Helius
MEDICAL TECHNOLOGIES

A Revolution in Mind

November 9, 2017

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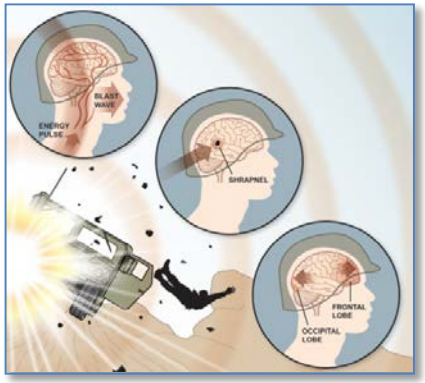
Traumatic Brain Injury

- **Large Population:** 2.1 million people with balance disorder related to non severe TBI
- **Unmet Need:** Current treatment paradigm offers few viable therapeutic options

Military



Common Types of TBI due to Military Activity:

- Explosive blast injury
- Penetrating injury
- Diffuse axonal injury

- 30,000/year active duty soldiers with TBI
- 200,000 retired soldiers diagnosed with TBI
- 20-30% of new cases result in chronic symptoms

Athletic / Civilian

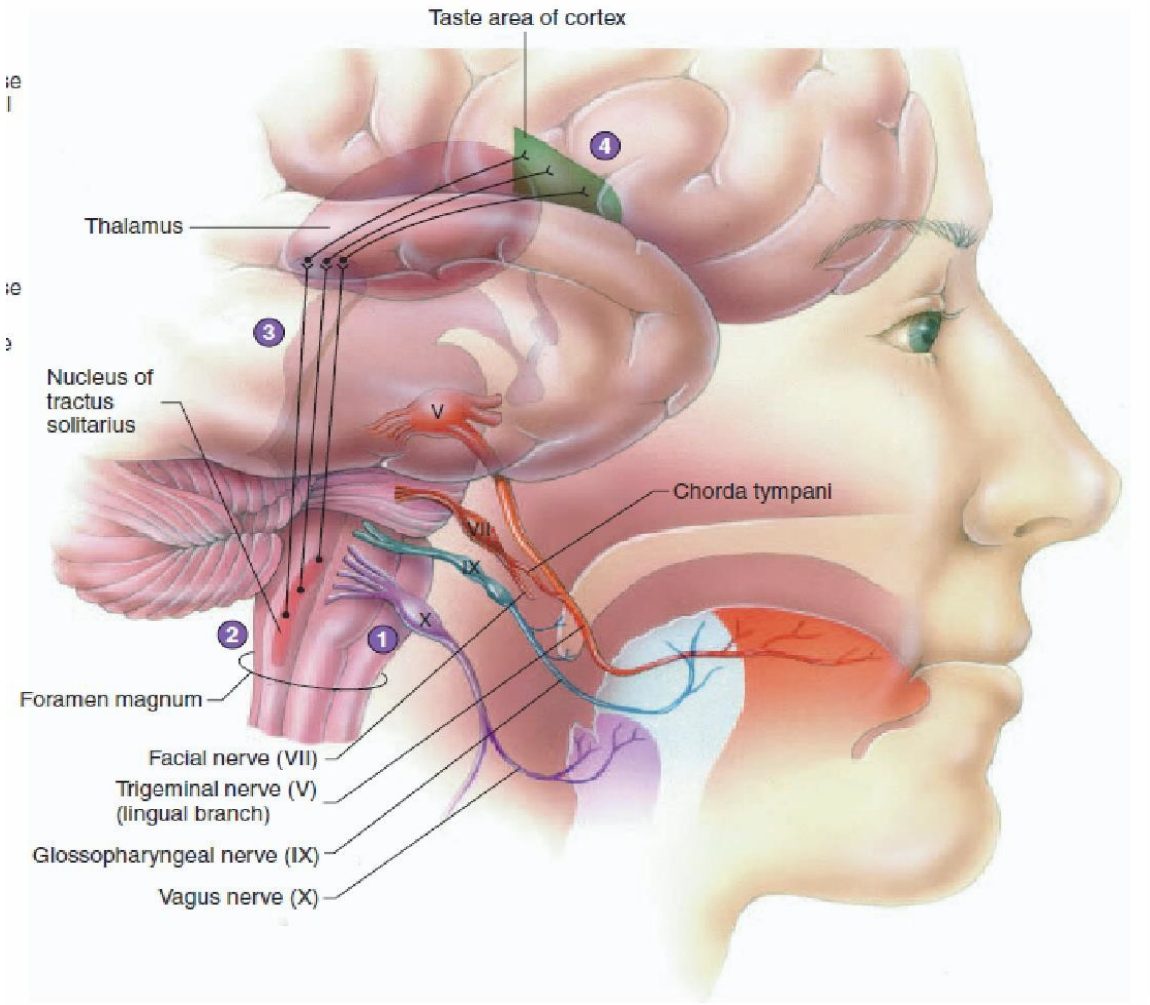
Causes of Civilian TBI:

- Blunt trauma
- Motor vehicle accident
- Sports related injury
- Violence/Assaults
- Falls

- 1.7M new cases of TBI reported in U.S. each year
- 20-30% of new cases result in chronic symptoms
- 3.2 - 5.3M living with TBI related disability

[1,2,3,4,5,6] *see appendix*

PoNS™ Designed to Stimulate the Trigeminal and Facial Nerves Through the Tongue



Neuroprotective Effects of Trigeminal Nerve Stimulation in Severe Traumatic Brain Injury

Nature Scientific Reports, Chiluwal A, Narayan R, Chung W et al. July 28, 2017

- Rat model of TBI
- Standardized injury
- With or without trigeminal nerve stimulation
- Improved blood flow
- Smaller lesion
- Better blood brain barrier
- Less edema
- Lower pro-inflammatory markers

"These data provide strong early evidence that activation of the trigeminal nerve system affords neuroprotection following brain damage."
"If the benefits of TMS in TBI can be replicated in ... humans, it could have tremendous impact in trauma resuscitation and TBI management."
Professor Raj Narayan, Chairman of Neurosurgery and TBI expert, chose to join our SAB in the wake of this publication

What is the Sensory Organization Test (SOT)

The Sensory Organization Test (SOT):

- Uses computerized posturography to quantify a patient's use of sensory input: vision, vestibular and somatosensory cues to maintain postural stability
- The SOT utilizes six "conditions" to interpret a patient's degree of sway, with a score of 100 implying excellent balance and 0 demonstrating none
- A change in score of ***8 points*** is deemed clinically significant (Wrisley, D. et al. 2007)
- SOT is referenced, reliable, reproducible and accepted as a metric for measurement tool for TBI it is the primary effectiveness endpoint for our trial
- In our studies, patients with TBI-induced balance issues scored approximately 40, at which point they may require walking aids and are at increased risk of further falls.

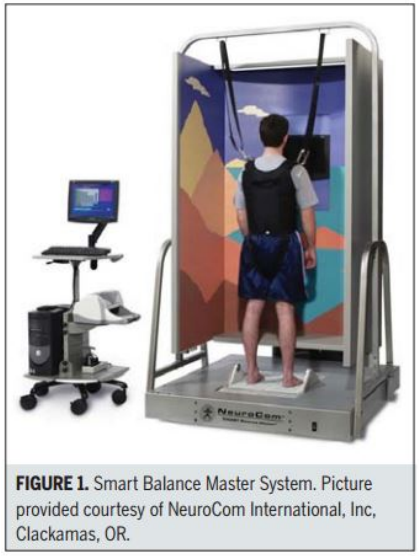


FIGURE 1. Smart Balance Master System. Picture provided courtesy of NeuroCom International, Inc, Clackamas, OR.

