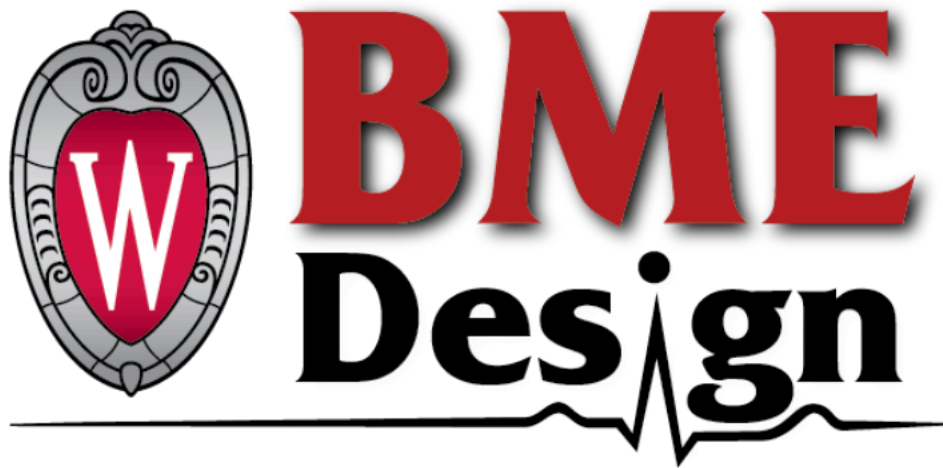




Preliminary Report

Lookin' Good - Iris Conformer

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BME 200/300

Abstract

Retinoblastoma is the most common primary intraocular malignancy of childhood and may require enucleation for treatment. The current process following enucleation involves placing an orbital implant and temporary clear plastic conformer to maintain the shape of the eye socket and support healing. However, the child has an asymmetric appearance until a permanent ocular prosthesis can be fitted 6-8 weeks later. Since appearance-related outcomes can influence long-term quality of life, this period of disfigurement presents an opportunity for improvement. The client requested a conformer that is biocompatible, low-cost, and resembles that of the contralateral eye for immediate placement following surgery. The team will design an iris conformer using injection molding to replicate the curvature of the existing clear conformers and will fabricate it from PMMA. A separate iris component will then be molded and colored to match the patient's unaffected eye, creating a more natural appearance while maintaining the function of the existing conformer. Testing will evaluate the biocompatibility of the materials through pH, stress, and toxicity testing, as well as the fit and fluid interaction of the conformer within a porcine eye model. These tests will determine whether the materials and design are suitable for use within the healing eye socket and whether the conformer can maintain appropriate placement without interfering with the surrounding anatomy. The results will guide further design improvements and determine the feasibility of progressing toward clinical testing in children following enucleation.

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Introduction

Retinoblastoma is the most common primary intraocular malignancy of childhood, requiring enucleation for many patients [1]. This particular pediatric cancer affects every 1 in 15,000-20,000 live births [2]. For patients who must have enucleation surgery, typically an implant is placed in the orbit that is attached to existing ocular muscles; this allows the implant to move similarly to a natural eye. These eye implants are commonly porous and permit the blood vessels and ocular tissue to grow in the implant, preventing migration of the implant. After placing this implant, the surgeon places a thin, plastic shield (conformer) in the eye socket, and the conformer remains in place for about 6-8 weeks. The conformer maintains socket shape, reduces swelling, and allows proper wound healing after surgery. After the conformer is removed, a permanent prosthetic is placed to match the contralateral eye [3]. The most widely used conformer design is clear and made of PMMA, comes in three sizes (small, medium, and large), and contains 2 holes for ointment application. However, it does not bear any resemblance to the patient's contralateral eye [4]. Another existing product is the Natural Iris Conformer from *Stryker Corporation*. This conformer comes in 3 different sizes (small, medium, and large) and 3 different colors (blue, brown, and green), and is overall successful in presenting similarly to a natural eye. However, Stryker discontinued this product, so it is no longer an available solution [5]. A third existing product is a natural iris conformer from *Insight Oculars*, which is fabricated by embedding an iris image onto opaque and sterile plastic. A drawback of this product is that it is expensive and difficult to access in lower-income communities [6]. The biggest challenges with the existing products are that they are unrealistic or costly due to the manual nature of manufacturing. This prototype of a natural iris conformer should resemble the contralateral eye while also remaining a safe, viable, and effective healing device following enucleation. It should also be under \$10 dollars to fabricate each individual conformer, so that it is accessible to lower-income countries where enucleation rates are highest for retinoblastoma treatment.

Background

Although the need for enucleation has significantly declined as treatment transitions to less aggressive modalities for eye salvage, surgeries are still very common in lower-income countries as the most viable treatment option for pediatric retinoblastoma [7]. During surgical enucleation, either a hydroxyapatite or acrylic implant is placed inside the orbit and attached to the extraocular muscles. Typically, a plastic PMMA conformer is placed on top of the implant for the 6-8 week healing process following enucleation [3].

The clients, Dr. Aparna Ramasubramanian, an ophthalmologist at Children's Wisconsin, and Eva Coughlin, a medical student at the Medical College of Wisconsin, are looking for a conformer that is fully biocompatible (specifically fabricated with either PMMA or some other medical-grade silicone), low-cost, and natural-appearing for immediate placement after surgical removal of the eye.

The proposed device will protect the ocular implant following an enucleation and allow for proper healing and limited growth of scar tissue, while also being the correct size to fit in the orbit without shifting position. The conformer will remain viable within typical pH conditions of the eye and will not deteriorate over its lifetime. The conformer must weigh slightly less than 1 gram, comparable to other conformers already on the market, so as to not cause sagging of the eyelid [8]. The device must comply with ISO 10993-1, which ensures that biomaterials used are biologically safe for contact with healing ocular tissue, and ISO 10993-5, which ensures any materials used will not have cytotoxic effects on the patient [9, 10]. A comprehensive outline of product specifications can be found in Appendix A.

