USAARL-TECH-FR--2024-05

UNITED STATES ARMY AEROMEDICAL RESEARCH LABORATORY

Environmental Sensors in Training: Lessons Learned

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Human Subject Use

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)*
31-10-2023	Final Report	10/01/2014 - 09/30/2019

4. TITLE AND SUBTITLE
Environmental Sensors in Training: Lessons Learned

5a. CONTRACT NUMBER
MOMRP 17220 (ESiT)

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER
MOMRP 17220

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

6. AUTHOR(S)
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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--2024-05

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]Katmai Government Solutions

14. ABSTRACT
Between 2000 and the fourth quarter of 2022, the number of reported traumatic brain injury (TBI) diagnoses totaled 472,785 for all military branches; of those, 82.3% are classified as mild TBI (mTBIs) (Traumatic Brain Injury Center of Excellence, 2022). Recent estimates indicate that as many as 80% of these mTBIs were diagnosed in garrison (potentially during training), as opposed to during combat operations (Helmick et al., 2015). In response, the Environmental Sensors in Training (ESiT) research program was initiated to evaluate wearable sensors designed to detect and quantify head acceleration exposures. The present report summarizes lessons learned through multiple studies conducted between 2015 and 2018 under the ESiT research program informing future device development and continued research involving wearable devices.

15. SUBJECT TERMS
environmental sensor; concussion; TBI; mTBI; wearable sensor; concussion monitor; head impact sensor; ESiT

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	21	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

REPORT DOCUMENTATION PAGE (SF298)
(Continuation Sheet)

14. Abstract (continued)
Care should be taken in use and interpretation of reported data and study results potentially confounded by poor human factors designs (e.g., devices out of position or uncomfortable), poor device performance (e.g., false-positives and large device-to-device variability), and time-consuming device administration. At this time, the available devices may be useful for identifying the level of exposure to the head or helmet; however, they are not capable of determining whether an injury occurred and cannot be used blindly.

Acknowledgements

The authors would like to thank the leadership and cadre of the 1-507th Parachute Infantry Regiment of the Ranger Training Brigade for their support and for allowing access to the trainees attending the Basic Airborne Course. Additionally, the authors would like to thank the leadership of 1-29th Infantry and the Combatives Master Trainers for their support and for allowing access to trainees attending Modern Army Combatives Program courses.

The authors would like to thank LTC(R) Chessley Atchison and MAJ(R) Walter Carr for their support and guidance as Program Managers during the development and management of the Environmental Sensors in Training (ESiT) Program. Additionally, the authors would like to thank Dr. Carol Chancey and Mr. Joe McEntire for their guidance and support during the data collections, analyses, and report generation conducted in support of the ESiT program.

The authors would like to thank the incredible group of researchers from the Injury Biomechanics and Protection Group who contributed to the long hours and weeks of travel for the data collection and long hours of data cleaning and analysis supporting the work under the ESiT Program.

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Table of Contents

List of Figures and Tables

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Introduction

Between 2000 and the fourth quarter of 2022, the number of reported traumatic brain injury (TBI) diagnoses totaled 472,785 for all military branches; of those, 82.3% are classified as mild TBI (mTBIs) (Traumatic Brain Injury Center of Excellence, 2022). While TBI is considered the "signature injury of Operations Enduring Freedom and Iraqi Freedom (OEF/OIF)," subsequent studies have revealed that the number of mTBIs sustained in garrison (potentially during training) account for up to 80% of mTBIs diagnosed since 2000 (Helmick et al., 2015). TBIs in the garrison setting may be the result of non-duty-related activities (e.g., vehicle crashes, falls, sports and recreational activities) or duty-related military training. Early and accurate injury identification is important for effective concussion management and has implications for extended return-to-duty timelines (Meehan et al., 2014; Asken et al., 2016). Despite the impact untreated TBIs have on military readiness, there is no reliable method of identifying potentially injurious events in real-time. Injuries are commonly identified after the fact through self-reported symptoms (which may be confounded by other conditions) or through observation of symptoms, both of which may lead to untreated TBIs.

In an attempt to improve management of TBI, the Department of Defense (DoD) established a DoD Instruction (DoDI) in 2012 (updated in 2019), which provides guidance for consistent reporting of potentially concussive events and concussions occurring in theater DoDI 6490.11) (DoD, 2012). This document also defines: 1) what constitutes a potentially concussive event, 2) evaluation procedures, and 3) return-to-duty standards. In 2013, Headquarters, Department of the Army (HQDA) released a new executive order (EXORD) for concussion and mTBI management in garrison (HQDA EXORD 165-13). Similar to DoDI 6490.11, HQDA EXORD 165-13 (expired in 2017) provided guidance not only for determining if a Soldier has been involved in a potentially concussive event, but also the medical assessment of a Soldier, if it is concluded they have been exposed to a potentially injurious event. Per HQDA EXORD 165-13, a medical evaluation by a medic or healthcare provider should be performed as soon as possible (i.e., within 12 hours) following the event. However, even with the DoDI 6490.11 for deployed settings and the HQDA EXORD 165-13 for in garrison, potentially concussive events continue to be subjectively defined and rely upon self- or observer-reporting, which is likely to be inconsistent and inaccurate. Wearable devices that are capable of accurately recording and indicating head exposures have the advantage of independence from self- or observer-reporting. A suitable wearable device could be an objective method for identification of potentially concussive events, particularly in the military training environment, creating an opportunity to improve both clinical outcomes for TBI and mTBI in Soldiers as well as Soldier readiness.

In response to the increased prevalence of TBI diagnoses in the military and in athletics, several helmet- or head-mounted environmental sensors (ES) designed to detect and quantify head exposures have been developed by both the DoD and commercial entities. These devices offer a seemingly simple technological way to assist in the identification of potentially injurious head exposures; however, these small acceleration-based devices, both those currently available and in development, are only starting points. Presently, there is no validated relationship between head exposure recorded via ES and concussion (Harmon et al., 2019). These devices may be useful for identifying the level of exposure to the head or helmet; however, they are not diagnostic devices capable of determining whether an injury occurred (Harmon et al., 2019). Furthermore, the military environment presents unique challenges to the development and implementation of ES: Environmental extremes; operational tempo; multiple concepts of operation; physical exposure during training and operational events; use of various personnel protective equipment; and physical and operational safety.

