

Final Design Report for the Emergency Eye Simulation Model
And Dr. Leonard Lamsen: Director Of The Medical Simulation
Center At The University of Tennessee Medical Center

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Executive Summary

The emergency eye simulation model is a product that mimics common eye pathologies encountered in emergency medicine. Physicians and students will use this model to practice ultrasound procedures of the eye. The user should be able to use an ultrasound machine directly on the surface of the model, image the eye correctly, and then diagnose the specific pathology seen in the ultrasound image. The stakeholder required three specific pathologies since they are the most common injuries in emergency room patients: lens displacement, vitreous hemorrhage, and retinal detachment. The model must also be reusable and have a long shelf-life so that practice procedures can be repeated multiple times.

To meet these needs, various design alternatives were considered. Physical models that could be palpated and imaged directly with ultrasound were the foundations of the design. Small dragon skin blocks that contained a ballistics gel eyeball in the center was a small portable design concept, however, the contour of the face and eyebrow could not be accurately represented with this model. Therefore, an anatomically correct face was the favored design choice to create physical challenges encountered when ultrasounding the orbital region of the face. Two approaches were debated and tested: CNC aluminum molds or 3D printed PLA plastic molds to be used for ballistics gel eyeball fabrication. The CNC aluminum molds were selected because of their ability to withstand heat which allows the ballistics gel to have less air bubbles in the finished product creating a clearer ultrasound image.

The current design and fabrication method involves CNC aluminum molds to fabricate ballistics gel eyeballs with three different eye pathologies along with a healthy eye. Each eyeball is placed into a dragon skin facial mold for permanent placement. The product results in a full anatomical face model including the nose and eyebrows along with eyeballs that mimic the three required pathologies along with a healthy eye control model. The current model produced ultrasound images that resemble clinical ultrasound imaging of the eye, but further changes need to be made to improve image quality and accuracy. The major selling points of this design are the anatomically correct facial features along with imaging capabilities of three common emergency eye pathologies which will help physicians feel comfortable performing eye ultrasounds to appropriately diagnose patients.

Along with the clinical significance of the model, practical features such as shelf-life and reusability are also key selling points. The silicone and ballistics gel materials used for the model have extremely long lives. Therefore, the model can be used and then stored in a cabinet at room temperature yet still produce clear ultrasound images months later. The ultrasound gel does not interfere or degrade the dragon skin material, so all necessary clinical equipment needed for ultrasound imaging can be used with the simulation model as well. The materials are also cheap for manufacturing purposes which allows the models to be sold within a reasonable price range and with long lasting material, hospitals should not need to repeatedly purchase the model for future use saving them money along the way.

Background

It has been estimated that about 2.5 million eye injuries yearly are seen in the United States. Because of this high statistic it is essential to develop an eye model that will prepare medical students and physicians for diagnosing and treating these eye injuries. Our stakeholder, Dr. Leonard Lamsen, is the director of the Medical Simulation Center at the University of Tennessee Medical Center. The simulation center is a laboratory designated for teaching and practicing medical procedures to improve physician proficiency. The center is currently lacking an eye model that would allow students and physicians to practice eye ultrasound procedures.

The current prototype is an anatomically correct dragon skin face with ballistics gel eyeballs that model three pathologies along with a healthy eye. This model can successfully fill the gap in the simulation center inventory. The model is completely ultrasoundable and intended to match eye pathologies that would be encountered clinically. The accuracy of the model still needs to be improved to allow students and physicians to practice procedures on a realistic model that better translates to the clinical setting. Along with the anatomical accuracy, the model has a long shelf life and can be used repeatedly. This allows thousands of practice procedures to be performed without any additional cost or specialized storage space.

Market analysis reveals that there is a lack of eye models that have ultrasound characteristics. Currently, no eye pathology model exists in the market. Literature review searches have identified five prototype models that attempt to mimic the clinical ultrasound of the eye, but their limiting factor is the lack of reusability and long term storage. Most of the models are made of gelatin which requires refrigeration and can deteriorate with multiple applications of ultrasound gel at room temperature. Also, none of the models have facial features that mimic the anatomical geometry of the face such as the brow and the nose that make the physical act of using an ultrasound probe more difficult. Therefore, the current prototype designed and developed by BiomedVol surpasses the aforementioned prototypes while still maintaining a low manufacturing cost and passing those savings to the customers.

By creating a long-lasting, reusable eye pathology model, many medical students and emergency physicians will be better prepared for eye injuries. Emergency medicine physicians encounter a wide range of injuries and diseases from cardiovascular emergencies to broken bones and anything in between. The breadth of patients they see requires them to be up to date on multiple different areas of medicine such as ophthalmology. This model will help current physicians stay seasoned in their ophthalmological skills and prepare students for the wide range of eye pathologies they will encounter in the emergency room. Adding the eye model to the Medical Simulation Center's repertoire also expands teaching capacity and their state-of-the-art facility.

Problem Definition

Goal

The goal of this project was to design an eye model that is able to replicate the ultrasounds of an eye with retinal detachment, vitreous hemorrhage, and lens dislocation. In addition, this eye model was to be able to mimic a fluorescein stain exam. This eye model should allow for students and physicians to practice diagnosing various eye pathologies.

Functions and Requirements

Need 1: Mimic the Anatomical Structure of the Eye Under an Ultrasound Exam

When patients go to emergency rooms or hospitals due to eye injuries it is common for an ultrasound of the patient's eye to be produced. Doctors and students are trained to distinguish what a healthy eye looks like and what an eye with injury looks like produced by an ultrasound. The proposed eye model will help train students to perform an ultrasound exam on an eye and recognize what the ultrasound of a healthy eye looks like. In order to have a fully functional and accurate representation of a human eye, it is important to create an eye that will mimic the ultrasound of a healthy human eye (Function 1). Because this model will be used to train medical students, it is critical to make the eye model as accurate as possible, mimicking both the ultrasound image and have a 1:1 ratio for the dimensions of the eye model to an average human eye (R1.1.2) . Hence, the ultrasound of BiomedVol's final eye model should look identical to the ultrasound of a healthy human eye (R1.1). In addition, BiomedVol proposes to make the eye model fit into the previous iTrainer mannequin head, be reusable, and have a long-term storability (R3.2, R3.3).

Need 2: Mimic the Pathological Structure of an Eye Under an Ultrasound Exam

Different eye pathologies are seen in emergency rooms, however, there is a lack of eye models that can help train students to recognize these pathologies. Because of this, the proposed eye model will include different eye pathologies including lens dislocation, retinal detachment, and vitreous hemorrhage (Function 2.1, 2.2, 2.3). Similar to the model of a healthy eye, the eye pathologies models will be developed to accurately mimic the ultrasounds of each eye pathology (Function 2) . Each final eye pathology will produce an ultrasound resembling an actual ultrasound of each pathology. Again, these eye models will be made to fit into the previous iTrainer mannequin head, be reusable, and have a long-term storability (R3.2, 3.3)

Need 3: Fluorescein Eye Staining Simulation

In traumatic eye injury, some corneal abrasions may be undetectable to the naked eye. Fluorescein eye stains are used to highlight scratches and abrasions on the corneal surface. We have been tasked with creating a model that mimics this stain for simulation purposes. From this

need, we must create a model that extends the iTrainer anterior eye models with a fluorescein stain mimic (Function 3). The model must also have multiple traumatic corneal pathologies represented (Function 3.1).

Following from these functions, there are a few requirements of this model. First, a performance requirement is that the model have pathologies that glow green when highlighted by a UV light (R3.1). There is also an interface requirement that the model be incorporated into the existing iTrainer mannequin (R3.2). Finally, a non-functional requirement of the model is that it be reusable and have long-term storability, if possible (R3.3).

		Needs		
		N1: Construct an ultrasoundable eye phantom	N2: Incorporate multiple pathologies of the eye into the ultrasoundable phantom	N3: Create a fluorescein eye staining mimic with multiple corneal pathologies
Functions	F1: Demonstrate correct anatomical structure under an ultrasound exam			
	F2: Demonstrate correct pathological structure under ultrasound exam			
	F2.1: Demonstrate Lens dislocation pathology			
	F2.2: Demonstrate Retinal Detachment Pathology			
	F2.3: Demonstrate Vitreous Hemorrhage			
	F3: Extend iTrainer model to include fluorescein staining simulation			
	F3.1: Incorporate multiple traumatic corneal pathologies			
Requirements	Performance	R1.1: Ultrasound image must resemble that of a human eye		
		R1.1.1: Image must be of a solid black sphere incased in a shadowy exterior		
		R1.1.2: Model must be constructed according to average dimensions of the human eye at a 1:1		
		R2.1: Pathologies must be identifiable across multiple planes		
		R3.1: Pathologies must glow green when highlighted by a UV light		
	Interface	R1.2, R3.2: Models must be incorporated into existing iTrainer mannequin		
	Non-Functional	R1.3, 3.3: Phantom must be reusable and have long-term storability		

Figure 1. Traceability Matrix of Functions and Requirements

Constraints

The model should be constructed so that it produces realistic ultrasound images. This includes a solid black vitreous space along with a blurry-grey periorbital region. All anatomies should be constructed at a 1:1 scale according to average ocular sizes.

Concept Development

*Ultrasoundable Eye Model**Design I*

Development of the ultrasoundable eye model began by understanding and researching the anatomy, physiology, and ultrasounds of the human eye. With an understanding of how ultrasounds are created and what affects the images produced, we further researched materials that would be able to replicate the ultrasound images. In addition, research found on other eye models, summarized in Appendix C, provided some insight for the development of our eye models.

The background on our device is the region outside of the eyeball representing the sclera, ocular muscles, and bone. In the ultrasound image, this region is hazy and highly echoic. Over the course of the design phase, the material we desired remained mostly unchanged. An outer layer of Dragon Skin silicone was selected for its shadowy ultrasound texture to act as a background material. Initial selection of this material was based on information provided by Dr. Lamsen. In our initial meeting, Dr. Lamsen discussed dragon skin being used for muscle simulation, which led the group towards its selection as a background material. Further research has shown it being used in multiple ultrasound phantoms. Table 1 is the design selection matrix for background material.

