Transcutaneous Stimulation and Mobility Device Use for Individuals With Neurologic Conditions

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STUDY PROTOCOL

Background

Mobility supports independence, participation, and exploration in daily life. However, mobility is often limited for individuals with neurologic injuries like cerebral palsy. The long-term goal of this research is to improve mobility and quality of movement for individuals with cerebral palsy. In this research, we aim to quantify how acute increases in sensory feedback, such as with external mobility devices and non-invasive spinal stimulation, can support and improve walking function. Mobility devices can be used to assist movement and make it easier, or they can resist movement to make it more challenging on the neuromuscular system. Novel devices like the Biomotum SPARK ankle exoskeleton can provide assistance or resistance during walking practice that is customized to each individual. Preliminary evidence suggests that spinal stimulation may be used to boost signals being sent by the nervous system during activities of daily living, like walking. Spinal stimulation has begun to be used in people with neurological injuries like spinal cord injury and cerebral palsy, but rarely is spinal stimulation combined with mobility devices. However, mobility devices may provide an ideal complement to spinal stimulation to increase quality and quantity of walking practice during stimulation. This combination may increase the challenge and support afferent feedback and neuroplasticity. However, the mechanisms by which spinal stimulation might be able to improve mobility and work with mobility devices are not well understood. Combining spinal stimulation during walking with an external mobility device may provide insight into how these devices work and the underlying physiological processes to support neuroplasticity and function. This research will provide the foundation to create evidence-based strategies to develop training protocols with spinal stimulation and mobility devices to support mobility and function for people with cerebral palsy and other neurologic injuries.

Human Subjects Involvement, Characteristics, and Design

We sought to recruit children with cerebral palsy to participate in this research at the University of Washington. Our inclusion criteria were a diagnosis of spastic cerebral palsy, ability to walk on a treadmill for at least six minutes at a self-selected speed, capacity to follow instructions and provide informed assent, and absence of acute or chronic pain in the lower extremities. Exclusion criteria include: history of selective dorsal rhizotomy, lower extremity orthopedic surgery within the prior 12 months, botulinum toxin injection in the lower extremities within the prior 12 months, current use of oral spasticity medications or other pharmacological agents that impact neuromuscular control, use of an implanted electronic devices (e.g., cardiac pacemaker, baclofen pump), history of uncontrolled seizure, and any contraindication to non-invasive transcutaneous spinal stimulation.

Each participant completed four visits in which they walked with or without an ankle exoskeleton (Exo) and transcutaneous spinal cord stimulation (tSCS). The four walking conditions were: No Device, tSCS only (tSCS), exoskeleton only (Exo), and the combination of tSCS and Exo (tSCS+Exo). The Exo trials with and with stimulation (Exo and tSCS+Exo) were used for primary reporting and analyses. An experienced pediatric physical therapist collected clinical exam data at each visit, including strength, spasticity (Modified Ashworth Scale), and joint range of motion. Plantarflexor maximum voluntary contraction was measured before and after each condition as the average of three trials using a handheld dynamometer with verbal encouragement. We placed wireless surface electromyography (EMG) sensors bilaterally on lower-extremity muscle groups, including the soleus, medial gastrocnemius, and tibialis anterior, to monitor muscle activity throughout each session. EMG data were collected at 2000 Hertz and band-pass filtered at 20 to 450 Hertz.

Walking trials were performed on an instrumented treadmill (Bertec, Columbus, OH). A self-selected preferred walking speed was determined for each participant at the first visit and held constant across all subsequent visits to support within-participant comparisons across conditions. Visits were performed on separate days, separated by at least five days to minimize potential carryover effects between conditions.

At each visit, participants were familiarized to the treadmill and device prior to data collection. Participants walked for a total of 20 minutes during each session. Condition order was randomized. Rest breaks were provided as needed. Participants were asked to report perceived exertion after each trial. EMG data were analyzed for the first 5-minutes, prior to any breaks to allow comparison of changes in co-contraction.

Transcutaneous spinal cord stimulation (tSCS) was delivered using a noninvasive surface stimulator from SpineX. Electrode were placed midline over the spinous processes of the lower thoracic/upper lumbar spine, and anode electrodes were placed bilaterally over the iliac crests. Stimulation parameters consisted of biphasic rectangular pulses with a 10 kHz carrier frequency delivered at 30 Hz; intensity was set for each participant during the first stimulation visit to the highest sub-motor-threshold level that was comfortable. The ankle exoskeleton was the Biomotum SPARK (Biomotum, Inc.), a powered untethered device that applied an experimenter-selected resistive plantarflexion torque during the stance phase of gait. The exoskeleton was fit and tuned by trained study staff prior to each Exo visit. During No Device and tSCS-only visits, participants walked in their standard footwear without the exoskeleton.

a. Potential risks:

There are minor risks associated with completing motion analysis, surface electromyography, transcutaneous spinal stimulation, and resistive ankle exoskeleton use while walking on a treadmill. The potential risks include: risk of tripping or falling while standing or walking on the treadmill; risk of skin discomfort, redness, or transient irritation from sensors and stimulation electrodes attached to the skin; risk of fatigue and muscle soreness from the exercise activity of walking; risk of mild discomfort, tingling, or transient muscle twitching at the stimulation site during tSCS; risk of skin chafing, pressure, or discomfort from the ankle exoskeleton cuffs; and risk of privacy breach.

