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TITLE: Human Head Impact Dose Concussion Risk Functions and Sensor-Based Military-Specific Environmental Monitoring System

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CONTRACTING ORGANIZATION: PREVENT BIOMETRICS

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14. ABSTRACT Study Aims: (1) Quantify head impacts across a variety of contact sports and activities using an Impact Monitoring Mouthguard (IMM) system. (2) Quantify a dose relationship between head impacts and changes in clinical assessments in non-concussed individuals. (3) Correlate head impact exposure with the onset and severity of concussion. (4) Quantify laboratory performance of IMM system under military conditions.						
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1. Introduction

This study has four (4) Specific Aims:

- (1) Quantify head impacts across a variety of contact sports and activities using an Impact Monitoring Mouthguard (IMM) system.
- (2) Quantify a dose relationship between head impacts and changes in clinical assessments in non-concussed individuals.
- (3) Correlate head impact exposure with the onset and severity of concussion.
- (4) Quantify laboratory performance of IMM system under military conditions.

Administrative functions of this study will be performed at the Medical College of Wisconsin (MCW) in Milwaukee, WI.

Data collection for this study will be performed through the following Institutions:

- United States Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL
- United States Air Force Academy (USAFA), Colorado Springs, CO
- United States Military Academy (USMA), West Point, NY
- Concordia University Wisconsin (CUW), Mequon, WI
- Carroll University (CU), Waukesha, WI
- Wisconsin Lutheran College (WLC), Milwaukee, WI
- Carthage College (CC), Kenosha, WI

2. Keywords

Environmental Sensors in Training (ESiT), Combatives, CARE, Concussion, Impact dose

3. Accomplishments

EXECUTIVE SUMMARY

The project is making tremendous progress toward successfully completing all Specific Aims within the time and budget allotted. In the past year, the following have been accomplished (**Figure 1**):

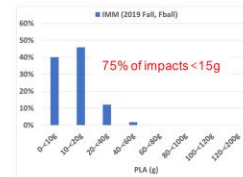
- Deployed 1135 impact monitoring mouthguards to n=718 athletes at six (6) sites: USAFA, USMA, Concordia College (WI), Lutheran College (WI), Carroll University (WI) and Carthage College (WI).
- Collected ~5,000 video-verified head impacts across American football, lacrosse, and rugby
- Identified ~30 large magnitude impacts where the subject has exhibited Obvious Performance Decrement (OPD)/"No-go" behavior.
 - These data comprise the first accurate dose-response curve for OPD for a military environment
 - The goal for the rest of the study is to broaden this risk curve by both breadth and depth in more subjects, and more military-specific activities.
- The IMM system accuracy has been validated in the field as evidenced by using it as the on-human Reference to quantify uncertainty in the Head Impact Telemetry System (HITS), used for five years by the DOD-funded CARE consortium.
- Preliminary laboratory testing of the IMM at USAARL is finished.
- Collaborative relationships with several DoD and non-DoD sites and groups (Naval Health Research Center, Marine CQT, Canadian Special Forces, WRAIR, SOCOM) have been established outside of the cooperative agreement populations. All these groups have a direct interest in the head impact data being collected and will serve to leverage the study into additional benefit for DoD research and soldier health and safety.

BA150149 Deliverables to Date

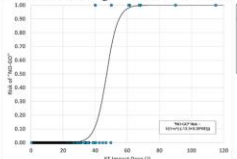
- Deployed 1135 impact monitoring mouthguards in n=718 athletes
- Collected ~5,000 video verified head impacts; first norms
- Identified ~30 single LARGE impacts with performance decrement
- Quantified performance of HITS helmet vs. IMM in 1,000 matched impacts



Left Tackle #77, 10-20g



Preliminary "No-Go" Risk



All "No-Go" impacts to side and rear

n=2072 Side/Rear Impacts

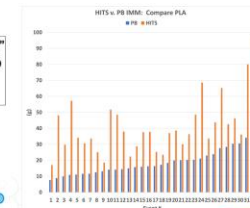


FIGURE 1. Deliverables in the past year include deploying over a thousand impact monitors to six (6) research sites and collecting data on n=718 athletes, video-verifying the first normative data in athletes from over 5,000 individually measured impacts, identifying about 30 high-gravity head impacts that appear to cause performance decrement and fit a dose-response model well, and using the impact monitoring mouthguard as an on-human Reference to quantify Head Impact Telemetry System performance.

