Impact Mouthguard Sensor to Detect Real Time Rotational and Linear Acceleration

An MQP Project

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Abstract:

Traumatic brain injuries, otherwise known as TBIs, occur when a force acts upon your head resulting in two forms of acceleration through the skull. These blows are characterized by linear and rotational acceleration. There is currently no prevention for TBIs, but there are treatments to aid the symptoms that go along with the injury. Studies show that the more TBIs that one person obtains, the more severe the damage could be, ultimately leading to CTE which could be fatal. The goal of this project is to produce a device that will measure head impact through a mouthguard sensor that will detect rotational and linear acceleration in real-time. This product can be utilized for any contact or collision sports for youth up to professional athletes. The mouthguard will contain accelerometers and gyroscopes to be able to collect the data, analyze the impact that occurred, and send the data over to parents, coaches, or medical staff on the sideline. The implementation of this device in sporting events of all ages could lead to a reduction in the incidence of additional traumatic brain injuries.

Table of Contents

Chapter 1: Introduction -IB

This project aims to develop a device to help all athletes in contact and collision sports to detect a potential TBI impact that occurs during play and disclose to the player, coach, parent, or trainer on the sideline of the severity of that blow to the head. This device will provide a sense of comfort for parents who are concerned about their children playing a contact sport, or for adult athletes that need to be aware of the head impacts they obtain while playing. Additionally, if the sensor can provide accurate real-time data it can be used for research purposes by the scientific community.

There is a large market of people ranging from youth to professional adult athletes that could significantly benefit from the creation of this mouthguard, with the ability to identify rotational and linear acceleration of the head, in addition to being cost effective and easy for any customer to use. The majority of sports, especially contact sports require the players to wear a mouthguard, so embedding the impact sensors into our mouthguard device will promote proper safety during the game and allow the effects of contact within the sport to be monitored efficiently.

The group hopes to establish a sensor that can provide more to the community without our product costing a large amount more than what is already on the existing market. If this can be done, the group can realistically tap into a growing market with a need for improved technology.

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Chapter 2: Background

Brain injuries are a subject where there are still many unknowns and variables yet to be uncovered. A concussion is a brain injury resulting from a direct or indirect blow to the head, typically resulting in transient neurologic impairment and neuropathologic symptoms (Cleveland Clinic, 2020). Concussions are also known as Traumatic Brain Injuries (TBI). TBIs occur very often during sports, especially when there is contact involved.

2.1 Traumatic Brain Injuries (TBIs)-IB

TBIs are a hurdle that everyone can face in their day to day lives. In 2014 the Centers for Disease Control and Prevention (CDC) conducted a study of TBIs, where about 2.87 million TBI-related emergency department (ED) visits, hospitalizations, and deaths occurred in the United States, including over 837,000 of these health events among children. Falls were the leading cause of hospitalizations among children 0 to 17 years and adults 55 years of age and older; while motor vehicle crashes were the leading cause of hospitalizations for adolescents and adults aged 15 to 44 years of age during 2014. From 2006 to 2014, the number of TBI-related emergency department visits, hospitalizations, and deaths increased by 53%. The CDC projects that TBI contributed to the deaths of 56,800 people, including 2,529 deaths among children (CDC, 2019).

2.1.1 Causes of TBI- IB

Any direct or indirect force to the head will typically result in some form of damage to the brain due to the soft nature of the brain tissue, so it is common to have a TBI. Motor vehicle accidents, falls, and sports injuries are common causes of concussions. Any sport that involves contact can result in a TBI. Among children, most TBIs happen on the playground, while bike riding, or when playing sports such as football, basketball, ice hockey, wrestling, or soccer (Cleveland Clinic, 2020). It is estimated that 1.6 million sports-related traumatic brain injuries occur annually in the United States alone. Thankfully, most are classified as mild traumatic brain injuries (mTBI) and do not result in severe damage to the brain (5). Athletes that decide to participate in collision or contact sports are at a significantly higher risk of receiving a TBI. In 2012, among the 23.6 million US youth athletes who were involved in organized athletics, 19% participated in collision sports, and 57% participated in contact sports (O'Connor, 2017).

From 2005-2006, High School Reporting Information Online (RIO), an internet-based surveillance system conducted a study to record high school sports-related injuries. In the 9 high schools studied over the course of the 2005–2006 school year, 4431 injuries were reported, 396 (8.9%) of which were concussions. This included 137 concussions (34.6%) that occurred in practice and 259 (65.4%) that occurred during competition. These injuries were sustained during the course of 1,730,764 athletic exposures (1,246,499 practice and 484,265 competition exposures) (21).

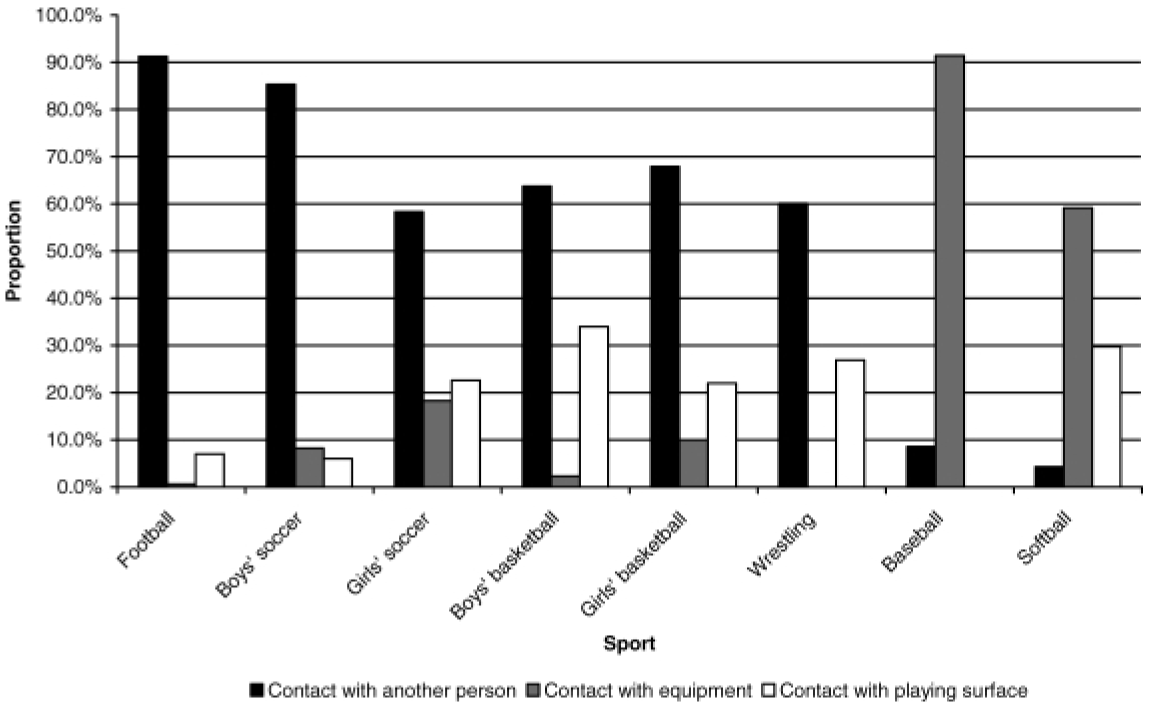


Figure 1: National estimates of the mechanism of concussion by sport for high school athletes

As shown above, in Figure 1, football has the highest chance of receiving a concussion due to contact with another person. Baseball was found to have the highest chance of receiving a traumatic brain injury due to contact with the equipment used in the sport. The study also shows that boys basketball, closely followed by softball has the highest likelihood of getting a TBI due to contact with the playing surface.

2.2 Biomechanics of a TBI - IB

Many different components can play a role in how damage occurs in the brain resulting in TBIs. The motion of the skull during an impact is essential for analyzing a TBI and the damage that is caused. There is considerable evidence showing that the primary cause of concussive injuries is the inertial, or acceleration, loading experienced by the brain at the moment of impact.

With the head/neck motions that occur during a typical impact, there are two components of acceleration that occur in nearly every instance of TBI— linear and rotational acceleration (Meaney, Smith,). Linear acceleration can correlate to pressure within the brain after the impact, as the acceleration increases so does the pressure in the skull. Several studies established that the transient increase in pressure within the brain causes neurologic dysfunction, with the level of dysfunction correlating with the peak pressure achieved during the injury period (Meaney, Smith,).

