A Randomized Controlled Trial of an Implantable 2-Channel Peroneal Nerve Stimulator on Walking Speed and Activity in Poststroke Hemiplegia

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Objective: To determine the effect of a new implantable 2-channel peroneal nerve stimulator on walking speed and daily activities, in comparison with the usual treatment in chronic stroke survivors with a drop foot.

Design: Randomized controlled trial.

Setting: All subjects were measured 5 times in the gait laboratory.

Participants: Twenty-nine stroke survivors with chronic hemiplegia with drop foot who fulfill the predefined inclusion and exclusion criteria were included in the study.

Intervention: The intervention group received an implantable 2-channel peroneal nerve stimulator for correction of their drop foot. The control group continued using their conventional walking device, consisting of an ankle-foot orthosis, orthopedic shoes, or no device.

Main Outcome Measures: Walking speed, assessed both by a six-minute walk test (6MWT) and by using a 10-m walkway, was selected as primary outcome measure and activity monitoring data, consisting of percentage time spent on stepping, standing, and sitting/lying were selected as secondary outcome measure.

Results: Functional electric stimulation (FES) resulted in a 23% improvement of walking speed measured with the 6MWT, whereas the improvement in the control group was only 3% (P_ .010). Comfortable walking speed measured on a 10-m walkway was also significantly improved in favor of FES (P_ .038). The percentage time spent on stepping deteriorated with 3% in the intervention and 0.8% in control group, which was not statistically significant between both groups (P_ .13).

Conclusions: The present study shows a clinically relevant effect of the implantable 2-channel peroneal nerve stimulator