DEVELOPING CLINICAL DEVICES FOR HEMIPLEGIC STROKE PATIENTS

E. Schuck, H. Friedman, W. Wilemon and D. McNeal

Summary

Rancho Los Amigos Hospital, Downey, California and Medtronic, Inc., Minneapolis, Minnesota have been cooperating since 1969 in the development of implanted devices for the stimulation of peripheral nerves to improve gait in hemiplegic stroke patients /2, 3, 4, 5, 6, 7/. This cooperative effort has resulted in the evolution of devices for the clinical treatment of "foot drop", a common disorder with many hemiplegic patients. Early experimentation with surface nerve and muscle stimulators /1, 8, 9/, led Rancho to the development of an implanted stimulation system in 1967. Medtronic joined the Rancho development team in 1969 based on our previous experiences with implantable pacemaker systems and desire to develop devices in the rehabilitation field. The present system consists of an implanted electrode that is wrapped around the proper branches of the peroneal nerve bundle and an implanted receiver that detects radio frequency (R.F.) energy pulses. The R.F. pulses are transmitted transcutaneously by an external stimulator worn on the patient's belt. The Peroneal Stimulator System is shown in Figure 1 with Figure 2 depicting the approximate equipment location on a right side hemiplegic.

Introduction

The purpose of this paper is to describe the hardware development process based on clinical application at Rancho Los Amigos Hospital.

Phase 1 (1969 - 1971) - Evolution of the hardware based on clinical treatment of "18" foot drop patients. The objective of this phase was to provide an assessment of the safety, efficiency and reliability (SER) of the design and its application for expanded investigation with humans. Basic considerations were design evaluation including material toxicity, device failure analysis, human factors, environmental considerations and reliability.

Phase 2 (1972) - Hardware implementation period when the hardware was redesigned based on findings of the Phase 1 program and evaluated by fifteen patients.

Phase 3 (1972 -) - Multiple center clinical testing. The objective of this phase is to provide an assessment of SER of the design and application as the treatment of choice at expanded clinical centers. Basic considerations include clinical evaluation plan, patient

selection criteria, product development, patient re-
nd product literature.

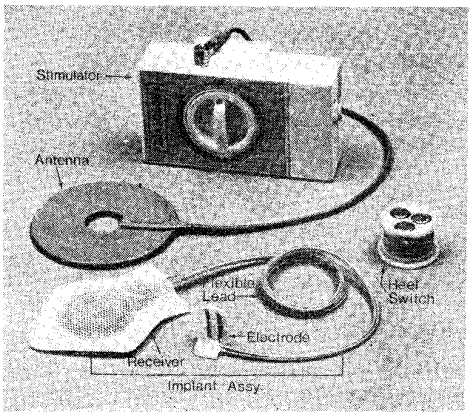


Fig. 1. Peroneal stimulator system.

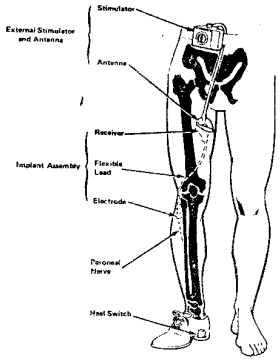


Fig. 2. Approximate equipment location in right side hemiplegia.

In addition to the treatment of the "foot drop" patients, other applications were evaluated at Rancho including:

Hip stabilization,

Peripheral nerve blocking,

Tendor repair.

Hardware Evolution

The hardware has evolved through three major developments shown in Figures 3 and 4.

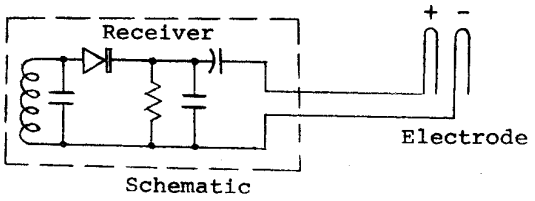
Figure 3 shows the implanted receiver/electrode assemblies. The major changes in the implant are:

(a) A coiled spring conductor welded to platimun foil electrode strips was replaced by a continuous 6 strand platinum wire reinforced with polyester yarn to increase reliability.

