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# Brainstorm Radiation Systems Inc

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# Honors Report

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*Brainstorm Radiation Systems Inc.*

Calia Battista, Cody George, Leah Krichbaum, Ryan Manges, Lauren Wickert

*4/8/2015*

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## **ABSTRACT**

Many different designs have been created to immobilize patients for radiation therapy of the head and neck. Options exist which result in varying degrees of patient comfort, radiation attenuation, and limitation of movement. While one requirement can be met effectively, it is difficult to design a system which adequately meets all requirements for radiation therapy. Brainstorm Radiation Systems aims to address all of these variables and transform the patient and technician experience during radiation treatment. The requirements for our head and neck immobilization design were to immobilize the patient within 3mm of movement for at least 30 minutes, and must be repeatable over the course of several weeks. The device must limit attenuation of the radiation and be comfortable for the patient. Our team worked to address these issues, and together, went through storming, norming, and performing as a group. We learned to communicate our ideas and goals effectively and efficiently through conflict resolution and teamwork. And through visits with radiation oncologist experts, brainstorming, designing, 3D modeling, and construction of prototypes, we were able to design a system of components which accomplishes our goals. Our system, which includes a bite-block, holds the patient in place and is unaffected by weight or facial change of the patient. Our design is easily integrated with Bionix's line of products and will create a better experience for both the patient and the technicians.

## **INTRODUCTION**

### **Problem Statement**

Often for cancer of the head and neck, patients must undergo radiation therapy to shrink the size of the tumor. In order for radiation to begin, the affected area must be immobilized; radiation can cause many problems if it penetrates undesirable areas and can cause memory loss, inability to taste or create saliva, nerve damage, among other complications. Therefore, immobilization is imperative. However, the existing solutions are uncomfortable, cause claustrophobia, and are ill fitting throughout the duration of therapy. The affected area must be immobilized within 3mm for at least thirty minutes, and each treatment must be repeatable and accurate. A need exists for a design which limits attenuation, increases patient throughput, and is comfortable for the patient.

### **Customer Information**

Bionix Development Corporation, located in Toledo, OH, designs, manufactures, and distributes their medical devices to healthcare customers. Bionix has four divisions: Medical Technologies, Radiation Therapy, Home Health, and National Safety Technologies. We are working with the Radiation Therapy division to add to their line of head and neck treatment products. They also have products for radiation of the pelvis, torso, lungs, and breasts. Hospitals must use a tabletop created by Bionix so that their other products can interface correctly. Bionix's products for head and neck immobilization include thermoplastic masks and a variation of the SecureVac system.

Our contacts for the project are Edward Markewitz (Product Development Program Manager) and Cody Harder (Product Development Engineer). They instructed us from the

beginning that they do not want us to improve their products, but to begin with a clean slate and add to their product line. Bionix is a forward-thinking company that wants to be a market leader with a novel product.

### **Why We Are Doing This Project**

As a team of biomechanical engineers, our project fits well with our set of skills and experiences. The prior familiarity that some of the members have with carbon fiber molding also served as an advantage as we knew that it was a material that causes negligible attenuation to radiation. Some of our teammates took an advanced biomaterials course last fall, so focusing on the materials aspect of this project, with low attenuation, was also a selling point for us.

The primary reason Brainstorm Radiation Systems is doing this project is the need that exists for a better head and shoulder immobilization system in the hospital. The masks that are currently used cover the entire head and neck region and successfully immobilize the patient; however, they also create problems with claustrophobia, shrinkage of the mask over time, and are greatly affected by any facial changes of the patient due to tumor shrinkage, weight gain, or weight loss. It is our duty as biomedical engineers to create a better treatment for patients, technicians, radiation planners, and doctors. We also see the need within the healthcare industry to create improved, efficient, and more effective devices while maintaining a feasible cost. Healthcare costs are at an all-time high in our country and our team wants to be a part of the solution rather than part of the problem.

## **BACKGROUND INFORMATION**

Products currently exist for immobilizing patients during radiation therapy. The need has existed since the first patient was treated with radiation for medical purposes. Most products currently on the market fall under two categories: Meshes and Frame Assemblies. With meshes, a plastic which can be molded to the individual's face will be formed through some means (such as submerging a thermoplastic in a hot water bath) and will "cure" as a rigid plastic in the shape of the patient's face. The mold will then be used to hold the individual in the same position throughout the weeks of treatment. Some problems with the mask immobilization system are associated with weight gain or loss of the patient; patients frequently lose significant amounts of weight due to the treatments they are undergoing. Loss of weight will cause the mold to fit more loosely around the patient's face, which would allow the patient to move around while undergoing radiation therapy in the future. Another problem with this design is that some of these patients are undergoing steroid therapy as well, which could cause them to gain weight, at which point the face mold will fit too tightly. A third issue with this system is that the mask shrinks as it cures. This also causes the mask to be too tight on the patient, and creates a phenomenon referred to by the technicians as "waffle face" because the individual has the mesh shape imprinted on their face for a few minutes after having the mold removed. This has serious medical complications associated with it, as it can cause pressure sores. Sores become dangerous to the patient because they are often undergoing autoimmune therapy and these sores can become infected. Additionally, a complete face mask is uncomfortable for the patient, especially during prolonged radiation sessions of over thirty minutes.

