Real-Time Concussion Diagnosis System for Contact Sports

A Major Qualifying Project

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  - Final Design Verification
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  - Conclusion and Further Development
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ABSTRACT

With an estimated 3.8 million sport and recreation-related concussions occurring annually, targeted prevention and diagnostic methods are needed. Biomechanical analysis of head impacts may provide quantitative information that can inform both prevention and diagnostic strategies. The goal of this project was to decrease the likelihood of repeated concussions in contact sports by designing a concussion sensing system for high impact sports. The goal of this project was not only to develop a device that measures impacts but to create an easy to use and inexpensive option so a larger portion of the stakeholders would have access to the device and encourage that population to choose the product. The team developed a head cap design with a Vernier Go Direct sensor to accurately measure x, y, and z-axis acceleration and rotation to identify concussions in high impact sports.

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1.0 Introduction

The idea for this product is a method in which dangerous impacts, both individual and combined, are detected and reported to users when participating in the sport of football. Since contact football players at all skill levels are at risk of developing head injuries, there is a large population that could benefit from the use of a new concussion diagnosis technology. The goal of this project is to not only develop a device that detects collisions, but to engineer it to be easy to use and inexpensive. This would allow a larger portion of the stakeholders to have access to the device and encourage that population to choose the product.

The sport of football is a widely popular sport across the nation with over 1,000,000 players (Navarro et al., 2017). At any level, there is a risk for concussion while playing contact football, but this has not caused the sport to decrease in popularity. Currently, all football players wear protective headgear when playing the sport, and this is usually considered by football players to be enough protection. Because of this, an improved device must not add excessive cost or design differences to the helmet; otherwise customers will choose to remain using existing football helmets without concussion sensing devices.

2.0 BACKGROUND

This chapter introduces the general information relating to Traumatic Brain Injuries, and more specifically the biomechanics involved with sports-related concussions. This chapter will discuss the recently increased awareness of concussions in sports and the inherent challenges of studying the effects of concussions. Information regarding the role of technology in the study of Traumatic Brain Injuries is discussed. Additionally, materials used in concussion diagnosis-related sensors are introduced.

2.1 TRAUMATIC BRAIN INJURIES

Traumatic brain injuries (TBI) are a major obstacle to the public and athletes around the world today. Annually, 1.7×10^6 people in the United States suffer a TBI that requires a visit to the hospital and in some cases, intensive medical care is required. TBI remains the most preventable cause of death in adults that are less than 45 years old but many times TBIs lead to long-term disability. Due to an increase in lifespan across the globe, TBIs have become more common in adults over the age of 65 years old and they only trail cancer as the leading cause of death for this age group. TBIs are present in all contact sports since players and their competitors are in varying levels of physical contact within a match. The American Association of Neurological Surgeons defines TBIs as a sports-related head injury and sports are responsible for more than 20% of all brain injuries in children and adolescents (Navarro et al., 2017).

Figure 1: Head to Head Contact in the National Football League

TBIs In Sports

Although sports injuries rarely contribute to fatalities, the leading cause of death from sports-related injuries is a traumatic brain injury.

TBIs can be grouped into three different categories, mild, moderate and severe. For a mild TBI, a player's mental state is changed briefly. Symptoms may only be present for a few minutes and many times the player isn't aware that they suffered a concussion. The most common type of a TBI is moderate TBIs which is when a person's mental state is changed for longer than a few minutes following a hit. Finally, a severe TBI can lead to periods of unconsciousness which can cause coma or death (Agoston et al. 2017).

One type of a mild to moderate form of TBI are concussions. In 2012, 3.8 million concussions were reported to The American Medical Society for Sports Medicine. Concussions are defined as a type of traumatic brain injury (TBI) as a result of a bump, blow or jolt to the head. Concussions can also occur by a hit to the body resulting in the head and brain to move back and forth quickly. This movement can make the brain bounce or twist inside the skull causing the creation of chemical changes in the brain which can cause brain cells to be stretched or damaged. Symptoms of a concussion include confusion, headache, dizziness, nausea, visual disturbance, vertigo or memory loss. Many times, these symptoms occur quickly, and neurologic function may be impaired right away but some concussion symptoms are not evident for a few minutes and in some cases, symptoms may not occur until hours after the injury (Meaney et al., 2014).

In order to properly treat concussions, the severity of the concussion must first be determined. First, the subject's state of consciousness must be determined. Next, the duration of time in which the subject lost consciousness must be identified. The severity of the concussion can be directly proportional to the duration of time in which a subject is unconscious. In sports, athletes often do not report concussion symptoms and a study at Harvard University and Boston University reported that 26 out of 27 college football players do not report their concussion symptoms if they occurred. This level of underreporting can be devastating to the player's well-being because many times the player will return into the game after suffering a concussion. If a person suffers a second concussion before symptoms from the first concussion are gone, that person can suffer from Second Impact Syndrome or SIS. SIS can cause vascular congestion and increased intracranial pressure that cannot be controlled and has the potential to be fatal (Duncan et al., 2017).

TBI Causes

TBIs can be caused in a variety of ways but they mainly occur when a subject's head makes sudden contact with another object. This causes the brain to accelerate inside the skull resulting in damage to brain tissue. Also, if the body is rapidly accelerated then a whiplash effect at the head and neck may occur. This has the same effect as a direct hit to the head because the brain will accelerate as well. TBIs can occur in all facets of life but they mainly occur in sports. (Duncan et al., 2017). The US Consumer Product Safety Commission tracks many sports-related injuries through the National Electronic Injury Surveillance System. In 2009, they estimated that more than 440,000 high school sports-related head injuries were treated at a hospital emergency room. This number represented an increase of approximately 95,000 sports-related head injuries from the previous year. Figure 2 below shows the four major sports with the largest number of head injuries in 2009.

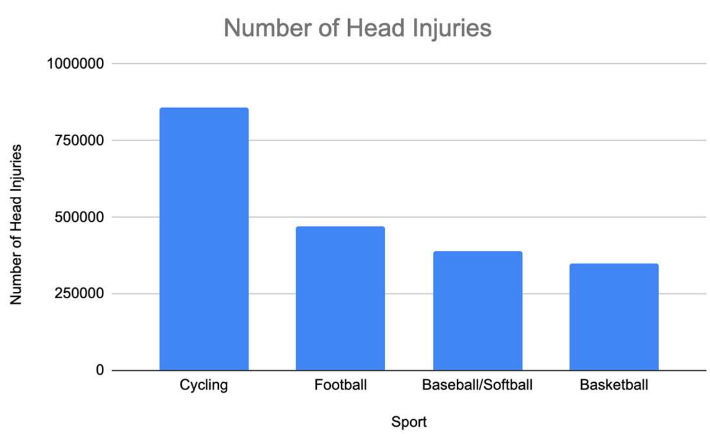


Figure 2: Sports with the Highest Number of Head Injuries in 2009

The major sports that experienced the highest increase of head injuries included water sports (11,239 to 28,716), baseball and softball (70,802 to 85,389) and basketball (26,964 to 38,394). These numbers may even be lower than the actual amount of sports-related head injuries that occur in sports because not all of the injuries are treated in the emergency room (Agoston et al., 2017).

BIOMECHANICS OF TBI

The biomechanics of TBI are defined as the interrelationships among the forces experienced during impact, head and neck movements, and the stiffness of the tissue that composes the head and neck during movement. Also, the biological responses to the various forces acting on the head is an important aspect of the biomechanics of TBI. These responses may be structural or functional and can occur right after contact or may be delayed in their onset (Camarillo et al., 2013).

TBIs, from a clinical standpoint, are classified either as a focal brain injury or diffuse brain injury. Focal injuries can be seen through standard imaging techniques such as a CT scan or MRI scan. Examples of focal brain injuries include those that cause bleeding within the brain, bleeding on the surface of the brain, or bleeding in the cortical gray matter. However, these injuries do not often appear in mild TBI cases and diffuse injuries are the main type of injury for a mild TBI. Diffuse brain injuries are not localized and can be found in all parts of the brain. The main type of diffuse brain injury being studied today is a diffuse axonal injury or DAI. A DAI is the appearance of axonal injury at the microscopic level in areas of the brain. These injuries can cause changes to the cytoskeleton, organelles, and membrane within the axonal compartment. DAI is currently the focus of mild traumatic brain injuries because of the change in brain networks that can appear without any other sign of brain damage to the patient (Chen et al., 2007).

THE INCREASE OF CONCUSSION AWARENESS AND CTE

Growing evidence of the psychological impact on players who have experienced concussions has dramatically changed the way head injuries are treated – from parental and coach involvement to mandatory state requirements. According to the American Medical Society of Sports Medicine (AMSSM), as many as 3.8 million concussions occur in the United States each year during competitive sports and recreational activities. Among children between the ages of 14 and 19, the number of concussion cases reported during emergency room visits has jumped 200 percent in the last 10 years, according to the American Academy of Pediatrics (AAP). Chronic traumatic encephalopathy (CTE) is a neurodegenerative disease caused by repeated head injuries (Navarro et al, 2017). Symptoms may include behavioral problems, mood problems, and problems with thinking. Symptoms typically do not begin until years after the injuries. CTE often gets worse over time and can result in dementia. CTE occurs when repeated head trauma leads to the buildup of abnormal proteins in the brain. These proteins negatively affect how the brain's blood vessels function and eventually erodes nerve cells themselves.

One of the first studies published specifically relating repeated concussions and brain damage was in March 1997 by the American Academy of Neurology. The study lays out three Grades of concussions: Grade 1 is characterized by "transient confusion," no loss of consciousness, and symptoms that last less than 15 minutes; Grade 2 is characterized by the same criteria as Grade 1 except symptoms must last more than 15 minutes; Grade 3 is characterized by any loss of consciousness. The study sets out guidelines for when a player should or should not return to the field. 2016 marked the first year in which the link between football and CTE was known and accepted throughout the scientific community (Navarro et al, 2017*)*. Furthermore, researchers were also able to form a link between the length of a football career and the severity of CTE. Players who did not play football as long, had less severe cases of CTE than those who played a longer career.