Table 1. Background Material Design Selection Matrix

<i>Ideal Properties:</i>	Dragon Skin	Other Silicones
<i>Realistic Hardness</i>	+	-
<i>Intrinsic Echogenicity</i>	+	-
<i>Easily Poured</i>	+	+
<i>Tolerates Additives</i>	+	+
<i>Long usage-life</i>	+	+
<i>Low-cost</i>	0	+
Total:	5	2

It is common to include solid and fluid additives within the silicone mixture to fine-tune the echoic properties of the materials. Solid additives include graphite, talcum, cornstarch, and sugar-free psyllium hydrophilic mucilloid fiber (Metamucil). Fluid additives that are commonly used are Vaseline Oil and silicone oil. While our team focused on solid additives, research showed that if a greater amount of solid additives are needed, fluid additives would become necessary. However, the amount of solid additives used in our case will likely not require any oils. In determining the optimal additive for our product, online research and a cursory ultrasound test was conducted, and Metamucil was then selected due to its ideal density and echoic properties. This process is shown in Table 2.

Table 2. Background Additive Design Selection Matrix

<i>Ideal Properties:</i>	Metamucil	Talcum	Graphite	Vaseline Oil	Silicone Oil
<i>Similar desnisity to silicone</i>	+	0	0	-	-
<i>High echogenicity</i>	+	+	0	0	-
<i>Cost-effective</i>	+	+	+	+	0
<i>Little effect on cure time</i>	+	+	+	0	-
Total:	4	3	2	0	-3

Moving towards the inside of the eye, the posterior chamber is depicted in an ultrasound as a dark sphere. To achieve this, ballistics gel was quickly identified as an ideal choice. Many ultrasound phantoms utilize gelatin as a phantom material. Regular organic gelatin suffers from an extremely short usage of life and requires refrigeration. However, it holds ideal echoic properties. To overcome the limitation with gelatin, the selected ballistics gel is fully synthetic and will have a long usage life. When viewed under ultrasound, ballistics gel is completely anechoic (disregarding bubbles) and has a similar speed of sound compared to water (1445.5 m/s). When evaluating other materials such as silicone rubbers, few alternatives were found. Though some silicone rubbers are fully anechoic, they typically have a low speed of sound which can affect the ultrasound image. The design selections matrix for the eyeball material is shown in Table 3.

Table 3. Eyeball material Design Selection Matrix.

<i>Ideal Properties:</i>	Synthetic Ballistics Gel	Gelatin	Silicone Rubber
<i>Realistic Hardness</i>	+	+	+
<i>Fully Anechoic</i>	+	+	+
<i>Easily Poured</i>	+	+	+
<i>Speed of Sound similar to H2O</i>	+	+	-
<i>Long usage-life</i>	+	-	+
<i>Low-cost</i>	0	+	0
Total:	5	4	3

To create the anatomy/pathologies within the eye, a few concepts were considered. Knowing that the important features to reproduce were the iris and lens (for a healthy eye), materials were evaluated on the ability to create thin interface lines on an ultrasound image. First, a PLA 3D-printed iris/lens combination was suggested. This was quickly removed from consideration due to its echoic center and low density. Then a test was devised to evaluate four other materials: construction paper, printer paper, Elmer's Glue, and multi-pours of the same material. During this test, an ultrasound procedure was conducted on the four samples and the materials were evaluated on the following criteria: line thickness, line consistency, and presence of artifacts. These qualities would then be compared to the ideal image: thin, consistent lines, with no artifacts present. Figure 2 shows the results of this test. Ultimately, the multiple material pours method was selected as the ideal method of creating the iris and the lens. This method will also be ideal for the creation of the lens and retinal detachments.

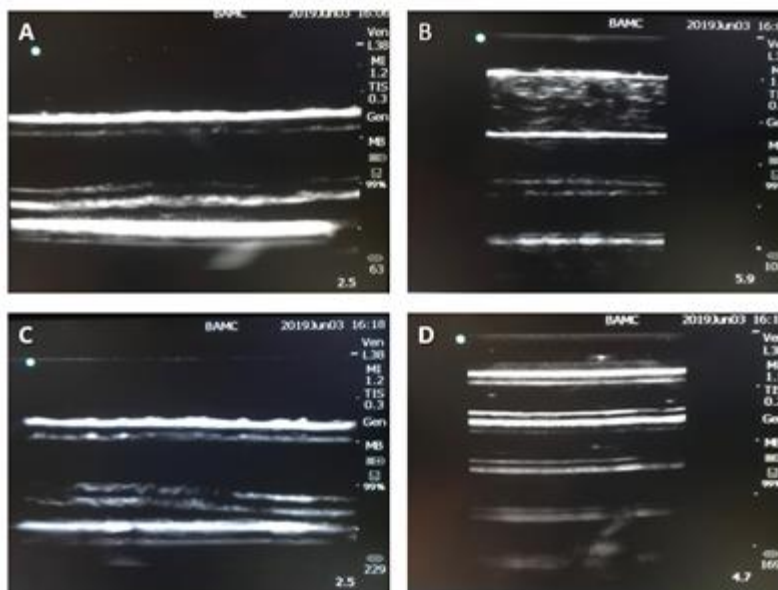


Figure 2. Ultrasound Images of Rough Material Combination Prototypes. (A) Ballistics Gel on Ballistics Gel. (B) Ballistics Gel on Dragon skin Silicone. (C) Two Ballistics Gel Layers separated by Elmer's Glue. (D) Ballistics Gel Layers Separated by Construction Paper.

Having determined the main materials needed to begin building a healthy ultrasoundable eye model, we began to develop how the eyeballs would be manufactured. For this design, we planned on building a plexiglass cube and pouring the background material around an eyeball-shaped cast positioned cornea up. Once the material cured, the cast would be removed, and the eyeball material inserted into the cavity. Figure 3 demonstrates a rough diagram of how the ultrasoundable eye model would be encased in the dragon skin/metamucil mixture. We decided that the final eye models would be compatible with the iTrainer mannequin head. In addition to determining the materials needed, a basic process flow for manufacturing, testing, and accepting the ultrasoundable eye models was created as represented in Figure 4. During the manufacturing process we came across several challenges: hot ballistics gel could harm the already cured background material, it would be difficult to create the lens and iris, and the addition of any posterior chamber pathologies would be nearly impossible. An alteration of this design was created with the anterior chamber on the bottom of the mold. This method still had the same limitations.

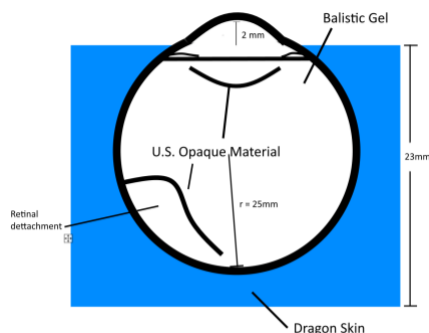


Figure 3. Original rough diagram for the ultrasoundable eye model.

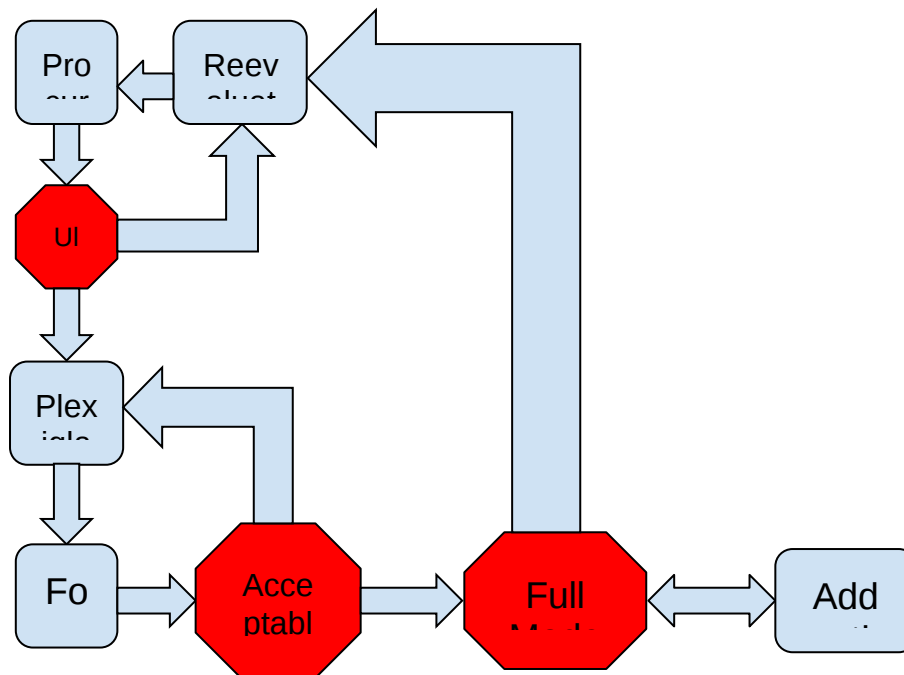


Figure 4. Basic process flow diagram for manufacturing, testing, and accepting ultrasoundable eye models.

Design II

In an attempt to solve the limitations seen in Design I, a new design was created with the eyeball being molded separately. This comes with several advantages: the eyeball can be fully formed before placing it in the background material, eyeball anatomy/pathologies will be more easily accessed and manufactured, and the eyeballs can be created for the fluorescein exam simulator. The box design was also reconsidered and replaced with an anatomically proportionate face model. This will allow for proper ultrasound technique to be practiced. Figure 5 shows the proposed final model for this design.

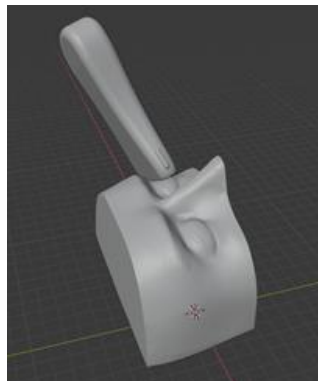


Figure 5. Mock-up of a potential face model design.

For this design we decided to incorporate 3D printed molds of the eyeball. The group decided on using 3D printed molds due to the fact that they are cost effective and time efficient

when it comes to manufacturing it. The 3D printed molds were made of PLA plastic and had dimensions that mimic the average adult human eyeball. Because the molds were 3D printed the inside of the mold that would hold the ballistics gel was not smooth enough to ensure a clean removal of the eye, we decided to incorporate the use of XTC-3D smoothing agent. A thin layer of this smoothing agent was applied on the inside surface of the 3D printed mold. The drawings and specifications for the 3D printed eye molds are shown in Figure 6 while the specifications for the bulk eyeball and its anatomical structures are shown in Figure 7.