To address the challenges of introducing devices capable of monitoring blunt impact and blast exposure into military training, the Military Operational Medicine Research Program developed and funded the Environmental Sensors in Training (ESiT) research program. A major goal of the ESiT research program is to evaluate the ability of available devices to identify potentially concussive events resulting from head acceleration exposures (resulting from impact or due to inertial motion), or blast exposures occurring in military training environments.

Over the course of several data collection activities from 2015 to 2018, as well as the subsequent data analysis in support of the ESiT Research Program, several lessons have been learned. These include (1) human factors concerns for different training environments; (2) device performance concerns in Army training environments; and (3) administration concerns for both the devices and neurophysiological tests in a field setting. The objective of this report is to summarize the lessons learned through multiple studies conducted under the ESiT research program to inform future device development as well as continued research involving wearable devices.

Materials

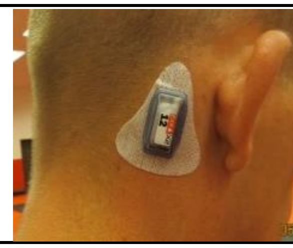
The primary devices used for data collections included the X2 Biosystems xPatch, the BlackBox Biometrics (B3) Linx, and the BAE Systems Headborne Energy Analysis and Diagnostics Sensor version II (HEADS II) (Table 1). Additional devices (not discussed in this report) included the Reebok Checklight and B3 Blast Gauge. The Checklight and Blast Gauge were excluded from further data collections following the first use due to the lack of data provided and compatibility issues with the environments being evaluated. Device names throughout this report do not constitute endorsement by the DoD. The xPatch and Linx are commercial off-the-shelf (COTS) devices originally designed for use in athletic environments, while the HEADS II device was developed for the DoD and is intended to be used in operational settings (Rooks et al., 2015).

The xPatch is a small device (approximately the size of a quarter) that adheres to the mastoid process using a two-sided adhesive patch. The xPatch records all events above a threshold of 10 G in any axis and stores full time-trace raw data for each event. The xPatch software application processes the raw data collected through a coordinate transformation to predict head motion at the head center of gravity (CG). Data provided at the head CG include summaries of each event, while time-trace data for each event is retained in the local (e.g., device) coordinate systems. The software also includes a proprietary algorithm that attempts to classify events as true head exposures (e.g., realistic head motion) or false positives; however, all events recorded by this device can be saved for further analysis and potential re-classification by the research team (Rooks et al., 2016; Rooks et al., 2019).

The Linx is a thin device (about 1.5 inches [in.] by 0.5 in. by 0.12 in.) inserted into a headband or skullcap, which is designed to keep the Linx device in a standard position above and behind the right ear when worn by the participant. The Linx records all events above a proprietary threshold of impact severity (approximately 40 G with an unspecified rotational component). The Linx device stores summary data for lower severity impacts and full time-trace data for higher severity impacts. Similar to the xPatch software, the software application for the Linx device processes the collected data through a coordinate transformation to predict the motion of the head CG. All data from the Linx device are provided in the head CG coordinate frame. Additionally, the Linx software classified events as true head impacts or false positives using a proprietary algorithm. Unlike the xPatch software, the Linx software originally retained only the algorithm-defined true head impact/inertial events (both time-trace and summary data for events above a specific threshold) for further analysis. Subsequent software updates enabled the capability to update the trigger threshold and retain all triggered impact events; however, this was completed after the period reported on in this report.

The HEADS II device is DoD-developed and mounts in the crown of an Advanced Combat Helmet (ACH). The HEADS II uses a customizable trigger threshold with a range of 60 to 80 G, in any axis. Data collected from the HEADS II device is analyzed using the provided software to predict head CG velocity and reports the maximum velocity for each event. In addition, the HEADS II device provides acceleration traces for further review and analysis. The HEADS II software also includes a classification algorithm that will notify users of a false event and does not calculate velocity for the false events (Wallace et al., 2012).

Table 1. Environmental Sensors Used for All Data Collections Included the X2 Biosystems xPatch, BlackBox Biometrics (B3) Linx IAS, and BAE Systems HEADS II Devices

Device	**Mount Type/Location**	**Primary Measurements, Battery Life, and Trigger Threshold**	
X2 Biosystems xPatch	Head – mastoid process (adhesive)	Linear Acceleration in X, Y, and Z axes Angular Rate about X, Y, and Z axes Battery Life: ~5-6 hours Trigger: 10 G in any single axis	
BlackBox Biometrics (B3) Linx IAS	Head (skull cap or headband as shown on right)	Linear Acceleration in X, Y, and Z axes Angular Rate about X, Y, and Z axes Battery Life: ~6-7 Hours Trigger: ~40 G (with proprietary rotational content)	
BAE Systems HEADS II	Helmet crown (epoxy)	Linear Acceleration in X, Y, and Z axes Angular Rate about X, Y, and Z axes Pressure Battery Life: ~12 Months Trigger: 60 G in any single axis	

Methods

As part of the ESiT research program, the U.S. Army Aeromedical Research Laboratory (USAARL) is responsible for evaluating the accuracy and efficacy of devices capable of monitoring head acceleration exposures. Head acceleration exposures may be the result of direct impact or inertial motion. The program began in 2013 with USAARL evaluating several devices under laboratory conditions (Rooks et al., 2014; Rooks et al., 2017), followed by several pilot studies evaluating the use of the devices and neurocognitive performance tasks in Army training environments (Rooks et al., 2015; Traynham et al., 2017). More recently, USAARL has been investigating DoD- and commercially-developed devices as tools for identifying potentially concussive events in Army training environments that may involve head impacts with the possibility of injury (Kelley et al., 2021; Bernhardt et al., 2019; Rooks et al., 2018b). Training environments included the Basic Airborne Course (BAC) and courses under the Modern Army Combatives Program (MACP) at Fort Moore, Georgia, formerly Fort Benning (Appendix A). Data were collected in support of multiple studies between 2015 and 2018.

