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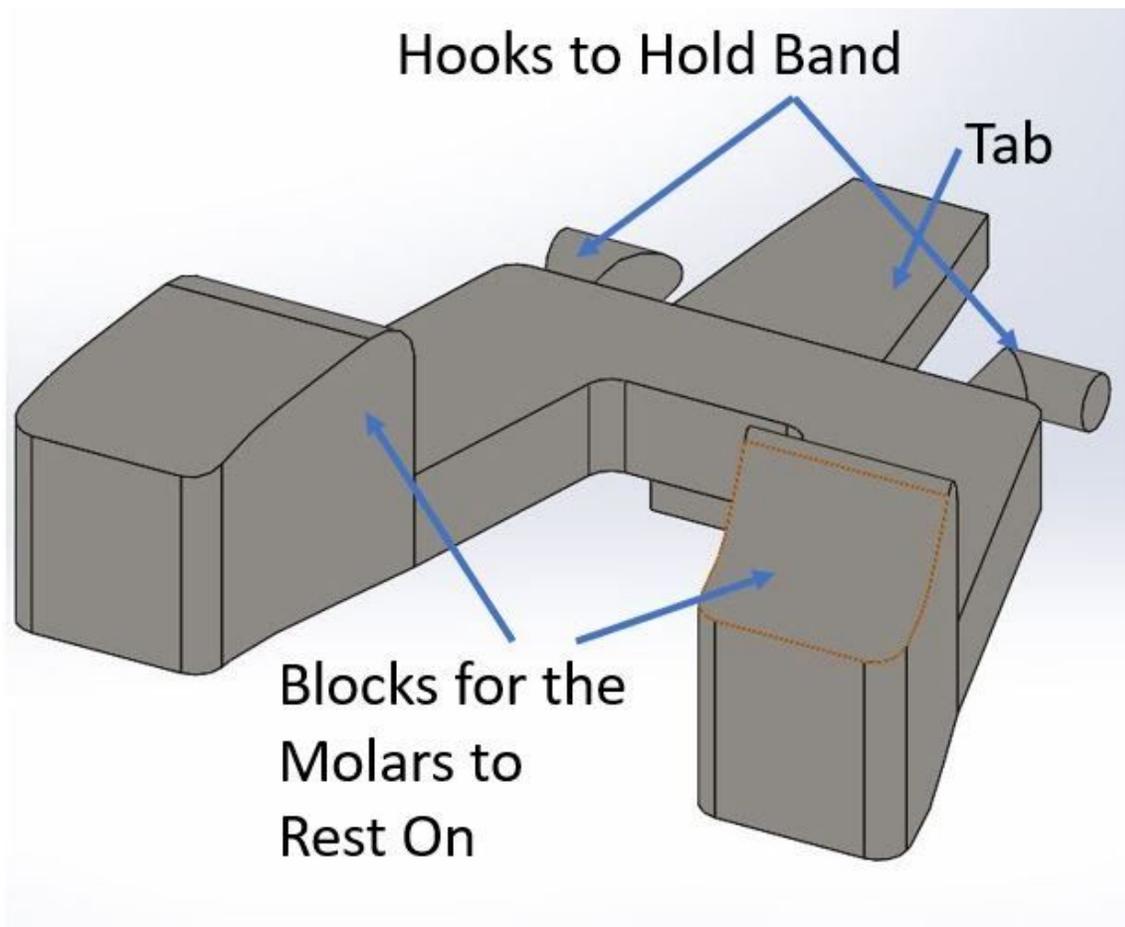
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# Redesigned Endoscopic Bite Block for Geriatric Patients

Kayla Fisher, Katie Gregory, and Owen Corey

March 23<sup>rd</sup>, 2020



## **Background**

Esophagogastroduodenoscopy (EGD) is an examination of the interior of the esophagus, stomach, and beginning of the small intestine. Upper gastrointestinal (GI) endoscopies are used to diagnose ulcers, cancers, and gastrointestinal tract diseases, as well as to collect biopsy samples. In 2008, over 55 million procedures were performed with GI endoscopic devices [1]. In order to keep the mouth propped open during this procedure, a bite block is used. This bite block ensures that the patient will not bite down on the endoscope during the procedure.

Endoscopies are the most commonly performed GI procedures [2]. An endoscope is the primary tool in an endoscopy procedure and is equipped with a light and a camera to look inside body cavities and organs. This procedure is minimally invasive and consequently provides a large advantage over exploratory surgery. A typical diagnostic endoscopy lasts 20 to 30 minutes, but some cases can last up to 4 hours.

During an upper GI procedure, an endoscope is inserted into the mouth and an image of the GI tract is sent to a monitor where the clinician can review the information and complete the required task. The current design of bite blocks rests on the anterior incisors and has a tube for the endoscope to go through allowing the endoscope to be protected from the front teeth. Even though this orientation protects the endoscope, this placement and orientation of the bite block may lead to the patient injuring their teeth. The rate of perioperative damage was found by some studies to be as low as 0.02% to as high as 12% in other studies. Even at the low estimate of 0.02% rate of injuries, there would still be 10,000 instances of dental damage due to bite blocks each year [3].

Stakeholders for this device would include anesthesiologists, dentists, gastroenterologists, insurance companies, and hospitals. During the later stages of the design process, we had a chance to talk with Dr. Bughrara, an anesthesiologist at Albany Medical Center. Dr. B. stressed that the primary concern of the gastroenterologist is the cost of the scope. As an anesthesiologist, he said he would be concerned with preserving the airway of the patient during the procedure. Finally, the patient, however, would be the most concerned about dental damage. Balancing these various concerns, we aimed to design a novel bite block that provides the needs of the various stakeholders.

#### Prior Art and Current Solutions for Adequate Tooth Protection

There are various bite blocks on the market that serve different purposes. Even though we are redesigning a bite block used for upper GI endoscopies, we decided to analyze all types of bite blocks to get ideas on how to innovate endoscopy bite blocks. Some types of bite blocks include hard round bite blocks, hard curved bite blocks, airway tube covers, and gauze rolled bite blocks. Both hard bite blocks and the airway tube covers put too much force on the anterior teeth which can cause these teeth to break. The current technology used in endoscopies, as seen in Appendix 2, is the Omni Block which is an example of a hard bite block. Gauze rolled bite blocks are typically placed on the molars and made by rolling gauze onto tongue depressors.

