphery of the device.

Recording from a freely-moving animal: Volitional signals.

When signals were recorded from actively swimming animals recovered from anaesthetic , in four channels of three animals, bursts synchronous with swimming movements could be readily observed. Each burst consisted of 2 to 20

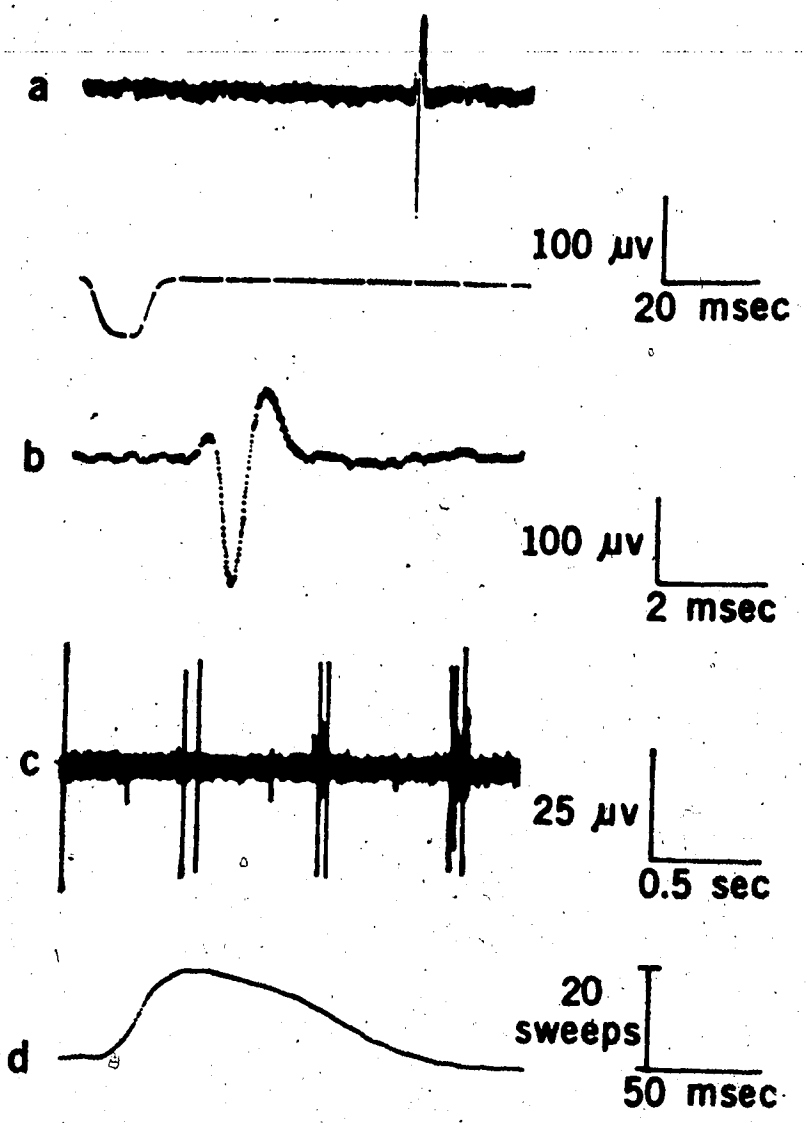


Fig. 3. (a) Upper trace: •Response of a single sensory nerve fiber penetrating the implant to a brief muscle stretch.
(a) Second trace down: Time of application of above stretch.
(b) Action potential shown in (a), Time scale expanded.
(c) Burst discharge recorded from a single implant-penetrating motor nerve fiber in a freely-swimming animal.
(d) Time course of a muscle twitch. (Computer averaged from an unknown number of gastrocnemius motor units, stimulating via the regeneration electrode neuroimplant.)

spikes, likely from single units, having waveforms resembling those recorded from afferents. Also, the temporal patterns of the bursts resembled those which are obtained from motor unit potentials in normal unoperated Xenopus. This activity was not the same as slower waves of variable amplitude seen on six occasions which may have been due to E.M.G. signals located near the implant site. The fact that the properties of any given train of impulses was specific to its own pair of channels also lends credibility to the concept that the bursts were not originating in muscles or bundles of non-penetrating axons. By keeping careful track of which leads were used, and by stimulating through the same leads from which previous records had been made, it could be shown that twitches would result at a given stimulus amplitude. That these were motor fibres rather than sensory became apparent when attempts to stimulate through neighboring channels did not elicit twitches even though the stimulus amplitude was raised ten times over the initial value.

Evaluation of Regeneration Electrode Implants in Mammals.

Experiments designed to explore the value of regeneration electrode units in mammals did not produce satisfactory recordings from sensory or motor fibres. Presumably, this was due to the higher conduction velocity and hence poorer

spatial voltage gradients for a given-sized device in warm blooded animals, the smaller size of the regenerated fibers, and the greater proliferation of connective tissue in mammals. It is possible that connective tissue blocked the holes before regeneration took place in the limited series of experiments attempted in cats. Nevertheless, mammalian nerve fibers can be shown histologically, (Holz, 1974,) (Stein et al, 1975.), to grow through such holes, although they show little or no myelination.

The use of the regeneration electrode technique, although it now appears to be almost of historical interest only, still set a precedent by providing a starting point for recording from the same fibers over a wider variety of conditions, including movement, development, conditioning, growth, stimulation, etc. It is to be expected that the experience gained from these early experiments, as well as many of the details, will be valuable in designing and producing a third generation electrode device of the future, such as a device designed to obtain not only cross-sectional sampling of information, and longitudinal information, but also improved volumetric and timing information. Although the transverse spatial array of electrode channels in the Neural Regeneration Electrode Unit offers the advantage of sampling discrete neural data from fibres of different function within a large bundle, it suffers from several major disadvantages, particularly when recording from mammals. The low signal level due to the more rapid

conduction velocity implicit in the higher-temperature mammalian environment is an important limitation, as is the potential blocking of channels by connective tissue prior to the successful penetration of the device by active axons.

But by far the most important single disadvantage of the Regeneration Electrode Unit is the requirement that the nerve be cut, thereby destroying the orderliness of its peripheral connections and interfering with normal signal flow in both afferent and efferent directions. Since the trophic influences of the end organ connections are not fully understood at this time, it cannot be determined to what extent re-innervation via the Regeneration Electrode Unit is representative of a normal physiological situation. It is highly unlikely that normal regeneration of fibres would ever occur, no matter how much time was permitted for re-innervation, because of the fact that such a high percentage of the fibres in the bundle would be blocked by the nonporous sections of the device.

It was therefore decided to measure the gross overall activity within a given nerve rather than specific cross-sectional samples of activity as a more practical solution to the problem of obtaining a functional neural implant. Although this is the method of choice at the time of writing, it is the author's belief that elements derived from both the cuff electrode and the regeneration electrode could be incorporated in recording devices in the future.

Specifically, the restricted extracellular space and

substantial recording lengths of the cuff electrode may be combined with the ability of the regeneration electrode to differentiate specific activity within different cross-sectional samples of the overall fibre diameter. Therefore, the description of the cuff electrode which follows should not be taken to be a final optimal recording device, but rather merely one step along the evolution of a more sophisticated and discrete method of recording and isolating specific signals from within a bundle. The very high level of uniformity and reproducibility of signals obtained from animals after implants lasting several years with the cuff electrodes which we have developed has resulted in a focus of attention on this method to the exclusion of continuing research on other electrode geometry variations which are possible. However, that very success does not by any means indicate that the ultimate recording configurations have been achieved.

III. CUFF ELECTRODE STUDIES.

A. METHODS: Cuff Electrodes.

Cuffs had previously been used to fix recording electrodes mechanically in place near nerves, (DeLuca and Gilmore, 1976), giving a means of stimulating and recording signals providing that no interfering E.M.G. signals were present. But these cuffs lacked a wiring configuration that would reject E.M.G. signals. They were either porous to the body fluids and electrical interference fields, or they were totally sealed in such a way that the nerve had to be cut to insert it through one end of a hollow tube. In a videotape presentation given by DeLuca and Gilmore which the author viewed in Boston Mass. in 1974, no clear neural signals could be heard from rabbit nerves which had been threaded through cuffs of the type that existed prior to the cuffs under discussion.

By the time that Regeneration Electrode Units had been implanted in the first 15 cats as of August 1974, the methods of constructing the cables and vitreous carbon percutaneous connector had been improved greatly, to the point that signal impedances and channel integrity were no longer dependent upon fortuitous circumstances to get dependable recordings. The major contribution made by this author to the cuff recording project following the

improvements in lead integrity was to design a cuff that could be opened down one side for insertion of the nerve, and which therefore permitted a nerve to be used which had not been cut. This was accomplished by sewing wires in the form of the letter "C" into the side of the interior surface of hollow silastic tubing, and aligning the open parts of the "C" configurations along one longitudinal line down the side of the tube so that a slit could be made along that side. This fundamental and important contribution has not been documented elsewhere and to the best of the author's knowledge it had never been used by any research team prior to ours.

Advantages of the Cuff Electrode Configuration.

For the purpose of control of artificial limb prostheses and for the study of certain aspects of neuromuscular activity during behaviour, it is desirable to record from a larger population of cells than traditional single-unit microelectrode studies have permitted. For these purposes, and for studying the spatial coding, time characteristics and correlation between various parameters of neural activity and muscle activity, the cuff electrode presents great advantages. The recordings made from it are stable over long periods of time, the animals do not have to be anaesthetized before running an experiment, several channels of data or independent stimulation are available at

the same time, and often through a single convenient connector. In addition, lower impedances than classical microelectrode techniques permit better control of amplifier blocking effects (caused by electrostatic charges overloading the front end of the Grass p-15 preamp,) less interference from 60 Hz and 120 Hz hum, rejection of impulses caused by static electricity and fur-rubbing artifacts and cable noise, and better interchannel isolation despite the use of multiconductor cable that does not have individually-shielded leads. In short, the cuff recording technique via a percutaneous connector is relatively simple and straightforward compared to the alternative of performing a surgical procedure each time data is to be obtained.

Construction of Cuff Electrodes.

(Refer to Figure 4.)

In an optimized cuff, stranded wire should be used for flexibility and increased surface area resulting in a lower impedance with respect to the nerve as compared with solid wire of similiar diameter, as well as helping avoid mechanical deformation of the nerve. Solid platinum-iridium wire of comparable strength is much too springy and difficult to work with. The wire, (Medwire Corp., Mt. Vernon N.Y. part number 101r9/49T) is supplied with four coats of Teflon for insulation. In handling the wire it is important

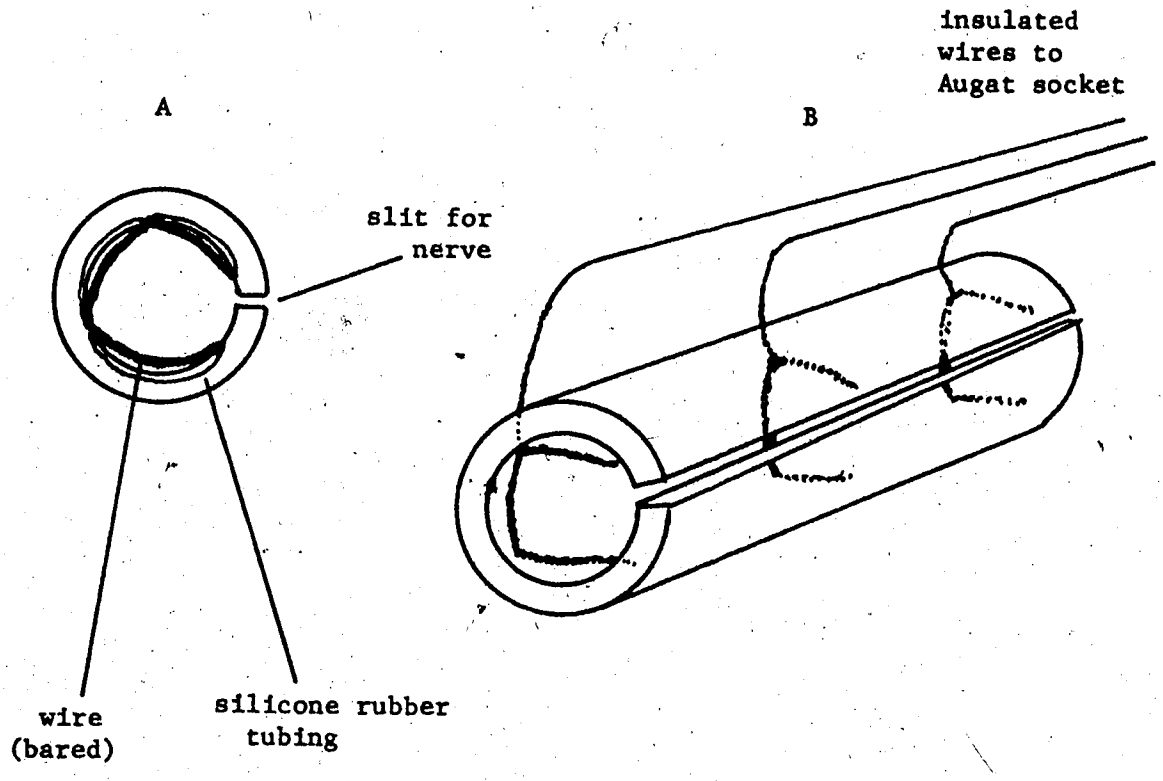


Fig. 4

Construction of a cuff electrode: A: End view showing 90° wire arcs. B: Side view showing placement of electrode arcs and slit for nerve.

to avoid abrading this insulation, which is relatively delicate in comparison with the hard metal inside. Contact with hard-surfaced tools or objects touching the wire between the time it leaves the spool and the time it is encased in the final protective tubing is to be avoided, and all surfaces that contact the wire should ideally be soft. A brief exposure to a small flame under very carefully controlled conditions may be used by some operators to remove the Teflon coating, but a safer procedure is to remove the coating using slightly-dulled forceps under a binocular microscope using good illumination. Extreme care should be taken to avoid causing even the smallest indentation in the wire beneath the insulation, as such an indent will weaken the wires and cause them to break at that point after implantation.

Using a curved small-diameter needle the wire is threaded into the inside of the silastic cuff in a series of short arcs. Depending on the diameter of the tubing, two, three or even four short arcs may be used, and an average number of three 90° arcs forming a conducting ring around approximately 270° of the inner wall circumference of the cuff was used in most cases. The remaining 90° of the cuff was reserved for a longitudinal slit in the cuff to permit insertion of the nerve into the cuff. A round section of rod of diameter slightly smaller than the inside of the cuff was then used to carefully press the wires against inside walls of the cuff so as to prevent them from occluding its

diameter . At least two coats of undiluted Dow Corning medical grade Silastic were then applied to the outside of the cuff to fix the wires permanently in place and provide additional insulation.

Insulation of Cuff Electrodes and Implant Signal Cable.

The combination of silicone rubber and Teflon has given the best results to date in preventing excessive chemical corrosion, and maintaining electrical integrity. The Teflon insulation on the wire with the Silastic applied externally appear to act together to control the water permeability and provide better biocompatibility in the outer layers, and relatively high resistance to water penetrating the actual immediate vicinity of the wire itself. It should be noted that the Dow Corning number 891 medical grade Silastic type A is by itself not a satisfactory barrier against the passage of moisture, but it does appear to slow down circulation of water around the critical structures enough for a second layer of insulation such as Teflon and/or epoxy to complete the insulating process. The use of either material alone, however, is not recommended. A smooth outer finish was provided to the cuff to discourage connective tissue adhesions by wrapping Teflon tape around the cuff while the Silastic was still in a liquid state, and then removing it after the Silastic had cured.

Cuff Ground Reference Electrode.

In all cuffs except the very smallest, at least one wire was sewn into the exposed back side of the cuff 180° from the position provided for the slit. These wires did not enter into the inside of the cuff, but were merely looped through the thickness of the outer wall of the cuff for mechanical fixation and bared throughout their length to serve as ground electrodes for the minimization of artifacts in future recording situations. A variety of cuff dimensions and lengths were made up, and some sixty-odd devices were constructed by the author including the devices that served to develop the optimal wire and cable arrangement in earlier series.

The Silicone Cuff.

Dow Corning "Silastic" (A trade name) tubing material types 601 and 602 were selected for their relative biological inertness and their proven clinical record in biological situations, as well as the dimensional stability and ease of handling this material exhibits. Internal diameters from 1.0 to 3.4 mm and lengths from 1.5 to 5 cm were selected on the basis of individual experimental requirements and the diameter of the nerve to be fitted. In general, the internal diameter of the cuffs was selected to fit the nerve with sufficient tightness to provide optimal recording

situations, but not so tightly as to cut off the nerve's circulatory supply. Experiments were done to determine if the ends of the cuff should be tapered to permit the cuff to bend with the nerve, but material of sufficient pliability and thinness was [illegible]able, as well as the fact that this technique was [illegible] of valuable nerve length, which had to be used [illegible]ng electrode spacing in order to optimize the electrical parameters. Therefore, a simpler cylindrical design for the cuffs eventually was adopted, although it is possible that a less abrupt terminating edge to the cuff material could be less traumatic to the nerve in some future re-design.

As the experimental series continued, the importance of two factors relating to optimizing the signals became clear. One was the diameter of the cuff, which had to be as tight as possible without damaging the nerve. The other was that the slit down the side of the cuff had to be restored to a moisture-proof condition as nearly completely as possible. The presence of a poorly-fitting cuff, or leakage down all or a portion of the slit, greatly degraded the excellent E.M.G. rejection of which a well-made cuff is otherwise capable. Techniques were therefore developed for improving the seal of the cuff, and suture threads were often sewn right into the walls of the device for improving the extent to which the cuff could be conveniently and efficiently sealed around the nerve, following insertion of the nerve into the cuff. A thin layer of Silicone was sometimes

applied over the slit in the cuff, and allowed as much as possible to cure before the cuff was re-inserted into the body cavity and allowed to contact the body fluids. In general, the minimum number of wires that can come from a given recording cuff is two, which are connected to form three rings for reasons that will be described later. However, the experimental nature of the entire project made it advisable to run each wire from a given ring independently in many cases so that specific measurements of nerve contact impedance and differential interactions could be made. For that reason, many cuffs were provided with at least three wires and sometimes a fourth for ground. The maximum number of wires that could come from any given cuff, array, or combination of neural and E.M.G. pickup sites was twelve, including the ground connection, due to the limitation imposed by the twelve pins on the Teflon integrated circuit socket which was used for all of these experiments.

Standardized skin interface socket.

The socket, (Augat type 8058-1G51, Augat incorporated, Attleboro, Mass. U.S.A.) has dimensions sufficiently well controlled during manufacture to eliminate excessive variations in fitting the percutaneous vitreous carbon skin connector through which it was inserted. It is readily available, fairly rugged, (except for an occasional

separation of two portions of the female contacts under extremely prolonged and repetitive use with plugs of less than optimum-diameter lead configurations.) The mechanical separation of contact components was not usually accompanied by any electrical disturbances, indicating that the inner connector was relatively well-secured in the Teflon surround, and replacing the connector components usually restored satisfactory service. Although the Teflon surface resists adhesion to the epoxy used to fix the socket in place because of a very slippery outer surface, separation of the socket from the percutaneous connector has not been a problem in practice. Small grooves cut laterally with a scalpel into the sides of the socket, and a roughening of the edges with emery cloth prior to mounting the two units together may have contributed to the ruggedness of the combination, by permitting a surface to which the epoxy could readily bond. The presence of an inner ring undercut on the inner surface of the vitreous carbon ring also permitted a better bond with the epoxy.

Construction of the reinforced spiral lead cable.

(Refer to Figure 5.)

The three to twelve wires were generally completed at the cuff end first, and then spiralled around a thin metal shaft of approximately 0.7 mm diameter. The windings were done close-wound, and then stretched out to approximately

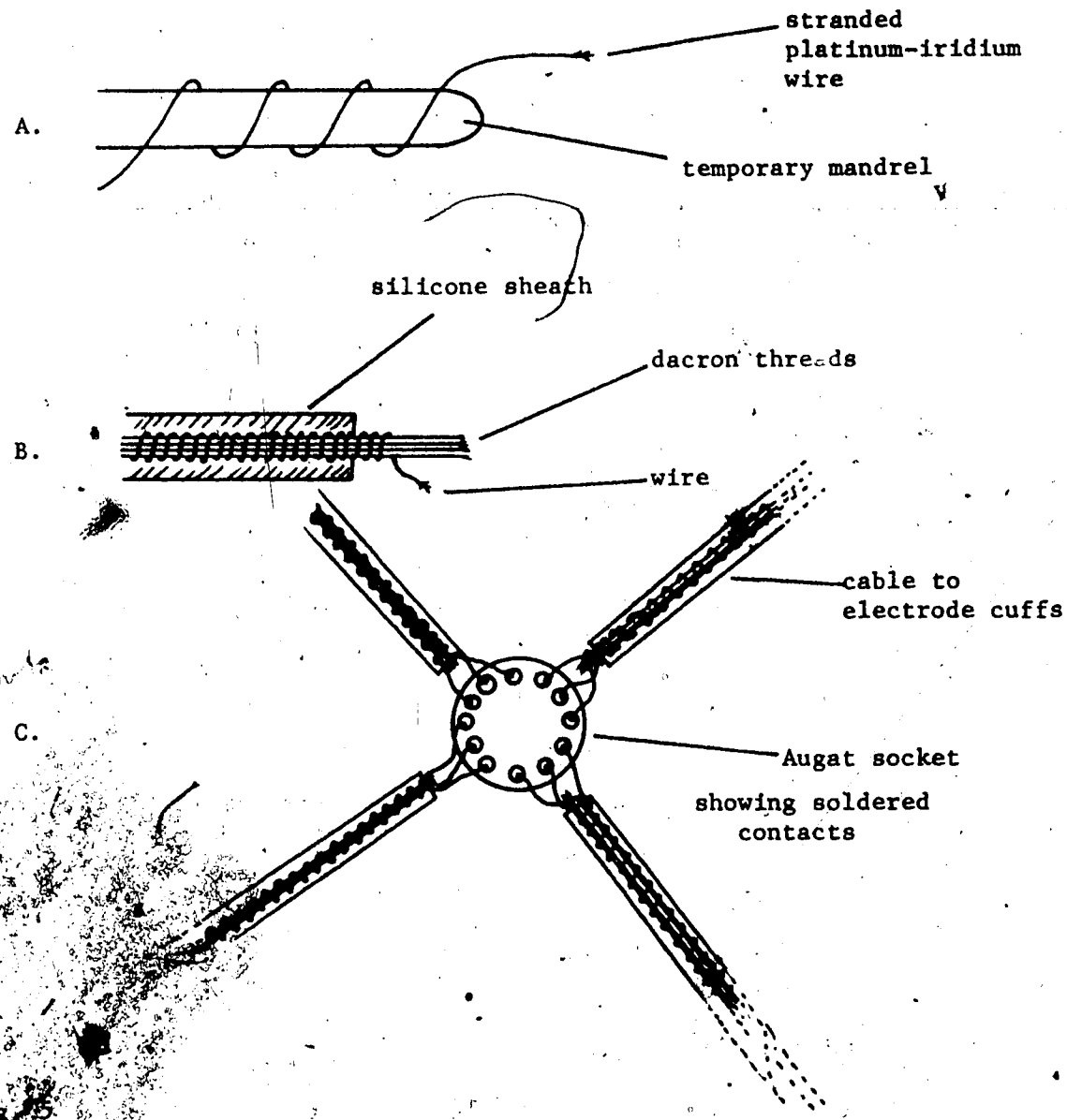


Fig. 5

A. Multiple stranded platinum-iridium wire wrapped around a mandrel, which will be withdrawn after wires are formed.

B. Protection of the wires spiralled around longitudinal dacron threads, all encased in silicone rubber sheath.

C. Connection of wires to rear of Augat socket, radially distributed.

two-thirds of what their straight length would have been. A group of three dacron fibres, which were originally dacron model airplane control cable chosen for its advertised resistance to elongation, were then laid in the centre, and the conductors loosely spiralled around them making use of the natural spiral left behind when the metal winding mandrel was removed. Since the author has turned over the fabrication of these devices to Dr. T. Gordon, several improvements in the efficiency and uniformity of the manufacture of the devices have been made, including a greatly improved method for winding the conducting wires neatly on the central fibres. Using a plastic jig for rotating both ends of the central fibres at the same rate of speed, a much more uniform winding of the platinum-iridium wires can be achieved. In addition, recent improvements by both Dr. J.A. Hoffer and Dr. T. Gordon have resulted in a perfectly smooth cylindrical sheath surrounding a cable of spirally wound reinforced conductors which are embedded in a virtually flaw-free cylinder of silastic. This procedure has the very considerable advantage over the simple application of liquid silastic, of providing a sufficiently smooth external surface to discourage the device from bonding to connective tissue, which may pull on the nerve. A short section of silicone tubing is cut to length, and then placed for a few seconds in solvent such as toluene to induce it to swell. The solvent and silicone tubing may remain in contact for up to several minutes, depending on the amount of

expansion and increase in flexibility of the tubing required, and then the leads are threaded through the limp silicone tubing using a 15 cm long .010" steel wire needle to guide them through. Silastic type 891 Medical Adhesive Type "A" is then immediately injected for the entire length of the tubing using a syringe and a blunt-ended needle of a size which fits snugly inside the silastic tube. The silastic will flow smoothly around the inner cable, totally encasing it in what will later become a smooth, flexible, solid core of cured medical grade silicone rubber. The metal tip of the blunt-ended needle does not present a problem in injecting the liquid silicone elastomer into the silastic tubing, because the silastic tubing has expanded in a longitudinal mode as well as transversely during its exposure to the toluene. ence, it is considerably longer at this stage of the manufacturing process than it would otherwise be, and any trauma to the Teflon coating of the wires occurs at a point where the Teflon will be later stripped from the wires anyway. When the silastic has fully cured, the outer tubing has been restored to a shorter length, and the protruding Teflon-covered wires can then be prepared for use. At the cuff end of the bundle, the wires are allowed to retain the wavy shape that results from previous spiralling. This ensures that excessive tensions will not be developed across the wires when the silicone elastomer is allowed to cure on the cuff at a later stage of construction. Only the exact portion of wire which is to

serve as a conductive electrode portion is stripped of its Teflon, and this portion varies with the length of the wire, since the cable extends from one end of the cuff rather than from its centre. The longest lead is the one which is furthest from the bundle, and the leads are trimmed progressively shorter as the nearer end of the cuff is prepared, always retaining enough extra slack in the wire for the waviness that will ensure long life in the implantation. After the wires at the cuff end have been sewn in place to form the triple 90 degree arc ring electrode configurations, a layer of silastic is placed over the cuff, and this may be then wound with a layer of Teflon tape to provide a smooth surface and a cuff with a minimum outside diameter. Dr. T. Gordon has found that minimizing the embedded length of the support bundle of dacron fibres does not materially reduce the strength or life of the cuff, and that it offers an advantage in helping the cuff to resist warpage due to the differential tensions developed in the cuff when the outer silastic layer cures. Running the dacron fibres the full length of the cuff as was done in previous designs causes a tendency for the cuff to assume an arc-shaped deformation when the silicone cures.

Connections to the Percutaneous Interface Socket.

At the opposite end of the bundle, individual wires are carefully separated and the ends prepared with equal

lengths, approximately 1.5 cm from the exit point of the bundle. Teflon was removed from approximately 4 mm of each lead, following which the wire was wrapped around the terminal of an Augat 12-pin integrated circuit socket, (Augat 8058-1G51, Attleboro, Mass.) and soldered in place using Ersin multicore solder and a fine-tipped iron, (Wahl Isotip rechargeable.) A mixture of catalyzed Epon 812 mixture "B" was then prepared by combining 89 ml of NMA with 100 ml of Epon 812 and 0.14 ml of DMP - 30 accelerator per 10 grams of the combined NMA / Epon 812 mixture. The 3-component epoxy was then very thoroughly mixed, and a small amount placed over the backs of the soldered terminals of the Teflon socket. In instances where dimensional tolerances of the socket and carbon percutaneous connector resulted in a looser fit, two applications of the catalyzed epoxy at separate times were required. In other cases, a single application resulted in full encapsulation of the terminals. Sufficient epoxy was always applied to completely cover the solder joints, because the tin-lead metal content of the soldered joints represents a serious potential for future problems and should be regarded as only a temporary method of obtaining electrical connections with integrity. The epoxy layer slows down, but does not prevent the attack of the solder joints by body fluids. Cured silicone rubber elastomer is known to permit moisture transpiration, and epoxy does so as well, but at a slower rate. It is expected that ceramics or glass may present a solution to this

problem in ultra-high quality devices of the future, but it will be important to locate materials that can be fired in place at temperatures below that which cause degradation of the Teflon.

Finishing of completed cuff electrode assemblies.

The epoxy is cured by placing it in a thermostatically controlled oven at 70° C overnight, and the second layer of epoxy is mixed, applied, and cured on a subsequent separate application using the same techniques as the first layer. Finally, a thin coating of silastic elastomer is applied to the entire rear surface of the completed assembly to seal the coated leads mechanically to the connector, and to help ensure biocompatibility of all surfaces exposed to the tissues.

In devices made in 1979 and 1980 Dr. T. Gordon has been distributing the leads with radial symmetry from the centre of the device, and paying special attention to making the back portion of the final connector assembly as thin as possible, to minimize the chances of the connector being pulled or thrust out of the tissues, either by non-symmetrical forces acting on the leads causing the device to tip, or by excessive bulk of thickness behind the device causing pressure from the underlying tissues to force the device out of the skin. The thin, flat, symmetrical distribution of the leads on the latest devices appears to

be an important factor in insuring their longevity in implanted situations.