Other products which currently exist are generally used to affix the patient's head in three dimensions. Fixation can be accomplished by a retainer, mouthguard, or other similar system because

if a solid body has three points defined (such as Right Molar, Left Molar, and Incisors) then the solid body is entirely defined in space. Systems including a mouth component for fixation do not see the negative effects of weight gain or weight loss due to other treatments the patient is undergoing. Currently, frame systems are less common because they are more complicated to set up for each patient and require some form of dental mold. However, because the position of the teeth is not altered by any form of therapy, there is no risk of the patient being located at a different point in space from therapy session to therapy session.

## **PROJECT OBJECTIVES AND GOALS**

Our team goals and end-project goals were identified early in the fall semester as we formed our team. Our goals can be broken into three categories: (i) long term goals for our small company, Brainstorm Radiation Systems, (ii) end goals for the final production product with Bionix, and (iii) team goals to complete by the end of the school year.

### **Long Term Goals**

Our long term goals for our small company, Brainstorm Radiation Inc., are to transform the radiation therapy experience for both medical professionals and the patients undergoing radiation treatment by providing radiation therapy devices through reliable and innovative solutions. We aim to provide assistance to medical professionals who seek user friendly and repeatable solutions for radiation therapy as well as provide comfort and security for those patients undergoing radiation therapy of the head and neck.

### **End Goals**

For our specific end goals for the product, our desired outcomes were formulated in conjunction with the engineers at Bionix Inc. These goals shaped our design process and

formulated the tangible end outcomes which we could test against. After meeting with the engineers from Bionix, we determined that our design should limit attenuation. Since attenuation affects treatment and is greatly influenced by material density and thickness, we also limited the scope to materials and designs which have a low density and small thickness in order to reduce attenuation. We specifically decided to limit the amount of material near the face and neck to decrease claustrophobia for patients.

We sought to design a small system compatible with the radiation machines already integrated in hospitals. One size limitation for our device was that it was no wider than the patients' shoulders, so it can fit within the radiation machines, and the device also had to work with Bionix's table for radiation therapy. We wanted our final system to be durable, the pieces which would be inside the patient's mouth to be sterilizable, and the system to fit a broad range of patient specific dimensions. Further, the group identified that the system would not be single use, but rather reusable for multiple patients. Our product life goal was at least three years but ideally within the five to ten year range. An imperative design goal was to limit movement within three millimeters for at least thirty minutes, and we identified that each treatment must be repeatable and accurate. Lastly, we needed to create a system which was comfortable for the patient during long, repeated sessions which could last for up to three hours. These were our goals for the final production of the system, manufactured for Bionix.

### **Team Goals**

Our specific team goals for the end of the year were to create a spatial analysis prototype on which we could conduct testing. We desired to file a patent with Bionix as a consequence of creating a novel and valuable invention. We also required detailed drawings of the system in the specific materials chosen for radiation therapy for Bionix's production. Our goals for the year



were ambitious but achievable, especially considering the many components which compiled our final design.

## **FUNCTIONAL REQUIREMENTS**

(All requirements apply to the system as a whole.)

### **Size requirements:**

1. It must fit into the machine and onto Bionix's table top.
2. It should not be wider than the shoulders.
3. It must be useful for adult head shapes and sizes, and is not used for pediatric treatments.
4. It must stabilize patient's head within 3mm of movement for at least 30 minutes.
5. It must provide stabilization in the x, y, z axes as well as all rotational axes.

### **Use requirements:**

1. It must be easily manipulated by no greater than two medical professionals (one is ideal).
2. Body positioning must be repeatable for all treatment sessions.
3. All parts that are not single use, must be cleanable with a non-alcohol based cleaner.
4. The product life must be at least 3 years.

### **Strength requirements:**

1. It must be rigid and stable throughout treatment.
2. It must support the weight of the head and neck over time (on average: 15 lbs).

### **Material requirements:**

1. It must have low density and/or thin material to limit attenuation.
2. Non-porous, sealed, easy to clean materials should be used.
3. Soft materials should be used where the device comes in contact with the patient to avoid pressure sores.

4. All materials that come in contact with the patient must be biocompatible.

**Patient comfort:**

1. It must not cause shearing pressure points.
2. It must not cause pressure sores over a length of time.
3. The head and neck should be restrained at an angle that is comfortable for the patient's spine.

**CONSTRAINTS AND LIMITATIONS**

Per the customer's requirements, the device must be no wider than shoulders, and it can go over the head to restrain the head and neck. It must be rigid and strong enough to withstand the weight of the head and neck, which is around fifteen pounds for the average adult. The device must be able to attach to the couch top/table provided by Bionix.

The designed system should focus on adults only with no pediatric patients, and the device should hold and position the head and neck in a repeatable position. Either prone or supine patient positioning is allowed, depending on tumor location, and tilting the patient at an angle is also possible, although not common. Comfort is the main concern of the customer, despite added cost.

Any material that can affect attenuation between the head and radiation device should be less than 2mm thick to limit attenuation. Materials may include, but are not limited to plastics, composites, and carbon fiber. The density of the material affects attenuation the most, and metal elements are not allowed due to reactions in an MRI machine.

The design should be minimalistic in material and should have consistent settings over a period of many treatments. It should be easy for one person to operate, and may be used for up to thirty treatments, so every setting should be indexed for repeatability.

