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Theoretical development and benchtop, in vitro and in vivo testing of an "Intelligent Mouthguard" head impact dosimeter

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ABSTRACT

Nearly 2 million Traumatic Brain Injuries (TBI) occur in the U.S. each year, with societal costs approaching \$60 billion. Including mild TBI and concussion, TBI's are prevalent in soldiers returning from Iraq and Afghanistan as well as in domestic athletes. Long-term risks of single and cumulative head impact dosage may present in the form of post traumatic stress disorder (PTSD), depression, suicide, Chronic Traumatic Encephalopathy (CTE), dementia, Alzheimer's and Parkinson's diseases. Quantifying head impact dosage and understanding associated risk factors for the development of long-term sequelae is critical toward developing guidelines for TBI exposure and post-exposure management. The current knowledge gap between head impact exposure and clinical outcomes limits the understanding of underlying TBI mechanisms, including effective treatment protocols and prevention methods for soldiers and athletes. In order to begin addressing this knowledge gap, Cleveland Clinic is developing the "Intelligent Mouthguard" head impact dosimeter to calculate head center of gravity (cg) kinematics. These engineering data will then be paired with objective clinical outcomes for vestibulo-ocular reflex, reaction time, task switching, memory, attention and balance. Testing indicated that the Intelligent Mouthguard can quantify linear acceleration with 3% error and angular acceleration with 17% error during impacts ranging from 10g to 174g and 850rad/s^2 to 10,000rad/s^2, respectively. Correlation was high (R^2 > 0.99, R^2 = 0.98, respectively). Near-term development will be geared towards quantifying head impact dosages in vitro, longitudinally in athletes and to test new sensors for possible improved accuracy and reduced bias. Long-term, the IMG may be useful to soldiers and athletes to be paired with neurocognitive clinical data quantifying resultant TBI functional deficits.

INTRODUCTION

Nearly 53 million (Sporting Goods Manufacturers Association, 2010) young athletes under the age of 18 participate yearly in mouthguard-wearing contact sports like football, ice hockey, soccer, lacrosse, basketball, field hockey and wrestling in the United States. Estimates vary, but between 173,000 and 3.8 million of these athletes (Centers for Disease Control, 2011; Langlois, 2006) sustain concussion and all athletes sustain unknown numbers of sub-concussive impacts. In the military, an estimated 20% of deployed service members, or approximately 320,000 soldiers (Ling, 2009) suffer from some form of traumatic brain injury (TBI), including concussion. This is a serious public health crisis as concussed young athletes and soldiers suffer headaches, memory problems, balance dysfunction, sensitivity to light, slowed reaction time, insomnia, and significant time lost from school (Arbogast, 2013). In some concussion cases, death due to second impact syndrome (Cantu, 1998; Cantu, 2011; Thomas, 2011) has occurred. And cumulative sub-concussive head impact doses in youth may be a cause of brain health deficits in the form of depression (Guskiewicz, 2007), suicide (Omalu, 2010), cognitive decline (Guskiewicz, 2005), chronic traumatic encephalopathy (CTE) (McKee, 2009; Omalu, 2005), dementia (Jordan, 2000), Alzheimer's (Plassman, 2000) and Parkinson's (Daneshvar, 2011) Diseases.

In spite of the prevalence of TBI, concussion and sub-concussive head impacts in youth athletes and soldiers, frontline caregivers like athletic trainers or physicians identify at-risk persons by subjective means and in football fail to identify over 50% of concussed players (Mansell, 2010; McCrea, 2004). Worse still, many young athletes participate with their coaches, parents or teammates acting as the frontline caregiver. Many soldiers sustain TBI while on patrol and without close proximity to comprehensive clinical care. In both sports and the military, the only tool currently available to monitor head impacts is the Riddell HITS helmet system, which has a suggested retail price of over $1,000 per user. Published head impact dosage research has focused exclusively on the HITS helmet (Beckwith, 2013; Daniel, 2012; Duma, 2011; Funk, 2012; Rowson, 2011; Rowson, 2009). But the HITS helmet has been shown to have single event errors upwards of 40% (Manoogian, 2005) to 100% (Beckwith, 2012). These clinical gaps and the lack of a low-cost head impact dosimeter result in arbitrary and inconsistent identification of at-risk athletes and soldiers, athletes and soldiers purposefully evading concussion assessment to continue when injured and athletes risking severe brain damage by playing in spite of dangerous accumulation of sub-concussive impacts.