(b) A dacron cover was placed over the receiver so that the receiver could be sutured to the facia to prevent migration in the medial lateral thigh.

(c) The edges of the receiver were tapered to minimize skin erosion.

Figure 4 shows the external hardware assemblies. The major



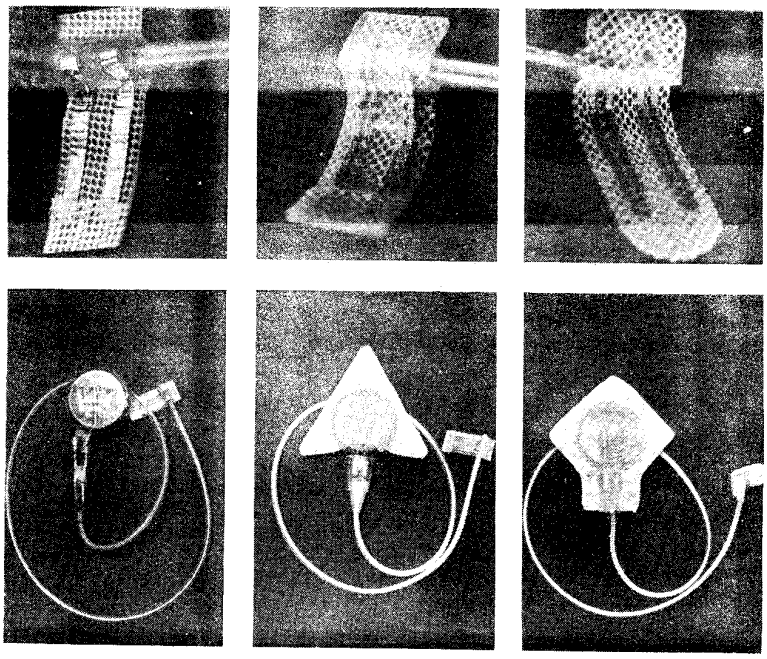


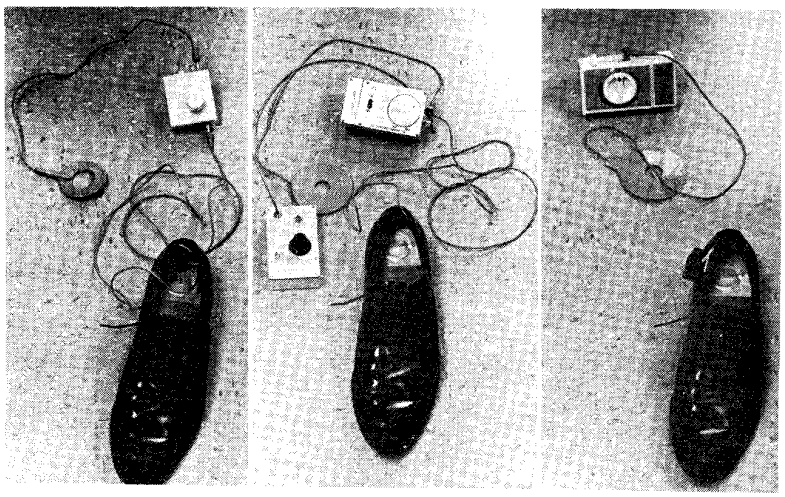
Fig. 3. Evolution of implanted receiver/electrodes
(a) Model 1199 - Date used 1 May 69 - 25 Sept. 69. Patients implanted-10
(b) Model 12008 - Date used 5 Nov. - 4 Dec. 70. Patients implanted-7
(c) Model - Date used 22 Oct. 71 - Present Patients implanted-12

changes in the external hardware are described as follows:

(a) An integral on/off switch and stimulation amplitude control to protect the patient against over stimulation during turn on.

(b) A ratchet detent on the amplitude control knob to prevent the knob from changing position when brushed against clothing.

(c) Maximum, minimum and rate potentiometer adjustments are accessable through a hole in the control knob for the therapist to titrate the patient (Fig. 5).