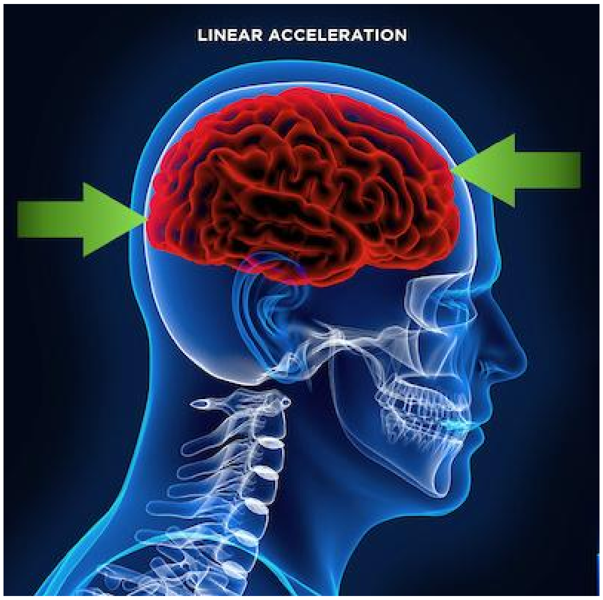


Figure 2: Linear Acceleration (4)

In addition to linear acceleration, the rotational acceleration can occur which ultimately has a different effect on the brain. Instead of causing an increase in pressure to the skull, rotational acceleration causes shear stress on the tissues in the brain. When an athlete experiences a rotational mechanism, it is thought that the rotation of the cerebrum about the brain stem produces a shearing and tensile strains (5). Brain tissue is extremely soft and is subject to deformation upon forces in the skull. With this being said, the brain tissue is very susceptible to shear-induced tissue damage due to the rotational acceleration, where the more rotational force, the more shear and tensile strain produced on the tissue.

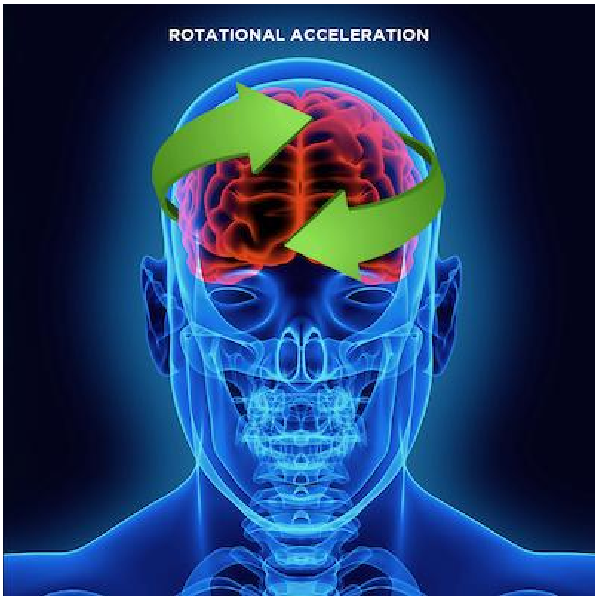


Figure 3: Rotational Acceleration (4)

The linear and rotational acceleration on the skull as shown in Figures 2 and 3 above will cause a buildup of pressure in the skull and shear-induced damage to the brain tissue leading to a TBI. The damage produced also gives rise to neurological and behavioral issues that will last generally based upon the severity of the impact.

Immediately after a biomechanical injury to the brain, abrupt, indiscriminate release of neurotransmitters and unchecked ionic fluxes occur. The binding of excitatory transmitters, such as glutamate, to the N-methyl-D-aspartate (NMDA) receptor, leads to further neuronal depolarization with efflux of potassium and influx of calcium. These ionic shifts lead to acute and subacute changes in cellular physiology (Giza, Hovda, 2001). Any abnormal changes to the patient after the impact is related to chemical changes that occur in the brain. The earliest changes are an indiscriminate release of excitatory amino acids (EAA) and a massive efflux of K^+, triggering a brief period of hyperglycolysis. This is followed by more persistent Ca^{2+} influx, mitochondrial dysfunction with decreased oxidative metabolism, diminished cerebral glucose metabolism, reduced cerebral blood flow (CBF), and axonal injury. Late events in the cascade include recovery of glucose metabolism and CBF, delayed cell death, chronic alterations in neurotransmission, and axonal disconnection. Clinical signs and symptoms of impaired coordination, attention, memory, and cognition are manifestations of underlying neuronal dysfunction, most likely due to some of the processes described above (Giza, Hovda, 2001) and shown in Figure 4 below.

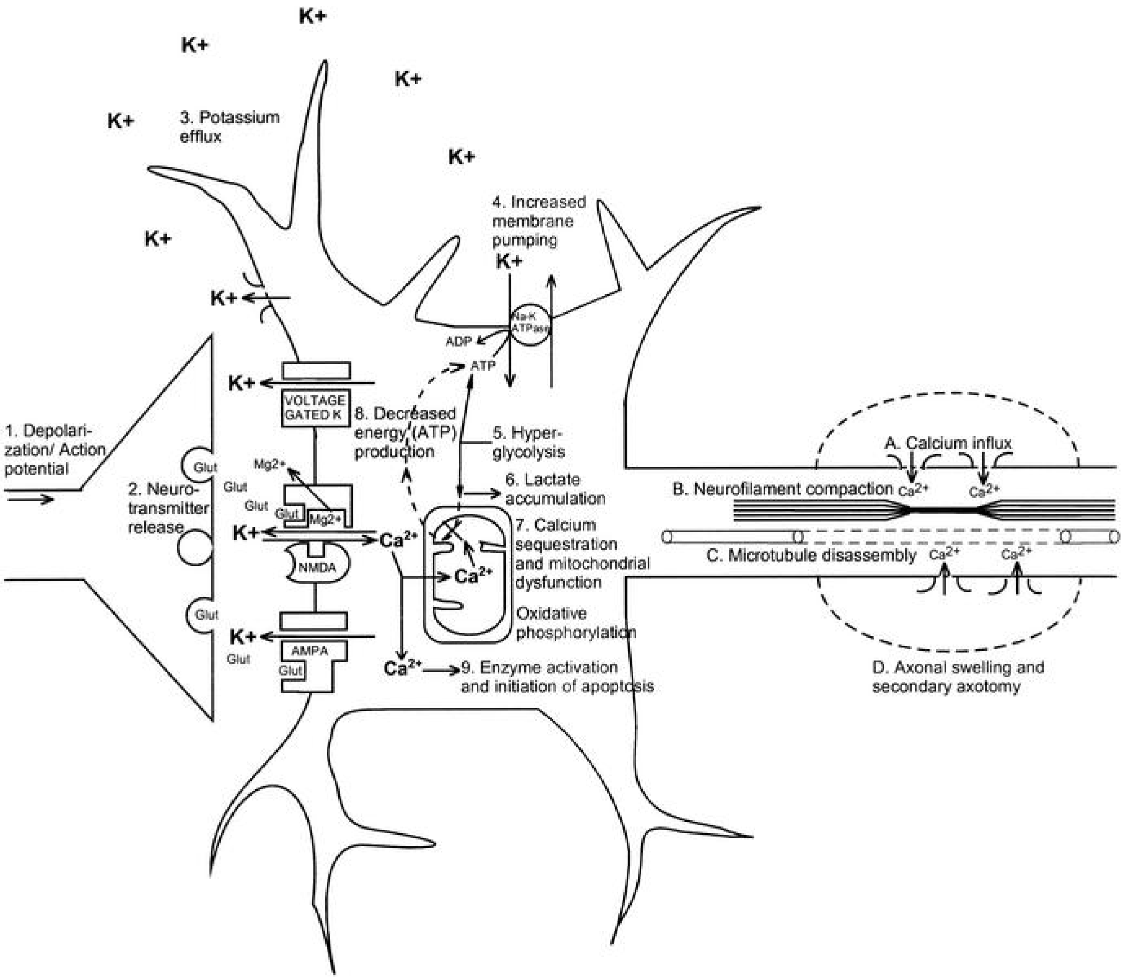


Figure 4: Neurometabolic cascade after a TBI (8)

There is also a chance of severe nerve damage due to the pressure and strain produced inside the skull from the impact that occurs. The cerebrospinal centres consist of the brain, or encephalon, contained within the skull, and the spinal cord, contained within the vertebral canal. The brain is in relation more or less directly with the periphery, by which is meant all the organs of receptivity and activity, by means of thirty-one pairs of spinal, and twelve (or, according to English anatomy, nine) pairs of cranial nerves. In addition to the cranial nerves, the spinal nerves are connected with the word by two roots; the one of which, the efferent or motor arises from the anterior or ventral aspect; the other, the afferent or sensory, from the posterior or dorsal aspect of the cord (Ferrier). The brain is the location in which most nerves originate eventually leading to damage to potentially many different nerves impairing motor or sensory functions.