b. Recruitment and informed consent:

Children with cerebral palsy will be recruited from the greater Seattle area through partnerships with the University of Washington, regional clinicians, and community providers, using flyers and brochures designed to describe the research and involvement. An experienced research coordinator assisted with recruiting and contacting potential participants. Before participation, each child and their parent or guardian received an explanation of the protocols from a member of the research team. We obtained informed permission from the parent or guardian and assent from the child. Information will be provided verbally and in writing. Individuals will be reassured of their right to withdraw at any time from the study.

c. Protection against risks:

We take numerous precautions to protect against risks associated with this research. To prevent tripping and falling, we ensure that the floor of the laboratory and treadmill is free from wires and other obstructions, and physical therapist guarding and treadmill handrails are used while walking on the treadmill. Surface electromyography sensors and reflective markers are safe and have been used extensively during similar research and clinical applications. Transcutaneous spinal stimulation electrodes are placed only after skin inspection, intensity is set to a comfortable sub-motor-threshold level, and the research staff can pause or stop stimulation at any time. The ankle exoskeleton is fit and inspected at each visit. We will inspect all wires, equipment, electrode sites, and exoskeleton components before every trial. Participants will be given rest breaks as needed during each session to avoid fatigue. For all experiments, individuals can terminate the session at any time. To protect against any breach in confidentiality, data collected for this study will be stored securely on password-protected computers. Codes instead of names of individuals will be used on all data files and reports. Any data used for publication or presentations will be de-identified.

This research involves children who represent a vulnerable population. According to age, assent or consent will be provided by each child in addition to consent from the parent or guardian. Participants will be reminded throughout the research that they can stop participation. Additional protections include minimal use of adhesives for placing electromyography sensors, stimulation electrodes, and reflective markers on the skin, size-adjustable safety harnesses and exoskeleton cuffs, and the use of perceived exertion scales to monitor participant comfort and energy throughout the experimental protocol. The parent or guardian will be allowed to stay with the child throughout all testing procedures.

d. Potential benefits of the proposed research to human subjects and others:

There are no immediate potential benefits to the participants in this study.

e. Importance of the knowledge to be obtained:

The potential risks associated with this study are reasonable in the context of the knowledge and advancement in our understanding of cerebral palsy that will be gained. We anticipate that the proposed experiments will provide fundamental insight into how transcutaneous spinal cord stimulation and ankle exoskeleton use, alone and in combination, influence neuromuscular function and walking in children with cerebral palsy. Understanding these mechanisms is critical for developing evidence-based training protocols that combine spinal stimulation and mobility devices to support mobility, motor learning, and participation across the lifespan. The results from this work will also be extendable to other clinical populations such as spinal cord injury, stroke, traumatic brain injury, and multiple sclerosis, which exhibit similar impairments in neuromuscular control and may benefit from combined spinal stimulation and mobility device interventions.

STATISTICAL ANALYSIS

We enrolled ambulatory children with spastic cerebral pals. As an exploratory and preliminary study to evaluate the acute, within-participant effects of spinal cord stimulation and ankle exoskeleton use on neuromuscular outcomes, the sample size was guided by feasibility and by prior studies of acute responses to spinal stimulation and ankle exoskeletons in this population. We enrolled 10 participants, which is consistent with similar within-subject studies of acute neuromuscular responses to noninvasive spinal stimulation and exoskeleton-assisted walking in pediatric cerebral palsy.

Our primary hypotheses are that (1) walking with tSCS reduces co-contraction between plantarflexor and tibialis anterior muscles relative to walking without stimulation, and (2) walking with the combination of tSCS and the resistive ankle exoskeleton produces larger acute reductions in spasticity and larger acute improvements in plantarflexor strength than walking with the exoskeleton alone. For each participant we will calculate change scores between conditions for each outcome of interest, including the co-contraction index from EMG recordings, the Modified Ashworth Scale score of the ankle plantarflexors, and plantarflexor maximum voluntary contraction measured with a hand dynamometer. As an exploratory pilot, we will compare conditions and will report effect sizes and 95% confidence intervals for each comparison. Secondarily, we will use linear mixed-effects models with participant as a random effect to evaluate the impact of condition on each outcome and to explore associations between participant characteristics (age, GMFCS level) and the magnitude of response. Given the within-subject design and limited sample size, secondary analyses will be considered exploratory.

Table 1: Variable definitions

Variable	Description
Muscle Coordination	Change in level of co-contraction between the plantarflexor and tibialis anterior muscles during gait monitored from electromyography recordings, comparing the trial with a mobility device and spinal stimulation to the mobility device alone.
Modified Ashworth Scale	Change in summed score of spasticity from ankle plantarflexors comparing trial with mobility device and spinal stimulation to mobility device alone. Lower values indicate less spasticity.
Plantarflexor Muscle Strength	Change in maximum voluntary contraction level of the plantarflexor muscles taken as the average of three trials where the participant exerts the maximum amount of force measured from a handheld dynamometer with verbal encouragement comparing trial with mobility device and spinal stimulation to mobility device alone.