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Mild Traumatic Brain Injury (mTBI) Study Analysis

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1.0 INTRODUCTION

This report analyzes data for the mild Traumatic Brain Injury (mTBI) study which included test participation from Naval Special Warfare Development Group (NSWDG) located at Dam Neck, Virginia and Naval Special Warfare Group Four, Special Boat Team Twenty Two (NSWG4 SBT22) located at Stennis, Mississippi. The analytical methodologies were developed early in the study using a subset of the NSWDG participants, designated the 1500 series.

1.1 Magnitude of Injury Problem in U.S. Military Personnel[1]

Over a decade ago, a report issued by the Armed Forces Epidemiological Board (AFEB) Injury Prevention and Control Work Group identified injuries as the most frequent cause of both morbidity and mortality among military service members (Jones et al., 1996). More recently, injuries have been described as "the biggest health threat confronting the U.S. Armed Forces" (Sleet et al., 2000), representing the leading cause of deaths, disabilities, hospitalizations, and outpatient visits (Jones et al., 2010). Each year, service members experience approximately 25 million limited duty days as a result of injuries, and the estimated annual costs are in the hundreds of millions of dollars (Rusico et al., 2006). Injuries have been clearly established as a significant threat to military health and combat readiness, prompting a great deal of interest in the development of effective injury prevention interventions for the military population.

1.2 Evidence-Based Public Health Approach to Injury Prevention

In considering their approach to the problem of injuries among military service members, the AFEB work group recognized the value of adopting a systematic process for characterizing the situation and choosing among alternative methods to respond to it (Jones et al., 2010; Jones et al., 2000). It was determined that the 5-step public health approach to injury prevention (Robertson, 1992; Mercy et al., 1993; Jones et al., 1999) would best fit their needs. Steps of the public health approach include: (1) Surveillance (determine existence and magnitude of problem); (2) Identify causes and risk factors for the problem (through research and field investigations); (3) Determine what interventions work to prevent the problem; (4) Implement and evaluate prevention strategies and programs; and (5) Evaluate and monitor programs and policies (involves continued surveillance).

A study of disability in the military used administrative rather than medical surveillance data to assess the role of injury, finding that injuries were likely responsible for 30–50% of disability cases across the services. Direct costs of compensation were estimated at $1.5 billion for fiscal year 1990 (Songer and LaPorte, 2000). Lauder et al. (Lauder et al., 2000) focused on hospital admissions for injuries suffered during sports and physical training among active duty Army personnel. They demonstrated the significant amount of lost duty time resulting from these injuries and emphasized the negative ImPACT on military readiness. Another study used an initial site visit followed by periodic medical record review to compare injuries and risk factors in four groups: infantry soldiers, construction engineers, combat artillery, and Special Forces during operational and fitness activities. While observed injury rates were highest among construction engineers, the Special Forces soldiers experienced a much larger number of limited duty days than any other group. The researchers noted that data on cause of injury was not

[1] Background and introduction from approved research protocol 1059_mTBI TEP 29AUG2013 V4_2 FINAL, Pierce et al., 2013.

always available in the medical record and that reports often did not provide adequate injury diagnosis (Reynolds et al., 2009). Skeehan et al. (Skeehan et al., 2009) conducted a survey of non-battle injury (NBI) among troops deployed to Iraq, Afghanistan, and the surrounding region from January 2005 through May 2006. Nearly 20% of respondents reported at least one NBI, and one-third of those who were grounded from flight status were grounded due to NBI. The authors described NBI as "a primary force health protection problem." Other studies have drawn similar conclusions regarding the importance of injury prevention in military populations (Hollingsworth, 2009; Sell et al., 2010; Jones, Canham-Chervak, and Canada et al., 2010).

Results of an evidence-based approach to evaluating interventions to prevent injuries during training were reported recently by the Joint Services Physical Training Injury Prevention Working Group, which was chartered by the Military Training Task Force of the DSOC (Bullock et al., 2010). The group identified 40 prevention strategies for possible inclusion in their evidence base. Critical components of successful injury prevention programs were determined to include: education, leadership support, injury surveillance, and research. Most recently mTBI has been identified as a serious injury in today's active duty forces, which can have long lasting effects (Schwab, et al., 2007).

1.3 Injury Patterns in Physically Active Environments

Physically active people, regardless of their activity environment, their physical readiness or their health history, expose themselves to the opportunity for an injury resulting from their participation. The most frequent types of injury sustained in these groups include musculo-skeletal injury and head injury. These injuries may require minimal medical care, have little or no restriction from daily activity, and produce no permanent physical disability. On the other hand, the injury may require hospitalization, surgery, extensive rehabilitation, personal and/or occupational disability or societal effects such as loss of a paired organ or even death. The people that participate in these physically active environments do so to fulfill occupational requirements, recreational behaviors, or health reasons. A review of the literature associated with sports injury pattern in the collegiate arena indicates that approximately 20% of injuries required a loss of participation time. Among these time loss injuries, over half of them require less than seven days of participation restriction and less than 1% result in long-term disability (Powell & Dompier, 2004).

Over the past two decades there has be an ever increasing concern for one type of injury that occurs in the sports environment and that is the concussion or mTBI. This injury results from ImPACTs and/or acceleration/deceleration forces that occur from collisions between players and/or environmental factors, e.g., sport-related equipment. The heightened awareness of these injuries has resulted in clearer identification of the nature of the injury and greatly improved the management of the injury. Much of the research in the competitive sports arena has focused on identifying the frequency of mTBI, the circumstances at the time of injury, managing the injury and modifying the activity to reduce exposure to events that lead to injury.

1.4 Brain Injury in the Military

As with top athletes, members of the armed forces create specific patterns of injury related to their physical activities during physical readiness training and during mission related activities during deployment. While the general nature of the musculo-skeletal injuries may be similar to the sports environment, the nature of the mTBI has unique conditions that do not appear in the sports environment, e.g., blasts waves, penetrating wounds, thermal exposure, and inhaled gases

(Bass, 2011). Like the sport-related mTBI, the effect on the person is a temporally related onset of symptoms such as headache, nausea, vomiting, dizziness/balance problems, fatigue, insomnia/sleep disturbances, drowsiness, sensitivity to light/noise, blurred vision, difficulty remembering, and/or difficulty concentrating. The biomechanical forces present under these conditions may result in an alteration of consciousness to include loss of consciousness (LOC), post-traumatic or retrograde amnesia (PTA or RGA) or being dazed/confused and post-traumatic stress disorder (PTSD). It is clear from the sports literature that a person with a history of concussion (e.g., mTBI) is more likely to suffer future injuries than those without a history (Guskiewicz et al., 2003) and that a history of previous mTBI is found to be associated with a poorer performance on neuropsychological tests as well (Collins et al., 1999). Because of multiple deployments to theatres of combat, the risk for troops to sustain more than one mTBI is elevated. The research literature available is unclear as to the risks associated with the cumulative effects of multiple undiagnosed mTBI during combat operations. The frequency patterns and effects of mTBI from solitary and multiple exposures to blast, chemicals, heat, penetrating injury, blunt trauma, etc have described (Bass, 2011, Panzer, 2012). Much of this research used retrospective analysis of injury reports, medical records, literature review, and animal modeling. As a result, research efforts are growing in the area associated with the cumulative effect of mechanical forces on the brain when there is no associated injury as well as the cumulative effect of low-level forces on the risk of injury. The following are a few of the questions that are unanswered and under active investigation by the research community.

- What are the specific conditions risk factors, both internal and external, that make the brain more susceptible to injury?
- What are the tools that can provide early recognition of increased risk of injury, e.g., screening procedures for recognition and neurocognitive impairment?
- Is there a threshold that identifies the nature and/or mechanical forces that result in an injury, decreased performance or permanent disability?
- What are the cumulative effects of multiple low energy forces with respective to the risk of injury and long-term neurocognitive function?

A large number of research programs on the national, state, and local levels actively engage these and other areas of study of the mTBI. Their focus is on knowledge that will improve prevention strategies and provide for stronger medical care programs.

1.5 Research Objectives

The objectives of the study are: 1) to describe the injury patterns and relative risk of injury during daily activities of Naval Surface Warfare (NSW) members; 2) to describe the effect of head shock and vibration on neurocognitive function operational readiness; 3) to evaluate the effect of head shock and vibration exposure on the relative risk of brain injury; and 4) to determine the feasibility of identifying an injury index based on study variables. The protocol uses health and injury data, training exposure data, shock and vibration exposure data, serial neurocognitive performance markers and balance characteristics, and data from individual recorded daily recreational activity logs to address the following questions:

1. Does shock and vibration exposure to the participant's brain during daily activities and mission readiness training, produce notable change in neurocognitive function among NSWDG members?

2. Does the accumulation of shock and vibration produce changes in neurocognitive function that pose an increased risk of injury for members of NSWDG?
3. Is there a Performance Disability Index (PDI) that describes an increased injury risk?
4. Are there specific techniques or procedures that would minimize the risk of injury or disability?

Volunteers were asked to wear ear mounted accelerometers, document daily activities, take performance tests, and permit access to their medical records. Navy and head modeling subject matter experts (SME) are currently using data gathered in this test to develop a neurocognitive performance based head model, suitable for predicting mTBI based on NSW exposure scenarios.

1.6 Performance Metrics

A number of activities and performance metrics were recorded during this study to assess impact environment, vestibular, oculomotor and cognitive response. Essential elements of this study included:

1. Daily Activity Logs
   These logs report daily details of potential exposure to occupational and recreational events that may impact physical or cognitive performance. The results from these logs are reported in Section 1.7.
2. Medical Assessments
   Medical assessments were performed from medical information in the volunteers' military medical data. Both baseline and post-study assessments were made by personnel including physicians involved in clinical practice. When appropriate, Military Acute Concussion Evaluation (MACE) assessments were made on personnel potentially suffering brain injury. The results from these medical assessments are reported in Section 3.
3. Balance Assessments
   Two types of balance assessments were performed to assess the potential for vestibular and balance issues affecting performance independent of the impact environment. These include a simple field balance and vestibular testing, termed Balance Error Scoring System (BESS), and a clinically used balance and vestibular test by NeuroCom (Sensory Organization Test – SOT). The results from these medical assessments are reported in Section 4.
4. Oculomotor Assessments
   Oculomotor assessments were performed that are analogous to those used in the Veteran Administration (VA) for assessment of neurotrauma and other conditions. The results from these medical assessments are reported in Section 5.
5. Cognitive Assessments – Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)
   This study utilizes a widely used neurocognitive device intended to assess cognitive performance following blunt head trauma. The test is intended to be given at regular intervals and evaluated relative to a baseline. The results from these cognitive assessments are reported in Section 6.
6. Accelerometer Measurements – Data Acquisition System – Head Response (DASHR)

Head accelerations and core body temperature were collected using a tightly head-coupled system developed by Duke University and Naval Surface Warfare Center Panama City Division. Sensors were imbedded within custom ear models which participants wore in their inner ear canals. For this study, two versions were delivered. One version was shaped such that the battery, memory-storage and associated hardware could be mounted behind the participant's ear. This version was primarily intended for use while performing physical training (PT). The second version was shaped so that the associated hardware could be mounted to whatever the participant wore on his head such as helmets and head sets. The results from these impact exposure assessments are reported in Section 7.

The Dam Neck cohort had 57 participants (Table 1) with data collected throughout the study. Participants varied in age from 23 to 45 years with a median age of 31 years. The maximum time in service was 22 years, and the minimum was 3 years with a median of 10 years. Most participants were experienced operators with 5 years or more in NSW. The median time with NSW was 9 years and the median time with NSWDG was 4 years. The median number of deployments in the Dam Neck cohort was 5 with a minimum of 1 and a maximum of 15 deployments.

The Stennis cohort had 26 participants (Table 2) with data collected throughout the study. Participants varied in age from 21 to 39 years with a median age of 25 years. The maximum time in service was 17 years, and the minimum was 1.25 years with a median of 4.5 years. There was a subset of experienced operators in NSW and a subset of relatively inexperienced operators. The median time with NSW was 4.25 years. The median number of deployments was 1 with a minimum of 0 and a maximum of 12 deployments. The experience level of the Stennis cohort was significantly less than that of the Dam Neck cohort on the basis of either time in service or deployments. Time in boat unit had widely variable estimates for both cohorts and was not deemed a reliable quantitative estimate.

One participant in the Dam Neck group dropped out of the study, and one participant in the Stennis group (C035) transferred out of the unit, these subjects were not included in the study analyses.

Table 1. Service History Information for Dam Neck Participants

ID	Age	Time In Service (years)	NSW (years)	NSWDG (years)	Combat (months)	Est. Boats (hrs)	Deployments
1201	30	7	7	2	14	1000	3
1202	45	21.5	16.5	9.5	16	5000	7
1203	35	16	12	5	12	2886	7
1204	31	13	9	5	13	4000	7
1205	26	8	7	4	16	5000	5
1206	25	7	7	4	4	10000	4
1207	36	12	9	5	16	14000	8
1208	40	16	12	3	10	24000	7
1209	34	8	6.5	2.5	7	1000	4
1210	30	11	10	3	6	9500	6
1211	26	7	7	6	7	NA	5
1212	23	5	4	1	0	800	1
1213	34	9	9	0.5	0	2000	2
1214	31	9	8	1	0	20000	3
1215	31	9	4	4	9	3000	6
1216	28	10	0.75	0.75	0	2000	3
1303	31	13	12	4	0	24000	9
1306	34	9.5	9	5	0	10000	7
1312	32	3	NA	NA	NA	2000	2
1313	25	7	NA	NA	NA	20000	4
1314	32	12	11	0.6	NA	10000	4
1402	35	17	12	7	24	1800	6
1403	31	13	12	6	8	8000	8
1404	32	11	7	3	1	3000	5
1405	29	10	9	6	12	10000	4
1406	30	12	7	6	16	5600	4
1407	27	8	6	4	1	4000	4
1408	30	11	5	4	0	9600	6
1409	25	8	6	3	10	6000	3
1411	35	13	7	1.5	NA	7000	4
1412	27	5	NA	NA	NA	2000	2
1413	32	11	10	0.6	18	5200	4
1414	30	6.5	6	0.5	8	15000	2
1415	35	3	NA	NA	0	4000	2
1502	32	14	11	7	10	10,000	7
1503	35	13	12	6	NA	1000's	7

ID	Age	Time In Service (years)	NSW (years)	NSWDG (years)	Combat (months)	Est. Boats (hrs)	Deployments
1504	34	14	13	7	18	10942.5	6
1505	29	10	6	6	36	8000	5
1506	37	12	9	3	23	8000+	5
1507	32	10	10	3	24	1500	5
1508	32	12	11	3	15	1200	6
1509	26	6	5	2	10	290	3
1510	39	5	4	2	NA	2000	4
1511	32	5	5	2	18	900	3
1512	28	7	7	7	0	5200	2
1513	27	8	7	1	0	1000's	3
1514	23	5	4	3	0	1000's	1
1515	28	4	3	1	9	50	2
1601	37	19	15	9	16	10000+	9
1602	30	8	7	6	8	8000	2
1603	31	12	10	7	8	2000+	6
1604	40	12	NA	NA	12	9000	8
1605	31	13.5	13	7.5	10	11000	11
1606	34	16	15	9	NA	2000+	8
1607	39	20	16	7	12	10000+	9
1608	35	15	13	7	32	21168	7
1609	41	22	15	7	64	11520	15

Table 2. Service History Information for Stennis Participants

ID	Age	Time In Service (years)	NSW (years)	Combat (months)	Est. Boats (hrs)	Deployments
C021	39	11	NA	1	10000	2
C022	26	4.5	3.5	0	800	1
C023	34	10	9	17	NA	4
C024	25	6	6	0	1000	1
C025	NA	NA	NA	NA	NA	NA
C026	25	6	NA	NA	800+	3
C027	38	17	NA	24	40000	12
C028	23	4	NA	0	4000	1
C029	33	15.5	13	17	25000	6
C032	26	7	NA	6	3600	3
C033	24	5	4	NA	3000	3
C034	22	4	3.5	0	3500	2
C037	26	4.5	4.5	8	100	1
C038	27	2	NA	0	500	0
C039	25	6	NA	12	2160	2
C040	26	1.25	1.25	0	200	0
C041	31	3.5	1	0	200	0
C042	22	3	NA	0	3000	1
C043	NA	NA	NA	NA	NA	NA
C044	22	2	2	0	500	0
C045	25	1.75	NA	0	700	0
C046	24	6	5	0	2000	3
C047	23	1.5	NA	0	500	0
C048	21	1.75	NA	0	500	0
C049	31	13	12	5	25000	3
C050	23	1.8	NA	0	500	0

1.7 Applied PDI/Risk Assessment Planning and Tracking Tool Feasibility

While onsite with the participant groups and their related planning and management chain of command entities, and concurrently with research protocol data collection visits, the feasibility of creating an integrated, operationally relevant PDI/risk assessment planning and tracking tool was examined by the Study Team. For any PDI that may describe increased injury risk and/or specific techniques or procedures that would minimize the risk of injury or disability, it was recognized that there would have to be an operational end-user-/warfighter-centered methodology or tool required to utilize and readily apply the mTBI/PDI planning and tracking information within the target groups' daily operations.

A user-centered design (UCD) approach and Top-Down Function Analysis (TDFA) methodology was employed to study the management chain of command overall planning and tracking tasks' major functions, the specific operational tasks performed by representative operational end-users, and what PDI/risk assessment planning and tracking methodologies or tools would readily integrate with their current operations. Several rounds of concepts development and representative end-user/warfighter feedback sessions were used in the feasibility study. The result was a first- article concept for a mTBI risk assessment and tracking methodology/software interface tool that would integrate readily within the target groups' current daily operations and planning cycles.

2 DAILY LOGS

The participants were instructed to submit logs when they had activities that might produce potential performance decrements, including recreational activities, but not for desk work. Dam Neck participants submitted a total of 821 daily activity logs, and Stennis participants submitted a total of 877 daily activity logs. The median number of logs per Dam Neck participant was 10 logs, the maximum number of daily logs submitted by a Dam Neck participant was 58 and the minimum was 0. The median number of logs per Stennis participant was 37, the maximum number of logs was 37, and the minimum number was 22.

General characteristics of the daily logs are discussed in this section, and the activity reports of the participants were correlated with the DASHR data as discussed in Section 7 below.

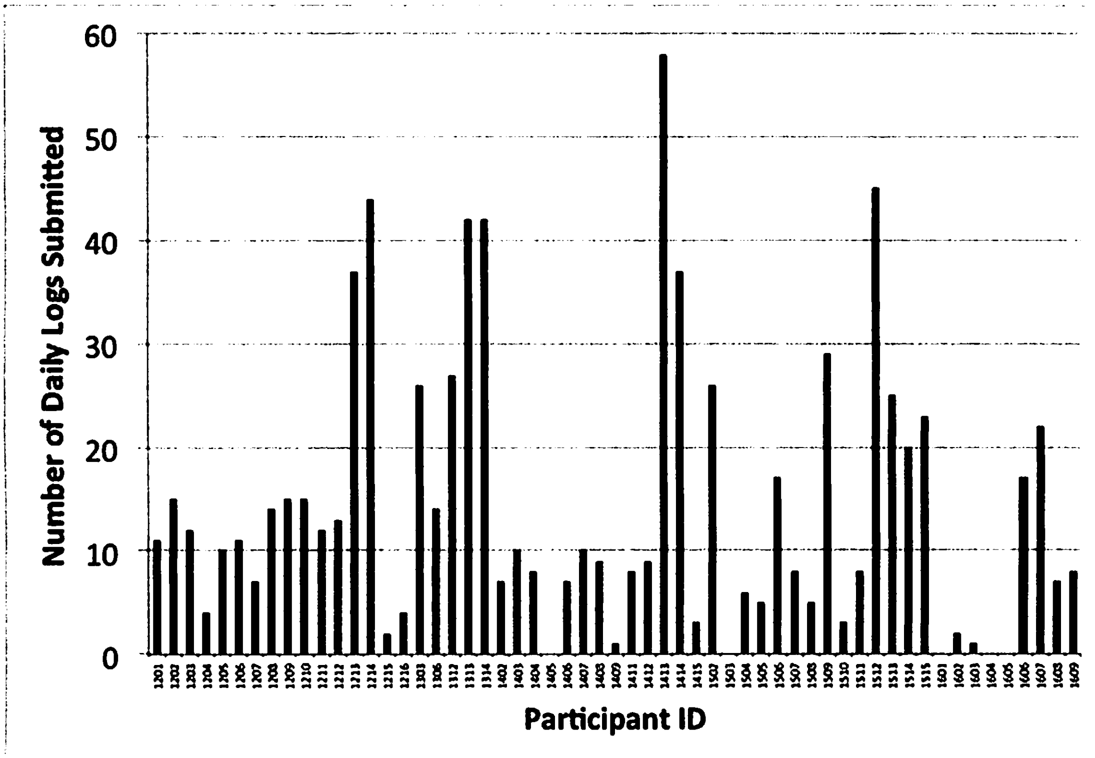

Figure 1. Number of daily logs by participant ID, Dam Neck participants. A total of 821 logs were submitted for these participants.