This report discusses data and observations collected during both test plan and research protocol data collection. All data collection activities were approved through official channels. The USAARL Regulatory Compliance Office and the U.S. Army Medical Research and Materiel/Development Command (formerly USAMRMC and now USAMRDC) Office of Research Protections approved the study plan for the test plans and research involving human subjects. All research data from human subjects were collected under an approved Institutional Review Board (IRB) protocol (reviewed and approved by the USAMRMC/USAMRDC IRB). Data were collected from Soldiers attending classes of the BAC and Basic Combatives, Tactical Combatives, and Combatives Master Trainer Courses (BCC, TCC, and CMTC) within the MACP. Overall, data were collected from 160 participants (95 airborne students and 65 combatives students) over 13 classes (6 airborne classes and 7 combatives classes).

Participants from both training environments were instrumented with multiple devices. A minimum of two devices were used for every participant. The Linx and xPatch devices were used in every data collection, while the HEADS II device was used in the BAC data collections. The HEADS II device was investigated for use in one out of three MACP data collections during the Test Plans. Use of the HEADS II device was not continued because students in the MACP courses only use helmets during one drill and the minimum trigger threshold (60 G) for the HEADS II device was determined to be too high to record any events. Data were collected during all drills conducted in the BAC. Data were collected during a subset of the drills from courses in the MACP, where the devices were compatible with the environment (primarily stand-up sparring). Participants wearing ES were videotaped while conducting drills to confirm whether a head impact/inertial event occurred. Video and device data were time synchronized to a National Institute of Standards and Technology (NIST) traceable time source (www.time.gov). Data recorded from the ES were categorized to identify events confirmed through video analysis and verified as acceptable impacts based on signal characteristics.

Lessons Learned

Human Factors and Environmental Observations

Several human factors and environmental concerns for the use of ES were observed during the data collection activities conducted. Observations reported below are separated into two general categories: (1) device compatibility and (2) device comfort. Device compatibility included multiple topics relating interactions with personal protective equipment (PPE) (e.g., helmets or boxing headgear) and functional equipment (e.g., parachute harness) as well as issues encountered with specific drills. Device comfort included multiple topics relating to the placement of the device, long-term comfort and wear, and issues encountered relating to environmental conditions (e.g., heat and humidity). Additional discussion and potential solutions to many of the human factors concerns are described in later sections.

Device compatibility.

A key concern for the use of ES in any environment includes the compatibility for use with the intended environment. An example from athletics is the development and use of the Head Impact Telemetry System (HITS), which was originally integrated with the football helmet only, limiting uses outside of that sport. Similarly, the HEADS II device in the military is integrated with the ACH, limiting its uses to training environments using that helmet. Recently, several new ES form factors that are not integrated with a helmet have become available. For the non-helmet-based ES, a new concern is the interaction with helmets and other equipment common to the intended environment.

Whether used in athletics or in the military, the interaction between a helmet or other protective equipment, and the ES is important to consider. For example, while collecting data with Soldiers attending a course in the MACP (Figure 1), we experienced issues when loosely worn boxing headgear caused headband or skullcap devices to rotate out of position and dislodged the adhesive device. Many PPE interaction issues were resolved by using better fitting (e.g., appropriately sized) headbands or skullcaps with higher quality elastic; however, protective headgear allowing user-adjustments for comfort still caused problems, as the Soldier controlled the fit of the headgear and excessive rotation could dislodge the xPatch device or cause the headbands/skullcaps to rotate (although to a lesser degree).

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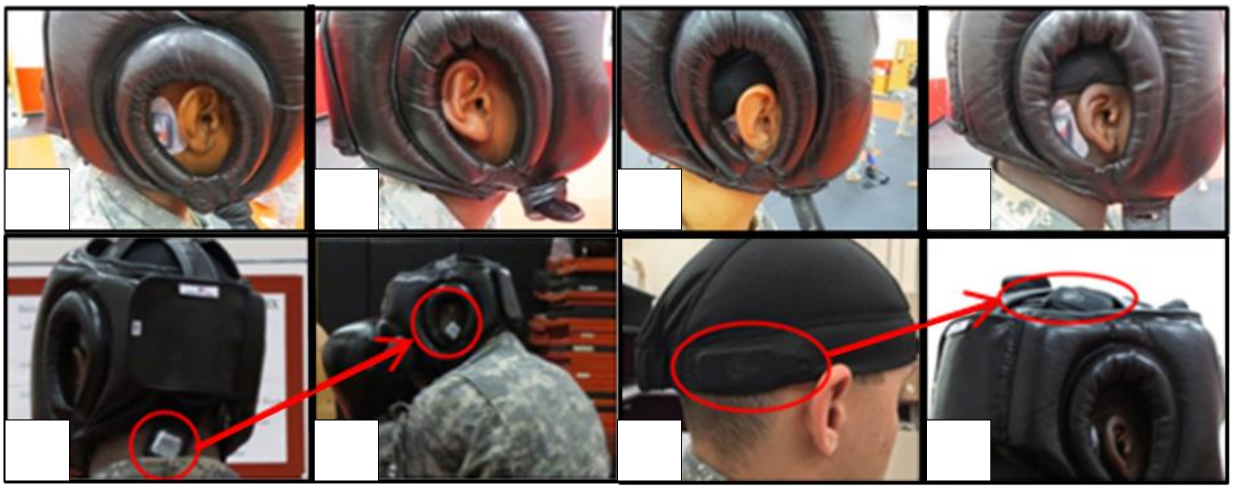

Figure 1. Combatives headgear interaction with ES: Illustrating variation in how the combatives headgear fits around the ear and xPatch device (A-D); and displacement of poor fitting skullcaps (Reebok Checklight and early versions of the Linx headband) from the correct position (E, G) to out of position (F, H).

Similarly, while collecting data with Soldiers attending the BAC, we found that the ACH (which is mandatory during the course) could cause the xPatch devices to fall off and cause the skullcap and headband devices to rotate as the ACH rotates excessively during some drills. The excessive rotation can be partially resolved by tightening the helmet retention system; however, since the Soldier controlled the fit of the helmet for comfort, there is a limit to the tightness of the retention system. An additional issue was observed with the ACH related to the location of the xPatch device; the xPatch was located at the mastoid process just above where the retention strap system connects the nape strap to the chinstrap (Figure 2). Many of the concerns listed above would be present in additional environments where an ACH or combat helmet is required and are not unique to the airborne environment.