Surgical implantation of the cuffs

These procedures were done by Dr. L. Davis, Dr. T. Gordon, and Dr. R.B. Stein. Whenever an experimental procedure required that the nerve cuff remain in an animal for more than two days, aseptic surgical techniques were used. The skin was first shaven clean of fur and the area washed with soap and water. In some cases, remaining hair was removed with a depilatory cream such as "Neet." A disinfectant such as "Betadine" was applied to the skin prior to making the first incision to improve the sterility of the operating field. The device to be implanted had previously been sterilized. The nerve to be used was dissected free of underlying tissues carefully with attention to minimizing damage to its blood supply. A location was chosen for the percutaneous connector that offered easy accessibility and minimal chances of damage, as well as convenient placement with respect to the nerve. Frequently this would be a flat portion of the hip on the outside of the animal. A channel was made from the nerve to the site of this connector under the skin and the leads were passed through it, being careful to allow sufficient lead length and positioning away from joints so as to avoid

future tension problems on the leads. If a cuff slit had not been made previously, it could be made at this time, and the two sides of the cuff would then be opened using either a set of forceps or suture threads which had been previously incorporated for the purpose into the outside of the cuff material. The nerve was then gently slid into the cuff and the edges of the cuff carefully brought together and sutured at 3 mm intervals to positively and evenly close the slit to all fluids. In the earliest series of animals, the cuffs had been sealed with silicone. The silicone prevented excessive tissue ingrowth into the slit edge of the cuff, and also helped prevent E.M.G. signal degradation in the early devices. From ten to fifteen minutes were allowed to elapse to ensure the acetic acid released during curing had dissipated. A few instances of nerve damage from this cause were noted when initial mechanical closure was insufficient, or when silastic was forced through the slit under pressure, and the silastic sealing procedure was discontinued on later implants. An incision was made at the site for the percutaneous connector, which was pushed out through the incision as far as the top rim holding the socket. The outer flange having the peripheral holes remained below the skin surface and only the portion holding the 12-pin Teflon socket protruded above the skin.

The percutaneous connector was fastened in place with a suture in order to hold it in place long enough for connective tissue to penetrate the outer holes and fix the

device solidly in place in the skin. The question arises as to why the connector is not fastened firmly to something solid such as a bone or cartilaginous tissue. The answer to this question is that it would be distinctly disadvantageous to not have the connector float with the surface of the skin when the skin is depressed. The tissue bonding between the percutaneous connector and the skin can be disrupted by differential movement between the skin and the connector, and fastening the connector to some firm underlying structure would only increase the relative motion between the skin and the connector.

After all the cuffs had been placed around their respective nerves, and sufficient time had elapsed to permit the dissipation of acetic acid from the silastic (when this procedure was in use,) the incisions were sutured closed and the implantation procedure was then completed. The total time elapsed from the initial incision to the final closure for the implantation of a single percutaneous connector with a device having three cuffs could be approximately two hours.

The time taken for a first implantation in a human subject was approximately five hours, because considerable attention was paid to the research aspects and documentation. It is likely that future implantations will be more efficient in the use of the time that the patient is under anaesthetic due to the fact that such extended documentation and exploratory aspects will be less

important. It is quite possible that the collection of documentation data, the positioning of the electrodes, and actual implant of the device in future implant operations may be streamlined to the point where the patient need not be in the operating room for much more than an hour.

Recording Methods: Cuffs.

RECORDING METHODS.

Recordings were made in both animal and human subjects by simply inserting a 12-pin plug connected to a flexible insulated shielded cable into the socket in the percutaneous connector.

Advantages of plug-in recording.

No surgical intervention was necessary to obtain electrical access for either input or output purposes to any of the nerve cuffs or E.M.G. probe sites. This procedure offers a considerable advantage over previous recording methods because recordings made using this method may be initiated and sustained with a subject in a fully-conscious state, or even while he is moving.

Plug-in stimulation in humans.

In the case of human subjects, verbal feedback to the experimenter provides a unique and valuable source of detailed information concerning the thresholds of stimulation and qualitative differences in the stimulus resulting from changes made in the stimulator parameters such as pulse width, pulse frequency, and pulse amplitude, even though the subject may be walking or exercising. These subjective differences may then be compared with the stimuli observed by the subject when different channels of the implanted device are used. Different sites of neural stimulation, or stimulation of different nerves gives rise to qualitatively different subjective responses effectively opening up new channels of information flow into the human subject. Thus one channel of proprioceptive feedback may be used to indicate the hand grip pressure to the subject, while yet another independent channel of feedback could be used to make the subject aware of a totally different function of his prosthetic appliance, such as the elbow position or the angle of the wrist rotation.

Recording volitional activity.

In the recording mode, as opposed to the stimulating mode, the population response of the nerve fibres obtained by recording from large numbers of nerve cells simultaneously offers the advantage of averaging out the excessive variability which would otherwise characterise a

traditional recording of single cell activity. During actual behavioural activity, such as walking or excercising a muscle group, the neural and E.M.G. activities can be compared. In addition, electrical stimulation can be applied at any phase of the walking or movement cycle that the experimenter wishes. The ease of recording with this plug-in arrangement contributes to the humane aspects of obtaining larger amounts of research data from a single animal, without the need to sacrifice an animal after each experiment is concluded. The ability to use the same animal repeatedly for consecutive experiments is valuable for another reason, because it permits the study of long-term aspects of neural growth and development. These studies may include research on the trophic aspects of nerves, the regeneration of sensory or motor neurones, degenerative or disease-induced modifications of the nervous system, or factors influencing specificity of connection to end organs, muscles, and receptors.

An additional advantage of the neural cuff and implant method is that it permits the same animal to serve as its own control data reference over long periods of time, and factors which may influence the outcome of long term or trophic experiments such as diet variations, climate or temperature fluctuations or variations in the general health of the experimental animal population are largely cancelled out. The ability to plug in several individual and separately connected percutaneous connector plugs into one

single animal permits the investigation of the influence of the neural innervation on other internal organs as well. The influence of the vagus nerve on kidney function, and the associated implications regarding high blood pressure and cardiovascular function is an important example of a clinically-relevant experimental procedure which the nerve-cuff / percutaneous connector technique could facilitate.

Plug-in connectors.

The standardization of the recording cuff plugs in all experiments and with the human implant as well throughout the series has permitted the easy interchangeability of the test equipment and testing situation. One advantage of this standardized technique is that a situation could otherwise arise in which recordings were required, and were delayed due to unavailability of the connectors needed. A long-term experiment which may require a single animal's progress to be monitored over a period of several years could easily be compromised if special connectors were required and could only be obtained from a single source. For this reason, and the initial tradeoff between component availability, pin connection density, second-sourcing, and long-term insurance against the withdrawal of the connectors from the marketplace, a relatively simple socket configuration has been chosen. The project standardization has used the Augat

12-pin socket type 8058-1G51. (Augat Corp., Attleboro, Mass. U.S.A.)

Male connectors to fit this socket are difficult to obtain, so several approaches have been tried to provide a satisfactory mating cable assembly. In one approach, leads from a discarded integrated circuit were inserted into a female socket and individually soldered into the contacts. Each lead was then trimmed to the correct length. This approach provides a plug which mates very satisfactorily with the socket, but which is time-consuming to construct and which has rather fragile pins. It provides a plug which gives minimal physical abuse, torque or pressure to the socket during insertion or removal, and gives excellent low-resistance and low-noise electrical contacts. In a different approach, a second female socket may be mounted in tandem, by plugging it directly into the master socket. This procedure gives an exceptionally tight fit and may protect the original pins of the implant socket from physical damage. It is possible that a commercial manufacturer of a plug to fit these miniature integrated circuit sockets will be become available in the future.

One additional plug and socket combination that has been investigated and is currently undergoing evaluation for these devices is the ITT-Cannon subminiature socket type type MDA1-9SS, and the matching plug MDA1-9PS. These are small linearly-oriented devices, with relatively high pin density but which are unfortunately difficult to obtain and

are expensive.

External signal cables from animal.

Several approaches are possible with respect to shielded cables to connect the plug from the subject to the switching box. In one, a single shield covers the entire cable, with 12 individual color-coded wires inside carrying stimulus signals to the animal and recording signals back from the animal. This cable, type MS-12, has proven to be flexible and durable, and does not exert too high a torque on the connecting percutaneous connector. So long as neural impedances are considerably below 10 k ohms at 1 KHz, a negligible crosstalk occurs between channels during steady-state recording. When using an older style preamplifier however, which suffers from blocking and poor time-constants in its design, (The Grass P-15,) an unacceptable amount of crosstalk has occurred with this cable when using the stimulator during recording of higher-impedance neural signals.

A different type of recording cable may be constructed from three cables each of which contains four conductors. While the conductors are not separately shielded from each other, they are nevertheless shielded in groups of four. Thus it would be possible in theory to assign a given set of cables to all the functions that could reasonably be expected to be used for stimulation, and a set of separately

sheilded wires could always serve the function of recording. This assignment of function before the construction of the device could give much better stimulus-to-signal isolation than is presently being experienced.

Finally, an ultimate cable connection system would be one in which each individual wire is separately shielded and isolated from its neighbors, even at the levels of the plug and connector. For the highest-quality laboratory research and technical measurements in all potential combinations of lead configurations, this is the only configuration that would give complete stimulus-to-signal isolation. The present recording situation depends to a large extent on the low source impedance of the neural cuff electrodes to shunt the artifacts picked up capacitatively between the cable conductors. Naturally, such an individually-shielded cable would be stiffer and less flexible than the ones presently being used, and careful attention would have to be paid to the animal harness in order to avoid trauma to the skin-percutaneous connector interface. In order to avoid compromising the high crosstalk rejection offered by the individual cable shields, it would be necessary to shield each pin of the connector independently, or to run each output wire to an individual percutaneous connector. It is not considered that this degree of signal isolation is necessary at the present time, and therefore this approach has not yet been tried.

A reasonable compromise may be to install more than one

percutaneous connector per animal, and to assign all stimulating functions to one connector, and all recording functions to the other. This approach would probably eliminate most of the stimulator-induced artifacts that may cause problems in critical recording situations such as low-output nerves, high impedance cuff configurations, or single-unit recording. Whereas problems due to stimulus artifact may not show up on a real-time recording of a single sweep, cross-correlation and averaging may reveal drift, potential D.C. offset problems immediately following stimulation, and other low-level artifacts.

Signal-switching matrix and assignment of leads.

Neural signals available at any of the twelve leads from a single percutaneous connector are customarily taken to a switching matrix board where any single lead may be selected for individual examination of signal content, any pair of two leads may be examined for differential signal content, or any three leads may be used for differential recording with respect to a common reference. Ground leads may be chosen to minimize artifacts, the cuff ground itself may be added or left floating, and individual leads or pairs of leads may be selected to be used as stimulator electrodes. The versatility and convenience that this matrix offers largely offsets the drawbacks associated with having such a large area of low-level high-impedance signal

conductors exposed to potential electrostatic and electromagnetic interference fields. In particularly difficult recording situations, the input signal leads may be run directly to their own preamplifier bypassing the matrix and permitting an improved signal-to-noise ratio to be obtained.

Future standardization of the stimulating and recording electrode configurations will be required to make optimum use of telemetry devices, because the signal wires will no longer be accessible for ready interchangeability. It would appear to be valuable at the present time, therefore, to obtain experience with the tradeoffs and compromises that are necessary when implementing a more-rigidly controlled standardization of the stimulating and recording circuits than has previously been the case.

Grounding considerations and Hum.

The ideal recording situation is difficult to obtain, because of contradictory requirements with respect to equipment mounting, shielding, A.C. Power supply safety considerations, room shielding, and ground loop prevention. A shielded room has metal walls and fixtures; standard equipment mounting calls for the metal frame of all equipment to be fastened to the rack mounting frame; and A.C. power requirements set up a common ground connection between all power-operated equipment through the third pin

of the A.C. power outlets. The power wiring which provides this common ground connection is run inside conduit in close proximity to heavy-gauge wiring which may be carrying a substantial A.C. current. A magnetic field capable of introducing several millivolts of noise and A.C. 60 Hz and 120 Hz hum is induced into this ground cable at very low impedances. Thus the third gounding wire does not in fact present a quiet reference potential for the connected equipment as is commonly supposed. Rather, it behaves as an exceptionally low impedance A.C. generator, capable of forcing substantial A.C. currents to flow between equipment which is theoretically dependent upon it for a quiet ground connection. Professional audio recording studios avoid this problem to some extent by the use of balanced floating isolation transformers, which unfortunately introduce problems of sufficient magnitude to preclude their use as standard coupling interfaces in neurophysiological work. It is commonly assumed that simply mounting the equipment on a metal rack solidly with heavy duty bolts will provide a common grounding situation which presents a low enough impedance to nullify the deleterious effects of the A.C. power line ground induced hum loop. Unfortunately, the low impedance of the interfering ground loop, and the fact that it may be duplicated many times in a practical recording setup, causes substantial currents to flow between chassis which are nominally at the same ground potential. The lower the impedance of the recording equipment preamplifier

inputs, and the larger the shared common ground loop resistance is with respect to the input stages, the more serious this problem becomes. Frequently, the response to the appearance of hum on an oscilloscope trace is simply to add more grounds to a preparation which may already be redundant with them. Simply eliminating grounds is not the answer either, because of the necessity of maintaining adequate prevention of both electrostatic radiated interference and electromagnetically-coupled interference.

Solutions to Grounding Problems.

The correct approach is to restrict the grounding connections specifically to the stages involved in the signal transmission. For example, the only ground to the preparation should be obtained through exactly the same ground connection that provides the reference for the emitters of the input transistors in the preamplifier, and consequently the same ground that provides the reference for the power supply of that same stage. It is unfortunate that this second requirement is implicit in the first, because the presence of the power supply ground for the D.C. requirements of the initial preamplifier stage usually implies a connection somewhere to the chassis of the equipment housing that power supply.

Neural Impedance Matching and Common-Mode Rejection.

Textbooks frequently advise that neural preamplifiers have as high an input impedance as possible. Except for noise considerations, this statement has value, because shunting imbalance caused by lower impedance inputs on a signal from an unbalanced source impedance, is more serious than the shunting caused by a higher impedance preamp. However, the preamplifier loading impedance is seldom the dominant cause of signal imbalance in a real recording situation. More frequently, the signals actually present at the differential inputs already have different amplitudes, and interfering signals being propagated through the tissues may have differing phase and amplitude characteristics depending on their relative attenuation by those tissues. Hence, the input impedance of the preamplifier is not the main source of error. Only if the interfering signals obtained from the two differential inputs can be made to have identical amplitudes and phase relationships at the point in the preamplifier circuit where they are compared can the common-mode rejection characteristics of the differential configuration have optimum value. There is often an assumption implicit in the textbook explanation of the action of the differential preamplifier that the mere provision of a sufficiently high enough input impedance will automatically ensure a condition of equal amplitude signals and equal phase signals at the two inputs. In animal

recordings that is seldom the case. In fact, the recommended high impedance preamplifier may actually be one of the main sources of a poor signal-to-noise ratio when trying to record neural signals in the microvolt range from predominantly low impedance sources.

Neural Impedance Matching and Signal-To-Noise ratio.

Earlier experiments done by the author and Dr. Stein using Hammond transformers type 585 D and 585 F have shown the value of improving the signal-to-noise ratio of neural recording preparations by adjusting the input impedance of the recording equipment to an optimal level for the particular preparation being measured. In contrast to the textbook recommendation of highest-possible input impedances for neurophysiological work, these low-impedance transformers have already permitted the recording of many signals which could not otherwise have been isolated from background artifacts and E.M.G. These transformers are normally employed in professional audio work, and the initial samples had been used by the author for eliminating hum and noise in music recording situations. There exists an optimum input impedance for the input stage connected to any given preparation, with respect to maximizing the signal-to-noise ratio. The "mismatch" which results when these transformers are used to optimise any given nerve cuff preparation for signal -to-noise ratio at a given

centre-band frequency also introduces a bandpass filtering effect which has both beneficial and deleterious results.

Transformers and Neural Cuff Recordings.

Low frequency attenuation results from the interaction of the transformer with the essentially capacitative electrode-saline interface. High frequency attenuation results from loading the preamplifier secondary with the input capacitance of the preamplifier stage and its associated shielding and R.F. protection bypass capacitors. In addition, the transformer's own internal winding capacitance loads the secondary due to the high number of turns required to achieve a high-impedance, and a condition of mid-band resonance in the transformer is allowed to develop a moderately high Q due to the high resistance at the source or across the secondary. It is important to not attempt to introduce this damping artificially, because the signal is already at a very low level, and additional losses cannot be tolerated.

It is unfortunate that high frequency components of the signal are lost by the transformer so early in the recording process, because the presence of high frequency components early in the chain of signal processing equipment is generally considered advantageous to permit moderate rolloff of high frequency noise developed in the chain at a later point. Magnetic recording techniques are particularly bad in

this respect, and even F.M. recording machines introduce a considerable amount of noise due to the modulation often incurred from tape scrape and speed irregularity.

The low-frequency cutoff of the entire recording channel, and consequently, the tilt of square waves used to test very low frequency information loss, increases as cumulative errors are encountered throughout the recording system. The best way to ensure against excessive cumulative low-frequency phase shift errors is to design the entire recording chain so that it can handle D.C. levels. One unfortunate problem with a fully D.C.-coupled approach is that the electrode-tissue interface can inject substantial amounts of D.C. offset, which can add to errors incurred from other sources of D.C. drift, such as temperature differentials across balanced differential amplifier semiconductor junctions, and power supply instabilities. Nevertheless, D.C. coupling is likely a worthwhile goal because it presents the possibility of eventual low-frequency phase integrity.

When using the transformer, the D.C. resistance of the primary shunts out the signal more and more as the frequency of the signal decreases, due to the essentially-capacitative nature of the electrode saline interface. Thus, very low frequency offset and blocking effects are eliminated along with the D.C. potential developed at the electrodes.

Current-Mode Differential Recording.

The transformer helps to accomplish implementation of a true differential input situation by a mechanism which has not been previously discussed. The very low impedance of the primary forces current flow under the influence of the neural signal. Thus the current differences across the primary are substantially responsible for the induction of the voltage recorded across the secondary, and therefore each differential input must develop a current with respect to the other one before a signal is recorded. In a traditional high-impedance recording situation, each input is independently voltage-sensitive with respect to a common ground point, in addition to the differential sensitivity possessed with respect to the other input. High level common-mode signals can still pass unimpeded by causing overload of one or more of the stages of preamplification and upsetting the common-mode rejection characteristics of the equipment.

Recording Cuff Configuration and Common-Mode Rejection.

The cuffs commonly used are frequently connected in a configuration in which the two end rings are connected to each other, and the centre ring is used primarily for the signal recording with respect to the other two. So far as the tissue interface is concerned, the impedance to ground

of the two outside rings is considerably lower than that of the inside ring. One reason for this is the parallel connection, which exposes a greater metallic surface are area to the body fluids. The second reason is that the cuff contains neural and connective tissues, which present a much higher A.C. impedance than saline does. Thus the present configuration of the cuffs contains an intrinsic source of differential imbalance, which can best be dealt with by utilizing a low-impedance or current-flow mode of preamplification input, as compared to the more classical voltage gradient methods.

The problem is compounded by the fact that in a real recording situation, any two or more rings within a multi-ring cuff may be selected at the switching matrix to be in parallel. Additional factors in the recording situation may also contribute to artifacts. The interfering source may be closer to one end of the cuff and also lower in impedance with respect to one end of the cuff than it is to the other.

If the centre electrode were exactly centered electrically, that problem would be minimized. But even then, the tissues inside and outside the cuff will probably present a substantially different signal level to one input than to the other. If the preamplifier uses ground as a reference in any way, even via stray capacitative or resistive coupling, then a situation of potential E.M.G interference results. The E.M.G. source is invariably closer

to one end of the cuff than to the other, the resistivity of the nerve and connective tissues provides less than perfect cancellation due to diameter variations, and a variation in fit of the nerve may exist along the inside wall of the cuff. The walls of any practical cuff cannot be perfectly straight and parallel and of completely uniform diameter throughout the entire length of the cuff. The centre electrode cannot be placed exactly in the middle, and there is no way to ensure that even the best possible placement of the cuff will remain electrically balanced as connective tissue grows around one or both ends of the cuff.

Transformer Secondary Loading and Efficiency.

It is important to connect the transformer to a preamplifier having a high input impedance. Otherwise loading of the secondary will occur. The resultant loading may cause a loss in signal amplitude and a loss of high frequency components as well. A general rule of thumb which has been employed in many of the preliminary experiments was to use a transformer having a secondary impedance nominally of 100 K ohms connected to a preamplifier whose input impedance was at least 10 M ohms, and preferably 100 M ohms per side. Preamplifiers having substantially less than 10 megohms input impedance present a sufficient load to the secondary of the transformer that an excessivly low resistance will be reflected back to the preparation through

the primary, to the detriment of the signal-to-noise ratio.

One reason why transformers appear to be efficient is that they are not being forced into a flat frequency response mode of operation by the application of matching load resistances as is the case in professional audio recording applications; but rather are being encouraged to operate in an underdamped mode in which their own winding inductance and capacitance results in a mildly resonant midrange boost with low and high frequency rolloffs.

Transformers and Filtering at Frequency Extremes.

The metal-saline interface has been explored thoroughly by Robinson (1968) and Pollak (1974) in which the complex impedance characteristics of a metal implanted in a living body can be predicted. In general, even for the very highest quality long-term archival storage, recordings in which information may be gleaned by future signal processing at a later date, it is advisable to include at least one stage of capacitative coupling to avoid the effects of movement artifact, metal-to-tissue polarization offsets, and galvanic or electrolytic currents which may be strongly temperature or movement dependent. Many of these signals may contain little or no potential information worth recording; they are frequently very large in comparison with the signals desired; and they vary with time in an annoying and unpredictable manner. Even when the moderate slopes of first

and second order filtering are used, artifacts generated by one of these factors could overload one or more stages of amplification and cause severe clipping, dynamic recovery problems, blocking, or gain nonlinearity in the A.C. signal measurements of interest. Hence, in contrast to the high frequency rolloff controls which should ideally be located later on in the signal processing chain to attenuate any high frequency hiss or noise that may have been introduced, it is generally considered good practice to rid the signal of its stray D.C. components as early in the signal processing chain as possible. A recent trend in professional audio recording circles is to make this D.C. rejection at the input the exclusive source of D.C. rejection, and so far as is practical within the constraints imposed by temperature and power supply drift, to extend the other time constants of the entire recording chain downwards as close to D.C. as possible. It is important to the preservation of gain calibration reproducibility that the gain must remain stable in spite of fluctuations in operating points of the amplification devices caused by D.C. signal coupling and offset.

B. RESULTS: Cuff Electrode Studies.

Between November 1974 and February 1976, a total of 11 devices containing 25 cuffs were implanted on 55 hindlimb

nerves in 26 cats. The nerves used included the tibial nerve below the exit of the calf muscle nerves, the common peroneal, the superficial branch of the peroneal, the sciatic nerve below the hamstrings, and the sural nerves. Up to four cuffs were placed on different nerves within a single animal and a single cuff was used on up to ten different cat nerves.

Figure 6 illustrates changes observed via light microscopic examination when a cross section of lateral gastrocnemius-soleus which had a cuff on it for over nine months is compared with a control section from the comparable nerve on the opposite side of the same animal. One may observe a reduction in density of the largest diameter fibres. An independent counting of surviving fibre diameters and the plotting of their distribution on a histogram confirmed this reduction in fibre density.

The small reduction in numbers of the largest diameter fibres may have resulted from a compression of the nerve by the cuff and surrounding connective tissue, since it would appear that the largest diameter fibres are those which are most sensitive to compression.

In earlier implants a 5% incidence of nerve blockage was observed. this has been improved in the more recent implants by redesigning the cuffs to have greater flexibility, slightly looser fits, and by providing them with highly flexible leads which present a smooth slippery surface to the surrounding connective tissues.

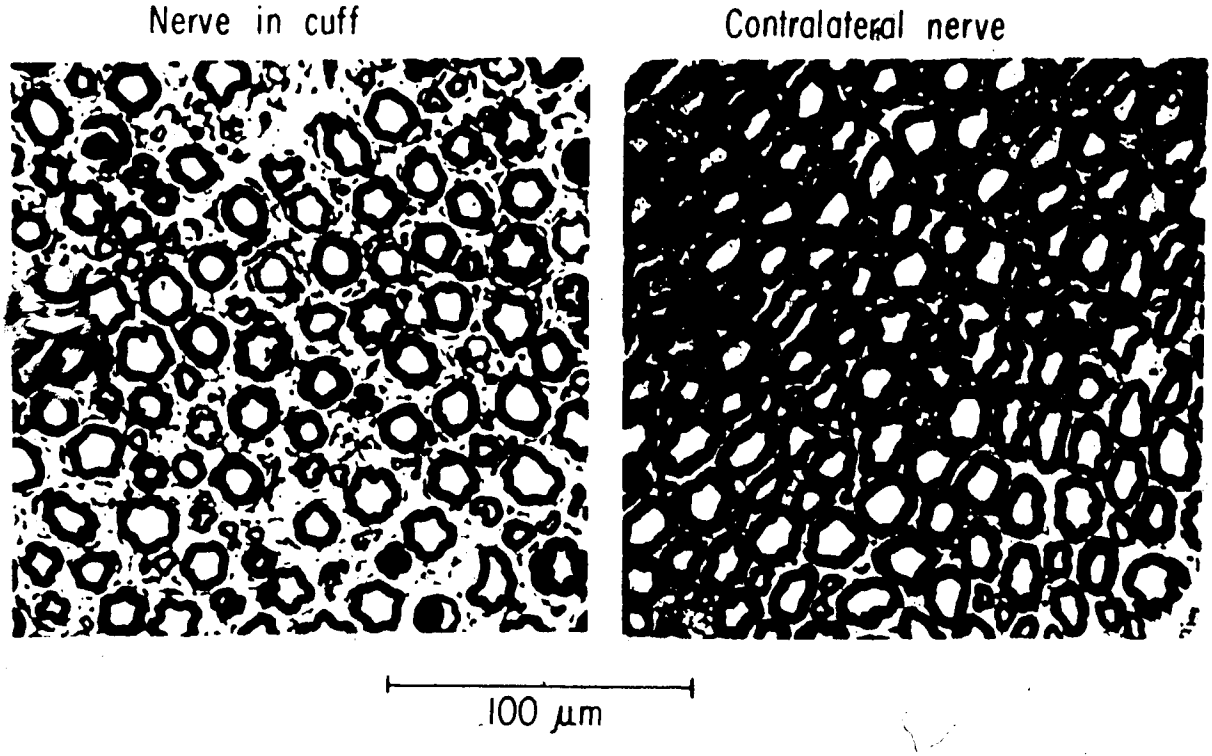


Fig. 6.
Light microscopy sections stained with methylene blue. Cross-sections taken from nerves (to lateral gastrocnemius and soleus muscles) which had been enclosed in a cuff for over nine months. and the corresponding nerve taken from the contralateral side of the same animal for comparison. Note the somewhat lower density of nerve fibres in the experimental nerve.

The implanted cuffs never caused infections, and careful examination for signs of inflammation or irritation showed only a few isolated examples of abnormal myelin growth or polymorphonuclear leucocytes in the nerve under examination by electron microscopy. The skin interface was acceptable in most instances, with connective tissue growing readily through the 2.5 mm holes provided in the flange of the most recent percutaneous connectors. Previous vitreous carbon percutaneous connectors had only been provided with 1.5 mm holes, and the tissue did not adhere as well as in the later devices. The improved methods for the construction of the leads resulted in no breakages in the 24 lead groups constructed for this study. This resistance to lead breakage was probably due to the helical windings of multiple-stranded platinum-iridium wire around central supporting fibres, as well as the wavy path followed by the leads within the body of the cuff itself.

Compound action potentials: Monophasic.

A classical compound action potential which is essentially monophasic except for a brief period of negative after-hyperpolarization is shown in Figure 7. This type of recording can be obtained by tying off a nerve, cutting the nerve, and then placing the end in a sealed cuff. A different cuff located proximally to the recording cuff may then be used for stimulation. One electrode was generally

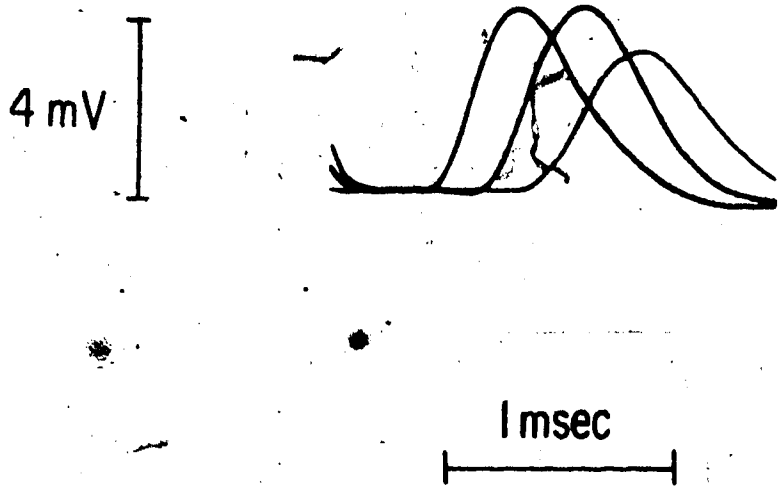


Fig. 7.

Compound action potentials recorded from cuffs monophasically. (With respect to a cut end in a cuff having one end sealed.) The electrode spacings for the above traces from left to right respectively were 5 cm, 3 cm, and 1 cm.

located near the cut end of the nerve, while others were spaced at intervals within the cuff at varying distances away from the point of ligation. The amplitude of the compound action potential with this arrangement was relatively independent of electrode spacing providing that the spacing was greater than 1 cm.

The spacing between the stimulating and recording electrodes and the particular nerves chosen for stimulating and recording influenced both amplitude and time course of the action potentials. Small signals, in the range of 4 to 8 millivolts resulted from stimulating the sciatic nerve while recording from the tibial nerve. Larger signals, however, were obtained from stimulating the sciatic nerve proximal to the point of hamstring emergence and recording more distally. These signals routinely produced action potentials of 10 millivolts or more.

The larger signals in this case result at least in part from the lack of dispersion in time of the action potentials due to the shorter distance between recording and stimulating electrodes and also by the fact that a tighter fitting cuff could safely be applied to the larger nerves without the danger of causing damage to them.

Compound action potentials: Biphasic.

Rather than using a cut nerve, two electrodes may be placed on an intact nerve and connected for recording. A

different waveform will be observed which is characterized by being the differential sum of two monophasic action potential pickup points. The new waveform may be termed "Biphasic." This waveform may be up to twice as large as the monophasic waveform, and is affected strongly by the distance between the electrodes, because the difference amplitude approaches the first differential of the action potential waveform. For very short distances between the recording electrodes, some cancellation takes place. As the distance is increased within limits, the amplitude increases. Measurements made on a living preparation agree well with theoretical predictions with respect to amplitude and waveform. The dependence on the interelectrode spacing distances of this type of recording configuration is shown in Figure 8.

Compound action potentials: Triphasic.