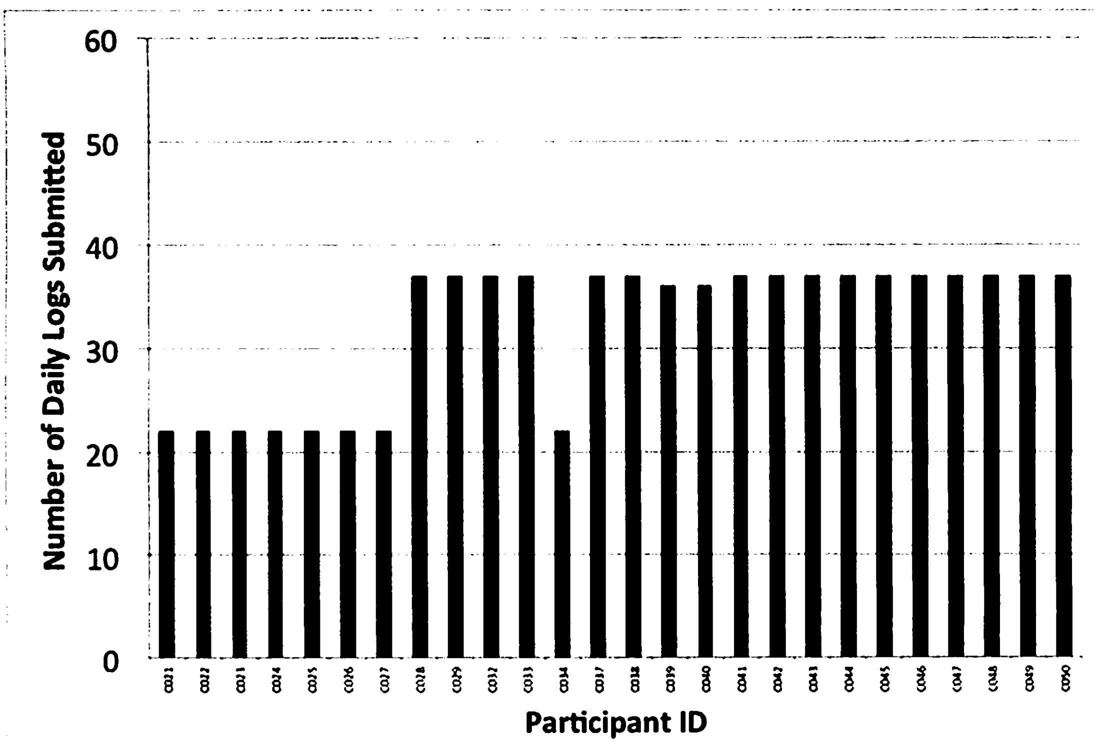

Figure 2. Number of daily logs by participant ID, Stennis participants. A total of 877 logs were submitted for these participants.

Twelve Dam Neck participants reported medical issues in the daily logs. Participants 1201, 1208, 1209, 1210, 1211, and 1413 reported an unspecified medical issues, generally associated with reported pain. Participant 1205 reported knee pain on 4 and 13 February 2014, but no pain in subsequent reports. Participant 1213 reported a visit to the Chiropractor on 7 November 2013, and no further reports. Participant 1507 reported an unspecified medical issue on 13 November 2013. Participant 1512 reported a series of increasing back pain beginning 7 October 2013. By 24 October 2013, reported pain including shoulder and bicep pain. By November 2013, the pain spectrum included groin pain. By March 2014, the participant was recovering from shoulder surgery. This is reflected in his daily log pain scores (Figure 1). These generally increased throughout October and November 2013 before surgery in January of 2014. Participant 1513 reported hip pain on 18 October 2014, and wrist pain on the 28–29 October 2014. His self-reported pain rating for the wrist pain was 5, suggesting substantial pain.

Pain ratings by Dam Neck participants ranged from 0 to 7. There was no association of pain with time in service or age of participant (Figure 4). Stennis participants reported no pain ratings on any daily log.

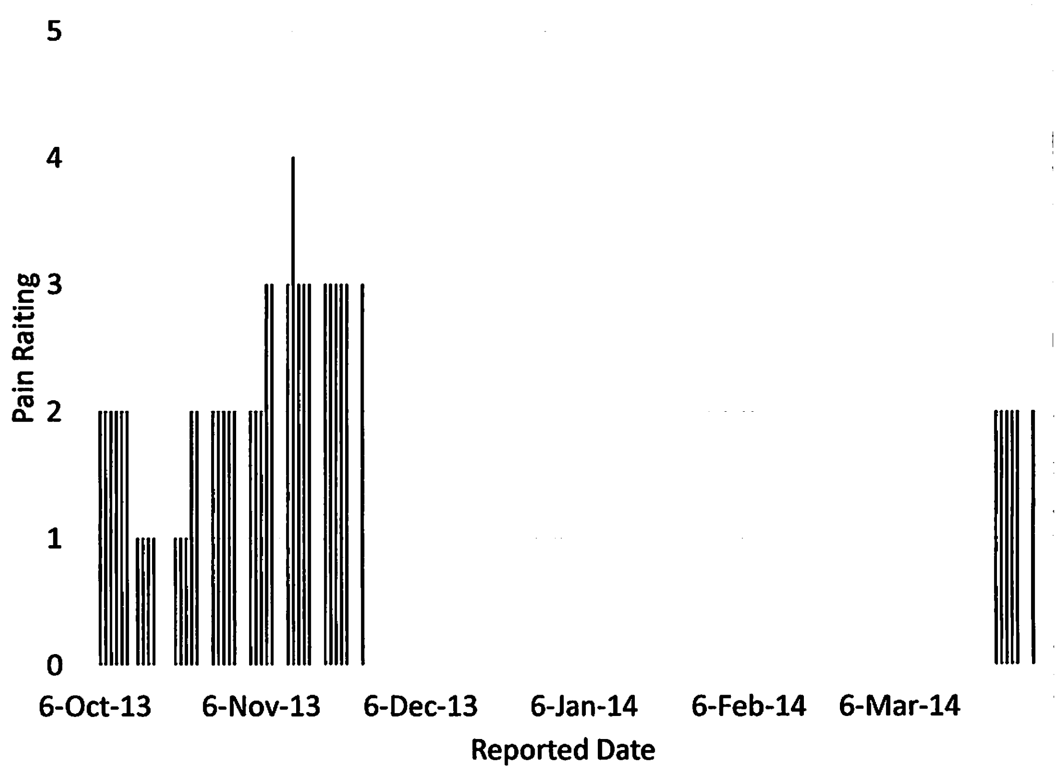

Figure 3. Pain scores for participant ID, 1512. This participant submitted 44 daily logs, the second highest number of daily logs for any participant.

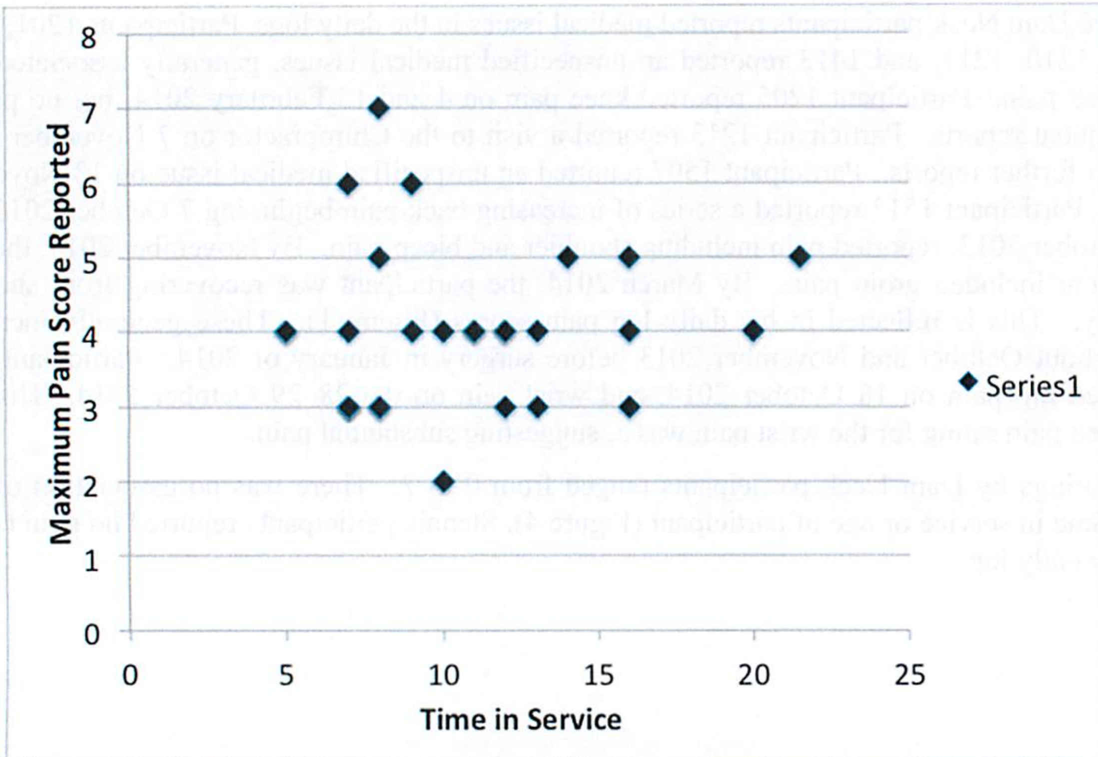

Figure 4. Maximum reported pain score by time in service. There was no association of pain with time in service or age of participant.

Just under half of the Dam Neck daily logs (44%) and all of the Stennis logs (100%) reported PT activities (Figure 5). Maritime activities and NavRun activities were reported by 60% and 23% of the Dam Neck daily logs, respectively. No boating activities were reported in the Stennis logs. Ground ops and air ops were reported in about one tenth of the Dam Neck daily logs. Live fire exercises were reported by 7% of the Dam Neck daily logs, and no daily log reported the use of grenades or demolition activities.

Figure 6 reports the daily activity logs by type of marine vehicle, only for the Dam Neck cohort. HSAC activities were the most common with 53% of logs reporting activity. MRV and Zodiac activities are reported by 10-15% of the daily logs, and other vehicle types are rarely reported (1%). Typical activities (Figure 7) include Stalk/Alongside (27%), OTB (14%), Clear&Pull (7%), with HALO (3%), Boat Drop (2%), and HAHO (1%) operations rarely reported. Hard parachute opening and hard landing were reported by five of the daily logs respectively, and one downwind landing was reported.

Ground mobility operations were occasionally reported by the Dam Neck cohort, with 10% of the 1500 series daily logs reporting. An unspecified ground vehicle was reported as 22% of the ground operations, HMMWV and JNTV operations were similar at 6%. The ground composition was most frequently reported as Other, but sand and gravel was nearly as frequently reported.

Weapons usage for the Dam Neck cohort included rifle, pistol, GMG, MK48, M240 and 50 cal. at rates below 20% (Figure 8). Approximately 6% of logs reported pistol use and 7% reported rifle use. Rifle use and pistol use were well correlated; the correlation coefficient of rifle activity with pistol activity was 92%. Rifle and handgun use correlated well with body armor use and ear protection use (63%). Body armor and ear protection use was 100% correlated.

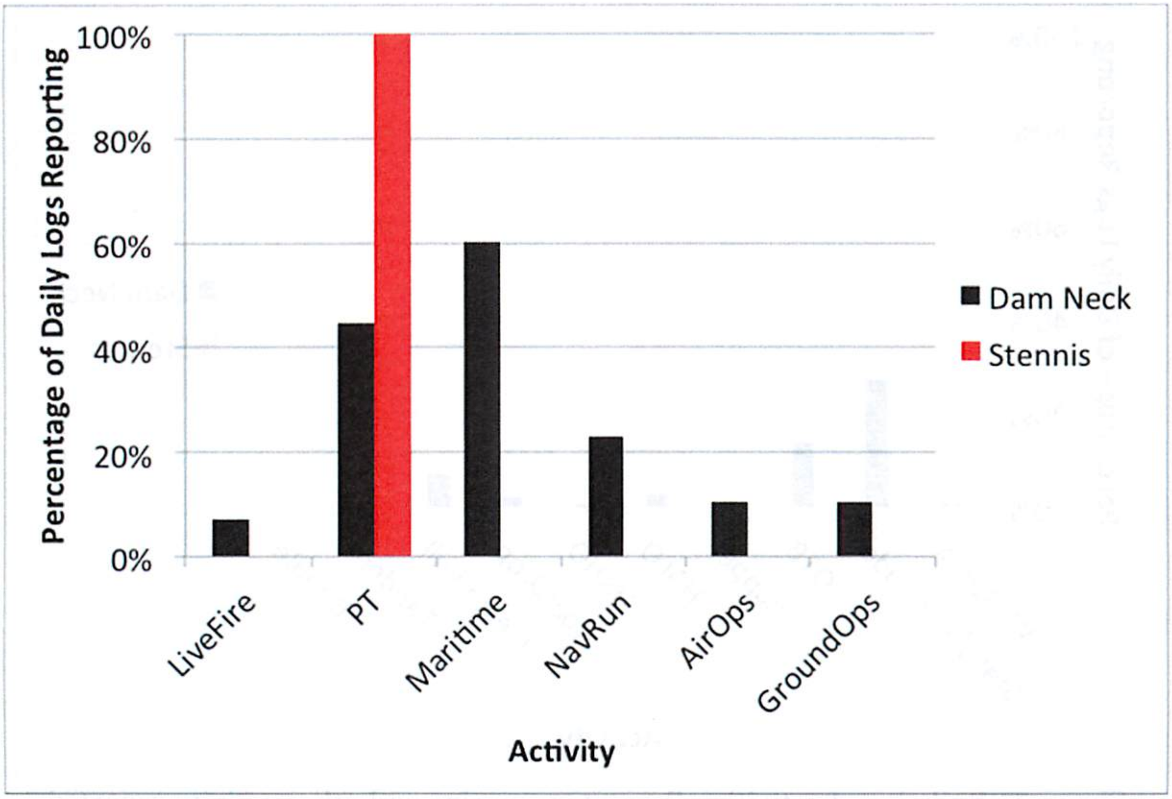

Figure 5. Daily log of activities. Percentage reporting given activity.

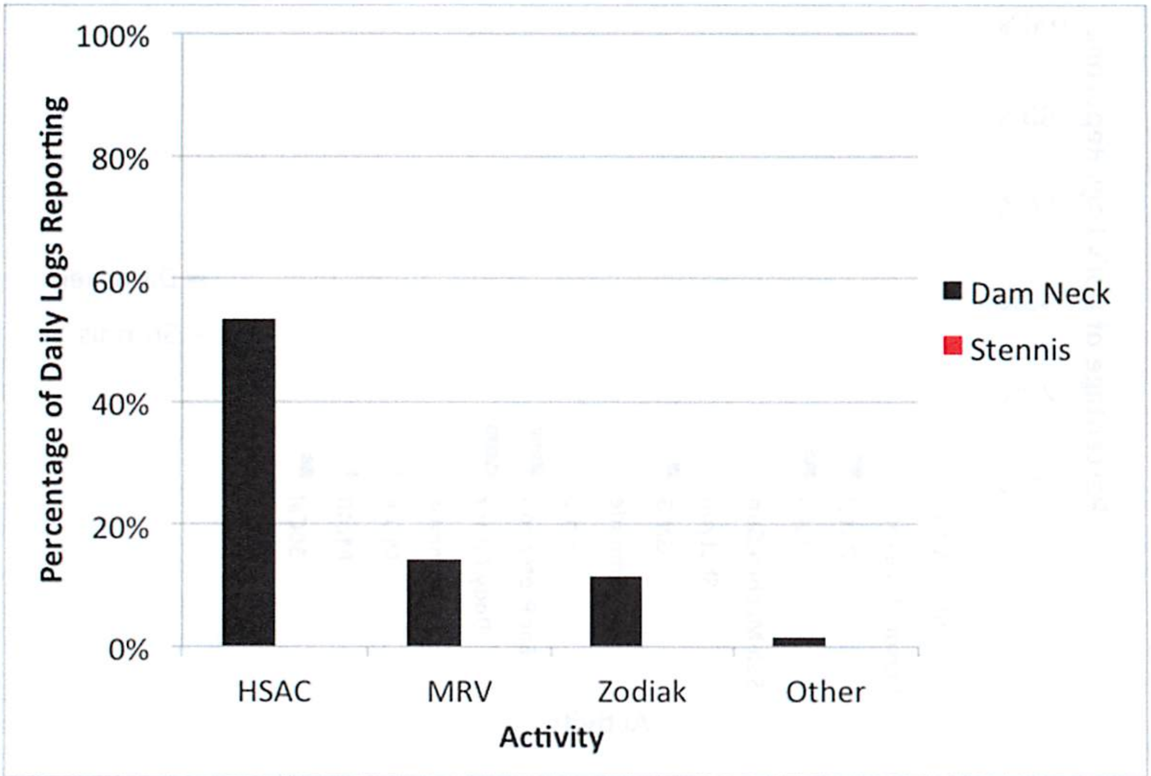

Figure 6. Daily log of activities. Percentage activity in given craft.

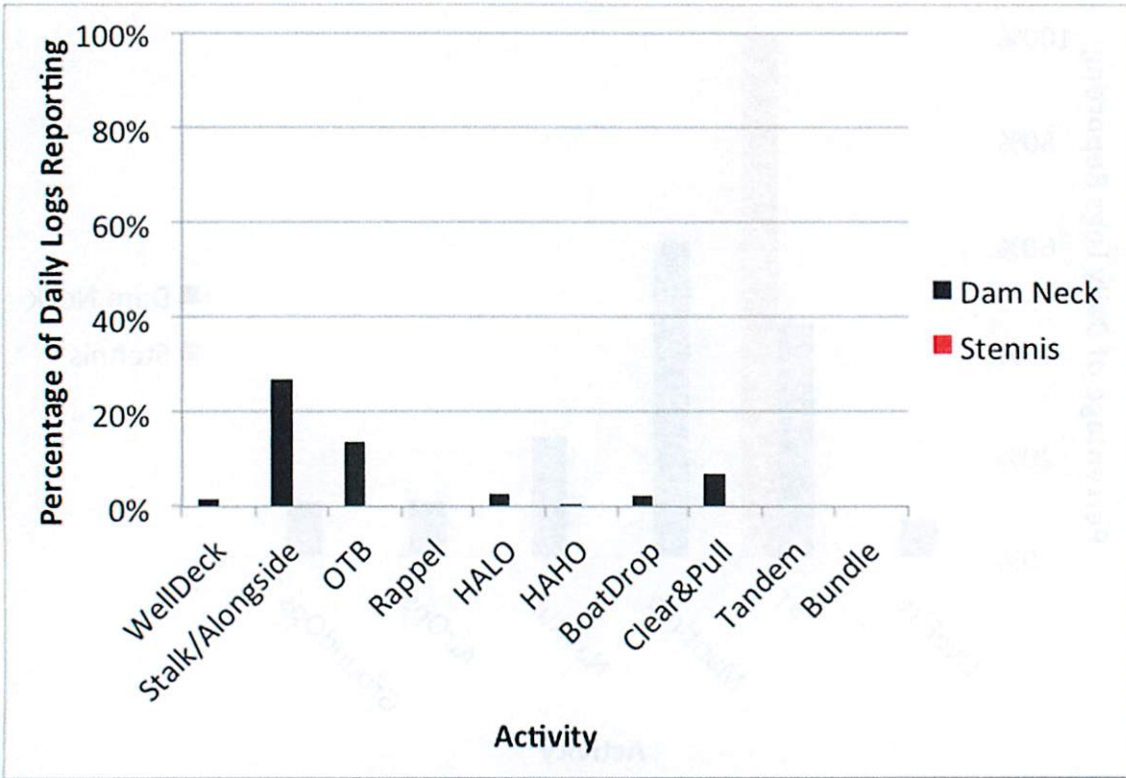

Figure 7. Daily log of activities. Percentage marine and other activity reported.

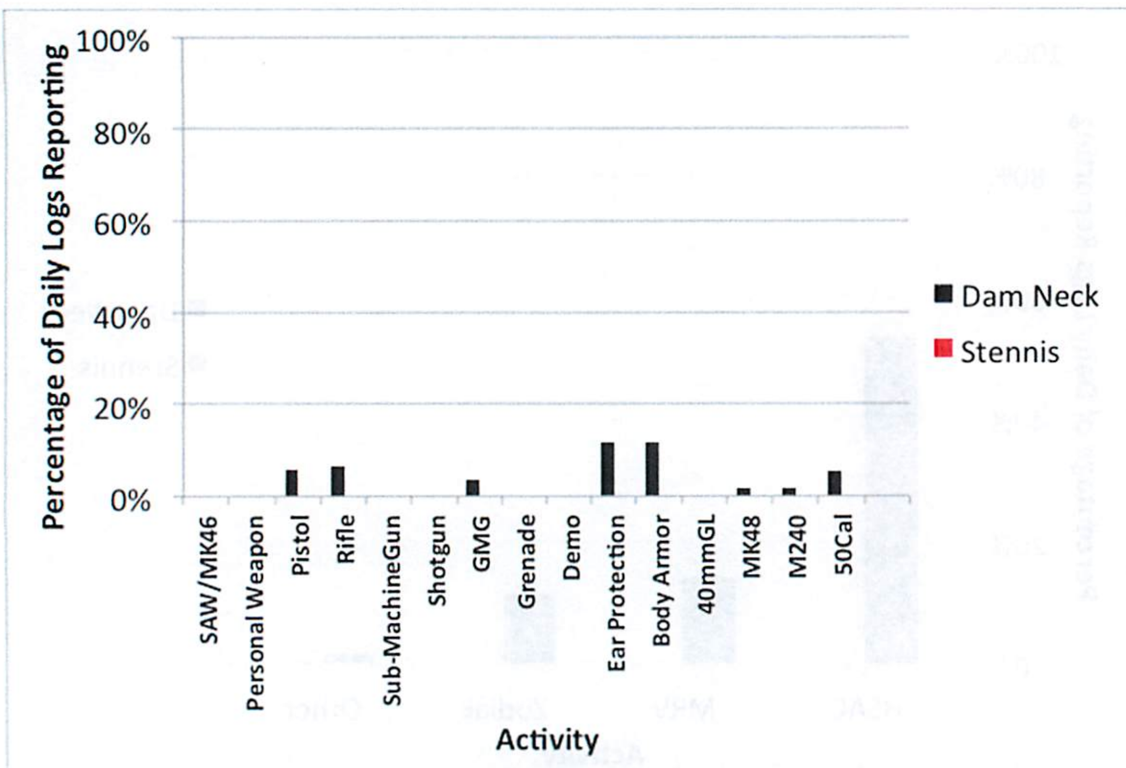

Figure 8. Daily log of activities. Percentage weapons activity reported.

3 MEDICAL RESULTS

Pre-test medical information (Table 3) shows that both the Dam Neck participants and the Stennis participants include numerous experienced operators, including substantial experience in high speed boats. Several participants reported tens of thousands of hours of estimated boat use, and several participants have over a decade in NSW. Preexisting orthopaedic injuries were common (18 Dam Neck participants, 5 Stennis participants). Preexisting TBI with and without loss of consciousness was less common (11 Dam Neck participants, 1 Stennis participant).

