An Implantable Foot Drop Stimulator

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Abstract – A novel partially implantable system for correction of foot drop has been developed and is being tested in three volunteer subjects. The system consists of a two-channel implantable stimulator, a multi-polar nerve cuff electrode implanted on the peroneal nerve proximal to the knee, and an external system including battery, control and telemetry unit and a heel switch. Although the work is still in progress and the first patient has used the system for only six months, the results are very promising.

Keywords: implant, foot drop, telemetry, cuff electrode

1. Introduction

One of the clinical sign of an upper motor neuron syndrome is a weakness of the muscles responsible for the dorsiflexion of the foot and ankle. This often leads to a footdrop during walking for which functional electrical stimulation (FES)-assisted walking using stimulation of the common peroneal nerve is used [Liberson et al, 1961]. Although the incidence of the upper motor neuron syndrome following a stroke has not been investigated thoroughly it can be speculated to be higher than 2.0 per 1000 [American Stroke Association, 2000; Thorvaldsen et al, 1995]. Furthermore, it has been suggested that 20% of stroke survivors could be candidates for using FES-assisted walking [Wade et al, 1987]. In UK there are approximately 100,000 incidents of stroke every year [Taylor et al, 1999] of whom over 80% survive. In other words, it can be postulated that in the UK alone more than 16 000 new patients per year, 1200 in Denmark, can be candidates for FES-assisted walking using a stimulation of the common peroneal nerve. Furthermore, a proportion of the population of spinal cord injured as well as persons with multiple sclerosis are also good candidates for FES-assisted walking.

In spite of the large potential market for a drop foot stimulator and the appearance of a number of different commercially available devices over the last few decades, there is still no major breakthrough for this type of device. Most probably because the devices have simply not met patients' expectations. External systems have had problems with skin irritation, pain, difficulty of donning and doffing, breakage and cosmetic appearance. A novel external stimulator with a number of new ideas for solving the problems was recently approved for commercial distribution [Wieler et al, 1999] but is no longer available. Of the few implantable systems available for hemiplegia [Water et al, 1975; Strojnik et al, 1987], all have only one stimulation channel leaving no means for readjustment of the movement should this change over time. The external equipment of the latter one also has to be mounted below the knee, which may decrease the user acceptance for cosmetic reasons.

The device presented in this paper is thought to remove the main problems associated with external systems and at the same time decrease some of the problems associated with previous implantable devices.

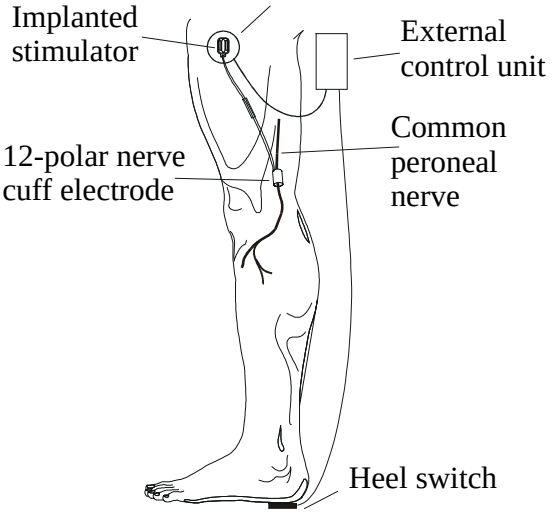

Figure 1 Schematic of implanted and external components of the drop foot system.

2. Methods

Subjects

Three participants, hemiplegic due to stroke, volunteered for this exploratory clinical trial. Two were male, age 67 and 57 and one was female, age 32. Two subjects had previously tried an external drop foot stimulator but stopped using it due to the discomfort and practical problems related herewith whereas the third subject was still using such system every day. All gave informed consent and the study was approved by the local ethics committee.

Implanted devices

The system consists of a two-channel implanted stimulator, connected via a cable to a 12-polar nerve cuff electrode which is placed on the peroneal nerve (see Fig. 1 and 2). The implant is powered and controlled by an

external control unit via an inductive link. Each channel produces charge-balanced pulses with fixed current and variable pulse width. The current is determined during the fabrication of the device, whereas the pulse width is controlled via the telemeter. The electronics are very simple, consisting of only seven discrete components for each channel. The components are mounted on a ceramic substrate, embedded in epoxy and dip-coated with silicone.

The 12-polar nerve cuff electrode is two centimeters long and has an inner diameter that is approximately 30% larger than the nerve (typically 5 mm). The 12 electrodes are configured as four tripoles placed at 0°, 90°, 180° and 270° around the nerve having the end-electrodes shorted within the cuff wall. The fascicles in the peroneal nerve at the location of the electrode are typically organised so that in one side of the nerve there are motor nerve fibers that go to the muscles that dorsiflex and/or evert the foot (m. peroneus and m. extensor digitorum longus) and in the other side there are mainly fibers going to muscles that dorsiflex and invert the foot (m. tibialis anterior and m. extensor hallucis longus). With the electrode configuration just described, this makes it possible to selectively activate the muscles that dorsiflex and at the same time either evert or invert the foot. By properly balancing the activation of two channels, it may be possible to produce pure dorsiflexion without any eversion or inversion.

External devices

The external control unit is based on a micro-controller that uses the input from a heel switch to produce a pre-set pattern of activity that is transmitted to the implant. For each channel it is possible to set the threshold and maximum pulse widths, the stimulation frequency, ramp-up and ramp-down time. These parameters can be programmed from a PC, via a serial cable ending in an optic link communicating through the transparent housing of the unit. The unit is powered from a set of NiMH rechargable batteries (four cells), and the battery pack is placed at the belt along with an on-off switch. A cable goes from the battery pack down to the external control unit that is placed in a pocket on a pair of bicycling shorts. This ensures correct and easy mounting of the unit every time. A cable continues goes from the external control unit down to the heel switch placed in the shoe.

