

Date: August 24, 2015

Title: Use of Neuroprosthesis to improve gait mechanics, walking speed, and physiological cost index¹

Clinical Question

- P (*Population/Problem*) In persons with foot drop resulting from Upper Motor Neuron (UMN) disorders or injuries
- I (*Intervention*) is a neuroprosthesis
- C (*Comparison*) more effective than an Ankle Foot Orthotic (AFO) or no history of orthotic use
- O (*Outcome*) at improving gait mechanics, walking speed and physiological cost index?

Definitions for terms marked with * may be found in the Supporting Information section.

Target Population for the Recommendation

Inclusion

(*Bioness 2013 [5], InnovativeNeurotronics 2013 [5]*)

For children, adolescents, and adults that are ambulatory with or without an assistive device (whose extremity appropriately fits in the neuroprosthetic) who experience foot drop resulting from UMN disorders or injuries including:

1. Stroke
2. Cerebral Palsy (CP)
3. Traumatic Brain Injury (TBI)
4. Incomplete Spinal Cord Injury (SCI) - (ASIA C or D)

Exclusion

(*Bioness 2013 [5], InnovativeNeurotronics 2013 [5]*)

1. Individuals with a pacemaker, defibrillator, electrical implants, or metallic implants
2. Individuals with orthopedic conditions including severe osteoporosis, recent fracture, or dislocation that is not yet healed
3. For those who are pregnant or plan to become pregnant
4. Individuals affected by a malignant tumor, lesion, or open wound on affected leg
5. Individuals with an irreversible contracture
6. Individuals with diagnosis of uncontrolled seizures
7. Individuals with peripheral nerve injuries

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Recommendations

Adults with Brain Injury (BI)

1. It is strongly recommended that for adults diagnosed with BI a neuroprosthesis be utilized to improve walking speed (International Classification of Functioning, Disability, and Health (ICF)*: activities and participation) (Roche 2009 [1b], Kottink 2004 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], Taylor 2013 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Shiels 2011 [4b], Everaert 2010 [4b], Laufer 2009 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a]).

Note 1: It is important to note, that utilizing a neuroprosthesis did not improve walking speed over the use of an AFO (Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sheffler 2006 [2b], van Swigchem 2012 [4a], Ring 2009 [4a], Sheffler 2007 [5a]).

Note 2: There were no formal studies determining recommended frequency, duration, or mode of delivery (home vs clinic), to improve walking speed (ICF: activities and participation) and gait mechanics (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

2. It is recommended that for adults diagnosed with BI a neuroprosthesis is more effective than an AFO at increasing patient satisfaction and quality of life (ICF: activities and participation) (Kluding 2013 [2a], Wilkie 2012 [2a], Everaert 2013 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Laufer 2009 [4a], WorldHealthOrganization 2002 [5]).
3. There is insufficient evidence and a lack of consensus to make a recommendation for adults diagnosed with BI that a neuroprosthetic is more effective than an AFO in improving physiological cost index (PCI)* (ICF: body structure & function) (Roche 2009 [1b], Everaert 2013 [2b], Sabut 2010 [2b], Sabut 2010 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], WorldHealthOrganization 2002 [5]).
4. It is recommended in adults with BI that a neuroprosthesis be used, regardless of a history of wearing or not wearing an orthotic, to improve ankle dorsiflexor strength, ankle range of motion (ROM), PCI, and gait mechanics (ICF: body structure and function) (Roche 2009 [1b], Everaert 2013 [2b], Sabut 2010 [2b], Sabut 2011 [3a], Sheffler 2013 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Springer 2013 [4b], Everaert 2010 [4b], Laufer 2009 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Israel 2011 [5b]).

Note: There were no formal studies determining recommended frequency, duration, or mode of delivery (home vs clinic), to improve gait mechanics (ICF: body structure & function) (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

Children diagnosed with CP

5. It is recommended that for children diagnosed with CP a neuroprosthesis be utilized to improve gait mechanics. (International Classification of Functioning, Disability, and Health, Child-Youth Version (ICF-CY): body structure & function) (van der Linden 2008 [2b], Prosser 2012 [4a], Durham 2004 [4a], WorldHealthOrganization 2002 [5]);

Note 1: There were no formal studies determining recommended frequency, duration, or mode of delivery (home vs clinic), to improve gait mechanics (ICF: body structure & function) (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

Note 2: Recommendations 5 and 6 refer to children that ambulate with or without an assistive device that are diagnosed with CP and present with foot drop either unilaterally or bilaterally (hemiplegic or diplegic).

6. It is recommended for children diagnosed with CP that a neuroprosthesis not be used to improve walking speed (ICF-CY: activities and participation) (Seifart 2009 [1b], Damiano 2013 [4a], Prosser 2012 [4a], Ho 2006 [4b], WorldHealthOrganization 2002 [5]).

Note 3: It is believed that this patient population is already ambulating close to their age appropriate functional velocity (Damiano 2013 [4a]).

Note 4: There were no formal studies determining recommended frequency, duration, or mode of delivery (home vs clinic), to improve walking speed (ICF: activities and participation) (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

Adults with SCI

7. It is recommended that for adults diagnosed with SCI a neuroprosthesis is more effective than an AFO at increasing:
 - a. Walking speed (ICF: activity and participation) (Stein 2010 [4a], Stein 2006 [4a], Kim 2004 [4a], WorldHealthOrganization 2002 [5])
 - b. Gait mechanics* and PCI(ICF: body structure and function) (Stein 2006 [4a], Kim 2004 [4a], WorldHealthOrganization 2002 [5])

Note: There were no formal studies determining recommended frequency, duration, or mode of delivery (home vs clinic), to improve walking speed (ICF: activities and participation) and gait mechanics (ICF: body structure & function) (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

All diagnoses

8. There is insufficient evidence and a lack of local consensus to make a recommendation regarding frequency, duration, mode of delivery (home vs clinic), to improve walking speed (ICF: activities and participation) and gait mechanics (ICF: body structure & function) in adults diagnosed with BI, children diagnosed with CP, and adults diagnosed with SCI (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], WorldHealthOrganization 2002 [5], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

Discussion/Synthesis of Evidence related to the recommendations

The articles that were reviewed varied in the types of comparison groups. Some studies compared and AFO to a neuroprosthesis (Sheffler 2006 [2b], van Swigchem 2012 [4a], van Swigchem 2010 [4a], Ring 2009 [4a], Kim 2004 [4a], Ho 2006 [4b]), while others compared a neuroprosthesis to walking with no device/orthotic (Embrey 2010 [2a], Sabut 2010 [2b], Sabut 2010 [4a], Stein 2010 [4a], Laufer 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Sabut 2011 [4b], Shiels 2011 [4b], Everaert 2010 [4b], Israel 2011 [5b]). Additionally, three of the articles were systematic reviews (Roche 2009 [1b], Seifart 2009 [1b], Kottink 2004 [1b]) and three articles were randomized controlled trials (Embrey 2010 [2a], Sabut 2010 [2b], van der Linden 2008 [2b]).

Adults with Brain Injury (BI)

In adults diagnosed with a BI, high level evidence suggests a neuroprosthesis can be used to improve walking speed. (Roche 2009 [1b], Kottink 2004 [1b], Embrey 2010 [2a], Sabut 2010 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], Taylor 2013 [4a], Sabut 2010 [4a], Stein 2010 [4a], Chen 2009a [4a], Laufer 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Shiels 2011 [4b], Everaert 2010 [4b], Laufer 2009 [4b], Dunning 2009 [5a]). Adults with BI demonstrated an increase in walking speed after using the neuroprosthesis based on the 6 Minute Walk Test (Embrey 2010 [2a], Hausdorff 2008 [4a], Laufer 2009 [4b], Dunning 2009 [5a]), the 10 Meter Walk Test (Stein 2006 [4a], Shiels 2011 [4b]) and the Modified Emory Functional Ambulation Profile (mEFAP) (Sheffler 2006 [2b], Sheffler 2013 [4a]). Mean velocity, cadence, stride length, and assistance needed during ambulation improved significantly ($p > 0.05$) with use of a neuroprosthesis (Chen 2009b [4a]). Walking speeds were reported to increase by 22.5-38.7% compared to baseline (Kottink 2004 [1b], Sabut 2010 [2b], Sabut 2010 [4a], Laufer 2009 [4b]).

Participants demonstrated improvement in stride time, gait asymmetry, swing time variability, and functional ambulation as measured by the mEFAP (Embrey 2010 [2a], Ring 2009 [4a], Sheffler 2007 [5a]); in other words, an improvement in overall gait mechanics was noted when utilizing the neuroprosthesis compared to the AFO.

Adults diagnosed with a BI, (Kluding 2013 [2a], Wilkie 2012 [2a], Everaert 2013 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], van Swigchem 2012 [4a], Laufer 2009 [4a]) demonstrated increased patient satisfaction with neuroprosthesis compared to an AFO. There is a moderate level of evidence to support adults using a neuroprosthesis for improved appearance and quality of gait (Wilkie 2012 [2a], van Swigchem 2012 [4a]) as well as, preference for using a neuroprosthesis over an AFO to normalize gait (Sheffler 2006 [2b]). In two studies, adults with brain injuries preferred the neuroprosthesis over an AFO during ambulation (Kluding 2013 [2a], Everaert 2013 [2b]). Adults with BI felt as safe with the neuroprosthesis as compared to the AFO (Everaert 2013 [2b]). After two months of using the neuroprosthesis, patients reported a 25.2% increase in community participation (Laufer 2009 [4a]). Patients reported a significant increase in quality of life as demonstrated by improved scores on the Stroke Specific Quality of Life Scale (Sheffler 2013 [4a]).