Effect of Physical Therapy Alone in Treatment of Balance Disorder in TBI

Dr. Deborah Backus, PhD

Director of MS Research at the Shepherd Center and President of the American Congress of Rehabilitation Medicine has more than 30 years of experience in neurological rehabilitation and research says:

"Most clinicians recognize that functional gains are significantly limited with physical therapy alone in treating balance deficits in TBI"

- Pattern of vestibular recovery for PT alone in TBI subjects:
  - In the literature, we observe a typical change of 8-13 points on the SOT Composite Score following vestibular rehabilitation therapy, and is usually progressively accomplished over a period of 6 to 9 months (Brown et al., 2001 and Badke et al., 2004)

Neuromodulation, Neuroplasticity and Trigeminal Nerve Stimulation

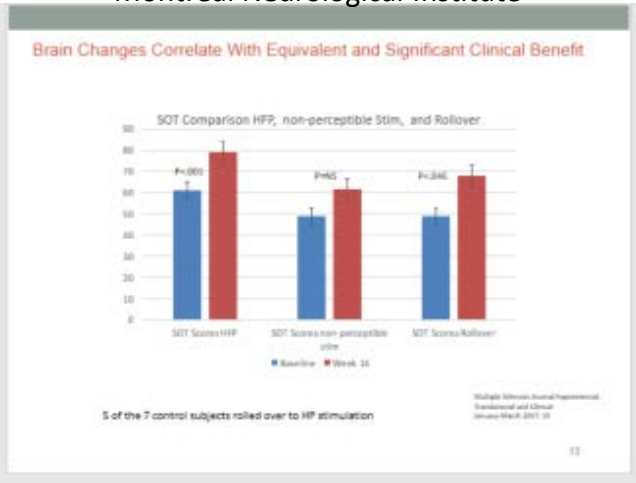
- Neuromodulation is the application of external stimuli to provoke changes in brain activity
- It occurs through two mechanisms: acute changes to how existing synapses work, and chronically by the creation of new synapses
- The trigeminal and facial nerve innervate the tongue, and stimulating these nerves sends impulses into the brain.
- PoNS™, the portable neuromodulation stimulator is a wearable investigational medical device that noninvasively stimulates the trigeminal and facial nerve (cranial nerve V, VII) though stimulation of the tongue
- Two iterations of the PoNS™ device were developed (through adjusting software), one delivering 25,740,000 pulses (High Frequency Pulse (HFP)) during a 20 minute treatment and the other, 13,728 (Low Frequency Pulse (LFP)). Despite these varying "pulse frequencies," a user can detect pulses from both devices.
- Study conducted in Surrey BC, Canada in ten healthy volunteers who were examined with 64 lead electroencephalography (EEG)
    - **Results demonstrated that in both groups the brain activity at baseline was comparable, but both LFP and HFP stimulation showed increased activity above baseline during stimulation. This led to the hypothesis that both pulse frequencies may have the potential to produce a therapeutic effect.**

Regulatory Science vs Clinical Science

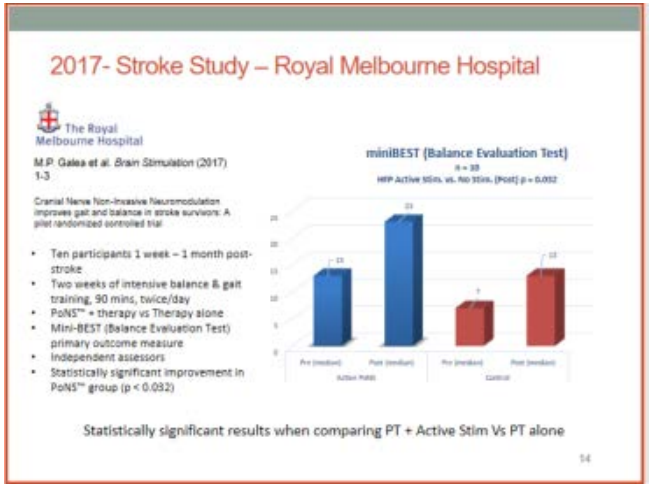
- Regulatory science is done to satisfy the need for regulatory authorities to determine the safety and efficacy of an intervention (Drug or medical device)
- Regulatory submissions require reliable data from randomized, controlled multicenter studies as standard for safety and efficacy i.e., study needs to have placebo or sham device
- In the medical device industry the "placebo" is very difficult to establish since medical devices are by definition a noticeable intervention
- In our case, we developed a Low Frequency Pulse (LFP) PoNS™ ***intended*** to be a non-therapeutic control
- Since we did not know whether it would be non-therapeutic or not we:
  - Ensured that patients participating in the trial would have done vestibular rehabilitation and plateaued in their recovery prior to inclusion
    - Would allow us to determine if LFP PoNS is clinically active
  - Prospectively decide in our statistical analysis plan how to evaluate the data if LFP PoNS showed clinical effect.

Independent Controlled Clinical Trials to Date Demonstrate

Montreal Neurological Institute

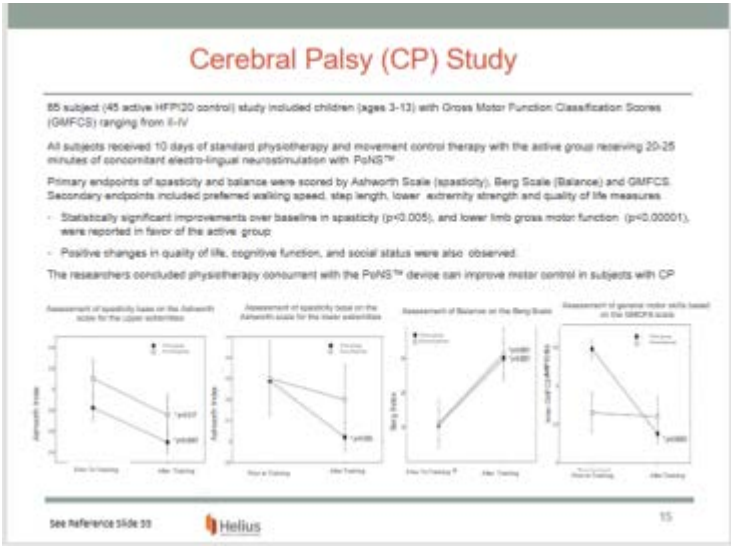


Royal Melbourne Hospital



- 3 independent randomized controlled clinical trials demonstrate statistically significant improvements in SOT scores when PT + High Frequency Pulse PoNS is compared to PT + no stimulation in multiple disease states

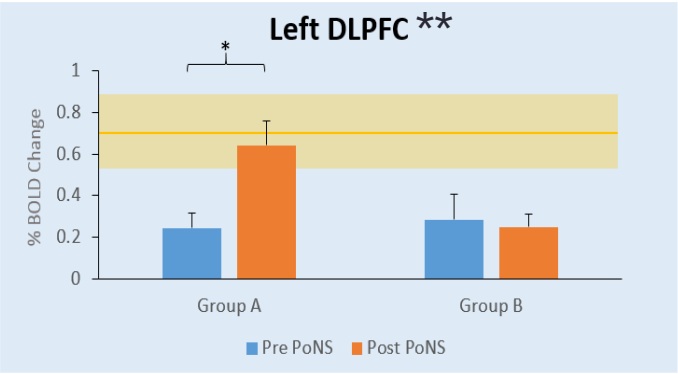
St. Petersburg State Health Institution «City Hospital №40»

