Training Models for Enucleation and Orbital Compartment Syndrome

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Abstract

Enucleation and lateral canthotomy are two ophthalmic surgeries with little or no training models. Residents learn these procedures in the operating room by watching faculty and then advancing to take over more steps. The goal of this project is to build training models that will give the residents realistic training on the most important steps of both procedures while also being reusable, high-fidelity, and inexpensive. The models will provide training to residents and doctors in low-resource countries as well as the US to reduce post-operative complications and improve surgical quality.

Executive Summary

Currently, there are no training models for two important ophthalmic surgical procedures, enucleation (removal of the eye) and lateral canthotomy (used to treat orbital compartment syndrome). Residents learn these surgeries in the operating room by watching a faculty member perform the procedure and then by taking over more and more steps. One way to eliminate this risky form of training and to help those in low-resource countries is to create training models that will focus on the most important, and often most difficult, parts of both surgeries. The identified requirements of high priority for the lateral canthotomy model were consistent user experience, simulating cutting the skin and tendons, simulating the intraocular pressure, being reusable, and the ability to be easily reset. Many requirements for the enucleation model were the same as the lateral canthotomy model, with some small differences. The requirements for enucleation with high priorities were easily resettable, low cost cost per use, and simulating the cutting of the optic nerve and eye muscles. After the requirements and specifications were solidified, brainstorming, the making of a morphological chart, and stakeholder input was used to generate potential solutions. After the concepts were generated, a gut check, more stakeholder input, and pugh charts were used to determine an alpha concept for both the enucleation and lateral canthotomy models. After the alpha concepts were developed, the team and Dr. Nelson tested the prototypes and found improvements, the team

iterated the designs, and made other models to retest. At the end of the semester, the simulators created achieved nearly all requirements and only need a few small future improvements to be finalized. After they are validated by Dr. Nelson and other residents and doctors, they will be used in classrooms as soon as July 2022.

Table of Contents

Background

Surgical Simulators

Currently, ophthalmic residents learn complex surgeries in the operating room by watching faculty perform the procedures and then advancing to doing more steps of the procedure. Surgical simulators represent an important step in the advancement of residency training as they allow for procedures to be learned without the need for a patient that could potentially be put at risk by an inexperienced surgeon. Previous studies have found a positive correlation between simulation-based assessments and patient-related outcomes [4].

Lateral Canthotomy

Lateral canthotomy, the first surgery we plan on simulating, is the surgical exposure and incision of the lateral canthal tendon, used to treat orbital compartment syndrome (OCS). OCS is an ophthalmic emergency characterized by an acute rise in intraocular pressure [5]. This rise in pressure damages ocular and other intraorbital structures, which may lead to irreversible blindness if not promptly treated. Studies suggest that 60–100 minutes of raised orbital pressure may cause permanent visual sequelae [11]. Common causes of OCS include acute orbital hemorrhage due to trauma, surgery, local injections, and pre-existing medical conditions. Because of the extreme effects of untreated OCS, lateral canthotomy procedures may have to be performed by emergency physicians, as well as ophthalmologists [14].

Lateral canthotomy is a relatively simple procedure, with only a couple steps. The first step is to prepare the skin on the lateral side of the eye with an antiseptic agent and then inject a local anesthetic into the incision site. From there, the operating physician will use a needle driver or hemostat to crush the tissue from the lateral canthus to the rim of the orbit, for about 20 seconds to 2 minutes. Crushing this tissue helps minimize bleeding and makes it easier to see where to cut when there is extensive traumatic edema. Next, they will use iris scissors to cut the skin from the lateral canthus to the rim of the orbit, about 10 to 20 mm. This step, known as the canthotomy, exposes the lateral canthal tendon. From there, the surgeon will cut the inferior and sometimes both crus of the lateral canthal ligament, which can be seen in Figure 1. This will release the intraocular pressure. Complications from this procedure may include mechanical damage of the eye, hemorrhage, and/or infection. The urgency of the procedure, combined with traumatic distortion of the anatomy and possible unfamiliarity with the procedure by non-ophthalmologists, may increase the risk of complications [5].

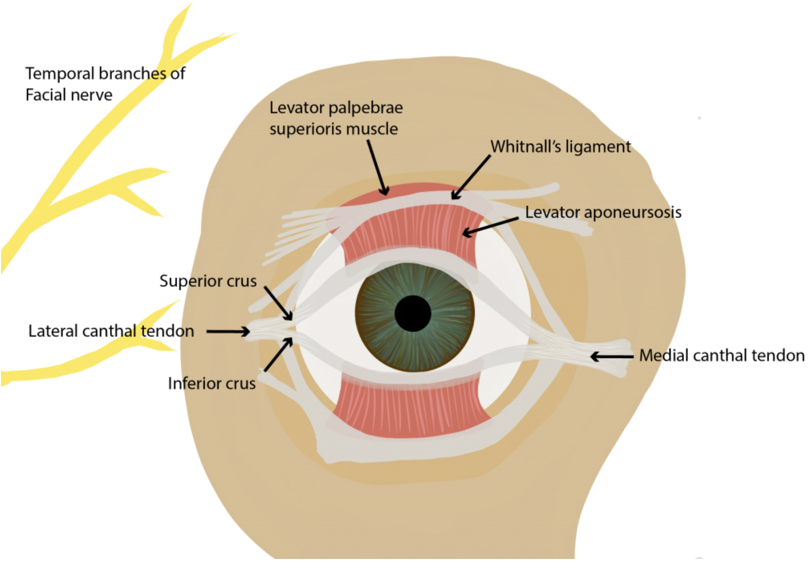


Figure 1: This is a diagram showing the soft tissue around the eye. The superior and inferior crus of the lateral canthal tendon, which are cut during a lateral canthotomy, can be seen to the left of the eye [21].

Enucleation

The second surgery we plan to simulate, enucleation, is the surgical removal of the eyeball from the eye socket. Unlike lateral canthotomy procedures, enucleations are planned procedures, and only performed by ophthalmologists. The indications for enucleation include a blind, painful eye; a painless, but disfigured, blind eye that causes psychological distress; sympathetic ophthalmia; and both diagnostic and therapeutic evaluation of intraocular tumors. The goals of enucleation involve elimination of pain, excellent cosmesis and restoration of orbital volume [17]. Enucleation is initiated by performing a 360-degree peritomy. This exposes the extraocular, or rectus, muscles, which are to be cut. Each rectus muscle is, in turn, isolated with a muscle hook, followed by placement of a second hook from the opposite direction. Sutures are attached to each muscle to secure it. Each muscle is then transected anterior to the suture. After the muscles are cut, the optic nerve needs to be cut to fully remove the eyeball from the eye socket. Locating and cutting the optic nerve is generally viewed as the most difficult step in this procedure [18]. While placing gentle upward traction on the globe with forceps grasping the medial and lateral rectus muscle stumps, the optic nerve is “strummed” behind the globe with a large curved hemostat to determine its location. Then, while the hemostat is pushed posteriorly, the optic nerve is clamped for one to two minutes. The optic nerve is then transected with the enucleation scissors and the eyeball is pulled out of its socket. A diagram of this procedure can be seen in Figure 2. Possible complications from enucleation include loss of extraocular muscle function with decreased motility of the prosthesis, orbital infection, implant extrusion, enophthalmos, pyogenic granuloma, ptosis and visual hallucinations [17].

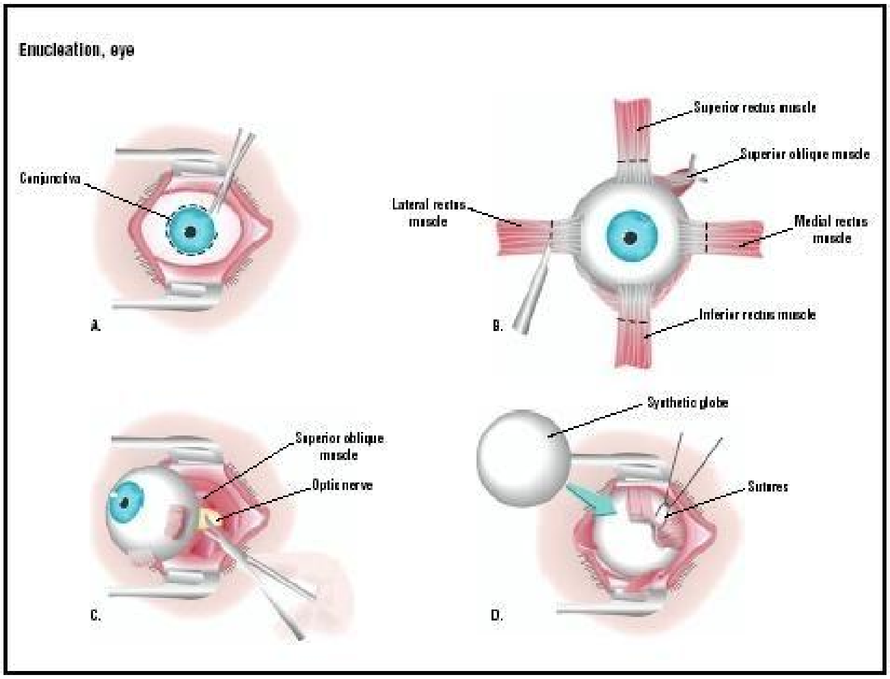


Figure 2: This is a diagram of the enucleation procedure. Part A shows the initial peritomy, Part B shows the cutting of the optic muscles, Part C shows the cutting of the optic nerve, and Part D shows the insertion of a prosthetic eye [8].

Benchmarking

Low Resource Surgical Simulators

The need to perform complex surgeries is not limited to just high-income countries. Thus, surgical training is needed all over the world, including low-income countries. These countries face challenges others don't, where high-fidelity surgical trainers are often too expensive to be purchased in these settings. As surgical simulators continue to prove to be helpful at teaching residents and surgeons the skills required for surgeries without the need of a patient, low-cost alternatives should be a priority for low-resource hospitals. It has been shown that low-cost surgical simulation training significantly improved initial live surgeries performed by novice trainees in low-resource settings [9].

Lateral Canthotomy and Enucleation Simulators

When looking for previous attempts to create simulators for lateral canthotomy and enucleation procedures, we were able to find multiple low-cost, low-fidelity simulators for lateral canthotomy, and one medium-cost, high-fidelity model for enucleation.

For lateral canthotomy simulation, there are high-fidelity cadaveric and commercially available models. However, these are very expensive and can only be used once due to the destructive nature of the procedure. For example, the *SynDaver™ Labs Lateral Canthotomy Trainer*, which costs $750, is a high-fidelity trainer with many tactile, visual and structural details, but provides only two opportunities to perform lateral canthotomy per trainer, and cannot be "reset" for additional uses [12]. This model can be seen in Figure 3.

Figure 3: Shown is an image of the *SynDaver™ Labs Lateral Canthotomy Trainer*, a high-fidelity, single-use model that costs $750 [23].

On the other side of the spectrum, there are low-cost, semi-reusable, low-fidelity models such as the ping pong ball [12] and hard-boiled egg [15] models. As seen in Table 1, these models significantly decrease assembly time and cost per model compared to cadaveric and current high-fidelity models. However, these models sacrifice realism for cost, and have other problems, such as needing to be held in place while being used. Overall, these trainers are good for beginners, but are "not appropriate for use in high-fidelity simulation, where tactile, visual and functional verisimilitude is an essential part of the learning experience" [12]. Images of these models can be seen in Figures 4 and 5.

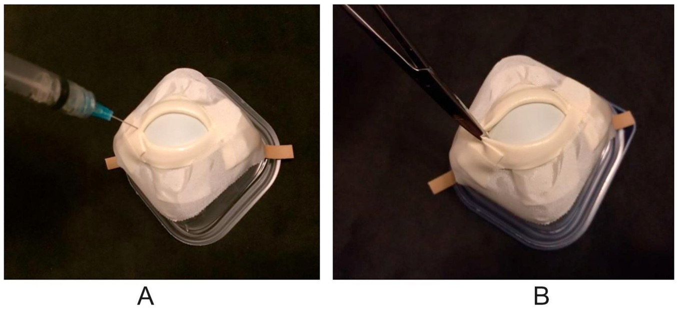


Figure 4: This image shows the ping pong ball model in use. In addition to a ping pong ball, the model also consists of a rubber band, a 10 ml Ziploc recyclable container, pressure foam tape, scotch tape, transpore tape 3 M™, and silk tape [12].

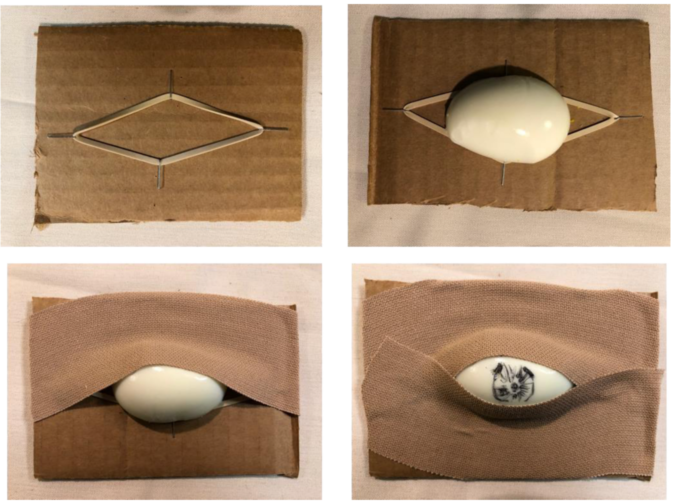
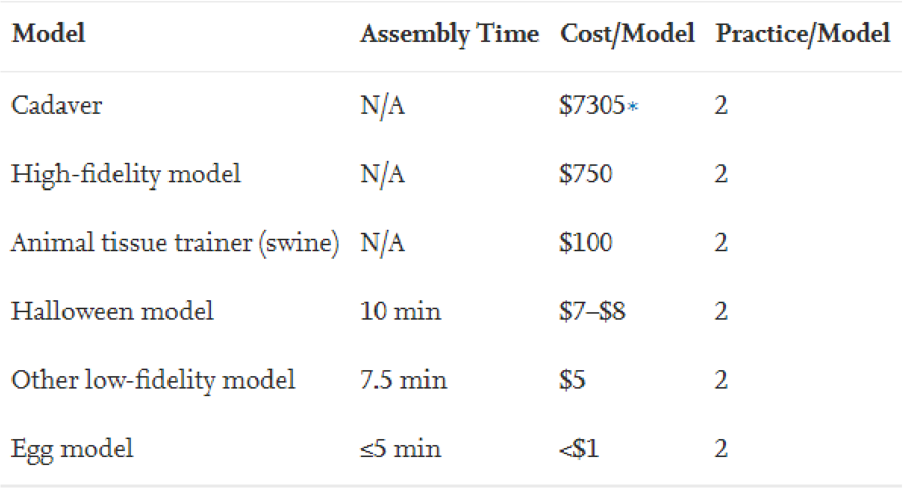


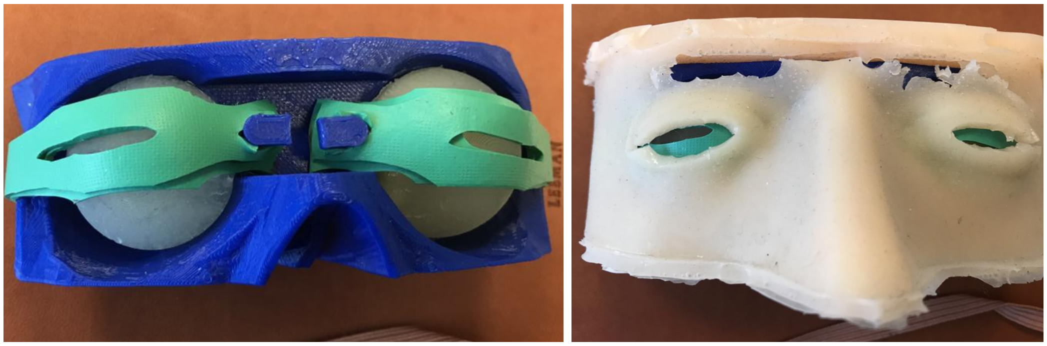
Figure 5: This image shows the construction of the Egg lateral canthotomy model. In addition to a hard-boiled egg and rubber band, this model consists of cardboard, staples, and Elastoplast [15].

