USAARL-TECH-FR--2024-11

UNITED STATES ARMY AEROMEDICAL RESEARCH LABORATORY

Environmental Sensors in Training: Head Acceleration Dose Response

Tyler F. Rooks, Amanda M. Kelley, Michelle Duffy, & Valeta Carol Chancey

Notice

Qualified Requesters

Qualified requesters may obtain copies from the Defense Technical Information Center (DTIC), Fort Belvoir, Virginia 22060. Orders will be expedited if placed through the librarian or other person designated to request documents from DTIC.

Change of Address

Organizations receiving reports from the U.S. Army Aeromedical Research Laboratory on automatic mailing lists should confirm correct address when corresponding about laboratory reports.

Disposition

Destroy this document when it is no longer needed. Do not return it to the originator.

Disclaimer

The views, opinions, and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy, or decision, unless so designated by other official documentation. Citation of trade names in this report does not constitute an official Department of the Army endorsement or approval of the use of such commercial items.

Human Subjects Use Statement

In the conduct of research involving human subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Department of Defense Instruction 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research) dated 8 November 2011.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
12-12-2024	Final Report	2015 to 2023

4. TITLE AND SUBTITLE
Environmental Sensors in Training: Head Acceleration Dose Response

5a. CONTRACT NUMBER
ESiT; MOMRP 17220; MO210028

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Rooks, T. F.[1], Kelley, A. M.[1], Duffy, M.[1,2], & Chancey, V. C.[1]

5d. PROJECT NUMBER
MOMRP17220; MO210028

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
U.S. Army Aeromedical Research Laboratory
P.O. Box 620577
Fort Novosel, AL 36362

8. PERFORMING ORGANIZATION REPORT NUMBER
USAARL-TECH-FR--2024-11

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Development Command
Military Operational Medicine Research Program (MOMRP)
810 Schreider Street
Fort Detrick, MD 21702

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRDC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Distribution Statement A. Approved for public release: distribution is unlimited.

13. SUPPLEMENTARY NOTES
[1]U.S. Army Aeromedical Research Laboratory, [2]Oak Ridge Institute for Science and Education

14. ABSTRACT

Within the military, it has been estimated that nearly 20 percent of Service Members deployed to Iraq or Afghanistan have sustained at least one mild Traumatic Brain Injury (mTBI). While concussion management and education have significantly improved in recent years, there is still a concern over the possibility of Soldiers with mTBI being missed for evaluation, diagnosis, and treatment. Over the past two decades, civilian and military researchers and clinicians have attempted to leverage environmental sensors, providing the capability to monitor head impact exposures in vivo, to develop a dose-response model for mTBI and concussion. The Environmental Sensors in Training (ESiT) research program evaluated the ability of available devices to identify potentially concussive events resulting from head acceleration events (HAEs) in the military. The present report summarizes the results of the U.S. Army Aeromedical Research Laboratory (USAARL)-led accelerative exposure arm of the ESiT Research Program aimed at developing a dose-response relationship for identifying PCEs with wearable device data.

15. SUBJECT TERMS
ESiT, environmental sensors in training, head impact, head acceleration event, concussion threshold, concussion, mild traumatic brain injury, mTBI

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Loraine St. Onge, PhD
UNCLAS	UNCLAS	UNCLAS	SAR	27	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

This page is intentionally blank.

Preface

Wearable devices are sensors that can be worn on the human body for the purpose of measuring physiological metrics (e.g., heart rate, temperature, activity, etc.), exposure to an individual (e.g., radiation or blast overpressure), or kinematic motion of an individual or body region (e.g., head motion resulting from blunt impact, etc.). Wearable devices include a wide range of sensors to measure specific parameters depending on the design and intent. The present report is focused on wearable devices designed to measure head acceleration events (HAEs) resulting from either blunt impact to, or inertial motion of, the head that may be related to potentially concussive events (PCEs). The devices can be incorporated into helmets, mouthguards, skin patches, or headbands/skull caps.

Wearable devices for monitoring HAEs and PCEs are designed to measure head motion resulting from blunt impacts (e.g., helmet to helmet strikes in football; boxing punches; falls to the ground; head impact to a vehicle structure during an accident; etc.) or from inertial motions (e.g., whiplash, parachute opening shock, falls to the ground with no physical contact, etc.). Head motion is characterized by the measurement of linear and rotational (or angular) acceleration and velocity about three primary axes (Figure 1). The devices commonly measure linear acceleration and rotational velocity where the device is located (e.g., in the mouth, on the surface of the head, or in the helmet), and then the measured data are converted to represent the motion of the head center of gravity (CG) using engineering principles of rigid body dynamics (see Brown et al., 2021).

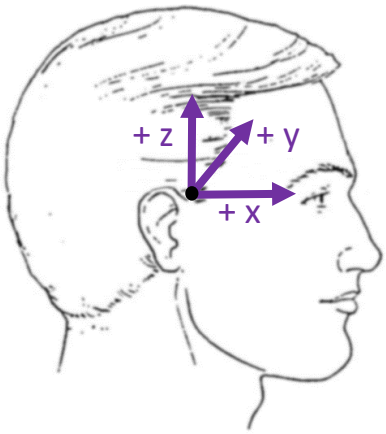

Figure 1. Local head coordinate system with three primary axes at head center of gravity. Measurements of linear motion along each axis and rotational motion about each axis describe head motion measured by the devices.

Many devices have been developed by both the Department of Defense (DoD) and commercial entities. The Head Impact Telemetry System (HITS) (developed by Simbex in 2004) was one of the earliest devices to be used widely. The HITS enabled on-field measurement of dynamic events in football (and later hockey) using a wireless system for the first time and has been cited in more than 100 scientific papers investigating brain injury and concussion (for review, see Le Flao et al., 2022; O'Connor et al., 2017; Patton et al., 2020). Similar helmet-based wearable devices to monitor real-time exposures relating to brain health in the military were developed following a 2007 directive from the Vice Chief of Staff of the Army, requiring that

Soldier combat helmets be fitted with technologies to sense and record helmet response to potentially concussive dynamic events. As a result of this order, two generations of helmet-mounted sensors (HMS) were fielded to deployed troops, and data were collected from helmet exposures. However, no clinical or field guidance was provided regarding how to use or interpret the data provided by the HMS units. Several technological limitations in both the HITS and the HMS systems have contributed to large amounts of uncertainty in the data collected. The primary technological limitations include (1) the inability to reliably identify false events (e.g., helmet or device motion with no head motion); (2) estimating the resulting head motion from the helmet-mounted sensor data; and (3) the inability to reliably time stamp events to link them with diagnosed or suspected concussions (Rooks et al., 2023; O'Connor et al., 2017; Rooks et al., 2015; Siegmund et al., 2016).

In 2014, the first study with a commercially available head impact monitoring system other than the HITS was published (Figure 2; Le Flao et al., 2022). Since 2014, greater than 100 peer-reviewed papers have been published using a variety of head impact monitoring systems (Figure 2), including skin patches, mouthguards, in-ear sensors, helmet-mounted sensors, and headbands or skullcaps (Le Flao et al., 2022; O'Connor et al., 2017; Patton, 2016). With the significant rise in commercially available technology, and the associated rise in research being performed, several challenges in research methodology have become apparent. One challenge in particular is determining the accuracy of the devices when measuring severity of impact and the ability of the devices (or researcher) to determine whether a reported event was truly the result of head motion or was a false-event, resulting from the device being impacted or moving independently of the head. The limited use of video verification of HAEs and accurate tuning of false-positive rejection algorithms has been a critical gap in the advancement of the state of the science for head impact monitoring programs (Kuo et al., 2022; Patton et al., 2020).

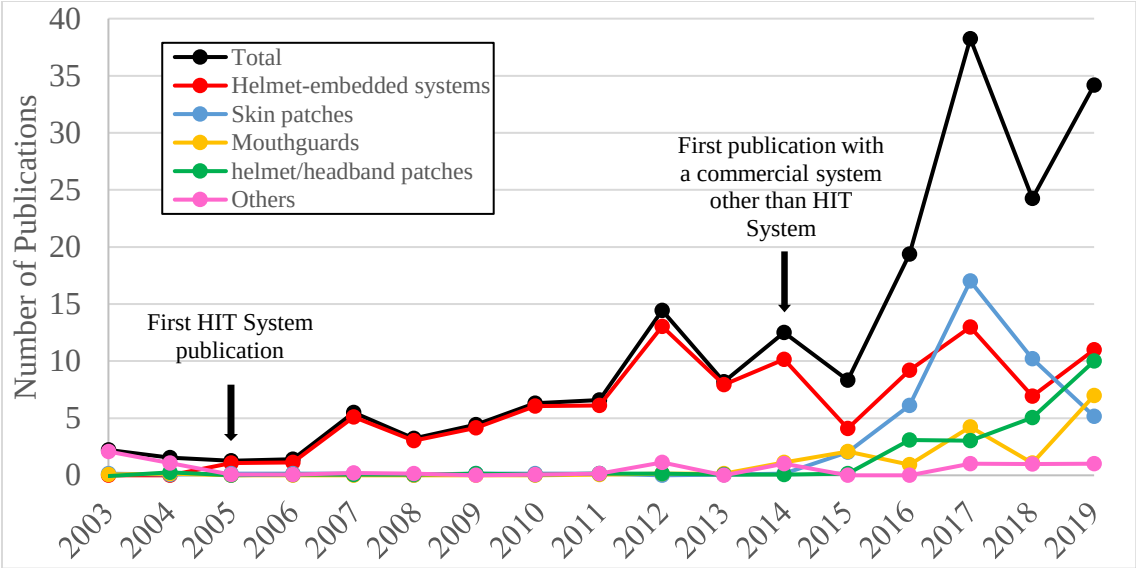

Figure 2. Number of publications by technology between 2004 and 2019. Figure adapted (with permission) from Le Flao et al. (2022). Highlighted in the figure is the sharp rise in publications in 2012, followed by the first publication from non-HITS devices and the subsequent rise in publications using skin patches, headbands, and mouthguards.

To prioritize data being captured from blunt impacts or inertial motions, the devices use a combination of trigger thresholds (i.e., collecting data only if peak linear acceleration or peak rotational velocity in any axis exceed a threshold) and false-positive filtering algorithms (Kuo et al., 2022; Le et al., 2023; Patton et al., 2020). A common challenge for interpretation of data from wearable devices is ensuring that data captured are the result of true head impacts or accelerations of interest (i.e., true events reporting device motion resulting from head motion) versus false events (e.g., those resulting from a device being impacted, or device motion with no head motion). In addition to false events, the wearable devices may capture low-severity events that are the result of head motion but are not indicative of a PCE. In general, these "activities of daily living" are below 10 to 15 g peak resultant linear acceleration. Examples of activities of daily living (ADL) type exposures include low severity bumps or taps to the head, inertial head motions of the head from running or jumping type activities (e.g., jumping jacks), or doing other types of physical activity (Bussone, 2005; Funk et al., 2011; Hernandez & Camarillo, 2019; Miller et al., 2020).

