NATIONAL INSTITUTE OF NEURAL DISORDERS AND STROKE (NINDS)
AND
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)
COMBAT CASUALTY CARE RESEARCH PROGRAM (CCCRP)

ENVIRONMENTAL SENSOR USE FOR QUANTIFYING NEURAL EXPOSURE TO INERTIAL AND BLAST FORCES

SNOWBIRD, UTAH
8 JULY 2017

EXECUTIVE SUMMARY

This executive summary was prepared by MAJ Walter Carr, Walter Reed Army Institute of Research (WRAIR) with support made available from the Army TBI Program of the U.S. Army Office of the Surgeon General

MODERATORS AND PRESENTERS

Dr. Kristy Arbogast	Children's Hospital of Philadelphia
Dr. Adam Bartsch	Prevent Biometrics
Dr. Patrick Bellgowan	National Institute of Neurological Disorders and Stroke, National Institutes of Health (NINDS/NIH)
Dr. David Camarillo	Stanford University
MAJ Walter Carr	Walter Reed Army Institute of Research (WRAIR)
Dr. Stefan Duma	Virginia Tech University
Dr. Candace Floyd	University of Alabama at Birmingham
COL Sidney Hinds	US Army Medical Research and Materiel Command (USAMRMC)
Dr. Patricia Janulewicz Lloyd	Boston University School of Public Health
Dr. Gary Kamimori	WRAIR
Dr. Susan Margulies	University of Pennsylvania
Dr. Matthew McAuliffe	Center for Information Technology, NIH
Dr. Stephen Recchia	US Army Armament Research, Development, and Engineering Center
Mr. Tyler Rooks	US Army Aeromedical Research Laboratory
Dr. Richard Shoge	Military Operational Medicine Research Program
Dr. Brian Stemper	Medical College of Wisconsin
Dr. Joel Stitzel	Wake Forest School of Medicine
Dr. James Stone	University of Virginia Medical School

MEETING OBJECTIVES

The NINDS and USAMRMC co-coordinated the workshop, “Environmental Sensor Use for Quantifying Neural Exposure to Inertial and Blast Forces,” at the Snowbird Resort on 8 July 2017 at the National Neurotrauma Society Annual Symposium. The primary objective of the workshop was to update the neurotrauma field about the state of the science for environmental sensors applied to diagnosis and prevention of brain trauma. Secondary objectives were to inform the community about the development of common data elements (CDEs) for sensor data reporting and sharing of sensor data via the Federal Interagency Traumatic Brain Injury (TBI) Research (FITBIR) informatics platform, as well as to lay the groundwork for an inter-agency working group supporting standards development and data sharing for sensor-related data.

The workshop expressly did not advocate for any sensor product or similar technology. The opinions or assertions contained herein are the private views of the author(s) and are not to be construed as official, or as reflecting true views of the Department of the Army, the Department of Defense, the Department of Health and Human Services, or any of the institutions to which the contributors are affiliated.

HISTORY AND UTILIZATION OF SENSORS

- Dr. Stefan Duma, Virginia Tech University, “Historical Development and Types of Data”
- Dr. Kristy Arbogast, Children’s Hospital of Philadelphia, “Accuracy and Context of Use (Research vs. Clinical Usage)”
- COL Sidney Hinds, USAMRMC, “Historical Development and Types of Data”
- Dr. Gary Kamimori, WRAIR, “Blast and Blast Sensors–Overview, Utilization, and Accuracy”

Dr. Duma presented a history of head impact sensor development during the last 60 years. He demonstrated how early research in automotive safety relied on cadavers and animal subjects to establish the relationship between impact force and head injury severity. With the development of self-contained sensors suitable for field use, small numbers of human volunteer athletes contributed to the design of helmet-mounted sensors. The introduction of the Head Impact Telemetry System (HITS) in 2003 led to sensors being widely adopted in sports. Within the last decade, large numbers of instrumented volunteers have produced a sufficient quantity and quality of data for sports management. The newest generation of sensors includes mouth guard and smaller retainer-style sensors, as well as earplug sensors refined to fit into the ear canal. These are now being applied to monitoring participants in non-helmeted sports.