These bite blocks are more efficient in redistributing the force back to the molars however these are typically handmade which can cause issues. Not only can having handmade bite blocks cause inconsistencies in sizing and cushioning, but it can also cause contamination and spread of disease from the person making the bite block to the patient. Due to the fact that the person making these bite blocks may not be in a sterile area, this is a concern for clinicians.

Another bite block we looked at was the “Soft BiteBlock” by RichmondDental. This bite block would again be placed on the molars similar to the gauze rolled bite block but this design is easily mass-producible and because it is produced in a clean and regulated environment, it lowers the chance of contamination [4].



Omniblock (see appendix 2)



Soft BiteBlock by RichmondDental [5]

When looking for prior art, we not only researched various types of bite blocks, we also researched mouthguards. Because mouthguards are used to decrease the impact of high contact sports on teeth, we believed that their design would help us reach our goal of decreasing the instances of broken teeth. A study conducted by Masahiro Morikawa in 1998 looked at the decay rate of frequency responses when wearing a mouthguard and when not wearing a mouthguard. The upper central incisor was stimulated by an electrodynamic shaker. The frequency response functions were put into a fast Fourier transform analyzer with the intention of seeing the modal shapes of the maxillary arch while wearing a mouthguard and compare it to not wearing a mouthguard. They made the mouthguard out of MOLTENO and made a cast of steel and wax that would fit the skull's teeth. They found that the decay rate was lesser when the mouthguard was not being worn. This suggests that the mouthguard decreased the concentration

of force per area on the front teeth by redistributing force. By redistributing the force placed on the front teeth outward, the vibrations on the teeth were reduced. The motivation for this study was the statistic that 103 out of 313 dental injury cases were from sports, and of these, the top incisors were most commonly damaged. It was also found that if a mouthguard works properly, it should protect the lips, teeth, tongue, cheeks, gums, and mucosa [6]. Due to the fact that mouthguards effectively redistribute the force away from the anterior teeth during high impact, we wanted to mimic the shape and use similar materials in our designs for our bite blocks. This study is applicable to our project because it shows that spreading out the force onto a larger area will cause less impact on individual teeth.

Another field of innovation that influenced our design was the design for the mouthguards in scuba regulators. These products are designed for divers that may be underwater for hours all the while keeping the regulator between their teeth. Lasting tooth and jaw pain can be a common side effect of diving. The mouthguards designed for this sport target the rear molars, but, like the EGD bite block, need to protect a tube passing through the guard. In this case, it is the regulator nozzle instead of an endoscope.

One of the major influences towards our final design was dental bite props, as seen in Appendix 2. These devices are mainly used during dental work or oral surgery in order to keep the mouth open. The basic principle lies in placing the prop at the back of the mouth to keep the mouth open. We saw the potential for these to be modified to suit our needs. Modifications were required to withstand the bite force and to prop open both sides. The current dental props are designed such that only one side of the mouth is supported so that the dentist or surgeon can do work on the opposite side of the mouth.

## Risk Factors for Dental Injury During Upper GI Endoscopy

When you eat foods that have sugar and starches in it, bacteria is triggered in your mouth to release acid. This acid eats away the enamel and the acid can't escape because the plaque confines the acid to the tooth [7]. This is normally kept in check by brushing your teeth, but for patients who do not have good dental hygiene habits or have memory problems, they will have weaker teeth. Also, the use of prescription medication can lead to dry mouth and other conditions that adversely affect oral health. Blood pressure medication and medication for incontinence are just two of the many medications that can lead to dry mouth. Due to the fact that saliva cleans the mouth and neutralizes the acid within your mouth [8], if there isn't enough saliva in your mouth, it can be damaging to your dental health.

### At-Risk Populations

A population that receives many EGDs and is the most likely to have bad hygiene habits, take prescription medications or have memory problems is the geriatric population. This group of patients, ages 65 and older, receives 33% of the annual EGD procedures [9]. Because of this, it is important that bite blocks accommodate for unique challenges presented by this patient population. For example, common risk factors for dental injury are osteoporosis and Alzheimer's disease [10]. These two diseases disproportionately affect individuals 65 and older and affect the patient in a variety of ways. Osteoporosis affects dental health through bone loss in patients. The loss of memory, associated with Alzheimer's, often leads the patient to ignore routine dental care.

We have designed a bite block that is safer for the entire adult population. Due to the single-use nature of the device, there is not an adjustability function that would open our specific

device up for children. However, we are focusing on designing a device that can be easily modified to support the need of the geriatric patient populace. This design will include the opportunity of adding a softer coating over hard plastic so that patients without teeth can bite down on the block. This is a feature that is not part of the current design on the market. Due to the hard plastic used on these bite blocks, biting down on this with soft tissue would cause intense pain and injury to the patient.

### **Problem Statement**

During this term, we further refined our problem statement in order to develop a device that solely reduces the instances of dental damage. We decided to just focus on the issue that some teeth break during endoscopy procedures, instead of the dislodgement of teeth, due to the lack of reporting of loose teeth being inhaled. Geriatric patients are more likely to have poor dental health due to medications they take, poor dental hygiene, or other underlying conditions. The current design places too much force on the anterior teeth, causing them to break. The structural differences between the anterior teeth and the molars [11] mean that the molars are better equipped to distribute the load put upon the teeth from the bite block, due to the fact that molars have more roots, giving them a stronger structure. In order to minimize the instances of tooth fractures in geriatric patients during procedures, the endoscopy bite block needs to be redesigned to ensure patient safety while continuing to protect the endoscope.