Table 1: Comparison of Lateral Canthotomy Models by Assembly Time and Cost [15]



Model	Assembly Time	Cost/Model	Practice/Model
Cadaver	N/A	$7305*	2
High-fidelity model	N/A	$750	2
Animal tissue trainer (swine)	N/A	$100	2
Halloween model	10 min	$7–$8	2
Other low-fidelity model	7.5 min	$5	2
Egg model	≤5 min	<$1	2

A previous University of Michigan Multidisciplinary Design Team has also created a low-cost, medium-fidelity lateral canthotomy simulator, furthermore referred to as the MDP Model and seen in Figures 6 and 7. We were not able to find any documentation on this model outside of verbal recollection of it from our project sponsor, as well as pictures of it. This model was able to simulate the cutting of the lateral canthal tendon, but not any of the steps before that. Additionally, it had issues with durability and ease of assembly [18].



Figures 6 and 7: These are images of a lateral canthotomy model developed by a University of Michigan Multidisciplinary Design Team, showing the model with and without itsF rubber “skin” cover. The green rubber bands represent the lateral canthal tendon, which can be replaced after each use [18].

We believe that because enucleation is a much less common procedure than lateral canthotomy, there have not been as many attempts to create a low-cost simulation model. The only model we were able to find is a high-fidelity model called the *Bioniko Exos Model for Enucleation and Excision*. The *Exos* costs $250 for a pack of four single-use models, plus an additional $350 for the reusable holder. While high-fidelity simulators provide a great way for physicians to practice surgical skills without patients, their high price point puts them out of reach for low-resource settings.

As seen in Table 2, there is an apparent need for low-cost, medium- to high-fidelity, reusable simulators that can be used for training physicians in low-resource settings.

Table 2: Comparison of Current Lateral Canthotomy and Enucleation Simulators

	Price	Fidelity	Reusable	Set-Up Time
SynDaver™ Labs Trainer	Medium	High	No	N/A
Ping Pong Ball Model	Low	Low	Yes	7.5 min
Egg Model	Low	Low	No	5 min
MDP Model	Low	Medium	Yes	<1 min
Cadaver	High	High	No	N/A
Bioniko Exos	Medium	High	Partially	10 min

Design Process

In this project, to produce the highest quality product at the lowest cost and with the shortest development time, a structured design process is followed. The flow chart of the process is shown in Figure 8. It is derived from Cross's model of the design process [6]. So far the problem definition is done by interviewing Dr. Nelson and relative background research. Constraint identification will be done when our requirements and specifications are fully determined. In the rest of the semester, the process of solution brainstorming, solution selecting, prototype generating, testing and communicating will be followed. The most useful process in our project is the constraint identification. This is because accurate data of material properties and biomedical structures are needed for making high-fidelity training models in this project. Huge amount of research is necessary before we develop the solution. At the end, those specifications are also the primary criteria for the verification. A loop between testing and solution selecting is also useful for our solution development. So this design process model fits our project. Our design process is quite similar to the standard design process introduced during the lecture on the first day of class except that we add a loop back to the solution selection. This is because the material selection can be adjusted to increase the fidelity without a big change to the whole project at the end stage.

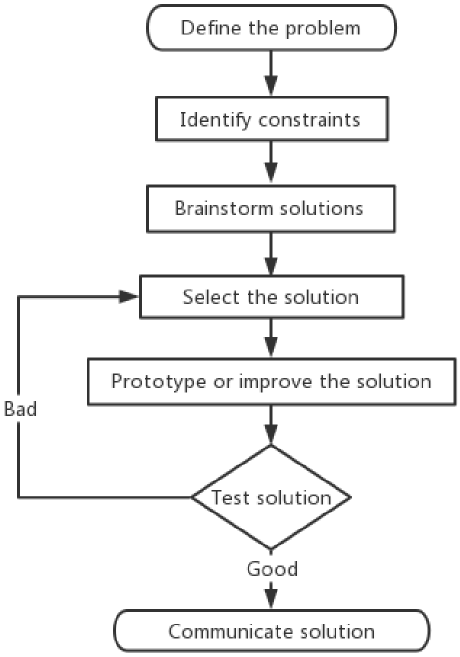


Figure 8. Flow chart of the design process for this project.

Design Context

Our project improves public health on a global level. In the immediate future these trainers will be deployed to train residents at the University of Michigan. Once COVID restrictions are lifted, Dr. Nelson plans to take these trainers to Ethiopia. Underdeveloped countries often have less access to medical technologies, which is a social challenge. In the case of these surgeries, a lower quality of instruction and ability to practice may lead to more mistakes and complications. By providing high-fidelity and low-cost trainers, we will be contributing to a higher standard of care. For both models, the environmental impacts will be minimal. For the canthotomy trainer, some surgical tape and one rubber band is consumed per practice run. For the enucleation trainer, a few centimeters of polypropylene rope and four rubber bands are consumed per practice run. For both trainers the rubber bands can be recycled, decreasing the environmental impact further. Both trainers will be made out of mostly PLA, roughly 300 grams each, and will be reusable hundreds of times. By increasing the reusability and durability of the models, the fixed costs are amortized to a greater degree which decreases the monetary and environmental cost per use. Economically these trainers are low-cost to fabricate and use, but we are not sure about their wide-scale appeal and marketability, which affects their sustainability and long-term adoption.

Ethically there are very few conflicts with these trainers, since they are being effectively donated at the end of the semester to the UM hospital and then to Ethiopian hospitals, and they are being used to improve public health. Our most important requirement is to make sure that they are high-fidelity and improve the capabilities of the people using them, and do not make them worse either through inaccuracies or by providing false confidence.

Stakeholders

Table 3: Stakeholders with their impact and influence

Stakeholder	Impact	Influence
Dr. Nelson	High	High
Residents	High	Medium
Surgeons/Doctors	Medium	Medium
Patients	High	Low

When brainstorming potential stakeholders, four came to mind. They are listed in Table 3. The first is Dr. Nelson. She will be the individual with the most influence in the design process as she will be the first one to use the model when she teaches her students and fellow doctors. Afterwards, she will be the main decision-maker on who uses the model apart from her, and who will be given our model. Along with being the main beneficiary, she is also our biggest source of information. Her experience of performing both surgeries and her knowledge of the procedures and the mistakes made during them will allow us to make the best model to learn from. Our plan to engage Dr. Nelson is through continued weekly meetings and in-person testing of the prototypes when they are made.

Our second stakeholder is ophthalmic residents. These students will be taught key steps of the procedures on our models and will gain experience and confidence through them. They can provide us a great deal of feedback and insight because of their inexperience. Dr. Nelson has done these surgeries for several years and is one of the best there is. However, there may be things that she overlooks or are second nature to her that are critical to include in our model. Residents can provide us this insight on what may be small but is needed to perform these surgeries correctly. We plan to engage the residents in meetings, surveys, and in-person testing of prototypes.

Our third stakeholder is doctors or surgeons who will have performed either the canthotomy or enucleation on a regular basis. They, like the residents, will be training on this device here in America and potentially in Ethiopia. Even though the doctors will be affected by the model in the same way as the residents, they share a great opportunity to get insight on our model and the procedures. Many of these doctors have performed one of the two procedures before and even if their confidence is not strong, their experience can help us make a better model for them to learn from. The strategies of engagement are the same as the residents with meetings, surveys, and in-person testing being at the forefront.

Our last stakeholder is the patients themselves. They have no significant influence in the making of the model but will be most affected by the model’s ability to fulfill its purpose. If the model teaches residents and doctors more about the procedures and teaches them key mistakes to avoid, more people will have their vision saved in the case of lateral canthotomy, or limited tissue and socket damage in enucleation. We have no current plans to engage patients but are very interested to see how our model influences patients' surgery experiences in the future.

Requirements and Specifications

Our engineering targets are expressed as requirements and specifications. Below are the requirements and specifications for a lateral canthotomy model and an enucleation model. Many requirements and specifications are shared between the two but for sake of space and clarity, the repeated ones will be only placed in the cantholomy portion. All the requirements were chosen using sources, either interviews with Dr. Nelson or peer-reviewed articles from scientific journals. Since training models for ophthalmic surgeries is such an unexplored area, and since it is only for training purposes, there were no standards, local or federal, that limit the opportunities for requirements to appear. The relative importance for each requirement is expressed by a high, medium, or low priority. These were determined by our group discussion first, and then verified by Dr. Nelson in interviews. Requirements with high and medium priority of importance must be met in our design and those with a low priority would be nice to include, but have not been deemed necessary for success. All requirements have been translated into engineering specifications. They are reasonable based on the interview with Dr. Nelson and DR1 presentation feedback from Prof. Sienko. However some of the specifications are not yet fully quantified due to the lack of accurate data support. The missing data will be collected in future research before DR2. Compared with existing training models listed in Table 2., our models reach a better compromise of realism and cost.

Lateral Canthotomy

Below are the identified requirements and specifications for a lateral canthotomy model. Each reqiurement’s source(s) are listed at the right. Along with a priority rating, each requirement has a stability rating. A requirement will be green if it is solidified and will not change, yellow if it is firm but can still change, and red if the requirement holds little weight and could be removed later on in the design process.

Table 4: Requirements and Specifications for a Lateral Canthotomy Model

Priority	Requirements	Specifications	Reference
High	Able to simulate cutting skin and lateral canthal tendons	Difference of material properties between model and actual biological structures is within **10%** Skin's Young's Modulus: **0.33MPa ± 0.04** Skin's Shear Modulus: **2-8 kPa** Tendons: Length: **10.6 ± 0.9 mm** Height: **6.6 ± 0.5 mm**	[10] [27] [28]
High	Able to simulate intraocular pressure	Pressure: **60 mmHg**	[1] [19]
High	Easy to reset	Takes **< 90 seconds** to reset	[19]
High	Reusable	Aside from consumables that are cut, nothing else needs to be replaced during normal use Lifetime **> 500 uses**	[18]
High	Consistent in user experience	Difference of material properties between each specimen is within **10%**	[19]
Medium	Able to reflect success	Able to give physical feedback to tell if release the intraocular pressure in training	[22]
Medium	Inexpensive	Consumable cost: **≤ $0.25 per use**	[18]
Medium	Portable	Volume: **≤2000 cm^3** Weight: **≤200g**	[2] [18]
Medium	Keep base from moving	Withstand 10 N force from the side without moving	[29]

Low	Durable	Able to withstand a drop from **1.5 meters** Able to be sterilized with alcohol/oxivir wipes	[19]
Low	Helpful in learning surgical techniques	Student survey/Dr. Nelson's feedback on teaching: **≥80%** satisfaction.	[18]

The first requirement is being able to simulate cutting skin and lateral canthal tendons, which is our foremost priority as it is the whole purpose of the model. Although it is the most important requirement, we want to provide some wiggle room for accuracy to keep costs low. Therefore, a 10% buffer was implemented. We had the Young's Modulus for skin since the first design review, and have since found the shear modulus of skin. Using this data we have a starting point for considering which synthetic materials to use to simulate the skin. We also found the length of height of the lateral canthal tendons.

The second requirement is being able to simulate intraocular pressure. It has high importance because feeling of a pressure similar to that in OCS provides further realism and higher fidelity to the model. The specification is that the simulator should present an internal pressure within 10% difference to the real pressure. According to literature, the diagnosis of OCS is an intraocular pressure of 30-45 mmHg. However, Dr. Nelson has stated that many cases of OCS tend to have an intraocular pressure closer to 60 mmHg. To meet the stakeholder's requirement, 60 mmHg is taken into account.

The third requirement is being easy to reset. This has a high importance because Dr. Nelson aims to use this model to train residents in low-income countries. There are large numbers of people lining up for training. A short resetting time for next use can strengthen the training efficiency. The specification is that it should take less than 90 seconds to assemble the consumable part and set it ready for the next trainer. The time is expected by Dr. Nelson.

The fourth requirement is being reusable. It has a high importance because this training model is mainly for low-income countries, Dr. Nelson hopes the majority of the simulator can be used for a long time to save cost. The specification is that the model should survive a lifetime over 500 uses and need no part to be replaced except the consumables that are cut. This is determined by the interview.

The fifth requirement is being consistent in user experience. This has a high importance because a qualified training model should provide the trainers the same feeling on every trial. The specification is that the difference of material properties between each specimen should be within 10%. This means that the selection of consumable parts should be fully considered. It can only be or easily manufactured by locally available materials. And it should not transform during the assembly that might cause inconsistent feeling. This is determined by an interview with Dr. Nelson.

The sixth requirement is being able to reflect success. The specification is that the model should be able to give feedback to the user after intraocular pressure has been released. It has a medium importance because this helps the trainer better judge if they command the operation. This is suggested by Professor Sienko in DR1 feedback.

The seventh requirement is being inexpensive. It has a medium importance because training efficiency is higher only if it is affordable to residents in low-income countries. According to Dr. Nelson, the specification is that the price for the consumable parts should be less than $0.25 per use.

The eighth requirement is being portable. It has a medium importance. As most of the training takes place in other countries, the models should be made as small and light as possible so that it is easier for Dr. Nelson to carry during the trip. The specification is that the volume should be less than 2000 cm^3 . That is the volume for a rectangular prism surrounding the average adult male face [2]. The height is from the nose to forehead, containing both eyes in width and the length is the depth of the orbit.

The ninth requirement is that the base is able to withstand a 10 N push force without being moved. The specification is based on the tool-tissue forces likely to be exerted during the surgery. The purpose of this requirement is twofold; resistance to motion makes it less likely the residents will move the trainer while practicing which increases the fidelity of the model, and it decreases the risk that the model will be knocked over, a safety concern that could also damage the model.