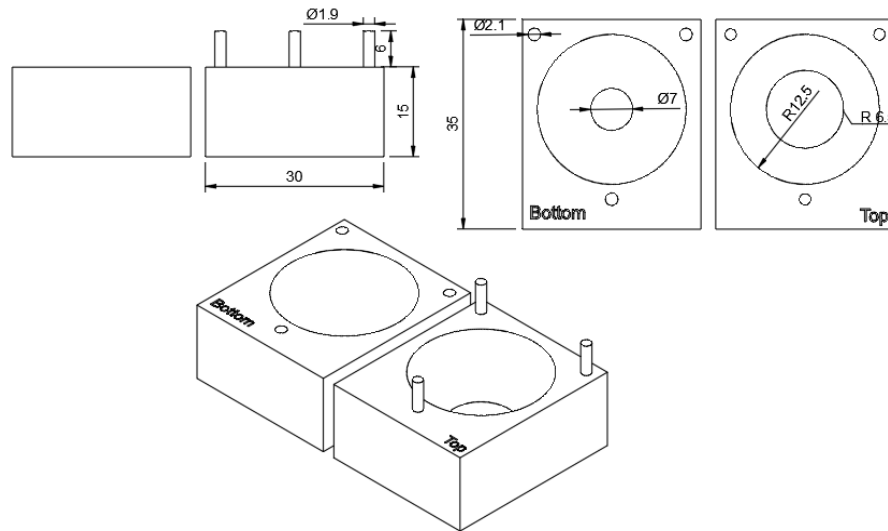


Figure 6. Drawings and specifications (mm) for ballistics gel eye mold.

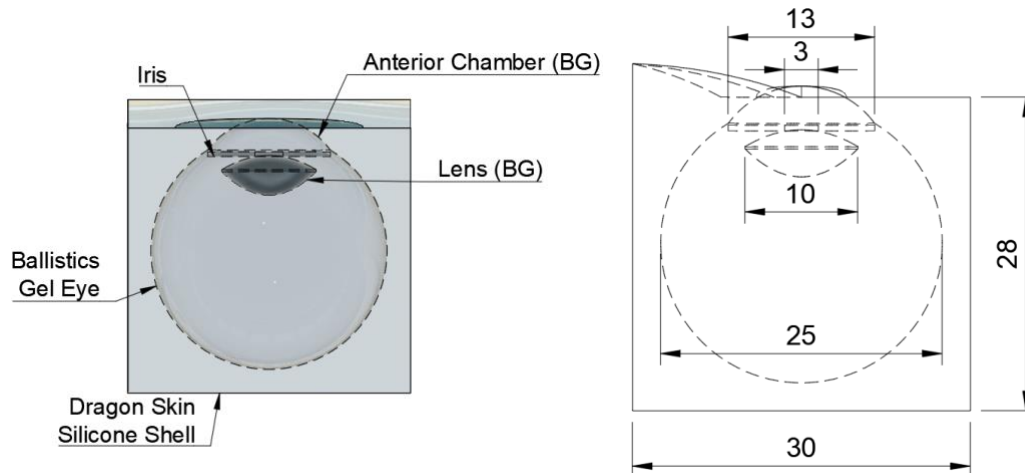


Figure 7. Diagram with materials (left) (BG indicated ballistics gel) and minimum specification required for ultrasound model (right)

The molds were used to shape the melted ballistics gel into the bulk eyeball shape. For this design, there would be a multi-step pouring process to ensure proper placement of specific materials. However, to ensure that the 3D molds would be able to produce an acceptable bulk eyeball, we began by manufacturing and testing the bulk eyeball first. Figure 8 shows the eye models created using the 3D printed eye molds.

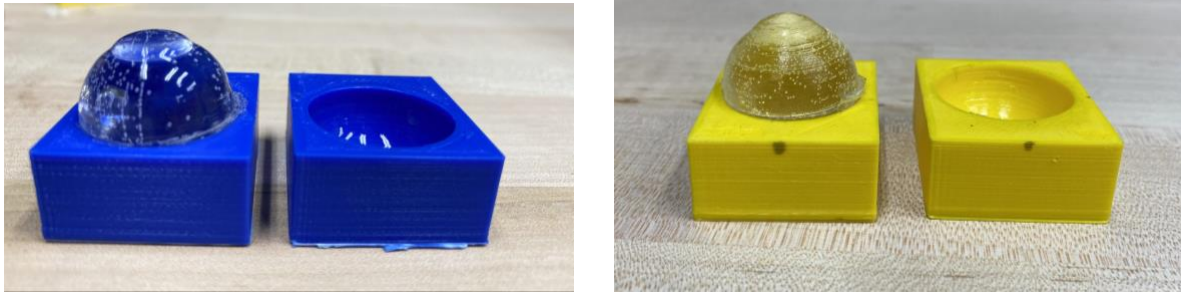


Figure 8. Eye models manufactured with the 3D printed eye molds.

During the manufacturing and testing process we came across some complications. We noticed that the eyeballs being produced contained air bubbles that interfered with the ultrasound images. Instead of the posterior chamber appearing dark, the air bubbles caused it to appear hazy and brighter than what we wanted. Before proceeding with adding the rest of the anatomical structures and pathologies, we decided to reevaluate the manufacturing or design of the eye mold. However, we developed a manufacturing process for the lens and pathologies and decided to begin the manufacturing and testing of these processes once the final eye mold has been developed. The following outlines this design.

Initial testing revealed that separate pours of ballistics gel (allowing one pour to solidify prior to pouring section two) creates a distinct white echoic interface line on an ultrasound machine. This finding would be utilized to create an interface between the anterior and posterior chamber which is separated by the iris. Following the same ideology, the lens would be molded separately from the bulk eyeball then placed into the PLA molds to have the posterior section of ballistics gel poured over the molded lens. Once each pour was completed, the PLA mold was clamped shut until the ballistics gel cured (~3 hours). The main pathologies would be modeled using the ballistics gel eyeball. The lens dislocation would be manufactured by placing the separately molded lens into a slightly unusual position in the posterior chamber of the eye then ballistics gel will be poured over the lens to secure it in place. The retinal detachment would be created by using an X-acto knife to cut a section of the posterior chamber off in order to refill the missing chamber with fresh ballistics gel. The multiple pours, again, would imitate the echoic image of retinal detachment in the posterior chamber. The vitreous hemorrhage would be imitated using elmer's glue. The glue would be injected into the solid posterior chamber of the eyeball. Elmer's glue is a suspension which creates a distinct difference in density with the ballistics gel which would create a distinct ultrasound image compared to ballistics gel alone.

Design III

In order to eliminate the air bubbles created in the ballistics gel, we decided to reevaluate the eye mold. We determined that in order to get rid of the air bubbles we would have to be able to reheat the eye mold with ballistics gel in the mold. Because the previous eye mold consisted of a 3D printed PLA plastic eye mold we would not be able to reheat the mold without risk of the

mold softening and possibly merging with the ballistics gel. For this reason, we redesigned the eye mold to be made out of aluminum. The idea of the eye mold from the 3D printed molds and the eyeball specifications would remain the same, however, the mold was redesigned to be compatible for radial milling. For this design we decided to also develop a mold for the lens to be used in the bulk eyeball. During the development of the aluminum eye molds, we considered a different approach to the design of the eye mold. The design would call for the bulk eyeball to be manufactured without the anterior chamber, which would be added later. This would allow for the posterior chamber of the eye to be manufactured first, and once cooled, hot ballistics gel would be added to create the anterior chamber. This design would incorporate the idea that two separate pours can create an interface. In this case, the interface between the two pours would be able to recreate the lens in an ultrasound. Figure 9 shows the cross-section of the two eye mold designs considered. The concave mold represents the mold that would create the whole bulk eyeball while the convex mold represents the would create only the posterior chamber.

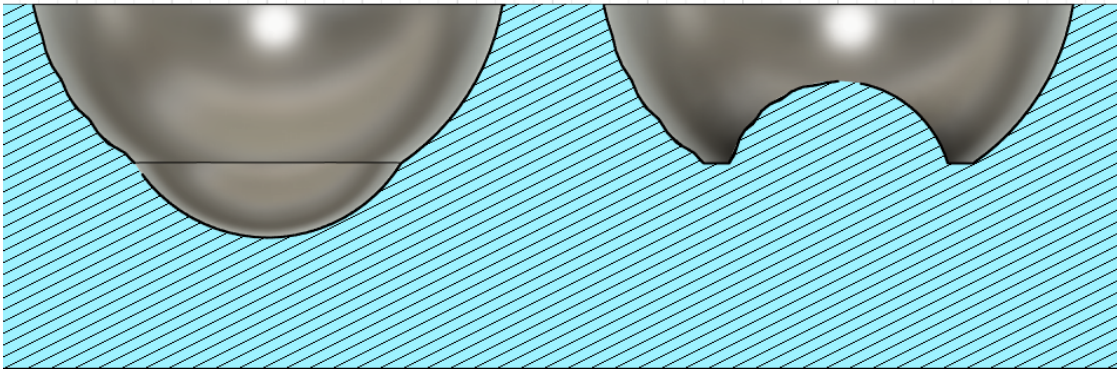


Figure 9. Cross-section of concave (right) and convex (left) molds.

In addition to redesigning the eye mold, the integration between the ultrasoundable eye models and the face model was also redesigned. In order to allow for the use of the Emergency Eye Simulation Model to be as realistic as possible, we decided to integrate the eye models into a full face model composed of a mixture of dragon skin and metamucil. This design would allow for users to work around the bony structures of the face as they would with a real patient. In order to create this face model, a hollow, plastic three dimensional face with a forehead, eyebrow, and nose features was cut in half with a band saw along the coronal plane just in front of the ear lobes. Two eye models were placed into the plastic mold behind the eyeball features and held in place. Dragon skin mixed with metamucil was then poured to surround the eye models and fill the face mold. The eye models integrated into the face model can be seen in Figure 10.



Figure 10. First face model created with healthy eye models incorporated.

