Functional Electrical Stimulation (FES) and Stroke – a review of the literature

A large and consistently increasing amount of evidence supports the utilization of FES to improve gait for individuals who have sustained a Cerebrovascular Accident (CVA). A great deal of that support is specific to the use of Peroneal Nerve (PN) FES to alleviate drop foot. The strength of that evidence has increased; the number of randomized clinical trials (RCT) has increased from 2 to 9 in recent years. Five of these RCTs investigate the use of FES as a therapeutic modality and compare FES to conventional physical therapy (PT).[1-5] Most therapeutic studies define a treatment group as FES and PT combined[1,5] or as FES alone[3-4] with the control group defined as conventional PT. However one study utilized a unique 3-arm randomization comparing FES alone to PT alone and to a "placebo FES group" (the FES device was worn but no stimulation was given).[2] RCTs investigating the use of FES as a neuroprosthetic for the correction of drop foot compare the effectiveness of FES to that of the current standard of care, an Ankle Foot Orthosis (AFO).[6-10]

Outcomes:

Gait Speed: Gait speed is an important indicator of overall functional mobility and has been shown to be a good discriminate measure of physiological and functional recovery for patients post CVA.[11] The support in the literature for changes in gait speed with the utilization of FES is very strong. A great deal of the research regarding the efficacy of FES has investigated changes in gait speed; these studies have consistently demonstrated statistically significant improvements.[1,3,5,7-10,12-21,29] The increases in gait speed noted with FES have been demonstrated in RCTs both with therapeutic[1,3] and neuroprosthetic FES applications.[7-10] The evidence demonstrates that significant changes with FES are noted after both short term (2 to 5 months)[3,5,12-14,20] and long term (6 to 12 months) applications.[7-10,15-19,29] Increases in gait speed seen with the use of FES are substantial and range from a low value of a 15% change at 3 mos[17] to a high of a 47% change at 1 year.[17] FES utilization has the capacity to effect significant changes in gait speed in a short amount of time, as evidenced in one study by an initial 17% change seen post fitting of the device and, in one of the most significant increases noted in the literature, a 37% change seen after only 8 weeks.[13] Several studies have even demonstrated that the utilization of FES can have a significant therapeutic effect, noting continued improvement in gait speed even with FES device turned off.[15,17,19-20,29]

Energy cost: The evidence shows that the use of FES has a significant and positive impact on the effort required to ambulate.[1,12,14,17-20,22] All but one of the studies[16] utilized the Physiologic Cost Index as a measure of the effort involved in gait. PCI is a measure that combines changes in heart rate and respiratory rate, with a decrease in PCI indicating a lower energy cost. The studies, ranging in duration from 4.5[20] to 12 months,[19] all found that gait required significantly less effort with the utilization of FES. The lowest reported percent change in PCI was 10%[18] and the highest 31%.[20] The study reporting the most significant findings was also the shortest at 4.5 months and one of the only studies to show a significant therapeutic effect for PCI, with a 19% decrease in PCI noted when the FES device was turned off.[20] Another study investigated subjects with chronic stroke who had utilized FES for 2 years. The results demonstrated a decreased energy cost using the measure of total work.[22] This study showed that the total work of walking was significantly less for the subjects with a CVA, both when the FES was turned on and off, than it was for normal controls.[22]

Gait Symmetry: Many studies have investigated the effect of FES on symmetry and quality of gait. FES has been shown to significantly improve gait symmetry as measured by the Gait Asymmetry Index,[13] a marker of interlimb coordination associated with balance status and fall risk.[13,15,24] Studies have also demonstrated that the use of FES can improve gait quality by decreasing the variability of gait. Swing time and stride time variability, measures associated with gait stability and fall risk, have been noted to improve with the use of FES.[13,15,24] One case report demonstrated improvement in hip and knee flexion angles and symmetry of hip and knee motion during gait.[23]

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These improvements, accompanied by an improved push off at terminal stance, combined to demonstrate a restoration of gait symmetry to near normal.[23] These results indicate that FES not only improves ankle dorsiflexion and symmetry of swing, but the entire lower extremity flexor pattern as well.[23] Another study showed that the use of FES resulted in improvements in the Rivermead Visual Gait Analysis, a tool that assesses the degree of asymmetry in the trunk, pelvis, hip, knee and ankle.[5] The improvements shown in all these studies demonstrate that utilization of FES can significantly impact gait quality and symmetry.