Figure 2. Advanced Combat Helmet interaction with the xPatch device.

In addition to interaction with PPE, any interaction with functional equipment used in the training environment is of concern. In the airborne training course, the risers for many of the parachutes and apparatus used would contact the upper portion of the neck and the ear and would knock off the xPatch device.

Another concern, particularly during the MACP courses, was compatibility of the ES with the drills performed. During the MACP courses, it was common for participants to be involved in drills learning to immobilize an opponent on the ground or standing and learning to throw an opponent to the ground. Devices mounted to the surface of the skull (e.g., skullcap/headband or skin patch) were quickly determined to be unusable due to how easily the ES can be disrupted (e.g., pulled off or rotated out of position) during these drills.

Device placement and comfort.

A second key concern for use of ES in any environment is the comfort for long-duration activities and the fit/placement of the ES. The COTS devices were developed for use primarily in an athletics environment, which has practice and game durations between two and four hours; however, military training environments (most notably the BAC) require a longer periods of wear with sessions lasting between six and nine hours. While the ES developed for use in athletics environments may be determined to be comfortable or unobtrusive during the shorter duration of activity, the long-term wear (e.g., longer hours for several days) common to military applications highlighted multiple comfort issues.

For both the BAC and MACP populations, the skullcap and headband devices had issues with placement and fit primarily due to comfort for long periods of wear (as stated above). While this was controlled as much as possible (through instruction on wear and on-the-spot corrections), the Soldier is ultimately responsible for the positioning and fit of the headband/ skullcap. Furthermore, since the headband/skullcap devices could be removed without the research team's involvement, participants would often remove the devices during breaks and replace them prior to returning. While infrequent, the repeated donning and doffing of the device may result in additional variability in the data that is not easily controlled as well as the increased possibility of the device not being worn during drills after a break.

The xPatch positioning was better controlled due to the need for direct interaction by the research team to apply the devices (initially as well as after potential disruption); however, it was reliant on application consistency from multiple research team members. Additionally, the location (left side of the head versus right side of the head) of the xPatch device had to be varied for morning and afternoon drills in the BAC in order to limit irritation of the skin not commonly seen in athletics environments due to the shorter duration of wear. The added task of tracking which side of the head the xPatch was applied introduces an additional step and criteria that must be tracked to ensure that data from each portion of the day are transformed to the head CG properly. For example, if a device was mislabeled in the xPatch management software as attached to the right side of the head versus the left it would provide incorrect predictions of head CG motion. The potential for errors resulting from incorrect positioning of the sensor is a concern for any environmental sensor, and not just the xPatch device.

Similar to many athletic environments, the Soldiers attending the BAC or MACP courses were often perspiring due to the level of activity during several drills as part of the course, which occasionally resulted in the xPatch device falling off due to loss of adhesiveness. Anecdotally, it was noted that the headband device helped keep sweat out of the participants' eyes; however, the amount of perspiration also contributed to how easily the ES would rotate out of position.

Device Administration

As stated previously, the development of COTS ES has focused primarily on athletics environments (e.g., football, ice hockey, lacrosse, soccer, etc.). Accordingly, their designs facilitate daily distribution and use, not single distributions with extended periods of monitoring (like the DoD-developed HEADS II device). Additionally, many of the COTS ES were developed to integrate with a cloud platform managed by the company and download data wirelessly (via Bluetooth, etc.). Many of the COTS ES available for use in our data collections (2015-2018) were designed to store data from a single game or practice (approximately 100 events) and the batteries are designed to last for a single athletic event (approximately 4 to 6 hours). The COTS ES focus on daily use and distribution resulted in multiple administrative burdens on the research team, including minimizing interference with training (time to distribute and number of distributions), resetting, and recharging the devices daily.

One of the primary administrative burdens for managing ES, in either the BAC or MACP courses, was the distribution of the ES. In order to limit the degree of interference, we worked with the course instructors and leadership to understand the best times to distribute ES to students. The BAC is a structured course with long training days and limited accessibility to students. Additionally, there is limited flexibility within the schedule due to the amount of material to cover and the number of students attending the course (maximum class size is typically 300 to 400 Service Members per company). During our data collections, we were constrained to distribute the ES prior to the start of the course (at student in-processing) or during long established breaks (e.g., breakfast and lunch). We did not routinely have access to students during the day to distribute the ES prior to targeted drills (i.e., drills where a head impact is expected or possible). The COTS-developed ES (i.e., xPatch and Linx) required multiple distributions per day for the BAC in order to ensure that data were captured during the drills of interest while also minimizing interference on the training schedule. The DoD-developed ES (HEADS II) used during the BAC required a single distribution at the beginning of the course (while students were in-processing). The in-processing day was the most flexible day during the course; however, not all students had arrived by this day. During the course, the COTS-devices were handed out as students returned from breakfast or during lunch over a roughly 30-minute span. Distribution of the HEADS II device (once at student in-processing) took longer than the xPatch and Linx devices due to the time required to initialize the device on-site. The MACP courses were more flexible due to the smaller class sizes (maximum class size is typically 36) and the structure of the courses. During data collections, the COTS-developed ES were distributed daily, prior to the sparring sessions or other compatible drills. Additional distributions may be required for an ES that is compatible with additional drills (e.g., grappling, wrestling, Jiu Jitsu, etc.). With a team of four researchers, we were able to distribute the xPatch and Linx devices to between 15 and 25 participants in 5 to 10 minutes, if they were all available at one time.

All of the COTS-developed ES required daily download, reset, and recharging in order to be used the following day. The DoD-developed ES required download at the completion of the course and did not require any recharging during the course. All of the ES discussed in this report can be re-initialized and used with new students. The COTS ES focus on cloud integration and wireless downloads resulted in multiple administrative and technical burdens on the research team, including acquiring software to manage COTS ES locally and management of data on non-cloud-based systems. Management of the COTS ES data using local applications required use of software that was not part of the original ES infrastructure. Additionally, since the data were managed locally, custom databases and storage solutions to maintain clear separation of the data for each subject required development.