Hence, frontline caregivers require an objective and low-cost head impact dosimeter that will help identify young athletes in helmeted and non-helmeted sports, as well as military members at home and abroad, who require further assessment post-impact. This dosimeter should also allow for clinicians to improve acute concussion and mild TBI diagnoses by relating symptoms to impact intensity and duration. Finally, a dosimeter will help define the relationship between cumulative head impacts and long-term clinical measures of brain health decline.

Recognizing these concussion and TBI knowledge gaps, the Cleveland Clinic began internal development of the "Intelligent Mouthguard" (IMG) head impact dosimeter in 2008. The IMG project goal is to provide frontline caregivers in athletics and the military with accurate head impact data to monitor young athletes in helmeted and non-helmeted sports as well as young soldiers pre-deployment and during deployment. Hence, IMG will improve scientific knowledge by quantifying acute concussion impact thresholds in helmeted and non-helmeted sports for young athletes. Longer term, the linkage between head impacts and risks of brain health decline will be established using IMG. The lower cost (<$250 for IMG vs. $1000+ for HITS) will lower the barrier to entry for clinicians to monitor head impact dose and clinical outcomes in soldiers and young athletes. Finally, data collected by the IMG can be linked to each athlete's Electronic Medical Record (EMR) to track impacts over weeks, seasons and career.

METHODS

The IMG monitors each user's unique three-degree-of-freedom (3DOF) temporal linear acceleration, 3DOF angular acceleration, 3DOF angular velocity, impact duration, impact direction, 250+ impact memory, 125 millisecond event capture, 4 hour continuous data collection, 4kHz sampling rate and impact bandwidth of 22kHz.During this study, the IMG printed circuit board (PCB) was tested on a benchtop apparatus to determine accuracy and bias error over head impact ranges in athletics from approximately 10g to 175g and approximately 850 rad/s^2 to 10,000 rad/s^2. This range of impacts spanned approximately 99% of all on-field collisions based on American football reconstructions (Viano, 2007). Custom software was written in Matlab (The Mathworks Inc., Natick, MA) for all data analysis. A custom single axis drop tower was constructed from extruded aluminum (80/20 Inc, Columbia City, IN) and bolted to an air-damped aluminum table (Figure 1). The drop tower permitted impacts from adjustable impact velocity of 0.7 m/s to 3.9 m/s. Linear acceleration tests were performed by dropping the rail-mounted IMG PCB onto foam pads of twelve (12) different stiffnesses, generating impact durations of 4.6 ms to 31.8 ms.

Angular acceleration testing used the sliding mass as a striker and the PCB was mounted to a stationary rotating block attached to a single degree-of-freedom (DOF) low friction lubricated industrial turntable (McMaster-Carr, Elmhurst, IL). Striking and struck weight, inertia, arm overlap and foam padding were kept constant for each test to generate impact durations ranging from 4.6 ms to 21.4 ms.

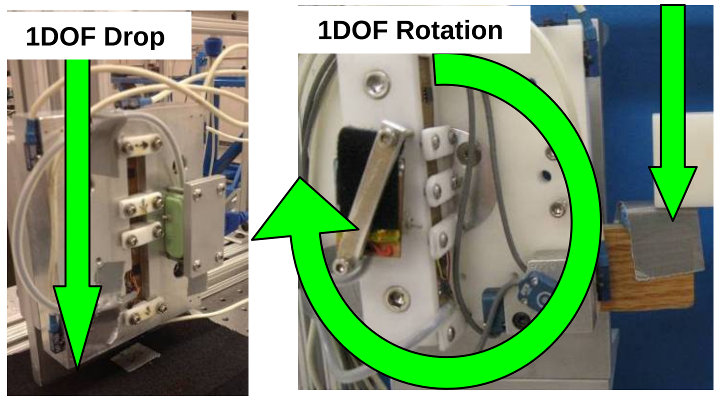

Figure 1: Aluminum Drop Testing Fixture Used in the Current Study.