Dr. Arbogast discussed topics of sensor accuracy and sensitivity. She presented findings in which data from head impact sensors were compared to reference data from an instrumented, helmeted dummy head/neck complex impacted by a linear impactor. Accuracy was calculated as the percent relative error between the reference values of linear acceleration and/or rotational velocity and the sensor values. Determining the best-fit mathematical relationship between the reference values and the sensor readings allows the investigator to define a calibration function of the sensor which may be able to be used to adjust real world data to more accurately reflect the kinematics experienced. Dr. Arbogast noted that sensors must have an appropriate measurement range for the expected impacts – which may differ across the settings studied (e.g. youth soccer vs elite football). Moving from the laboratory to the field, she emphasized that sensors need to be able to measure the kinematics of real world impacts which may consist of two impacts closely experienced in time. Further, she emphasized the need for sensors to demonstrate good coupling to the head to ensure that the kinematic data obtained accurately represented head kinematics. While optimistic about the promise of sensor technology, she cautioned that sensors should not yet be considered a diagnostic tool, citing recent research from Dr. Jason Mihalik's and colleagues at the University of North Carolina which demonstrated that for a given sensor studied, the positive predictive value for concussion was very low – less than 2 percent.

COL Hinds outlined the history of the USAMRMC Blast Injury Research Program Coordinating Office (PCO), established to coordinate activities of research and operational communities in addressing the outcomes of blast injuries from conflicts in Southwest Asia and Afghanistan. In the absence of a Food and Drug Administration-approved blast sensor, the Army chose to deploy early-generation helmet sensors to collect data with potential value for line leaders. COL Hinds emphasized that these sensors are not diagnostic and invited stakeholders and interested parties to visit the PCO website to review reports from its annual State of the Science meetings and to learn about identified research gaps. In addition to the PCO coordinating activity, USAMRMC also has an Environmental Sensors in Training (EsiT) program for the execution of USAMRMC research efforts with these wearable technologies.

Dr. Kamimori is USAMRMC's lead field scientist for the ESiT program's measurement of blast exposure, specifically, low-level blasts in standard training protocols for military and law enforcement. Although not clinically diagnosed with injury from these exposures, affected personnel do report headache, fatigue, memory problems, and other symptomology that overlaps with that observed for concussion. Dr. Kamimori illustrated how the angle of the blast wave influences the measured blast force and demonstrated that some of the sensors on individuals could be shielded by their companions. He cautioned that, in such situations, averaging the readings of multiple sensors worn by any one person or using the highest observed reading could provide a significant underestimation (missed injury) or overestimation (false positive for injury leading to removal of operator from the field) of blast exposure.

Noting that Department of Defense acquisition strategy calls for both head impact and blast sensors, MAJ Carr asked the panelists whether they believed these two types of sensors should be combined. There was consensus that consolidated research on both kinds of sensors was practical due to similarities in electronics and design needs, such as wearability and robustness. There were doubts as to whether a single sensor could be effectively designed for both blunt impact and blast. However, given evidence that military service members experienced both types of threat, the panelists felt that a combined sensor should be pursued.

The panelists and the audience discussed what had been shown about sensor capability and agreed that sensors were not yet appropriate for diagnostic use due to varying ability to accurately capture impact force, limited understanding of the association between sensor measurement and a clinically documented injury, and individual variability in response to impact. They agreed that the potential for chronic injury in long-term exposure was a concern.

ABILITY OF SENSOR DATA TO PREDICT PATHOLOGY AND BRAIN DYSFUNCTION

- Dr. Susan Margulies, University of Pennsylvania, "Pre-Clinical Testing and Relationship to Human Outcomes (Experimental and Computational)"
- Dr. James Stone, University of Virginia Medical School, "Pre-Clinical Biomechanics and Outcomes"
- Dr. Steven Recchia, US Army Armament Research, Development, and Engineering Center, "Computational Structural Predictions of Energetic Loading in an Enclosed Space"
- Dr. Joel Stitzel, Wake Forest School of Medicine, "Impact Model and Imaging"

Sensors can detect inputs such as linear or rotational velocity, peak velocity, hit density, and head movement direction. Dr. Margulies explained that detailed study of biomechanical factor contribution to injury can guide sensor development. Sensor outputs are often binary, based on threshold levels. Because many neurofunctional outcomes are graded, there is no obvious "yes/no" injury threshold. Dr. Margulies expressed her opinion that clinicians and behavioral scientists must work with engineers to establish thresholds appropriate for societal needs to detect injury, as well as to protect individuals from injury. Animal data are valuable in determining injury metrics because researchers can examine exposure across lifetimes under controlled conditions. To facilitate scaling results to humans, animal physiology, injury loads, and outcome metrics should be matched closely to humans. For neurofunctional metrics, non-verbal summative assessments such as serum/urine biomarkers, actigraphy, and imaging are expected to be most translatable from animals to humans. As an example, similar white matter distribution in pigs and humans have afforded important discoveries about white matter deformation and are being used to improve understanding of how sensors can detect injury.