Fluorescein Eye Model

Design I

At our initial meeting, Dr. Lamsen discussed the previous iTrainer designers' difficulty with creating a fluorescein mimic. While this team planned on using real fluorescein dye to stain a ballistic gel eye, our initial plan was different. Our plan was to simulate fluorescein dye using green, invisible, black-light paint. Using this black-light paint we planned on painting the pathologies seen in a fluorescein eye stain exam onto the ocular surface of an eye model. This design would allow for the student or physician to simulate inserting fluorescein on the eye with the use of water or saline. However, after the creation of these prototypes, it was brought to the group's attention that the slit lamps use blue light filters and not UV lights. Most black light paints are only responsive to UV light, limiting our initial idea.

Design II

It was determined that the original idea of the use of black-light paint would not be responsive to the blue light filters that are used in slit lamps. Due to this complication, we decided to redesign the fluorescein eye model design to incorporate fluorescein powder. In order to be able to use fluorescein powder we determined that we could mix fluorescein powder with a solution that would dissolve the powder while still retaining the illuminating characteristic of the fluorescein. Research of fluorescein informed us that fluorescein is activated with water. With this knowledge, we determined that we would need to mix fluorescein with a water based liquid. We tested several different adhesives for miscibility and dissolution and found that Elmer's glue, specifically clear Elmer's glue, produced the best results due to the fact that it is a water based product. The manufacturing process of the fluorescein eye model began with mixing fluorescein powder with Elmer's glue. This mixture was then placed on a sheet of wax paper in a manner that mimicked the pathologies that would be used for the fluorescein eye model, shown in Figure 11. Once this mixture was dried it would be placed onto an eye that was manufactured using the

iTrainer's manufacturing process. The finished fluorescein eye model using this manufacturing process is shown in Figure 12.

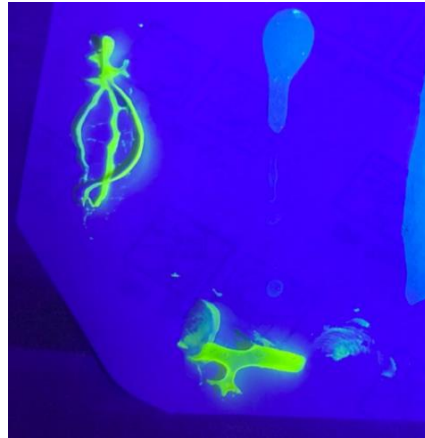


Figure 11. Fluorescein-glue mixture placed onto a sheet of wax paper.

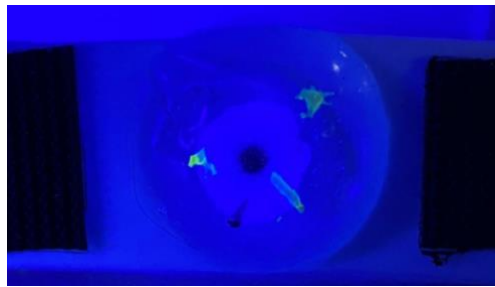


Figure 12. Final fluorescein eye model under a blue light.

The next section will further explain the final design and manufacturing process that is a result of the concept development process.

Product Manufacturing

After initial prototyping, BiomedVol settled on a final design for manufacturing that included a machined aluminum mold for the eyes and the lens. A full step-by-step manufacturing guide can be found in Appendix B. Figure 13 shows the concept designed by BiomedVol and Figure 14 shows the final manufactured form of the mold. This mold has twelve concave features with varying geometries across two halves. When placed atop each other, the mold is capable of being used to create four eyes and four lens. This section will focus on how the aluminum mold is used during the manufacturing of the ultrasound eye.

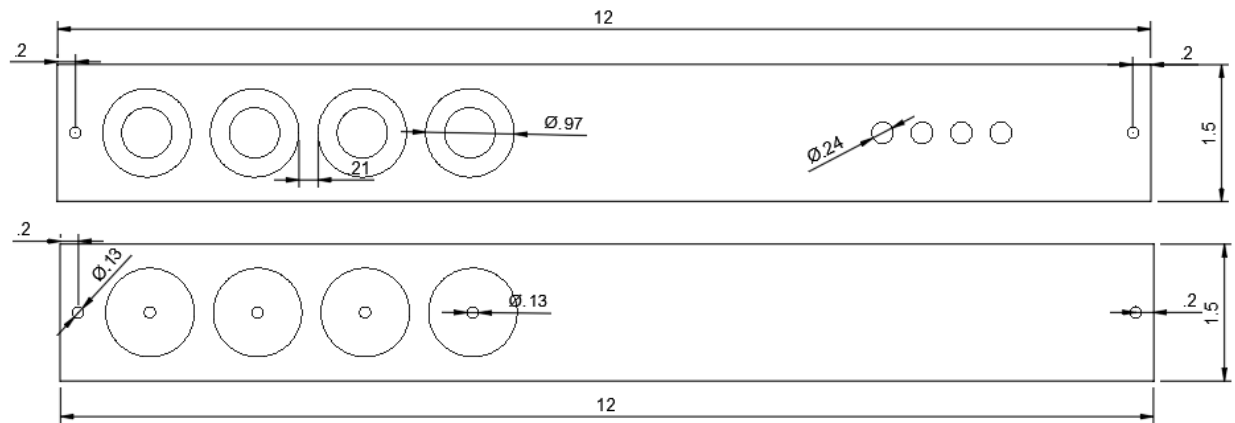


Figure 13. Schematic of aluminum eye/lens mold. Mold consists of two 12 in pieces with four eye molds and four lens molds. Eye molds have a 1/8in whole to fill with ballistics gel. Edges of the bar have alignment holes which position the pieces accurately.



Figure 14. Final manufactured form of the bar mold..

Manufacturing was begun by heating the aluminum mold to 150°F in an oven. As mentioned previously, this is done to help remove any air bubble caused during the molding procedure. The first item that was molded was the lens. Using the four lens molds, a small amount of synthetic ballistics gel was deposited into the cavities. After around an hour of being heated, the mold was cooled and the lens removed. It is convenient to make an initial batch of lens before simultaneously molding lens alongside eyes.

Next, healthy eyes were made to ensure the manufacturing process was producing consistent results. The first step in making the eyes was to heat the aluminum mold to 150F in an oven. Once warm, a small amount of synthetic ballistics gel was used to fill the anterior chamber. While this was still liquid, the lens was placed atop this material. Next, the second half of the aluminum mold was placed on top of the bottom piece and secured with the alignment pins. Finally, the posterior chamber was filled with ballistics gel using the hole placed on top of the

mold. This is done simultaneously four times. After heating the mold for around two hours, the mold is cooled and the eyes removed.

If successful, this process creates a synthetic ballistics gel eye with no unusual pathologies. Unfortunately, BiomedVol was unsuccessful in the manufacturing of these prototypes, which will be discussed in the next section. Ideally, the process is similar for those eyes with pathologies. For lens dislocation, the lens is simply placed at an angle from its ideal position. For vitreous hemorrhage, the eye is injected with watered-down Elmer's glue while in the oven. Finally, for retinal detachment, the fully cooled eyes are cut and glued together with a transparent super glue. A full manufacturing flow chart can be found in Figure 15.

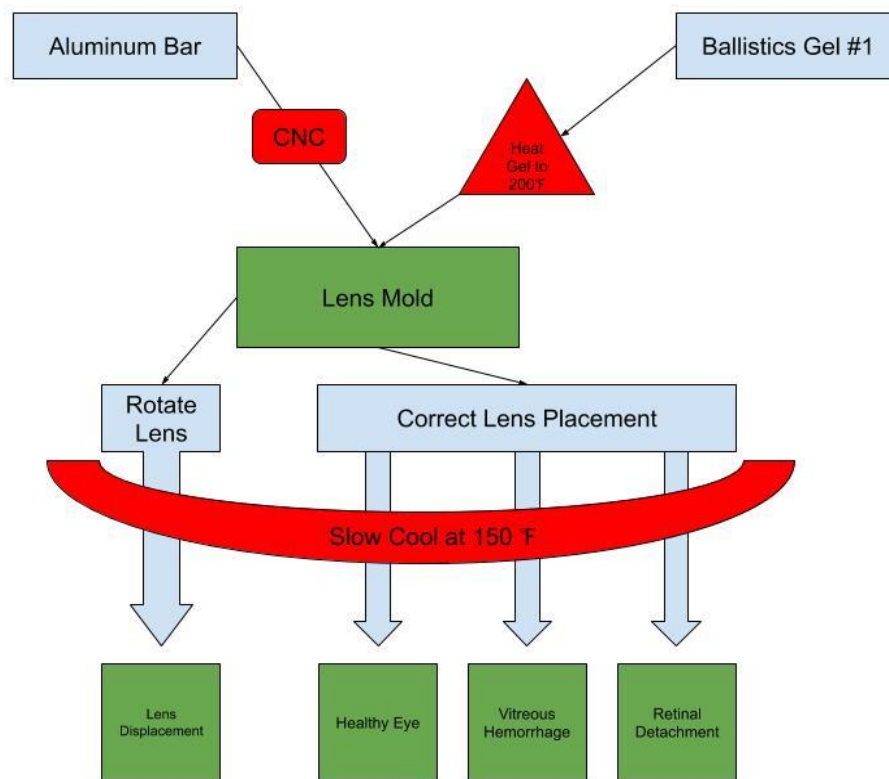


Figure 15. Flow chart of ultrasound eye manufacturing. This chart ends with the common steps for manufacturing each pathology.

The fluorescein exam eyes were designed to be much more simple to create. This can be seen in Figure 16. Utilizing previous work by the iTrainer creators, EngineerinGirls, BiomedVol designed an easily reproducible exam eye. This eye incorporates the manufacturing method of the iTrainer eyes. First, a mold provided in the iTrainer kit is filled with melted synthetic ballistics gel. This created a half-eye with a cavity in the front. Next, a printed iris was placed in this cavity and

the cavity was filled with ballistics gel until a dome formed atop the eye. Next, BiomedVol's fluorescein paint was used to paint the eyes with any of the patterns seen in Figure 17. The eyes are then adhered to paper with velcro to be used in the iTrainer mannequin.

