

**AWARD NUMBER:** W81XWH-14-2-0012

**TITLE:** Treatment of Vestibular Dysfunction Using a Portable Stimulator

**PRINCIPAL INVESTIGATOR:** Jorge M. Serrador, PhD

**CONTRACTING ORGANIZATION:** Veterans Biomedical Research Institute  
East Orange, NJ 07018

**REPORT DATE:** April 2018

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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<b>REPORT DOCUMENTATION PAGE</b>			<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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<b>1. REPORT DATE</b> Apr 2018		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED (From - To)</b> 1Apr2017 - 31Mar2018
<b>4. TITLE AND SUBTITLE</b> Treatment of Vestibular Dysfunction Using a Portable Stimulator			<b>5a. CONTRACT NUMBER</b>	
			<b>5b. GRANT NUMBER</b> W81XWH-14-2-0012	
			<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Jorge M. Serrador, PhD Kelly Brewer, MS  Email: jorge.serrador@rutgers.edu			<b>5d. PROJECT NUMBER</b>	
			<b>5e. TASK NUMBER</b>	
			<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Veterans Biomedical Research Institute 385 Tremont Ave East Orange, NJ 07018			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research & Materiel Command 810 Schreider Street Frederick, MD 21702-5012			<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
			<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for Public Release Distribution Unlimited				
<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> 124 participants have been enrolled in this research study. 56% (63 of 112) subjects tested have been found to have otolith hypofunction.				
<b>15. SUBJECT TERMS</b> None listed				
<b>16. SECURITY CLASSIFICATION OF:</b> U			<b>17. LIMITATION OF ABSTRACT</b>  UU	<b>18. NUMBER OF PAGES</b>  17
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC	
			<b>19b. TELEPHONE NUMBER (include area code)</b>	

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## 1. INTRODUCTION

Vestibular symptoms seem to be a common problem with ~20% of veterans complaining of dizziness and those with dizziness demonstrating increased risk of Motor Vehicle Accidents. To treat veterans with vestibular dysfunction we will optimize stimulation using a portable stochastic noise electrical stimulator and determine the effectiveness of subsensory electrical stimulation in a population of veterans with verified impaired vestibular function. We will perform experimental and sham stimulation on patients with impaired function to improve clinical vestibular and balance function during testing. We will assess the effectiveness of using this portable stochastic noise electrical stimulator to improve driving performance and determine what effect subsensory electrical stimulation has on vestibular function.

## 2. KEYWORDS

None to report

## 3. ACCOMPLISHMENTS

### Major Goals of the Project

#### **Major Goal 1 - Develop a portable stimulator which can be worn continuously and used to improve vestibular function (April 2014 to June 2016)**

##### Subtask 1: Establish Project Management System/Develop Logistical Plan (April – Aug 2014)

- a. Train the current members of the team (research assistant and research engineer) on vestibular screenings, balance assessments, and electronic stimulation.
- b. Research engineer will optimize equipment and write analysis scripts for Aim 1.

#### **Milestone #1: Establish project management system, hire and train research staff (Planned Completion Aug 2014) – 100% complete**

##### Subtask 2: Regulatory Review and Approval Process (April – Sept, 2014)

- a. Finalize IRB paperwork including application, protocol and consent form.
- b. Submit any revisions requested by the regulatory board prior to approval.
- c. Obtaining DoD HRPO approval.

#### **Milestone #2: Regulatory review and approval obtained (Planned Completion Nov 2014) – 100% complete**

##### Subtask 3: Recruitment Plan (Sept 2014 – Jan 2015)

- a. Develop plan to meet recruitment goals. **(completed)**
- b. Mail IRB approved recruitment letters to Veterans seen at the WRIISC; follow up with phone calls.

**(A total of 533 veterans have been contacted by phone to participate in the study, with 249 interested in participating and 163 eligible for study visits)**

- c. Distribute flyers to all VA facilities and their ambulatory services including community-based outpatient clinics to publicize the study. **(completed)**
- d. Work with NJ VA Physical Medicine & Rehabilitation Department (TBI clinic) to recruit from their patient population. **(completed)**
- e. Contact Veteran Service Organizations for support on best way to perform outreach. **(completed)**