2.2.1 Analyzing Impact - ZX

To quantify concussion injury, it is important to evaluate the feasibility of one of them instead of using full degrees of freedom accelerations. According to the previous study, Figure 5 below shows the simulation of strain levels for measuring full degrees of freedom accelerations, isolated rotational acceleration, and isolated linear acceleration in four different views of head:

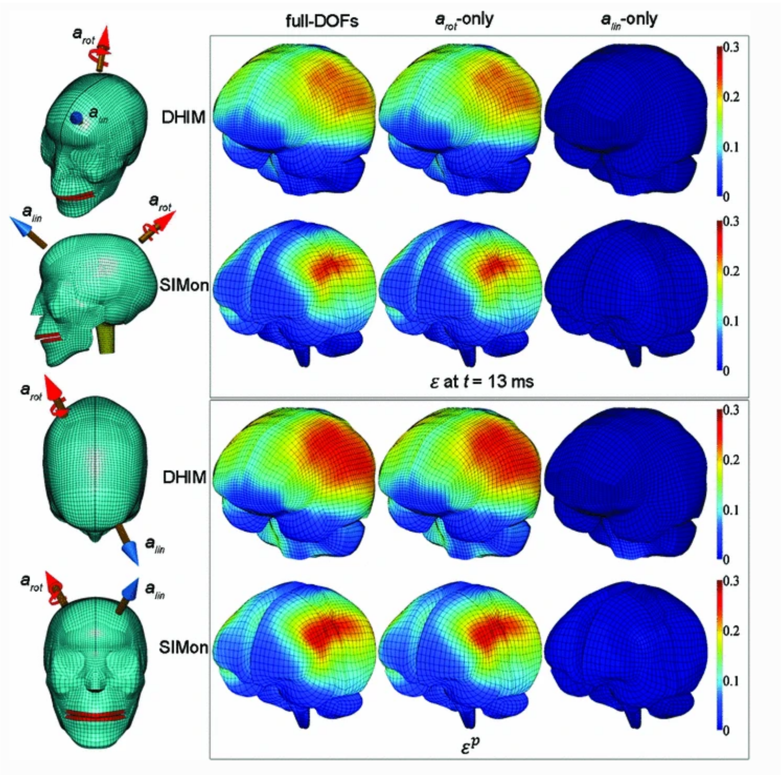


Figure 5: Comparisons of strain components for full-DOFs, rotational acceleration only and linear acceleration only in the four views (22)

As a result, the magnitude and duration of rotational acceleration components were suggested to assess regional brain value strain level and then to quantify the risk of this injury. The widely used metrics Wayne State Tolerance Curve (WSTC) and Head Injury Criteria (HIC) are not accurate enough since they measure injury severity based on the magnitude and duration of linear acceleration. The equation of Power Rotational Head Injury Criterion (PRHIC) is a suitable metric for quantifying concussion by angular acceleration. This equation was created based on the equation of Head Injury Power (HIP). Both equations are listed below:

$$\mathrm{HIP} = \sum m \cdot a_i \cdot \int a_i dt + \sum I_{ii} \cdot \alpha_i \int \alpha_i dt$$

Where *m* is mass of the head (kg), *a i* is linear acceleration (m*s^2), *I ii* is the moment of inertia (MOI) (kg*m^2), and *α i* is angular acceleration (rad*s^2) when the head is assumed to be a rigid body. Considering inertial properties of mid-sized males, the coefficient of mass is 4.5 kg, and those of MOI for *x*, *y*, and *z* directions are 0.016, 0.024, and 0.022 kg*m^2, respectively.

$$\mathrm{PRHIC} = \left[(t_2 - t_1) \left\{ \frac{1}{(t_2 - t_1)} \int_{t_1}^{t_2} \mathrm{HIP\_rot}\, dt \right\}^{2.5} \right]_{\max}$$

Where t1 and t2 are the initial and final times. (Kimpara, Iwamoto, 2012)

Finite element (FE) models of human heads have been widely used in the field of injury biomechanics of TBI. In recent years, numerous FE head models have been developed enormously that they can simulate realistic geometries, reliable material properties, and detailed anatomical structures. These models can provide rich information about responses from brain tissues that cannot be measured directly. Therefore, a well-sophisticated head injury model will be used in this project to provide brain response for injury analysis as secondary research. An effective response sampling is essential for making the best use of FE models. The two most widely used metrics are Peak Maximum Principal Strain (MPS) and cumulative strain damage measure (CSDM).

2.2.2 Symptoms of a TBI- IB

Impacts to the head cause a combined linear and angular acceleration of the skull. These accelerations result in transient pressure gradients and strain fields within the soft tissue of the brain. If the pressure gradients or strains exceed the tolerable limits of the brain tissue, injury occurs (Cleveland Clinic, 2020). It is difficult to truly understand and study the effects of an impact on the brain because impacts affect every person differently. An impact of the same force induced on two people can result in different symptoms for one and other symptoms or possibly no symptoms at all for the other person. Another essential component to causing TBIs is the rotational acceleration of the skull. Rapid head rotations generate shear forces throughout the brain, and, therefore, rotational accelerations have a high potential to cause shear-induced tissue damage (Meaney, Smith,).

As previously stated, symptoms can vary from person to person. The most common symptoms after an impact to the head include headaches, nausea or vomiting, confusion, sensitivity to noise or light, balance issues, dizziness, and changes to your sleeping patterns. More severe symptoms include loss of consciousness (greater than 1 minute), severe headaches, seizures, bleeding from the ears, severe dizziness and loss of balance, numbness in the legs or arms, and unusual behaviors (CDC,). The location of the impact is also important to be able to link the symptoms of the patient to injuries they ensued. Different areas of the brain control different functions, so blows to your head can predict your symptoms. A TBI to the back of the brain causes balance issues, fogginess, neck pain, and difficulty concentrating. These symptoms usually predict a longer recovery from a concussion (CDC,). More severe damage to the brain can result in a long recovery time or may result in permanent symptoms that will not go away. TBIs can be very serious and should be properly taken care of.

2.3 TBI Awareness and Long-Term Impacts - ZX

Physiological treatment is important in TBI patients in their mental and physical conditions. Chronic Traumatic Encephalopathy (CTE) and Post-Concussion Syndrome (PCS) are two extensions related to a long-term TBI's impacts. CTE is a neurodegenerative disease associated with TBIs over a long period of time, especially if they are not recognized or adequately treated. Clinical features of CTE show years or even decades after the initial TBI. Symptoms include the jeopardization in mood (depression), behavior (violence), cognition (memory impairment), and motor functioning (weakness). In confirmed cases of CTE, 90% occurred in athletes (McKee, Cantu, Nowinski, 2020), such as in American football, boxing, hockey, soccer, and rugby. Treatment is usually based on lessening the impact of the symptoms on day-to-day functioning and includes therapies and medication. (Stein, Alvarez, McKee, 2015) However, CTE has a heterogeneous clinical presentation. Some people who suffer from frequent repetitive mTBI do not show CTE symptoms, while others experience early quick progression of CTE. Currently, CTE can only be diagnosed through histopathological analysis postmortem after athletes sign agreements to donate their brains for research. It is not practical to perform an autopsy on every athlete under mTBI. There are only 153 confirmed cases of CTE by neuropathological criteria from 1954 to 2013, while study has found that 80% of examined athletes' brains develop symptoms of CTE. (Stein, Alvarez, McKee, 2015)

PCS occurs when the following concussion symptoms persist over three months: Fatigue, sleep disturbance, headache, dizziness, irritability, affective disturbance. These symptoms can present at different times and at different levels of intensity. Fifteen percent of mTBI patients will suffer from PCS, and a small minority of those patients will experience persistent PCS requiring further evaluation and treatment. Treatment of PCS is individualized to each patient's situation. (Permenter, Fernandez, Sherman, 2020) Both diseases progressed over decades with increasing abnormalities in behavior and personality. Therefore, it is essential to design a sensor measuring the concussion in order to alarm people in the beginning.

2.4 Analysis of Current Sensors - KP

Today’s impact sensor market is one that is filled with various options. Some of the devices on the market have clear and distinct advantages over others, and when developing a new device it is important to know what is and is not important when it comes to the functionality of an impact sensor. These various impact sensors consist of helmets, mouthguards, headbands, and even ear and skin patch design concepts that can be used in various sports. It is important to note that all of these devices can detect impact in some form, but only some are able to gather important scientific data that can be used in research and future studies.

