



Product Design Specification

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

Team members

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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.
- The iris conformer must be biologically safe for the patient.
- The iris conformer must have small slits for ointment application.
- The iris conformer must be natural appearing.

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 – as to not cause additional issues during the healing process – and colored iris for the patient's eye
- iii. Must be porous to encourage favorable interactions with extraocular muscles and tissue, while also preventing migration in the 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 4 - 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.
 - 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 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. 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.

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].

References:

- [1] “Retinoblastoma,” Mayo Clinic,
<https://www.mayoclinic.org/diseases-conditions/retinoblastoma/symptoms-causes/syc-20351008>
(accessed Sep. 17, 2026).
- [2] M. D. P. Willcox et al., “TFOS Dews II Tear Film Report,” The ocular surface,
https://pmc.ncbi.nlm.nih.gov/articles/PMC6035753/?utm_ (accessed Sep. 17, 2026).
- [3] “Total weight of both eyes for reference adult male and female,” Total weight of both eyes for reference adult - Human Homo sapiens - BNID 110325,
<https://bionumbers.hms.harvard.edu/bionumber.aspx?s=n&v=4&id=110325> (accessed Sep. 17, 2026).
- [4] T. V. Dave et al., “Low-cost three-dimensional printed orbital template-assisted patient-specific implants for the correction of spherical orbital implant migration,” Indian journal of ophthalmology,
<https://pmc.ncbi.nlm.nih.gov/articles/PMC6213664/> (accessed Sep. 17, 2026).
- [5] ISO 10993-1:2018 - biological evaluation of Medical Devices — part 1: Evaluation and testing within a risk management process, <https://www.iso.org/standard/68936.html> (accessed Sep. 18, 2026).
- [6] ISO 10993-5:2009 - biological evaluation of Medical Devices — part 5: Tests for in vitro cytotoxicity, <https://www.iso.org/standard/36406.html> (accessed Sep. 18, 2026).
- [7] J. Reinhard, P. Urban, S. Bell, D. Carpenter, and M. S. Sagoo, “Automatic data-driven design and 3D printing of custom ocular prostheses,” Nature News,
<https://www.nature.com/articles/s41467-024-45345-5> (accessed Sep. 17, 2026).