An additional administrative concern for both courses was management and sanitation of the headbands/skullcaps. In order to minimize the additional burden to the students participating in the data collection activities, the research team issued and collected both the headband and Linx sensor each day of activity rather than providing a single headband to the participant at the start of the course and re-issuing only the sensor daily. Since headbands were re-issued, the research team was responsible for managing the sanitation of the headbands between uses. For a small sample size, managing to clean the headbands between days or providing a new headband that was not previously worn was feasible; however, for much larger classes, or uses of the device, sanitation could become significantly more difficult if the headbands were not issued as equipment for the participants to maintain responsibility over.

Device Performance

Confidence in the quality of the data provided by the ES is critical for long-term use of the devices. An ideal use for an ES device is to indicate when a potentially concussive event has occurred, which would then lead to a point of injury evaluation using a field portable concussion assessment battery and an informed decision for further clinical diagnoses. An unreliable ES device that: (1) provides false readings; (2) does not provide readings when it should have; or (3) fails to collect and store data due to connectivity issues or hardware malfunctions, will not have widespread use. Unreliable data from ES may result in students or operational Service Members being removed from training or duty for no reason or may miss potentially concussed individuals.

False positive identification.

In addition to distribution of the devices, false positive identification is one of the primary burdens associated with current COTS- and DoD-developed devices. A false positive is an event reported by the ES device that did not result from a physical exposure to the Service Member. Instead, it is an event resulting from some other event recorded by the device. False positive events pose a problem for long-term use of an ES for monitoring head impacts because of the uncertainty they introduce in all impacts recorded (Patton et al., 2020). Many ES currently employ classification algorithms aimed at removing the false positive events; however, they may not be appropriate for military training environments. The COTS-developed ES have tuned the filtering algorithms to athletics environments, and many are held as proprietary information, limiting further verification of their reliability. One method for filtering false positive events is through the triggering algorithms or based off signal characteristics; however, this method is susceptible to the possibility of missed events as it will either not collect events, or it may delete events not meeting specified criteria. Triggering and filtering algorithms can be tuned to be very restrictive, allowing only guaranteed events to pass through; or the filtering algorithms can be tuned to be very permissive, possibly allowing false events through. The advantage to triggering and filtering algorithms is the ability to run them on the ES device to provide real-time assessments of exposure.

Another method for identifying false positive events is through video confirmation. Video confirmation is less likely to miss events; however, it requires a significant amount of time to process the video and the method does not facilitate real time assessments of head impact events. Recent work from the athletics community has included video analysis as a metric for verifying reported events (Gabler et al., 2020; Carey et al., 2019; Kuo et al., 2018; Cortes et al; 2017; Hernandez, Wu et al., 2015; Hernandez, Shull et al., 2015; Rowson et al., 2012; Koh & Watkinson, 2002). Kuo et al. (2018) advocate for use of combined ES and video metrics rather than looking at ES data and video data individually. The combination of an ES device and video metrics aims to reduce the limitations inherent in each individual approach. Similarly, work performed in the ESiT program has advocated for use of video confirmation of events while keeping the video as the "gold-standard" (Rooks et al., 2018b; Rooks et al., 2017; Rooks et al., 2016). Additionally, a working group established by the National Institutes of Health (NIH) developing common data elements (CDEs) for use with biomechanical devices recommended use of video verification as a component in field deployments of ES (Wu & Rooks, 2017). Future processes may include more sophisticated filtering algorithms (e.g., machine learning) and sensors (e.g., position or proximity sensors to indicate the ES device is in use) to limit the collection of false positive events (Patton et al., 2020; Rooks et al., 2019; Wu et al., 2017; Motiwale et al., 2016). The more sophisticated methods are currently in development for athletics environments and will require additional tuning for military environments.

Device-to-device variability.

Another major consideration for use of ES is the device-to-device variability. As identified during data collections performed with just two environments (BAC and MACP courses), there is not a "one-size-fits-all" solution for an ES device to use in all training environments. The devices used each had limitations and developmental devices that overcome some of the limitations for one environment may not be suitable in other environments. For example, based off early interactions with training cadre from the BAC, it was determined that a mouthguard-based device was not suitable due to the interference with clear communication, which is an important safety measure for airborne operations (Rooks et al., 2014). Similarly, a helmet-mounted device is not suitable for combatives training environments where a helmet is not part of the standard kit for a significant portion of the training.

During data collections with the BAC, we used three available ES: Two COTS devices that mount directly to the head (xPatch and Linx) and one DoD device that mounts to a helmet (HEADS II). For 40 subjects, during the first two weeks of training (ground week and tower week) the xPatch device recorded and saved 4246 events compared to the Linx device, which recorded and saved 265 (Figure 3). After cleaning the data to compare events that were confirmed via video analysis and classified as good events, we found that the xPatch and Linx devices had significantly different average peak resultant linear accelerations across both weeks of training (14 G versus 80 G, respectively; Figure 4), and peak resultant rotational velocities (750 degrees per second [deg/s] versus 1300 deg/s, respectively; Figure 5) (Rooks et al., 2018b). The HEADS II device was not included in the above analysis investigating head linear accelerations and rotational velocities, as it only provides an estimation of the head velocity. The linear accelerations and rotational velocities recorded by the helmet are incomparable with those recorded by the head-mounted devices.