### **Milestone #3: Recruitment Plan Executed (Planned Completion Jan 2015)**

**– 100% complete**

#### Subtask 4: Development of Portable Stimulator (April 2014 – March 2016)

- a. PI to meet with Dr. Breen at University of Western Sydney to go over specifications for Portable Stimulator Design. **(completed)**
- b. Development of initial prototype design at University of Western Sydney. **(completed)**
- c. Production of first generation prototype portable stimulator at University of Western Sydney to be shipped to New Jersey for testing. **(completed)**
- d. Redesign of prototype unit at University of Western Sydney based on findings from experiments performed in New Jersey. **(completed)**
- e. Production of second generation prototype vestibular stimulators at the University of Western Sydney for further testing in New Jersey. **(completed)**
- f. Redesign of prototype unit at the University of Western Sydney based on findings from experiments performed in New Jersey. **(completed)**
- g. Production of third generation prototype vestibular stimulators at the University of Western Sydney for shipping to New Jersey for further testing. **(completed)**
- h. Redesign of third generation stimulators for fabrication of units for use in Specific Aim 2 performed at National University of Ireland Galway. **(completed)**
- i. Fabrication of 20 units based on final design specifications at the National University of Ireland Galway. **(completed)**
- j. Testing of initial fabricated units from the National University of Ireland Galway in New Jersey to ensure they are meeting required standards and creating desired improvement. **(in progress)**
- k. Shipment of remaining units from National University of Ireland Galway to New Jersey for use in Specific Aim 2. **(pending)**

### **Milestone #4: 20 portable stimulators received (Planned Completion March 2016)**

**– 90% Completion**

#### Subtask 5: Enroll subjects and conduct testing on Sub-sensory Galvanic Stimulation Study (Oct 2014 – June 2016)

- a. Screen subjects/ collect data: total of 250 subjects
  - 3 subjects per week/ 3 study visits (3 hours each)
  - Vestibular testing, balance assessments

**(124 subjects have been enrolled and completed study screening visit, 42 have completed the experimental trial out of 42 planned.)**

- b. Data analysis (Post-doctoral fellow/research assistant will continually analyze data as collected). **(90% completed)**
- c. Biomedical engineer will continue to modify equipment and MATLAB analysis scripts as needed. **(completed)**
- d. Present/publish work. **(in progress)**

**Milestone #5: Enrolled and tested subjects (Planned Completion April 2016) – 100% Complete**

**Milestone #6: Data analysis completed (Planned Completion May 2016) –90% Complete**

**Milestone #7: Data presented/published (Planned Completion June 2016)**

**Major Goal 2 – To examine long term improvement of vestibular function in veterans with electrical stimulation (April 2016 to March 2017)**

Subtask 1: Examine effects of Stochastic Noise Over a 2 Day Stimulation Paradigm (April 2016 – April 2017)

- a. Screen subjects/collect data: total of 42 subjects
  - 3 unique subjects per week
  - Subjects return every 3 weeks for balance/vestibular testing
  - Subjects to wear portable stimulator over 2 day trial
- b. Data analysis
  - Analysis will be performed throughout data collection
- c. Present/publish work

**Milestone #8: Enrolled and tested subjects (Planned Completion Jan 2017) – 0% Completion**

**Milestone #9: Data analysis completed (Planned Completion Feb 2017) – 0% Completion**

**Milestone #10: Data presented/published (Planned Completion March 2017) – 0% Completion**

**Major Goal 3 – To improve driving performance using Electrical Stimulation**

Subtask 1: Effect of Improving Vestibular Ocular Reflex on Driving Function (Sept 2016 to March 2018)

- a. Initial testing and safety verification previously completed on driving simulator
- b. Institutional approvals obtained
- c. Pilot motion profiles to obtain optimal motion profiles to test role of vestibular function in driving performance
- d. Engineer will write analysis scripts to measure reaction time, stopping time and trajectory, collision avoidance and emergency braking for driving simulator to measure driving performance
- e. Engineer will develop analysis system which will track acceleration of participant and eye movements to obtain vestibular ocular reflexes while performing driving task

- f. Screen subjects/collect data: total of 42 subjects
  - 3 subjects per week
  - Complete driving simulator protocol (sham and stimulator trials)
- g. Data analysis
- h. Present/publish work