A total of 439 linear acceleration and 235 angular acceleration tests were conducted. For linear acceleration tests, a uniaxial 500g linear accelerometer (MEAS 64B-500, Measurement Specialties, Hampton, VA) was used as reference. For angular acceleration, a pair of 500g linear accelerometers was spaced 78.5mm apart and two (2) 210 rad/s angular rate sensors (DTS-ARS 12k, Diversified Technical Systems, Seal Beach, CA) were mounted along the rotating axis. Reference angular acceleration was calculated as the difference between accelerometer pair linear acceleration divided by distance between sensors for a 1DOF motion. Reference linear acceleration data were acquired at 10kHz and all IMG data were acquired at 4kHz. Linear acceleration was filtered with a four-pole low-pass Butterworth filter as described in SAE J211/1 (Society of Automotive Engineers, 2003), with bandpass limits of 0Hz and 250Hz. For angular acceleration, the reference data was similarly filtered but with bandpass limits of 0Hz and 160Hz. The IMG angular velocity was also filtered, but with band-pass limits of 0Hz and 300Hz to preserve signal integrity. Post-filtering, the IMG angular velocity was differentiated via a finite difference algorithm in Matlab to calculate angular acceleration. This IMG filtering methodology was verified against a similar routine applied to the Reference angular rate sensors.

RESULTS

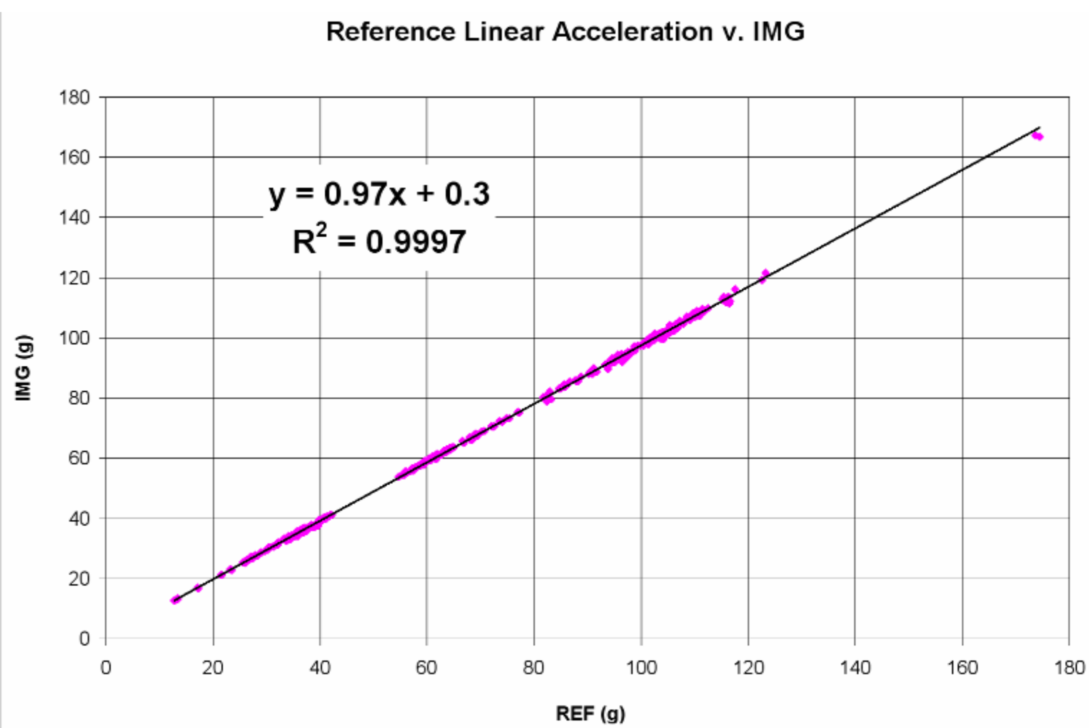

Figure 2: Peak Reference Linear Acceleration vs. Peak IMG PCB Linear Acceleration (n=439 tests).