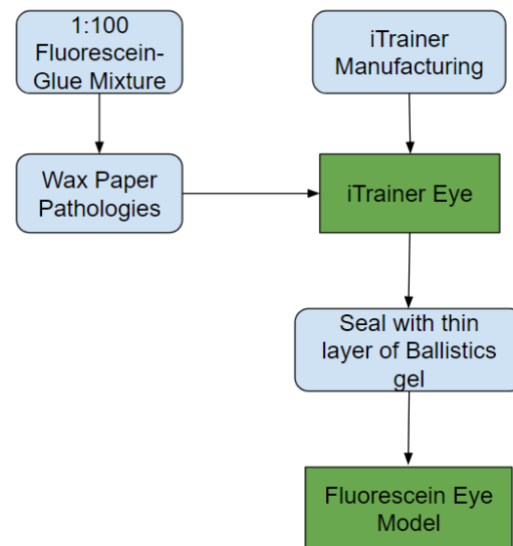


Figure 16. Flow chart for the manufacturing of the fluorescein eye staining simulator.

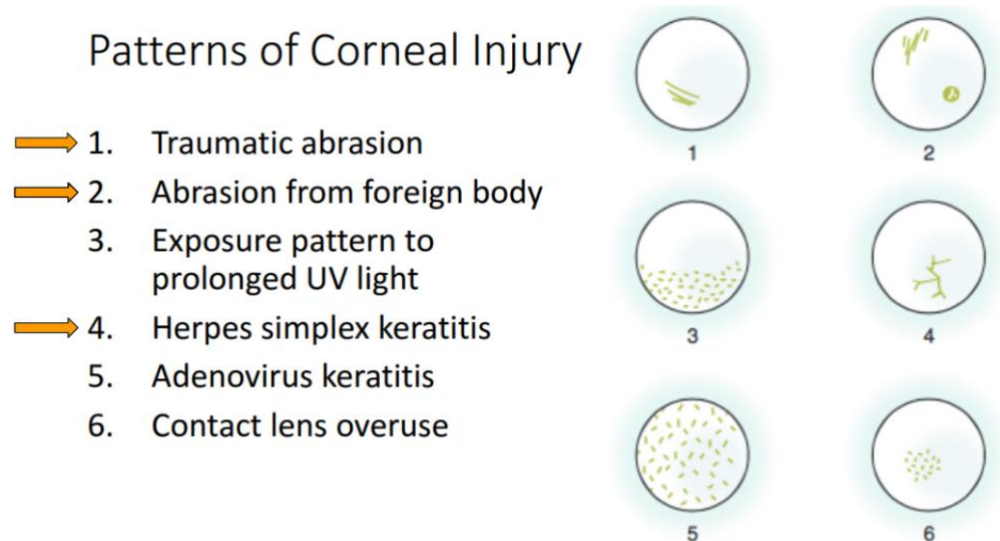


Figure 17. Patterns of pathologies mimicked in creation of the fluorescein simulator.

Design Evaluation

Ultrasound Model

The current prototype does not meet the essential design requirements established prior to testing. However, the prototype does show promise and is on track to be able to meet the needs of the stakeholder and pass product evaluation standards in the near future. The current model does satisfy other existing requirements such as an extended shelf life and accurate three-dimensional

facial features which demonstrates that the chosen materials are effective (Figure 18). However, the key aspect of the design is high resolution ultrasound images of three distinct pathologies: retinal detachment, lens dislocation, and vitreous hemorrhage. The current manufacturing methods do not result in high quality ultrasound images that match clinical images in a comparison test.



Figure 18. The current model that matches the three dimensional anatomy of the face.

Figure 19 displays the side by side comparison of a clinical image of retinal detachment compared to the current emergency eye simulation model. The white echoic line is visible in the ultrasound (marked by a blue arrow), but the outline of the eyeball is not well defined in the model. The lens also appears larger and more pronounced in the simulation model. The bubbles surrounding the artificial lens cause the lens to look larger than the clinical image. Overall, the retinal detachment model does reveal a white echoic line in the posterior chamber of the eye, but the surrounding features of the model hinder the model's complete replication of the clinical image. Further testing needs to be done to create a clearer boundary between the eyeball and the surrounding soft tissue while also reducing the footprint of the lens.

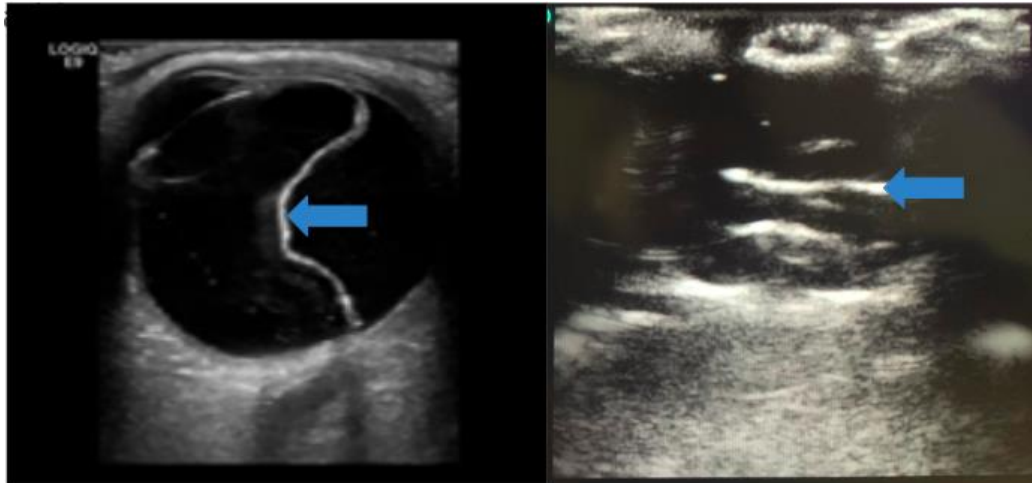


Figure 19. A side by side comparison of the clinical retinal detachment image (left) and the emergency eye simulation image (right) using ultrasound.

Figure 20 compares the clinical ultrasound image of a lens dislocation pathology to the emergency eye simulation model. The key aspect of the model is the existence of the lens in an abnormal anatomical orientation. The lens imitation in the model does have an abnormal orientation by appearing diagonal in the ultrasound image (marked by a blue arrow). Therefore, the pathology is closely mimicked by the model, but similar to the retinal detachment, the surrounding characteristics of the ultrasound model are lacking. The opaqueness of the center of the lens is not consistent with the clinical image where the lens appears hollow. This is due to the existence of air bubbles surrounding the artificial lens. The contrast between the eye body and the soft tissue is not present either which must be addressed in future versions of the simulation model.

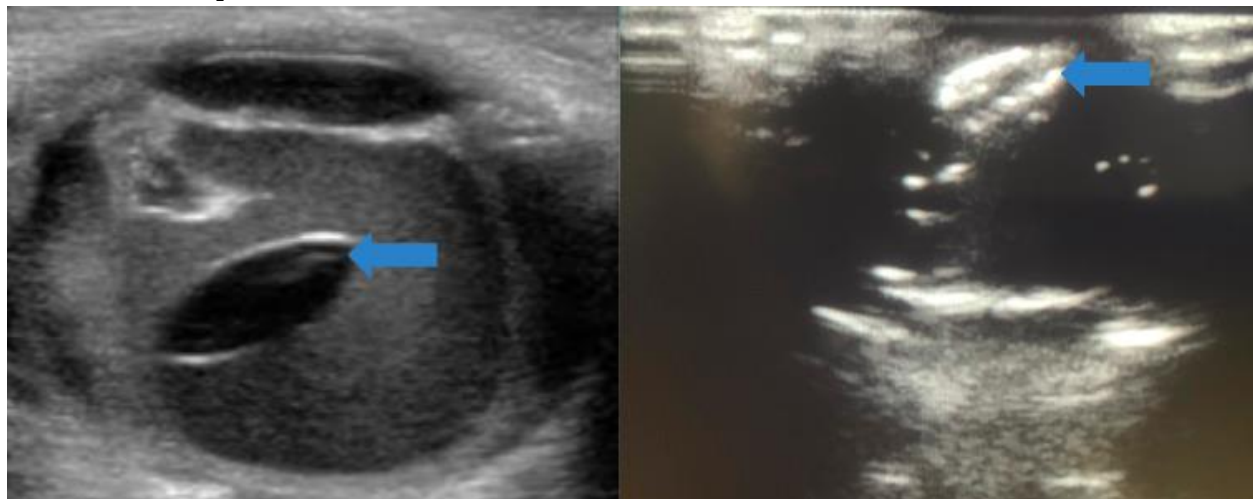


Figure 20. A side by side comparison of the clinical lens dislocation image (left) and the emergency eye simulation image (right) using ultrasound.

Figure 21 compares the clinical ultrasound image of vitreous hemorrhage to the emergency eye trainer model. Vitreous hemorrhage is represented by a slight grey, hazy appearance in the

posterior chamber of the eye as indicated by the blue arrow in the images. Out of the three pathologies, the vitreous hemorrhage most closely matches the clinical presentation. The outline of the body of the eye is also more distinct in this specific model which indicates that there is no uniformity between the ballistics gel eyeballs being produced. The reproducibility of desired eyeball characteristics needs to be explored further so each molded ballistics gel eyeball has qualities such as the one presented in the figure.

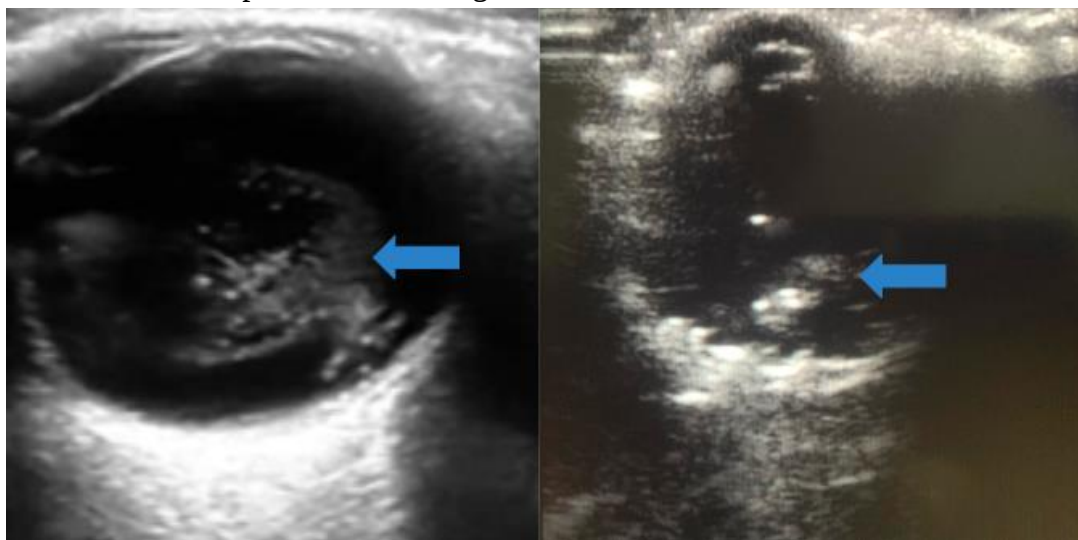


Figure 21. A side by side comparison of the clinical vitreous hemorrhage image (left) and the emergency eye simulation image (right) using ultrasound.

