Introduction to the Portable Neuromodulation Stimulator (PoNS™) Device and Effects on Balance and Gait for Individuals with Traumatic Brain Injuries

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Abstract

The Cranial Nerve Non-Invasive Neuromodulation (CN-NINM) intervention is a novel rehabilitation tool to improve functional gait and balance for people with traumatic brain injuries. The intervention has been tested on various disability groups and is being evaluated around the world. This review and case study highlights the need to document carry-over effects in addition to reporting benefits. During this A-B-A-B-A study, scores during the second withdrawal period are expected to stay slightly higher than the first withdrawal. This study adds to available research on the new intervention device and technique which may have significant effects on rehabilitation services.

Theoretical Background

Neurorehabilitation utilizes neuroplasticity of the brain to restructure and relearn information after a neurotrauma. A related field, neuromodulation, alters the nervous system with the use of electricity or medications. Commonly used neuromodulation interventions include baclofen pumps, spinal cord stimulators, deep brain stimulators and transcranial magnetic stimulation. These interventions are not thought to have long lasting effects [4,5], however, the effects noted during and directly after the application of the medication or electricity have substantial effects.

Figure 1: Transcranial Magnetic Stimulation

Figure 2: Deep Brain Stimulator

Sensory Substitution:

In the 1960's, Bach-y-Rita, a founding sensory substitution scientist, provided visual information to people with occluded vision and vision impairments using electrical stimulation. The stimulation was applied to the fingers, back, abdomen, forehead, and tongue. The tongue and mouth had the most favorable results due to the following characteristics. They:

- **Provide a secure, discreet, isolated environment**
- **Maintain a relatively constant temperature**
- **Requires less stimuli than elsewhere on the body**
- **Are not affected by environmental stimuli**
- **Saliva maintains a constant pH+ and reduces the stimulation required for perception and interpretation [1].**

BrainPort™ Balance Device

During sensory substitution studies, researchers and participants noted additional changes in function such as reduced pain, improved gait, and improved concentration. These changes led to another line of research for additional uses of this technology. The first device that came from this line of research, the BrainPort™ balance device, used electrical stimulation of the tongue to provide biofeedback for balance. Participants again reported additional functional changes in addition to improved balance, leading researchers to initiate another line of research that provided information-free stimulation. This intervention was called Cranial Nerve Non-Invasive Neuromodulation (CN-NINM) and used the Portable Neuromodulation Stimulator (PoNS™) device. The PoNS™ was the first device to provide information free stimulation.

Figure 3: BrainPort™

CN-NINM

CN-NINM, a neuromodulation intervention, was created at the University of Wisconsin-Madison in the Tactile Communications & Neurorehabilitation Laboratory (TCNL). This intervention has two primary components: 1) the use of the Portable Neuromodulation Stimulator (PoNS™) device to deliver small, safe doses of electric current to the tongue, and 2) targeted training activities that are personalized for each participant based on presenting symptoms and typically performed concurrently with the stimulation.

Targeted Training Activities + **PoNS™ stimulation** = **CN-NINM intervention**

The targeted maximal challenge training activities are similar to activities performed during standard neurorehabilitation but are maintained for 20 minutes each and coupled with the stimulation to maximize neuroplastic effect. Previous research using the PoNS™ device and CN-NINM intervention have addressed impairments in balance and gait for several disability categories including traumatic brain injury, Parkinson's disease, and stroke, among others. Currently, all completed studies have examined the effects of the CN-NINM intervention on balance and gait, and used balance and gait targeted training activities [2, 6-8].

PoNS™ Device

The PoNS™ device has been optimized for usability and safety. The case is 68 mm wide by 45 mm long by 15 mm thick and weighs 56 grams. The oral tab that provides the stimulation contains 143 electrodes and fits on the anterior portion of the tongue, held lightly in place by the lips. The PoNS™ device uses an unbalanced biphasic waveform designed to ensure net zero current [3] to reduce the chance of tissue irritation and has 19 V max and 6mA operational limits. Pulses are delivered to the tongue in triplets of pulses at 5 ms intervals every 20 ms. The subject can control the pulse-width (0.4-0.6 µs) by adjusting the intensity buttons on the device. The buttons on the device allow the stimulation to be turned on and off and increased or decreased in intensity. Each time the device is turned off, the intensity resets to the lowest level, requiring the subject to adjust it to a comfortable level each time [3].

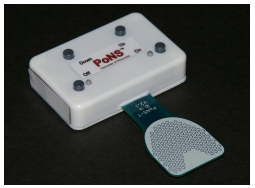

Figure 4: An enlarged photo of the Portable Neuromodulation Stimulator (PoNS™) Device

The PoNS™ does not monitor or record any information. Unlike the BrainPort™ or sensory substitution devices, the PoNS™ provides information-free stimulation. Thus, it is not possible, or necessary, to monitor or record the level of stimulation each participant receives.

The PoNS™ device uses a rechargeable lithium-ion battery. The device cannot be used while charging, thereby preventing the risk of electrical shock. The tab, except for the electrodes, is covered with an FDA approved USP Class VI biocompatible polymer to prevent saliva from harming the electronics. The device is cleaned with isopropyl alcohol after use.

Participants have not indicated that the sensation of the stimulation is unpleasant or painful. It is sometimes described as similar to the sensation of drinking a carbonated beverage.

TBI Case Study

An ongoing study at UW-Milwaukee is testing the effect of CN-NINM on balance and gait for individuals with traumatic brain injuries. One participant has begun the study, with up to four total participants being recruited. The study is a 5 week, A-B-A-B-A design to study benefits and carry-over effects of the CN-NINM intervention. Participants complete a daily gait assessment and weekly self-report measures about community integration and confidence with gait.

The current participant had a brain injury more than 35 years ago. He uses an AFO and occasionally a cane. The participant has currently completed 2 full weeks of the study. Noticeable changes have occurred in patient report and in gait quality. The afternoon of the first day using the PoNS™, the participant indicated a reduction in tone of his lower extremity and a reduction of tightness in his heel cord. This tightness had previously been substantial enough for the participant to seek botox injections. The participant indicated his AFO seemed to fit better and better supported his foot because of the reduced tone. The participant also indicated by the second day that he previously could not use the treadmill without pain prior to using the device and that he would not have been able to complete the gait activities, but he did not have pain during the study.

Figure 5: Completion of the crouch and walk task during the baseline and first intervention week.

Initially, the participant was unable to crouch to pick up an object without significant pain in his lower extremity and lower back. On the third day of the intervention, the participant crouched to pick up an object pain free. However, the participant went back to kneeling to pick up the object after this out of habit.

Overall the patient experienced improved gait quality, reduced toe drag, reduced tone in the lower extremity, and increased pain free endurance during gait.

Conclusions & Implications

Although a case report, several components of this study warrant additional studies and research. The participant indicated an almost immediate reduction in the tightness of his heel and a reduced time required to stretch in the mornings even after not using the device overnight before stretching. The participant also indicated an increased tolerance for exercise without pain in his lower extremity. Each of these components has significant application in rehabilitation.

Limitations: The primary limitation is the confounding variables within the participant. Although he is 30+ years post injury, the injury involved significant orthopedic injuries that the participant is still vigilant about at the time of the study, which limits his willingness to complete various tasks and makes him resistive to trying select additional or modified tasks, such as those that would require plantar flexion.

Implications: This case study and previous research support the use of the CN-NINM intervention as a rehabilitation tool to improve gait and possibly as a tool to reduce spasticity and tone. A drug-free and non-invasive pain reduction intervention would have significant implications and benefits in rehabilitation.

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