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An Implantable Two Channel Drop Foot Stimulator: Initial Clinical Results

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Abstract: This article reports preliminary results of pilot studies of a new implantable two channel drop foot stimulator. The stimulator consists of an externally worn transmitter inductively coupled to an implanted receiver unit located in the lower leg, lateral and distal to the knee. The receiver is connected to electrodes located under the epineurium of the deep and the superficial peroneal nerves. Stimulation is triggered by detection of heel lift and terminated at heel strike in a manner similar to surface mounted systems. The location of the electrodes allows for a degree of selectivity over the resultant moment about the ankle joint that is not possible with surface stimulation of the common peroneal nerve. The two subjects used the stimulator on a regular basis and showed increases in walking speed of between 10% and 44% when compared to their baseline measurements. Isometric tests have demonstrated that the stimulator allows selective and repeatable stimulation of ankle joint muscles. **Key Words:** Drop foot—Implant—Functional electrical stimulation—Stroke patients.

There is a growing body of evidence, including 1 randomized controlled trial, supporting the orthotic benefits of using the single channel, surface-mounted drop foot stimulator for cerebral vascular accident (CVA) patients and others (1,2). The clinical benefits now are being seen by growing numbers of patients in the U.K. and mainland Europe, not just at the centers with a direct research interest in the technology but also elsewhere. This move away from the research centers into more widespread clinical use can be seen as a coming of age for the technology. However, this has been a very slow and patchy process, and even in the U.K. where clinical use is now relatively widespread, the total number of patients being treated remains quite small (2). While less than desired funding is undoubtedly a factor, technical limitations also have caused problems, chiefly those inherent with the use of surface electrodes.

In the past, surface stimulators have suffered from a number of practical problems, particularly associated with the footswitch and leads. Despite considerable effort on the part of engineers to replace the footswitch with an alternative, for now it remains the sensor of choice in clinical drop foot systems. The traditional problem with the footswitch and leads was lack of robustness with fatigue failures commonplace. In recent years, this low-tech, practical, but important problem has been tackled, and footswitches and leads are now available that typically last in excess of 6 months of daily use.

Nevertheless, the problems inherent to stimulating the common peroneal nerve using surface electrodes remain. These include a lack of selectivity over the muscles and nerves recruited, sensitivity of muscle recruitment to electrode placement, and pain and tissue irritation associated with passage of current through the skin. Taylor et al. (3) identified problems with locating the electrodes as the most common nonphysiological reason for discontinuing use

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of the surface stimulator. These issues long have been recognized, and various attempts have been made to implant a single channel drop foot stimulator system on the common peroneal nerve (4,5). However, this approach failed to solve the selectivity problem as it was not possible to control the relative recruitment of the various muscles that act about the ankle joint. This current project attempts to resolve this problem by stimulating the two branches of the common peroneal nerve separately. The deep peroneal nerve innervates muscles that primarily dorsiflex and invert the foot while the superficial innervates primarily everting muscles.

EQUIPMENT AND METHODS

Stimulator development

The stimulator, which is based on transcutaneous radio frequency coupling, was developed over several years at the University of Twente and at Roessingh Research and Development (6). It is based on a very simple receiver design using basic passive components encapsulated in silicon rubber. The novel aspect of the design lies in the type and location of the electrodes. The electrodes are a subepineural type developed for this application but similar in design concept to certain electrodes used in pain relief applications. The location of the subcutaneous receiver distal to the knee avoids the need for the cabling to cross a joint, a common cause of failure in similar applications. The transmitter is located over the site of the receiver and is triggered in the same manner as the conventional surface stimulator, using a footswitch.

Clinical protocol

The pilot study was intended to investigate the following questions. Does the stimulator function as predicted, is it safe for use in humans, and are there any side effects. The predicted functions were that its use would result in an improvement in gait, that stimulation response would be relatively insensitive to minor (1–2 cm) changes in transmitter positioning, and that selective stimulation of the 2 branches of the common peroneal nerve could be achieved. Ethics and regulatory approval for both trials were granted from the appropriate authorities.