Fluorescein Model

The current fluorescein model passed all design requirements established prior to testing. This model is a supplement to the emergency eye simulation model to expand the breadth of procedures students and physicians can practice while in the simulation center. A clinical fluorescein staining exam is used to identify corneal abrasion on the surface of the eye. During a slit-lamp exam a light that ranges from blue to ultraviolet is used to fluoresce the fluorescein solution that is applied to the eye. Areas of yellow lines or dots indicate a corneal abrasion. The current model is capable of providing students and physicians with realistic pathology imitations and is capable of repeated application of the fluorescein solution.

Figure 22 shows the side by side comparison of the fluorescein model and a clinical fluorescein stain exam. The areas that are fluorescent yellow indicate the cornea has been damaged, and both images look extremely similar in the presentation of the yellow staining. This indicates that the model does accurately imitate a positive fluorescein stain exam. To expand the model, the lone eyeball model can be placed into a three-dimensional mannequin head to create a more realistic representation of the exam. The model head fits into the slit lamp so that the head can be stabilized just like a patient's would be. This allows students and physicians to use a fully functional slit-lamp for the examination procedure further expanding the effectiveness of the

model. Future modification could include adding eyelashes and eyelids that open and close to continue to improve the realism of the model.

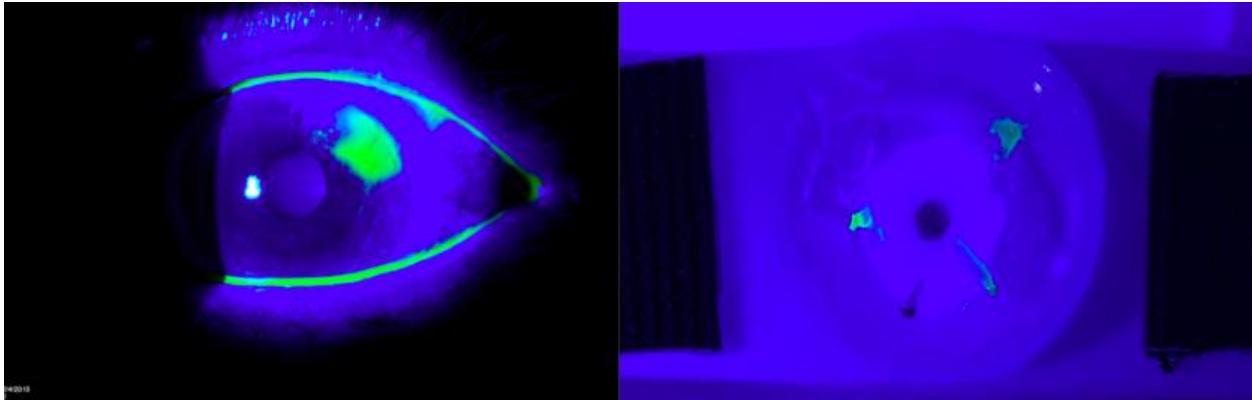


Figure 22. A side by side comparison of the clinical fluorescein stain image (left) and the fluorescein model (right).

Future Improvements and Lessons Learned

Through the design process of the emergency eye simulation model, BiomedVol achieved certain aspects of the design, but other design criteria fell short of the quality desired. The current prototype was fabricated even with the disruption of the COVID-19 pandemic, but particular results of the design were subpar. For example, the product evaluation and testing exposed the existence of air bubbles around the inserted lens in the ballistics gel eyeballs. There were some positive results from our current prototype evaluation though. BiomedVol fabricated an anatomically correct face model that held the various eyeballs in place, and the material used has an extremely long shelf life to make the model reusable and easily stored. A supplemental fluorescein staining model was successfully manufactured to add more versatility to the emergency eye simulation model capabilities. Certain roadblocks were not anticipated such as the COVID-19 pandemic and the hindered capability of machine shops on campus to continue fabrication processes. These outcomes result in lessons learned and future modifications of the design process that can improve the quality of the final product.

To improve the existing prototype, BiomedVol plans to continue the use of the aluminum mold fabrication process, but reevaluate the lens imitation section of the design. Multiple approaches to the lens imitation section of the design should be developed and tested prior to redefining the current manufacturing process. The key limitation of the current lens design is the formation of air bubbles surrounding the lens once the ballistics gel is cooled. Should the bubbles be removed, the interface between the dragon skin lens and the ballistics gel should result in a well defined lens outline that imitates the clinical images. Developing new techniques to manufacture the lens images to a finer resolution will also improve the model as a whole. A new approach can be the use of a vacuum chamber that the aluminum mold can be placed inside of to allow the remnant air bubbles to be pneumatically removed from the ballistics gel. Not only would the lens

be more defined, but removing air bubbles from any area of the mold would improve image quality and clarity.

The manufacturing process as a whole is straightforward and combines the ballistics gel eyeball with the dragon skin facial mold in a seamless manner, but a few improvements must be made to allow the process to be more streamlined. The aluminum mold is a success for quickly manufacturing four ballistics gel eyes at one time. The only downfall of the mold is that the heated ballistics gel expands and flows out of the seam connecting the two sides of the aluminum bars. The intention of the design was to allow the excess gel to escape through an $\frac{1}{8}$ " hole in the top of the mold. To combat this problem, bolts will be drilled on each side of the aluminum mold as well as the center to add force to the plates using nuts to tighten the two individual aluminum bars together to prevent the gel from escaping the sides of the mold. This will help control the release of excess gel during the heating process and force air bubbles to escape the gel from the same $\frac{1}{8}$ " hole when placed in the vacuum chamber.

Reflecting on the current design and previous design and development processes allows BiomedVol to identify areas of improvement to fabricate a model that better satisfies the needs of the stakeholder. While keeping most of the manufacturing plan the same, mechanically clamping the mold, adding the mold to a vacuum chamber, and redesigning the lens imitation method will improve the overall outcome of the design. The areas of improvement should allow the emergency eye simulation model to mimic clinical pathologies with precision. Thus, the model will be practical for use in the University of Tennessee's Center for Advanced Medical Simulation, so that students and physicians can be trained on a product that prepares them for the various emergency eye procedures they will encounter during their careers as emergency medicine physicians.

Appendices

Appendix A - Product List

Product Name	Quantity	Price (\$)	Units	Source
Ultrasound Machine	1	Free	N/A	Dr. Lamsen
Eyeball Mold	1	Free	N/A	Dr. Lamsen
Gel Sample Pack	1	9.98	pack of samples	https://humimic.com/
Ballistics Gel	2	21.98	per lb	https://humimic.com/
Silicon	1	33.45	per 2 lbs	https://www.amazon.com/
Dragon Skin	1	30.42	per 2 lbs	https://www.amazon.com/
Ultrasound Gel	1	13.11	per L	https://www.amazon.com/
Appoxy	1	\$14.20	3 pack	https://www.amazon.com/
XTC-3D Smoothing Agent	1	\$28.59	24oz bottle	https://www.amazon.com/
Xacto Knife	1	\$4.68	1 Knife	https://www.amazon.com/
UV Flashlight	1	\$6.99	1 Flashlight	https://www.amazon.com/
Disposable Mixers	1	\$9.99	300 count	https://www.amazon.com/
Unisex Head Form	1	\$29.50	1 Head	https://www.ebay.com
Aluminium Stock	3/4" Thick x 1-1/2" Wide	\$21.28	2ft bar	https://www.mcmaster.com/standard-aluminum-sheets
Uncoated Carbide Ball End Mill (88825A31)	1 - 3 Flute, 1/8" Mill Diameter, 2-1/4" Overall Length End Mill	\$14.10	1 end mill	https://www.mcmaster.com/88825A31
Uncoated Carbide Ball End Mill (88825A27)	3 - 3 Flute, 1/4" Mill Diameter, 2-1/2" Overall Length End Mill	\$17.88	1 end mill	https://www.mcmaster.com/88825A27
Fluorescein Sodium Salt	100 G	\$32.50	1 bottle	https://www.sigmaaldrich.com/catalog/product/sial/f6377?lang=en&region=US
Remaining Budget:	\$556.34			

Appendix B -Manufacturing Plan

Manufacturing Overview of the Ultrasoundable Model:

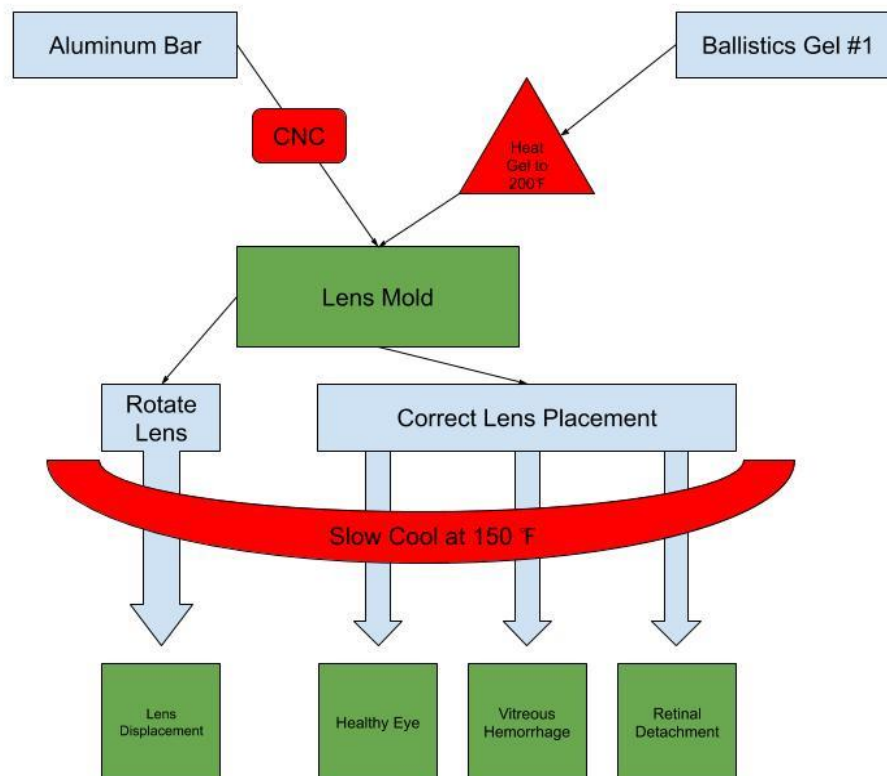


Figure B1. Flow chart detailing the steps in the productions of our ultrasoundable model.

