Senior Project:

Concussion Indication Device

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1.0 Executive Summary

In this document we summarize our intent to design and manufacture a device that will be used in conjunction with a football helmet, will detect impact forces to the head, and notify the user to seek out further medical attention when subjected to forces large enough to cause concussions. We describe the large market including all levels of football players and the need for improved technology that will not only be effective in elucidating risks but encouraging players to use the device over the alternatives. To design the device, we have researched the problem of concussions in football and have evidence that there is sufficient technology available to us. In our report we provide all of our documentation available at this stage of development.

2.0 Introduction and Background

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 [2], there is a large population that could benefit from the use of this 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. Below, we first describe the market for our device and the existing methods that are being employed in football helmet technology. We then summarize what our design requirements are for the device and explain how each of the aspects of the product were chosen based on customer needs. Finally, we present the project plan and summarize how we will complete each step in a timely manner, without compromising the integrity of our product.

The sport of football is a widely popular sport across the nation with over 1,000,000 players [1]. At any level, there is a risk for concussion while playing contact football, but this has not caused the sport to decrease in popularity [2]. Currently, all football players wear protective headgear when playing the sport, and this is usually considered by football players to be enough protection [3]. 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.

Currently, there are several football helmet manufacturers that make helmets with different designs. Riddell helmets are commonly used in the NFL, with around two-thirds of professional players using them [4]. Riddell helmets are designed to be a perfect fit on each player, and they have technology similar to our design that monitors impacts and alerts coaches. This is called the Riddell Insight and IQ [5], but is costly and usually only in the budget of college and professional teams [6]. Schutt helmets are also commonly used on all levels, and have a variety of design technologies using custom materials. However, they do not employ any impact sensing technologies [7]. Xenith is another helmet manufacturer that makes helmets with suspension technology that disperses force away from the user's head [8]. Overall, there are many options for superior head protection in all three major football helmet manufacturers, but they are often too expensive and uncomfortable. For this reason, less protective headgear is still widely used [4].

Table 1: *Current Related Patented Technologies*

Patent No.	Name	Abstract
10,092,237	Performance of a diagnostic procedure using a wearable computing device	The present disclosure describes example systems and methods for identifying an indication of an injury of a user of a wearable computing device. The systems and methods may be directed to determining that an acceleration experienced by the wearable computing device exceeds a threshold value. In response, the wearable computing device may perform a diagnostic procedure in order to identify an indication of an injury experienced by the user of the wearable computing device. The diagnostic procedure may include one or more of an eye response test, a verbal response test, a motor response test, and a visual diagnostic test.
10,092,054	Helmets or other protective headgear and related methods	Disclosed is a helmet that is aesthetically appealing and that is capable of decelerating impacts from any direction. In a preferred embodiment, the helmet features: a shell with a head cavity that is lined with shock absorbing material, wherein the shell is outfitted with a halo of deceleration plates.
10,051,910	Method, system and device for monitoring protective headgear	A sensor module generates sensor data in response to an impact to protective

		headgear, wherein the sensor module includes an accelerometer and a gyroscope and wherein the sensor data includes linear acceleration data and rotational velocity data. A device processing module generates event data in response to the sensor data. A device interface sends the event data to a monitoring device when the device interface is coupled to the monitoring device.
10,039,338	Impact absorbing apparatus	Some embodiments described herein relate to an athletic helmet. The athletic helmet can include a shell, a suspension chassis, and several impact-absorbing pads. The suspension chassis can be disposed within the shell and configured to couple the pads to the shell. Each pad can include a membrane defining an interior volume. A valve can place the interior volume in fluid communication with the exterior of the membrane. In some embodiments, two or more structural members can be disposed within the interior volume. One structural member can be at least partially deformed when the athletic helmet is worn by a user.
9,987,544	Safer football helmet	A football helmet comprises a rotatable outer shell, an inner shell and a fastener assembly. The inner shell comprises an upper portion and a lower portion. The

		rotatable outer shell is of a hollow hemisphere shape. The rotatable outer shell has a cavity to receive the upper portion of the inner shell. An air gap is between the upper portion of the inner shell and the rotatable outer shell. A predetermined torque is applied to a nut of the fastener assembly so that the nut is loosely tightened to a bolt of the fastener assembly. The rotatable outer shell is in a pogo stick motion when a force is applied to the rotatable outer shell so that the ring rotates along the rim track and an outer shell hole deflects toward an inner shell hole.

There is substantial technical literature describing methods to achieve our goal of concussion indication. An accelerometer is a device which measures acceleration in a given axis, and is proven to be effective as a wearable device to detect motion [10]. In addition, there is transducer technology to transmit the data into a signal for data processing [11]. There has already been testing showing that it is possible to accurately measure strain in soft materials such as fabric, which could then be applied to measure strain in the padding inside football helmets. [12]. In our device it would be necessary to obtain accurate data. There is research that accelerometer data is positively correlated with kinematic data obtained in a weightlifting study [13]. Finally, there are studies of the application of transducer data specifically measuring impacts in football, showing that this technology can be used for this application [14].

There are no industry regulations on the accelerometer and the data it collects. There are codes on the strength and safety helmets enforced by the National Operating Committee on Standards for Athletic Equipment, which ensure that helmets are constructed to dissipate force imparted effectively and to be hygienic [15]. In order to follow these regulations, our product must minimally modify the design of existing football helmets.

3.0 Customer Requirements and Design 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 in order for the modified helmets to pass certification by regulatory bodies. Additionally, the device should not add significant cost to the helmet in order 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 customer requirements is 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

3.1 IFU

The concussion-prevention football helmet can be used to identify football players who are at high risk of concussion due to strong collisions while playing.

The helmet uses an accelerometer with a battery and user interface to calculate impact forces from collisions experienced by football players in gamel. An external data processing unit calculates concussion probability for each impact and displays the data to the player or coach.

This helmet 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.

3.2 Product Design Specifications

Table 2: *Product Specifications Matrix*

Customer Requirements	Engineering Metrics	Specification	Rationale
Device cannot alter shape or overall size of the helmet	< 5% change in total helmet volume and interior and exterior contour	Integrate accelerometer into empty space between player's head, padding, and shell	Too much change will discourage football players from using the helmet
Device calculates/measures total force imparted onto player's head and indicates individual forces great enough to cause a concussion	Measures acceleration and calculates/measures force with 95% accuracy	Ensure that during testing, device measures forces within 95% of forces imparted onto device by equipment, resolution of device is .05gs	Accurate readings are necessary to alert personnel that a player is at risk for concussion or has suffered a concussion and needs further medical attention
Device cannot compromise the structural integrity of the helmet	< 5% change in yield strength of helmet material	Ensure that method of insertion of electronics does not structurally compromise helmet	Helmet must still be protective as well as diagnostic
Device should not generate false positive results	< 5% movement of accelerometer relative to head	Adhesive must be secure, and have a high enough elastic modulus to prevent movement	False positive results would cause players to be taken out of the game unnecessarily and discourage players from using the helmet
Device should not add significant weight to helmet	Device should add less than 10% weight to helmet	GoDirect Acceleration Sensor weighs 26 grams	Added weight would hinder player's performance and discourage players from purchasing the helmet
Battery should be easily replaceable and inexpensive	Time spent replacing battery less than 20 seconds and battery replacement cost less than 5 dollars	Sensor powered by Li-Poly Battery that can collect data for 24 hours, and can be removed for replacement	Too much extra maintenance and cost would discourage players from purchasing the helmet
Results should be able to be viewed on a smartphone or other easily accessible display	Less than 30 minutes spent learning how to use device and no prior knowledge necessary	Information displayed in Graphical Analysis software and exported into Excel	Having readable data by non-medical professionals will encourage users or coaches to purchase the helmet
Device must be able to withstand high impact forces	Yield strength must exceed 200gs	GoDirect Accelerometer yield strength exceeds 200gs as it measures up to 200gs of acceleration	Device cannot break or affect the function after undergoing high impact forces
Device must not injure player	Electrical systems must be grounded	Sensor will be protected by waterproof tape, sensor and battery is encased and grounded	Players will not purchase device if there is risk of injury

3.3 House of Quality

Table 3: *Customer Requirements and Engineering Characteristics*

		Engineering Characteristics									
Improvement Direction		↓	↑	↓	↓	↓	↓	↓	↓	↑	↓
Units		%	%	%	m	%	%	s	s	Pa	Volts, Pa
Customer Requirements	Importance Weight Factor	< 5% change in total helmet volume and interior and exterior contour	Measures acceleration and calculates/ measures force with 95% accuracy	< 5% change in yield strength of helmet material	Accelerometers should not accelerate more than the total mass of the player's head or body. Strain gauges should not be subjected to more force than the head	Device should add less than 10% cost to a helmet	Device should add less than 10% weight to helmet	Time spent replacing battery less than 20 seconds and battery replacement cost less than 5 dollars	Minimal time spent learning how to use device and no prior knowledge necessary	Yield strength must exceed stresses experienced during collisions	Electrical systems must be insulated and mechanical systems must be encased and protected
Not alter physical shape of helmet	3	9		3							
Accurately calculate impact great enough to cause CTE	4		9	3	9						
Does not compromise structural integrity	4	1		9						9	
Does not generate false positives	5		9	3	9					3	
Low Cost	5					9					
Low Weight	3	3					9				
Replaceable and inexpensive battery	3							9	3		
Smartphone User Interface	3								9		
Withstands impact forces	3	3		3						9	
Device does not	5			3						9	9

injure player										
Raw Score (607)	49	81	96	81	45	27	27	33	123	45
Relative Weight Percent	8.07	13.3	15.8	13.3	7.41	4.45	4.45	5.44	20.3	7.41
Rank Order	5	3	2	3	6	9	9	8	1	6

Table 4: *Customer Assessments of Competing Products*

	Competitor Rankings: 1 - Poor, 3 - Average, 5 - Excellent			
Customer Requirement	Riddell Insite and IQ	Schutt Helmets	Patent Application 20110144539 - Concussion Warning Apparatus	Patent 10,051,910 - Method, system and device for monitoring protective headgear
Not alter physical shape of helmet	2	5	2	5
Accurately calculate impact great enough to cause CTE	5	1	3	4
Does not compromise structural integrity	5	5	2	5
Does not generate false positives	4	1	3	3
Low Cost	1	3	3	2
Low Weight	2	3	4	4
Replaceable and inexpensive battery	3	1	1	2
Smartphone User Interface	5	1	1	3
Withstands impact forces	5	5	1	3
Device does not injure player	5	5	5	3

4.0 Stage Gate Process

4.1 Concept Review

Our device will be comprised of a tight, elastic swim cap worn on the head under the football helmet, and an array pressure sensors attached to the cap with a strong adhesive. The pressure sensors will be located on areas of the head that are in contact with the helmet padding, as this is the area in which forces are conveyed onto the head. Pressure on each sensor will be recorded, and the data will be input into a series of equations that have been derived to calculate concussion probability [18]. The pressure values recorded will then be converted into pressure values on the skull. The coefficient of conversion will be determined through strain gauge testing of materials subjected to pressure with a swim cap as the intermediate material. Stress values will be converted to strain values using the elastic modulus of cortical bone (20.7 GPa [17]), which is the primary bone type in the skull. This data point can then be inserted into equations shown in section 6.1, and concussion probability is then determined and displayed to the user or coach.

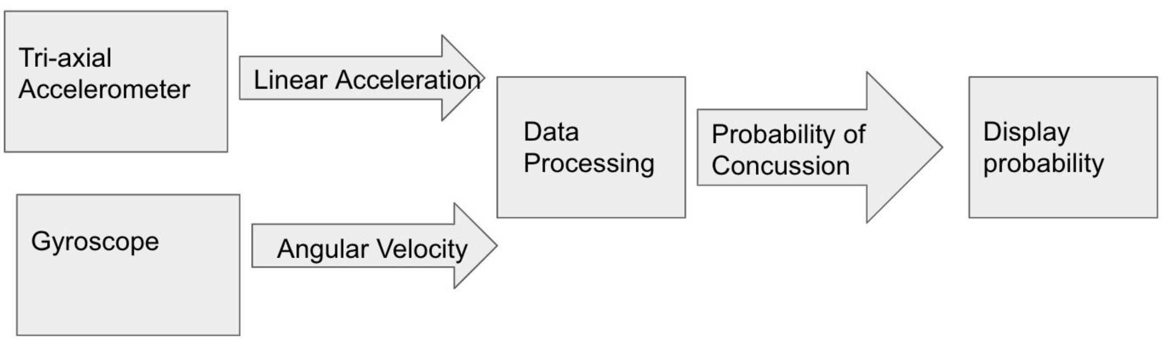


Figure 1: *Diagram of functional components of proposed concept*

4.2 Design Freeze

- Waterproof Enclosure
    - #ADC-12 alloy die cast aluminum box
    - UL Listed NEMA Type 4X, 6, 6P, 12 & 13 (File E194432)
    - Rated to IP67 / IP68
    - Watertight gasket (installation required)
- Vernier’s GoDirect Acceleration Sensor
    - 3-axis accelerometer and gyroscope
    - Wireless, rechargeable battery
    - 68 mm × 27 mm × 17 mm
    - Measures 200 g’s
    - Resolution of 0.05 g’s

4.3 Design Review

The accelerometer model will not be able to be integrated with a swim cap since the accelerometer is only available in a bulky box form rather than a flat chip form. This leaves only an accelerometer-helmet model available for further development.