Helmet-based impact sensors are currently an extremely viable option for anyone interested in using an impact sensor in a sport such as football or hockey. An example of a helmet that is leading the way is Riddell’s HITS Device shown in Figure 6, which is even being used in soccer, snow sports, and boxing on top of football and hockey (O’Connor, Rowson, Duma, Broglio,). According to Riddell’s website, the device is able to fit six single-axis accelerometers inside of a helmet. Having an accelerometer inside of the device is extremely advantageous because of what it can calculate. An accelerometer can calculate static forces, the continuous force of gravity, and even acceleration which is extremely important in identifying a potential concussion. The sensor in the helmet is able to gather data from 8ms before and 32ms after impact meaning there are about 40ms of acceleration data available to evaluate from each impact. From this period of data, the sensor is able to gather linear and rotational acceleration (Riddell,). Being able to gather rotational acceleration straight from the sensor is an incredibly valuable insight to identify a potential concussion if a threshold is passed on the rotational acceleration.

Figure 6: Riddell HITS Device

Another option on the market currently are mouthguard based sensors, more specifically the group analyzed the Biometrics Vector Mouthguard shown below in Figure 7. This mouthguard uses an ESP to determine the location and impact of each blow to the head. The Biometrics Vector Mouthguard also uses accelerometers similar to Riddell’s HITS Device. However, the mouthguard also uses a gyroscope and microprocessors that are able to give real-time decisions to the user on whether or not they should stay in the game and play or be removed from the game (Densford, 2016).

Figure 7: Biometrics Vector Mouthguard (17)

The X2 impact mouthguard shown in Figure 8 is an additional impact sensor specifically instrumented with a triaxial accelerometer and gyroscopes as well, samples linear acceleration at 1kHz and 800 Hz during impact(Patton, 2016). The mouthguard is able to then generate a calculation for angular acceleration through the interpretation of angular velocity(Patton, 2016). Mouthguards are an interesting option in the market because it could feasibly be used in every sport that is played to detect concussions. With that being said, there are some concerns currently with its drawbacks. There have been developing issues with mouthguards and their accuracy, or lack thereof. Since the mouthguard is inside of someone's mouth there is a concern in research that the saliva potentially leads to damage to the sensor and there is concern the sensor may trace impacts that are non-significant and will eventually need to be filtered out.

Figure 8: X2 Impact Mouthguard Sensor (16)

Following the group began to dive into sensors that were either headbands or patches attached to helmets. An option for this on the current market is the “Brain Sentry” device shown in Figure 9 which is intended to be attached to a helmet. Unfortunately compared to the competitors in the industry, the Brain Sentry does not have the same computation power. It is able to alert the user when there is a rapid acceleration or deceleration in the brain and show how many impacts there have been in a day, week, month, etc (Riddell). In theory, the Brain Sentry is a good idea, but there is no feasible way to scientifically argue that it is a quality device.

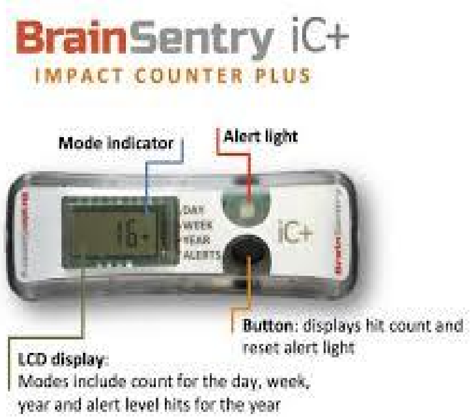


Figure 9: Brain Sentry Impact Sensor (MomsTeam,)

The last group of devices that were analyzed by the team were ear and skin patches. More specifically the group looked into the Xpatch Head Management System which monitors head impacts with an intention to study cumulative brain damage (Rains, 2016). The Xpatch can operate on a six-degree-of-freedom that measures linear acceleration, rotational velocity, HITsp, and impact locations (Rains, 2016). Unfortunately, rotational acceleration can not be directly calculated by the sensor, but can be through mathematical analysis. The Xpatch additionally has a six-hour battery life and needs to be charged before each use

Figure 9: Xpatch Head Management System

2.4.1 Comparison Charts: - KP

The following Table 1 is a Pairwise Comparison chart, the purpose of this chart is to objectively compare the user needs against each other to assign overall weights to how important the team considers each objective.

This is accomplished by the team deciding collaboratively what the user needs are and discussing which the team considers more important by assigning 1 for more important and 0 for less important. The sum of these numbers in the right-most column is the overall weight of that user need. The weighting is important when taking into consideration which design concept to develop and the ways the team will go about developing it.

Table 1: Pairwise Comparison Chart:

	Rotational Velocity	Rotational Acceleration	Force of Impact	Comfortability	Linear Acceleration	Linear Velocity	Cost Effective	**Total**
Rotational Velocity	x	0	1	1	1	1	1	**5**
Rotational Acceleration	1	x	1	1	1	1	1	**6**
Impact Tracking	0	0	x	1	1	1	1	**4**
Comfortability	0	0	0	x	0	0	1	**1**
Linear Acceleration	0	0	0	0	x	1	1	**2**
Linear Velocity	0	0	0	1	0	x	1	**2**
Cost Effective	0	0	0	0	0	0	x	**0**

The ranking of each user needs was determined to be in this order from most important to least important: Rotational Acceleration (6), Rotational Velocity (5), Impact Tracking (4), Linear Acceleration (2), Linear Velocity (2), Comfortability (1), Cost Effective (0).

The reason for Rotational Acceleration being the highest weighted user need is because rotational acceleration is a sound way to calculate for a potential concussion or TBI, which is the sensor's main function. Rotational Velocity followed as the second highest because it can be used to calculate rotational acceleration through mathematical equations and analysis.

Cost Effective was ranked last with 0 as a score because the group is currently on a constraint of $1000 budget ($250 each member). The team will work on this budget during the MQP Project, therefore the team decided that other design needs would be placed ahead of cost effectiveness.

The following Table 2 is a Pugh Comparison chart, the purpose of this chart is to rank the existing designs on the market against each other based on how the options are able to meet the user needs ranked above. This is done to avoid any complications resulting from a bias towards a certain design concept. The selection was carried out by the team collaboratively by looking at each user's need and design concept. The team then assigned a value depending on how well it could reach the user's need being assessed. A score of 1 would be given if the design could reach a desired need and a score of 0 was given if the design was not able to satisfy a need. The sum of the numbers in the bottom comes to add up the overall weight of the sensor being assessed. The higher the value, the more the team felt that it could reach the user's needs.

Table 2: Pugh Comparison Chart

	Weight	Helmets	Mouthguards	Patch	Headband
Rotational Velocity	5	1	1	1	0
Rotational Acceleration	6	1	1	0	0
Impact Tracking	4	1	1	1	1
Comfortability	1	1	1	1	1
Linear Acceleration	2	1	1	1	0
Linear Velocity	2	1	1	1	0
Cost Effective	1	0	1	1	1
Total	**21**	**18**	**19**	**15**	**6**

2.5 Material Selection - KP

The material selection process is a very important part of the equation in developing a quality impact sensor. There are various mechanical properties that make up a well made mouthguard that is effective in use. The group has determined a criteria of properties that is believed to be important in developing a mouthguard, these include biocompatibility, high elasticity, high hardness, stiffness, water absorption, tensile strength, and tear strength (Knapik, 2007) . It is important to understand that no one material will have favorable properties for all of these criterias, but there is certainly a most well-suited material to choose from.

In a mouthguard, elastic properties are extremely important to the effectiveness. Elasticity of the copolymer determines how well the mouthguard will absorb the impact energy of a blow or impact (Westerman, Stringfellow, Eccleston, 1997). If the elastic limit of the copolymer was to be exceeded, it would result in permanent deformation or rupturing of the material and mouthguard. Biocompatibility is extremely important to a mouthguard for obvious reasons as it will always be inside of the mouth of the user. The user can not afford to have a negative reaction to the material or even have potential toxins released into their body because of the mouthguard's material. Hardness of a material is how well the material can resist localized deformation when subject to a force. This is important because when developing a mouthguard you do not want the mouthguard becoming deformed immediately after any serious impact or force has occurred on it. Hardness can be related with elasticity, if a material has a high elasticity this means it returns to its normal shape after being stretched or compressed better than other materials. It is often found as the elasticity of a material increases, the hardness increases along with it meaning the two are proportional together. The stiffness of a material is important because it is indicative of the protective capability (Knapik, 2007). The tensile strength of a material measures how much force is required to pull the material apart until failure, while the tear strength is indicative of how durable the material is (Knapik, 2007). Lastly, water absorption was chosen as a criteria for obvious reasons, the sensors inside of the material can't be impacted by any liquid as the user will be drinking liquids consistently when playing sports and he will be producing large amounts of saliva inside of his mouth.