Step 1: Machining the Eye Mold

1.1 Facing

Using stock material, Aluminum 6061 (1.5" x .75" x 24.435"), complete facing operation with 73.5 mm facing bit to achieve clean, level surface for milling.

1.2 Radial Milling

Radial milling is conducted with a $\frac{1}{8}$ " bit to carve out each feature of the eye mold: four concave molds, three convex molds, seven back molds, and four lens molds.

1.3 Finishing

Water jet (.5 mm) is used to cut two 12" pieces from a machined piece. Four ($\frac{1}{8}$ ") holes are drilled for the rod to stabilize parts. Sanding/Polishing will also take place during this step if necessary.

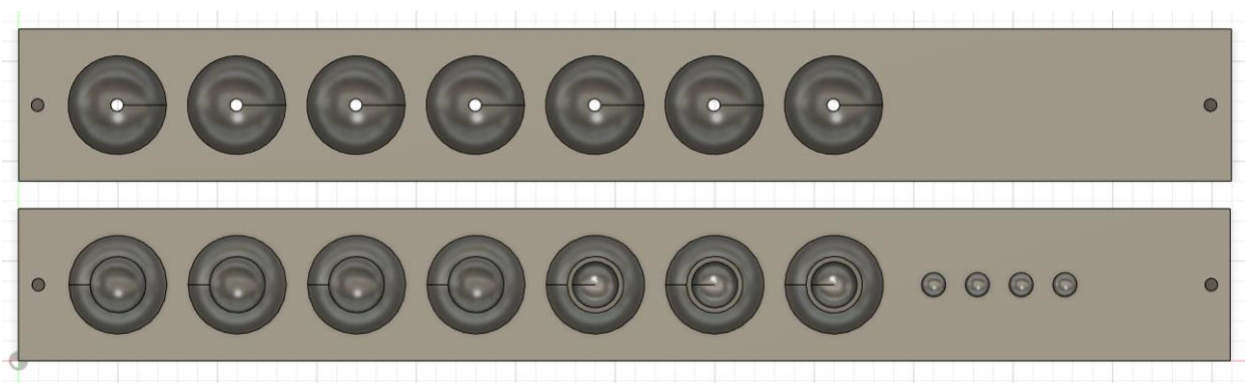


Figure B2. Top view of Aluminum Mold.

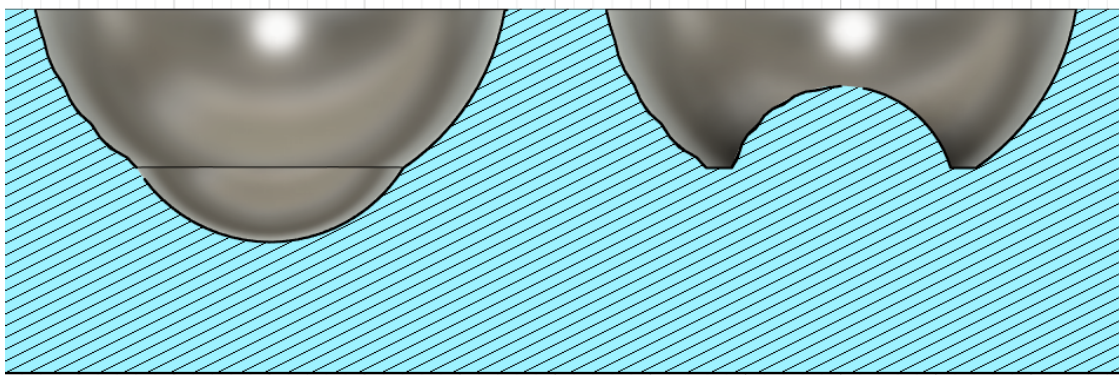


Figure B3. Cross-section of concave (right) and convex (left) molds.

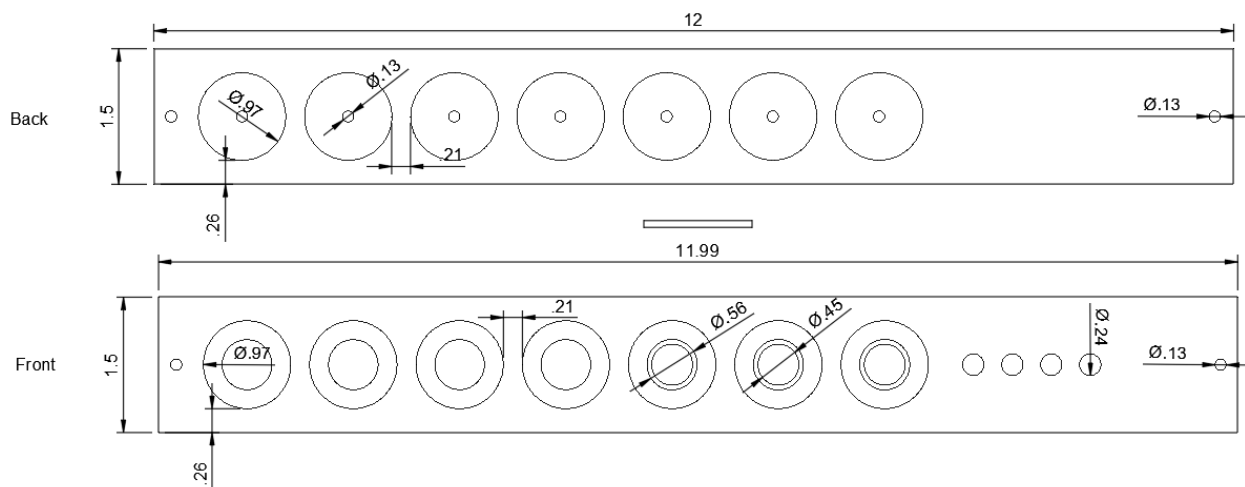


Figure B4. Drawing of aluminium molds with corresponding dimensions.



Figure B5. Original eye model used with resulting molded eye.

Step 2: Material Preparation

2.1 Heating

Ballistics gel is cut into small cubes and placed on a hot plate heated to 200°F for two hours.

2.2 Pouring

Heated ballistics gel is poured into the aluminium anterior chamber and lens molds. The ballistics gel is allowed to cool and harden.

2.3 Finishing

Lenses are placed in the appropriate location for the corresponding eye model. More heated ballistics gel is poured into the posterior chamber. The eye mold is reheated to eliminate bubbles from gel.

Step 3: Production of Eye Models

3.1 Healthy Eye Model

Pour 200°F ballistics gel into the aluminum mold in two locations: anterior chamber and lens molds. Take the hardened gel out of the lens mold and place it on top of the anterior chamber gel. Turn the heat of the hot plate down to 150°F and pour ballistics gel into the posterior chamber. Allow the gel to solidify for two hours.

3.2 Lens Dislocation Model

Pour 200°F ballistics gel into the aluminum mold in two locations: anterior chamber and lens molds. Place the lens into the aluminum mold in a random position to mimic the randomness of lens dislocation. Turn the heat of the hot plate down to 150°F and pour ballistics gel into the posterior chamber. Allow the gel to solidify for two hours.

3.3 Vitreous Hemorrhage

Pour 200°F ballistics gel into aluminum mold in two locations: anterior chamber and lens molds. Take gel out of lens mold and place on top of the anterior chamber gel. Pour gel into the posterior chamber of the aluminum mold, and then inject 0.1cc of elmer's glue into the posterior chamber. Turn the heat of the hot plate down to 150°F and allow the gel to solidify for two hours.

3.4 Retinal Detachment

Pour 200°F ballistics gel into the aluminum mold in two locations: anterior chamber and lens molds. Take the gel out of the lens mold and place it on top of the anterior chamber gel. Turn the heat of the hot plate down to 150°F and pour ballistics gel into the posterior chamber. Allow the gel to solidify for two hours. Use the X-acto knife to cut a hemisphere from the posterior chamber with a radius of 5 mm. Connect the ballistics gel together by placing 2 mL of 200°F ballistics gel on one piece and combine each back together. Then, allow to cool at room temperature.

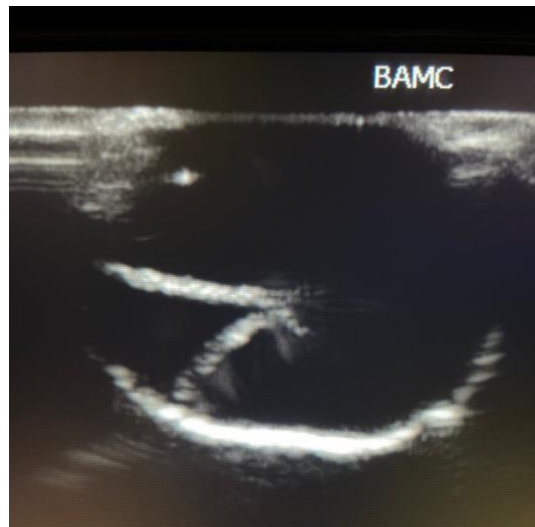


Figure B6. Resulting ultrasound of our retinal detachment pathology eye.

Step 4: Integration into a Realistic Model

4.1 Creating Face Mold

Procure a hollow, plastic three dimensional face with a forehead, eyebrow, and nose features. Cut the plastic face in half with a band saw along the coronal plane just in front of the ear lobes. Gather two pieces of plywood (9" x 4" x 1/4"). Trace the outline of the head onto one piece of plywood, then cut the plywood along the trace. Mark two holes 3 1/4" from each side and 2" from the top in the second piece of plywood and drill a 1/8" hole in each spot. Fit the cut pieces of plywood to the outline of the face on each side. Glue the cut plywood to the solid piece of plywood and insert a 1/8" diameter aluminum rod in each hole with a length of 5".