Preliminary Designs

Design 1 - Silicone Molded

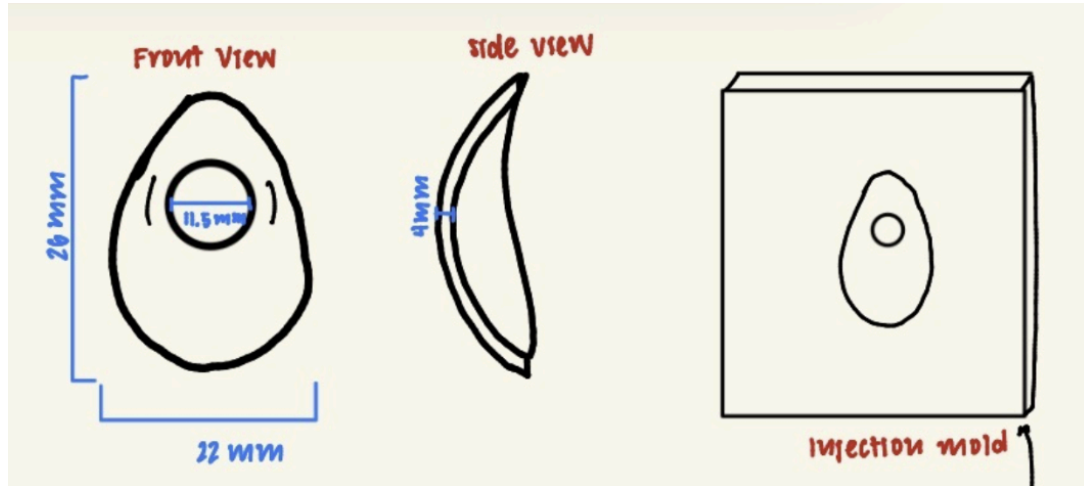


Figure 1: Drawing of Medical Grade Silicone Iris Conformer and Mold

The first design entails using medical-grade silicone and fabricating a conformer via injection molding. There would be three separate molds for small, medium, and large sizes of conformers. After fabrication of the silicone, the iris color would be painted onto the silicone, matching that of the patient's contralateral eye. Additionally, there would be slits on either side of the iris to allow for regular ointment application.

Design 2 - PMMA 3D Printed



Figure 2: Drawing of 3D Printed Polymethyl Methacrylate Iris Conformer

This conformer design features a personalized iris based on imaging taken of each patient's contralateral eye. This software uses an AS-OST device to scan the patient's eye and eye socket, and includes a color camera to document the color of the iris and sclera, as well as the shape. It also includes the use of veining parameters such as thickness and branching to create realistic veining in the conformer. This data is then transferred to CAD software and is finally sent to a 3D printer for fabrication using PMMA. While this process would be ideal in theory, the team had concerns regarding the safety of these conformers, due to possible abrasions that the 3D printer would leave on the product. There are also licensing issues regarding obtaining the 3rd party software used to develop these iris designs, which are necessary for the completion of this design idea.

Design 3 - PMMA Molded

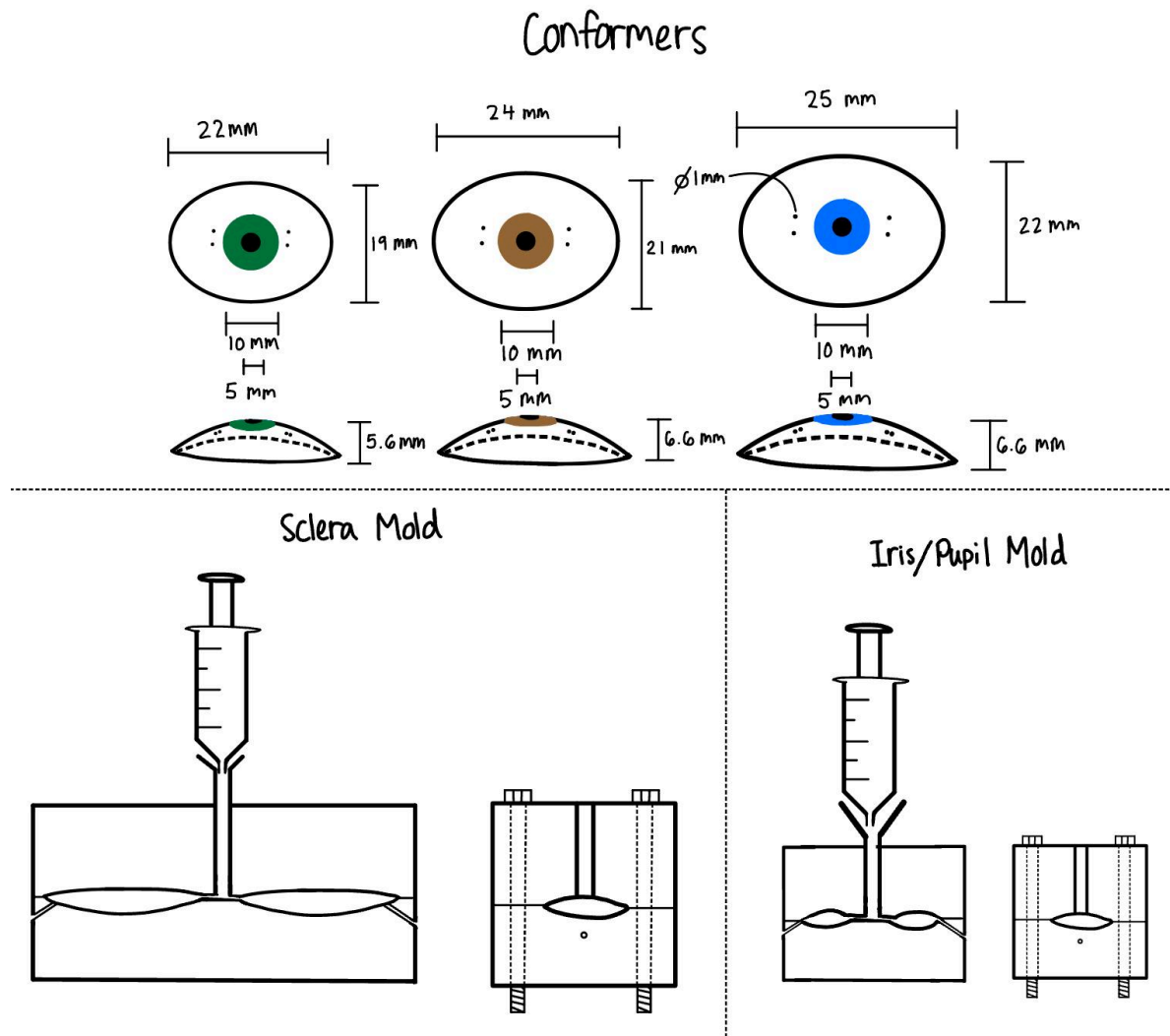
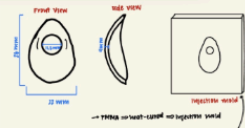
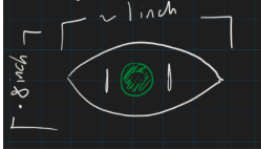
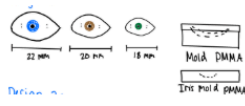