(a) (b) (c)

Fig. 4. Evolution of the external hardware
(a) 1969-1970. Pulse transmitter and heel switch attached by extension cables.
(b) 1970-1971. Pulse transmitter, cycler and heel switch attached by extension cables.
(c) 1972- . Modular designed pulse transmitter with modules for a cycler and wireless heel switch link.

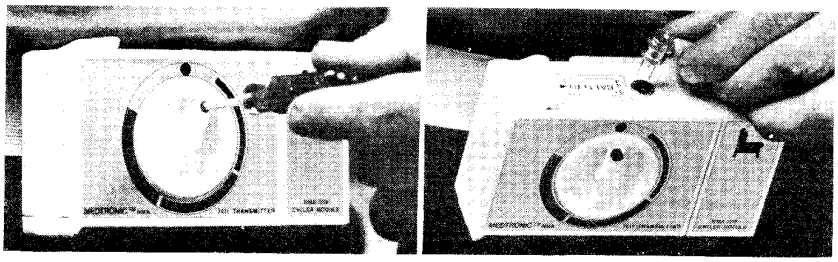


Fig. 5. Maximum, minimum and rate potentiometer adjustments are accessable through a hole in the control knob for the therapist to titrate the patient.

Fig. 8. Antenna connector can be easily removed with one hand.

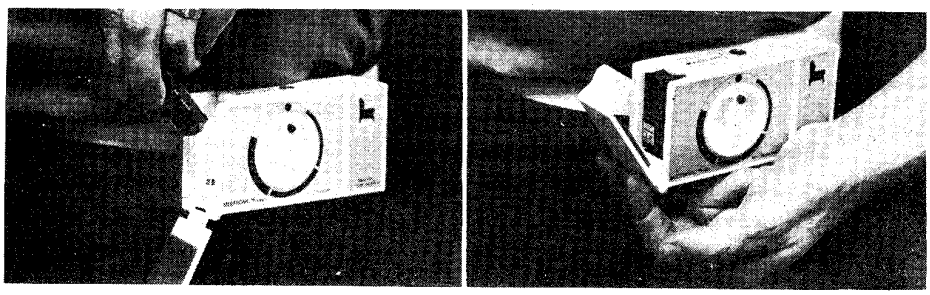
(d) The battery compartment has a hinged cover for easy battery replacement with one hand (Fig. 6). This is important because most hemiplegic patients have the use of only one hand.

(e) A dove tail modular design concept was adopted so that individual modules could also be replaced with one hand (Fig. 7). The modular design provides versatility in patient application. Separate modules are provided for a remote heel switch link and the cycler as described below.

(f) A wireless heel link is provided to eliminate wires from the shoe.

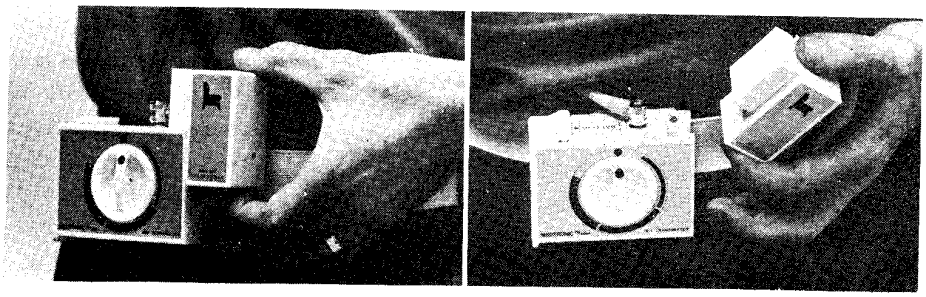
(g) An automatic cycler is provided for therapeutic applications including the build up of muscle bulk.

(h) Antenna connector can be easily plugged in and out with one hand (Fig. 8).



(a) (b)

Fig. 6. The hinged battery compartment allows replacement of



(a) (b)

Fig. 7. The modular design allows a one handed patient to remove and install the remote heel switch receiver or the cycler module.

Hardware Implementation

We considered that it was very important to include the design features listed in the Phase 1 discussion. The crucial consideration was to develop the design and manufacturing techniques to build 100-200 devices for expanded clinical evaluation. The implantable receiver electrode assembly utilizes manufacturing techniques similar to the implantable pacemaker; therefore, production was completed in our laminar flow clean room facility. The external hardware, on the other hand, is specialized for the hemiplegic stroke patient and requires special tooling and construction techniques.

