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TITLE: Sensory Integration Balance Deficits in Complex mTBI: Can Early Initiation of Rehabilitation with Wearable Sensor Technology Improve Outcomes?

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CONTRACTING ORGANIZATION: Oregon Health and Science University
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES)

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14. ABSTRACT

Objectives: 1) To determine the role of timing in rehabilitation of balance deficits in people with mTBI 2) To determine if home monitoring improves outcomes 3) To develop a novel feedback system using wearable sensors to provide physical therapists with real-time information about quality of head and trunk movement during exercise.

Plan: This is an interventional study on people with mTBI. Aim I examines whether initiating interventional physical therapy earlier rather than later improves outcomes. Aim II, nested within Aim I, examines whether home monitoring of vestibular rehabilitation improves outcomes. Aim III develops a system capable of delivering real-time feedback on quality to improve outcomes.

Aims and Hypotheses:
Aim I. Early Intervention: To determine the effects of early versus late rehabilitation for balance deficits in mTBI. We hypothesize that early rehabilitation will improve outcomes more than standard of care.
Aim II. Home Monitoring: To compare traditional balance rehabilitation versus balance rehabilitation with sensor-based home monitoring. We hypothesize that providing physical therapists with objective measures on performance of prescribed exercises at home will improve outcomes in rehabilitation.
Aim III. Real-time Monitoring for Training: To develop and evaluate a novel sensor system that provides real-time feedback to physical therapists. We hypothesize that real-time feedback on head and trunk movements during exercise will be feasible for use by a physical therapist.

Methods:
Aims I & II: These aims involve 160 participants who have sustained an mTBI. They will complete questionnaires to identify their perceived problems, as well as undergo clinical tests of vestibular function and balance and gait. Motion sensors, force platforms, and clinical assessments will be used to measure balance and gait.
Intervention: Participants will be randomly assigned to begin physical therapy immediately or within the standard of care timeline. During these sessions, the participant will be evaluated by the physical therapist while performing exercises around common impairments after concussion. People will perform either standard vestibular rehabilitation exercises or standard vestibular rehabilitation exercises using wearable sensors to track head movements.
Aim III: 5 physical therapists will be trained to use the biofeedback sensor system and, along with 25 people with mTBI, will be asked to provide feedback about the system. 50 people without mTBI will be asked to perform specified exercises that require head movements during standard balance and vestibular exercises to obtain normative values.

Results: We have screened 8 subjects and enrolled 5 subjects in this study. In Aim I, 3 subjects (1 home monitored/2 not monitored) have been randomized in to the early intervention group and 2 subjects (1 home monitored/1 not monitored)in the standard of care group.

15. SUBJECT TERMS
mTBI, Rehabilitation, Brain Injury, Inertial Sensors, Balance, Central Sensory Integration, Concussion, Eye Tracking

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1. INTRODUCTION:

Mild traumatic brain injury (mTBI) is common both in civilian and military populations and can be debilitating if symptoms do not resolve after injury. Balance problems are one of the most common complaints after sustaining an mTBI and often prevent people from returning to their previous quality of life. However, we currently lack clear guidelines on when to initiate physical therapy rehabilitation and it is unclear if early physical therapy is beneficial. We believe that the underlying problem of imbalance results from damage to parts of the brain responsible for interpreting sensory information for balance control. We hypothesize that retraining the brain early, as opposed to months after injury, to correctly interpret sensory information will improve recovery. We also believe this retraining is limited when rehabilitation exercises are performed incorrectly, and that performance feedback from wearable sensors, can improve balance rehabilitation. The researchers in this project are experts at understanding and treating complex balance problems and have developed novel and portable ways to measure balance using new technology. There are three of objectives of this proposal: 1) To determine how the timing of rehabilitation affects outcomes after mTBI 2) To determine if home monitoring of balance exercises using wearable sensors improves outcomes and 3) To develop a novel feedback system using wearable sensors to provide the physical therapist information, in real-time during training, about quality of head and trunk movements during prescribed exercises.

2. KEYWORDS:

mTBI, Rehabilitation, Brain Injury, Inertial Sensors, Balance, Central Sensory Integration, Concussion, Eye Tracking

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Goal	Target Completion Date	Percentage of Completion/ Date of Completion
Specific Aim 1 & 2 (Assessment of late vs early intervention & home monitoring)		
Major Task 1: Launch Study Activities	*March 2018*	98%
Major Task 2: Recruitment and Testing	*March 2021*	18%
Major Task 3: Randomized Interventions	*March 2021*	2%
Major Task 4: Assess Efficacy of Interventions	*March 2021*	0%

Major Task 5: Data Analysis & Publications	*September 2021*	0%
Specific Aim 3 (Real-Time Monitoring)		
Major Task 1: Develop & Evaluate the wearable system for feedback	*September 2021*	5%
Major Task 2: Launch Study Activities	*September 2020*	0%
Major Task 3: Data Collection	*September 2019*	0%
Major Task 4: Data Analysis & Publications on Interventions	*September 2021*	0%

What was accomplished under these goals?