**Milestone #11: Testing and safety confirmed (Planned Completion Sept 2016)**

– 0% Completion

**Milestone #12: IRB approval obtained (Planned Completion Dec 2016)**

– 85% Completion

**Milestone #13: Pilot testing completed (Planned Completion Feb 2017)**

– 0% Completion

**Milestone #14: Data collection completed (Planned Completion Sept 2017)**

– 0% Completion

**Milestone #15: Data analysis completed (Planned Completion Oct 2017)**

– 0% Completion

**Milestone #16: Data presented/published (Planned Completion March 2018)**

– 0% Completion

## **ACCOMPLISHMENTS DURING THIS ANNUAL PERIOD**

### **Major Activities**

#### Regulatory Review and Approval Process

- a. NJ VA IRB approval for Specific Aim 2 on Nov. 6, 2017.
- b. Submitted HRPO documents for Specific Aim 2 on Jan 12, 2018.
- c. Submitted NJ VA IRB amendment for HRPO requested modifications to Specific Aim 2 on March 15, 2018.
- d. Submitted IRB documents to NJ VA for Specific Aim 3 on Jan. 19, 2017.
- e. NJ VA IRB approval for Specific Aim 3 on Nov. 6, 2017.
- f. Submitted HRPO documents for Specific Aim 3 on Jan 26, 2018.
- g. Submitted NJ VA IRB amendment for HRPO requested modifications to Specific Aim 3 on March 15, 2018.

#### Subtask 4: Development of Portable Stimulator

- a. Redesign of a third generation prototype of the vestibular stimulator has been accomplished and is being tested at VANJ.
- b. Dr. Jorge Serrador (PI) traveled to Australia in Feb. 2018 to review design on the portable stimulators to be used in Aim 2.

**Milestone #4: 20 portable stimulators received (Planned Completion March 2016)**

– 90% Completion

#### Subtask 5: Enroll subjects and conduct testing on Sub-sensory Galvanic Stimulation Study (Oct 2014 – June 2016)

- 124 subjects have been enrolled into the study and have completed the study screening visit.
- Screening visits of 112 subjects have been fully analyzed for eligibility for stimulation visits.
- 63 subjects are eligible to return for stimulation visits.
- 42 subjects have completed stimulation testing.

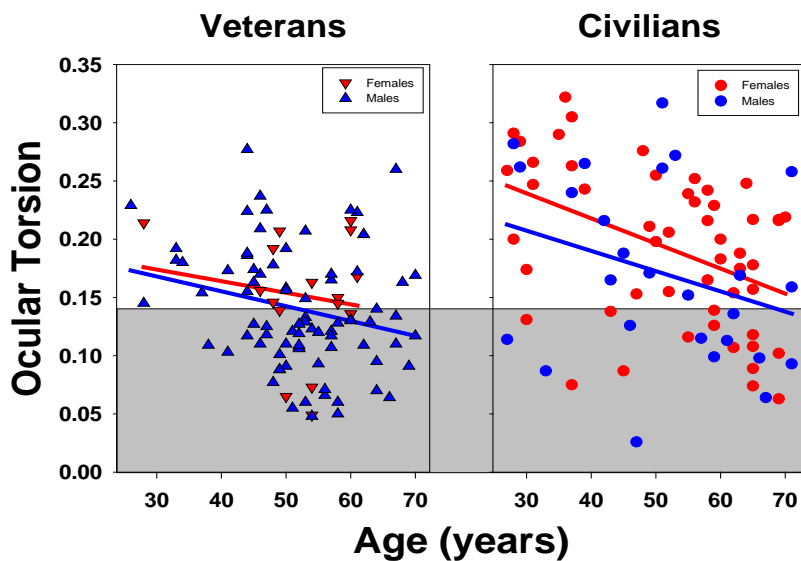
**Milestone #5: Enrolled and tested subjects (Planned Completion April 2016) – 100% Complete**

**Milestone #6: Data analysis completed (Planned Completion May 2016) –90% Complete**

### Significant Results of Year 4

- 1) Enrollment has stopped for specific aim 1 while data is being analyzed. Enrollment for Specific Aim 2 and 3 will commence once IRB and HRPO approvals are granted.
- 2) Overall, we have been able to analyze the screening visits of 112 participants. Of these, 63 show vestibular hypofunction and were/are able to participate in visits using stochastic noise.
- 3) Testing of the miniaturized portable stimulator redesign has proceeded with minor modifications required to move forward.
- 4) Final design specifications have been developed for the production of the 20 units.
- 5) A total of 42 subjects have completed stimulation visits and we are in the process of analyzing these results.