Figure 3: Drawing of PMMA Iris Conformers and Injection Molds

The third design contains the iris conformer being produced using acrylic PMMA and cast by injection molding. It would contain 2 separate molds: one mold for the iris and pupil, and another mold for the sclera. The two pieces will then be bonded together to create the iris conformer. This design also allows for 3 different sizes of iris conformers: small, medium, and large. There will be 3 main color options for the PMMA iris; however, there is flexibility in the color because different liquid PMMA colors can be mixed to match the patient's eye color. The iris conformer contains 4 slot holes for the patient's application of ointment/medication.

Preliminary Design Evaluation

Table 1: Design Matrix

		Design 1: Medical-grade silicone using injectable mold, Iris painted 		Design 2: 3D printed PMMA, Iris based on patient/software 		Design 3: Molded using PMMA, Iris molded first then filled over 	
Design Criteria		Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Safety	35	5/5	35	4/5	28	5/5	35
Ergonomics	25	4/5	20	3/5	15	4/5	20
Realism	20	5/5	20	4/5	16	4/5	16
Ease of Manufacturing	15	2/5	6	3/5	9	3/5	9
Cost	5	2/5	2	3/5	3	4/5	4
Total	100	83		71		84	

Safety:

The most important criterion for this project is the safety of the iris conformer. It is weighted 35/100 because the conformer must prevent infection, tissue shrinkage, and allow the wound to heal properly. The design must also contain holes or slits in order to administer topical ointments to prevent infection.

Design 1 scored a 5/5 on safety because the injection molding allows for a consistent finish on the conformer, minimizing risk of irritation or improper sizing. This consistency of design would also enable proper healing of scar tissue and daily ointment applications to prevent the possibility of infection.

Design 2 scored a 4/5 on safety; the use of 3D printing when creating this eye slightly lowers the safety of the device. This is because 3D printing allows for small bumps, ridges, and other abrasions on the conformer that may irritate the eye and prolong or prevent complete

healing. However, it performs well in all other aspects of the safety criteria - the conformer would be biocompatible and easy to remove and clean if necessary.

Design 3 scored a 5/5 for the safety criteria. The design contains only PMMA, which is a medical-grade acrylic, and it prevents infection, tissue shrinkage, and allows the wound to heal properly. Injection molding allows for a consistent finish on the conformer, minimizing risk of irritation or improper sizing.

Ergonomics:

Ergonomics and comfort relate to the ability of the device to be used for extended periods of time without causing discomfort to the user. The device should be less than a gram, with an almost identical shape to the current conformer. The conformer should contain no rough edges and also avoid causing an allergic or chemical reaction, even when in the eye for extended periods.

Design 1 scored a 4/5 on ergonomics. Injection molding creates an overall smooth finish on the medical-grade silicone, maximizing user comfort and eye likeness. Medical-grade silicone is also approved for use within the eye, so it will not react chemically with the conditions in the eye.

Design 2 scored a 3/5 in ergonomics. Due to the 3D-printed nature of the product, the design will be less comfortable than the injection-molded designs, because there will be more ridges, bumps, and other flaws from the 3D printing device.

Design 3 scored a 4/5 for ergonomics. Molding results in a smoother surface with fewer ridges than a 3D printer would create, which allows the iris conformer to lack sharp edges. Sharp edges would cause discomfort in the patient over extended periods of time.

Realism:

A realistic appearance is a very important factor for patients who will be using the conformer, which is why it has a weight of 20/100. The design itself specifies that the conformer should be “iris-matched”, which means that the conformer should look reasonably similar to the contralateral eye from a distance of about 10 feet. The current design of iris conformers is clearly

artificial, which can harm the social and mental health of children who wear the conformer for the 6-8 week period. Children are often unfiltered and may comment on the unusual appearance of the visible socket, so designing the conformer to have the same color and shape as the contralateral eye is important.

Design 1 scored a 5/5 on realism. The painting of the iris on top of the conformer allows for elaborate customization of the iris from patient to patient. It makes it possible to go into greater detail than simply a standard blue, brown, or green conformer. This design would also allow for the sclera to maintain its translucent appearance.