## **Design Objectives**

We have two main objectives which are to make our bite block safe and marketable. Under the marketable category, it needs to be mass-producible, easy to use and used for various types of dentition. By various types of dentition, we mean patients that have teeth or dentures, and people with no teeth or the clinician decides to take out the dentures for the procedure. Due to the fact that taking out dentures is a personal choice for the anesthesiologist, as product developers, we must be able to provide both choices for the clinician to use. Specifically for the easy to use objective, we need the bite block to be easy to place and maintain its spot, as well as easy to take out. After meeting with Dr. Bughrara this term, we found an additional aspect that was needed for our goal of having a bite block that was easy to use. One of these was a tab added to the front of our bite block. We originally had stated that the bite block should be easy to place in a patient. However, Dr. B said it's also important to have something that is easily taken out in case the patient needs to be intubated. For this, he advised that the tab should be substantial so the clinician can easily grab onto it in emergency situations.

For the safe objective, we want this bite block to be safe by protecting the endoscope, be biocompatible and to have a low risk of injury. By protecting the endoscope, this is ensuring the patient's safety by eliminating the chance of the teeth breaking through the endoscope. Since the endoscope is made of many metal and electrical fibers, this would be very dangerous for the patient if it was broken. By having a bite block that is biocompatible, we want our device to be made of a material that will not only have the mechanical properties we need but also will not cause any adverse reactions in the mouth during procedures. Finally, having the objective be a low risk of injury requires us to design a bite block that can withstand the force of a human bite

as well as properly redistribute the force to the back teeth. Our ideal objective would be to have an injury rate of zero but our main objective is to have an injury rate less than what is reported currently. During this term, we got rid of a device objective to be able to retain any fragments. We decided to just focus on the breaking of teeth issues instead of the dislodgement of teeth due to the lack of reporting of loose teeth being inhaled.

### **Device Functions and Specifications**

Some key elements of our design include rear supports for molars, a tab for easy removal for the doctor, a reduced profile along the anterior, anchor points to keep the block in place with a band, and sloping angles to decrease force on the teeth. The BiteSafe bite block has many functions. One function is that it will stay in place, and therefore not slip out of the mouth at any point during the procedure. The bite block must also sit on the molars during the entirety of the procedure. If the bite block doesn't do this and slides horizontally, this would cause one side of the jaw to not be supported and it could make contact with the scope. Another function is that it will not put as much force, if any, on the anterior teeth. The importance of protecting the endoscope is a basic function because of the central role it plays in the procedure. Without this function, our bite block would not be a viable option for the procedure.

For a similar reason, the redistribution of force is also a basic function. We chose to measure this function by comparing force along the anterior teeth to the force along the posterior teeth. This comparison was chosen because there is always going to be incidental force applied to the anterior teeth, but if the majority of the force is experienced by the rear teeth it is less likely that tooth damage will occur. The testing was done to withstand the maximum bite force

of 800 N. This value provided a standard for us to use throughout. Our final function was comfort. Although this may seem less important, propping the mouth open for extended periods of time could result in lasting jaw pain for the patient after the procedure, especially if they have a temporomandibular joint disorder [12].

Table 1: A list of the functions and the corresponding specifications of BiteSafe. We also address how we plan on testing each function.

<u>Function</u>	<u>Specifications</u>	<u>How We Will Test The Function</u>
Protects Endoscope (B)	Yes/No	Deformation Tests on SolidWorks
Redistributes Force to Decrease the Chance of Breaking Teeth During Procedure (B)	Newtons at Anterior Teeth less than Newtons at Posterior Teeth	SolidWorks
Withstands Maximum Bite Force (B)	Newtons (~800 N)	Human Testing and SolidWorks
Be Comfortable For Long Periods of Time	Yes/No	Human Testing

## **Design Requirements**

Throughout our research, we found that the maximum bite force was upwards of 800 Newtons. Therefore, we did all of our testing and simulations at 800N so that we knew that our bite block would not break or collapse under this force. This 800 N value was taken as the maximum human bite force. It should be noted that the maximum bite force of the geriatric population is theoretically lower. By designing up to a higher bite force we aim to produce a product that has wider uses outside the targeted application of geriatric patients. Another design requirement is the addition to a tab in the front of the bite block. This tab can be used to easily place the bite block, move it to the necessary position and, most importantly, take the bite block out quickly in emergency situations. An emergency situation could be characterized as the patient needing to be intubated. When testing on human subjects, we observed that the tab was used often to find the best position and to take out the bite block, thus giving evidence to the fact that clinicians will find it helpful for placement.

Furthermore, we want to make sure the bite block, when anchored in place with a band, does not go too far in the back of the mouth. That is why we have added a bar in the front of the bite block. This bar will add a “catch” and prevent the bite block from being pushed too far into the mouth by the band holding the block in place. This can be tested by simulating the situation in SolidWorks. By incorporating the tension on the bite block put in place by the band and the bar, we can see if this bar will successfully keep the bite block in place. In addition to these requirements, we require that our bite block provide plenty of room for the endoscope to pass through. EGD endoscopes can be up to 10mm in size. Because our device lacks the tube to

guide the scope in, our bite block actually gives the gastroenterologist more room to move the endoscope through the digestive tract.

### **Documentation of the Proposed Design**

As shown in Figure 1, our final design presents a drastically altered EGD bite block than the one currently on the market, as seen in Appendix 2, drawing influence from dental bite props. This new design aims to protect the scope by propping open the mouth to the extent that when the teeth rest on the block, a natural opening is created for the scope. The blocks towards the back of the bite block will make contact with the upper and bottom molars, and the bottom part of the bite block will rest on top of the bottom jaw. The slope of the blocks on the back of the bite block is meant to maximize comfort for the individual while holding the mouth open. Since the mouth opens on a hinge, we decided that an angled block would fit best. The original angle chosen for the bite block was derived using the Pythagorean Theorem based on measurements of the average human jaw found from our research. You can see in Appendix 3 the calculations we did to find this angle. We ended up decreasing the angle based on feedback that the angle was too steep.