EXPLANATION OF SIGNIFICANT RESULTS

SEE APPENDIX #1

4. Impact

We have successfully implemented this Project as an additive and complimentary component to the DOD's investment in the CARE Consortium. This Project is allowing expanded monitoring of military members and deeper knowledge of head impact doses and exposures to potentially injurious effects beyond the already impressive scope of CARE Consortium.

The capture of normative data – most specifically in American football – along with the single, high-gravity video-verified head impacts is a real breakthrough in the science.

We are seeing consistently that a single large magnitude impact to the side and rear of the head is causing obvious performance decrement (OPD) in the subjects.

We are also noticing that a similarly high-gravity impact to the forehead does not appear to cause OPD, but we think may cause later issues due to emotional state that is not observable on video.

It is highly likely that computational simulation of these data sets will reveal affected regions within the brain tissue. Collaborations with simulation groups would be facilitated using a data sharing agreement with this study and would be another novel breakthrough in the science.

Finally, we think that in capture of low-g head impacts in military environments that there will also exist a shock wave signature in the data. Going forward we will capture the kinematics for head impact and be on the lookout for shock/acoustic signatures that accompany many military training environments where we will collect data.

5. Changes/Problems

- Because of such tremendously high enrollment at USAFA, USMA and the four (4) Wisconsin sites managed by Medical College of Wisconsin, we predict that the line item in the budget for impact monitors will be exhausted by August/2020.
- The budget has approximately \$1.4 million remaining thru the current end date of October/2020
 - This can re-budgeted to accommodate personnel and supplies to collect data in an additional ~2,000 subjects during the 2020-2021 academic year.
- Therefore, since we have sufficient budget remaining for personnel thru ~Oct/2021 (assuming a no-cost extension were available), we are proposing to re-allocate some of the budget to allow monitoring of an additional ~2,000 subjects during the 2020-2021 academic year.
- We are also proposing to modify the current SoW to provide rationale and justification for the no-cost extension, re-budgeting, and expansion of effort to deliver on the Specific Aims in DoD-relevant populations of interest.
- **SEE APPENDIX #2 for details on the revised SoW**

6. Products, Inventions, Patent Applications and/or Licenses, SEE APPENDIX #3 FOR PDF COPIES

The results have been disseminated to communities of interest as follows:

Type of Product	Site/Journal	Title	Date
Poster	MHSRS Symposium	Laboratory and On-field Results of Athlete Head Impact Monitoring	Aug-18
Podium	BMES Annual Meeting	Head Impacts in American Football and Combat Sports	Oct-18
Publication	Biomed Sci Instrum	Estimates of High-risk Single and Cumulative Head Impact Doses in American Football [ISSN: 0067-8856 04 55 2]	Apr-19
Publication	ASTM Ice Hockey Summit	Summary of accurate and precise head impacts collected on-ice in hockey players and how these data will be used to improve equipment and rules for safer play [in press]	May-19
Publication	IEEE Annual Conference	Laboratory and On-field Data Collected by a Head Impact Monitoring Mouthguard [doi: 10.1109/EMBC.2019.8856907]	Jul-19
Poster	National Neurotrauma Society	Athlete "No-Go" Head Impacts to the Side and Rear Cause Visible Deficits	Jul-19
Podium	SB3C Conference	Estimates of High-risk Single and Cumulative Head Impact Doses in American Football	Jun-19
Poster	AAN Concussion Meeting	High Energy American Football Head Impacts to the Side and Rear are more Damaging than Impacts to the Front	Jul-19
Poster	ASB/ISB Meeting	Machine Learning can Improve Accurate Monitoring of Head Impacts in American Football	Jul-19
Poster	MHSRS Symposium	Athlete "No-Go" Head Impacts to the Side and Rear Cause Visible Deficits	Aug-19
Publication	IRCOBI Conference	Regional Brain Injury Vulnerability from Two Finite Element Models of the Human Head [http://www.ircobi.org/wordpress/downloads/irc19/pdf-files/89.pdf]	Sep-19
Podium	BMES Annual Meeting	Athlete Spatial and Temporal Impact Characteristics Influence Brain Strain Response	Oct-19
Poster	BMES Annual Meeting	Engineering Characteristics of Single and Cumulative Head Impacts in Sport that Cause Functional Impairment	Oct-19
Podium	FAA Triennial Conference	High Energy Impacts to the Side/Rear Cause "No-Go" Observations	Oct-19
Podium	IMECE Annual Meeting	Engineering Characteristics of High Energy Head Impacts in Athletes that Cause Functional Impairment	Nov-19
Podium	IMECE Annual Meeting	Sensor Enabled Cloud Based Computational Modeling of the Brain	Nov-19
Publication	Military Medicine	Measuring Blunt Force Head Impacts in Athletes [doi: 10.1093/milmed/usz334]	Feb-20
Podium	NCA TBI Conference	Quantifying Head Impacts and Blast Exposures Using and Impact Monitoring Mouthguard	Mar-20