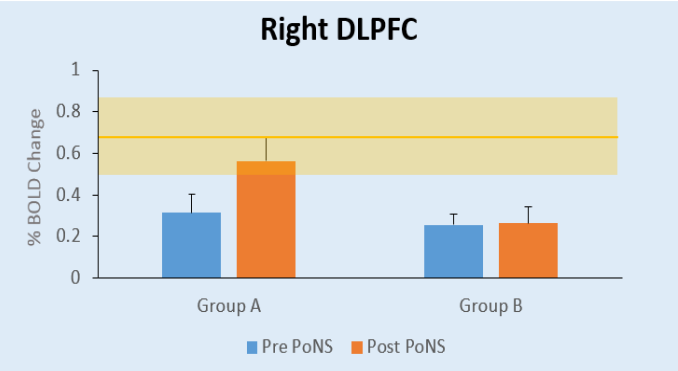


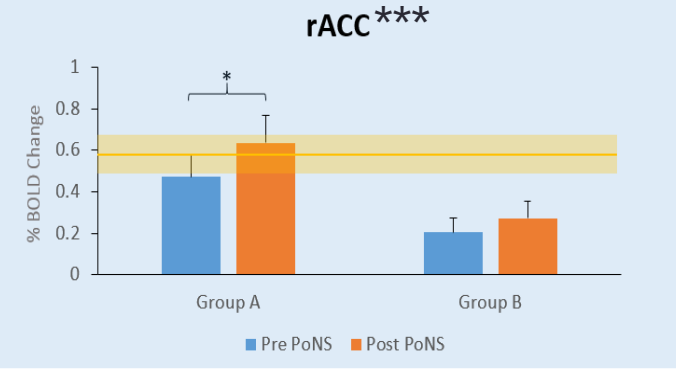
Results from Multiple Sclerosis Study
fMRI Changes in Group A, B vs Healthy Controls

14 subject (7/7) study: All received physiotherapy with Group A receiving HFP PoNS™ stimulation and Group B non-perceivable stimulation PoNS™

VOIs BOLD signal vs. Healthy Controls







Multiple Sclerosis Journal Experimental, Translational and Clinical
January-March 2017: 19

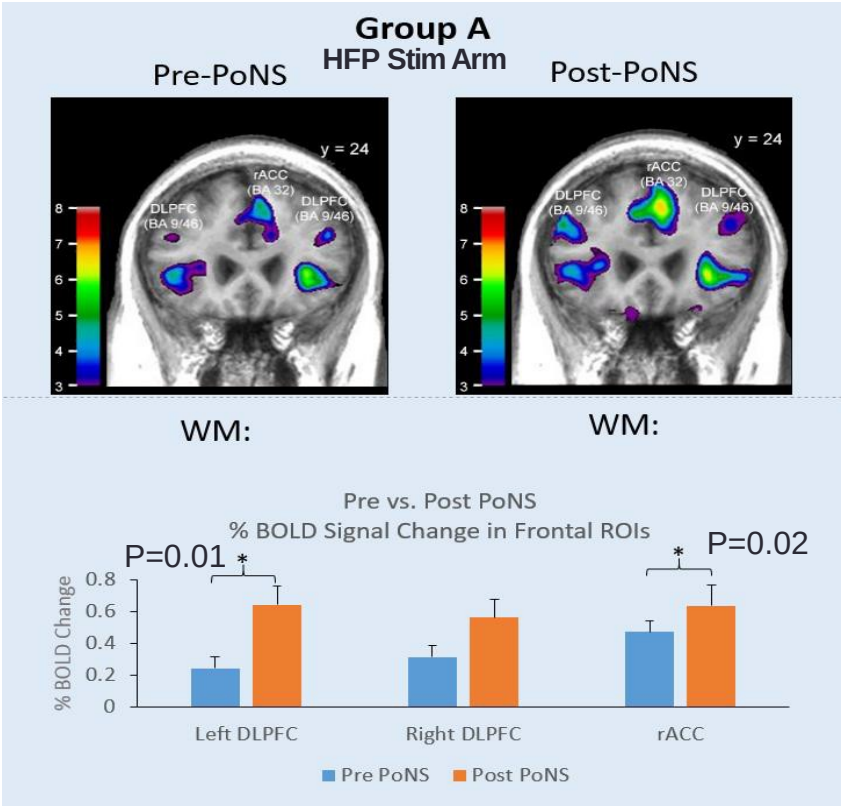
***dorsolateral prefrontal cortex (DLPFC)*
****rostral anterior cingulate cortex (rACC)*

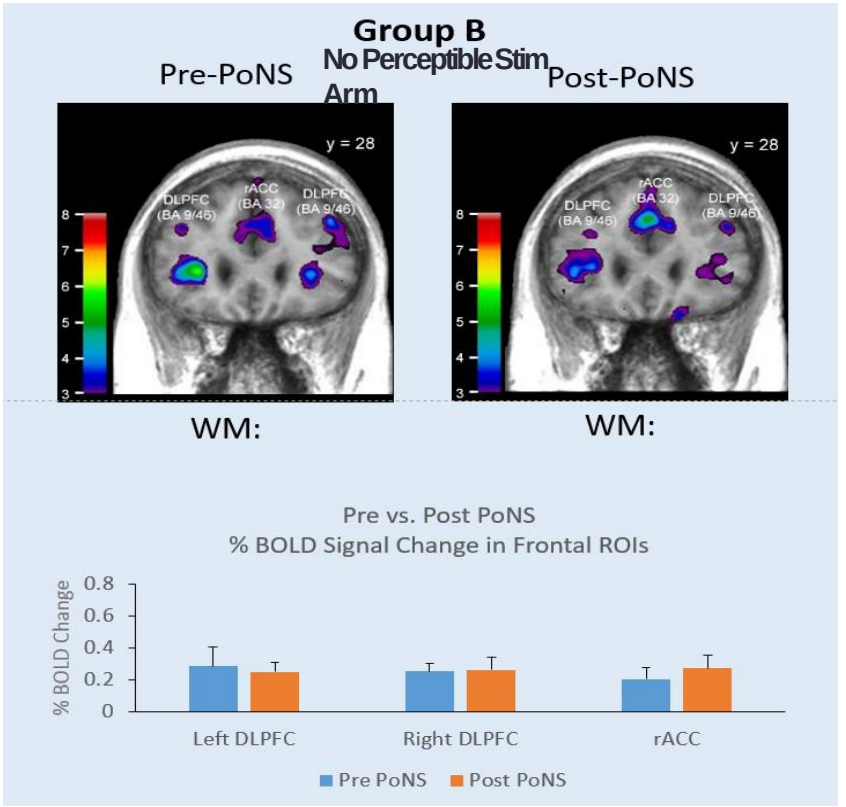
Mean and 95% quantile of healthy control's BOLD signal change

Results from Multiple Sclerosis Study Working Memory fMRI

Group A: Post PoNS™ device training fMRI shows significant increase in BOLD signal in the left DLPFC** (t=3.55, p=0.01), rACC*** (t=3.057, p=0.02) and a trend for significance in the right DLPFC (t=2.3, p=0.06).

Group B: Baseline as well as post-PoNS™ fMRI shows sub-threshold peaks in bilateral DLPFC and rACC. Paired-t tests comparing pre and post PoNS™ scans did not reveal any significant changes.