Table 3. Participant Preexisting Medical Information for Dam Neck Participants

ID	Age	Time In Service (years)	Est. Boats (hrs)	Deployments	Comments
1201	30	7	1000	3	None
1202	45	21.5	5000	7	Shoulder separation and surgery, recurrent otitis media, right ear
1203	35	16	2886	7	Head injury, headaches, Dec 2012 (Mace 27/30)
1204	31	13	4000	7	Left clavicle fx
1205	26	8	5000	5	None
1206	25	7	10000	4	Various orthopaedic injuries
1207	36	12	14000	8	Various orthopaedic injuries, mTBI as teenager
1208	40	16	24000	7	Shoulder dislocation, hand injury
1209	34	8	1000	4	None
1210	30	11	9500	6	Various orthopaedic injuries, surgery
1211	26	7	NA	5	None
1212	23	5	800	1	Struck head, stitches, no apparent change of mentation or other symptom
1213	34	9	2000	2	2006 scalp laceration, brief LOC, Various orthopaedic injuries
1214	31	9	20000	3	Head injury at 15, brief LOC, Various orthopaedic injuries
1215	31	9	3000	6	Various orthopaedic injuries
1216	28	10	2000	3	Various orthopaedic injuries
1303	31	13	24000	9	None
1306	34	9.5	10000	7	None
1312	32	3	2000	2	Scalp laceration with no TBI
1313	25	7	20000	4	2010 TBI with LOC
1314	32	12	10000	4	None
1402	35	17	1800	6	TBI from motor vehicle collision, amnesic
1403	31	13	8000	8	None
1404	32	11	3000	5	None

ID	Age	Time In Service (years)	Est. Boats (hrs)	Deployments	Comments
1405	29	10	10000	4	Scalp laceration with no TBI
1406	30	12	5600	4	Scalp laceration with no TBI
1407	27	8	4000	4	None
1408	30	11	9600	6	Orbital blowout fx
1409	25	8	6000	3	TM rupture from blunt trauma, no TBI
1411	35	13	7000	4	None
1412	27	5	2000	2	None
1413	32	11	5200	4	None
1414	30	6.5	15000	2	None
1415	35	3	4000	2	None
1502	32	14	10,000	7	None
1503	35	13	1000's	7	None
1504	34	14	10900	6	None
1505	29	10	8000	5	Blunt trauma to head, 2006, various orthopaedic injuries
1506	37	12	8000+	5	None
1507	32	10	1500	5	Headaches, various orthopaedic injuries
1508	32	12	1200	6	Headaches, ringing in ears
1509	26	6	290	3	None
1510	39	5	2000	4	Shoulder injury from parachute jump, 2010
1511	32	5	900	3	None
1512	28	7	5200	2	Hearing loss, ringing in ears, 2012
1513	27	8	1000's	3	No DASHR data, Blunt trauma from hockey puck, 2008, various orthopaedic injuries
1514	23	5	1000's	1	None
1515	28	4	50	2	None
1601	37	19	10000+	9	Hearing lost right ear, shoulder pain
1602	30	8	8000	2	None
1603	31	12	2000+	6	Various orthopedic injuries, atypical chest pain
1604	40	12	9000	8	2006, 2008, 2012 reported mTB, 2007 TBI with MACE
1605	31	13.5	11000	11	None
1606	34	16	2000+	8	2006 foreign body in left eye
1607	39	20	10000+	9	1987 TBI, blowout fx, hearing difficulty
1608	35	15	21168	7	2012 TBI, 2012 neck pain
1609	41	22	11520	15	2000, 2004, 2009-2013 multiple TBI

Table 4. Participant Preexisting Medical Information for Stennis Participants

ID	Age	Time In Service (years)	Deployments	Comments
C021	39	11	2	None
C022	26	4.5	1	None
C023	34	10	4	Tinnitus
C024	25	6	1	Lumbar discectomy
C025	NA	NA	NA	None
C026	25	6	3	None
C027	38	17	12	2013 TBI from MVA, lumbar pain, complex history of sinusitis
C028	23	4	1	None
C029	33	15.5	6	Labrum repair
C032	26	7	3	None
C033	24	5	3	None
C034	22	4	2	None
C037	26	4.5	1	None
C038	27	2	0	None
C039	25	6	2	None
C040	26	1.25	0	None
C041	31	3.5	0	None
C042	22	3	1	None
C043	NA	NA	NA	NA
C044	22	2	0	None
C045	25	1.75	0	None
C046	24	6	3	Elbow injury
C047	23	1.5	0	None
C048	21	1.75	0	None
C049	31	13	3	Various orthopaedic injuries
C050	23	1.8	0	None

Participant end of study data (Table 5 for Dam Neck participants, Table 6 for Stennis participants) includes numerous acute sprains and strains and other relatively minor musculoskeletal injuries (29 Dam Neck participants, 4 Stennis participants), fractures (4 Dam Neck participants, 0 Stennis participants). There was one diagnosed mTBI during the study period (1503). There were a number of lumbar spinal injuries of various severities diagnosed during the study period (12 Dam Neck participants, 1 Stennis participant) including a disk herniation (1605).

Table 5. Participant End-of-study Medical Information for Dam Neck Participants

ID	Age	Comments
1201	30	None
1202	45	Foot fx (not on duty)
1203	35	None
1204	31	Medial condyle contusion
1205	26	Shoulder tendonitis
1206	25	Knee quadriceps strain, shoulder ac joint pain
1207	36	Abdominal hernia-surgically repaired
1208	40	None
1209	34	Rotator cuff strain
1210	30	None
1211	26	Achillies inflamation
1212	23	None
1213	34	None
1214	31	None
1215	31	Foot contusion, dorsal
1216	28	None
1303	31	Neck sprain
1306	34	None
1312	32	None
1313	25	Metacarpal fx
1314	32	None
1402	35	None
1403	31	Treatment for residual existing condition
1404	32	Lumbar facet joint sprain, deg 1, Gastrocnemius, soleus strain Coracoacromial strain, deg 3 (not on duty)
1405	29	Shoulder impingement, Shoulder rotator cuff strain, posterior capsule sprain
1406	30	Elbow lateral epicondylitis
1407	27	Scapulo-thoracic nerve inflammation, back spasm, hip piriformis strain, hip ilio-tibial band syndrome
1408	30	None
1409	25	Tibia fx (off duty)
1411	35	Lumbar facet syndrome

ID	Age	Comments
1412	27	None
1413	32	Ankle strain/sprain, deg 2, hand contusion
1414	30	Elbow contusion/olecranon bursa, knee tendonitis, peroneal strain
1415	35	None
1502	32	Cervical C5-C7 impingement, Thoracic left facet joint sprain, deg 1, rotator cuff tendonitis/strain
1503	35	Concussion/mTBI in Sept/Oct 2013, no details, received stellate ganglion block for anxiety, Thoracic facet joint sprain, deg 1, Talus fx
1504	34	None
1505	29	Lumbar nerve impingement, knee strain, deg 1
1506	37	None
1507	32	Lumbar facet joint sprain, deg 1, bicep tendonitis
1508	32	Ankle ligament sprain
1509	26	Patella femoral syndrome
1510	39	Thoracic facet joint sprain, left ear discomfort, ring finger sprain/strain
1511	32	Lumbar sciatica, ulnar nerve entrapment with sensory loss
1512	28	Hip strain, deg 1, shoulder tendonitis, shoulder strain, deg 2
1513	27	Lumbar paraspinal strain, wrist strain, deg 1
1514	23	None
1515	28	None
1601	37	None
1602	30	Elbow lateral epicondylitis
1603	31	AC sprain, deg 1, shoulder impingement, meniscus lateral posterior horn tear
1604	40	Elbow epicondylitis/lateral, Shoulder sprain, Deg 1
1605	31	Lumbar disc herniation (L2-L3)
1606	34	Elbow epicondylitis/lateral
1607	39	Unspecified sleep clinic
1608	35	Lumbar paraspinal strain, deg 1
1609	41	None

Table 6. Participant End-of-study Medical Information for Stennis Participants

ID	Age	Comments
C021	39	None
C022	26	Unspecified orthopaedic injury
C023	34	Unspecified orthopaedic injury
C024	25	Unspecified back injury
C025	NA	None
C026	25	None
C027	38	None
C028	23	None
C029	33	None
C032	26	None
C033	24	Unspecified peripheral neurology, right shoulder pain
C034	22	None
C037	26	None
C038	27	None
C039	25	None
C040	26	None
C041	31	None
C042	22	None
C043	NA	None
C044	22	None
C045	25	None
C046	24	None
C047	23	None
C048	21	None
C049	31	None
C050	23	None

4 BALANCE, VESTIBULAR ASSESSMENT RESULTS

4.1 Field Balance Testing – BESS

Full field balance testing (BESS) at study initiation, midpoint, and end was performed on 50/57 Dam Neck participants and 17/26 in the 1500 series (Table 7, Table 8, and Table 9). The remaining participants had orthopaedic or other injuries that prevented balance assessments or were not available for one or more of the BESS assessments. As expected from foundational studies of BESS, the median firm surface scores were generally better (lower scores are better) than the median foam surface total scores (Figure 9). Similar results were found for participants at the beginning of study, mid-study, and end-of-study assessments.

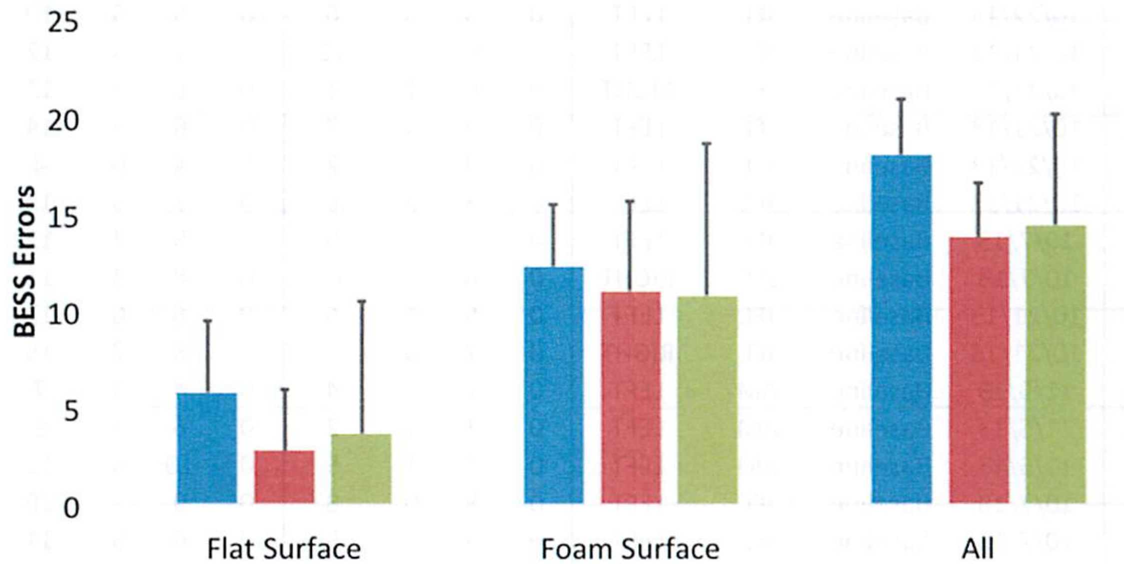

Figure 9. BESS foam surface vs. firm surface totals, Dam Neck participants' baseline to 12 months. As expected, statistically significant differences (p<0.01) were found between rigid surface and foam surface totals for all study periods.

General linear model statistical analyses of the test data shown in Table 7, Table 8, and Table 9 found that the observer was a statistically significant factor across the dataset for BESS total ($p=0.04$) and sub-tests ($p=0.0$). As a group, there were no statistical differences found for dominant foot or between pre-study, mid-study and post-study BESS total, firm surface or foam surface results ($p=0.4$).

Table 7. Baseline BESS Field Balance Test Results, Dam Neck and Stennis Participants
(DL=Double leg stance, SL=Single leg stance, T=Tandem stance, NP=Not present, IN=Injured)

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS
					DL	SL	T	Total	DL	SL	T	Total	Total
1201	10/21/13	Baseline	JFL	RIGHT	0	2	1	3	0	7	5	12	15
1202	10/21/13	Baseline	JFL	LEFT	0	5	3	8	0	7	7	14	22
1203	10/21/13	Baseline	JFL	LEFT	0	5	1	6	0	6	4	10	16
1204	10/21/13	Baseline	JFL	LEFT	0	4	1	5	0	6	5	11	16
1205	10/21/13	Baseline	JFL	LEFT	0	0	1	1	0	4	3	7	8
1206	10/22/13	Baseline	JFL	LEFT	0	2	3	5	0	6	6	12	17
1207	10/22/13	Baseline	JFL	LEFT	0	3	3	6	0	5	5	10	16
1208	10/21/13	Baseline	JFL	LEFT	0	6	5	11	0	7	5	12	23
1209	10/21/13	Baseline	JFL	RIGHT	0	0	1	1	0	6	7	13	14
1210	10/21/13	Baseline	JFL	LEFT	0	3	4	7	0	8	6	14	21
1211	10/21/13	Baseline	JFL	LEFT	0	2	0	2	0	4	0	4	6
1212	10/21/13	Baseline	JFL	LEFT	0	3	3	6	0	7	6	13	19
1213	10/7/13	Baseline	JFL	LEFT	0	7	2	9	0	5	7	12	21
1214	10/7/13	Baseline	JFL	RIGHT	0	6	4	10	0	8	3	11	21
1215	10/21/13	Baseline	JFL	LEFT	0	5	1	6	0	6	6	12	18
1216	10/21/13	Baseline	JFL	RIGHT	0	7	0	7	0	8	7	15	22
1303	11/5/13	Baseline	AM	LEFT	0	2	2	4	0	4	3	7	11
1306	11/5/13	Baseline	AM	LEFT	0	1	1	2	0	6	3	9	11
1312	11/5/13	Baseline	AM	LEFT	0	4	1	5	0	10	5	15	20
1313	10/7/13	Baseline	JFL	LEFT	0	8	0	8	0	9	7	16	24
1314	10/7/13	Baseline	JFL	LEFT	0	4	1	5	0	6	5	11	16
1402	11/7/13	Baseline	AM	LEFT	0	7	3	10	1	10	9	20	30
1403	11/6/13	Baseline	AM	LEFT	0	10	4	14	0	10	10	20	34
1404	11/6/13	Baseline	AM	LEFT	0	2	1	3	0	7	7	14	17
1405	11/6/13	Baseline	AM	LEFT	0	5	2	7	0	10	8	18	25
1406	11/6/13	Baseline	AM	LEFT	0	1	2	3	0	9	5	14	17
1407	11/6/13	Baseline	AM	LEFT	0	4	1	5	0	5	6	11	16
1408	11/6/13	Baseline	AM	LEFT	0	4	1	5	2	8	8	18	23
1409	11/6/13	Baseline	AM	LEFT	0	10	7	17	0	10	10	20	37
1411	11/6/13	Baseline	AM	LEFT	0	4	2	6	0	5	4	9	15
1412	11/5/13	Baseline	AM	LEFT	0	2	1	3	0	5	4	9	12
1413	10/7/13	Baseline	JFL	LEFT	0	5	0	5	0	6	5	11	16
1414	10/7/13	Baseline	JFL	LEFT	0	1	3	4	0	5	5	10	14
1415	11/6/13	Baseline	AM	LEFT	0	5	6	11	0	10	10	20	31
1502	10/7/13	Baseline	JFL	LEFT	0	1	1	2	1	5	4	10	12
1504	10/7/13	Baseline	JFL	LEFT	0	3	1	4	0	7	4	11	15
1505	10/21/13	Baseline	JFL	LEFT	0	3	1	4	0	7	7	14	18
1506	10/7/13	Baseline	JFL	LEFT	0	5	4	9	0	6	6	12	21
1507	10/7/13	Baseline	JFL	LEFT	0	1	1	2	0	4	4	8	10
1508	10/7/13	Baseline	JFL	LEFT	0	6	5	11	0	6	6	12	23

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS
					DL	SL	T	Total	DL	SL	T	Total	Total
1509	10/7/13	Baseline	JFL	LEFT	0	6	2	8	0	7	7	14	22
1510	10/7/13	Baseline	JFL	LEFT	0	1	2	3	0	4	3	7	10
1511	10/7/13	Baseline	JFL	LEFT	0	3	0	3	0	5	7	12	15
1512	10/7/13	Baseline	JFL	LEFT	0	5	6	11	0	10	8	18	29
1513	10/7/13	Baseline	JFL	LEFT	0	1	1	2	1	9	3	13	15
1514	10/7/13	Baseline	JFL	LEFT	0	4	0	4	0	7	5	12	16
1515	10/7/13	Baseline	JFL	LEFT	0	9	0	9	0	7	7	14	23
1601	10/8/13	Baseline	JFL	RIGHT	0	2	1	3	0	7	3	10	13
1602	10/7/13	Baseline	JFL	LEFT	0	3	0	3	0	6	5	11	14
1603	10/7/13	Baseline	JFL	LEFT	0	1	0	1	0	6	5	11	12
1604	10/7/13	Baseline	JFL	LEFT	0	4	7	11	3	10	6	19	30
1605	10/7/13	Baseline	JFL	LEFT	0	1	0	1	0	6	2	8	9
1606	10/7/13	Baseline	JFL	LEFT	0	3	2	5	0	9	5	14	19
1607	10/7/13	Baseline	JFL	LEFT	0	3	0	3	0	6	6	12	15
1608	10/21/13	Baseline	JFL	LEFT	0	4	2	6	0	5	3	8	14
1609	10/7/13	Baseline	JFL	LEFT	0	5	3	8	0	8	5	13	21
C021	4/15/14	Baseline	EP	RIGHT	0	4	2	6	0	7	4	11	17
C022	4/15/14	Baseline	EP	LEFT	0	4	1	5	0	4	3	7	12
C023	4/15/14	Baseline	EP	LEFT	0	4	1	5	0	7	6	13	18
C024	4/15/14	Baseline	EP	RIGHT	0	2	0	2	0	9	2	11	13
C025	4/15/14	Baseline	NP										
C026	4/15/14	Baseline	EP	LEFT	0	2	0	2	2	7	8	17	19
C027	4/15/14	Baseline	EP	LEFT	0	7	5	12	0	10	10	20	32
C028	12/11/13	Baseline	JFL	LEFT	0	2	0	2	0	7	4	11	13
C029	12/10/13	Baseline	JFL	LEFT	0	5	2	7	0	8	4	12	19
C032	12/10/13	Baseline	JFL	LEFT	0	2	4	6	0	4	4	8	14
C033	12/11/13	Baseline	JFL	LEFT	0	2	2	4	0	8	5	13	17
C034	4/15/14	Baseline	NP										
C037	12/10/13	Baseline	JFL	LEFT	0	3	2	5	0	7	5	12	17
C038	12/11/13	Baseline	JFL	LEFT	0	4	2	6	0	8	6	14	20
C039	12/11/13	Baseline	JFL	RIGHT	0	IN	3	3	0	IN	6	6	9
C040	12/10/13	Baseline	JFL	LEFT	0	8	1	9	0	9	7	16	25
C041	12/11/13	Baseline	JFL	RIGHT	0	5	1	6	0	9	6	15	21
C042	12/11/13	Baseline	JFL	LEFT	0	5	3	8	0	9	4	13	21
C043	12/11/13	Baseline	JFL	LEFT	0	2	0	2	0	6	4	10	12
C044	12/10/13	Baseline	JFL	LEFT	0	2	2	4	0	7	5	12	16
C045	12/11/13	Baseline	JFL	LEFT	0	4	1	5	0	7	5	12	17
C046	12/10/13	Baseline	JFL	LEFT	0	4	2	6	0	8	6	14	20
C047	12/11/13	Baseline	JFL	LEFT	0	1	1	2	0	5	5	10	12
C048	12/11/13	Baseline	JFL	LEFT	0	4	3	7	0	9	6	15	22
C049	12/11/13	Baseline	JFL	LEFT	0	4	0	4	0	6	5	11	15
C050	12/10/13	Baseline	JFL	LEFT	0	1	0	1	0	6	5	11	12

Table 8. Mid-Study BESS Field Balance Test Results, Dam Neck and Stennis Participants (DL=Double leg stance, SL=Single leg stance, T=Tandem stance, NP=Not present, IN=Injured)

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS Total
					DL	SL	T	Total	DL	SL	T	Total	
1201	4/3/14	3 Month	EP	RIGHT	0	2	0	2	0	6	4	10	12
1202	4/3/14	3 Month	EP	LEFT	0	4	0	4	0	6	7	13	17
1203	4/1/14	3 Month	JFL	LEFT	0	5	2	7	0	6	4	10	17
1204	4/2/14	3 Month	EP	LEFT	0	1	3	4	1	6	8	15	19
1205	4/2/14	3 Month	EP	LEFT	0	4	2	6	0	8	2	10	16
1206	4/3/14	3 Month	EP	LEFT	0	5	3	8	0	7	6	13	21
1207	4/29/14	3 Month	JB	LEFT	0	3	0	3	0	10	5	15	18
1208	4/4/14	3 Month	EP	LEFT	0	10	6	16	3	8	7	18	34
1209	4/4/14	3 Month	EP	RIGHT	0	1	5	6	0	8	7	15	21
1210	3/31/14	3 Month	JFL	LEFT	0	7	3	10	0	7	7	14	24
1211	4/4/14	3 Month	EP	LEFT	0	0	0	0	0	1	0	1	1
1212	4/4/14	3 Month	EP	LEFT	0	1	0	1	0	7	5	12	13
1213	4/2/14	3 Month	EP	LEFT	0	4	3	7	0	9	9	18	25
1214	4/2/14	3 Month	EP	RIGHT	0	9	8	17	0	10	10	20	37
1215	4/2/14	3 Month	EP	LEFT	0	3	2	5	0	6	5	11	16
1216	4/29/14	3 Month	JB	RIGHT	0	1	0	1	0	4	2	6	7
1303		3 Month	NP										
1306	2/18/14	3 Month	JFL	LEFT	0	3	1	4	0	6	5	11	15
1312	2/18/14	3 Month	JFL	LEFT	0	4	2	6	0	7	7	14	20
1313	2/18/14	3 Month	JFL	LEFT	0	5	2	7	0	6	5	11	18
1314	2/18/14	3 Month	JFL	LEFT	0	5	1	6	0	7	3	10	16
1402	3/31/14	3 Month	JFL	LEFT	0	2	0	2	0	6	6	12	14
1403	4/3/14	3 Month	EP	LEFT	0	3	0	3	0	10	9	19	22
1404	4/3/14	3 Month	EP	LEFT	0	7	2	9	0	9	3	12	21
1405	4/1/14	3 Month	JFL	LEFT	0	5	2	7	3	8	6	17	24
1406	3/31/14	3 Month	JFL	LEFT	0	2	2	4	0	8	7	15	19
1407	4/1/14	3 Month	JFL	LEFT	0	4	0	4	1	6	5	12	16
1408	4/1/14	3 Month	JFL	LEFT	0	4	2	6	1	8	6	15	21
1409	NA	3 Month	JB	IN									
1411	3/31/14	3 Month	JFL	LEFT	0	3	2	5	0	7	5	12	17
1412	4/1/14	3 Month	JFL	LEFT	0	3	2	5	0	6	5	11	16
1413	3/31/14	3 Month	JFL	LEFT	0	3	0	3	0	6	4	10	13
1414	4/3/14	3 Month	EP	LEFT	0	0	0	0	0	7	5	12	12
1415	4/4/14	3 Month	EP	LEFT	0	1	0	1	0	10	9	19	20
1502	4/2/14	3 Month	EP	LEFT	0	2	4	6	0	7	4	11	17
1504	4/2/14	3 Month	EP	LEFT	0	5	4	9	4	6	8	18	27
1505	4/1/14	3 Month	JFL	LEFT	0	2	2	4	0	5	3	8	12
1506	4/2/14	3 Month	EP	LEFT	0	6	2	8	0	10	0	10	18
1507	4/4/14	3 Month	EP	LEFT	0	1	0	1	0	3	7	10	11
1508	4/29/14	3 Month	EP/JB	LEFT	0	2	3	5	0	4	3	7	12
1509	4/2/14	3 Month	EP	LEFT	0	1	3	4	0	8	7	15	19