In adults with BI, high grade evidence supports the use of a neuroprosthesis to address lower extremity strength and range of motion, suggesting that a neuroprosthesis improves lower extremity structure and function, and the ability to participate in activities (van der Linden 2008 [2b], Durham 2004 [4a]). However, due to the heterogeneity of the studies regarding the history of wearing or not wearing an orthotic, it was not possible to make a strong recommendation (Roche 2009 [1b], Kottink 2004 [1b], Kluding 2013 [2a], Wilkie 2012 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], Taylor 2013 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Chen 2009a [4a], Chen 2009b [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Everaert 2010 [4b], Laufer 2009 [4b], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]). Participants that wore a neuroprosthetic for all functional activity found significant ($p < 0.05$) improvements in active ankle dorsiflexion (Chen 2009b [4a], Sabut 2011 [4b], Everaert 2010 [4b]). A significant ($p < 0.05$) improvement in dorsiflexion range of motion was found when traditional rehabilitation was combined with a neuroprosthetic versus the neuroprosthetic alone (Sabut 2011 [4b]). Improvements in range of motion were found with significant ($p < 0.05$) gains in ankle dorsiflexion and plantarflexion strength (Sabut 2011 [4b], Chen 2010 [5a]), suggesting that improved peroneal activation may contribute to increased ankle strength and range of motion.

Overall, evidence supports the use of a neuroprosthesis to help normalize gait in adults with brain injury. Improvements in gait symmetry with use of a neuroprosthetic were found (Laufer 2009 [4b]), utilizing the Swing Asymmetry Index which improved significantly ($p < 0.001$) by 28%, and by 45% after 8 weeks (Hausdorff 2008 [4a]). Following the use of a neuroprosthesis dynamic improvements in foot drop analyzed the heel-strike phase of the gait cycle and found a significant ($p < 0.05$) decrease in plantarflexion angle at heel-strike (Israel 2011 [5b]). When comparing traditional rehabilitation to utilization of a neuroprosthesis significant improvements in step length (21.27%; $p < 0.001$) and stride length (20.41%; $p < 0.001$) were found in the neuroprosthetic group and the control group, with no significant ($p = 0.334$) differences noted between groups (Sabut 2010 [2b]). Improvements in stride length ($p = 0.01$) were found when utilizing a neuroprosthetic (Springer 2013 [4b], Chen 2010 [5a]). Unfortunately, due to the nature of these investigations, no comparison to a control group was present (Springer 2013 [4b], Chen 2010 [5a]). Improvements were found in the functional measure of obstacle avoidance utilizing a neuroprosthetic on the affected limb in order to negotiate objects dropped on a treadmill (van Swigchem 2010 [4a]).

PCI is associated with efficiency and was utilized by several studies in order to determine the effect of the use of a neuroprosthetic on efficient mobility. A positive trend was found in PCI values ($P=0.031$) when individuals wore a neuroprosthetic for all activity (Roche 2009 [1b], Stein 2006 [4a]). A positive trend in PCI values was also found in individuals that combined neuroprosthetic and traditional therapy (23.3%) versus traditional therapy alone (10.61%) (Sabut 2010 [2b]). Participants who utilized a neuroprosthetic for daily activities were found to have statistically significant ($P < 0.05$; $P < 0.001$) improvements between initial and final PCI values (Hausdorff 2008 [4a], Stein 2006 [4a]).

Children Diagnosed with CP

In children with CP, low grade evidence suggests that use of a neuroprosthesis improves gait mechanics. The evidence supports improvement in foot contact pattern, dorsiflexion during swing phase, and partial preservation of ankle plantarflexion during toe off. Additionally, improvements in stance time, swing time, and overall swing symmetry have been shown. The literature has further demonstrated increased impulse generated during push off phase of the gait cycle. However, the reviewed evidence did not compare effectiveness between the neuroprosthesis and AFO (van der Linden 2008 [2b], Prosser 2012 [4a], Durham 2004 [4a]). Statistically significant results were not found in walking speed for children with CP (Seifart 2009 [1b], Damiano 2013 [4a], Prosser 2012 [4a], Ho 2006 [4b]). The above evidence consisted of multiple studies with weaker designs including case studies, general reviews, and a singular RCT that demonstrated consistent results. Overall low statistical power was demonstrated due to small sample sizes.

Adults with SCI

A low grade of evidence supports the use of a neuroprosthesis to improve gait speed, gait mechanics, and PCI in patients with an incomplete SCI. After 3 months of wearing a neuroprosthesis for all activity, significant improvements in walking speed ($p < 0.01$) were demonstrated by the figure 8 and 10 m walk test (Stein 2006 [4a]). Gait mechanics were examined under 4 conditions: AFO, Functional Electrical Stimulation (FES) via neuroprosthesis, AFO and FES via neuroprosthesis, and no orthosis. Gait speed significantly increased with FES via neuroprosthesis ($P < .05$) and with the AFO ($P = .06$). There was no difference between the 2 forms of orthoses in either gait speed or endurance. The greatest increase in gait speed and endurance from the non-orthotic condition occurred with the combined AFO and neuroprosthetic condition. Foot clearance improved with neuroprosthetic but not with AFO (Kim 2004 [4a]). A study that implemented neuroprosthesis for all activity over the course of 3 months noted a significant ($p < 0.05$) improvement in PCI (Stein 2006 [4a]). The above evidence consisted of multiple studies with weaker designs including case reports, case studies, and general reviews that demonstrated consistent results. Low statistical power was demonstrated due to small sample sizes.

All Conditions

Additional research is needed to determine appropriate dosing due to the broad spectrum of frequencies and durations employed throughout the literature. There is a general trend that adults with BI or SCI as well as children diagnosed with CP who used the neuroprosthesis at home for 8-12 weeks increased walking speed and improved gait mechanics (Seifart 2009 [1b], Kluding 2013 [2a], Embrey 2010 [2a], Everaert 2013 [2b], Sabut 2010 [2b], van der Linden 2008 [2b], Sheffler 2006 [2b], Damiano 2013 [4a], Sheffler 2013 [4a], Taylor 2013 [4a], Prosser 2012 [4a], van Swigchem 2012 [4a], Sabut 2010 [4a], Stein 2010 [4a], van Swigchem 2010 [4a], Laufer 2009 [4a], Ring 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Durham 2004 [4a], Kim 2004 [4a], Springer 2013 [4b], Sabut 2011 [4b], Shiels 2011 [4b], Ho 2006 [4b], Chen 2010 [5a], Dunning 2009 [5a], Sheffler 2007 [5a], Israel 2011 [5b]).

In determining the strength of the recommendation, the development group made a considered judgment in a consensus process which was reflective of critically appraised evidence, clinical experience, and these dimensions:

Given the dimensions below and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statement above reflect the strength of the recommendation as judged by the development group. (Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)

1. Grade of the Body of Evidence	<input type="checkbox"/> High	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> Low
<i>Rationale:</i> The overall body of evidence is moderate. There was a high body of evidence and consistency to support improvements in walking speed.			
2. Safety/Harm (Side Effects and Risks)	<input checked="" type="checkbox"/> Minimal	<input type="checkbox"/> Moderate	<input type="checkbox"/> Serious
<p><i>Rationale:</i></p> <p>Patients may experience:</p> <ol style="list-style-type: none"> 1. Decreased tolerance of electrical stimulation 2. Skin irritation, an allergic reaction or hypersensitivity due to the electrical stimulation or the electrical conductive medium. In some cases irritation may be avoided by changing the stimulation parameters or altering the electrode placement (performed by the treating clinician). 3. Inflammation in the region of the neuroprosthesis may be aggravated by motion, muscle activity, or pressure from the cuff. Use of the device should be temporarily halted until the inflammation is resolved completely. <p>Use caution in the following situations:</p> <ol style="list-style-type: none"> 1. Patients with suspected or diagnosed heart problems. 2. When there is a tendency to hemorrhage following acute trauma or fracture. 3. Following recent surgical procedures when muscle contraction may disrupt the healing process in the affected extremity. 4. Over areas of the skin that lack normal sensation 5. Patients with suspected or diagnosed epilepsy or seizures. (<i>Bioness 2013 [5], InnovativeNeurotronics 2013 [5]</i>) 			
3. Health benefit to patient	<input type="checkbox"/> Significant	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> Minimal
<i>Rationale:</i> Improved independence with ambulation (<i>Roche 2009 [1b], Kottink 2004 [1b], Embrey 2010 [2a], Sabut 2010 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], Taylor 2013 [4a], Sabut 2010 [4a], Stein 2010 [4a], Chen 2009a [4a], Laufer 2009 [4a], Hausdorff 2008 [4a], Stein 2006 [4a], Shiels 2011 [4b], Everaert 2010 [4b], Laufer 2009 [4b], Dunning 2009 [5a]</i>)			
4. Burden to adhere to recommendation	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Unable to determine	<input type="checkbox"/> High
<i>Rationale:</i> Unable to determine secondary to current standard of practice is an AFO; Neuroprosthetic requires a similar level of adherence			
5. Cost-effectiveness to healthcare system	<input type="checkbox"/> Cost-effective	<input checked="" type="checkbox"/> Inconclusive	<input type="checkbox"/> Not cost-effective
<i>Rationale:</i> Decreased coverage by insurance companies at this time			
6. Directness of the evidence for this target population	<input checked="" type="checkbox"/> Directly relates	<input type="checkbox"/> Some concern of directness	<input type="checkbox"/> Indirectly relates
<i>Rationale:</i> Evidence directly relates to PICO question as delineated appropriately between adults and pediatrics in the recommendations.			
7. Impact on morbidity/mortality or quality of life	<input type="checkbox"/> High	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> Low
<i>Rationale:</i> Studies reported improved quality of life with Neuroprosthetic compared to AFO (<i>Kluding 2013 [2a], Wilkie 2012 [2a], Everaert 2013 [2b], Sheffler 2006 [2b], Sheffler 2013 [4a], van Swigchem 2012 [4a], Laufer 2009 [4a]</i>).			