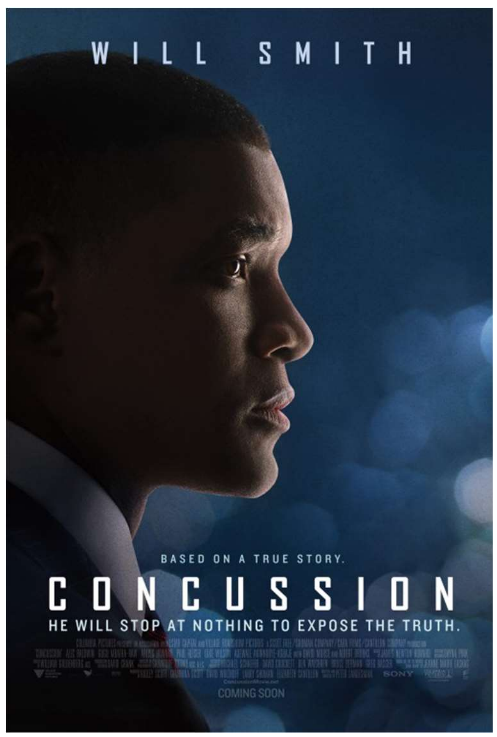


Figure 3: Concussion Movie Poster in the Wake of NFL Changes

INHERENT CHALLENGES OF RESEARCH ON TRAUMATIC BRAIN INJURIES

There continues to be many inherent challenges of research on TBIs, mainly because of the difficulty of researching live human brains. A head injury can be influenced by acceleration, change in momentum, and duration of impact. Currently reported peak acceleration values are only part of the equation. Current biomechanical research on the head has largely focused on high school and collegiate athletes; therefore, the findings of these studies have limited generalizability to athletes younger than high school and to all females (Agoston et al., 2017). Understanding concussive injury in younger athletes is important because children and adolescents may have prolonged recovery periods. Female athletes sustain concussions at twice the rate of their male counterparts in some sports.

Changes in levels of many potential blood biomarkers have been proposed to correlate with brain injury, but differences in study design and interpretation have made it difficult to validate TBI-specific markers. Although numerous blood biomarkers are under intense investigation, to date there are no US FDA approved biomarkers for brain injury. One problem with identifying a suitable biomarker has been the sensitivity and specificity of TBI. Diversity across cohort-based studies impedes the utility of large database repositories in making diagnoses based on blood marker changes reported in the literature. In this context, some studies propose to combine measures from several biomarkers to gain more clear insight into changes in biological processes post-TBI (Agoston et al., 2017).

There are substantial challenges at the technical level for imaging in TBI. The main challenge is standardization or how to consider the differences between various laboratories using different acquisition rates, resolutions, and scanning parameters. The human brain contains approximately 100 billion neurons and ten-times more glial cells (Agoston et al., 2017). Thus, high-fidelity modeling of TBI that includes detailed molecular responses to mechanical forces cannot be accomplished without considerable use of BDA approaches.

In general, TBIs have been incredibly difficult to study making concussion research extremely minimal and assumption based.

2.2 The Role of Technology in the study of TBIs

Concussions can be very hard to classify due to their lack of visual cues when one may occur Their assessment depends on the continuation of post-concussive symptoms. Thus, concussions are measured by a series of cognitive tests and impact measuring devices. This is a contributing factor as to why so many concussions go undiagnosed.

HISTORY OF DEVICES USED TO MEASURE CONCUSSIONS

For cognitive tests, there are several commonly used tools to diagnose concussions immediately or soon after they occur. These include the Post-Concussion Symptom Scale (PCSS), the Standard Assessment of Concussion (SAC), the Standard Concussion Assessment Tool (SCAT), and the Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) (Kuo et al., 2018).

The PCSS is an objective chart utilized to analyze potential concussions. In uses several concussive symptoms such as headache, nausea and visual impairment in order to assess the likelihood of a concussion (Chen, 2007).

The SAC is a tool for highlighting the effects of mild traumatic brain injuries. Similarly, to how The PCSS is used, the SAC attempts to gather data from the participant in specific areas as they relate to symptoms. These include orientation questions rated by numerical scales, short-term memory testing, neurological screening, concentration tests, and delayed recall. In total, the SAC results are a score out of thirty. This sideline test requires no neuropsychological training (Joseph, 2010).

The SCAT is for evaluating injured athletes thirteen years and older. The SCAT is a slightly more in-depth series of tests than the ones previously mentioned. It begins with the Glasgow coma scale which assesses eye responses, verbal responses, and motor responses. It is followed by the Maddocks Score that asks a series of questions and rewards points for correct answers. It is important to note that it is only used for sideline diagnosis and not in serial testing. Next, the cognitive assessment analyzes orientation, immediate memory, and concentration. The neck, balance, and coordination are examined before ending with the delayed recall test.

ImPACT is a tool utilized by a multitude of organizations to assess and manage concussions. The baseline test is administered online and tests the participant in interactive games that assess word memory, design memory, speed & memory, and color matching. This device has been FDA cleared and is the most sensitive out of previously mentioned tests. ImPACT is able to gain objective results as it has the participant constantly reacting to prompts rather than have them chose to describe their systems or subjectively assess them on a form.

Symptom severity, neuropsychological function, and postural stability are not always affected to the same degree so tests must be multifaceted. As effective as these tests can be when utilized together, only half of all concussions get reported (Takhounts et al., 2008). It is crucial that new systems be developed in order to detect these injuries the moment they occur so that medical professionals do not need to rely on the inflicted athlete to self-diagnosis themselves. There are several technological developments looking to achieve this.

Approximately 1.6 to 3.8 million sports-related concussions occur every year in the United States. American Football contains many collisions between players in each game and it is labeled as a concussion prone sport. Required helmets and pads attribute to protecting participants but they do not eliminate concussions. Some companies have created devices like mouth guards that can be used by the athletes in order to have a better understanding of football and concussions.

X2 Impact Incorporated was one of the pioneer companies in creating instrumented mouth guards. They are comprised of wearable sensors to collect data on concussions. Through location and their design, mouth guards more accurately capture head impact accelerations than instrumented helmets can (Lahart, 2009). Specifically, the placement of the embedded sensors in front of incisors reduces kinematic errors. Still, there is still room for inaccuracies when recording impact data since most devices more heavily consider linear acceleration over rotational acceleration.

Figure 4: Prevent Concussion-Sensing Mouth guard

SIMon Finite Element Head Model

The finite element (FE) method has been widely used to understand the injury mechanism of TBI. For the FE method to generate reliable simulations, the models must include realistic geometries, reliable material properties, and physiological boundary/loading conditions of the biological systems. Over the last three decades, tremendous progress has been made in the development of FE models in the investigation of injury mechanisms and in the design of head protective systems (Takhounts et al, 2008). The human head–brain modeling has progressed from early models with linear material properties and simplistic geometries to the current sophisticated models including nonlinear and time-dependent material properties, realistic geometries, and detailed anatomical structures. FE models have been applied to solving practical problems.

The SIMon finite element head model (FEHM) is a new tool being developed to assess the potential of traumatic brain injuries. To make the concept of predicting injury a viable and useful process, it was decided that the complexity of the finite element model should be reduced to represent only the essential components of the head.

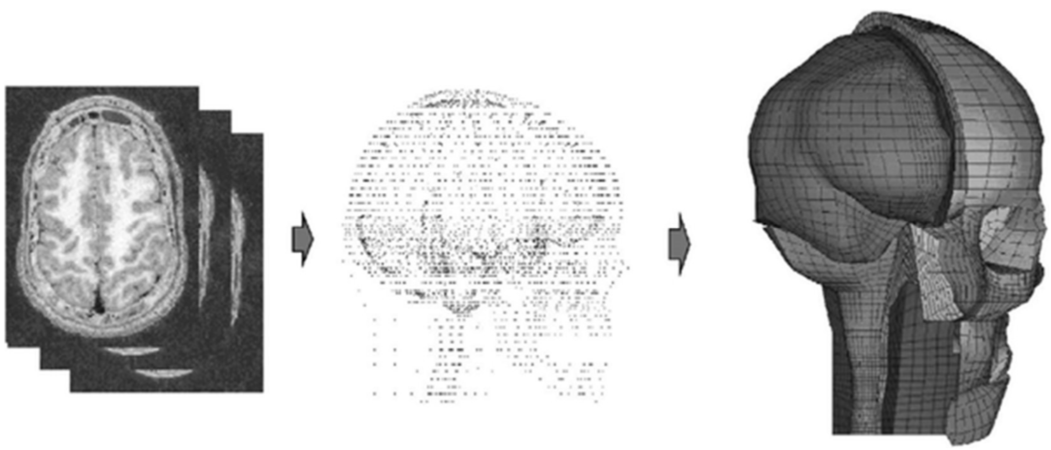


Figure 5: The brain mapping process was used to generate the FEHM

This approach allows for a simulation of a typical impact event within a reasonable amount of time on a personal computer without sacrificing the accuracy of the injury prediction (Takhounts et al, 2008). To meet this goal, the model was designed to be able to simulate the brain's response to an impact event of up to 150 milliseconds within 2 hours on a dedicated high-end PC. To use the SIMon process, the kinematic data from a new or existing crash test is entered into SIMon. This data is then used to create load curves that drive the FE model of the head. Once the calculations are complete, the model outputs a value for each injury metric. These values are evaluated against the critical value for each injury metric to predict if an injury has occurred. If a critical value is exceeded, then an injury is assumed to have occurred.

The SIMon finite element head model is an essential tool for assessing concussions and using the data that is gathered from different concussion tracking devices.

Limitations and Challenges presented from non-wearable devices

Many sideline and self-assessment concussion tests include room for error. They are often informally administered and could be done so by someone who is not guaranteed to have a neuropsychological understanding (Patton et al., 2012). In addition, much of the data is subjectively achieved. The PCSS may fall short as there is no baseline or control to measure. Everyone has different tolerances, so it is difficult to calibrate any recorded data. The results of these tests are often only enough for sideline diagnosing but not accurate enough for serial data acquisition. In addition, the user error of taking these tests for the first time while also trying to understand what's being asked can be attributed to the data recorded.

Limitations and Challenges presented from wearable devices

Acceleration and loading of the head place strain on brain tissue that may cause a concussive injury. Given that directly measuring brain strain in vivo in humans is not possible, impact sensors aim to couple with the skull and measure skull motion, an indirect measure of brain movement. Even in the ideal scenario with sensors affixed directly to the cranial bones, brain movement cannot be measured because the brain moves independently within the skull cavity. The helmeted design of HITS uses spring-loaded accelerometers to maintain contact with the skull as the helmet moves and deforms. The HITS device assumes that the helmet and skull move as a single rigid body (O'Connor et al, 2017). Consequently, HITS accuracy depends on good helmet fit because if the helmet is too loose, too much extraneous movement that is not coupled to the head will be present. In this scenario, acceleration values may be overestimated because the helmet moves more than the skull. The non-helmeted designs of the X2 X-Patch and X-Guard attempt to address the limitations of helmeted designs and overcome the limitation of measuring head accelerations in non-helmeted sports by placing sensors in the upper jaw or behind the ear. These designs have their own limitations related to skin motion, mouth guard fit, saliva accumulation preventing data acquisition, and a 50% error rate (O'Connor et al 2017).