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS
					DL	SL	T	Total	DL	SL	T	Total	Total
1510	4/2/14	3 Month	EP	LEFT	0	0	1	1	0	6	0	6	7
1511	4/2/14	3 Month	EP	LEFT	0	5	2	7	0	9	6	15	22
1512	4/2/14	3 Month	EP	LEFT	0	0	0	0	0	10	3	13	13
1513	4/2/14	3 Month	EP	LEFT	0	0	0	0	0	6	8	14	14
1514	4/2/14	3 Month	EP	LEFT	0	0	0	0	0	5	4	9	9
1515	3/31/14	3 Month	JFL	LEFT	0	6	1	7	0	6	6	12	19
1601	4/3/14	3 Month	EP	RIGHT	0	0	0	0	0	10	3	13	13
1602	4/2/14	3 Month	EP	LEFT	0	2	1	3	0	6	0	6	9
1603	4/29/14	3 Month	JB	LEFT	0	0	0	0	0	2	10	12	12
1604	4/3/14	3 Month	EP	LEFT	0	0	3	3	0	6	5	11	14
1605	4/3/14	3 Month	EP	LEFT	0	3	0	3	0	6	2	8	11
1606	3/31/14	3 Month	JFL	LEFT	0	4	1	5	0	8	5	13	18
1607	4/1/14	3 Month	JFL	LEFT	0	3	2	5	1	5	5	11	16
1608	4/3/14	3 Month	EP	LEFT	0	3	2	5	0	9	6	15	20
1609	4/4/14	3 Month	EP	LEFT	0	7	4	11	0	7	4	11	22
C021	7/15/14	3 Month	NP										
C022	7/16/14	3 Month	EP	LEFT	0	5	0	5	0	10	9	19	24
C023	7/15/14	3 Month	EP	LEFT	0	6	3	9	0	7	9	16	25
C024	7/16/14	3 Month	EP	RIGHT	0		0	0	0		10	10	10
C025	7/15/14	3 Month	EP	LEFT	0	9	0	9	0	10	6	16	25
C026	7/15/14	3 Month	EP	LEFT	0	6	7	13	0	9	7	16	29
C027	7/15/14	3 Month	NP										
C028	4/15/14	3 Month	EP	LEFT	0	2	0	2	1	10	6	17	19
C029	4/15/14	3 Month	EP	LEFT	0	6	0	6	0	9	4	13	19
C032	4/15/14	3 Month	EP	LEFT	0	0	1	1	0	4	2	6	7
C033	4/15/14	3 Month	EP	LEFT	0	2	0	2	0	6	0	6	8
C034	7/16/14	3 Month	EP	LEFT	0	2	2	4	0	10	2	12	16
C037	4/15/14	3 Month	EP	LEFT	0	1	2	3	0	8	10	18	21
C038	4/15/14	3 Month	EP	LEFT	0	6	0	6	0	10	8	18	24
C039	4/15/14	3 Month	EP	RIGHT	0	3	4	7	0	6	7	13	20
C040	4/15/14	3 Month	EP	LEFT	0	4	1	5	0	8	7	15	20
C041	7/15/14	3 Month	EP	RIGHT	0	0	0	0	0	9	6	15	15
C042	4/15/14	3 Month	EP	LEFT	0	6	0	6	0	8	4	12	18
C043	4/15/14	3 Month	EP	LEFT	0	3	2	5	0	7	5	12	17
C044	4/15/14	3 Month	EP	LEFT	0	0	2	2	0	8	4	12	14
C045	4/15/14	3 Month	NP										
C046	4/15/14	3 Month	NP										
C047	4/15/14	3 Month	EP	LEFT	0	2	0	2	0	5	5	10	12
C048	4/15/14	3 Month	NP										
C049	4/15/14	3 Month	EP	LEFT	0	5	0	5	0	7	4	11	16
C050	4/15/14	3 Month	EP	LEFT	0	1	0	1	0	5	3	8	9

Table 9. End-of-Study BESS Field Balance Test Results, Dam Neck and Stennis Participants

(DL=Double leg stance, SL=Single leg stance, T=Tandem stance)

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS
					DL	SL	T	Total	DL	SL	T	Total	Total
1202	9/5/14	6 Month	JFL	LEFT	0	6	4	10	0	8	6	14	24
1203	6/4/14	6 Month	JKS	LEFT	0	3	2	5	0	4	4	8	13
1204	9/4/14	6 Month	JFL	LEFT	0	3	0	3	0	4	2	6	9
1207	9/4/14	6 Month	JFL	LEFT	0	3	2	5	0	6	7	13	18
1208	9/4/14	6 Month	JFL	LEFT	0	8	5	13	0	8	4	12	25
1209	9/3/14	6 Month	JFL	RIGHT	0	0	2	2	0	7	3	10	12
1210	9/4/14	6 Month	JFL	LEFT	0	4	2	6	0	6	7	13	19
1211	9/3/14	6 Month	JFL	LEFT	0	0	0	0	0	3	3	6	6
1212	9/4/14	6 Month	JFL	LEFT	0	4	0	4	0	5	5	10	14
1213	9/3/14	6 Month	JFL	LEFT	0	4	4	8	0	5	6	11	19
1214	9/4/14	6 Month	JFL	RIGHT	0	9	2	11	0	9	4	13	24
1215	9/4/14	6 Month	JFL	LEFT	0	2	0	2	0	7	3	10	12
1216	9/4/14	6 Month	JFL	RIGHT	0	1	0	1	0	5	4	9	10
1303	9/4/14	6 Month	JFL	LEFT	0	2	0	2	0	5	3	8	10
1306	9/4/14	6 Month	JFL	LEFT	0	0	1	1	0	6	4	10	11
1312	9/4/14	6 Month	JFL	LEFT	0	1	2	3	0	6	5	11	14
1313	9/4/14	6 Month	JFL	LEFT	0	2	1	3	0	5	2	7	10
1314	9/4/14	6 Month	JFL	LEFT	0	4	1	5	0	6	3	9	14
1402	9/4/14	6 Month	JFL	LEFT	0	1	0	1	0	5	4	9	10
1403	9/2/14	6 Month	JFL	LEFT	0	5	3	8	0	6	6	12	20
1404	9/2/14	6 Month	JFL	LEFT	0	4	3	7	0	8	5	13	20
1405	9/2/14	6 Month	JFL	LEFT	0	6	1	7	4	8	9	21	28
1406	9/2/14	6 Month	EP	LEFT	0	1	1	2	0	7	9	16	18
1407	9/2/14	6 Month	EP	LEFT	0	0	0	0	0	10	5	15	15
1408	9/2/14	6 Month	EP	LEFT	0	0	2	2	9	7	5	21	23
1409		6 Month	NP										
1411	9/5/14	6 Month	JFL	LEFT	0	4	3	7	0	6	3	9	16
1412	9/3/14	6 Month	JFL	LEFT	0	5	1	6	1	7	5	13	19
1413	9/2/14	6 Month	JFL	LEFT	0	2	2	4	0	6	5	11	15
1414	9/2/14	6 Month	EP	LEFT	0	1	0	1	4	10	7	21	22
1415	9/5/14	6 Month	JFL	LEFT	0	3	3	6	0	7	3	10	16
1502		6 Month	JKS	LEFT	0	4	1	5	0	4	5	9	14
1504	5/28/14	6 Month	JFL	LEFT	0	2	3	5	0	6	5	11	16
1505		6 Month	JKS	LEFT	0	3	1	4	0	2	1	3	7
1506		6 Month	JKS	LEFT	0	3	1	4	0	6	3	9	13
1507	9/4/14	6 Month	JFL	LEFT	0	3	0	3	0	4	2	6	9
1508	5/28/14	6 Month	JFL	LEFT	0	3	5	8	1	6	7	14	22
1509	5/28/14	6 Month	JFL	LEFT	0	3	1	4	0	8	6	14	18
1510	5/28/14	6 Month	JFL	LEFT	0	2	0	2	0	6	3	9	11
1511	5/30/14	6 Month	JKS	LEFT	0	5	0	5	0	4	4	8	13

ID#	Date	Type	Obs.	Foot	Firm Surface				Foam Surface				BESS
					DL	SL	T	Total	DL	SL	T	Total	Total
1512	5/28/14	6 Month	JFL	LEFT	0	4	3	7	0	7	6	13	20
1513	5/28/14	6 Month	JFL	LEFT	0	1	0	1	0	4	2	6	7
1514	5/28/14	6 Month	JFL	LEFT	0	0	0	0	0	6	4	10	10
1515	9/2/14	6 Month	JFL	LEFT	0	3	1	4	0	5	6	11	15
1602	5/28/14	6 Month	JFL	LEFT	0	1	1	2	0	6	3	9	11
1603	9/4/14	6 Month	JFL	LEFT	0	2	0	2	0	5	4	9	11
1604	9/4/14	6 Month	JFL	LEFT	0	0	1	1	0	9	8	17	18
1605	9/4/14	6 Month	JFL	LEFT	0	1	0	1	0	4	4	8	9
1606	9/6/14	6 Month	JFL	LEFT	0	4	0	4	0	9	4	13	17
1607	9/4/14	6 Month	JFL	LEFT	0	5	4	9	0	6	6	12	21
1608	9/2/14	6 Month	JFL	LEFT	0	1	1	2	0	4	3	7	9
1609	9/4/14	6 Month	JFL	LEFT	0	5	2	7	0	7	5	12	19
C021	9/9/14	6 Month	JFL	RIGHT	0	3	0	3	0	6	1	7	10
C022		6 Month	NP										
C023	9/9/14	6 Month	JFL	LEFT	0	3	3	6	0	6	5	11	17
C024		6 Month	NP										
C025	9/9/14	6 Month	JFL	LEFT	0	3	0	3	0	5	4	9	12
C026	9/9/14	6 Month	JFL	LEFT	0	1	2	3	0	6	5	11	14
C027		6 Month	NP										
C028	7/16/14	6 Month	EP	LEFT	0	4	3	7	0	10	10	20	27
C029	7/16/14	6 Month	EP	LEFT	0	6	5	11	0	10	4	14	25
C032	7/16/14	6 Month	EP	LEFT	0	1	6	7	0	1	5	6	13
C033	7/16/14	6 Month	EP	LEFT	0	5	0	5	0	9	7	16	21
C034		6 Month	NP										
C037	7/15/14	6 Month	EP	LEFT	0	3	0	3	0	10	2	12	15
C038	7/15/14	6 Month	EP	LEFT	0	4	5	9	0	8	8	16	25
C039	7/15/14	6 Month	EP	RIGHT	0	2	0	2	0	10	4	14	16
C040	7/15/14	6 Month	EP	LEFT	0	2	0	2	0	9	6	15	17
C041	9/9/14	6 Month	JFL	RIGHT	0	3	0	3	0	7	3	10	13
C042	7/16/14	6 Month	EP	LEFT	0	5	0	5	0	10	3	13	18
C043	7/16/14	6 Month	EP	LEFT	0	2	0	2	0	9	3	12	14
C044	7/15/14	6 Month	EP	LEFT	0	0	0	0	0	9	0	9	9
C045	7/15/14	6 Month	EP	LEFT	0	2	2	4	0	8	2	10	14
C046	7/15/14	6 Month	EP	LEFT	0	0	2	2	0	8	4	12	14
C047	7/15/14	6 Month	EP	LEFT	0	0	2	2	0	7	0	7	9
C048	7/15/14	6 Month	EP	LEFT	0	3	0	3	0	3	3	6	9
C049	7/15/14	6 Month	EP	LEFT	0	0	0	0	0	10	8	18	18
C050	7/15/14	6 Month	EP	LEFT	0	0	0	0	0	9	6	15	15

For the most difficult test, there were no statistically significant differences between the performance of the participants on the foam portion of the test between beginning, mid and end study assessments (p=0.4) (Figure 10). There were also no statistically significant differences between Dam Neck and Stennis participants (p=0.67).

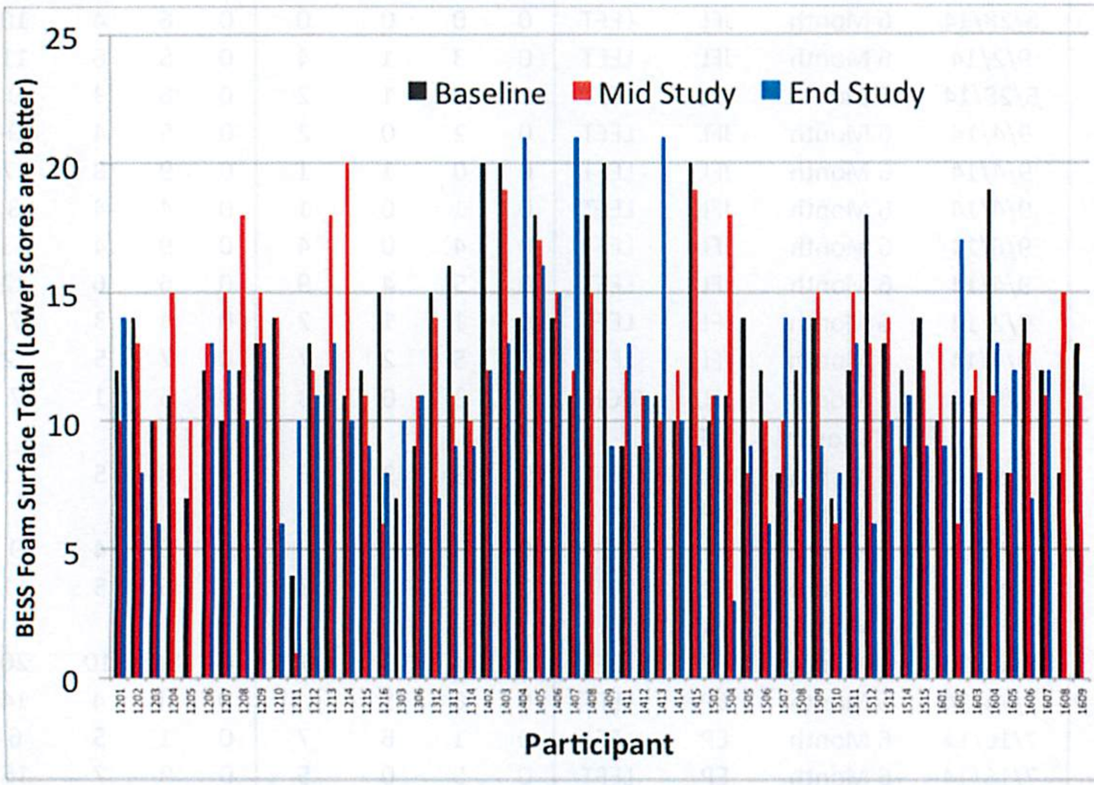

Figure 10. BESS foam surface total, Dam Neck participants. No statistically significant differences were found between the baseline and end-of-study totals.

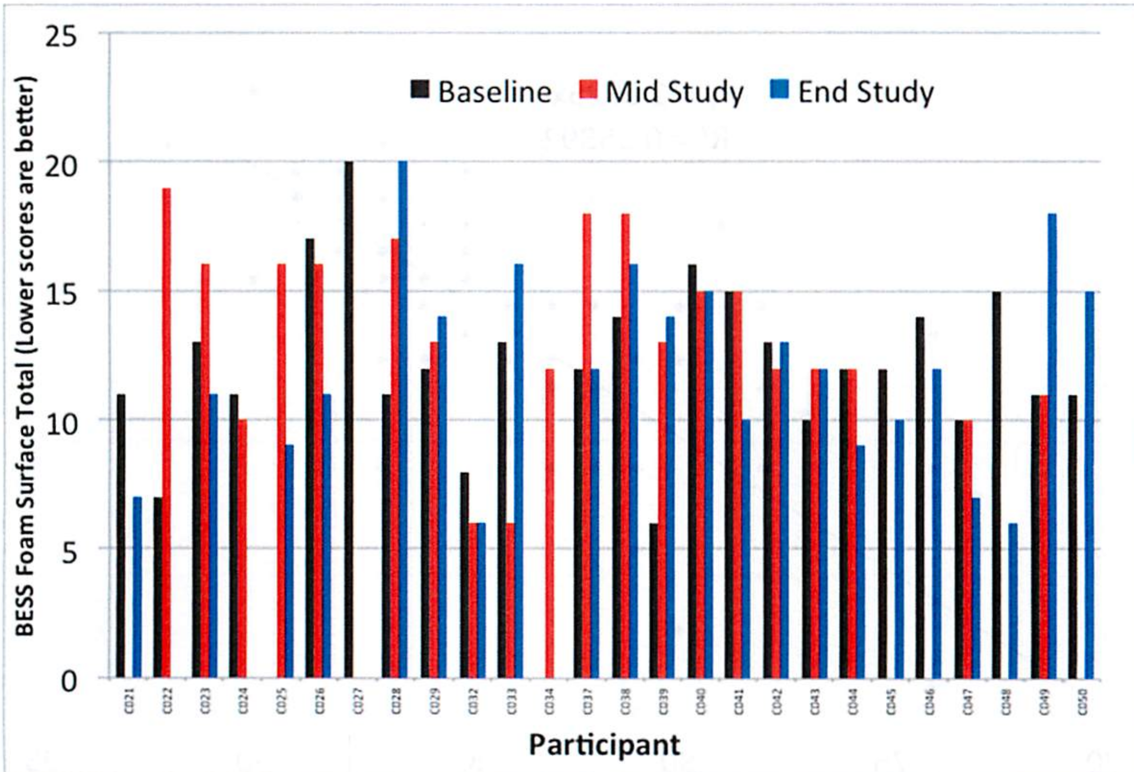

Figure 11. BESS foam surface total, Stennis participants. No statistically significant differences were found between the baseline and end-of-study totals.

4.2 Clinical Balance Testing – Neurocom (SOT)

SOT scores showed similar trends to BESS testing. There were no statistically significant differences among participants from baseline to end of study (p=0.83) (Figure 12). The initial composite balance scores were well correlated with the final score for the 1500 group with an R^2 value > 0.85. No age or group dependence was found in SOT results (Figure 13).

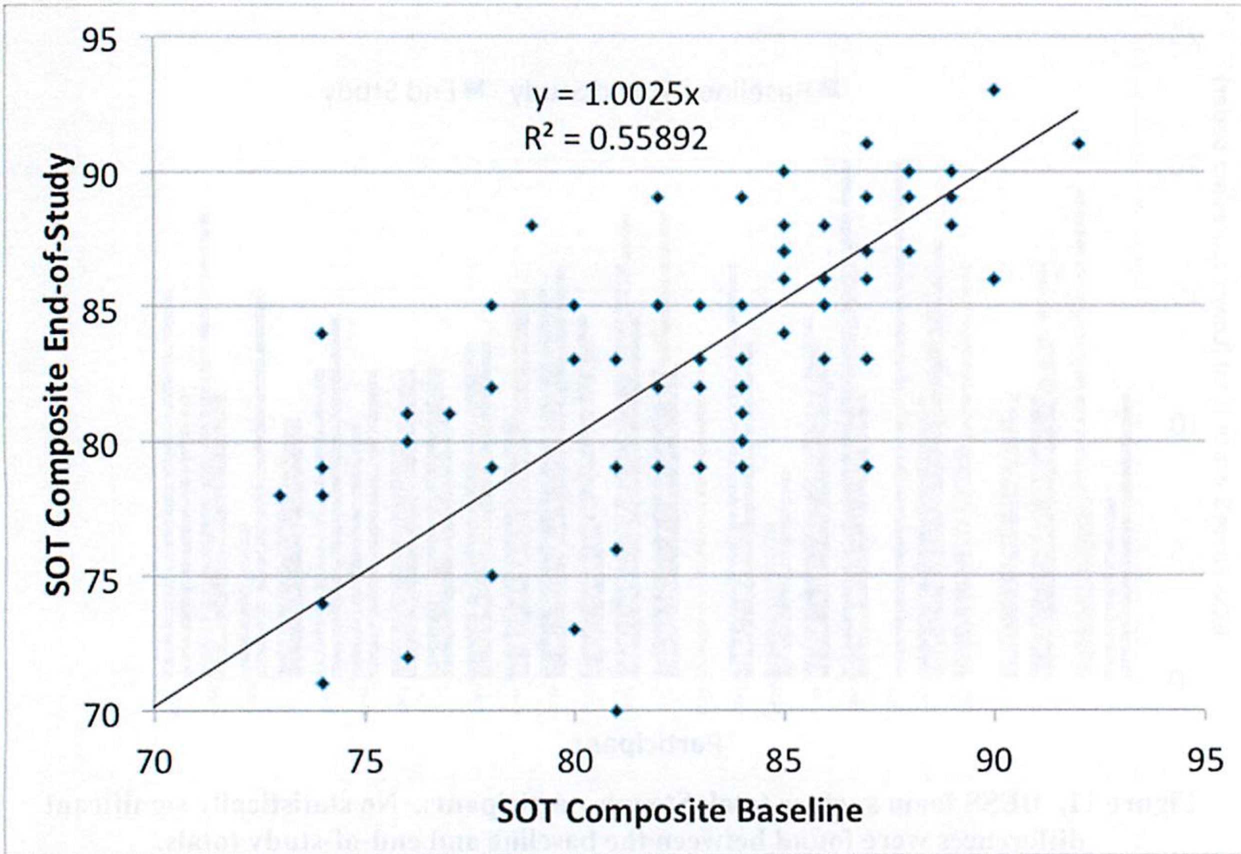

Figure 12. SOT composite score, all participants. No statistically significant differences were found between the baseline and end-of-study totals (p=0.83). Baseline and end-of study for each participant was well correlated.