Because of the large transmitter coils, the system is robust to misplacement of the external control unit. If the implant is placed less than 1.5 cm below the skin surface, the center of the external control unit can be allowed to move maximally three centimeters away from the implant in any direction on the skin without changing the performance. However, if the implant is deeper, due to fat-tissue under the skin, there is a decrease in the performance. If the implant should be more than four centimeters below the skin, then it will not be possible to fully activate the stimulator.

When running at full pulse width with a 20 Hz stimulation rate on both channels, the system draws 20mA from the batteries and when not stimulating it uses 17mA. A typical set of NiMH rechargable batteries has a capacity of 1000mAh or more. This gives approximately 50 hours of operation per charge. As most people don't walk contionuously all day, it means that usually one recharge per week is enough (as is reported from our first patient).

Figure 2 Photograph of the implanted stimulator/electrode and the external control unit

Surgical procedure

The implantation is divided into two separate procedures, 6-8 weeks apart. This is due to the limitation of having only two channels in the stimulator while the nerve cuff electrode has four channels. In the first procedure the electrode is placed on the nerve and the connector on the cable is fitted with percutaneous wires. In the period after this procedure tests are made by connecting the percutaneous wires to an external four-channel stimulator. Once the electrode has stabilized (as seen from measurements of impedances and recruitment curves), the two channels that in combination give the best control of the foot movement are chosen. Furthermore, the optimum stimulation current is set for each of the two channels. In the second surgical procedure, the percutaneous wires are disconnected from the cuff electrode and an implantable stimulator with the chosen channels and currents is fitted on the connector instead. The first procedure takes about one hour whereas the second can be done in half an hour.

3. Results

During the period of evaluation of the stimulation parameters it was found that most electrodes produce eversion/dorsiflexion whereas inversion/dorsiflexion has only been seen for one electrode in two of the patients and only for a limited period after the implantation. However, in all three patients it has been possible to find one or a combination of electrodes that produced good dorsiflexion of the foot (as exemplified in Fig. 3).

All three hemiplegic patients are presently using the system at home. One has been using it since October 1999

and two have just started. All three are happy with the system and have until now reported no serious complications. It takes 2-3 minutes for the patients to put on the external components of the system, which is usually done as part of dressing in the morning. We have not timed donning of an external system, but it does take significantly longer.

Figure 3 Photograph of the affected leg of the first patient during gait with the implanted stimulator active.

The patients report some sensation of paresthesia at the toes and dorsum of the foot. This corresponds well with text-book descriptions of the peroneal nerve containing some cutaneous fibers going to this area. None of the patients find this to be a significant problem, especially when comparing with the pricking/ burning sensation of the surface stimulator.

The difference between an external and the implanted stimulator on the orthotic effect was measured as the increase in walking speed during sustained walking with FES-assisted walking (>5 min). Although the data is still limited, it may be seen from Fig. 4 that the orthotic effect seen with the an external system is variable (probably depending on the exact placement of the electrodes) but for the implanted stimulator it is almost constant and at the level of the strongest effect obtained with the external stimulator. However, in the limited number of evaluations with the implanted stimulator there were no changes seen in the therapeutic effect as measured by the walking speed when the stimulator is turned off.

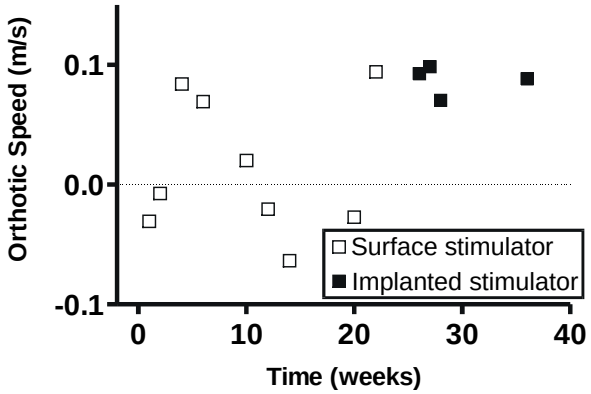

Figure 4 Differences in walking speed during sustained walking (5 min.) when using a drop foot stimulator (surface or implanted) compared to when not using one. The average speed without the stimulator was approximately 0.8m/s.

4. Discussion and Conclusions

We have developed a partially implantable drop foot stimulator, that solves some of the main problems associated with the use of an external stimulator and adresses some of the problems associated with previous implanted devices.

The device is easy to mount as it is insensitive to the precise position of the external unit. It is located above the knee, so that it is easy to reach and is cosmetically less of a problem compared to systems mounted below the knee. It uses a nerve cuff electrode for stimulation, - an electrode that has shown to provide a stable nerve interface for years in previous animal and human implantations. Until now all three participating patients are happy with the system and no significant complications have appeared. Although preliminary, it is suggested by our data that the system consistently has a positive orthotic effect in contrast to some other studies [Ladouceur & Barbeau, 2000; Merletti et al, 1979]. The comparison of the therapeutic effect between the surface stimulators and implanted stimulators will be made in future reports when more data will have been gathered with the use of the implanted stimulator.

Obviously the two-step surgical procedure is not optimal and is caused by the limitations of the analog electronics of the implantable stimulator. We are currently developing a digital version of the device, which will have four channels and telemetric control of both pulse width and stimulation current. Once this is ready, only one surgical procedure would be necessary. However, in spite of the present device being non-optimal in this aspect, we believe that the results show the viability of an implantable drop foot system with the same overall design.

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