5.0 Description of Final Prototype Design

5.1 Overview

The final prototype design consists of a 3-axis accelerometer and gyroscope that is enclosed in a waterproof aluminum casing. The bottom of the metal case was glued to a convex piece of wood to improve the amount of surface area in contact with the shape of the helmet, which was then glued to the helmet with gorilla glue. For additional security, zip ties were placed horizontally and vertically across the face of the accelerometer case. The ends of the zip ties were placed through existing holes on the helmet and secured.

5.2 Design Justification

This specific design was optimal because the accelerometer obtained was already pre-programmed to include a data collecting software, LabQuest 2. LabQuest 2 is a data analysis software and includes built-in graphing capabilities. This device can collect and process linear acceleration and angular velocity. The accelerometer was inserted into an aluminum case that included a water-tight gasket to prevent water from leaking into the case and four screws at each corner of the case to keep the contents inside the case secure. This design was chosen because it had the highest chance of both gathering and sending accurate data, as well as ensuring that the accelerometer and casing were firmly attached to the helmet.

5.3 Analysis

In order to get accurate data, the casing and accelerometer must not move relative to the helmet and the player’s head. Because of this, it was important to design a secure casing and attachment that would allow the accelerometer to experience only the exact accelerations experienced by the player’s head. In our mathematical model, the most important factor in determining concussion probability is rotational acceleration, which is the same value across an entire rigid body. Therefore, as long as our casing was attached in manner that caused it to be a part of the helmet and head rigid body, accurate data would be gathered.

5.4 Cost Breakdown

- Integrated accelerometer system: $99
    - Includes battery, USB cable, tri-axial accelerometer, gyroscope, A-D converter, Bluetooth module, and microprocessor with embedded firmware

- Waterproof case ~ $6.64
- Putty ~ $2 / assembly
- Graphical Analysis 4 Software: $0
- Microsoft Excel Software: already have access

5.5 Safety Considerations

The components identified for possible failure for the Concussion Prevention Football Helmet are the attachment mechanism, battery, accelerometer, bluetooth module, and display. Issues that could prevent the device from functioning are the calibration of the accelerometer, precision of the accelerometer, sliding of the attachment mechanism, incorrect voltage production by the battery, and inability of the device or display to connect wirelessly. The calibration and precision of the accelerometer are important metrics because they determine the accuracy of device readings, thus influencing the sensitivity and specificity of the system. Sliding of the attachment mechanism is considered an important issue because it may create inaccurate accelerometer measurements, also leading to inaccurate readings. Incorrect battery voltage is also an important error to correct because it may render the system unusable and potentially destroy the accelerometer if it causes too much current to go through the accelerometer. Lastly, the connection between the device and display is an important metric because without the display to show the data generated by the device, no action can be taken based on device readings.

Critical effects that could result in patient injury include:

- Device interference with the shock-absorbing properties of the helmet
- Device causing injury to the player upon impact
- Damage to device resulting from impact
- Electrical system shocking user due to improper insulation or exposure to water
- Burning user from heat buildup due to improper thermal insulation

The critical issues will be prioritized during design and manufacturing. Steps will be taken to ensure that the proper materials will be used in order to separate the interior system from the exterior of the helmet and the player. Specifically, materials and design that prevents the battery from coming in contact with the outside will be used, the electrical systems will be grounded, insulated electrically and thermally, and the helmet will be designed to house the system without being compromised structurally.

The Failure Mode Effect Analysis (see Appendix D) will reduce the possibility of future medical device recalls because it identifies key risks in the hardware, software, and mechanical components of the device and provides ways to mitigate these risks. Additionally, a hazard and risk assessment is provided in Appendix D.

6.0 Prototype Development

6.1 Model Analyses

A curve fit derived from a correlation of accelerations obtained by video analysis to concussion outcome in football players [19] was implemented in MATLAB as in Equation 1, where a is maximum linear acceleration, α is maximum rotational acceleration, and CP is concussion probability.

$$CP = \frac{1}{1+\exp\left[-(-10.2+0.0433a+0.000873\alpha\ -0.000000920a\alpha)\right]} \qquad (\boldsymbol{Equation\ 1})$$

6.1.1 Model Implementation

A simplified multi-step series model translating accelerations to concussion probability [18] was also implemented in MATLAB. This model includes a human head finite element analysis model, a micromechanics model, an axon signaling model, and a dose-response model [18]. These models are used in series, with the output of one model used as the input to the next. A simplifying assumption to neglect linear acceleration is used in the model, since rotational acceleration often has a much greater effect on probability of concussion than does linear acceleration [18]. The first component of the model is a tissue response model to derive time-dependent axial strains from kinematic data. This component is a simplification of an FEM model, which aims to increase the speed and simplicity of the model. The tissue response model was implemented as shown in Equation 2, where ω_p is peak angular velocity, a(t) is time-dependent angular acceleration, and ε is axial strain.

$$a\ddot{\varepsilon}+\left(b+c\omega_p\right)\dot{\varepsilon}+d\varepsilon = \ -\alpha(t) \qquad (\boldsymbol{Equation\ 2})$$

The *ode45* function in MATLAB was used to solve the second order differential equation given by Equation 2 for axial strain with initial conditions e(0) = 0 and e'(0) = 0, or zero axial strain and zero time rate of change in strain at the initial time of impact. The parameters a, b, c, and d were given in the parametric study by Phohomsiri et al. as 3.3, 250, -2.2, and 74800 for x-axis rotation and -3.0, -230, 3.6, and -67320 for y-axis rotation, respectively [18]. Rotation about the z-axis is considered insignificant for impacts in football studies due to probable angles of impact. For reference, the x-axis is in the lateral direction, the y-axis is in the ventral direction, and the z-axis is in the cranial direction.

The second component of the model is a micromechanics model, which translates the axial strain obtained in the previous step into strain at the Nodes of Ranvier. The micromechanical behavior can be modeled as viscoelastic as shown in Figure 1 [20].

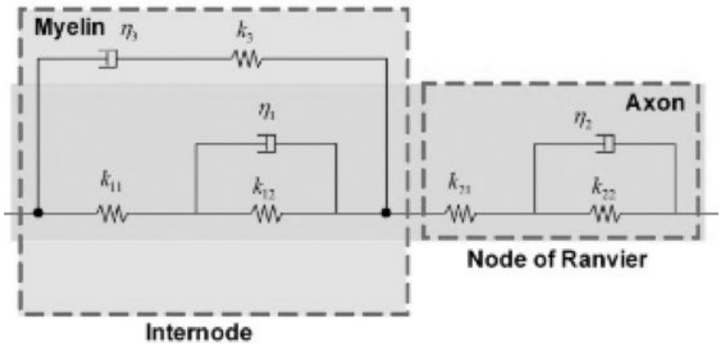


Figure 2: Micromechanical behavior of an axon modeled as a viscoelastic system. Spring and damping constants were determined using the material properties (elastic modulus and viscosity, respectively) of a dorsal root ganglion neuron [20].

Equation 3 was used to determine spring and damping constants, where elastic moduli E_1 = 19.9 kPa, E_2 = 0.42 kPa, and E_3 = 50 kPa, and viscosities h_1 = 2.256 MPa/s and h_3 = 1 kPa/s. The internode length used was 125 microns (internode length varies between 50 and 200 microns) and the node length was 1 micron. Cross sectional areas of the node, internode, and myelin were assumed to be 7.85e-11, 7.85e-11, and 7.54e-11 meters, respectively [20].

$$k_{11} = \frac{E_1 A_{\text{internode}}}{L_{\text{internode}}}, \quad k_{12} = \frac{E_2 A_{\text{internode}}}{L_{\text{internode}}}, \quad \gamma_1 = \frac{\eta_1 A_{\text{internode}}}{L_{\text{internode}}} \qquad \textbf{(\textit{Equation 3a})}$$

$$k_{21} = \frac{E_1 A_{\text{node}}}{L_{\text{node}}}, \quad k_{22} = \frac{E_2 A_{\text{node}}}{L_{\text{node}}}, \quad \gamma_2 = \frac{\eta_1 A_{\text{node}}}{L_{\text{node}}} \qquad \textbf{(\textit{Equation 3b})}$$

$$k_{31} = \frac{E_3 A_{\text{myelin}}}{L_{\text{internode}}}, \quad \gamma_3 = \frac{\eta_3 A_{\text{myelin}}}{L_{\text{internode}}} \qquad \textbf{(\textit{Equation 3c})}$$

A system of equations was derived using the viscoelastic model (derivation shown in Appendix J) to solve for the strain at the output of the Nodes of Ranvier, using the axial strain computed by the tissue response model as the input strain at the internode. Three first order ordinary differential equations were solved using the *ode45* function in MATLAB to obtain strains at each of the dampers, with the initial conditions that the strain at each damper at the initial time of impact was zero. The system was then solved for the output strain using the results from the *ode45* solver. The maximum of the time-dependent solution was found to determine maximum strain at the Nodes of Ranvier.

In the axon signaling model, the factor of reduction in action potential voltage amplitude, DA, was calculated using the maximum strain at the Node of Ranvier, ε_{NR}, as in Equation 4 [18].

$$\Delta A = \begin{cases} 1.5826{\varepsilon_{NR}}^2 + 0.2138\varepsilon_{NR}, & \varepsilon_{NR} < 0.73 \\ 1, & \varepsilon_{NR} > 0.73 \end{cases} \qquad (\textbf{\textit{Equation 4}})$$

A dose-response curve determined by Phohomsiri et al. [18] was then used to predict concussion probability, CP, using Equation 5 when input the reduction in action potential magnitude, ΔA, determined in the previous step.

$$CP = \frac{\exp(x)}{1 + \exp(x)}, \qquad x = 7.6182 + 2.4587w, \qquad w = \ln\left(\frac{\Delta A}{1 - \Delta A}\right) \qquad (\textbf{\textit{Equation 5}})$$

6.1.2 *Data Simulation*

Kinematics were derived using a Monte Carlo simulation from means and standard deviations of empirical data. This data was obtained in a study that used an in-helmet system with six accelerometers to collect data on linear and rotational accelerations in eight football players who incurred a total of 347 impacts during one game [21]. Maximum linear accelerations were measured at 21.5 ± 19.7g, maximum rotation about the x-axis were 769.9 ± 1082.7 rad/s^2, and maximum rotation about the y-axis were 1382.8 ± 1547.3 rad/s^2 [21]. Impact duration (duration of positive acceleration) was found to be 6 ± 2 milliseconds [21]; however, a constant impact duration of 6 milliseconds was used as an experimental control in this study. Probability density functions (PDFs) were used to create a normal distribution for each variable, and a set of 1000 randomly selected values from each PDF was chosen to represent the kinematic values for the simulated data points. An assumption was made that the rotational acceleration about each of the x and y axes can be represented as a scalar multiple of linear acceleration in order to minimize variation in the results and more accurately represent a real impact; thus, the values for angular acceleration were generated based upon scaling by mean experimentally derived values. A histogram of angular acceleration magnitudes generated by the Monte Carlo simulation is shown in Figure 10. Since negative values were produced by the PDF due to high standard deviations, the absolute value of accelerations was taken to produce positive acceleration values as an experimental control, which is reflected in the skewness of the histogram.

6.2 Evolution of Prototypes

Concept 1- Accelerometer worn on the head

An accelerometer would be attached to the player's head in various locations either as a head cap or an adhesive. The accelerometer would take measurements and send them to the software which would use the data to calculate forces imparted onto the head.

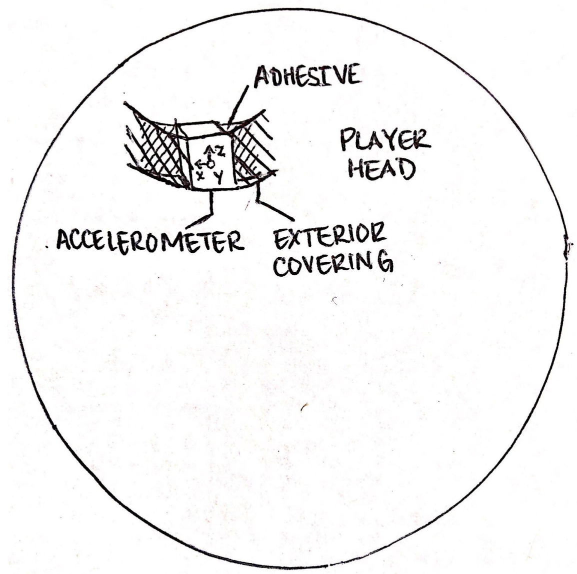


Figure 3: *Concept 1, an accelerometer worn on head*

Concept 2- Strain gauge attached to helmet padding

A strain gauge would be integrated into the padding of the helmet, and would take measurements of displacement of the padding when the player experiences collisions. The measurements would then be sent to our software, and forces experienced by the player's head would be calculated using the padding's material properties.

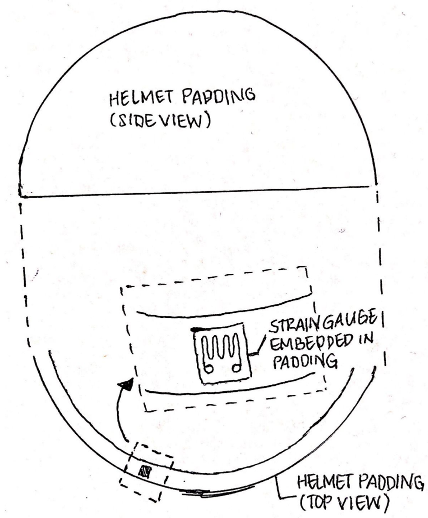


Figure 4: *Concept 2, a strain gauge embedded in helmet padding*

Concept 3- Pressure sensor head cap

The player would wear a head cap with pressure sensors embedded at various locations. Measurements would be taken, sent to our external software, and forces would be calculated.