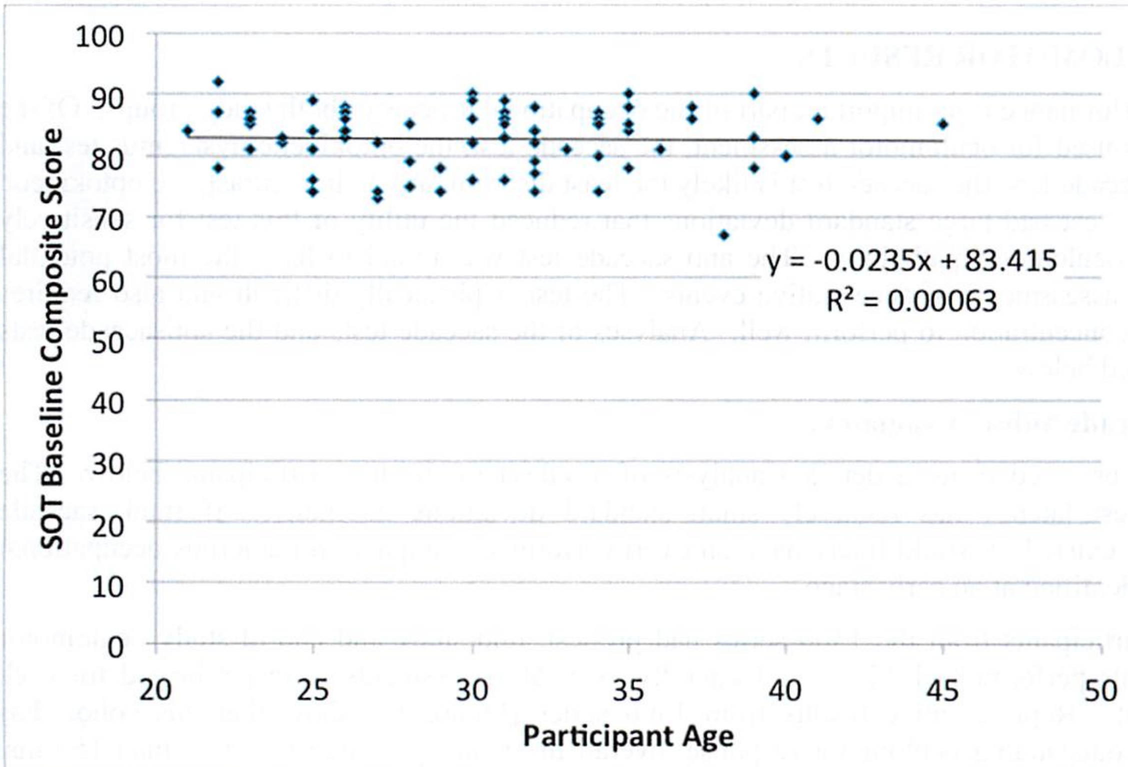

Figure 13. SOT composite score vs. participant age, all participants. There was a poor correlation of age with SOT composite score (R^2=0.0006).

5 OCULOMOTOR RESULTS

Visual performance is an important part of the occupational aspects of both study groups. Of the three tests used for oculomotor assessment, the saccade test, the optokinetic nystagmus test and the antisaccade test, the saccade test is likely the least discriminative. In contrast, the optokinetic nystagmus test had large standard deviations that reduced the utility of this test for sensitively assessing oculomotor pathology. The anti-saccade test was found to have the most potential utility for assessments of accelerative events. The test is physically difficult and also requires extended concentration to perform well. Analyses of the saccade tests and the antisaccade tests are reported below.

5.1 Saccade Subset Evaluation

This was assessed using a detailed analysis of a subset of the test participants below. The saccade test latency has relatively small standard deviations internally. If frank saccade pathology existed, it would likely have an overt performance impact on numerous occupational aspects, identified at an early stage.

Eleven participants from the 1500 series had pre-test, mid-study and end-of-study oculomotor assessments performed (Table 10). Generally, over 50 assessments were performed for each time point. Representative results from 1500 series (Figure 14) show that this cohort has generally outstanding oculomotor response, overall mean saccade latency is less than 150 ms. Typical results show little difference between left eye and right eye response, and no general statistical trend with study assessment point.

A general linear model was fit with eye, assessment timepoint and participant. The only statistically significant coefficient was for participant ID with $p<0.01$. Adjusted R^2 of the general linear model with participant ID is ~0.68. Without participant ID, adjusted R^2 of the model was 0.0. The interaction term timepoint*participant ID was found to be statistically significant ($p<0.01$) and increased the adjusted R^2 of the general linear model to 0.86. This suggests that there is a statistically significant interaction for time point by participant. Much of this interaction appears to be a subtle, but statistically significant learning effect across the assessments. The magnitude of this learning effect is small, about 1 ms in latency across the tests and all participants.

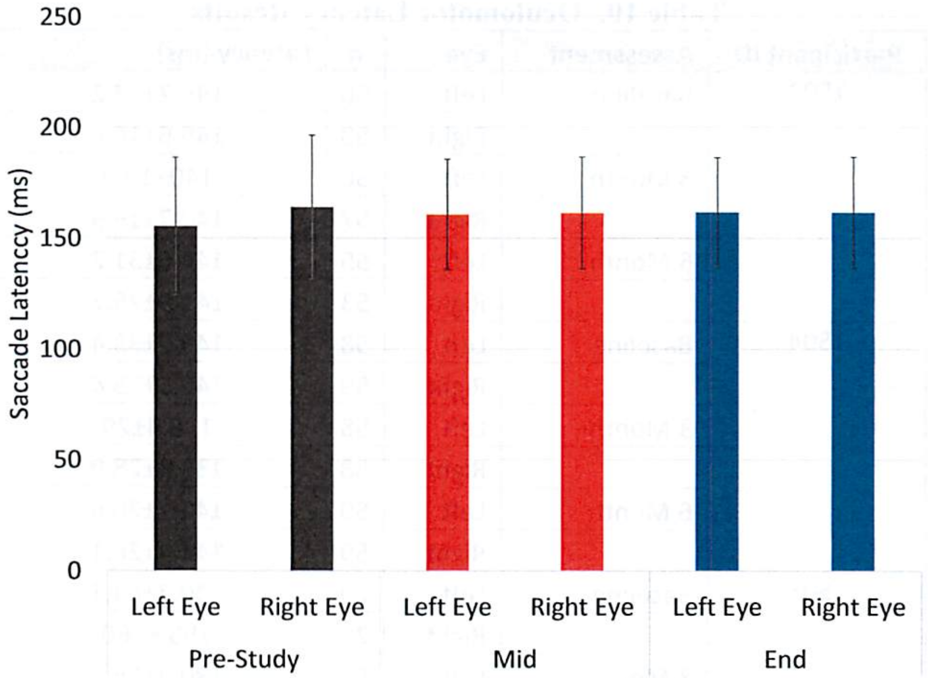

Figure 14. Typical mean oculomotor saccade grouped results, participant 1502. No statistically significant differences were found for eye (p=0.94) or for pre-study to end-of-study results (p=0.27).

Table 10. Oculomotor Latency Results

Participant ID	Assessment	Eye	n	Latency (ms)
1502	Baseline	Left	56	143.2±17.2
		Right	58	145.6±16.6
	3 Month	Left	56	140±19.9
		Right	57	140.7±19.9
	6 Month	Left	55	144.6±31.2
		Right	53	141.9±25.7
1504	Baseline	Left	58	149.7±33.4
		Right	59	146.5±35.4
	3 Month	Left	58	138.4±29
		Right	58	138.8±28.9
	6 Month	Left	59	141.1±26.6
		Right	59	141.4±26.1
1505	Baseline	Left	29	140.7±63.1
		Right	28	155.5±60
	3 Month	Left	57	180.4±56.7
		Right	57	181.5±54.1
	6 Month	Left	57	177.9±39.9
		Right	58	176±41.8
1506	Baseline	Left	59	159±13.7
		Right	59	159.2±13.1
	3 Month	Left	59	154.3±16.6
		Right	59	154.6±16.7
	6 Month	Left	59	150±12.7
		Right	59	150.6±12.4
1508	Baseline	Left	56	149.5±22.2
		Right	56	149.8±22
	3 Month	Left	43	154.3±44.7
		Right	41	118±24.2
	6 Month	Left	57	152.3±22.8
		Right	58	150.9±24.5
1509	Baseline	Left	59	161.6±21.7
		Right	58	162.5±20.7
	3 Month	Left	48	161.6±43.7
		Right	57	163.2±40.8
	6 Month	Left	57	159.4±29.2
		Right	57	159.1±29.1
1510	Baseline	Left	58	188±22.9
		Right	58	188.3±22.9
	3 Month	Left	57	182.3±29.8

Participant ID	Assessment	Eye	n	Latency (ms)
		Right	57	182.6±29.9
	6 Month	Left	58	179.8±36
		Right	58	180.1±36.1
1511	Baseline	Left	59	167.2±31.7
		Right	59	172±31
	3 Month	Left	33	182.5±40.5
		Right	31	182.3±42
	6 Month	Left	58	170.5±38.4
		Right	59	173.3±40.5
1512	Baseline	Left	54	152.6±30.8
		Right	53	150.4±28.2
	3 Month	Left	52	168±40.5
		Right	52	170.5±39.3
	6 Month	Left	57	162±32.4
		Right	57	162.4±31.9
1513	Baseline	Left	51	162.2±34.3
		Right	38	171.2±32.2
	3 Month	Left	46	160.5±59.6
		Right	52	149.3±61.5
	6 Month	Left	57	165.7±35.7
		Right	58	165±35.9
1514	Baseline	Left	59	155.4±31
		Right	46	164±32.4
	3 Month	Left	59	160.6±24.8
		Right	59	161.2±25.1
	6 Month	Left	58	161.5±24.5
		Right	53	161.4±24.9

Participant oculomotor saccade latency results showed no obvious trends during the study assessments (Figure 15). General performance level for each participant was consistent, with a small learning effect seen in some participants. This learning effect was discerned because of the large number of tests and was less than 1% of the mean response for the entire dataset.

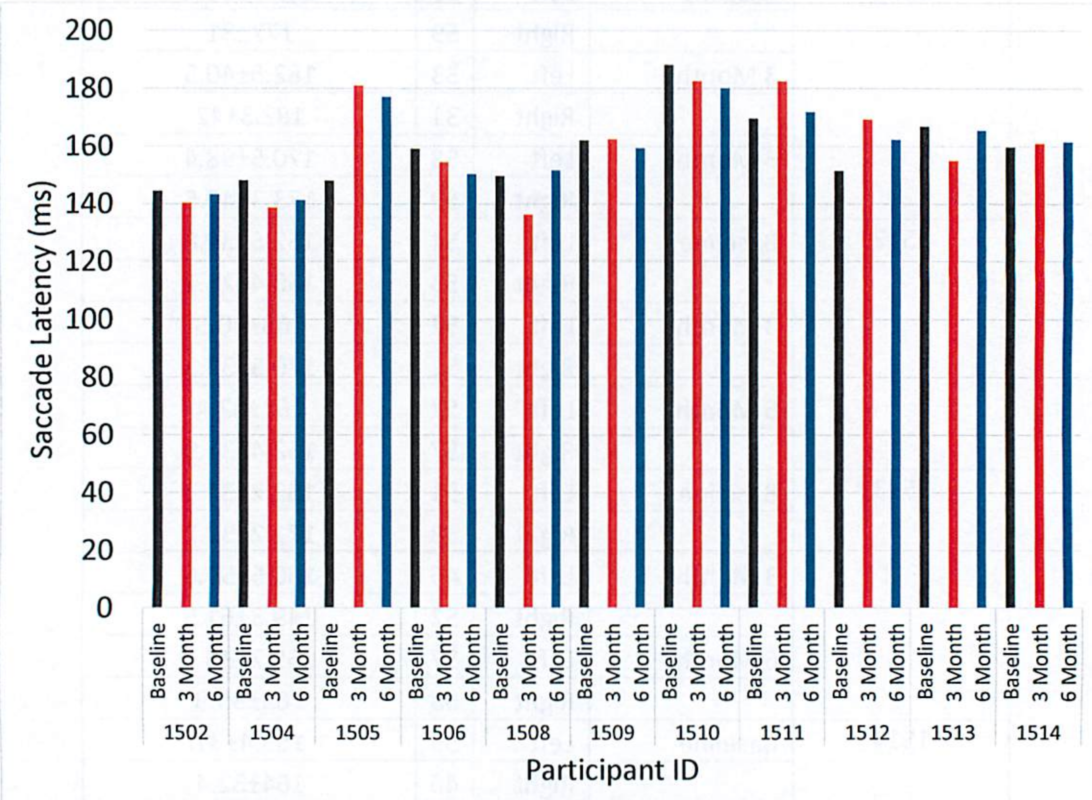

Figure 15. Oculomotor saccade grouped results, participants in the 1500 series. No statistically significant differences were found for eye (p=0.87) or for pre-study to end-of-study results (p=0.60). An interaction term of participant ID*timepoint was found to be significant (p<0.01) This is attributable to a small learning effect.

5.2 Antisaccade Evaluations

There were over 10,000 separate antisaccade tests across the two groups of participants. For wrong way eye motions (Figure 16), there were no statistically significant differences between Dam Neck and Stennis groups (p=0.5), and there were no statistically significant differences across the group (learning effect) from the baseline evaluation to the end of study evaluation for antisaccades (p=0.3). Left and right eye motions were generally correlated across all groups of participants. Both right way gains (Figure 17) and wrong way gains (Figure 18) show high correlation of left and right eye motion.

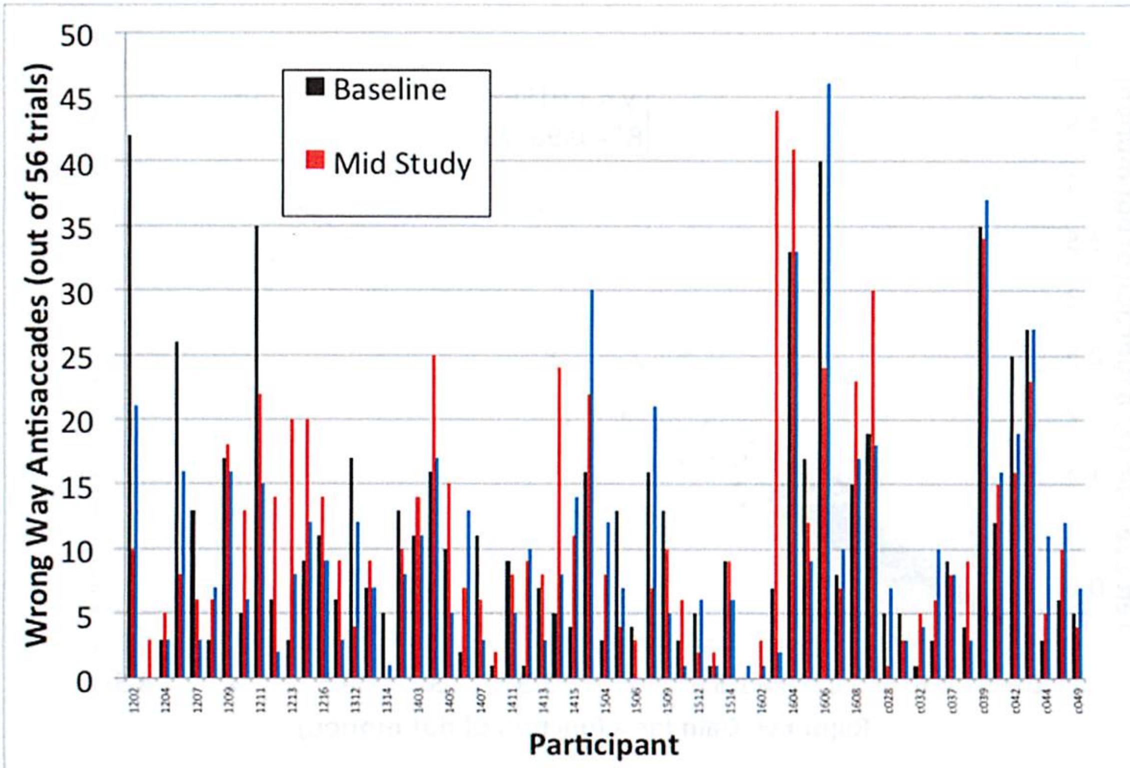

Figure 16. Oculomotor antisaccade wrong way grouped results, all participants. No statistically significant differences were found for group (p=0.87) or for pre-study to end-of-study results (p=0.60). An interaction term of participant ID*timepoint was found to not be significant. This is no learning effect seen in this data.

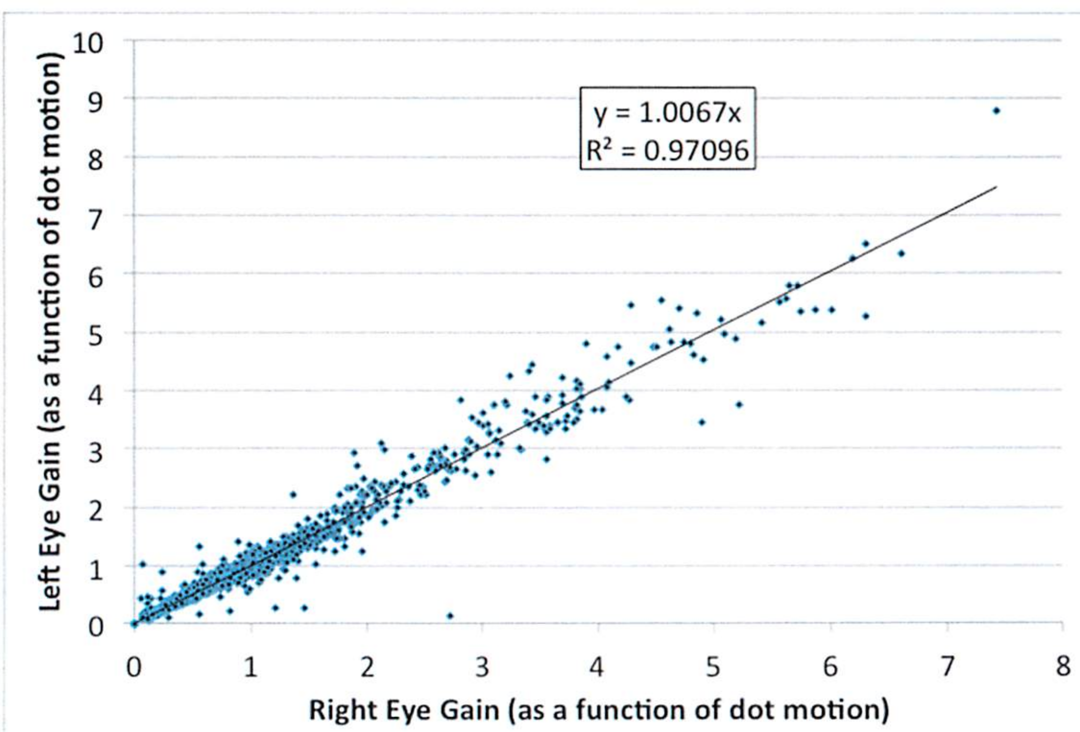

Figure 17. Right Way Left Eye Gain vs. Right Eye Gain

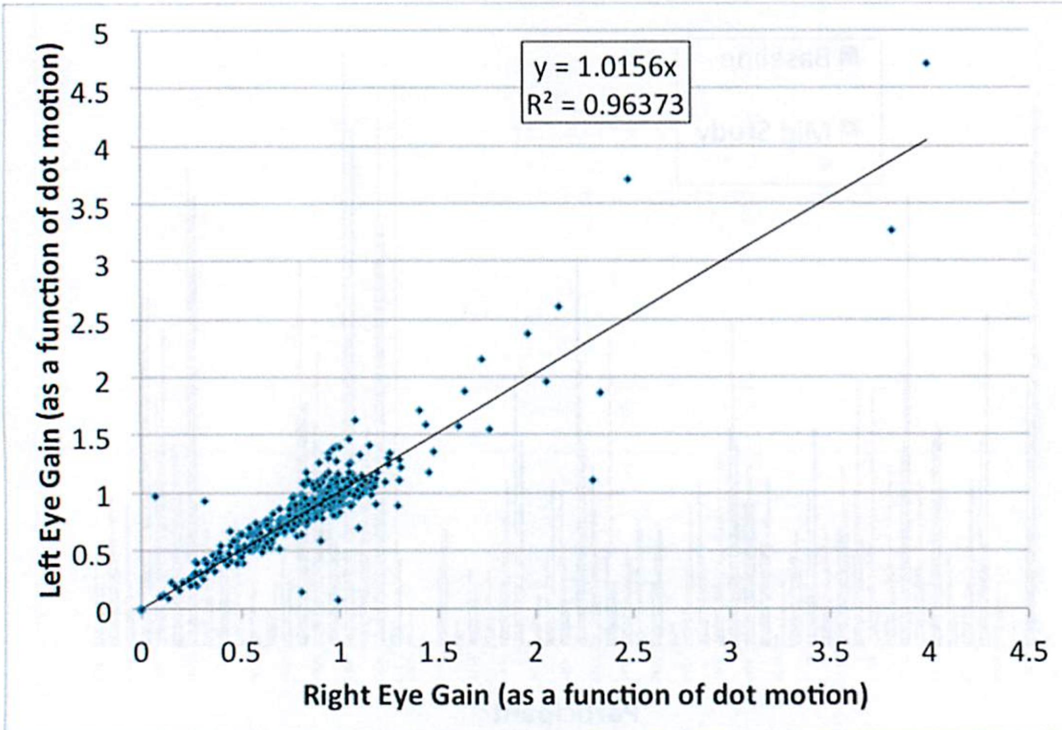

Figure 18. Wrong Way Left Eye Gain vs. Right Eye Gain

6 COGNITIVE TEST RESULTS (IMPACT TEST)

6.1 Preliminary Analyses with 1500 Participant Subset

To assess the best ImPACT variables for ImPACT response, a subset of the participants was investigated, the group of 1500 participants from Dam Neck. The test schedule for 1500 series participants in the 1500 series is shown in Table 11. All of the participants performed ImPACT testing during the baseline testing and during the 6 month testing, but none performed the nominal 3 month midpoint assessment. For this preliminary assessment, only the baseline and 6 month time points will be used in the analysis. The four central measure normalized scores are used as principal parameters for ImPACT test comparisons. These are MEMVRB (Verbal Memory), MEMVIS (Visual Memory), REACT (Reaction Time), and MOTOR (Motor Control). Each parameter measures performance in an independent cognitive domain associated with performance decrements from blunt trauma and other potential conditions.