Validation testing of the football HITS has shown that the rotational acceleration was within 4% of those values measured using a standardized head form. In more recent validity tests, Simbex, the manufacturer of the HITS, attempted to simulate National Football League impacts by using impact sites and velocities identified by the league. When compared with a Hybrid III head form, HITS overestimated the linear acceleration by 0.9% and underestimated angular acceleration by 6.1%. Using specific impact locations and velocities possibly reduced the error compared with other studies. In another validation study, Rowson et al investigated the HITS and DOF devices. Compared with the previous studies, Rowson found that resultant AA was overestimated, leading to a correction factor that has been applied to all HITS datasets since 2013. The error associated with individual data points is greater than the aggregate distributions of the data. The pooled measurements are more representative of the distribution of the resulting angular acceleration. It is recently reported that the HITS measures impact the front-most accurately and perform worse when measuring impacts at the crown of the head. They observed that 55 of 64 impacts were in the direction opposite the actual impact direction (O'Connor et al, 2017).

High Profile Concussion Studies

Measuring the overall impact that a head injury has on a person's brain is not an easy thing to do. First off, most concussions are caused by repetitive trauma to the head, which is very common in contact sports even with proper equipment. But it is important to note that direct head contact is not the only source of major head injuries.

In sports such as American football, it is very common for there to be head contact. The average reported head acceleration from an impact in American football was recorded at over 250 g while the overall number of head impacts in a season range from 200 g – 1900 g (Breedlove et al., 2012) While these numbers have been recorded in football, not much is known about a player's head trauma over the course of a season.

A study was conducted by to compare head injuries and impacts of multiple NCAA college female soccer players to female high school players. In this study, head movement and impacts were recorded using *xPatch* sensors placed behind both ears along with a headband. The results of the study concluded that the left and right ear sensors had a root mean squared error of around 53% for peak transitional acceleration and peak angular acceleration. The headband recorded a RMSE of 41.7% for peak transitional acceleration and 305.4% for peak angular acceleration (McCuen et al., 2015). From the instruments used in this particular study, it is evident how some inaccuracies may occur in head trauma measurement. These measurements fail to include information such as what part of the brain suffered the most damage or how the brain was strained from the impact.

In order to be more accurate in recording concussion data, other devices can be used in various scenarios. Video-based analysis is another way head injuries are recorded by allowing the observer to look at factors such as precisely where the subject was hit and how their head and body responded to the impact. This type of assessment requires several trained viewers to track factors such as helmet contact, body contact, no contact, and obstructed view. What was found from this type of assessment was that it created a "new head impact exposure metric" for football and other contact sports (Kuo et al., 2018). This is because this method provides independent information that is verified and confirmed with wearable sensors. While this assessment does not provide full statistical evidence from video review, it does allow coaches and trainers to analyze dangerous head injury scenarios so that they can be avoided.

A very common way of getting head impact data is using impact recording helmets, mouth guards, and other body wear (HITS device, X2 Biosystems X guard and X Patch). Devices such as the Riddell HITS device have six accelerometers and record impacts of around 10g while X2 X-Patch and X-Guard use triaxle accelerometers and gyroscopes. These types of instruments measure skull motion, which does not fully represent brain motion because the brain moves independently inside the skull. For many helmet devices, accelerometers are used to record how the skulls move, and although this data may be accurate for the head movement, it cannot properly diagnose the effects of an impact on the actual brain. While these devices are great for catching head impacts, they can have error rates of around 50% as previously mentioned (O'Connor et al., 2017), but they are still a valuable resource for preventing concussions as well as progressing in concussion research.

2.4 Materials

Sensors are commonly used to measure the effect of a concussion. They are mainly attached to a helmet or mouthpiece during physical activity. Sensors like accelerometers and gyroscopes measure the magnitude, direction, and type of head motion that occurs with an impact. However, many sensors only measure the head’s movement (i.e. acceleration or velocity) after an impact or they measure the head impact forces directly. In order to properly measure the severity of a concussion, both of the above measurements must be obtained. Currently, there are many limitations to the design of equipment on the market. Current sensors struggle because the sensor might move between its position aligned with the head leading to an inability to measure linear motions independently from angular motions (McCuen et al., 2015).

Gyroscopes

Gyroscopes are instruments that maintain their orientation and angular velocity. They contain an axis, frame, rotor, and gimbal. The main spin axis is unaffected by motion or position of the other parts of the gyroscope which allows them to constantly align themselves up-right while in motion. The precision of this device has allowed them to be electronically compacted into micro-packaging for electronic devices. As rotational motion attributes to traumatic brain injuries an instrument that measures this, like a gyroscope, would be essential in building a device to analyze impacts that may cause concussions (Lahart, 2009).

Accelerometers

Accelerometers are electromechanical instruments that measure forces by the change in velocity over time. These measured forces may be dynamic like vibration or movement or static-like gravity. As sensors, they can be compound yet accurate to use in a wide range of applications. They may be utilized to analyze linear acceleration forces that are partially responsible for traumatic brain injuries (Lahart, 2009).

Arduino

Arduino is an open-source hardware and software company. They design a wide series of single-board microcontrollers and kits to aid the project and user community that they foster (Justin, 2009). Arduino boards are designed with a multitude of controllers and microprocessors that allow the user to modify them in any way they see fit. The input or output pins allow for expansion to a variety of electronic devices, breadboards, and even other circuits. The vast maker community utilizes these boards and open code to achieve whatever specific requirements they set.

BALLISTIC GEL

For our experiments, we used ballistics gel material which is very similar to human and animal muscle tissue. There were a few options, but plastic and Styrofoam head molds would crack after 1 or more impacts of our tests. We also concluded that materials such as plastic and Styrofoam not only have no deformation properties in common with human's skin, but we could not mount anything inside of those materials. The ballistics gel was more lenient in allowing us to have a variety of options when testing our prototype(s).

Since our testing did not involve human subjects, we wanted to get as close as possible to simulating an environment where a dummy head takes the recorded impacts instead of an actual human. Generally, ballistics gelatin is used for testing how much tissue damage and strain occurs from different caliber bullets. (Nicholas and Welsch, 2004). The reason why ballistic gel is so useful in impact testing is because it can deform in similar ways to how human skin would deform. The dummy head we used weighed around 11.8 pounds which is very close to the weight of an actual human head at around 10-11 pounds. It is important to highlight that the ballistics gel is used in a head mold shape in order to represent a human head, not the brain. We interpreted that the ballistics gel's elasticity would survive multiple rounds of strain through testing. Although it is a very elastic material, it is not as elastic as real human skin, but because these tests were not involving penetrating the gelatin's surface, it perfectly fit the role of human skin as our "dummy" head for concussion impact testing. This gel was used in multiple impact tests including swinging a heavy pendulum and dropping weights onto it, so it was crucial that the dummy head stay intact after each impact. The ballistic gelatin should be strong enough to sustain enough trauma that it should not cause any problems to the area where the post is mounted. We would like this setup to be as efficient and quality as possible, allowing us to conduct multiple tests as quickly as possible without much permanent deformation/damage to the head, neck, and prototype(s).

VERNIER GO DIRECT SENSOR

The Vernier Go Direct Sensor comes with a 3-axis accelerometer with both high and low channels (x-acceleration, y-acceleration, z-acceleration, x-acceleration-high, y-acceleration-high, z-acceleration-high), a 3-axis gyroscope, an altimeter, and an angle sensor. This device was used to record data for each of our trials using a Bluetooth only connection. Bluetooth connection was used to test how high the sample rate could record at without affecting the sensor readings.

While it is much easier for data to be transferred through a wired connection, it was important that we tested using Bluetooth to get an accurate representation of what our device could accomplish from varying connection ranges. While a USB connection is more reliable for collecting all samples, the Bluetooth connection worked when the sampling rate was set to read less than or equal to 1,000 Hz. It is important to take note of which acceleration channels are in use. The low acceleration channels only capture a range of $\pm$ 16 g, which is not large enough to diagnose concussion thresholds. For large impact testing, the higher acceleration channels with reading ranges of $\pm$ 200g should be used.

The Go Direct sensor is compatible with the free Vernier software called Graphical Analysis 4. This software is very user friendly and allows any or all 11 sensor channels to be enabled. The Graphical Analysis 4 Software can graph any sensor channels on both the x and y axis. Equations and calculations can be added to a new calculated column to allow for data analysis within the program.

3.0 Project Strategy

Traumatic brain injuries (TBI) are a major obstacle to the public and athletes around the world today. According to the American Medical Society of Sports Medicine (AMSSM), as many as 3.8 million concussions occur in the United States each year during competitive sports and recreational activities. Early Diagnosis of concussions in contact sports has become incredibly important recently to doctors, trainers, parents, and players. There is an increasing amount of research being done about the devastating impacts of undiagnosed concussions and CTE. Currently, the market is flooded with different sensors (mouth guards and helmets) that are not able to live diagnose concussions with a high degree of confidence. They do not keep track of head impact data based on a brain model. There is a need for accurate live field concussion diagnosis devices for head contact sports (.

3.1 Initial Client Statement

The initial client statement given by the project holders was to create a better approach for brain mechanical responses. This requires transforming head impact kinematics such as accelerations into brain deformation via a computer model.

3.2 Design Requirements (Technical)

The technical design requirements needed for this project have been identified by the team taking into account statements of the client's needs and objectives related to the need and impact of the project as a whole. The design parameters and constraints of the project were also identified. Operations and functions, as well as, specifications related to operational ranges, limits, tolerances, and specific material requirements are explained and determined.

Objectives

The current market need is a live field concussion diagnosis for athletes with confidence. Early diagnosis for concussions to determine treatment is extremely important due to the devastating impacts of multiple trauma to the brain and the effects of CTE. Current sensors on the market that advertise live field concussion detection have an error rate of over 50% (O'Connor et al., 2017). There is a need for a new sensor that uses multi-modal sensing and combines multiple accelerations and head impact data to accurately diagnose concussions within the first five minutes of impact. Accurate thresholds must be used to correctly interpret the data and real-time data integration is needed to quickly diagnose with a high degree of confidence. The device must be cost-effective for use on youth and high school programs while also qualified for professional use for the NCAA and NFL. The device must be easily usable for players, trainers, and coaches.