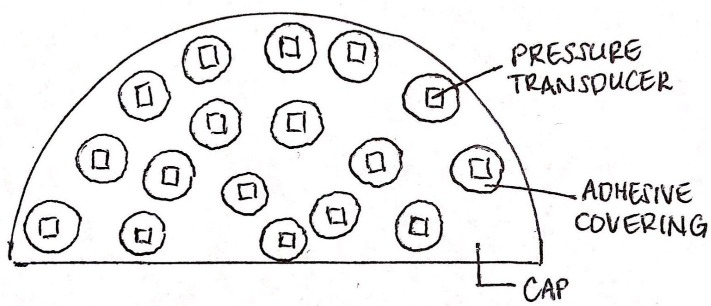


Figure 5: *Concept 3, an array of pressure sensors on a cap in direct contact with head*

Best Concept from Pugh Chart- Concept 2.

We arrived at the strain gauge concept from our Pugh chart because it had more pluses and less minuses than concept 3. Although the pluses and minuses were equal, putting the datum as a possible competitor, we determined that the accuracy of measurements and avoiding player injury were more important customer requirements than false positives and withstanding high impact forces. However, all of these customer requirements are important and we will consider both concepts further. We believe that the force-displacement model using material properties in the helmet padding will provide more accurate measurements than an accelerometer model. This is due to the possibility of the accelerometer moving relative to the head and skewing the data. We also believe that there is less of a chance of injury in the strain gauge model because the device would be embedded into the helmet padding and have less contact with the player's head. The other two concepts involve our device being directly placed onto the player's head, and cause more injury due to decreased proximity between the device and head.

*Note that this final concept was diverged from later in the development process.

The first manufactured prototype consisted of the accelerometer and casing glued directly into the helmet casing. After impact testing, this design failed.

Finally, a prototype was manufactured with additional attachment mechanisms that can be viewed in section 6.4.

6.3 Manufacturing Process

6.3.1 Device

1. Charge accelerometer via USB to a computer
2. Set accelerometer into aluminum casing bottom
3. Secure silicone gasket into casing top by pressing firmly
4. Place plastic strip under and up one side of accelerometer so that ¼ inch of the strip remains above the accelerometer.
5. Insert putty into sides of aluminum casing in order to fill gaps on either side of accelerometer
6. Glue casing into helmet with Gorilla Glue

__Figure 6:__ Accelerometer inside protective metal casing

6.3.2 Impact Tester

1. Obtain 7-8ft 2x4s (qty. 9). Cut one 2x4 into three 2.5ft pieces at 90°.
2. Cut two 2x4s to 6ft at 90°.
3. Cut four 2x4s to 6ft, with one side at 30° and the other at 60°.
4. Assemble using two 3.5” all purpose wood screws at each joint as shown.
5. Wrap 10 ft of rope around top bar two times and secure with a square knot.
6. Tie helmet to rope using a square knot.
7. Repeat steps 5 and 6 with kettlebell.

The resulting structure is as pictured in Figure 6.

Figure 7: Construction of the impact tester is shown.

Table 6: MPI

MPI Steps	Deviations	Completed By	Date
1-5 (Device)	None	Isabel Jellen	2/12/19
6 (Device)	After failure of glue, added a small wooden block between casing and helmet to increase surface area interface between glue and casing	Eric Shechter	2/20/19
1-7 (Impact Tester	None	Taylor O'Donoghue, Eric Shechter, Isabel Jellen	2/15/19

6.4 Divergence Between Final Design and Final Functional Prototype

The final functional prototype includes zip-ties surrounding the case in order to further support the casing.

In addition, a wood piece was sanded to the same curvature as the helmet to increase the interface between the flat casing bottom, glue, and curved helmet casing.

7.0 IQ/OQ/PQ

7.1 DOE

Table 7: *Design of Experiments - Concussion Prevention Football Helmet*

Engineering Metric	Specification	Test Method	Test Apparatus Location	Apparatus Experience / Training	Sample Size	Power
Measures acceleration/ force with 95% accuracy	Use a transducer that produce measurements with 95% accuracy, ensure that accelerometer does not move with respect to player's	Impart controlled forces onto helmet, compare calculated accelerations/forces and measured accelerations/forces	Drop test machinery or weight (location TBD)	Drop Test knowledge	N=100	0.95

	head, ensure that strain gauge is secured and cannot move relative to player's head					
Device should add less than 10% cost to a helmet	Device costs under $35 extra by using inexpensive technology to measure impact forces	Compare the total cost of the new helmet with the cost of helmets being currently used	Anywhere with a computer to calculate the difference in cost	Use a calculator	N=1	0.95
Device should add less than 10% weight to helmet	Device weighs under 0.3 lbs using small, lightweight materials and miniaturized electronic	Calculate the weight of both helmets (New and Old) and compare the weight	Scale - Engineering IV	Use a scale	N = 2	0.95
Device must withstand high impact forces (200 g's) by a safety factor of 1.5	Electronics and casing do not yield under large loads	Drop test device in helmet and casing from appropriate height to experience approximately 300 g's	Cal Poly Mechanical Engineering Lab	Knowledge of drop test safety	N = 5	0.80

Range of wireless connection must be at least 110 m (the length of a football field)	Range of accelerometer in case >= 110 m	With accelerometer in case, measure distance from receiver at which connection is lost.	Engineering IV	Fully assembled device, computer	N = 3	0.80
Concussion probability must be accurate to 10% given an acceleration	Less than 10% RMS error between concussion model and empirically derived results	Perform MATLAB simulations using both the model and empirical curve on the same data and calculate RMS error in results	Engineering IV	MATLAB package, knowledge of usage of MATLAB	N = 1000	0.95

7.2 Verification and Validation

7.2.1 Impact Testing

7.2.1.1 Impact Testing: Methods

Part I: Impact tester construction

1. Obtain 7-8ft 2x4s. Cut one 2x4 into 3-2.5 foot pieces at 90 degrees.
2. Cut two 2x4s to 6ft at 90 degrees
3. Cut four 2x4s to 6ft, with one side at 30 degrees and the other at 60 degrees.
4. Assemble using 2-3.5” all purpose wood screws at each joint as shown.
5. Wrap 10 ft of rope around top bar two times and secure with a square knot.
6. Tie helmet to rope using a square knot.
7. Repeat steps 5 and 6 with kettlebell.

The resulting impact tester should appear as shown in Figure 7.

Figure 8: Construction of impact tester is shown.

Part II: Data Collection and Analysis

1. Secure accelerometer in helmet, drawing a box around the case.
2. Place marker on helmet and calibrate with cameras
3. Ensure that the helmet and weight are in the same plane
4. Raise 5 lb weight at increments of 5 degrees from 5 to 90 degrees, release to impact helmet
5. Repeat each trial three times, and repeat all trials with 10 lb weight
6. Offload data from accelerometer and fit against data from cameras.

Following each trial, inspect the attachment of the device to the helmet to ensure that no movement has occured from its original position by ensuring that the box drawn around the case is within 1mm of the case on all sides. Note any movements or detachment of the accelerometer.

7.2.1.2 Impact Testing: Results

Impact testing was performed in the Human Motion Biomechanics lab at Cal Poly in order to produce a calibration curve for the accelerometer which ensures maximum acceleration input into the model for data processing. The accelerometer was placed inside the helmet near the back of the user’s head. Markers 2, 3, and 4 for motion camera detection were placed on the outside of the helmet on the top, back, and side, respectively, equidistant from the accelerometer. Marker 1 was placed on the opposite side of the helmet from the accelerometer. The pendulum setup was used to produce accelerations on the helmet, and resulting data was collected from both the motion cameras and accelerometer during each test. Two impact tests were performed for each of the following angles and kettlebell weights:

- 30 degrees, 8.8 lbs
- 60 degrees, 8.8 lbs
- 90 degrees, 8.8 lbs
- 30 degrees, 17.5 lbs
- 60 degrees, 17.5 lbs
- 90 degrees, 17.5 lbs

Acceleration curves were also generated from both the camera and accelerometer data in order to visually demonstrate the similarity between the curves, shown in Figure 8. The following curves are generated from the second trial of the higher weight dropped from 60 degrees. Note that the camera acceleration is measured in mm/s^2 and accelerometer acceleration is in m/s^2. Also note that there was a difference in the start time of each data collection, so alignment of time could be determined by aligning the peak impact values.

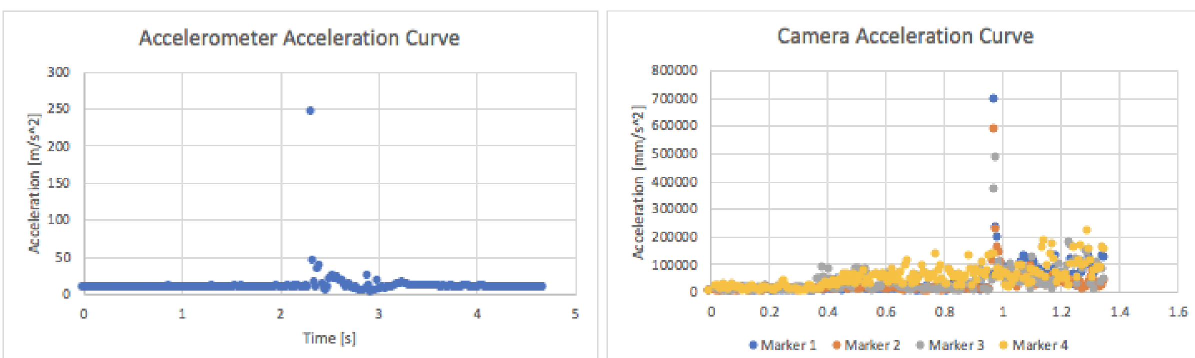


Figure 9: A visual comparison of the accelerometer and camera impact acceleration curves is shown.

Since concussion is based upon the maximum acceleration experienced by the user, it is beneficial to base the collected data upon the maximum possible concussive acceleration at any point of the helmet, not just the acceleration at the location of the accelerometer. As such, a calibration curve was produced of the accelerometer data to the maximum acceleration of all four markers obtained from camera data, shown in the Figure 9. Note that one outlying data point (the second trial of the impact test with the higher weight) was omitted from the calibration curve. The sensor calibration determined from the curve is y = 1.8637x + 222.59 [m/s^2], where y is the corrected acceleration and x is the original offloaded acceleration from the accelerometer. The maximum acceleration as reported during the testing by the motion cameras was 745 m/s^2, or 75.94 g's.

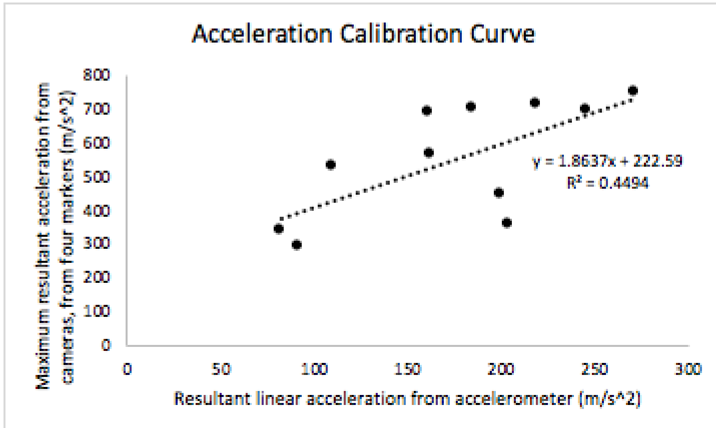


Figure 10: Accelerometer calibration curve, based upon the maximum acceleration found from motion cameras.

A paired two-tailed t-test was performed between unadjusted peak acceleration values obtained from the accelerometer and camera outputs, with each pair corresponding to one of the twelve trials. The resulting p-value was 2.29E-06, which demonstrates statistically significant difference between the two datasets with a threshold of significance at $p = 0.05$. A similar paired two-tailed t-test was performed between peak acceleration values obtained from accelerometer adjusted as specified in the calibration curve and the camera output. The resulting p-value was $p = 0.518$, which demonstrates no statistically significant difference between the calibrated acceleration values and accelerations obtained from the motion cameras with a threshold of significance at $p = 0.05$. This demonstrates the need to utilize the calibration curve in order to obtain accurate results from the accelerometer.

An important note from the impact tests was that the accelerometer device became detached from the helmet when the first impact test at 60 degrees with the 17.5 lb kettlebell. This trial was subsequently performed again for the purposes of impact data, and data from the first trial was not used in analysis. The point of failure of the attachment was shearing of a zip tie connecting the device to the helmet through vent holes. There was no movement of the device prior to this attachment failure. Figure 10 shows the zip tie failure at 60 degrees with the 17.5 lb kettlebell.