7. Participants & Other Collaborating Organizations

Name:	<i>Adam Bartsch PhD PE</i>
Project Role:	<i>PI</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to Project:	<i>Dr. Bartsch is the Principal Investigator</i>
Funding Support:	Prevent Biometrics, NIH
Name:	Brian Stemper PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Dr. Stemper is a co-Investigator at MCW
Funding Support:	MCW, NIH, DOD
Name:	Michael McCrea PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. McCrea is a Co-Investigator at MCW
Funding Support:	Prevent Biometrics, NIH
Name:	Jerry McGinty DPT
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. McGinty is a Co- Investigator at USAFA
Funding Support:	USAFA
Name:	Jon Jackson MD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Jackson is a Co- Investigator at USAFA
Funding Support:	USAFA
Name:	Ken Cameron PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Cameron is a Co-Investigator at USMA
Funding Support:	USMA
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Project Role:	Co-Investigator

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Houston is a Co-Investigator at USMA
Funding Support:	USMA
Name:	Tyler Rooks MS
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Mr. Rooks is a Co-Investigator at USAARL
Funding Support:	USAARL

8. Special Reporting Requirements

This project is required to report to FITBIR. Consent language has been included for this project and is incorporated by reference from the consents that have been collected on all subjects. As part of this process, and following the NCAA-DoD CARE model, global unique identifier (GUID) information has also been collected on subjects for de-identification and storage of data. Common Data Elements have been collected in clinical assessments, and do not currently exist for many of the head impact parameters but are under review by NINDS. Dr. Bartsch is a co-chair of this NINDS committee and it is anticipated that when head impact CDE's are finalized that the data collected under this project for head impact dose (e.g. linear/angular velocity/acceleration, impact energy, impact location, video observations et al.) will be available to immediately upload into FITBIR.

This project also requires a Quad Chart to be submitted. This Quad Chart (*QuadChart_W81XWH-17-1-0019Rev02*) has been submitted as a separate attachment in **APPENDIX #4**.

9. Appendices

APPENDIX #1 – EXPLANATION OF SIGNIFICANT RESULTS (*embedded PDF, double click to open*)



W81XWH-17-1-0019: DESCRIPTION OF 2019 ACCOMPLISHMENTS

Adam Bartsch PhD PE
22 January 2020

W81XWH-17-1-0019 REVISED STATEMENT OF WORK #3 – 31 MARCH 2020

[Original SoW: 15 JUNE 2015,
 Revised SoW #1: 28 JUNE 2016
 Revised SoW #2: 06 APRIL 2018]

Site 1 (Prime):	Prevent Biometrics	Site 2:	Medical College of Wisconsin
	4530 West 77 th St		5000 West National Ave
	Minneapolis, MN 55435		Milwaukee, WI 53295
	PI: Adam Bartsch, PhD PE		PI: Brian Stemper, PhD Co-I: Mike McCrea, PhD Co-I: Lindsay Nelson, PhD
Site 3:	US Army Aeromedical Research Laboratory	Site 4:	US Air Force Academy
	PO Box 620577		4102 Pinion Dr
	Fort Rucker, AL 36362		Colorado Springs, CO 80840
	PI: Valeta Carol Chancey, PhD Co-I: Joe McEntire, MS Co-I: Tyler Rooks, MS		PI: Lt. Col. Gerald McGinty, DPT Co-I: Lt. Col. John Jackson MD
Site 5:	US Military Academy		
	Army West Point Athletics		
	639 Howard Rd. West Point, NY 10996		
	Co-PI: Col. Steven Svoboda, MD Co-PI: Kenneth Cameron, PhD Co-I: Megan Houston, PhD		