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IMPLEMENTATION

Applicability & Feasibility Issues

Facilitators to implementation of Recommendations include: (1) having leadership support which may include strategic objectives to increase utilization of neuroprosthetics, (2) focused training using the neuroprosthetic device(s), (3) physicians understanding and support for the use of Neuroprosthetics, and (4) research to contribute to the evidence and improve insurance funding.

Barriers to implementation include: (1) support from physical therapist secondary to change in his or her practice and knowledge base, (2) access to equipment and having enough staff trained to utilize equipment, (3) decreased coverage by insurance companies, and (4) lack of evidence in pediatrics.

Resource Needs: Specializing training, access to expensive equipment, referral sources.

Tools or processes that need to be developed: flow chart for determining eligibility for Neuroprosthetic trials, scheduling processes, referral processes, Electronic Medical Record (EMR) documentation tools and outcome data collection processes.

CHMC Knowing Notes and Device Reference Manuals

- Knowing Note – Lower Extremity Neuroprosthesis
- BionessH200 Operation Reference 2013
- WalkAide (R) Operator Manual
- Bionesss NESSL300 Operator Manual

Population Outcome Measures and Process Measures

The percent of persons with foot drop resulting from UMN disorders that receive neuroprosthesis interventions who demonstrate an improvement in gait mechanics as measured by 3d gait analysis (see [Appendix 2](#)).

The percent of persons with foot drop resulting from UMN disorders that receive neuroprosthesis interventions who demonstrate an improvement in walking speed as measured by 6 minute walk test and 10 meter walk test (see [Appendix 2](#)).

The percent of persons with foot drop resulting from UMN disorders that receive neuroprosthesis interventions who demonstrate an improvement in efficiency as measured by PCI (see [Appendix 2](#)).

The percent of persons with foot drop resulting from UMN disorders that receive neuroprosthesis interventions whose medical record indicates that a follow up appointment was scheduled at the time of the evaluation.

Expected improvements based on published literature and local consensus:

	Incomplete SCI (ASIA C or D)		BI		CP	
	<i>Evidence</i>	<i>Local Consensus</i>	<i>Evidence</i>	<i>Local Consensus</i>	<i>Evidence</i>	<i>Local Consensus</i>
Gait Speed	Improvement		Improvement		No change	
Muscle strength	Not studied	Improvement	Improvement		Not studied	Improvement
Range of Motion	Not studied	Improvement	Improvement		Not studied	Improvement
PCI	Improvement		Improvement		Not studied	Improvement
Functional Mobility	Not studied	Improvement	Not studied	Improvement	Not studied	Improvement
Patient Reported Outcome	Improvement		Improvement		Not studied	Improvement
Gait Mechanics	Improvement		Improvement		Improvement	

Legend: SCI = Spinal Cord Injury; BI = Brain Injury; CP = Cerebral Palsy.

There was no defined target in the literature for the amount of improvement expected in the above measures. The changes noted above were either found in the literature or anticipated based on local consensus.

Optional Individual Clinical Outcome Measures to evaluate treatment efficacy:

1. Gait Mechanics: Motion Analysis Lab (force plates, 3D gait data) (Roche 2009 [1b]), Subjective video analysis (LocalConsensus 2015 [5]).
2. Gait Speed: Figure eight (Roche 2009 [1b]), Modified Emory Functional Ambulation Profile (Roche 2009 [1b])

SUPPORTING INFORMATION

Background/Purpose of BEST Development

Decreased swing phase clearance of the lower extremity, or foot drop, is a common gait dysfunction in children with upper motor neuron neurological disorders or injuries such as CP, CVA, Incomplete SCI, and TBI. Physical therapists commonly manage insufficient dorsiflexion associated gait dysfunction with the application of an AFO. While the AFO is the current standard of practice for managing this gait abnormality, there are significant limitations to its use. AFOs are cumbersome, restrict ankle active and passive range of motion, may increase muscle weakness and atrophy, can result in skin breakdown, and may lead to further loss of function over time (Sheffler 2006 [2b]). In contrast, there is a growing body of evidence supporting the use of FES neuroprosthetic devices. These devices function to provide active muscle contraction via electrical stimulation of the peroneal nerve. They are not restrictive to ankle ROM and provide active stimulation to the nervous system that has the potential to increase strength and to improve motor control via repetitive stimulation and neuroplasticity (Prosser 2012 [4a]).

The clinical question was created by physical therapists to examine the available evidence and potential benefits for use of neuroprosthetics over that of the traditionally used AFO.

Definitions

Brain injury: Includes stroke and TBI. Excludes: Multiple Sclerosis and Parkinson’s.

Functional Electrical Stimulation (FES): Small electrical impulses that are utilized to activate nerves and the corresponding muscles that they innervate. This muscle activation is used to produce meaningful, functional movement.

Gait mechanics: Stride length, consists of both joint angle and force production during particular stages of the gait cycle.

International Classification of Functioning, Disability, and Health: known more commonly as ICF, provides a standard language and framework for the description of health and health-related states. In ICF, the term functioning refers to all body functions, activities and participation, while disability is similarly an umbrella term for impairments, activity limitations and participation restrictions.

Components of ICF

The ICF framework consists of two parts: Functioning and Disability and Contextual Factors. These parts are further broken down in the following manner:

Functioning and Disability includes:

- Body Functions are physiological functions of body systems (including psychological functions).
- Body Structures are anatomical parts of the body such as organs, limbs and their components.
- Activity is the execution of a task or action by an individual.
- Participation is involvement in a life situation.

Contextual Factors include:

- Environmental Factors make up the physical, social and attitudinal environment in which people live and conduct their lives. (For example, social attitudes, architectural characteristics, legal and social structures, as well as climate, terrain and so forth.)
- Personal Factors include gender, age, coping styles, social background, education, profession, past and current experience, overall behavior pattern, character and other factors that influence how disability is experienced by the individual. They are included in the framework, however, because although they are independent of the health condition they may have an influence on how a person functions.

The International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY): a WHO approved “derived” classification based on the International Classification of Functioning, Disability and Health (ICF). As a derived classification, it includes further detailed information on the application of the ICF when documenting the relevant aspects of functioning and health in children and youth (*WorldHealthOrganization 2002 [5]*).

Neuroprosthetic: A portable device that utilizes FES to peroneal nerve and dorsiflexor/evertor muscle groups in order to restore typical dorsiflexion during gait. During the swing phase of walking, the device electrically stimulates the appropriate muscles that cause ankle dorsiflexion, effectively lifting the foot at the appropriate time. These devices are activated at the correct time during gait via a tilt sensor or heel switch. (Adapted from WalkAide® website: <http://www.walkaide.com/en-us/medicalprofessionals/pages/aboutneuroprosthetics.aspx>)

Physiological Cost Index (PCI): Physiologic-cost index (PCI) is calculated by taking the difference in an individual’s walking and resting heart rate and dividing it by the person’s walking speed. PCI is therefore associated with efficiency.

Search Strategy & Evidence Table – See Appendix

Group/Team Members

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Conflicts of Interest were declared for each team member and

No financial or intellectual conflicts of interest were found.

The following conflicts of interest were disclosed:

Note: Full tables of the LEGEND evidence evaluation system are available in separate documents:

- Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality (abbreviated table below)
- Grading a Body of Evidence to Answer a Clinical Question
- Judging the Strength of a Recommendation (dimensions table below and Rationale)

Table of Evidence Levels (see note above):

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength (see note above):

Language for Strength	Definition
It is strongly recommended that... It is strongly recommended that... not...	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations)
It is recommended that... It is recommended that... not...	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.
There is insufficient evidence and a lack of consensus to make a recommendation...	

Copies of this Best Evidence Statement (BEST) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: <http://www.cincinnatichildrens.org/service/i/anderson-center/evidence-based-care/bests/>

Examples of approved uses of the BEST include the following:

- Copies may be provided to anyone involved in the organization’s process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization’s website;
- The BEST may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at EBDMinfo@cchmc.org for any BEST adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

Please cite as: Clay, M., Cincinnati Children's Hospital Medical Center: *Best Evidence Statement Use of Neuroprosthesis to improve gait mechanics, walking speed, and physiological cost index*, <http://www.cincinnatichildrens.org/service/i/anderson-center/evidence-based-care/recommendations/default/>, BEST 194, pages 1-30, 8/24/15.

This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration.

Conflict of interest declaration forms are filed with the CCHMC EBDM group.

The BEST will be removed from the Cincinnati Children’s website, if content has not been revised within five years from the most recent publication date. A revision of the BEST may be initiated at any point that evidence indicates a critical change is needed.

Review History

Date	Event	Outcome
8/24/15	Original Publication	New BEST developed and published

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at EBDMinfo@cchmc.org.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

APPENDIX: EVIDENCE SEARCH STRATEGY, RESULTS, & EVIDENCE TABLE

Criteria for considering studies for this review

Types of Studies

No specific criteria were used for determining inclusion of a particular study design. Included studies consisted of randomized controlled trials, case studies, longitudinal studies, cross sectional studies, within subject designs, systematic reviews, mixed methods designs, and retrospective cohort studies.

Types of Participants

Pediatric and adult subjects were included.