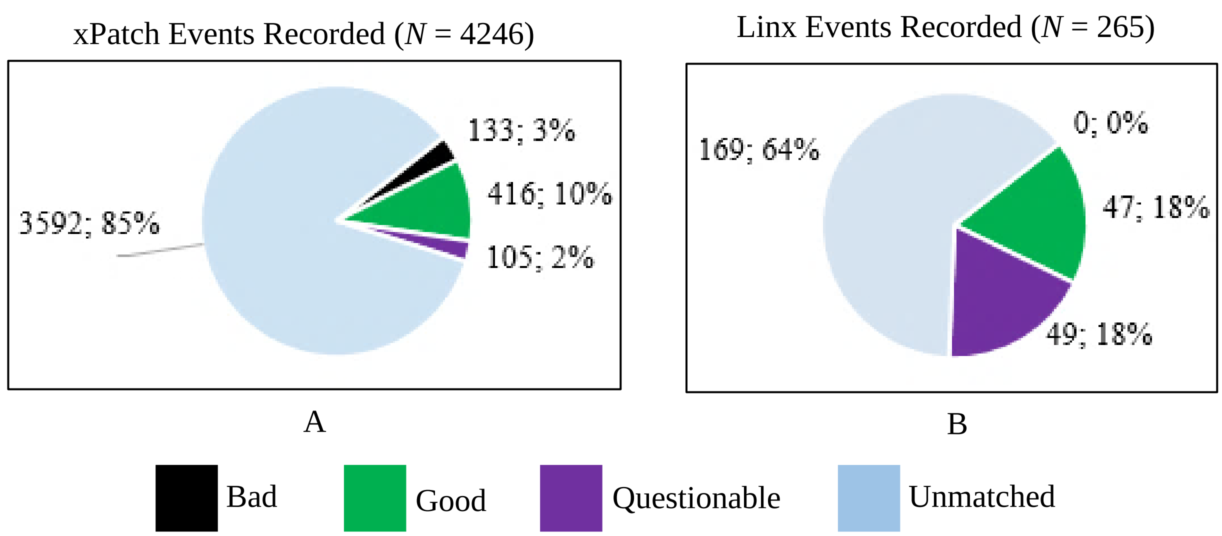

Figure 3. Summary of events recorded by the non-helmet mounted (A) xPatch and (B) Linx devices: Good events (that matched to video and with quality signal traces), bad events (poor quality signal traces), questionable events, and events that did not match to a video confirmed event.

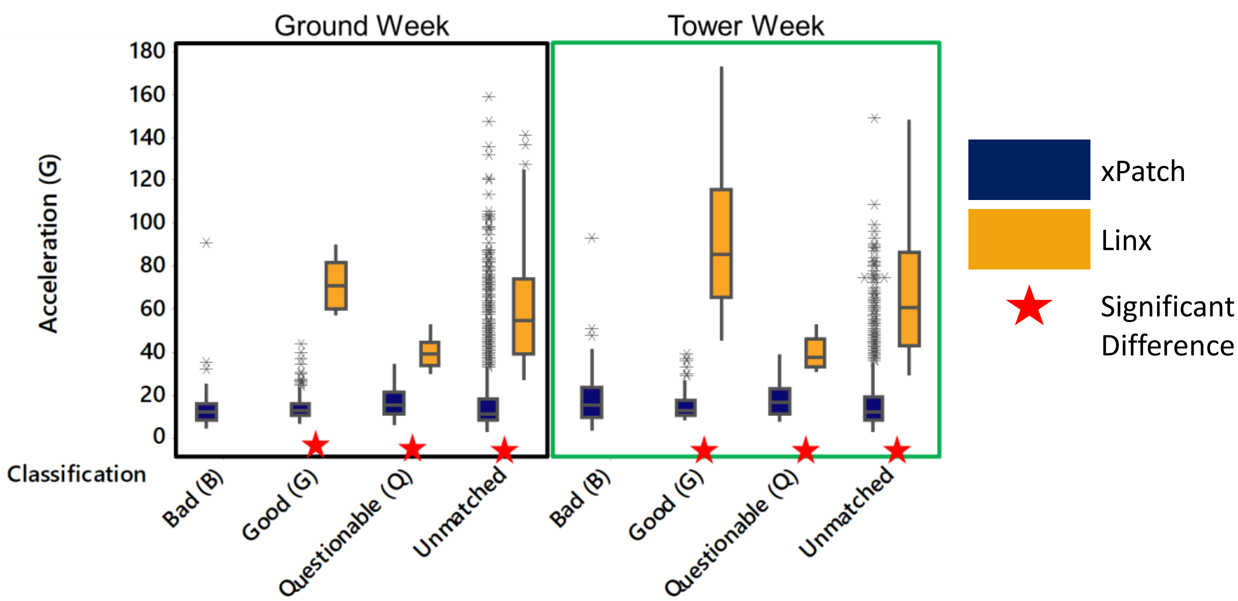

Figure 4. Peak linear acceleration comparison for the xPatch and Linx devices during ground and tower weeks at the BAC. Significant differences (red star) in mean peak resultant linear acceleration were found during both ground and tower weeks.

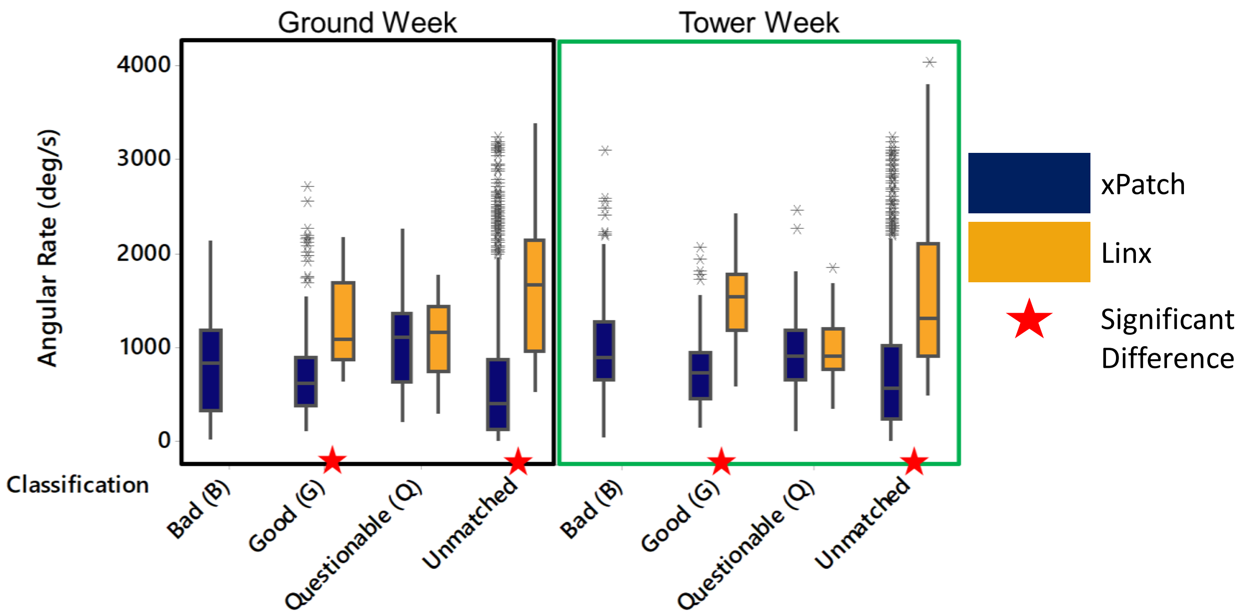

Figure 5. Peak rotational velocity comparison for the xPatch and Linx devices during ground and tower weeks at the BAC. Significant differences (red star) in mean peak resultant rotational velocity were found during both ground and tower weeks.