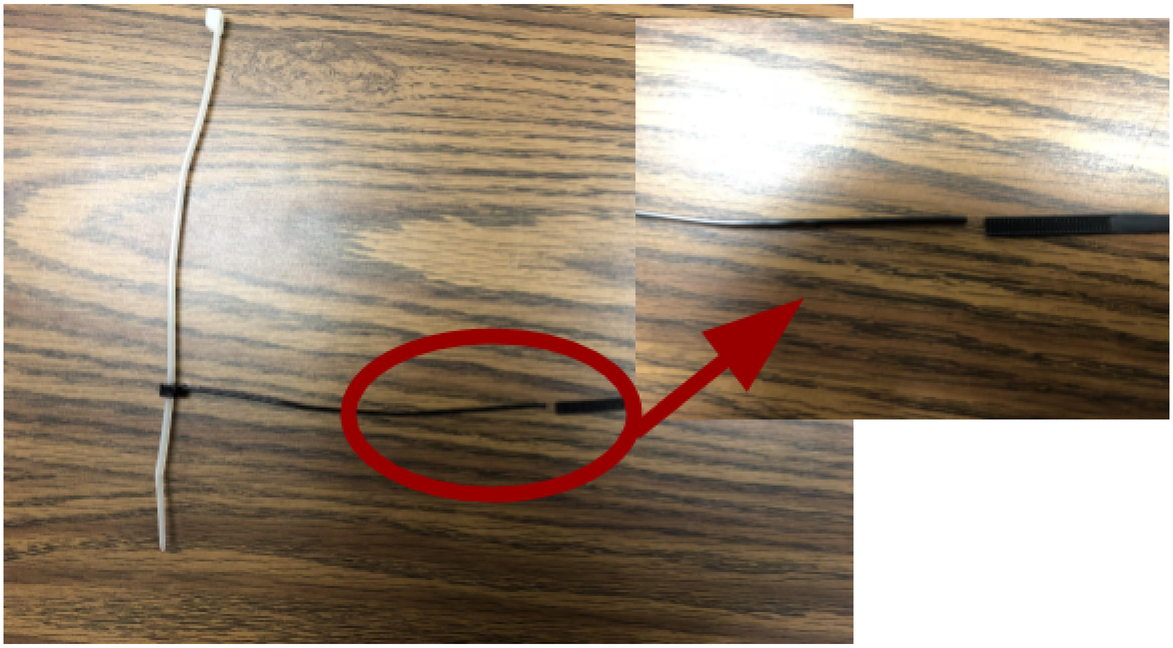


Figure 11: The failure of the zip tie attachment is shown, as encountered on the first trial dropping from 60 degrees with the 17.5 lb weight.

7.2.2 Range Testing

The accelerometer is advertised to have a range of 30 m. However, Bluetooth is generally inhibited by passing through metal, so the waterproof aluminum casing enclosing the device was expected to inhibit the range of the accelerometer. Range testing was performed by enclosing the accelerometer in the case, beginning data collection via paired Bluetooth, walking slowly away with the device, and observing disconnection on the computer interface. The device was found to disconnect at an average of 20.5 m (from three trials) from the computer when in the aluminum case.

7.2.3 Waterproof Testing

The procedure for waterproof testing is as follows:

1. Place strip of pH paper in waterproof case
2. Close casing, fasten screws on casing, and submerge in water for five minutes
3. Remove paper and view color changes on the paper, comparing it to the provided chart
4. If pH registers 7 (the pH of water), the test has failed. If there is no change in pH, the test has passed.
5. Repeat five times

The waterproof testing has been completed. After each trial of the five trials, no signs of water were present inside the main case cavity and the pH strips were untouched and therefore, did not register a pH level of 7. These series of trials were deemed successful and the aluminum case is considered waterproof as set by the specification.

7.2.4 Software Simulation

7.2.4.1 Software Simulation: Methods

7.2.4.1.A Curve Fit

A curve fit derived from a correlation of accelerations obtained by video analysis to concussion outcome in football players [19] was implemented in MATLAB as in Equation 1, where a is maximum linear acceleration, α is maximum rotational acceleration, and CP is concussion probability.

$$CP = \frac{1}{1+\exp\left[-(-10.2+0.0433a+0.000873\alpha\ -0.000000920a\alpha)\right]} \qquad (\boldsymbol{Equation\ 1})$$

7.3.4.1.B Model Implementation

A simplified multi-step series model translating accelerations to concussion probability [18] was also implemented in MATLAB. This model includes a human head finite element analysis model, a micromechanics model, an axon signaling model, and a dose-response model [18]. These models are used in series, with the output of one model used as the input to the next. A simplifying assumption to neglect linear acceleration is used in the model, since rotational acceleration often has a much greater effect on probability of concussion than does linear acceleration [18]. The first component of the model is a tissue response model to derive time-dependent axial strains from kinematic data. This component is a simplification of an FEM model, which aims to increase the speed and simplicity of the model. The tissue response model was implemented as shown in Equation 2, where ω_p is peak angular velocity, a(t) is time-dependent angular acceleration, and ε is axial strain.

$$a\ddot{\varepsilon}+\left(b+c\omega_p\right)\dot{\varepsilon}+d\varepsilon = -\alpha(t) \qquad (\boldsymbol{Equation\ 2})$$

The *ode45* function in MATLAB was used to solve the second order differential equation given by Equation 2 for axial strain with initial conditions e(0) = 0 and e'(0) = 0, or zero axial strain and zero time rate of change in strain at the initial time of impact. The parameters a, b, c, and d were given in the parametric study by Phohomsiri et al. as 3.3, 250, -2.2, and 74800 for x-axis rotation and -3.0, -230, 3.6, and -67320 for y-axis rotation, respectively [18]. Rotation about the z-axis is considered insignificant for impacts in football studies due to probable angles of impact.

For reference, the x-axis is in the lateral direction, the y-axis is in the ventral direction, and the z-axis is in the cranial direction.

The second component of the model is a micromechanics model, which translates the axial strain obtained in the previous step into strain at the Nodes of Ranvier. The micromechanical behavior can be modeled as viscoelastic as shown in Figure 1 [20].

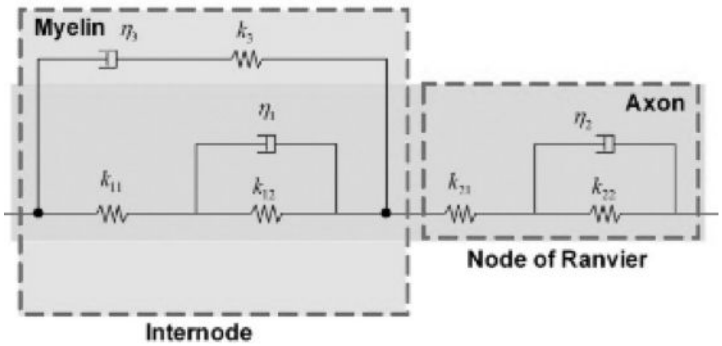


Figure 12: Micromechanical behavior of an axon modeled as a viscoelastic system. Spring and damping constants were determined using the material properties (elastic modulus and viscosity, respectively) of a dorsal root ganglion neuron [20].

Equation 3 was used to determine spring and damping constants, where elastic moduli E_1 = 19.9 kPa, E_2 = 0.42 kPa, and E_3 = 50 kPa, and viscosities h_1 = 2.256 MPa/s and h_3 = 1 kPa/s. The internode length used was 125 microns (internode length varies between 50 and 200 microns) and the node length was 1 micron. Cross sectional areas of the node, internode, and myelin were assumed to be 7.85e-11, 7.85e-11, and 7.54e-11 meters, respectively [20].

$$k_{11} = \frac{E_1 A_{\text{internode}}}{L_{\text{internode}}}, \quad k_{12} = \frac{E_2 A_{\text{internode}}}{L_{\text{internode}}} \quad , \quad \gamma_1 = \frac{\eta_1 A_{\text{internode}}}{L_{\text{internode}}} \qquad \textbf{(\textit{Equation 3a})}$$

$$k_{21} = \frac{E_1 A_{\text{node}}}{L_{\text{node}}}, \quad k_{22} = \frac{E_2 A_{\text{node}}}{L_{\text{node}}}, \quad \gamma_2 = \frac{\eta_1 A_{\text{node}}}{L_{\text{node}}} \qquad \textbf{(\textit{Equation 3b})}$$

$$k_{31} = \frac{E_3 A_{\text{myelin}}}{L_{\text{internode}}}, \quad \gamma_3 = \frac{\eta_3 A_{\text{myelin}}}{L_{\text{internode}}} \qquad \textbf{(\textit{Equation 3c})}$$

A system of equations was derived using the viscoelastic model (derivation shown in Appendix J) to solve for the strain at the output of the Nodes of Ranvier, using the axial strain computed by the tissue response model as the input strain at the internode. Three first order ordinary differential equations were solved using the *ode45* function in MATLAB to obtain strains at each of the dampers, with the initial conditions that the strain at each damper at the initial time of impact was zero. The system was then solved for the output strain using the results from the *ode45* solver. The maximum of the time-dependent solution was found to determine maximum strain at the Nodes of Ranvier.

In the axon signaling model, the factor of reduction in action potential voltage amplitude, DA, was calculated using the maximum strain at the Node of Ranvier, ε_{NR}, as in Equation 4 [18].

$$\Delta A = \begin{cases} 1.5826{\varepsilon_{NR}}^2 + 0.2138\varepsilon_{NR}, & \varepsilon_{NR} < 0.73 \\ 1, & \varepsilon_{NR} > 0.73 \end{cases} \qquad (\textbf{\textit{Equation 4}})$$

A dose-response curve determined by Phohomsiri et al. [18] was then used to predict concussion probability, CP, using Equation 5 when input the reduction in action potential magnitude, ΔA, determined in the previous step.

$$CP = \frac{\exp(x)}{1 + \exp(x)}, \qquad x = 7.6182 + 2.4587w, \qquad w = \ln\left(\frac{\Delta A}{1 - \Delta A}\right) \qquad (\textbf{\textit{Equation 5}})$$

7.2.4.1.*C Data Simulation*

Kinematics were derived using a Monte Carlo simulation from means and standard deviations of empirical data. This data was obtained in a study that used an in-helmet system with six accelerometers to collect data on linear and rotational accelerations in eight football players who incurred a total of 347 impacts during one game [21]. Maximum linear accelerations were measured at 21.5 ± 19.7g, maximum rotation about the x-axis were 769.9 ± 1082.7 rad/s^2, and maximum rotation about the y-axis were 1382.8 ± 1547.3 rad/s^2 [21]. Impact duration (duration of positive acceleration) was found to be 6 ± 2 milliseconds [21]; however, a constant impact duration of 6 milliseconds was used as an experimental control in this study. Probability density functions (PDFs) were used to create a normal distribution for each variable, and a set of 1000 randomly selected values from each PDF was chosen to represent the kinematic values for the simulated data points. An assumption was made that the rotational acceleration about each of the x and y axes can be represented as a scalar multiple of linear acceleration in order to minimize variation in the results and more accurately represent a real impact; thus, the values for angular acceleration were generated based upon scaling by mean experimentally derived values. A histogram of angular acceleration magnitudes generated by the Monte Carlo simulation is shown in Figure 10. Since negative values were produced by the PDF due to high standard deviations, the absolute value of accelerations was taken to produce positive acceleration values as an experimental control, which is reflected in the skewness of the histogram.

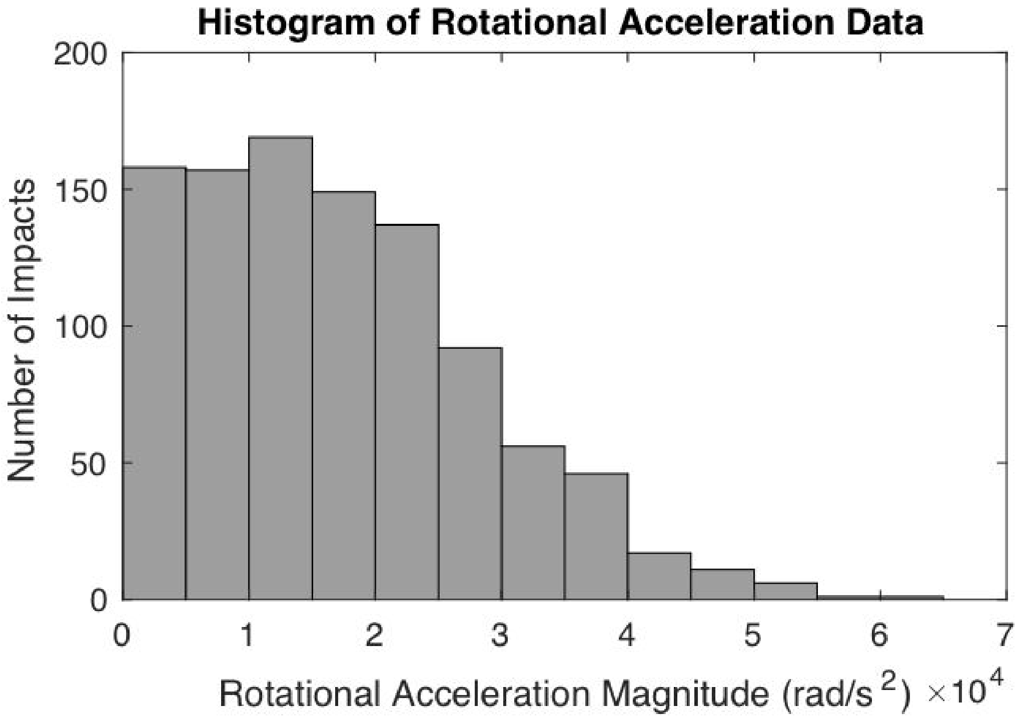


Figure 13: Histogram of angular acceleration magnitudes generated for the study. Data given by PDFs of experimental means and standard deviations was randomly generated. Rotational acceleration was scaled based on the assumption that it can be estimated as a scalar multiple of linear acceleration in a given impact.

Additionally, a head acceleration shape function [18] representative of kinematics from the collected data was used as a multiplier for the maximum acceleration. This shape function, shown in Figure 11, generated accelerations as a function of time given positive impact duration and maximum acceleration.