STP: Selected Technical Papers



Summary of accurate and precise head impacts collected on-ice in hockey players, and how these data will be used to improve equipment and rules for safer play

Journal:	STP: Selected Technical Papers
Manuscript ID:	STP-2019-0056.R1
Manuscript Type:	Full Length Paper
Date Submitted by the Author:	n/a
Complete List of Authors:	Bartsch, Adam; Prevent Biometrics Benzel, Edward; Cleveland Clinic Samorezov, Sergey; Cleveland Clinic Miele, Vincent; University of Pittsburgh Medical Center
ASTM Committees and Subcommittees:	F08.15 Ice Hockey < F08 Committee on Sports Equipment and Facilities
Keywords:	Concussion, Impact Monitor, Sensor, Accuracy, Precision
Abstract:	In this study we used a laboratory-calibrated impact monitoring mouthguard (IMM) system and video review to document the presence of seventy-seven (77) potential blunt and inertial head impacts across 291 athlete-exposures in ice hockey players aged 14-18. Our rate of impacts per athlete-exposure was one to two orders of magnitude lower than prior studies, and we did not measure any high gravity impacts in the range 100g to 200g. We found four (4) cases where the athlete sustained a "No-Go" impact per the National Football League video review criteria. The "No-Go" cases were of similar impact dose severity and direction with "No-Go" athletes in American football and combat sport. We also measured a high energy frontal impact dose that resulted in no visible impairment, and this also was on par with visibly normal athletes in American football and combat sport studied previously. The inertial and blunt impact time trace data collected in this study give a full six-degree-of-freedom kinematic profile of true ice hockey head impacts measured in the "living laboratory". This detailed knowledge for the first time permits creation of helmet tests per the on-ice exposures where designs can acutely focus on reducing impact energy dose. Assuming skull fracture risks have been sufficiently minimized, reduction of energy transfer to the brain in side and rear impacts should be the paramount design constraints. We suggest that for players to be monitored using a mouthguard-based system, Coaches and Referees must enforce current safety on mouthguard use during play. Stringent enforcement of rules against checking from behind would help further reduce instances of the already rare "No-Go" impacts. And while relatively few impacts occurred in our ice hockey population, it would be prudent to investigate effects of

<https://mc04.manuscriptcentral.com/astm-stp>

Laboratory and On-field Data Collected by a Head Impact Monitoring Mouthguard

Adam J. Bartsch, Member, IEEE, Daniel S. Hedin, Senior Member, IEEE, Paul L. Gibson, Member, IEEE, Vincent J. Miele, Edward C. Benzel, Jay L. Alberts, Sergey Samorezov, Alok Shah, Brian S. Stemper, Michael M. McCrea

Abstract— Although concussion continues to be a major source of acute and chronic injury in automotive, athletic and military arenas, concussion injury mechanisms and risk functions are ill-defined. This lack of definition has hindered efforts to develop standardized concussion monitoring, safety testing and protective countermeasures. Recent research has provided evidence of the role of repetitive head impact exposure as a predisposing factor for the onset of concussion using developed instrumented helmets and mouthguards.

To overcome this knowledge gap, we have developed, tested and deployed a head impact monitoring mouthguard (IMM) system. In this study, we deployed the IMM system to gather high quality estimates of athlete head impacts in situ. And with enough longer-term data collection, potential concussive events or mild traumatic brain injuries (mTBIs) will be gathered and ideally will provide actionable risk-based threshold.

I. INTRODUCTION

Sports participation results in an estimated 1.6-3.8 million concussions annually [1] and the Centers for Disease Control and Prevention has designated concussions as a 'silent epidemic' [2]. Concussion incidence is as high as 20% annually in some sports [3], making athletic events ideal settings for concussion research [4-6].