Major task 1: Launch Study Activities

Subtask 1: prepare regulatory documents and research protocol

- Set up sub award at OHSU and VA; The sub award for APDM has been set up-100% complete
- Prepare screening and testing forms for subject database; All screening and testing forms have been finalized-100% complete
- Create REDCap database to store screening and testing forms; The Research Coordinator worked with OCTRI services to design and organize the REDCap database for this project. It has gone into production-100% complete
- Prepare randomization into REDCap for both Aim I and Aim II; The study team's Statistician created an Excel workbook that allows randomization for both Aims. The Research Coordinator and PI have been trained-100% complete
- Prepare forms for FITBIR; Forms have been submitted to FITBIR and we have created the study profile. We are waiting for a approval letter from FITBIR to finalize- 90% complete
- Meet with all sites to establish role of research assistants (RA) in clinic for recruitment; RA's are using the Best Practice Advisory (BPA) in EPIC as the main recruitment tool. They are also in communication with providers at the OHSU Concussion Clinic for referrals-100% complete
- Prepare eCRIS for subject tracking; eCRIS has been set up-100% complete
- Prepare OHSU petty cash/log to track payments of research subjects; Clincard payments instead of petty cash are being used to pay research subjects-100% complete
- Obtain without compensation clearance at the VA for new hires; All study team members have obtained their WOC giving them VA clearance-100% complete

Subtask 2: prepare technology for study

- Purchasing and test software of Opals; All opals needed have been purchased-100% complete

- Develop Kinematics algorithms with APDM sensors; APDM completed development and review of the requirements and specifications of the system and its performance. This includes the movement monitors, sensor synchronization accuracy, and kinematics accuracy level. This also includes design and review of the system validation and verification protocol. They also completed the design of the tracking algorithm that uses inertial sensor data offline-100% complete
- Validate sensor-based kinematics with Motion Analysis (n=10); Validation data from five subjects with mTBI and five healthy study subjects has been collected using inertial sensors and an optical motion capture system, as the reference system. Inertial data analysis is complete and results have been generated including head and trunk range of motion (ROM) and maximum velocity during assessment and training exercises. Manuscript is in progress - 80% complete
- Prepare user interfaces for at-home exercise with sensors; User interfaces for both in-home study subjects and home control subjects have been implemented with a simplified user interface and custom instructions for exercises. APDM implemented changes to test sequence and self-administration protocol based on testing and feedback from physical therapists and collaborators at OHSU-100% complete
- Develop reports with visual displays for the physical therapists; APDM completed various cycles of implementation and improvements based on feedback received from OHSU collaborators. APDM implemented a simplified user interface for subjects to self-collect data at-home during exercises. Test types and condition with instructions for the different exercises were added to enable the user to choose the exercise and level of difficulty to perform-100% complete

Subtask 3: prepare research protocols

- Prepare testing protocol; Testing protocol has been finalized and implemented-100% complete
- Register trial in Clinictrials.gov; This study has been registered on Clinicaltrials.gov-100% complete
- Finalize vestibular assessment battery; The vestibular battery has been finalized and implemented-100% complete
- Finalize and prepare written protocol for physical therapy training; PT training has been finalized and implemented- 100% complete

Subtask 4: hiring and training personnel

- Train RA's in data collection and protocol; We had 2 RA's leave the study and have since trained 2 new RA's on the protocol-100% complete
- Order exercise equipment; All exercise equipment needed has been ordered and received-100% complete

Major Task 2: Recruitment & Testing

Subtask 1: recruitment

- Prepare brochures for subject recruitment; Brochures have been IRB approved and printed-100% complete
- Make contacts with sources of referrals through OHSU Primary Care, Family Medicine, and other sites; Dr. Chesnutt and Jenny Wilhelm (PT) have been developing plans with other

OHSU providers on how to refer participants to our study. This will be an ongoing process- 50% complete
- Meet with primary sources of referral; Our primary source of referral is utilizing OHSU's BPA system that alerts us whenever a patient has been seen with a mTBI or related injury. This has been our most successful recruitment tool. This will be an ongoing process- 30% complete
- Meet with clinic MAs for logistics of recruitment; OHSU Concussion Clinic is aware of our recruitment and screening process. This will be an ongoing process- 40% complete
- Finalize recruitment strategy; Most recruitment will come from EPIC's BPA and In-Basket service. We also will continue to work closely with the OHSU Concussion Clinic and continue to connect with providers and the community- 100% complete
- Create Epic screening logs; All study team members use the same screening log document to track potential study subjects. This allows for easy communication as we are stationed at different locations and to ensure we are recruiting all potential participants- 100% complete
- Add project to researchmatch.org; This project has been registered on researmatch.org- 100% complete