4.2 Pouring Face Mold

Place a healthy eyeball and one pathology eyeball into the plastic mold behind the eyeball features. Place the dowel holder behind the face and insert aluminum rods until the rod makes firm contact with each eye. Mix 210 g of Part A and 210 g of Part B from the Smooth-On FX Pro Dragon Skin package with 25 g of metamucil. Mix thoroughly. Pour the mixture into the chin section of the mold until the entire mixture is in the plastic mold. Allow to cure for 1 hour. Remove the dowel rods from the mold and allow the curing process to finish.



Figure B7. First face model created with healthy eye models incorporated.

Manufacturing Overview of the Fluorescein Model:

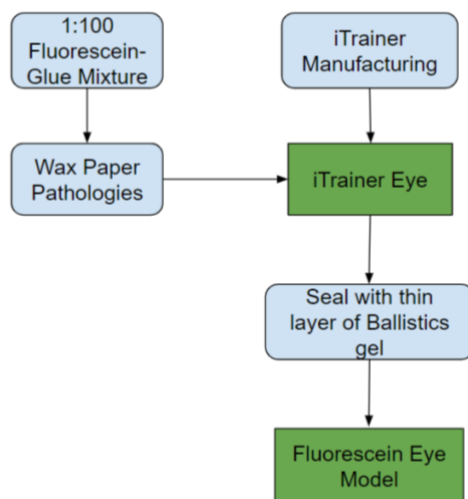


Figure B8. Flow chart detailing the manufacturing process of the fluorescein model.

Step 1: Creating Fluorescein Pathologies

1.1 Mixing

Mix Fluorescein powder with Elmer's clear glue using a 0.228 g/L concentration₁ (fluorescein:glue). Mix thoroughly.

1.2 Wax Paper Pathologies

Using a thin tipped paint brush, apply the fluorescein-glue mixture to a sheet of wax paper mimicking typical patterns of corneal injuries. Allow the mixture to dry.

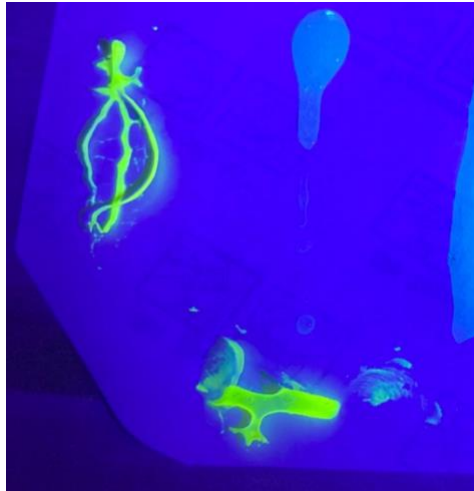


Figure B9. Fluorescein-glue mixture placed onto a sheet of wax paper.

Step 2: Creating the iTrainer Eye

1.1. Heating

The ballistics gels is cut into small cubes and placed on a hot plate heated to 200°F for two hours.

1.2 Pouring

The heated ballistics gel is then poured into the iTrainer eye mold, shown in Figure B10. Let it set for 15 minutes or until ballistics gel is firm to touch.



Figure B10. Heated ballistics gel in the iTrainer eye mold.

1.3 Iris Insertion

Once the ballistics gel has cooled down and is firm, remove the ballistics gel from the mold. The ballistics gel created by the mold should look like the model shown in Figure B11, a semicircle with a cavity on the round side of the model. Place a printed iris into the cavity of the eye model created by the mold.



Figure B11. Molded eye model without the printed iris.

1.4 Finish

Once the iris has been properly positioned use a small spoon to place more heated ballistics gel on top of the iris, creating a dome. Allow this to dry. Figure B12 shows the final iTrainer eye model.

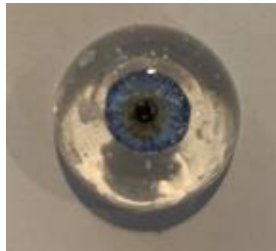


Figure B12. Final iTrainer eye model.

Step 3: Fluorescein and iTrainer Integration

1.1 Placement of Corneal Pathologies

Remove the dried fluorescein-glue from the sheet of wax paper and place the desired pathologies onto the iTrainer eye.

1.2 Seal

Once the fluorescein corneal patterns have been properly positioned, apply a thin coat of ballistics gel onto the surface of the eye in order to seal the fluorescein-glue corneal patterns onto the iTrainer eye. Figure B13 shows the final fluorescein eye model under a blue light.

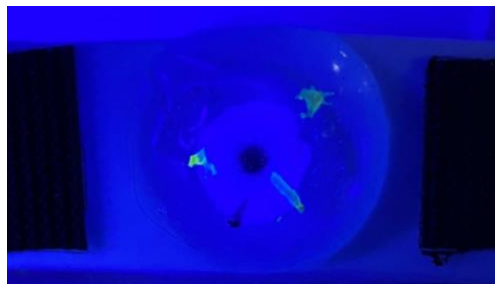


Figure B13. Final fluorescein eye model under a blue light.

Step 4: Fluorescein eye model and iTrainer mannequin integration.

1.1 Integration

Once the fluorescein eye model is completed, glue it onto a strip of cardstock. On the cardstock, attach velcro on either side of the eye, shown in Figure B14. This will allow for attachment with the iTrainer mannequin.

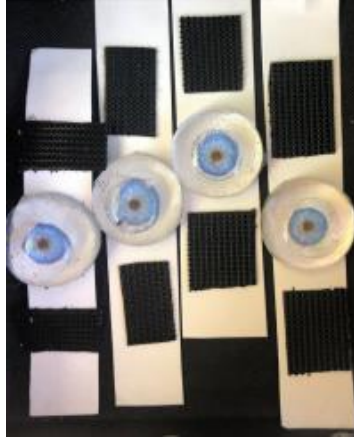


Figure B14. iTrainer eye models glued onto cardstock. Velcro attached onto the cardstock on either side of the eye models. (Note: iTrainer eye models shown do not have the fluorescein corneal patterns.)

Appendix C - Competitive Analysis

After extensive searching, very few competitors with ultrasoundable eye phantoms were found. Four ultrasound phantoms, most using gelatin-based construction methods, were identified. All of these phantoms were published through academic journals within the last 10 years. Using Google Patents, a search for related patents was conducted. After a thorough search, no patents for similar products were found. One ultrasound biometric device was investigated and is included within the list of competitors, despite its inability to produce an ultrasound image.

Gonzales et al. published a paper in the *Critical Ultrasound Journal* in 2012. This eye ultrasound phantom is composed of a block of unflavored gelatin. Multiple eye models and

pathologies are cut from the material using metal rods and stencils in one solid block of gelatin. This model is able to cheaply and effectively create unreasonable eye models with multiple pathologies. The models can be created in mere minutes and melted and re-worked after use. However, only axial ultrasounds may be performed on this model. The shelf-life is extremely limited (3 weeks in the fridge) and the appearance of the ultrasound image is noticeably different than a real eye ultrasound. The use of a cutting technique to create the anatomy of the eye would lower the cost and time of model construction. However, in a fully 3D model, there is limited ability to accomplish this method.

Jafri et al. published an “Easy Simulation Model of Ocular Ultrasound that Mimics Normal Anatomy and Abnormal Ophthalmologic Conditions.” This inexpensive simulation model was made for the purpose of educational instruction to detect normal and abnormal ocular conditions in bedside emergency settings. This model simulates the normal eye as well as an eye with retinal detachment, a foreign body, an increased optic nerve sheath diameter, vitreous hemorrhage, and retrobulbar hematoma.

The globe of the eye is made out of water, sugar-free psyllium powder, and unflavored gelatin. A round plastic container, typically used as packaging of small toys, was used as the mold for the globe. An elliptical incision was made into the globe in order to represent the ocular lens. This incision created a model-air interface creating a hyperechoic line. The retinal detachment was created using a similar method, making an incision along the posterior of the globe. The metal tip of an electrocardiographic (ECG) chest adhesive was used to mimic the optic nerve and cutting this metal lead to have a larger diameter mimicked an increased optic nerve sheath diameter. The vitreous hemorrhage was mimicked by injecting Elmer’s glue or casting plaster dissolved in water into the globe while cooling. Finally, the retrobulbar hematoma was recreated by placing a latex glove filled with fluid underneath the posterior portion of the model.

This model was created using a simple design and inexpensive materials to make an ultrasound model of the eye and five ophthalmologic conditions. This model was able to produce realistic representations of normal ophthalmologic ultrasound anatomy for both the normal eye and five ophthalmologic conditions. However, like Gonzales’s model this model is mainly composed of food-grade gelatin, resulting in the need for storage under refrigeration. This model also does not simulate the anterior chamber of the eye.

Another eye phantom was Zeiler et al.’s “Ultrasound Phantom for Assessment of Optic Nerve Sheath Diameter”. This model is a hemispherical model of the posterior chamber constructed using a gelatin globe placed atop a gelatin background within a Styrofoam cup. It was published in 2013 in the *Canadian Journal of Neurological Sciences*. This model used multiples pours of gelatin stacked atop each other to create interface lines on the ultrasound image. 3D Printed discs were used to simulate the optic nerve sheath for measurement. Again, a limitation of the phantom is that this model is composed of food-grade gelatin. Due to this fact, it must be stored

under refrigeration. Also, this model does not possess an anterior chamber. This phantom shows us an opportunity for our design. As we have already learned from our own testing, utilizing multiple pours of gelatin (in our case, ballistic gel) creates interface lines on an ultrasound image. Therefore, this method is likely to be used in our model. Our own attempt at an optic nerve sheath dilation simulation model will likely use a similar 3D printing method. However, our model is likely to be much more expensive than this model. The inclusion of an anterior chamber and increased storage-time will add value to our product, as well as increased usage-life.

Finally, our competition research discovered a commercial product called an Ultrasonic Biometric Device by Gampt Ultrasonic Solutions. This device utilizes the measurement of travel times of ultrasonic signals in an eye phantom at an enlarged scale demonstrating a typical biometric ultrasonic application based on the A-Scan method in medical diagnostics in ophthalmology. This eye model consists of a lens and the vitreous body with different sound velocities. The geometric dimensions of these objects can be determined by the distance of the echoes and an injury with a diffuse echo structure close to the fundus of the eye can be detected. However, the device does not produce an ultrasound image, but is instead intended for measuring distance within the eye.