Lacking real-time, trustworthy impact monitoring data, many concussions that occur during sports such as American football and soccer go unreported [6]. This is because concussions do not always result in loss and consciousness and athletes are reluctant to report symptoms so they can stay in the game. Un-assessed and undiagnosed head impacts can lead to death [7] and increase long-term risks for chronic traumatic encephalopathy (CTE) [8], Alzheimer's and Parkinson's [9]. Long term problems such as CTE developing later in life can have devastating results including personality changes, destroyed relationships and suicide [10]. CTE severity appears to be correlated with the number of years of playing football more so than the number of concussions reported [11]. Researchers therefore have

suggested that more sophisticated techniques than symptom assessment alone are needed to accurately assess damage due to head impact as it occurs especially when looking at long term problems [12].

II. BACKGROUND

Recent studies of football athletes, even in the absence of diagnosed concussion, have implicated repetitive head impact exposure (RHIE) in the onset of cognitive and brain structural changes [13]. As more is learned about the biomechanics of head impacts studies such as [13] suggest that accurate risk assessments can be provided which can be used to change behavior, techniques, rules, and reduce concussions. Paramount to achieving this is the development of a head impact monitoring system that is inexpensive, sport-agnostic, mass produced, reliable, easy to use, accurate, and able to reject non-head impact data.

III. METHODS

Impact Monitoring Mouthguard (IMM)

The IMM systems (Fig. 1) has been designed with two types of sensing packages. The first has twelve channels of linear acceleration ("12a", ADXL375 or ADXL372) and the other is instrumented with three channels of linear acceleration and three channels of angular velocity ("3a3ω", ST4200D, BMG250). The IMM samples at 3.2kHz, has real-time wireless data offload via BLE and stores 460 impacts on-board. Both systems have also been described elsewhere in detail [14-15]. Each IMM has an embedded flexible printed circuit board sealed between layers of FDA-grade mouthguard material. The IMM attaches to the upper dentition using slight interference fit between the mouthguard and the tooth embrasure spaces.



Figure 1. Head Impact Monitoring Mouthguard (IMM) System.

*Research supported by NICHD grant R44HD090763.
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V. J. Miele is with the University of Pittsburgh Medical Center, Pittsburgh, OH.
A. Shah, B. S. Stemper and M. M. McCrea are with the Medical College of Wisconsin, Zablocki VA Center, and Marquette University, Milwaukee, WI.

Measuring Blunt Force Head Impacts in Athletes

Adam Bartsch, PhD, PE¹; Rajiv Dama, PhD²; Jay Alberts, PhD¹; Sergey Samorezov, MS¹; Edward Benzel, MD¹; Vincent Miele, MD¹; Alok Shah, MS³; John Humm, MS³; Michael McCrea, PhD³; Brian Stemper, PhD³

ABSTRACT Introduction: Although concussion continues to be a major source of acute and chronic injuries, concussion injury mechanisms and risk functions are ill-defined. This lack of definition has hindered efforts to develop standardized concussion monitoring, safety testing, and protective countermeasures. To overcome this knowledge gap, we have developed, tested, and deployed a head impact monitoring mouthguard (IMM) system. Materials and Methods: The IMM system was first calibrated in 731 laboratory tests. Versus reference, Laboratory IMM data fit a linear model, with results close to the ideal linear model of form $y = x + 0$, $R^2 = 1$. Next, during on-field play involving $n = 54$ amateur American athletes in football and boxing, there were tens of thousands of events collected by the IMM. A total of 890 true-positive head impacts were confirmed using a combination of signal processing and National Institute of Neurological Disorders and Stroke/National Institutes of Health Common Data Elements methods. Results: The median and 99th percentile of peak scalar linear acceleration and peak angular acceleration were 20 and 50 g and 1,700 and 4,600 rad/s^2 , respectively. No athletes were diagnosed with concussion. Conclusions: While these data are useful for preliminary human tolerance limits, a larger population must be used to quantify real-world dose response as a function of impact magnitude, direction, location, and accumulation. This work is ongoing.

INTRODUCTION

Although concussion continues to be a major source of acute and chronic injuries in military, athletic, and automotive arenas, concussion injury mechanisms and risk functions are ill-defined. This lack of definition has hindered efforts to standardize concussion assessment, laboratory safety testing, and develop protective countermeasures.