Design 2 scored a 4/5 in realism. It relies on iris design and creation that is individualized to each patient; in this way, it is much more realistic than other design ideas that have a set number of iris colors available. The reason it does not score a 5/5 is that the design does not include ideas for veining and color discoloration on the sclera, which would increase realism.

Design 3 scored a 4/5 for the realism criteria. Using injection molding, the team would be able to customize the color to match the color of the patient's eye, which would result in a more accurate appearance. However, 5/5 was not achieved because the texture and color variance within the iris would be difficult to match with molding.

Ease of Manufacturing:

For this project, ease of manufacturing is a decently important consideration, weighted at 15. The two main manufacturing types the team has narrowed down to are 3D printing and injection molding. Both of these have their pros and cons. The main goal of this project is to eventually mass-produce our conformer, but for the current scope, just manufacturing the mold and iris conformer will be sufficient.

Design 1 scored a 2/5 on ease of manufacturing. The creation of the injection mold is relatively simple when considering a small, medium, or large conformer, but it would become much more difficult if the sizing were to become fully customizable to each patient. It is also a manual process and would require someone with expertise in injection molding to properly fabricate the conformers. Additionally, the hand-painted nature of the irises would make them

time-consuming and complicated to construct, even though it contributes to the realism of the product.

Design 2 scored a 3/5 in ease of manufacturing. While 3D printing is an easy fabrication technique to adapt to a larger scale, individually creating each iris based on patient scans is not something that can be easily replicated.

Design 3 got a 3/5 for the ease of manufacturing criteria. The manufacturing process would require multiple steps of hands-on work and requires machining. Though once the molds are made, the PMMA injection process is more straightforward.

Cost:

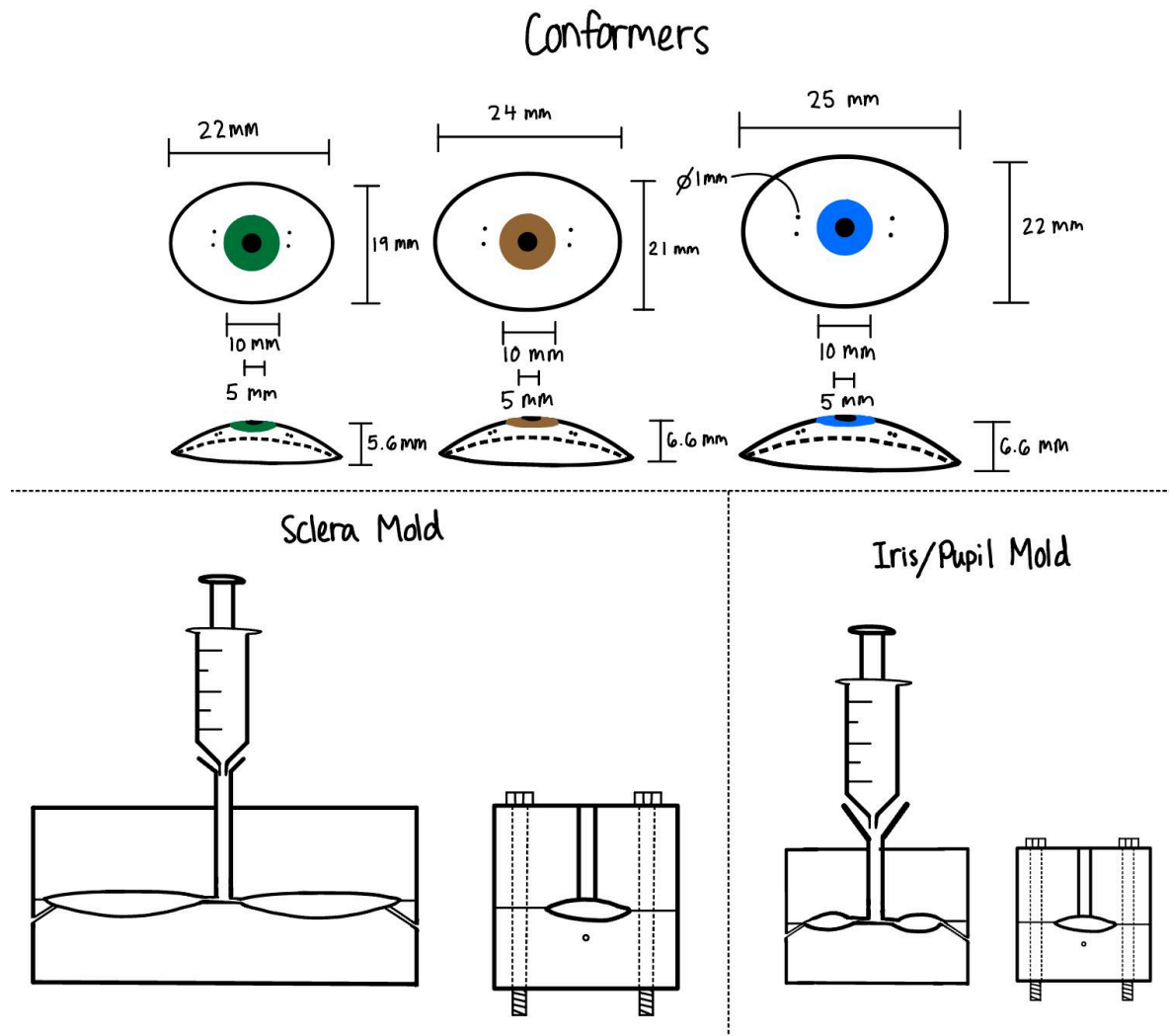
While the cost of manufacturing and the two main materials are factors, it is not the most important aspect of the design at this stage. The team is aware that most enucleations do happen in lower-income countries; however, at this prototyping stage it is only weighted at 5/100. For this project, the budget is currently \$15,000 with a goal of each unit costing less than \$10.