CONSTRAINTS

Due to equipment rules in many contact sports, there were constraints and design parameters that needed to be incorporated into the team's design. The device cannot alter the shape or overall size of the helmet being worn because too much change will discourage athletes from using the device. There should be less than a 5% change in total helmet volume and interior and exterior contour. The device needs to calculate the total force imparted onto the player's head and indicate individual forces great enough to cause a concussion with at least 95% accuracy. Accurate readings are crucial to alert personnel that players are at risk for a concussion and need further medical attention. The device cannot compromise the structural integrity of the helmet. The helmet must remain protective and maintain yield strength. There should be less than a 5% change in yield strength of helmet material. The device should not generate false-positive results, false-positive results would cause players to be taken out of the game unnecessarily and discourage players from using the device. There should be less than 5% movement of the accelerometer relative to the head. The device should not add significant weight to the helmet, the added weight would hinder the player's performance and discourage players from using the device. The device should ass less than 10% weight to the helmet. The battery powering the device should be easily replaceable and inexpensive, too much extra maintenance and cost would discourage players from using the device. The time spent replacing the battery should take less than 20 seconds and should be rechargeable.

The results generated from the device should be easily viewed on a smartphone or other easily accessible display, having readable data by non-medical professionals encourages users and coaches to use the device. Less than 30 minutes of training should be required to use the device and comprehend outputs. The device must be able to withstand high impact forces; the device cannot break or be affected after undergoing high impact forces. The yield strength must exceed 200 grams. The device must not injure the player, the electrical systems must be grounded and protected by waterproofing.

Functions and Specifications

The display of data should be intuitive and easy to read in a high-pressure situation such as a football game. The coach will need to be able to readily access data from the helmets of members of the team, so communication must be wireless and mobile-based. The device should not significantly change helmet shape or structural integrity for the modified helmets to pass certification by regulatory bodies. Additionally, the device should not add significant cost to the helmet for it to be accessible to varying levels of football teams. Finally, the device must be able to withstand forces sustained in daily use. A list of customers requirements are as follows:

- Little change in helmet shape and structure
- Wireless availability of data
- Force measurements at least 90% accurate
- Low cost added by device
- Uncomplicated battery replacement
- Very small and lightweight
- Intuitive user interface
- Device withstands regular impact forces

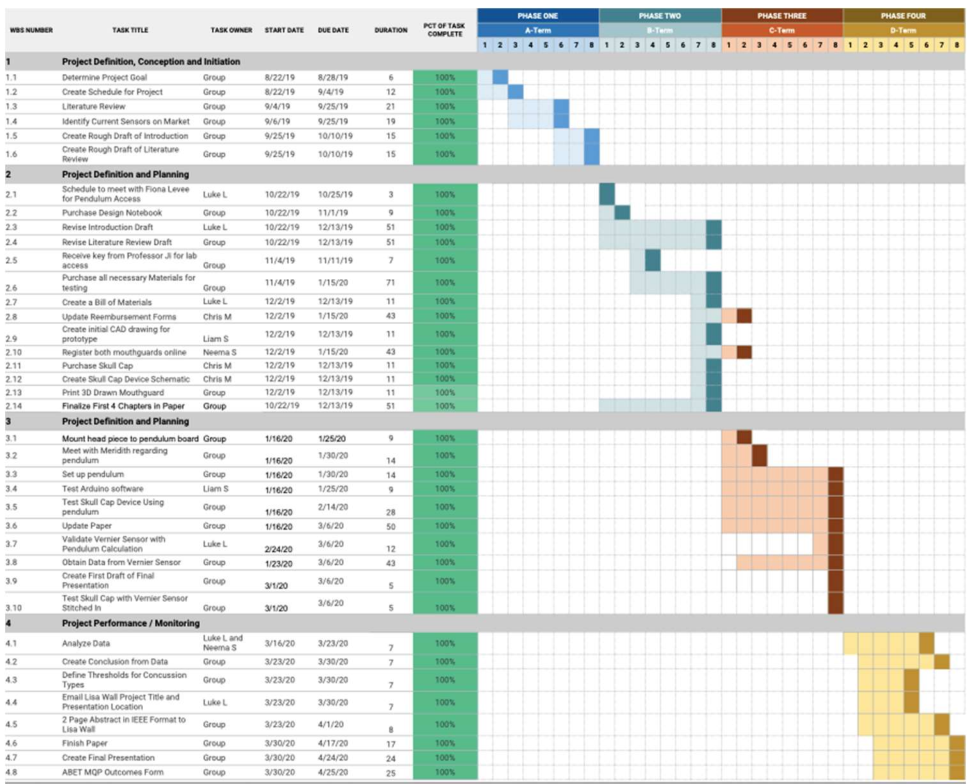
The concussion-prevention device can be used to identify football players who are at high risk of concussion due to strong collisions while playing. The device uses multi-modal sensing and user interface to calculate impact forces from collisions experienced by football players in game. An external data processing unit calculates concussion probability for each impact and displays the data to the player or coach. This device is intended to prevent Chronic Traumatic Encephalopathy in football players resulting from the additive impact of multiple undetected concussions. It will be used as an initial first-response system to notify professional personnel that the individual needs further medical attention. This technology can be used by all football players and teams ranging from middle-school age to the NFL and can be adapted for all contact sports or activities in which head protection is worn.

3.3 Revised Client Statement

Since contact players at all skill levels are at risk of developing head injuries, there is a large population that could benefit from the use of a new concussion diagnosis technology. The need is a diagnosis device that works with high accuracy and uses real-time data integration to give live results seconds after an on-field impact. The device needs to be designed for professional use but also be cost effective.

3.4 Management Approach

In order to complete the project goals in an efficient manner, the team implemented the use of a Gantt Chart in order to properly keep track of team performance and completed objectives. The Gantt Chart can be seen in fig. 6 below.



WBS NUMBER	TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION	PCT OF TASK COMPLETE
1	**Project Definition, Conception and Initiation**					
1.1	Determine Project Goal	Group	8/22/19	8/28/19	6	100%
1.2	Create Schedule for Project	Group	8/22/19	9/4/19	12	100%
1.3	Literature Review	Group	9/4/19	9/25/19	21	100%
1.4	Identify Current Sensors on Market	Group	9/6/19	9/25/19	19	100%
1.5	Create Rough Draft of Introduction	Group	9/25/19	10/10/19	15	100%
1.6	Create Rough Draft of Literature Review	Group	9/25/19	10/10/19	15	100%
2	**Project Definition and Planning**					
2.1	Schedule to meet with Fiona Levee for Pendulum Access	Luke L	10/22/19	10/25/19	3	100%
2.2	Purchase Design Notebook	Group	10/22/19	11/1/19	9	100%
2.3	Revise Introduction Draft	Luke L	10/22/19	12/13/19	51	100%
2.4	Revise Literature Review Draft	Group	10/22/19	12/13/19	51	100%
2.5	Receive key from Professor Ji for lab access	Group	11/4/19	11/11/19	7	100%
2.6	Purchase all necessary Materials for testing	Group	11/4/19	1/15/20	71	100%
2.7	Create a Bill of Materials	Luke L	12/2/19	12/13/19	11	100%
2.8	Update Reembursement Forms	Chris M	12/2/19	1/15/20	43	100%
2.9	Create initial CAD drawing for prototype	Liam S	12/2/19	12/13/19	11	100%
2.10	Register both mouthguards online	Neema S	12/2/19	1/15/20	43	100%
2.11	Purchase Skull Cap	Chris M	12/2/19	12/13/19	11	100%
2.12	Create Skull Cap Device Schematic	Chris M	12/2/19	12/13/19	11	100%
2.13	Print 3D Drawn Mouthguard	Group	12/2/19	12/13/19	11	100%
2.14	**Finalize First 4 Chapters in Paper**	**Group**	10/22/19	12/13/19	51	100%
3	**Project Definition and Planning**					
3.1	**Mount head piece to pendulum board**	**Group**	**1/16/20**	**1/25/20**	9	100%
3.2	Meet with Meridith regarding pendulum	Group	**1/16/20**	1/30/20	14	100%
3.3	Set up pendulum	Group	**1/16/20**	1/30/20	14	100%
3.4	Test Arduino software	Liam S	**1/16/20**	1/25/20	9	100%
3.5	Test Skull Cap Device Using pendulum	Group	**1/16/20**	2/14/20	28	100%
3.6	Update Paper	Group	**1/16/20**	3/6/20	50	100%
3.7	Validate Vernier Sensor with Pendulum Calculation	Luke L	**2/24/20**	3/6/20	12	100%
3.8	Obtain Data from Vernier Sensor	Group	**1/23/20**	3/6/20	43	100%
3.9	Create First Draft of Final Presentation	Group	**3/1/20**	3/6/20	5	100%
3.10	Test Skull Cap with Vernier Sensor Stitched In	Group	**3/1/20**	3/6/20	5	100%
4	**Project Performance / Monitoring**					
4.1	Analyze Data	Luke L and Neema S	3/16/20	3/23/20	7	100%
4.2	Create Conclusion from Data	Group	3/23/20	3/30/20	7	100%
4.3	Define Thresholds for Concussion Types	Group	3/23/20	3/30/20	7	100%
4.4	Email Lisa Wall Project Title and Presentation Location	Luke L	3/23/20	3/30/20	7	100%
4.5	2 Page Abstract in IEEE Format to Lisa Wall	Group	3/23/20	4/1/20	8	100%
4.6	Finish Paper	Group	3/30/20	4/17/20	17	100%
4.7	Create Final Presentation	Group	3/30/20	4/24/20	24	100%
4.8	ABET MQP Outcomes Form	Group	3/30/20	4/25/20	25	100%

Figure 6: Gantt Chart of team's goals and objectives

4.0 Design Process

This chapter discusses how the design process and prototyping for the concussion sensor system was formatted. The needs analysis, conceptual design, design concept prototyping, and modeling are included for the current two alternate designs.

4.1 Needs Analysis

One of the first steps that the team took in the design process was to perform some forms of analysis based on our design criteria to identify what factors would have the largest influence in our final design. One form of analysis that our team performed was Value Factor Analysis. Value Factor Analysis is an important tool in our final design because it allows the user to determine the weight of each variable being assessed at first and then this weight is multiplied by whatever value the user assigns in terms of satisfaction. When looking at the various features, we identified the most important features as quality features, convenience features and cost components. Quality features were defined from our design criteria as aspects of the design that reflect how efficient the device is and how it is manufactured. Important quality features for our device and the current devices on the market include:

- Low Error Rate for Concussion Diagnosis
- Concussion Diagnosis within 5 Minutes of Impact
- Multiple Modal Sensing
- Weight
- Size
- Manufacturability
- Extreme Conditions Capability
- Strength

Next, convenience features were defined from our design criteria as well as from the devices on the market as aspects of the design applicable to the user. The important convenience features for our device include:

- Device does not affect play
- Use of current phone and tablets
- Easy application use

- Little training needed
- Trust of brand
- Safety
- Availability
- Cleanliness
- Storability

Finally, cost components of the various devices were compared as this is essential in our final design selection. The cost components that we identified to be relevant to our device and the devices on the market include:

- Purchase Price
- Shipping / Delivery Chargers
- Cost of Peripherals
- Cost of Application
- Training Costs
- Warranties

These three different comparisons between quality features, convenience features and cost components were all relevant in our design process. The completed Value Factor Analysis can be seen in Figure 7 below.