A very strong learning effect was seen in the MEMVRB (Verbal Memory) parameter in the 1500 series (Figure 19). Performance increased for each 1500 series participant. A general linear model for the normalized visual memory score produced statistically significant coefficients for participant ID ($p<0.01$) and test date ($p<0.01$). The model had an adjusted R^2 of 0.73.

The parameter MEMVIS (Visual Memory), the participant was statistically significant ($p<0.01$), but the test was not. For the 1500 series, this parameter produced inconsistent results. Some participants showed improvement, but some did not. This measure will be correlated with outcome measures including medical assessments and acceleration measurements. A general linear model for the normalized visual memory score produced statistically significant coefficients for participant ID ($p=0.01$) and test date ($p=0.05$). The model had an adjusted R^2 of 0.60.

No consistent learning effect was seen in the REACT (Reaction time) parameter for the 1500 series (Figure 21). A general linear model was constructed as above, and neither participant ID ($p=0.13$) nor date of test ($p=0.97$) were statistically significant. Approximately half of the participants showed decreases in performance between baseline and 6 month assessments. Model R^2 was poor at 0.28. Performance scores for reaction time showed substantial differences between participants, suggesting either a poor performance measure or one that is sensitive to cognitive state. This will be investigated using the acceleration outcome measure below.

No consistent learning effect was seen in the MOTOR (Motor control) parameter for the 1500 series (Figure 22). A general linear model for the normalized visual memory score did not produce statistically significant coefficients for participant ID ($p=0.13$) and test date ($p=0.61$). Fewer than half of the participants showed improvement. Model R^2 was poor at 0.32. Performance scores for motor control showed the most difference between participants, suggesting either a poor performance measure or one that is sensitive to cognitive state. This will be investigated using the acceleration outcome measure below.

Table 11. Cognitive Testing Completed (IMPACT Testing)

ID	Baseline		1 Month		2 months		3 months		4 months		5 months		6 months		7 months		Complete
	Y/N	Date	Y/N	Date	Y/N	Date	Y/N	Date	Y/N	Date	Y/N	Date	Y/N	Date	Y/N	Date	
1502	Y	07/10/13	N		Y	12/18/13	N	JAN	N	FEB	N	MAR	Y	04/02/13	Y	05/28/14	4/8
1503	Y	07/10/13	N		Y	12/19/13	N		N		N		Y	04/01/13	Y	09/04/14	4/8
1504	Y	07/10/13	N		Y	12/18/13	N		N		N		Y	04/02/13	Y	05/28/14	4/8
1505	Y	07/21/13	N		Y	12/18/13	N		N		N		Y	04/01/13	Y	05/30/14	4/8
1506	Y	07/10/13	N		Y	12/19/13	N		N		N		Y	04/02/13	Y	06/04/14	4/8
1507	Y	07/10/13	N		N		N		N		N		Y	04/04/13	Y	09/04/14	3/8
1508	Y	07/10/13	N		Y	12/18/13	N		N		N		Y	04/29/13	Y	05/28/14	4/8
1509	Y	07/10/13	N		Y	12/18/13	N		N		N		Y	04/02/13	Y	05/28/14	4/8
1510	Y	07/10/13	N		Y	12/19/13	N		N		N		Y	04/02/13	Y	05/28/14	4/8
1511	Y	07/10/13	N		N		N		N		N		Y	04/02/13	Y	05/30/14	3/8
1512	Y	07/10/13	Y	11/4/13	Y	12/18/13	N		N		N		Y	04/02/13	Y	05/28/14	5/8
1513	Y	07/10/13	Y	11/4/13	Y	12/18/13	N		N		N		Y	04/02/13	Y	05/28/14	5/8
1514	Y	07/10/13	Y	11/4/13	Y	12/18/13	N		N		N		Y	04/02/13	Y	05/28/14	5/8
1515	Y	07/10/13	Y	11/4/13	Y	12/16/13	N		N		N		Y	03/31/13	Y	09/05/14	5/8

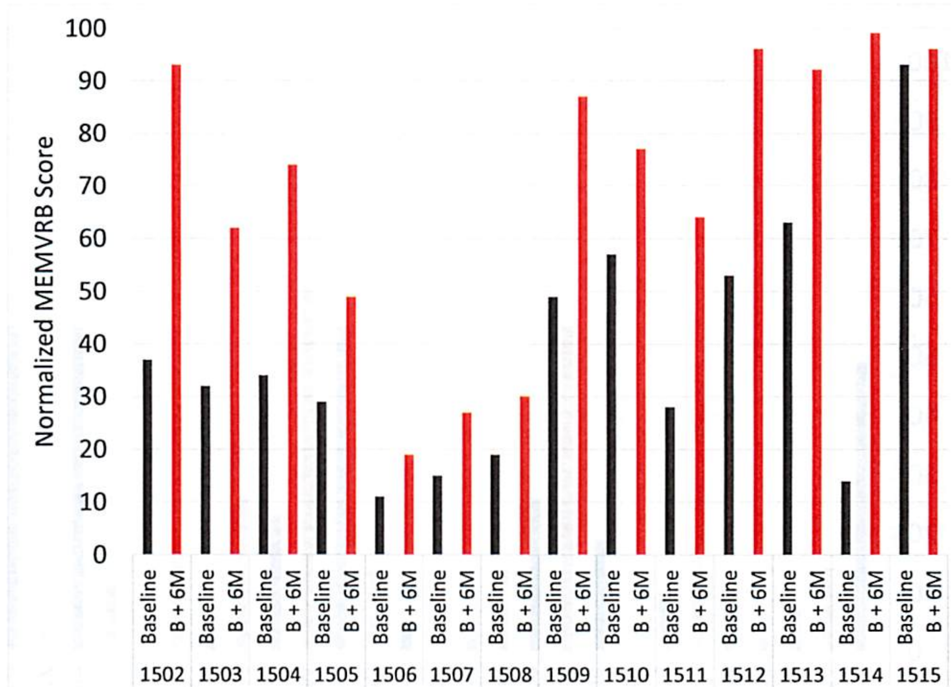

Figure 19. ImPACT test normalized MEMVRB (Verbal Memory) score for the 1500 series showed a very strong learning effect for all participants from baseline to 6 months. Higher scores indicate better performance. Both participant ID and date of test were statistically significant ($p<0.01$).

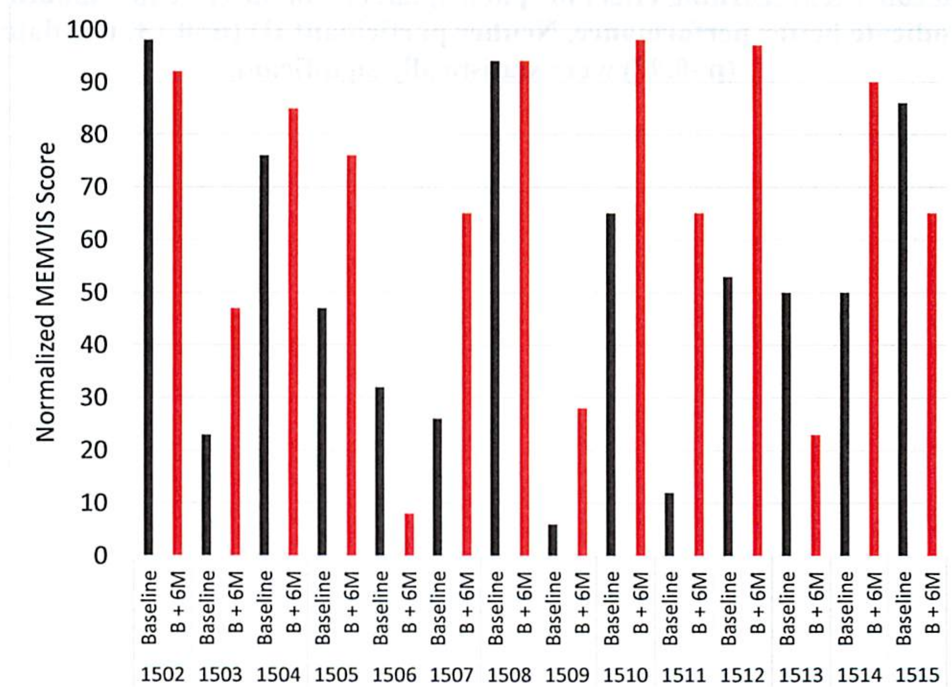

Figure 20. ImPACT test normalized MEMVIS (Visual Memory) score for the 1500 series showed a general learning effect for participants from baseline to 6 months. Higher scores indicate better performance. Both participant ID ($p=0.01$) and date of test were statistically significant ($p=0.05$).

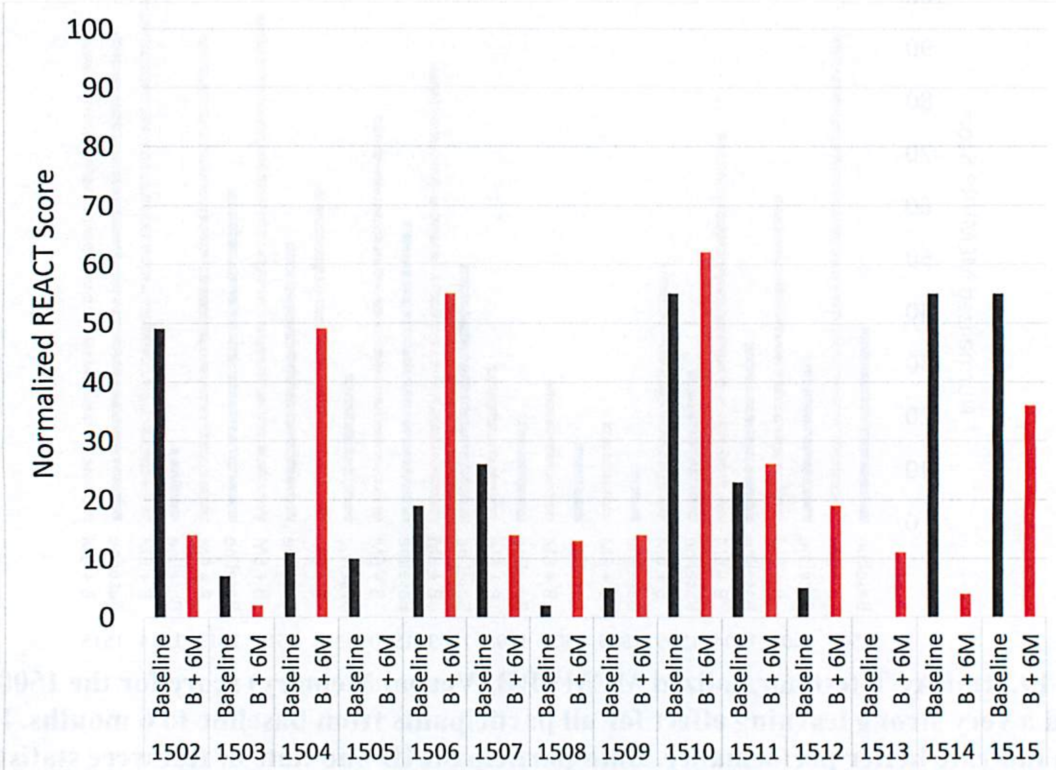

Figure 21. ImPACT test normalized REACT (Reaction Time) score for the 1500 series showed no consistent learning effect for participants from baseline to 6 months. Lower scores indicate better performance. Neither participant ID (p=0.13) nor date of test (p=0.97) were statistically significant.

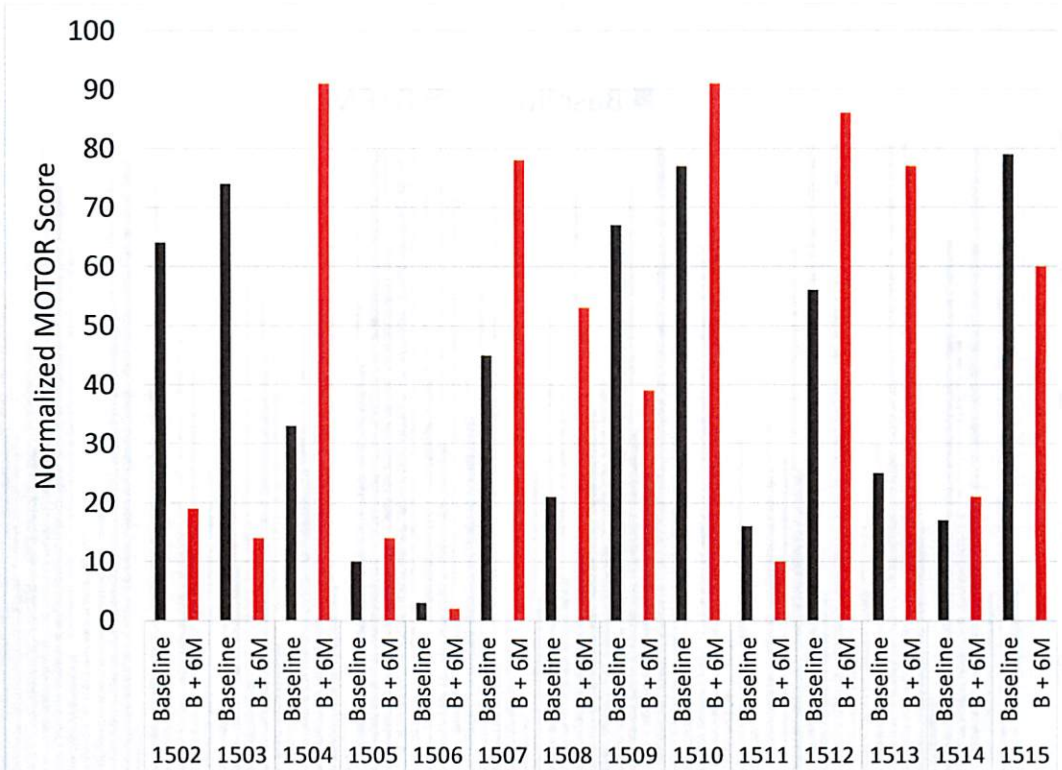

Figure 22. ImPACT test normalized MOTOR (Motor Control) score for the 1500 series showed a learning effect for all participants from baseline to 6 months. Lower scores indicate better performance. Both participant ID and date of test were statistically significant ($p<0.01$).

6.2 Full ImPACT Analysis

A similar trend to the limited series analysis was seen in the larger dataset. MEMVRB showed a strong learning effect (Figure 23), and MEMVIS showed a weak learning effect (Figure 24). The reaction time (REACT) did not have a statistically significant learning effect (Figure 25), but there was a weak learning effect in the motor control variable (MOTOR) (Figure 26). There were no significant differences between Dam Neck and Stennis Group in the baseline assessment.

There was a single diagnosed mTBI among the participants (1503). The participant's ImPACT scores are shown in Figure 27. Higher scores indicate better performance for MEMVIS and MEMVRB. Lower scores indicate better performance for REACT and MOTOR. The participant improved in all measures from baseline to end of study.

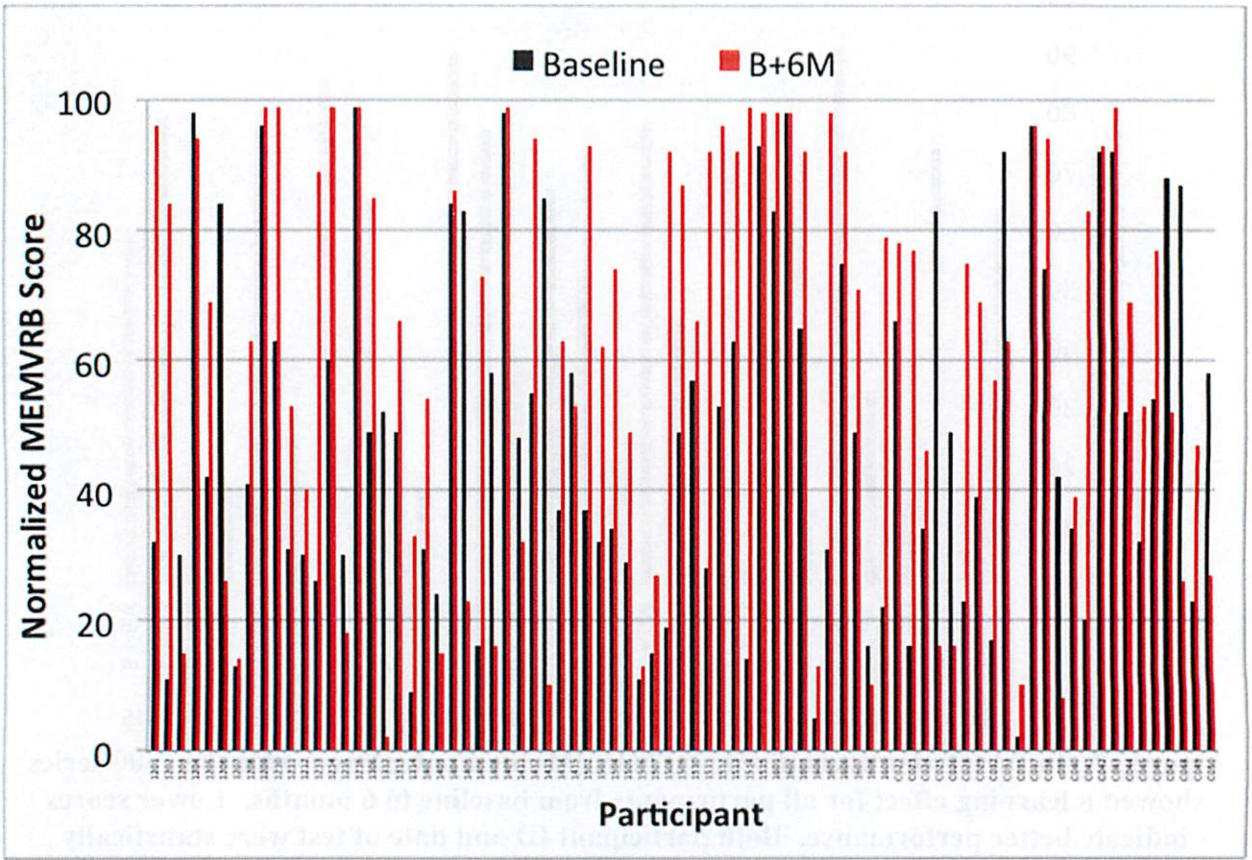

Figure 23. ImPACT test normalized MEMVRB (Verbal Memory) score for all participants showed a very strong learning effect for all participants from baseline to 6 months. Higher scores indicate better performance. Both participant ID and date of test were statistically significant (p<0.01).

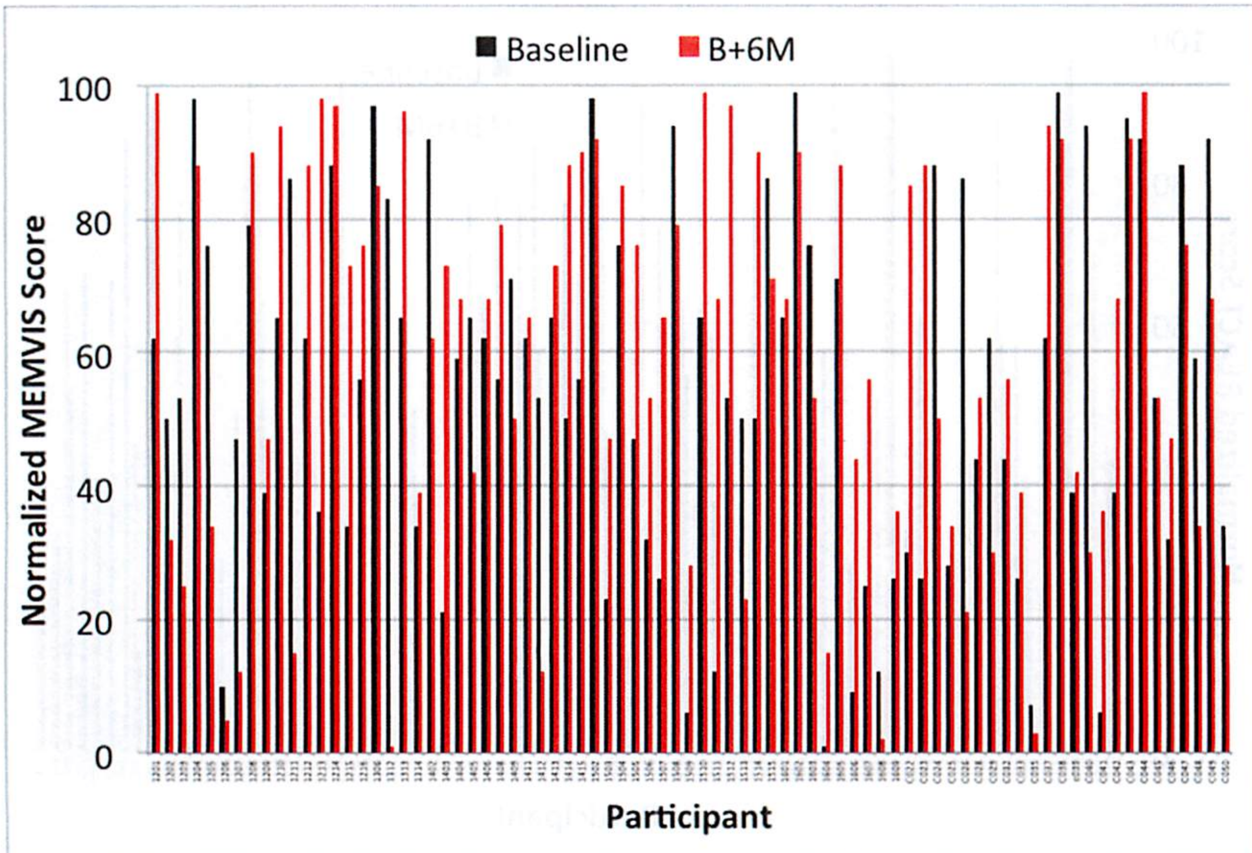

Figure 24. ImPACT test normalized MEMVIS (Visual Memory) score for all participants showed a general learning effect for participants from baseline to 6 months. Higher scores indicate better performance. Both participant ID and date of test were statistically significant.