Currently, the most commonly used materials for a mouthguard are ethylene vinyl acetate (EVA), polyvinyl chloride, latex rubber, acrylic resin, and polyurethane. However because the more modern materials listed above can be easily manipulated to have favourable properties there is no clear superior material (Knapik, 2007). Based on this research the cost effectiveness of the materials must come into consideration as well, because the group is on a $1000 budget. With the budget being considered it would be best for the group to use EVA copolymer as it is the cheapest of the materials listed above. If the EVA proves to be lackluster and fails, the group can reevaluate their standards and rechoose from one of the materials listed above.

The group could also potentially improve the product more by using a pressure laminated mouthguard, which would improve shock absorption and stress distribution (Kosinski,). Additionally, pressure laminated mouthguards are of the highest dental fit there is, they are layered to to give a high quality fit and protection. With the pressure laminated mouthguard, nothing will have to fundamentally change and it can just be an addition to benefit the user as it only improves the device and allows for the same level of breathing and talking as a normal mouthguard.

2.5.1 Accelerometers - KP

Accelerometers are electromechanical instruments that have the ability to measure forces by the change in velocity over time. These forces that are measured can be dynamic, such as vibration, movement, or a static-like gravity. They can be used together accurately in a wide range of applications and can be specifically used to analyze linear and rotational acceleration or velocity forces as these are the forces that contribute to significant blows.

In today's market, there are currently three different types of accelerometers that are available for commercial use. The three types consist of a Capacitive MEMS accelerometer, a Piezoresitivie accelerometer, and a Piezoelectric accelerometer. These three types of accelerometers all have different qualities and downsides to them, so it is crucial that the group evaluates them properly to ensure the correct type is being used for the project. Another important aspect is the group needs to use a DC response accelerometer. This is because a DC response accelerometer is required for shock applications in which you are looking to integrate the acceleration data for velocity or displacement as well (1).

The first type of accelerometer is a Capacitive Micro-Electro-Mechanical System (MEMS) which is a fabrication of technology that is used to create accelerometers. MEMS is important because it has led to lower manufacturing costs and smaller sizing of accelerometers. MEMS are commonly used in surface mount devices (SMDs), phones, and other retail electronics because of their small size or low pricing. Capacitive MEMS are DC coupled which means it is well suited for measuring low-frequency vibration, motion, and steady acceleration. However, there are distinguished disadvantages of this accelerometer. It has a poor signal to noise ratio, limited bandwidth, and is restricted to smaller acceleration levels.

Another type of accelerometer is a piezoresistive accelerometer. These operate on a DC-Response accelerometer, this is advantageous for the group's goals as the DC-response has the properties that excel in areas that the group will be experimenting in. The piezoresistive accelerometers have an extensive bandwidth that allows for them to be used for measuring short duration (high frequency) shock events i.e. a blow to the head while playing a sport. The piezoresistive has the ability to measure down to zero hertz (hZ). This type of accelerometer is best for impact and impulse testing.

2.5.2 Gyroscopes - KP

Gyroscopes are instruments that maintain their orientation and angular velocity. They are able to contain an axis, frame, rotor, and gimbal. The device is able to assume orientation by itself, when rotating the axis is unaffected by tilting or rotation. They are now able to electronically compact into micro-packaging to use in electronic devices.

2.5.3 Arduino - KP

An Arduino is an open-source hardware and software company that designs a wide variety of single-board microcontrollers and kits to help the project and user community that they promote. Arduinos are designed with controllers and microprocessors that allow the user to modify them in a way that fits their needs. The Arduino has input and output pins that allow for expansion to a variety of electronic devices, breadboards, and even other circuits. Many people who use the Arduino utilize these boards and create open code to reach their specific requirements. This makes the Arduino an ideal choice for the group to pair with the accelerometers to gather data from.

Chapter 3: Methodology

3.1 Initial Client Statement - KP

The initial client statement given by the project holders was to create a device that can better track and acquire data from blows to the head. To do this the group needs to use impact kinematics such as velocity and acceleration of the brain and the deformation that occurs from this. The intent of this is to develop a device that can identify when these kinematics occur at a higher level than can cause brain damage or injury to a person.

3.2 Design Requirements (Technical)

3.2.1 Objectives - IB

Athletes who participate in contact sports currently need a device that can detect impact in real-time with accuracy that a player may encounter in games or practice. Having this impact information and location of the blow can help medical professionals better assess and diagnose possible concussions. Devices that are currently on the market have large error rates and complications arise such as skin motion or movement of a helmet independent of the impact. The mouth guard will allow for minimal outside complications to occur when collecting data due to the fact that the arch of the teeth couple with the skull to obtain the impact on the skull. The concept of a mouth guard allows athletes from all different sports to utilize this device in comparison to a helmet or patch. An easy to understand with little to no training device is ideal to ensure that the customers are getting correct results. The mouth guard aims to be cost-effective and available for athletes of all ages, youth to professional leagues.

3.2.2 Constraints - IB

There are certain parameters and constraints that our device must follow to ensure our product is safe and works efficiently. The accelerometer and gyroscope used in the device needs to be small enough to fit the dimensions of the mouthguard, but also give reliable results upon impact. The device needs to record impact with an error percentage of less than 5% to ensure that the information being documented is accurate. The data needs to use Bluetooth to transfer from the mouth guard to an app that will display the linear and rotational acceleration values. The display of the data and the overall usability of the device should be easy for the coaches, trainers, or parents to be able to understand the results without a major medical background. The battery life of the mouth guard needs to last well beyond the duration of a game or practice and be easily recharged. It is important that the device is able to withstand high forces of impact, as well as high-temperature resistance when the mouth guard is boiled. The mouth guard is in the athlete's mouth which means that the device needs to be waterproofed to guarantee there are no issues with the electrical system that is within the mouth guard.

3.2.3 Functions and Specifications - IB

The goal of our team's device is to accurately measure force impacts that are experienced during a course of an athletic event through a mouthguard. There is a link between TBIs and concussions when experiencing severe enough blows to the head. A key function of the device will be to alert the user if there is an impact above a certain threshold that is classified as "severe". This is to help ensure that there are serious impacts that remain going unnoticed in the future of sports.

Because the device is related to the public health of people, it will need to be approved and meet the standards of the Food and Drug Administration's Center for Devices and

Radiological Health (CDRH). The CDRH ensures the public has confidence that their health and safety are ensured whenever a product is approved and meets their standards.

Outside of these main specifications, the group still has functions it aims to create for the device. This device has to be high speed and effective in order to quickly and accurately alert those on the sideline of a potential injury. The data that is delivered via Bluetooth to the app will be easy to read and interpret to be able to take any necessary precautions. An interesting aspect of our device is the fact that we do not change the overall design of the mouthguard itself so it will not interfere or add discomfort for the user. The fact that the design stays consistent with that of a normal mouth guard, there will not be that much added to the device cost-wise. The device will be easily charged, but will also have a battery life long enough to last a game or practice. The device will be able to ensure that the results that are being transferred via Bluetooth to the app are within 95% accuracy to eliminate any poor data from being transported. Below are some of the crucial specifications for our device:

- High speed device with Bluetooth capabilities
- User-friendly interface
- Withstand regular forces upon impact
- No alterations to mouth guard design
- Low amount added to price compared to a normal mouthguard
- Simple and easy charging process
- Device is able to determine impact with 95% accuracy

3.3 Design Requirements (Standards)

3.3.1 Engineering Standards - KP

As the design process has gone along, the group has identified current engineering standards that need to be met in order for our device to reach safety requirements, minimum performance, is repeatable, and can interact with other standards-compliant equipment that is used along with it. The engineering standards the group identified as important to be followed were software standards related to CAD file and their creation, the ASTM International Standards for testing of materials, the Institute of Electrical and Electronics Engineers standards for the computer and electronic equipment, and then lastly the FCC regulations for wireless devices and data transmission.

The group currently understands that it does not have specific requirements. However, as the team enters the testing phase there will be more specific outlines that will be updated to be specific to our device's design.

The team has found a patent of mouthguard that can determine physiological conditions of a subject and systems. The following design methods are great examples for the team during modeling.

3.3.2 Functions and Specifications - ZX

The mouthguard can comprise a U-shaped element with an outside wall, the inner sidewall, and at least one biting surface. These structures should cooperate with at least one channel configured to receive the upper teeth of the subject. The channel can be formed from a mold of the subject. When in use, the mouthguard should be tightly fitted to the upper teeth and gums of the subject and can be configured for loose engagement with the lower teeth of the subject.