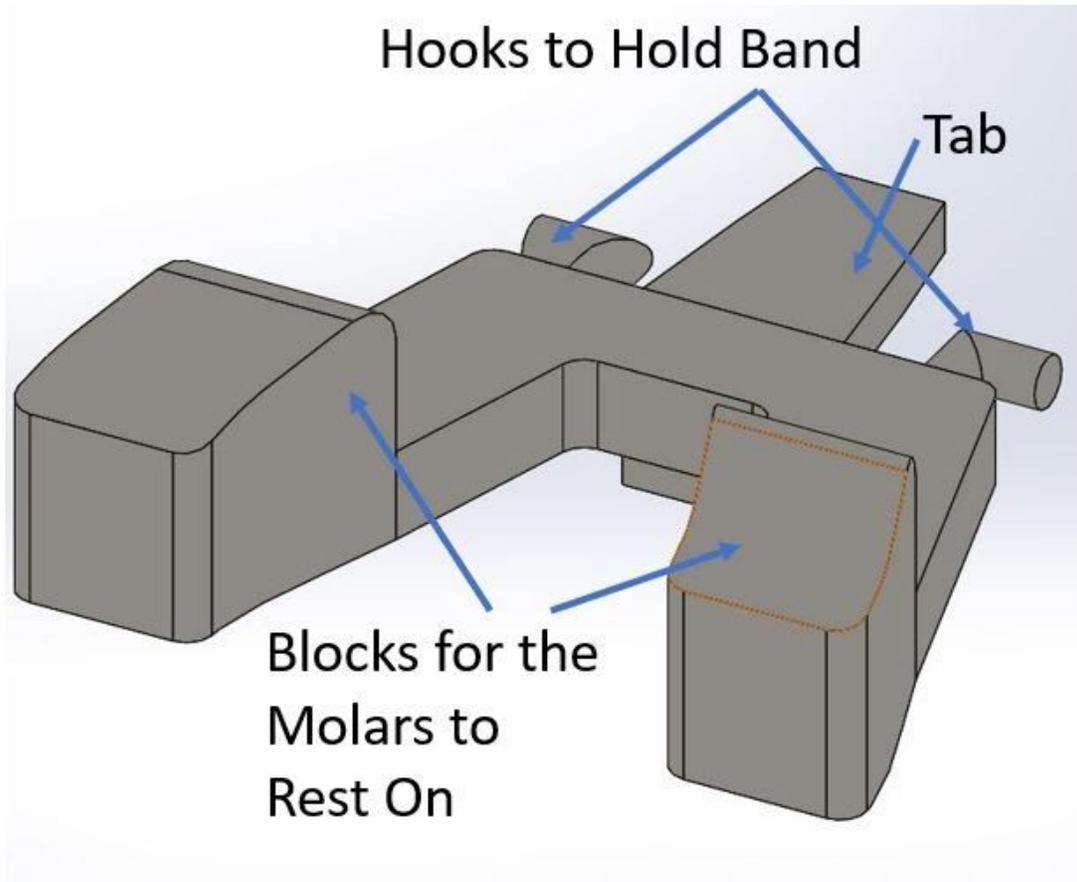


Figure 1. The labeled isometric drawing of our bite block from SolidWorks clearly showing the main components of our drawing.

This design prohibits the top anterior teeth from coming into contact with the scope. Because the current products on the market require the anterior teeth to clench down on the bite block which could easily cause breakage of the anterior teeth, we wanted to avoid this scenario. In order to avoid the bite block from dislodging and moving around in the mouth during the procedure, we added hooks that are built onto the front of the bite block which are designed to attach onto a band. This band will keep the bite block in the mouth and these bands are currently used with other EGD bite blocks on the market.

As you can see below in Figure 2, we designed the bite block so that it follows the curvature of the jaw in order to increase comfort for the patient. Again, this curvature is lacking in the current design used because the current design only interacts with the front teeth.