Value Factor Analysis™

The Approach: What is your product or service?	Live Concussion Sensor for Impact Sports
The Target Market: Who is your end user?	Youth, College, and Professional Impact Sports Atheletes and the Trainers

	Quality Features	Market	Prevent Mouthguard		Vector Mouthguard		Mouthguard Prototype		Skull cap Prototype	
		Importance	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total
1	Low Error Rate of Conussion Diagnosis	5	2	10	2	10	2	10	4	20
2	Diagnosis within 5 Minutes	5	3	15	3	15	3	15	4	20
3	Multiple Modal Sensing	4	3	12	3	12	3	12	4	16
4	Weight	3	3	9	3	9	3	9	3	9
5	Size	3	3	9	4	12	4	12	3	9
6	Manufacturability	3	3	9	3	9	3	9	2	6
7	Extreme Conditions Capability	4	4	16	3	12	3	12	2	8
8	Strength	4	3	12	3	12	4	16	2	8
9				0		0		0		0
10				0		0		0		0
	Total			**92**		**91**		**95**		**96**
	Convenience Features	**Market**	Prevent Mouthguard		Vector Mouthguard		Mouthguard Prototype		**Skull cap Prototype**	
		Importance	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total
1	Does not Effect Play	5	4	20	4	20	4	20	3	15
2	Use of Current Phone and Tablets	3	5	15	5	15	4	12	3	9
3	Easy Application Use	3	4	12	4	12	4	12	3	9
4	Little Training Needed	3	3	9	3	9	3	9	4	12
5	Trust of Brand	1	1	1	1	1	1	1	1	1
6	Safety	5	4	20	3	15	3	15	3	15
7	Availability	4	3	12	2	8	3	12	1	4
8	Cleanability	3	5	15	5	15	5	15	2	6
9	Storability	3	5	15	5	15	5	15	2	6
10				0		0		0		0
	Total			**119**		**110**		**111**		**77**
	Cost Components	**Market**	Prevent Mouthguard		Vector Mouthguard		Mouthguard Prototype		**Skull cap Prototype**	
		Importance	Expense	Total	Expense	Total	Expense	Total	Expense	Total
1	Purchase Price	5	$$$$	20	$$$$	20	$$$$	20	$$	10
2	Shipping/Delivery Charges	3	$$$	9	$$$	9	$$	6	$	3
3	Cost of Peripherals	4	$$$	12	$$$	12	$$$	12	$$	8
4	Cost of Application	4	$$	8	$$	8	$$	8	$	4
5	Training Costs	4	$$	8	$$	8	$	4	$	4
6	Warranties	3	$$	6	$$	6	$$	6	$$	6
7				0		0		0		0
8				0		0		0		0
9				0		0		0		0
10				0		0		0		0
	Total			**63**		**63**		**56**		**35**
	Customer Value: (Quality*Convenience/Cost)			**174**		**159**		**188**		**211**

Quality and Convenience Ratings	
Level of Importance	
Critical Importance	5
Most Important	4
Very Importance	3
Average Importance	2
Low importance	1
Level of Satisfaction	
Superior Satisfaction	5
Excellent Satisfaction	4
Good Satisfaction	3
Fair Satisfaction	2
Poor Satisfaction	1

Cost Component Ratings	
Level of Importance	
Critical Importance	5
Most Important	4
Very Important	3
Average Importance	2
Low Importance	1
Expense	
Very Expensive	$$$$$
Moderately Expensive	$$$$
Somewhat Expensive	$$$
Low Expense	$$
Inexpensive	$

Figure 7: Value Factor Analysis Comparing Important Device Features

4.2 INITIAL DESIGN - MOUTH GUARD

To create a visualization of our prototype design, we used a number of different software that are useful for 3D modeling. For the mouth guard design, we started with the AutoCAD2020 edition. The mouth guard itself was intended to be able to hold any Arduino boards, accelerometers, gyroscopes, and power supply, as well as be able to fit in the average human's mouth. The first draft of this was 30mm thick, 60mm wide, and 50mm high. The original design was not intended for comfort as much as allowing all the necessary parts to fit. Figure 8 shows the first draft of the mouth guard design in CAD while Figure 8 is a CAD drawing of the original Arduino Uno R3 board which is about 68.5mm in width which we found to be very large compared to the mouth guard itself.

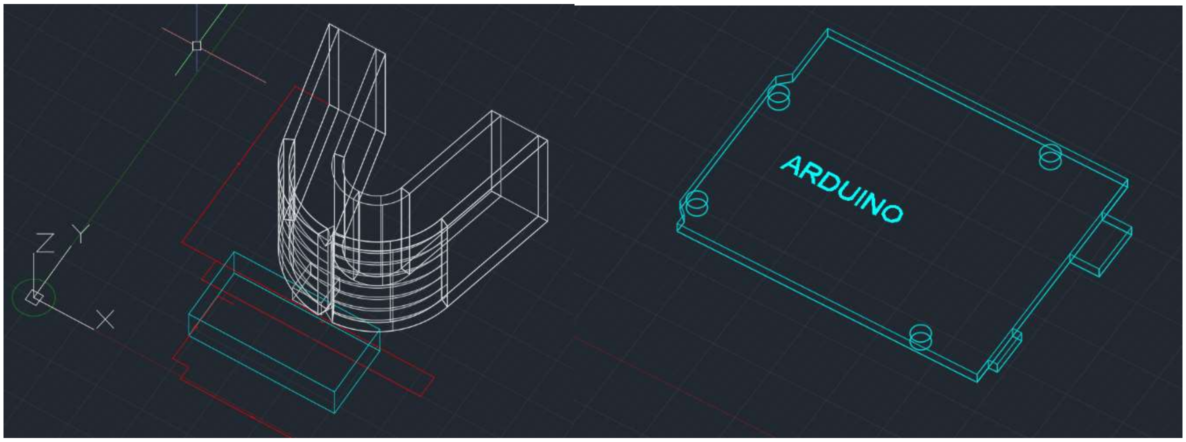


Figure 8: AutoCAD20 Uno R3 Arduino Board and Mouth Guard

The next step of our visualization involved using Solidworks to 3D model the CAD file to make it printable in 3D. While CAD served as good software for wireframe drawings, Solidworks is much better for generating a tangible product. Using Solidworks, we could add better curvature to all the edges to make it more comfortable for the wearer. It was also important to take into account the depth of the part of the guard where your teeth bite down. Human's average tooth heights range from around 7-11mm, the gap we created was just over 10mm. In the newer Solidworks file shown in Figure 9, additional curves were added at the top and bottom of the mouth guard that put less strain on the front of a person's lips. The protruding box at the front of the mouth guard was increased in overall volume and sits halfway up the mouth guard. This is intended for any sensors, boards, or batteries that need to go in the mouth guard but can only fit outside of it. Currently, we are waiting for testing results to determine what type of Arduino boards we are going to use.

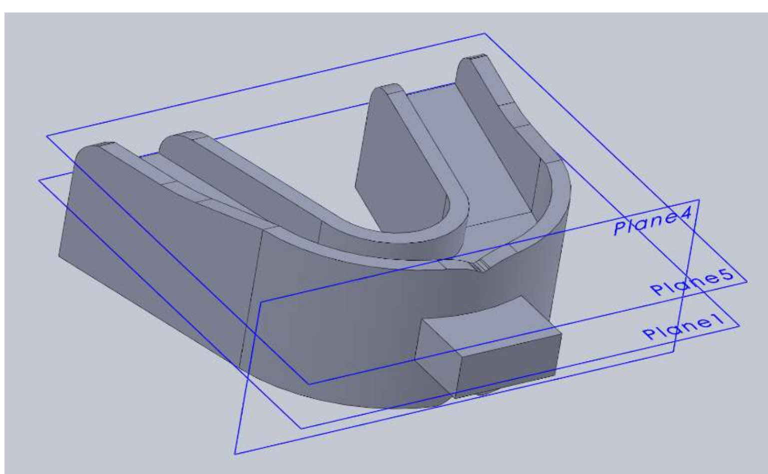


Figure 9: Solidworks 3D Mouth Guard Draft

Both the AutoCAD and Solidworks files were 3D printed for a more accurate visualization of our mouth guard dimensions. PLA and ABS are types of filaments that get heated by the printer nozzle to create thin layers over each other to create a plastic model. The use of these filaments allowed us to successfully transfer our 3D model into a tangible prototype. This allowed us to observe which features we prefer on one mouth guard over the other.

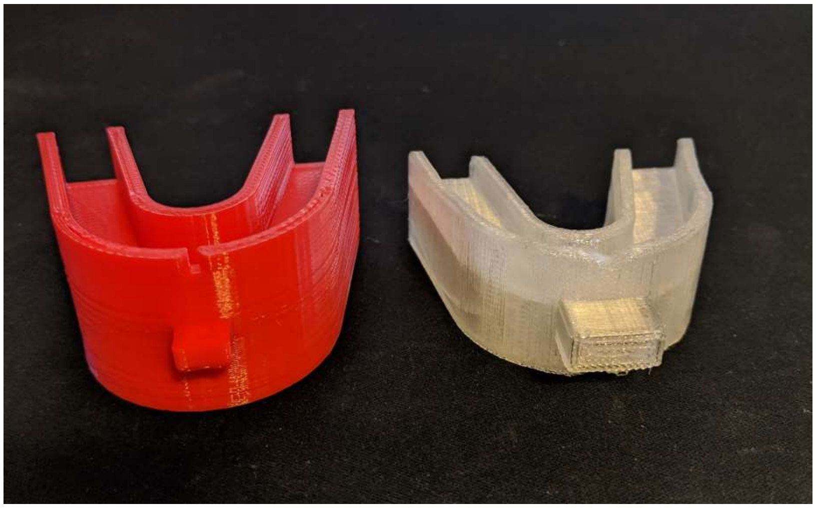


Figure 10: 3D Printed Prototypes

In addition to the instrumented mouth guard our team has chosen to develop an external sensing device as well. This has been achieved through the use of an Arduino microcontroller and its accompanying coding software. This resource allowed the team to implement specific sensors to record desired values. For this application the measurement of linear and angular acceleration requires an accelerometer and gyroscope, both of which exists in a form compatible with Arduino boards.