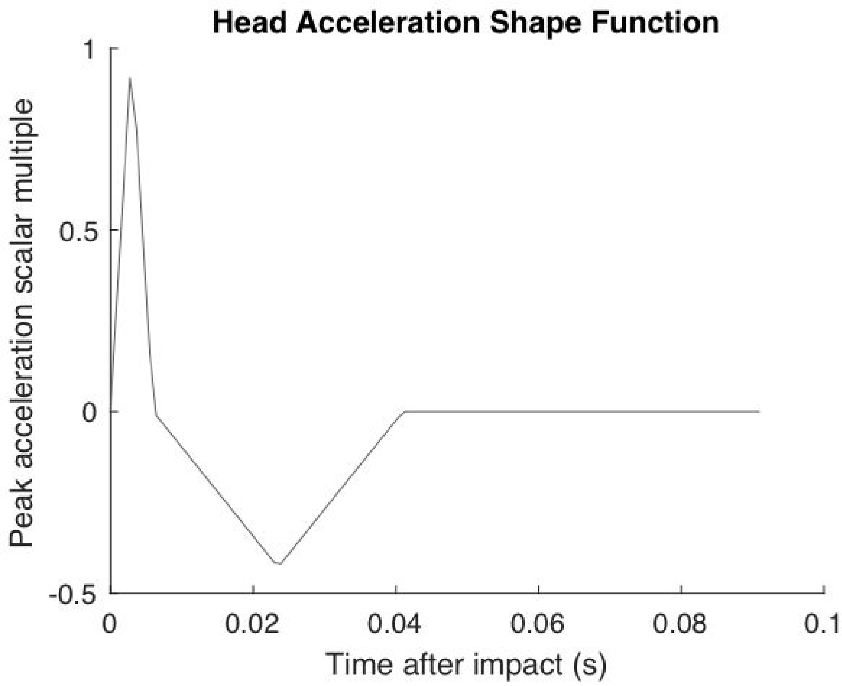


Figure 14: Head acceleration shape function was used as a multiplier for maximum acceleration to generate a time function. The positive impact duration (a constant 6 ms in this simulation) and maximum angular acceleration of an impact were input into the shape function along with a constant negative impact duration of 35 ms and subsequent zero acceleration period of 85 ms in order to generate angular acceleration as a function of time.

7.2.4.1.D Model Validation Methods

i. Comparison to Curve Fit

Percent difference in concussion probability was determined in MATLAB for each simulated data point between the curve fit and model. A paired two-sample t-test was run between the curve fit and model to determine if there was significant difference between the curves. Additionally, a root mean square error analysis was performed between the curve-fit and model outputs to determine the degree of similarity between the two curves.

ii. Introduction of Noise and Propagation of Error

Error was introduced which simulated data collection from an accelerometer with 95% accuracy. Concussion probabilities for each of 1000 data points using the “noisy” acceleration data were collected and compared against the original model and curve fit outputs. Noise was introduced by scaling acceleration values for each data point with a random number between 0.95 and 1.05, or ± 5%. A root mean square error analysis was performed between the original and noisy data for both the model and curve fit in order to determine the error propagation introduced by noise in acceleration data readings.

iii. Timing

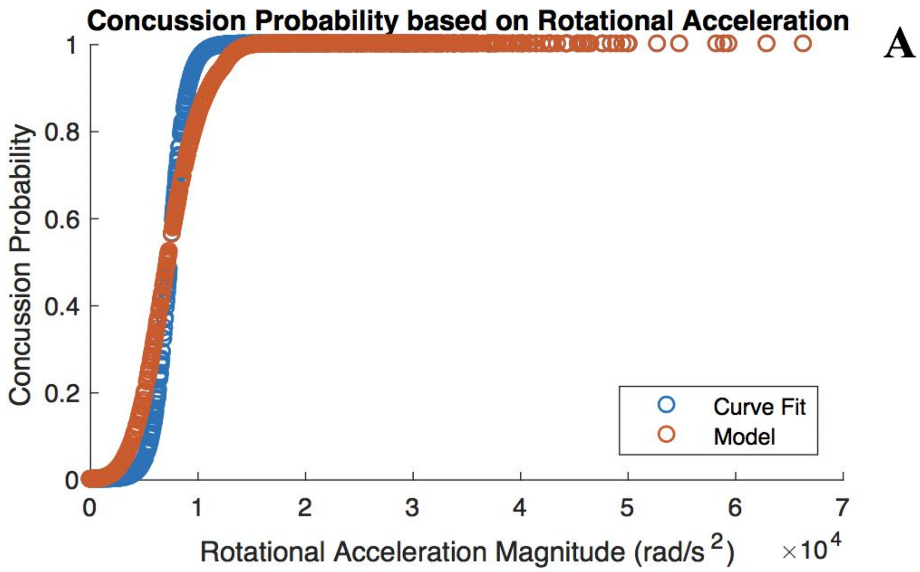
The runtime of both the model and curve fit were determined using the *tic* and *toc* MATLAB timing functions for 1000 data points. Additionally, a simulation was performed to time the model for 1 – 30 data points, in increments of 1. A linear fit was used to describe run time as a function of the number of data points. This fit was then used to determine maximum sampling frequency for the model to run in real-time by setting the time equal to one second and solving for number of data points.

A link to MATLAB scripts for the curve-fit, model, data generation, validation, and analysis is provided in Appendix I.

7.2.4.2 Software Simulation: Results

i. Comparison to Curve Fit

A plot of concussion probability based on the magnitude of angular acceleration for both the experimental curve fit and model is shown in Figure 12, along with a plot of residuals between the two curves as a function of acceleration. A paired two-sample t-test between the two sets of generated concussion probabilities (via experimental curve fit and model, respectively) resulted in a p-value of 0.88, which fails to reject the null hypothesis that the curves are statistically similar. Additionally, the average root mean square error (RMSE) was found to be 0.064 between the two curves, which is 6.4% of the range of possible output values (zero to one) and maximum RMSE was 18%. A distinct pattern was found in RMSE values between the curves, as shown in Figure 12b.



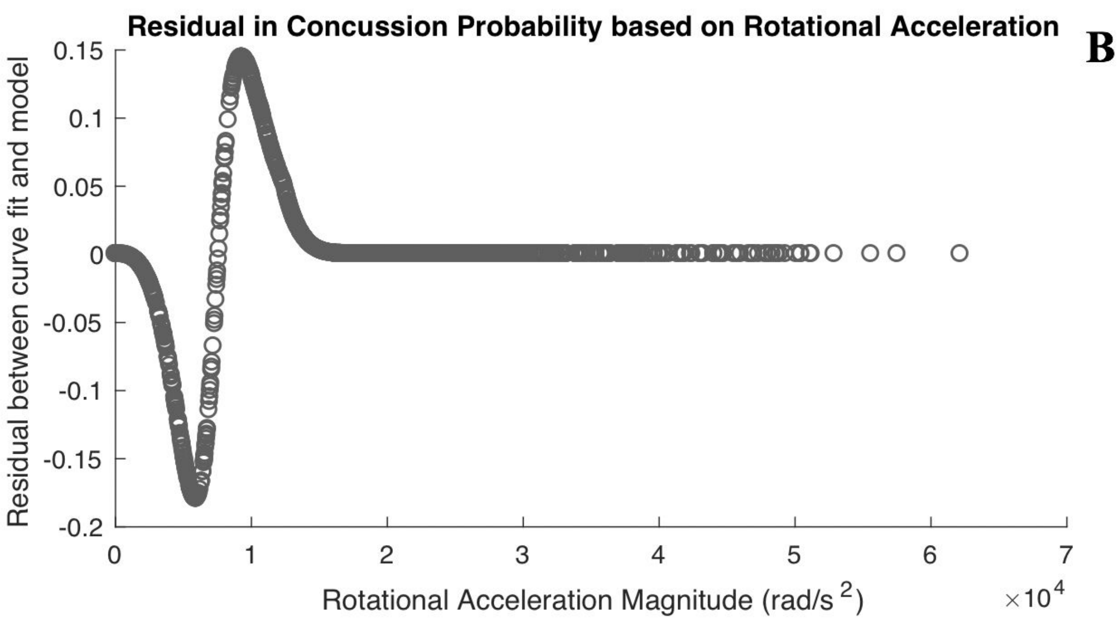


Figure 15: Concussion probability based on rotational acceleration magnitude from generated data for curve-fit and model. (A) 1000 samples randomly generated from probability density functions were used to calculate concussion probability based upon a model and curve fit. (B) Residuals from this data plotted as a function of acceleration show a higher degree of correlation between the curves for very high and low accelerations and a varying degree of correlation for accelerations resulting in concussion probabilities in between 0 and 1. Average RMSE (root mean square error) between the two series for this simulation was 0.064, or 6.4% of the possible output range, and maximum RMSE was 0.18, or 18%.

ii. Introduction of Noise and Propagation of Error

A plot of concussion probability based on the resultant magnitude of angular acceleration for the original model and curve fit results along with the results with up to ± 5% error introduction in acceleration is shown in Figure 13. Average RMS error in the result between the original and noisy data for was 0.016, or 1.6% for the curve fit and 0.012, or 1.2% for the model.

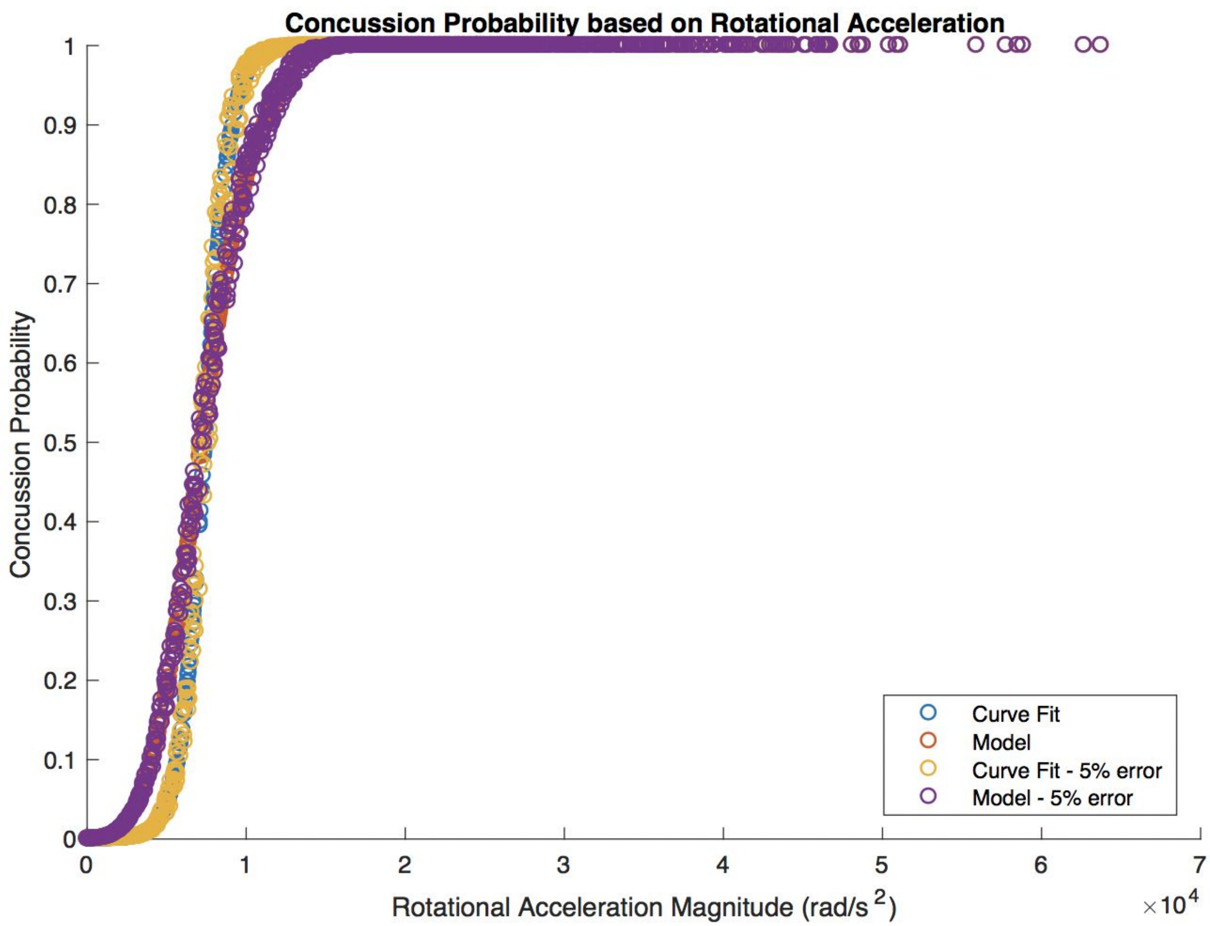


Figure 16: Concussion probability based on rotational acceleration magnitude for curve fit and model with ± 5% acceleration noise introduced. Error was randomly introduced within ± 5% by scaling the accelerations at each data point by a random number between 0.95 and 1.05. RMSE between the original and "noisy" data in the resulting concussion probabilities was 1.6% for the curve fit and 1.2% for the model.

iii. Timing

The runtime of the model for 1000 data points was 104 seconds and for the curve fit was 10.4 milliseconds. Figure 14 shows a plot of runtime of the model based on dataset size for dataset sizes of 1 to 30 in increments of 1. A linear fit was determined as shown in Equation 6 for small data sizes, which was used to calculate an approximate maximum sampling frequency for the model to run in real time of 7.5 Hz.

