An implantable 2-channel lower-extremity neuroprosthesis: long-term clinical follow-up in five patients

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Abstract

Objective: Earlier we have performed a clinical safety trial with an implantable two channel peroneal nerve stimulator in patients with a drop foot. The objective of the current study was to evaluate the long-term use and outcome of this new stimulator system.

Materials and Methods: Five patients with a drop foot caused by a CVA were implanted with the 2-channel peroneal nerve stimulator between 2000 and 2002. The stimulator consists of an external transmitter unit, a footswitch and an internal receiver unit with 2 leads of which the electrodes are attached under the epineurium of the peroneal nerve branches that innervate the muscles for dorsiflexion and eversion movements. Functionality and complications of the system were observed long-term in these users.

Results: After ending the safety trial we collected user information over a period of 24 months on average. One user needed replacement of the internal receiver 20 months after implantation as a result of a broken lead in one channel. Another user needed surgical repositioning of one electrode that may have been shifted as a result of a severe fall. All 5 patients still use the system regularly. Three use the system constantly every day. The other two use the system three to four days per week, dependent on their activities. Stimulation channel selectivity and stimulation intensity remained constant over time. Overall user satisfaction is high.

Conclusion: Long-term evaluation of use of the implantable drop foot stimulator shows that the system is reliable, easy to use and needs little attention during the day. As a result of this user satisfaction is high, and as a consequence it is used regularly.

1 Introduction
Dropped foot is a common mobility problem amongst patients after a cerebro vascular accident (CVA). The condition arises from paresis of the muscles that control the foot movement during the swing phase of gait. In Enschede we performed a clinical safety trial with an implantable 2-channel stimulator for restoration of normal foot balance between 1999 and 2002 [1][2]. The outcome of that trial was that the system is safe to use and functions as predicted. In this study we evaluated the long-term use and functionality of the drop foot stimulator in these patients.

2 Methods
The stimulator system (Finetech-Medical, Welwyn Garden City, Hertsforthshire, England) consists of a receiver-stimulator, a transmitter (+ battery charger), and a foot switch [3]. The receiver is a passive device, receiving information carried by the radio frequency signals and converting them to the stimulation pulses (300 micros) of the desired amplitude (5-8 V) and frequency (30 Hz). It is secured under the skin on the lateral side of the affected lower leg. The stimulation pulses are passed along a pair of leads to two electrode sets located under the epineurium of the superficial and the deep peroneal nerve branches. The transmitter is located over the site of the receiver, and is triggered using a foot switch.

The implants took place at MST hospital (Enschede) were performed between July 2000 and December 2001. The subjects, aged between 31 and 48 years, were all CVA patients with a stable neurology. To determine the long-term use and functional outcome of the stimulator in these patients, they were regularly
(every 6 months) interviewed to gain insight into their every day use of the stimulator system.

3 Results

After ending the safety trial in 2002 the subjects were allowed to continue the use the drop foot stimulator system at home. Average follow-up time after ending of this trial was 24 months (range 23-27 months). During this follow-up one patient needed a new receiver as a result of continuous problems with the channel controlling dorsiflexion. Analysis of the explanted system showed a broken lead in the sub-epineural electrode paddle. It is not clear what could have caused this. A second patient needed surgical repositioning of one of the electrodes, which may have shifted as a result of a severe fall during which she hurt the leg with the implanted receiver. No other complications were recorded. The heel switch needed most replacement/repair, about once every 4-6 months. Functional analysis showed that throughout the follow up period, all users had sustained good functional dorsiflexion and eversion movements. Furthermore, stimulation intensities had remained stable during this period.

All subjects still use the stimulator regularly. Two subjects use the stimulator 3 to 4 days per week, mostly when they are away from home. Three others use the system almost every day, during most of the day. User satisfaction is high.

4 Discussion and Conclusions

Long-term evaluation of use of the implantable drop foot stimulator shows that the system is reliable, easy to use and needs little attention during the day. As a result of this user satisfaction is high, and as a consequence it is used regularly.

The stimulation intensities on both channels have remained stable during this follow-up period. This indicates that no significant impedance changes in the electrode-nerve interface have occurred.

References


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