By recording from one central electrode with respect to two other electrodes spaced parallel and equally on either side of the central electrode, potentials termed "Triphasic" may be recorded. Normally, the centre electrode is placed midway between the two end electrodes in a cuff configuration, and equal spacing may be used for recording from a cut nerve in a sealed cuff. In designing a cuff for a specific nerve recording application, several factors must be taken into account because the amplitude depends strongly

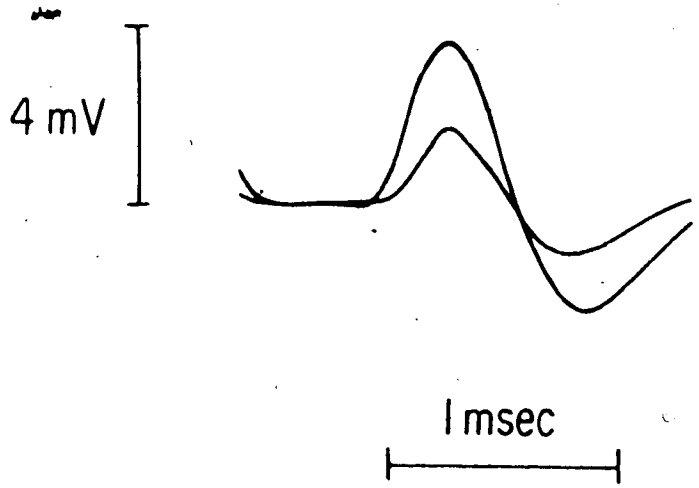


Fig.8.

Compound action potentials recorded from a nerve within a cuff using two electrodes placed on an intact nerve. (Biphasic recording.) The higher amplitude potential is recorded with an interelectrode spacing of 3 cm. The lower amplitude potential is recorded with an interelectrode spacing of 1 cm.

on the electrode spacings. For short nerve exposures the advantages of good E.M.G. rejection when feeding the signal into a classical balanced differential input can only be obtained at the expense of loss of signal amplitude. As the spacings between electodes are increased, the triphasic potentials recorded approach approximately 1.5 times the potential of the monophasic signals. The increase with distance is approximately proportional to the square of the distance for short interelectrode spacings.

[1] The recording configuration in which the two end rings of a cuff are shorted to each other can give information about the direction a neural impulse is travelling if absolute phase integrity is preserved throughout the recording channel. An inadvertent phase reversal would result in a potential misinterpretation of signal direction.

---

[1] It is proposed that the terms Monopolar, Bipolar, and Tripolar be distinguished from the terms Monophasic, Biphasic, and Triphasic by the following criterion:

The monopolar, bipolar and tripolar terms may be used to describe the recording electrode configuration, while the terms monophasic, biphasic, and triphasic could be reserved to describe the time course. Signals obtained would present respectively one peak, two peaks, and three peaks of amplitude with respect to time. Using this criterion, a monopolar recording would be one made with a single pickup point referred to a remotely located and truly indifferent electrode. A bipolar recording would be one made with two electrodes, and a tripolar recording would be one made with three electrodes. In this paper, the terms will be used interchangeably as they were in previously published work. However it is felt that a reduction in ambiguity may be afforded by a future implementation of more specific terminology.

Triphasic neural amplitudes as a function of interelectrode spacing changes are shown in Figure 9.

The frequency spectrum of signals obtained is affected by the choice of recording electrode configuration. The relative amplitude of the higher frequency components of the composite neural signal as compared to the lower frequency components increases when the change is made from monophasic to biphasic. An increase is observed when going from biphasic to triphasic. This effect is due to the progressive cancellation of the lower frequency components by the differential recording configuration caused by their broader spatial wavelength distribution within the nerve bundle. Shorter wavelength action potentials may be recorded more selectively by the relatively closer-spaced electrodes. The dispersion increases along the bundle the further away from the stimulating site the recording is taken. When the spectral content of various neural recording situations is compared, it may be noted that a maximal spectral peak observed for neural signals elicited by the stimulator is found at approximately 1 KHz. The spectral content of nerves carrying volitional signals having a wider dispersion and greater randomness within the bundle may be higher, say at 2 KHz for example.

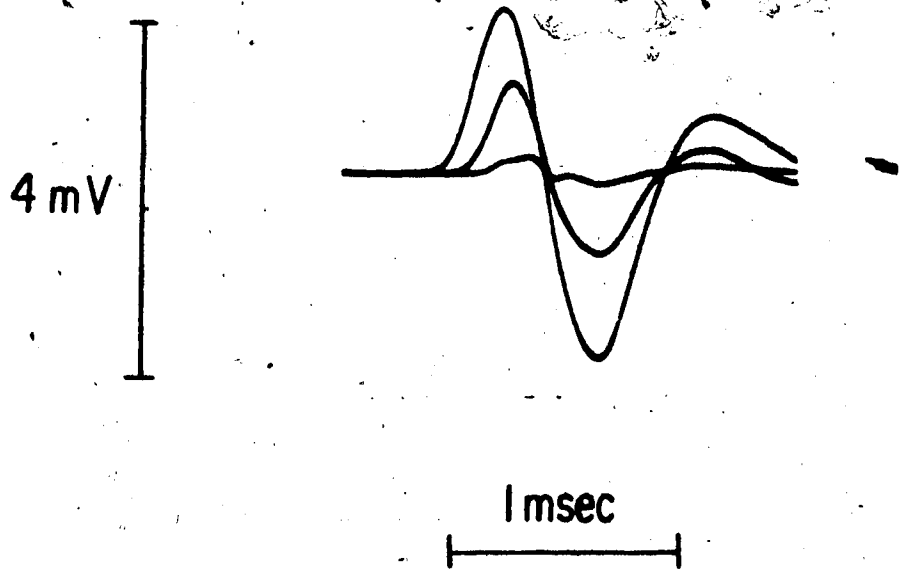


Fig. 9.

Compound action potentials recorded from an intact nerve within a cuff having three electrodes. The two outer electrodes are connected to each other, and the signal is recorded differentially between the centre pickup electrode and the two outside ones. The largest amplitude of signal represents an interelectrode spacing of 5 cm. The medium size amplitude of signal is recorded with interelectrode spacing of 3 cm. The smallest potential of all is recorded with an interelectrode spacing of only 1 cm. Note the marked dependence of the triphasic potentials on electrode spacing.

Stability of the Neural signals over longer time periods.

By applying a stimulus to one cuff, and recording in the tripolar configuration through a different cuff, the stability of the neural signals was studied over a 6 month period. Figure 10 illustrates the stability of action potentials both with respect to latency and amplitude in an experimental animal in which signals were recorded from the sural nerve while stimulating the sciatic nerve, and vice versa.

Figure 11 A illustrates the E.M.G. signals present at the centre of a typical cuff on a tibial nerve when recording with respect to an external ground electrode on the outside of the cuff. From 10 to 30 millivolts of compound action potential of muscle origin can be observed, occuring later in time than the associated neural signal. The delays are due to the neuromuscular transmission and the delays associated with the propagation of the contraction within the muscle group.

When the surrounding muscles were carefully denervated, a clean neural signal could be observed, of approximately one-third the amplitude that the E.M.G. signals had exhibited. Since the E.M.G. signals characteristically arise from muscle membranes which have a higher capacitance than neural membranes and a greater volume through which the activity must propagate, their longer lasting potentials are

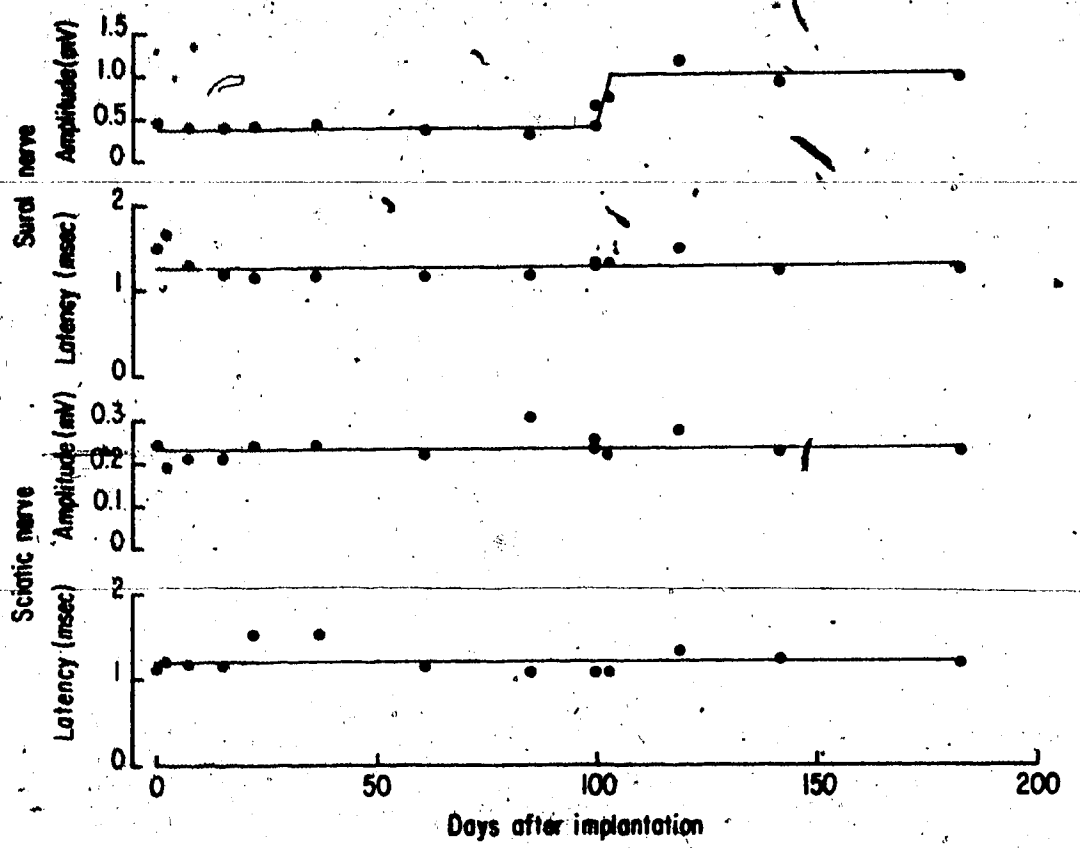


Fig.10.

Stability of neural signals recorded via cuff electrodes on the sural nerve while stimulating the sciatic nerve via a different cuff. (Top two traces.) All recordings were made using the tripolar cuffs.

Stability of neural signals recorded via cuff electrodes on the sciatic nerve while stimulating the sural nerve via a different cuff. (Bottom two traces.) Note long-term stability of both amplitude and latency.

readily recognizable when compared to the shorter time course of the neural potentials.

Figure 11 B illustrates a recording having a poor ratio of neural to E.M.G. signals. This was made using two leads in a bipolar configuration within a cuff on an intact tibial nerve. The relatively close spacing of the leads results in some cancellation of signal, and the increase in E.M.G. pickup may be accounted for by the positioning of the electrodes in a linear spacing rather than essentially parallel and separated by an insulating surface as they were in the first instance.

Figure 11 C illustrates the remarkable improvement that can be obtained with the use of three electrodes inside the recording cuff. In this case, the recording is made from the centre one with repect to the two outside ends, after the two outside ends are connected in parallel with each other.

A very much improved ratio of neural signal to E.M.G. signal results, with the neural signal predominating, and the E.M.G. signal sppressed almost completely. This connection gives such excellent rejection of outside interference that neural recordings of good stability and fully suitable for detailed analysis were consistently obtained even from animals walking on a motor-driven treadmill. The room in which these recordings were made contained two digital computers, fluorescent lighting, unshielded power wiring and other serious sources of electromagnetic and electrostatic interference. In addition,

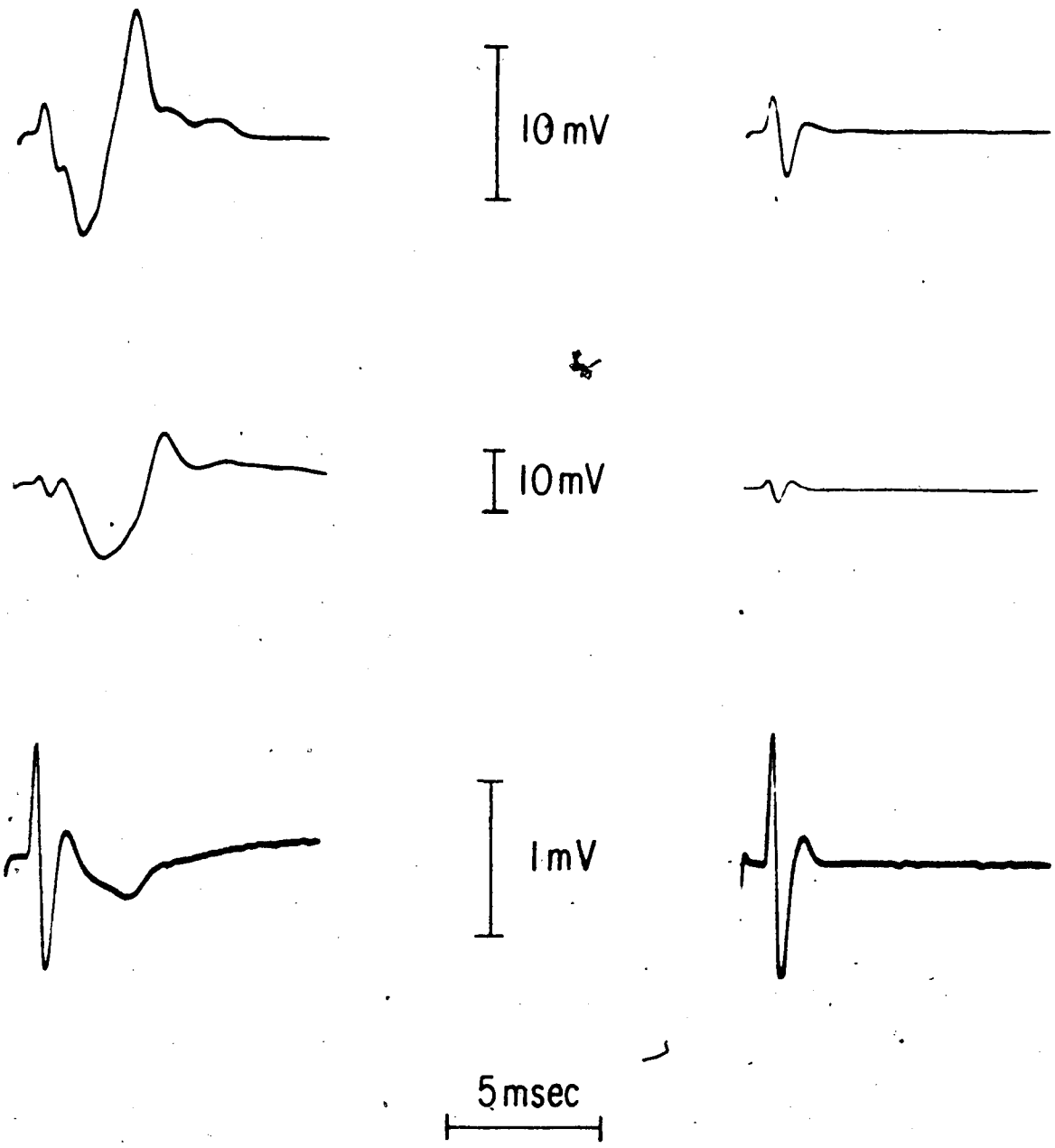


Fig. 11A (Top) Monopolar recording with respect to cuff ground

Fig. 11B (Centre) Bipolar recording. Two leads in cuff on tibial.

Fig. 11C (Bottom) Tripolar recording, note improved signal.

the animal's own fur represented a significant source of high-voltage static electricity impulse discharge. Nevertheless, useful recordings could be made, illustrating the power of the three-electrode cuff configuration for rejecting interference.

Single Unit Recordings.

In order to explore the contributions from different types and sizes of fibres to the compound action potentials discussed, an arrangement was made to record single fibres.

Figure 12 shows a relatively long portion of a tibial nerve (5cm.), which was inserted in a cuff having multiple electrodes. In this example, three separate preamplifiers could be connected to provide simultaneous monopolar, bipolar, and tripolar recordings from the same nerve. On-line averaging was used to improve the signal-to-noise ratio of the outputs of these preamplifiers. A Tektronix (Model 5403,) storage oscilloscope was used to visually identify the presence of an all-or-none neural signal. Stimulus rates of 20-30 per second were employed and the use of averaging at several different stimulus intensities was employed to check that the waveforms were of the correct shape and invariability. By recording from the roots instead of the peripheral ends of the nerves, back stimulation was used in some cases. An all-or-none criterion for the identification of single units was used. Noise obscured the

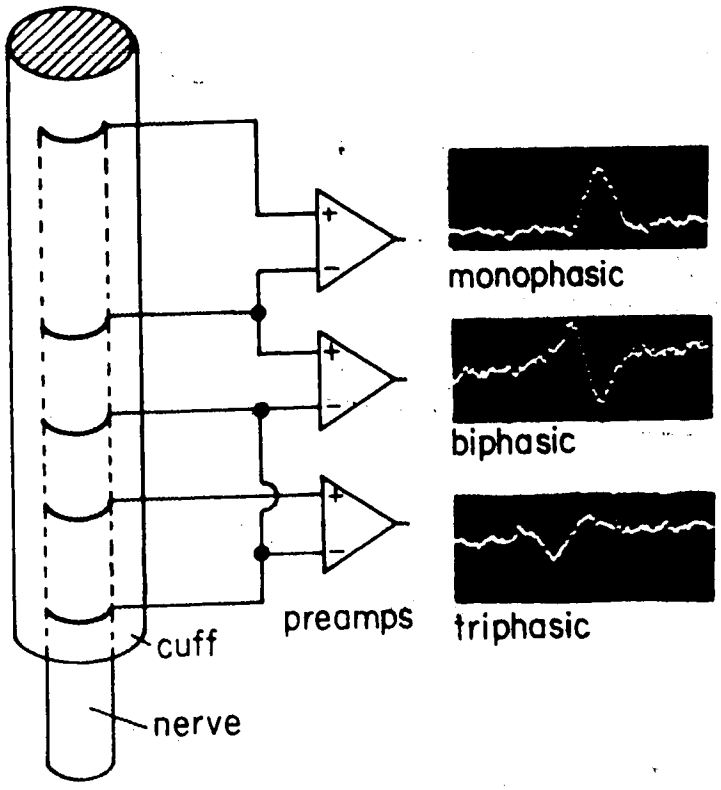


Fig. 12.

Cuff electrode arrangement for recording simultaneous monopolar, bipolar, and tripolar signals from the intact tibial nerve. Single-unit neural recordings may be obtained from this configuration using on-line signal averaging techniques.

positive corroboration of this criterion in some cases particularly where very small fibres with slow conduction velocities and slow amplitudes were encountered. The spacing of the electrodes in the earlier cut-nerve experiments was approximately 2 cm. 108 single units were identified from sciatic, tibial, and sural nerves by the stimulation of individual dorsal root filiaments.

Figure 13 illustrates the peak-to-peak amplitudes of a number of units with respect to conduction velocities. The closeness of the slopes to the value 2 for all three methods of recording implies that the amplitude of the action potential increases approximately as the square of the conduction velocity of the fibres. In five experiments using the tibial nerve, the mean + / - S.D. of the slopes were measured as follows:

1. Monopolar:
2. Bipolar: 2.12 +/- 0.417
3. Tripolar: 1.7 +/- 0.122

Except for larger amplitudes from the sural nerve and smaller amplitudes from the sciatic nerve, the results were similiar on other nerves. The contributions to volitional activity come mainly from the larger fibres because of the relationship between fibre diameter and conduction velocity.

Although the slope on a log-log plot did not differ significantly from the value "2" for monopolar or bipolar recording configurations, the departure from the second

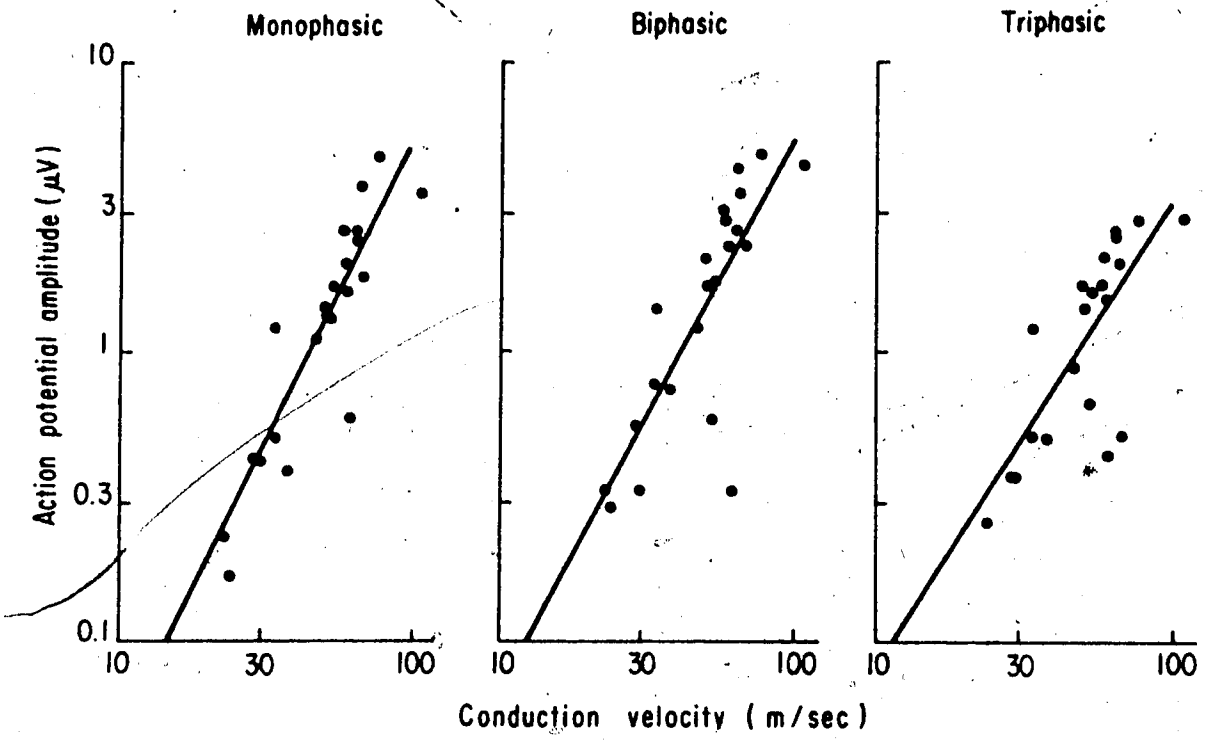


Fig. 13.

The peak-to-peak amplitudes of action potentials from single sensory fibres are plotted as a function of the conduction velocities of the fibres. The method used is that described in the preceeding illustration. The best fitting straight lines in the sense of least mean square deviations have been drawn on double logarithmic scales. The slopes are all near the value of two, which implies that the amplitude increases approximately as the square of the conduction velocity of the sensory fibres. All sensory fibres shown were isolated in one acute experiment.

power relationship in the tripolar recording configuration may be accounted for by the fact that a 2 cm spacing between the electrode rings cannot provide a sufficient length for the signals to devlop their maximum value. Slower conducting fibres approach the maximum amplitudes with shorter interelectrode spacings than do the faster conducting fibres.

For most monopolar recordings the amplitude V may be given by the following equation.

$$V = Vi\ (a/d)^2.$$

(Where "Vi" is the intracellularly recorded action potential, "a" is the fibre diameter, and "d" is the internal diameter of the cuff.)

If the peak to peak amplitude of the intracellular action potential were assumed to be 120 mV, "a" measured in micrometers, and "d" in millimeters, the equation becomes

$$V = 0.12\ (a/d)^2 \text{ Microvolts.}$$

For example, the predicted amplitude for a fibre of 10 micrometers in diameter having a conduction velocity of approximately 60 meters per second in a cuff with a diameter of 2.6 mm would be 1.78 microvolts. A 5 micrometers diameter fibre having a conduction velocity of 30 m/sec would give an amplitude of 0.44 microvolts.

Comparison of these values with a straight line of best fit applied to the data of Figure 13 results in values of 1.8 microvolts and 0.43 microvolts respectively, showing an

excellent agreement of the practical measurements with those that had been predicted.

Consideration of the theoretical minimum noise level which could be expected at any given value of impedance implies that easy detection of a single unit would require an amplitude of at least double the noise value. The inference is that single units in the tibial nerve for example would require diameters of at least 10 micrometers to be detected, but with a fine nerve such as the sural nerve, fibres having conduction velocities less than 20 m/sec might be detected. The implications for prosthetic applications are that smaller-diameter fibres and cuffs might prove applicable for discrete prosthetic control applications, such as individual digit control. Finer operation of the prosthetic devices could result from such applications.

Cuffs 0.9 mm in diameter could be predicted to give signals almost 9 times larger than cuffs with 2.6 mm internal diameter. When working with nerves this fine, however, it is necessary to use extreme care to ensure that there is no mechanical trauma to the nerve. Ducker and Hayes recommend cuffs 40% larger than the nerve to be used in clinical nerve resuturing operations. Tighter fitting cuffs may result in the loss of larger fibres, It may be assumed that further improvements in the design of nerve cuffs will result in less trauma to the nerves.

One method by which this might be accomplished would be

to make the cuffs from lighter, thinner and more flexible material. The nerve could have increased freedom to move within the cuff by making the conducting surfaces part of a flat deposit on the inside of the cuff rather than as tight wires which can stretch across the diameter of the cuff and cut into the edge of the nerve. Even finer stranded wire could be used, and further improvements to the cabling method used to prevent breakage will help prevent tugging on the nerve. The coreless spiral wire configuration originally used by Hoffer without a central wire support may also be useful in fabricating cuffs for the smallest most delicate nerves, since this method produces a connecting cable of superior ductility and flexibility as well as a desired degree of limpness which the standard cables do not possess.

It would also appear that the absence of nerve block is very much a function of the skill and experience of the surgeon doing the implant procedure. The most rapid implantation technique is not necessarily the most gentle or careful one. Operating procedures are subject to ongoing revision. Modifications in operating technique are based on the outcome of implant operations with regard to the functionality of the nerve and the longevity of the implanted devices.

Future telemetry and other transcutaneous coupling techniques will presumably still require that the neural cuff be connected to the transponder capsule via a flexible connection. Similiar constraints on cuff tightness, sealing

methods, suture techniques and methods of holding the implant at the desired location will presumably still apply. Therefore, experience gained in these areas in the present experiments will still have value when the vitreous carbon connector is no longer used exclusively.

Impedance Measurements.

By repeating a standardized impedance measurement technique at intervals over a period of several months, it was possible to monitor changes in the condition of the nerve and the electrode itself, as well as certain other physiological changes such as the growth of connective tissue, the presence of shunting fluid, or the displacement of the electrode.

The impedance of all leads was routinely measured at a frequency of 1000 Hz to check for continuity, shorts, wire breakage and leakage.

Certain electrodes were selected individually and in combinations to study the effects of frequency on impedance variations. For example, two otherwise identical cuffs were compared for impedance variation as a function of wire material. Figure 14 shows the impedance of 75 micrometers platinum-iridium and silver wires three to four weeks after implantation in a cuff around the sciatic nerve. The recordings were made between the central electrode and the

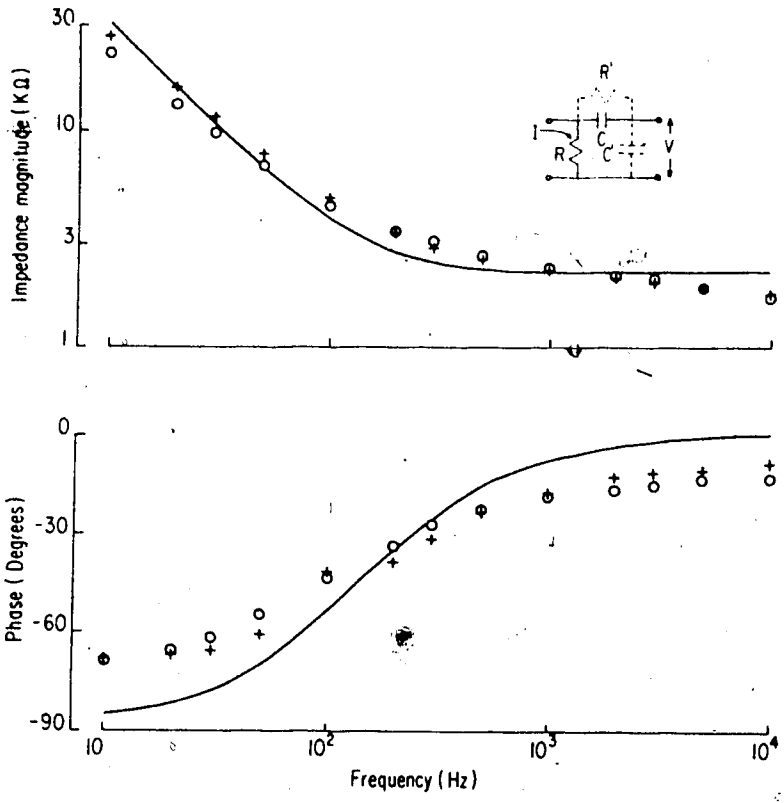


Fig. 14.

Impedance and phase shift introduced by silver (+) and by platinum-iridium electrodes (o) after three to four weeks of time in cuff implanted around cat sciatic nerve. Impedance and phase shift are plotted as a function of frequency from 10 Hz to 10 k Hz. Solid line curves are predictions from the simple model R - C circuit shown in inset where R = 2.2 k ohms, C = 0.51 microfarads.

two end electrodes connected in parallel.

The effective resistivity increases in the first few weeks after implantation to values of 200 to 250 ohm-centimeters with either silver or platinum-iridium electrodes. This increase may be due to the replacement of fluid in the cuff by connective tissue rather than to any properties associated with the electrodes themselves.

Changes in low-frequency impedance are shown in Figure 15. These are different between silver electrodes and platinum-iridium electrodes. They are probably a function of the electrode material properties. The impedance of silver remained constant or increased over a period of time; likely due to a formation of ever-increasing thicknesses of silver chloride. The impedance of the platinum-iridium electrodes on the other hand declined slowly over a few months and then stabilized at a value approximately 25% lower than its original value. The cause for this may be the gradual increase in the effective surface area of the wire electrodes due to a roughening effect caused by platinization. After a few months, (typically two to four months), the silver electrode wires became brittle and disintegrated. On removing them for examination from the animals, they were found to be white and powdery in texture and the remaining wire easily fractured into tiny sections at the slightest touch.