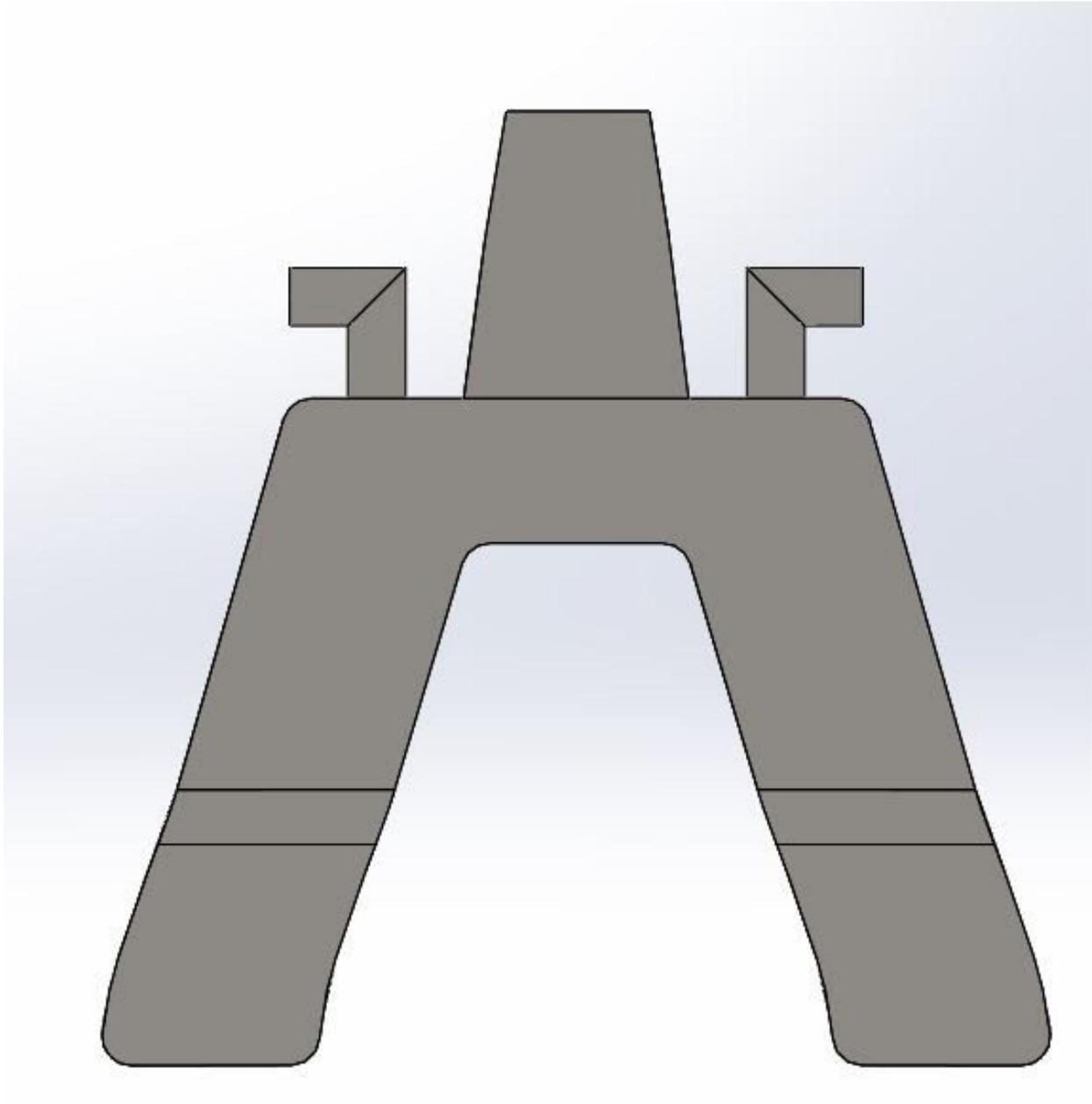


Figure 2. The top-down view of our bite block in SolidWorks.

In addition, there is a bar that extends down, as seen below in Figure 3, that is used to make sure the block does not extend too far into the mouth. This bar will act as partial lip protection for the patient. The current bite block on the market has minimal lip protection, and as a result, many patients end up with abrasions on their lips. Therefore, we wanted to try to reduce the chances of lip damage for patients. Due to the fact that maintaining position and avoiding injuries are key during an endoscopy, these two components were added to the design.

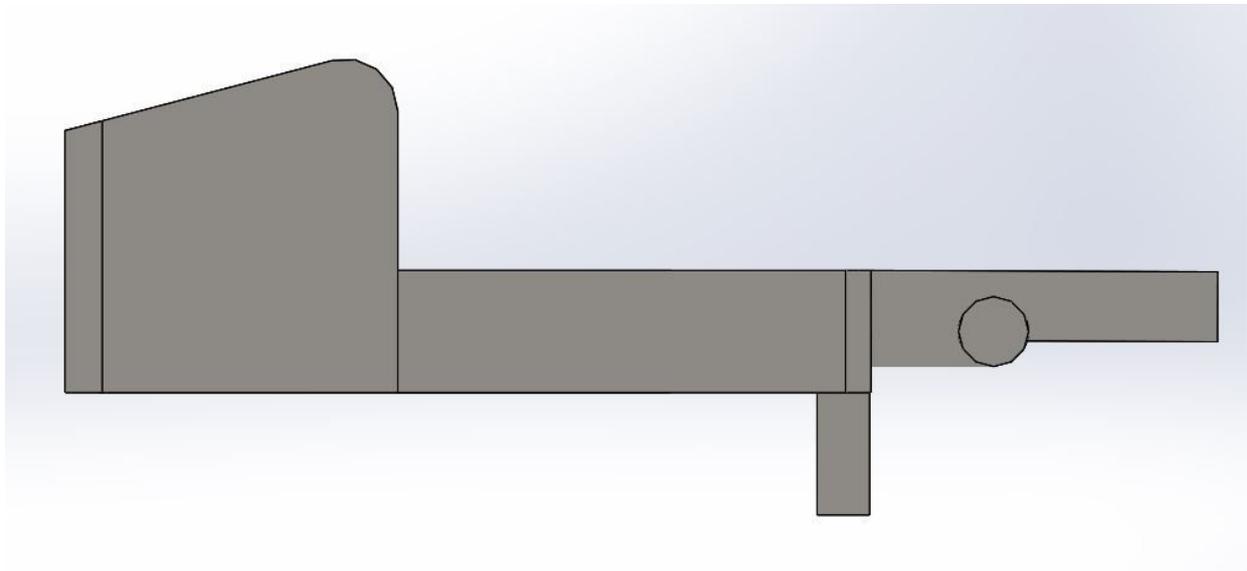


Figure 3. The side view of our bite block from SolidWorks.

Even though it is not shown below in Figures 1-3, we plan on coating the bite block with a softer material, where it would make contact with the teeth or soft tissue. This addition of material will increase comfort as well as reduce the chances of injuring soft tissue that a patient with no dentures or teeth may encounter. The amount of material would range in-depth due to the type of patient we were dealing with. For all patients with normal dentition, we would use our bite block model with some soft material on the blocks as well as on the bottom of the bite

block. However, for the patient that has their dentures out or has no teeth, this patient would require a bite block that can take up the volume lost from having no dentures or teeth. In addition, we would want there to be more of the softer material so that there is no risk of damaging the patient's gums. These patients with dentures would have their gums directly interacting with the bite block when the dentures were removed. For more clarification and images, see Appendix 1.

### **Validation of Design**

We used two different methods to validate our design. We conducted simulations on SolidWorks and we conducted human testing. Mechanical validation was done using Solidworks to simulate an 800 N load evenly applied across the two faces where molars contacted the design. The bottom surface was fixed. The load was only applied to the blocks because, in the event that the patient bit down, these surfaces would be the first to bear the load.

To do the human testing portion, we went through the human subjects review committee and got their approval before beginning our experiment. We printed three different sizes, small, medium and large, of the bite block for people to use. We asked eighteen people to place the device in their mouth for fifteen minutes. We chose this time due to the similarity in the time period of the typical endoscopy procedure. We would have liked to get more people to test the bite block, but due to the COVID-19 outbreak, people were hesitant about participating even after reassuring them that we were constantly sanitizing the bite blocks. We asked the participants to fill out a survey that asked a variety of questions; we asked them to rate on a scale of 1 (being the worst) to 5 (being the best) how the bite block felt in their mouth and if the bite

block felt like the perfect size for your mouth (1 being strongly disagree and 5 being strongly agree). The other questions we asked were if the bite block did not feel like the perfect size, was it because it was too wide or too narrow? We also asked if they felt any pain, and if so, where they felt it. Our final question was if they had any comments or concerns with our newly designed bite block. The results we received from our human testing showed that about 72% of our human subjects rated the bite block as comfortable. For the rating to be called comfortable, the person needed to put a 4 or a 5 as a rating for how the bite block felt in their mouth. The only other score we received was one 3.