The system specifications are summarized in Table 1 and individual component assemblies are shown in Figure 9. All assemblies are inspected by our quality control department for workmanship and all electronic components are screened and approved by our reliability department.

Plastic case parts became our major problem area because the low quantity required and general complexity of the design was not suitable for injection molding techniques. The plastic parts were also very difficult to machine out of solid plastic stock; therefore, we needed an alternate technique. The technique we selected is an epoxy casting process. Metal molding masters were machined out of brass and positive molds were made from the master using unique silicon rubber material as shown in Figure 10. Then epoxy is poured into silicon rubber molds to yield the final parts.

Multiple Center U.S. Clinical Evaluation

We are currently arranging a clinical evaluation program, sponsored by the Committee on Prosthetics Research and Development (CPRD) of the National Research Council, to be held in the fall of 1972 at four U.S. Rehabilitation Centers. The purpose of this clinical evaluation program will be to assess the safety, efficacy and reliability of the design and application as treatment for hemiplegic foot drop condition.

Patient selection criteria is extremely important because the device is not applicable to all hemiplegic patients with foot drop condition. Table 2 outlines some of the selection criteria which will be used by the surgeon, physical therapist, nursing staff and other members of the rehabilitation staff to select the proper candidates for the upcoming clinical program.

Table 1

System specifications

GENERAL

The Model 7010 Peroneal Stimulator has been developed for clinical treatment of "Foot Drop" in hemiplegic patients. The system includes an implanted receiver and nerve lead which is wrapped around the proper branches of the Peroneal nerve bundle. The implant intercepts radio frequency (R. F.) energy pulses transmitted transcutaneously by an external stimulator worn on the patient's waist.

FEATURES

Modular Concept	-	Device function changed by substitution of a plug-in module package.
Wireless Heel Switch	-	Miniature battery operated transmitter provides "heel lift" signal.
Cycling Module	-	Therapeutically maintains muscle bulk.
Walking Module	-	Receives heel switch signal, triggers stimulation.
Adjustable output Voltage	-	"Min." and "max" each adjustable to avoid over and under stimulation.

Hemiplegic patient considered in design of -

- Battery replacement
- Output adjustment knob and adjustment scales
- Antenna connector and leg attachment
- Module shape, usage and markings
- Donning and suspension of equipment.

Manufacturing process features -

- Low inertia (change orientated) production facility.
- Cast epoxy case parts
- High reliability electronics minimize field problems.

SPECIFICATIONS

Stimulator

Output	0-3.0 volts (adjustable)
R. F. carrier frequency	450±2 Kilohertz
Stimulation pulse width	220 micro seconds
Repetition rate	20 to 50 pps (adjustable)
Battery	9 V DC type 146. 100-150 hour life (continuous duty, 500 ma hr. capacity)
Weight	160 grams with battery
Case material	Cast epoxy
Dimensions	3.5 x 2 60 x 1.3 inches (without module)

Walking Module

Receiver band width	6.0±1.0 Kilohertz
Connector	Microdot MCDM 1 - 9 pin.
Power required	1.5 ma (off) 3.0 ma (on) at 9 VDC
Weight	50 gms. max.
Case material	Cast epoxy
Dimensions	1.0 x 2.60 x 1.3 inches

Cycling Module

Cycling times	Off 25±5 sec. On 5 to 15 sec. adjustable.
Connector	Microdot MCDM 1 - 9 pin
Power required	2.6 ma (on or off) at VDC
Weight	30 grams max.
Case material	Cast epoxy
Dimensions	1.0 x 2.6 x 1.3 inches