Blunt impacts and inertial motions resulting in head motion are commonly referred to as either head impacts or HAEs. A head impact is generally defined as a measured HAE with greater than 10 g peak linear acceleration (PLA) at the head CG. An HAE with PLA less than 10 g are considered minor kinematic motions representative of ADL described above. While ADL may reach up to 15 g, a threshold of 10 g is commonly employed as a conservative estimate to capture low-severity head impacts that may be of interest for repetitive exposures (Kuo et al., 2022; Le Flao et al., 2022; Le et al., 2023).

This page is intentionally blank.

Acknowledgements

This research was supported in part by an appointment to the Research Participation Program at the U.S. Army Aeromedical Research Laboratory administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Army Medical Research and Development Command.

This page is intentionally blank.

Table of Contents

List of Figures

List of Tables

This page is intentionally blank.

Introduction

Within the military, it has been estimated that nearly 20 percent of Service Members deployed to Iraq or Afghanistan have sustained at least one mild traumatic brain injury (mTBI) (Stein et al., 2016). The TBI Center of Excellence (TBICoE) tracks the number of diagnosed TBIs across the Department of Defense (DoD) with data available starting in the year 2000 through Quarter 1 of 2023. The TBICoE reports that a total of 479,953 TBIs of all severities have been diagnosed in that time. Of these, 82.3% (394,591) were classified as mild (TBICoE, 2023). The number of documented TBIs peaked in 2011, with greater than 30,000 diagnoses in the year (greater than 25,000 were classified as mild). In 2013, it was recognized that an estimated 80% of TBI diagnoses were made in a nondeployed (i.e., Garrison) setting (Helmick et al., 2015). TBI diagnoses in nondeployed settings may be the result of vehicle crashes (private or military-owned), falls, sports and recreational activities, or military training.

The TBICoE refers to mild TBI (mTBI) and concussion as synonymous in their reporting. Immediate symptoms associated with mTBI (concussion) include loss of consciousness lasting less than 30 minutes, alteration of consciousness lasting less than 24 hours, or post-traumatic amnesia lasting up to 24 hours (O'Neil, 2013). Comparatively, moderate to severe TBI is characterized by increased severity of symptoms, notably longer durations of loss or alteration of consciousness and positive results on medical imaging (e.g., computed tomography [CT] or magnetic resonance imaging [MRI]) (TBICoE, 2023; McCrory et al., 2017; Patricios et al., 2023). For all severities of TBI, symptoms may last from a couple of days to multiple years following the injurious event. Moreover, repeated TBIs may result in more severe and long-term consequences (Caccese et al., 2019; Patricios et al., 2023). Multiple mTBIs could potentially increase the risk of neurodegenerative disorders (McAllister & McCrea, 2017); while no link has definitively been established between Alzheimer's disease and repetitive mTBI, earlier onset of Alzheimer's was observed in a study of retired football players versus the general population (Guskiewicz et al., 2005).

The need for early and accurate diagnosis of mTBI has been well recognized and has implications for return-to-duty timelines (Asken et al., 2018; Asken et al., 2016; Meehan III et al., 2013; Stein et al., 2016). Additionally, the need for guidance on when military personnel should seek or be directed to seek evaluation and treatment (if needed) has been a consideration of DoD policy for concussion management (Department of Defense Instruction [DoDI] 6490.11; Headquarters Department of the Army [HQDA] Executive Order [EXORD] 165-13; Warfighter Brain Health [WBH] DOTmLPF-P Change Request [DCR] and Initial Capabilities Document [ICD]).

While concussion management and education have significantly improved in recent years through the efforts of multiple research programs, policy updates, and educational programs, there is still a concern over the possibility of injuries in Soldiers and athletes to be missed (Meehan III et al., 2013). Diagnoses for concussion may be missed through (1) a lack of self-reported exposure; (2) Soldiers and athletes intentionally performing poorly on baseline assessments (e.g., "sandbagging") in order to improve their chances of passing a concussion assessment post-injury; or (3) intentionally responding to screening questions in a way to guarantee a negative concussion screening without further assessment (Hainsworth et al., 2023; Higgins et al., 2017; Rizzo et al., 2021). Several efforts to minimize the effects of sandbagging,

or avoiding the screening questions, have been attempted; however, there remains a need for an objective indicator of PCEs to ensure Soldiers and athletes are appropriately assessed and enter treatment as early as possible.

Over the past two decades, civilian and military researchers and clinicians have attempted to leverage wearable devices to monitor head impact exposures in situ (see Preface) to develop a dose-response model for mTBI and concussion. However, research efforts have largely been unable to come to a consensus for a threshold or dose-response relationship of concussion. The lack of consensus is likely caused by concerns over the number of falsely predicted concussions (i.e., the false-positive rate) of many proposed metrics combined with the large number of concussions occurring at low severities (O'Connor et al., 2017; Rowson et al., 2018; Siegmund et al., 2021; Stemper et al., 2019; Tierney, 2022). In 2017, the Fifth International Conference on Concussion in Sport noted the limited utility of wearable devices (helmet-based or not) for clinical applications, citing the continued debate over the accuracy and precision of head kinematic measurements, with reported peak linear and rotational acceleration values varying widely in concussed individuals (McCrory et al., 2017).

Several helmet- or head-mounted wearable devices have been developed by the DoD and commercial entities to quantify head impact exposures and detect PCEs. As noted in the Preface, the advancement and development of technology, as well as the amount of research, has significantly accelerated in recent years (Figure 1). As a result, the limitations of wearable devices noted by the Fifth International Conference on Concussion in Sport may have been overcome, enabling the definition of clinically useful dose-response relationships between exposure and risk of injury or potential injury (Arbogast et al., 2022; Arbogast et al., 2023).

The Military Operational Medicine Research Program (MOMRP) funded the Environmental Sensors in Training (ESiT) research program to address the challenges of introducing wearable devices (i.e., environmental sensors) capable of monitoring HAEs or blast exposures in military environments. A major goal of the ESiT research program was to evaluate the ability of commercially available devices to identify PCEs resulting from head acceleration or blast exposures. The present report summarizes the results of the U.S. Army Aeromedical Research Laboratory (USAARL)-led accelerative exposure arm of the ESiT research program aimed at developing a dose-response relationship for identifying PCEs with wearable device data.

Methods

To investigate the development of an acceleration-based dose-response relationship, data were analyzed from three distinct research efforts, the ESiT Core study, the ESiT United States Military Academy (USMA) study, and the Prevent Biometrics study. The ESiT Core study collected HAE data during training at the basic airborne course (BAC) and combatives master trainer course (CMTC) using multiple wearable devices. In addition, the ESiT Core study collected neurophysiological performance assessments from all volunteers at the end of each week of training (BAC) or following each sparring session (CMTC). For additional details on the BAC and CMTC courses, see Appendix A. The ESiT USMA study collected HAE data during men’s and women’s rugby, and during introductory boxing courses using the Prevent Biometrics impact monitoring mouthguard (IMM) (Prevent Biometrics, Minneapolis, MN, US). In addition

to the HAE data, the ESiT USMA study captured concussion diagnoses from enrolled subjects (diagnoses were performed by clinical providers). Finally, the Prevent Biometrics study, funded through a broad agency announcement (BAA) grant (contract number W81XWH-17-01-0019), collected HAE data from multiple military and athletics environments (the military environments are the focus of the present report) (Bartsch et al., 2022). The Prevent Biometrics study was a collaboration with USAARL, and the results are being leveraged by the ESiT research program. Data were collected by Prevent Biometrics in several military training environments (airborne, combatives, and boxing) but without neurophysiological performance measures. All PCEs were based on video-observed indicators of concussion characterized by a consensus guide for sideline medical spotters to identify individuals at risk of concussion through video or observation (Davis et al., 2019).

ESiT Core Study

The study was reviewed and approved by the U.S. Army Medical Research and Development Command Institutional Review Board (IRB). Data were collected during the BAC, which taught Service Members to conduct static line parachute operations, and during the CMTC, under the Modern Army Combatives Program, which taught Service Members close-quarters hand-to-hand combat. Service Members attending the BAC and CMTC were recruited, consented, and received baseline neurophysiological assessments on their in-processing day, or at the start of the training course, prior to any drills involving the potential for HAEs. Subjects in the BAC received follow-up evaluations at the completion of each week of training for a total of four evaluations. Subjects in the CMTC received follow-up evaluations following each sparring session, averaging two per week, for three weeks. Baseline and follow-up evaluations for both the BAC and CMTC included the Military Acute Concussion Evaluation (MACE) and completion of a virtual reality (VR)-based assessment platform (integrated Display Enhanced Testing for Cognitive Impairment and mTBI [iDETECT]; Georgia Tech Research Institute [GTRI], Atlanta, GA). The iDETECT platform is a VR-based neurological performance assessment, including a neuropsychological test battery, a non-postural balance/sensory integration test battery, and a vestibular and oculomotor test battery (Figure 3). Additionally, subjects completed the military version of the Post-Traumatic Stress Disorder Check List-Military (PCL-M) and a concussion history questionnaire during the baseline assessment (Bernhardt et al., 2019; Kelley et al., 2021). Detailed methods and descriptions of the baseline and follow-up assessments are available in Bernhardt et al. (2019) and Kelley et al. (2021).

For both the BAC and CMTC, volunteers were instrumented with two head-mounted wearable devices to record HAEs. The commercially developed X2 Biosystems xPatch and the BlackBox Biometrics®, Inc. Linx (Appendix B) were originally designed for athletics applications and are capable of measuring head accelerations and rotations through internal sensors and storing the data locally for retrieval at the end of the exercise or upon connection to a Bluetooth-enabled device (for the Linx only). The two devices used in this study (1) can measure linear accelerations and angular rates of the head in three axes; (2) allow the ability to download the data and view the impact (either through wired or wireless methods); and (3) are compatible with existing personal protection equipment and equipment for both the BAC and CMTC (Rooks et al., 2023). Metrics reported by the xPatch and Linx include resultant peak linear acceleration (PLA), resultant peak rotational acceleration (PRA), and resultant peak rotational velocity (PRV). All metrics were reported as estimates at the head CG using rigid body kinematics

transforms implemented by the device manufacturers. A third (helmet-based) wearable device was tested with the BAC volunteers; however, these data are not included in the present report due to incompatibility in the CMTC course, as well as limited data available for analysis in the BAC (Rooks et al., 2023).