Figure 4 shows the results of the SolidWorks compression simulation test. The 800N force was equally distributed over the two blocks where the molars would be in contact with the bite block. As you can see from the colors, there was no pressure on the front part of the bite block where the anterior teeth could come in contact with the bite block, which was our goal. In addition, from the colors (mainly blue and green), you can see that there is minimal deformation from the molars. This test proved that our design would not collapse under the strongest bite force using polycarbonate material.

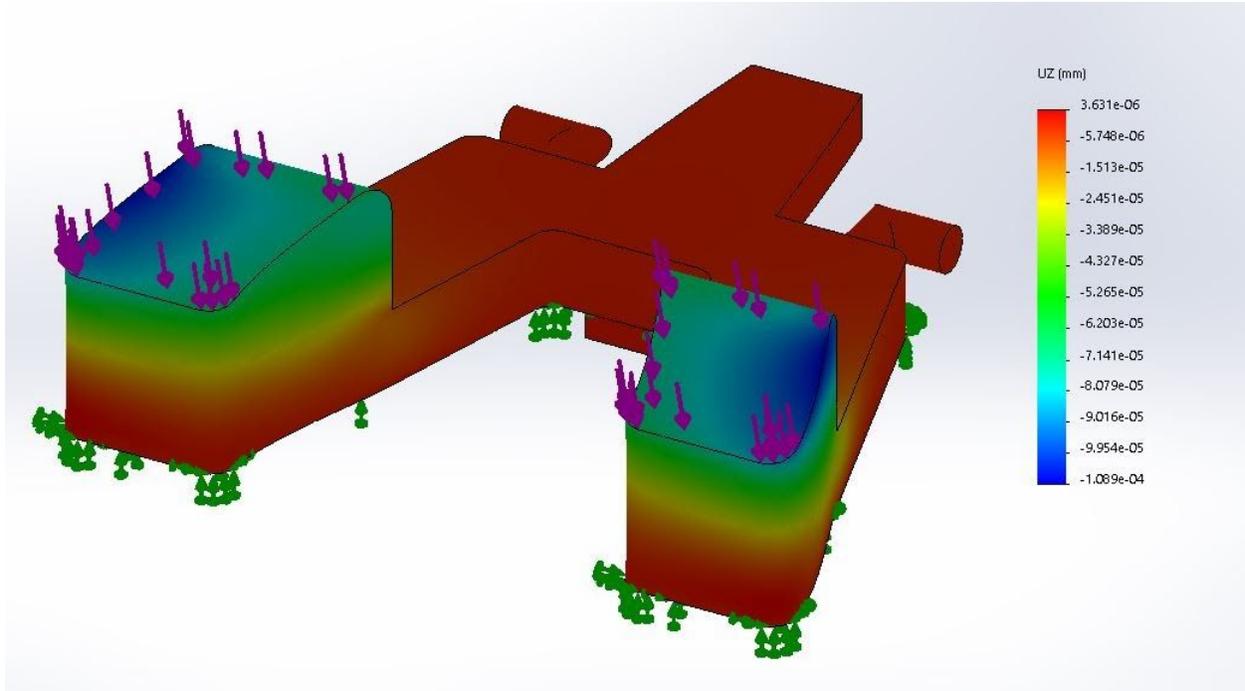


Figure 4. The compression simulation test run in SolidWorks using an 800 Newton force on the blocks where the molars rest.

Polycarbonate was selected as the material in Solidworks. Although we discussed several materials as the potential end material, we selected polycarbonate because this was the most readily available material that satisfied our design requirements and was available on Solidworks. The resulting deformation of the load-bearing blocks was minimal. This validated our design under the maximum bite force conditions. Also, we had discussed the possibility of using a polycarbonate-polyurethane blend as our final material. Since this was not available in SolidWorks, we chose polycarbonate.

## **Anticipated Regulatory Pathway**

When searching for a 510(k) device that would be applicable to our device, we searched ‘bite block’ and we found an application from ENDOSCOPIX for a device called Endoscopic Bite Block. The 510(k) number is K896691. The applicant’s contact is Michael Bradbury. The device name is bite block. The regulation number is 876.1500 and the classification product code is MNK. The date the application was received by the FDA was November 28th, 1989 and they declared that it was substantially equivalent on February 20th, 1990. The 510(k) review panel is Gastroenterology/Urology and they viewed it as a traditional type. This product was not reviewed by a third party nor is it a combination product [13]. When we detailed in on the regulation number, it brought us to the official identification and classification of the device. Under Part 876 Gastroenterology- Urology Devices, Subpart H - Diagnostic Devices, Section 876.1500 Endoscope and accessories, the FDA identifies the endoscope as a tool that allows the clinician to visualize, enter, diagnose and treat areas that are usually inaccessible. An endoscope is a broad categorization of many different tools that when introduced into the body that provides a visual experience.

The attachments that you can get for an endoscope enable the clinician to go farther into the body cavity or manipulate the area they are working within. These tools range in stiffness to allow the endoscope to keep its shape but also easily maneuver through the human body. Devices that are considered examples of endoscopes consist of rinsing attachments, camera attachments, optic attachments, power sources, specialty endoscopes and coatings that decrease friction during the procedure. The FDA classifies the endoscope itself as a class II but the attachments and other supplies needed for the endoscope including a bite block are rated as a

class I. They go on to say that products listed were excused from any premarket notification procedures and that this device does not need FDA clearance before going to the marketplace [14].