One very important fact which may be drawn from this observation is that the external silicone tubing, the

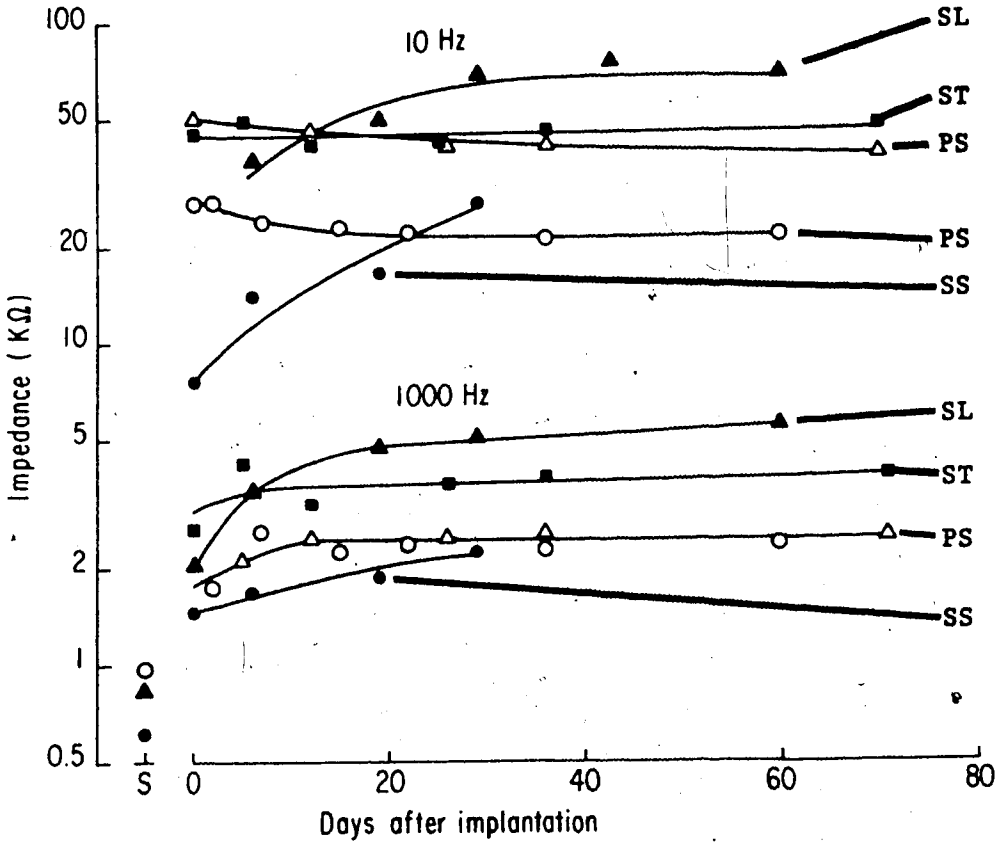


Fig. 15.

Magnitude of the impedance of electrodes at a low frequency, (10 Hz) and at a relatively high frequency (1000 Hz) as a function of time after the implantation of the devices. The impedance of some of the devices were measured prior to implantation at 1000 Hz in physiological saline. The impedances were measured between an electrode in the centre of the cuff with respect to the two end electrodes tied together. Metals and nerves are identified as follows:

1. Silver, tibial nerve:"ST"
2. Silver, sciatic nerve:"SS"
3. Silver, lateral gastrocnemius-soleus nerve: "SL"
4. Platinum-Iridium sciatic nerves: "PS"

internal silicone coating, and the Teflon insulation were insufficient to prevent the passage of chemically active substances across the insulation. It is known that Dow Corning Medical Adhesive (Type "A") liberates acetic acid while it is curing, and that water is absorbed from the atmosphere during this process. Although the material is generally thought of as being biocompatible, it is not a good insulator, since it permits the passage of body fluids. It is not a good barrier to the passage of ions which may react chemically with the wire surface. It should be noted that Teflon coating of the thickness encountered on the wires used is also insufficient to thoroughly isolate the highly reactive body fluids. Future implant improvements could implement an increased thickness of this layer. There may be other materials having better chemical and moisture resistance than the two tested to date. The severe corrosion encounted with silver that was presumably well-protected illustrates the necessity of having absolutely perfect hermetic seals in any future telemetry implant devices.

Once the chemical susceptibility of silver wires had been established, all subsequent electrode assemblies intended for long-term implant use were made from the platinum-iridium alloy 10% iridium, 90% platinum, (Medwire part number 10Ir/49T, stranded.)

The electrical impedance properties of the platinum-iridium alloy electrodes were studied over a period of five months, during which impedances of electrodes in

eight cuffs were assessed.

Figure 16 shows the changes in impedance plotted as a function of time over a period of 150 days as well as standard error of the mean at 10 Hz and 1 KHz. The use of sciatic cuffs of a standard length and diameter permitted a calculation of the resistivity of the tissues, which ranged from 200 ohm-cm to 250 ohm-cm. The 1 KHz impedance of the electrode-tissue interfaces increased approximately 30% in the first two months following implantation, and began to gradually decrease along an approximately parabolic curve in the two months that followed. The later decline was not seen as clearly in a variety of smaller cat nerves studied, and also was not observed in mouse nerves similiarly studied. The impedance of all electrodes at 10Hz was exceptionally stable, indicating a very low chemical change in the surface of the platinum-iridium material under biological conditions.

Since all of these recordings had been made with intact normal nerves, it was of interest to explore what impedance variations could be observed when severed nerves were used, as would be the case when these techniques were applied to prosthetic control applications in amputees. For this purpose, cuffs 5 cm in length were placed on the posterior tibial nerves of cats. The nerves were cut, and the difference in impedance between any two leads at 1 Hz was set as a criterion for the monitoring of any possible changes in tissue resistivity. The impedance changes over a

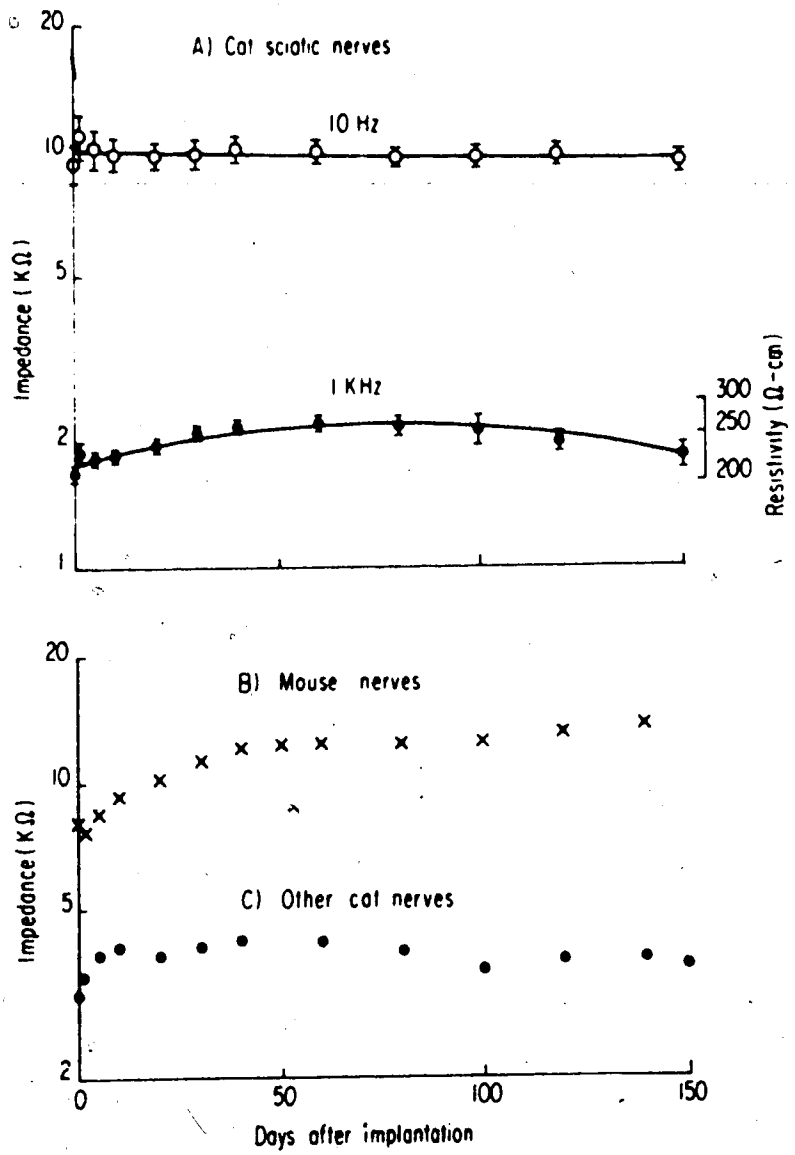


Fig. 16. A. Changes in impedance of eight platinum-iridium electrodes implanted on sciatic nerves of cats. The symbols give the means and the standard errors of the mean (shown by the vertical extent marks in "A"). The changes in impedance are plotted at 10 Hz and at 1 KHz for 150 days.

B. Changes in impedance at 1 KHz of three electrode units implanted on nerves in mice. (Small sample does not permit statistical analysis.)

C. Changes in impedance at 1KHz of ten electrode units (Pt-Ir) impanted on branches of sciatic nerves in cats. No statistical analysis or curve fitting because of the wide variety of smaller nerves used.

period of five months following implantation are shown in Figure 17.

The cut end of the nerve in each instance was next to electrode "A". Within two days from the time of cutting the nerve, a marked change occurred in the first centimeter of the nerve, possibly due to the swelling of the nerve caused by blockage of axoplasmic transport next to the ligature. A less-marked increase in impedance occurred the further away from the cut the measurements were taken. This change became negligible a few centimeters from the cut end. In the two weeks that followed, a marked decrease in impedance was observed, particularly in the first centimeter. This observation is consistent with the histological observation that a cut nerve first degenerates back to the first node of Ranvier.

Within three weeks a smaller increase in impedance was often observed, followed by a slow and gradual decline of impedance as fibres gradually decreased in diameter.

A less pronounced change in impedance further from the cut end was attributed to an ingrowth of connective tissue similiar to that observed when recording from intact nerves. This was manifested as a slow increase in impedance measurements. The reason for the slow decline in cat sciatic nerve impedance after two or three months of implantation however, is less clear. One possibility is that some nerve fibres degeneratated, resulting in replacement of high impedance tissues such as myelin with tissues of lower

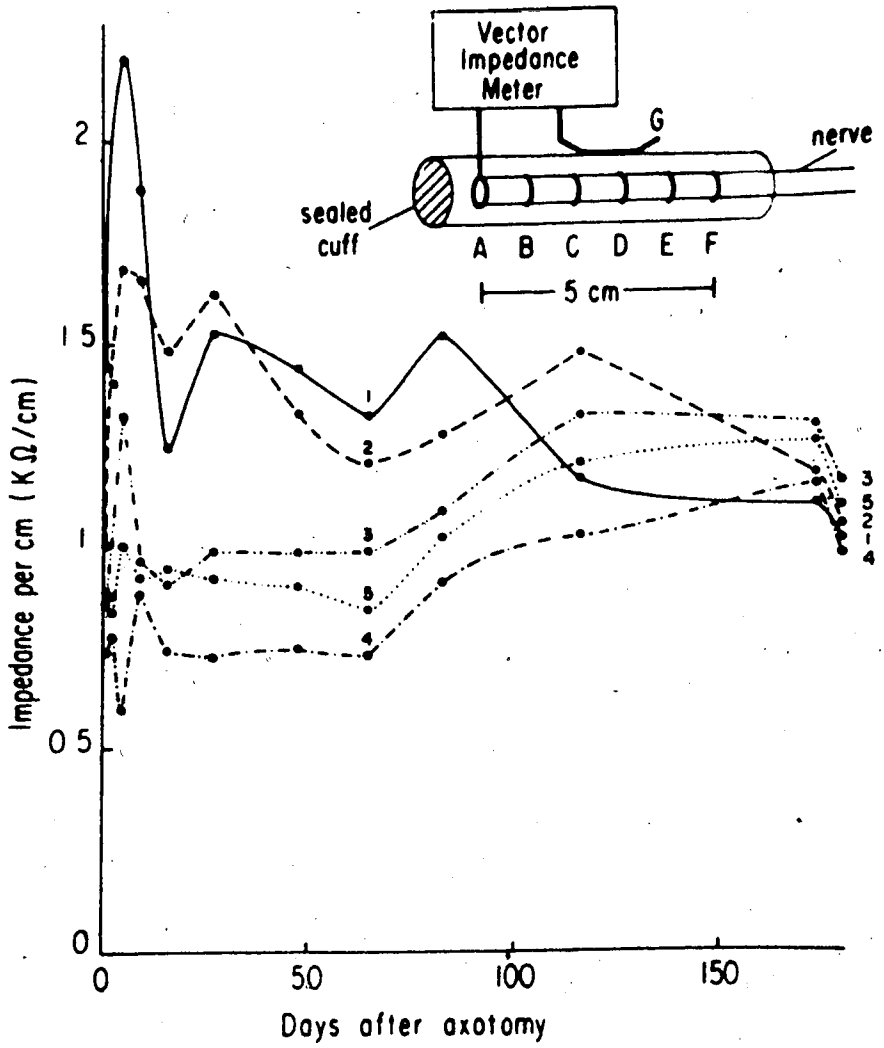


Fig. 17.

Impedance changes over time at varying distances from the sealed end of a cuff containing a cut tibial nerve. The differences in impedance between any two leads adjacent to one another at 1 Hz gave a measure of the resistance of the tissue within the cuff, measured in ohms x 10^3 per centimetre. Initial changes are most pronounced closest to the cut end which is placed inside the sealed end of the cuff. (Curve 1.). Later rise in impedances due to connective tissue ingrowth is more pronounced towards the open end of the cuff (Curves 3 to 5.).

impedance or fluid. In nerve cuffs which had been fitted in accordance with the recommendations of Ducker and Hayes (1968), at a size 40% larger in diameter than the peripheral nerves to be fitted, a later decline in impedance was less obvious or absent. Those sciatic nerves which exhibited the impedance decline had filled the cuffs relatively tightly. The impedance decline and inferred degeneration was of a small degree, however, and not of sufficient magnitude to preclude their use in either clinical or research studies.

The changes associated with the surface effects on the metal of the electrodes themselves, and their chemical interaction with the tissues is best understood in terms of a model of the interface. The model adopted offers the simplest theoretical approximation that can explain the behaviour of the metal-tissue interface.

Figure 18 shows a model circuit in which the complex impedance of the metal-tissue interface is reduced to its simplest resistive and capacitative components. The resistance R is due to the fluid and tissue within the cuff because the resistance of the metal wires is negligible by comparison. D.C. wire resistances were routinely measured at less than 10 ohms. The capacitance C may be considered to be due to the well-known double layer formation at the electrode-fluid interface, which has been extensively studied by physical chemists. (Bockris, J. and Reddy, A. 1970.)

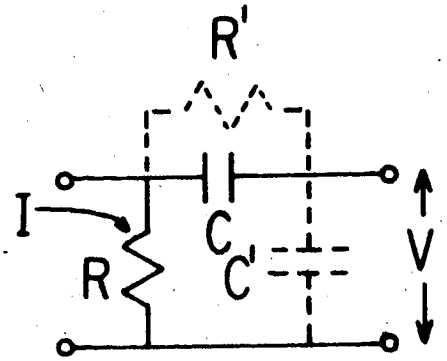


Fig. 18

Schematic diagram of the simplest circuit which may be used to model the complex impedance of the metal-tissue interface in terms of only its resistive and capacitative components. The capacitance "C" is due primarily to the double layer which forms at the metal-fluid-tissue interface as explored by Bockris and Reddy. Resistance "R^1" is only significant with non-polarizable electrodes such as chlorided silver wires. Capacitance C^1 is due to stray capacitances to ground in the connecting leads, the neural cuff and the preamp.

In a situation where the electrodes are rendered non-polarisable by a surface coating such as silver chloride in the case of silver wires, then the resistance R1 is also a factor in the model circuit. This resistance acts to limit the impedance at low frequencies to a finite value. An unchlorided silver wire or a noncorroded platinum-iridium wire is a polarizable electrode which does not pass small D.C. currents. For voltages in the range of biological signals, the impedance becomes very high as the frequency approaches zero. Over the frequency range from 10 Hz to 10,000 Hz this resistance did not become a factor in the experimental procedures used.

As the recording equipment is improved in low-frequency response and as interest is extended to examine wider ranges of electrode impedances it is likely that this initial model will be expanded. Nonlinearity can occur at higher voltages, such as are encountered during stimulation, and electrolytic polarization effects probably take place, with some possibility of metal ions being released at the surface of the electrode. How these trace materials affect the physiological function of normal tissues or the more sensitive regrowth of regenerating neurons is a field for future study. It is likely that electrolytic rectification or polarization effects introduce considerable distortion of waveforms at very low frequencies or at higher voltage levels and tests have not yet been done to determine whether these are a function of different electrode materials or

different surface treatments of the wires, such as platinized or electrodeposited surfaces. The direct current produced by metal to tissue contact has also not been explored for its effect on tissue regeneration or normal function in the present studies. The use of any dissimiliar metals can cause appreciable current flow in tissues which until recently have been considered to be of negligible physiological consequence. It has been shown however that even very minute currents influence tissue development to a surprising degree. (Marino et al, 1977.)

The only physical location in the present implant series where dissimiliar metals are encountered is on the interior surface of the Teflon socket where the platinum-iridium wires are fastened to the brass and gold plated pins with tin-lead solder. It is assumed that the relatively thick layer of epoxy and silastic that has been applied over this surface is sufficient to prevent any substantial ionic effects. There is, however, no hard and fast proof that such a condition actually exists outside of a casual examination of the connections following extended implant periods. As the socket bulk and thickness are reduced, to help eliminate percutaneous long-term displacement, the protective layers may become thin enough for ionic currents to be generated that influence neural regeneration. The presence of the epoxy and silastic insulation would serve to prolong this effect and extend the electromotive capabilities of the buried dissimiliar metals

over a period of years. Visual inspection of the terminals discloses no corrosion, but the possibility should not be discounted nevertheless.

The signals coupled into the platinum-iridium wire by the capacitative interface of the double-layer function "C" are already limited in their ultimate low frequency response by the time constant formed by the preamplifier or transformer input resistance.

Since the biological preparation is inherently capacitatively coupled by the physical and chemical characteristics of the saline-electrode interface, further capacitative coupling into the preamplifer causes little degradation of the signal, providing that sufficiently long time constants are employed. Up to 22 microfarads of capacitance into an input impedance of one megohm have been used. This long a time constant preserves low-frequency detail in the signals being recorded, yet passes only a small amount of the movement artifact.

The stray shunt capacitance to ground and to other leads in the electrode assembly and cable is interpreted as a sum and represented by capacitor C1 of the theoretical model. In practice, this capacitance is not negligible and is detected as an influence which decreases the upper frequency components of the recorded signals. It may be seen as a capacitative reactance which is measurable on the Hewlett-Packard Vector Impedance Meter (Model 4800A.). The instrument also registers a change in high frequency phase

angle which becomes apparent using frequencies in the vicinity of 10 KHz. The absolute values of this capacitance are difficult to measure, in part because the high frequency phase angle measurements of the instrument are sensitive to the stray capacitances to ground of either or both of its inputs.

Instructions provided with the Hewlett-Packard Mode 4800 Impedance Meter leave no doubt that measurements made of small capacitances at high frequencies with this unit should be done only with a preparation which is truly isolated from all ground surfaces in both a resistive and capacitative sense. Practical considerations of data collection make this criterion difficult to achieve on a day-to-day basis, but it represents one area of instrumentation which holds promise for future improvement.

The extent to which the actual preparations deviated from the theoretical capacitative coupling could be inferred from the fact that the phase angle would frequently be in the vicinity of 70 degrees, as illustrated in Figure 14. A true capacitor would give a phase lag of 90 degrees. The departure of the impedance from a linear function at very low frequencies is also an indication that the physical chemistry of the electrode-fluid interface is in effect in the experimental situation.

The magnitude of these low frequency nonlinearities was, however, not considered sufficient to prevent using low frequency impedance changes over long periods of time as an

indication of electrode and tissue changes.

The model circuit predicts constant impedance as frequency is increased and a phase angle approaching zero. The practical experimental measurements give a changing impedance as frequency is increased, and a phase not approaching zero. The mechanisms postulated to account for the difference include the effects of stray capacity and the Warburg impedance. (Pollak, V. 1974).

The Warburg impedance would exhibit a constant phase lag of 45 degrees. Metal needle electrodes generally exhibit a decrease in impedance v.s. frequency which results in a slope of -1/2 on log-log plots. The dependence of impedance on frequency was not as steep in the present series as it would be with wire electrodes possibly because of the increased surface area exposed in the present electrodes. This would result in a larger effective coupling capacitance C1. Tissue and fluid filling the cuff are the major sources of measurable impedance at a frequency of 1 KHz, whereas the changes in impedance at 10 Hz allow a measurement of the properties of the metal electrode surface itself. The values calculated for the impedance of the tissues agrees well with those previously obtained by Tasaki. (Tasaki, I. 1964.)

IV. PROSTHETIC APPLICATIONS.

A. IMPLANTABLE PROSTHETIC CONTROL DEVICES

Neural considerations: Survival and Impulse Conduction.

The concept of providing neuroelectric control for a powered prosthesis is related to studies on long-term trophic interactions between nerve and muscle because prosthetic applications require that the nerve survive and conduct useful impulses. Three important questions arise when a nerve is severed, as would be the case in an amputation.

1. When nerve cells are deprived of their end organ, do they survive?

2. Is this survival more or less indefinite over a period of years ?

3. If nerves survive, do they retain the ability to conduct action potentials?

4. Are action potentials actually generated and transmitted down nerves even though no end organs may have been present for many years?

5. Do these action potentials exist during phases of voluntary movement when they would normally be expected to occur?

Although many studies have been done using other techniques, only one other study previously had approached the problem from the direct and unambiguous method of chronic recording. (DeLuca and Gilmore, 1976.)

A wide disparity of opinion existed in the literature. Ranson (1906), has stated that nerve fibres survive axotomy for many years.

Studies quoted in Sunderland (1972), show variations in survival from 6% to 83%. This wide a range indicates wide differences of opinion on the matter.

As recently as 1972, Ernst Guttman stated that in the absence of regeneration, the nerve cell atrophies entirely and is replaced by neuroglial cells. (Guttman, E. 1972.)

More agreement exists regarding the second question, the ability of nerve cells to conduct after axotomy where conditions exist for their survival. In cut nerves ending in neuromas, the conduction velocities proximal to the point of section are reduced to 50% to 80% of the previous control values by 300 days following axotomy. (Cragg & Thomas, 1961.)

Methods which allowed individual animals to be monitored for activity during that time were not used in that study, and the scattering of data obtained suggests

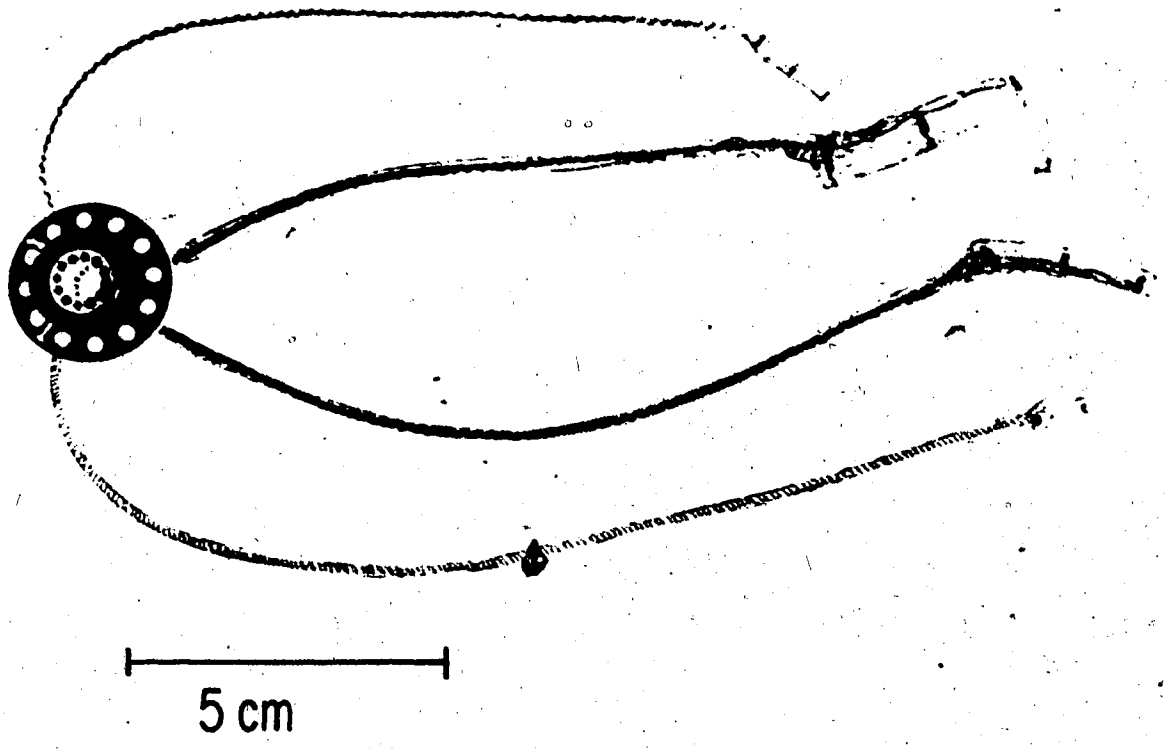


Fig. 19

Photograph of teflon 12-pin socket in vitreous carbon percutaneous connector, having flexible cables reinforced with dacron to three nerve cuffs of different sizes, and one unreinforced flexible cable to an E.M.G. probe, (Bottom.) This device may be used to explore questions basic to neuromuscular connections and eventually to answer questions basic to the control of powered prostheses from neural and/or E.M.G. implants.

that the cuff recording method may be of considerable value during future studies of that type.

The answer to the question of whether amputated nerves continue to fire with signals that would normally be present during movements in which they previously participated is the most interesting and pertinent one with respect to neural control of prosthetic appliances.

Mendell, Munson, and Scott, (1976), have described a drop ranging from 94% to 70% in the connection between muscle spindle primary afferent fibres and motoneurons within 1 to 2 months following axotomy.

Purves. (Purves, D. 1976.) found that following the cutting of post-ganglionic fibres a 70% loss of synaptic connections occured so that even a supramaximal stimulation to the preganglionic nerve would not activate more than a quarter of the ganglion cells. If a relatively large number of connections were required to remain intact for the co-ordinated activation of electrically powered and neurally controlled prosthetic devices, it is possible that enough control would be lost to render the procedure impractical.

Thus studies were done and still continue in our laboratory to answer some of these pertinent questions. Figure 19 illustrates three nerve cuffs of different sizes designed to fit around different peripheral nerves, and one E.M.G. probe. Each nerve cuff is fitted with three ring electrodes as previously described.

Animals were anaesthetized with Fluothane and

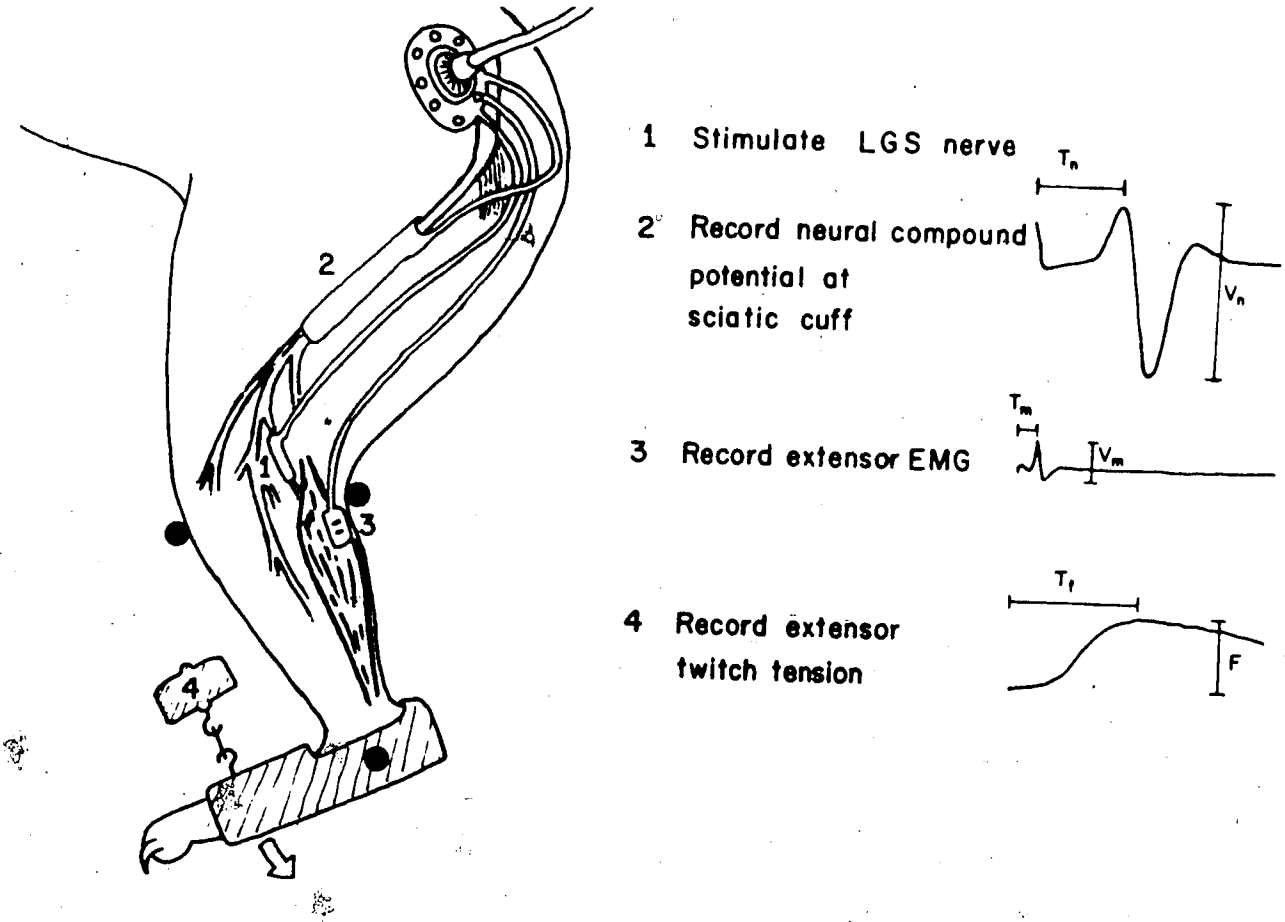


Fig. 20.
Methods for measuring nerve and muscle activity in chronic animals. In the example shown nerve cuffs were implanted on the sciatic and lateral gastrocnemius-soleus nerves. An E.M.G. probe was implanted on the ankle extensors. Tension was measured when required with a special boot.

individual nerves were stimulated while other nerves and muscles were monitored for the purposes of recordings.