***dorsolateral prefrontal cortex (DLPFC)*
****rostral anterior cingulate cortex (rACC)*

Clearly Defined Regulatory Pathway

FDA deemed the study of the PoNS™ for mild-moderate TBI a 'non-significant risk (NSR) device study' under the IDE regulations

- Assessed the study as not posing a significant risk to human subjects
- FDA guidance points to 120-day regulatory review upon submission for de novo clearance for Class II

FDA indicated that a request for de novo classification into Class II for the mild-moderate TBI indication would be an appropriate path to seek marketing authorization

- Balance disorder related to non-severe TBI
- FDA reviewed and provided feedback on the registrational trial protocol

Concurrent with FDA filing, seeking EU CE Mark, Health Canada MDL and TGA approval

ISO 13485 received in December 2016 from LRQA an independent organization to review companies quality systems; Passed Surveillance Audit 1 – 9/7/17

So, what does an SOT of 40 look like?

- The mean baseline SOT in our clinical trial was approximately 40 (42.1 and 41.1 in HFP and LFP respectively)
- This video is of a patient that did not participate in our clinical trial
- It is shown to demonstrate the clinical presentation of a person with an SOT score of 40
- Every subject is different and there are many different potential contributions to an SOT result. This is just one example.

What does an SOT Score of 40 look like?

PoNS™ Registrational Trial in TBI

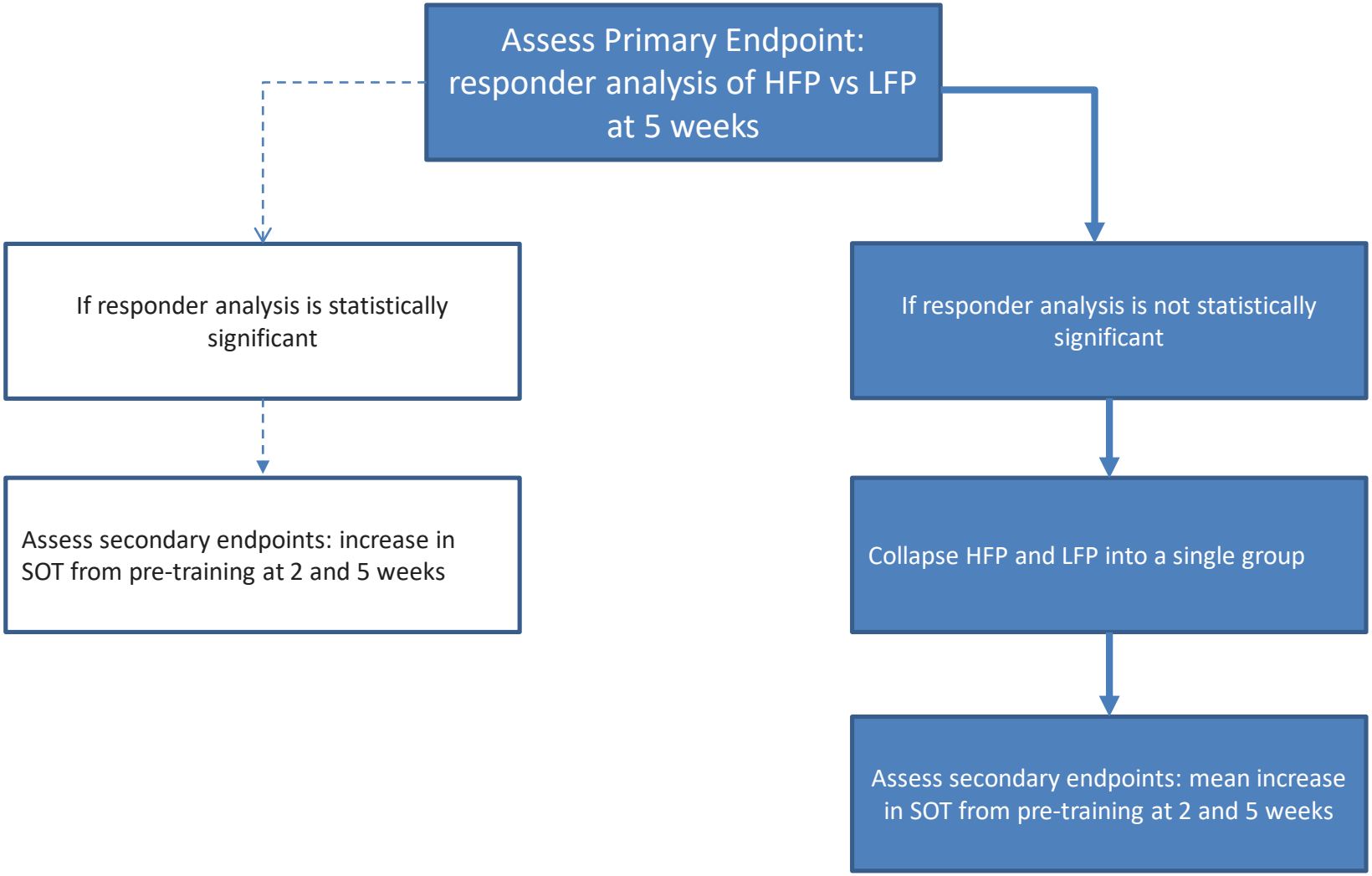
Clinical Study	**A double-blind, randomized, controlled* study of the safety and effectiveness of the PoNS™ device for translingual noninvasive neuromodulation stimulation ("TLNS") training in subjects with a chronic balance deficit due to mTBI.**
Indication	Chronic balance deficit due to non-severe TBI
Start Date	August 2015
Treatment Completion	August 18, 2017
Description	Helius as sponsor launched a Pivotal clinical trial in conjunction with US Army Medical Research and Material Command at: • Montreal NeuroFeedback Centre (Montreal, QB) • Oregon Health and Science University (Portland, OR) • Orlando Regional Medical Center (Orlando, FL) • HealthTech Connex (Surrey, BC) • VCU (Richmond, VA) • MedStar National Rehabilitation Center (Washington, DC) • University of Wisconsin (Madison, WI)
Study population and Endpoints	• 120 patient double-blind, controlled study (HFP vs LFP) • Primary endpoint is improvement comparison HFP Vs LFP of responders SOT ≥15 at 5 weeks. Responder = increase in SOT ≥ 15 • Secondary Endpoints are improvement in SOT scores from baseline at week 2 and week 5

***- PoNS 4.0 versus same device with low perceivable stimulation *intended* to be ineffective.**

Important Inclusion Criteria For the Study

- All subjects were *at least* one year post injury
- Further spontaneous recovery unlikely
- All subjects had to:
  - have participated in a focused physical rehabilitation program for their TBI related balance disorder and have been deemed by the treating clinician to have reached a plateau
  - still have significant balance issues as they entered the study