Upon researching in the FDA database, we found that the endoscopic bite block is categorized as a Class I Device [15] whereas a neurological bite block used when a patient is experiencing a seizure is a Class II Device [16]. An issue we expect to have is the ability to use the final material we would like. Polycarbonate-polyurethane blends are used in orthopedic implants in Europe currently [17] and have mechanical properties that would easily suit our bite block. However, this material has not yet been used in any products in the United States so we predict that this may be an issue for our product.

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## Appendix 1: Next Steps

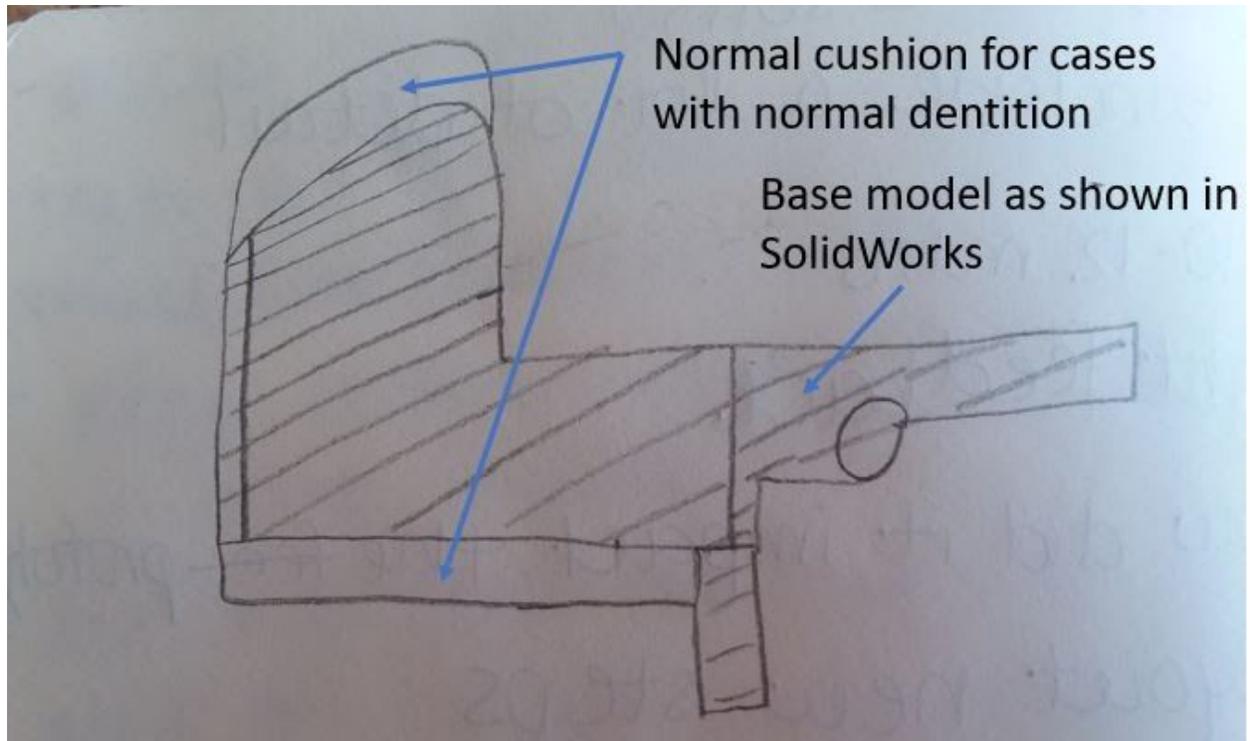


Figure 5. Hand drawing showing where the soft outer material would be located.

This drawing is showing where the soft material would be placed on the bite block to provide comfort for the patient. This picture is representing the normal or baseline model that would be used on patients that have all of their teeth or if they are wearing dentures during the procedure.

