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LONG-TERM FOLLOW-UP OF PERONEAL NMA PATIENTS

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Abstract

Twenty-eight patients who were surgically implanted with a Neuromuscular Assist (NMA) for correction of footdrop have been recently reviewed. This paper presents a brief description of the equipment and selection criteria used in this project and then summarizes our experience and the long-term results with this group. Problems encountered included unbalanced dorsiflexion, "gadget intolerance," and excessive tissue reaction to the implant in some patients. Despite these problems, seven patients continue to use the system for an average of more than 12 years, thus demonstrating the feasibility of chronic peripheral nerve stimulation with a wrap-around nerve electrode.

Introduction

Traditionally, orthopaedic surgeons have used orthotic devices or surgical procedures, such as tendon transfers, to create substitutes for paralyzed muscles. In upper motor neuron disease such as stroke, electrical stimulation can restore function in the paralyzed muscles themselves, and several clinicians have developed devices capable of correcting footdrop in hemiplegic patients by stimulating the ankle dorsiflexor muscles through superficial skin electrodes.(1,2) However, when these devices are used there is the problem of repeated difficulty in locating the correct points for stimulation, as well as that of physical discomfort from the stimuli experienced by some patients.

Electrodes surgically implanted directly on the peroneal nerve provide a consistent muscular response to stimulation and eliminate pain by reducing the amount of current required. Accordingly, in 1968, a project was initiated to develop an implantable neuroelectric stimulator which could be used to correct footdrop by stimulation of the peroneal nerve. This early work led to a system called the Neuromuscular Assist (Medtronic, Inc.), which has undergone evaluation since 1971. Our preliminary clinical results have been previously reported.(3)

The Equipment

The Neuromuscular Assist is an electronic device, part of which is worn externally and part implanted. When it is functioning, it stimulates the ankle dorsiflexor muscles during the swing phase of gait to correct footdrop. Each time the patient takes a step, electrical stimuli are delivered to the peroneal nerve, dorsiflexing the foot. The stimuli are synchronized with the swing phase by a heel switch, which is worn inside the shoe.

The device consists of three main parts: 1) an external stimulator and antenna that generate and transmit a radio-frequency signal through the skin; 2) a heel switch transmitter which triggers the stimulator; and 3) a surgically implanted receiver and electrode which receives the signal and converts it to a train of electrical pulses delivered to the peroneal nerve.

The stimulator generates a radio-frequency signal which is delivered transcutaneously from the antenna to the implant assembly. Two interchangeable modules, one for walking and one for exercising, can be attached to the control box. The stimulator is powered by a standard nine-volt battery. With normal usage, the average battery life is approximately four weeks.

The function of the transmitter is controlled by the modules. With both modules removed, the transmitter produces a continuous stimulus. With the walking module in place, the transmitter delivers a stimulus each time the patient lifts the heel from the floor. The exercising module is used to exercise the muscles. It makes the transmitter deliver a five-second stimulus every twenty-five seconds.

The stimulator is approximately the size of a small transistor radio and weighs 236 grams with the walking module. It is worn at the waist, attached to the patient's belt. The antenna is passed underneath the patient's clothing and is taped to the skin directly over the surgically implanted receiver while the patient is standing.

The implant assembly is a passive (no batteries) device that receives the radio-frequency signals from the external antenna and converts them to a train of rectangular electrical impulses applied by an electrode to the peroneal nerve. The receiver is embedded in epoxy resin and the entire assembly is encased in silicone rubber. Additionally, there is a cover of Dacron mesh for suturing the receiver to the fascia lata. The bipolar electrode consists of two platinum tinsel wires mounted on a silicone rubber flap. At surgery, this flap is wrapped around

the peroneal nerve.

A control knob on the stimulator unit enables the patient to turn the stimulator on and off and to adjust the voltage to obtain the desired amount of dorsiflexion. In addition, there are two controls adjusted by the physician: one, a MIN. potential to set the threshold; and the other, a MAX. potential to limit the applied voltage. The voltage used for walking ranges between 0.4 and 0.8 volt. Pulse duration is set at 0.20 millisecond. Pulse frequency is thirty-three pulses per second. The stimulator is capacity-coupled to the electrodes to prevent net current flow, which might cause tissue damage due to changes in pH, ionic concentrations, or both.

