Therapeutic or carryover effects due to the use of a functional electrical stimulation unit on patients with an upper motor neuron lesion

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Clinical Question

Is there evidence to support the existence of "therapeutic" or "carryover" effects associated with sustained use of cutaneous functional electrical stimulation technology (FES) in the treatment of foot drop?

Background

Recent years have seen an increased availability of single channel, cutaneous FES units for the management of footdrop secondary to upper motor neuron dysfunction. FES utilizes electric pulses to artificially stimulate motor neurons to elicit a mechanical response. These technologies include the Oddstock Dropped Foot Stimulator, the NESS L300 and the WalkAide. In addition to the "orthotic effects" associated with this technology, or the benefits experienced while the devices are worn and utilized, it has been suggested that with sustained usage, patients may experience some functional benefit even when they are not actively wearing the device. These improvements have been variably described as "therapeutic," "training," "carry over," or "practice" effects. Carryover effects of FES were first documented by Liberson et al. in 1961. He observed that "on several occasions, after training with the brace, patients acquired the ability of dorsiflexing the foot by themselves, although the periods of spontaneous activity reported were only transitory". In some instances, articles have described a therapeutic effect as the improved orthotic effect over time, that is, the increased functionality of the individual from baseline while using the device. For clarity, this examination has excluded these results; therefore only therapeutic effects while the FES systems are non-functioning are included.

Search Strategy

Databases searched: Pubmed, JPO, google scholar
Search Terms: "therapeutic" OR "carryover" AND "FES" OR "functional electronic stimulation" OR "neuroprosthesis" OR "drop foot." Additional articles were added from review of identified article references.
Inclusion/Exclusion criteria: Inclusion: English, original research, articles that examined upper motor neuron lesions; examined functional benefit in walking. Exclusion: articles using FES as a treatment modality, such as in physical therapy, rather than a functional device; articles that used percutaneous or subcutaneous stimulation.

Synthesis of Results

Carryover with respect to mobile FES units were examined in three recent articles from 2010 to 2015. Test-retest protocols were followed for all of these investigations which noted baseline measurements and then followed up with participants over time, with subsequent testing for comparison. Three out of three investigations found improvements between test and retest differences, indicating positive carryover effect.

Additionally, it is particularly evident, as shown by Stein et al in 2010, that differences exist between progressive and nonprogressive disorders. Authors concluded that patients with nonprogressive disorders have consistent improvement in therapeutic improvements at up to one year whereas patients with progressive disorders have a peak of improvement at three months, which then declines, suggesting the progression of disease continuing to affect patient functionality.

Clinical Message

To the extent that it has been formally evaluated, the "therapeutic" or "carryover" effects of FES systems across variable walking surfaces and tasks have been supported in recent literature, although appreciable differences seem to vary between progressive and non-progressive disorders. Patients with progressive disorders appear to have a spike in benefit followed by decreasing therapeutic effects over time, while evaluations of patients with nonprogressive disorders continue to show improvement at the extent of at least one year.

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References

1. Liberson W, Holmquest H, Scott M. Functional electrotherapy: stimulation of the common peroneal nerve synchronized with the swing phase of gait of hemiplegic subjects. *Arch Phys Med Rehabil* 1961;42:202-205.
2. Stein RB, Everaert DG, Thompson AK, et al. Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. *Neurorehabil Neural Repair.* 2010:24(2):152-167.
3. Everaert DG, Stein RB, Abrams GM, et al. Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multicenter randomized controlled trial. *Neurorehabil Neural Repair.* 2013:27(7):579-591.
4. O'Dell MW, Dunning K, Kluding P, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. *Physical Medicine and Rehabilitation.* 2014:6(7):587-601.

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Evidence Table

	Stein, 2010	Everaert, 2013	O'Dell, 2014
Population	Number of subjects: Nonprogressive (41), Progressive (32) Ages: Nonprogressive (52.0), Progressive (54.2) Gender: Nonprogressive: male (61%), Progressive: male (53%) Condition: Stroke (26), SCI (9), Other (6), MS (31), Familial paraparesis (1) Time since onset: at least 6 months; Nonprogressive (10.7 years), Progressive (11.5 years)	Number of subjects: 93 Age: 57 years Gender: Male 67% Condition: Stroke 93 Times since onset: less than 1 year, mean: 6.4 months	Number of subjects: 99 Age: 60.71 years Gender: Female: 32 Male: 37 Condition: Stroke 99 Time since onset: at least 3 months
Recruitment source	3 participating centers	9 rehabilitation centers in the United States	11 sites throughout the United States
Study Design	Test-Retest, comparison between progressive and non-progressive groups	Test-Retest	Test-Retest
Intervention	WalkAide	WalkAide	Bioness Ness L300
Comparison	Walking speed before and after long term usage of the device, carryover effect	Comparison between AFO and WalkAide usage after long term usage of both devices	Comfortable Gait Speed before and after long term usage of the device, carryover effect
Relevant Outcome(s)	10 m walking velocity, 4 minute figure 8 test, PCI *Note: decrease in PCI denotes functional benefit	Figure 8 Speed, PCI, 10 m walking velocity *Note: decrease in PCI denotes functional benefit	10 m walking velocity
Key Findings	Figure 8 test (Percent improvements from baseline) 3 months Nonprogressive: 17.8% Progressive: 9.1% 11 months Nonprogressive: 28.0% Progressive: 7.9% 10m Velocity test 3 months Nonprogressive: 12.0% Progressive: 5.3%	Mean figure 8 walking speed increase at 6 weeks (m/sec): WalkAide (arm1): 0.094 AFO (arm 2): 0.065 AFO (arm 3): 0.042 PCI changes were not significantly different The authors concluded that both the WalkAide and the AFO had significant orthotic, therapeutic and combined	A 28.6% increase in comfortable gait speed was seen for 30-week therapeutic effect. Clinically important gains in comfortable gait speed were seen in 18%-29% of subjects for 30-week therapeutic effect.

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	11 months Nonprogressive: 24.2% Progressive: 5.6% PCI 3 months Nonprogressive: -6.8% Progressive: -3.8% 11 months Nonprogressive: -15.9% Progressive: 1.9% Authors concluded that subjects with both progressive and nonprogressive disorders show a therapeutic effect of using foot drop stimulators, and that nonprogressive disorders continue to increase up to at least a year, whereas the therapeutic effects in progressive disorders appear to be largest at about 3 months and then may be offset by the progression of the disease.	effects. The WalkAide had a larger therapeutic effect over time, whereas the AFO had a larger immediate orthotic effect.	
Key Limitations	Author is the president of a company who developed the WalkAide, 11 subjects dropped out after the 3 month mark	Study sponsored by WalkAide manufacturer, crossover design, subject randomization, early intervention, subject variability	Selective subjects chosen for clinical trial