Subtask 2: data collection & management
- Complete vestibular testing at OHSU and VA for data collection; We have tested 5/160 participants -3% complete
- Complete gait and balance testing for data collection at OHSU and VA; We have tested 5/160 participants -3% complete
- Data back-up onto server including manual data entry into Redcap; Data has been placed on the server and also manually entered into Redcap for all study participants- 3% complete
- Screen and verify data on server and check for accuracy; 0% complete
- Validate and submit forms to FITBIR quarterly; 0% complete

Major Task 3: Randomized Interventions on 160 mTBI Patients

Subtask 1: intervention
- Enroll Subjects in rehabilitation intervention; as subjects enroll they are being randomized in to either early or standard of care rehab - 3% complete
- Complete 6 week interventions; 1 subject has completed the 6 week intervention- 1% complete
- PT's document compliance, adverse events and progression of exercise for each subject; PT's are keeping a detailed record of progression through rehab and are required to fill out a summary sheet for each visit documenting any AE's or protocol deviations- 2% complete
- Optimize system user interface and reports based on input from users; 0% complete

Significant Results/ Key outcomes:

Main Study Update:

During this reporting period a total of 8 participants were screened for participation in this study. 5 of those screened were enrolled for participation, and 5 participants completed baseline testing.

Demographic information for these participants is provided in Table 1.

Table 1. Demographics for subjects enrolled, provided as mean (standard deviation).

	mTBI
Gender (n, %female)	5, 100%
Age (years)	33 (15)
Height (m)	1.664 (0.061)
Mass (kg)	65.136 (7.820)
BMI	23.517 (1.210)
Time since injury (days)	34 (25)

No data analyses on these subjects has taken place.

Validation Study Results:
Our study involves the use of Inertial Measurement Units (IMUs) for home-exercise monitoring of head and trunk movements (range of motion (ROM) and peak rotational velocity) in individuals with mTBI during a prescribed vestibular exercise program. To know that the IMUs are providing accurate information, we conducted a validation study comparing the ability of the IMUs to estimate the movement against a gold-standard criterion of 3 dimensional motion capture. Head and trunk motions were assessed when turning to the left and right (L/R), and up and down (U/D). Data were validated across eight walking conditions: 1) Standing with L/R head turns; 2) Standing with U/D head turns; 3) Standing while performing a L/R vestibulo-occular reflex (VOR) task; 4) 3) Standing while performing a U/D VOR task; 5) walking with L/R head turns; 6) walking with U/D head turns; 7) walking in tandem with L/R head turns; and 8) walking in tandem with U/D head turns.

The inertial sensors showed very good agreement with the criterion measurement system for head motions. The IMU data strongly represented the criterion motion capture data for the head ROM and peak rotational velocity across all conditions, as shown by an intra-class correlation coefficient (ICC) > 0.9. Root mean squared error (RMSE), which provides an estimate of the absolute error in the signal remained low for head ROM across conditions, but increased in the walking L/R and tandem walking L/R conditions for peak rotational head velocity (see Table 2). Despite the higher RMSE, the percent error for the head remained low across all conditions (<5%). Figure 1 provides a subplot of the optical signal (black) and IMU (signal) overlaid in the upper figure, and the error within the signal below. A) ROM for walking with head turns (L/R); B) Peak rotational velocity of the head for walking with head turns (L/R); C) ROM for walking with head turns (U/D); and D) Peak rotational velocity of the head for walking with head turns (U/D).

Table 2 Validity results comparing IMU to motion capture for head ROM and peak rotational velocity (ω_p)

	ICC(A,1)		RMSE		% error	
Condition	ROM	ω_p	ROM	ω_p	ROM	ω_p
Standing L/R	0.993	0.994	2.39	11.58	-1.5	-1.6
Standing U/D	0.997	0.991	1.36	9.59	-0.4	-2.3
Standing VOR L/R	0.992	0.994	3.78	6.73	-1.8	-0.3
Standing VOR U/D	0.998	0.992	1.29	5.55	0.02	-2.0
Walking L/R	0.991	0.986	3.55	20.26	-2.0	-4.0
Walking U/D	0.985	0.991	2.71	12.52	-1.2	-3.2
Tandem walking L/R	0.994	0.987	2.93	17.04	-1.9	-4.4
Tandem walking U/D	0.985	0.988	3.11	10.84	-0.4	-2.3
Mean across conditions	0.992	0.990	2.64	11.76	-1.1	-2.5
SD across conditions	0.005	0.003	0.86	4.61	0.8	1.3