BACKGROUND

In 2011, after considering scalar peak acceleration-based thresholds, leading concussion clinicians concluded “Recent studies suggest that a concussive injury threshold is elusive, and may, in fact, be irrelevant when predicting the clinical outcome”.¹ In 2014, the Institute of Medicine concluded that “Available studies of head injury biomechanics have identified the importance of linear and rotational movements of the head in injury causation . . .” and “there are currently inadequate data to define the direction- and age-related thresholds for linear and rotational acceleration specifically associated with concussions . . .”.² The collection of trustworthy impact

monitoring data as a means to address these inadequacies has also been acknowledged by many recently “accurate measures of individual exposure will yield a direct estimate of the human tolerance.”³ “as more accurate sensors are designed . . .”⁴ “valid methods of measuring the direction and severity of on-field head impacts are needed.”⁵

These conclusions have been informed by scalar head impact dose distributions as opposed to spatial/temporal data from individual impacts. Impact scalar distributions indicate that scalar values of peak resultant accelerations alone are insufficient descriptors of head impact dynamics. When considering the vector nature of acceleration and velocity, as well as momentum-energy-restitution balance during impact, two substantially different spatially and temporally impacts, with the same scalar acceleration magnitude, may be correlated with substantially different tissue-level injuries due to complex anatomy and physiology of a human brain. Preclinical rodent and finite-element modeling studies have also highlighted the importance of temporal characteristics of the head rotational acceleration pulse by identifying significantly different behavioral outcomes and brain strains from head accelerations with identical peak acceleration magnitudes but differing durations.^{6,7}

A next step in correlating concussion and collision severity is to quantify, with the lowest practically achievable uncertainty, single head impact doses by time-dependent kinematic vectors of skull acceleration and velocity through their spatial and temporal parameters. Impact doses can then be applied as the skull boundary conditions in a finite-element brain model to estimate tissue level injury.⁸ Thus, the single or cumulative head impact dose, described in sufficient spatial/temporal detail, can be associated with injury risk in the “passive biomechanics laboratory”³ of an athletic field or military environment.

I. INTRODUCTION

Finite element (FE) models of the human head provide unparalleled rich information about brain mechanical responses upon head impact. The most frequently used injury metrics derived from FE models are either the peak magnitude of maximum principal strain or cumulative strain damage measure (CSDM). However, they do not inform how brain strains are distributed. Strain measures in specific regions of the brain have been proposed to predict injury [1-2]. Most recently, this included the use of a co-registered neuroimage atlas to analyse strains in the 50 deep white matter (WM) regions of interest (ROIs)[2]. Using the Worcester head injury model (WHIM) [3], the relative injury vulnerabilities of the deep WM ROIs were evaluated in terms of nine strain-based injury metrics [2]. Of note, the reconstructed National Football League (NFL) head impacts [4] used in that study were found to be associated with errors [5], which necessitate re-evaluations. In addition, as head injury models could have significant disparities [6], it is also necessary to investigate whether relative brain regional vulnerability depends on the head injury model used. Therefore, the purpose of this study is to reanalyse brain regional vulnerabilities using two versions of the WHIM based on a large impact dataset measured in American high school football. We also extend the evaluation of regional vulnerabilities to both the WM and gray matter (GM) ROIs.

II. METHODS

The isotropic [3] and anisotropic [7] WHIMs were used to simulate 314 head impacts measured from high school football using an Impact Monitoring Mouthguard (IMM) [8]. All of the head impacts were verified by time-synchronised video recordings. Any events collected when the athlete was not being impacted in the head were identified as false positives and were discarded. The remaining true positive events were further scrutinised based on published methods to confirm a head impact occurred in the video and that the computed motion was physically realistic and matched with the video [9]. The impacts were not necessarily associated with a diagnosed concussion, as the purpose of our study was to identify ROIs with the highest likelihood of experiencing largest strains, regardless of whether a concussion actually occurred. This may be important to provide insight in developing a cumulative injury metric based on localised tissue responses to predict concussion in the future.

For each simulated head impact, the 50 deep WM and 54 cerebral GM ROIs were localised via a co-registered WM atlas [10] and a separate GM atlas [11], using techniques described previously [2]. For each head impact, peak magnitude of maximum principle strain (ϵ_1) was obtained for each WM and GM ROI. For each ROI, tied rank values were assigned to score ϵ_1 in the order of their magnitudes. ROI-wise average rank values across all impact cases were then calculated to evaluate their overall relative vulnerabilities. For both WM and GM, their respective top five most vulnerable ROIs were identified that would indicate the ranks experiencing the highest strains.