Dr. Stone discussed the use of animal models to study the neuropathology of blast. Cerebral vasospasm and edema were observed in combat-associated TBI. To study this phenomenon, animals were exposed to a shockwave using a gas-driven shock tube and examined at the microscopic and molecular level. Results indicated several direct effects on the vasculature leading to edema, including several mechanisms in disruption of the blood–brain barrier (BBB). The use of focused ultrasound to the cranium to directly disrupt the BBB replicated the cerebral vascular effects seen in blast, suggesting further that transcranial blast waves are the primary mechanism for vascular injury in blast.

Dr. Recchia described his role as providing an outside view on environmental sensors, which he uses in munitions development. His goal is to reduce the blast overpressure in explosive charges used by service members so that they may more safely stand closer to their target. He illustrated how his test facilities and sensor placement allowed better determination of the blast force delivered to the sensor, especially in enclosed spaces. Environmental sensors have been tested in his facility to compare against known sources.

Dr. Stitzel's research combines computational modeling with collecting data from human volunteers. The human brain is soft, with a different mechanical texture from the membranes that surround it, and these characteristics are important in modeling brain interactions with the skull. He provided a survey of available finite element (FE) head models and described his model. Sensor data from six football helmet locations were used as input to the model to evaluate brain deformation. The linear acceleration and rotational velocity varied widely by impact location, direction of motion, and impact magnitude. Importantly, the extent of deformation varied more with the impact location than the impact force. An evaluation of strain distribution in the brain led to the conclusion that determining the proportion of the brain in which strain exceeded the 95th percentile was a more valid measure of impact effect than the maximum strain experienced.

The panel had differing opinions on the value and translatability of animal research. Dr. Stone raised differences in mass scale, skull anatomy, and material properties as major impediments to applying animal research to humans, arguing that better molecular-based imaging in the human would be more valuable than animal research. Dr. Margulies proposed that use of animal studies in combination with FE modeling was a strong approach. The limitations of point sensors in measuring impact effects on the entire body were discussed. Because flat sensors able to withstand high pressures have not been developed, the current recommended solution to this problem is to site point sensors at anchor points and use FE modeling to create a pressure map.

ANALYTICS AND TECHNOLOGIES

- Dr. Patricia Janulewicz Lloyd, Boston University, "Characterizing Head Impact Exposure Data from a Public Health Perspective"
- Mr. Tyler Rooks, US Army Aeromedical Research Laboratory, "New Technologies US Armed Services"
- Dr. David Camarillo, Stanford University, "Getting from Field Data to Research Papers – How to Make Sense of Your Data"
- Dr. Brian Stemper, Medical College of Wisconsin, "Design Targets for New Sensor Technologies Based on the CARE and Head-to-Head"
- Dr. Matthew McAuliffe, National Institutes of Health, "Data Sharing"

Dr. Janulewicz Lloyd demonstrated how exposure assessment, a tool used in environmental health, could be applied to head impact exposure. This model traces an exposure from its source to its ultimate effect in the body. Applying the model allows the researcher to detect an association between the exposure and the health outcome, determine a dose-response effect, and identify potential intervention points in the exposure pathway. Her preliminary survey of the head impact literature revealed large amounts of data that were not being consistently reported using the same measures. She recommended that researchers adopt exposure assessment as a framework for their studies, which she suggested would result in more consistent data reporting.

The DoD ESiT program was established in response to the realization that the majority of TBI injuries occur in garrison rather than in a combat theater. Mr. Rooks' contribution to ESiT is as the Army's lead for testing commercially available wearable impact sensors for use in military training. Overarching concerns involve ensuring the sensors do not compromise the protective abilities of military helmets or interfere with communication. Extremes of temperature and humidity in the training environment can have adverse effects on sensors. The sensitivity of inertial motion recording can result in capturing many non-impact incidents, so he has used video screening and screening based on signal characteristics to remove these incidents. Mr. Rooks presented lessons learned in working with two types of trainees: "combatives" practicing hand-to-hand combat and "airborne" subjects training for air assaults. In spite of demands of the training environments, including duration of some training events and sensor vulnerabilities to direct contact (e.g., grappling during combat), Mr. Rooks concluded that sensors were providing usable data when used in controlled research protocols.