### Major Findings, Developments, Conclusions, and Other Achievements



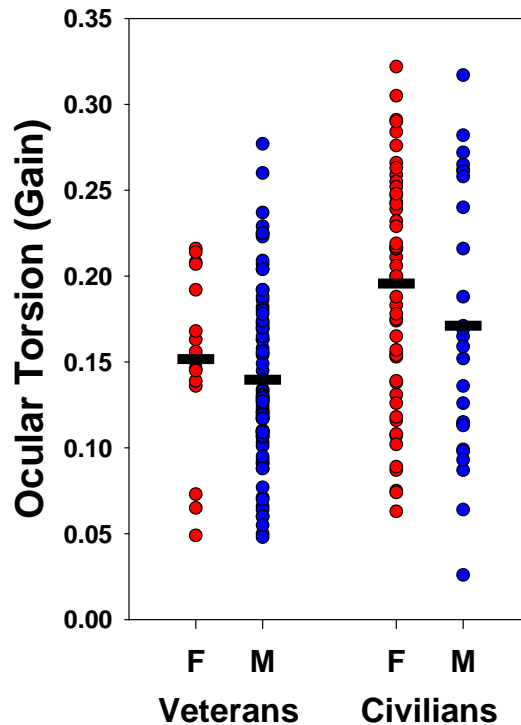
**Figure 1:** Ocular torsion of veterans screened for aim 1 and a group of civilians from previous work. The gray box indicates those having low otolith function. Veterans have a significantly lower level of vestibular function as shown by a greater percentage with low ocular torsion.



- There are several findings that are developing out of the first specific aim data. We have found that there has been a significantly greater level of vestibular hypofunction than we originally anticipated. Figure 1 demonstrates the subjects screened so far and the associated ocular torsion.

- Comparing the veteran data to a group of civilians of similar age that were part of a previous study the PI completed in Boston, we see that the veterans have significantly lower levels of ocular torsion (Figure 2). In fact the mean values in the female and male veterans were 0.15 and 0.14, compared to 0.20 in the female civilians and 0.17 in the male civilians. These data also indicate that female veterans may be at greater risk for vestibular hypofunction. Although larger numbers are needed to confirm this.

### Comparison of Ocular Torsion in Veterans vs Civilians

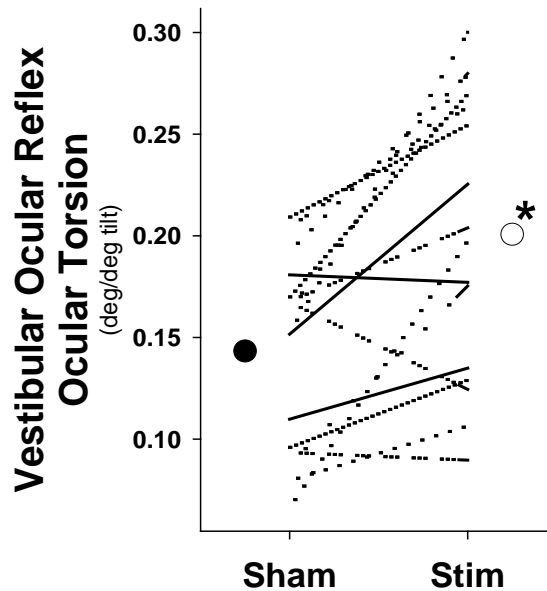


**Figure 1** – Ocular torsion in veterans (left) vs civilians (right) of similar age. Note that the veterans have significantly lower ocular torsion than the civilians. These data suggest that veterans may be at risk for vestibular hypofunction.

- We also examined the effect of the stimulator (V1) on ocular torsion and balance function. We stimulated the veterans using a low level (subsensory) of random electrical noise with 95% of the power banded below 2 Hz. Stimulation levels were set for each individual to either 20, 40, 60, 80 or 100% of sway threshold (level at which sinusoidal GVS at 0.1 Hz caused sway). Level chosen was based on the optimal level for that individual. Stimulation levels varied but were a mean of  $\pm 0.20$  mA (Range 0.02 – 0.62 mA).

