A NEW AND INNOVATIVE THERAPY FOR RESTORATION OF DROPPED-FOOT WITH A 2-CANAL ELECTRICAL STIMULATION IMPLANT: DESCRIPTION AND OUTCOME IN TWENTY PATIENTS

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BACKGROUND: Dropped foot is a condition often found in several patient groups, including Multiple Sclerosis, incomplete spinal cord lesion and most notably, stroke. A dropped foot occurs when the muscles of the lower leg are not able to voluntarily lift the foot during the swing phase of walking because they are no longer under control of the central nervous system. As a result, the patient’s gait pattern is inefficient, unstable and uncoordinated. This results in a higher chance of stumbling and falling, a low walking speed, and pain in the joints and muscles around the hip.

We performed a clinical trial with an implantable 2-channel stimulator system for restoration of normal foot balance during swing phase. The primary objective of this study was to evaluate the safety and efficacy of this implantable electrical stimulation implant in patients with a dropped foot.

METHODS: The 2-channel dropped foot stimulator system (STIMSTEP) includes an implanted stimulator with two electrode sets that are placed underneath the epineurium and a transmitter unit that supplies and controls power to the receiver via an inductive link. Stimulation is timed to the gait cycle using a footswitch placed in the user’s shoe. Amplitude of stimulation to each channel is controlled via a panel on the front of the transmitter.

The pulse generator delivers electrical signals to the two branches of the common peroneal nerve using electrodes, and allowing independent control of dorsiflexion and eversion movements. The stimulator is implanted in a subcutaneous pocket on the lateral side of the lower leg slightly distal to the capitulum fibulae.

The study was designed as a controlled study in which each patient was his/her own control. Data were collected at baseline, at implant and at regular intervals during 12 months follow-up. The predicted functions were that selective stimulation of the two branches of the common peroneal nerve could be achieved and balancing of the dorsiflexion and eversion would result in an improvement in gait.

FINDINGS: Twenty subjects, 14 males and 6 females had the stimulator implanted. The subjects, mean age 54 [SD 11] years, were all stroke patients with a stable neurology. All patients had previously used braces and surface stimulation systems but had discontinued its use for various reasons. The stimulators used in the first group of 5 patients were found to fail at an unacceptable rate. Design modifications appear to have solved this problem.

Average follow-up time was 21 [SD 16] months. Analysis in all users showed that setting of the dorsiflexion and eversion movements could be performed independently and with high accuracy. Over long time use all users had sustained good functional foot balance during the swing phase of the gait cycle. Furthermore, it was reported that the system is reliable, easy to use and needs little attention during the day. Complications other than the technical failures reported above, were reported in three patients. One patient needed a new receiver as a result of a broken lead. Another patient needed surgical repositioning of shifted electrode, which may have caused by a fall and a third patient is experiencing problems that also may be related to a shifted electrode. The heel switch needed most replacement about once every six months. All patients use the system regularly in daily life.

CONCLUSIONS: Peroneal nerve stimulation with the 2-channel implantable electrical stimulator offers an effective therapy for restoration on dropped foot. The therapy may provide a solution for patients with a ‘central’-dropped foot and has advanced over conventional treatments.