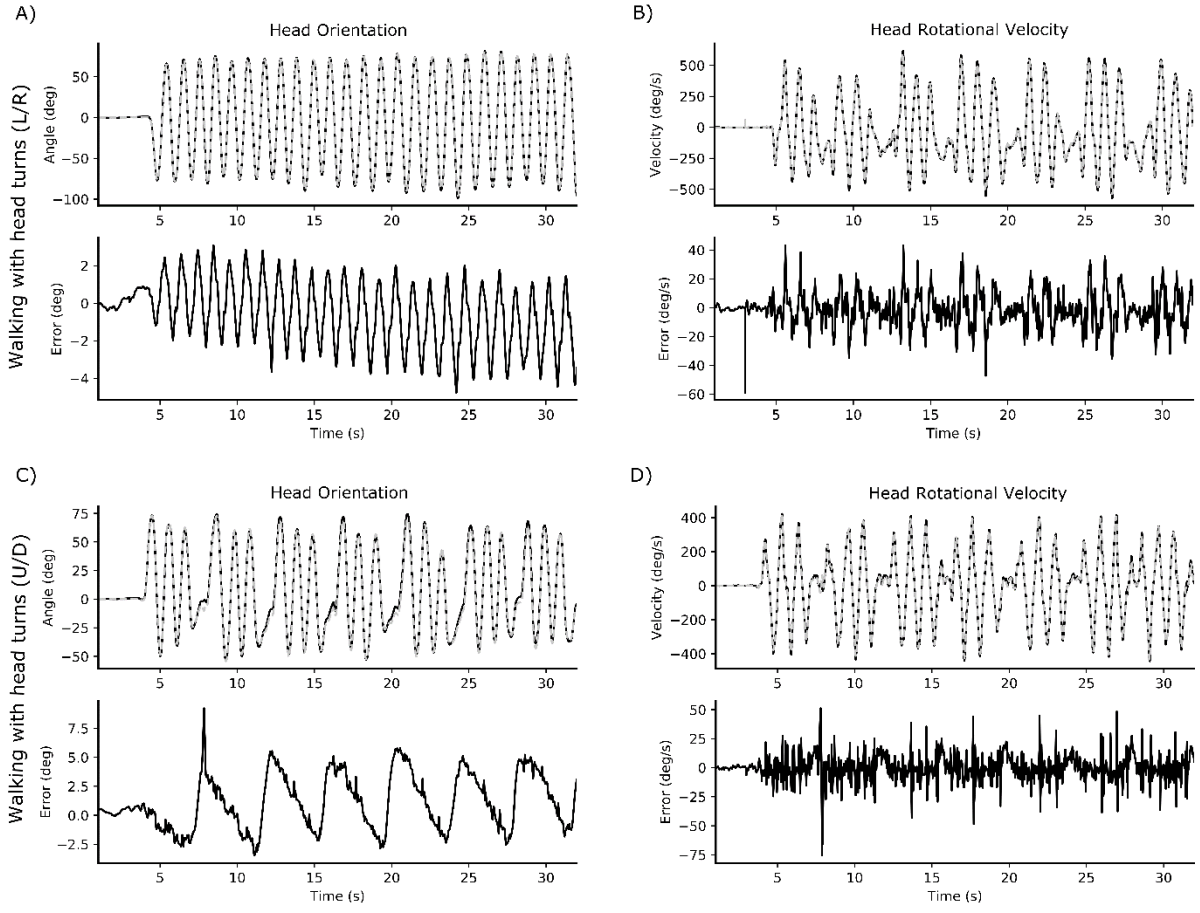
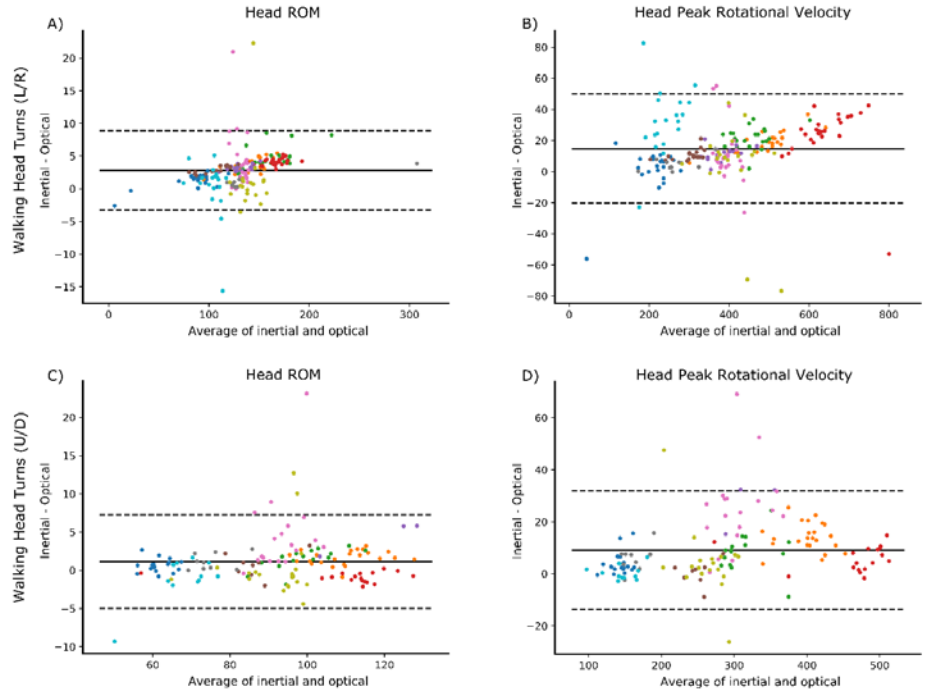