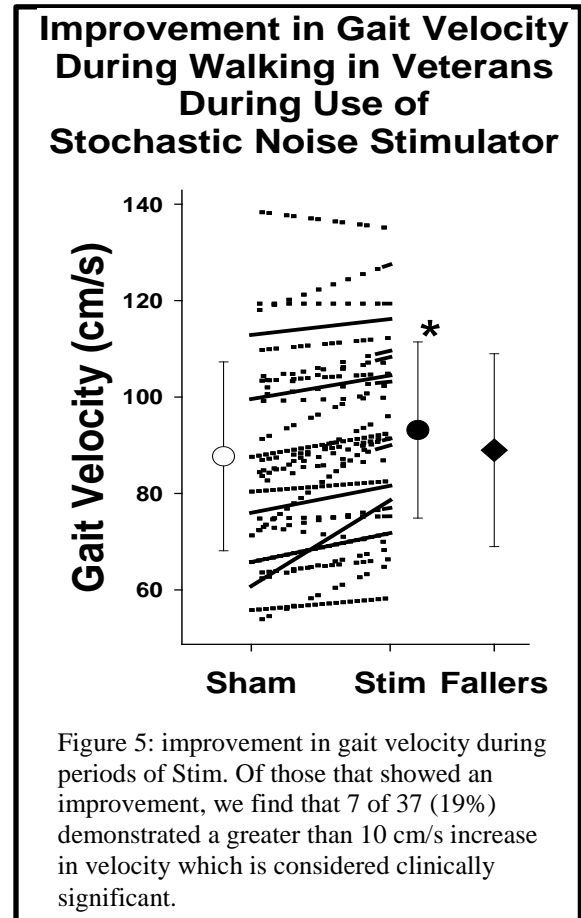
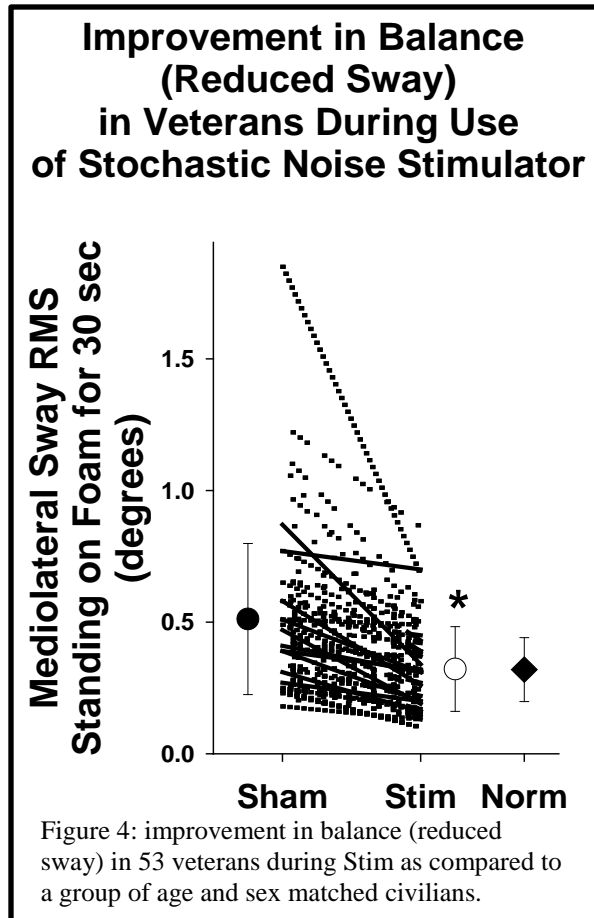
- Examining ocular torsion we found that stochastic noise improved ocular torsion significantly (mean +58%, range 21-198%), compared to sham trials (Figure 3). In addition, we also measured static balance in 14 of the veterans who demonstrated improved ocular torsion. Examining mediolateral sway, all of them demonstrated a decrease in sway (mean 44%, range 8-61%) during two thirty second trials standing on a foam block. Thus, not only did the stochastic noise improve the measure of vestibular function (i.e. ocular torsion) it also improved the functional response by improving balance (i.e. reduced sway). These data demonstrate that we can use this paradigm to improve vestibular function and balance in veterans with impaired vestibular function. This is a significant finding since at the moment there are NO current treatments that are able to improve the vestibular ocular reflex of ocular torsion.

- We have successfully **improved balance in 98%** (65/66 trials) of 53 veterans with impaired vestibular function that we tested as part of our current funding examining vestibular loss in a veteran population. The results clearly demonstrate the effectiveness of the current stimulator. In this group of veterans we were able to reduce their sway by  $44 \pm 16\%$  which reduced their sway from being significantly greater than age matched norms to exactly the same. As can be seen in Figure 4, during sham stimulation the veterans had significantly greater sway ( $0.54 \pm 0.29$ ) then a group of age and sex matched civilians ( $0.32 \pm 0.12$ ) from our previous work. However, during stimulation their sway reduced to  $0.35 \pm 0.16$ , which was not statistically different than the healthy civilian group. In addition, the variance in sway in the population reduced by 44% so that all veterans had similar sway values. These data strongly support the finding that the stimulator may be a useful rehab device that could be used to reduce fall risk. In fact, previous work has demonstrated that Mediolateral Sway is higher in those at risk of a fall compared to non-fallers. Based on those findings, reducing Mediolateral Sway in these veterans could reduce their fall risk.