Design 1 scored a 2/5 on cost. It is expensive to create various different injection molds out of properly sterile material. Medical-grade silicone is also more expensive than PMMA because of its material purity and compliance requirements. It would also be an additional expense to purchase paint and painting materials that are biocompatible and will remain viable for the entire lifetime of the conformer.

Design 2 scored a 3/5 in cost. The cost of materials in regard to 3D printing is relatively cheap compared to other methods of manufacturing. However, using individually matched irises raises the cost of this design, as it requires more manpower, coding, and technology to implement correctly.

Design 3 scored a 4/5 for cost because the design includes PMMA for the iris and the sclera, which is less expensive relative to medical-grade silicone. A comprehensive outline of the design matrix can be found in Appendix B.

Proposed Final Design



Design 3 scored the highest in safety, ergonomics, ease of manufacturing, and cost, receiving the highest score overall. Because of this, we have decided to proceed with the fabrication of Design 3.

This proposed final design contains the iris conformer being produced using acrylic PMMA and cast by injection molding. It would contain 2 separate molds: one mold for the iris and pupil, and another mold for the sclera. The two pieces will then be bonded together to create the iris conformer. This design also allows for 3 different sizes of iris conformers: small, medium, and large. There will be 3 main color options for the PMMA iris; however, there is flexibility in the color because different liquid PMMA colors can be mixed to match the patient's

eye color. The iris conformer contains 4 slot holes for the patient's application of ointment/medication.

Fabrication

Materials:

The iris conformer product and fabrication process will require 2 main materials: PMMA and silicone. PMMA will be used for the sclera, iris, and pupil for the conformer. It is a medical-grade material that is biocompatible and typically used under ocular conditions [11], and is relatively inexpensive. The clear iris conformer that Dr. Aparna Ramasubramanian currently uses consists of PMMA as well. The silicone would be needed to create the mold for the iris conformer. The different types of silicone vary vastly; however, a medical-grade and biocompatible silicone will be ideal as it will be in contact with the PMMA while casting and curing [12]. A comprehensive outline of the materials and expenses can be found in Appendix C.

Methods:

Casting the PMMA into the final product will require multiple tedious steps. The molds will be created using a medical-grade silicone casting kit, which will contain two-part silicone and a mold enclosure. The mold enclosure allows the mold to have a parting line to easily access the parts before and after molding. The mold will be created by casting the clear iris conformers that Dr. Aparna Ramasubramanian currently uses for her patients. A separate mold will be created for the pupil/iris, which will be the same shape, but scaled down. White liquid PMMA will be used for casting the sclera, while black liquid PMMA and PMMA of the patient's eye color will be layered for the iris and pupil. The liquid PMMA will be poured into each mold and cured for about 15 minutes [13]. Additional silicone will be used to bond the cured sclera to the iris and pupil. Finally, the conformers will be inspected and measured using calipers and compared to original clear conformers to ensure accuracy of the mold. Final sterilization of the PMMA will be needed using CO₂ sterilization before potential animal and human studies [14].

Testing and Results

There are a series of tests that need to be performed on our fabricated prototype to prove both the safety and effectiveness of our design before it can be used in a patient setting. The first of these tests will be a test for biocompatibility: testing the product to determine if the material causes irritation or degrades inside the eye. In accordance with ISO 10993-13, which tests degradation of polymeric medical devices, the material used in our design must not degrade or undergo changes in mass distribution while in the eye socket [15]. Due to the wide usage of medical silicone and PMMA in ophthalmological devices [16], a detailed toxicological report showing that the material does not degrade in faux tears or saline will be appropriate. This test will entail submerging the prototype in a saline solution, measuring the mass of the device before submerging, and then measuring it each day over the next 7 days. Any loss of mass or a change will be recorded, and depending on the findings of these tests, changes to the material used will be made if necessary.

The second test will evaluate the fit of the conformer on a porcine eye socket. Due to the fact that porcine and human eyes and eye sockets are similar in anatomy and size, porcine eye sockets are an ideal way to test designs in vivo before a human clinical trial is implemented. A porcine orbital socket has an average height of 53.0 mm and an average width of 34.1 mm [17], while humans have an average socket of about 41 mm in height and 35 mm in width [18]. While these measurements differ slightly, they are similar enough that, along with the knowledge of the porcine eye anatomy, this method can be used to test the conformer. The team will measure the degree to which the design curves, and then match this to the porcine orbital implant curvature. The angles will then be compared, with the goal of 1% difference in measurements. The team will also test for abrasions on the eyelid or surrounding the eye after insertion or removal; this test will be more qualitative in nature and will involve the counting and documentation of any scratches or abrasions observed.

The third test performed will also be a qualitative test to determine the resemblance of the conformer to a real eye - specifically, a real iris. This test will be performed using a sample of 10 students; they will be asked to look at pictures of the team's iris conformer, as well as a picture of the discontinued Stryker iris conformer. The students will then be asked if they can tell the

difference between the Stryker model and the team's model, and their responses will be recorded from 1 foot away, 5 feet away, and 15 feet away. The team aims to have a conformer similar enough to the Stryker conformer that 60% of participants will not be able to tell the difference between eyes from 15 feet away.

Although not in the scope of this project, the conformer will need to be tested in a human clinical trial before being approved for widespread usage. If one would like more details on this process, Dr. Aparna Ramasubramanian, as well as medical student Eva Coughlin, will be taking control of this stage of testing and will have more information if necessary.