To further evaluate the robustness of the ranking, a repeated random subsampling technique was adopted to generate 100k random samples by halving the sample size to 157 impacts. For each random sample, the same ranking analysis was repeated to identify the top five most vulnerable WM and GM ROIs experiencing the highest strains, respectively. From all of the random subsamples, we evaluated the consistency in ranking.

III. RESULTS

Using the isotropic WHIM, the genu (GCC) and main body (BCC) of corpus callosum, and cingulum

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ESTIMATES OF HIGH-RISK SINGLE AND CUMULATIVE HEAD IMPACT DOSES IN AMERICAN FOOTBALL

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ABSTRACT

In this study we conducted laboratory calibrations and retrospectively analyzed 2851 video-verified head impacts in American football players over 445 player-games using an impact monitoring mouthguard (IMM) system to estimate high-risk impact doses.

In 731 laboratory tests versus Reference, the IMM fit a linear model, with results close to the ideal linear model of form $IMM=0.97*REF+1g$, $R^2=0.97$.

During gameplay, the median peak scalar linear acceleration (PLA), peak angular acceleration (PAA), peak linear velocity (PLV), peak angular velocity (PAV), kinetic energy transfer (KE) and Risk-Weighted Exposure (RWE) were 21g, 1600rad/s², 12rad/s, 1.5m/s, 6J and 0.00002, respectively. Approximately 90% of impacts were to the front and sides of the head.

Notable single play (n=4 players) and cumulative full-game (n=3 players) impact doses were examined for players observed on video meeting the National Football League's "No-go" criteria. High energy doses from single play impacts to the side of the head in the coronal plane, in the range of 40J to 110J, caused players to immediately meet "No-go" criteria. High cumulative energy dosing from a game's worth of impacts – when players were mostly struck to the front of the head in the sagittal plane, range 100J to 320J – also met the "No-go" criteria.

Future data collection will focus on monitoring head impacts in a broader set of athletes to verify these preliminary findings, and to explore single play sensitivity to sagittal impacts and cumulative dosing in the coronal plane.

Keywords: Head impact monitoring, American football, Concussion, Cumulative, Impact dose

INTRODUCTION

In 2011, after reviewing scalar on-field kinematics data leading concussion clinicians concluded "Recent studies suggest that a concussive injury threshold is elusive, and may, in fact, be irrelevant when predicting the clinical outcome".[1] In 2014 the Institute of Medicine concluded that "Available studies of head injury biomechanics have identified the importance of linear and rotational movements of the head in injury causation..." and "there are currently inadequate data to define the direction- and age-related thresholds for linear and rotational acceleration specifically associated with concussions...".[2] The collection of trustworthy impact monitoring data as a means to address these inadequacies has also been acknowledged by many recently "accurate measures of individual exposure will yield a direct estimate of the human tolerance".[3] "as more accurate sensors are designed...".[4] "valid methods of measuring the direction and severity of on-field head impacts are needed".[5] It is likely that higher fidelity estimates of spatial and temporal impact parameters will clarify the currently unclear impact dose-response relationship.

The aim of this study was to investigate spatial and temporal estimates of head impact doses collected with a laboratory-calibrated impact monitoring mouthguard (IMM) system in American football. We first calibrated the IMM system in n=751 laboratory American football tests against instrumented Reference headforms. Next, we analyzed time-synchronized video and IMM data collected during n=445 player-games of high school and collegiate American football. Summary statistics on all impacts were synthesized. Cases where a player sustained impacts during a single play, or during a

Athlete "No-Go" Head Impacts to the Side and Rear Cause Visible Deficits

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Background

DEBATE IN LITERATURE:

- Holbourn (1941), Newman et al. (1999) & Elin et al. (2018)
 - High energy impacts to the side/rear most dangerous
 - Front impacts not as dangerous
- Guskiewicz & Mihalik (2011)
 - Head impact monitoring data "clinically irrelevant"

Objectives

- Use a laboratory-calibrated head impact monitoring mouthguard system to accurately and precisely quantify video-verified head impacts in athletes.
- Summarize impact dose, direction and location responsible for any players who meet the National Football League's (NFL) "No-Go" criteria (NFL, 2018).