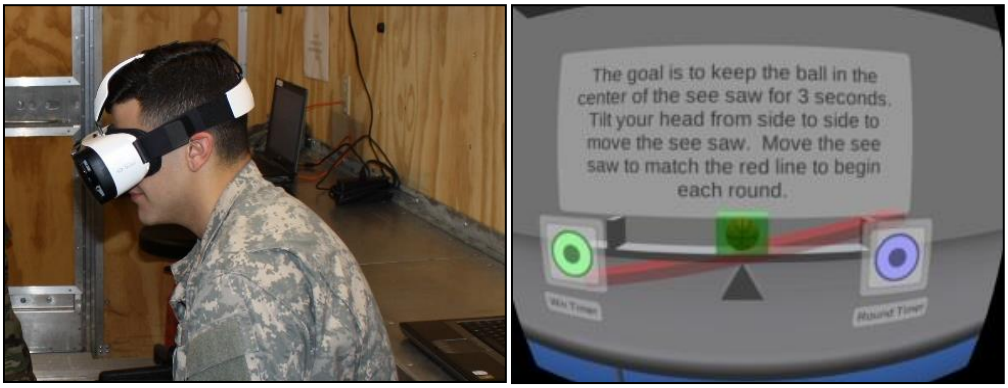

Figure 3. GTRI's VR-based integrated Display Enhanced Testing for Cognitive Impairement and mTBI (iDETECT) neurophysiological performance assessment device (left) allowed quick, focused individual assessments (e.g., non-postural balance/sensor integration test; right) immediately following training without the need for computer infrastructure and limiting the influence of external stimuli.

To screen out non-HAE datasets, volunteers from both the CMTC and BAC were videotaped during the drills to visually identify and verify that an HAE occurred. Within the BAC, wearable device data and video were both synchronized to a National Institute of Standards and Technology traceable time source (www.time.gov). For the BAC dataset, time-synchronized video was reviewed to identify instances where the volunteers hit their heads against the ground or another surface. The timing of each video-identified head impact was marked and then compared with device data from the xPatch and Linx devices. Wearable device HAEs occurring at the same time as an observed event on video were then used for further analyses.

A similar approach was attempted during the CMTC courses; however, errors synchronizing time between the wearable devices and video at the time of collection limited the ability to complete video verification of HAEs for that dataset. While video verification was not possible for the CMTC dataset, the measured HAEs were analyzed for quality based on signal characteristics and through in-house machine learning classification algorithms. For the current analyses, "good" HAEs were characterized by a bell curve shape with smooth transitions, limited spikes, no DC offset (i.e., no amplitude displacement from zero), and pre-trigger data. While "bad" HAEs were characterized by single or multiple short duration spikes (less than 1 or 2 milliseconds), significant DC offset with no additional response, or substantial noise in the signal representative of the device moving independently of the head. In addition, the xPatch data were classified as "good" or "bad" using a previously developed machine learning algorithm with improved performance over the manufacturer's classification algorithm (Rooks et al., 2019). Finally, as the xPatch device provides both raw data and processed data, HAEs were excluded from the analysis if the reported peak acceleration (from the xPatch system) did not match in-house processed peak accelerations. Several HAEs contained markers of both "good" and "bad"

events and were classified as a third level, "questionable." The "questionable" events were also excluded from our current analysis to limit the potential for false-events to affect the data analysis. Following data cleaning procedures to obtain "good" HAEs for both the BAC and CMTC, data were checked for impossible values or technical errors that remained prior to statistical analyses.

Detailed methods for data analysis from the ESiT Core study with the BAC data collections are described in Kelley et al. (2021) (statistical analyses) and Bernhardt et al. (2019) (neurophysiological performance assessments). Briefly, the "good" HAEs were inspected for normality and assumptions of parametric tests prior to analyses. Relationships between wearable device outputs for "good" HAEs and performance outcomes on the non-postural balance tasks from the iDETECT VR platform (GTRI, Atlanta, GA) were assessed using Pearson's *r* correlation coefficients (Kelley et al., 2021). The alpha level for analyses was set at $p = 0.05$. Non-postural balance performance outcomes required normalization to individual performance for analysis. Non-postural balance performance outcomes from weeks 1 and 2 (see Appendix A for details on training weeks) were normalized to the baseline performance (i.e., baseline-adjusted data) to control for individual differences and measure changes from baseline. Additionally, performance outcomes from week 2 were normalized to values recorded at the end of week 1 (i.e., week 1-adjusted data) to control for any changes in performance between baseline and week 1. Next, for each wearable device (i.e., Linx and xPatch), the Pearson's *r* correlation coefficients between the device data (e.g., number of impacts, mean and maximum values of peak linear acceleration, peak rotational acceleration, and peak rotational velocity) and baseline- and week 1-adjusted performance were calculated. Due to challenges verifying the measured data (i.e., confirming "good" events), performance outcomes at the end of week 3 were not used. Sensor data for weeks 1 and 2 included head impacts incurred in the 3 days prior to testing. Given the discrepancies between the outputted data between the two devices, correlational analyses were conducted separately for each (Kelley et al., 2021).

In addition to the above analyses, a subsequent analysis of the BAC data was completed; a hierarchical regression analysis was used to determine the ability of the wearable devices to predict neurophysiological performance deficits. The CMTC data were also analyzed following similar methods; however, analyses are ongoing to refine these data further.

ESIT USMA Study

The ESIT USMA study was reviewed and approved by the Naval Medical Center Portsmouth IRB Office. Data were collected during men's and women's spring and fall rugby practices and games and during required introductory boxing courses for cadets. Rugby data were collected during the fall and spring semesters of 2019 and 2020. Boxing data were collected during the fall and spring semesters of 2021. HAEs were measured using the "boil-and-bite" IMM developed by Prevent Biometrics (Prevent Biometrics, Minneapolis, MN, US; Appendix B). As the IMM system matured, multiple versions of the device were used under the ESIT USMA study. The first three seasons of rugby data collection were completed by an older version of the IMM (v1.0) that did not include a robust false-positive rejection algorithm. Data from the final rugby season and the boxing courses were collected with a newer IMM (v1.4) that included a proximity sensor to detect when the device is worn on the teeth. The combination of the proximity sensor and signal classification techniques based on signal characteristics (e.g.,

frequency content, duration, magnitude, etc.) significantly improved the performance of the Prevent Biometrics (Minneapolis, MN) false-positive rejection algorithm (Fetchko et al., 2022). In addition to the false-positive rejection algorithms used, the IMM data from both rugby and boxing were video reviewed to verify that HAEs were true events and not false positives (additional details for the video verification methods are described in Fetchko et al. [2022] and Fetchko et al. [2023]).

For both rugby and boxing environments, all volunteers were monitored for HAEs, and only those with a clinically diagnosed concussion received further neurophysiological performance assessments. For the present report, only the diagnosis of concussion was considered (versus the additional neurophysiological performance assessments) due to the limited sample size of subjects with a concussion who were wearing an IMM that provided "good" data.

Prevent Biometrics Study

Data collected in the Prevent Biometrics study were collected through two primary protocols that were reviewed and approved by either the Medical College of Wisconsin IRB or the U.S. Army Medical Research and Development Command (USAMRDC) IRB (both protocols received USAMRDC Human Research Protections Office review). All HAEs were measured using the "boil-and-bite" IMM developed by Prevent Biometrics (Prevent Biometrics, Minneapolis, MN; Appendix B). The IMM is worn on the upper dentition and is custom fit to each volunteer. Subjects were recruited from activities across multiple military training environments (parachute operations, combatives, and boxing) with a potential risk of head impact exposure.

To screen out non-HAE data sets, video and IMM hardware were used to confirm that an HAE occurred on video and that the IMM was on the teeth during the HAE at the time in the video. Metrics reported for each HAE captured by the IMM include resultant PLA, resultant peak linear velocity (PLV), resultant PRA, and resultant PRV. All metrics were reported as estimates at the head CG using rigid body kinematics transforms implemented by the device manufacturer.

No neurophysiological performance measures were collected during the study; however, during video review to verify the presence of head impact exposures, observed indicators of potential concussion were identified by trained staff at Prevent Biometrics. Video reviewers identified the indicators of concussion according to documented guidelines for video review used by independent sideline medical personnel from multiple professional sporting leagues (Bartsch et al., 2020; Davis et al., 2019). Video verification methods for identifying observable indicators of concussion included a range of visible signs indicative of a potentially concussive event (Table 1).

This space is intentionally blank.

Table 1. Video Observation of Concussion – Sideline Spotter Categories

Immediate incapacitation	• convulsion • tonic posturing • suspected loss of consciousness • confirmed loss of consciousness • clearly dazed (i.e., blank or vacant look) • ataxia
Altered balance or movement	• slow to get up • gross motor instability • functional disturbance (i.e., staggering, stumbling, tripping, falling) • movement (i.e., slow, labored, abnormal, or unstable movement)
Atypical behaviors and other signs	• head clutch • confusion/disorientation • irregular action (e.g., line up on wrong side, avoiding contact, unsure of location, etc.) • seeks out caregivers

Results

ESiT Core Study

Within the BAC, data were collected from 40 subjects. The xPatch device recorded 4246 total HAEs; 654 ultimately were matched with a confirmed event on video. Of the 654 HAEs, 417 were then confirmed as "good" HAEs with quality signal traces. Per subject, the xPatch recorded between 1 and 38 good HAEs, with one subject having no "good" HAEs matched to the video. From the "good" HAEs, the mean resultant PLA (14.5 ± 5 g) and the mean resultant PRV (12.8 ± 7.7 radians per second [rad/s]) were calculated (Figure 4). The maximum resultant PLA was 43 g (with a resultant PRV of 27 rad/s) and the maximum resultant PRV was 47 rad/s (with a maximum resultant PLA of 17 g).

The Linx device recorded 265 total HAEs; 96 ultimately were matched with a confirmed event on video. Of the 96 HAEs, 47 were then confirmed as "good" HAEs with quality signal traces. Per subject, the Linx recorded between 1 and 17 good HAEs (notably, 22 of the 40 subjects had zero HAEs recorded). From the identified good HAEs, the mean resultant PLA (86.5 ± 29 g) and the mean resultant PRV (24.8 ± 7.4 rad/s) were calculated (Figure 4). The maximum resultant PLA was 172 g and the maximum resultant PRV was 42 rad/s (both maxima from the same event).

This space is intentionally blank.