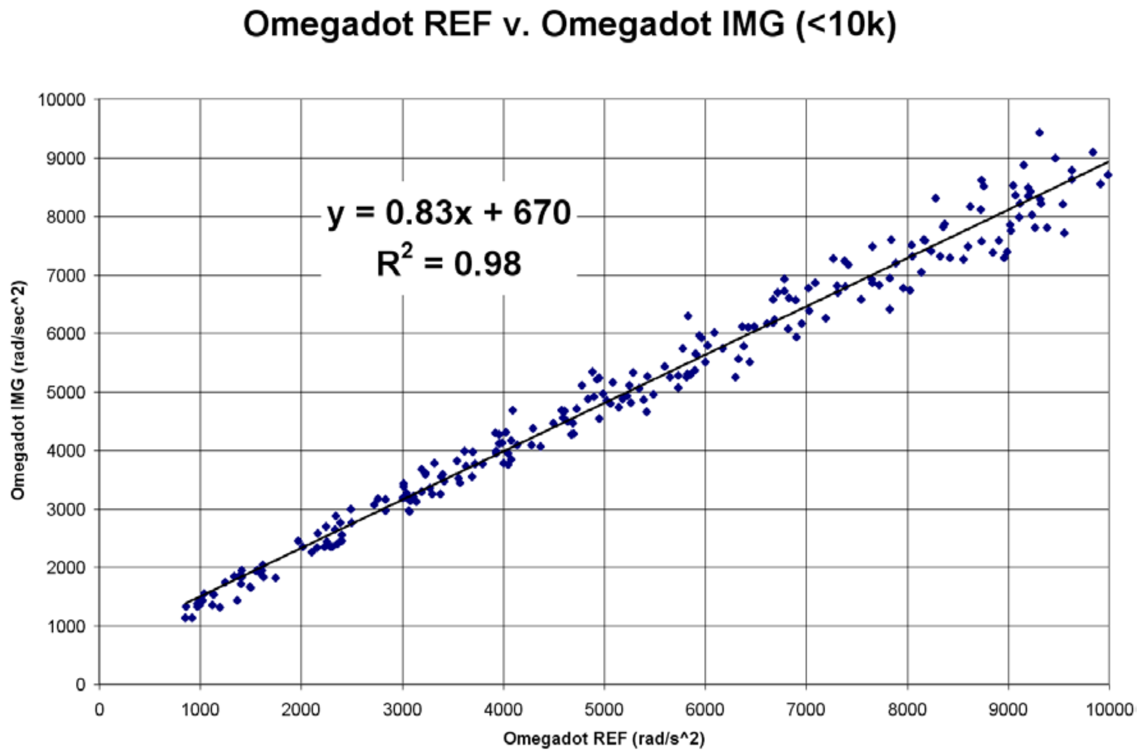

Figure 3: Peak Reference Angular Acceleration vs. Peak IMG PCB Angular Acceleration (n=235 tests).

DISCUSSION

Linear acceleration results (Figure 2) showed high agreement between Reference and IMG linear accelerometer measurements; IMG under predicted Reference by 3% with a bias of 0.3g and high correlation (R^2 >0.99). Because sampling rate and sensor bandwidth was high enough to avoid aliasing, it was possible that slight misalignment differences between Reference and IMG sensor mounting could have been responsible for the 3% IMG under prediction.

Angular acceleration results (Figure 3) demonstrated larger inaccuracy, with IMG under predicting Reference by 17%, bias of 670 rad/s^2 and high correlation (R^2 = 0.98). The reason for the larger under prediction of peak Reference values was that the IMG gyro did not have sufficient bandwidth to quantify all impacts over the time durations studied (4.6 ms to 21.4 ms). The larger bias was likely due to insufficient sensor bandwidth and lower output data rate than is needed.

CONCLUSIONS

Testing of the Intelligent Mouthguard printed circuit board (PCB) demonstrated high correlation for both linear acceleration and angular acceleration (R^2 >0.99 and R^2=0.98, respectively). But in spite of this high correlation, angular acceleration measurements suffered from higher inaccuracy (17%) over the range of impacts tested (<10,000 rad/s^2). Sensors soon to arrive on the market may provide improved accuracy and reduced bias by offering analog outputs, increased sensing bandwidth, finer precision and increased digital output data rate. Future work will involve (1) benchtop testing of new-to-market digital and analog accelerometers and gyroscopes; (2) in vitro testing of the 9-DOF response of the IMG under high energy collision conditions recreated in the laboratory and (3) in vivo clinical trials of human IMG prototypes. While the initial focus is on an athletic market and concussion quantification, future studies will also leverage IMG high-frequency measurement capacity to integrate with a blast dosimeter for measurement in soldiers.

Long term, IMG will help clinical practice to improve as frontline caregivers should be more able to identify athletes sustaining high head impact intensity, frequency or duration. Longer term, clinicians will begin to link cumulative head impacts with declines in brain health. Integration with the electronic medical record will track athletes over seasons and years; clinicians will have encyclopedic impact data to compare with clinical outcomes. Ultimately, safe and unsafe impact thresholds generated by IMG will advise clinicians when to remove athletes to avoid further head injury.

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