The mouthguard can be able to comprise a plurality of measurement assemblies operatively associated with the U-shaped element. Each electrode of the plurality of electrodes can be configured for a contact with a portion of the mouth of the subject. It is contemplated that the electrodes can be secured to the inner sidewall of the U-shaped element by a spring or other conventional coupling means such that the pressure is maintained between the electrodes and the gums of the subject. Electrodes can also be secured to the outer side wall of the U-shaped element using conventional means. There are three distinct locations at which the electrodes and the measurement assemblies are positioned can correspond to:

1) A position just outside the right molars of the subject

2) A position just outside the left molars of the subject

3) A position just in front of the central incisors of the subject

The plurality of measurement assemblies of the mouthguard can comprise a plurality of accelerometers. The accelerometers can comprise MEMS accelerometers. MEMS accelerometers should be provided on a chip. The mouthguard can optionally comprise nine single-axis accelerometers which are able to measure linear acceleration in a single axis at the three distinct locations with a cluster of three at each location. Alternatively, three three-axis accelerometers can also be used with one at each distinct location.

The disclosed mouthguard can comprise one or more hard acrylic materials formed over a cast made from impressions of the subject's teeth and gums and hard and soft palate according to conventional methods. It can comprise one or more thermoplastic materials heated by an infrared heating lamp and be vacuum formed. The thermoplastic materials can be softened in hot water and then placed in the upper teeth of the subject. The electrodes, sensors, accelerometers, and processing circuitry should be configured to withstand temperatures far above the boiling point of water and can easily survive such a fitting.

3.4 Revised Client Statement - KP

Now, the client statement is more focused on the objectives stated above. The device is now aimed to gather real-time data that can be evaluated to determine if someone may or may not experience a blow to the head. The device needs to be accurate enough so that the data can be trusted by professionals, and has to be cost effective to the group's budget.

3.5 Management Approach - IB

In order to stay on task and track our performance, the team has created a gantt chart to organize the project goals. The gantt chart can be seen below in figure 10 with all of our progress up to date.

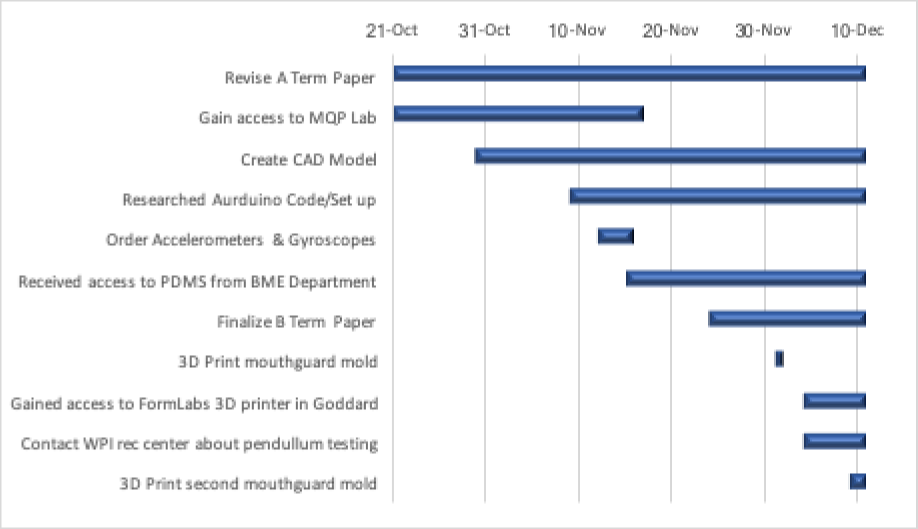


Figure 10: B Term Gantt Chart of Goals and Objectives

Chapter 4: Design Process

4.1 Needs Analysis - KP & IB

The group took an early initiative in our design process to focus on an analysis that was based on the design criteria. This was done to create a quantitative way to see what factors were more important than others. From this, the group created a Value Factor Analysis shown in figure 11, which allowed the team to determine the weight of each variable being assessed, and then the weight is multiplied by the value assigned in terms of satisfaction met. The features were separated into three separate types. These types were quality features, convenience features, and cost components.

Quality features were defined by any feature that was taken into consideration during our design princess. It represents how efficient the device is and how it is manufactured.

The important quality features are as follows:

1. Device Accuracy (Less than 5% Error)
2. Weight
3. Size (Dimensions)
4. Manufacturability
5. Extreme Conditions Capability (Within the mouth)
6. Strength
7. Lifespan (Reusable)
8. Real-Time Results

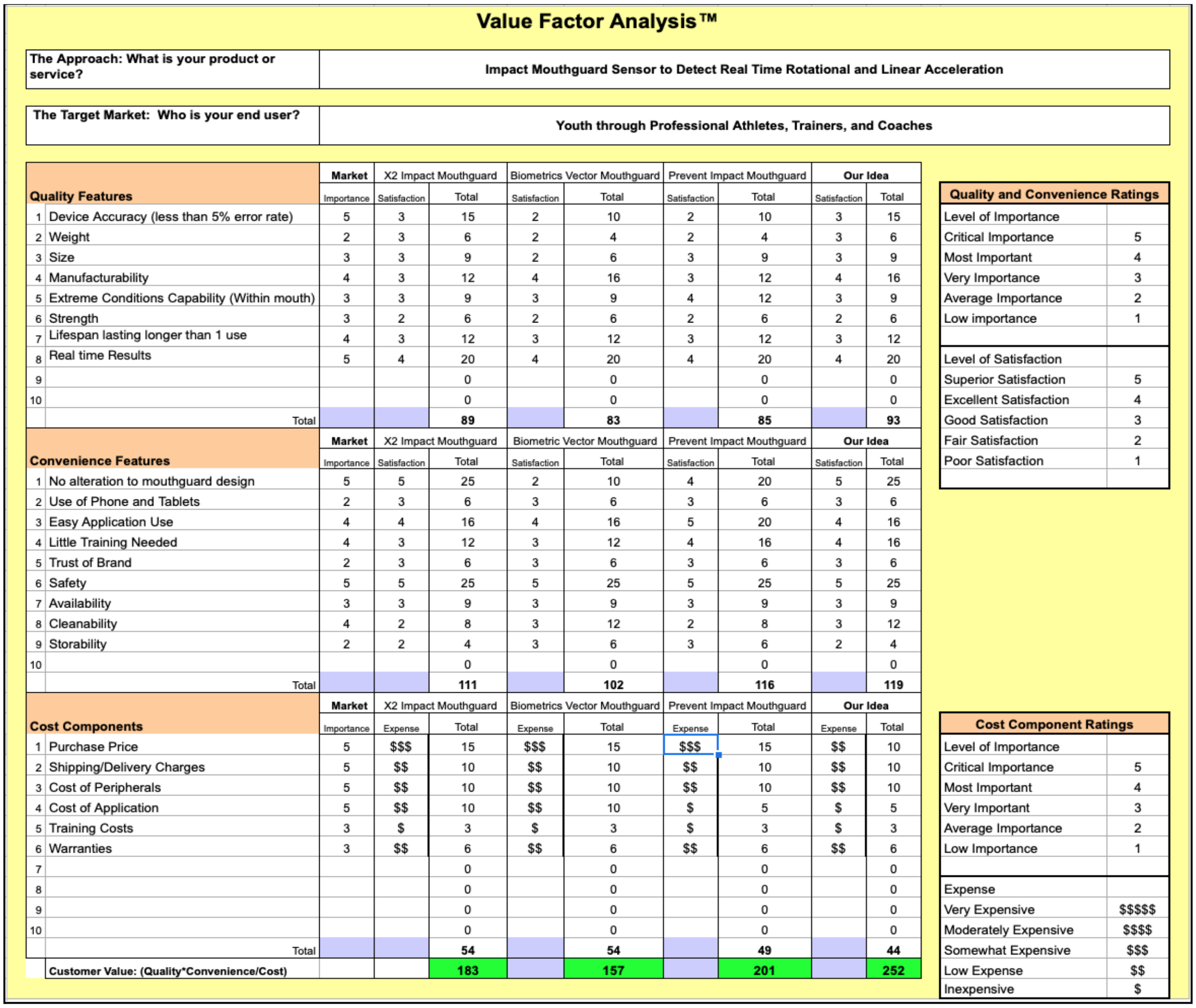
The Convenience Features as follows:

1. No alteration in mouthguard design
2. Use of Phone and Tablets
3. Easy Application Use
4. Little Training Needed
5. Trust of Brand
6. Safety
7. Availability
8. Cleanability
9. Storability