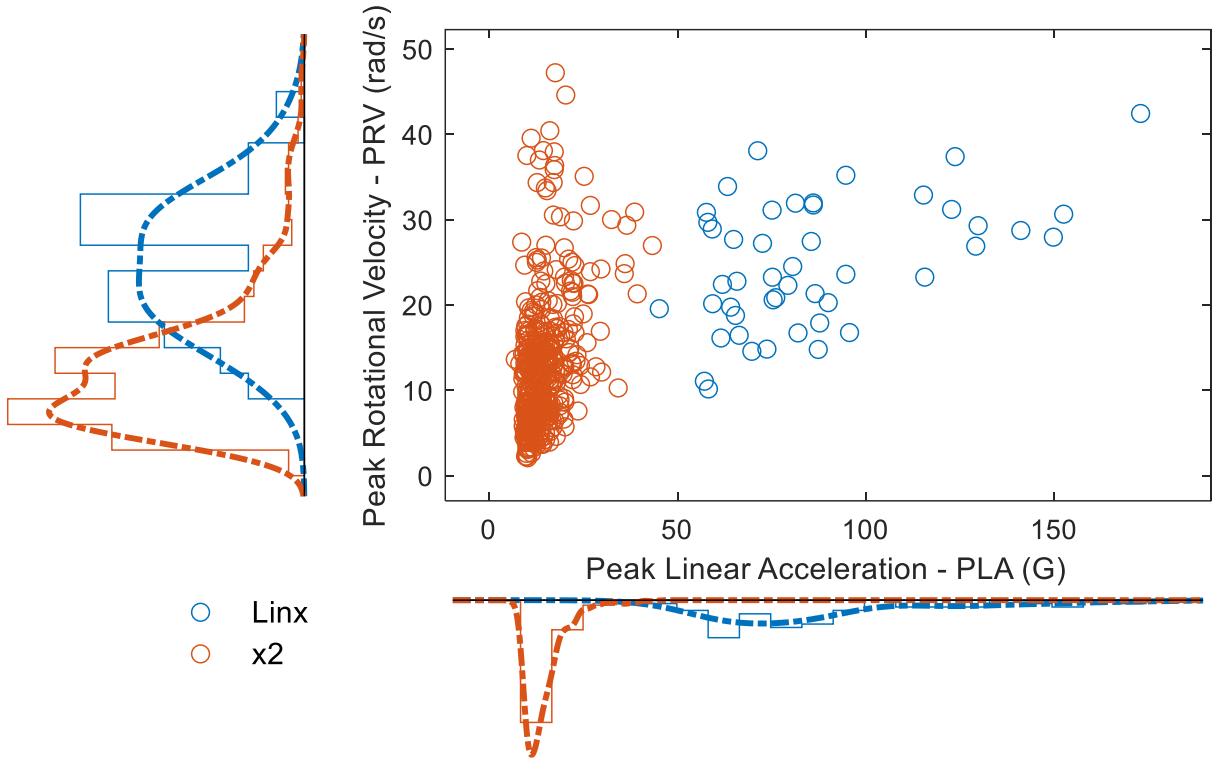

Figure 4. Range of resultant PLA and resultant PRV for "good" HAEs measured by the xPatch device (orange) and Linx device (blue) from the BAC. The differences in PLA and PRV between the xPatch and Linx is visualized through the scatter plot of PLA versus PRV with histograms of the frequency of PLA or PRV magnitudes on each axis, respectively. No concussions were diagnosed or suspected for the BAC dataset.

Results and detailed methods from the ESiT Core BAC data collection can be found in our previous work (Kelley et al., 2021). A review of the major resulting relationships between kinematics and performance are described below. For the xPatch, Pearson's *r* correlation showed a negative relationship between maximum resultant PRV ($r(33) = -0.41$, $p = 0.018$), as well as the number of impacts ($r(33) = -0.46$, $p = 0.007$), and week 1 and week 2 (baseline-adjusted) non-postural balance performance. This suggests that greater resultant PRV values and increased number of impacts corresponded to decreased performance. Additionally, number of impacts was negatively correlated with week 1 and week 2 (baseline-adjusted) ($r(33) = -0.45$, $p = 0.003$) and week 2 (week 1-adjusted) non-postural balance performance ($r(33) = -0.44$, $p = .010$) (Kelley et al., 2021). For the Linx, maximum resultant PLA and resultant PRV correlated with week 2 (week 1-adjusted) non-postural balance performance such that greater HAE values corresponded to decreased performance; $r(12) = -0.63$, $p = 0.03$, and $r(12) = -0.60$, $p = 0.04$, respectively. Additionally, the mean resultant PRA correlated with week 2 (week 1-adjusted) performance such that greater HAE values corresponded to decreased performance, $r\ (12) = -0.67$, $p = 0.01$ (Kelley et al., 2021).

Subsequent analyses of the xPatch and Linx data versus the week 1 (baseline-adjusted), week 2 (baseline-adjusted) and week 2 (week 1-adjusted) non-postural balance performance were completed to investigate whether the HAE data from the xPatch or Linx devices are

predictive of performance deficits. Hierarchical linear regression models predicting performance on the non-postural balance task in the most challenging condition showed mean peak rotational acceleration measured by the xPatch device to be a significant predictor such that performance decreased with increases in PRA (standardized Beta = 1.07, $p = 0.01$). This finding was limited to the xPatch data and was not replicated with the Linx data.

Within the CMTC, data were collected from 32 subjects. The xPatch device recorded 7756 total HAEs; 1047 were classified as "good" through our custom machine learning algorithm. Of the 1047 HAEs, 626 were then confirmed through additional review of the data (instead of video analysis). Per subject, the xPatch recorded between 3 and 70 HAEs. The mean resultant PLA (13.0 ± 3.8 g) and the mean resultant PRV (14.3 ± 6 rad/s) were calculated (Figure 5). The maximum resultant PLA (50.4 g) and the maximum resultant PRV (57 rad/s) were from the same event.

The Linx device recorded 806 total HAEs; 648 were classified as "good" through a secondary review of the data (instead of video analysis). The Linx recorded between 2 and 134 HAEs per subject. The mean resultant PLA (49.4 ± 16.4 g) and the mean resultant PRV (17.8 ± 7.0 rad/s) were calculated (Figure 5). The maximum resultant PLA was 121 g (with resultant PRV of 21 rad/s) and the maximum resultant PRV was 65 rad/s (with resultant PLA of 88 g).

Three subjects from the CMTC cohort were referred to the local clinic for a concussion evaluation during the course. The final clinical diagnoses were unavailable to the research team. Of the three subjects referred for evaluation, two had HAE data available for analysis (Figure 5; Table 2). The third subject had no data recorded by the Linx device, and all data from the xPatch device were classified as "bad" through both the machine learning classification algorithm and secondary review. For Subject 1, the xPatch and Linx each captured three HAEs classified as "good" on the day of the suspected concussion. For Subject 2, the xPatch captured seven HAEs classified as "good," while the Linx captured three HAEs classified as "good" on the day of the suspected concussion (Table 2).

Preliminary analyses of baseline-adjusted non-postural balance performance from subjects in the CMTC correlated with HAE data from the xPatch and Linx devices show similar trends to the BAC, an increased number of impacts and increased rotational severity correlated with decreased performance. Analyses are ongoing to further refine these data.

This space is intentionally blank.

Table 2. Summary Data for HAEs Classified as "Good" From the Days of Suspected Concussions for Two Subjects

	Device	HAE Number*	PLA (g)	PRV (rad/s)
Subject 1	xPatch	1	26.1	18.0
		2	9.5	9.1
		3	11.9	10.3
	Linx	1	28.6	10.6
		2	51.0	21.6
		3	72.9	22.2
Subject 2	xPatch	1	21.6	24.9
		2	9.8	11.5
		3	12.6	17.6
		4	23.4	21.7
		5	9.4	15.5
		6	20.7	34.8
		7	12.4	18.7
	Linx	1	46.7	12.9
		2	30.9	8.2
		3	34.3	12.5

**Note.* HAE number is a generic representation of the number of "good" events matched to video and are not comparable between the xPatch and Linx devices.

This space is intentionally blank.

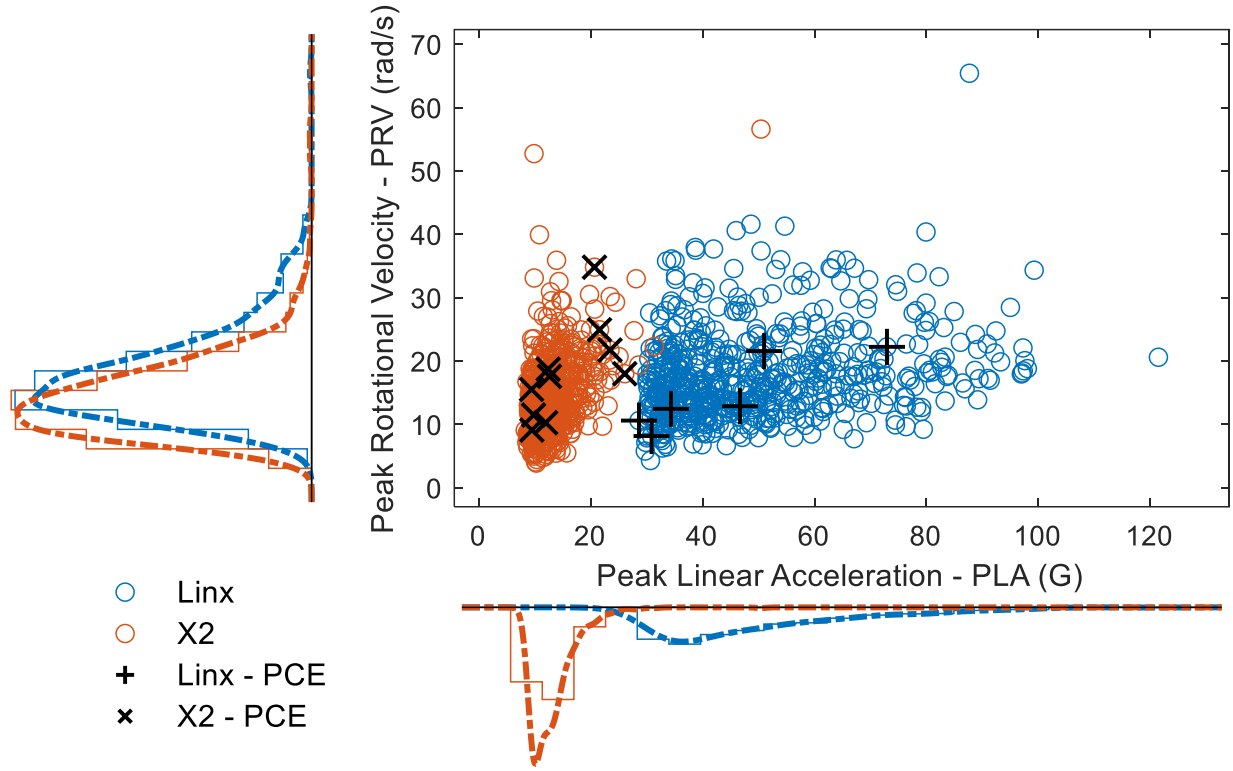

Figure 5. Range of PLA versus PRV for "good" HAEs measured by the xPatch device (orange) and Linx device (blue) from the CMTC. The differences in PLA and PRV between the xPatch and Linx is visualized through the scatter plot of PLA versus PRV with histograms of the frequency of PLA or PRV magnitudes on each axis, respectively. In addition, the head acceleration events associated with suspected concussions from two subjects are shown in black "x" and black "+" symbols.

