A NOVEL TWO-CHANNEL IMPLANTED DROP FOOT STIMULATOR – INITIAL CLINICAL RESULTS


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Introduction

For patients with drop foot, a condition typically found in stroke patients, walking is slow and energy inefficient. The term foot drop comes from an inability to adequately dorsiflex the ankle resulting either from a weakness of the dorsiflexor muscles, spasticity in the plantar flexors, or a combination of the two. The normal orthotic treatment is to brace the ankle joint with an ankle foot orthosis. However, there remains some considerable debate about their effectiveness and clinical experience shows that patients often dislike them.

An alternative approach, first demonstrated by Liberson in the 1960s is to use electrical stimulation to stimulate the dorsiflexors during the swing phase of walking. The original concept was to apply stimulation to the common peroneal nerve via surface electrodes, as it passes close to the surface near to the fibula head. Detection of the swing phase was achieved by means of a simple switch placed below the patient’s heel. The current generation of surface stimulators is based on this design.

Although it has been shown that significant orthotic benefit is gained from use of a drop foot stimulator [1], there are fundamental limitations associated with the current embodiment of the technology. These include difficulty in locating the correct points for stimulation, inability to stimulate the deeper lying nerves, lack of selectivity, variation in skin impedance, physical discomfort, and low energy efficiency. Patients who use the surface drop foot stimulator have ranked the problems of correctly locating the electrodes as the primary non-physiological reason for discontinuing usage of the stimulator [2]. Therefore attempts have been made by various groups to develop an implantable version of the stimulator. Groups in the USA and former Yugoslavia implanted single channel devices, but problems with the technology and a lack of selectivity led to these attempts being abandoned. This paper reports on initial results of two parallel pilot trials of a new two-channel device, developed at the University of Twente [3]. The two trials are taking place in The Netherlands (Roessingh Research and Development) and the UK (Salisbury District Hospital).

Aims

To investigate the functional benefits and safety of a new implantable stimulator.

Method

Hardware

The stimulator (figure 1) is implanted under general anaesthetic on the lateral side of the affected leg, distal to the knee. The transmitter is positioned over the receiver and power introduced via an inductive link. Stimulation is controlled in the same manner as the conventional surface stimulator, using a foot switch.
The two electrodes (circled in figure 1) are attached to the two branches of the Common Peroneal Nerve. The superficial branch innervates the muscles that primarily evert the foot, whilst the deep branch innervates the muscles that invert and dorsiflex the foot. By balancing the levels of stimulation to the two electrodes, it was proposed that a natural, moderately everted dorsiflexion movement could be achieved during the swing phase.

Trial design and patient selection
Regulatory and Ethics Board approval from the UK and Dutch authorities were obtained for the study. A single case study design was adopted with walking speed and endurance being the main outcome measures. Isometric measurements of ankle response to stimulation were also taken to investigate the issues of selectivity and sensitivity. Nerve integrity was measured pre and post implantation. The first subjects were all CVA patients with a stable neurology, at least 6 months post stroke. A total of 4 patients have received the implant, two in the Netherlands and two in the UK.

Results
Results from the first patient in the Netherlands and the first patient in the UK are discussed. Both patients gained orthotic benefit from the use of the device. Walking speed and endurance both increased, as detailed elsewhere [4]. With practice, both patients were able to determine the correct settings on the two channels for themselves. Isometric measurements showed that smooth dorsiflexion combined with moderate eversion was repeatedly achievable for both patients.

Conclusions
The initial results indicate that the system provides the functional benefit predicted, namely an increase in walking speed and endurance and an ability to control the balance between eversion and inversion, whilst maintaining a strong dorsiflexion moment.

The pilot trials have currently been suspended pending resolution of a problem with the receiver. The problem has now been identified and a solution implemented. The pilot trials will recommence following appropriate regulatory approval.

Reference List


3. Holsheimer J, Bultstra G, Verloop AJ et al. Implantable dual channel peroneal nerve electrodes


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