Dr. Camarillo presented methods for data acquisition and processing from an instrumented mouth guard to illustrate how he addresses the challenges described by Mr. Rooks. Machine learning is being used to automate identification of signals of interest from among 10 million data points collected by each sensor during a typical football game. Signal characteristics being used to identify impacts include impulse frequency and duration, power spectral density, and signal decay. Initial validation of the method by video screening required 10 hours to screen 1 hour of video, highlighting the value of automating the process. Filtering to remove frequencies likely representing voluntary movement is also employed. In laboratory tests to determine the lowest acceptable bandwidth for signal capture, Dr. Camarillo's team determined that insufficient bandwidth in existing sensors unacceptably reduces the angular acceleration signal. They used this information to modify their mouthguard sensor. In an iterative process, data from human volunteers and laboratory studies of dummies and cadavers are input to an FE model of the brain, which leads to further insights on the mechanical stresses to the brain during impact.

Dr. Stemper discussed his experience with large studies of collegiate football players. The correlation between repetitive head impact exposure and the onset of concussion was explored by evaluating HITS sensor data. Although the G force and angular acceleration measured in concussed subjects were consistent with a concussion, there was a large standard deviation in magnitude and variability in the types of head impact in the concussive events. The season-long data for concussed players were compared to non-concussed controls matched for the same team and field position. This analysis demonstrated that concussed players sustained more impacts per session than non-concussed players, and in 63% of concussed players, their first or second most severe head impact exposure for the season occurred shortly before their concussion. Dr. Stemper continues to explore this phenomenon and plans to extend the analysis to additional sports. He noted that it will become important to cross-validate sensors used in different sports in these types of analyses.

Dr. McAuliffe, co-director of the Federal Interagency Traumatic Brain Injury Research (FITBIR) database, emphasized the value of data-sharing though FITBIR. He highlighted the use of CDEs to report data, FITBIR's validation process for data uploaded to the data repository, and the ability to query data across studies. FITBIR employs a globally unique identifier to enable use of subject data that are de-identified but consistently associated with the subject. Acknowledging the reluctance of researchers to share data, he explained that their uploaded data are protected for a period of time before they are shared with other researchers.

The panel discussion touched on the process for developing CDEs and the potential for increased workload on investigators to submit data to FITBIR. Dr. McAuliffe noted that many CDEs were now established and that investigators who used standard instruments as designed should experience few issues. There was interest from the audience in the willingness of subjects to participate in research with wearable sensors. Panelists agreed that willingness to volunteer was contingent on sensor use not interfering with performance, for both athletes and Service members. Improving understanding of volunteer choice was recognized as important for avoiding selection bias.

COMMUNITY BUILDING PANEL DISCUSSION WITH AUDIENCE

Dr. Bellgowan encouraged workshop participants to work together on pilot studies based on data sharing to demonstrate the power of this approach. He explained that sensor data were not yet housed in FITBIR as CDEs, but that raw sensor data were available. Acknowledging the effort required to develop CDEs, he expressed confidence that the sensor community was capable of prospectively defining CDEs to enable data uploading and sharing through FITBIR. The panel discussed how this process could be facilitated by involving scientific societies and could be publicized through letters to the editors of scientific journals. The role of cross-discipline publications in advancing the field was discussed. Increasing the content of electronic journal supplements to include more details on data management was promoted, as was requiring submission of all data to peer reviewers. Based on NIH experience in facilitating public/private partnerships in which proprietary data were shared, the panel members were optimistic that sensor companies would be willing to cooperate in data sharing.

There was general interest in continuing the dialogue, which Dr. Bellgowan suggested could be facilitated by the NIH. Noting that the National Neurotrauma Society's annual meetings appeared to be a natural home for the sensor community, he stated that he would present this idea to Dr. Floyd, the Society's president.

CONCLUSIONS

Overall, the workshop provided a review of research and technologies by leading investigators with expertise and experience in this field. The Biomechanical Device CDE development effort was introduced to the broader TBI research community and has since been accomplished, with CDEs for head impact sensors and blast sensors formally released through NINDS in March 2018. Also, as of the date of this report, multiple research teams using either head impact sensors or blast sensors are actively working with FITBIR on archiving sensor data from human subjects' research protocols. This work is directly aligned with the 2013 National Research Action Plan, "Vision for Accelerating TBI Research to Improve Health Care and Outcomes," and with the 2018 National Defense Authorization Act, Section 734 "Longitudinal medical study on blast pressure exposure of members of the Armed Forces." The consensus on these technologies was that they are important tools for current research on traumatic brain injury in settings where there is known risk and these tools hold promise for future application as aids in brain injury diagnosis and prevention, especially with standardization of methods afforded by CDEs and greater power in by research data sharing and aggregation afforded by FITBIR and other repositories