The tenth requirement is being durable. It has a low importance because this only prevents the damage when shipping or using. According to Dr. Nelson, the specification is that it should be able to withstand a drop from 1.5 m and it can also be sterilized.

The last requirement is being helpful in training. This has a low importance because it is a user feedback. Our team hopes our design reaches a satisfaction of over 80%. However the grading rubric and its meaning needs to be determined in future.

Enucleation

Below are the requirements and specifications for an enucleation model. Many of them are the same as the lateral canthotomy table above such as reusability, consistency in user experience,ability to reflect success, portability, durability, and being helpful in learning surgical techniques. How expensive the model is and easily resettable are also in the canthotomy table but through an interview with Dr. Nelson, it was decided more time and money per use was allowed.

Table 5: Requirements and Specifications for an Enucleation Model

Priority	Requirements	Specifications	Reference
High	Able to simulate the optic nerve and muscles	Optic Nerve Simulator: Diameter: **3-5 mm** Length:**20-25 mm** Shear stress needed to cut: **0.4-6 MPa** Location: connected to the back of the eyeball with an angle Muscles: Diameter: **3mm** **difference ≤10%** Eyeball can be rotated and lifted	[16] [18] [24] [25] [26]
Medium	Inexpensive	Consumable cost: **≤ $5 per use**	[19]
Low	Easy to reset	Takes **< 5min** to reset	[19]

During our first interview with Dr. Nelson, she stressed the purpose of the model was to help residents feel more confident blindly cutting the optic nerve. Therefore, this has the highest priority for the enucleation training model and has the most detailed and specific specifications. Since the previous design review we found a wide range for the shear stress required to cut the optic nerve based on dura matter [24][25]. Dr. Nelson also told us that cutting the optic nerve felt similar to cutting a pencil, which led us to finding the material properties of cedar[26], the wood used in pencils which fits comfortably in the middle of our existing range. It has been challenging to find more specific values for the optic nerve since it consists of layers of different tissues. We will continue to do research and physical tests to further refine this requirement until we have a final material selected.

Dr. Nelson also told us that after cutting the muscles around the eye she grasps a part still connected to the eye to lift and rotate it in order to better access the optic nerve behind it. In order to improve the fidelity of the model, we added a requirement to have a way to grasp and lift the eye.

Next, the cost of each reset is extended from \$0.25 to \$5 since only ophthalmologic residents will use them instead of the several types of residents that can use the canthotomy model. The same reason applies to the reset time as Dr. Nelson will have less pressure to get all the students enough practice during a class.

Concept Generation

With a fully defined problem, our next step was concept generation. This was the process of identifying as many potential solutions as possible to our design problem. In order to do this, we employed three different concept generation processes: brainstorming, functional decomposition and morphological analysis, and stakeholder input. Through these processes, we were able to ensure that we had identified all possible solutions to creating our two ophthalmic simulators.

To start, each team member individually brainstormed on their own, with the only stipulation being to generate as many concepts as possible. This led team members to explore multiple avenues of concept generation, including bulleted lists, webs of ideas, and basic drawings. We were intentionally vague with setting up rules for this phase, as that allowed freedom to explore as many concepts as possible, ensuring no stones were left unturned. Additionally, by completing this phase individually, team members were able to avoid the pressures of conformity that come with being in a group, which was clear with the distinct styles presented in different team members' ideas and drawings, some of which can be seen in figure 9.

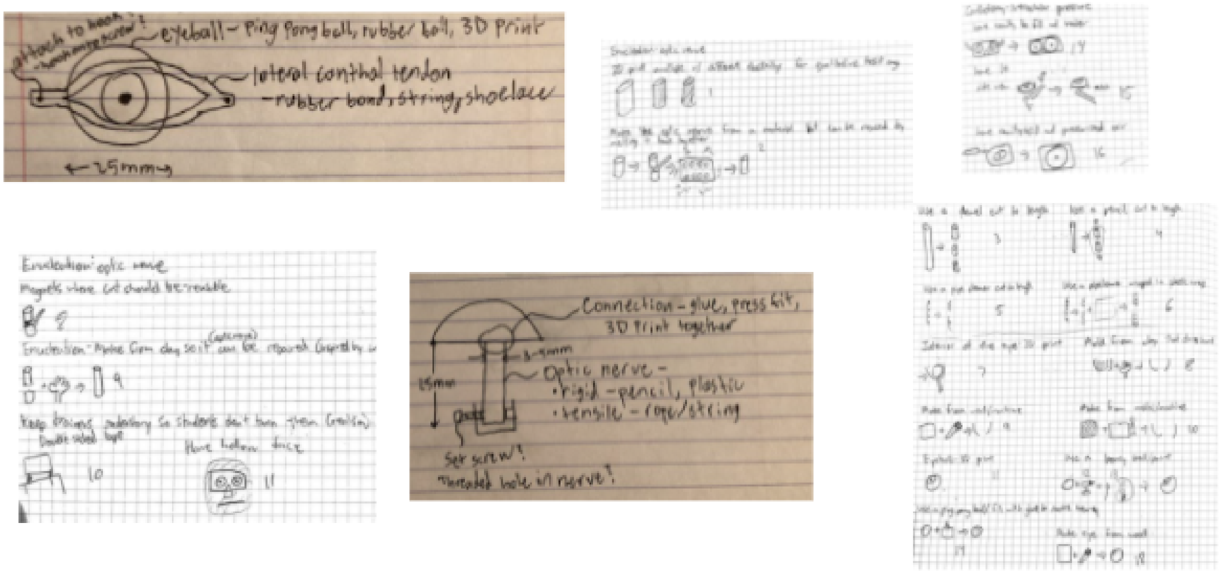


Figure 9: Pictures of different brainstorming notes taken by various members of the team. These pictures showcase the wide array of methods used by different team members.

After individual brainstorming, the team came together to collaborate through a functional decomposition and morphological analysis. Functional decomposition consists of breaking the large design down into smaller subfunctions and morphological analysis yields a matrix of functions and components. Through functional decomposition, we broke down canthotomy simulation into 8 sub-systems and enucleation simulation into 7 sub-systems. We then filled in 3-5 possible solutions for each sub-system. By combining different solutions from each sub-system, our morphological analysis yielded over 102,400 possible solutions for canthotomy simulation and 24,000 possible solutions for enucleation simulation. A portion of each morphological matrix can be seen in tables 6 and 7, full matrices can be seen in Appendix A. This collaboration allowed us to share our ideas and build off of everyone's individual concepts from brainstorming. Additionally, this structured approach made concept selection easier, as we were able to pick the top few solutions for each sub-system into full design ideas.

Table 6: Part of the Morphological Matrix for Lateral Canthotomy

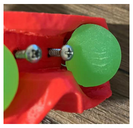
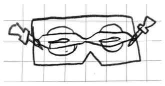
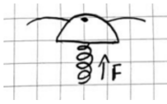
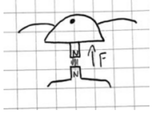
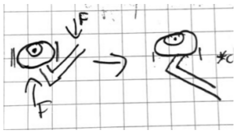
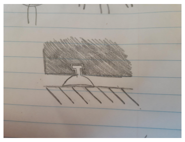
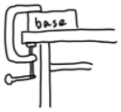
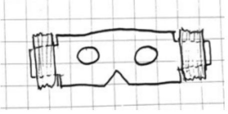
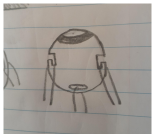
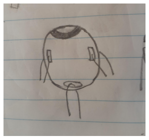
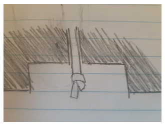
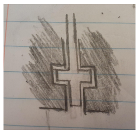
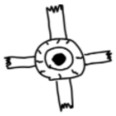
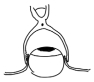
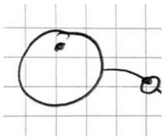
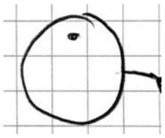
Subsystem	Solutions			
Skin (consumable)	Foam tape 	Gauze 	Paper napkin 	
Lateral Canthal Tendon	Rubber band 	Paper napkin 	String 	
Connect Lateral Canthal Tendon to base	3D-printed hooks 	Screws 	Clips 	Tacks 
Intraocular pressure	Spring 	Magnet 	Lever 	
Connect base to table	Suction cups 	Clamp 	Tape 	

Table 7: Part of the Morphological Matrix for Enucleation

Subsystem	Solution					
Eye	3D printed (open end hook) 	3D printed (close end hook) 	Rubber ball 			
Optic Nerve	Rope 	Hot glue stick 	Wooden dowel 	Eraser rope 	Rubber 	Plastic tubing 
Connect Optic Nerve to Base	Set Screw 	Tie under base 	Lock into base 			
Muscles	Rubber band 	String 	Tape 			
Connect Muscles to Base	Nail 	Clip 	Close end hook 	Open end hook 		

Concept Selection Process

Three different selection processes were used to narrow all the generated concepts for both enucleation and lateral canthotomy to one alpha concept for each surgery. The first process was a simple gut check to eliminate concepts that were unfeasible due to cost, properties, availability, or a number of other reasons. For the canthotomy, the gut check eliminated 12 potential concepts for 6 different subsystems. For the enucleation, it eliminated 9 concepts for 5 different subsystems. The eliminated concepts can be seen in tables 8 and 9.

Tables 8 and 9: Eliminated Concepts in the Gut Check Process for Enucleation and Canthotomy

Eliminated in Gut Check (Canthotomy)	
Eye	3D Printed Eye, Hard Boiled Egg
Skin	Paper Napkin, Cloth
LCT	Cloth, Paper Napkin
LCT to Base Connection	Clips, Staples, Tacks
Skin to Base Connection	Tape
IOP	Magnet, Lever

Eliminated in Gut Check (Enucleation)	
Eye	Ping Pong Ball
Skin	Tape
Muscle	Paper Napkins, Tape
Base to Optic Nerve Connection	Glue, Lock into Base, Tie end of nerve under base
Muscle to Base Connection	Nail, Clip, Screw

After the gut check was performed, we met with Dr. Nelson to get her input on the concepts. With Dr. Nelson's knowledge of how the surgeries are performed and the forces needed to cut the muscles,skin, and nerve, she eliminated materials that she thought were not representative of these tissues. The concepts she eliminated are shown in the tables 10 and 11.

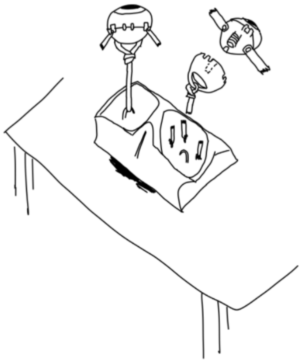
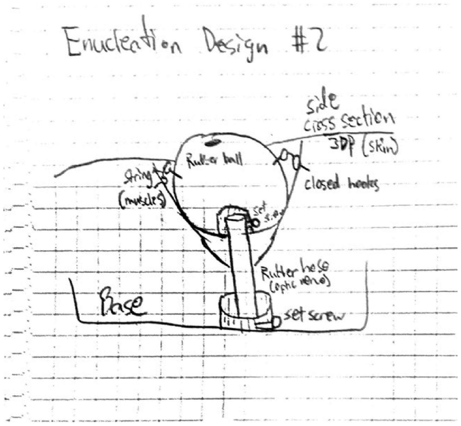
Tables 10 and 11: Eliminated Concepts in the Stakeholder Input Process for Enucleation and Canthotomy

Eliminated in Stakeholder Input (Enucleation)	
Optic Nerve	Hot Glue Stick, Pencil, Wooden Dowel, eraser rubber, plastic tubing

Eliminated in Stakeholder Input (Canthotomy)	
Skin	Gauze. Cloth

For our third concept selection process, we made three different full model designs using surviving concepts from the first two selection processes for both enucleation and canthotomy and compared them in a Pugh chart. When creating the designs, we selected a concept from each of the subsystems for that model and combined them together. Some subsystems only had one surviving concept but others had several. For the subsystems that only had one concept, the concept was used in each design, but for the others, one of the several concepts was chosen for that subsystem for each of the three designs for that surgery. If a subsystem had more than there surviving concepts, we reviewed the results of the gut check and Dr. Nelson's input to rank the top 3. The three designs for enucleation and canhotomy are shown below with their specific subsystem concepts.

Table 12: The three designs for Enucleation

Enucleation Designs	Concepts Used
	Eye - Closed Hook 3-D Printed Eye Muscles - Rubber Bands Optic Nerve - Nylon Rope Nerve Connections - Tie into Hook
	Eye - Rubber Ball Muscles - String Nerve - Rubber Hose Nerve Connection - Set Screw

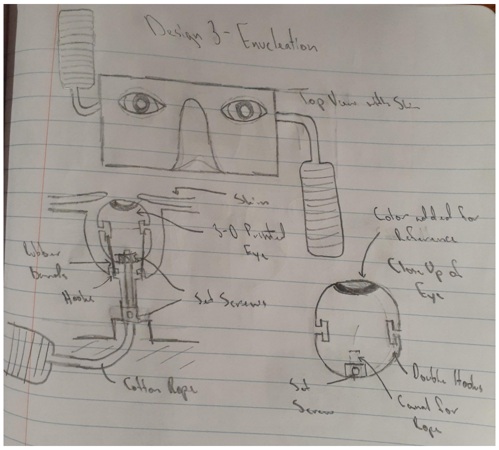
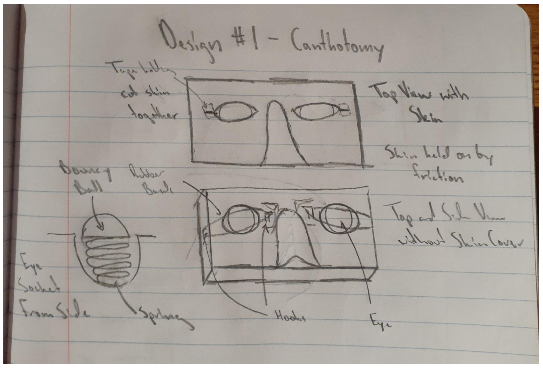
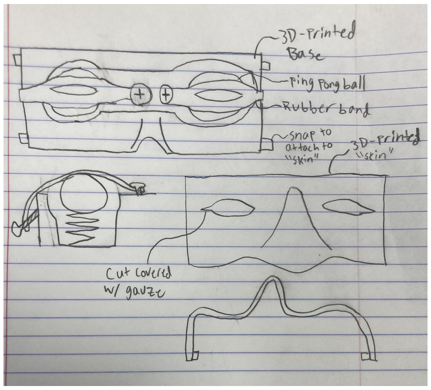
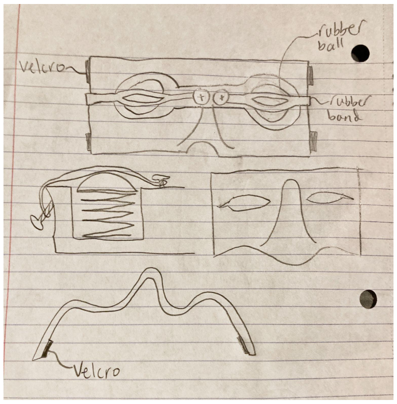
	Eye - Open Double Hook 3-D Printed Eye Muscle - Rubber Band Nerve - Cotton Rope Nerve Connection - Set Screw

Table 13: The three designs for Canthotomy

Canthotomy Designs	Concepts Used
	Cut Part of Skin - Tape Eye - Rubber Ball Connecting Skin to Base - Friction Connecting Tendons - Hooks
	Cut Part of Skin - Gauze Eye - Ping Pong Ball Connecting Skin to Base - Snap Connecting Tendons - Screws

	Cut Part of Skin - Cloth Eye - Rubber Ball Connecting Skin to Base - Velcro Connecting Tendons - Screws

After the sketching of the designs, they were compared in a Pugh chart. All three designs were compared in every requirement with the first design providing the baseline and then scoring (by using a +1 or -1) the other two based on if it fulfills the requirement better than the first design. The requirements were weighed by assigning them a 1, 2, or 3 based on if they were of low, medium, or high priority. Once all the scores were given, the -1's and +1's were multiplied by the weight of that requirement and then all the weighted scores for that design were added together for a final score. Abbreviated Pugh charts containing only requirements that had different scores for different designs can be viewed in tables 14 and 15. The complete Pugh charts can be found in Appendix B.