Statistical Analysis Plan for TBI Study

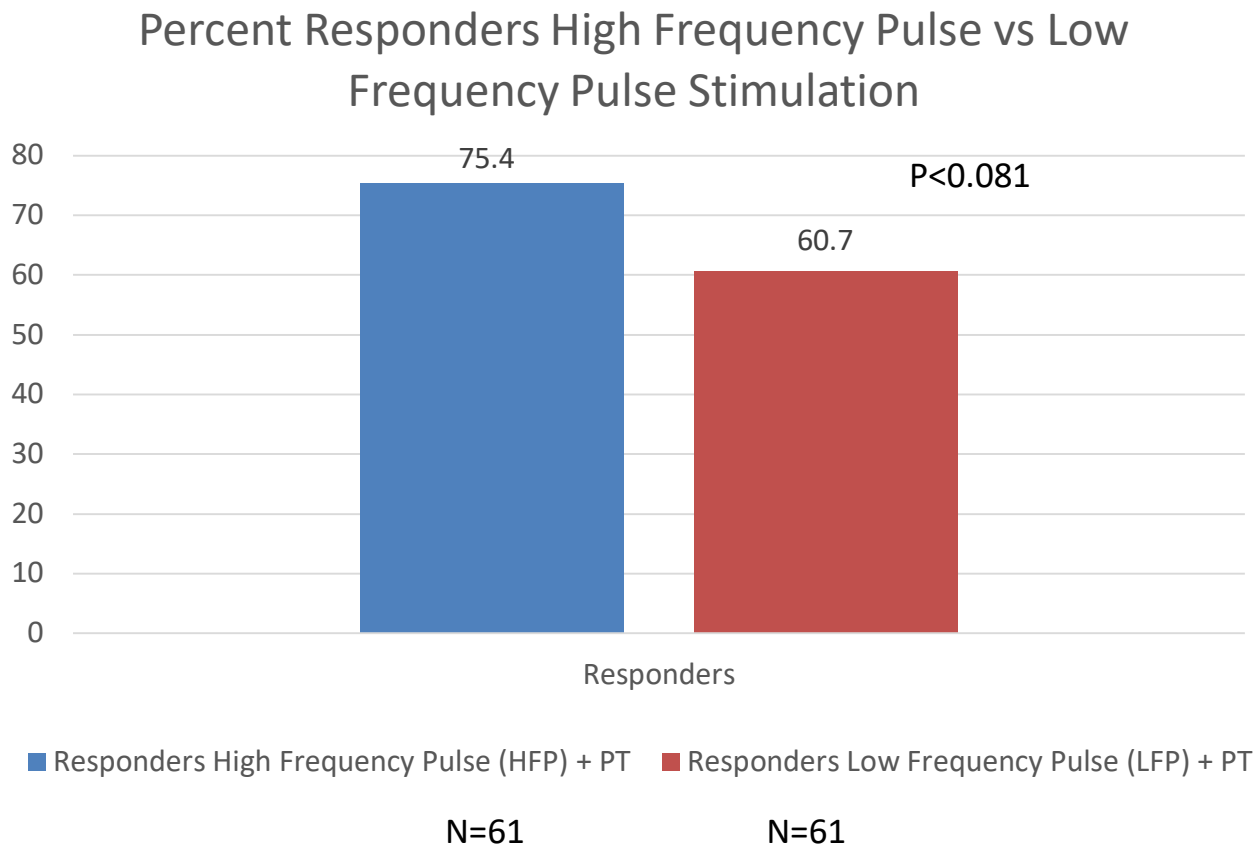


Statistical Analysis Safety Endpoints

- **Primary:** Frequency of falls, as determined by daily event recording on the subject data case report form during the in clinic phase. Fall is defined as an episode where a subject lost his or her balance and fell or would have fallen, were it not for another intervention, such as stabilization on the back of a chair or the wall. Stabilization to restore balance during therapy will not be considered a fall.

- **Secondary:** Frequency of headache, as measured by the Headache Disability Index (HDI) at baseline and at the end-of-treatment (5 weeks).

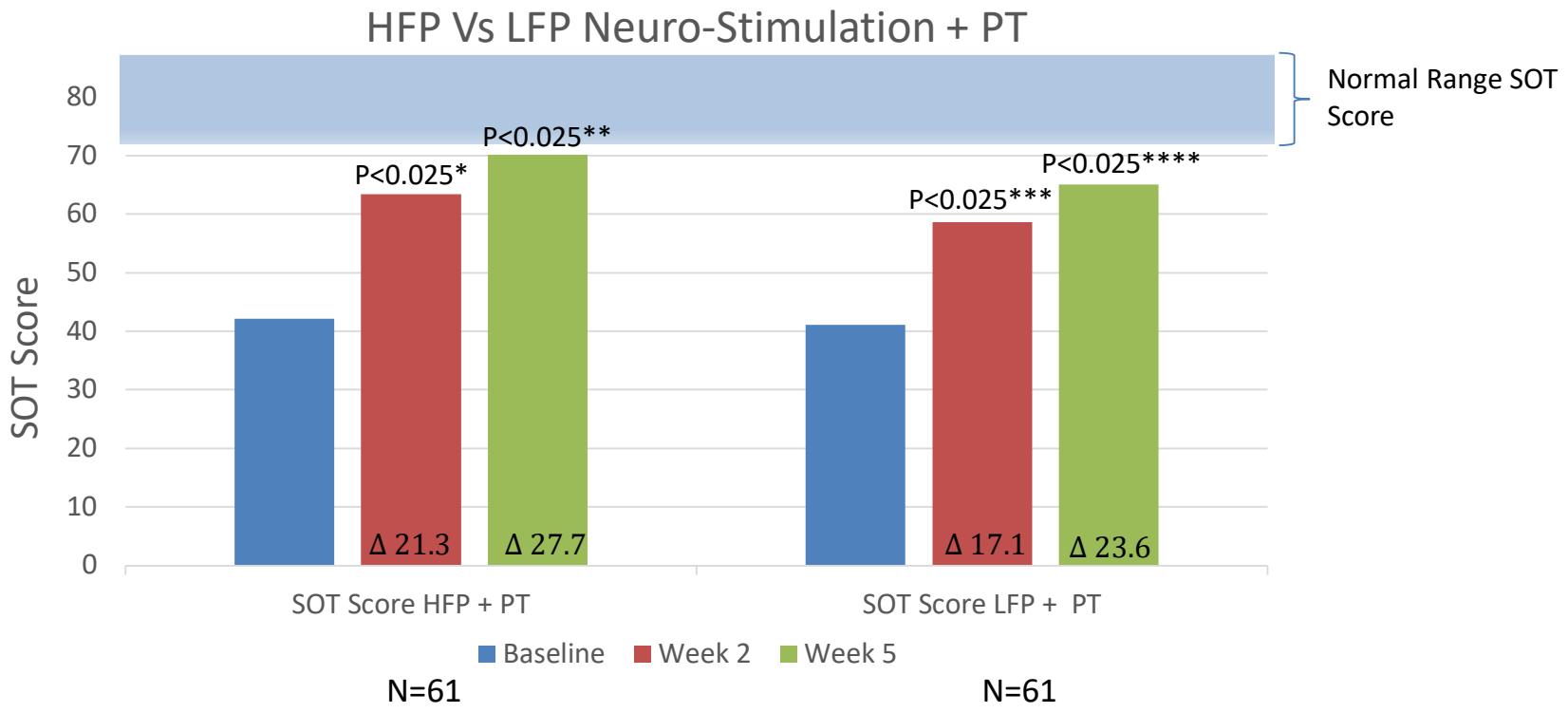
PoNS Responder Analysis – Primary Endpoint



Responders = 15 point improvement in SOT above baseline

HFP PoNS group response showed a trend to significant change vs response of LFP PoNS Group

PoNS Study Data Efficacy



*HFP: Mean increase over baseline at end of Week 2 = 20.9 with 95% lower confidence limit of 16.6, p< 0.025
**HFP: Mean Increase over baseline at end of Week 5 = 27.3 with 95% lower confidence limit of 23.1, p<0.025
***LFP: Mean Increase over baseline at the end of Week2 = 15.7 with 95% lower confidence limit of 11.4, p<0.025
****LFP: Mean Increase over baseline at the end of Week5 = 21.7 with 95% lower confidence limit of 16.7, p<0.025

Is the LFP Device Demonstrating Therapeutic Activity?