In Figure 20 the lateral gastrocnemius-soleus nerve was stimulated and the latency and amplitude of the compound action potential was recorded from the sciatic nerve. Simultaneous recordings were made of the E.M.G. from the muscles of the ankle extensors as well as a monitoring of the neural signals associated with the movement. These same nerves could also be monitored while the animal walked in a normal manner. Thus sensory and motor impulses from all fibres in the nerve could be obtained under actual volitional activity originating from higher centres, as the animal performed the reproducible task of walking on a treadmill.

Figure 21 shows the separation of sensory from motor components obtained by the use of cross-correlation techniques. Two sets of electrodes in one cuff could be used for recording, or two separate cuffs could be compared for the time of arrival of signals. Sensory impulses conducting in a given direction with velocity "v." will arrive at one set of electrodes a short time

(Delta t = l/v),

before arrival at the second set of electrodes (Where l = the distance between the central electrodes in each set).

Motor impulses, on the other hand, conduct in the opposite direction and will arrive at the second set of electrodes first. The cross-correlation method reveals two

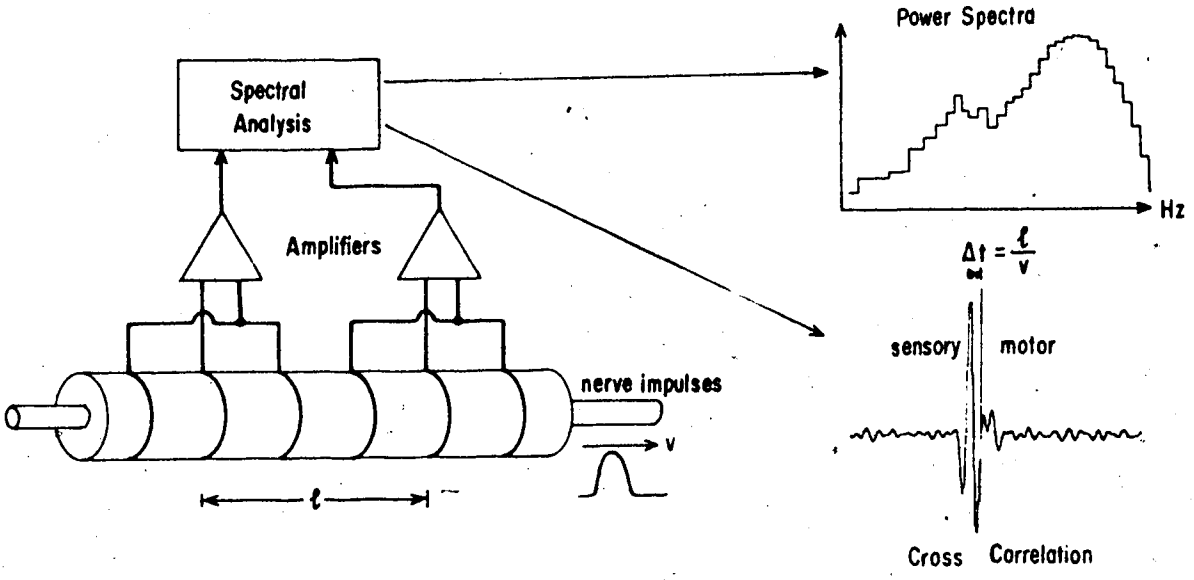


Fig. 21.

Using two sets of recording electrodes and spectral analysis, sensory nerve impulses conducting from left to right can be distinguished from motor nerve impulses conducting from right to left. The amount of each type of activity during a behavioural task can be measured from the peaks in the cross-correlation function shown on the right.

positive peaks on either side of the origin corresponding to motor and sensory information. The cross correlation function was calculated via the method of spectral analysis described by French and Holden. (French, A.S. and Holden, A.V., 1971.)

Electrical studies on pressure-induced nerve block.

The convenience and reproducibility of the recordings obtained via the percutaneous connector technique led to a routine of regular monitoring of neural activity in all animals underging implant. The evoked compound action potentials under anaesthesia could be studied with the reproducibility afforded by electrical stimulation, or true behavioural / volitional signals could be studied as the animal walked on a treadmill. In many animals the values remained useful and steady following implantation. In some, trauma to the nerve during surgery or tension on the device due to movements of the limb resulted in a pressure block of neural activity.

Sometimes nerve block would recover spontaneously, and at other times surgical procedures were undertaken to determine the cause of the trauma and insofar as possible relieve the pressure.

The fine details of the recovery or decline of the neural potentials could be followed throughout the months, and the effects of the surgical interventions to relieve

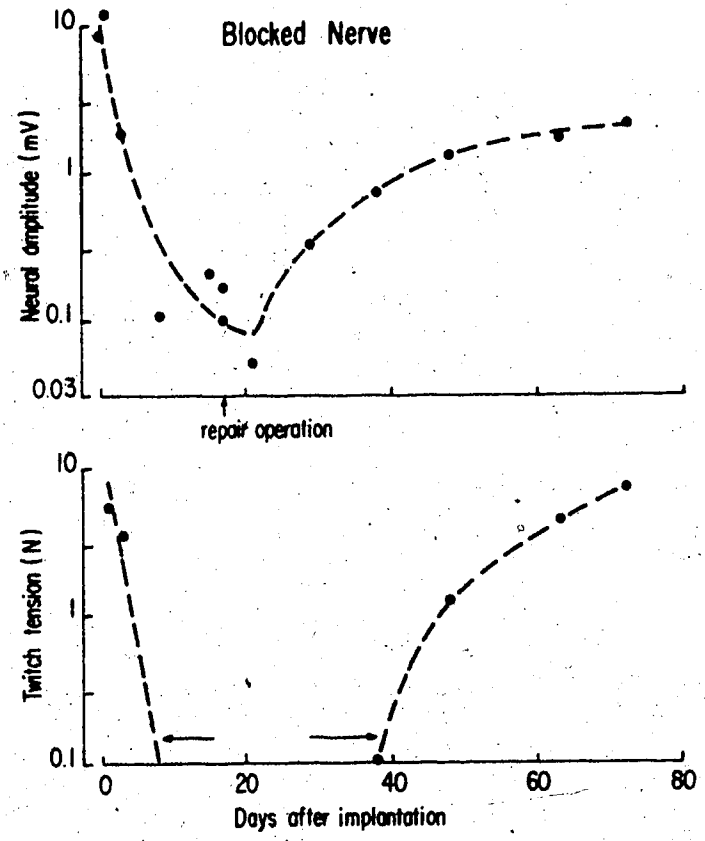


Fig. 22.

Compound neural potential (upper part) and twitch tension (lower part) recorded after a nerve block on a common peroneal nerve. The full time course of the changes in the nerve could be studied even during the period when neuromuscular transmission was blocked. Ordinates are logarithmic.

pressure block could be studied and compared. Surgical intervention usually did not change the time-course of the recovery with respect to electrical potentials obtained but it did increase the final amplitude

Table 1

shows results in 14 nerves studied. The surgical revisions of the pressure situation resulted in a 62% attainment of the original control values whereas implants that were not revised only recovered on the average to 38% of the control. The exponential shape of the recovery curves permitted an extrapolation to be made to predict the final amplitudes to be expected. Even when the amplitude of the compound action potential did not recover fully, as in Figure 22, . the tension frequently recovered to control values. This result may be due to the innervation of all available muscle fibres by those motorneurons which were successful in regenerating back as far as the muscle.

Some nerves were cut and ligated, with a section removed distal to the ligation to hinder regeneration. When these nerves were monitored with cuff electrodes, the changes following the cut and ligation could be observed. Latency increased about 30% as shown in Figure 23, . and the amplitude of the compound action potentials decreased to about a quarter of control values. An exponential curve fitted these amplitude changes, with a time constant of about 45 days. Individual nerves monitored for over a year

TABLE 1

Comparison of amplitude recovery in nerves fitted with cuff electrodes. Amplitudes are compared between seven nerves in which a subsequent use of surgical intervention attempted to releive pressure block or other trauma, and seven nerve implants in which this was not done.

	Revision	No Revision
Number of nerves:	7	7
Initial amplitudes: (geometric means in mV)	1.88	2.27
Minimum amplitudes, mV:	0.08	0.09
Percentage of initial value before block:	4% (*)	4% (*)
Last measured values, mV:	1.17	0.87
Last measured values expressed as percentage of initial value before blockage:	62%	38% (*)
Projected recovery value, mV:	1.90	1.15
expressed as percentage of initial vlues before block:	101%	51% (*)

(Values that were significantly different from the initial values before block are indicated by (*) with $P < 0.001$.)

showed no further substantial decline.

This result proves that cut nerves do, in fact survive and retain the ability to conduct action potentials for long periods of time even when they are not allowed to regenerate to suitable end organs.

The implications of this finding for prosthetic research are that a great improvement could be made in the naturalness and usefulness of present powered prosthetic appliances. This is assuming, of course, that the answers to the other questions raised are positive.

Nerves were cut cleanly and then resutured to their distal stumps to imitate the situation which frequently occurs in surgical nerve repair procedures. For a comparative procedure, other nerves were cut and sutured into the fascia of nearby muscle which had just been denervated. Following the nerve-to-nerve sutures, both motorneurones and sensory fibres grew back and eventually reinnervated their own appropriate end organs.

As shown in Figure 24, the results could be fitted with two exponential curves. The decay of amplitudes recorded had the same time constant as if the nerves had been tied but an additional exponential recovery process may be seen extending over a period of three to four months. The process took longer than recovery from a nerve block and the amplitudes obtained later in recording were not usually as high.

Measurements of amplitude and latency did not show any

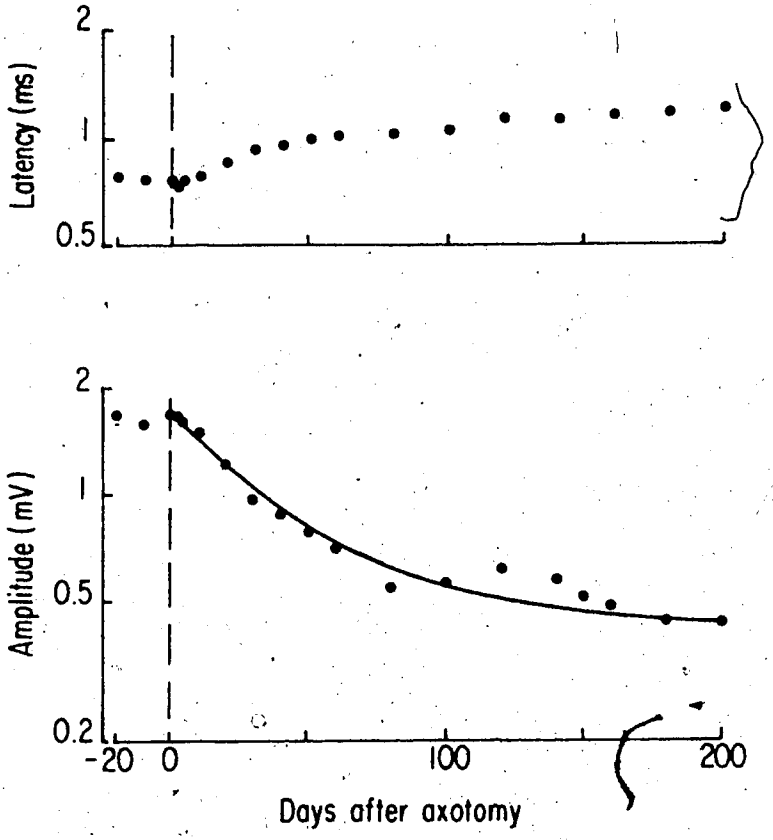


Fig. 23.

Mean latency to peak and amplitude of compound action potentials for three ligated nerves which were followed for over 200 days after axotomy. The decline in amplitude is fitted with a single exponential with a time constant of 45 days and a final value one-fourth of the control value before axotomy.

significant differences between the results of nerve-nerve resuturing and nerve-muscle suturing. Both procedures resulted in a recovery of compound action potentials and an improvement in conduction velocity. Figure 25 , illustrates the comparison between compound action potentials obtained via synchronous stimulation under anaesthesia, with the asynchronous volitional nerve impulses which were obtained during walking on the treadmill.

The asynchronous activity was much smaller in amplitude, measuring in microvolts rather than the millivolts that are obtained under the more artificial conditions of the synchronous volleys elicited by the stimulator. In order to obtain comparable units for both volitional and non-volitional neural activity, it was necessary to multiply the values of the compound action potentials by themselves. This gave the units of mV^2 shown in Figure 25. This procedure was implemented because the motor potentials obtained by the cross-correlation technique are in uV^2 due to having been obtained from two sets of electrodes and correlated.

The compound action potentials elicited by the stimulator declined as shown in Figure 25 for ligated nerves and recovered after the re-suturing of the nerve. Volitional activity followed a similiar pattern, but with important differences. The motor signals tended to decline more rapidly during the first month than did evoked potentials but then the motor signals declined less rapidly or even

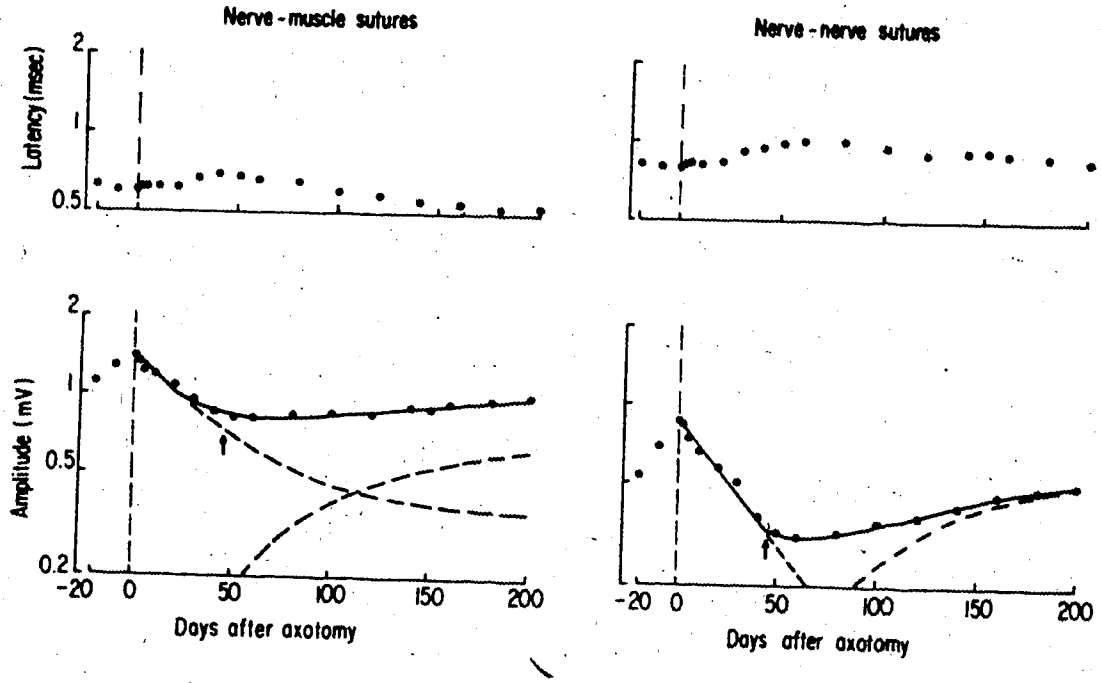


Fig. 24.

Changes in latency and amplitude as when nerves were cut and either sutured into a muscle (left) or resutured to the distal nerve stumps (right). The arrows indicate the mean time at which reinnervation occurred. Note the recovery in amplitude and decline in latency which began within a week or so of innervation. The dashed lines in each part represent a decaying exponential with the same time constant as shown previously, and an exponential recovery curve with longer time constants (3-4 months.). The solid lines represent the sums of these two exponential curves.

recovered afterwards. The ligated peroneal nerve example illustrates this phenomenon. Even though the evoked potentials continued to decline, the motor activity first declined rapidly then actually recovered.

This rapid initial decrease in motor activity is consistent with the concept that synaptic contacts are lost from motorneurones due to chromatolytic reactions following neural damage.

Improved performance of the motor signals at 150 days suggests that some physiological process is taking place more or less simultaneously throughout the affected neural population and that the observed improvement may be due to a partial return of these synaptic contacts to a functioning state.

Another possibility is that the lack of discrimination in the evoked potentials results in the inclusion of both sensory and motor fibres in the impulse population. By 150 days, sensory activity components may still be missing from the evoked potential recordings, as indicated by the fact that at 30 days sensory activity could not be found. Control recordings from motor volitional potentials do not depend on this component for their amplitude, and hence are not valid as an indicator of its absence when sensory reinnervation does not occur.

One may infer that nerve section may have more severe effects on sensory fibres than on motor fibres. In other experimental studies, (Gordon, Hoffer, Jhamandas, and Stein,

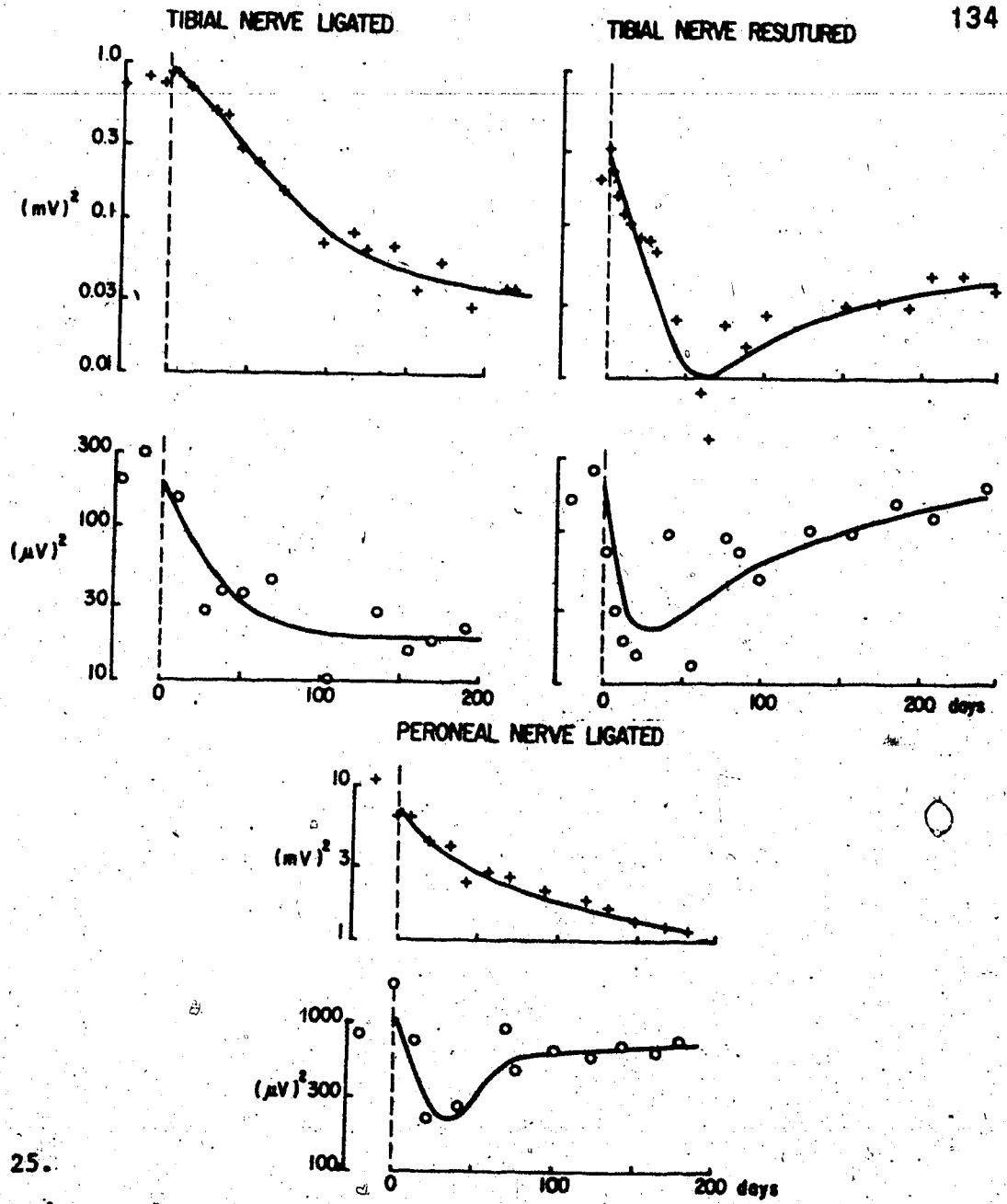


Fig. 25.

Comparison of compound action potentials (Upper traces in mV^2.) and asynchronous motor activity, (Lower traces in microvolts^2) from cats walking on a treadmill. Motor activity was measured using the cross-correlation technique between two sets of electrodes and the compound action potentials measured at the same two sets of electrodes were multiplied for comparison. Note that the motor activity declines more than the compound action potentials in the first month, but declines less (or recovers more) at later times (100-200 days). A transformer with a turns ratio of 1:20 was used during walking as described in the text. The values in the lower traces have not been corrected for the amplitude difference introduced by the transformer.

1980), the spinal cord had been exposed for the recording of action potentials in both dorsal and ventral roots during the stimulation of peripheral nerves on both sides of the body. It was noted that dorsal root values were reduced from 2.5 to 10 times that of the ventral root values when the same nerve on the contralateral side was used as a control during stimulation.

Implantation in a human amputee.

The fact that results obtained up to this time indicated a positive answer to all three questions asked earlier with respect to the validity and usefulness of neural impulses and long term nerve function following axotomy suggested that information be obtained from a clinical trial in a human amputee. Since one important area of powered prosthetic improvements deals with questions of sensory feedback, these areas are of paramount concern even though they do not easily lend themselves to numerical quantification.

The first patient to be selected for neural / E.M.G. implants was a 63 year old Caucasian who, during the second world war, had sustained a short left below-elbow amputation. The remaining extremity showed no evidence of neuromata and had a well-healed non adherent painless scar tissue covering. Proximal portions of the muscle groups extensor carpii radialis brevis and longus muscles were

present and strong. Flexor carpi ulnaris and flexor carpi radialis were present but weak. Minimal pronation or supination of the extremity was possible although the range of motion of the elbow was normal.

Portions of pronator teres and supinator muscles were examined by needle E.M.G. tests by Dr. R.G. Lee and these were found to be available and functional. Since the original amputation the subject had worn a number of different prosthetic appliances including a conventional cosmetic "working hand," which offered little functional value and was difficult to use.

The patient had been fitted in 1974 with an Otto Bock Myoelectric hand in Minneapolis. This hand had the conventional single degree of freedom, in that it could be opened and closed, but no active wrist rotation existed.

Adjustment of the hand angle had to be made by the patient stopping whatever work he was doing, gripping the artificial hand with his real hand, and actively twisting the artificial hand to a new angle.

The hand functioned reasonably well in many body positions, but the short extremity offered poor skin contact and a completely reliable prosthesis did not appear possible with reasonable degrees of comfort. Although pronator and supinator muscles could be found, and were more or less functional, the position and depth of these muscles within the extremity and their very low signal outputs made their use impractical for controlling a wrist rotation unit.

Discussions with the patient were initiated, and he expressed an interest in the wrist control function. The pros and cons of the procedure were fully discussed with the patient before proceeding and he was also encouraged to examine in detail the results of the animal experiments in order to provide him with a maximal amount of information on which to make his decision. The risks of the operation were explained to him, and the possibility was also mentioned that the implant could offer him little or no long-term value.

The patient elected to proceed with the operative option, which took place at the University of Alberta Hospital on October 19, 1977.

The device to be implanted and the operative procedure had both been approved by the ethics committee of the University of Alberta Hospital.

The operation included many stimulation tests designed to ensure positive identification of the muscle groups involved, and included a number of features for research purposes and documentation purposes as well. The operation lasted a total of 5 and one-half hours, which could probably be shortened in future operations. (The length of time which an older patient is kept under anaesthetic should, of course, be minimized, and it is expected that this time will be improved on future implants).

The full documentation, however, served a useful purpose in this case, because this operation set a

precedent, being the first time a fully functional multiple-degree of freedom prosthetic appliance had ever been successfully controlled by a long-term implant.

One group, (Tucker, F.R., and Peteleski, N. 1977.) had previously implanted one electrode assembly in one muscle of a human patient with a limited success.)

The implanted device used at the University of Alberta by the present team included four E.M.G. probes which were individually sutured to the fascia of the muscles used. (See Figure 26.) The bellies of the long wrist flexors and extensors pronator teres and supinator were chosen for two of these electrodes.

Stimulation tests were done to provide accurate confirmation that these sites were active and independent. The later connection to the wrist extensor muscles provided the function of opening the hand, and the later connection to the wrist flexor muscles was assigned to the function of closing the hand.

In practice, these assignments were easily changed, and were tested in various combinations to provide optimum function and easy learning. A total of four E.M.G. probes were thus implanted and fortunately all of them provided useful signals at a later date. In future implants, it would probably be wise to locate and provide a signal output for any additional potential sites as well. Some of the sites chosen were marginal for certain control applications, and

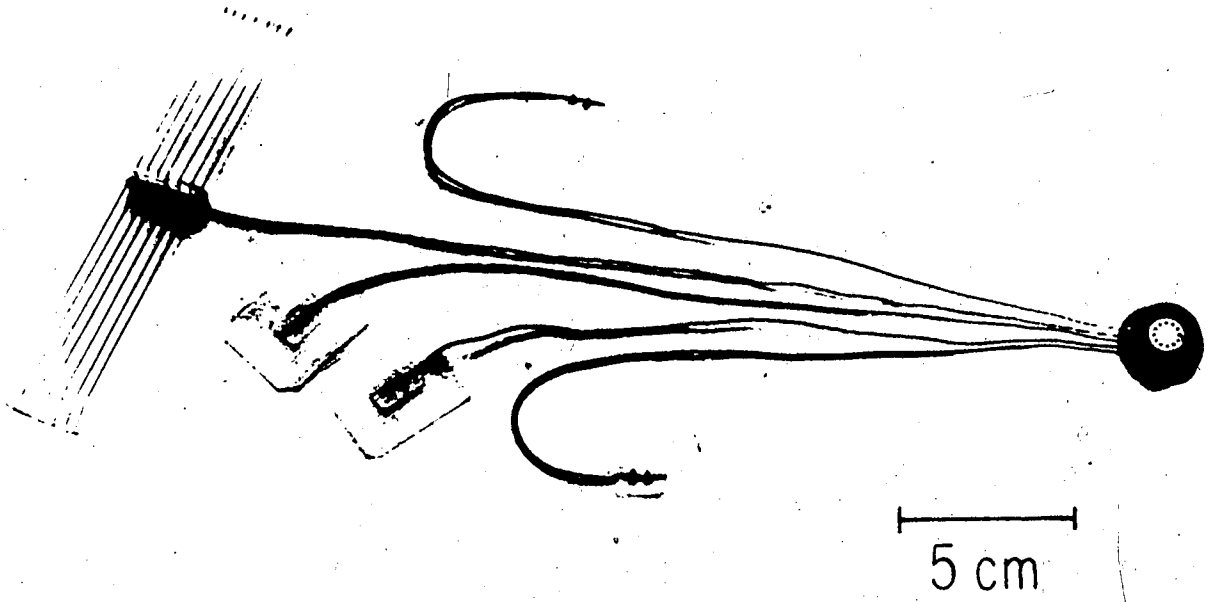


Fig. 26.

The initial device implanted in a human subject for exploration of the practical aspects of powered prosthetic control and sensory feedback. Four E.M.G. probes are shown, and a single nerve cuff with suture threads protruding from either side of the cuff. Five flexible cables connect the implants to the rear terminals of the Augat 12-pin teflon socket in the centre of the percutaneous connector. In previous devices that had been constructed by the author, the connecting leads had been distributed radially at equal angles around the connector to equalize skin tensions and provide additional support for the device.

additional sites may have provided more secure control. Additional control sites would forestall the possibility that a patient would undergo a risky, painful, and inconvenient surgical event and yet obtain only marginal improvement in prosthetic function because of device malfunction, misplacement, later migration of electrode position, crosstalk, insulation breakdown, or other unforseen eventuality. The projected life of implants is not known, and it would be good planning to allow for any possible redundant channels of information that could be found.

Four sites were needed, and in the initial implant patient, four were found, and all were functional. The use of implanted electrodes in this situation meant that direct skin contact was not necessary for control of the prosthesis, so it could theoretically be made more comfortable, as well as offering potential improvements in operation whenever the hand is used above the body or at unusual angles.

In addition to the implantation of the E.M.G probes, a nerve cuff was placed on the ulnar nerve just distal to the last functional motor branch, (Flexor carpi ulnaris). A neuroma could be clearly seen during the operation, but no connection from the nerve to the skin could be found. The nerve distal to this branch was dissected free from muscle and deep tissues, as was the neuroma.

The nerve cuff had been constructed with a longitudinal slit which was opened for the insertion of the nerve by pulling on suture threads which were imbedded in the cuff. When this cuff was in place, the threads were tied around it to provide a good mechanical closure for the cuff which would help to isolate the neural signals from contamination by nearby E.M.G. activity.

One purpose of the nerve cuff was to test the feasibility of using graded electrical stimulation in the prosthesis to provide the amputee with proprioceptive information about the gripping force, velocity, or position of the hand.