Lastly, the Cost Components were:

1. Purchase Price
2. Shipping/Delivery Charges
3. Cost of Peripherals
4. Cost of Application

5. Training Costs
6. Warranties



Value Factor Analysis™

The Approach: What is your product or service?	**Impact Mouthguard Sensor to Detect Real Time Rotational and Linear Acceleration**
The Target Market: Who is your end user?	**Youth through Professional Athletes, Trainers, and Coaches**

		Market	X2 Impact Mouthguard		Biometrics Vector Mouthguard		Prevent Impact Mouthguard		**Our Idea**	
Quality Features		Importance	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total
1	Device Accuracy (less than 5% error rate)	5	3	15	2	10	2	10	3	15
2	Weight	2	3	6	2	4	2	4	3	6
3	Size	3	3	9	2	6	3	9	3	9
4	Manufacturability	4	3	12	4	16	3	12	4	16
5	Extreme Conditions Capability (Within mouth)	3	3	9	3	9	4	12	3	9
6	Strength	3	2	6	2	6	2	6	2	6
7	Lifespan lasting longer than 1 use	4	3	12	3	12	3	12	3	12
8	Real time Results	5	4	20	4	20	4	20	4	20
9				0		0		0		0
10				0		0		0		0
	Total			**89**		**83**		**85**		**93**

		Market	X2 Impact Mouthguard		Biometric Vector Mouthguard		Prevent Impact Mouthguard		**Our Idea**	
Convenience Features		Importance	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total	Satisfaction	Total
1	No alteration to mouthguard design	5	5	25	2	10	4	20	5	25
2	Use of Phone and Tablets	2	3	6	3	6	3	6	3	6
3	Easy Application Use	4	4	16	4	16	5	20	4	16
4	Little Training Needed	4	3	12	3	12	4	16	4	16
5	Trust of Brand	2	3	6	3	6	3	6	3	6
6	Safety	5	5	25	5	25	5	25	5	25
7	Availability	3	3	9	3	9	3	9	3	9
8	Cleanability	4	2	8	3	12	2	8	3	12
9	Storability	2	2	4	3	6	3	6	2	4
10				0		0		0		0
	Total			**111**		**102**		**116**		**119**

		Market	X2 Impact Mouthguard		Biometrics Vector Mouthguard		Prevent Impact Mouthguard		**Our Idea**	
Cost Components		Importance	Expense	Total	Expense	Total	Expense	Total	Expense	Total
1	Purchase Price	5	$$$	15	$$$	15	$$$	15	$$	10
2	Shipping/Delivery Charges	5	$$	10	$$	10	$$	10	$$	10
3	Cost of Peripherals	5	$$	10	$$	10	$$	10	$$	10
4	Cost of Application	5	$$	10	$$	10	$	5	$	5
5	Training Costs	3	$	3	$	3	$	3	$	3
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			**54**		**54**		**49**		**44**
	Customer Value: (Quality*Convenience/Cost)			**183**		**157**		**201**		**252**

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 11: Value Factor Analysis for Mouthguards

4.1 Conceptualization of Design - JS & ZX

As part of designing our mouth guard, we had to take into consideration a few different things to get a workable product in the Solidworks software. We started off by creating a mold to cast our mouth guard, originally we just made a mold directly based on a standard mouthguard.

We then had to take those standard measurements and alter them so that we could fit our sensor in the mouth guard. To do this we had to thicken the outer walls of the mouthguard to fit the sensors and give them a cushion. Additionally, we had to extend the height of the outer wall to fit the sensor because the sensor was taller than a traditional mouthguard. From there we printed the mold on a Form 3D printer in high temp resin so it could stand the curing process of the PDMS and polymer because it will have to be heated to a temperature of 60 degrees Celsius. The team will then place the sensors in the mold and pour the liquid PDMS into the mold and make sure the sensors are positioned properly and then start the curing process. The sensors will be placed in particular positions with the PDMS solidifying around the sensor. Once our design final is made and testing is complete, the team will then transition to using a polymer instead of PDMS to make the final product. Figure 12 shown below is the CAD model of our mouthguard mold that has been 3D printed in Goddard Hall.

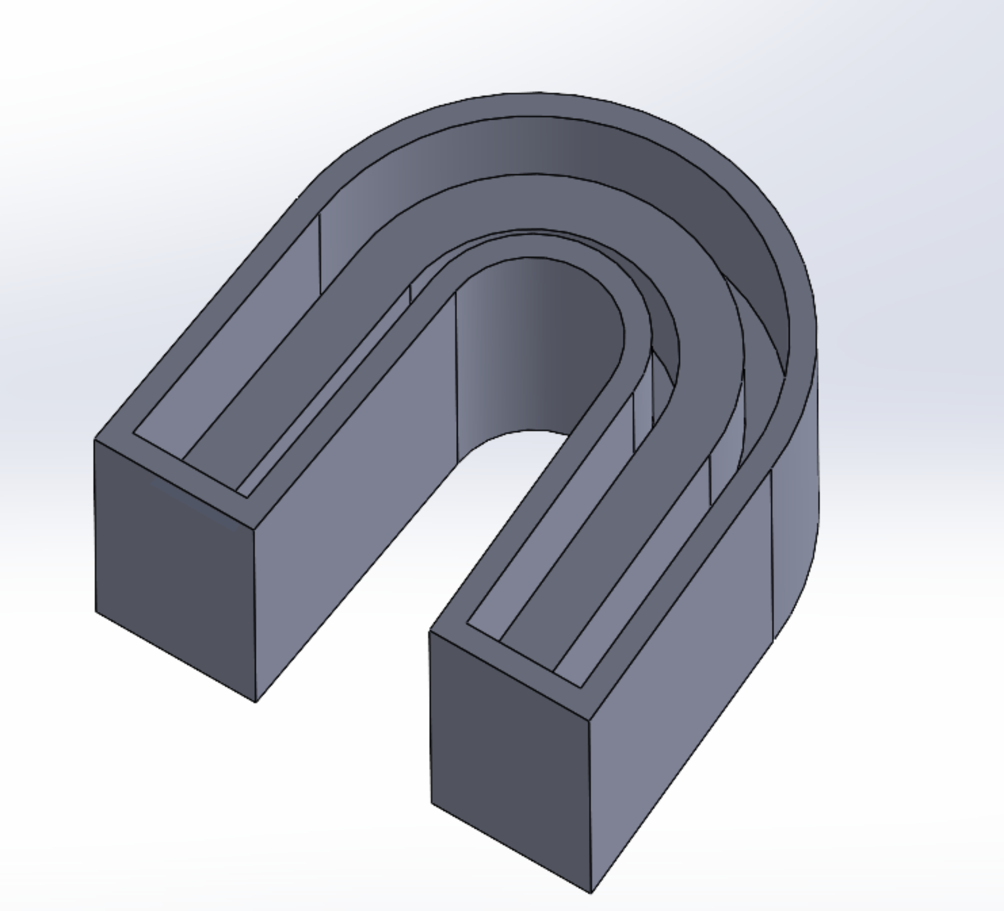


Figure 12: CAD Model of Mouthguard Mold

4.3 Future Tests - KP & JS

In order to properly test the accuracy of the sensors and our prototype, the group needs to perform impact force testing on the mouthguard. Two of the more common impact force testing strategies are the drop weight impact test and the pendulum impact test. Both of these tests will allow for similar forces to be examined, but each of these forces will be delivered in a different manner by each test.

The drop weight impact test is simple to complete, all it involves is a weight to be dropped on to an item to simulate real-time forces that will be exhibited. This test needs to be done because it will replicate as if there were vertical forces acting upon the sensor. This will allow for testing and the findings of the linear acceleration that occurs at different forces. The force of the impact can be assumed by using values for gravity, the height of the drop, and the mass of the object. The force that is calculated will be directly correlated to the values above, finally, this will allow the group to use the equation for conservation of energy and calculate potential energy before the weight is dropped and the recorded kinetic energy at impact.

On the other hand, the pendulum impact test will be calculated in a similar manner to the weight impact testing, by using the conservation of energy to calculate impact velocity. The benefit of using the pendulum testing is the horizontal impact that will be induced on to the sensors. The horizontal acceleration is important because this means the sensors will be more likely to experience a rotational acceleration which as emphasized in the background is extremely important in helping understand and identify a TBI. Additionally, the group needs to modify the pendulum test so that instead of having the first impact then many after until the object breaks; the group intends to stop the pendulum immediately after the initial impact and record that data only.