Figure 1. Representative time series data from one participant.

The inertial sensors showed generally good agreement with the criterion measurement system for trunk motions. The agreement between the IMU and motion capture for the trunk were stronger in the L/R direction for both ROM and peak rotational velocity ICC > 0.9, than in the U/D direction (ROM ICC = 0.580 to 0.907; peak rotational velocity ICC = 0.436 to 0.787) across conditions. The reduced strength of the relationship is also mirrored in the RMSE and percent error scores for the U/D motions, shown in Table 3. Bland-Altman plots did not indicate any clear patterns of bias. Examples are provided below for the head ROM and peak rotational velocity during walking with head turns (Figure 2).

Table 3. Validity results comparing IMU to motion capture for trunk ROM and peak rotational velocity

	ICC(A,1)		RMSE		% error	
Condition	ROM	ω_p	ROM	ω_p	ROM	ω_p
Standing L/R	0.986	0.960	0.59	2.31	-6.0	-6.9
Standing U/D	0.580	0.815	1.82	5.41	-29.3	-11.7
Standing VOR L/R	0.985	0.997	3.55	4.16	1.9	0.6
Standing VOR U/D	0.907	0.787	6.49	12.71	19.2	5.3
Walking L/R	0.997	0.976	1.17	5.47	0.8	-6.3
Walking U/D	0.843	0.746	2.60	12.08	-13.2	-17.1
Tandem walking L/R	0.998	0.976	0.96	3.69	-1.5	-3.5
Tandem walking U/D	0.639	0.436	2.66	13.14	-2.9	0.2
Mean across conditions	0.867	0.837	2.48	7.37	-3.9	-4.9
SD across conditions	0.169	0.189	1.78	4.20	13.8	7.2



Each participant is represented by a different color within the plot. A) ROM, walking with head turns (L/R); B) Peak rotational velocity, walking with head turns (L/R); C) ROM, walking with head turns (U/D); and D) Peak rotational velocity, walking with head turns (U/D). Solid lines represent the mean difference, and dashed lines represent ±1.96*SD.

Figure 2. Bland-Altman plots for walking conditions.

Our findings suggest excellent validity for the IMU system when capturing head movements in both the L/R and U/D conditions and excellent validity capturing trunk movements in the L/R conditions. Inertial sensors showed moderate to excellent ability to estimate trunk ROM in the U/D conditions, and was good at capturing peak rotational velocity in U/D conditions except during tandem walking, which showed poor agreement.

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

Members of the research team had the opportunity for training and professional development through attendance at specific military based conferences. Drs. King and Stuart attended the Federal Interagency Conference on mTBI in Washington D.C., USA, and Drs. King, Stuart and Parrington each attended the Military Health System Research Symposium (MHSRS). These key meetings offered the opportunity to listen and engage with experts in the field of research. More specifically, the attendees at MHSRS were invited to attend a session about return to duty decisions and mTBI and allowed the opportunity to continue to build countrywide networks with other experts who are conducting research in the area.

How were the results disseminated to communities of interest?

Information regarding the study has been documented on the following websites, which are available to the public:

- ClinicalTrials.gov
- ResearchMatch.org

This work has resulted in the following journal publication(s):

- Jehu DA, Fino PC, Chesnutt JC, El-Gohary M, VanDerwalker J, Pearson S, Peterka R, Wilhelm J, Pettigrew N, Murchison C, Parrington L, Hullar T, Stuart S, Horak FB, King LA. Rehabilitation of complex mild traumatic brain injury; can early initiation of rehabilitation with wearable sensor technology improve outcomes? A study protocol for a randomized controlled trial. (Under Review)

- Parrington, L, Fino, PC, Jehu, DA, Pearson, S, El-Gohary, M, King, LA. Validation of an inertial sensor algorithm to quantify head and trunk movement in healthy young adults and individuals with mild traumatic brain injury. Sensors. (In Preparation).