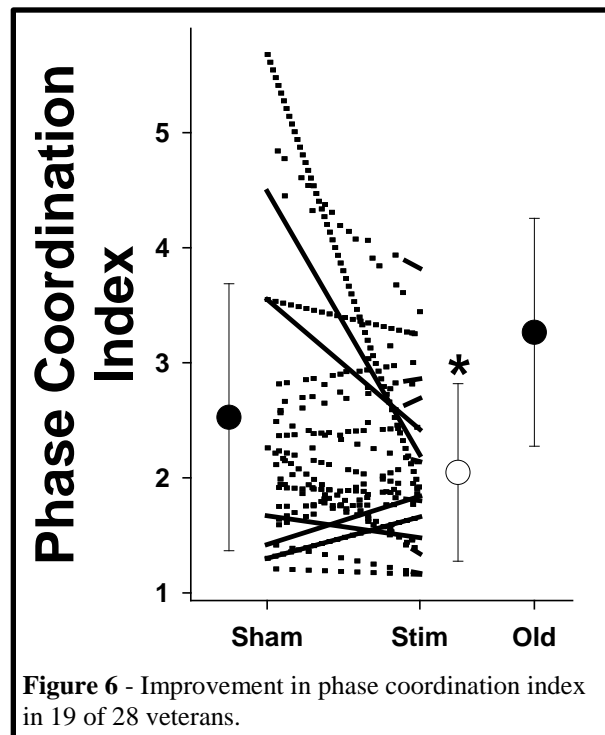


**Figure 3** – Response of ocular torsion to stochastic noise stimulation (Stim) compared to no stimulation (Sham). We were able to improve ocular torsion in 15 of 18 Veterans with an average increase of 58% (range 21-58). Note that no treatments have previously demonstrated an increase in ocular torsion. Circles represent mean values during Sham and Stim. \* indicates significant reduction in sway during stim,  $p < 0.05$ .

- Since the goal of our work is to develop a portable rehabilitation device, we were very interested in possible effects on gait. Since we know that gait can be very predictive of fall risk we examined several variables that have been shown to be related to fall risk. Slow walkers are at much greater fall risk so we examined effect of our stimulator on gait velocity. Figure 5 demonstrates that our stimulator was able to produce a significant improvement in gait velocity, and **increased gait velocity in 90%** (37/41) of the veterans, resulting in an increase of  $6.3 \pm 5.0$  cm/s ( $8.0 \pm 7.6\%$ ). Examining those that showed improved gait velocity, we find that 7 of 37 (19%) demonstrated a greater than 10 cm/s increase in gait velocity which is considered a clinically significant improvement in gait.



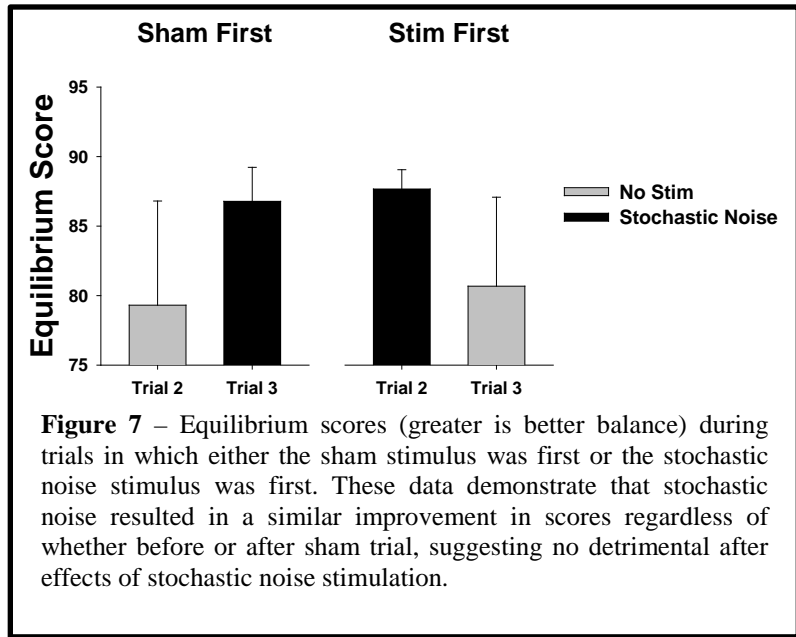
- We also found that our stimulator was able to reduce gait variability, which is also highly related to fall risk. We were able to improve phase coordination index in 19 of 28 (68%) veterans (Figure 6). As can be seen, our veterans went from a value closer to those shown in elderly to an even lower value than younger individuals. In fact we were able to get improvements of  $26 \pm 12\%$  which is significantly greater than a recent paper that showed an  $8 \pm 9\%$  improvement in phase coordination index in patients with vestibular loss using a different type of stimulator.