The discrepancies in the data from the two commercially-developed head-mounted devices were primarily due to differences in processing algorithms (e.g., automatic filtering of true versus false events) and trigger thresholds. At this stage, the ability to compare data from multiple devices is more reliant on how the device handles data than on physical design (e.g., mounting location or method) or specifications (e.g., quality of the electronics) of the devices. Many recent efforts using ES for monitoring head impacts have started to place a greater emphasis on the quality of the data provided by the device (including video verification and signal quality); however, few studies have investigated the translatability between different devices. The disparity in data provided by the ES highlighted above indicates that additional work may be required when evaluating exposure severity using different ES. Understanding device capability, performance, and the data provided is an important step in developing a dose-response relationship for exposure and neurological performance decrements or concussion.

Recommendations

Devices for monitoring head impacts are usable; however, they should not be used blindly, and they still require a research team to support the interpretation of the data collected. Far-future goals for these devices are to enable military personnel, athletic teams, and medical personnel to identify when a Soldier/athlete is at risk due to an impact (or impacts) and then be able to recall the severity of the exposure during diagnosis and treatment. In addition to development of a validated dose-response relationship between exposure and risk of concussion, several significant device improvements are required prior to achieving the far-future goals. In addition to improving the human factors design of devices (e.g., compatibility with military training environments and comfort for long durations), research involving the use of head impact monitoring devices should focus on three main areas: 1) improving the device administration to improve efficiency of using the devices, 2) improving false positive identification, and 3) improving device-to-device translatability. With improved translatability between devices, many of the human factors concerns may be addressed by the ability to choose specific devices for specific environments.

Human Factors

Many of the human factors lessons described can be solved by identifying the best device for the environment. Unfortunately, within the military, there may not be a perfect device, which results in the need for compromise. Not all training environments are the same and not all training environments have the same requirements for compatibility with a device. For example, for static line airborne environments (e.g., the BAC), a device that does not substantially influence the Jump Master's Primary Inspection (JMPI) is important. Additionally, a device that does not interrupt communication is important. For combatives environments, a device that is not easily dislodged is required. For all environments, comfort and unobtrusiveness are important factors for continued use/wear of the devices by the volunteers. Regardless of training environment, any ES under consideration for use cannot degrade the protection or performance provided by the head protection or other military PPE, gear, or equipment.

One method for addressing interaction effects with protective equipment (helmet or boxing headgear) or functional equipment (parachute risers) is to incorporate the device directly into the helmet (similar to the HEADS II device in the military or the HITS in football). The use of a helmet-mounted sensor, however, raises many other questions concerning the quality of the data obtained and how well it reflects actual exposure to the Soldier since it is more accurately recording events occurring to the helmet and not the subject's head, directly (Rooks et al., 2017; Siegmund et al., 2015). Predicting head motion correctly is reliant on knowing the position of the device relative to the head during the entire event. Devices that are able to move freely, or are not well coupled to the head, are more likely to result in inaccurate data that is impossible to correct or predict. An alternative method, that improves coupling with the head, is to incorporate the sensor into form factors that are not located on the exterior of the head (e.g., mouthguards or earpieces). Recent developments using mouthguard and earpiece-based devices may address these concerns for the BAC and MACP type environments; however, they were not available during the time the studies included in the present report were conducted. Additionally, these form factors may introduce other concerns, such as limitations in communication, long-term comfort, and the need for customized devices (e.g., one device per Soldier) versus reusable devices.

Device Administration

Many of the available ES were developed for use in sports or recreational activities resulting in design and operational choices that may not be the best options for use in military training. For example, the COTS ES used had to be distributed twice per day during the BAC in order to capture exposures from training drills of interest. The administrative burden of handing out ES (i.e., amount of time and interference in the training day) is one of the biggest burdens to use of the COTS ES in the military. While collecting data, we identified two means of shortening the amount of time required to distribute ES. First, routine played a large part in the time required. As the courses progressed, the students participating in our data collection became accustomed to the routine and were able to find the research team much faster. The routine forced the participants to find us rather than requiring us to find them for each distribution. Second, easy identification of the participants was very helpful for both the BAC and MACP courses (roster numbers or other information prominently displayed). The clear identification enabled us to rapidly locate the participants to distribute devices. Easy identification was also a requirement for video analysis of drills to confirm true impacts.

The daily reset for each device required substantial amounts of time following each data collection activity. The data had to be downloaded from all devices and the devices had to be recharged for the following day of drills. Many of the available ES were developed for integration with cloud-based platforms and wireless data transfer. Due to DoD requirements at the time of data collection, we were unable to transfer data wirelessly or use the existing cloud infrastructure and were required to use manual data transfer and storage methods. The ability to transfer data wirelessly following approved DoD protocols, as well as the ability to transfer data from multiple devices at the same time (either wirelessly or wired), would substantially reduce the administrative burden to reset the devices between data collections. Furthermore, the ability to transfer data wirelessly (within approved DoD protocols) could enable real-time notifications of substantial exposures to be logged. Finally, the ability to connect with the devices wirelessly would enable an external clock to be used to maintain an accurate clock on the devices, which is critical for comparisons to synchronized video as well as identifying events relating to PCE in training or practice. The devices were required to be plugged in or connected to the power source to recharge. The ability to use wireless charging technology and place the devices near a charging coil to recharge would also reduce the administrative burden and required equipment (cables, USB hubs, etc.) to be transported with the devices.