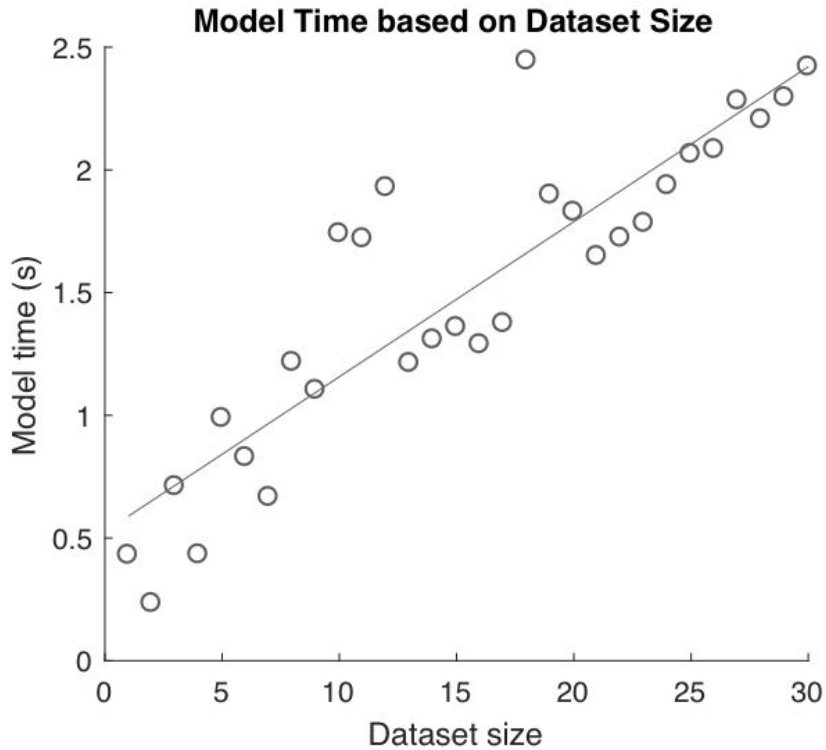


Figure 17: Runtime of model and curve fit for various dataset sizes. The model and curve fit were timed using the *tic* and *toc* functions in MATLAB in order to generate the timing data. Results of timing for dataset sizes of 1 to 30 in increments of 1 were plotted as a function of data size, and *polyfit* and *polyval* were used to determine a linear fit of y = 0.063x + 0.53, with an R^2 value of 0.787.

8.0 Conclusions and Recommendations

8.1 Recommendations

For future prototypes, a different attachment mechanism would be more effective at ensuring the device stays attached to the helmet. Glue is strong but weak in shear, and experienced high shears during impacts and failed. Alternatives include drilling through the helmet casing with screws into a manufactured metal plate containing the accelerometer with similar curvature to the helmet, and manufacturing the entire metal casing with a space for the accelerometer. Screwing through the casing might cause helmet failure, so it would be optimal to manufacture the whole helmet with accelerometer integration in mind.

8.2 Conclusions

8.2.1 Conclusions based on Impact Test

One conclusion that can be drawn based on the impact test is that the device withstood a maximum linear acceleration of 75.9 g's in impact testing, based upon data collected from the motion cameras. Although the specifications for the device require that the device withstand impacts up to 300 g's, the team found it impractical to design a testing fixture that could deliver a 300 g impact, as the existing testing fixture already was constructed of 6 foot 2x4's, and the fixture had to be moved through standard doors pre-assembled. One future direction for testing of this device is to determine a way to test the viability of the design and sensor to 300 g's. This may involve a larger testing fixture, larger weights, or a combination of the two.

One observation from the impact tests was that each impact only produced approximately one large value of acceleration from both the accelerometer and camera data sets, as shown in the figure visually demonstrating the impact curves. This begs the question: is the frequency of data collection sufficient to accurately reconstruct an acceleration curves for short impact durations as would be experienced in a concussive impact? The average duration of a concussive impact is 6 ms [18], so by the Nyquist theorem, data must be sampled at half of that duration, or 3 ms. However, the data collected from the accelerometer device is sampled at approximately every 20 ms, which is significantly greater than the maximum duration of 3 ms needed to accurately reconstruct the curve. The data collected from the motion cameras was sampled every 6 ms, which is improved from the accelerometer collection, but still insufficient to accurately reconstruct a concussive impact. The effect of undersampling for both camera and accelerometer data is that "peak" acceleration values obtained for both data sets may be significantly less than the actual peak acceleration. Since there was greater undersampling in the accelerometer, this effect would be more pronounced for the accelerometer data, leading to the accelerometer peak values being significantly less than the camera results, and thus leading to the need to use an additive correction factor. Based upon this observation, one suggestion for future study is obtaining an accelerometer that can sense and transmit data at less than 3 ms in order to accurately reconstruct concussive impact.

An additional observation from the impact test was that the zip tie attachment mechanism failed catastrophically in the middle of testing, with the device falling completely out of the helmet. Although zip ties should never be a permanent solution, this further reinforced the need for a more robust attachment mechanism. As such, CAD was drawn for a potential future improvement for the attachment of the device to a helmet, as shown below in Figure 15.

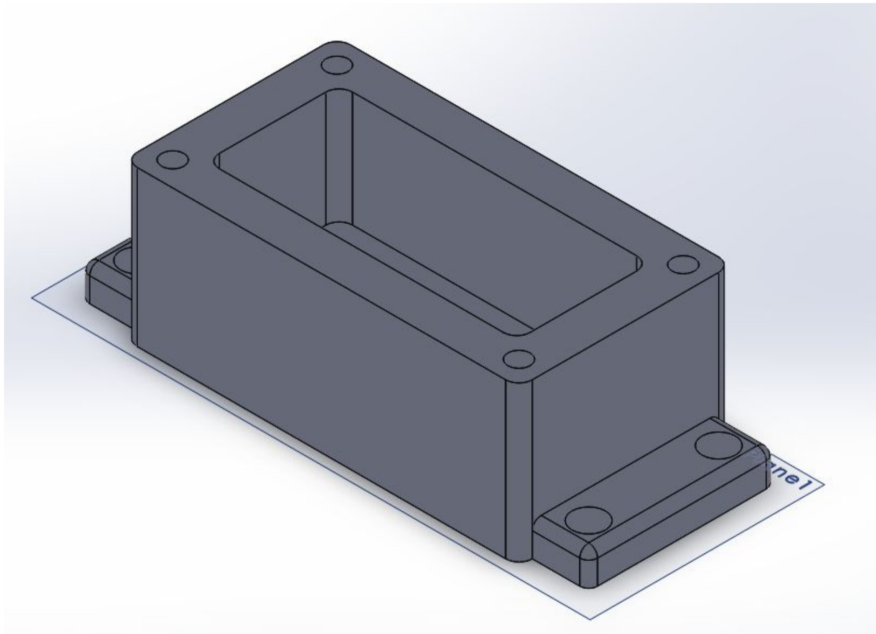


Figure 18. Modified accelerometer case with mounting flanges. The extended flanges on left and right side of the case will allow for a more secure attachment mechanism between the case, accelerometer and helmet. The flange dimensions are: 42mm x 12.7mm x 7.5mm with two 7.5mm diameter holes centered at the top and bottom of the flange.

Improving the design of the metal case will allow for the case to be in direct contact with helmet. Screws and washers will be used to distribute the applied load. The case will be attached to the helmet through existing slits in the helmet. The dimensions of the flanges are subject to change with respect to the helmet in use, which can be viewed in Figure 16. This particular method will also minimize shear stress failure by using four screws and washers rather than the gorilla glue and zip ties.

This method is not a final means and testing after prototype production will be required before it can be available to users.

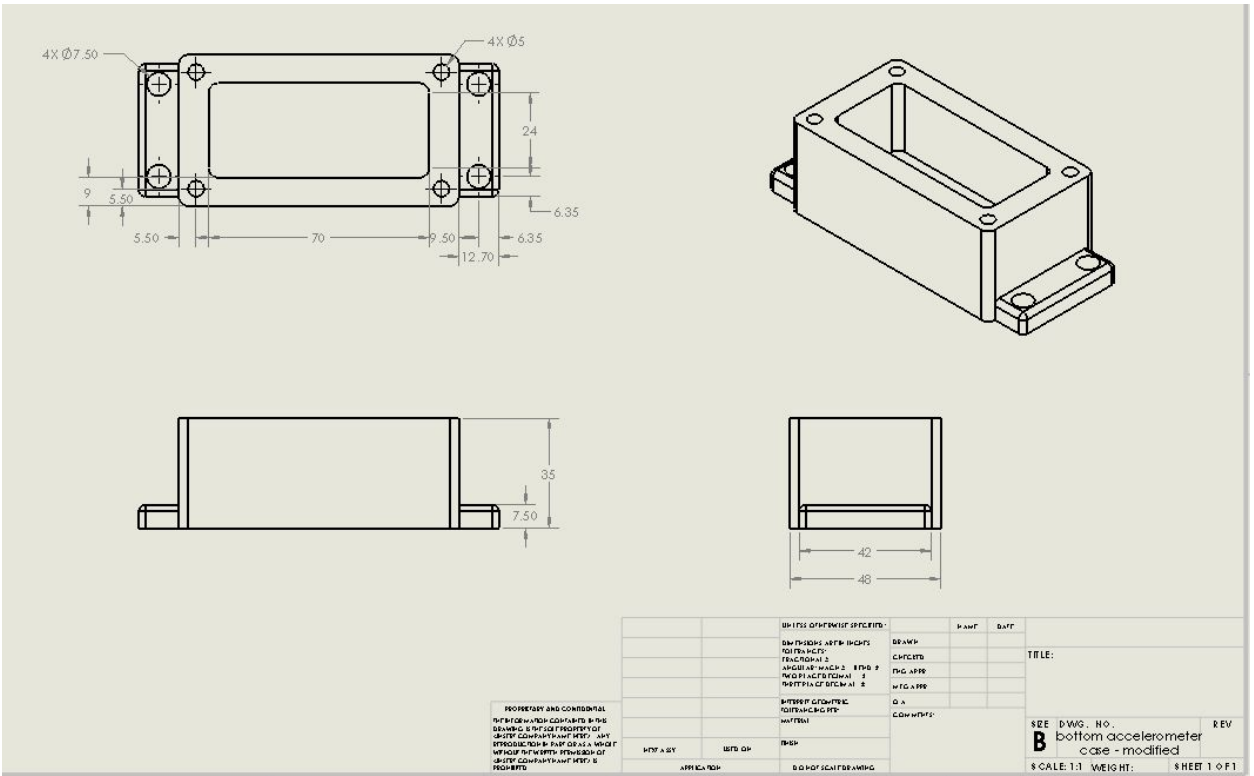


Figure 19. Drawing of the Modified Accelerometer Case. The flanges on the accelerometer case are subject to change depending on the helmet used in application.

8.2.2 Cost Assessment

The specifications require that the device adds less than 10% cost to the helmet, which would be $35 assuming a helmet price of $350. The cost to manufacture a single device is $107.64; $99 for the accelerometer, $6.62 for the waterproof case, and $2 for putty. Therefore, this prototype does not meet the cost specification. One future direction is to manufacture an accelerometer device from less expensive parts, such as a tri-axial accelerometer, gyroscope, bluetooth module, microcontroller and A/D converter. Purchasing components separately and wiring them on a custom circuit board may help decrease the cost of the accelerometer from $99 to a cost that comes closer to meeting the specification.

8.2.3 Weight Assessment

The specifications require that the device adds less than 10% weight to the helmet, or 0.3 lbs. However, the waterproof case alone weighs 0.32 lbs, and the accelerometer and putty add weight to the device, making the prototype not meet the weight requirement specification. A future direction is finding a way to waterproof the device which does not add significant weight.

8.2.4 Conclusions based on Range Test

As the range of the device in its aluminum case was found to be 20.5 m, this would likely be insufficient to wirelessly collect data in a football game in practice. A standard football field is rectangular, with a length of 109.1 m and a width of 48.5 m. Therefore, even if the data receiving device was placed in the center of the football field (which would be impractical), the devices on players would regularly lose connection with the receiving device. Additionally, when the device loses the Bluetooth connection, the pairing process must be performed again, which takes time and requires the device to be in close proximity to the receiver. Therefore, based upon range, the device would be impractical for use in a football game. One suggestion for future direction is add a micro-SD card to the device instead of providing a Bluetooth connection. Then, the micro-SD card could be used to offload data after the game. This design would minimize the risk of loss of data due to Bluetooth disconnection. However, one drawback of this design is that it does not allow for the potential of real-time data collection.

8.2.5 Conclusions based on Software Simulation

The multi-component model accuracy, error propagation, and run time were tested in this study and compared to those of the empirically derived curve-fit. The curve-fit and model were found to produce different curves to correlate acceleration data to probability of concussion as seen in Figure 4. Although the root mean square error (RMSE) between the model and curve fit was relatively low at 6.4% of the possible range of output values, there was a distinct pattern in the error between the models, shown by Figure 4b. This showed that the models were well-correlated for very low or high rotational acceleration magnitudes but varied in degree of correlation up to 15% error between the model and curve fit for rotational acceleration magnitudes around 1e4 ± 5e3 rad/s^2. This correlation may still be sufficient for some applications, given that the application for this model would likely be in concussion indication as opposed to concussion diagnosis, which must be performed by a medical professional. If indication is made in 33% increments (concussion probability of 0-33% = low risk, 34-66% = medium risk, 67-100% = high risk), 15% error would be less than half of the increment size.

The simulation performed to show error propagation given noise in acceleration data within 5% of the original acceleration value showed relatively low RMS error values in the resulting concussion probabilities for both the model and curve fit – 1.6% of the possible output range for the curve fit and 1.2% for the model. This shows that the model is slightly less sensitive to noise in data than the curve fit.