- While our data and that of others has found that stochastic noise vestibular stimulation is able to improve balance, we theorize the effect will only be present when the stimulation is on. One possibility is that after the stimulator is turned off, that balance function could get worse. Thus, we would actually increase the risk of falls in individuals after the stimulus is turned off.

To test this we looked at the order effect of stimulation on balance measures from our modified clinical test of sensor organization on balance. In this test we had each veteran complete four 30 sec quiet standing trials in four conditions:

- 1) Eyes open on stable surface
- 2) Eyes closed on stable surface
- 3) Eyes open on unstable surface
- 4) Eyes closed on unstable surface



During each of these condition veterans were randomized to either two sham trials followed by two trials with stochastic noise or two trials with stochastic noise followed by two sham trials. Thus trial 1 and 2 were either sham or stim and trial 3 and 4 the reverse. So we could compare trials 2 and 3 since in one condition trial 2 would be sham and trial 3 would be stim and in the other condition the opposite. Since trials occurred immediately following each other with ~15 seconds in between. Thus, this comparison would allow us to see if there was any negative effect on balance immediately after turning off the stimulation. Thus in trials with sham first, the participants balance would show improvement from trial 2 to trial 3 with the stochastic stimulus. In contrast if stimulation was first and there is a negative after effect we would expect balance to decrease even more than the increase we saw during the sham to stim trials. Figure 7 demonstrates that when sham stimulation was first Equilibrium scores increased significantly as expected with the stimulation. During the stim first trials, the Equilibrium scores started high and reduced to similar levels as seen during the sham trial in the sham first randomization. In fact sham values were extremely similar (Sham First:  $79.3 \pm 7.5$  vs Sham Second:  $80.7 \pm 1.4$ ) as were stimulation values (Stim Second:  $86.8 \pm 2.4$  vs Stim First:  $87.7 \pm 1.4$ ). Furthermore, there were no order effects for stimulation on any of the balance measures obtained. Thus these data suggest that stochastic noise stimulation does not result in any negative effects on postural control after the stimulation is turned off. This has recently been confirmed by Fujimoto et al who found testing balance after 30 min of continuous stochastic noise stimulation did not result in any decrements in balance (i.e. increases in standing sway).

**What opportunities for training and professional development has the project provided?**

This project has provided training for all research staff to be competent at vestibular screenings, balance assessments, and electronic stimulation procedures. Our biomedical engineer has been able to develop an improved stimulator prototype under guidance of Dr. Breen.

**How were the results disseminated to communities of interest?**

- Nothing to Report

**What do you plan to do during the next reporting period to accomplish the goals?**

- 1) Continued execution of recruitment plan by phone calls, posting flyers, and recruiting from VA TBI patient populations.
- 2) Enrollment of subjects and data collection.
- 3) Analysis of collected data.
- 4) Test miniaturized units produced by Dr. Breen in lab to ensure they are ready for use in Specific Aim 2.
- 5) Continue testing using sub-sensory stimulation.
- 6) Analysis of sub-sensory stimulation data.
- 7) Begin process of gaining HRPO approval for Specific Aim 2 and 3.
- 8) Develop driving simulator protocol for Specific Aim 3.
- 9)

**4. IMPACT**

**What was the impact on the development of the principal discipline(s) of the project?**

- Nothing to Report

**What was the impact on other disciplines?**

- Nothing to Report

**What was the impact on technology transfer?**

- We are currently exploring with the technology transfer offices at both Western Sydney University and Rutgers the possibility of patenting some of the technology involved. No concrete plans have yet been made.