- It was prospectively contemplated that LFP device might potentially have a therapeutic effect.
- Thus, in the statistical analysis plan it was proposed that if secondary effectiveness endpoints did not generate p-value of less than 0.05, (data showed $p<0.087$, $p<0.081$ respectively for both secondary endpoints), subjects in the HFP and LFP groups would be analyzed vs the baseline to determine if the LFP had therapeutic activity.
- **The results showed that the HFP PoNS had** Mean Increase at the end of Week 2 = 20.9 with 95% lower confidence limit of 20.9. Increase in SOT score from baseline at the end week 2 is significantly greater than zero with p-value < 0.025.
- **Control**: Mean Increase at the end of Week 2 = 15.7 with 95% lower confidence limit of 11.4. Increase in SOT score from baseline at the end week2 is significantly greater than zero with p-value < 0.025.
- **This indicates that the LFP PoNS is not a pure placebo, but has statistically significant activity, which may be not as strong as in HFP.**
- The analysis was also performed for the data at the end of week 5 with very similar results.

Secondary Effectiveness Endpoint Combined Data Analysis at Week 2

Device	N	Mean	SD	SE	95% Conf. Interval		p-value
HFP	61	20.9	16.66	2.13	16.6	25.2	
LFP	61	15.7	16.65	2.13	11.4	20.0	
Combined*	122	18.3	16.79	1.52	15.3	21.3	P<0.0005

- When mean of the combined data set is significantly greater than zero, it indicates that results for both devices combined demonstrate statistically significant improvement in SOT scores.

Secondary Effectiveness Endpoint Combined Data Analysis at Week 5

Device	N	Mean	SD	SE	95% Conf. Interval		p-value
HFP	61	27.6	17.42	2.23	23.1	32.1	
LFP	61	21.7	19.58	2.51	16.7	26.7	
Combined*	122	24.6	18.69	1.69	21.3	28.0	P<0.0005

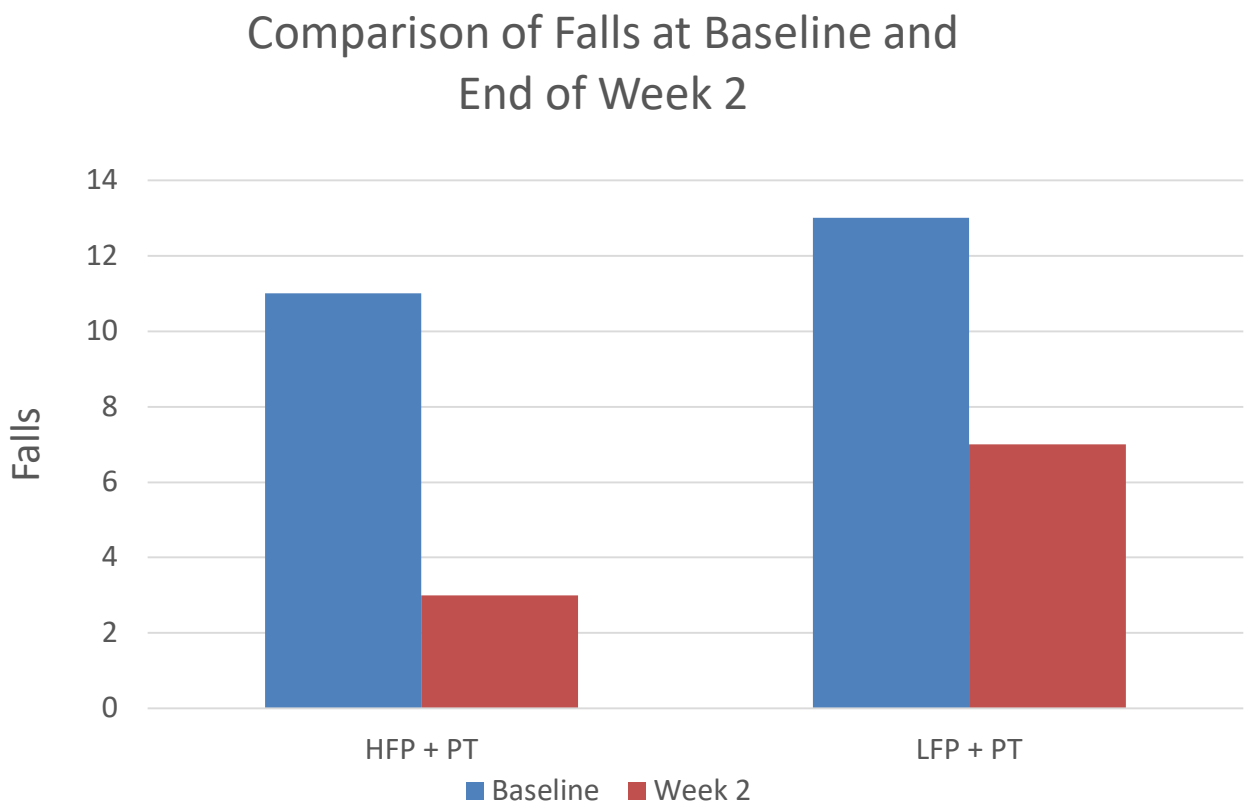
- When mean of the combined data set is significantly greater than zero, it indicates that results for both devices combined demonstrate statistically significant improvement in SOT scores.

IP Portfolio Covers all forms of Stimulation

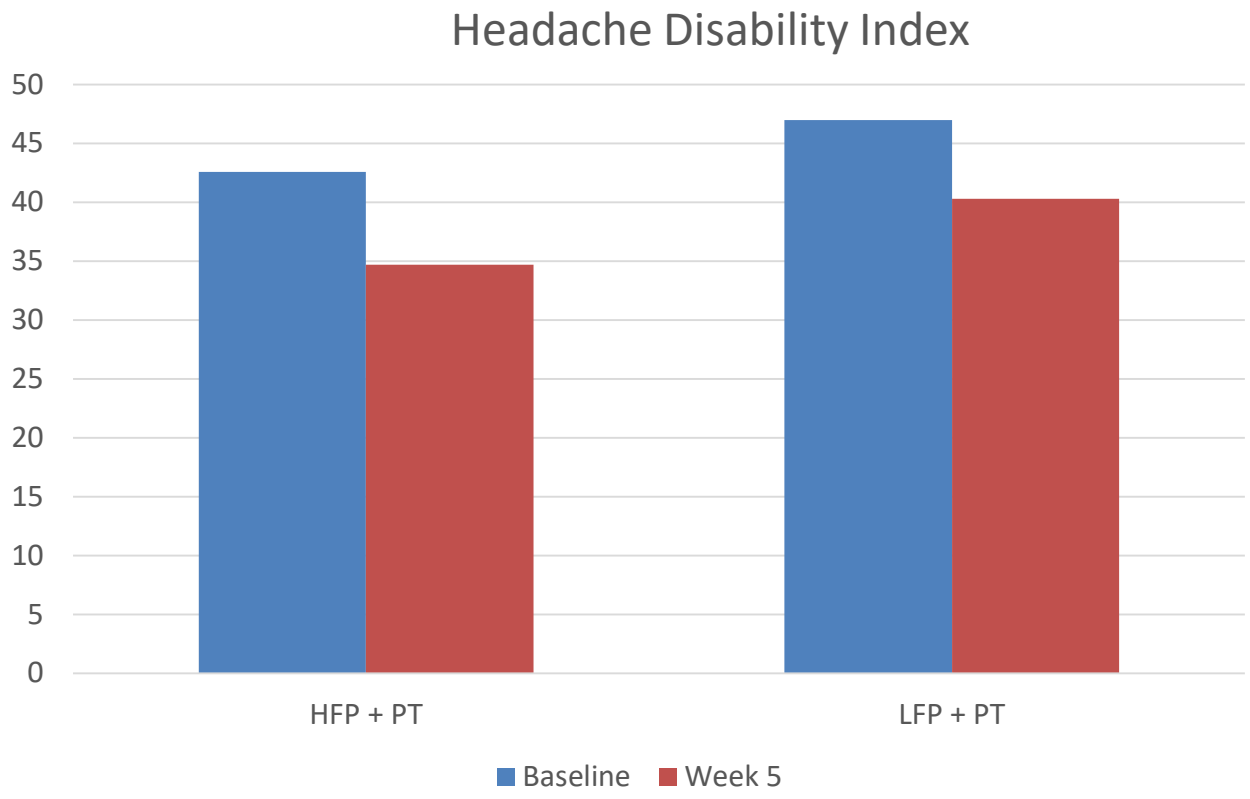
- 7 US Medical Method Patents Issued
  - ❖Skin Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖Skin Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖Oral Cavity Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖Oral Cavity Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖Oral Cavity Stimulation with Pulse Generator + Exercise = Therapeutic Outcome
  - ❖Oral Cavity Stimulation + Cognitive Therapy = Treatment of Tinnitus and other Neurological Disorders
  - ❖Oral Cavity Stimulation + Exercise = Enhanced Human Performance