Table 14: The Pugh chart for Enucleation

Requirements	Weight	Design #1	Design #2	Design #3
Able to simulate optic nerve	3	0	-1	0
Consistent in user experience	3	0	-1	0
Able to simulate muscles	2	0	-1	+1
Ability to reflect success	2	0	+1	0
Easy to reset	1	0	+1	+1
Portable	1	0	0	-1
Durable	1	0	0	-1
Total		0	-5	1

Table 15: The Pugh chart for Canthotomy

Requirement	Weight	Design 1	Design 2	Design 3
Able to Simulate Cutting Skin	3	0	0	-1
Easy to Reset	3	0	0	+1
Durable	1	0	+1	+1
Helpful in learning surgical techniques	1	0	0	-1
Total		0	1	0

Selected Concepts

After creating the Pugh charts, we compared the scores of all 3 designs and shared our opinions. For the enucleation, Design 3 had the highest score and although it will be slightly harder to bring on an airplane and not as durable as the other two designs, it’s ability to simulate muscles and as it’s ease of resetting with the spool of rope made it the best option for our alpha design. Design #1 was close but both the other designs were believed to have the ability to reset easier. Design #2 was by far the worst as it lacked the ability to simulate the optic nerve and muscles and have a consistent user experience. Design #3 is shown again below for reference.

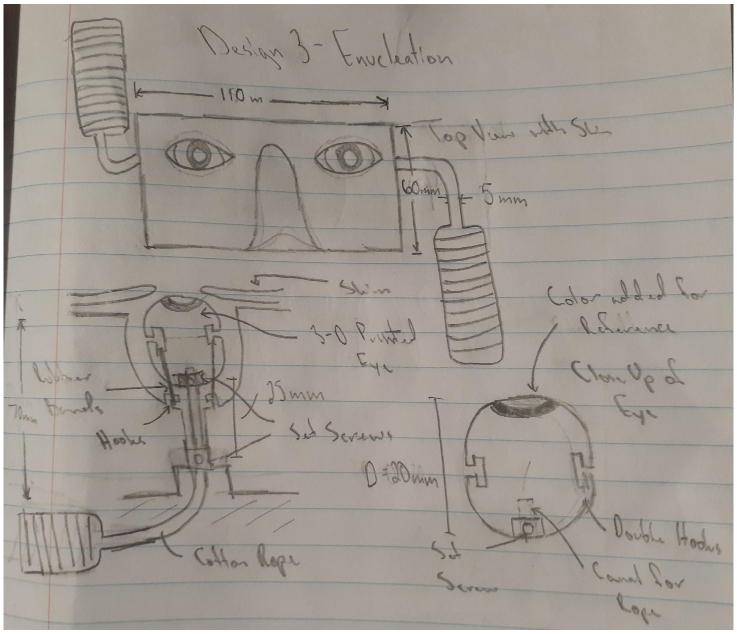
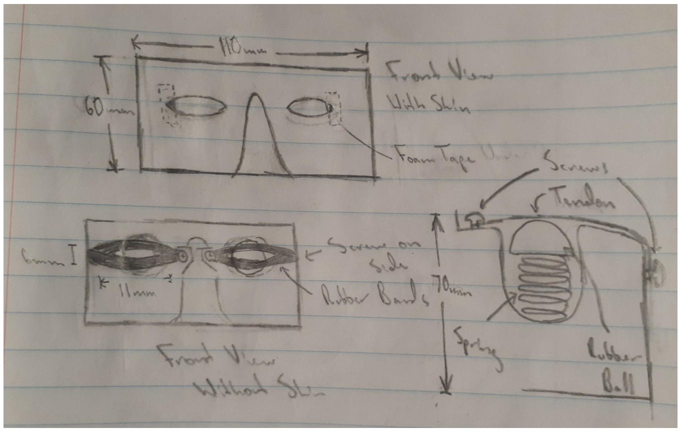


Figure 10: Our alpha design for enucleation with added dimensions. The top drawing shows what the resident or doctor would see while performing the procedure. The bottom left drawing is a cross-sectional view from the side showing the skin covering, the eye sitting in the socket with the rubber bands and optic nerve attached, and then the optic nerve popping out of the bottom of the model. A close up of the eye, the hooks, and the set screw at the bottom are shown on the bottom right.

For canthotomy, the Pugh chart didn’t reveal a clear winner as all three designs scored within a one point range. With Design #1 as the baseline, Design #2 showed only an improvement in durability while Design #3 had improved ease to reset and durability but lacked the ability to simulate cutting the skin and being helpful in learning surgical techniques. With all three scores being so close, we decided to take the best concepts for each subsystem and combine them into a new design. The new design included the foam tape from Design #1 and the rubber ball, velcro, and screws were included from Design #3. The hope is to benefit from the pros of Design #3 while eliminating the cons with the addition of the tape. The new alpha design for lateral canthotomy is shown below.

Table 16: Picture of the Alpha design for canthotomy and its components.

	Cut Part of Skin - Foam Tape (From #1) Eye - Rubber Ball (From #3) Connecting Skin to Base - Velcro (From #3) Connecting Tendons - Screws (From #3)

In this sketch, the upper drawing shows the model with the skin on which is what the resident or doctor will see when doing the procedure. The bottom left drawing is what the top of the model will look like without the skin, revealing the tendons and the screws that hold them. The bottom right drawing is a cross-sectional view of the eye socket showing the rubber ball eye connected to a spring and being restricted by the tendons. This view also shows the side screws which the tendons hook on to.

Engineering Analysis

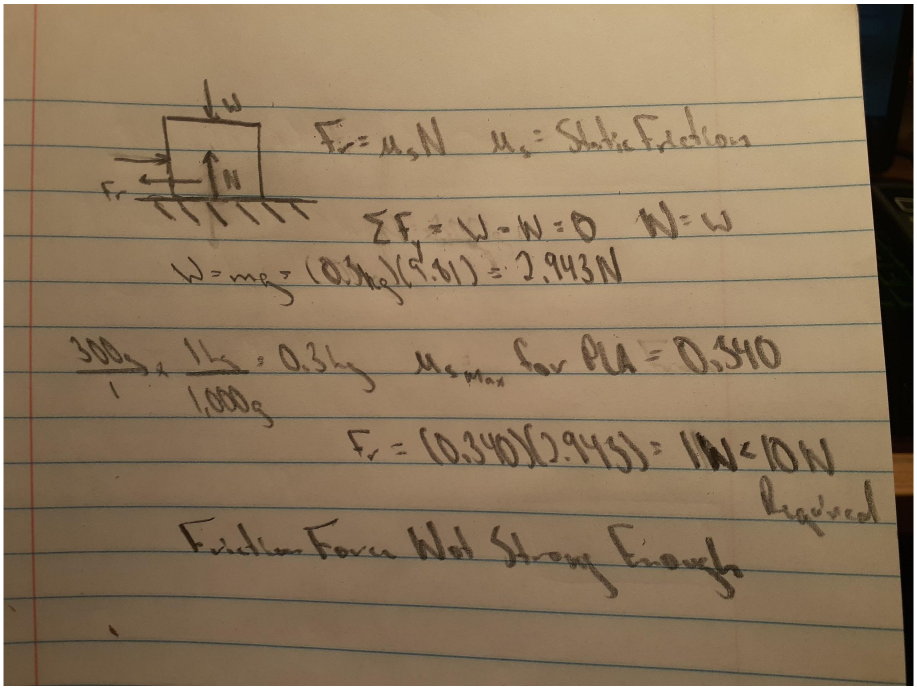
The engineering analysis for this project is based on our concept selection. The final solution is determined by the results. The strategies and schedules are introduced in Worries, Design for ‘X’ and Risk and Safety.

Worries

There are a couple of worries about if our solution can fulfill all our requirements and specifications. As most of the worries for enucleation are similar to those for canthotomy, worries in common for both simulators are introduced first. Then the separated ones for canthotomy are discussed.

For both the simulators, the first worry is if the simulated organs are realistic when cutting. To solve this problem, physical dimensions for each real organ are researched first. After that, some candidate material with similar properties would be collected and shown to Dr. Nelson for a test cut. The prior material can be determined by her cutting feedback. If all candidates are not realistic, the material selection process will be iterated until satisfaction. The selected materials are shown in Tables 18 and 19.

The second worry is if the base will slip on the table. A back of the envelope calculation was done to determine if the friction between the base and table would be enough to keep the base from moving while under a 10N force. The static coefficient of friction was found to have a maximum of 0.340 and the friction force can be seen below [46].



$F_r = \mu_s N$ μ_s = Static Friction

$\sum F_y = W - N = 0$ $N = W$

$W = mg = (0.3\,kg)(9.81) = 2.943\,N$

$\frac{300\,g}{1} \times \frac{1\,kg}{1{,}000\,g} = 0.3\,kg$ $\mu_{s_{Max}}$ for PLA $= 0.340$

$F_r = (0.340)(2.943) = 1N < 10N$ Required

Friction Force Not Strong Enough

Figure 11: Calculations for the friction force between the base of the model and the table.

The friction force was found to be only 1 newton, which is 9 newtons lower than the 10 newton specification. Therefore something must be added to hold the base down.

The third common worry is if the hooks on the base can withstand the drag force provided by the simulated tissues. A larger separation between the hooks on both ends of the tissue results in a more stretched tissue with higher tensile pressure. The high pressure may break the hook if it is not strong enough. However if the tissue is too loose, the cutting is not realistic. This worry will be solved by deciding the hook positions and selecting the right material. After optional solutions are made, some solid mechanism will be applied to the calculation. The Mohr's Circle will be used to get von Mises effective normal stress. It is expressed as:

$$\overline{\sigma_H} = \sqrt{\frac{1}{2}\left[(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_1 - \sigma_3)^2\right]} \qquad (1)[37]$$

The result will be compared to the material yield strength. If the structure doesn't fail, the solution will be taken and tested empirically afterwards.

The first worry for canthotomy is if accurate intraocular pressure is simulated. An accurate pressure makes the training more realistic and able to reflect success. The pressure is designed to be provided by a spring and a rubber band. A free body diagram of the structure is shown in figure 12.

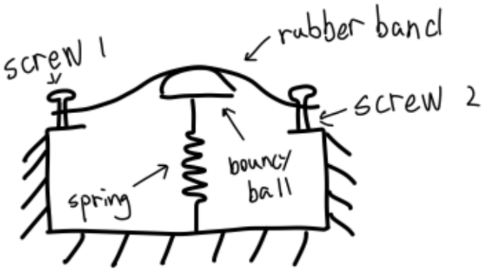


Figure 12: Shown is the structure in the simulated eye orbit. The rubber band is fixed on the base by two screws and the spring is compressed by the tensile force of the rubber band.

To select the best type of spring and determine the position of the screws, the equivalent force provided by the pressure is calculated first. The actual intraocular pressure is caused by the increased tissue fluid inside the eyeball. The tendon prevents the eyeball from expanding so the liquid is compressed and then generates extra pressure. To measure this force, we assume that the pressure only acts on a half of the eyeball and its geometry is hemisphere. The pressure acting on the surface results in the same magnitude of force as the pressure acting on the cross sectional area of the sphere. The force can then be calculated as below.

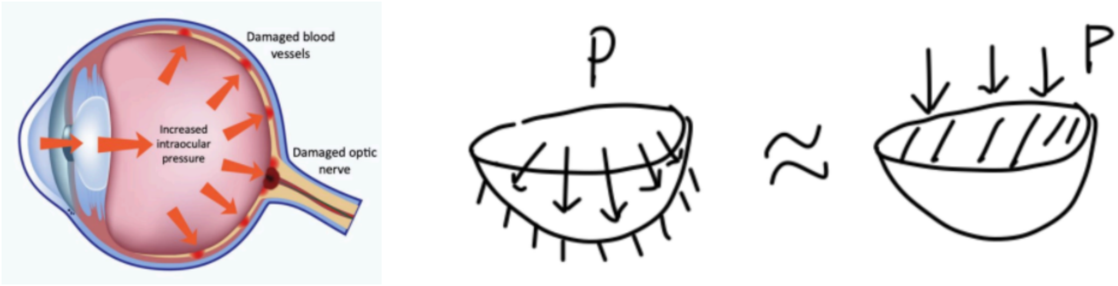


Figure 13: Shown on the left is the mechanism of the intraocular pressure [52], shown on the right is the free body diagram of the hemisphere eyeball.

$$F_{spring} = \oint_{Surface} \rho dA = P \times Area \qquad [2][37]$$

$$F_{spring} = P \times \pi \times \left(\frac{D}{2}\right)^2 \approx 3.927N \approx 0.9lbs$$

Where D is the diameter of the eyeball which is 25mm, P is the intraocular pressure which is 60 mmHg according to Dr. Nelson. Then the spring formula will be applied to calculate the deformation needed for each type of spring. The equations are expressed as:

$$F = k \times \Delta x \qquad (3)[37]$$

A list of springs with their dimensions and spring rate on McMaster is used to determine the candidate. The spring with 39 mm length and 11 mm diameter is taken. Its spring rate is 0.27 lbs/mm and the deformation is calculated as 3.33 mm. After that, the position of the screw and the length of the rubber band need to be determined. We used the #82 rubber band based on the dimension of the real eye tendon. The system is shown below.