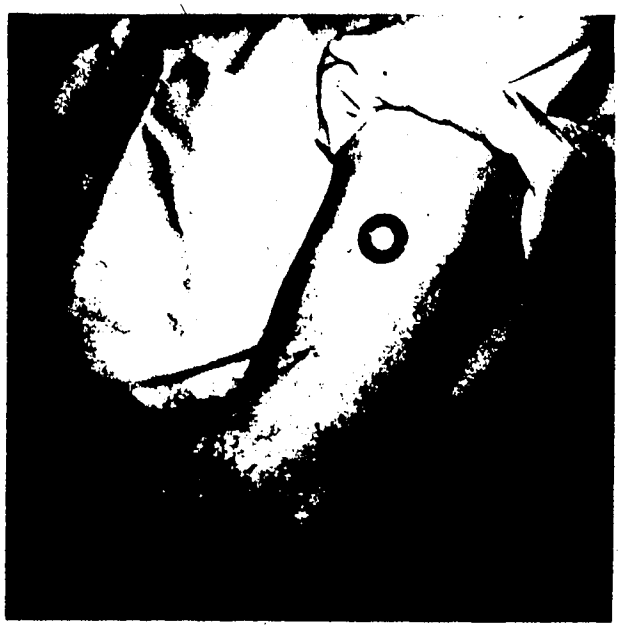
A second purpose of the nerve cuff was to explore the possibility that future electrically-powered prostheses might be controlled by signals obtained from such amputated nerves. Electrical stimulation of skin has been explored before by several groups, (Scott 1977,) (Clippinger 1974.) Others have tried using nerves with implanted electrodes. (Mann and Reimers 1970), (Reswick et al 1975). The number of amputees tested was small however, and only rarely had the implant for neural stimulation been tested over any reasonably long period of time.

The skin connector used for the human implant experiment was a 10 mm high concentric ring of Pyrolite carbon, (General Atomic) which was fabricated with an external flange of 25 mm diameter having 12 holes through the rim to allow subcutaneous connective tissue to grow °

through the holes and anchor the connector in place. To insert this skin connector, a small circular incision was made on the lateral surface of the upper arm between the flexor and extensor compartments. Part of the skin connector was pushed through this circular incision, and sutured in place with only the top part protruding, using a purse string suture. The larger-diameter outer flange of the connector remained beneath the surface of the skin in subcutaneous tissue. No post-operative problems were encountered. The amputee recovered rapidly from the operation with minimal trauma, the skin healed well around the percutaneous connector and the edema and swelling of the extremity proceeded to abate normally over a period of a few weeks.

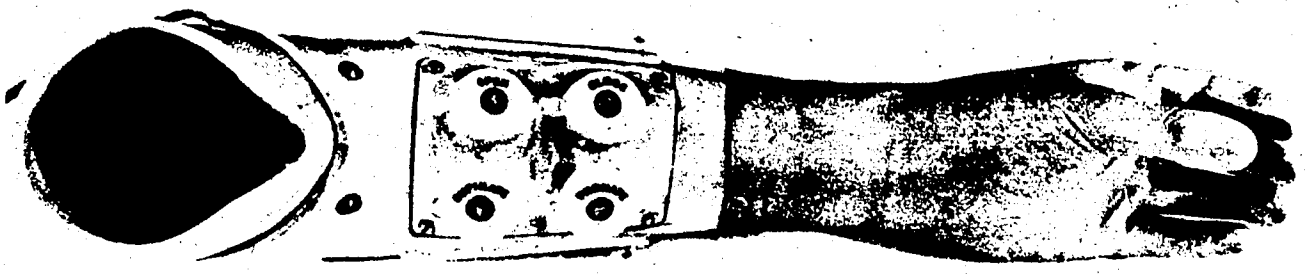
Training and measurement procedures were initiated as soon after the operation as possible. A pair of Otto Bock E.M.G. meters were used to offer visible indication of independent activity of each of the four muscles. Four large open-scale analog meter needles indicated the muscle activity by deflecting to the right when the patient activated the muscles. The amputee reported minimal difficulty in activating the desired muscles, even though some of these muscles had not been used in functional activities for more than thirty years. The fitting of the prosthesis is as shown in Figure 27.

The signals obtained on the E.M.G. meters ranged from 40 microvolts on the wrist flexors to over 100 microvolts on



A

B



C

Fig. 27.

A short below-elbow amputee in whom E.M.G. probes and a neural probe were implanted in Oct. 1977. The condition of the extremity is shown as of February 1978. in photo A. Note that the skin has healed around the percutaneous interface button. B. Shows the prosthesis on the patient. Note that the prosthesis is plugged into the skin connector on the patients arm. C. Detailed view of the prosthesis wired by the author. Note individual adjustments for the sensitivity for hand opening, hand closing, wrist supination, and wrist pronation. The module PCL-1 is located inside the prosthesis out of sight.

the wrist extensors. Actual values in excess of those readily measureable on the E.M.G. meter or required for the operation of the myoelectric signal processing modules were obtained.

The impedances measured from the implanted electrodes was a desirably low 1 K or 2 K ohms at 1 KHz. This impedance remained constant with the passage of time. By comparison, ordinary surface electrodes commonly used to control electric hands vary widely in their impedance and signal levels depending on air temperature, skin temperature, humidity, moisture content of the skin, presence of skin graft tissue, mechanical pressure, positioning accuracy, corrosion of the electrode surfaces, and variation in the loading effects of the internal components of the electrode circuitry. The steady amplitude output offers advantages in both laboratory measurements of the condition of the implant and also gives a more predictable control over the artificial prosthesis.

The stability of signal amplitudes obtained when the arm is held at extreme angles away from the body or over the head is much better than that obtained with traditional surface electrodes. The importance of this stability is increased when using multiple-threshold control circuitry, because these advanced signal processing techniques function best when accurately predictable amplitude and time discriminations can be attained. This stability will also improve the success rate of the patient's subjective

threshold discriminations during learning the operation of multiple-threshold controls and will probably increase patient satisfaction with his prosthetic devices.

The progress of the patient's learning was an important factor in assessing the operation of the implant. On different days the amount of crosstalk observed on the meters showed variations. This apparent crosstalk could be seen to arise within the patient's own nervous system rather than from any electrical deficiency in the implant. A surface maximal stimulation of the ulnar nerve gave rise to excellent signals from the muscles it supplied (Over 200 microvolts), while simultaneously less than 10 microvolts could be observed on the other E.M.G. electrodes.

Since some of these muscles are normally used in combination with the others their co-activation is to be expected. The learning process required a conscious effort to activate them separately, and the fact that the patient could learn to do so is an important aspect of this procedure. Each muscle could be activated to give at least twice the desired signal on its own channel to that produced on any of the other three channels. This ratio was more than sufficient to allow for setting the thresholds of the switching circuitry to discriminate in favor of the desired prosthetic movements.

The prosthesis itself was fitted to the amputee in January of 1978. It initially contained a 6 volt Otto Bock hand type 8E17, an Otto Bock wrist rotator type 10S12=6, and

four standard Otto Bock Preamplifier type myoelectrodes.

An interruption in the initial testing of the device occurred when it was discovered that the newer version of the Otto Bock electrodes (Type 13E67=G,) was unreliable when driven by very low impedance sources. This fault was eventually traced to a design problem in the printed circuit pattern of the electrode assembly.

The availability of four discrete control signals in the first human long-term implant patient necessitated certain innovations in the actual prosthesis itself. The order of priority for the degrees of freedom provided for an upper extremity amputee is as follows: (Dependent, of course, upon the level of the amputation.)

1. First Priority: Hand opening and closing
2. Second Priority: Wrist rotation, pronation and supination.
3. Third Priority: Powered elbow flexion and extension.
4. Fourth Priority: Humeral rotation.
5. Fifth Priority: Wrist flexion and extension or arm extension.

Since the patient already possessed fair ability to implement most functions of the last three movments due to the level of his amputation, the next level of prosthetic improvement to be investigated was the wrist rotation function.

The wrist rotation unit as supplied from the Otto Bock factory does not contain any power switching circuitry. The reason for this omission is that it was originally intended to be operated by a relatively simple mechanical rotary switch assembly.

PCL-1 Power Control and Logic Module.

The author developed the first of a series of Prosthetically oriented modular components specifically for the patient under discussion. The module contains an amplifier and switching arrangement which is capable of bi-directional control of prosthetic motors, and which also incorporates a type of logic circuitry to be described later. This module was revised and improved several times, until a standard commercially available version resulted which offers several features of convenience and reliability with respect to prosthetic appliances.

The amputee made use of his prosthesis until November of 1978. By that time, the percutaneous skin connector had begun to tilt at an angle to the surface of the skin, and the flange of the carbon button was starting to protrude through the skin. The subcutaneous tissue had become thinner and slightly necrotic and the risk of skin infection became an important consideration. A potential infection was averted by deciding to remove the percutaneous connector .

The leads and cuffs were left in place because they were not causing any problems. A test was done to determine bacteriological activity, and no deep infection was present. Only the normal skin bacteria on the surface including staphylococcus epidermidis could be cultured. Nevertheless the removal of the connector at this time was a prudent and necessary step taken to avoid potential complications, and was undoubtedly the correct decision to make at the time. It should be noted that all electrical connectors and subcutaneous cables were functioning perfectly up to that time, and showed every sign of continuing to do so for the indefinite future.

Although detractors of the technique would call it a failure because of the limited time that the implant provided functional assistance to the patient, several important points should be noted:.

1. The information provided by the implant technique could not have been obtained in any other way. Verbal information regarding sensory feedback and subjective observations on the ease of control of the prostheses does not apply to animal experiments.

2. The nerve cuff illustrated the viability of a nerve which had been isolated from its end organs for over thirty years, and demonstrated conclusively that the nerve was still alive.

3. The ability to stimulate the nerve of the patient while using the E.M.G. sites for simultaneous control of a multiple-channel prosthetic device proves beyond a shadow of a doubt that the troubles with positive feedback that has been observed by other workers who have attempted to combine these functions is largely caused by poor parameters of design and not by any intrinsic incompatibility between E.M.G. control and neural stimulation.

Sensory feedback from powered prostheses.

Sensory feedback stimulation is an exceptionally desirable feature to incorporate in future powered prostheses, because it not only provides useful information to the patient about limb position, angle, or gripping force or velocity, it also provides a substantial psychological advantage in reminding the patient to learn to regard the prosthesis as a true portion of the body, a valid and real extension of the self.

Note that no accidental co-stimulation of the associated muscles could be elicited using electrical nerve stimulation even when pulses of 6 volts at 10 microsecond duration were applied in bursts.

The amputee reported that the sensation evoked by this stimulation was localized to the ulnar aspect of his phantom limb in a region under his fourth and fifth fingers and that the sensation was one of scratching or stroking, although

not identical to that normally perceived by others. These subjectively reported sensations correlate very well with the anatomical area served by the nerve stimulated.

The amputee's subjective impression of the separation of impulses fused at the relatively low rates of 10 to 20 per second. Higher rates and amplitudes caused the sensation to fade quickly. If reasonable input voltages were to be maintained, it was necessary to apply the stimulus in a non-continuous fashion to maintain perception.

The experimental situation did not afford enough time to do a serious exploration of the effects of different patterns of burst activity, different forms of modulation of the stimulus bursts, or of other parameters designed to elicit differential psychophysical sensations. The author finds such experiments to be extremely interesting and the qualities of sensory perception and the direct mapping of these parameters from a neural viewpoint is a rich and fascinating field for future investigation.

If one considers the possibilities inherent in being able to apply various stimulus patterns to a series of electrodes within a cuff, or to apply phase-encoded information to a series of cuffs, the excitement of uncovering some of the more puzzling aspects of the qualities of sensory perception becomes apparent.

The initial laboratory experiments done with the co-operation of this patient are important in exploring the value of sensory stimulation applied directly via implanted

nerve cuff while the amputee actually wore a fully-functional multiple degree of freedom prosthesis. The main reason for not incorporating the sensory stimulation device into the prosthetic arm was the absence of a sufficient number of electrical commutating slip rings at the connection into the hand, a situation which requires improved communications with Otto Bock in Germany to resolve. The stimulator circuitry worked perfectly, and an opportunity was provided to test two alternative modes of operation.

Two modes of operation of the sensory feedback stimulator.

In one mode of operation, it was decided that simplicity and ready adaptability to off-the-shelf unmodified hands would take primary consideration. Otherwise, there would be a necessity to have a removal of the hand covering glove, removal of the internal hand cover, removal of the cosmetic external glove, removal of the heavy-duty internal hand protective covering, mechanical modification of the finger grip lever arm, and bonding of paired strain-gage transducers to the finger metal lever.

Such an approach which does not use standard off-the-shelf hands, is one which has been favored by Scott (1977), and has been investigated by other researchers as well. (Schmidl, H. 1977.)

That procedure requires one of three alternative methods to get the grip force pressure transducer signals out of the hand, and all of them have serious disadvantages for a large-scale prosthetics program.

1. First, it is possible to run a wire from the transducer directly through the hand glove and shell. This is consmetically unsightly, and it precludes using a wrist rotator, because the wire will be sheared off.

2. Secondly, it is possible to remove the motor-switching electronics from the hand and use two of the four slip rings just for the motor.

   The motor electronics then add extra weight and bulk outside the hand. Nevertheless, this approach is probably the only one that is possible at the present time.

3. Thirdly, it may be possible to transmit the finger pressure signals out of the hand by telemetry, either electromagnetically or by radio such that the hand may rotate indefinitely without snagging any wires.

The latter procedure may be the most practical in the long run, because the pressure transduction apparatus and

transmitter could be made as one small integral package and draw its power from circuits already in the hand.

The second mode of operation of the sensory feedback stimulator involved no changes to the off-the-shelf standard Otto Bock hand. This is a very desirable attribute, because hospital staff and space cannot be tied up waiting for component modifications to be made.

In this second mode, the current drain of the hand motor was used as an indicator of finger grip pressure, and the pulse frequency was modulated by the change in motor current. The system would have to be modified to reject changes in current when the hand was held open against the resistance of the glove, and it would have to differentiate between an opening mode and a closing mode, but basically it functioned as designed. This series of sensory feedback experiments resulted in the development of a circuit suitable for neural stimulation studies from a portable battery-operated power source. The commercial version of the circuit is ST-4, a neural stimulator developed fourth in a series of limited-production modules. The more important of these modules for the present prosthetic uses will be described in detail. The modules not described in detail are suitable for laboratory experiments rather than prosthetic applications.

B. MODULES FOR PROSTHETIC USE.

Modules Designed by Author.

PCL-1: TC-2: TRI-3: ST-4: QT-5: QT-5B: E.M.G. System VII:

TABLE 2: MODULES DEVELOPED BY AUTHOR

As of August, 1980, seven commercially-produced systems related to prosthetics and physiological research have been designed by the author. These are presently being manufactured commercially by Leaf Electronics Ltd., and the first three modules have been released in quantity for use on patients in clinical applications.

1. *PCL-1 Power Control and Logic Module, providing bi-directional control and low standby power consumption for motors in prosthetic appliances which are to be run by electronic signal controls.

2. *TC-2 Touch Control with two outputs. Produces a standardized control signal on either of two outputs when touched by the skin. The skin of the shoulder

shrug movement may be used, the movement of a phocomelic digit may be used, or any other moveable part of the body avaiable for control purposes. TC-2 is sufficiently sensitive that skin of poor conductivity may often be used, such as skin that has been grafted.

3. *TRI-3 Tri-state E.M.G. preamplifier and controller. To be used for allowing a single muscle control site to generate the three conditions of
   a. "A"=OFF,
   b. "B"=Low level / proportional range,
   c. "C"=High Level / digital control range. (With logic suppression of level "B"). Permits the use of additional degrees of freedom in amputees where only a limited number of control sites are available.

4. *ST-4 Sensory feedback stimulator. (Research application only at present), For studies of sensory feedback in prosthetic applications, and also for studies of neural growth, regeneration, trophic actions and neuromuscular specificity experiments.

5. *QT=5 (A) Low noise preamplifier optimised for preparations having impedances in the range of 10 K to 100 K Ohms per input. Differential inputs, High

stability and good freedom from blocking and D.C. offset effects.

6. *QT-5 (B) Ultra Low-noise preamplifier optimized for neural or E.M.G. preparations of low impedance, typically below 10K ohms per input. Differential inputs, noise level approaching the theoretical minimum, Excellent R.F. rejection and freedom from blocking or D.C. offset bias.

7. *SYSTEM VII An E.M.G. system of 4 independent channels designed for moving subject applications such as athletics, physical education, or rehabilitation medicine.

An illustration of the first three modules (which are prosthetically-oriented,) is shown in Figure 28. The remaining four modules are intended for research applications at the present time, but are being developed as potential clinical devices for future use.

PCL-1, Power control and logic module.

This module is a small, totally encapsulated and insulated circuit which contains active power bridge circuitry and signal routing logic. It incorporates two sets of Otto-Bock compatible input pins, each of which has the necessary

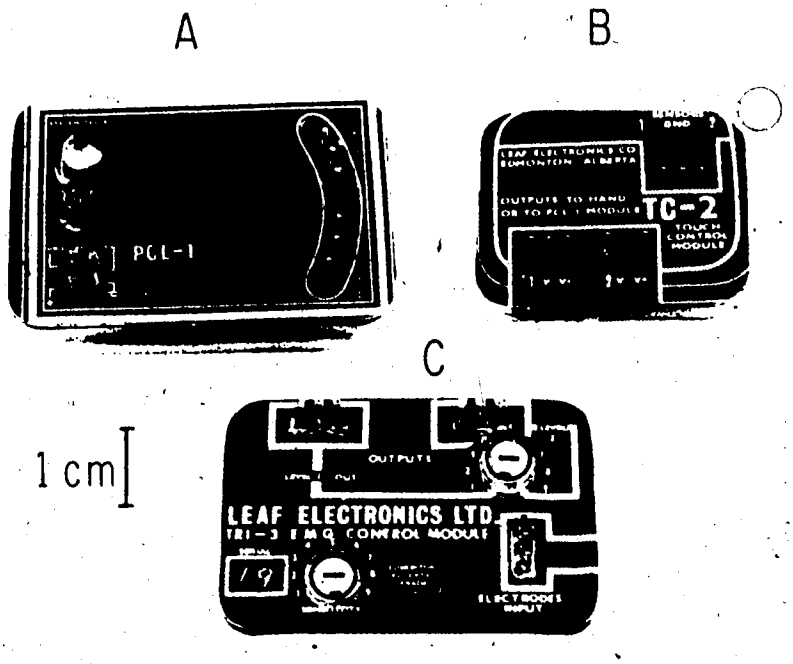


Fig. 28.

Three of the modules invented by the author and produced for the last three years in commercial quantities are illustrated actual size.

A: PCL-1 (Power control and logic module.) Is used to drive electric motors typically in wrist rotators and elbow units, humeral rotators, etc.

B: TC-2 (Touch control module.) Is used to derive on-off control signals from simple skin contact at very low battery current drains.

C: TRI-3 (Tristate myoelectric control module.) Is used to obtain the appropriate signals for operating more than one control function from a single muscle site, thereby adding more potential degrees of freedom.

ground, battery voltage, and signal input leads in the correct order to ensure complete compatibility with off-the-shelf components. A standard TTL logic level input may be applied to either of the inputs, or alternatively, each of the inputs may be overdriven by signals as large as the battery voltage, without damage to the module.

Alternatively, a proportional control voltage may be applied to either of the inputs, and this proportional control voltage may be pulse-width or amplitude modulated as desired. If proportional control is chosen, it need not be applied to both inputs.

The circuit is stable and provides predictable outputs even if completely different types of transducers are used at different inputs. Thus one input could be driven by the output of a Bock Myoelectrode assembly, another input could be driven by the output of a Tri-State control device (To be described later) -or even by the output of a touch control unit or an illuminated light-dependent resistor.

Logic functions of PCL-1

One of the inputs to PCL-1 is termed "Priority." As this term implies, a signal applied to this input, from any source, takes precedence over the signal applied to the other input, no matter how strong the signal to the other input may happen to be. For instance, in the first human implant patient, one muscle was much easier to activate than

the other one and coactivation was frequently a problem. The logic circuitry of PCL-1 made it relatively easy to minimize the effects of this coactivation, by assigning the priority to the weaker and less-frequently activated muscle thereby maximizing the patient's opportunities of generating correctly assigned signals to operate the intended prosthetic movement.

Indicators for field reliability.

The PCL-1 module incorporates two light-emitting diodes: one red LED and one green LED. When one input is activated, with motor power applied in one direction, the red LED becomes illuminated. When the polarity is reversed by applying a signal to the other input, the green LED is illuminated. These indicators simplify the use of the device by prosthetic and nursing personnel who need not have any knowledge of electricity or electronics to make full use of the devices.

Compatibility considerations.

In addition to the two sets of Otto-Bock compatible three-pin inputs, the PCL-1 contains a four-pin output and power connector which is fully compatible with all Otto Bock wrist rotators and their associated connector cords. This means that no additional wiring is necessary to incorporate

the PCL-1 into a prosthesis. It simply plugs into the connector provided for the original Bock rotary switch to provide all the advantages of electronically-controlled operation for the wrist rotator or elbow motor.

The PCL-1 module may be operated satisfactorily by any voltage from 6 to 18 volts so that a separate stock is not needed for 12 volt hands or for compatibility with the Variety Village 12 volt elbow units or the Boston arm 12 volt elbow unit. It has been tested in the Boston Arm unit and is much more reliable than the original electronics supplied with the Boston Arm. Also, it occupies much less space in the prosthesis and offers full electrical insulation in place of the previous exposed wiring.

Since the application of the PCL-1 module to the original human implant patient, more than 100 of these modules have been commercially manufactured, and an increasing number of them are being specified for use at such institutions as the Saskatchewan Council for Crippled Children and Adults, The Ontario Centre for Crippled Children, The National Research Council of Canada, the Winnipeg Rehabilitation Centre, and by independent prosthetists in Canada and the United States.

The PCL-1 is currently undergoing tests to determine its suitability in applications for quadraplegics and other wheelchair patients.

An additional benefit of the logic circuitry is that a prosthesis can be designed in such a way that if conflicting

or simultaneous signals arrive at the prosthesis for any reason whatsovever, that the elbow motor will automatically go into the extend mode, making it easier to remove the clothes from the patient and disentangle the prosthesis for examination and adjustment. The logic circuitry also protects the modular components themselves from damage due to incorrect signals.

The necessity of removing the percutaneous skin connector and hence rendering the implant non-functional could have left both the patient and the research team in an awkward position. The justification for the use of the implant procedure was that a valuable wrist rotation function would be provided to the patient. This additional degree of freedom does in fact improve the usefulness of the prosthesis in many patients because it eliminates the necessity of releasing both hands from the task being accomplished, grasping the electric hand with the real hand and performing an inconvenient manual wrist rotation movement. In most cases, the amputee would just rather not be bothered with the extra trouble, and therefore uses the electric hand for fewer tasks than would otherwise be possible.

It could be argued by detractors of the implant technique that the additional degree of freedom was not worth the risk, pain, and time lost represented by a five and one half hour operation under general anaesthesia

together with the recovery time needed from the operation.

Initially, it appeared that the new degree of freedom would have to be withdrawn from the patient after less than twelve months of benefit had been obtained. The author suggested that a multiple level myoelectric system could provide the additional degrees of freedom even following the removal of the implant. The initial reaction to this suggestion was that it would not work. Previous experience obtained with systems developed by Dr. H. Schmidl (1977), using a multiple-level E.M.G. control, and also experience which had been obtained using the Otto Bock single state system indicated that the patient had signal levels which were too low, too unreliable, and had too much crosstalk for this system to ever be of value.

The criticism would be valid for these existing systems, because the Schmidl system of multiple-level myoelectric control depended upon electromagnetic relays for two extremely important parameters of operation, hysteresis and time delay. These parameters were fixed by the characteristics of the relay, and could not be adjusted to suit the individual requirements of the patient. In addition, previously-existing multiple state mypelectric controls depended exclusively upon an amplitude discrimination threshold as the criterion of the multiple state output.

One objection to a myoelectric control system in which only amplitude is used as a parameter of threshold criterion

is that the myoelectric signal obtained from skin electrodes is highly variable for reasons which have already been discussed. When the available range of myoelectric signal from a single site is divided into several threshold levels in order to provide multiple control signals, this variability can cause a greater unreliability of prosthetic function than a single threshold control device. A consideration of the parameters of a multiple-level control device will illustrate some of the problems that must be solved before adequate prosthetic control can be obtained.

Improved Myoelectric Controllers: Requirements.

1. The device must function with a wide range of skin contact conditions, including dry skin, conditions of low humidity and dryness such as are encountered during winters in Alberta.

2. The device must not malfunction when grossly unbalanced conditions exist at the input connections to the skin electrodes, and must present a true balanced differential input impedance to the E.M.G. control signals in order to prevent changes in function when the skin electrode is installed in an inverted orientation, and also to permit maximum rejection of interfering signals from power lines, fluorescent lights, radio transmitters, and other

sources of interference encountered daily.

3. The device must reject radio frequency signals covering a range from 20 KHz to several hundred megahertz, and must not malfunction even in the presence of radar signals or microwave signals. It must not rectify these signals or demodulate them in any way, yet it must be capable of being controlled by skin and implant-derived E.M.G. signals in the 10's - 100's of microvolts and low millivolt ranges.

4. The device must not create or amplify any electrolytic or metal-to-skin interface movement artifacts. It must not inject leakage current into the skin or cause the electrodeposition of even minute amounts of metal at the skin interface, because patients differ greatly in their sensitivity to traces of foreign metals in the surface of the skin. It has been found that some persons tolerate stainless steel electrodes excellently, while others break out in a rash where they are present. Similiarly, some persons have excellent tol[redacted] for electrodes which consist of a heavy gold plating over brass, while others do not.

5. The device must be capable of rejecting 60 Hz and 120 Hz A.C. signals which have been differentiated

or modulate pulses of high risetime, as in the situation created by thyristors, silicon-controlled-rectifiers, and light dimmers and industrial apparatus. This condition actually requires a combination of two rejection characteristics, that of A.F. (Audio Frequency) range rejection and that of R.F. (Radio Frequency) range rejection. The situation is so common, however, and so frequently misunderstood in prosthetic applications that it is emphasized here with a separate category. This rejection may be accomplished in a prosthetic control device by careful attention to the input stages to avoid R.F. rectification in combination with optimally-designed filtering characteristics in the later control circuitry.

6. The device must not consume an inordinate amount of standby supply current. The hand motor may draw up to several hundred mA. during operation. (Typically 200 to 500 mA, depending upon accuracy of the clutch adjustment.) The wrist rotator may draw an additional 100 to 300 mA during operation. It is reasonable if bandwidth and sensitivity tradeoff characteristics are taken into consideration that the multistate control module may draw a standby current in the range of 1 or 2 mA.

7. The device should permit the amputee to exercise a positive and reproducible control over each of its output levels. This is not such an easy requirement as a casual consideration might lead the reader to believe. Let us consider the various ranges of operation in sequence.

a. (*) NO OPERATION: FIRST LEVEL = OFF: "A"
The patient does not desire any movement. The prostheses must remain immobile despite low-level changes in the background E.M.G., minor interference, crosstalk from other muscle groups, and movement artifact.

b. (*) SECOND LEVEL OPERATION: = Proportional range: "B"
Typically a hand closing operation, this movement must be elicited with reliability. It usually is represented by a low-level volitional E.M.G. signal obtained by a conscious moderate contraction of the control muscle.

c. (*) THIRD LEVEL OPERATION: = Suppresses other output: "C"
Typically a hand opening operation, this movement also must be elicited with reliability. Some workers believe that a second "deadband"

should be inserted between the first level operation and the second level operation in order to clearly separate them and increase the ease with which the patient can identify and separate these functions.

It will be shown that this deadband can be implemented as a time-domain function rather than as an amplitude function for the purpose of improving control over the multiple threshold levels.

A careful consideration of the three states of the multiple-level controller will reveal several interesting facts. Let us suppose that a patient wanted to open his hand and leave it in the open position without any continuing effort. A high level E.M.G. signal obtained by a strong muscle contraction would place the output in the category (C) above.

Let us now suppose that the patient relaxes his muscle in order to leave the hand in an open position. If the multistate controller is sensitive only to changes in amplitude, and has no time-dependent functions, the hand will close as the E.M.G. signal decreases and passes through the zone represented by condition (B).

This situation will happen even if the multistate controller contains a deadband between state B and C. Therefore it is clear that the multistate control device

must contain a means for holding the output at level (C) long enough to give the patient time to relax his muscle and return to either state (A) or (B) as desired. It is important that this holding function should not impose any time delay while the patient is attempting to reach level (C) or a slowness of operation would be noticed in the hand function. The variability of the E.M.G. signal envelope is typically quite severe when a muscle is held in its higher tension position, and fatigue may cause the amplitude of the E.M.G. to randomly move in and out of the threshold ranges. Thus the holding function implemented to give the amputee time to cross range (B) when returning to a quiescent condition serves an additional valuable function, in that it prevents jerky movement of the prosthesis due to the excessive variability of the E.M.G. signal.

It can be seen that a simple amplification system is insufficient to implement the desired functions, because it is important that no signal be present at the low-level output represented by (B) during a strong muscle contraction intended to produce level (C).

Therefore, a system of logic must be implemented within the myoelectric controller to suppress any output at level (B) while level (C) is in effect. It is desirable to hold this suppression active even after level (C) is no longer activated so that the patient can open his hand a controlled moderate amount and still return to level (A) which is the equivalent of "OFF" without any further hand opening.

In the event that proportional control capabilities are desired for future improvements in prosthetic control accuracy and naturalness of movement, additional factors must be taken into consideration. It is important not to waste any of the available range of E.M.G. signals, since most patients find that the level of concentration required to operate their prosthetic device is already quite high, and only a simple controlling protocol is acceptable.

It is therefore natural in operation and reduces the training time and fatigue of the patient to assign the proportional range to the low level E.M.G. functions between (A) and (B). The smoothing filters which must be employed to reduce the effects of E.M.G. variability then can be employed for an additional function to provide a smoothly controllable variable range for the speed of the prosthesis in one direction of its operation.

This control system is similiar in concept to that recommended by Dr. H. Schmidl (1977) who has pointed out that full proportional control need not be implemented symmetrically on both directions of each movement to still be of value. Proportionality over finger closing may well be of considerable value when a faster hand or elbow becomes available, particularly when sensory feedback is also used to control the degree of finger pressure or velocity. Thus, the movement of the arm towards the face must be controlled with some precision, while the movement of the arm away from the face may not need quite so much sophistication of

control.

Proportionality with respect to wrist rotation, and factors of priority and speed are areas for future investigation which have not been examined systematically in the present study.

Compatibility

The present delivery system for prosthetic appliances includes people who specialize in many different fields. The clinical prosthetist, the orthopedic surgeon, the research team, the occupational therapist, nursing and hospital staff, suppliers of raw components, all have their own viewpoints and particular functions. It is important within such a system that all new research components be upwards-compatable from preexisting prosthetic devices, particularly with those which have been standardized and are available on the market. There is no justification for keeping a patient waiting in a hospital bed while research is done on a totally new incompatible device. Bilateral amputees are particularly dependent upon other people for their basic needs, and the ready availability of standardized, modularized interchangeable components greatly decreases the time required for successful fittings. Since the Otto Bock system is the only commercially-available powered prosthetic system using modularized components, it was mandatory that any new developments be compatable with

Bock components on a simple plug-in replacement basis, and preferably be compatable with other prosthetic components available in both experimental and commercial stages of development.