- **Our independently validated Medical Method patents cover all forms of skin or oral cavity stimulation.**

Primary Safety Endpoint Met – Decrease in Number of Falls



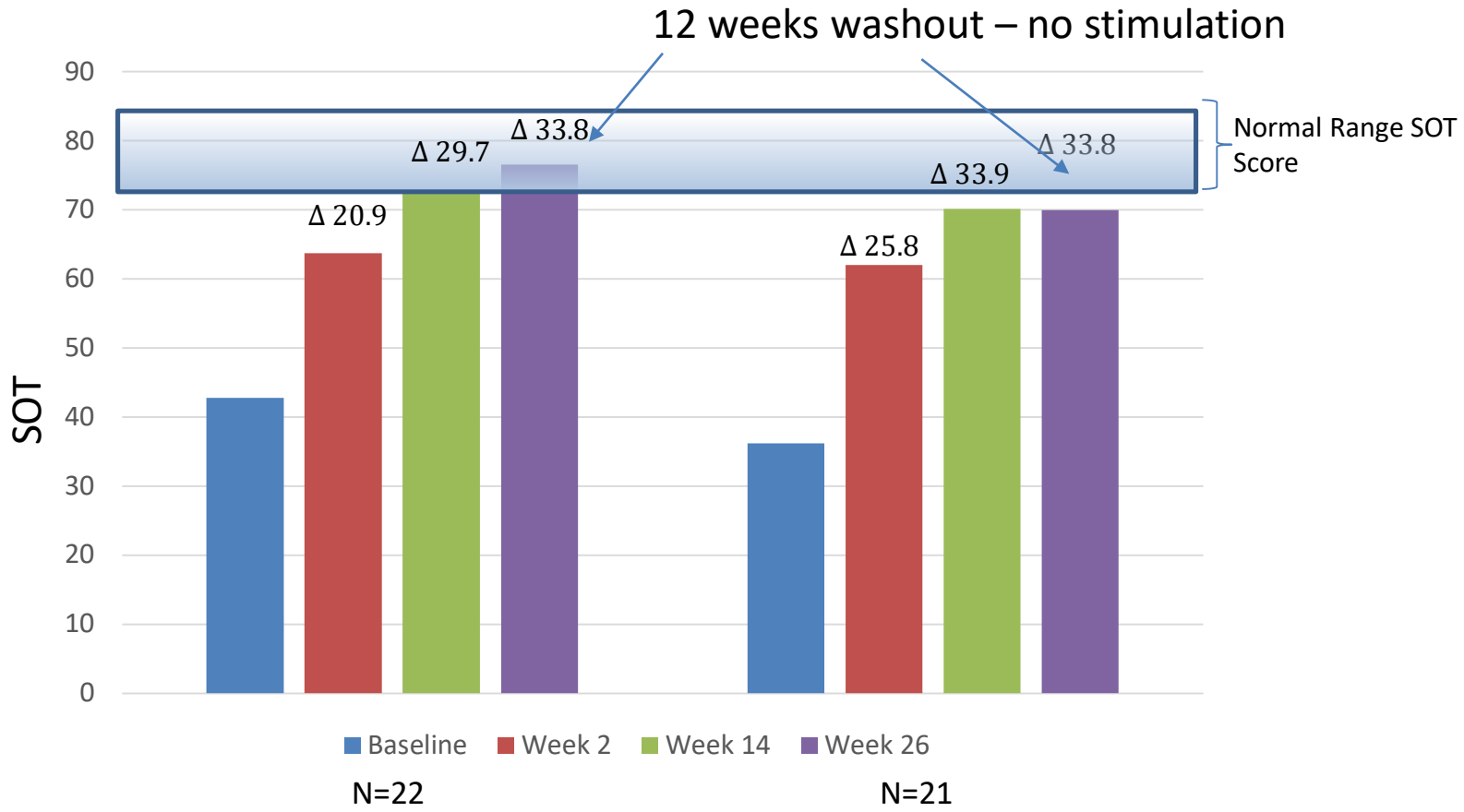
Secondary Safety Endpoint Met - Headache Disability Index Showed a General Lowering in Both Groups



Long Term Treatment Study

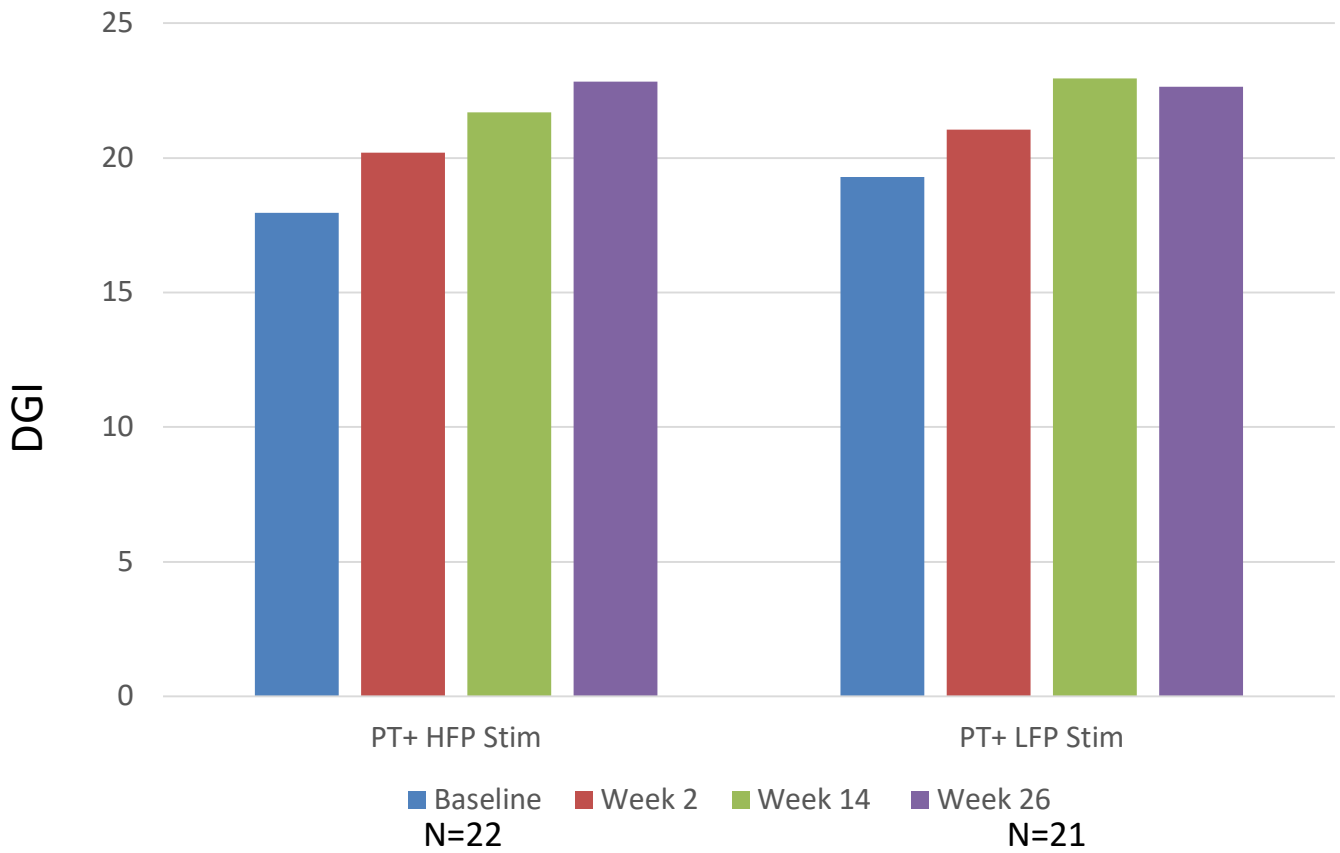
- Study completed May 28th, 2017
- Tactile Communication Neurorehabilitation Laboratory at University of Wisconsin-Madison
- Sponsored by US Army
- Double blind randomized controlled trial in patients with mild to moderate TBI
- 22/21 patients High Frequency Pulse stimulation Vs Low Frequency Pulse stimulation
- 14-weeks active treatment, 12-week washout
- Study designed to determine what happens after chronic treatment (14 weeks) if subjects discontinue therapy
- Study included a 12 week washout period following 14 weeks of active treatment