The heel switch transmitter is a self-contained device. When the heel is on the floor it transmits a signal that inhibits the stimulator. When the heel is lifted during swing, the heel switch transmitter is turned off and the peroneal nerve is stimulated. The stimulator is turned off when the patient is sitting.

Criteria for Patient Selection

The patient should be evaluated at least six months after onset of the stroke to assure that the medical and neurological conditions are stabilized. Patients with a history of transient cerebral ischemia or other progressive neurological disease, such as multiple sclerosis, are not suitable candidates.

Because the prospective users must be able both mentally and physically to operate the equipment, it is important to ascertain that they have sufficient cognition, motivation, and dexterity to use it and enough "gadget tolerance" to accept it as a part of their person. Gross perceptual difficulties and poor dexterity can be demonstrated simply by asking the patient to put on the equipment. Inability to put on and operate the device are contraindications to its use.

The following physical characteristics must be present in patients selected for peroneal stimulation:

1. Footdrop due to inactive ankle dorsiflexor muscles during walking.

2. Sufficient ankle plantar-flexion strength to raise the heel and stand on the fore part of the foot of the involved extremity using one or both upper extremities for balancing but not for antigravity support. (Patients with plantar-flexion weakness require a below-the-knee orthosis with a rigid ankle joint to prevent excessive ankle dorsiflexion during stance with resulting ankle and knee instability.)(4)

3. Not more than 5 degrees of fixed plantar-flexion while standing or during the stance phase of gait. Patients with spastic plantar-flexion contractures may be candidates for the assist but require concomitant heel-cord lengthening.

4. Intact proprioception at the ankle and big toe. (Patients with defective proprioception require a below-the-knee orthosis which provides additional proprioceptive cues by translating ankle excursion into tactile pressure sensed at the shank cuff.)(5)

5. Although the ankle dorsiflexors are inactive during walking, the patient is able to dorsiflex the foot voluntarily in a mass flexion synergy of the hip, knee, and ankle. This indicates that the peroneal nerve and dorsiflexor muscles are intact. This can also be checked by applying cutaneous stimulation over the peroneal nerve and seeing that the ankle dorsiflexes.

Patients

Twenty-eight patients who underwent surgical implantation of NMA have been clinically reviewed during the past year. Thirteen patients were males and 15 were females. At the time of implant surgery, the mean age was 49.5 years, ranging from 24 to 66 years of age.

All subjects were hemiplegic due to stroke (22 patients), head trauma (2 patients), spinal cord injury (1 patient), cerebral palsy (1 patient), resected cerebral meningioma (1 patient), and transverse myelitis (1 patient). The average time from the onset of the neurologic syndrome to surgical implantation averaged 59.3 months, ranging from 3 months to 312 months in the one subject with cerebral palsy.

Details of the surgical procedure have been previously reported.(3)

Associated Surgical Procedures Performed at Time of Initial Implantation

Seven patients had tenonomy or lengthening of the Achilles and/or toe flexor tendons performed at the time of implantation for excessive spasticity or contracture. Achilles tendon lengthening was performed in three patients and toe flexor release was performed in six of seven patients.

Medical Complications

Twenty-five of the patients had no medical complications related to the surgery. One patient had an initial smooth post-operative course and satisfactory function of the implant but developed GI bleeding due to a stress ulcer. This ultimately lead to pneumonia and death. Another patient developed pain and partial nerve injury after surgery and never obtained satisfactory dorsiflexion. Finally, one patient developed a peroneal nerve palsy 12 hours following surgery. Initially she had balanced dorsiflexion. She was immediately returned to surgery and the nerve was seen to be severely swollen within the silastic cuff electrode. The electrode was wrapped more loosely around the nerve, and in ensuing months she regained recovery of nerve function. Prior history revealed that she had had a previous reaction to silastic, utilized to reconstruct facial bones, which manifested itself by severe edema in this region. We concluded she manifested a similar allergic reaction to the silastic resulting in nerve edema and nerve constriction within the cuff electrode.