**What was the impact on society beyond science and technology?**

- Nothing to Report

**5. CHANGES/PROBLEMS**

- Nothing to Report

**Changes in approach and reasons for change**

- Nothing to Report

**Actual or anticipated problems or delays and actions or plans to resolve them**

- Now that we have identified 100% of the required number of Veterans with vestibular hypofunction to be tested in Aim 1, we have finished the process of submitting the IRB for Aim 2 and Aim 3. There was a 9 month delay in starting Aim 1 due to delayed HRPO approval and as such, we were approved for a 12-month Extension With Out Funds (EWOFF) in March 2018. We will continue to make strides towards accomplishing milestones.

**Changes that had a significant impact on expenditures**

- There were no changes in expenditures.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents:**

**Significant changes in use or care of human subjects**

- No changes to use or care of human subjects to report.

**Significant changes in use or care of vertebrate animals.**

- No animal use research will be performed to complete the Statement of Work.

**Significant changes in use of biohazards and/or select agents**

- No biohazards and/or select agents will be used to complete the Statement of Work.

## **6. PRODUCTS**

### **Publications, conference papers, and presentations**

- PI has been invited to present on the results of this study at the DoD Complex TBI In-Progress Review Meeting on Apr. 12, 2018.
- “Veterans without mTBI are more likely to benefit from bilateral electrical vestibular stimulation” abstract accepted for presentation at the 2018 Experimental Biology conference. “Subsensory Neuromodulation Improves Vestibular Function in Bilateral or Unilateral Hypofunction” abstract accepted for presentation at the 30<sup>th</sup> Barany Society Meeting, 2018.

### **Journal publications.**

- Nothing to Report.

### **Books or other non-periodical, one-time publications**

- Nothing to Report.

### **Other publications, conference papers, and presentations.**

- Nothing to Report.

### **Website(s) or other Internet site(s)**

- Nothing to Report.

### **Technologies or techniques**

- Nothing to Report.

### **Inventions, patent applications, and/or licenses**

- Nothing to Report.

### **Other Products**

- Nothing to Report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name: Jorge Serrador, PhD  
Project Role: PI  
Nearest person month worked: 2  
Contribution to Project: no change

Name: Kelly Brewer, MS  
Project Role: Study Coordinator  
Nearest person month worked: 9  
Contribution to Project: no change

Name: Bishoy Samy, MS  
Project Role: Research Engineer  
Nearest person month worked: 3  
Contribution to Project: no change

Name: Leslie De La Cruz, BS  
Project Role: Research Assistant  
Nearest person month worked: 6  
Contribution to Project: performing subject recruitment, testing, data analysis.

Name: Maran Shaker, MS  
Project Role: Research Assistant  
Nearest person month worked: 1  
Contribution to Project: performing subject recruitment, testing, data analysis.

### Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

- Nothing to Report

### What other organizations were involved as partners?

1. Organization Name: University of Western Sydney- Paul Breen, PhD  
Location of Organization: Australia  
Partner's contribution to the project:
  - Financial support – Nothing to report
  - In-kind support – Dr. Breen's salary is covered by UWS as detailed in original proposal.
  - Facilities – Nothing to report
  - Collaboration – Designed a novel low power stochastic noise stimulator that will be used to improve vestibular function in our patients.



- Personnel exchanges – Nothing to report
- Other – Nothing to report

2. Organization Name: National University of Ireland Galway- Gearóid Ó Laighin, PhD

Location of Organization: Ireland

Partner's contribution to the project:

- Financial support – Nothing to report
- In-kind support – Prof. Ó Laighin's salary is covered by NUIG as detailed in original proposal.
- Facilities – Nothing to report
- Collaboration – Assist Paul Breen in the design of a novel low power stochastic noise stimulator.
- Personnel exchanges – Nothing to report
- Other – Nothing to report

3. Organization Name: Azusa Pacific University- Scott Wood, PhD

Location of Organization: California

Partner's contribution to the project:

- Financial support – Nothing to report
- In-kind support – Nothing to report
- Facilities – Nothing to report
- Collaboration – Provided expertise in scientific protocol development specifically with regards to driving performance assessment.
- Personnel exchanges – Nothing to report
- Other – Nothing to report

## 8. SPECIAL REPORTING REQUIREMENTS

- None

**QUAD CHARTS: N/A**

## 9. APPENDICES: None.