Research findings have been disseminated through the following oral presentations:

- Stuart, S. Oculomotor function in concussion. TBI Symposium: From Research to Recovery, Oregon Health and Science University. September 21 2018.
- Wilhelm, J. Updates on Concussion Assessment and Treatment. College of Health Professions Faculty Seminar Series at Pacific University. February 7 2018.
- Wilhelm, J. Active Concussion Rehabilitation. Annual Primary Care Review. Oregon Health and Science University. February 14 2018.
- Jehu, D. How Does The Body Control Balance? The International School. March 23 2018.
- Wilhelm, J. Progressive Rehabilitation Associates: Brain Injury Rehabilitation Center. May 23, 2018.

- Wilhelm, J & Pettigrew, N. Vestibular and Balance Problems after mTBI. TBI Symposium: From Research to Recovery, Oregon Health and Science University. September 21 2018.

Research findings have been disseminated through the following outreach event:

- Information table at OHSU's TBI Symposium (September 21 2018). Informational handouts about the project were provided, and members of our research team discussed the project with community members and OHSU symposium attendees.

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

We had a major delay with setting up the sub award for APDM. This has been resolved and we plan to increase recruitment this next year to reach our projected numbers. We plan to use EPIC's Best Practice Advisory (BPA) and recruit from OHSU's Concussion Clinic in order to reach this goal.

Engineers at APDM will continue to make progress on the remaining tasks related to technology development, verification, and validation. More specifically:

- Complete validation of the sensor-based kinematics with optical motion capture
- Complete development of the real-time algorithms
- Complete validation of the real-time algorithms using optical motion capture system
- Update the system for real-time interface to provide visual biofeedback (details below)

Aim III - Subtask 1: System development for Feedback
The primary goal of Aim III is to develop a wearable sensor-based feedback system to provide real-time information to the physical therapist regarding head and trunk stability during the training phase of rehabilitation. Specific tasks to accomplish this goal is to:

- Develop Real-time algorithms. The algorithm developed to collect and analyze data offline has been validated and will form the basis for real-time analysis.
- Continuous improvement and optimization of the algorithm for real-time will continue through the second year of this project. This will include: validating the system with data collected from Motion Analysis, updating the system for real-time interface using a systematic, iterative process to develop and tune the visual biofeedback prototypes, developing various plots for visual feedback including display of moving avatars, dynamic bars, analog and digital meters.

We also plan to hire a new postdoctoral scholar in January to help with testing and analyses of data.

4. IMPACT:

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

This project will influence the base knowledge and theory of physical therapy treatments for people who suffer from mTBI. This project will give insight on patient recovery for those receiving early intervention versus those receiving standard of care treatment. Clinical practice may also be impacted through the implementation of wearable sensors to more accurately measure and assess gait and balance during both at-home activity, as well as in clinical and rehabilitative settings.

What was the impact on other disciplines?

Sam Stuart (post-doctoral fellow) presented information about our current eye-tracking technology and research methodology at the 2018 TBI Symposium at Oregon Health & Science University. There were a wide range of disciplines at the symposium, including attendees from Family Medicine, Physical Therapy, Occupational Therapy, Audiology, Neurology, Statistics, Sports Sciences, and Basic Sciences.

Additionally, our research team meets monthly throughout the year with a wide range of practitioners who treat patients with mTBI. These meetings allow our team to disseminate research findings, and help to translate knowledge into clinical practice. Meeting with clinicians also allow our team to gain insight, and discuss how research can help to influence clinical practice.

What was the impact on technology transfer?

Throughout this reporting period we have been working closely with APDM Wearable Technologies to 1) validate an algorithm capable of tracking head, neck and trunk motions, and 2) generate an easy user interface for providing objective information to physical therapists and the patient. While in the early stages of development (the technology is only being used within this study), we believe this is a large step toward being able to monitor mTBI recovery in the home environment. The inertial systems in use provide information beyond the typical activity tracker, by providing information not only on quantity (eg. of steps), but on quality of movement. This capability has big implications for both future research and work in the clinic.

What was the impact on society beyond science and technology?

Many of our research team attended the OHSU Brain Fair. At this year's annual event held at the Oregon Museum of Science and Industry (OMSI), we demonstrated our eye-tracking capabilities and explained how this information could be used to help understand more about mTBI.

Our research team has continued to help mentor the development of young researchers completing undergraduate and high-school programs of education. Specifically, we have had students engage in projects relating to the validation of the inertial sensors and eye-tracking procedures.