Device Performance

Until sufficient confidence in software algorithms is obtained, the best approach for identifying false events, while not missing possible true events, is the use of video analysis combined with a simple trigger algorithm on the device. Use of events confirmed via video will help the development of more advanced software filtering algorithms with the ability to run on an ES device. Video confirmation of events requires that: (1) high quality video of the drills be available (or obtainable by the research team); (2) video and ES are synchronized in time; (3) participants are identifiable in the video obtained; and (4) the research team has a significant amount of time to complete the analysis. While video confirmation of events is currently the best available method for identification of false positive events, it does have its own drawbacks. Time synchronization between the devices and the video is critical and, when using devices that are not wirelessly synchronized in time, non-trivial. The devices used in the current work all suffer from drifting clocks and require regular synchronization to a time source. Additionally, video confirmation is incredibly time-consuming. Kuo et al. (2018) reported an estimated 1000 man-hours to analyze 160 hours of video for confirmation of impact events. The data collected in the BAC and MACP courses required a similar amount of time devoted to identifying impact events. In addition to the time required for completing the analysis, there are no data available to our knowledge about the test-retest reliability and inter-rater reliability of using video to identify and verify recorded impacts.

Similar to an inability to reject false events, device-to-device variability has many ramifications for both decision making (i.e., is a Soldier/athlete injured) as well as trust in the devices. There is a significant amount of research being performed to identify a dose-response threshold for concussion using an ES device (e.g., Stemper et al., 2019; O’Connor et al., 2017; Brennan et al., 2016; Nevins et al., 2015; Hernandez, Wu et al., 2015; Beckwith et al., 2013;

Rowson et al., 2012). Many of the ongoing studies use only one device and the same device is used across multiple studies. If two devices do not report the same exposure for a given event, a dose-response relationship between exposure and concussion developed using one device will not be compatible with other devices. One device may alert a medic to pull the Soldier from training, while the other may never provide an alert; which raises the question of which device was correct? One possible solution to the problem is to develop a transfer function between the devices; however, this presents its own challenges and errors. While it provides a solid foundation, laboratory testing alone may not be sufficient to develop a robust transfer function. Data collected during the ESiT work, as well as several academic studies, have shown many ES perform well in a controlled laboratory setting and then fail to collect reliable data in the field (Kieffer, et al., 2020; Rooks et al., 2018a; Rooks et al., 2017; Siegmund et al., 2015; Press et al., 2017). Additional work investigating device-to-device variability in ES in a field setting should focus on collecting data from multiple compatible devices on the same subject to identify discrepancies between devices. If developing a transfer function between devices were not possible, then individual dose-response relationships would be required for each fielded device, which is scientifically impractical due to the unpredictability of concussion occurrence and the number of volunteers a robust dose-response relationship would require.

Conclusion

USAARL has a long history of using and evaluating ES for use in military training environments involving head impacts. Between 2015 and 2018, USAARL performed several laboratory, field pilot, and human subjects data collections evaluating newly developed COTS ES and existing DoD ES. The major concerns identified for use of the ES include: 1) human factors concerns, 2) device administration, and 3) device performance. The primary human factors concern was interaction effects with PPE required by the training activity. Many activities required either a helmet (e.g., ACH required for use in the BAC) or other form of headgear (required for use in MACP courses). Both forms of head protection caused the ES to either move out of position or fall off regularly. The severity of the interaction was manageable with better fitting PPE and monitoring the ES; however, not all problems were resolved. The primary device administration concern was the amount of time required to manage the devices (e.g., distribution, charging, video recording of events, managing data, reviewing video, etc.). Finally, the two primary device performance concerns were 1) false positive identification, and 2) device-to-device variability. Identification of false positives is important for trust that a device is providing data when head movement occurs and not when the device is bumped or dropped. Device-to-device variability is important for widespread use of the devices being developed. If a dose-response relationship developed for one device is not applicable to other devices, widespread use will be nearly impossible due to the human factors constraints for different training/athletic environments. Finally, all of the supplemental administration tasks (e.g., device deployment and redeployment, data management, event verification, etc.) required to manage the devices took a large team to support a small number of volunteers.

With the evolving understanding of concussion prevalence in the military and athletics, several academic institutions and the DoD are conducting a significant amount of research investigating the use of wearable devices attached to the head as potential indicators of injury. These devices offer a seemingly simple technological way to assist in identification of potentially injurious head exposures. However, the small acceleration-based devices currently available, and in development, are only starting points. Care should be taken in the use and interpretation of results that may be confounded by out-of-position devices, false-positives, and device-to-device variability. At this time, the devices may be useful for identifying the level of exposure to the head or helmet; however, they are not diagnostic devices capable of determining whether an injury occurred, and they cannot be used blindly. Furthermore, the military environment presents unique challenges that must be considered in ES design and use: environmental extremes; operational tempo, concepts of operation, and physical exposure during training and operational events; use of various protective equipment; and physical and operational safety.

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Appendix A. Army Training Environments

Basic Airborne Course (BAC)

The BAC is a structured airborne training environment where varying levels of head impact are likely. The BAC consists of three weeks of exercises teaching Service Members (SM) to jump from a plane and land safely. During the training, SMs may be at risk for head impacts while landing. During the first two weeks, SMs learn the Parachutist Landing Fall (PLF) as a technique to minimize injury during landing and must perfect the technique while falling in multiple directions. The first week of exercises are the SM's first exposure to PLFs and include many repetitions while students learn the new technique. The second week of exercises build on experience from the first week and introduces new skills requiring fewer repetitions. In the final week, SM's combine skills learned in the first two weeks to perform six complete jumps from an airplane.

Modern Army Combatives Course (MACP)

The MACP is an Army-wide combatives program with multiple training sites. The MACP consists of several courses starting with an introduction to combatives (Basic Combatives Course – BCC), followed by a more intensive course teaching tactical applications of combatives (Tactical Combatives Course – TCC), and finally progressing to a master trainer certification (Combatives Master Trainer Course – CMTC). The BCC is a one-week course, taught at the local battalion level, during which students learn the basics of hand-to-hand combat including a drill providing instruction on how to immobilize an opponent. During this drill, probability of a mild head impact is increased. The TCC is a two-week course during which subjects learn the basics of striking and grappling. Finally, the CTMC is four weeks in duration and involves multiple sparring and grappling sessions where students practice striking and grappling skills. Mobile Training Teams (MTTs) will teach both the TCC and CMTC courses at selected Army posts.

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