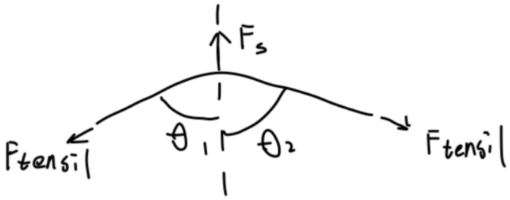


Figure 14: Shown is the free body diagram of the rubber band. $\theta_{1,2}$ are the angle between the vertical axis and the tangent direction. $F_{tensile}$ is the tensile force in the rubber band.

$$F_{spring} = (cos\theta_1 + cos\theta_2) \cdot F_{tensile} \tag{4}$$

$$F_{tensile} = \frac{3.927N}{(cos\theta_1 + cos\theta_2)}$$

Since there are three unknown variables in one equation, no absolute solution can be found except for a relationship between them. So an empirical test on a foam board is made to determine the dimensions. The test is shown in Figure 15.

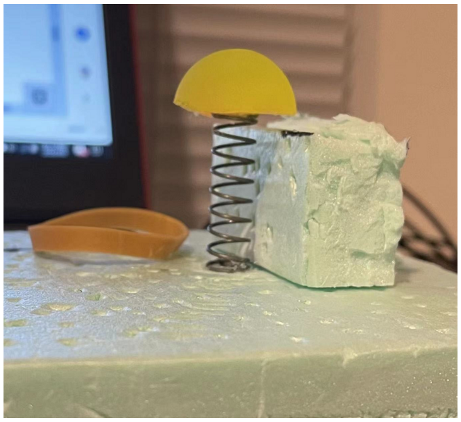


Figure 15: Shown is the foam board test. The step wall is 35 mm high.

Once the bouncy ball touches the step, the force gauge measures a 4.3N force. Then the rubber band is fixed on different positions to compress the ball to the step. Those couples of end positions are recorded and taken into the design of the base CAD model. The length of the rubber band is 55 mm. The left end is 25 mm away from the centroid of the eyeball and the right end is 20 mm away. Both ends are lined up with the centroid of the eyeball.

The second worry for canthotomy is if the simulated tendon can withstand the intraocular pressure. The rubber band is tightened to simulate the intraocular pressure. However there is a hole in the middle of the rubber band to simulate the real shape of the lateral canthal tendon. Besides the normal stress equation, a creep law equation is also applied to ensure the rubber band will not crack before cutting. The equations are expressed as:

$$\sigma = \frac{F}{A} \tag{4}$$[37]

$$\varepsilon = A\sigma^{n} exp(-\ q/kT) \tag{5}$$[37]

If the result shows it doesn’t fail during its lifetime, the solution will be taken and tested empirically afterwards.

Design for ‘X’

According to our requirements and specifications. In this project, we mainly focus on the manufacturing, assembly and cost fields.

Design for manufacturing

At this stage, the base for both simulators and the eyeball for enucleation are planned to be 3D printed. When drawing the CAD model, we should prevent some unfeasible features like inner corners or too many suspended structures. After the prototype is made, DFMpro for Solidworks is used to check the manufacturing feasibility.

The rest of the simulators are all easily manufactured with consumable parts. No too much attention is needed at this stage.

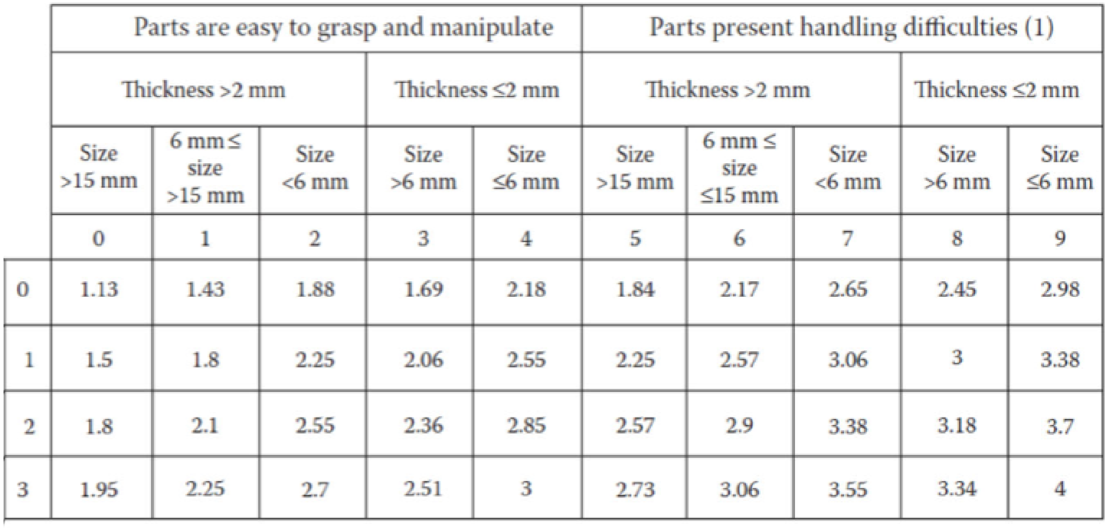
Design for assembly

Since there is an important requirement to minimize the reset time. We plan to apply the manual assembly time formula to see if we fulfill the specifications. The equation is expressed:

$$T_{total} = \sum_{j=1}^{N_P} (th_j + ti_j) \tag{6}$$[40]

Where N_p is the number of parts, th_j is handling time for part j and ti_j is insertion and fastening time for part j. The value for th_j and ti_j can be obtained in an engineering chart. A portion of the chart is shown in Table 17. When the prototype is built, an empirical test will be taken to check this.

Table 17: A portion of the manual assembly code chart.[40]



	Parts are easy to grasp and manipulate					Parts present handling difficulties (1)				
	Thickness >2 mm			Thickness ≤2 mm		Thickness >2 mm			Thickness ≤2 mm	
	Size >15 mm	6 mm≤ size >15 mm	Size <6 mm	Size >6 mm	Size ≤6 mm	Size >15 mm	6 mm ≤ size ≤15 mm	Size <6 mm	Size >6 mm	Size ≤6 mm
	0	1	2	3	4	5	6	7	8	9
0	1.13	1.43	1.88	1.69	2.18	1.84	2.17	2.65	2.45	2.98
1	1.5	1.8	2.25	2.06	2.55	2.25	2.57	3.06	3	3.38
2	1.8	2.1	2.55	2.36	2.85	2.57	2.9	3.38	3.18	3.7
3	1.95	2.25	2.7	2.51	3	2.73	3.06	3.55	3.34	4

Design for cost

There is the requirement to be inexpensive. A bill of material is used to see if we fulfill the specifications. An estimation of the BOM at this stage is shown in tables 18 and 19. From these estimates, we’ve determined that the reusable parts of the canthotomy simulator will cost about \$30 to manufacture, and the consumable parts will cost about \$0.07 per simulation. The reusable parts of the enucleation simulator will cost about \$38 to manufacture, and the consumable parts will cost about \$0.23 per simulation.

Table 18: Canthotomy Bill of Materials

Part	Description	Quantity	Price
PLA	3D-printing material for the base and mold for the skin	~300g	~$20 per kg [33]
Size #82 Rubber Bands	½”-thick rubber bands to simulate the lateral canthal tendon	2 rubber bands per simulation	~$8 per pack of 600 [34]
25 mm Rubber Ball	Simulates eye	1 ball per simulator (½ ball per eye)	$1 per pack of 2 [35]
1” #4 18-8 Stainless Steel Phillips Rounded Head Thread-Forming Screws for Plastic	Screws used to attach rubber bands	3 screws per simulator	$8.50 per pack of 25 [36]
3M Microfoam Surgical Tape	Used to simulate consumable skin	25 mm^2 per simulation	$24 per box of 3 rolls (5000 mm^2 per roll) [42]
Spring	Used to simulate the intraocular pressure	2 per simulator	$13.28 per pack of 5 [53]
Dragon Skin FX-Pro silicone	Molded reusable skin	1 per simulator	$35 for 1 pint of silicon [50]
Mann Release Technologies Ease Release 200	Releasing agent for molding silicon	1 per simulator	$22 for 1 14 fl. Oz. can [51]
Thread-On Feet	Attaching the base to table	4 per simulator	$9.67 per pack of 10 [55]

Table 19: Enucleation Bill of Materials

Part	Description	Quantity	Price
PLA	3D-printing material for the base, eye, and mold for the skin	~300g	~$20 per kg [33]
Size #62 Rubber Bands	¼” thick rubber bands to simulate the medial rectus muscle	1 rubber band per simulation	$5 per pack of 100 [38]
$^3/_{16}$”-Diameter	Used to simulate	~2” per simulation	$8 per 50’ spool [39]

Polypropylene Rope	optic nerve		
1” #4 18-8 Stainless Steel Phillips Rounded Head Thread-Forming Screws for Plastic	Used to hold optic nerve in place in the base, as well as attach medial rectus muscle to base	4 per simulator	$8.50 per pack of 25 [36]
3mm-Diameter Elastic Cord	Used to simulate the rectus muscles	~6” of rope per simulator	$5 per 10-yard spool [
Dragon Skin FX-Pro silicone	Molded reusable skin	1 per simulator	$35 for 1 pint of silicon [50]
Mann Release Technologies Ease Release 200	Releasing agent for molding silicon	1 per simulator	$22 for 1 14 fl. Oz. can [51]
Thread-On Feet	Attaching the base to table	4 per simulator	$9.67 per pack of 10 [55]

Risk and Safety

As a part of the engineering ethics, we analyzed some possible risks our simulator might have. Failure Modes Effective Analysis was used. The results are shown in Table 20.

Table 20: Failure Modes Effective Analysis table

Failure Mode	Effects	Severity	Probability	Detection Rate	RPN
Spring fails to simulate IOP	Result can’t be reflected	5	2	3	30
Rubber band breaks under IOP	Training fails	8	1	2	16
Base slips during training	Training fails Trainer might get injured	10	2	7	140
Base cracks during training	Training fails Trainer might get injured	10	1	3	30
Sharp corners on simulator	Trainer might get injured	10	1	1	10

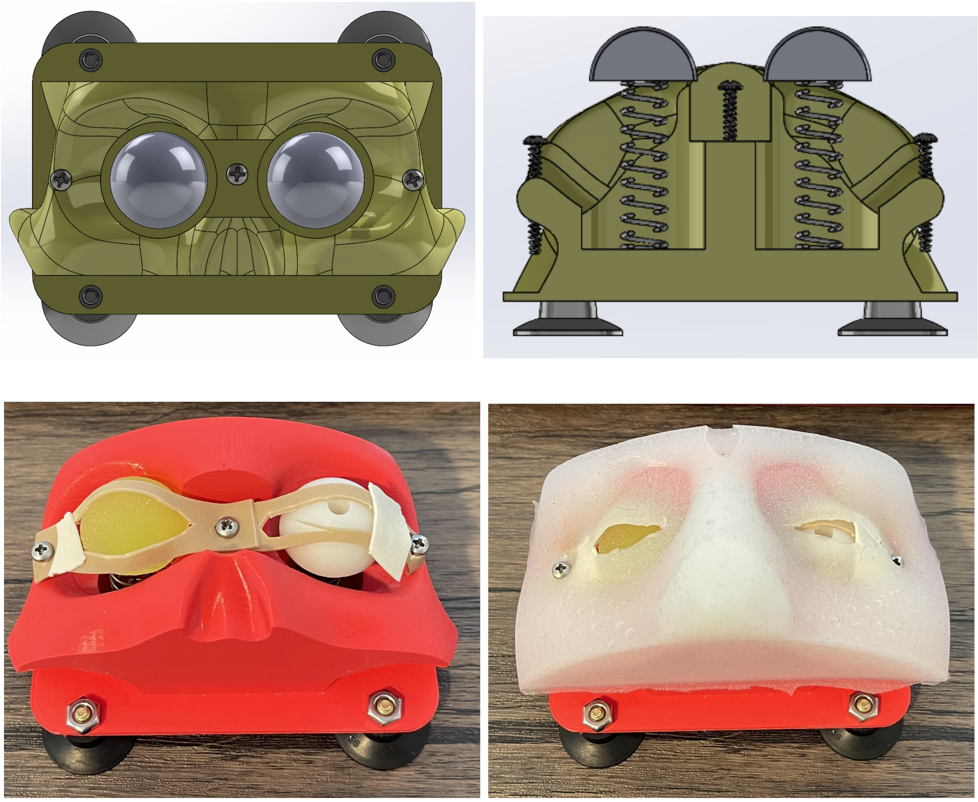
The severity is rated based on how severe the consequence of each failure is. It goes up to 10 when the failure affects safe operation or regulatory requirements, without warning. Probability is rated based on how often the failure occurs. The higher the rate is, the more likely it will happen. The detection rate is how hard it will be to diagnose the problem. The rate goes to the highest if there is no chance of detection prior to release to customers. Risk Priority Number (RPN) is the product of the severity, probability, and detection rate. The failure is considered as reasonable if its RPN is lower than 30 and is seen as almost certain to occur if its RPN is higher than 100. In this project, base slipping during training has the highest RPN at 140. This is because if the base slips, the trainer's hands might get scratched by the hard sharp corners or edges when pushing the base hard. And it is more likely to happen than other failures because some of the operation tables have a smooth surface while others do not, so the attachment method may not work well for all cases. In addition, this slip can only occur during operation which is hard to predict. To solve this problem, we are going to select the strongest attaching method in our final solution and we may apply a higher push force during the empirical test to ensure it will not slip in training.

As a conclusion, our alpha design is well defined to be analyzed rigorously using engineering concepts. This project involves solid mechanics, material behavior, manufacturing process, and design for manufacturing fields. It is not extremely difficult even under the ME 450 constraints. If there are no constraints we may test the real organ in the laboratory to get more accurate material properties. And then we may be able to select simulting material from a broader source.

Build Design

Lateral Canthotomy Build Design

The lateral canthotomy build design will consist of a 3D-printed base, two springs, three 1” #4 18-8 screws, one 25mm-diameter rubber ball cut in half, two size #82 rubber bands, foam tape, and a silicon rubber face. We fabricated a 3D-printed base based on the ocular area of the skull. One spring is placed in the middle of each eye socket to emulate the intraocular pressure caused by Orbital Compartment Syndrome. Half a rubber ball is then put on top of each spring to represent the eyeball. Screws are inserted on the inside and outside corner of each eye. A rubber band is then stretched between the inner and outer screws of each eye to mimic the lateral canthal tendon and place the spring under tension. Molded silicone rubber is placed over the 3D-printed base, representing the skin and nose over the skull that is not to be cut. Foam tape is placed on the outer corner of each eye between the silicone rubber and the rubber band to simulate the skin that must be cut in order to access the lateral canthal tendon underneath. Some crucial dimensions are listed in Figure C1. All dimensions are within acceptable tolerance, adjustment on the vertical position of the screws can ensure the spring to be compressed to the target length.



Figures 16, 17, 18, and 19: Shown at the top are top and front views of the canthotomy base with springs, rubber ball eyes, and screws shown. Shown at the bottom are the perspective views of the manufactured trainer with and without the rubber skin.