The device should be durable and not be completely consumable per patient. It should also have the ability to be cleaned between patients. Non-alcohol based cleaner and a non-porous or foam structure with a sealed surface is recommended.

The customer gives a three year guaranteed product life on all products they sell, and on average, the life of Bionix's products is about 5-10 years.

## **METHODS/PROCEDURES/MANUFACTURING**

The final design was divided into three components: a frame connecting the device to the VersaBoard already in production at Bionix, a chin strap connected to the frame, and a mouthpiece which is specifically molded to the individual patient's teeth. Each of these parts is detailed below.

### **Frame:**

Carbon fiber was chosen as the best material to use for the frame. There are several reasons for this decision. The first is the ease of manufacturing for Bionix, as Bionix already creates many of their products from carbon fiber and have such capabilities in house. The second is the high strength to weight ratio of carbon fiber. This has two advantages: it makes maneuvering of the frame easier for clients and gives the frame a lot of structural rigidity. The final reason for choosing carbon fiber is that the amount of attenuation it causes is negligible.

In order to create the frame, we have separated the construction into four components: feet to attach to the table, a set of wide bars, a set of narrow bars, and a sliding bar. The purpose for the wide and narrow bars is to attach to holes on Bionix's Versa Board which attaches to the table top.

Each of the pieces will be created in a mold for the basic shape, and then the pieces can be shaped and cut like wood. The proper pieces will be drilled and punched out of the carbon fiber to create holes. To assemble the frame, first the feet can be glued to the posts with the notches lining up. Then the sliding bar will slide onto the piece with the narrow posts. The other post piece will be attached to the first via the female and male parts and glued. The frame assembly is attached to the VersaBoard via the Panel Rivet Lock Pin and the Panel Rivet Lock Housing, both of which are Bionix pre-designed parts. The frame assembly can be seen in the appendix (Figures 1-5).

### **Chin Strap:**

The chin strap will be made of three main components: a cup to cradle the mandible at the apex of the chin, straps on each side to attach the cup to the frame, and adjustment slides on each strap. The cup will be made of a hard thermoplastic which will be manufactured by injection molding. The straps will be made of a weaved polyester similar to the straps of standard backpacks. These polyester straps will have the functional requirement of carrying the load of the patient pressing against the chin cup. The tension load will be transferred to the frame through thermoplastic snaps which are attached to the sides of the frame. This will cause the snaps to have a shear load applied which is what the manufacturer of these snaps recommends. (See Figures 6, 7, 8.)

### **Bite block:**

The bite block is the point of connection between the patient and our device. It consists of a molded mouthguard (Figure 9) which is made of a thermoplastic similar to what is currently used for the radiation masks and an extrusion piece which will attach the mouthguard to the

frame (see Figure 10). The extrusion will be made of a biocompatible plastic such as PVC and will be threaded on the farthest end in the Z-direction (Figures 11, 12). These threads will serve to fix the mouthguard in the Z-direction through the use of three nuts. Two of the nuts will go on the threaded portion which is below the frame and one will go on the top. The two on the bottom will be set in place when the mouthguard is first molded to the patients teeth. By tightening them against each other with a wrench, it is possible to keep them in position throughout the duration of treatment. The top nut will be removable at the end of each treatment to allow the bite block to be removed from the frame between uses (see Figures 13 and 14).

For the bite block manufacturing, we plan to use overmolding. We spoke with a plastics professor and manufacturing engineer, and he suggested the process because it will attach the components simply and rigidly, and the parts will be inexpensive once the mold is purchased. The extrusion piece on the bite block will have a barbed end and will fit into the bite block mold. The bite block mold would be injection molded around the extrusion with a thermoplastic material, and the barbed end would hold the extrusion in place. Once the thermoplastic hardens, the assembly forms a dispensable and customizable piece; the mouth guard and extending piece will be rigid and “disposable” per patient (Refer to Figure 12).

Ultimately, the mouthpiece will have to be made according to the final design (through the overmolding process) in order to test the attachment strength and rigidity of the design. However, the funding required for an injection mold is not within the scope of our budget for this project. For prototyping we will use a biocompatible adhesive to attach the mouth guard to the extruded piece as shown in Figure 10 to test functionality and rigidity of the design.

## **PERFORMANCE TESTING**

In order to test the functionality of the device proposed, it is essential that we create a prototype of the design (See Figures 13 and 14). It is not necessary for our purposes that the prototype be made out of exactly the materials we plan on creating the final product out of, as the majority of the features of our device are not material based. Material matters only in regards to the effect they have on attenuation as well as the rigidity of the frame. We intend on making the frame out of carbon fiber, which has a greater stiffness and strength than the prototype material PVC, which allows us to assume the PVC as a worst case scenario.

Three primary functional requirements must be evaluated in the prototype. The first is ensuring that all the mechanisms connecting our parts work properly. This includes the connection of the frame to the VersaBoard and the connections of the chin strap and mouthpiece to the frame. This is a testing of fit; therefore, material selection is irrelevant. The second functional test is for ease of adjustability of the device. It is important that a single technician be able to easily work with our device, and that our device is able to be adjusted on a per-patient basis. The third is a test of patient comfort. The parts which come into contact with the patient are the mouthguard and the extrusion, which we are prototyping from the same materials we intend to make the final product out of; therefore these parts will be accurate representations of comfort for the patient.