Types of Interventions

Surface FES with and without orthotics were included as interventions.

Types of Outcomes

Studies were not included or excluded based on specific outcomes reported. Included outcome measures consisted of temporal-spatial gait measures, musculoskeletal measures such as range of motion and strength, quality of life measures, and satisfaction measures as described above.

Search Strategy

Search Databases	Search Terms	Limits, Filters, & Search Date Parameters	Date of Most Recent Search
<input checked="" type="checkbox"/> MedLine <i>via PubMed or Ovid</i>	<ul style="list-style-type: none"> "neuroprosthesis" AND "functional e-stim" OR "neuroprosthetic" AND "functional e-stim" OR "neuroprosthesis" AND "FES" OR "neuroprosthetic" AND "FES" OR "foot drop stimulator" OR "Bioness" OR "radiofrequency controlled foot drop stimulator" OR "Walkaide" OR "Walk-aide" OR "self-adaptive foot drop corrector" OR "BION walkaide" OR "peroneal functional electrical stimulation" OR "Odstock dropped foot stimulator" OR "ODFS pace" NOT "cycling" NOT "pedaling" AND "last 10 years"[PDat] AND Humans[Mesh] AND English[lang] 	Publication Dates or Search Dates: <ul style="list-style-type: none"> 01/2002 to 12/1202 <input checked="" type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <input checked="" type="checkbox"/> Other Limits or Filters: <ul style="list-style-type: none"> 10 year time frame 	02/07/2015
<input checked="" type="checkbox"/> CINAHL	<ul style="list-style-type: none"> "neuroprosthesis" OR "neuroprosthetic" OR "functional e-stim" OR "FES" OR "foot drop stimulator" OR "Bioness" OR "radiofrequency controlled foot drop stimulator" OR "Walkaide" OR "Walk-aide" OR "self-adaptive foot drop corrector" OR "BION walkaide" OR "peroneal functional electrical stimulation" OR "Odstock dropped foot stimulator" OR "ODFS pace" 	Publication Dates or Search Dates: <ul style="list-style-type: none"> 01/2002 to 12/1202 <input checked="" type="checkbox"/> English Language <input type="checkbox"/> Pediatric Evidence Only: <input type="checkbox"/> Other:	12/31/2012

Search Results & Methods

The initial search for evidence identified 441 articles.
37 articles met the inclusion criteria above.

Evidence Table for Included Articles

Citation, First Author & Year	Purpose	Research Design and Study Sample	Results	Conclusions	Evidence Level
Chen, 2009 Patient driven loop...	In this study, a patient-driven loop control in a non-invasive FES system was designed to restore ambulation function of patients with stroke.	A case study was performed on a single subject with hemiplegia to design a patient-driven loop control FES. The FES was manipulated by subject's residual capabilities to produce appropriate electrical stimuli for ambulation.	Mean velocity, cadence, stride length, active ankle motion range and functional ambulation category improved significantly. Differences in the EMG of the TA and the gastroc between patient's disabled and normal foot are not significant ($p>0.05$) after 12 wks.	In this study, the patient with hemiplegia used his residual capabilities to restore ambulation functions (such as dorsiflexion and plantarflexion) by the strategy of patient-driven loop control using a noninvasive FES system. In the experimental results, subject voluntarily controlled and adjusted the plantar positions by himself with the motion-oriented modules.	5A
Damiano, 2012 Muscle Plasticity And Ankle Control After Repetitive Use Of A FES Device For Foot Drop In Cerebral Palsy.	The primary goal was to determine whether repetitive FES for unilateral foot drop increases tibialis anterior (TA) muscle size compared with an untreated baseline and the contralateral side in cerebral palsy (CP). Secondary goals were to determine whether positive changes in muscle size and gait, if found, accumulated during the 3 intervals during which participants used the device.	Longitudinal Study. 14 subjects with unilateral or asymmetrical CP ages 8-19	No significant correlations were found between changes in muscle size and ankle motion or gait velocity with or without the FES device across any of the time intervals, nor were there correlations with the amount of device use and magnitude of changes.	From these data, it appears that intense and repetitive use of FES may lead to improvement in ankle motion over time when the device is worn regularly for 5 to 6 h/d, although some improvement may have been a result of increased stimulation amplitude or pulse width in a few participants. Wearing the FES device for several hours per day may also help prevent decline in ankle function when walking without the device, but this effect may also lessen over time or if intensity of the intervention wanes.	4a
Durham, S., et al., 2004 "Effect of FES on asymmetries in gait of children with hemiplegic cerebral palsy." <u>Physiotherapy</u> 90(2): 82-90.	The aims of the study were to describe the nature of the asymmetry that results from toe walking, and to assess the immediate and long term effect of FES on gait asymmetry in an ambulant group of hemiplegic children.	Longitudinal Study. Data was collected in an ABA format, with No neuroprosthesis during A. Subjects began with barefoot walking then normal footwear in the gait lab to get baseline data at week 1 and week 12. All measurements were then repeated with and without the neuroprosthesis. The child was instructed to gradually increase use of the neuroprosthesis during the first week then use it instead of any other orthosis.	FES improved foot contact pattern on the affected side and symmetry of the most asymmetrical temporal and spatial parameters of gait in this group of hemiplegic children. FES was generally well tolerated and may be a useful alternative to a conventional orthosis	This study noted improved symmetry during gait with use of the neuroprosthesis in children with CP. This study allowed the patient's to use the neuroprosthesis at home and/or school as much as they wanted. As a result, the exact amount of time the children wore the device varied. Statistical data to determine statistical or clinical significance was not provided.	4a

Citation, First Author & Year	Purpose	Research Design and Study Sample	Results	Conclusions	Evidence Level
<p>Embrey, D. G., et al., 2010 "FES to dorsiflexor and plantar flexors during gait to improve walking in adults with chronic hemiplegia." <u>Arch Phys Med Rehabil</u> 91(5): 687-696.</p>	<p>The purpose of this study was to determine whether stimulating both dorsiflexors and plantar flexors, timed to approximate typical gait, could help adults with chronic hemiplegia improve their functional ability and their daily participation in community activities, and minimize impairments.</p>	<p>RCT: Intervention "A" included 3 months of wearing the FES system, which activated automatically during walking for 6 to 8h/d, 7d/wk, plus walking 1h/d, 6d/wk. Intervention "B" included 3 months of walking 1h/d, 6d/wk without FES. Of the 28 patients who completed the study, 15 were randomly assigned to group A-B, 13 to group B-A. Crossover occurred at 3 months.</p>	<p>The time to complete the Emory Functional Ambulatory Profile approached a statistically significant difference by decreasing 23.7 23.9 seconds in the A-B group compared with 9.8 8.9 seconds in the B-A group. Analyses showed statistically significant improvement in the 6MWT after 3 months of training, with mean SD scores of 47.7 40.3m and 18.4 16.5m for A and B interventions, respectively. The overall gains (pre-post comparison) of each group in the 6MWT were 57.1, 35.7m and 32.3, 20.5m for the A-B and B-A groups, respectively. Emory Functional Ambulatory Profile times decreased 30.9 24.4 seconds (A-B) and 21.6 11.4 seconds (B-A), while SIS scores increased by 45.4 47.0 (A-B) and 33.4 30.7 (B-A). All changes were significantly higher (P .01) at the end of the study compared with initial assessments</p>	<p>This clinical trial documents improved walking ability in patients with chronic hemiplegia by applying an FES system that stimulates both the dorsiflexor and plantar flexor muscles during gait. Combining this dual channel FES with intensive, repetitive walking translates into improved function and participation in life skills, even after the FES is discontinued for 3 months.</p>	<p>2a</p>
<p>Everaert, 2010 FES strengthens corticospinal connections?</p>	<p>To determine the effect of long-term use of a foot drop stimulator on residual corticospinal connections in people with central nervous system disorders.</p>	<p>Longitudinal: The participants for this study were a subset of the larger group that participated in the multicenter trial (WalkAide trial). Before the participants started using the WalkAide at home, data were collected for walking performance and the electrophysiological measures. All participants came back for testing after 3 months of WalkAide use. Those who were willing and able to participate in a longer follow-up were tested again at 6 months and at 12 months.</p>	<p>MEPmax after WalkAide use was 48% +/- 17% (P=.003) for the non-progressive group and 17% +/- 11% (P =.046) for the progressive group. Out of 36 participants, 19 (53%) had an increase in MEPmax of greater than 20%, and 11 participants (31%) had an increase greater than 40%. Whereas the non-progressive group had significantly higher MEPmax values before and after FES use (P=.033 and .020, respectively) than the progressive group. The mean increases in MVC after WalkAide use were similar to the</p>	<p>Several participants reached the point where their voluntary dorsiflexion was sufficient, so that they didn't need the foot-drop stimulator after the trial. Others found that their voluntary control weakened again if they didn't use FES. Some reported that using the stimulator every few days, particularly when they were planning to do a lot of walking, was sufficient to maintain function.</p>	<p>4B</p>