TRI-3: a commercially-available multistate E.M.G. controller.

TRI-3 Description.

The Tristate module TRI-3 is a multiple-channel prosthetic controller which meets the criteria outlined in the preceeding section describing the desirable qualities for such a unit. Module TRI-3 has been manufactured and distributed by Leaf Electronics Ltd. of 11804-124 Street Edmonton Alberta for approximately three years. As of July 1980 more than one hundred of these modules have been constructed and tested, and have been used by a number of prosthetists in the field. A continuing program has been implemented of seeking information from prosthetists using these modules, and incorporating improvements in their design and function as a result of the experiences of workers in the field. These modules have been fitted by Mr. John Arseneault, Mr. Tony VanDerWaarde, The Worker's Compensation Board, The National Research Council, The Saskatchewan Council for Crippled Children and Adults, The Ontario Crippled Children's Centre, Mr. William Sauter, and

other prosthetists and prosthetic centres in Canada and the United States.

The amputee is fitted with a set of two input electrodes that share a common ground connection. This device is held over the muscle of interest by the prosthetic shell fitting. Good skin contact is essential, and the prosthetic appliance will not function properly without a proper fit. Many workers in the field have emphasized the importance of the need for a fit that is superior to that required for normal prosthetic appliances. The electrode assembly of choice is usually an empty Otto Bock electrode shell which fits conveniently into a circular opening in the inner shell of the prosthesis. Bock part numbers 13E76 and 13E77 provide the fronts and backs of these electrodes, and are held together with screws having Bock part number 501 S57=M7X8. Mr. William Sauter frequently chooses stainless steel electrodes in conjunction with the multistate controllers used at his institution and reports good results. The particular materials of which the electrodes are made are not critical to the operation of the TRI-3 multistate controller so long as patient comfort is provided.

Standard Otto Bock empty electrode shells may be adapted for convenient use with TRI-3 by soldering on a standard 13E46=300 electrode cable with the three linear inline pin connector at the end of the cable that plugs into the TRI-3 module. (Additional details are available in the

TRI-3 instruction manual).

Sensitivity

Even though the patient may have appreciable scar tissue and moderate to severe muscle damage, sufficient signal is usually present to activate the TRI-3 unit. Early versions of the TRI-3 module had sensitivity down to the microvolt range, but it was discovered from field application that this high a sensitivity was rarely needed and sometimes caused prosthetists difficulty in obtaining the correct settings on the sensitivity and balance controls of the device. The control ranges have been expanded to more useful angles of rotation in subsequent improved versions of the device. Nevertheless, the development of sensitivity beyond that which was previously available has permitted the fitting of the module in cases where even single-state Otto Bock electrodes would not be considered to give adequate control function as judged by readings obtained on the Bock E.M.G. meter.

The signals obtained from the patient's skin are passed through a special proprietary filtering circuit which is exceptionally effective in the elimination of 60Hz and 120 Hz hum components while still retaining a high amount of electromyographic information. Additional filtering rejects R.F., V.H.F., F.M., T.V., and microwave signals including those generated by citizens band radio and other

transmitters, and another filtering circuit eliminates the effects of movement artifact and skin-to-electrode noise fluctuations. The signal is then passed through a sensitivity control and amplified before being rectified with a controlled amount of deadband to provide additional rejection of artifacts. The output signal obtained from the first level output is level shifted to accomodate the range required for correct operation of both 6 and 12 volt Otto Bock hands as well as the range required for present analog proportional control and future pulse-width proportional control applicatfons. A signal range from [illegible] to almost the full battery voltage is available from the low level output, termed output "(B)" above.

This filtered, smoothed D.C. signal is proportional to the effort exerted in the voluntary muscle contraction and may be set to cover any portion of the muscle contraction range with the sensitivity and balance controls. The presence of the controlled deadband region ensures that battery current will not be wasted by minor involuntary muscle contractions or incidental noise of a non-voluntary nature. When the signal from this first level output is fed to an Otto Bock hand which is normally controlled by an all-or-none signal, the hand is triggered into the closing mode the first time the D.C. signal level from the low level output reaches the threshold of the Bock hand.

The hysteresis normally present in the hand causes this hand function to continue operating until the voltage drops

below the hand hysteresis threshold, or until it is shut off by the internal logic of the TRI-3,(whichever happens first).

Once a signal has been applied to one input of a Bock hand, it must be removed before the other signal can take effect. Thus a signal which directs the Bock hand to close will cause continuing closing so long as it is present, even though a simultaneous signal may be telling the hand to open at the other hand input. Only when the prior signal is interrupted can the second one take effect, and then it will remain in effect until it is in turn interrupted. These actions are an intrinsic feature of the logic inside the Otto Bock hand, and the output levels and timing considerations of the TRI-3 module are compatible with them.

The wide range of output levels and sensitivity adjustments afforded by the TRI-3 module permits it to be applied in many other situations than just the operation of the Bock hand. It may be fed to circuitry accepting proportional input, such as the PCL-1, for operation of wrist rotators or elbow motors, humeral rotators, or robotic manipulator motors, wheelchair drives, etc. This general applicability means that the unit may be stocked in reserve for general purposes rather than tying up valuable hospital time while custom-built circuitry is designed.

Threshold discrimination improvement.

A likely area for improvement of the Otto Bock hand

function is in the area of speed. Some patients complain that it is too slow. However, when it is speeded up, proportional control will become essential, because finer control over gripping speed and force will be needed.

If the module were made sensitive only to amplitude changes, the patient would experience difficulty in adequately judging the E.M.G. levels to be reached. A centre deadband between levels "B" and "C" is provided by other workers to eliminate this potential problem. However, this wastes some of the valuable E.M.G proportional range which may become increasingly important for faster hands and elbow motor drives. Therefore to maintain compatibility with future developments, a different method of assisting the amputee to delineate the desired voluntary movements was developed. This method depends upon a differentiation of the E.M.G. control signal envelope, and does not waste a part of the E.M.G. control range available.

An amputee has control over the rate of onset of E.M.G. signals as well as partial control over their eventual amplitudes. A muscle contraction may easily be made gradually, or it may also be made in a sudden way. Time discriminations in muscle contractions appear to be subjectively easily discriminated, and may be more readily controlled by at least some subjects than the absolute value of E.M.G. amplitudes sustained. The inherent difficulty in maintaining a very tight muscle contraction and the fatigue it engenders preclude any fine accuracy in multiple-level

control functions which depend for their discrimination exclusively on multiple level amplitude judgements at high levels of muscle tension. The rate of muscle tightening, however, is a natural and easily-learned task. Patients are asked to gradually increase muscle tension until the hand begins to close.

Next, they are asked to suddenly tighten up the same muscle and observe the hand open. The sudden tightening creates a faster increase in E.M.G. amplitude, and the amplitude reached is invariably higher than that reached with the gradual signal. The TRI-3 module has been provided with circuitry capable of reacting to the changes in E.M.G. envelope rate, and the higher level output is able to easily latch into an "ON" state when a signal having these subjective qualities is present. This task appears easier for many subjects to learn than to ask them to identify multiple amplitude bands of device operation, and it preserves the full range of available E.M.G. control signals.

Once the higher level output has been energized, a hysteresis feature within the module latches it into the output state "C" which suppresses any output at level "B" and eliminates the possiblity of faulty motor operation. The hysteresis simply means that the E.M.G. signal must fall below a predetermined threshold both in amplitude and in the time domain before either the "OFF" state or the "LOW LEVEL/PROPORTIONAL" state are permitted to take effect. The

presence of this hysteresis also tends to help smooth out variability in the muscle tension in the high level state and compensate to some extent for the effects of muscle fatigue.

The time constants are chosen in such a way that it is possible for the amputee to go directly to the higher level without generating an effective output on the lower level. A casual inspection of the system would make it appear that it is necessary to go through the lower level when entering or leaving the higher level. In fact, this is not the case, and the patient can easily enter the high level state or leave it without activating the movement associated with the lower level output.

When the lowest level state "A" or "OFF" is reached, the various capacitors responsible for the time constants involved are discharged immediately so that the patient can instantly initiate a new cycle without having the residual effects of the previous actions influence the operation.

Cross-connection operation of two TRI-3 modules.

The TRI-3 multiple state controller was originally developed with the concept of increasing the number of degrees of freedom by freeing up additional muscle control sites from their previous assignment of individual open-close functions. The original application used one of the two available muscles for hand opening and closing, and

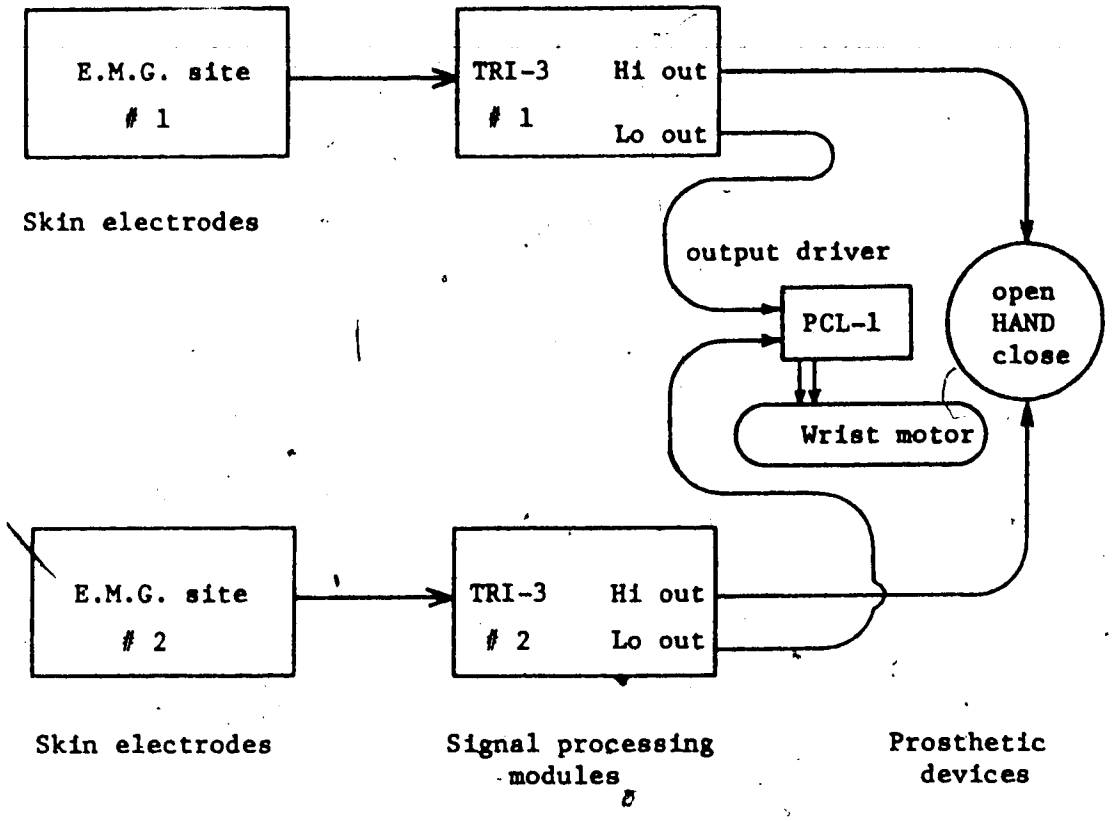
the other one to control the wrist rotation in both directions. This connection, while easy to describe and simple to connect, is not a natural control mode so far as the patient is concerned. It is instead desirable to arrange the control connections so that a more natural and easily-learned situation prevails.

Fortunately, the compatible wiring arrangement permits simple re-connection of the modules, and a connection such as that shown in Figure 29 solves the problem of natural control of more than one degree of freedom.

Low level gradual-onset contractions of the wrist extensor and supinator muscles cause wrist supination. Low level contractions of the wrist flexor and pronator muscles cause wrist pronation.

High level rapid-onset contractions of the same muscles cause hand opening and closing, and unwanted movement of the wrist rotator is prevented by the logic and hysteresis features in the TRI-3 module. This configuration was first applied by Dr. R.B. Stein, and it has proven to be of great value in fitting patients who had previously been fitted with a myoelectric prosthesis and who wished to add the advantages of a wrist rotator at a later date. The upgrading of the original powered prosthesis could therefore be accomplished with minimal re-training.

The subjective effect of the cross-connection configuration is pleasing to the amputee because the hand



(All connections shown are made without soldering using standard Otto Bock plug-in prosthetic interconnection cables. Directions and assignments of function may be made in the field at will.)

Fig. 29

Cross-connection operation of two TRI-3 modules. Low levels of E.M.G. from different muscle sites rotate wrist in either direction. High levels of E.M.G. from those sites open and close the hand.

functions remain substantially as they were before. The patient reports that the degree of control remains much as it was with the previous single-state electrodes, but that a new function has been added to the lower E.M.G ranges.

The new connection appears to increase the overall responsiveness and function of the prosthesis, because now moderate gentle contractions of the wrist pronators or supinators accomplish the same purpose for which they were originally biologically intended. The psychological advantages of the effect of natural body image extension into the powered limb are quite noticeable in most patients. They incorporate these advantages into their prosthetic management with a minimum disruption of their normal activities because very little additional training is required.

Example of a successful high-level fitting.

Mr. M.C., a 34 year old farm operator, suffered a partial forequarter amputation on the left side with retention of most of the scapula but with large areas of skin grafting. and a right above-elbow amputation as the result of a farm accident involving a hay baler in September 1976. Originally fitted with a cable-controlled mechanical elbow and hook on the right side, he was not fitted on the left side by conventional means because the high level and bilateral nature of the amputation would not have provided useful function. A surface E.M.G. examination was unable to

disclose any useful signals from biceps on the right side, but did show suitable signals from triceps and from a small remaining portion of coraco-brachialis. To fit his right side myoelectrically, it was determined that three joints representing elbow wrist and hand would have to be controlled from only two muscle sites.

Dr. H. Schmidl of Vigorso di Budrio, Italy made the suggestion that a cable-operated elbow be retained. A Hosmer outside locking elbow, (well-known within the prosthetic industry,) was used with a mechanical excursion multiplier to reduce the range of shoulder movement needed for a full range of elbow angle. Dr. Schmidl also was kind enough to provide evaluation samples of a multiple-state E.M.G. control circuit in which a small-amplitude E.M.G. signal controls one prosthetic movement and a larger E.M.G. signal energizes a relay to provide control of a different movement. Circuits which use one muscle to control two movements have also been developed independently by Scott (1977) and others.

The patient was trained to use coraco-brachialis at low levels of contraction to close a hand, and higher levels of E.M.G. from the same muscle to open the hand. Similiarly, low and high levels of contraction in triceps provided pronation and supination of the wrist rotator. The amputee uses his myoelectric prosthesis for many daily activities and has worked as a supervisor on a road asphalt crew. He has driven a tractor successfully with his myoelectric

prosthesis and has done various tasks of different kinds daily in connection with the farming community. He is presently employed by the Alberta Department of Agriculture as a lecturer on farm safety.

His left side was initially fitted with a non-functional prosthesis for cosmetic purposes and for balancing the weight on the two sides of the body. The provision of balance, even by a passive prosthesis is a recommended procedure because it helps prevent curvature of the spine.

In November of 1978 the patient returned to the University of Alberta to be fitted with an electric elbow, electric wrist rotator and an electric hand which were to be controlled by a combination of myoelectric tristate devices and skin-contact touch control devices. By that time, the new TRI-3 E.M.G. modules were available, which were incorporated into the design of his new prosthesis. The medial portion of the deltoid muscle is used to provide signals to TRI-3 to open and close the myoelectric hand. The right side, which had been fitted with the tri-state components obtained from Dr. Schmidl in Italy, performed satisfactorily and the patient reported that he was pleased with the prosthesis in general terms, but that he was able to discern a difference in operation between the two sides when he was in the presence of strong interfering electrical fields. The side fitted with the myoelectric controls from Italy was susceptible to the interference, whereas the side

fitted with the more recently developed TRI-3 modules was not affected by interference. Dr. Schmidl recommends the use of metal screening or conductive graphite between the laminations of the prosthesis to guard against such interference, and that shielding had not been provided in the construction of the prosthesis, because of the cost and inconvenience associated with the additional time and effort involved. Thus, even though the lower E.M.G. signals on the left side necessitated much higher gain sensitivity settings than the Schmidl-equipped side, the interference rejection capabilities of the newer modules were noticeably superior. After the patient had been fitted for several months, some problems developed with the relays, which are frequently a source of problems in other electronic circuits. The patient frequently attended church services, where the quiet environment rendered the clicking of the relays objectionable, and he appreciated the quieter operation of the side which had been fitted with totally solid state devices.

This patient offered an excellent opportunity for us to test the hypothesis that touch control and E.M.G. control could be used together in the same prosthesis without interference. It had been suggested that the minute skin currents which flow when skin-contact touch control is used might be picked up as undesirable transients by the sensitive preamplifiers in the TRI-3 E.M.G. control unit. In fact, no such interference effects were observed, even under

worst-case conditions. The touch control devices and the TRI-3 devices operate completely independently of each other at all times.

One problem which did develop as a result of the cold Canadian winters has not been fully resolved to date. Certain considerations of comfort and clothing convenience caused the amputee to leave the touch contact area of his prosthesis access to the outside air. Moisture condensed on the metal contacts, and the skin froze to them when the patient touched the contacts to control the prosthesis. The skin areas involved had been grafted, and were fragile as well as being insensitive to feeling, so the amputee was unaware that he was hurting himself while trying to operate the prosthesis. The delicate skin grafts took a long time to heal, and the prosthesis was not used in that particular mode for several months.

The fact that this patient has been fitted successfully for over two years as of November 1980 indicates that severe bilateral high level amputees can be fitted with success, even though factors of motivation and fitting appropriateness play a major role in the eventual outcome of the procedure. Statistically, complex high level amputee fittings have at present a low rate of acceptance, and the reasons for this trend will be discussed later. The presence of at least one functioning successful patient however, indicates that the procedure is not without merit. The patient comes in to our prosthetic centre at intervals for

minor repairs and adjustments, and the condition of the prostheses when inspected at these times indicates that he is obtaining practical use from it, and that it is not in storage . The fact that the hands and wrist rotators have wheat chaff and farm dust in them, and that the elbow was worn out from extended use, indicates strongly that his prosthesis is a valuable, functioning part of his daily life, and that he is experiencing continuing long-term benefits from it that an ordinary non-powered unit could not give. His dependency on other people to do daily living tasks has been considerably reduced from his former totally-dependent state, and he frequently relates anecdotes which illustrate how completely the prosthesis is incorporated into his perception of self and daily routine.

Example of an unsuccessful high-level fitting.

Mr. M.O.C. had a right unilateral amputation just below the shoulder in July of 1977. The amputation resulted from a farm accident with a hay baler. Burns were also incurred, causing scar tissue with poor conductivity. The amputee required skin grafts, which interfered severely with the range of motion available from his remaining extremity. An earlier conventional mechanical prosthesis which had been fitted previously required operation by movement of his sound side, due to the limited range of motion available on the amputated side. The interaction between the two sides created an undesirable limitation on usefulness of the prosthesis and hindered the range of movement of his good side.

In October 1978 he was referred to us for evaluation of a possible powered prosthetic fitting. This evaluation disclosed the presence of large areas of skin graft, high electrical resistance of the grafted skin, and serious attenuation of the myoelectric signals in the skin grafted areas. It was noted that the skin grafted areas were not strong enough to withstand the repeated abrasion that would be required for operation of conventional mechanical pressure switches, and it was decided to try skin contact touch control to obtain the necessary control signals.

Skin contact points were installed within the shell of the shoulder portion of the prosthesis, which function as

follows:

A central circular contact, (see Figure 30) is provided with an insulated support so that it protrudes slightly above the average level of the inside surface of the prosthetic shell. This contact is made of conductive metal and is the first contact made by the skin of the shoulder when the humerus is moved towards it. The contact is wired through one side of the TC-2 touch control module which is connected so that the hand will open.

A further movement of the shoulder towards this electrode assembly causes the skin to indent slightly and permits the surrounding skin to make additional contact with a circular metal ring which is set slightly further back from the primary central electrode and insulated from it. When this second contact is made, the second input of TC-2 is activated and a new signal is sent to the hand causing it to open. It does not matter that the skin is continuing to touch the first contact, because an auxiliary logic circuit inserted between the hand and the TC-2 outputs directs the appropriate signals to the correct inputs of the hand and overcomes the effects of the hand's built-in priority circuits. When the TC-2 is used in conjunction with any of the other functions, such as the wrist rotator or the elbow motor, this logic function is provided automatically by the priority circuit in the PCL-1 Power Control and Logic module.

In patient M.O.C., three basic degrees of freedom were

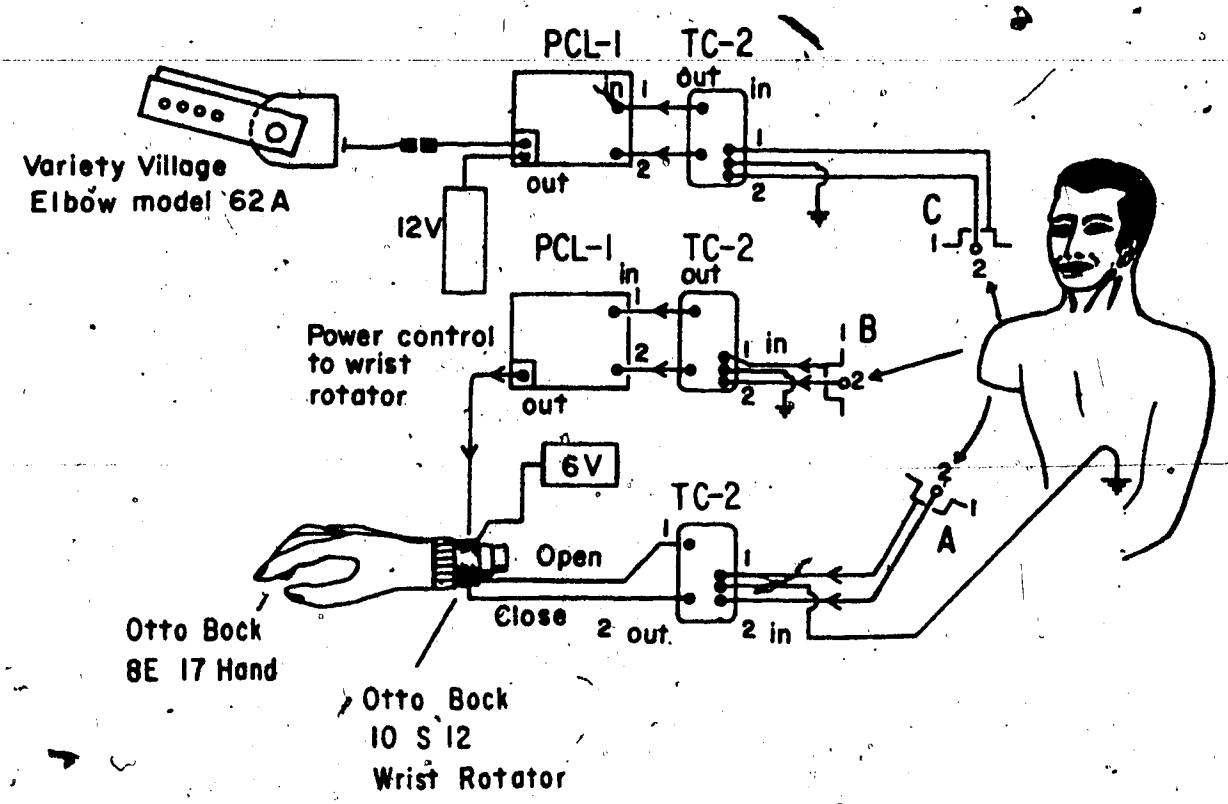


Fig. 30.

Schematic diagram of components used to obtain three degrees of freedom with high level amputees not having good E.M.G. signals.

A: The humerus is moved forward, causing the skin to contact the inner electrode. Further forward movement causes the skin to be a small amount stretched and indented, touching the outer concentric electrode as well. This second contact is connected so as to cancel the effect of the first one via a priority/logic circuit. If non-priority is connected to the "close" function of the hand, a slow skin withdrawal will not cause the hand to drop an acquired object.

B: The humerus is abducted (away from the body.) The skin contacts number 2 (non-priority) first, to pronate the wrist and with further motion contacts number 1 (priority) to supinate the wrist.

C: The humerus may be retracted (backward movement) to operate the electrically powered elbow. The skin contacts number 2 (non-priority) first to flex the elbow, and with further motion, number 1 to extend it.

needed. These included opening and closing the hand, pronating and supinating the wrist, and flexing and extending the elbow. When the "OFF" state is included as a valid condition for each of these three degrees of freedom, it can be seen that a total of nine possible circuit states are needed. Applying these requirements to the available range of motion of the remaining portion of the amputee's extremity reveals the need to use this range of motion very efficiently. An examination of the range of motion available showed that small degrees of protraction, retraction, and abduction of the humerus were available at the scapulo-humeral joint. These three movements must be assigned to a total of nine possible circuit states as described above. Therefore, the two-level concentric skin contact electrode was chosen for each of the sites, and these three electrode assemblies were positioned as carefully as the mechanical construction of the prosthesis would allow, to permit the patient relatively easy control over the arm and hand movements.

Amputee M.O.C. underwent a surgical release procedure to improve his ability to control the prosthesis by increasing his range of humeral motion. It was noted that he touched the contact points inadvertently, and that his posture and body position interacted with his control functions. Sometimes merely sitting down would cause sufficient shifting of the prosthesis on his body that false triggering would occur, due to unintentional contact with

the control sites. The contact sites were moved during several re-evaluation sessions, but it became apparent that this patient did not obtain much benefit from his prosthesis. In a clinical setting, he sometimes stated that he used it often, but the wear and tear on the prosthesis was minimal, and careful interviews revealed that he was not using it as often as he said.

Factors influencing successful / unsuccessful outcome.

There are many factors that can influence the outcome of a prosthetic fitting, and these factors are only partially understood at present. Technical considerations play an important role, but so do many other factors which are not of a technical nature. Sometimes the prosthesis functions mechanically and electrically perfectly, and yet is not really suitable for the patient.

Some of the factors influencing the outcome include:

1. Limitations of powered prosthetic appliances available.
2. Suitability of patient to the techniques presently possible.
3. Bilateral or unilateral amputee?
4. The motivation of the patient.
5. The employment of the patient.

6. The patient's lifestyle: Active, sedentary.
7. The level of the amputation.
8. The patient's expectations and "set" prior to assesment.
9. History of previous fittings: Discarded unpowered prosthesis?
10. Presence of complicating factors: Neurological, Scar tissue, metastases, health problems, distance from treatment centre, etc.

Human aspects are frequently underrated in clinical evaluations, and attention is too often directed solely to the technical aspects of the prosthesis. Nevertheless, several factors stand out regarding the shortcomings of the hands and elbows available. Powered prostheses are still bulky and inconvenient to use. They require too much effort and motivation to even put them on, and continuing concentration to operate them, particularly while the patient is learning to operate them. The amount of benefit an amputee actually obtains is in no small part a function of his level of motivation. He can learn to use the prosthesis in many life situations only if he tries it out in these real situations. He may have to use imagination and accept outside help to train him to see new ways of manipulating objects and making use of accessory tools to interact with his environment. Unilateral amputees often

would just rather not be bothered. They will use the real hand with tactile sensation to hold and manipulate objects whenever possible, and tend to relegate the prosthetic hand to the role of a positionable vise or clamp, or even a merely cosmetic aid and psychological boost.

The powered hand is often capable of more use, but the patient never tries that capability because habit patterns have already displaced the motivation to try. Acceptance of a powered prosthesis is a complex situation, involving tradeoffs in areas of cosmetic value, positioning and grasping speed, strength, and limitations implicit in the grip of the hand and glove. More than anything else, the outcome is often decided by the patient's true (and sometimes hidden) value judgements and opinions towards the device. The prosthesis may have a reasonable range of movements, and an acceptable -(if weak), range of power, and be within the patient's ability to control it, and yet still be rejected.

Factors of appearance may play a more important role than was previously assumed. A surprising number of patients, (-in fact, almost all of them), are genuinely concerned about the appearance of their cosmetic glove. Originally considered a minor point, of much less concern than function or fit, interviews that have been done with the patients by the occupational therapist and during follow-up assessments have revealed that the shortcomings of the cosmetic glove are in fact real, and of sufficient

importance to many patients that the dirty glove is by itself grounds for rejection of the prosthesis. This fact alone should indicate the importance of the appearance of the prosthesis to the amputee population that for one reason or another, eventually use myoelectric prostheses.

A fully-functional prosthesis which causes an unsightly bump on the shoulder or back, (because space has been left inside it so that shoulder movement can operate touch control points), is often rejected solely because of its unsightliness. The patient may not actually say that he or she is not using the prosthesis because it "Makes me look like a hunchback," but in reality, that is the opinion held. Training and occupational therapy session may help the patient to get somewhat more value out of a prosthesis than he did when it was first fitted, but a really effective approach to the problem of post-prosthetic care would require an intensive interdisciplinary team communication and intensive interaction which is impractical in an essentially research-oriented situation. A rigorous protocol of powered prosthetic training would ideally be augmented by feedback of technical details to the design team so that changes in the prosthesis could be implemented before the patient had been discouraged by negative experiences.

Some negative experience is implicit in any prosthetic program however, no matter how well structured it may be, and special pre-fitting instruction given to patients to avoid excessive expectation levels and motivate them

realistically may result in a higher rate of acceptance.

Many phocomelics may never accept a prosthesis at all, no matter how well it works, because they have already learned highly-effective techniques of manipulating their environment since birth. Some use their feet, others grasp objects closer to the body than non-phocomelics do, while others have developed compensatory techniques of manipulating their environment by involving the help of other people.

Others are rightfully proud of their accomplishments with their present phocomelic digits. Many phocomelics appear to be especially discouraged by the lack of tactile sensation in prosthetic hands, and miss the ability to feel shape, size, texture, and temperature of objects using an artificial limb. It acts more as a barrier between them and their environment than as as extension of body image.

These statements should not be taken to mean that powered prosthetic appliances are of no value to any and all phocomelics or amelia patients, or that they never will be developed to that point. Instead, these statements are intended to represent initial observations, and hopefully have some value in indicating important areas where additional research and development is needed.