4.4 Design Iterations

The group developed 3 different iterations of the mouthguard as we ran into design problems during the testing stages of its development. The group was mainly concerned with the elements from the need analysis which consisted of quality features, convenience features, and cost components. Having three different design iterations was beneficial to the group as it helped show the group what could or could not be done with the mouthguard. This process additionally helped the group understand every little detail of a design is crucial to its success as we experienced design failures because dimensions were off by 1mm or because of a faulty design within the molding of the mouthguard. However, the group was able to develop a final design that was able to fulfill the priorities of our needs analysis which was incredibly important to the group.

4.4.1 Cast of mouthguard - KP & IB & ZX

The first of the three iterations the group designed there was an issue with the molding (Figure 13 shown below). The mold was not properly printing because of support issues from the design itself and how it had to be printed. The group decided to innovate away from this mold and re-develop the prototype as this design would fail even before the testing.

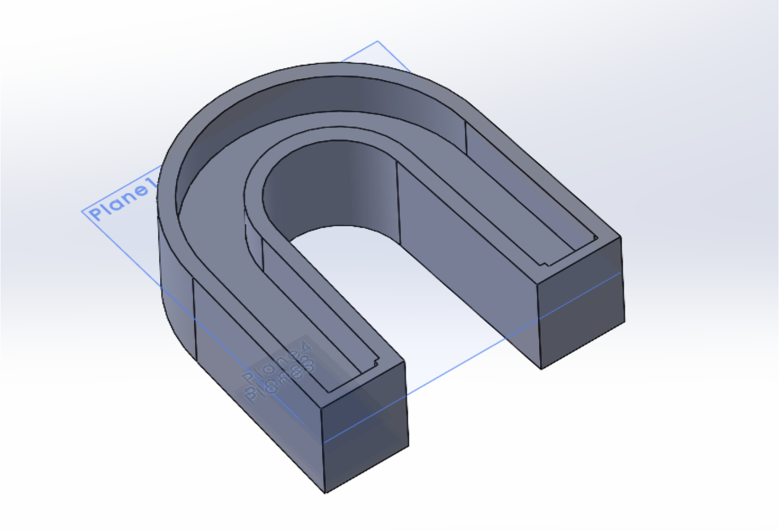


Figure 13 : Design Iteration 1

Following the group's design issues, the group remodeled the mouthguard to have grooves within itself so the mold could support itself as it was being printed as shown below in Figure 14. The group found this mold to print successfully, however there was an issue still. The group realized halfway through C-term there would need to be an additional area constructed to fit an easily accessible to the public, usb charging port and battery to power the arduino in the mouthguard without being connected to a computer.

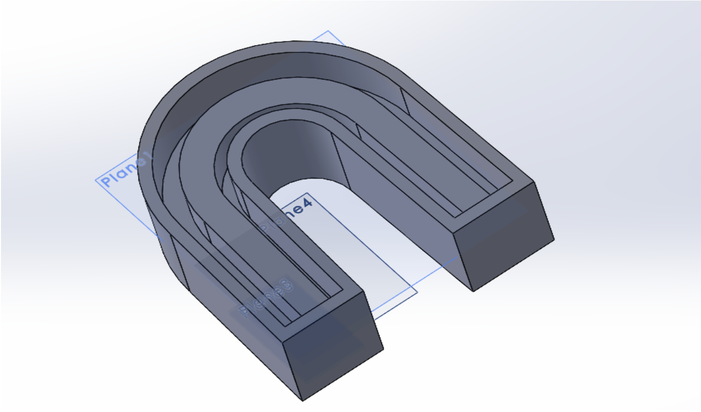


Figure 14: Design Iteration 2

The group then designed iteration 3 which also happened to be the final chosen design shown in Figure 15. This design iteration incorporated space for the battery and usb charger port that was now needed for the mouthguard, as well as being able to be printed and then properly put in the oven to withstand the curing process. This iteration proved to be the most successful as it met the quality features, convenience features, and cost components expectations that were set out originally.

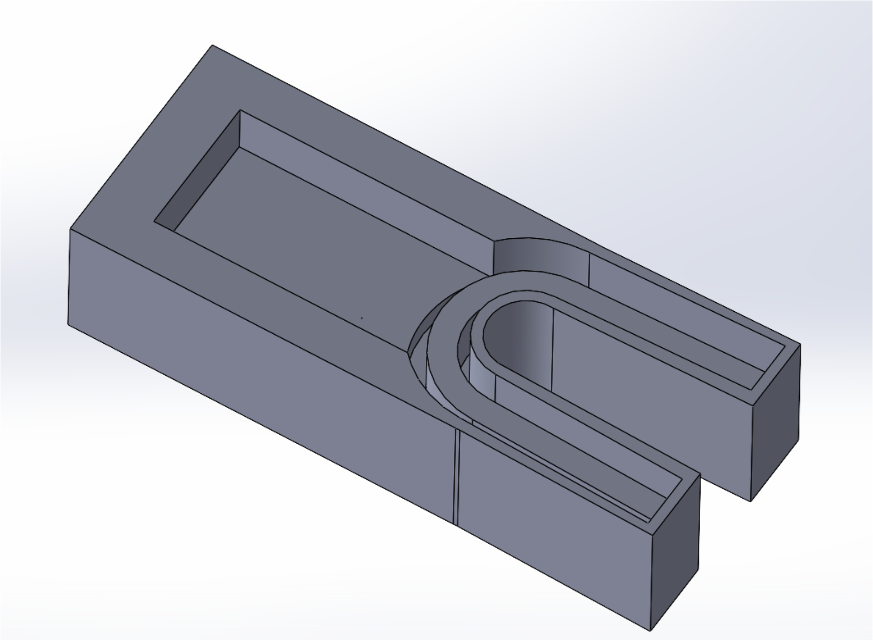


Figure 15: Design Iteration 3

4.4.2 Sensor selection- KP & IB

The group needed to finalize what sensors we would specifically be using for the mouthguard. The group then decided to use the Nano 33 BLE Sense, which is a 9-axis interior sensor with an accelerometer, gyroscope and bluetooth capabilities already in it. This would allow for the group to collect and send via bluetooth data in real time accurately. The sensor is a reasonable size; 45 mm in length and 18 mm wide, which we were able to work into our CAD model design known above in Figure 15. The CAD model in Figure 15 has room for a battery and usb charger port which the team allows selected to go with the Nano 33 BLE sensor. The battery will allow for the Arduino board to work wirelessly without having to be plugged into the computer, but still receiving a power source. The usb charger port is an essential aspect to the design because it allows for the device to be recharged in a simple and effective manner. The usb port is a universally used charging port that is very commonly used which serves as a benefit to the user.

4.4.3 Coding- IB

The Arduino Nano BLE 33 is a very complex device for such a small board. One very special component of this sensor is the bluetooth capabilities. Our code is written to allow the Arduino device to communicate via bluetooth with any BLE (bluetooth low energy) app that can easily be downloaded onto your phone, ipad, or computer. The code is uploaded onto the Nano device which will allow for the BLE to be activated on the Nano. The BLE within the device will search for an outside device to connect to on the receiving end, in this case, the BLE app. Once the app successfully connects to the Nano device, the app will be able to begin communication with the device. When the Nano device encounters an impact, the IMU inside the Nano detects the linear and rotational acceleration using the accelerometer and gyroscope within the device. The accelerometer and gyroscope can both obtain values from the x, y, and z axis when it detects an impact. This data is then sent over to the app and displayed to the viewer in real time as the impacts occur. The device will acknowledge any big impacts and peaks within the collected data and save that data to a csv file. This file can later be used to analyse the impact that was recorded on a deeper level.

4.4.4 Final Product of mouthguard-JS

The final product was created from the CAD model shown in Figure 15. Once this model was 3D printed on a form printer with high temperature resin, it was sanded down and washed to create a smooth and sterile surface. The mold was then cured to allow for use in the oven later to cure the PDMS. A ratio of 1:6 was used to mix the PDMS and hardening solution. The battery was placed in the long portion in front of the mouthguard. The arduino was placed on the left side of the mouthguard portion. The PDMS was added to the mold and placed in a vacuum sealer to remove the air bubbles. This was then placed in the oven for 2 hours to cure. Once removed from the oven, the mold was placed in a UV oven to finish the curing process. Once the PDMS was cured, it was removed from the mold. This created the final mouthguard with the arduino sensor and battery. The final product can be seen in Figure XX. This device will allow for the arduino sensor to detect a concussion once placed in the mouth of the user. The mouthguard will fit around the upper teeth of the user, with the arduino between the lips and teeth, allowing for the sensor to detect the signal that translates to a concussion.

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