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			MEPmax increases: 50% +/- 20% (P=.008) for the non-progressive group and 27% +/- 18% (P=.013) for the progressive group. MEPmax was significant (12% +/- 4%; P=.018; Figure 4) in the non-progressive group but not significant (6% +/- 10%; P=.52) in the progressive group. Walking speed increased with the stimulator off (therapeutic effect) by 24% (P=.008) and 7% (P=.014) in the non-progressive and progressive groups		
Evraert, 2013 Effect of A Foot Drop Stimulator And Ankle Foot Orthosis On Walking Performance After Stroke: A Multicenter Randomized Controlled Trial	To compare changes in walking performance with the WalkAide (WA) foot drop stimulator and a conventional ankle-foot orthosis (AFO).	RCT: Subjects in arm 1 used the WalkAide first, then the AFO. Subjects in arm 2 used the AFO first, then the WalkAide. Subjects in arm 3 used an AFO in both phases. Subjects were tested at an initial visit (week 0) and at 3, 6, 9, and 12 weeks.	Both WA and AFO had significant orthotic (On-Off difference), therapeutic (change over time when Off), and combined (change over time On vs baseline Off) effects on walking speed. An AFO also had a significant orthotic effect on Physiological Cost Index. The WA had a higher, but not significantly different therapeutic effect on speed than an AFO, whereas an AFO had a greater orthotic effect than the WA (significant at 12 weeks). Combined effects on speed after 6 weeks did not differ between devices. Users felt as safe with the WA as with an AFO, but significantly more users preferred the WA.	The WalkAide had a larger therapeutic effect over time, whereas the AFO had a larger immediate orthotic effect. Both devices produced similar functional gains after 6 weeks use (combined effect). People felt as safe with the WalkAide as with an AFO, but more people preferred the WalkAide.	2B
Hausdorff, J. M. and H. Ring, 2008 "Effects of a new radio frequency-controlled neuroprosthesis on gait symmetry and rhythmicity in patients with chronic hemiparesis." <u>Am J Phys Med Rehabil</u> 87 (1): 4-13.	Investigate the effects of the NESS L300 on walking in patients with foot drop. In particular, they studied whether the neuroprosthesis enhances walking symmetry and rhythmicity in this group of patients.	Longitudinal Study gradually increases the use of the neuroprosthesis to 1 hr by the end of the first week, to 4 hrs by the end of the second week, and to a whole day from the fourth week on.	The swing asymmetry index improved by 28% immediately after application of the neuroprosthesis, reaching a 45% change after 8 wks, the test time effect was significant. Initial application of the neuroprosthesis reduced stride time variability by 23%, and	This study demonstrates that the NESS L300 neuroprosthesis enhances gait and improves gait symmetry and rhythmicity in chronic hemiparetic patients. The findings suggest that stroke and traumatic brain injury survivors who suffer from hemiparesis that causes foot drop can gain	4a

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			<p>this measure continued to improve by 27% and 33% after 4 and 8 wks, statically significant. There was a significant increase in gait speed in each of the three tests with the neuroprosthesis. While wearing the FES neuroprosthesis, average gait speed during the 6-min walk test initially improved by 17%, increasing to 34% after 8 wks. Effort of walking was significantly lower after 8 weeks with the neuroprosthesis.</p>	<p>meaningful benefits by using the neuroprosthesis on initial use, and that continued use further improves mobility.</p>	
<p>Ho, 2006 FES changes dynamic resources in children with spastic cerebral palsy</p>	<p>The purpose of this study was to determine the effects of FES applied to the gastrocnemius-soleus muscle complex on the ability to produce appropriately timed force and reduce stiffness (elastic property of the body) and on stride length and stride frequency during walking.</p>	<p>Cross sectional: Children with CP were randomly assigned to either a group that walked with FES for 15 trials followed by no FES for 15 trials or a group that walked without FES for 15 trials followed by FES for 15 trials. The children who were developing typically walked without FES. The control group walked 30 trials without FES. All trials were conducted in one experimental session</p>	<p>The FES significantly increased speed-normalized dimensionless impulse from 10.02 to 16.32 when comparing walking conditions for the children with CP. No significant differences were found between walking conditions for stiffness, stride length, and stride frequency. The children who were developing typically had significantly lower median speed-normalized dimensionless impulse than the children with CP in the FES condition (P=.02). The children who were developing typically showed significantly longer median stride length than the children with CP in either the FES condition (P=.02) or the no-FES condition (P=.03). The children who were developing typically showed significantly higher median dimensionless stride frequency than the children with CP in the FES condition (p=.05).</p>	<p>The major finding is that FES successfully increases the impulse generated during the push-off phase of the gait cycle. However, translating that energy into increased speed and stride length and decreasing the adapted stiffness may require a longer period of training with FES than was used in this study</p>	<p>4b</p>
<p>Isakov, 2002 Influence of a Single FES Treatment on Hemiparetic Legs.</p>	<p>This present study investigated whether immediate advantages may be obtained from</p>	<p>Cross Sectional: 12 subjects with CVA. FES was delivered to the affected leg muscles for</p>	<p>Mean walking speed of the subjects was 14.7 m/min (SD 3.6) before and 14.3 m/min (SD</p>	<p>Positive effects of a single FES treatment, applied to the affected leg muscles of patients</p>	<p>4A</p>

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	<p>a single FES treatment to stroke patients. It was assumed that hemiparetic standing balance and walking might improve as a result of a decrease in spasticity, achieved by a single FES treatment. To verify this assumption the following parameters were evaluated: bilateral anteroposterior standing sway and bilateral knee range of motion during the gait cycle.</p>	<p>30 minutes with the subjects in the supine position. The selected muscles were repeatedly activated in the following sequence: quads, hamstrings, DFs and PFs. Each muscle was activated for four seconds, generating only a slight muscle contraction, and the level of intensity was adjusted according to subject consent</p>	<p>2.8) after the FES treatment. This difference was not statistically significant. Symmetry between anteroposterior activity in the hemiparetic and sound legs significantly improved following FES treatment (from 0.707 before FES to 0.810 after FES, $p < 0.05$). Differences between range of the hemiparetic knee (mean 34.5°, SD 9°) and of the sound knee (mean 47.7°, SD 4°) were significant only before FES treatment. This discrepancy in range became insignificant after FES (mean 41.4°, SD 7° hemiparetic knee; mean 48.3°, SD 4° sound knee) since the range of motion of the hemiparetic knee increased by approx. 7° (from 34.5°, SD 9°, to 41.4°, SD 7°)</p>	<p>with spastic hemiparesis, have been shown. A decrease in spasticity improved participation of the affected leg in self-balancing during standing, as well as improving gait quality by allowing a larger range of movement of the affected knee during swing phase.</p>	
<p>Israel, S., et al., 2011 "The therapeutic effect of outpatient use of a peroneal nerve FES neuroprosthesis in people with stroke: a case series." <u>Top Stroke Rehabil</u> 18(6): 738-745.</p>	<p>To determine the effect of gait training with a pFES neuroprosthesis 3 times per week for 6 weeks on functional ambulation, kinematics, and temporal-spatial characteristics of gait including velocity.</p>	<p>Case Study. Both subjects were seen for 60 minutes, 3 times per week for 6 weeks. The intervention focused on over ground gait training with the neuroprosthesis. Activities included walking at self-selected speed, at fast speed, on level terrain, on carpet, on tile floor, up and down stairs, up and down ramps, and outdoors</p>	<p>Both subjects showed decreased time to complete the mEFAP, decreased ankle PF at heel strike. One subject showed increased gait velocity.</p>	<p>This article only looked at 2 subjects and only examined over the ground gait training. The FES improved gait velocity, PF at heel strike and mEFAP when used only in the clinic as compared to all the time.</p>	<p>5B</p>
<p>Kim, 2004 Effects of a simple functional electric system...</p>	<p>To compare the effect of functional electric stimulation (FES) with that of a hinged ankle-foot orthosis (AFO) for assisting foot clearance, gait speed, and endurance and to determine whether there is added benefit in using FES in conjunction with the hinged AFO in persons with incomplete spinal cord injury (SCI).</p>	<p>Within subject comparison of walking under 4 conditions: AFO, FES, AFO and FES, and no orthosis. 19 subjects were volunteers with partial SCI. An 8-m walk test and a 6 min walk test were performed under the 4 conditions. LE MMT's were performed as well. Measurements were taken at 0, 3, 4, and 7 mos.</p>	<p>Gait speed increased with FES ($P < .05$) and with the AFO ($P = .06$). Six-minute walk distance also increased with the AFO ($P < .05$). No difference was found between the 2 forms of orthoses in either gait speed or endurance. The greatest increase in gait speed and endurance from the no-orthosis condition occurred with the</p>	<p>Although the use of either type of orthosis promoted walking, the AFO and FES used in combination provided greater benefit in overall gait function than either device alone. The FES was only superior to the hinged AFO in improving limb clearance during swing; however, this increase in foot clearance did not translate into a further increase in function when the 2</p>	<p>4A</p>