ESiT USMA Study

Results and detailed methods from ESiT USMA study with the rugby (subset of the men's data only) and boxing data collections at the USMA are described in Fetchko et al. (2022) and Fetchko et al. (2023). A total of 431 "good" HAEs were collected from 33 rugby players (12 men and 11 women) across three seasons. Boxing data were collected from 22 male volunteers, with a total of 809 "good" HAEs recorded. In this current work, we further examined the cases of reported concussion from both datasets. The rugby dataset included five subjects who sustained a concussion. However, only two subjects had data available from the day of the suspected concussion. For the two concussions with available data, no video-verified impacts greater than 30 g were identified. Due to repeated issues with mouthguard compliance (e.g., mouthguards not worn for all drills, games, etc.) and mouthguard performance (e.g., devices not working or storing data), the remaining three concussion cases had no associated data available and further analyses were not possible.

In addition to the reported rugby concussions, there was one concussion documented within the boxing dataset. Both IMM data and video data (enabling video verification of HAEs) were available on the day of the suspected concussion. Additional details are described below as a case study of the boxing concussion with a low-magnitude HAE.

The subject presented with persistent headache symptoms that worsened when studying and viewing computer screens. The subject was an intramural athlete and was enrolled in the boxing class. The subject had no prior history of concussion and no previous contact sporting experience. The suspected day of injury was the third session of light contact drills and the second session of live sparring in the boxing course. The bouts consisted of two rounds lasting 45 and 35 seconds, respectively. The subject was matched to a similarly sized and skilled opponent for the sparring bout at the time of the suspected injury. Three days after the day of the suspected injury, the subject visited the clinic and reported symptom onset occurring approximately 10 minutes after the bout, but anticipated symptoms would resolve. Upon review of the study video of the day, there were no visible signs of concussion after the bout. There were no HAEs over 10 g during the first sparring session. The IMM data for the injured subject included only four HAEs greater than 10 g (12.0 g and 10.1 rad/s; 12.2 g and 9.4 rad/s; 12.3 g and 12.0 rad/s; and 15.8 g and 3.8 rad/s) that were video matched. An additional 13 HAEs with resultant PLA between 5 g and 10 g were recorded and matched with video (resultant PRV ranged from 2.5 to 10.5 rad/s). During the pre-sparring light contact instructional drills, the IMM recorded an additional three HAEs with resultant PLA of 10.1, 11.0, and 15.2 g and resultant PRV of 7.6, 4.4, and 5.3 rad/s. The video analysis recorded a total of 24 potential head impacts, with none being remarkable, or resulting in any “obvious performance deficits” or behavioral changes.

Prevent Biometrics Study

Data were collected from 573 subjects across military environments, with a total of 29,274 HAEs recorded. The 29,274 HAEs included 18,999 (65%) ADL (HAE < 10 g) level exposures and 10,275 (35%) head impact exposures (HAE > 10 g). Of the 10,275 head impact exposures, 19 were identified as associated with potential indicators of concussion on video. Of the 19 observed indicators of concussion, 1 was a suspected loss of consciousness, 8 were suspected alterations of consciousness (e.g., clearly dazed, confused, or showing behavioral changes, etc.), and the remaining 10 included suspected loss or alteration of consciousness but with lower confidence (e.g., second-hand reports or uncertainty in video review). The 19 head impacts with associated indicators were all high severity in terms of peak linear response; however, there was more spread in peak rotational responses (Figure 6). Per subject, the IMM recorded as few as one event (e.g., a single parachute landing fall) and up to 868 HAEs (e.g., multiple combatives or boxing sparring sessions). The mean resultant PLA (16.4 ± 6.9 g) and the mean resultant PRV (7.5 ± 4.1 rad/s) were calculated (Figure 6).

This space is intentionally blank.

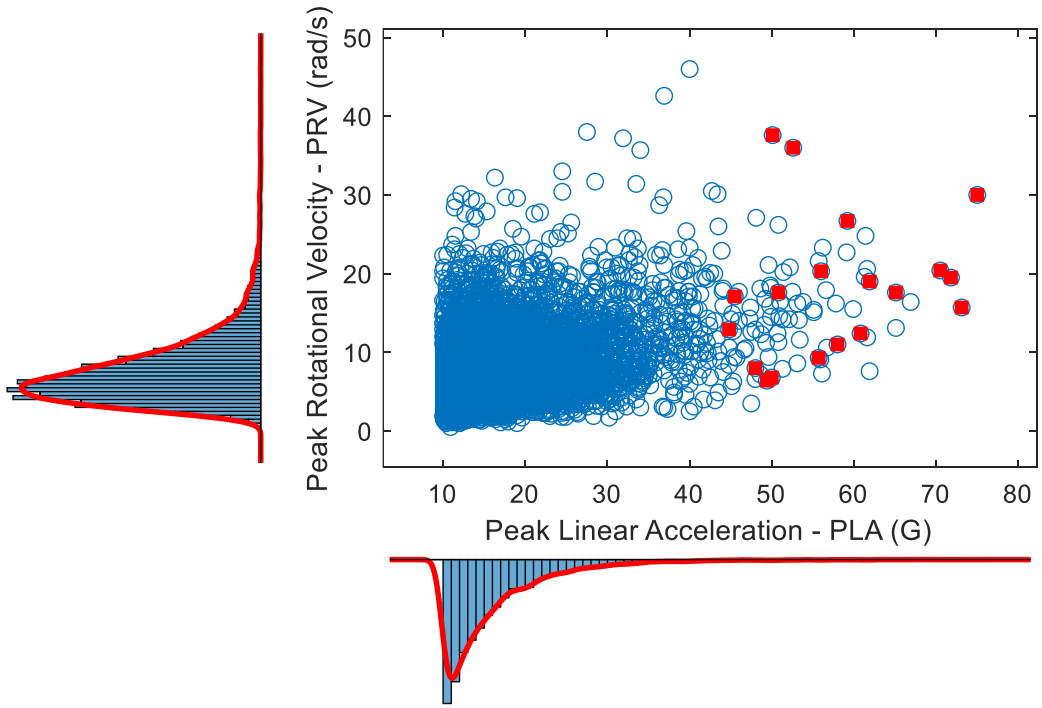

Figure 6. Range of PLA versus PRV for all HAEs greater than 10 g and for HAEs with associated video indicators of potential concussion (red squares) from the impact monitoring mouthguard (IMM). Axes include histogram responses of each variable with kernal density estimates (red lines) of the distribution. All HAEs with observed indicators of concussion were greater than 40 g or 6.4 rad/s.

Discussion

The present report summarizes results from the USAARL-led accelerative exposure arm of the ESiT research program. Data were collected between 2015 and 2021 through two main efforts (ESiT Core and ESiT USMA studies) and one leveraged effort (Prevent Biometrics study). The ESiT Core study used two wearable devices to capture HAEs from each volunteer. One device used an adhesive patch to attach the device to the skin at the mastoid process (X2 Biosystems xPatch) and the other used an elastic headband with the device embedded (BlackBox® Biometrics Linx). The ESiT USMA and the Prevent Biometrics studies used a mouthguard-based device for all volunteers (Prevent Biometrics IMM). Data were collected from approximately 700 volunteers across all studies with fewer than 30 concussions or PCEs noted.

The use of multiple devices on all subjects within the ESiT Core study is unique compared to many studies employing wearable devices to monitor HAEs. Many studies use one device and report on the range of exposures from that device (Le Flao et al., 2022; O'Connor et al., 2017; Patton et al., 2020). For HAEs measured from both the BAC and CMTC populations, there were clear differences in the ranges of resultant PLA and resultant PRV between the xPatch and Linx devices (Figures 3 and 4) as well as the distribution of HAEs for both resultant PLA or resultant PRV magnitudes (Figures 3 and 4 axes). Compared with prior research and other devices, the distribution of HAEs from the xPatch is more representative of those commonly reported from instrumented mouthguards with a skewed distribution that is characterized by a

high number of HAEs at low magnitude and relatively fewer HAEs at high magnitudes (Bartsch et al., 2020; Broglio et al., 2017; Caccese et al., 2019; Fetchko et al., 2022; Le Flao et al., 2022; Siegmund et al., 2021; Tierney et al., 2018). The xPatch measured only one "good" HAE greater than 40 g in both the BAC (43 g) and CMTC (50.4 g) environments. Comparatively, the lowest measured "good" HAE from the Linx was 45 g for the BAC and 28 g for the CMTC. Despite the significant differences in magnitude, both the xPatch and Linx data show correlations with the non-postural balance performance outcomes. However, as noted above, only the xPatch data were predictive of performance outcomes on the non-postural balance task.

As noted above, the three efforts had a limited number of clinically diagnosed concussions (fewer than ten overall), limiting the correlation of exposure to injury outcomes. While the concussion cases are included as case studies, surrogate measures for clinically diagnosed concussions were necessary. Within the ESiT Core study, all subjects were administered a neurophysiological performance assessment at multiple time points, and these data were correlated with HAEs measured by two different wearable devices. For subjects in the BAC, adjusted performance on a non-postural balance task was correlated with both the number of impacts and the rotational velocity measured by the xPatch device. Comparatively, adjusted performance was correlated with peak linear acceleration, peak rotational velocity, and peak rotational acceleration measured by the Linx device. While peak severity and number of measured HAEs from the xPatch and Linx devices were correlated with reduced performance on the non-postural balance task, only HAE data from the xPatch device was found to be predictive of changes in performance. Similar results were found in preliminary analyses of data collected in the CMTC environment. While correlations were identified, the number of subjects and available "good" data from the CMTC limited the ability to calculate a dose-response relationship to provide a threshold for PCEs.