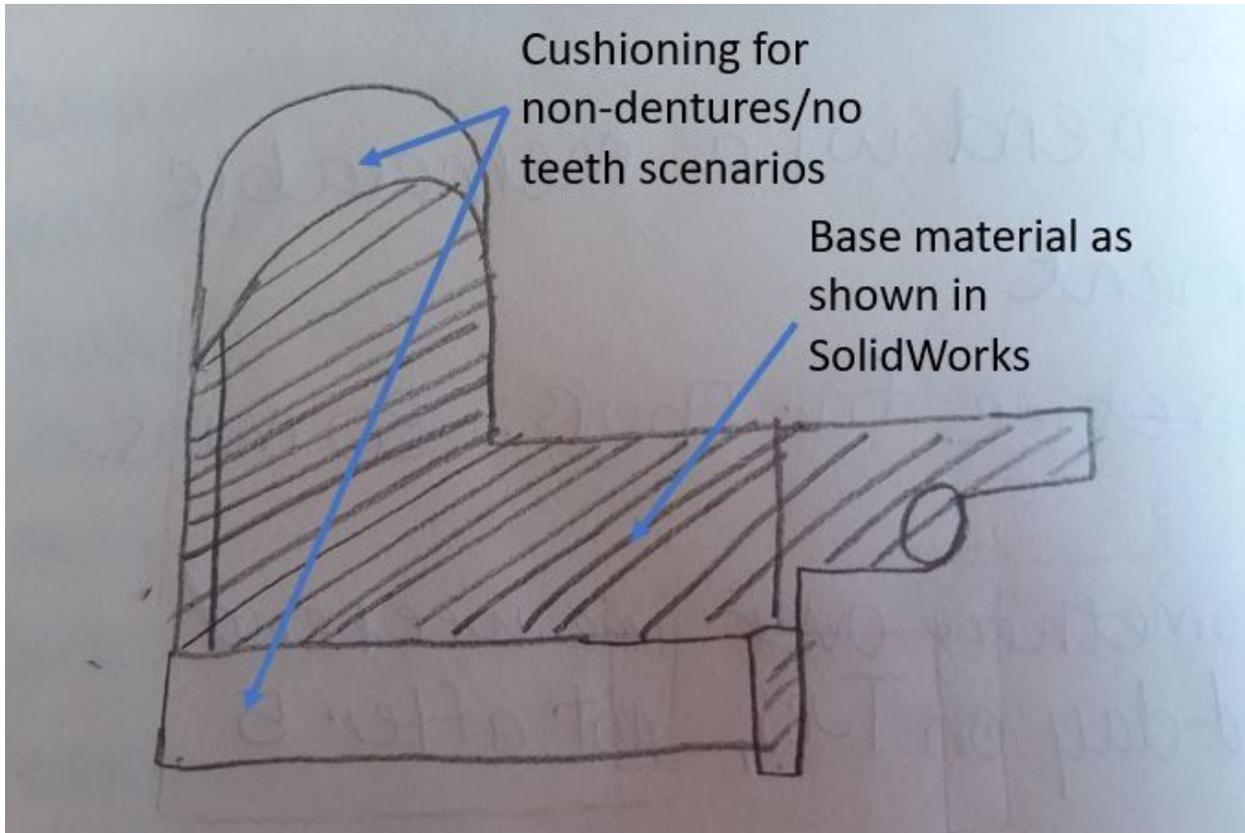


Figure 6. Hand drawing of our bite block for patients without teeth.

This drawing represents the model that would be given to patients with no dentition or the clinician decided to take out the dentures for the procedure. The extra cushioning shown on the bottom of the bite block, as well as the tops of the blocks, will avoid any potential damage to the gum area.

## Appendix 2: Current Technologies



Figure 7. The current EGD bite block [18].

This is the current EGD bite block on the market. You can see that it is made from one uniform material, which happens to be very hard plastic. The hooks on the side are where a strap can be attached in order to keep the bite block in place. The hole in the middle is where the endoscope goes through. The longer part, that extends backward, is where the patient's anterior teeth bite down onto the block.



[19]

Figure 8a. Dental bite prop in a patient's mouth.



[20]

Figure 8b. Dental bite prop. The largest one is shown in a jaw model.

### Appendix 3

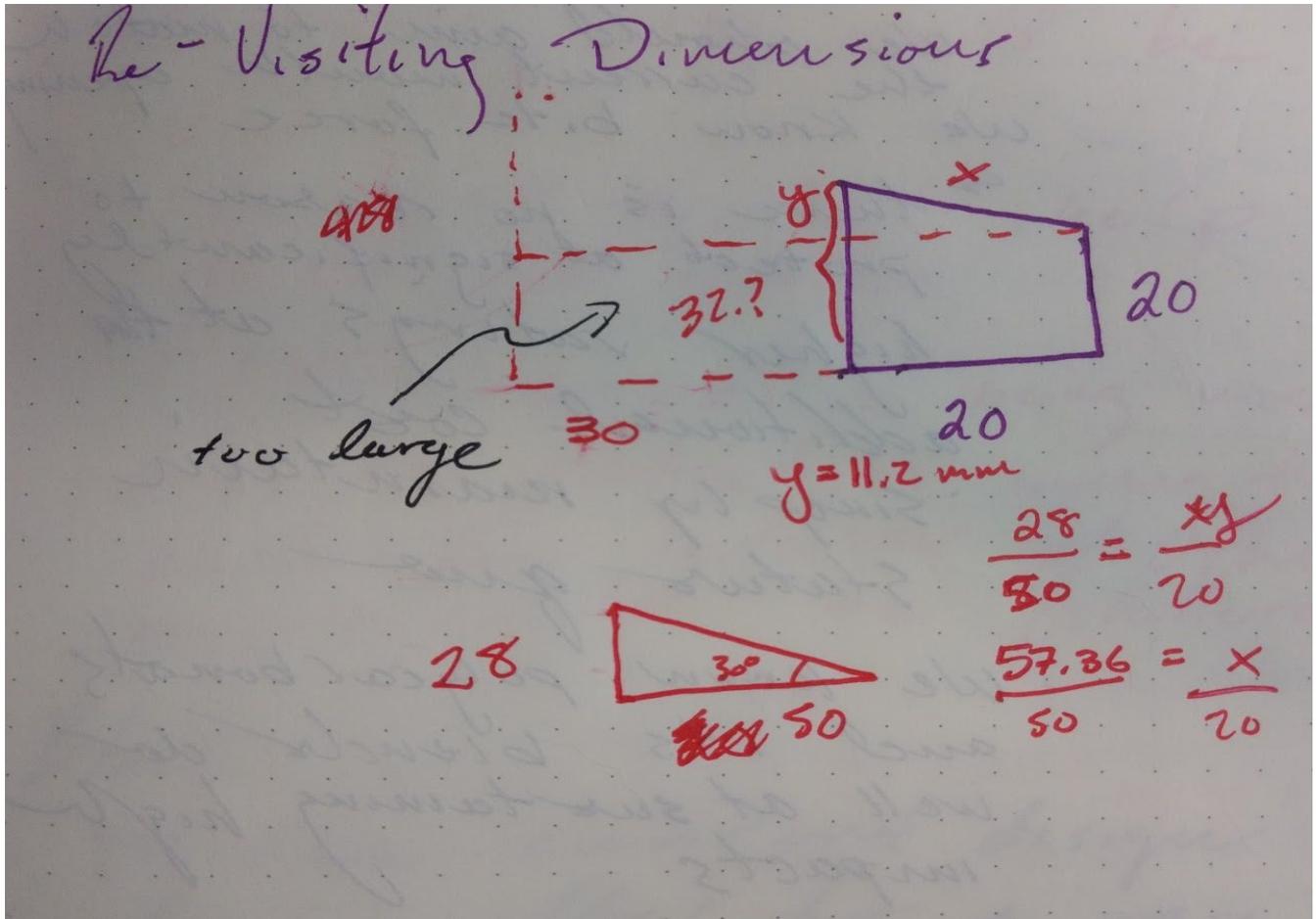


Figure 9. Example calculations using the maximum mouth opening in order to create a preliminary angle.

These calculations show how we originally determined the angle for the block where the molars would rest on. After analysis of the 3D-printed block and human testing, we constantly made adjustments from here to the angle. In the end, the angle was less than the original angle calculated here.