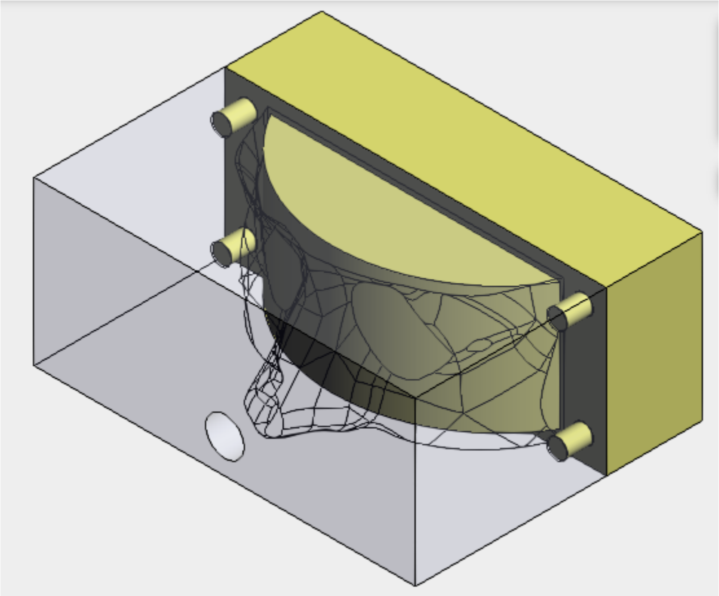
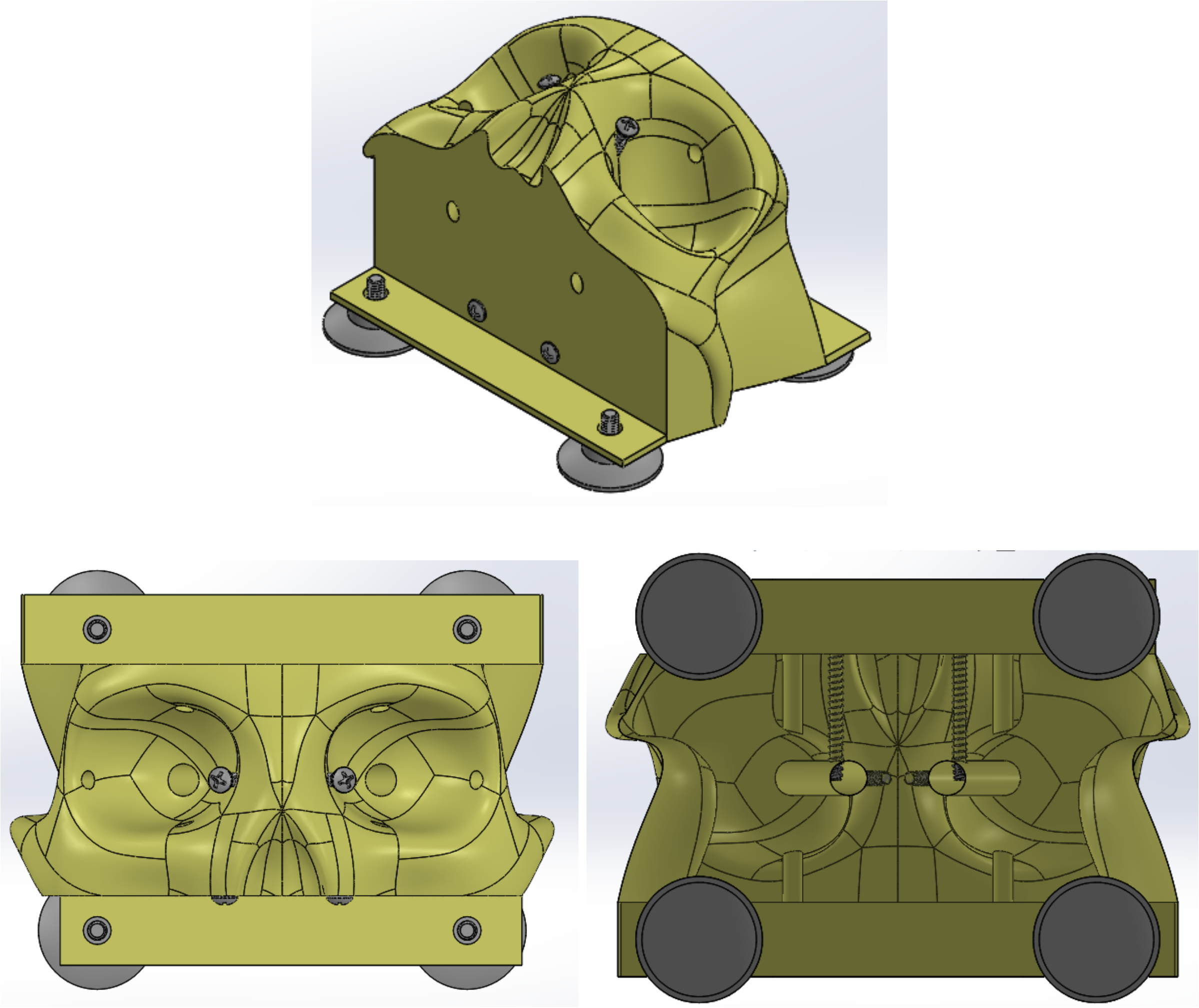


Figure 20: Perspective view of the mold used for injection molding of the silicone rubber.

Enucleation Build Design

The enucleation build design consists of a 3D-printed base, two 3D-printed eyes, a ¼” rubber band cut into four 6 mm pieces, two spools of $^{3}/_{16}$”-diameter polypropylene rope, four four 1” #4 18-8 screws, 3mm-diameter elastic rope, and silicon skin.

The 3D-printed base, which can be seen in figures 21, 22, and 23 resembles an anatomically correct ocular region of a human skull. Inside the orbit of each base, there are 3 through holes for the elastic rope, which simulate the rectus muscles of the eye, one hole to insert a screw to attach the medial rectus muscle, and a hole in the back of the orbit, leading out of the bottom of the base. This tunnel houses the polypropylene rope, which simulates the optic nerve and can be locked into place using a set screw.



Figures 21, 22, and 23: Isometric (18), top (19), and bottom (20) views of the enucleation base. The through holes, orbital holes, and screw locations can be seen from the isometric and top view, while the bottom view shows the path the rope will take to get from the side of the base up to the orbit.

The 3D printed eye, seen in figure 24 consists of three protrusions to allow the elastic bands be tied to, a hook to attach the rubber band acting as the medial rectus muscle, and a hole through the eye to allow the rope simulating the optic nerve to enter and be attached by tying a knot at the end of the rope after threading it through the eye. Similar to the lateral canthotomy simulator, a molded silicone rubber face will be placed on top of the device to resemble a patient’s facial skin. An image of the built simulator can be seen in figure 25. Dimensioned drawings of all 3D-printed parts can be found in Appendix C.

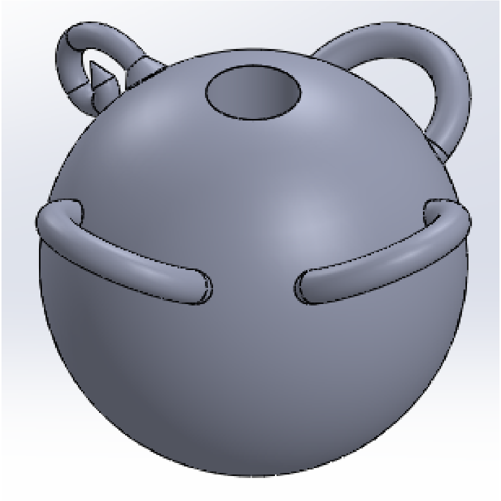


Figure 24: An isometric view of the 3D-printed eye, showing the hooks which will attach to the elastic rope and rubber band, as well as the hole for the rope.

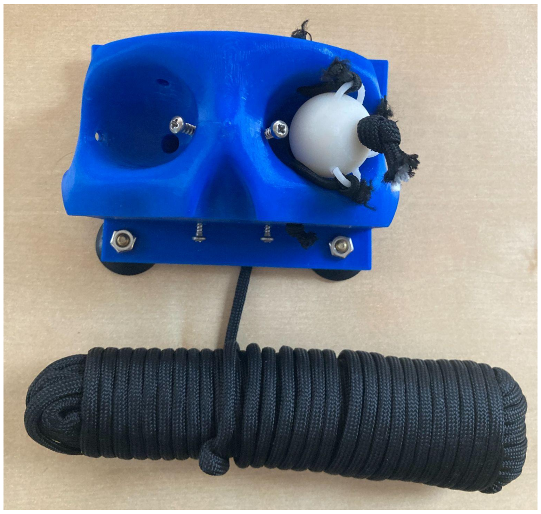


Figure 25: A picture of the built enucleation design. Elastic rope holds the three outer hooks on the eye. The polypropylene rope representing the optic nerve is threaded throught the bottom of the base and 3D-printed eye. The rubber band representing the medial rectus muscle is not pictured because the hook holding it on the 3D-printed eye fractured before this picture was taken.

Verification

For verification, we did small empirical tests to check if each specification is met. For the Canthotomy model, we tested how easy it is to restock by performing a time trial of timing ourselves as we reset the model after a use. On average, the time of reset was 25 seconds with the majority of the time being used to cut and place the foam tape. For simulating the intraocular pressure, we used a force gauge to see if the force is 4N when the spring is compressed to the target position where the rubber band is added. It achieved 4.3N which is within 10% difference. However, when Dr. Nelson cut the rubber band she requested the force be increased to at least 100mmHg as well as the eye being increased to the size of the original team's eye so the scissors can slide across the eye easier. As a result, we will replace the current spring with a stiffer one and use a larger rubber ball as the eyeball in future. For simulating the cutting of the skin and tendon, our verification came from Dr. Nelson. Dr. Nelson pointed out our first set of rubber bands (#60 rubber bands) were not thick enough to properly simulate the tendons. We then switched to the #80 rubber bands which allowed us to cut a slit to make the two tendons. After being shown this new rubber band, Dr. Nelson approved it as a good replacement for the tendons.To see if the simulator is portable, we showed the simulator to Dr. Nelson and Professor Sienko and with their experience of taking models on planes and to other countries, approved the model for portability. For reusability, there is not much we can do in class as this specification requires a long period of time. We verified it will be durable by performing a drop test from a 5 foot table which it survived. The specification of less than $1 per use was confirmed by adding the cost per use through the prices in our bills of materials. Assuming each $8 bag of rubber bands can be used for 300 uses and each roll of tape can be used for 50 uses, the per use cost for the consumables is $0.35 which is much less than the $1 required. For verification in aiding in learning surgical procedures and consistent user experience, residents will need to use the simulators and their feedback can verify these specifications or point to the simulator needing more work.

One area of improvement that was determined in the engineering analysis was the base slipping. Since the friction force of the base is too small, something must be added to hold the base. Our team discussed different options including taping the base down, screwing it to the table, using suction cups, attaching velcro, using a c-clamp, adding rubber feet, and more. An empirical test was conducted to see if tape could be used by taping the base to the table using three different kinds of tape (duct, foam (from the canthotomy materials), and electrical) and then pushing on it with a force gauge until it moved. Four tests were taken with each kind of tape with two sets of tape each. The first test was with new tape, the second test was with the first set but resecured, the third with a new set, and the fourth reusing the second set. This method of reusing tape was used to see how the tape would respond if it was already moved before. The results of the test and the setup with all three tests are shown below.

Table 19: Results for the base slipping testing with the slip. The specification asks that the tape can resist a force of 10 newtons (N) or 2.25 pounds (lbs).

Kind of Tape	Force Required to Move Base (lbs)	Average
Duct	17.5	23.375
	28	
	27	
	21	
Foam Tape	11	9.5
	9	
	6	
	12	
Electrical	6.5	6.75
	6.5	
	7.5	
	6.5	

Figures 26, 27, and 28: The experimental setup for all three kinds of tape. Duct is used on the left, foam tape in the center, and electrical on the right.

All three tapes were verified that they could reach the 10N (2.25 lbs) specification. This cements them as a viable option to secure the base. After more team discussion, rubber suction cup feet were used to hold the base down. These easily surpassed the 10 N requirement and received a positive reaction from Dr. Nelson.

For enucleation, many of the tests will be the same as the canthotomy as many specifications are the same. For the reset time of 5 minutes, another “time trial” was planned in the same way the canthotomy trial was performed, just with a different procedure. However, since the hook broke on all our 3-D printed eyes we were not able to performed the test. We do have confidence that the reset time will be below 5 minutes as the only resettable parts are the string for the optic nerve and string for the medial rectus muscle. The specification for cost of reusables is also different but with the costs from the bill of materials, each use will cost $0.41 which is much lower than the $5 limit. The only independent requirement is simulating the optic nerve, which was verified by Dr. Nelson early in the concept selection process, and blindly locating the nerve which can be verified when the residents test the simulator.

Validation

Our validation will involve giving the simulators to Dr. Nelson and having trained doctors use them. Doctors should be the first ones to test the model as they have been through the training before and know its pros and cons. If the doctors believe these simulators drastically improve the training experience and will help residents gain more confidence when performing the surgeries, it can then be given to the residents. The residents will be in the midst of training and will be able to tell us if the model helps their understanding of the surgeries and how to perform them. If both groups give the model a good score and are happy with the training it provides, it has been validated that we have tackled the problem of a lack of high fidelity models with a low price point.

Discussion

Problem Definition

If we, as a team, had more time and resources for this project, we would like to have a greater understanding of the eye and the two surgeries. An example of this would be to attend a live enucleation. This idea floated around early in the semester but we were unable to attend one because of schedules and project timing. A live enucleation would help us understand the surgery in more detail as well as what the surgeon must do during it. This new understanding will allow us to make the simulator more accurate for the surgeon and improve its effectiveness. Although viewing a live canthotomy would also be interesting and helpful, an enucleation is planned and would allow the doctor to know all factors they would have to deal with. More research or a formal training on the procedure would be a good replacement for a live surgery. And the we would further improve the fidelity of the trainers. To do this, firstly we will measure the material properties of tissues in a lab instead of looking for the estimated data from literature. Then we will collect more material candidates for cutting pieces. After that we will measure their properties again in the lab and compare them to the reference data to get the best fit option instead of simply getting results from Dr. Nelson’s test cut. One another improvement is on the solid mechanism analysis. Instead of using a single formula to calculate the pressure, stress, and strain we will use a software based finite element analysis to measure the whole system. Then we can verify our trainers’ persistence by the pressure contour map in addition to the empirical tests. Besides, we would fabricate a larger number of trainers. This would make the trainers available to more residents, doctors, and emergency personnel as a learning tool. Rather than relying on surveys to verify their educational usefulness, we would develop performance metrics for the speed and accuracy of the surgery performed that could be scored by either the instructor or by the student themself. Given even more time, clinical data supporting less mistakes and complications being made by those who used the trainers when actually performing the surgeries would be the ultimate standard of the fidelity and usefulness of the trainers.