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			combined AFO and FES condition. Foot clearance improved with FES but not with AFO.	types of devices were compared. In general, subjects who presented with less leg muscle strength appeared to benefit more from the FES system than those with stronger leg muscles	
Kluding, 2013 Foot Drop Stimulation Versus Ankle Foot Orthosis After Stroke: 30 week outcomes	The purpose of the study was to compare a Foot Drop Stimulator (FDS) (Bioness L300) and AFO for drop foot among people ≥ 3 months after stroke, with a gait speed ≤ 0.8 m/s.	RCT; Participants ≥ 3 months post stroke with gait speed ≤ 0.8 m/s were randomized to 30 weeks of wearing either a surface FDS (treatment group) or a standard AFO (control group). At 30 weeks, the control group crossed over to receive an FDS and was followed for an additional 12 weeks whereas the original treatment group continued to use their FDS.	(1) Primary outcome gait speed: both comfortable and fast gait speed improved significant within both the FDS and AFO groups for total effect, as well as training and therapeutic effect. In addition, the immediate effect was significant within groups. No significant effects were found between groups for gait speed. Note - therapeutic effect trending to greater impact on FDS group. (2) Secondary outcomes - all outcome measures had similar patterns of change, with significant improvements noted within both groups but no significant between-group differences. User satisfaction: was significantly higher in the treatment group than the control group.	AFO and FDS demonstrated a significant change in gait speed; No significant difference between AFO and FDS.	2A
Kottink, 2004 The Orthotic Effect...	Analysis of the available evidence on the improvement of walking in stroke patients with a dropped foot when using peroneal nerve stimulation.	A systematic review was performed to identify trials that investigated the orthotic effect of FES on walking in patients with a dropped foot. The review included one RCT, two crossovers, and a within-subject comparison.	The pooled analysis of both controlled and uncontrolled trials showed an improvement of 38% in walking speed with a confidence interval of 22.18–53.8%. Despite variance across studies, a significant improvement in walking speed occurred: 0.13 m/s (0.07–0.2).	The present review suggests a positive orthotic effect of FES on walking speed.	1b
Laufer, 2009 Effects of a Foot Drop...	To determine the long-term effects of a neuroprosthesis used to correct a foot drop on functional ability in activities of daily living, social participation, and gait velocity.	Prospective, single group, repeated measures 1-yr follow-up of 16 patients (aged 55 +/- 14.6 yrs) with chronic hemiparesis who used a neuroprosthesis for 1 yr and were available	Significant increases of 18.0% in physical functioning and of 25.2% in participation in community life were attained 2 mos after the application of the neuroprosthesis. The gains were maintained	The present study demonstrates that the use of the NESS L300 neuroprosthesis by patients with chronic hemiparesis results in significant improvements, both in their functional activities	4a

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		<p>for follow-up. Each subject was assessed three times: (1) just before receiving the FES neuroprosthesis, when gait performance was assessed with no assistive device (either the AFO or the FES neuroprosthesis) (T1); (2) 2 mos later (T2); and (3) after 1 yr (T3). Gait performance at T2 and T3 was assessed with the neuroprosthetic device operating.</p>	<p>at the 1-yr follow-up. Gait velocity increased significantly by 29.2% by 2 mos, with significant further increases of 22.6% observed at the 1-yr follow-up.</p>	<p>of daily living and in their social participation. The positive effects achieved after 2 mos of application were maintained with continued use of the L300 FES device 1 yr later. Gains in gait velocity continue to improve over the 1-yr span. These findings emphasize the benefits of using the neuroprosthesis in patients with TBI and post-stroke.</p>	
<p>Laufer, Y., et al., 2009 "Gait in individuals with chronic hemiparesis: one-year follow-up of the effects of a neuroprosthesis that ameliorates foot drop." <i>J Neurol Phys Ther</i> 33(2): 104-110.</p>	<p>(1) To compare the short-term and long-term effects of an FES neuroprosthesis designed to correct foot drop after its daily application for two months and one year and (2) to determine the carryover effect of applying the neuroprosthesis daily for one year on gait when examined without the assistance of the stimulation.</p>	<p>Longitudinal Study: After the initial application of the device, subjects were instructed to gradually increase their daily use of the neuroprosthesis, so that by the end of the first week they were using it one hour per day, by the end of the second week they were using it four hours per day, and by the end of the fourth week they were using it throughout the day. Each subject was evaluated at three time points: before the fitting of the neuroprosthesis (T1), two months later (T2), and one year after initial application of the device (T3).</p>	<p>Significant long-term impact on gait velocity, as well as on temporal gait parameters, leading to a more symmetrical and less variable gait pattern. 10-m gait velocity improves even further with the progression of time and that improvements in gait velocity and single stance time are carried over to gait without the device. Application of FES induces significant improvements in ambulation endurance, which is vital for independent community ambulation.</p>	<p>Although the gait velocity of our participants never reached the level of aged-matched norms, it seems that both the initial and the long-term improvements were clinically significant.</p>	<p>4b</p>
<p>Prosser, 2012 Acceptability and potential...</p>	<p>The primary objective of this study was to conduct the first trial in CP examining the acceptability and clinical effectiveness of a novel, commercially available device that delivers FES to stimulate ankle dorsiflexion.</p>	<p>19 individuals mean age 12yr 11mos underwent gait analyses in FES and non-FES conditions at two walking speeds over a 4 month period of device use. Measures included ankle kinematics and spatiotemporal variables.</p>	<p>Improved dorsiflexion was observed during swing (mean and peak) and at foot-floor contact, with partial preservation of ankle plantarflexion at toe-off when using the FES at self-selected and fast walking speeds. Gait speed was unchanged.</p>	<p>This FES device was well accepted and effective for foot drop in those with mild gait impairments from CP.</p>	<p>4a</p>
<p>Ring, H.; Treger, I.; Gruendlinger, L.; and Hausdorff, J. M. Neuroprosthesis for foot drop compared with an ankle-foot orthosis: effects on postural control during walking. <i>J Stroke Cerebrovasc Dis</i>, 18(1): 41-7, 2009, [3]</p>	<p>Sought to compare the effects of a radio frequency-controlled neuroprosthesis on gait stability and symmetry to the effects obtained with a standard ankle-foot orthosis (AFO).</p>	<p>Longitudinal Study: Subjects completed a four week training session in which they were instructed to increase their daily use of neuroprosthesis and continue using the AFO</p>	<p>After the 4-week adaptation period, there were no differences between walking with the neuroprosthesis and walking with the AFO (P .05). After 8 weeks,</p>	<p>This study compared the use of AFO and neuroprosthesis. It discovered that there was a significant change in stride time, gait asymmetry, and swing time. However, there</p>	<p>4a</p>

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		<p>the remainder of the time. Measurements were taken using the only the neuroprosthesis then only the AFO. Subjects then had another 4 weeks in which they were only instructed to use the neuroprosthesis. Measurements were taken again with only the neuroprosthesis and only the AFO.</p>	<p>the effects of the neuroprosthesis on gait were significantly greater than those seen with the AFO in 3 of the 4 outcomes that were measured. Although there was no significant difference in gait speed with the neuroprosthesis, there was a significant change in stride time, gait asymmetry, and swing time variability. The stride time was shorter (P 5.02), the gait asymmetry index (Fig 1) was improved (P .05), and the single limb support of the paretic leg (swing time of the non-paretic leg) also became less variable and more consistent (P .01).</p>	<p>was no significant difference in gait speed.</p>	
<p>Roche, 2009 Surface applied...</p>	<p>The aim of this systematic review was to source and evaluate the current available evidence for both the orthotic and therapeutic effect of surface-FES for the correction of drop-foot after stroke.</p>	<p>Systematic Review including adult patients with foot drop from stroke who receive FES to dorsiflexor.</p>	<p>There was a positive orthotic effect particularly for gait speed and physiological cost index (PCI), in chronic post-stroke patients. Research supporting a therapeutic effect of FES post-stroke is less conclusive. Some support exists for FES in combination with 'conventional rehabilitation' or treadmill training or for increasing the effectiveness of Botulinum toxin injections.</p>	<p>FES can have a positive orthotic effect particularly for gait speed and physiological cost index (PCI), in chronic post-stroke patients.</p>	<p>1b</p>
<p>Sabut, 2010 Restoration of gait</p>	<p>To evaluate the clinical efficacy of FES therapy of the tibialis anterior (TA) muscle on gait restoration and enhancing motor recovery with stroke patients.</p>	<p>RCT: All study subjects received the conventional stroke rehabilitation program of PT based on the neurodevelopmental facilitation approach and occupational therapy focused on ADLs during the treatment for 60 min a day, 5 days a week, and for follow-up study of 12-weeks. The FES group also received electrical stimulation to the tibialis anterior (TA) muscle of the paretic</p>	<p>There was a significant increase walking speed: 26.28% in the FES group and 11.51% in the control group. Significant increase in cadence: with an increase of 17.71%, step length of 21.27%, and stride length of 20.41% in the FES group and a significant increase in mean cadence of 7.59%, step length of 8.03%, and stride length of 8.24% in the control group. PCI decreased 10.61%</p>	<p>Subjects who have a foot drop as a result of a stroke, which hinders walking ability, may find they could walk more quickly with less effort by using the FES device.</p>	<p>2b</p>

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		limb 30 min per session	in the control group and 23.3% in the FES group. The results of the Fugl-Meyer a change of 45.93% in the FES group and a change of 19.5% in the control group.		
Sabut, 2011 FES of DF muscle	The purpose of this study was to investigate whether combining FES therapy with a conventional stroke rehabilitation program is more effective than a conventional program alone in reducing plantarflexor spasticity, improving dorsiflexor muscle strength, voluntary ankle dorsiflexion active, and facilitating recovery of lower-extremity motor functions in stroke patients.	Longitudinal study. The study included 51 consecutive stroke patients with spastic foot drop, ranging in age from 37 to 65 years.	MAS score showed significant decrease in the plantarflexor spasticity ($p < 0.05$) within both FES and control groups. Decreased by 37.5% in the FES group and 21.2% in the control group. The ankle AROM increased significantly in both groups, with an increase of 47.1% in FES group and 24.2% in control group. The difference between groups in terms of the percentage change, was found significant ($p < 0.05$), resulted better improvement in FES group than the control group. The PROM also improved significantly by 35.1% in the FES group and 21.7% in the control group. DF strength was increased by 75.8% in the FES group, and 27.7% in the control group. Fugl-Meyer lower-extremity score was increased by 32.8% and 11.6% in the FES and control group.	This study also revealed that the combination of FES therapy along with CRP was more effective in improving gait characteristics, effort of walking; improve in active/passive ankle joint range of motion, dorsiflexor strength, reduction of plantarflexor spasticity, and improving lower-extremity motor functions.	4b
Sabut, Lenka, 2010 Effect of FES...	To investigate the effects of FES combined with conventional rehabilitation program on the effort and speed of walking, the surface electromyographic (sEMG) activity and metabolic responses in the management of drop foot in stroke subjects.	A longitudinal study utilized 15 post-stroke subjects to investigate the effects of FES combined with conventional rehabilitation program on the effort and speed of walking, the surface electromyographic (sEMG) activity and metabolic responses in the management of drop foot in stroke subjects.	The experimental results showed a significant improvement in mean-absolute-value (21.7%), root-mean-square (66.3%) and median frequency (10.6%) of TA muscle EMG signal, which reflects increased muscle strength. Mean increase in walking speed was 38.7%, and a reduction in PCI of 34.6% between the beginning and at end of the trial. Improvements were	This study demonstrated that the FES therapy has a potential as a therapeutic intervention to correct drop foot in stroke subjects. FES resulted in therapeutic benefits on increasing the walking speed and reducing the effort of walking measured as PCI on a 10-m walkway. In addition, patients who have had a stroke experience a short term "carry-over" effect when they are not using the stimulator, after treated with FES for 12-weeks.	4A