The device must be tested to ensure that it places the patient repeatedly in the same location throughout the length of the treatment, and that the assembly meets the requirement of stabilization within 3 millimeters of movement. It should be done in the same manner that the mask has been tested.

In conclusion, Brainstorm Radiation Systems is working to find a solution to immobilization and comfort requirements for radiation therapy of the head and neck. We believe that we have designed a system which is more comfortable for the patient than current options, repeatable from treatment to treatment, easily manipulated by one technician, integratable with Bionix products, and which may be a viable product for Bionix Inc. in the years to come.

## **APPENDIX**

Frame:

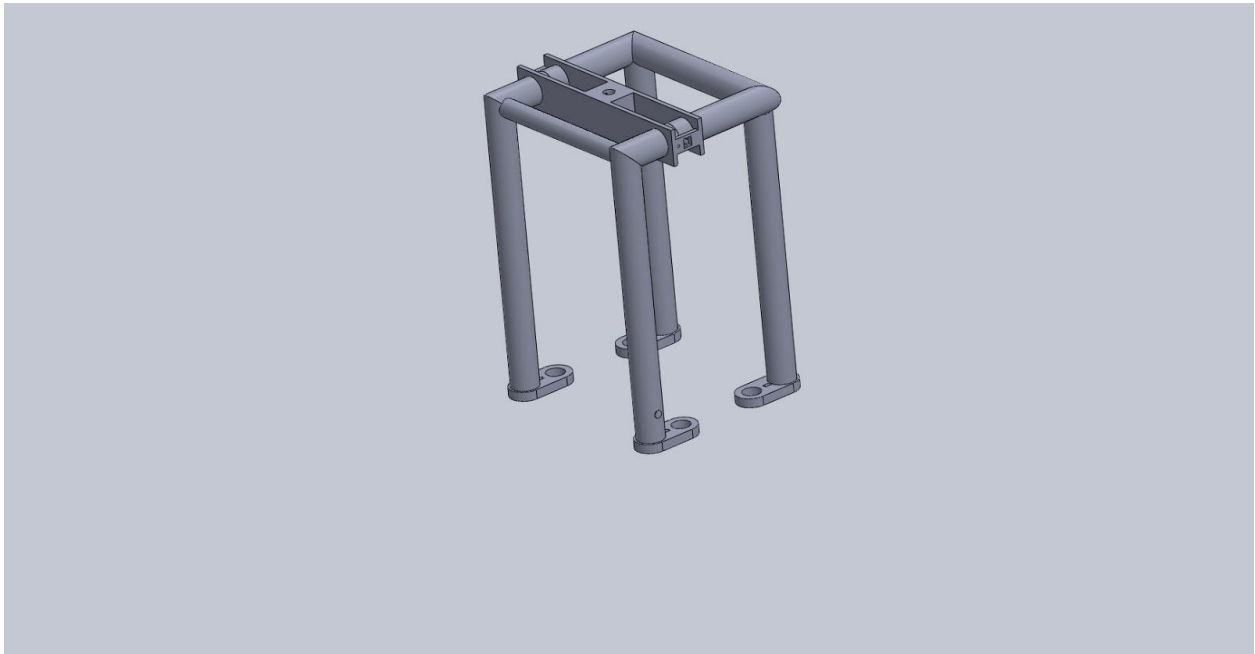


Figure 1: Assembled Frame

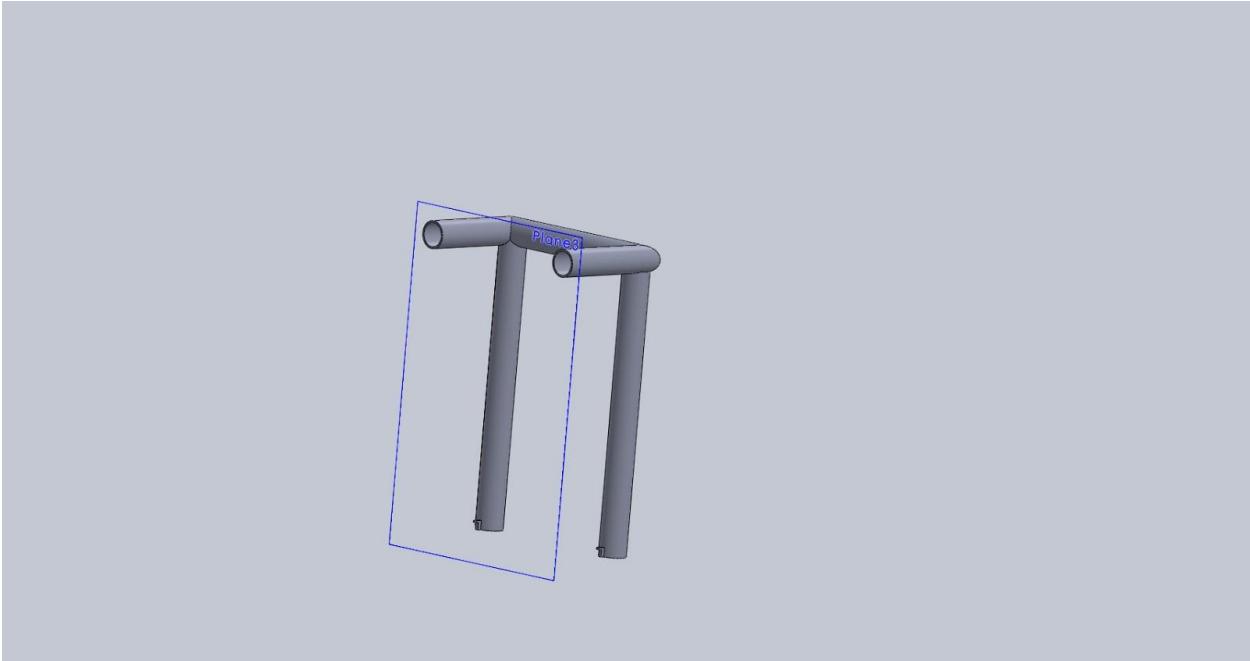


Figure 2: Female part of frame

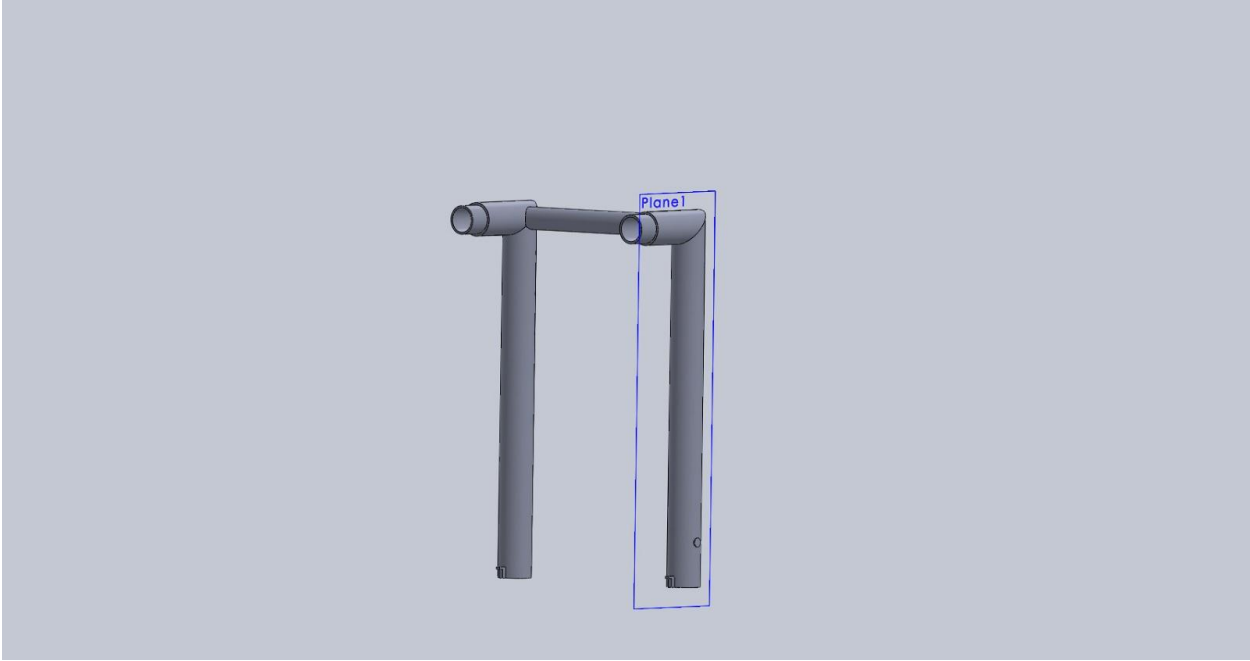


Figure 3: Male part of frame



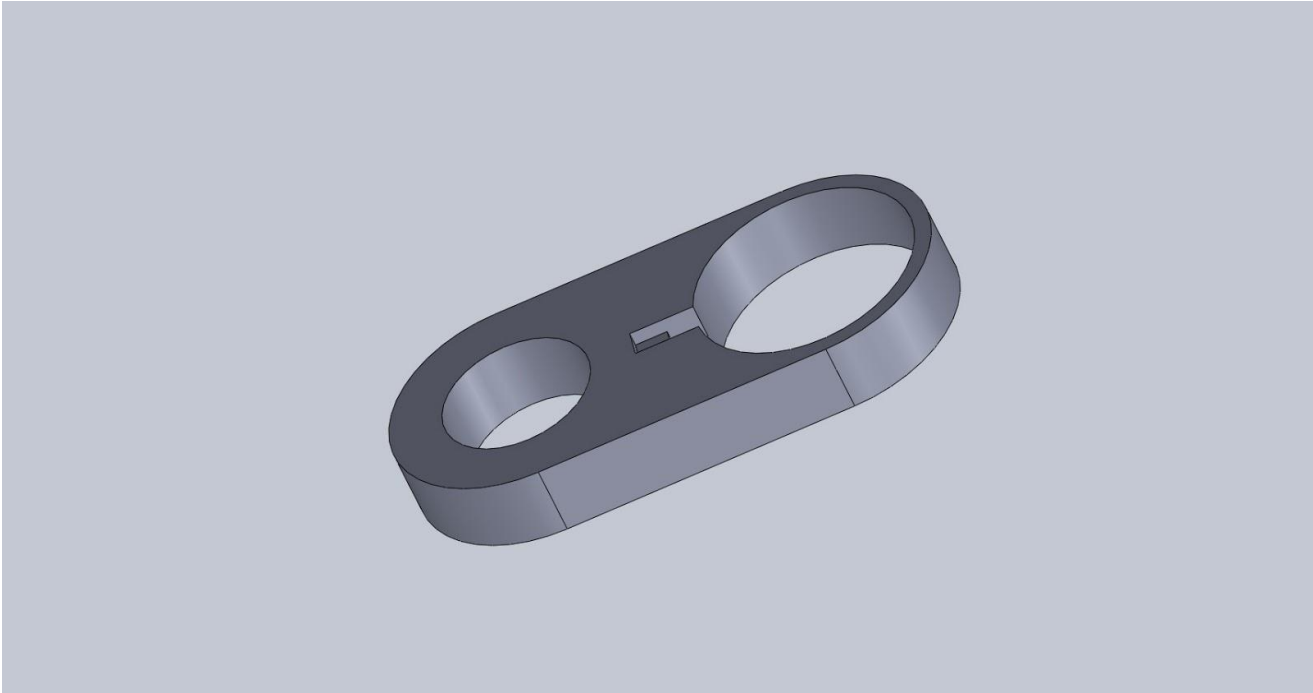


Figure 4: Frame footpiece

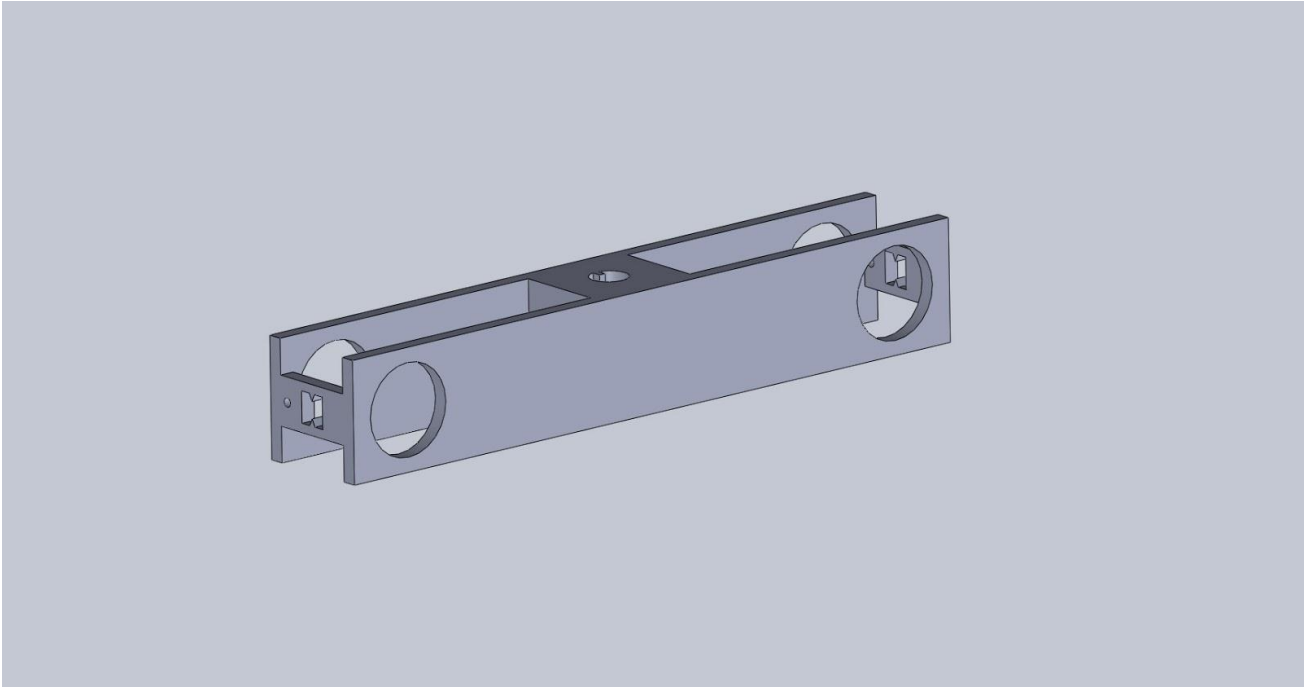


Figure 5: Sliding bar from frame

Chin Strap:

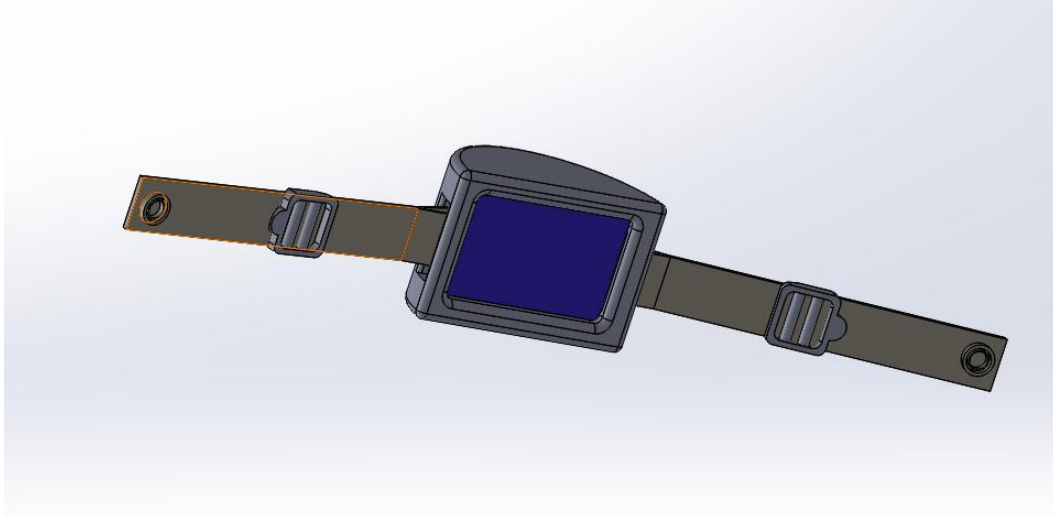


Figure 6: Assembled Chin Strap

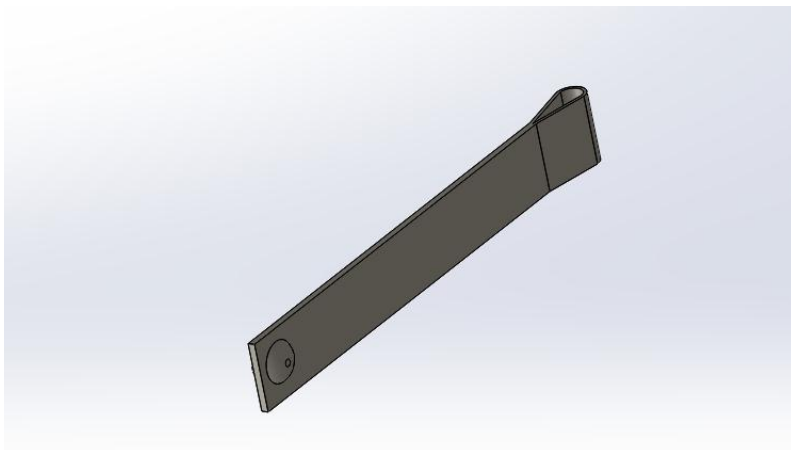


Figure 7: Strap

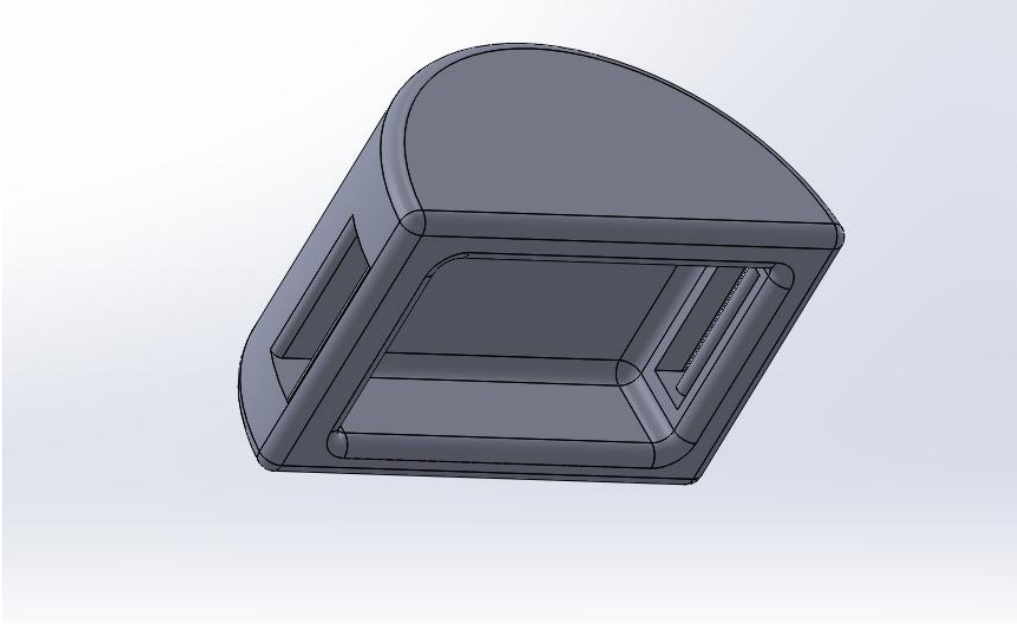


Figure 8: Chin Cup

Bite Block



Figure 9: Bite piece

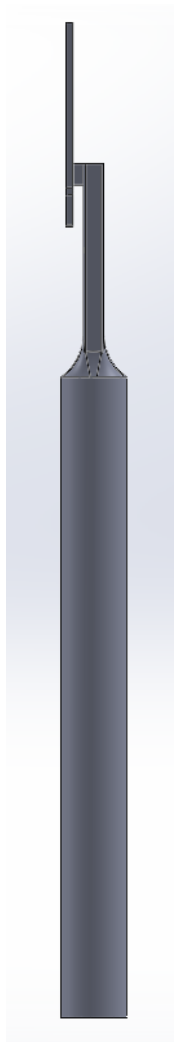