Discussion

The main concerns of this project are the fit and safety of the material chosen for the conformer. The team will be basing the dimensions of the design off of the dimensions of the existing conformers on the market, which for the medium size are 22 mm in length, 19 mm in width, and roughly 6.6 mm in depth [4]. While PMMA is generally considered medical grade and chemically inert, there is minimal possibility of inflammation when in contact with human tissue [19]. However, the short time frame of 6-8 weeks that the conformer will be in place means that most complications will arise from foreign particles or improper fit of the conformer. As mentioned in the Preliminary Designs section, the goal is to create small, medium, and large sizes. Complications could possibly arise from these designs not being tailored specifically to the patient's unique eye socket. Foreign particles are always a possibility, but the low porosity of PMMA and the fact that patients will be applying ointment to the eyes as well will help to reduce the chances of infection to a minimal amount. The range of sizes is in place to prevent this, but in a large-scale manufacturing setting, the conformers would ideally be custom-fit to the child's eye. This is something that will be considered after production of the prototypes and after thorough testing of the three sizes. Another point of interest is the natural appearance of the conformer.

Conclusion

The overall goal of the iris-matched conformer is to create a temporary and naturally appearing medical-grade conformer to fit in the empty eye socket and promote normal eye development matching that of the contralateral eye during a child's growth following enucleation. The proposed final design will be most successful at appearing natural, promoting normal growth around the eye socket, and being able to be manufactured in lower-income countries for a reasonable price. It will consist of an injection-molded conformer matching the curvature of the eye, made from PMMA, with the iris then molded separately to match the patient's eye color. The iris will also be molded out of PMMA, and the conformers will be available in three sizes: large, medium, and small. PMMA was chosen as the primary material both at the request of the client, and testing that has proven its inertness and low possibility of inflammation that lend to its biocompatibility [19]. Medical-grade silicone is another option for the material, but the use of PMMA is preferred due to its cost and easier access for both injection molding and 3D printing, should one decide to 3D print the conformer. Further designs will include more customizable sizing to more accurately match a specific child's eye, but the prototypes will feature three testable sizes to display the appearance and biosafety of the conformers before moving to more specifically tailored eye measurements.

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Appendix

Appendix A: Product Design Specifications



Product Design Specification

Iris-matched conformer for immediate placement following pediatric enucleation for retinoblastoma

Team members

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Communicator: Matthew Klysen

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BWIG: Lucy McArdle

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Client: Dr. Aparna Ramasubramanian
Advisor: Prof. Jonathan Soucy

September 17th, 2026

Section 308

Function

The overall goal of the iris conformer is to reduce the effect enucleation has on a young child. Retinoblastoma is the most common primary intraocular malignancy of childhood, requiring enucleation for many patients [1]. Following enucleation surgery, an orbital implant is placed, and a temporary clear plastic conformer shell is inserted to maintain the socket shape and permit wound healing. The child then has an asymmetric appearance until the final prosthesis can be fitted in 6 to 8 weeks. Appearance-related outcomes measurably influence long-term quality of life in this patient population, yet this period of disfigurement has not been sufficiently addressed. The iris conformer will be fabricated to be biocompatible, low-cost, and natural-appearing for immediate placement after surgical removal of the eye.

Client requirements

- The iris conformer must fit snugly and be 3 different sizes to accommodate youth age-range: 22mm - 25mm.
- The iris conformer must be biologically safe for the patient and not degrade once in a pH of 6.8-8.2 [5].
- The iris conformer must have small slits for ointment application.
- The iris conformer must be naturally appearing and match that of the contralateral eye.
- The iris conformer must be affordable as this is targeted on a global scale to low-income countries.
 - Target cost of \$10 per conformer

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

- i. The conformer must provide protection over an implant following an enucleation procedure, creating a sufficient barrier between the implant

and the outside world that allows for proper healing and limits growth of scar tissue

- ii. The conformer must be the correct size (22mm-25mm in length) – as to not cause additional issues during the healing process – and colored iris for the patient’s eye

b. Safety

- i. The conformer must be made of biocompatible materials that do not irritate the eye or make the patient prone to infection
- ii. Must be safe for sleeping; can not shift or get misplaced when eyes are closed

c. Accuracy and Reliability

- i. Conformer must be durable and remain viable for entire life in service, without possibility of degradation while in the eye
- ii. Must be fabricated with consistent measurements across trials to ensure there is no obstruction of the eye and the eyelid

d. Life in Service

- i. The conformer should last 6 - 8 weeks, or the duration of wound healing immediately following enucleation.
- ii. The conformer will be worn at all times by the patient, including sleeping.
- iii. After the patient’s wound is fully healed, they will no longer need the conformer; the conformer will either be discarded, or sterilized and used in a future patient.

e. Shelf Life

- i. The conformer will only need to be stored immediately before it is inserted following surgery. It will need to be sturdy enough to transport from the fabrication site to the ophthalmologists office or OR room.
- ii. In some cases, if the conformer slips out of the socket, the conformer will need to be able to withstand cleaning and possible exposure to the elements until it is placed back in the eye.

f. Operating Environment

- i. The iris conformer will mainly be used in the eye. Typical basic conditions in the eye socket include a pH of 6.8 - 8.2 and a temperature around that of the rest of the body [2]. In addition, the conformer will be in a moist environment, and cannot interfere with any of the other functions of the eye.
- ii. If the conformer falls out of place, it will need to withstand being cleaned with warm soapy water, and last until it is able to be re-inserted.

g. Ergonomics

- i. The fit and appearance are some of the most important aspects of the conformer. The iris should match that of the contralateral eye, and the

implant beneath the conformer should be able to move similarly to the other eye as well to increase symmetry.