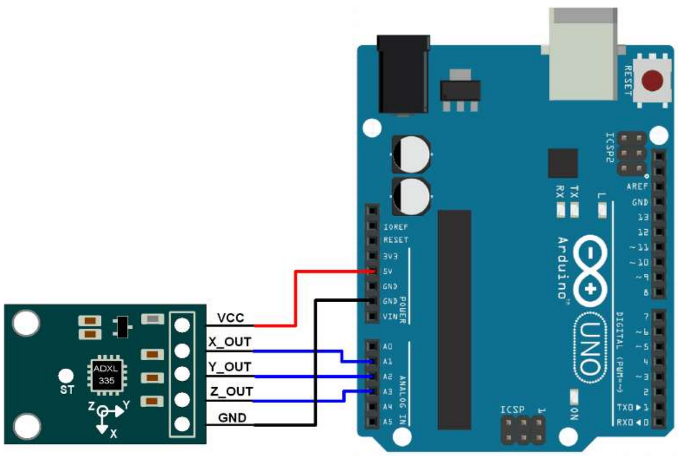


Figure 11: Arduino Board

Impact Tests

In order to properly test how accurate each sensor is, various impact force exercises were performed. One common impact test is the pendulum impact test. This testing method will allow us to simulate forces on the various sensors in order to assess their accuracy and to determine where they are most effective.

A pendulum impact test will be the first type of test used with the various sensors. Similarly, to the drop weight impact test, the conservation of energy is used in order to calculate impact velocity. Using a pendulum, the weight will be swung from a known height allowing for the sensors to receive a horizontal impact. A horizontal impact can be more useful than a vertical impact due to the fact that rotational acceleration is more likely to be experienced. This allows the sensors to be tested for multiple accelerations. A normal pendulum impact test is used to break an item. Following the break, the pendulum will swing back to a lower height than its initial height. Using the conservation of energy allows someone to calculate the amount of energy taken to break the item. For our tests, we plan to modify the pendulum by attaching a mechanism that catches the pendulum after the initial impact. This will allow the impact to solely be applied to the subject.

4.3 Alternative Design - Skullcap

In addition to this implemented mouth guard our team worked on an additional design in parallel. It was essential for us to create a distinct construction for the alternative device as we can better test them against each other.

This new design consists of an accelerometer and gyroscope sensor mounted in a head cap as seen in Fig 12. It has a compact, non-invasive design as to easily fit in with existing equipment. The device sends information through Bluetooth allowing the user to not be tethered during play. Additionally, it’s external use allows it to be easily shared between players in a clean and safe manner.

Figure 12: Skullcap with Sensor

To achieve this our team has utilized the Vernier Sensor. Fig 13 shows what our wireless sensor looked like. This device contains an accelerometer, a gyroscope, Bluetooth, and compatible software. It can effectively obtain a sampling rate of 1000 Hz for each channel. It has a range of up to 30 meters for sending data which is sufficient for current testing but not long term implementation.

Figure 13: Vernier Go Direct Sensor

In line with this device our team began conceptualizing a separate device with similar sensors using Arduino code. Building our device this way allows us to see where the Vernier is most accurate and implement its best features in ours. Furthermore, we can design the size of our device and better format it to work with a wider range of software.

4.4 Final Design Selection

To help choose our final design to continue developing, our team created a criteria list that satisfies a series of needs analysis. These elements range from functionality and safety to price and comfort. To assure certain features were prioritized over others they were weighted differently. Functionally and safety were higher priority so points in categories like this would award more points.

A series of trials were conducted first on the Arduino UNO R3 board MPU-650 accelerometer and gyroscope chip. These tests were short setup tests to get the device working the way we intended. While the MPU-650 was a very barebones sensor that allowed Arduino programming capabilities. Fig 14 shows that the chip itself was small enough to fit anywhere in the base of the mouth guard or skullcap. While it was a good starting sensor, it had to be connected to the UNO R3 board by a wired connection., meaning it was very awkward to place in/on a mouth guard or skullcap.

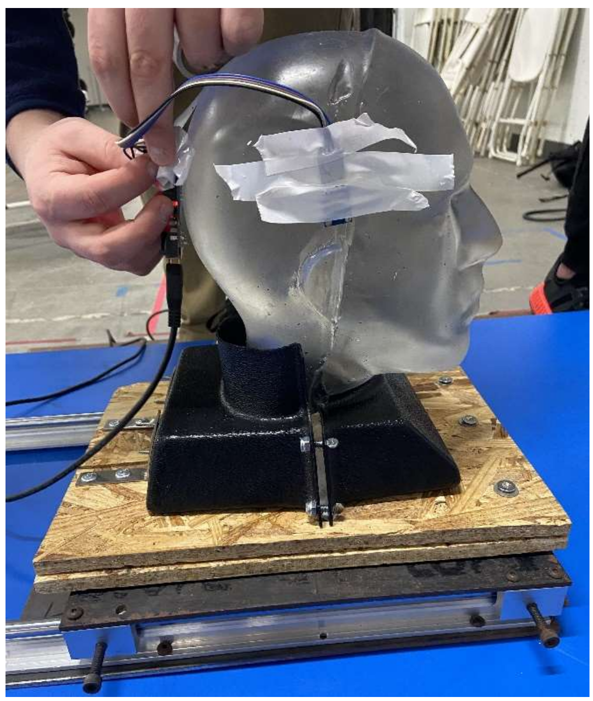


Figure 14: Ballistic Head with Sensor

We planned on scaling the Arduino board size down throughout each iteration of our prototype, but it was this reason that swayed up to use a wireless sensor that does not require a chip to be wired to a circuit board. We knew this would prevent wiring from being knocked out of place after each trial, as well as allow us to use Bluetooth to receive raw data from a distance.

After constructing and testing these devices our team judged them to assess what device to finally pick and continue to develop. Evaluating these devices and comparing their final point values lead to the head cap design that uses the Vernier Go Direct sensor.

5.0 Final Design Verification

Our team collected 100 data sets using the pendulum testing apparatus. First, our team placed the Vernier sensor on the back of the head and collected 40 data sets. The average maximum linear acceleration magnitude at the back of the head was 26.0 ± 8.3 g. The average maximum angular velocity magnitude at the back of the head was 27.7 ± 6.0 rad/s. Next, our team placed the Vernier sensor on the top of the head and collected 60 data sets. The average maximum linear acceleration magnitude at the top of the head was 64.6 ± 14.8 g. The average maximum rotational velocity magnitude at the top of the head was 33.6 ± 7.4 rad/s. In total, 100 data sets were collected; the average maximum linear acceleration magnitude for all data sets was 49.1 ± 22.8 g and the average maximum rotational velocity magnitude was 31.4 ± 7.4 rad/s. Fig. 12 and 13 below show the peak linear acceleration and peak angular velocity magnitude by trial.

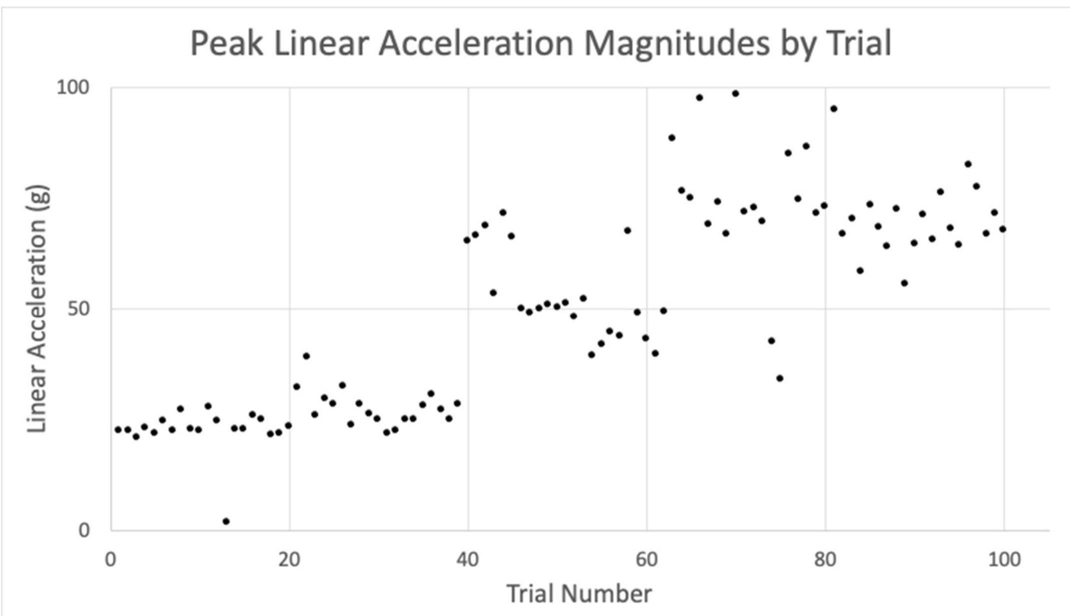


Figure 15: Peak Linear Acceleration Magnitudes by each trial

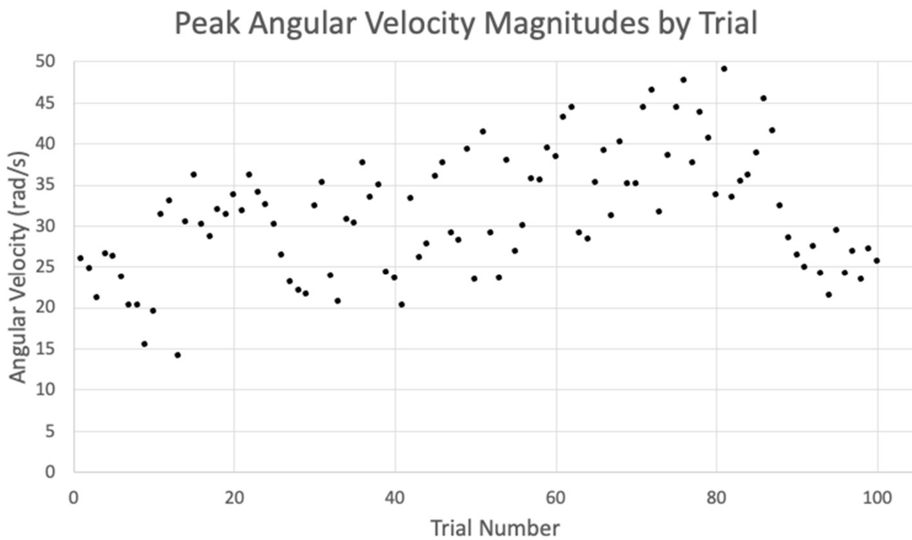


Figure 16: Peak Angular Velocity Magnitudes by each trial

The team took the data and organized it by sensor location. A statistical analysis including a F-test for variances, a two-tailed t-test assuming unequal variances and descriptive statistics was performed on the linear acceleration data and the angular velocity data between the two sensor locations. The results of the statistical analysis can be seen in table 1 below.