Within the Prevent Biometrics study, a secondary review of video was used to identify exposures associated with observed signs of a potential concussion using sideline spotter guidelines for multiple sports leagues (Davis et al., 2019). Kinematic metrics measured by the Prevent Biometrics IMM show a potential threshold for PCEs above approximately 40 g and 6.4 rad/s. It should be noted that several exposures (n = 106 HAEs) above this threshold were measured without observed indicators of concussion, and it is unknown whether any of the exposures below this threshold may have resulted in non-visible indicators of concussion (e.g., memory or cognitive deficits).

Estimates for human tolerances to concussion based on automotive safety work from Stapp et al. (1961) and Patrick et al. (1965) range from 40 g to 80 g. Similar work at the time from Gurdjian et al. (1964) investigating severe head injury tolerances and skull fracture proposed 100 g to 200 g as life threatening exposures. The work by Gurdjian et al. (1964) was ultimately used to develop the Wayne State Tolerance Curve that proposed that a 90 g impact could produce a concussion. From military applications, Slobodnik (1980) proposed a threshold of 150 g as a loss of consciousness threshold, though loss of consciousness is now considered to be at the higher end of the mild TBI spectrum. More recently, several studies sponsored by the National Football League estimated concussions to occur in the ranges of 50 g and 140 g PLA (Newman & Shewchenko, 2000; Pellman, 2003; Pellman et al., 2003; Viano et al., 2007). Using data collected with the HITS, Rowson and Duma (2013) proposed an injury risk curve for concussion that combines peak resultant linear and rotational acceleration values (Rowson &

Duma, 2013). Depending on the associated rotational acceleration, the study showed a 50% risk of injury (i.e., concussion) as low as 50 g (with 10,000 rad/s^2 rotational acceleration) and up to 200 g (with 2000 rad/s^2 rotational acceleration). A recently completed secondary analysis of HITS data indicates a median PLA of 66.7 g with an interquartile range (IQR) of 42.8 g for concussed (N = 51) individuals (Mihalik et al., 2020). The wide IQR highlights one of the many challenges with a single metric concussion threshold. Further, a computational modeling study from Zhang et al. (2004) proposed thresholds of 66 g, 82 g, and 106 g for 25%, 50%, and 80% probability of injury. Finally, a recent paper discussing concussion limits from reconstructed equestrian falls proposed concussion limits at approximately 60 g (Clark et al., 2020).

While the range for risk based on this literature summary is large, approximately 40 g to 100 g for mTBI (concussion) and approximately 100 g to 200 g for moderate/severe TBI, the low end of the range aligns with the low end of measured HAEs from the Prevent Biometrics study with observed indicators of concussion. Further, the low end of the range is above the highest measured HAEs from the xPatch BAC data within the ESiT Core study (with no concussions or observed indicators). While this range does not address the potential for concussion at lower-severity impacts (such as those discussed in both the ESiT Core CMTC and the ESIT USMA case studies), especially when there are no obvious clinical indicators present, it does provide a starting point to identify PCEs that may be of concern based on head impact severity. However, caution must be taken when interpreting this range as it does not account for the case study results identified in the ESiT Core and ESIT USMA studies above or literature showing the prevalence of concussions occurring at low severities (O'Connor et al., 2017; Siegmund et al., 2021).

Several studies have proposed an alternative mechanism for concussion that accounts for repetitive head impact exposures as well as single traumatic exposures (Broglio et al., 2017; Caccese et al., 2019; Rowson et al., 2018; Stemper et al., 2019; Tierney, 2022). In particular, a recent summary from Tierney (2022) proposed three potential mechanisms for traumatic brain injury. The first mechanism relates the risk of injury to kinematic severity and assumes a single traumatic event causes injury by exceeding a mechanical load threshold. The second mechanism identifies a "cumulative head impact index" associating lifetime exposure based on estimated numbers of impacts with the risk of neurodegenerative disease. The final mechanism proposes that the accumulated effects of repetitive exposure to HAEs on the day of injury or the season leading up to injury may lower the threshold for injury. Notably, the final mechanism proposes that injury criteria should account for both the number and magnitude of HAEs and the time between exposures versus a single exposure (Tierney, 2022). The thresholds discussed above and from the leveraged study by Prevent Biometrics are based on the theory of the first mechanism for injury. Comparatively, proposed injury metrics for a risk weighted exposure (Stemper et al., 2019) or head impact density (Broglio et al., 2017) work on the theory of the third mechanism for injury. The injury metrics based on the third mechanism may provide a possible explanation for the apparently "low-severity" concussions discussed in the case studies above; however, more work is needed to investigate this relationship.

Limitations

Data collected under the ESiT Core study used early-generation wearable devices that were susceptible to common issues with wearable devices for head impact (for a more thorough discussion, please refer to Rooks et al., 2023). Briefly, the two head-borne devices were susceptible to significant time drift, and the false-positive rejection algorithms did not perform well. While the xPatch device provided all data for further review, enabling the research team to review each event and leverage alternative methods for event classification, the Linx device excluded suspected false-positives and did not store them for further review. Despite the care taken to synchronize video and device data, substantial hurdles with maintaining an accurate clock between the video and device data were encountered. The time drift from the devices ultimately resulted in an inability to fully video-verify device data from the CMTC dataset, limiting the overall confidence in the device data. While video review was not possible, the xPatch data were reclassified as "good" versus "bad" using an in-house developed machine learning classification algorithm (Rooks et al., 2019). A comparable machine learning classification algorithm for the Linx was not available for use. In addition, multiple reviews of signal characteristics were completed, resulting in a conservative dataset for further analyses correlating exposure with neurophysiological performance.

Similar challenges were encountered with early versions of the IMM used with the rugby test cohort under the ESIT USMA study. Multiple issues with device compliance, device performance, false-positive rejection algorithm performance, and time drift were encountered. The issues were prevalent during the 2018 and 2019 seasons using an early version of the boil-and-bite mouthguard and circuitry that were too large for most subjects to wear comfortably and were susceptible to circuit failures during use. The circuit failures caused issues during the data synchronization for the devices resulting in substantial loss of data. During the fall 2019 men's 15-man roster rugby season, a new version of the device was employed with significantly better fit, compliance (updated form factor to a hybrid boil-and-bite system that was more comfortable), and performance (updated sensors and circuitry were more durable). In addition to the improved comfort and performance, the new generation of devices incorporated a proximity sensor to determine when the device was worn on the teeth. The inclusion of the proximity sensor with other (proprietary) false-positive rejection algorithm steps resulted in significant improvement in the device performance and the ability to reject false-positive events (Fetchko, 2022).

Finally, the present study included a limited number of concussions and relied on alternative methods of identifying PCEs. The Core study used measured neurophysiological performance deficits for all subjects as a potential measure of degraded performance and found relationships between increased severity of exposure (in particular rotational velocity) as well as an increased number of exposures and reduced performance. The correlations align with the first and third proposed mechanisms of concussion identified by Tierney (2022). Further, the ESiT Core study also found that the HAEs measured by the xPatch were predictive of performance deficits, but not the Linx device. The leveraged study from Prevent Biometrics included observable indicators of potential concussion commonly used by sideline spotters as the markers for a PCE. While no additional information regarding clinical diagnoses was available, the use of sideline spotters is common practice for identifying individuals at risk of concussion (Davis et al., 2019). While clinical diagnoses are unavailable, the observable indicators of concussion (i.e.,

PCEs) provide a comparable alternative to the main aim of the ESiT program, which is looking to use wearable devices to indicate PCEs.

Conclusion

The present report highlights the continued challenges with using wearable devices to capture HAEs associated with mTBI (concussion) to develop a concussion dose-response threshold (Rooks et al., 2023). Despite data being collected from approximately 700 volunteers across all three efforts and approximately 12,000 HAEs above 10 g being recorded, only three subjects had suspected concussions with data available for analysis. Further, for the three subjects with suspected concussions, the highest magnitude HAE recorded on the suspected day of injury was from the Linx device measuring 73 g (22 rad/s). However, as seen in the ESiT Core BAC and CMTC datasets, the Linx device reports substantially higher magnitudes of exposure compared with the xPatch device. The highest magnitude xPatch HAE from the day of suspected concussion was 26 g (18 rad/s). An additional 19 subjects had observed indicators of possible concussion (i.e., PCE), but no additional clinical diagnoses or evaluations. However, the dataset with 19 PCEs did not capture information about all subjects and may have missed concussions at lower magnitudes comparable to the case studies reported.

The three suspected concussions with low magnitude exposures on the day of injury may be representative of the "third mechanism of injury" (i.e., repetitive exposure resulting in an accumulation of damage) proposed by Tierney (2022); however, the available sample size is insufficient to investigate possible metrics and dose-response relationships for injury. Additional research investigating the third proposed mechanism of injury from Tierney (2022) is recommended and may enable further analyses of these data (Broglio et al., 2017; Caccese et al., 2019; Rowson et al., 2018; Stemper et al., 2019; Tierney, 2022). Similarly, the 19 PCEs (based on observed indicators of concussion) may be representative of the "first mechanism of injury" (i.e., single traumatic exposure-caused injury) proposed by Tierney (2022). Additional research investigating both the first and third proposed mechanisms of injury is needed to develop a complete model and dose-response relationship for concussion.

As noted in the Preface, the state of the technology has significantly accelerated in recent years, and the comparatively older technologies (i.e., the xPatch and Linx devices) used in the ESiT Core study had several challenges during their implementation and use (Rooks et al., 2023). While more advanced, the IMM had similar challenges during early implementations (though it improved substantially over the course of the study). As the technology continues to improve, research should leverage the current state of the science to improve the predictive capacity of the devices and identify a single traumatic event threshold (i.e., Tierney's first mechanism of injury) as well as the role of repetitive exposures and recent exposure history on changing individual thresholds (i.e., Tierney's third mechanism of injury).

References

Arbogast, K. B., Caccese, J. B., Buckley, T. A., McIntosh, A. S., Henderson, K., Stemper, B. D., Solomon, G., Broglio, S. P., Funk, J. R., & Crandall, J. R. (2022). Consensus head acceleration measurement practices (CHAMP): Origins, methods, transparency and disclosure. *Annals of Biomedical Engineering, 50*(11), 1317–1345.

Arbogast, K. B., Funk, J. R., Solomon, G., & Crandall, J. (2023). Measuring head acceleration like a CHAMP. *Journal of Athletic Training, 58*(4), 283–284.