- ii. The conformer needs to match the curvature and size of the contralateral eye to promote symmetrical growth, as well as preventing tissue shrinkage.

h. Size

- i. The conformer should have adjustable sizes to accommodate children receiving the enucleation procedure at different levels of development. Size is crucial to ensure that there is not excessive exposure of eye tissues to foreign particles. The conformer will range from 22mm-25mm in length.
- ii. Most conformers have ranges of size from small to large, which will ideally be possible if 3D printing is used to marginally change the size of the conformer to fit the patient's eye socket.

i. Weight

- i. As the conformer will be placed along with an orbital implant, the conformer will need to be lightweight (~1gram) to prevent outweighing the contralateral eye.
- ii. One eye alone weighs approximately 7.5 grams [3].
- iii. Most orbital implants weigh around 2 - 3 grams so as not to cause sagging of the lower eyelid, and most conformers on the market weigh slightly less than 1 gram [4].

j. Materials

- i. The materials chosen must be biocompatible, easily sterilized, and fit comfortably in the eye of the client
- ii. The materials are required to be safe for the patient, not causing skin irritation, inflammation, or infection post enucleation.
- iii. The client has proposed the use of hard acrylic or medical grade silicone.

k. Aesthetics, Appearance, and Finish

- i. The iris conformer must appear natural and as close to the contralateral eye as possible.
- ii. The conformer finish must be smooth so as not to damage the eye further, as well as maintain a shiny finish in order to replicate the appearance of a human eye.

2. Production Characteristics

a. Quantity

- i. Client has requested two completed prototypes in hopes to test on recently enucleated patients

- ii. Eventually, the overall goal is to manufacture the conformer on a larger scale in order for lower income countries to have further access to the device.

b. Target Product Cost

- i. The iris conformer is intended for Dr. Aparna Ramasubramanian's patients and to go into production for a wider population. As such, the limiting factor in terms of cost is simply the provided budget of \$15,000 from the client and \$50 from the design program. The target total cost is under \$15,050.
- ii. Since the conformer is targeted on a global scale to low-income countries, the conformer must be affordable and kept around \$10 per unit.

3. Miscellaneous

a. Standards and Specifications

- i. The iris conformer must adhere to ISO 10993-1, which assesses a device's biological safety, to ensure that the biomaterial used is biologically safe for contact with healing ocular tissue [5]. ISO 10993-5 will also be referenced to ensure that the material will not cause any cytotoxic effects on the patient [6]. The design must prioritize patient safety, comfort, and prevent any irritation or reactions.

b. Customer

- i. The primary customer is Dr. Aparna Ramasubramanian, representing the Ophthalmology department. The conformer will be worn by the patient for 6-8 weeks at a time, so it should not cause any discomfort. The conformer also should be tailored to each patient's personal eye dimensions.

c. Patient-related concerns

- i. The client's comfort and safety is the driving cause behind this solution. The iris conformer should be biocompatible and easy to insert into the eye crevice. The conformer should look as natural as possible to reduce the asymmetry following enucleation. Ease of use, comfortability, and hygiene should be taken into consideration.

d. Competition

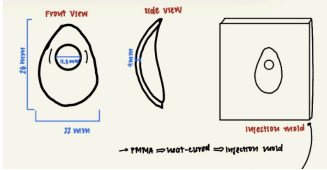
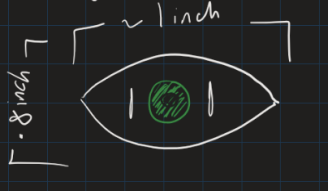
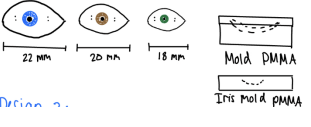
- i. Following enucleation surgery, an orbital implant is placed, and a temporary clear plastic conformer shell is inserted to maintain the socket shape and permit wound healing. This current method leaves errors for appearance-related outcomes, negatively affecting long-term quality of life. Another current method is relying on manual artist-driven fabrication to hand-paint conformers. This costly process is a limitation for low-income countries where enucleation rates are highest for retinoblastoma treatment. A 2024 *Nature Communications* study developed an automated digital process for designing and 3D-printing

custom ocular prostheses. The system uses optical coherence tomography (OCT) to capture the socket and imaging of the normal eye to reproduce its shape and appearance. A digital model is then generated and produced using a multi-material 3D printer [7].

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Appendix B: Design Matrix

		Design 1: Medical-grade silicone using injectable mold, Iris painted 		Design 2: 3D printed PMMA, Iris based on patient/software 		Design 3: Molded using PMMA, Iris molded first then filled over 	
Design Criteria		Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Safety	35	5/5	35	4/5	28	5/5	35
Ergonomics	25	4/5	20	3/5	15	4/5	20
Realism	20	5/5	20	4/5	16	4/5	16
Ease of Manufacturing	15	2/5	6	3/5	9	3/5	9
Cost	5	2/5	2	3/5	3	4/5	4
Total	100	83		71		84	

Safety: The most important criteria for this project is the safety of the iris conformer. It is weighted 35/100 because the conformer must prevent infection, tissue shrinkage, and allow the wound to heal properly. The design must also contain holes or slits in order to administer topical ointments to prevent infection.

Ergonomics/Comfort: Ergonomics and comfort relate to the ability of the device to be used for extended periods of time without causing discomfort to the user. The device should be less than a gram, with an almost identical shape to the current conformer. The conformer should contain no rough edges, and also avoid causing an allergic or chemical reaction, even when in the eye for extended periods.

Realism: A realistic appearance is a very important factor for patients who will be using the conformer, which is why it has a weight of 20/100. The design itself specifies that the conformer should be “iris-matched”, which means that the conformer should look reasonably similar to the contralateral eye from a distance of about 10 feet. The current design of iris conformers are clearly artificial, which can

harm the social and mental health of children who wear the conformer for the 6-8 week period. Children are often unfiltered and may comment on the unusual appearance of the visible socket, so designing the conformer to have the same color and shape as the contralateral eye is important.