The timing simulation showed that run time for the model was relatively linear (with a linear fit given by Equation 6) and was approximately four orders of magnitude greater than the run time of the curve fit. The increase in computation time between the curve fit and the model is likely due to the mathematical complexity of the model, which requires solving two systems of ordinary differential equations, creating an acceleration time function and performing many simple calculations, while the curve fit only performs a single calculation. The impact of the difference in computation time between the model and curve fit is seen in the sampling frequency. The maximum sampling frequency for the model is 7.5 Hz, while that of the curve fit is orders of magnitude greater. The average duration of a concussive impact is 6 milliseconds [18], so the Nyquist Theorem suggests sampling at half of that period, or 3 milliseconds, in order produce accurate results. This demonstrates that the 7.5 Hz sampling frequency necessary for the model to produce accurate results in real time is insufficient considering the low duration of concussive impacts. The curve fit, however could easily compute results every 3 milliseconds, or at approximately 333 Hz.

An additional consideration in comparing the model and curve fit is the input data to each function. The inputs to the model are peak rotational acceleration about each axis and the duration of the impact, and the inputs to the curve fit are peak rotational acceleration magnitude and peak linear acceleration magnitude. Additionally, the model could be modified by omitting the first step which converts rotational acceleration to axial strain in order to input a time-varying strain function into the model. These differences in input values could also govern the ability of the model and curve fit to perform for various applications. For example, if pressure sensors (which can be used to find strain) were used as opposed to accelerometers to collect data, it would be inappropriate to use the curve fit but would be sensible to use the modified model with strain input to calculate concussion probabilities.

Thus, choosing between the model and curve fit in an experimental setting would likely depend on the logistics of the experiment. For wide indication increments, the model would be appropriate but, due to up to 15% error rates between the model and curve fit, the curve fit would be more appropriate for more narrow indication increments. Noisy data may necessitate use of the model, which showed lower error rates given noise in the inputs. The need to make computations in real time would render the curve fit more appropriate due to the high computation time of the model and low duration of concussive impacts. Finally, the inputs available from the experimental data may govern the choice between the model or curve fit.

Future research related to this study could include a simulation that derives correlation coefficients of each of the primary model of curve-fit inputs – linear acceleration, rotational acceleration about each axis, and impact duration – to concussion probability. This would determine the relative importance of each input, which could be used to analyze the validity of the assumption made in the tissue-response step of the model that linear acceleration can be neglected when predicting concussion outcome

9.0 Acknowledgments

We would like to acknowledge our sponsors Dr. Michael Whitt and Dr. Chris Heylman for overseeing our project, and Dr. Self and the students in his biomechanics lab for assisting us in testing our device accuracy.

10.0 Appendices

10.1 Appendix A: References

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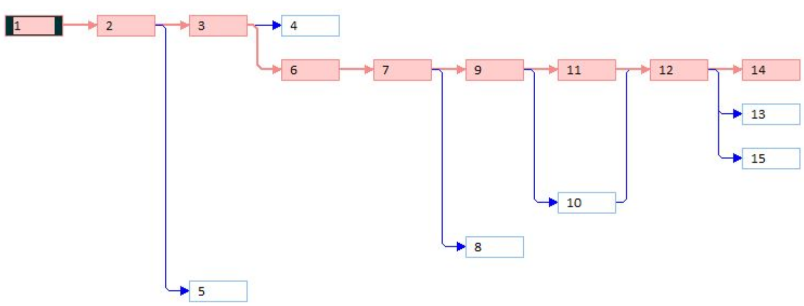
10.2 Appendix B: Project Plan (PERT Chart)

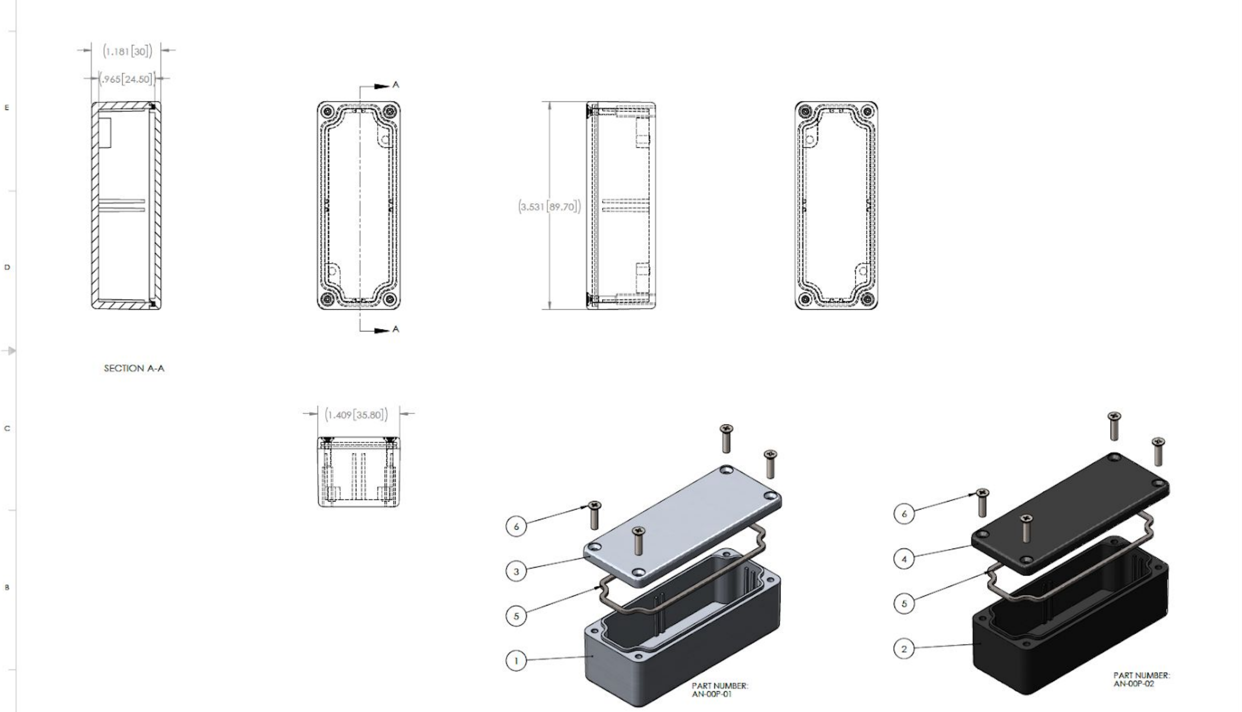


Indications for Use	3 days	Mon 10/1/18	Wed 10/3/18	
Project Specification Matrix	2 days	Thu 10/4/18	Fri 10/5/18	1
Hazard and Risk Assessment	2 days	Mon 10/8/18	Tue 10/9/18	2
Introduction to Sponsor	2 days	Wed 10/10/1	Thu 10/11/18	3
Conjoint Analysis	4 days	Mon 10/8/18	Thu 10/11/18	2
Sponsor Meeting #1	1 day	Wed 10/10/1	Wed 10/10/1	3
Design Experiments	2 days	Thu 10/11/18	Fri 10/12/18	6
Front-runner House of Quality	4 days	Mon 10/15/18	Thu 10/18/18	7
Pugh Chart	3 days	Mon 10/15/1	Wed 10/17/1	7
Helmet Attachment Design	14 days	Thu 10/18/18	Tue 11/6/18	9
Software and Hardware Design	16 days	Thu 10/18/18	Thu 11/8/18	9
Final Prototype	32 days	Fri 11/9/18	Mon 1/14/19	10,11
Risk Reliability and Safety	4 days	Tue 1/15/19	Fri 1/18/19	12
Quality, Robustness and Optimization	5 days	Tue 1/15/19	Mon 1/21/19	12
Economic Decision	3 days	Tue 1/15/19	Thu 1/17/19	12

10.3 Appendix C: CAD Drawings

I. Waterproof Case Drawing

BOM Table							
ITEM NO.	PART NUMBER	Rev.	Description	Material	Color	AN-00P-01/QTY.	AN-00P-02/QTY.
1	AN-00BP-01	-	BASE	ALUMINUM ADC12	NATURAL	1	-
2	AN-00BP-02	-	BASE	ALUMINUM ADC12	BLACK	-	1
3	AN-00C-01	-	COVER	ALUMINUM ADC12	NATURAL	1	-
4	AN-00C-02	-	COVER	ALUMINUM ADC12	BLACK	-	1
5	GASKET-100-01	-	GASKET	SILICONE	GRAY	1	1
6	SCREWS-033-4	-	M3X0.5 X12mm FHMS 4-PACK			1	1



REV.	DESCRIPTION	ZONE	BY	APPR'D	DATE
REVISIONS					

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN: INCHES[mm]
TOLERANCES: ANGULAR: ±2°
TWO PLACE DECIMAL: ±.010
THREE PLACE DECIMAL: ±.005
PRINTED GRAPHICS: ±.010

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CAD FILE: AN-00P

PART NO.
AS NOTED

MATERIAL

FLAME RATING
-

	NAME	DATE
DRAWN	D.M.F.	11/14/2016
CHECKED	C.C.B.	12/27/2016

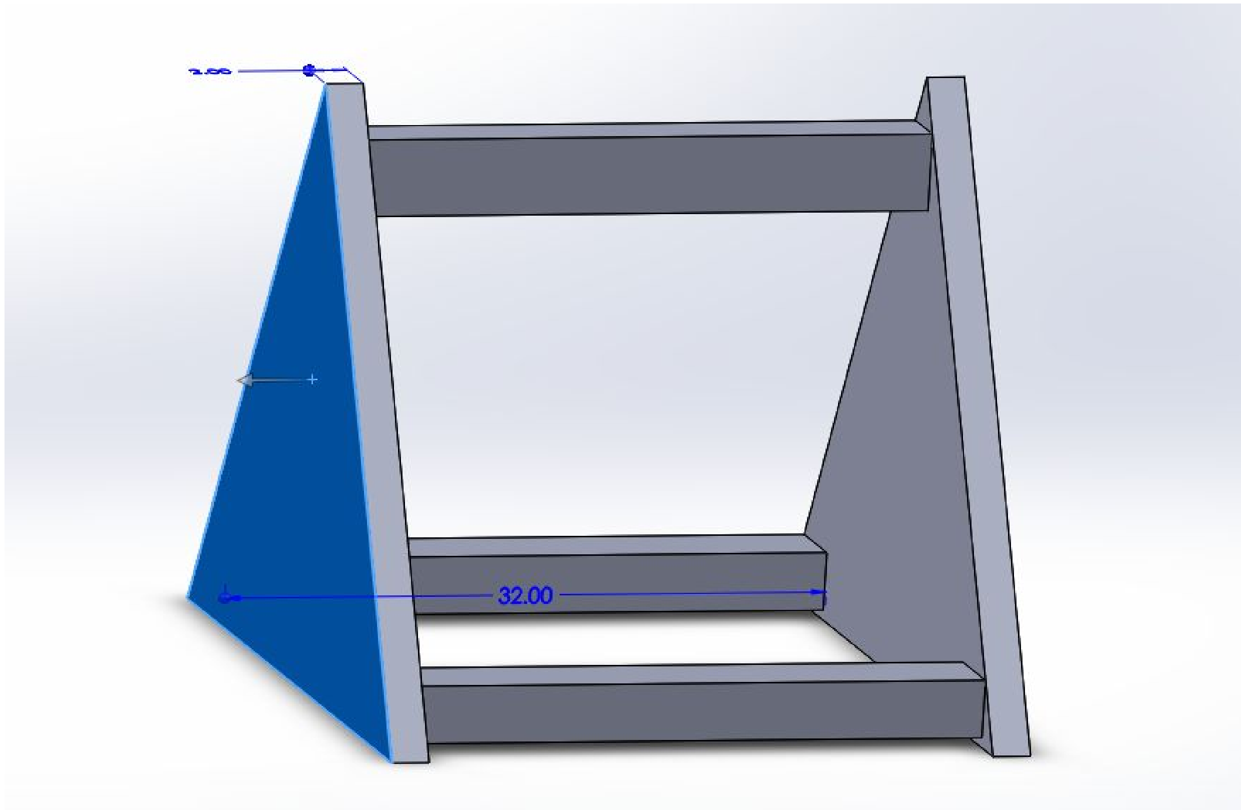
SIZE C

REV -

SCALE: 1:1

SHEET 1 OF 1

Pendulum Impact Tester



10.4 *Appendix D: FMEA, Hazard & Risk Assessment*

FMEA

Component Name	**Possible Failure Mode**	**Type**	**Cause of Failure**	**OCC**	**DET**	**SEV**	**RPN**	**Effect of Failure on System**	**Failure Improvement Alternative Actions (actions to fix the problem)**
Attachment Mechanism	Shearing	Mechanical	Excessive shear stress	3	1	3	9	Inaccurate sensor readings due to mispositioning	Secure device to helmet to minimize shear stress incurred