There may be still other factors that cause one high level bilateral amputee to routinely use his prosthesis on a regular day-to-day basis, while yet another, who may not be as severely handicapped, rejects his completely.

Some high-level bilateral amputees may derive enough benefit from a carefully-designed powered prosthesis to master the drawbacks, if the device offers sufficient practicality to become a tool whereby he achieves a measure of independence.

The unilateral amputee can manipulate his environment with his sound side. The bilateral must depend upon his prosthesis or call for outside aid. A properly-fitted, well-motivated bilateral can achieve some measure of independence with a powered prosthesis. More research needs to be done to determine why this situation applies to so few cases. It seems likely that signals obtained from nerves will have a greater degree of separation, discreteness of signal content, and freedom from crosstalk than could be obtained by skin or subcutaneous E.M.G. recordings. The number of control sites available with present day E.M.G. controlled prostheses is still limited, and these control sites decrease in number the higher the level of the amputation. Unfortunately, the higher the level of the amputation, the more acute the need for additional control sites becomes, because higher level amputees require more powered joint movements or degrees of freedom.

The situation which existed in the early 1970's was that prosthetists could not find enough control sites to justify additional degrees of freedom in powered prostheses.

In 1980, it would appear that a lack of suitable hardware is becoming a potential bottleneck with respect to

these new prosthetic developments.

In many patients examined recently, control sites sufficient to accomodate most of the important degrees of freedom can be found, and the likelihood is that implants would extend this range even further. Unfortunately, the powered hands, wrist rotators, elbow joints, and other motor-driven prostheses currently available are frequently not strong enough and accurate enough to really give the patient a substantial enough improvement in his lifestyle to justify the additional weight, discomfort, concentration and effort that they require. A significant improvement in hardware design now appears appropriate and necessary, as we approach a situation in which the control sites are no longer the limiting factor.

Only one company in the world presently supplies modular interchangeable prosthetic components, and that firm is the Otto Bock Orthopedic Industry of Duderstadt, Germany. The company has a relatively conservative policy regarding development and implementation of powered prosthetic components, partly because these components represent only a small portion of the wide range of lower limb and other prosthetic appliances it manufactures, and partly because experience has shown that the field of powered prosthetics best evolves by the process of gradual improvement and modification to already-existing devices in order to provide time for adequate feedback to be obtained from workers in the field. An apparent company policy also is to implement

commercial realization of prosthetic innovations only from developments generated within its own internal organization. It is possible, however, that a policy of long-term, detailed, and reliably repeated communications with this company might result in useful improvements being made on the present modular components. Certainly it would be a waste of money and time to attempt to design electric hands, elbows, and wrist rotators of greater versatility, power, and speed than those already on the market. Difficult machining problems, material availability problems, and the problems of component accuracy and reproducibility over long periods of time make this potential project much more complex and expensive than it would initally appear at a first glance. A much more productive approach would be to work closely with the present suppliers of the prosthetic equipment and attempt to convince them that sufficient control site improvements have been made that by the time they introduce better hands on the market, the control site procedures would be ready for them. It is not likely that the firm of Otto Bock receives regular news of the depth and importance of the developments being done in our laboratory or of the implications for future development at that firm. It is instead likely, that the news that reaches them second-hand is neither reliable, unbiased, or complete, and that they are only made aware at irregular intervals of the direction of our research. Full interchange and co-operation with them may materially assist the long-term success of

this project. if their apparent reticence and conservativeness continues to be a major impediment in the development of a neurally-controlled prostheses, it would be very unfortunate, because the firm of Otto Bock has shown what may well be the best approach to date in dealing with the problems of interchangeability and field-repair practicality in powered prostheses.

Below-Elbow Amputees.

Below-elbow amputees appear to have a much higher acceptance rate for powered prostheses. Good cosmetic value offsets the social stigma associated with a hook, and the utility of the grasp and position functions may offset the discomfort associated with the weight and bulk of a prosthesis.

Powered Prostheses and the Prosthetist.

One frequently hears: "A good fit is essential for myoelectrics," - which may be easier said than done. The fit for myoelectric devices as compared to conventional prostheses, is much more demanding on the prosthetist. More patience and accuracy are required, as well as more revisions than with standard prostheses. Wrapping the extremity with an incorrect pressure or angle while taking

an impression is frequently a cause of poor electrode contact at a later stage. Many aspects of myoelectric fitting are a true craft in themselves, not replacing the need for expertise in other areas of conventional fitting, but rather requiring from the prosthetist new attitudes and techniques compatible with the different requirements. A common misconception is that the prosthetist requires complex and intensive training in electricity or electronics. Although a rudiimentary familiarity with such components as switches, batteries, and insulation is an asset, It is not electronic knowledge that the powered-prosthetic specialist requires, but rather experience and good judgement, and an awareness of the limitations and appropriateness of the available components, as well as attention to details of fit and comfort, that are central to the art of good myoelectric fittings. The specialized training offered by Otto Bock in Minneapolis, Minn. U.S.A., emphasizes the processing of lamination materials for good fit, and the interconnection of the modular components. The prosthetist must balance the tight fit needed for good electrode-to-skin contact against the requirement for patient comfort. The importance of a good fit is emphasized again and again by the leading myoelectric prosthetists, including Mr. William Sauter of the Ontario Centre for Crippled Children, and Dr. H. Schmidl of Vigorso di Budrio in Italy. Craftsmanship at every stage of a fitting is a valuable goal, and the pride of the prosthetist

in his work can often make the difference between a successful and an unsuccessful fitting, particularly when the motivation of the patient is marginal.

One area which is frequently overlooked in powered prosthetic fittings is the area of personality relationships. Frequently considered as areas of marginal importance in clinical situations, the fact remains that good interpersonal relationships between the patient and the prosthetist and other members of the team can have a decided influence on the outcome. Factors which may be involved here include the motivation of the prosthetist to do revisions when requested by the patient, and the possibilities that a patient may be malingering and projecting frustration or discontent on the prosthetist, or may never be satisfied with any fitting.

These situations are not easy to resolve, and may interfere with the patient receiving proper service to his unit. Sometimes the only way to resolve personality-based problems is simply to rearrange the assignments of patients and prosthetists. The acceptance or rejection of a prosthesis is not a hard and fast mechanical or technological problem. Instead it involves meshing of personalities, motivations, and emotions. One frequently believes that a sensitivity to these factors exists when in fact that sensitivity may stand improvement. Prosthetists, patients, and other members of a team are human beings, and sensitivity to their viewpoints may make a large difference

in the final outcome. There are patients who will not be satisfied with anything less than a replacement of their original biological arm or hand. When differences of opinion arise as to the cause for non-acceptance of a prosthesis, objective measurements help to resolve the problem.

One technique which helps to resolve differences of opinion regarding fit and adequate skin-to-electrode contact is to measure the E.M.G. levels. To do this with the prosthesis in place, which is the only valid measurement, the E.M.G. meter may be used, when it is provided with a relatively simple modification. By adding a socket to accomodate the same connector that the electrodes in the prosthesis use, the E.M.G. signal may be monitored while the prosthesis exerts its normal weight and pressure on the tissues within the extremity. The patient may be asked to move the extremity to different positions, such as; behind his back, over his head, etc. The signals obtained from the E.M.G. meter may be compared with the visual examination of the skin indent mark and any apparent looseness or play in the socket, and the patient may be asked specific questions regarding any pressure points or irritation. This procedure is of great value in resolving problems of fit.

Tests for comfort of fit are more subjective than the skin E.M.G. measurement technique. Transparent materials may be tried, but a final prosthesis would not use them because they are not cosmetically acceptable to many patients. Holes can be drilled in the prosthesis to see how close the skin

is to touch points or E.M.G. electrodes, or the arm may be removed from the prosthesis after an extended time has passed and the skin examined for the depth and color of the characteristic mark left behind by the Otto Bock electrode assembly. After some experience, it is possible to judge skin electrode pressure with fair accuracy from these markings. Red marks, irritation, rashes or swelling of the skin can indicate other problems and these can include allergy to the material used as well as excessive pressure or rubbing caused by a poor fit. Patients have an extremely wide ranges of shapes and sizes of extremity, and some are very much more difficult to fit than others. The problems encountered in obtaining a good myoelectric fit are not insurmountable in most cases however, and should not be cited as excuses for not doing myoelectric fittings by those who are opposed to myoelectric control programs. The residual muscle groups in the presently existing amputee population represent a valuable source of control sites which should not be wasted. Amputations done in a hospital setting in future may include a protocol designed to minimize muscle trauma. Neuromuscular connections should be retained, and as many independent muscle groups as possible should be retained functioning in the extremity. The value of these muscle groups for control functions may only be discovered several years after the amputation.

TABLE 3: TABLE OF PROSTHETIC OPTIONS.

In general the following protocol has been a useful guide to choose component combinations that offer value to the amputee. Rather than a rigid unalterable scheme, it is offered as an interim guide to potential powered prosthetic fittings while the research progresses.

1. SHORT BELOW-ELBOW

   a. Myoelectric hand alone: Two Bock electrodes on Forearm.
   b. Myoelectric hand and wrist rotator:
      Tristate control if space available permits.
      One tristate electrode on wrist flexors and one on extensors.

2. MID-FOREARM BELOW ELBOW

   a. Hand and Wrist with Tristate control.
   b. Wrist controlled by Bock rotary switch, Two-site Bock electrodes for control of hand open / close.
      Choice of (a) or (b) influenced by amount of space available and by the amount of residual pronation / supination.

3. LONG BELOW ELBOW WRIST DISARTICULATION.

a. Bock Myoelectric control hand fitted with split-socket control of rotation using the limited range of pronation / supination remaining.

b. Dorrance powered hook, (Not tested.) . Use depends on patient's requirements for natural appearance, occupational requirements for ruggedness or simplicity, etc.

c. Future powered hook. Not yet commercially released by Otto Bock.
Presently-available powered hooks are slow and of limited use.

4. LONG TO MEDIUM ABOVE-ELBOW

a. Cable-controlled conventional elbow plus Tristate control of both hand and wrist. Uses "cross-connection" mode of TRI-3 interconnect providing low level E.M.G. signals to control wrist movements, high level E.M.G. signals control hand opening-closing function.

b. Cable-controlled conventional elbow plus two-site two-state Bock control of hand opening and closing.

c. Cable-controlled conventional elbow plus single tristate control of hand opening and closing when

muscle sites cannot be easily differentiated.

d. Touch-control or switch control of hand alone when signal levels are low.

5. SHORT ABOVE-ELBOW OR NEAR-FOREQUARTER AMPUTATION.

a. Depends upon the control available. Scar tissue may prohibit use of myoelectric control if muscles have been almost completely removed. Deltoid or pectoral muscles may still be used in some cases even for TRI-3 control. Other muscles have not yet been explored thoroughly by this team yet. Schmidl believes there are many unused muscles to tap.

b. Touch control: Depends on the range of motion remaining at the humerus. Depends on the ability of the prosthetist to construct an aesthetically-acceptable housing which still permits accurate touch control. Shoulder hump must be as small and unobtrusive as possible, especially with female patients or patients who are appearance-conscious.

Neural Implants: Wider Implications.

Even when the usefulness of these new developments for the handicapped has been described, there are still those who do

not comprehend the full scope of these developments and what they imply. The recording and stimulation of entire behavioural patterns from the peripheral nervous system may develop eventually into an entirely new image by man of himself and his relationship to society. Neural signals are the stuff that dreams are made of. The fabric woven on Sherrington's magic loom is made of the threads of millions upon millions of tiny neural impulses. Movement, posture, locomotion, speech, sight, hearing, and thought itself are all mediated through neural impulses.

Adequate safeguards against the abuse of devices arising out of these developments will only come about through communication, education, and informed discussion. Few investigators are aware or admit that an area of important potential abuse may eventually develop, and the author is unaware of any conference dealing specifically with these concerns. Many individuals believe that scientific publications are an improper forum in which to discuss the moral and ethical responsibilities of those who develop innovations that may one day have far-reaching social consequences. Yet the specific publications which deal with these matters do not have as wide a readership as technical journals do, and it is not customary to include these issues in most publications or seminars. In a world which suffers from many problems including growing population, shrinking food and natural resources, artificially inflated economic values and precarious

individual civil liberties, it is of utmost importance that direct neural connections shall never be used for situations in which the dignity, privacy, freedom or individuality of the subject is abused. The author joined with Dr. R.B. Stein as co -inventor of the first implantable multi-channel neural device to publish a statement setting a precedent for responsible use of these devices.

POSTSCRIPT

"Many human beings throughout the world are finding relief from pain through electrical stimulation; their hearts are paced, they are able to walk more freely without crutches or canes, they are receiving respiratory support, they are able to control the elimination of wastes, they achieve improved upper extremity function, their muscles are strengthened and kept in a healthy state, contractures are relieved, their blood pressure is kept under control, they are anaesthetized, and -what is somewhat frightening to contemplate- in some cases their behaviour and personalities are altered.

The future holds no limits. The blind will see, the deaf will hear, the paralyzed will walk and use their arms. Certainly, impaired sensory and motor systems in man will be aided by a wide variety of electrical stimulation systems. To what degree the pleasure centers, and the centers of will, reaching into the very substance of personality and behaviour, will be manipulated by means of electrical stimulation and for what purposes raises issues which will challenge the moral fiber of mankind in a way that even the atomic bomb has not approached."

-JAMES B.RESWICK, SC.D.

Professor of Bimedical Engineering and community medicine, University of Southern California. Director, Rehabilitation Engineering Center, Rancho Los Amigos, California. (Quoted verbatim from NEURAL ORGANIZATION AND ITS RELEVANCE TO PROSTHETICS.) Symposia specialists, 1973. Edited by William S. Fields, M.D.

Bibliography

Aaron, S.L., and R.B. Stein. "Comparison of an EMG-Controlled Prosthesis and The Normal Human Biceps Brachii Muscle." *American Journal of Physical Medicine.* Vol. 55, No. 1 Williams & Wilkins, Pub. (1976).

Allan, A.R: "Regeneration Electrode Impedance Analysis and Recording Amplification Method." *M.Sc Thesis,* Department of Electrical Engineering, University of Alberta, (1976).

Allan, R. "Electronics Aids the Disabled." *IEEE Spectrum.* 37-40 Nov. (1976).

Alderson, S.W.: "The Electric Arm." In *Human Limbs and their Substitutes.* Hafner Publishing Co., New York, (1968).

Battye, C.K., A Nightingale, and J. Whillis: "The use of Myoelectric Currents in the Operation of Prostheses." *J. Bone and Jt. Surg.,* 37B: 506-510, (1955).

Bockris J. and A Reddy, *Modern Electrochemistry.* Plenum Press: New York, (1970).

Brindley, G.S., "Electrode arrays for making long-lasting electrical connexion to spinal roots." *J. Physiol. (Lond.)* 222: 135P-136P (1972).

Childress, D.S., and J.N. Billock: "Self-Containment and Self-Suspension of Externally-Powered Prostheses for the Forearm." *Bull. Prosth. Res.,* 14: 4-21, (1970).

Clippinger, F.W., R. Avery, and B.R. Titus: "A Sensory Feedback System for an Upper-Limb Amputation Prosthesis." *Bull. Prosth. Res.,* 22: 247-258, (1974).

Committee for Prosthetics Research and Development:" Rehabilitation Engineering: A Plan for Continued Progress." *Nat. Acad. Sci., Washington,* (1971).

Cragg, B.G. and P.K. Thomas, "Changes in Conduction Velocity and Fiber Size Proximal to Peripheral Nerve Lesions," *J. Physiol. Lond.* vol. 157, pp. 315-327, (1961).

Crago, P.E., Mortimer, J.T., and Peckham, P.H., "Closed-Loop Control of Force During Electrical Stimulation of Muscle." *IEEE Transactions on Biomedical Engineering*, Vol. BME-27, No. 6 June, (1980).

Davies, P.W. in *Medical Physiology*, ed. Mountcastle, V.B. 12th edition, Chapter 51 1064-1081 (1968).

Davis, L.A., T. Gordon, J.A. Hoffer, J. Jhamandas, and R.B. Stein: "Compound Action Potentials Recorded from Mammalian Peripheral Nerves Following Ligation and Resuturing." *J. Physiol.*, 285: 543-559, (1978).

DeLuca, C.J. and L.D. Gilmore: "Voluntary Nerve Signals From Severed Mammalian Nerves: Long-term Recordings." *Science* 191: 193-195, (1976).

Dorcas, D.S., Dunfield, V.A., and Scott, R.N., "Improved myoelectric control system." *Med.Biol. Eng.* 8, 331-341 (1970).

Ducker, T.B. and G.T. Hayes, "Experimental Improvements in the use of Silastic Cuffs for Peripheral Nerve Repair." *J. Neurosurg.* 28: 582-587, (1968).

Dymond, A.M. "Characteristics of the Metal-Tissue Interface of Stimulation Electrodes." *IEEE Trans. Bio. Med. Engng. BME.* 23: 274-280, (1976).

Evarts, E.V., "Pyramidal Tract Activity Associated With a Conditioned Hand Movement in The Monkey, " *J. Neurophysiol.* 29: 1011-1027 (1966).

French, A.S., "Automated Spectral Analysis of Neurophysiological Data Using Intermediate Magnetic Tape Storage." *Comp. Prog. Biomed.* 3: 45-47 (1973).

French, A.S., and Stein, R.B. A Flexible Neural Analog Using Integrated Circuits. *I.E.E.E. Trans. Bio-Med. Engin.*, 17: 248-253 (1970).

Gordon, T., Hoffer, J.A., Jhamandas, J., and Stein, R.B., "Long-term effects of axotomy on neural activity during cat locomotion." *J. Physiology.*, 303, pp. 243-263, (1980).

Hagbarth, K.A. and A.B. Vallbo, "Single-unit recordings from muscle nerves in human subjects." *Acta Physiol. Scand.* 76: 321-334 (1969).

Herberts, P., Almstrom, C., Kadefors, R., and Lawrence P.D. "Hand Prosthesis Control Via Myoelectric Patterns. *Acta Orthop. Scand.*, 44: 389-409 (1973).

Hoffer., J.A., Marks, W.B., Rymer, W.Z., "Nerve fiber activity during normal movements." *Proc. Soc. for Neuroscience.* 4th meeting, 300: p.258 (1974).

Hoffer, J.A.: "Long-Term Peripheral Nerve Activity During Behaviour in the Rabbit: The Control of Locomotion." Ph.D. Thesis, Johns Hopkins Univ., #76-8530, University Microfilms, Ann Arbor, Mich., U.S.A. (1975).

Hoffer, J.A. and Marks, W.B.. "Long-Term Peripheral Nerve Activity During Behaviour in the Rabbit." *Adv. Behav. Biol.* 18: 767-768, (1976).

Hoffer, J.A., T.E. Milner, and R.B. Stein. "Long-Term Peripheral Nerve and Muscle Recordings in Intact Mice." *Neurosci. Abstr.* vol. 2, No. 1040, (1976).

Holz, A. "Regenerative splitting of peripheral nerves; an attempt towards multichannel prostheses control." *Digest of the 10th International Conference on Medical and Biological Engineering.* Session 38-6, P. 116 (1973).

Holz, A. "Regeneration peripherer Nerven durch implantierte Vielfachcapillaren." In *Res. exp. Med.* 164. 321-323. Springer-Verlag. (1974).

Ives, D.G. and Janz, G.J. "Reference Electrodes." *Reference Electrodes.*, Academic Press, N.Y. and London. P 106-123 (1961).

Jacobsen, S.C., R.B. Jerard, and D. Krutti: "Development and

Control of the Utah Arm." *Proc. 5th Int. Symp. on External Control of Human Extremities:* Dubroynik, Yugoslavia, (1975).

Jung., W.G., "The Pitfalls of the General-Purpose I.C. Operational Amplifier as Applied to Audio Signal Processing." *Journal of Audio Engineering Society.* 21: 706-714 (1973).

Kadefors, R. and Reswick, J.B., "A Percutaneous Electrode for Long-Term Monitoring of Bioelectric Signals in Humans." *Med.Biolog. Eng.* 8, 129-135. (1970).

Kato, I., S. Yamakawa, K Ichikawa, and M. Sano: "Multi-Functional Myoelectric Hand Prosthesis with Pressure Sensory Feedback System. The WASEDA Hand." *The Proceedings of the Third Int. Symp. on External Control of Human Extremities:* Dubrovnik, Yugoslavia, (1970).

Kato, I.: "Trends in Powered Upper Limb Prostheses." *Prosth. Orthot. Int.*, 2: 64-68, (1978).

Llinas, R., Nicholson, C.J., and Johnson, K., "Implantable Monolithic Wafer Electrodes for Neurophysiology." In *Brain Unit Activity During Behavior.* University of Iowa, (1973).

Loeb, G.E., Bak., M.J., and Duysens, J. "Long-Term Recording from Somatosensory Neurons in the Spinal Ganglia of the Freely Walking Cat." *Science,* 197: 1192-1194 Sept. (1977).

Mann, R.W.: "Prosthesis Control and Feedback Via Noninvasive Skin and Invasive Peripheral Nerve Techniques. " In *Neural Organization and Its Relevance to Prosthetics.* edited by W.S. Fields and L.A. Leavitt. Intercontinental Medical Book Corp.: New York, pp. 177-190, (1973).

Mann, R.W., and Reimers, S.D. "Kinesthetic Sensing for the EMG Controlled 'Boston Arm,' " In: *Advances in External Control of Human Extremities,* ed. M.M. Gavrilovic, and A.B. Wilson Jr., pp. 231-243. Belgrade, Yugoslav Committee for Electronics and Automation, (1970).

Mannard, A., R.B. Stein, and D. Charles. "Regeneration

Electrode Units: Implants for Recording From Peripheral Nerve Fibers in Freely-Moving Animals." *Science (N.Y.)* vol.183: 547-549, (1974).

Marion, L. "Artificial Arm's Processor Recognizes Different Body Signal Waveforms." In: *Electronics* Vol. 52: No.8., April 12. McGraw-Hill pub. (1979).

Marino, A.A., Berger, T.J., Austin, B.P., Becker, R.O., and Hart, F.X.. "In Vivo Bioelectrochemical Changes Associated with Exposure to ELF Electric Fields." *Physiol. Chem. and Physics*, 9, 433-441. (1977).

Marks, A.F., "Bullfrog Nerve Regeneration into Porous Implants." *Anat.Rec.* 163: 226 (1969).

Marks, A.F., "Acceptance of Implanted Plastic Structures by the Brain of the Mature Rat." *Anat. Rec.* 169: 375 (1971).

Marks, A.F., "Regenerative Reconstruction of Tracts in the Adult Rat's Brain." *Anat. Rec.* 172: 363 (1972).

Marks, A.F., "Optic Tract Regeneration in the Adult Rat." *Society for Neuroscience 2nd Annual Meeting Program & Abstracts.* 8.1 (1972).

Marks, A.F., "Rapid Axon Elongation in Injured Mammalian Brain." *Anat. Rec.* 175: 383-384 (1973).

Marks, A.F., "Recovery of Structure in Injured Mammalian Brain." *Society for Neuroscience, 3rd Annual Meeting Program & Abstracts.*

Mark, R.F., "Matching Muscles and Motorneurons." *Brain Research.* 14: 245-254. (1969).

Marks, W.B., "Some methods for simultaneous multiunit recording." *Symp. on Info. Processing in Sight Sensory Systems.* P.W. Nye, ed., Caltech, Pasadena, pp.200-206. (1965).

Marks, W.G. and G.E Loeb . "Action Currents, Internodal

Potentials, and Extracellular Records of Myelinated Mammalian Nerve Fibers Derived from Node Potentials." *Biophys. J.* (1976).

Mintz, R.S., "Noise Considerations in Audio Amplifiers." *DB., The Sound Engineering Magazine.* Vol. 8, (1974).

Murphy, E.F., "The history and philosophy of attachment of prostheses to the musculo-skeletal system and of passage through the skin with inert materials." *J. Biomed. Mater.Res. Symp. 4* 275-296, (1973).

Neff, G.: "Prosthetics Principles in Bilateral Shoulder Disarticulation or Bilateral Amelia." *Prosth. Orth. Int.*, 2: 143-147, (1978).

Northmore-Ball, M.D., Heger, H., Hunter, G.A., "The below-elbow myo-electric prosthesis." *J. of Bone and Joint Surgery.*, Vol. 62-B, No.3, August, (1980).

Pollak, V. "Computation of the Impedance Characteristics of Metal Electrodes for Biological Investigations." *Med. Biol. Engng.* vol. 12: 460-464, (1974).

Pollak, V. "Impedance Measurements on Metal Needle Electrodes." *Med. Biol. Engng.* vol. 12: 606-612, (1974).

Ranson, S.W. "Retrograde Degeneration in the Spinal Nerves." *J. Comp. Neurol.* 16: 265-293, (1906).

Reswick, J. et al.: "Sensory Feedback Prosthesis Using Intraneural Electrodes." *Proc. 5th. Int. Symp. on External Control of Human Extremities.* Dubrovnik, Yugoslavia, (1975).

Robinson, D.A. "The Electrical Properties of Metal Microelectrodes." *Proc. IEEE* 56: 1065-1071, (1968).

Salcman, M. and M.J. Bak. "Design, Fabrication and Behavior of Chronic Recording Intracortical Microelectrodes." *IEEE Trans. Biomed Engng. BME* 20: 253-260 (1973).

Schlesinger, G.: "Der mechanische Aufbau der kunstlichen

Glieder." *Erstsglieder und Arbeitshilfen*, Springer Verlag: Berlin, (1919).

Schmidl, H.: "The INAIL-CECA Prostheses." *Orth. Prosth.*, 27: 6-12, (1973).

Schmidl, H.: The Importance of Information Feedback in Prostheses for the Upper Limbs." *Prosth. Orth. Int.*, 1: 21-24, (1977).

Schmidl, H.: The I.N.A.I.L. Experience Fitting Upper-Limb Dysmelia Patients with Myoelectric Control." *Bull. Prosth. Res.*, 10: 17-42, (1977).

Scott, R.N., Myoelectric Energy Spectra. *Med. Biol. Engin.*, 5: 303-305 (1967).

Scott, R.N. *et al.* "Development of a System to Provide Sensory Feedback of Pinch Force from a Prosthetic Hand. " *Univ. New Brunswick Bio-Engineering Institute., Progress Report #15: Monckton, N.B. Canada.* (1977).

Scott, R.N. *et al.* "Clinical Evaluation of UNB 3-State Myoelectric Control." *Univ. New Brunswick Bio-Engineering Institute., Progress Report* #16: Monckton, N.B. Canada, (1978).

Sprigings, E., D.Charles, S. Mendryk. "An EMG Measurement System for Moving Subjects." *Canadian Journal of Applied Sport Sciences.* Vol.2. 149-151 (1977).

Stanitski, C.L. & Mooney, V.: "Osseus Attachment to Vitreous Carbons." *J. Biomed. Mater. Res. 7: (Biomed. Mater, Symp. 4: 97-108)* (1973).

Stein, R.B., D. Charles, L. Davis, J. Jhamandas, and T.R. Nichols, "A Method for Chronic Recording from Nerve Fibers in Experimental Animals and Man." *Can. Fed. Biol. Soc.* 18: 39 (1975).

Stein, R.B. "Peripheral Control of Movement." *Physiol. Rev.* 54: 215-243 (1974).

Stein, R.B., and K.G. Pearson, "Predicted Amplitude and Form of Extracellularly Recorded Action Potentials from Unmyelinated Nerve Fibers." *J. Theor. Biol.* 32: 539 (1971).

Stein, R.B., D. Charles, L. Davis, J. Jhamandas, A. Mannard, and T.R. Nichols: "Principles Underlying New Methods for Chronic Neural Recording." *Can. J. Neurol. Sci.*, 2: 235-244, (1975).

Stein, R.B., D. Charles, T. Gordon, J.A. Hoffer and J. Jhamandas: "Impedance Properties of Metal Electrodes for Chronic Recording from Mammalian Nerves." *I.E.E.E. Trans. Biomed. Engineering.*, BME. 25: 532-537, (1978).

Stein, R.B., J.A. Hoffer, T. Gordon, L.A. Davis, and Dean Charles: "Long-Term Recordings from Cat Peripheral Nerves During Degeneration and Regeneration: Implications for Human Nerve Repair and Prosthetics." In *Nerve Repair: Its Clinical and Experimental Basis*, Ed. D.L. Jewett and H. R. McCarroll. C. V. Mosby: St. Louis, (1979).

Stein, R.B., J. Jhamandas, and T.R. Nichols. "Long-Term Recording of Electrical Activity of Mammalian Nerves Following Axotomy." *Soc. Neurosci. Abstr.* vol. 1: No. 795, (1976).

Stein, R.B., T.R. Nichols, J. Jhamandas, L.Davis, and D. Charles: "Stable Long-Term Recordings from Cat Peripheral Nerves." *Brain Research.*, 128: 21-38, (1977).

Strain, R.E. Jr., and W.E. Olson. "Selective Damage of Large Diameter Peripheral Nerve Fibers by Compression: an Application of Laplace's Law." *Exp.Neurol.* vol. 47, 68-80 (1975).

Tasaki, I. "A new Measurement of Action Currents Developed By Single Nodes of Ranvier." *J. Neurophysiol.* 27: 1199-1206 (1964).

Teresi, D., "The Real Bionic Man." *Omni*. Vol.1, No. 2 Omni Publications International Ltd., N.Y. U.S.A. 44-48., Nov. (1978).

Tucker, F.R., and N. Peteleski: "Myoelectronic Telemetry Implant for Myoelectric Control of a Powered Prosthesis." *Can. Elec. Eng. J.*, 2(4): 3-7, (1977).

Walker, C.F., G.R. Lockhead, D.R. Markle, and J.H. McElhaney: "Parameters of Stimulation and Perception in an Artificial Sensory Feedback System." *J. Bioeng.*, 1: 251-260, (1977).

Wirts, R.W., D.R. Taylor, and F.R. Finlay: "Pattern-Recognition Arm Prosthesis: A Historical Perspective - A Final Report." *Bull. Prosth. Res.*, 30: 8-35, (1978).

Wong, E.Y.M. "Theoretical and Experimental Studies on Frog Skeletal Muscle." *M.Sc. Thesis.*, Department of Physiology, University of Alberta, Edmonton, Alberta, Canada. (1972.)

Wise, Angell, Starr. "An Integrated Circuit Approach to Extracellular Microelectrodes." *IEEE Transactions on Biomedical Engineering*, Vol. 17, 238-246 (1970).

Index