Figure 10: Bite Block Prototype assembly



Figure 11: Bite block prototype extrusion

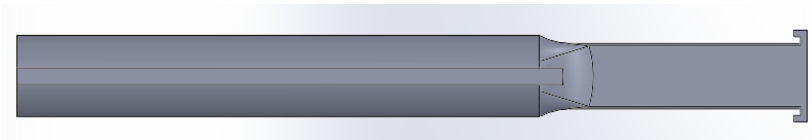
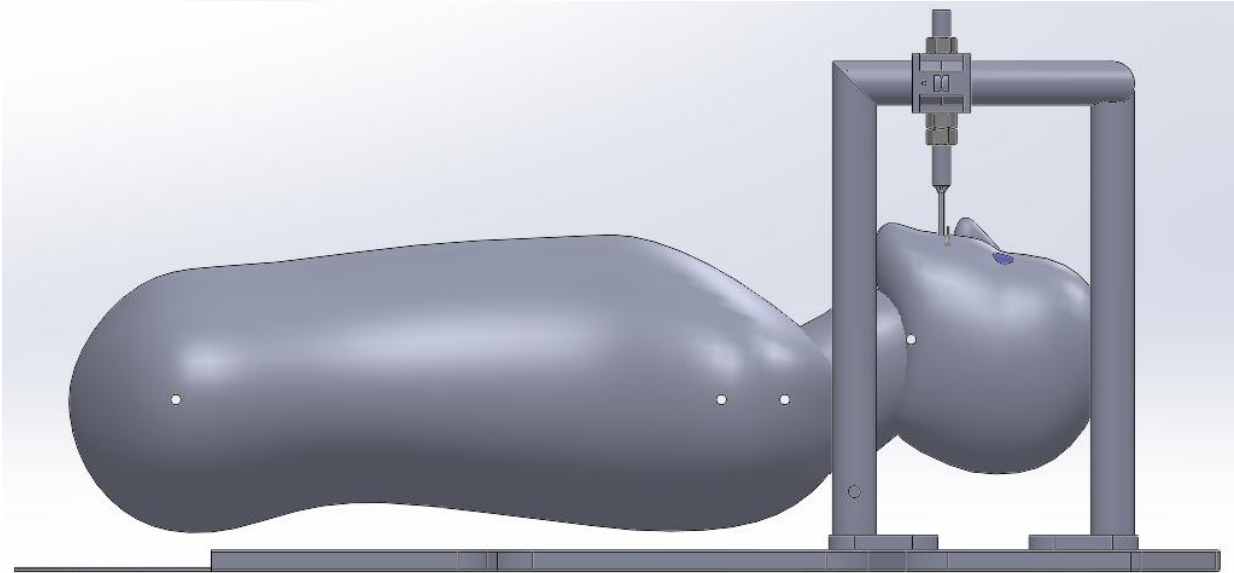
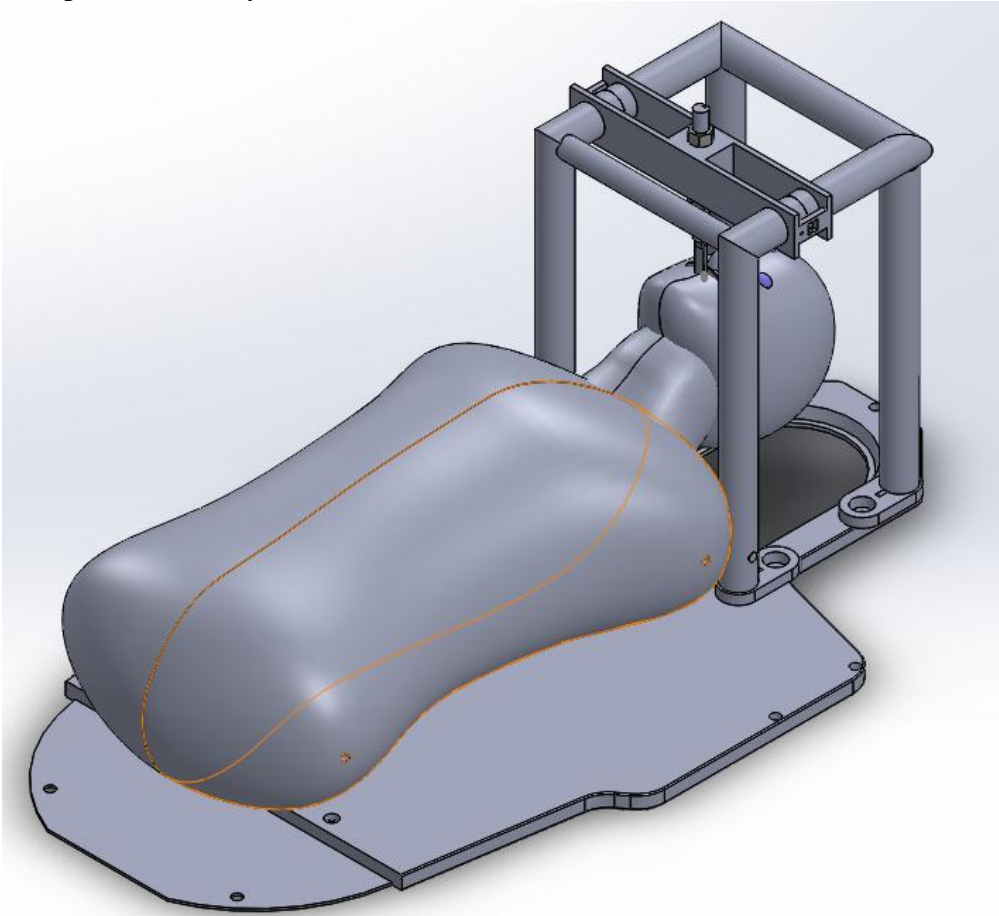


Figure 12: Bite block production extrusion

Complete Assembly



Figures 13 and 14: Complete assembly