Methodology

- Conducted laboratory calibration of a head impact monitoring mouthguard system (IMM)
 - n=1024 tests using Hybrid III and NIOSAE headforms
 - Compared IMM spatial and temporal outputs to Reference via linear model fit
- Deployed IMM in American football, combat sport, ice hockey and lacrosse to collect video-verified head impacts
 - Kinematic traces confirmed by methods from Bartsch et al. (2014)
 - Video verification and false positive removal methods from Kuo et al. (2018)
 - "No-Go" criteria from NFL (2018)
- Summary and "No-Go" statistics compiled for impact dose (J) and impact direction/location

IMM System

Impact Monitoring Mouthguard (IMM)

Solo, Team Charging Cases

Mobile App

IMPACT DATA

Calibration

Laboratory Testing

muRata

Pendulum

Impactor

Shaker Testing

Impact Testing

"No-Go" Impacts

Results

"No-Go" Impact Doses

"OK" Impact Doses

Conclusions

- High-dose impacts to the side/rear caused "No-go" observations
- High-dose impacts to the front did not cause "No-go" observations
- Contradicting prior acceleration-based research, we found that impact dose energy and impact location correlated to observed deficits

Disclosures

AB is an employee of Prevent Biometrics. AB, EB, VM and SS are co-inventors of the IMM technology and have rights to equity and royalties from Cleveland Clinic. The authors receive research support from the United States Department of Defense (DOD), National Institutes of Health (NIH) and Department of Transportation (DOT).
 IRB approval was obtained from Cleveland Clinic, Medical College of Wisconsin and University of Pittsburgh Medical Center.

Human Head Impact Dose Measurement

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PI: Bartsch, Adam

Org: Prevent Biometrics Award Amount: \$2,886,201



Study Aims

- *Quantify head impact exposure during military training and sporting activities in military service cadets, civilian athletes, active duty persons
- *Correlate head impact exposure with onset and severity of concussion
- * Correlate head impact exposure with clinical outcomes in absence of concussion
- * Quantify head impact exposure during basic training and combat training activities
- * Conduct laboratory testing to quantify impact monitor accuracy

Approach

- The Study Team is monitoring head impacts at the US Air Force Academy (lacrosse, football), US Military Academy (rugby, football) and four (4) Division III colleges in Wisconsin (football, ice hockey, lacrosse). The Team is also working with USAARL to monitor head impacts in combat training activities and to conduct the laboratory testing. The total impact monitors shipped is 811 out of 1180 allocated for the study as of November/2019.

Typical Football Impacts: 10-20g and 20-30g



EARLY IMPACT (10-20g)



LATE IMPACT (20-30g)

Accomplishment: We have confirmed that approximately 75% of ~5,000 video verified head impacts have a magnitude of about 5g to 15g. This is comparable to the head acceleration from jumping on a trampoline or sledding down a hill. This confirms most head impacts are very minor. However, we are still measuring infrequent (~1/1000) and high magnitude (>50g) single head impacts that impair performance.

Timeline and Cost

Activities	CY	17	18	19	20
Head Impacts in Cadets				[Progress bar]	
Correlating to Clinical Data				[Progress bar]	
Combat Training Impacts					[Progress bar]
Laboratory Tests USAARL				[Progress bar]	
Estimated Budget (\$K)		\$700	\$700	\$700	\$786

Updated: (14 Feb 2020)

Goals/Milestones

CY19 Goal #1 – Rollout of monitoring to Sites

- Usage of >800 Impact Monitors with data collected
- Summary of ~5,000 head impacts with video
- Confirmation of dual-instrumentation data (IMM+HITS)

CY19 Goal #2 – Begin laboratory testing

- Confirm test procedure USAARL
- Provide software, mouthguards and train USAARL staff

CY20 Goal – Increase enrollment

- Increase USAFA football from 25 to 250 players
- Increase combative enrollment to >100 users
- Increase combat training enrollees (low-g, parachute)

Comments/Challenges/Issues/Concerns

- 2020-2021 Academic Year does not align with budget period end
- Plenty of budget available, consider no-cost extension

Budget Expenditure to Date

Projected Expenditure: \$1,440,000

Actual Expenditure: \$1,210,667 (thru Jan/2020)