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			also found in cardiorespiratory responses with reduction in oxygen consumption (24.3%), carbon dioxide production (19.9%), heart rate (7.8%) and energy cost (22.5%) while walking with FES device.	We concluded that the FES therapy is a clinically effective treatment option combined with conventional rehabilitation program for hemiplegics who present with difficulty walking because of drop foot. We assume that within normal rehabilitation conditions, it would be necessary for patients to continue FES therapy along with conventional rehabilitation program in their daily lives.	
Seifart, 2009 The Effect of...	To examine the effect of lower limb FES in children with cerebral palsy.	Systematic Review: Five articles were included in this review, including 3 case reports, 1 single subject, and 1 crossover design. Within each study, the stimulation had to have been applied to any lower leg muscle(s) during a functional activity by either S-FES or P-FES as a treatment program, and subjects had to have been younger the age of 18 years with a diagnosis of CP.	Functional improvements were anecdotal. No statistically significant results were reported.	Among the wide range of stimulation protocols, stimulation of the gastrocnemius with or without the tibialis anterior muscle may effect greater gait improvements than stimulating the tibialis anterior muscle alone. Future research differentiating between optimal FES and neuromuscular electrical stimulation protocols as well as more rigorous research designs are needed to provide clinically relevant results.	1b
Sheffler, 2007 Improvements in...	To evaluate the use of a peroneal nerve stimulator (PNS) on 2 subjects with hemiplegia using the mEFAP.	2 chronic stroke survivors who used AFO prior to study entry were evaluated at baseline and after 4 weeks of daily use of a surface PNS. Participants were assessed without their dorsiflexor assistive device, using the mEFAP.	The composite score and all 5 individual subscores of the mEFAP improved at 4 weeks relative to baseline for both patients (Tables 1 and 2).	These case reports indicate that enhanced functional ambulation may be an important therapeutic effect of peroneal nerve stimulation.	5b
Sheffler, 2006 Peroneal nerve stimulation versus an ankle foot orthosis for correction of foot drop in stroke: impact on functional ambulation. [Team]. Neurorehabil Neural Repair, 20(3), 355-360	Primary objective of this study is to compare the effects of the ODFS and an AFO to each other and to using no device in improving functional ambulation of chronic stroke survivors as measured by the modified Emory Functional Ambulation Profile (mEFAP). A secondary objective is to solicit feedback from	Repeated measures design.	Functional ambulation with the AFO was significantly improved, relative to no device, on the floor (P=0.000), carpet (P=0.013), and "up and go" test (P=0.042). There was a trend toward significance on the obstacle (P=0.092) and stair (P=0.067) trials. Functional ambulation with the ODFS was	No apparent difference btw AFO and FES with primary outcome but both better than no device. Patients satisfied with FES.	3b

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	long-term AFO users on the ease of application and perceived utility of the ODFS as compared to the AFO.		significantly improved, relative to no device, on the carpet (P=0.004). A trend toward significance on floor (P=0.081), obstacle (P=0.092), and stair (P=0.079) trials was observed. The difference in functional ambulation between the AFO and ODFS showed a trend toward statistical significance on floor (P=0.065) and up and go (P=0.082) trials only.		
Sheffler, 2013 A Randomized Control...	To compare the motor relearning effect of a surface peroneal nerve stimulator (PNS) versus usual care on lower limb motor impairment, activity limitation, and quality of life among chronic stroke survivors.	Subjects were stratified by motor impairment level and then randomly assigned to ambulation training with either a surface PNS device or usual care (ankle-foot orthosis or no device) intervention. Subjects were treated for 12 weeks and followed up for 6 months post treatment.	There was no significant treatment group main effect or treatment group by time interaction effect on FM, mEFAP, or SSQOL raw scores (P>.05). The time effect was significant for the 3 raw scores (P<.05). However, when comparing average change scores from baseline (t1) to end of treatment (t2, 12wk), and at 12 weeks (t3) and 24 weeks (t4) after end of treatment, significant differences were noted only for the mEFAP and SSQOL scores.	There was no evidence of a motor relearning effect on lower limb motor impairment in either the PNS or UC groups as measured by the FM. However, even in the chronic phase of stroke, both the PNS and UC groups demonstrated significant improvements in functional mobility and quality of life that were sustained at 6 months.	4a
Shiels, 2011 A mixed method...	To undertake a service evaluation of the pilot Lothian FES clinic using both quantitative and qualitative methods and clinical practice reflection.	Mixed methods: Phase 1: Before and after service evaluation of FES. Gait velocity and cadence were recorded initially and 6 months after FES. Phase 2: Qualitative research exploring patients with stroke and carers' experiences. Phase 3: reflection of FES experience.	Statistically significant improvements (p<0.001) were demonstrated in gait velocity and cadence. Qualitatively, one theme 'The FES clinic met my needs' emerged.	The results of this service evaluation would indicate that overall the pilot FES clinic design met the needs of chronic patients with stroke and carers with only minor modifications identified. In addition, in line with the current literature, it produced highly statistically significant improvements in physical outcomes comparing before and after FES application.	4b
Springer, 2012 The effects...	The objective of this study was to investigate the effects of daily peroneal and hamstrings muscle FES on the kinematic aspects of gait performance during the	Sixteen subjects (aged 54.2 ± 14.1 years) with hemiparesis (7.9 ± 7.1 years since diagnosis) demonstrating a foot drop and hamstrings muscle weakness were fitted with a dual	Results with the dual-channel FES indicate that in the subgroup of subjects who demonstrated reduced hip extension but no knee hyperextension (n =9), hamstrings FES	The results suggest that dual channel FES for the dorsiflexor and hamstring muscles may affect lower limb control beyond that which can be attributed to peroneal stimulation alone.	4b

Citation, First Author & Year	Purpose	Research Design and Study Sample	Results	Conclusions	Evidence Level
	stance phase in individuals with hemiparesis. In particular, we tested the hypothesis that the studied dual-channel FES application would enhance walking performance by improving hip extension and restraining knee hyperextension in patients with hemiparesis.	channel FES system activating the dorsiflexor and hamstring muscles. Measurements of gait performance were collected after a conditioning period of 6 weeks, during which the subjects used the system throughout the day.	increased hip extension during terminal stance without affecting the knee. Similarly, in the subgroup of subjects who demonstrated knee hyperextension but no limitation in hip extension (n=7), FES restrained knee hyperextension without having an impact on hip movement. Additionally, step length was increased in all subjects.		
Stein, 2006 A multicenter trial of foot drop stimulator controlled by a tilt sensor	To test the efficacy and acceptance of a foot drop stimulator controlled by a tilt sensor.	Longitudinal: A nonrandomized, test-retest study of 26 subjects with foot drop of more than 1 year's duration, resulting from various central nervous system disorders, was performed in 4 centers for at least 3 months. Speed of walking in a straight line, speed around a figure of 8, and physiological cost index (PCI) were measured with and without the device. Hours/day and steps/day using the device were recorded.	On average, the straight walking speed increased from 0.69 m/s without WA initially to 0.77 m/s with WA after 3 months. The difference between walking speed with and without the WA initially was not significant. However, the difference in walking speed over 3 months using the WA was highly significant (paired Student's test, $P < 0.01$), as was the difference between the speed with and without the WA at the end of 3 months. The walking speeds around the figure of 8 were slower, as expected, but showed a similar increase over 3 months from 0.49 to 0.56 m/s. The statistical significance was also higher. A trend was seen in the PCI toward lower values (from 1.06 to 1.01), but only the difference between the initial and final values with the WA was statistically significant ($P < 0.05$).	Both efficacy and acceptance of the stimulator were good in a population of subjects with chronic foot drop.	4A
Stein, 2010 Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and non-progressive neurological disorders	To compare the orthotic and therapeutic effects of a foot drop stimulator on walking performance of subjects with chronic non-progressive (e.g., stroke) and progressive	Longitudinal: Subjects ambulated with Walk aide for 3 to 12 months while walking in the community. Walking speed was measured with a 10-m test and a 4-minute figure-8 test;	After 3 months of FES use, the non-progressive and progressive groups had a similar, significant orthotic effect (5.0% and 5.7%, respectively, $P < .003$; percentage	We conclude that subjects with both progressive and non-progressive disorders show a therapeutic effect of using foot drop stimulators. In response to the second question,	4A

