The sensitivity and selectivity of an implantable 2-channel peroneal nerve stimulator system for restoration of dropped-foot

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Abstract

Stimulation responses on each channel of an implantable 2-channel stimulator were evaluated in the first CVA subject with the stimulator. A force sensor measured the three components of moment generated at the ankle joint. The results indicate that the stimulation response is both adjustable and stable over a prolonged period.

1. Introduction

Dropped foot is a condition often found in patients with a lesion of the central nervous system. Recently, we reported on the development of an implantable system that stimulates the two branches of the peroneal nerve separately in order to restore the ability to raise the foot during the swing phase of the gait [1,2].

Currently five patients in the Netherlands are using this system. Two of them have used the system for more than one year.

In this study we evaluated the selectivity and sensitivity of the two channels that stimulate the peroneus nerve branches innervating the muscles for dorsiflexion and eversion movements. This was carried out by investigating the relationship between stimulus intensity and isometric torque generated at the ankle joint.

2. Methods

2.1 The stimulator system

The stimulation system consists of an external transmitter with built in antenna, a foot switch, and an implantable part consisting of the stimulator, the two leads and the bipolar intra-neural electrodes [3].

2.2 Transmitter

The transmitter uses a single 40-mm diameter transmission coil, that transmits alternately on two frequencies. This switching results in a pulse repetition rate of 30 Hz on each channel. The amplitudes of the monophasic pulses modulated on each carrier wave are controlled separately [3].

The transmitter weighs approximately 0.1 kg and is attached with straps on the lateral side of the lower leg, over the site of the implant, just below the knee. The footswitch determines the on-and-off switching of the stimulation.

2.3 Receiver/stimulator

The implantable two-channel nerve stimulator is a passive device, receiving information carried by the radio frequency signals and converting them into the stimulation pulses of the desired amplitude and frequency.

The implanted receiver is produced by Finetech-Medical (Welwyn Garden City, Hertsfortshire, England).

2.4 Electrodes

The electrodes are designed for sub-epineural application. This design takes advantage of the mechanical stabilising properties of the epineurium around the nerve. Further, the close proximity of the

electrodes to the nerve fascicles minimises the required stimulation current.
The electrodes are surgically positioned at two distinct locations, which are determined during test stimulation with a hook electrode combined with visual inspection of the generated movement. One electrode is placed on the superficial peroneal nerve (eversion) and one on the deep peroneal nerve (dorsiflexion).

2.5 Patient group
Five Dutch patients have received the implant. All patients had a drop foot as a result of stroke and used an orthosis and surface stimulation prior to implantation. All patients currently use the stimulator system in daily life. The measurements for this study were carried out in the patient with the longest follow-up period (> 1 year).

2.6 Two-channel sensitivity measurement
To evaluate the sensitivity of the stimulation intensity of the two channels, isometric ankle torque measurements were carried out. For this a test rig was used, incorporating a six-axis force transducer, the design of which was based on a previously reported device [4]. The rig was designed to measure the moments across the ankle joint in three dimensions (figure 1). The foot was held in place by a cut-down ski boot, bolted to a base plate. In this way the orientation of the foot with

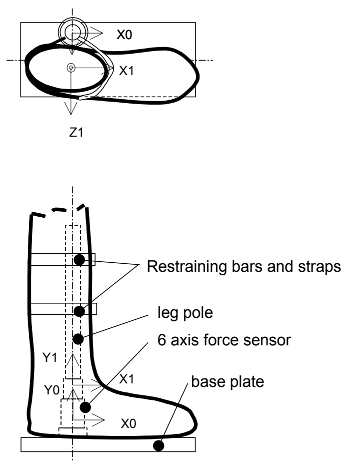

Figure 1: Schematic of the ankle test rig for isometric measurements

respect to the lower leg was kept fixed. The lower leg was held in place by restraining straps, attached to a metal rod attached to that same base plate. The forces generated by the muscles were recorded by the force transducer in the metal rod close to the ankle joint centre.
Data collection and analysis were carried out as described earlier [5].
For these measurements the users own transmitter was used. For both channels the threshold values and saturation values were determined. All intermediate values were chosen as a percentage of the maximum (20%, 40% etc.). Suitable stimulation combinations of the two channels were then randomly applied.
A digital trigger initiated stimulation 3 seconds after the data collection started, allowing for a baseline value to be recorded. Stimulation continued at the pre-set intensities for 4 seconds.

3. Results
An example of the results of the isometric torque measurements of the two channels at different settings is shown in figure 2.
It shows the moments recorded for dorsiflexion and plantarflexion resulting from thirty-six different stimulation intensity combinations of channels 1 and 2.

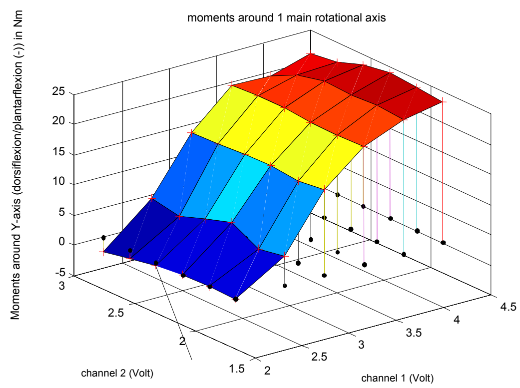

Figure 2: Recorded dorsiflexion/plantarflexion moments upon stimulation of several stimulation intensity combinations of channel 1 and 2

The graph shows that the forces produced in these directions are almost entirely determined by the stimulation setting of channel 1.

Similar results were obtained for eversion and inversion but in this case force intensity was determined by the setting on channel 2 (not shown).

Abduction and adduction, being the result of combined movements, appeared to be determined by the stimulation settings on both channels.

4. Discussion and conclusion

The results indicate that the forces produced by the muscles that are stimulated by the implanted 2-channel stimulator can be set with great accuracy. As was shown in figure 2 the torque produced increased almost linearly with increasing stimulation intensity. Furthermore, our data show that the movements needed to balance the foot during walking can be set independently of each other. These results are in accordance with the original design purposes of the stimulator system that specified that the balancing of the foot should become possible by independent adjustment of the dorsiflexion and eversion movements of the foot. This balancing option is a major advantage over the current surface stimulation systems that use only one stimulation channel. Our results furthermore indicate that the force production due to stimulation has been stable over the one year period during which the system has been used. The short-term results observed in the other users are similar to the results presented here. The stable stimulation characteristics over time may be the result of the sub-epineural application of the electrodes that may prevent the ingrowth of collagen tissue between the electrode surface and the nerve [3,6].

We conclude that the implantable 2-channel peroneal nerve stimulator provides a stable and easy to adjust functional dorsal flexion of the foot and as such it is good therapeutic device for restoration of a dropped-foot during walking.

Acknowledgement

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