Design Critique

In hindsight, our canthotomy model performed very well with all the requirements being fulfilled and gave us a great confidence our model will help residents and ER doctors perform the surgery well. A few improvements can be made though. One improvement is a more consistent slit in the middle of the rubber bands . We made most of the tendons at the design expo and had no template to base our cuts. This led to inconsistency and although there always will be some inconsistencies with cheap consumables, we can eliminate a good amount if we had something to help us make good cuts each and every time. Some improvements Dr. Nelson proposed right before the design expo was a stronger spring and a larger eyeball for the canthotomy model. She wanted the spring force to be greater and the eyeball to glide her scissors to the tendon. We have already ordered new springs and plan to order new bouncy balls or at least find the correct size online.

Our enucleation was not as far along as the canthotomy. However the canthotomy model already had a semester of work on it and the enucleation was a brand new project. Some improvements are the hook which the medial rectus muscle connects to, how to neatly connect the other three tendons without taking up too much space on the simulator,, improve the process of replacing the optic nerve, and finalize a material for the medial rectus. Because we had made the one hook and three loops design change so late, we have not had the opportunity to fully test the new model and eye which many of these improvements are from. For example, Dr. Nelson liked the elastic rope we had chosen for the other rectus muscles and asked if we could use that rope for the medial rectus instead of a rubber band. This question was made after we sent in the last model base of the semester for printing so this is an improvement that has previously had no testing or formulation.

Reflection

Public health, safety, and welfare are at the core of our project. Our goal has been to improve surgical outcomes worldwide. This will be realized by creating a device that allows ophthalmic residents to practice surgeries without the need for a patient, without being cost-prohibitive in lower-resource settings. In the short term the simulators will be used to train residents here at the University of Michigan, in the long term it will be used to train medical students in Ethiopia. By making our trainers low-cost to manufacture and use they are more accessible to the maximum number of people globally. Due to the surgeries involving cutting, some consumables are unavoidable, but have been minimized and the simulators have been designed to maximize their life cycle. Throughout our project all the team members worked together to bring their own perspectives and experiences which was beneficial to the project overall. Some of us are good at drawing CADs, some are good at engineering calculations, some are good at manufacturing. We cooperate efficiently and harmoniously. Our primary stakeholder, Dr. Nelson was critical throughout this process through contributing her knowledge about the surgeries and the aspects that residents most often struggle with. We keep in good contact with her for the whole semester and meet many times to have test cuts or get feedback. We also raised a survey on the knowledge about those two surgeries for Dr. Nelson's residents. At the same time other stakeholders getting involved, we better understand what we need to do in this project. We don't have many ethical dilemmas in this project, there is no pollution or harm either in manufacturing, use or disposal.

Recommendations

As we move on from this project, we'd like to leave behind a few recommendations for Dr. Nelson and future groups who may continue working on these simulators. For the enucleation, we recommend additional iterations be done to the 3D-printed eyeball design. Creating hooks outside the body of the eye added interference when fitting it into the orbit. Additionally, the small hooks required to connect the rectus muscles to the eye were very brittle and could not withstand the typical loading to reset the simulator.

For both simulators, further validation is required. We have created a validation survey based off a previously validated survey for a canthotomy trainer [15], but were not able to get our simulators into the hands of residents and ophthalmologists to test them out and complete the survey. We believe this would be the best way to validate our designs and confirm that they will be useful in training future ophthalmologists.

Conclusions

For enucleation and lateral canthotomy surgeries there currently exists no low-cost high-fidelity trainers for residents to practice. Our goal was to design trainers for both surgeries that are useful educational aids without being cost prohibitive to use in low-resource settings. Through database research and talking with Dr. Nelson we created design requirements and specifications to accurately simulate the surgeries. There were challenges creating two trainers in parallel, which required additional planning and organization. We designed, built, and tested our two alpha designs, using mathematical and physical models in order to verify and validate the performance of individual sub-systems. Throughout the design process we acquired feedback from Dr. Nelson, Professor Sienko, and our peers to improve the fidelity and usefulness of the model while maintaining a low cost of the design overall as well as the cost per use. We iterated on both base designs and the enucleation eye's design multiple times. Some aspects of both designs still require further iterations, as well as a more complete validation process. Overall, this project has been successful, and we look forward to seeing the completion of our work by future design teams.

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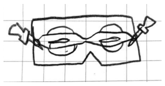
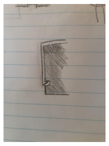
Appendix A

Complete Morphological Matrices for Each Design

Table A1: Complete morphological matrix for the lateral canthotomy simulator

Subsystems	Solutions				
Eyeball	Ping pong ball	Rubber ball 	3D Print	Hard-Boiled Egg	
Skin (reusable)	3-D Printed Material 	Tape 	Injection molding 	3-D Printed Material (precut) 	
Skin (consumable)	Foam tape 	Gauze 	Paper napkin 	Cloth	
LCT	Rubber band 	String	Cloth	Paper napkin 	
Connect LCT to base	3D-printed hooks 	Screws 	Clips 	Staples	Tacks 
Connect Skin to base	Friction	Snaps 	Velcro (Can make drawing if need be)	Tape	
IOP	Spring	Magnet	Rubber band	Lever	

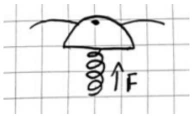
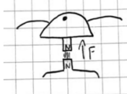
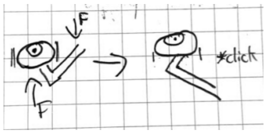
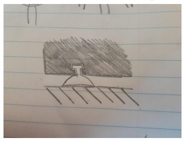
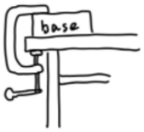
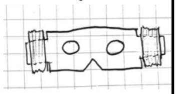
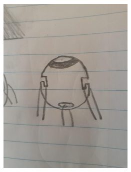
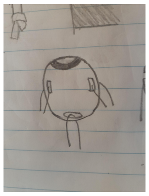
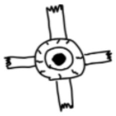
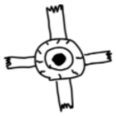
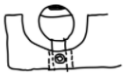
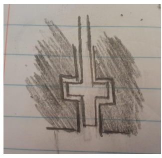
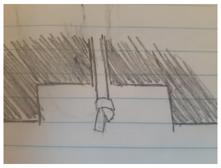
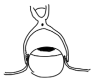
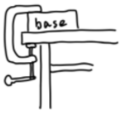
					
Connect base to table	Suction Cups 	Screws	Velcro (Can make drawing if need be)	Clip 	Tape 

Table A2: Complete morphological matrix for the enucleation simulator

Subsystems	Solutions					
Eyeball	3D printed open end hook 	3D printed close end hook 	Rubber ball 	Ping pong ball		
Skin (reusable)	3-D Printed Material	Injection molding 				
Optic nerve	Rope 	Hot glue stick 	Pencil/wooden dowel 	Eraser rope 	Rubber	Plastic tubing 
Muscle	Rubber bands	String	Paper napkin 	Tape 		
Connect Optic Nerve	Set Screw	Tie around opening	Glue	Lock into base	Tie end of nerve under base	

to Base						
Connect muscles to Base	3D printed hook (open end)	3D printed hook(close end)	Nail 	Clip 	Screw	
Connect base to table	Suction Cups	Screws	Velcro	Clip 	Tape	

Appendix B

Complete Pugh Charts for Both Designs

Table B1: Complete Pugh chart for the lateral canthotomy simulator

Requirement	Weight	Design 1	Design 2	Design 3
Able to simulate cutting skin	3	0	0	-1
Able to simulate cutting LCT	3	0	0	0
Able to simulate IOP	3	0	0	0
Easy to Reset	3	0	0	+1
Reusable	3	0	0	0
Consistent in user experience	3	0	0	0
Ability to reflect success	2	0	0	0
Base doesn’t move	2	0		
Portable	2	0	0	0
Durable	1	0	+1	+1
Helpful in learning surgical techniques	1	0	0	-1
Total		0	1	0

Table B2: Complete Pugh chart for the enucleation simulator

Requirement	Weight	Design 1	Design 2	Design 3
Able to simulate optic nerve	3	0	-1	0
Able to simulate muscles	2	0	-1	+1

Inexpensive	2	0	0	0
Easy to reset	1	0	+1	+1
Reusable	3	0	0	0
Consistent in user experience	3	0	-1	0
Ability to reflect success	2	0	+1	0
Base doesn’t move	2	0		
Portable	1	0	0	-1
Durable	1	0	0	-1
Helpful in learning surgical techniques	1	0	0	0
Total		0	-5	1

Appendix C
Dimensioned Engineering Drawings

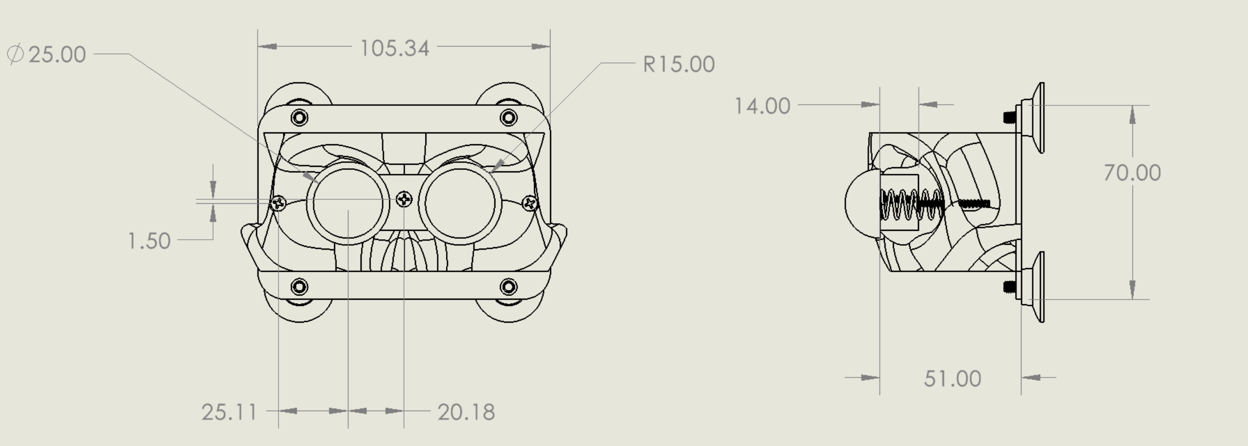


Figure C1: Dimensioned drawings of the lateral canthotomy base. This base is approximately 110x70x60mm, with the center of the orbit located 25.21mm from the top plane.

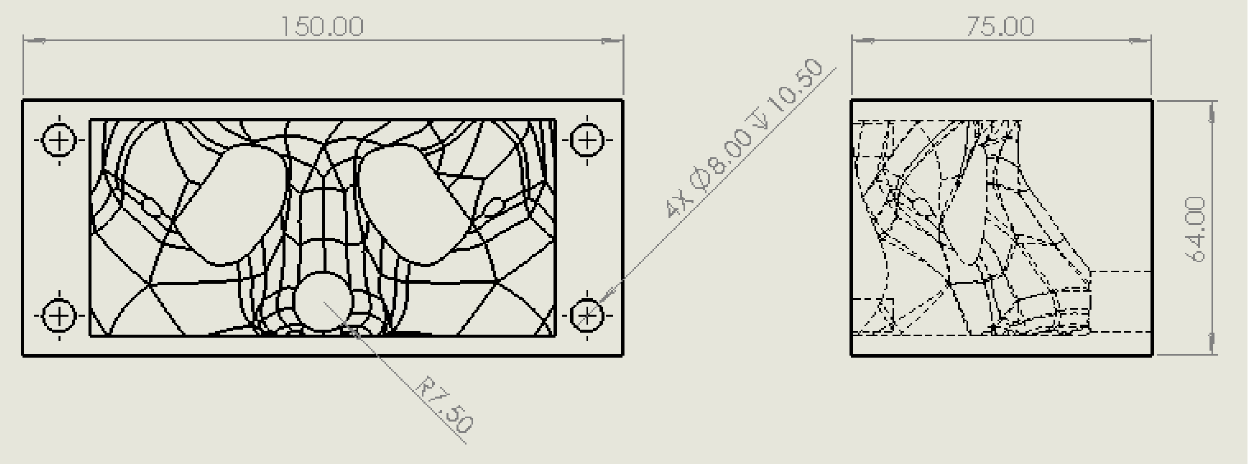


Figure C2: Dimensioned drawing of the face side of the skin mold.

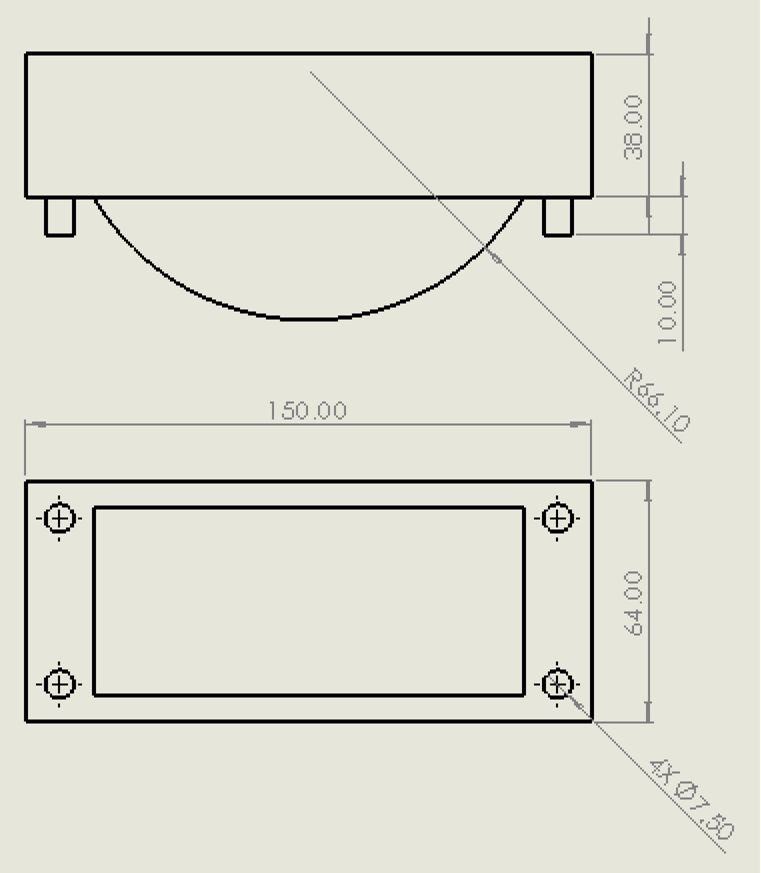


Figure C3: Dimensioned drawing of the skull side of the skin mold.

