Therapeutic Effect of an Implantable Peroneal Nerve Stimulator in Subjects With Chronic Stroke and Footdrop: A Randomized Controlled Trial

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Background and Purpose
Footdrop, characterized by a person’s inability to raise the foot at the ankle, is a common problem in patients with stroke. A randomized controlled trial was performed to determine the therapeutic effect of using a new implantable, 2-channel peroneal nerve stimulator for 6 months versus an ankle-foot orthosis (AFO).

Subjects
Twenty-nine patients with chronic stroke and footdrop participated in the study. The mean time from stroke was 7.3 years (SD 7.3), and all subjects were community ambulators.

Methods
The study used a randomized controlled trial design. The functional electrical stimulation (FES) group received the implantable stimulation system for correction of their footdrop. The control group continued using their conventional walking device (ie, AFO, orthopedic shoes, or no walking device). All subjects were measured at baseline and at weeks 4, 8, 12, and 26 in the gait laboratory. The therapeutic effect of FES on the maximum value of the root mean square (RMSmax) of the tibialis anterior (TA) muscle with both flexed and extended knees and walking speed were selected as the primary outcome measures. The RMSmax of the peroneus longus (PL), gastrocnemius (GS), and soleus (SL) muscles with both flexed and extended knees and muscle activity of the TA muscle of the affected leg during the swing phase of gait were selected as secondary outcome measures.

Results
A significantly higher RMSmax of the TA muscle with extended knee was found after using FES. No change in walking speed was found when the stimulator was not switched on. A significantly increased RMSmax of the GS muscle with both flexed and extended knees was found after using FES.

Discussion and Conclusion
Functionally, no therapeutic effect of implantable peroneal nerve stimulation was found. However, the significantly increased voluntary muscle output of the TA and GS muscles after the use of FES suggests that there was a certain extent of plasticity in the subjects in this study.

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