Wireless Heel Switch

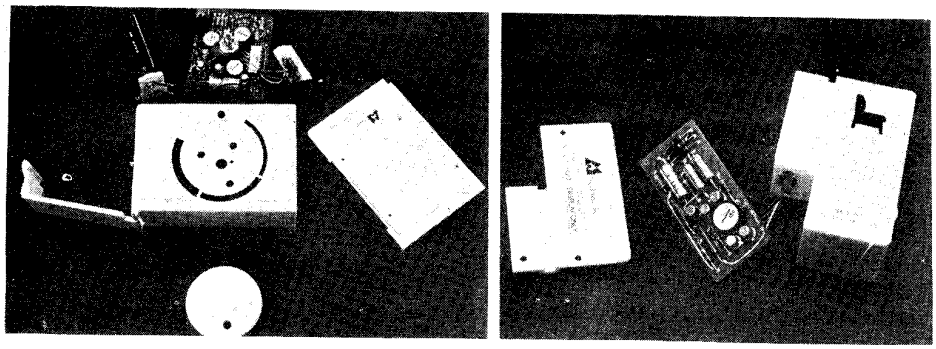
Batteries	3 type RM41H
Frequency	6.0±0.1 Kilohertz
Transmission range	50 inches
Dimensions	1.4 dia. x .9 inches (preliminary)
Weight	10 grams max.

Implant

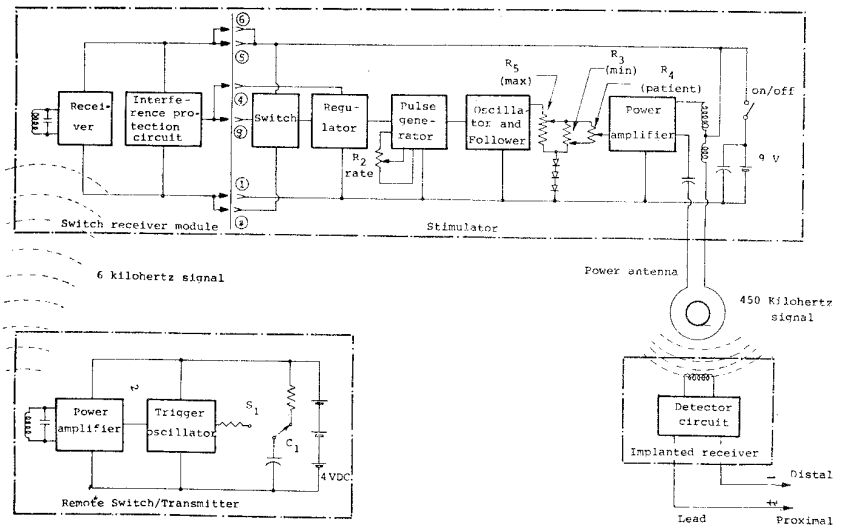
Receiver	Detects 450 Kilohertz
Dimensions	1.6 dia. x .3 inches (approximate) thick covered with Dacro scrim for tissue attachment
Nerve lead	Platinum tinsel wire. Molded silicon construction. Wrap around termination. Attached to receiver.

Antenna Coil

Flat coil provides transcutaneous R. F. link with implant. 3.0 O. D. x 1.5 I. D. x 1/8 thick.



(a) (b)



(c)

Fig. 9. Component assemblies and block diagram
(a) Stimulator sub-assemblies
(b) Cycler sub-assemblies
(c) Electrical circuit block diagram.

Table 2

Selection criteria applied in evaluating prosceptive implant candidate

SELECTION CRITERIA APPLIED	MEASURES:
General Medical Evaluation	
• General Patient Evaluation	• Total suitability of patient as implant candidate based on medical history, rehabilitation prognosis, home situation
• Neurological Evaluation - EMG - Nerve Conduction Times	• Presence of intact spinal reflex arc, functional musculature, and absence of peripheral nerve damage
Physical Function Testing	
• Control, Strength, and Range of Motion (hip, knee, ankle, subtalor joint)	• Can patient walk? • Range of motion of involved extremity in degrees • Selective versus patterned control - Presence and degree of selective control - Grading of patterned motion (whether flexion or extension pattern, whether weak, strong, or moderate)
• Tone Analysis	• Spasticity of involved muscle groups (whether major deforming force, whether static or dynamic)
• Gait Analysis	• Gait dysfunction as a result of lesions - Clinical assessment of gait - Walking EMG - Walking speed - Step length - Step frequency
• Sensation	• Position sense - Body image - Balance - Proprioception
Perceptual Testing	
• Gadget Test	• Ability to put on equipment • Ability to operate equipment
Psychological & Intelligence Evaluation	
• Patient Interviews	• General intelligence level • Memory • Personality • Motivation • Emotional tolerance levels • Equipment reaction (gadget tolerance)