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

Reported problems/delays from Year 1, Quarter 1:

1) Delay in grant set up, which delayed the project start date
2) The Balance Disorders Lab was under construction for a month
Resolution: Even though we started behind schedule, we were able to get all "Launch Study Activity" tasks completed

Reported problems/delays from Year 1, Quarter 2:
1) Due to construction in the Balance Disorder Lab, this delayed APDM's validation of algorithms
Resolution: Once the construction was completed, we were able to quickly complete the validation data collection and provide APDM with the necessary data

Reported problems/delays from Year 1, Quarter 3:
1) There was a continued delay with the sub award for APDM
Resolution: This has been resolved and APDM has been able to proceed with developing the algorithms, home interfaces, and visual displays

Problems/delays from Year 1, Quarter 4:
1) We had two postdocs and one RA leave the study team, which extended our enrollment start date for this project
Resolution: We have hired new study teams members that are familiar with the protocol and recruitment strategies. We plan to use EPIC's In-Basket and BPA to increase recruitment and we plan to reach our targeted enrollment by the end of this year

Changes that had a significant impact on expenditures

Nothing to Report

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

Nothing to Report

Significant changes in use or care of human subjects

No significant changes have been made.

6. PRODUCTS:

Publications, conference papers, and presentations

Journal publications.
The following publication has been submitted and is under review:

Manuscript submitted to Physical Therapy (journal):

- Jehu, DA, Fino, PC, Chesnutt, JC, El-Gohary, M, VanDerwalker, J, Pearson, S, Peterka, R, Wilhelm, J, Pettigrew, N, Hullar, T, Stuart, S, Horak, FB, King, LA. Rehabilitation of complex mild traumatic brain injury; can early initiation of rehabilitation with wearable

sensor technology improve outcomes? A study protocol for a randomized controlled trial. Phys Ther. In Review.

The following publications has been prepared and will be under review in the next reporting period:

Manuscript to submit to Sensors:

- Parrington, L, Fino, PC, Jehu, DA, Pearson, S, El-Gohary, M, King, LA. Validation of an inertial sensor algorithm to quantify head and trunk movement in healthy young adults and individuals with mild traumatic brain injury. Sensors. In Preparation.

Books or other non-periodical, one-time publications.

The following invited book chapter has been submitted:

- King, LA. Neurological Rehabilitation, 7th Ed. DA Umphred (Eds). The Emerging Role of Wearable Inertial Sensors for Neuro-rehabilitation. In Review.

Other publications, conference papers and presentations.

The following oral presentations have been completed during the reporting period:

- Wilhelm, J. Updates on Concussion Assessment and Treatment, Feb 7 2018, College of Health Professions Faculty Seminar Series at Pacific University
- Wilhelm, J. Active Concussion Rehabilitation, Feb 14 2018, Annual Primary Care Review
- Jehu, D. How Does The Body Control Balance, March 23 2018, The International School
- Wilhelm, J. Progressive Rehabilitation Associates: Brain Injury Rehabilitation Center: May 23, 2018
- Wilhelm, J & Pettigrew, N. Vestibular and Balance Problems after mTBI A Closer Look: Sept 22, 2018

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

As outlined by the schedule of work, our team has been working with APDM Wearable Technologies in the development of a user interface for at-home implementation of vestibular therapy exercises. During this reporting period, in the system interface was developed and tested, and algorithms for data processing have been validated. We are now using this technology within the interventions of the study.

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: Sharna Donovan
Project role: Research Assistant
Nearest person month worked: 2
Contribution to project: Sharna will be involved in the screening and consenting process. She will also manage study recruitment.

Daniel Putterman, Au.D. – no change
Natalie Pettigrew P.T, D.P.T – no change
Sam Stuart Ph.D – no change
Lucy Parrington – no change
Laurie King, Ph.D., P.T. – no change
Robert Peterka, Ph.D. – no change
James Chesnutt, M.D. – no change
Timothy Hullar, M.D. – no change
Nicholas Kreter, B.S. – no change
Jennifer Wilhelm, P.T., D.P.T., N.C.S. – no change
Shelby Martin, M.A. – no change
Edward King, M.S. – no change
Sean Kampel, Au.D – no change
Mahmoud El-Gohary – no change
Deborah Jehu, Ph.D – no change

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?

Organization Name: APDM Wearable Technologies
Location of organization: 2828 SW Corbett Avenue, Portland, OR 97201
Partner's contribution to project: Partners have developed the Opals, which are the wearable sensors that detect movement, gait, and balance. They have developed kinematic algorithms and the home exercise interface for this study.

8. SPECIAL REPORTING REQUIREMENTS

9. APPENDICES

Rehabilitation of Complex TBI with Sensory Integration Balance Deficits; Can Early Initiation of Rehabilitation with Wearable Sensor Technology Improve Outcomes?