Table 1: Relevant statistics from each sensor location

Statistic	BOH Linear	TOH Linear	BOH Angular	TOH Angular
Observations	40	60	40	60
Mean	25.99	64.57	27.73	33.81
Variance	68.21	223.88	35.88	54.31
Standard Error	1.31	1.93	0.95	0.95
Median	24.95	67.15	29.37	34.43
Standard Deviation	8.26	14.96	5.99	7.37
t Stat	-16.54	-16.54	-4.53	-4.53
P(T<=t) two-tail	9.9711E-30	9.9711E-30	1.7037E-05	1.7037E-05
t Critical two-tail	1.9853	1.9853	1.9855	1.9855

6.0 Final Design Validation

The final design validation explains how original objectives were met as well as the economical, societal and ethical implications of the project, health and safety issues concerning the team's project, and the manufacturability of the product.

6.1 How Objectives Were Met

Our team operated on a basis of weighted criteria to assess our project process. In addition to the design elements mentioned, it includes accuracy in testing as well as meeting certain industry standards. Each form of the prototype and design was scored and examined before moving forward or being altered to satisfy all these needs. The head cap design scored the highest of these criteria thus it was chosen to continue to be our final design.

6.2 Testing

For testing our team has utilized a pendulum with a swinging arm with a ballistic gel head mounted to a sliding track as presented in Fig. 17. A form fitting harness was designed around the ballistic head to allow it to be securely mounted to the sliding weight so it may experience the full weight of the pendulum while the arm has the ability to complete its swing through. The sensor device was then mounted to the head before being covered by a helmet to simulate the situation in which a player would be struck during play. The length of the pendulum arm and its weight, along with the added mass, and angle before it's drop should be recorded so that the inertia may be calculated. This is necessary to assure the forces translated to the sensors on the ballistic head are accurate.

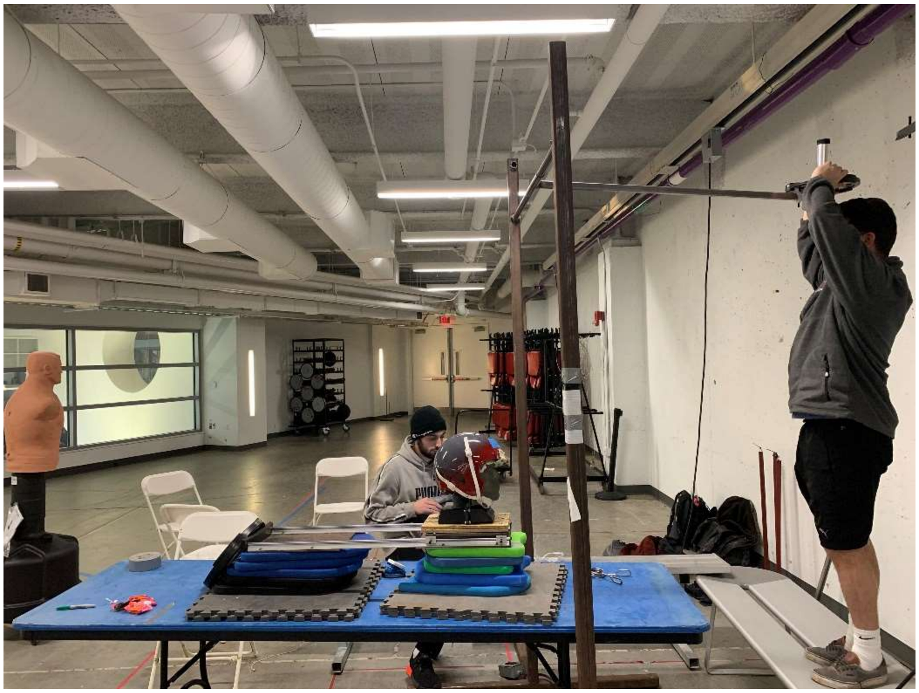


Figure 17: Sensor Testing Set Up

The testing procedure is as follows:

- Set desired weight on pendulum arm
- Turn on sensor and mount to ballistic head
- Mount head to the sliding track and move it to the impact position (approximately 1 inch in front of the pendulum arm in resting position.)
- Assure sensor is receiving data (only g force at resting)
- Pull pendulum arm back to desired launch angle, using a level to measure
- Release pendulum arm and stand clear
- Assure data was collected and reset everything to initial position

6.3 Standards Met and Used

Throughout the design process and verification, current engineering standards were identified in order to ensure that our proposed devices met basic safety requirements, minimum performance, was repeatable and able to interact with other standard-compliant equipment. The following engineering standards were identified as relevant to our device:

- Software standards associated with CAD files
    - ISO 13567
    - BS 1192

- ASTM International standards for testing of materials
    - F2537-06
- IEEE - Institute of Electrical and Electronics Engineers, standards for computer and electronic equipment
    - IEEE 802.15
- FCC regulations for wireless devices and/or data transmission

Since we are still early into the design process, we believe that as time goes on, our team will identify more specific engineering standards relevant to our device design.

Specifications

The goal of our team's device is to accurately measure force impacts that are experienced by athletes during active play. Severe impacts in these scenarios have been linked to cause concussions so the function of this device is to alert the user if the recorded impact is over a certain threshold known to be enough to cause this. Many concussions go undiagnosed and unreported so this device could assist in the public being more attentive to this issue.

As this device is related to public health and wellbeing it would need to meet the standards and approval of the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). As their mission statement, the CDRH is responsible for the protection and promotion of public health (CDRH). They oversee medical devices ensuring best practices are utilized and make sure accessible, well founded information is available to the public who would use these devices. Through their regulation they allow radiation-emission devices to continually innovate and expand the medical field all while maintaining consumer confidence. While this monitoring may halt the process of new products being available on the market it is essential for maintaining the well-being of all potential patients.

6.4 Economics

A real-time concussion sensing system will have a large influence on the economy for everyday living. When an obvious injury does occur, there are also short-term costs from the injury itself such as medical costs, time lost from various activities, and costs associated with the pain and suffering. These economic costs are often overlooked in the broader debate about the safety of football and other sports. However, the long-term costs are often overlooked and could be much higher in annual damages caused by contact sports-related injuries. The ability to diagnose sub-concussive hits would lead to less major concussions in high school and college athletes as well as the terrible effects of CTE. Eliminating a high percentage of concussions in football would have estimated annual savings of up to $1.5 billion for college and $19.2 billion for high school, not counting possibly much larger long-run savings (Joseph, 2010).

6.5 Societal and Ethical Influence

There is currently no uniform objective test of concussion, so there's a need to remove subjectivity from an issue made more serious by deaths from Second Impact Syndrome, which is the acute risk arising when a person receives a second concussion shortly after the first. Building a sensor that can diagnose concussions and prevent second impact before recovering from the first. Currently without sensors athletes, youth, college, and professional, risk long term degenerative brain diseases, including chronic traumatic encephalopathy, dementia, personality and mood changes, and psychological disturbance including depression. Only an estimated 42% of high school teams have access to a certified athletic trainer for both games and practices. That means a professional isn't always present to carefully watch or even administer aid if impacts of concern occur. Even when they are present, many of the time coaches and athletic trainers don't have access to appropriate tools to monitor, track and quantify potentially harmful impacts. Injuries then go undetected or unnoticed and players are allowed to continue to play, though already exposed to potentially dangerous impacts. Fans and players do not want to change the rules for current contact sports, however since head injuries have become so prevalent, a new live-action concussion sensor would make it safer for athletes and educate sports teams and the community about head injuries. Concussion sensing in contact sports, will have a large impact and influence on trainers, parents, and youth, college, and professional athletes. In production, sales, and marketing, the concussion device will be distributed as a potential brain injury saving device. This is because that once a concussion is assessed, a standard rest-time procedure can be followed, and players can return to health without risk multiple concussions.

6.6 Health and Safety Issues

Removing injured athletes from participation close to the time of injury reduces the risk of secondary injury when they are vulnerable to the cumulative effect of concussions. However, given underreporting, transient symptoms, delayed onset of symptoms, and the few concussions occurring with loss of consciousness, concussions are often difficult to detect and diagnose. Therefore, objective and quantitative diagnostic tools that are more sensitive and specific to concussive injury are needed. This concussion sensor project will influence the health and personal safety of people in a good and helpful way. By monitoring impact exposure of athletes, the device promotes interventions to reduce the number of head impacts a player sustains over a season or their career. Accurately diagnosing levels of concussion can prevent long term injuries that many youth and professional football players deal with after their careers. High contact sports can remain entertaining while being safe and not detrimental to players' long term health.

6.7 MANUFACTURABILITY

The manufacturability of the team's device would be like any other clothing sensor implantable. This is like Nike+ shoe implant devices and Catapult Vector sports vest implant. Similar devices that combine sports polyester material and implant electronics already exist so manufacturing of the team's product would not be a new concept. Using conductive materials enables comfortable monitoring for athletes and efficiency for practitioners. Some barriers with manufacturing could be creating chipsets that were small enough, strong enough, and provided clear and high distance Bluetooth signals. The sensors would need to be manufactured with high quality and high accuracy because of the dangers of inaccurate data.

7.0 Discussion

The team began this project seeking to achieve a number of objectives with a few constraints in mind. The primary goal was to create a device to assist with diagnosing concussions soon after they were received in sport related events. The device should combine numerous accelerations as to be accurate in analyzing complex impacts. In pairing with this, establishing thresholds to better assist diagnoses to convey whether the player is safe to return to play or not after an impact. In an effort to make a safety device such as this available to everyone it was significant to keep this device cost effective.

In creating our final prototype of our second design our team satisfied our initial goal of creating a device in analyzing impacts to assist in concussion diagnosing. The device records and displays data live which is significant to assisting these diagnosis during the event where it was received. The sensor utilized measures both liner and rotation acceleration so complex impacts may be measured although the parameters still need more adjusting. The prototype itself consisted of an athletic skull cap and a sensor a third of the cost of the current on market devices in use for contact sports. Even with our prototype not being in its finalized package form the team accounts that it would be very affordable in comparison to these devices, thus meeting our cost effective goal.

Many of the constraints our team operated under related to making sure our device did not interfere with current equipment. The device should record accurate results and not report false positives. These recordings should be easily viewable and interpretable without excessive training to understand. Also, the device cannot alter the size or structure of current helmets nor add any significant additional weight. Additionally, the device should be wireless and be functional covering the entirety of the field of play.

After a number of trials and altering parameters the team believes our device accurately records and displays data. The size is not a slim as initially planned but it still fits under a standard issue helmet. The device is wireless but it currently does not have a range capable of covering an entire athletic field. The team created a script to translate the data into easily viewable results but a proper polished application would be our final goal.