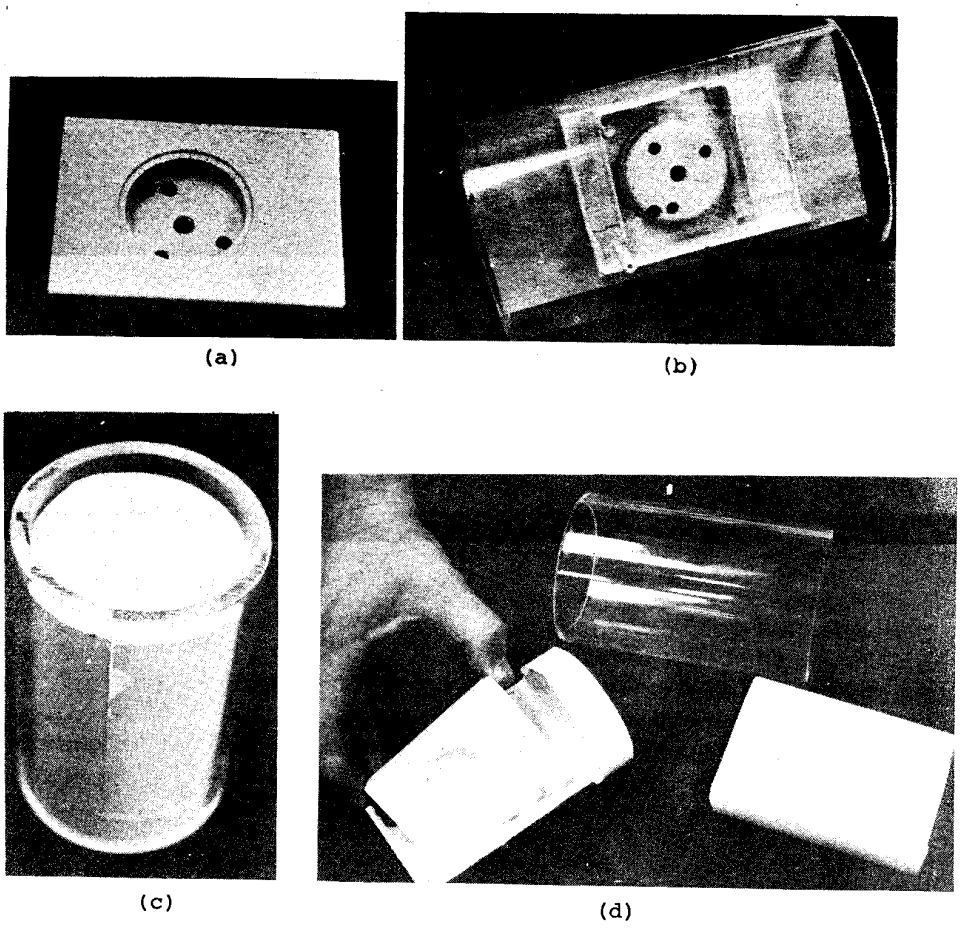


Fig. 10. Epoxy Molding of the case parts
(a) Metal Master is machined from brass
(b) Metal Master is inserted into a plexiglass tube to make a positive rubber mold
(c) Rubber mold is then prepared for pouring the epoxy liquid
(d) The epoxy is cured for 12 hours and then the final plastic part is removed.

A general clinical protocol will be followed to help insure that uniform patient selection criteria, patient's consent, data collection, and consistent hardware is used during the clinical evaluation. The goal will be to evaluate at least fifteen patients at each clinical center with CPRD publishing a final report, including device performance and patient benefit.

A very important part of implementing all phases of the pro-

gram with Rancho is communications because the team is separated both by distance and specialities. Medtronic personnel frequently travel to Rancho with some members averaging one trip a month.