Ease of Manufacturing: For this project, ease of manufacturing is a decently important consideration, weighted at 15. The two main manufacturing types the team has narrowed down to is 3D printing and injection molding. Both of these have their pros and cons. The main goal of this project is to eventually mass produce our conformer, but for the current scope, just manufacturing the mold and iris conformer will be sufficient.

Cost: While the cost of manufacturing and the two main materials is a factor, it is not the most important aspect of the design at this stage. The team is aware that most enucleations do happen in lower income countries, however at this prototyping stage it is only weighted at 5/100. For this project the budget is currently \$15,000.

Design 1:

The first design entails using medical-grade silicone and fabricating a conformer via injection mold. After creating this mold, the iris would then be painted on to the silicone afterwards. There would be three separate molds for small, medium, and large sizes, and then customized to the patient's iris. There would be slits on either side of the iris to allow for ointment application. This design scored a 5/5 on safety because the injection molding allows for a consistent finish on the conformer, minimizing risk of irritation or improper sizing. This consistency of design would also enable proper healing of scar tissue and daily ointment applications to prevent possibility of infection. This design scored a 4/5 on ergonomics. Injection molding creates an overall smooth finish on the medical-grade silicone, maximizing user comfort and eye likeness. Medical-grade silicone is also approved for work within the eye, so it will not react chemically with anything in the eye. This design scored a 5/5 on realism. The painting of the iris on top of the conformer allows for elaborate customization of the iris from patient to patient. It makes it possible to go into greater detail than simply a standard blue, brown, or green conformer. This design would also allow for the sclera to maintain its translucent appearance. This design scored a 2/5 on ease of manufacturing. The creation of the injection mold is relatively simple when considering a small, medium, or large conformer, but it would become much more difficult if the sizing were to become fully customizable to each patient. It is also a manual process and would require someone with expertise in injection molding to properly fabricate the conformers. Additionally, the hand-painted nature of the irises would make them time-consuming and complicated to construct, even though it contributes to the realism of the product. This design scored a 2/5 on cost. It is expensive to create various different injection molds out of the properly sterile material. Medical-grade silicone is also more expensive than PMMA because of its material purity and compliance requirements. It would also be an additional expense to purchase paint and painting materials that are biocompatible and will remain viable for the entire lifetime of the conformer.

Design 2:

The second design proposes a 3D printed iris conformer made of PPMA. This design would individualize the iris patterns to each patient, and come in three sizes. It would have slits on either side of the iris to allow for topical ointments to be added to the eye, and would be relatively flexible to avoid eye irritation. This design scored a 4/5 on safety; the use of 3D printing when creating this eye slightly lowers the safety of the device. This is because 3D printing allows for small bumps, ridges, and other abrasions on the conformer that may irritate the eye and prolong or prevent complete healing. However, it performs well in all other aspects of the safety criteria - the conformer would be biocompatible, and easy to remove and clean if necessary. This design scored a 3/5 in ergonomics. Due to the 3D printed nature of the product, the design will be less comfortable than the injection molding designs, because there will be more ridges, bumps, and other flaws from the 3D printing device. This design scored a 4/5 in realism. It relies on iris design and creation that is individualized to each patient - in this way, it is much more realistic than other design ideas that have a set number of iris colors available. The reason it does not score a 5/5 is because the design does not include ideas for veining and color-discoloration on the sclera, which would increase the realism. This design scored a 3/5 in ease of manufacturing. While 3D printing is an easy fabrication technique to adapt to a larger scale, individually creating each iris based on patient scans is not something that can be generalized easily. For this reason, the design loses two points. Finally, this design scored a 3/5 in cost. The cost of materials in regards to 3D printing is relatively cheap compared to other methods of manufacturing. However, using individually matched irises raises the cost of this design, as it requires more manpower, coding, and technology to implement correctly. Due to the scores above, design #2 scores a 71/100 in the design matrix, and will most likely not be the design idea we move forward with in the next stages of this project.

Design 3:

The third design contains the iris conformer being produced using acrylic PMMA and injection molding. It would contain 2 separate molds, one mold for the iris and pupil, and another mold for the sclera. The two pieces will then be assembled together to create the iris conformer. This design also allows there to be 3 different sizes of iris conformers, small, medium, and large. The iris conformer contains 4 slot holes for the patient's application of ointment/medication. This design got a 5/5 for the safety criteria. The design contains only PMMA, which is a medical grade acrylic, and it prevents infection, tissue shrinkage, and allows the wound to heal properly. This design got a 4/5 for ergonomics. Molding results in a smoother surface with less ridges than a 3D printer would create, which allows the iris conformer to lack sharp edges. Sharp edges would cause discomfort in the patient over extended periods of time. This device also got a 4/5 for the realism criteria. With molding, we would be able to customize the color to match the color of the patient's eye, which would result in a more accurate appearance. However 5/5 was not achieved because the texture and color variance within the iris would be difficult to match with molding. This design got a 3/5 for the ease of manufacturing criteria. The manufacturing process would require multiple steps of hands on work, and requires machining. Though once the molds are made, the PMMA injection process is more straightforward. Finally, this design got a 4/5 for cost because the design includes PMMA for the iris and the sclera, which is cheap relative to medical grade silicone. Overall, this design scored the highest score with an 84/100, therefore was the design chosen from the design matrix.

Appendix C: Material Expense Sheet

Item	Description	Manufac - turer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1: Molding/Casting Materials										
Molding Rubber	Rubber molding materials to create the mold for conformer to fill	Alumilite	SMN29 244	Alumilite	SMN29 244	10/9/ 26	1	37.97	\$37.97	https://alumilite.com
Category 2: PMMA for device										
PMMA Beads	PMMA Beads will be melted, then cured in mold to create conformer	Millipore Sigma	CAS901 1147	Millipore Sigma	182265	10/9/ 26	1	38.07	\$38.07	https://www.sigmaaldrich.com
								TOTAL:	\$76.04	