The first implant took place in The Netherlands in July 2000 (7). Since then, a further 3 implants have taken place, 1 in The Netherlands and 2 in the U.K. The subjects are all CVA patients with a stable neurology, at least 3 years poststroke, and between 31 and 48 years old. Baseline data on walking speed and endurance were gathered on at least 3 separate occasions, both without and with the patients' normal walking aids (if any). The U.K. group also measured Physiological Cost Index data. Prior to the implant operation nerve conduction measures were taken to check the integrity of the deep and superficial peroneal nerves (8). Following implantation all measurements were repeated. Furthermore, isometric torque measures were taken following a period of recovery and at regular time intervals at follow-up. Isometric measures of ankle moment were taken using custom-built devices described elsewhere (9,10).

RESULTS

The results for the first 2 implanted subjects, 1 in the Netherlands and 1 in the U.K., are presented. Figures 1 and 2 show the results of the walking speed and 6 min endurance measurements pre- and postimplant, respectively, for the Dutch and English patient. The Dutch patient was an occasional walker with an ankle foot orthosis (AFO), and therefore measurements with and without the orthosis were taken. When using the implanted system in both patients, the walking speed and distance were increased by respectively 10% (English) and 44% (Dutch) from mean baseline values. Figures 3 and 4 show typical graphs of the isometric moments about the ankle plantarflexion/dorsiflexion and inversion/eversion axes to stimulation at "optimal" setting for the 2 subjects. The patients themselves defined the optimal setting. The stimulation times and ramping varied between the Dutch and U.K. transmitter due to minor changes in the settings for the 2 patients. These graphs show that at the onset of stimulation the force produced increased rapidly and was maintained at a stable level. After termination of stimulation, the force rapidly declined.

The sensitivity of isometric response to transmitter movement was also investigated. In the case presented here, sensitivity was defined as change in dor-

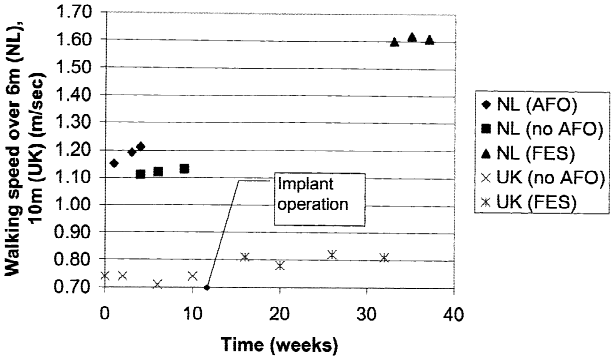

FIG. 1. The graph shows walking speed (NL: Netherlands, UK: United Kingdom, AFO: define, FES: functional electrical stimulation).

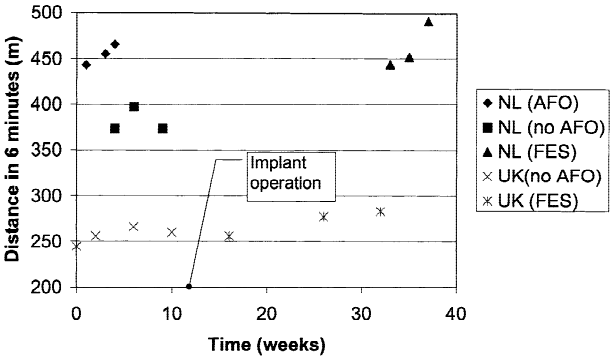

FIG. 2. The graph shows distance covered in 6 min (NL: Netherlands, UK: United Kingdom, AFO: define, FES: functional electrical stimulation).

siflexion moment with proximal/distal displacement. Results from the U.K. and Dutch patients are shown in Fig. 5 (second order polynomial curve fitted to data). This graph shows that a displacement of about 1 cm would not significantly affect the moment produced, indicating that the implantable system is relatively insensitive to minor positioning errors.