	Moveme nt / sliding	Mechani cal	Poor adhesion /attachm ent between the device and helmet	4	1	3	12	Moveme nt of the device would result in accurate readings	Use an alternativ e adhesion /attachm ent method to ensure minimal moveme nt of the device
	Material degradati on	Materials selection	Material is not able to withstan d the excessiv e forces of impact	3	1	3	9	Large impact forces on material would result in a broken device or inaccurat e readings	Substitut e for a high energy absorbin g material
Battery	Insufficie nt voltage productio n	Electrical	Wrong battery type	2	3	2	12	Sporadic and inconsist ent readings	Choose correct battery
	Excessiv e voltage productio n	Electrical	Wrong battery type	1	3	4	12	May cause injury to patient; Potential to short the devices/s ystem & result in system failure	Choose correct battery
	Excessiv e heat	Electrical / materials selection	Battery chemical malfuncti on	1	2	5	10	Potential to short the devices/s ystem & result in	Choose a well-rate d battery

								system failure	
Accelerometer	Inaccurate readings	Calibration	Incorrect device calibration	3	3	3	27	Increase in error of device readings	Calibrate the device according to standard protocol before each use
	Inconsistent readings	Electrical	Insufficient precision of accelerometer	2	3	3	18	Increase in error of device readings	Choose an accelerometer with the appropriate desired precision
	No readings	Electrical	Electrical short	1	2	5	10	Inability to collect data	Set up circuitry to protect accelerometer from too much current
Bluetooth module	Inability of sender to connect to receiver	Computational / Electrical	Code failure or bluetooth failure of receiver	2	2	3	12	Inability to view data for unknown duration	Improve code robustness and select long-range receiver
	Inability of receiver to connect to sender	Computational / Electrical	Code failure or bluetooth failure of sender	2	2	3	12	Inability to view data for unknown duration	Improve code robustness and select long-range sender

	No connecti on	Computa tional / Electrical	Bluetoot h failure	2	2	2	8	Tempora ry inability to view data	Select long-ran ge bluetooth transmitt er
Display	No battery power	Electrical	Battery failure of smart phone or other bluetooth display device	1	1	2	2	Tempora ry inability to view data	Select a display device with a good battery or charge device while in use
	No connecti on	Computa tional	Bluetoot h failure	2	1	2	6	Tempora ry inability to view data	Select long-ran ge bluetooth
	Applicati on crash	Computa tional	Segment ation fault, or other unrecove rable error	2	1	2	4	Tempora ry inability to view data	Focus on code robustne ss and error handling

Hazard and Risk Assessment

Description of Hazard	Planned Coercive Action	Date to Complete
The device will constantly experience high accelerations due to head-on collisions with other helmets during football games and practices.	The device must be properly padded and protected to withstand the large forces being placed on the helmet and dissipate the force across the entire device	11/14/18
There will be a small battery in the device to power the electrical	The battery enclosure must open unless intended, and the electrical systems must	11/14/18

system.	be insulated appropriately	
The system will be subjected to many weather conditions such as fog, rain, heat, and cold	There must be appropriate separation between the electrical system and the exterior of the helmet, with electrical and thermal insulation as well as a physical barrier in which water cannot cross	11/14/18

10.5 Appendix E: Pugh Chart

Selection Criteria	Concepts		
	Benchmark (Design 1)	Design 2	Design 3
Alteration of shape	DATUM	S	S
Accuracy of measurements		+	–
Structural Integrity		S	S
False Positives		–	+
Cost		S	S
Weight		S	S
Battery Replaceability		S	S
Result Viewability		S	S
Withstand high impact forces		–	–
Player Injury		+	–
# of Pluses		2	1
# of Minuses		2	3

10.6 Appendix F: Vendor Information, Specifications, and Data Sheets

Accelerometer: https://www.vernier.com/files/manuals/gdx-acc/gdx-acc.pdf
Casing: https://www.polycase.com/uploads/3481482947857.pdf

10.7 Appendix G: Budget

Item Description	Product Number	Purpose	Associated Task	Planned				
				Unit	Quantity	Cost/Unit	Total Cost	Notes
Strain Gauge with A/D converter	CN_DG	Strain measurement	Electronics Implementation	EA	20	$1.25	$25	Buy in sets of 4
Battery	406-ASR00008 (Mouser)	Power	Electronics Implementation	EA	5	$7.47	$37.35	
Development Board with BLE module	485-2479 (Mouser)	Bluetooth communication	Electronics Implementation	EA	5	$17.50	$87.50	
Solderless Breadboard	854-BB830 (Mouser)	Electronics Development	Electronics Implementation	EA	3	$8.80	$26.40	
Helmet Liner	3K1B0SO	Materials characterization	Materials Testing	EA	1	$49.99	$49.99	
Accelerometer	912-KX220-1071 (Mouser)	Acceleration Measurement	Electronics Implementation	EA	20	$1.45	$29.04	Buy in sets of 10
Head dummy	N/A	Materials and mechanical testing	Mechanical testing	EA	1	$19.99	19.99	https://www.amazon.com/dp/B0171OMRWG/ref=sspa_dk_detail_5?pd_rd_i=B0171OMRWG&pf_rd_m=ATVPDKIKX0DER&pf_rd_p=f52e26da

								-1287-4616-824b-efc564ff75a4&pf_rd_r=AXAD6BNAJ5RQD11QYFFA&pd_rd_wg=1GdWl&pf_rd_s=desktop-dp-sims&pf_rd_t=40701&pd_rd_w=tcrOc&pf_rd_i=desktop-dp-sims&pd_rd_r=6887a12c-cf12-11e8-b42b-1db580407759&th=1

10.8 Appendix H: DHF

10.8.1 Preliminary Testing Plans

Currently, testing is not in the immediate future. Prototyping and project buildings need to be created first before testing can be executed. However, it is known that drop tests and simulated force testings will be performed on the helmet and devices. These tests will occur on the campus of California Polytechnic State University - San Luis Obispo, specifics are still to be determined.

10.8.2 IFU

The IFU is provided in **Section 3.1**.

10.8.3 Project Plan

Initially, the goal was to produce a product in which a football helmet had the capabilities to detect and notify the user when a concussion had been sustained by the individual wearing the device. However, it was concluded that the overlying issue that is being addressed is in regards to the individuals head rather than the helmet. This realization also resulted in design changes for the device. There are currently three design concepts which can be found in **Section 6.2 - Evolution of Prototypes**.

Based on the three prototypes, the necessary equipment will be purchased such as: the transducers, a swim cap, accelerometers, breadboards, and strain gauges. The extensive list of all of the items to be purchased can be found in **Section 10.7 - Budget**.

Taylor is in charge of testing and acquiring all of the necessary materials for testing and prototyping. Isabel is in charge of configuring the instrumentation. Eric is in charge of the engineering specifications for the prototypes. Each team member has a set of responsibilities that need to be completed on their own, however there are many aspects that will be done as a team. The team will continue to remain in contact with one another, ensuring that all deadlines are met and to keep one another updated on the status of their assignment. Two additional individuals will also kept in the loop, the team sponsors: Drs. Heylman and Whitt. In-person meetings with the sponsors occur once every two to three weeks, however both sponsors are easily available via email.

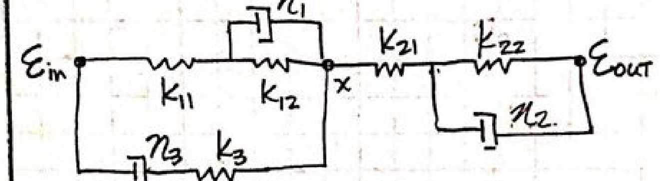
10.8.4 Preliminary Build Plans

At this current moment in time, no set build plans have been created aside from beginning the prototyping stage. The primary step is acquiring all materials and ensuring that the team has access to all necessary tools, equipment and funds that are needed in order to execute the desired prototype ideas. Once the materials have been acquired, the team will gather to begin working on the prototyping together and staying up-to-date on the status of such activities.

10.9 Appendix I: Link to MATLAB scripts for testing

All source code is available at https://github.com/Isabel-0000/concussion_model

10.10 Appendix J: Viscoelastic Micromechanics Model for the Axon



$$\sigma_{in} = \sigma_x = \sigma_{OUT} = \sigma_{\eta 3} + \sigma_{K11}$$
$$= \sigma_{K3} + \sigma_{K11}$$
$$= \sigma_{\eta 3} + \sigma_{K12} + \sigma_{\eta 1}$$
$$= \sigma_{K3} + \sigma_{K12} + \sigma_{\eta 1}$$
$$= \sigma_{K21}$$
$$= \sigma_{K22} + \sigma_{\eta 2}$$

(1) $\varepsilon_{in} + \varepsilon_{K11} + \varepsilon_{K12} + \varepsilon_{K21} + \varepsilon_{K22} = \varepsilon_{OUT}$
(2) $\varepsilon_{\eta 3} + \varepsilon_{K3} = \varepsilon_{K11} + \varepsilon_{K12}$
(3) $\varepsilon_{K12} = \varepsilon_{\eta 1}$
(4) $\varepsilon_{K22} = \varepsilon_{\eta 2}$

$\sigma = \eta \dfrac{d\varepsilon}{dt}$ FOR A DAMPER

$\sigma = K\varepsilon$ FOR A SPRING

(5) $K_{21}\varepsilon_{K21} = \eta_3 \dfrac{d\varepsilon_{\eta 3}}{dt} + K_{11}\varepsilon_{K11}$

(6) $= K_3\varepsilon_{K3} + K_{11}\varepsilon_{K11}$

(7) $= \eta_3 \dfrac{d\varepsilon_{\eta 3}}{dt} + K_{12}\varepsilon_{K12} + \eta_1 \dfrac{d\varepsilon_{\eta 1}}{dt}$

(8) $= K_3\varepsilon_{K3} + K_{12}\varepsilon_{K12} + \eta_1 \dfrac{d\varepsilon_{\eta 1}}{dt}$

(9) $= K_{22}\varepsilon_{K22} + \eta_2 \dfrac{d\varepsilon_{\eta 2}}{dt}$

SUB DAMPERS INTO SPRINGS IN EQS 5,7-9 USING EQS 2-4, 6

$\varepsilon_{K12} = \varepsilon_{\eta 1}$ $\qquad$ $\varepsilon_{K3} = \varepsilon_{K11} + \varepsilon_{\eta 1} - \varepsilon_{\eta 3}$

$\varepsilon_{K22} = \varepsilon_{\eta 3}$ $\qquad$ $= K_{21}\varepsilon_{K21} - K_{11}\varepsilon_{K11}$

$\varepsilon_{K11} + \varepsilon_{\eta 1} - \varepsilon_{\eta 3} = K_{21}\varepsilon_{K21} - K_{11}\varepsilon_{K11}$

$K_{21}'\varepsilon_{K21} = + \varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+K_{11})\varepsilon_{11}$

$\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + \varepsilon_{11} = \eta_3 \dfrac{d\varepsilon_{\eta 3}}{dt} \rightarrow \varepsilon_{11} = \eta_3 \dfrac{d\varepsilon_{\eta 3}}{dt} + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}$

$\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + \quad \varepsilon_{11} = K_3(\varepsilon_{K11} + \varepsilon_{\eta 1} - \varepsilon_{\eta 2})$

$\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+K_{11})\varepsilon_{11} = \eta_3 \dfrac{d\varepsilon_{\eta 3}}{dt} + K_{12}\varepsilon_{\eta 1} + \eta_1 \dfrac{d\varepsilon_{\eta 1}}{dt}$

$\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+K_{11})\varepsilon_{11} = K_{22}\varepsilon_{\eta 3} + \eta_2 \dfrac{d\varepsilon_{\eta 2}}{dt}$

$$(i)\quad \varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1-k_3)\left(\eta_3 \frac{d\varepsilon_{\eta 3}}{dt} + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}\right) = k_3(\varepsilon_{\eta 1} - \varepsilon_{\eta 2})$$

$$(ii)\quad \varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+k_{11})\left(\eta_3 \frac{d\varepsilon_{\eta 3}}{dt} + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}\right) = \eta_3 \frac{d\varepsilon_{\eta 3}}{dt} + k_{12}\varepsilon_{\eta 1} + \eta_1 \frac{d\varepsilon_{\eta 1}}{dt}$$

$$(iii)\quad = k_{22}\varepsilon_{\eta 3} + \eta_2 \frac{d\varepsilon_{\eta 2}}{dt}$$

$$\frac{d\varepsilon_{\eta 3}}{dt} = \left(\frac{k_3(\varepsilon_{\eta 1} - \varepsilon_{\eta 2}) + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}}{1-k_3} + \varepsilon_{\eta 1} - \varepsilon_{\eta 3}\right)\left(\frac{1}{\eta_3}\right)$$

$$\frac{d\varepsilon_{\eta 1}}{dt} = \left(k_{22}\varepsilon_{\eta 3} + \eta_2 \frac{d\varepsilon_{\eta 2}}{dt} - \eta_3 \frac{d\varepsilon_{\eta 3}}{dt} - k_{12}\varepsilon_{\eta 1}\right)\left(\frac{1}{\eta_1}\right)$$

$$\frac{d\varepsilon_{\eta 2}}{dt} = \left(\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+k_{11})\left(\eta_3 \frac{d\varepsilon_{\eta 3}}{dt} + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}\right) - k_{22}\varepsilon_{\eta 3}\right)\left(\frac{1}{\eta_2}\right)$$

TO ODE45

FIND ε_{OUT} USING OUTPUT

$$\varepsilon_{k11} = \eta_3 \frac{d\varepsilon_{\eta 3}}{dt} + \varepsilon_{\eta 3} - \varepsilon_{\eta 1}$$

$$\varepsilon_{k21} = \left(\varepsilon_{\eta 1} - \varepsilon_{\eta 3} + (1+k_{11})\varepsilon_{11}\right)\left(\frac{1}{k_{21}}\right)$$

$$\varepsilon_{k22} = \varepsilon_{\eta 2}$$

$$\varepsilon_{k12} = \varepsilon_{\eta 1}$$

10.11 Appendix K: Raw Data from Impact Tests

Available upon request.