In terms of statistics, we first ran a F-Test in order to determine that the variances between samples was not the same. Once this was confirmed, a two-sample t-test assuming unequal variances was running with 5% confidence in order to see if there was a relationship between the data collected at the two different sensor locations. The t-statistic comparing linear acceleration data across sensor location was 16.5 and the t-statistic comparing angular velocity data was 4.5. This shows that sensor location effects linear acceleration values more than it do angular velocity values. The two tailed p-value was less than the t-critical value for both locations portraying that we can reject the null hypothesis and that there were differences in the means for linear acceleration and angular velocity across sensor locations.

The average peak linear acceleration magnitude with the sensor located at the back of the head was approximately 26 g and the average peak linear acceleration magnitudes with the sensor located at the top of the head was approximately 65 g. The average peak angular velocity magnitude with the sensor located at the back of the head was approximately 28 rad/s and the average peak angular velocity magnitude with the sensor located at the top of the head was approximately 34 rad/s. Previous studies conducted by the HITS database and NFL found that if a player experienced a hit causing a peak linear acceleration magnitude that exceeds or meets a threshold of 52 g's accompanied with an angular velocity equal to approximately 34 rad/s, then there is a 95% chance that the player will obtain a concussion (Patton, et al., 2012). This portrays that our sensor was able to record both impacts above and below this threshold possibly showing its potential in identifying concussive hits.

Overall, our data gave insight on our prototypes ability to detect concussive impacts and how its output changed with sensor location on the skull cap but more datasets would need to be completed in order to prove device efficacy.

7.4 Project Limitations

The team dealt with numerous limitations during the course of the project. First the ballistic gel head constantly needed repair due to the force of the pendulum and mounting procedure. The ballistic gel head began to separate at the neck because of all the force that was centralized at the plastic neck mount. The team would either need to purchase a higher quantity of ballistic gel heads and constantly cycle them in and out or rebuild the neck mounting system. The ballistic gel head is very expensive, so rebuilding the neck mounting system is the best option, by using a delineator post that runs through the head or more protection to the neck region of the head.

The consistency of testing started to be in question due to the pendulum wear and tear from numerous uses from the team and multiple other MQP groups. Because of this the pendulum would constantly need to be reset and assured that swinging force was consistent among test. As the pendulum began to be used more by the team and other groups performing similar projects, swings started to become off axis and did not strike the same spot on the head consistently. The best option to solve this is to rebuild the pendulum from scratch, instead of using a previously build pendulum, to ensure that all forces and velocities are consistent throughout testing.

Finally suspended access from on-campus resources from Covid-19 meant that no new experiments were able to be performed. The WPI administration chose to vacate faculty, students, and staff from campus. Academics and thus project work has moved to an online format. Due to the hands-on nature of the project the remainder of its progress was limited.

8.0 Conclusion and Further Development

The conclusion and future development sections explain the team's global conclusions on the results and summarizes what accomplishments we have made. The team also suggests remedial actions for this problem with further specific studies and measurements.

8.1 Conclusion

In review, our team created a wireless and wearable linear and rotational impact measuring device. This is done wirelessly through Bluetooth at a range up to thirty meters. The device transmits the data onto a graph for interpretation and analysis. The electronic parts are paired with a flexible athletic head cap that fits under existing helmets. The final design is sturdy, of low weight and size, and relatively cost effective in comparison to other similar on market devices. Fuck you Liam. - dad Additionally, the device is non-invasive like mouth guard devices so it may be easily cleaned and shared in a safe manner.

8.2 Further Development

Through limitations, there are many recommendations that can further enhance the project's data validations and accuracy. There are also different pathways for further development of this project for the further enhancement of the device.

Develop New Testing Methods

One way to further validate the project data is to develop new testing methods to track velocity and acceleration to help further detect impact and concussions. This would help simulate different types of impact sports collisions, such as helmet to helmet, helmet to ground, and padding to helmet. Also using a mechanical testing tool with electronic monitors will help regulate all consistency.

Creating Compatible Application for Trainers

Along with the skull cap device a compatible application is necessary for live diagnosis from trainers on the field of action. This application would combine multiple different aspects of medical need for trainers. First, it would provide accessibility to medical resources to identify thresholds for concussions, as well as additional medical information. The application would be compatible with trainers' laptops and mobile devices, so it can be used on and off the field and at any budget restriction. Finally, the application would capture player data and create player history profiles that are customizable and trackable for trainers, and can be expanded to players and parents.

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APPENDICES

APPENDIX A - ARDUINO CODE (GY-01)

arduino_uno

```
const int xpin = A3;                  // x-axis of the accelerometer
const int ypin = A2;                  // y-axis
const int zpin = A1;                  // z-axis (only on 3-axis models)
void setup()
{
 // initialize the serial communications:
 Serial.begin(9600);
}
void loop()
{
 int x = analogRead(xpin);  //read from xpin
 delay(1); //
 int y = analogRead(ypin);  //read from ypin
 delay(1);
 int z = analogRead(zpin);  //read from zpin

 float zero_G = 338.0; //ADXL335 power supply by Vs 3.3V:3.3V/5V*1024=676/2=338
//Serial.print(x);
//Serial.print("\t");
//Serial.print(y);
//Serial.print("\t");
//Serial.print(z);
//Serial.print("\n");
float zero_Gx=331.5;//the zero_G output of x axis:(x_max + x_min)/2
float zero_Gy=329.5;//the zero_G outgput of y axis:(y_max + y_min)/2
float zero_Gz=340.0;//the zero_G output of z axis:(z_max + z_min)/2

float scale = 67.6;//power supply by Vs 3.3V:3.3v /5v *1024/3.3v *330mv/g =67.6g
float scale_x = 65;//the scale of x axis: x_max/3.3v*330mv/g
float scale_y = 68.5;//the scale of y axis: y_max/3.3v*330mv/g
float scale_z = 68;//the scale of z axis: z_max/3.3v*330mv/g

Serial.print(((float)x - zero_Gx)/scale_x);  //print x value on serial monitor
Serial.print("\t");
Serial.print(((float)y - zero_Gy)/scale_y);  //print y value on serial monitor
Serial.print("\t");
Serial.print(((float)z - zero_Gz)/scale_z);  //print z value on serial monitor
Serial.print("\n");
delay(200);  //wait for 1 second
```

APPENDIX B - ARDUINO CODE (MPU-650)

MPU6050_DMP6

```
#include <helper_3dmath.h>
#include <MPU6050.h>
#include <MPU6050_6Axis_MotionApps20.h>
#include <MPU6050_9Axis_MotionApps41.h>

#include <I2Cdev.h>

#include "Wire.h" // This library allows you to communicate with I2C devices.
const int MPU_ADDR = 0x68; // I2C address of the MPU-6050. If AD0 pin is set to HIGH, the I2C address will be 0x69.
int16_t accelerometer_x, accelerometer_y, accelerometer_z; // variables for accelerometer raw data
int16_t gyro_x, gyro_y, gyro_z; // variables for gyro raw data
char tmp_str[7]; // temporary variable used in convert function
char* convert_int16_to_str(int16_t i) { // converts int16 to string. Moreover, resulting strings will have the same length in the debug monitor.
  sprintf(tmp_str, "%6d", i);
  return tmp_str;
}
void setup() {
  Serial.begin(115200);
  Wire.begin();
  Wire.beginTransmission(MPU_ADDR); // Begins a transmission to the I2C slave (GY-521 board)
  Wire.write(0x6B); // PWR_MGMT_1 register
  Wire.write(0); // set to zero (wakes up the MPU-6050)
  Wire.endTransmission(true);
}
void loop() {
  Wire.beginTransmission(MPU_ADDR);
  Wire.write(0x3B); // starting with register 0x3B (ACCEL_XOUT_H) [MPU-6000 and MPU-6050 Register Map and Descriptions Revision 4.2, p.40]
  Wire.endTransmission(false); // the parameter indicates that the Arduino will send a restart. As a result, the connection is kept active.
  Wire.requestFrom(MPU_ADDR, 7*2, true); // request a total of 7*2=14 registers

  // "Wire.read()<<8 | Wire.read();" means two registers are read and stored in the same variable
  accelerometer_x = Wire.read()<<8 | Wire.read(); // reading registers: 0x3B (ACCEL_XOUT_H) and 0x3C (ACCEL_XOUT_L)
  accelerometer_y = Wire.read()<<8 | Wire.read(); // reading registers: 0x3D (ACCEL_YOUT_H) and 0x3E (ACCEL_YOUT_L)
  accelerometer_z = Wire.read()<<8 | Wire.read(); // reading registers: 0x3F (ACCEL_ZOUT_H) and 0x40 (ACCEL_ZOUT_L)
  gyro_x = Wire.read()<<8 | Wire.read(); // reading registers: 0x43 (GYRO_XOUT_H) and 0x44 (GYRO_XOUT_L)
  gyro_y = Wire.read()<<8 | Wire.read(); // reading registers: 0x45 (GYRO_YOUT_H) and 0x46 (GYRO_YOUT_L)
  gyro_z = Wire.read()<<8 | Wire.read(); // reading registers: 0x47 (GYRO_ZOUT_H) and 0x48 (GYRO_ZOUT_L)

  // print out data
  Serial.print("aX = "); Serial.print(convert_int16_to_str(accelerometer_x));
  Serial.print(" | aY = "); Serial.print(convert_int16_to_str(accelerometer_y));
  Serial.print(" | aZ = "); Serial.print(convert_int16_to_str(accelerometer_z));
  // the following equation was taken from the documentation [MPU-6000/MPU-6050 Register Map and Description, p.30]
  Serial.print(" | gX = "); Serial.print(convert_int16_to_str(gyro_x));
  Serial.print(" | gY = "); Serial.print(convert_int16_to_str(gyro_y));
  Serial.print(" | gZ = "); Serial.print(convert_int16_to_str(gyro_z));
  Serial.println();

  // delay
  delay(1000);
}
```

APPENDIX C - JAVA PROCESSING CODE

MPU6050_processing

```
import processing.serial.*;

PrintWriter output;
Serial udSerial;
int prevHour = hour();
int prevMinute = minute();
int month = month();
int day = day();



void setup() {
  udSerial = new Serial(this, Serial.list()[0], 115200);
  output = createWriter(month + "_" + day + "_" + prevHour + "_" + prevMinute + "_" + "DataSheet.txt");
}

void draw(){
  if (udSerial.available() > 0) {
      String value = udSerial.readString();
      if (value != null){
      output.println(value);
      }

    }
}

void keyPressed(){
  output.flush();
  output.close();
  exit();
}
```

Appendix D – Vernier Graphical Analysis 4