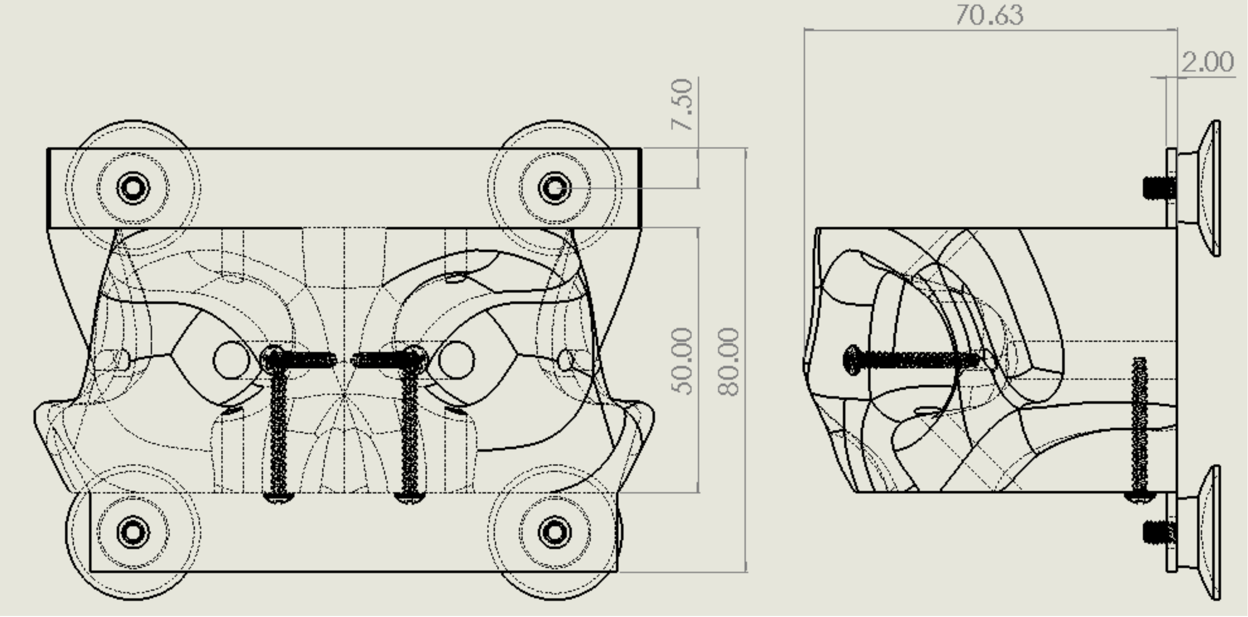


Figure C4: Dimensioned drawing of the 3D-printed base for the enucleation design

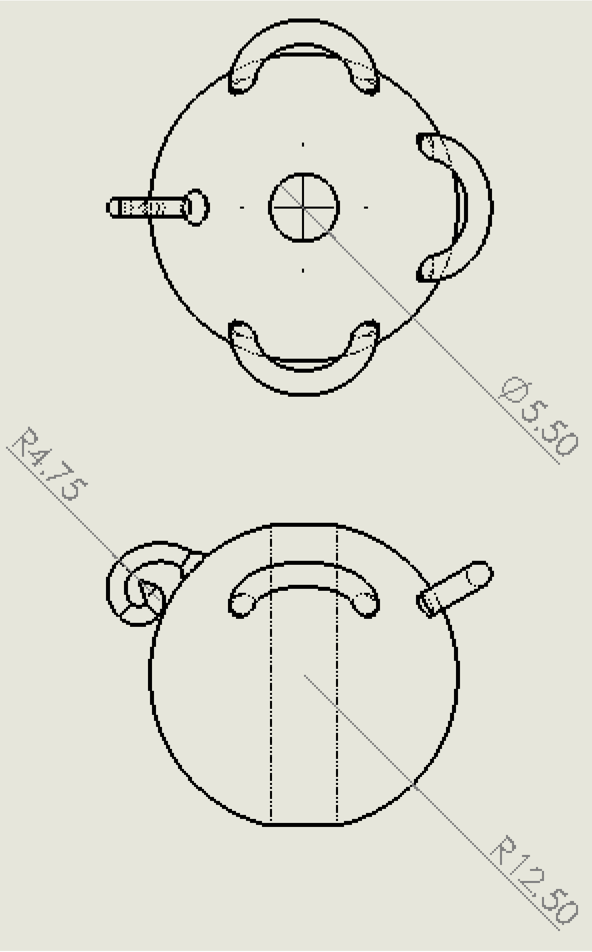


Figure C5: Dimensioned drawing of the 3D-printed eye for enucleation.

Appendix D

Assembly plan

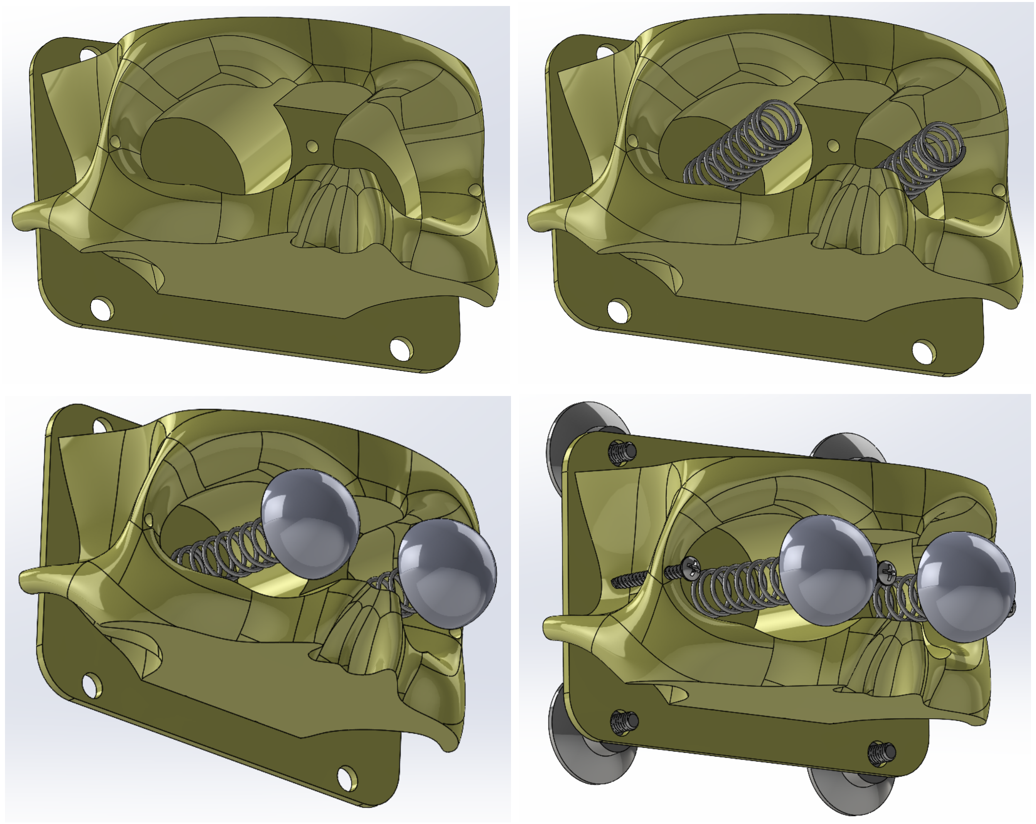


Figure D1: Shown is the assembly plan for the reusable system in canthotomy simulator. First, the 3D printed canthotomy base is placed on a flat surface. Next, the compression springs are stuck to the orbit bottom by super glue. The spring should be concentric with the orbit. After that, the screws are inserted into the holes. Then, the hemisphere rubber balls are stuck to the springs by super glue. Finally, the thread-on feet are inserted in holes at the bottom surface.

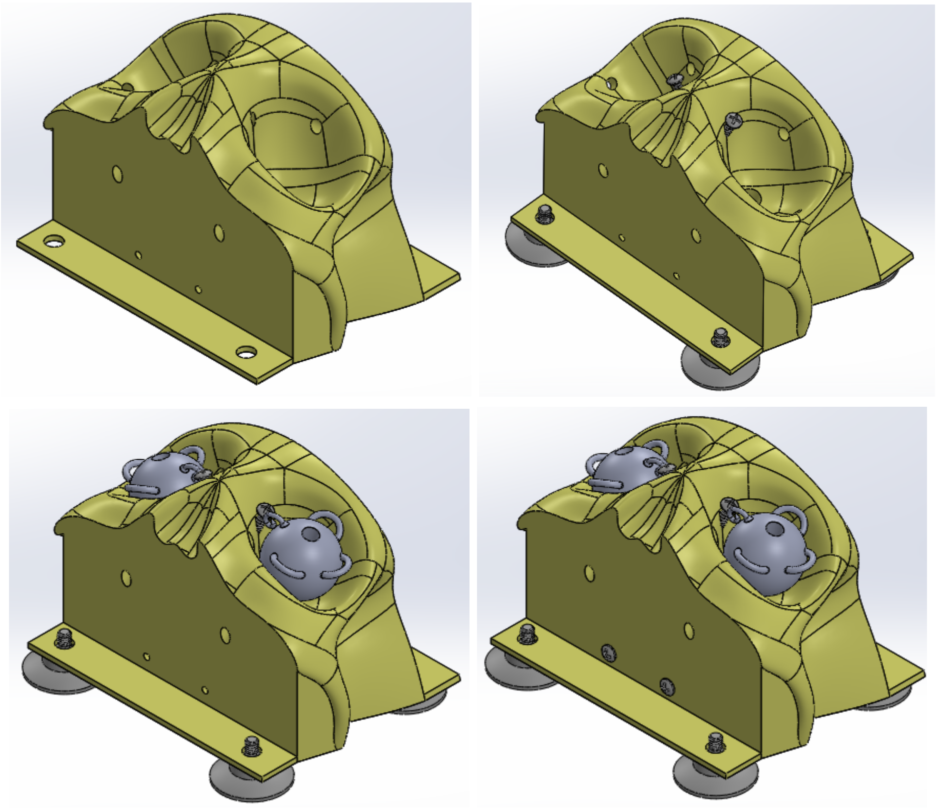


Figure D2: Shown is the assembly plan for the enucleation simulator. First, the 3D-printed base is placed on a flat surface and the four rubber feet are attached. Next, screws are inserted into the medial orbital holes. After that, the 3D printed eyes are placed in the orbit.The elastic rope is threaded through the other three orbital holes and tied to the 3D-printed eye. The polypropylene rope is then threaded through the bottom of the base and 3D printed eye, tying a knot at the end afterwards to prevent the rope from slipping back through the eye. The set screws are then inserted to hold the rope in place. Finally, a rubber band is attached to the medial screw and medial hook on the eye, representing the medial rectus muscle.

Appendix E

Bill of Materials

Table E1: Canthotomy Bill of Materials

Part	**Description**	**Quantity**	**Price**
PLA	3D-printing material for the base and mold for the skin	~300g	~$20 per kg [33]
Size #82 Rubber Bands	½”-thick rubber bands to simulate the lateral canthal tendon	2 rubber bands per simulation	~$8 per pack of 600 [34]
25 mm Rubber Ball	Simulates eye	1 ball per simulator (½ ball per eye)	$1 per pack of 2 [35]
1” #4 18-8 Stainless Steel Phillips Rounded Head Thread-Forming Screws for Plastic	Screws used to attach rubber bands	3 screws per simulator	$8.50 per pack of 25 [36]
3M Microfoam Surgical Tape	Used to simulate consumable skin	25 mm^2 per simulation	$24 per box of 3 rolls (5000 mm^2 per roll) [42]
Spring	Used to simulate the intraocular pressure	2 per simulator	$13.28 per pack of 5 [53]
Dragon Skin FX-Pro silicone	Molded reusable skin	1 per simulator	$35 for 1 pint of silicon [50]
Mann Release Technologies Ease Release 200	Releasing agent for molding silicon	1 per simulator	$22 for 1 14 fl. Oz. can [51]
Thread-On Feet	Attaching the base to table	4 per simulator	$9.67 per pack of 10 [55]

Table E2: Enucleation Bill of Materials

Part	**Description**	**Quantity**	**Price**
PLA	3D-printing material for the base, eye, and mold for the skin	~300g	~$20 per kg [33]
Size #62 Rubber Bands	¼” thick rubber bands to simulate the	1 rubber band per simulation	$5 per pack of 100 [38]

	medial rectus muscle		
$^{3}/_{16}$”-Diameter Polypropylene Rope	Used to simulate optic nerve	~2” per simulation	$8 per 50’ spool [39]
1” #4 18-8 Stainless Steel Phillips Rounded Head Thread-Forming Screws for Plastic	Used to hold optic nerve in place in the base, as well as attach medial rectus muscle to base	4 per simulator	$8.50 per pack of 25 [36]
3mm-Diameter Elastic Cord	Used to simulate the rectus muscles	~6” of rope per simulator	$5 per 10-yard spool [
Dragon Skin FX-Pro silicone	Molded reusable skin	1 per simulator	$35 for 1 pint of silicon [50]
Mann Release Technologies Ease Release 200	Releasing agent for molding silicon	1 per simulator	$22 for 1 14 fl. Oz. can [51]
Thread-On Feet	Attaching the base to table	4 per simulator	$9.67 per pack of 10 [55]

Biographies

Evan Benedek

I am a senior in mechanical engineering, with a minor in biology. I'm originally from Clarksville, MD. I’m interested in mechanical engineering because I want to design products that will benefit people around the world. Outside of school, I am an assistant coach for the Ann Arbor Huron High School Men’s Ice Hockey team. After graduation, I will be working as a development engineer at OrthoPediatrics, working on orthopedic devices for children, in Warsaw, Indiana.

Tejas DeBolle

I’m a senior Mechanical Engineering student. I’m originally from Los Altos Hills, California, about half an hour south from San Francisco. Both of my parents are engineers, so I’ve been exposed to engineering since I was young. Originally, I was studying Biomedical Engineering, and although I switched to Mechanical Engineering, I still want to work on prosthetics after college. I plan on going into industry after graduation for a few years before returning to graduate school. I enjoy martial arts, piano, and reading in my free time.

Matthew Rosolowski

I'm a senior in Mechanical Engineering from Chelsea, MI. I originally attended Washtenaw Community College before transferring to Michigan when I was a sophomore. I chose to study mechanical engineering because of the many opportunities to work in many different industries. Currently, I plan to enter the workforce after graduation. Outside of school, I am part of the Michigan Running Club and my church's student group and enjoy following motorsports. My running goal is to qualify for the Boston Marathon and my favorite race I run each year is the Michigan Outback Relay which is a 10 man, 3 day, 275 mile relay race across Northern Michigan.

Tao Wang

I am a senior student majoring in Mechanical Engineering. I come from Shanghai, China. I have been interested in vehicle structure and appearance since I was a child so I am willing to devote myself into the automobile industry. I am 1.9 meters tall and I like playing basketball outside the classroom. Besides this, I have been fascinated by vlogs recently. I am trying to learn some shooting skills to record my life. After my bachelor years, I will continue on with my master degree still at University of Michigan.