Asken, B. M., Bauer, R. M., Guskiewicz, K. M., McCrea, M. A., Schmidt, J. D., Giza, C. C., Snyder, A. R., Houck, Z. M., Kontos, A. P., McAllister, T. W., Broglio, S. P., Clugston, J. R., Investigators, C. C., Anderson, S., Bazarian, J., Brooks, A., Buckley, T., Chrisman, S., Collins, M., DiFiori, J., Duma, S., Dykhuizen, B., Eckner, J. T., Feigenbaum, L., Hoy, A., Kelly, L., Langford, T. D., Lintner, L., McGinty, G., Mihalik, J., Miles, C., Ortega, J., Port, N., Putukian, M., Rowson, S., & Svoboda, S. (2018). Immediate removal from activity after sport-related concussion is associated with shorter clinical recovery and less severe symptoms in collegiate student-athletes. *American Journal of Sports Medicine, 46*(6), 1465–1474. https://doi. org/10. 1177/0363546518757984

Asken, B. M., McCrea, M. A., Clugston, J. R., Snyder, A. R., Houck, Z. M., & Bauer, R. M. (2016). "Playing through it": Delayed reporting and removal from athletic activity after concussion predicts prolonged recovery. *Journal of Athletic Training, 51*(4), 329–335. https://doi. org/10. 4085/1062–6050–51. 5. 02

Bartsch, A. J., Hedin, D., Alberts, J., Benzel, E. C., Cruickshank, J., Gray, R. S., Cameron, K., Houston, M. N., Rooks, T., & McGinty, G. (2020). High energy side and rear American football head impacts cause obvious performance decrement on video. *Annals of Biomedical Engineering, 48*, 2667–2677.

Bernhardt, K. A., Kelley, A. M., Mathews, C., Novotny, B., & Rooks, T. F. (2019). *Evaluation of environmental sensors in training: Performance outcomes and symptoms during airborne and combatives training* (USAARL 2019-15). U.S. Army Aeromedical Research Laboratory.

Broglio, S. P., Lapointe, A., O'Connor, K. L., & McCrea, M. (2017). Head impact density: A model to explain the elusive concussion threshold. *Journal of Neurotrauma, 34*(19), 2675–2683. https://doi. org/10. 1089/neu. 2016. 4767

Brown, B. A., Daniel, R. W., Chancey, V. C., & Rooks, T. F. (2021). *Parametric evaluation of head center of gravity acceleration error from rigid body kinematics assumptions used in environmental sensors.* ASME International Mechanical Engineering Congress and Exposition.

Bussone, W. (2005). *Linear and angular head accelerations in daily life* (Doctoral dissertation, Virginia Tech).

Caccese, J. B., Best, C., Lamond, L. C., Difabio, M., Kaminski, T. W., Watson, D., Getchell, N., & Buckley, T. A. (2019). Effects of repetitive head impacts on a concussion assessment battery. *Journal of Science and Medicine in Sport, 51*(7), 1355–1361. https://doi. org/10. 1249/MSS. 0000000000001905

Clark, J. M., Adanty, K., Post, A., Hoshizaki, T. B., Clissold, J., McGoldrick, A., Hill, J., Annaidh, A. N., & Gilchrist, M. D. (2020). Proposed injury thresholds for concussion in equestrian sports. *Journal of Science and Medicine in Sport, 23*(3), 222–236.

Davis, G. A., Makdissi, M., Bloomfield, P., Clifton, P., Echemendia, R. J., Falvey, É. C., Fuller, G. W., Green, G., Harcourt, P., & Hill, T. (2019). International consensus definitions of video signs of concussion in professional sports. *British Journal of Sports Medicine, 53*(20), 1264–1267.

Department of Defense (2012). *DoD policy guidance for managmenent of mild traumatic brain injury/concussion in the deployed setting* (Report No. 6490.11). Department of Defense.

Fetchko, T., Boudreau, G., Roach, M., Cameron, K., & Rooks, T. (2022). *Video verification of an instrumented mouthguard in american collegiate men's rugby* [Oral presentation]. ASME International Mechanical Engineering Congress and Exposition.

Fetchko, T. J., Hart, G. J., Aderman, M. J., Ross, J. D., Malvasi, S. R., Roach, M. H., Cameron, K. L., & Rooks, T. F. (2023). Measurement of head kinematics using instrumented mouthguards during introductory boxing courses in U.S. Military academy cadets. *Journal of Military Medicine*, Warfighter 2022 Supplement.

Funk, J. R., Cormier, J. M., Bain, C. E., Guzman, H., Bonugli, E., & Manoogian, S. J. (2011). Head and neck loading in everyday and vigorous activities. *Annals of Biomedical Engineering, 39*, 766–776.

Gurdjian, E. S., Lissner, H. R., Hodgson, V. R., & Patrick, L. M. (1966). Mechanism of head injury. *Neurosurgery*, 12(CN_suppl_1), 112–128.

Guskiewicz, K. M., Marshall, S. W., Bailes, J., McCrea, M., Cantu, R. C., Randolph, C., & Jordan, B. D. (2005). Association between recurrent concussion and late-life cognitive impairment in retired professional football players. *Neurosurgery, 57*(4), 719–726.

Hainsworth, J. B., Johnson, A., Godfred-Cato, S., Smolinski, G. J., & Jorgensen-Wagers, K. (2023). The 8 January 2020 theatre ballistic missile attack on US soldiers stationed at Al Asad Air Base, Iraq: Case series using a concussion subtypes framework to approach a real-world, chaotic blast-related TBI mass casualty event. *British Medical Journal: Neurology Open, 5*(1).

Headquarters, Department of the Army. (2013). *Department of the Army guidance for managmeent of concussion/mild traumatic brain injury in the garrison setting* (EXORD 165-13). Department of the Army.

Helmick, K. M., Spells, C. A., Malik, S. Z., Davies, C. A., Marion, D. W., & Hinds, S. R. (2015). Traumatic brain injury in the US military: Epidemiology and key clinical and research programs. *Brain Imaging Behaviors, 9*(3), 358–366. https://doi. org/10. 1007/s11682-015-9399-z

Hernandez, F., & Camarillo, D. B. (2019). Voluntary head rotational velocity and implications for brain injury risk metrics. *Journal of Neurotrauma, 36*(7), 1125–1135.

Higgins, K. L., Denney, R. L., & Maerlender, A. (2017). Sandbagging on the Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) in a high school athlete population. *Archives of Clinical Neuropsychology, 32*(3), 259–266.

Kelley, A. M., Bernhardt, K., Hass, N., & Rooks, T. F. (2021). Detecting functional deficits following sub-concussive head impacts: The relationship between head impact kinematics and visual-vestibular balance performance. *Brain Injury, 35*(7), 812–820.

Kuo, C., Patton, D., Rooks, T., Tierney, G., McIntosh, A., Lynall, R., Esquivel, A., Daniel, R., Kaminski, T., & Mihalik, J. (2022). On-field deployment and validation for wearable devices. *Annals of Biomedical Engineering, 50*(11), 1372–1388.

Le Flao, E., Siegmund, G. P., & Borotkanics, R. (2022). Head impact research using inertial sensors in sport: A systematic review of methods, demographics, and factors contributing to exposure. *Sports Medicine*, 1–24.

Le, R. K., Lempke, L. B., Anderson, M. N., Johnson, R. S., Schmidt, J. D., & Lynall, R. C. (2023). Quantifying head impact biomechanical differences between commonly employed cleaning levels: A critical research interpretation consideration. *Brain Injury*, 1–6.

McAllister, T., & McCrea, M. (2017). Long-term cognitive and neuropsychiatric consequences of repetitive concussion and head-impact exposure. *Journal of Athletic Training, 52*(3), 309–317.

McCrory, P., Meeuwisse, W., Dvorak, J., Aubry, M., Bailes, J., Broglio, S., Cantu, R. C., Cassidy, D., Echemendia, R. J., & Castellani, R. J. (2017). Consensus statement on concussion in sport—the 5th international conference on concussion in sport held in Berlin, October 2016. *British Journal of Sports Medicine, 51*(11), 838–847.

Meehan III, W. P., Mannix, R. C., O'Brien, M. J., & Collins, M. W. (2013). The prevalence of undiagnosed concussions in athletes. *Clinical Journal of Sport Medicine, 23*(5), 339.

Mihalik, J. P., Chandran, A., Powell, J. R., Roby, P. R., Guskiewicz, K. M., Stemper, B. D., Shah, A. S., Rowson, S., Duma, S., & Harezlak, J. (2020). Do head injury biomechanics predict concussion clinical recovery in college American Football players? *Annals of Biomedical Engineering, 48*, 2555–2565.

Miller, L. E., Urban, J. E., Whelan, V. M., Baxter, W. W., Tatter, S. B., & Stitzel, J. D. (2020). An envelope of linear and rotational head motion during everyday activities. *Biomechanics and Modeling in Mechanobiology, 19*, 1003–1014.

Newman, J. A., & Shewchenko, N. (2000). *A proposed new biomechanical head injury assessment function-the maximum power index* (No. 2000-01-SC16). SAE Technical Paper.

O'Connor, K. L., Rowson, S., Duma, S. M., & Broglio, S. P. (2017). Head-impact-measurement devices: A systematic review. *Journal of Athletic Training, 52*(3), 206–227. https://doi. org/10. 4085/1062-6050. 52. 2. 05

O'Neil, M. E. (2013). *Complications of mild traumatic brain injury in Veterans and military personnel*. Department of Veterans Affairs.

Patrick, L. M., Lissner, H. R., & Gurdjian, E. S. (1965). *Survival by design: Head protection.* In: Proceedings of the 7th Stapp Car Crash Conference. Society of Automotive Engineers, pp. 483–499.

Patricios, J. S., Schneider, K. J., Dvorak, J., Ahmed, O. H., Blauwet, C., Cantu, R. C., Davis, G. A., Echemendia, R. J., Makdissi, M., & McNamee, M. (2023). Consensus statement on concussion in sport: The 6th International Conference on Concussion in Sport–Amsterdam, October 2022. *British Journal of Sports Medicine, 57*(11), 695–711.

Patton, D. A. (2016). A review of instrumented equipment to investigate head impacts in sport. *Applied Bionics and Biomechanics, 2016*.

Patton, D. A., Huber, C. M., Jain, D., Myers, R. K., McDonald, C. C., Margulies, S. S., Master, C. L., & Arbogast, K. B. (2020). Head impact sensor studies in sports: A systematic review of exposure confirmation methods. *Annals of Biomedical Engineering, 48*(11), 2497–2507. https://doi. org/10. 1007/s10439–020–02642–6

Pellman, E. J. (2003). Background on the National Football League's research on concussion in professional football. *Neurosurgery, 53*(4), 797–798.