DISCUSSION AND CONCLUSIONS

As may be seen in Figs. 1 and 2, both patients gained orthotic benefit using the stimulator. Taylor et al. (11) showed a mean change in walking speed among CVA patients of 12% (0.07 m/s) at 6 weeks and 27% (0.16 m/s) at 4½ months use of the surface stimulator. The results obtained in the present study are comparable to those reported by Taylor et al. (11). Figures 3 and 4 show that stimulation on user-defined optimal settings resulted in a response characterized by smooth dorsiflexion with moderate eversion. These results were repeatable both within and between test sessions (10).

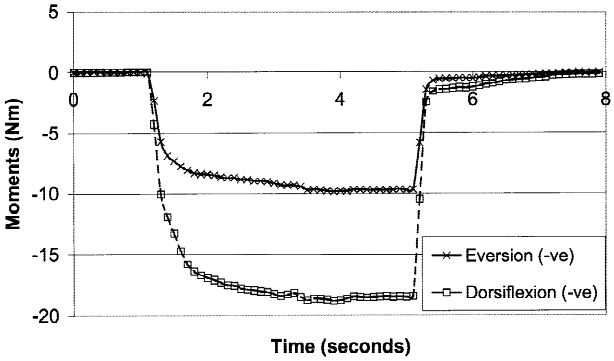

FIG. 3. The graph shows isometric moments from combined stimulation of the deep and superficial peroneal nerves (Dutch patient). The axes definitions for Figs. 3 and 4 are as described in Fig. 3 in Ref. 9, with the ankle joint (ϕ_A) at 0 degrees and the knee (ϕ_K) at 90. The sign convention for Figs. 3 and 4 is that eversion and dorsiflexion moments are both negative.

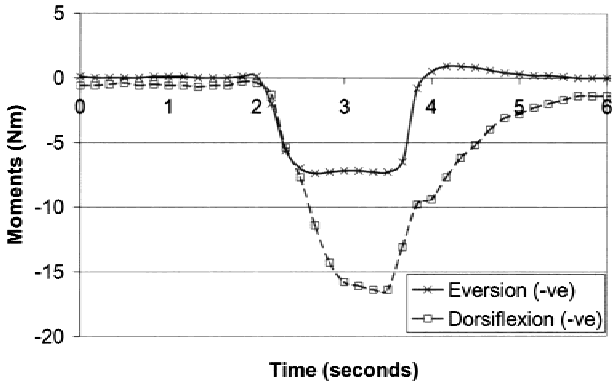

FIG. 4. The graph shows isometric moments from combined stimulation of the deep and superficial peroneal nerves (English patient).

The sensitivity of ankle moments to transmitter placement was determined to be relatively low. There are no reports in the literature quantifying typical sensitivity of ankle moments to surface stimulation of the common peroneal nerve, but experience suggests that it is significantly higher. This ease of positioning may be of specific benefit when we consider that typical CVA patients also have less control over their upper extremities. This new system may therefore also help these subjects to gain more independence.

The implants in 2 other patients have shown failures after having functioned properly for periods of months. An investigation of 1 of the explanted systems has shown that the system failure was caused by a fault in the receiver manufacturing process. Prior to failure, both of these patients also showed orthotic benefit from the device and similar isometric results to those reported here. The manufacturing process now has been adapted, and a new receiver version has been produced. Regulatory approval now has been received, and the clinical trials have started again.

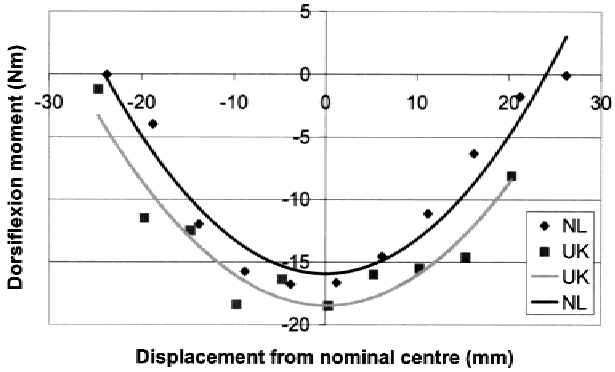

FIG. 5. The graph shows sensitivity of dorsiflexion moments to transmitter placement.

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