PI: Laurie King, PhD, PT **Org:** Oregon Health & Science University **Award Amount:** $4,652,124

Study/Product Aim(s)

Our central hypothesis is that rehabilitation after mTBI is suboptimal due to late initiation of and inadequate performance of exercises that do not adequately challenge vestibular and sensory integration function. Our long-term goal is to clarify best practices for the rehabilitation of balance deficits in people with mTBI by comparing early vs late (standard of care) initiation of physical therapy with and without wearable sensors on balance deficits after mTBI.
Aim I) Early Intervention: To determine the effects of early versus late rehabilitation for balance deficits in complex mTBI.
Aim II) Home Monitoring: To compare traditional balance rehabilitation versus balance rehabilitation with sensor-based home monitoring of the quality of prescribed exercises.
Aim III) Real-time Monitoring for Training: To develop and evaluate a novel, wearable sensor system to provide real-time feedback to physical therapists on head and trunk movement during training.

Approach

We will randomize, at the first physician visit (< 12 weeks post injury), 160 patients with mTBI to receive either early (within 2 weeks from physician visit) or late (standard of care ~60 days after physician visit) rehabilitation. People will be further randomized into either: 1) home exercise program or 2) the same home exercise program with wearable sensors worn on the forehead and trunk to monitor compliance and quality of performance during home exercises. Our primary outcome to measure efficacy of rehabilitation is the Dizziness Handicap Inventory (DHI). Secondary outcomes will be structured along the International Classification of Function and Disability (ICF) models framework and will include novel objective measures of balance and gait, central sensory integration and eye movements.

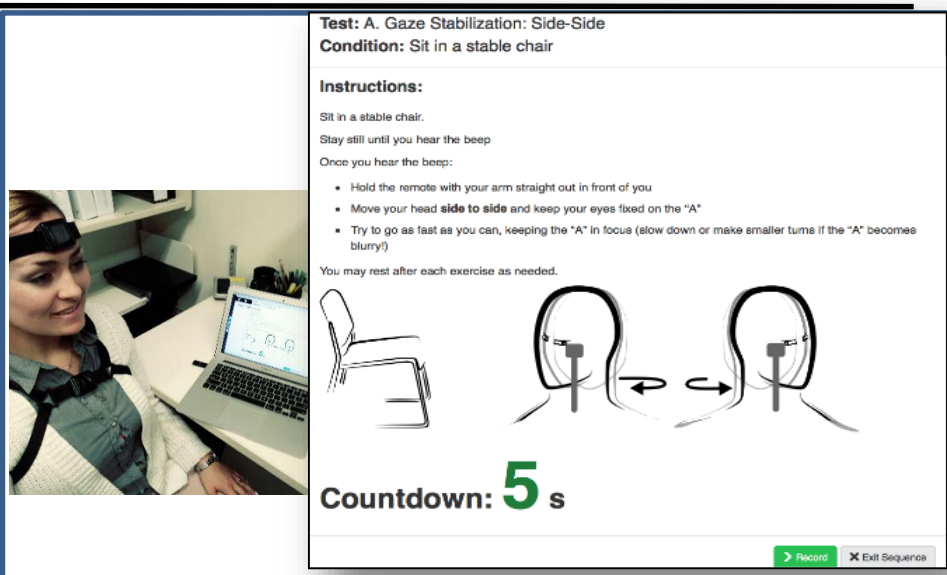


Figure 1. Home-exercise program set-up for participants assigned to the wearable inertial sensor group.

Timeline and Cost

Activities / CY	17	18	19	20
Study setup, Hiring, Training, Purchasing, IRB				
Recruitment				
Aims I and II: Balance Assessment and Rehabilitation 160 Randomized mTBI				
Aim III: Development and Evaluation of Real-time Monitoring 25 mTBI; 25 Control				
Data Analysis				
Manuscript Preparation and Submission				
Estimated Budget ($K) $4,523	$1,007	$1,117	$1,148	$1,251

Updated: Portland, OR; 30 October 2018

Goals/Milestones

CY17 Goal – Study set up and launch
☒ All IRB, finalize protocols, order and test all equipment
☒ Begin balance assessment and rehabilitation (Aims I and II)
☒ Begin development of real-time feedback monitoring system (Aim III)
CY18 Goals – Clarify best practices for mTBI balance rehabilitation
☒ Continue testing and rehabilitation of subjects with mTBI
❑ Test and evaluate prototype feedback system on mTBI and control subjects
CY19 Goal – Clarify best practice for mTBI balance rehabilitation
❑ Continue testing and rehabilitation of subjects with mTBI
❑ Continue testing/evaluating feedback system and refine as directed
CY20 Goal – Complete all testing, analysis and dissemination of results
❑ Complete rehabilitation and all long term follow up testing
❑ Analyze results and disseminate findings
Comments: Recruitment and testing have begun, 5 people are now enrolled in the study
Projected Expenditure: $775,354
Expenditures to Date: $570,507