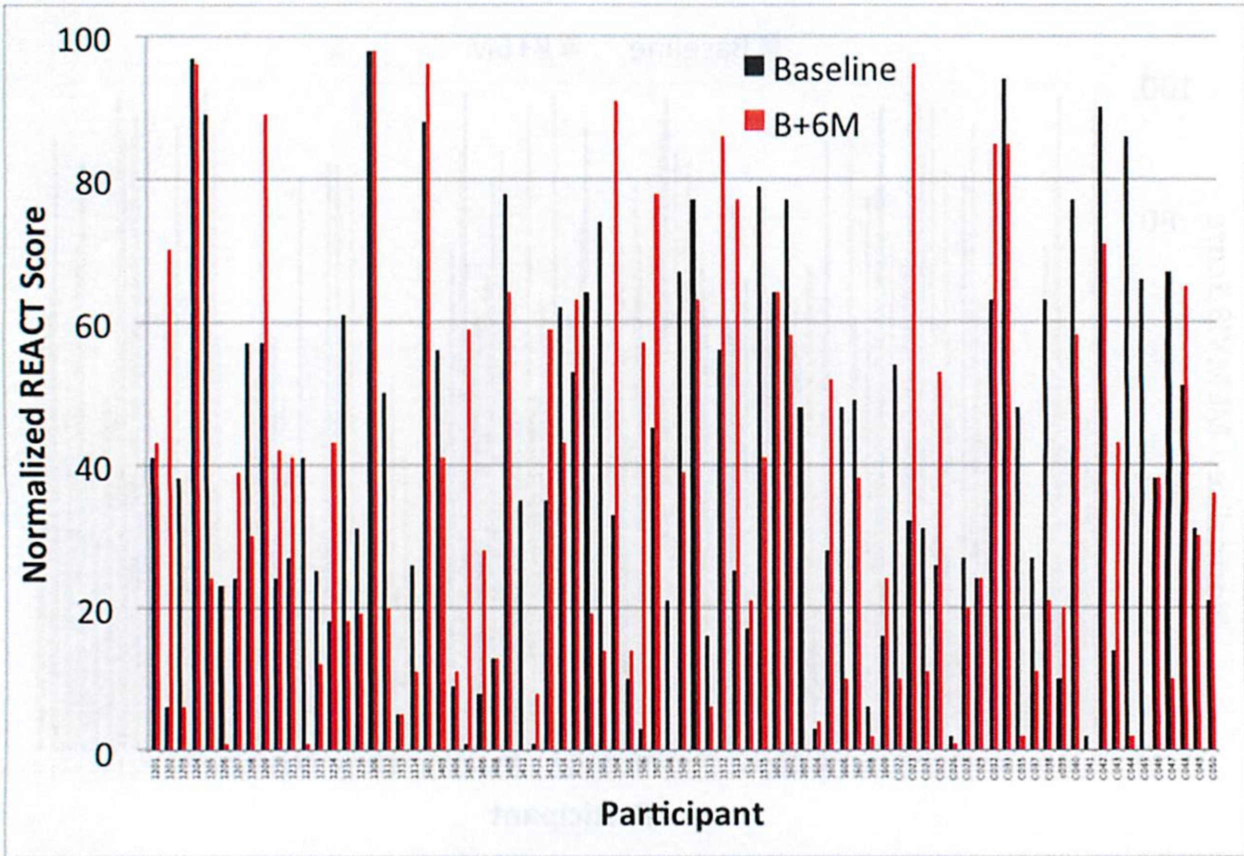

Figure 25. ImPACT test normalized REACT (Reaction Time) score for all participants showed no consistent learning effect for participants from baseline to 6 months. Lower scores indicate better performance. Neither participant ID nor date of test were statistically significant.

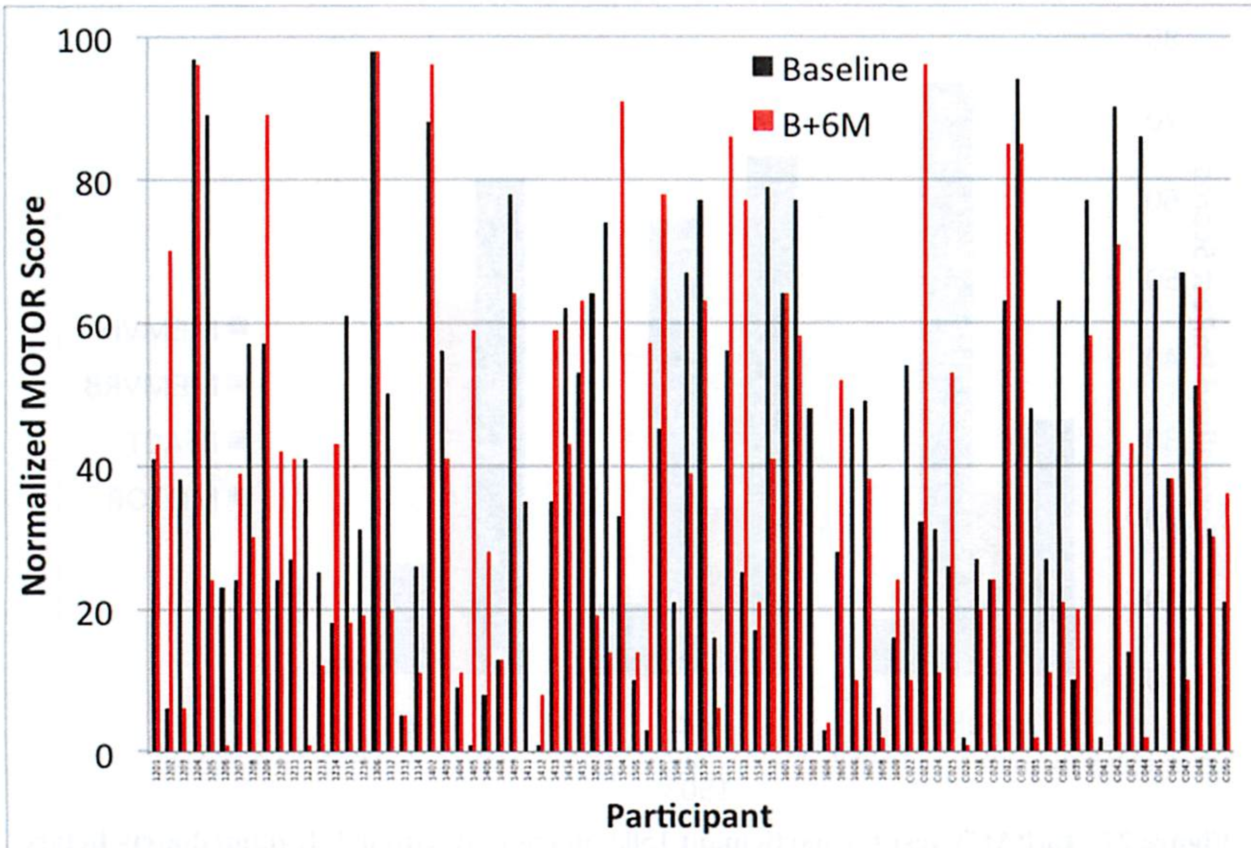

Figure 26. ImPACT test normalized MOTOR (Motor Control) score for all participants showed a learning effect for all participants from baseline to 6 months. Lower scores indicate better performance. Both participant ID and date of test were statistically significant ($p<0.01$).

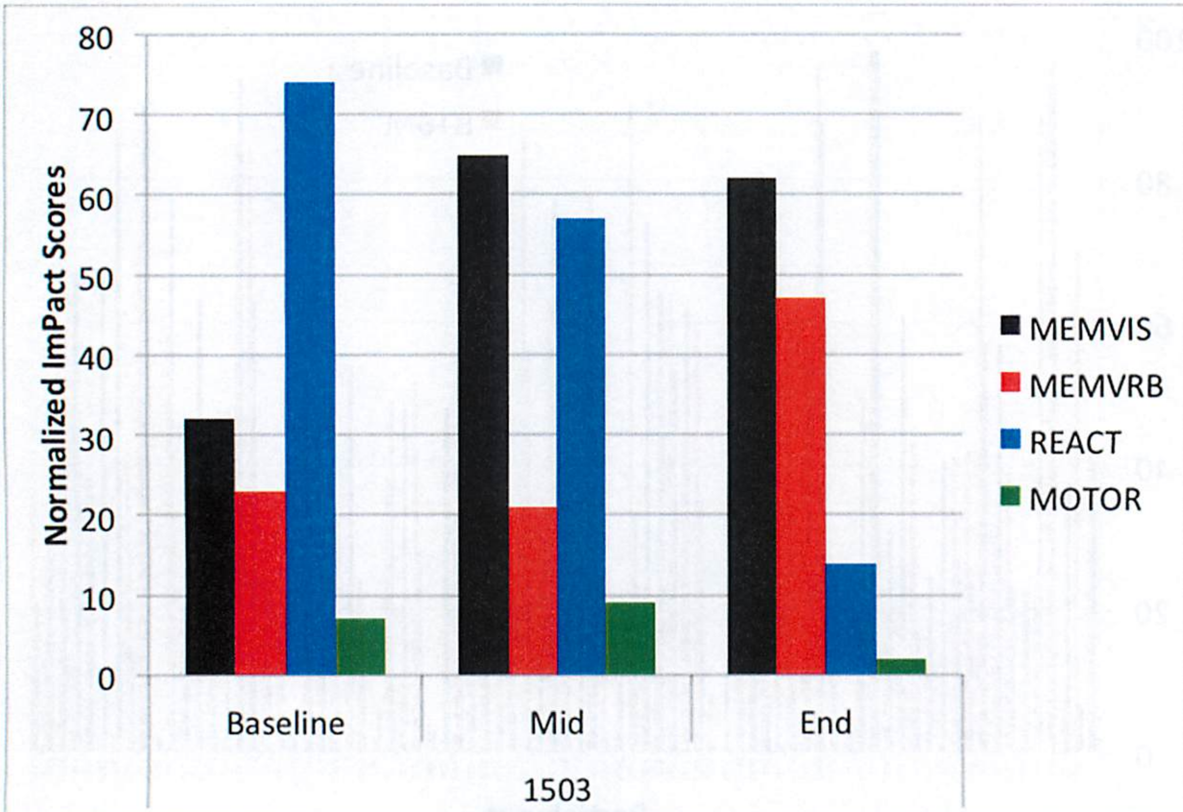

Figure 27. ImPACT test for participant 1503, diagnosed with mTBI immediately before the test labeled 'Baseline'. Higher scores indicate better performance for MEMVIS, MEMVRB. Lower scores indicate better performance for REACT and MOTOR. The participant improved in all measures from baseline to end of study.

7 ACCELERATION RESULTS

Participants were instructed to wear the DASHR units during training or other events in which accelerative events were likely, including during physical activities such as PT that might result in an accelerative event. They were instructed to not wear the DASHR units during sedentary activities such as office work or other situations in which accelerative events, including falls, were unlikely.

Assessments reported here include analysis of traditional peak acceleration resultant and HIC, a measure of head translational acceleration used for automobile impact injury assessment. The HIC measures are an aggregated measure recognizing that the influence of acceleration is not linear in impact acceleration and that shorter duration impacts are more tolerable than longer duration impacts at the same a celebration levels.

All participants were issued both helmet (H) and behind-ear (BTE) versions of the DASHR instrumentation. The majority of the participants from both the Dam Neck and Stennis participants used both versions. There were a total of 214,000 accelerative events recorded DASHR units. As expected, most of the acceleration levels were below 2g peak. The source occupational level running, low level jumping, or other physical activities. Peak acceleration bins plotted on a linear and a log scale respectively for Dam Neck and Stennis participants (Figure 28, Figure 29) show impact events greater than ~20 g for some participants (Figure 31).

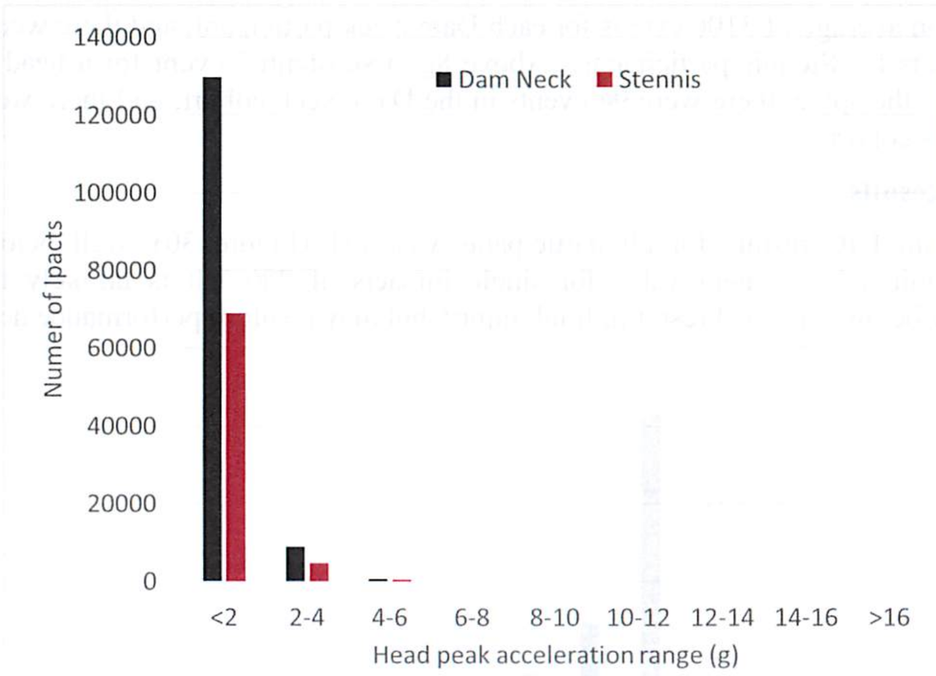

Figure 28. Significant peak impact acceleration for Dam Neck and Stennis series participants, linear scale. The impact data range from 2 g impacts of >16 g in 2 g bins.

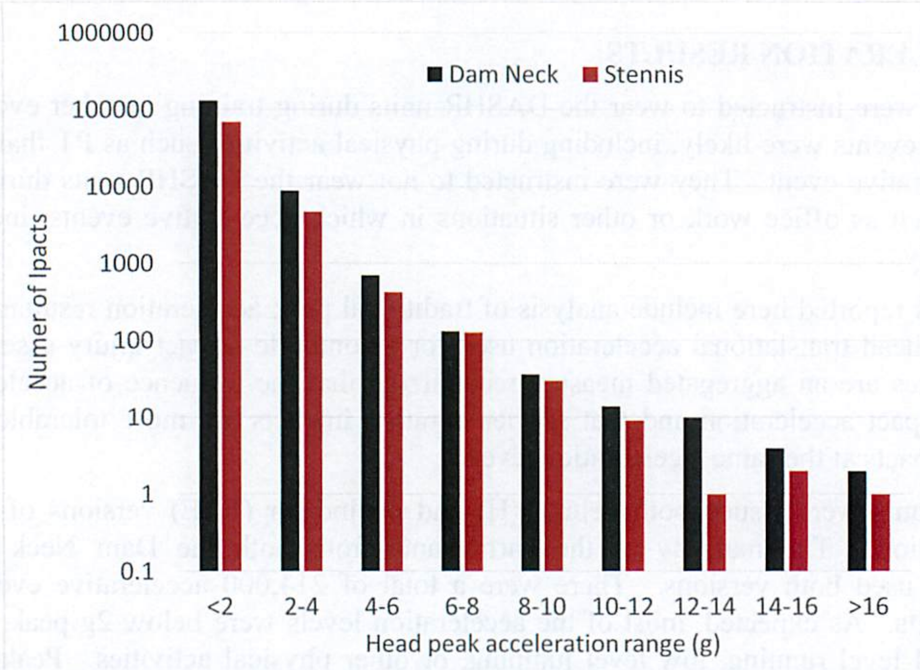

Figure 29. Significant peak impact acceleration for Dam Neck and Stennis participants, log scale. The impact data range from 2 g impacts of >16 g in 2 g bins.

There were an average of 3100 events for each Dam Neck participant, and there were an average of 1300 events for Stennis participants. Above 8g, a substantial event for a head acceleration referred from the spine, there were 94 events in the Dam Neck cohort, and there were 56 events in the Stennis cohort.

7.1 HIC Results

The maximum HIC results for all participants was 131 (Figure 30), well below the usual automobile injury assessment value for single impacts of 750. It is unlikely that repeated impacts at or below this level result in frank injury, but may result in performance decrements.

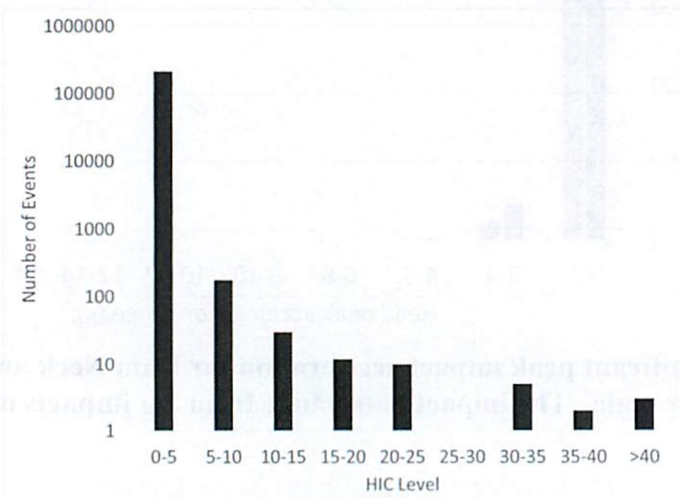

Figure 30. Number of acceleration events by HIC level for all events. The ImPACT data HIC values range from to 0–131 in bins of 5.

7.2 Participant 1602

Participant 1602 had the most impacts above 8 g (Figure 31). This is one of the few participants whose verbal score decreased on the impact test regardless of learning effect. In addition, there is a statistically significant association of impacts these above 8 g and increases in impact MOTOR score. This parameter showed limited learning effect, important for assessing performance without accounting for learning effects. There was no statistically significant association with saccade latency or gain.

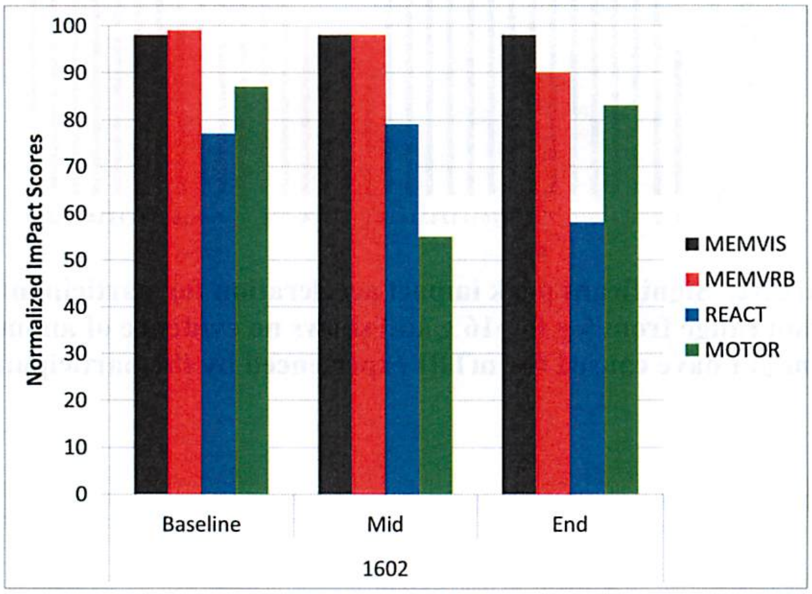

Figure 31. ImPACT scores for participant 1602, the series participant with the most impacts above 8 g

7.3 Participant 1503

Though participant 1503 reported an mTBI during the reporting period, there is no evidence that the event is recorded during the time the DASHR was worn. Figure 32 shows a bar chart of the significant events for both helmet and BTE DASHRs. Peak impact events range from ~5 g to >16 g. These acceleration levels are not expected to cause mTBI for single impacts.

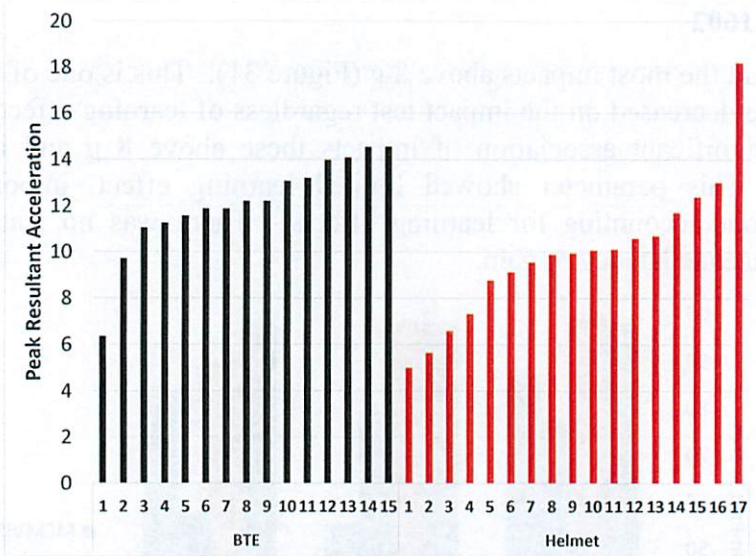

Figure 32. Significant peak impact acceleration for participant 1503. The impact data range from 5 g to >16 g and shows no evidence of an impact event that might have caused the mTBI experienced by the participant.