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	(e.g., multiple sclerosis) disorders.	physiological cost index (PCI) and device usage were also measured. The subjects were tested with FES on and off (orthotic effect) before and after (therapeutic effect) stimulator use.	change in mean values) and therapeutic effect with FES off (17.8% and 9.1%, respectively, $P < .005$) on figure-8 walking speed. Overall, PCI showed a decreasing trend ($P = .031$). The therapeutic effect on figure-8 speed diverged later between both groups to 28.0% ($P < .001$) and 7.9% at 11 months. The combined therapeutic plus orthotic effect on figure-8 speed at 11 months was, respectively, 37.8% ($P < .001$) and 13.1% ($P = .012$); PCI decreased 18.2% ($P = .038$) and 6.5%, respectively	an important new finding is that the benefits in the non-progressive 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 process.	
Tanovic, 2009 Effects of FES In Rehabilitation With Hemiparesis Patients.	The purpose is to determine the role of the functional electrical simulation (FES) in the rehabilitation of patients with hemiparesis, which occurred as a consequence of a cerebrovascular accident	CCT: Two groups of patients in rehabilitation were formed. The control group includes the patients who were only treated with kinesiotherapy. The tested group is composed of patients that were treated with kinesiotherapy and FES of the disabled extremity. The FES method was applied five times per week. Conditions observed 4 and 8 weeks	After 8 weeks of rehabilitation the group of patients who were treated with kinesiotherapy and FES showed better statistically significant results of rehabilitation in respect to the control group with both the BI index and the RAP index.	Walking rehabilitation is faster and more successful with FES.	3b
Taylor, 2013 The Long-Term Cost-Effectiveness Of The Use Of FES For The Correction Of Dropped Foot Due To Upper Motor Neuron Lesion	FES for correction of dropped foot has been shown to increase mobility, reduce the incidence of falls and to improve quality of life. This study aimed to determine how long the intervention is of benefit, and the total cost of its provision.	Retrospective Cohort: One hundred and twenty-six people with spastic dropped foot (62 stroke, 39 multiple sclerosis, 7 spinal cord injury, 3 cerebral palsy, 15 others) who began treatment in the year 1999	People with stroke walked 0.08 ms ⁻¹ faster with FES ($p < 0.001$, 17%, continuing orthotic effect) and also increased their walking speed without FES by 0.11ms ⁻¹ ($p < 0.001$, 24%, training effect), resulting in an overall increase of 0.18 ms ⁻¹ ($p < 0.001$, 45%, total orthotic effect) when compared to the start of treatment without FES. Twenty two (20%) patients improved their functional walking category the first time FES was used. This increased to 42 (38%)	This study does not provide the actual amount of time each subject wore the FES but it does provide information on the long term effects of FES, including cost of FES.	4a

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			over the next 16.5 months. Twenty-nine (26%) patients experienced a training effect sufficient to increase their functional walking category when walking without FES. No correlation was found between duration of use and initial walking speed, time since disease onset, age or maximum walking distance at start.		
Tong, 2006 Gait electro-training + FES	The purpose of this case report is to describe and discuss the gait training and performance details of 2 patients who underwent combined FES and gait training intervention in their rehabilitation, with a focus on the application of daily FES-gait training intervention sessions and follow-up methods.	Case Report: N of 2 patients with ischemic stroke. 4 wk intervention: 20-minute training session every day from Monday to Friday on the electromechanical gait trainer coupled with simultaneous FES. The pts stayed in the hospital during the 4-wk intervention & also received 40-minute sessions of physical therapy and 1.5-hour sessions of the multidisciplinary rehabilitation program.	Pt A: 0.14 m/s, and the speed was steadily increased to 0.34 m/s toward the end of the 4-week period. Body weight support decreased from 5.3% on day 1 to 0% on day 15; on day 16, he had continuously progressed to walk without any hand support; by the last session, he was able to walk independently on the gait trainer with FES; BBS score improved to 42 out of 56. He could walk independently using a cane and had a gait speed of 0.35 m/s, His independence in ADL improved, as shown by his BI score of 75. Pt. B: Body weight support decreased from 13.0% on day 1 to 1.8% at the last session, and gait speed increased from 0.17 to 0.31 m/s during the 4-week period, last session was able to walk independently on the gait trainer with FES without holding the front horizontal bar for support. His BBS score increased from 16 to 42, at end could walk independently and required only verbal encouragement or supervision, Motricity Index leg score increased from 38 to 48.	Both patients had a faster walking speed and displayed better functional performance than at the end of the 4-week FES-gait training intervention and discharge from the hospital. Their independence in ADL also improved compared with that before the intervention.	5a

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Van Swigchem, 2012 Effect of Peroneal Electrical Stimulation Versus an Ankle-Foot Orthosis on Obstacle Avoidance Ability in People With Stroke-Related Foot Drop	This study aimed to identify potential benefits of peroneal FES over an AFO with respect to the ability to negotiate a sudden obstacle.	Longitudinal: Comfortable walking speed over 10 m was measured at baseline, 2, 8 wks with the AFO & FES The level of physical activity was assessed with a pedometer, and patients' satisfaction was assessed with a questionnaire.	Ankle-foot orthosis and FES were equally effective with regard to walking speed. The participants experienced benefits of FES over their conventional walking device with regard to comfort, appearance of the device, quality of gait pattern, walking distance, effort of walking and stability during gait [all p values <0.05]	Low leg muscle strength is a possible indicator of a good response to peroneal FES concerning obstacle avoidance ability. Participants with low Motricity Index scores showed greater benefits than those with higher Motricity Index scores.	4A
Van Swigchem, 2010 Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. [Jennie]. J Rehabil Med, 42(2), 117-12	The aim of this study was to evaluate whether community-dwelling chronic stroke patients wearing an ankle foot orthosis would benefit from changing to FES of the peroneal nerve.	Longitudinal Study: 24 community-dwelling people with stroke who regularly used an AFO were fitted with a trans-cutaneous FES device. The participants' obstacle avoidance ability was tested after 2 and 8 weeks. They had to avoid 30 obstacles that were suddenly dropped on a treadmill in front of the affected leg while walking with either FES or an AFO. The obstacle avoidance success rates were determined.	Obstacle avoidance ability can be improved by replacing the AFO with peroneal FES. In addition, within our group of relatively good walkers, lower-leg muscle strength was associated with greater benefits from FES with regard to obstacle avoidance ability. Specifically, in people with low leg muscle strength (Motricity Index score <64) due to stroke. The observed gains in obstacle avoidance ability appear to be clinically relevant.	The patients judged FES to be superior to the AFO, but measurements of walking speed and level of physical activity could not objectify the perceived benefits of FES. The patients experienced greater stability of gait with FES, which may be related to a feeling of safety during transfers, walking on inclines, or over uneven terrain. FES was also judged superior with respect to the effort of gait.	4a
Vander linden, Ml; Hazlewood, E.; Hillman, S. J.; and Robb, J. E. FES to the dorsiflexor and quadriceps in children with cerebral palsy. <i>Pediatric Physical Therapy</i> , 20(1): 23-29, 2008, [3]]	The aim of this exploratory trial was to provide effect sizes and data on the orthotic and therapeutic effects of FES required for a future appropriately powered randomized controlled trial. A second aim of this study was to investigate the feasibility of using FES equipment at home and school for children with CP.	RCT: The treatment group received 2 weeks of neuromuscular electrical stimulation followed by 8 weeks of FES used at home and school. The control group continued with its usual physiotherapy program. Assessment took place at baseline and before and after the treatment period. Both control and treatment groups were fitted with FES for gait analysis at the second and final assessments.	This exploratory trial showed that FES applied to the dorsiflexor resulted in significant improvements in the gait of children with CP. The researchers also reported on both the positive and negative experiences of parents and children who used FES every day for 8 weeks.	FES for children with CP can be a practical treatment option to improve gait kinematics in a carefully selected group of children, receiving adequate support from therapist, parents, and teaching staff.	2b
Wilkie, 2012 FES Impacted On Important Aspects Of My Life" A Qualitative Exploration Of Chronic Stroke Patients' And Carers' Perceptions Of FES In The Management Of Dropped Foo	Explore the impact of FES in the management of dropped foot on patients with chronic stroke and their caretakers.	Qualitative semi-structured interviews, using a focused interview guide, were conducted by an experienced independent researcher who had no	Overarching theme is "FES impacted on important aspects of my life". 4 subthemes resulted: "Walking with FES is much better", "FES helped regain control of life", "Feeling	Participants linked FES use to improvement in normal appearance and quality of their walking	4A

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		involvement in the FES service. The interview was broad and enabled participants to freely express their views. Interviews were digitally recorded, anonymized and transcribed verbatim.	good comes with using FES", and "FES is not perfect but it is of value".		

Appendix 2

Individual Clinical Assessments and Outcome Measures:

1. Gait Speed: 6 minute walk test, Timed Up and Go (TUG), 10 meter walk (Roche 2009 [1b], Kottink 2004 [1b]), Time up and down stairs (TUDS), Standardized walking obstacle course (LocalConsensus 2015 [5])
2. Muscle Strength: Manual Muscle Test (MMT) (Sabut 2011 [4b]), Dynamometry (Embrey 2010 [2a])
3. Range Of Motion: Goniometry (Roche 2009 [1b])
4. Physiological Cost Index: PCI (Roche 2009 [1b])
5. Functional Mobility: Gross Motor Function Measure (GMFM), Functional Independence Measure for Children (WeeFIM), Functional Independence Measure (FIM), (LocalConsensus 2015 [5])
6. Patient Reported Outcome: Stroke specific quality of life scale (SSQOL)(Sheffler 2013 [4a]), Stroke Impact Scale (Embrey 2010 [2a]), Nottingham Quality of Life (QOL) (Roche 2009 [1b]), Goal Attainment Scale (GAS), Canadian Occupational Performance Measure (COPM), Cerebral Palsy Quality of Life (CPQOL) (LocalConsensus 2015 [5])