Revision of Surgical Implant

Five patients underwent revision of the implanted hardware. In two patients, who had an excessive varus during stimulation, additional motor branches to the peroneal muscles were included within the electrode to obtain balanced dorsiflexion. A third patient had previously undergone placement of the electrode around the common peroneal nerve, with resulting excessive eversion and pain in the distribution of the peroneal nerve. In this case, the electrode was positioned more distally, excluding some of the motor branches to the peroneal muscles. Satisfactory pain relief and balanced dorsiflexion was obtained.

A fourth patient developed intermittent electrical malfunction of the implant. Balanced dorsiflexion was obtained after the implant was replaced. A fifth patient developed a seroma around the receiver. Movement of the receiver within the fluid filled sac resulted in an inconsistent electrical stimulation pattern. Excision of the bursal sac eliminated this problem. Satisfactory function was restored in all five patients following revision of implanted hardware.

Additional Soft Tissue Procedures to Correct Foot Imbalance

Three patients underwent Achilles tendon lengthening following surgery to delete obstructive spasticity preventing satisfactory dorsiflexion to neutral. Four patients underwent release of the long toe flexors to correct for excessive clawing which resulted from stimulation. A final patient underwent release of the peroneus longus tendon following surgery to

correct for excessive eversion and depression of the first metatarsal head.

Long Term Follow-Up

Removal of surgically implanted hardware was performed in ten patients. In three patients, the device was removed despite the fact that it performed satisfactorily and a balanced dorsiflexion response was obtained. These patients found the device inconvenient to don and/or operate and preferred to wear a brace or walk without any correction. These patients represent the extreme of "gadget intolerance" which was present to a lesser extent in all patients. "Gadget intolerance" also resulted from a frequent malfunction of externally worn equipment requiring repairs, inconvenience of donning and operating the external hardware.

Three patients required hardware removal following development of a seroma around the peroneal electrode progressing to late wound infection. Another required removal of malfunctioning hardware because of chronic dermatitis underneath the antenna. Two additional patients had removal after developing pain in the distribution of the peroneal nerve and requiring increasing amounts of current to obtain the same dorsiflextion response indicative of nerve damage. A final patient refused to continue use of the implant for cosmetic reasons, despite satisfactory function. Dense epineural fibrosis was observed in the majority of patients in whom equipment was removed.

Long-Term Follow-Up in Patients with Implant Left in Place

Seven patients remain alive and continue to use their implant on a daily basis. Their average duration of use is 12.3 years. Five other patients successfully utilized their implants an average of 20 months prior to deaths not related to the surgical implantation. A final patient was a successful user until he moved from Los Angeles.

A total of five patients who did not have equipment removed were considered failures because of pain with stimulation (2 patients), mental confusion precluding independent use (2 patients), and death following surgery (1 patient).

Conclusion

1. Successful long-term results in seven patients who have used the device an average of more than 12 years indicates that successful long-term results can be obtained in some patients via electrical stimulation of the peroneal nerve.

2. Difficulty in obtaining balanced dorsiflexion due to the

availability of a single stimulation channel was a problem. At the time of surgery the electrode was adjusted to obtain a balanced dorsiflexion response. However, while walking, other muscles affecting balance, such as the posterior tibialis, soleus, toe flexors, come into play and upset the balance obtained at surgery. A dual-channel system is needed in which one electrode is placed around the motor innervation to the anterior tibialis and the other around the nerve supply to the peroneal muscles. Stimulation of the peroneal muscles could be set to precisely balance the varus pull of the anterior tibialis.

3. "Gadget intolerance" was present in all patients. Four patients discontinued use of the implant, despite a successful surgical result because of "gadget intolerance" and the appearance of the externally worn portion of the device. All patients complained of this problem to a greater or lesser extent, even successful users. Difficulty of patients coping with external hardware and gadget intolerance suggests that future FES systems will need to be totally surgically implanted to obtain patient compliance.

4. Development of pain and a decreased response to stimulation indicative of nerve damage developed in two patients following prolonged stimulation. Removal of the implant revealed extensive fibrosis around the nerve at the electrode site. Continued research in electrode design and tissue response is needed.

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