Spasticity: FES can positively affect spasticity levels as well. Three studies have investigated the effect of FES on extensor spasticity, measuring the level of spasticity found in the antagonist gastroc-soleus muscle.[2,4,28] Two studies found improvement in spasticity scores (the Modified Ashworth Scale and the Composite Spasticity Score),[2,4] and one noted increased inhibition of the affected side gastroc-soleus muscle spasticity when PN FES was utilized to activate the affected side anterior tibialis muscle.[28]

Neuroplasticity: Perhaps the most exciting outcomes noted with the use of FES come from studies demonstrating positive neuroplastic changes in cortical activity and motor control. Two studies looked at cortical activity, measured by changes in Motor Evoked Potentials (MEP), and found improved MEPs with the use of FES.[18,29] Plasticity of motor control was demonstrated in 4 studies whose results noted an increase in voluntary muscle activity and maximum voluntary contractions (MVC) of the anterior tibialis.[2,6,18,29] These increases in cortical activation and muscle activity were attributed to central nervous system changes and not to training or isolated strengthening of the affected side anterior tibialis muscle. Neuroplastic changes in motor control can also be measured by improvements in gait speed that occur even when the FES device has been turned off. Several studies[15,17,19-20,29] have found therapeutic effects of FES on gait speed, noting increases in gait speed that remain without FES stimulation and range from a 14%[20] to a 31%[17] change.

Quality of Life (QOL) and patient preference: The evidence supports that the use of FES can have a positive effect on QOL. In 3 RCTs, a significant number of subjects preferred FES to an AFO.[7-8,25] The evidence cites other study results demonstrating that patients feel safer when using FES,[7,13,32] report fewer falls[13] and have a decreased fear of falling.[27] In one study of patients with chronic stroke and their caregivers, both groups recognized FES as having a positive impact on disability post CVA and overall QOL.[26]

Recent RCT evidence: Four recent RCTs trials comparing FES to the usual standard of care present evidence that FES is at least equivalent to the AFO for treating drop foot post CVA.[7-10] All of these studies show FES to be as effective in improving gait speed and as safe as an AFO for long-term use. In one study the FES group also showed significant improvements on the Berg Balance Scale,[9] 6-Minute Walk Test[9] and Modified Emory Functional Ambulation Profile tasks[9,10] that were not seen in the AFO group. Studies have also noted that FES, when used as a neuroprosthesis or as part of a rehabilitation program, is cost effective, decreases time to complete rehabilitation, improves rehabilitation outcomes and increases the number of patients discharged to home.[2,30,31] These studies support that FES is at least an equivalent alternative to bracing and may perform better than an AFO on some measures of function and balance. Given the efficacy of FES and the positive impact of FES use on the course of rehabilitation, FES should be an assessable option for patients with drop foot after CVA especially for those patients who are not successfully treated with an AFO.

Key Points: The effects of FES on drop foot for patients post CVA have been studied since the inception of PN FES in 1961 and the literature continues to strongly support the benefits of FES.[19] Dramatic increases in gait speed have been repeatedly shown to be well above the range of the minimal clinically important difference (MCID) established for the stroke population.[33-34] The literature also shows that FES improves gait speed at no additional energy cost. Reported decreases in PCI, which indicate that individuals using FES walk faster and father with less effort, have significant and positive implications and improve the prognosis for functional mobility. Even more exciting is the capacity of FES to facilitate neuroplastic changes. The positive outcomes noted in studies of cortical activation and motor control represent true CNS recovery, even in patients many years post CVA,[7,18] making the neuroprosthetic application of FES a viable option for any patient suffering from decreased mobility after CVA. The positive effects of PN FES on functional mobility, motor control and the balance of muscle tone is substantial; this technology presents incredible implications for neurological rehabilitation and offers potential for recovery previously thought impossible.

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