8 RISK ASSESSMENT PLANNING AND TRACKING TOOL FEASIBILITY STUDY

8.1 Overall Approach

For any PDI that may describe increased injury risk and/or specific techniques or procedures that would minimize the risk of injury or disability, it was recognized that there would have to be an operational end-user-/warfighter-centered methodology or tool required to utilize and readily apply the mTBI/PDI planning and tracking information within the target groups' daily operations. In the general address and treatment of mTBI in the medical community, the major factors of mTBI exposure and long-term effects assessment are: (a) severity of the instant mTBI exposure, (b) cumulative effects of multiple mTBI exposures over time, and (c) time lapses and body/brain healing period provided between mTBI multiple exposures. Thus, the creation of an mTBI exposure risk or PDI would allow for pre-planning of exposure events in military training, mission-readiness, and mission-execution activities and the tracking of actual prior activities to evaluate the potential mTBI risks of further, future exposure events.

The mTBI planning and tracking cycle could be visioned of as an analogous process to the time-weighted exposure to noise or radiation areas. As with noise, exposure effects from auditory sources are a function of exposure level (loudness) and duration (exposure time), with cumulative effects appearing over multiple exposures or without adequate auditory system recovery and healing time. The higher the noise level, the longer the exposure, or the less time allowed for recovery, the higher the chance for longer-term or permanent disability. Likewise, in radiation exposure and monitoring, the amount and duration of radiation exposure affects the severity or type of potential health effects, with short-term, instant exposure and cumulative, long-term exposure limits set. In the communities that deal with radiation sources and/or radioactive materials, tracking and monitoring programs are put in place to monitor exposure events, dosage of exposure, and exposure durations (both instant and cumulative) to monitor risk levels and maintain personnel safety and long-term health. A similar level-duration-recovery time exposure risk planning and PDI tracking system could be readily applied to mTBI exposure events using a mathematical mTBI exposure model.

Development of a first-article mTBI risk assessment and tracking tool concept followed a user-centered design (UCD) approach, wherein the needs and tasks of the operator-system user drive user-system interaction and the resultant human interface designs. A graphical depiction of the UCD design cycle is provided in Figure 33, below.

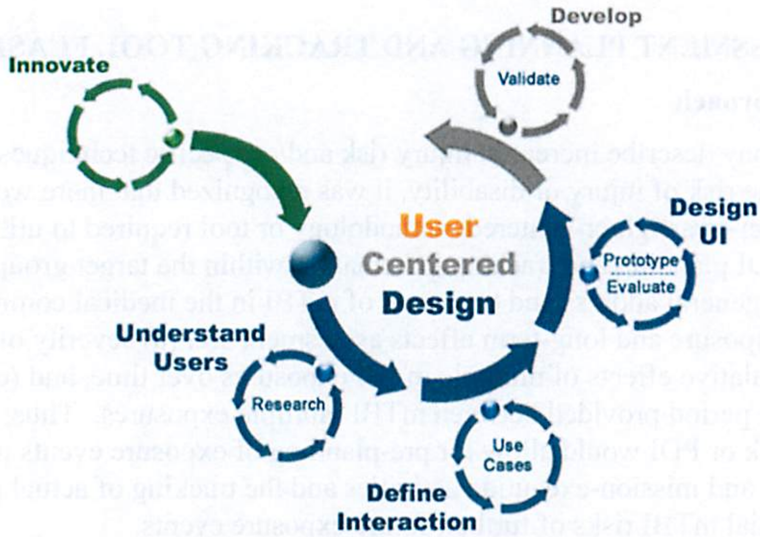

Figure 33. User-Centered Design (UCD) spiral/process.

Further, a Top-Down Function Analysis (TDFA) methodology was employed to break down the specified system missions into gross system functions, those functions were allocated between human (user) and machine, human-machine interface functions were broken down into specific user tasks, and those specific user tasks then drove the design of the system human-machine interfaces. The TDFA process is shown in further detail in Figure 34, below.

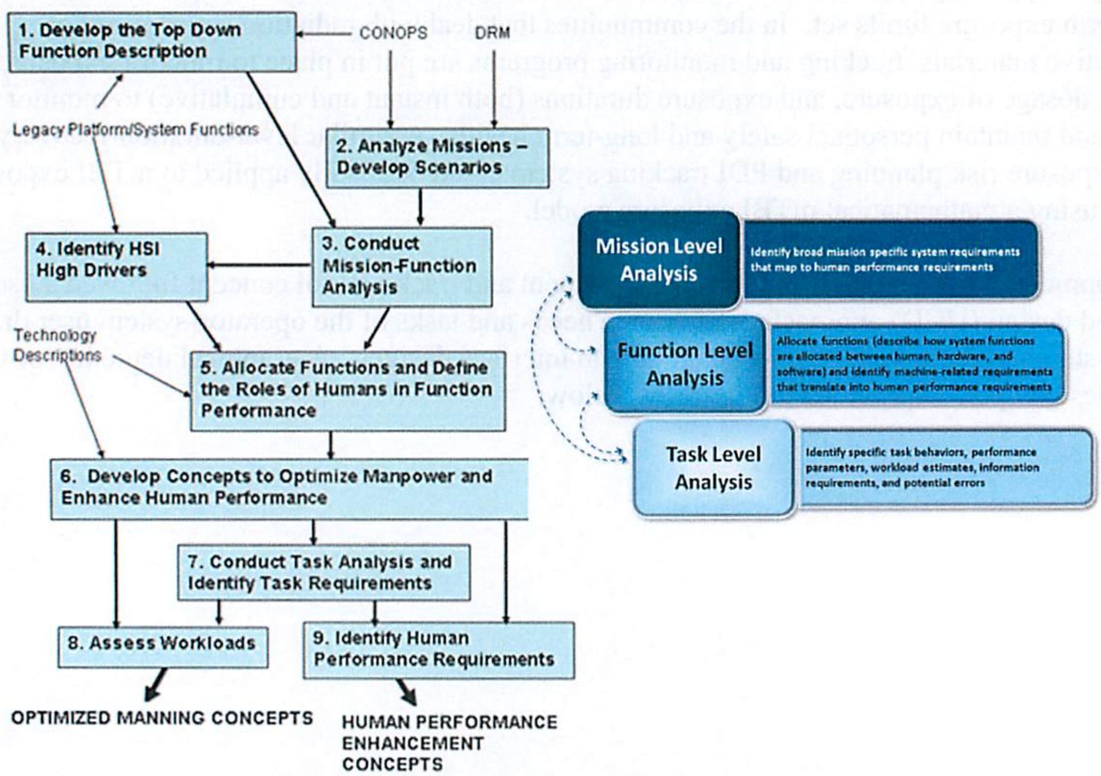

Figure 34. Top-Down Function Analysis (TDFA) methodology for specifying human-system functions and specific user tasks to drive user interface designs.

8.2 Specific Design Drivers

The high-level mission tasks of a first-article mTBI risk assessment and tracking were to enable personnel responsible for planning and managing Fleet operator training, mission-readiness, and mission-execution activities where mTBI effects may be present to:

- Pre-plan an operator activity and gauge the resulting potential mTBI exposure risk and PDI advisory level for individual operators;
- Pre-plan multiple operator activities over time and predict the cumulative mTBI exposure risk and PDI advisory level for individual operators based on the activity type(s), exposure level(s), exposure durations, and interspersed recovery period(s);
- Input on-going actual mTBI exposure information for individual operators to maintain a cumulative mTBI exposure risk and PDI advisory level and more accurately inform further, future pre-planned operator activities' mTBI exposure risk level predictions; and
- Mitigate or prevent mTBI exposure risk and PDI advisory levels outside of a permissible range by providing a clear, intuitive, gradated caution and warning indication for an individual operator's mTBI exposure level.

To bound the first-article mTBI risk assessment and tracking tool concept development effort, a number of initial design parameters and project constraints were specified. These parameters and constraints were developed though interplay between the mTBI Project Management Team, the mTBI Study Team, and through focus group sessions with representative end user groups and operational personnel. In light of the specified system mission, the projected system users, target operating environments, and the projected required overall human-machine system functions, the following general software tool design parameters and project constraints were specified to govern development of a first-article mTBI risk assessment and tracking tool.

Table 12: mTBI Risk Assessment Planning and Tracking Software Tool Design Parameters

Item	Description
Operating platform	Deployed and used on a Microsoft Windows-based PC (laptop or workstation)
Operating System	Microsoft Windows operating system (likely target of MS Windows 7)
Application Platform	Targeted to be developed as a plug-in application ("app") to Microsoft Outlook to integrate with target operational users' current primary calendar and planning tool
Graphical User Interface (GUI) Design	Consistent with Microsoft Corporation Windows User Experience - Official Guidelines for User Interface Developers and Designers, Windows User Experience Interaction Guidelines for Windows 7 and Windows Vista (see Reference Documents, Table 1-1 above), and Standard Microsoft Outlook menu items, tools, controls, interaction structures, and styles

Item	Description
Number of Covered "Operational Personnel"	The application should provide the capability to create a database of, and easily plan and work with, approximately 60 "covered operational personnel" (a normal operational tempo), with a maximum number of around 100 "covered operational personnel" (an upper level, "maximum" operational tempo)
Number of Simultaneous Events on Any Single Day	The application should provide the capability to create entries for, and easily plan and work with, approximately 3-4 simultaneous planned events on any single day (a normal operational tempo), with a maximum number of around 6-7 simultaneous planned events on any single day (an upper level, "maximum" operational tempo)
Software Usability	Readily intuitive user interfaces salient to the target user community developed by consistent application of User-Centered Design (UCD) processes
System Training	Goal of "zero training" required to use the tool; User interface design supports transfer of training from users' prior PC and other, common Microsoft programs (MS Word, Excel, Outlook, etc.) and leverages user knowledge of the iconography, user interface constructs, and operating paradigms from other, known software products
Security Classification	Software will not be developed to run under any specific security classification; Software will be developed to commercial software development standards (as with any commercially-available software product, Microsoft Outlook, etc.) and then will be subject to integration under security classification and information/data protection protocols as with a commercial software product
Network Capability	Software app, running as a plug-in to Microsoft Outlook, will utilize the same network capability as available with the host Outlook application (i.e., if Outlook is networked and allows sharing of calendars, events, etc. then plug-in application will have capability for calendar and event sharing, group calendar posting, etc.)

8.3 First-Article Risk Assessment Planning and Tracking Tool Concept Design

Taking together the TDFA results from the system mission definition, projected system users specifications, target operating environments, required overall human-machine system functions, and the specific user tasks in the system, an initial set of concept mockups was created for an mTBI risk assessment and tracking tool set of user interfaces. These mockups were then vetted through a focus group session with mTBI project engineers and researchers and were iterated to better meet user and mTBI planning and tracking system needs. The updated concept mockups were then presented over focus group sessions with representative end user groups and operational personnel. The focus group reviews with end users included cognitive walkthroughs of the mockups using representative user tasks and informational needs and open feedback sessions with all user classes.

The mockup for the front end, main GUI of the mTBI risk assessment and tracking software tool plug-in app is presented in Figure 35, below.

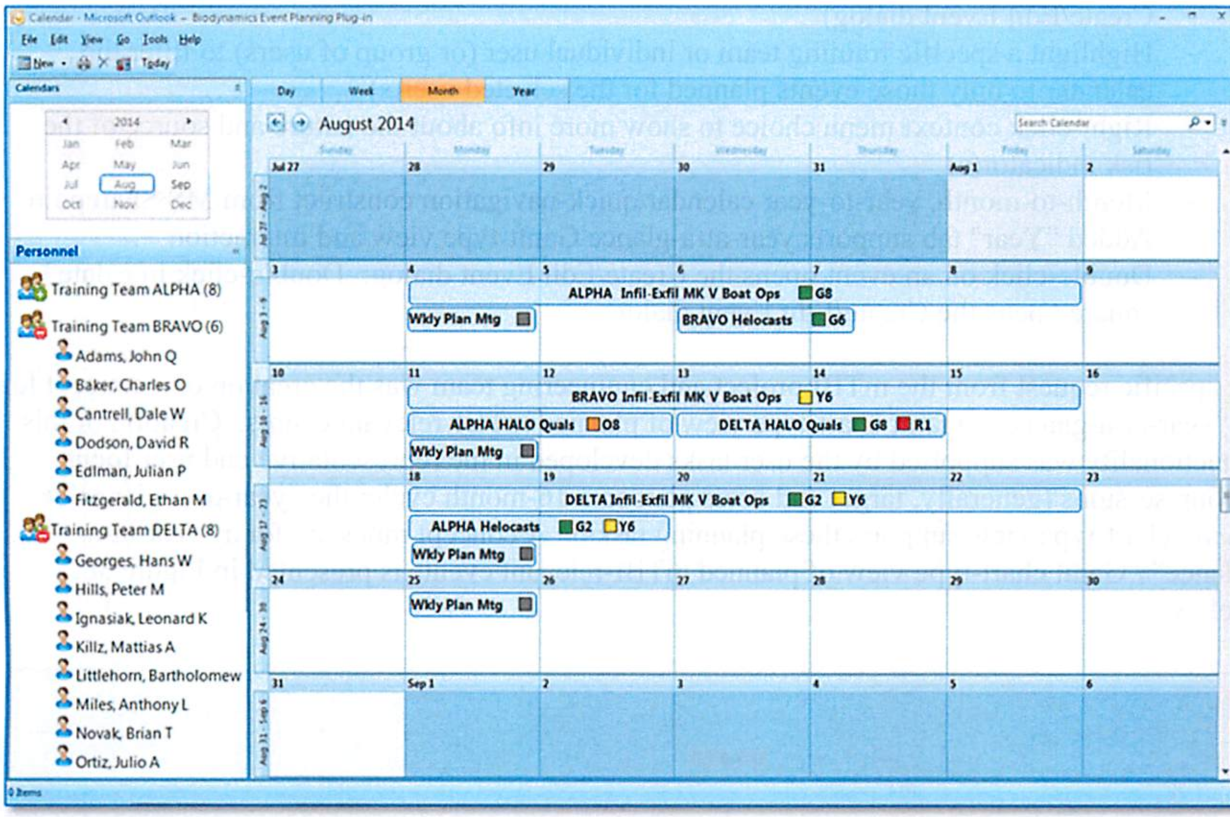

Figure 35. mTBI Risk Assessment and Tracking tool front end / main GUI mockup

<u>Key design attributes for this interface include</u>:

- Standard Microsoft Outlook menu items, tools, controls, interaction structures, and styles
- Consistent with Microsoft Windows User Experience Interaction Guidelines
- Provides PDI advisory level indicators for predicted mTBI- (and MSI-) induced "performance degradation levels" as a GREEN-YELLOW-ORANGE mTBI/MSI PDI advisory system [NSW DEVGRU concept review feedback]
- mTBI/MSI PDI advisory system for level of performance degradation indicators (GREEN-YELLOW-ORANGE) coupled with an indicator showing the number of personnel in that risk category for each event
- RED indicator available to flag personnel restricted from specific (or all) activities (by Medical, etc.) [SBT-22 concept review feedback]
- Redundant indicator of color-name-first-letter ("G-Y-O-R") also used for clarity of information presentation and to support where color alone is not a sufficient display (number of personnel in each advisory level indicated beside color-name-first-letter)
- GRAY Advisory Level indicator used for an event where no mTBI information is planned ("no information" indicator included to clearly display absence of mTBI ImPACT for that event); also no color-name-first-letter or number of personnel present

- Drag planned events to other time periods (same duration) to generate PDI advisory level changes in the indicators and perform what-if analyses of mTBI risk changes
- Drag-and-drop from the personnel list (either whole groups or person-by-person) database to add to events (first drag to empty date creates a new event and opens Create/Edit Event dialog)
- Highlight a specific training team or individual user (or group of users) to filter the calendar to only those events planned for the selected user(s)
- Right-click context menu choice to show more info about the nature and source of the risk indicator(s)
- Month-to-month, year-to-year calendar quick-navigation construct from MS Sharepoint
- Added "Year" tab supports year-at-a-glance Gantt-type view and interaction
- Double-click on an event opens the Create/Edit Event dialog; Double-click in a date square opens the Create/Edit Event dialog

A specific request from the mTBI project and engineering team was the creation of a concept for a "year-at-a-glance" / Gantt chart-type view of planned mTBI-relevant events. Creation of this functionality was supported by the user tasks developed in the representative end user focus group sessions (generally, target end users plan on a 16-month cycle; the "year-at-a-glance" / Gantt chart-type view supports these planning tasks). A concept mock-up for a "year-at-a-glance" / Gantt chart-type view of planned mTBI-relevant events is presented in Figure 36, below.

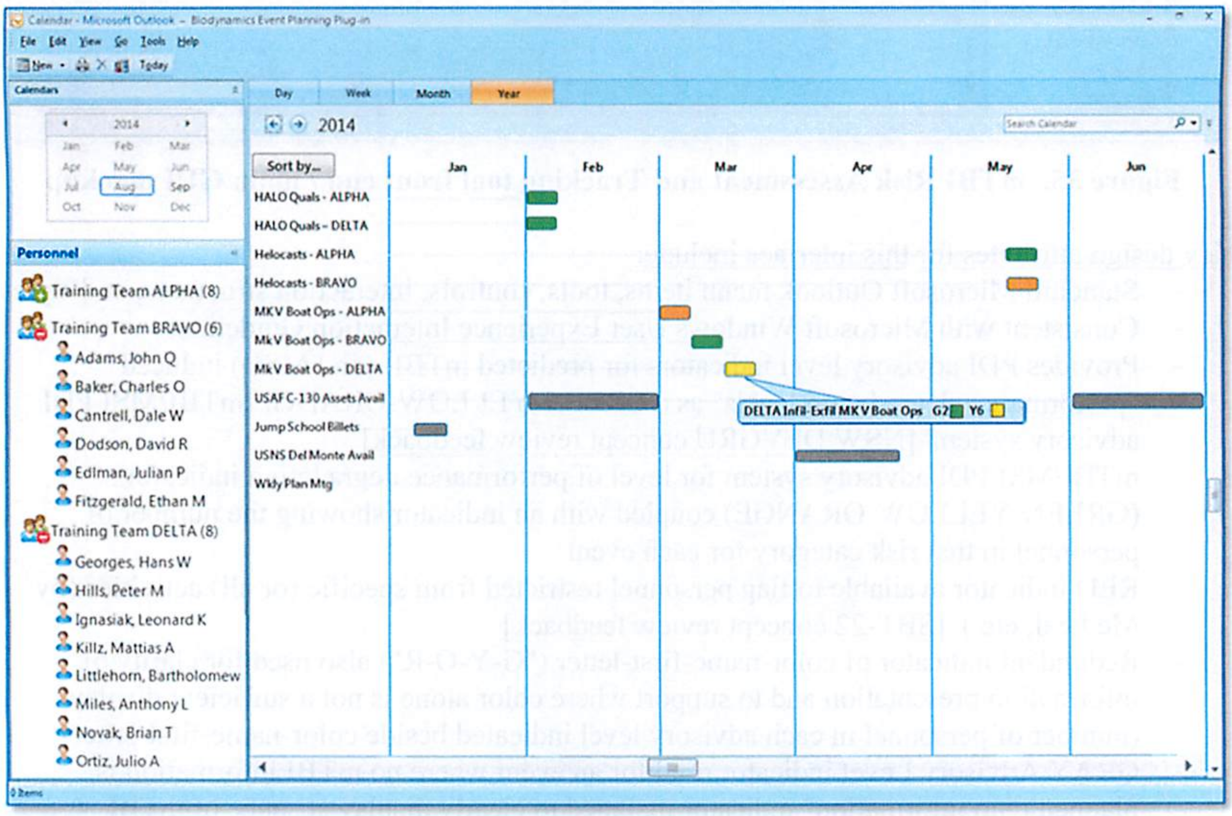

Figure 36. "Year-at-a-Glance" / Gantt view functionality GUI mockup

Key design attributes for this interface include:

- Added "Year" tab supports year-at-a-glance Gantt-type view and interaction
- Bar color for planned events in the calendar indicates the status of the highest PDI risk level indicator among the personnel assigned to the event
- Specific information about each event is provided as a pop-up on mouse-over
- Can plan events around specific assets availability (aircraft, boats, ranges, etc.) and then add in personnel and set the correct mTBI attributes
- [SBT-22 concept review feedback]
- Sort the list by user selectable criteria [by Event Type, Training Team, etc.]
- Witness lines to each event for readability

8.4 mTBI Assessment and Tracking Tool Development – Next Steps

The next steps in the design and specification of the mTBI risk assessment and tracking tool include the development of the first-iteration alpha software prototype of the tool and then follow-on re-testing and interfaces iteration with representative end user groups. This testing cycle with users should include further cognitive walkthroughs, with representative end users performing operational tasks with the tool, and limited interface usability testing utilizing concurrent verbal protocol. The approach to designing the mTBI risk assessment and tracking tool should continue to follow the UCD development path of:

1. ~~Survey user needs and tasks to drive software functionality~~
2. ~~Create initial GUIs concepts based on prior user experience~~
3. ~~Review and iterate initial concepts~~
4. ~~Low-fidelity mock-up review with representative end-users~~
5. ~~Iterate GUIs concepts~~
6. Alpha prototype coded
7. Review alpha prototype GUIs and functionality with representative end-users
8. Beta software coded
9. Beta software usability testing with representative end-users
10. First-article software release
    [new development spiral begins]

9 SUMMARY

This report outlines analyses for all mTBI study participants. There is limited evidence of general ImPACT related performance decrements across the study group. Only one participant reported a frank concussive event or mTBI during the study, and the DASHR data for that participant does not appear to record that concussive event. A substantial number of events were recorded during the study period (~200,000 accelerative events). Key conclusions include:

- Several ImPACT test variables showed strong learning effect.
- For the ImPACT test, there was a statistically significant association of the ImPACT test variable REACT with larger acceleration impacts measured for the participants. This variable did not show a large learning effect for the participants and should be a primary variable of interest for future assessments of accelerative injury.
- There was no statistically significant of accelerations with saccade latency or gain. Anti-saccade results were significant by personnel.

- A concept design for an end-user-/warfighter-centered risk assessment planning and tracking tool was identified to utilize and readily apply mTBI/PDI planning and tracking information within target operational user groups' daily mission activities and tasks.