The following are typical agenda items covered at Rancho during these trips:

Attend design reviews,
Witness surgery,
Attend patient equipment fitting clinics,
Observe animal research,
Conduct patient interviews,
Review hardware failures, and
Provide hardware training and service.

Other Applications

The hardware developed for the peroneal implant program has been used for other peripheral nerve stimulation applications at Rancho including:

Hip Stabilization of Stroke Patients

A major problem in hemiplegic gait is hip extensor weakness. Presently no surgical or bracing techniques are available to adequately control this problem. One patient at Rancho has had an electrode implanted to contract the gluteus maximus muscle to provide hip extension. Initial indications are encouraging and considerations are now being given to simultaneous stimulation of the hip adductors to provide additional assistance.

Peripheral Blocking

Feasibility of controlling spasticity with electrical stimulation is currently under investigation. Prelinimary experimental results will be presented in a separate paper at this conference.

Tendon Repair

Surgical repair of tendons sometimes fail because of the reluctance or inability of the patient to adequately exercise the involved hand. A receiver/electrode was implanted in a patient who's previous tendon graft was unsatisfactory because of the patient's unwillingness to move his hand. The patient's therapeutic program was initiated three days following surgery with a cycling module that had variable ON time (1-10 sec.) and variable OFF time (5-15 sec.) adjustable by the therapist. It is interesting to note

that the patient has not complained of any pain or discomfort either from the stimulation or the resulting movement of the fingers. This was a patient that previously would not voluntarily flex his hand because of discomfort.

Conclusion

Rancho and Medtronic have successfully tested an implantable system for the treatment of foot drop condition in twenty five (25) hemiplegic stroke patients. Committee on Prosthetic Research and Development (CPRD) will sponsor multiple center U.S. evaluation program in the fall of 1972 at four U.S. centers to determine the safety, efficacy and reliability of the design and application on 75-100 patients.

References

/1/ Liberson, W.T., Homquest, H.J., Scott, D., and Dow, M.,"Functional Electrotherapy: Stimulation of the Peroneal Nerve Synchronized with the Swing Phase of the Gait of Hemiplegic Patients", *Arch. Phys. Med.*, 42:101-105, 1961.

/2/ McNeal, D., Wilemon, W.K., Mooney, V., Boggs, R. and Tamaki,T., "The Effect of Peripheral Nerve Implanted Electrical Stimulation on Motor Control in Stroke Patients", *World Congress of Neurological Sciences*, New York, New York, September 1969.

/3/ Monney, V., A Rationale for Rehabilitation Procedures Based on the Peripheral Motor System", *Clinical Orthopaedics and Related Research*, No. 63, J.B. Lippincott Company, 1969.

/4/ Wilemon, W.K., Monney, V., McNeal, D. and Reswick, J., "Surgically Implanted Neuroelectric Stimulation - Two Years' Experience Rancho Los Amigos Hospital", Paper presented to committee on Prosthetics Research and Development, Houston, Texas, June 1970.

/5/ Wilemon, W.K., McNeal, D., Friedman, H., and Mooney, V., "Selective Patient Control of Spastic Musculature by means of Surgically Implanted Peripheral Nerve Stimulation Devices", *Neuroelectric Conference*, Las Vegas, Nevada, March 1970.

/6/ Tamaki, T., McNeal, D. and Wilemon, W.K., "Recorded Neurophysiological Effects of Patient Implanted Peripheral Nerve Stimulators", *Neuroelectric Conference*, Las Vegas, Nevada, March 1970.

/7/ Yergler, W.G., Wilemon, W., McNeal, D., "An Implantable Peroneal Nerve Stimulator to Correct Equinovarus During Walking", *The Journal of Bone and Joint Surgery*, December 1971.

/8/ Vodovnik, L., "Functional Electrical Stimulation of Extremities", *Advances in Electronics and Electron Physics*, Vol. 30, 1971.

/9/ Jeglič, A., Smolnik, M., Brodnik, L., "Implantable Stimulator Technology; Development of Orthotic Systems Using Functional Electrical Stimulation and Myoelectric Control", Final Report, Project No. 13-P-58391-F-01, University of Ljubljana, Yugoslavia, December 1971.