Pellman, E. J., Viano, D. C., Tucker, A. M., & Casson, I. R. (2003). Concussion in professional football: Location and direction of helmet impacts—Part 2. *Neurosurgery, 53*(6), 1328–1341.

Rizzo, J. R., Hudson, T. E., Martone, J., Dai, W., Ihionu, O., Chaudhry, Y., Selesnick, I., Balcer, L. J., Galetta, S. L., & Rucker, J. C. (2021). How sandbag-able are concussion sideline assessments? A close look at eye movements to uncover strategies. *Brain Injury, 35*(4), 426–435.

Rooks, T. F., Novotny, B. L., Winegar, A. J., & Chancey, V. C. (2023) *Environmental sensors in training: Lessons learned* (USAARL-TECH-FR--2024-05) U.S. Army Aeromedical Research Laboratoy

Rooks, T. F., Dargie, A. S., & Chancey, V. C. (2019). *Machine learning classification of head impact sensor data* [Oral presentation]. ASME International Mechanical Engineering Congress and Exposition,

Rooks, T. F., Logsdon, K. P., Kamimori, G. H., Olaghere da Silva, U. B., McEntire, B. J., & Chancey, V. C. (2015). *Environmental sensors in training: Pilot field studies* (USAARL 2015-17). U.S. Army Aeromedical Research Laboratory.

Rowson, S., & Duma, S. M. (2013). Brain injury prediction: Assessing the combined probability of concussion using linear and rotational head acceleration. *Annals of Biomedical Engineering, 41*(5), 873–882. https://doi. org/10. 1007/s10439-012-0731-0

Rowson, S., Duma, S. M., Stemper, B. D., Shah, A., Mihalik, J. P., Harezlak, J., Riggen, L. D., Giza, C. C., DiFiori, J. P., Brooks, A., Guskiewicz, K., Campbell, D., McGinty, G., Svoboda, S. J., Cameron, K. L., Broglio, S. P., McAllister, T. W., & McCrea, M. (2018). Correlation of concussion symptom profile with head impact biomechanics: A case for individual-specific injury tolerance. *Journal of Neurotrauma, 35*(4), 681–690. https://doi. org/10. 1089/neu. 2017. 5169

Stapp, J. P. (1961). Human tolerance to severe, abrupt deceleration. In O.H. Gauer & G. D. Zuidema (Eds.), *Gravitational Stress in Aerospace Medicine* (pp. 165-188). Little Brown and Co.

Siegmund, G. P., Elkin, B. S., Bonin, S. J., Yu, A. W., & Bartsch, A. J. (2021). *The effects of oversampling non-independent data on concussion injury risk functions*. Proceedings of the 2021 International Research Counsel on Biomechanics of Injury.

Siegmund, G. P., Guskiewicz, K. M., Marshall, S. W., DeMarco, A. L., & Bonin, S. J. (2016). Laboratory validation of two wearable sensor systems for measuring head impact severity in football players. *Annals of Biomedical Engineering, 44*(4), 1257–1274. https://doi. org/10. 1007/s10439-015-1420-6

Slobodnik, B. A. (1980). *SPH-4 helmet damage and head injury correlation* (Report No. 80-7) U.S. Army Aeromedical Research Laboratory.

Stein, M. B., Ursano, R. J., Campbell-Sills, L., Colpe, L. J., Fullerton, C. S., Heeringa, S. G., Nock, M. K., Sampson, N. A., Schoenbaum, M., & Sun, X. (2016). Prognostic indicators of persistent post-concussive symptoms after deployment-related mild traumatic brain injury: A prospective longitudinal study in U.S. Army Soldiers. *Journal of Neurotrauma, 33*(23), 2125–2132.

Stemper, B. D., Shah, A. S., Harezlak, J., Rowson, S., Mihalik, J. P., Duma, S. M., Riggen, L. D., Brooks, A., Cameron, K. L., Campbell, D., DiFiori, J. P., Giza, C. C., Guskiewicz, K. M., Jackson, J., McGinty, G. T., Svoboda, S. J., McAllister, T. W., Broglio, S. P., McCrea, M., & Care Consortium Investigators. (2019). Comparison of head impact exposure between concussed football athletes and matched controls: Evidence for a possible second mechanism of sport-related concussion. *Annals of Biomedical Engineering, 47*(10), 2057–2072. https://doi. org/10. 1007/s10439-018-02136-6

Traumatic Brain Injury Center of Excellence (TBICoE). (October 2, 2023). *Total (2000-2021 Q3) DoD numbers for traumatic brain injury worldwide.* Retrieved from https://www. health. mil/Military-Health-Topics/Centers-of-Excellence/Traumatic-Brain-Injury-Center-of-Excellence/DOD-TBI-Worldwide-Numbers

Tierney, G. (2022). Concussion biomechanics, head acceleration exposure and brain injury criteria in sport: A review. *Sports Biomechanics*, 1–29.

Tierney, G. J., Richter, C., Denvir, K., & Simms, C. K. (2018). Could lowering the tackle height in rugby union reduce ball carrier inertial head kinematics? *Journal of Biomechanics, 72*, 29–36. https://doi. org/10. 1016/j. jbiomech. 2018. 02. 023

Department of Defense. (2022) *Warfighter brain health DOTmLPF-P change recommendation (DCR) and initial capabilities document (ICD)*. Department of Defense.

Viano, D. C., Casson, I. R., & Pellman, E. J. (2007). Concussion in professional football: Biomechanics of the struck player-part 14. *Neurosurgery, 61*(2), 313–327. https://doi. org/10. 1227/01. NEU. 0000279969. 02685. D0

Zhang, L., Yang, K. H., & King, A. I. (2004). A proposed injury threshold for mild traumatic brain injury. *Journal of Biomechanical Engineering, 126*(2), 226–236.

Appendix A. Training Environments

The BAC consists of three weeks of exercises of increasing levels of difficulty, progressing from jumping off of a two-foot-tall wall during the first week (ground week), jumping from a platform, swinging in a mock suspension system before landing (tower week), and finally jumping from an airplane during the final week (jump week). Several of the exercises conducted may result in HAEs. The first week of exercises are the first exposure to parachutist landing falls and may result in a high number of mild head impacts to the ground while students learn the new technique. The second week of exercises builds on experience from the first week and introduces new skills. Drills during the second week of training include the potential for a lower number of, but harder, impacts with the ground. As difficulty increases, so should the trainees' ability to land properly, until the final week when the trainees jump from a plane in order to graduate.

The CMTC consists of four weeks of training with increasing levels of difficulty. The CMTC is designed for personnel experienced in combatives principles to become trainers for the basic combatives course (BCC) and tactical combatives course (TCC). The first week is a review of principles for the BCC and the second and third weeks include a review of principles for TCC. The final week combines the skills learned into a tactical application. Throughout the course, Service Members conduct both sparring sessions, including kicks and strikes, and grappling sessions.

Appendix B. Wearable Sensor Details

The X2 Biosystems xPatch is a small device that is mounted to the skin over the mastoid process using a dual-sided adhesive patch (Rooks et al., 2015). The xPatch device records all HAEs above a threshold of 10 g (acceleration) in any axis and stores full time-trace data for each event. The software application provided with the device attempts to classify HAEs as true events (i.e., measured HAEs resulting from head motion) or false positives (i.e., measured HAEs resulting from device motion in the absence of head motion). All HAEs are saved for further review and reclassification. The xPatch is easily peeled off following a game, practice, or data collection series. Because the xPatch uses skin adhesives and nickel alloy contacts, it should not be used with individuals who have skin sensitivity to common skin adhesives (e.g., BAND-AID® adhesive), nickel allergies, or any skin disorders (e.g., psoriasis or latex allergies) (Rooks et al., 2015). Service Members who self-reported skin allergies were excluded from participation.

The BlackBox® Biometrics Linx system is embedded in the headband portion of a skullcap or a headband worn on the head. The Linx records all HAEs above a proprietary severity of approximately 40 g (for field mode) or above approximately 10 g (for test mode) in any axis. During the data collection for the ESiT Core study, the "test mode" was unavailable for use. All data in the present study were collected under "field mode," with the approximately 40 g trigger severity. The Linx device stores summary data for lower severity impacts and full time-trace data for higher severity impacts. The software application provided with the device classifies HAEs as true events or false positive events using a proprietary algorithm and only the true HAEs are saved for further analysis when configured in field mode (Rooks et al., 2015).

The Prevent Biometrics IMM is a mouthguard-based wearable device used to measure kinematics at the head CG resulting from exposure. The IMM is worn on the upper dentition and is custom fit to each volunteer. The IMM device records all HAEs above a 5 g threshold in any axis and stores full time-trace data for each event. The IMM software uses a proprietary algorithm based on signal characteristics combined with proximity devices embedded in the device that detect when worn on the teeth to classify HAEs as true events or false positives. All HAEs are saved for further review and reclassification.

Sensor specifications for all three devices are provided in Table B1.

This page is intentionally blank.

Table B1. Environmental Sensor Application Description

Sensor	Current Uses	Application	Specifications	Image
xPatch (X2 BioSystems)	athletics, including football, soccer, boxing, and lacrosse, among others	adhesive – uses a hypo-allergenic adhesive similar to BAND-AID® adhesive. Affixed directly to the head at the mastoid process	linear acceleration in *X*, *Y*, and *Z* axes (± 200 g) angular rate about *X*, *Y*, and *Z* axes (± 2000 deg/s) battery life: ~ 5-6 hours trigger: 10 g in any single axis sample rate: 1000 Hz	
Linx (BlackBox Biometrics – B3)	athletics, including football, soccer, boxing, and lacrosse, among others	skull cap or headband – worn under the combat helmet	linear acceleration in *X*, *Y*, and *Z* axes (± 200 g) angular rate about *X*, *Y*, and *Z* axes (± 2000 deg/s) battery life: ~6-7 Hours trigger: ~40 g (with proprietary rotational content) sample rate: 1600 Hz (accelerometer) and 2000 Hz (gyroscope)	
IMM (Prevent Biometrics)	athletics, including football, soccer, boxing, and lacrosse, among others	mouthguard	linear acceleration in *X*, *Y*, and *Z* axes (± 200 g) angular rate about *X*, *Y*, and *Z* axes (± 2000 deg/s) battery life: ~8-9 hours trigger: 5 g in any single axis sample rate: 3200 Hz	

U.S. ARMY AEROMEDICAL RESEARCH LABORATORY

FORT NOVOSEL, ALABAMA

Optimizing

HUMAN PROTECTION AND PERFORMANCE

since 1962

All of USAARL's science and technical informational documents are available for download from the Defense Technical Information Center.
https://discover.dtic.mil/results/?q=USAARL

U.S. ARMY

FUTURES COMMAND

MRDC