Patients in both Groups were Significantly Clinically Better at 2 weeks, 14 weeks and 26 weeks



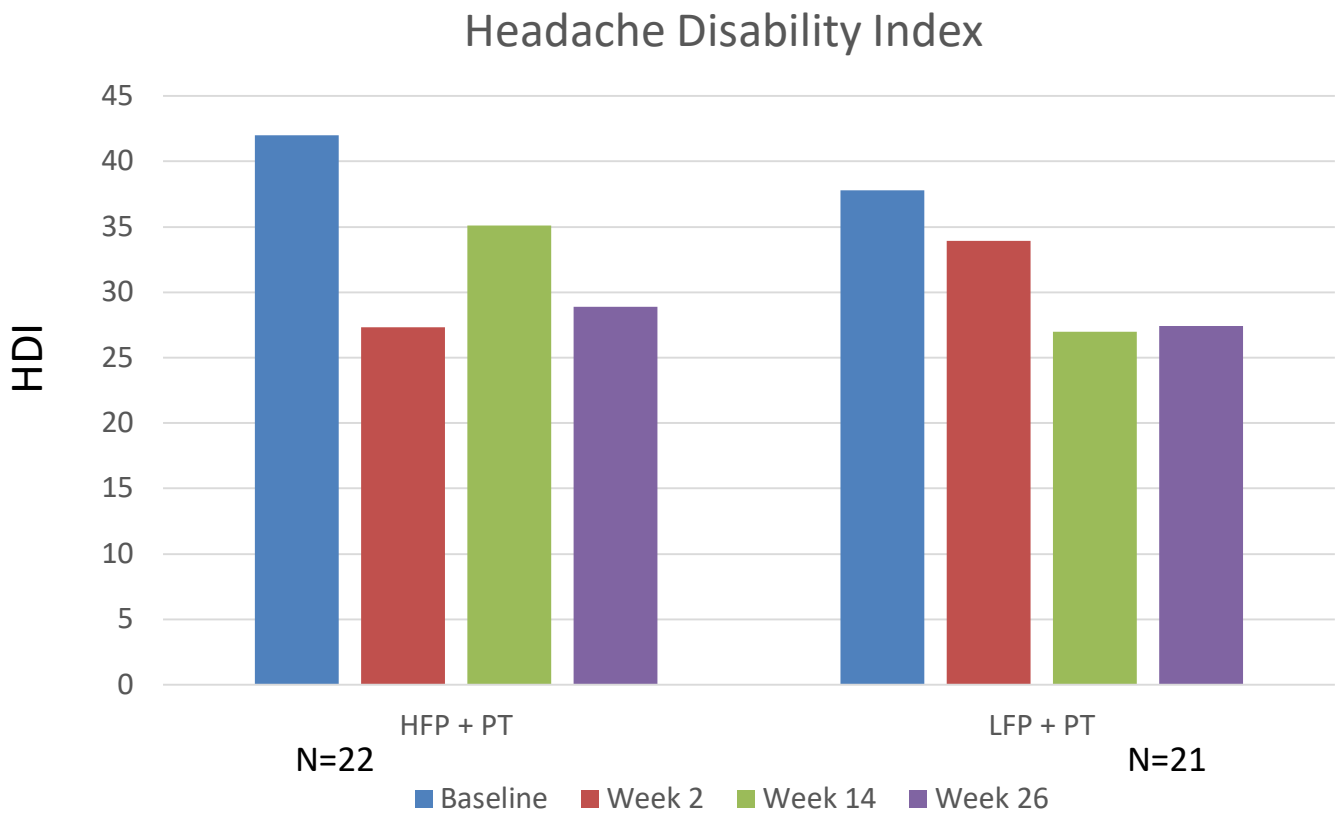
- On Average Patients improved from an impaired SOT score to normal SOT Score in 14 weeks of treatment with HFP
- Normal Score was maintained throughout 12 week washout period for HFP

Dynamic Gait Index



- Both treatment groups had baseline scores in the 'elevated risk of fall category' (≤ 19; normal=24)
- By the end of participation, the scores for both groups approached normal levels (Active: 22.82; Control: 22.65)

Patients in both Groups Demonstrated an overall Reduction in Headaches



So, what does a normal SOT score look like?

- This video is of a patient that did not participate in our TBI clinical trials but had previous experience with the therapy
- It is shown to demonstrate the clinical presentation of a person with a Normal SOT score
- Every subject is different and there are many different potential contributions to an SOT result. This is just one example.

Video of Subject with SOT Score in Normal Range

Overall Conclusion

In three previously published independent controlled clinical trials:

- PT + HFP PoNS therapy has been observed to be statistically significantly superior to PT with no stimulation in SOT scores
- HFP PoNS therapy produced FMRI confirmed statistically significant neuro plastic change to the brain, while PT alone + non stimulating PoNS did not produce any changes to the brain.

In registrational trial:

- Response Rate of High Frequency PoNS (75.4%) showed a trend to be superior to Low Frequency PoNS ($p<0.081$)
- We did not reach our primary endpoint because the LFP treatment had a significant therapeutic effect
- Achieved secondary efficacy endpoint: HFP and LFP PoNS therapy resulted in a highly statistically significant improvement vs baseline measurement at all measurement timepoints ($p<0.0005$)
- PoNS therapy achieved the primary safety endpoint, reduction in falls at week 2
- There were no device-related serious adverse events

In long term treatment trial:

- HFP PoNS therapy subjects achieved normal SOT scores at the end of 14 weeks of treatment which was sustained over 12 weeks of washout

- These results provide encouraging evidence of PoNS Therapy in the treatment of balance disorder in patients with mild to moderate TBI and we look forward to discussing the data with FDA to secure marketing clearance for the device. We now anticipate that our 510(K) application to the US FDA will be submitted in the first half of 2018, with clearance expected in the second half of 2018.