Adjustable Extraocular Muscle Implant Device

Phase 3: Detailed Design

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Abstract

The Department of Ophthalmology at the University of Alberta requested that Luminous Engineering design a device to allow for post-operative adjustments of rectus muscle length without using general anesthesia. This report presents the detailed design of a device—known in promotional materials as the RectifEye—that meets all of the client's design specifications.

The device is a base with notches that connects directly to the globe of the eye and a locking catch attached to the rectus muscle. Nine notch sets allow for an adjustment range of ±4mm from the center position in increments of 1mm. The catch can be moved using standard surgical instruments under local anesthesia.

Biocompatibility is ensured through the selection of common implantable materials, namely, PEEK Optima and silicone. The lid, when closed, creates a smooth surface which will minimize eye irritation. The design is fail-safe and practical with few moving parts.

Finite-element analysis was used to examine the stresses acting on the device. A maximum muscle tension of 1.37N was applied, and a safety factor of four was achieved for all components of the design.

The device will be manufactured through a microinjection molding process. The approximate setup cost is $50,000, with an additional $13.64 per unit cost thereafter.

Through this analysis, the client is assured of a design that is safe and suitable for human implantation pending successful testing results.

2500 words

(Yes, exactly)
The Final Design

Design Description

The final design, shown in Figure 2, is a base with notches that connects directly to the globe of the eye, and a catch that engages these notches in the base. There are nine of these notches on the base, providing for an adjustment range of ±4mm from the center notch in increments of 1mm.

The backbone of the base is a hard section made from PEEK Optima, a medical grade of polyetheretherketone suitable for permanent implantation. PEEK provides the necessary strength to withstand the forces present in the rectus muscle, as shown in the Analysis section and Appendix C. This hard base is encased in a silicone coating that provides a smooth surface and prevents eye irritation. Stiffening arms project from the base into the silicone to provide extra strength, as shown in Figure 3.

Figure 2: Illustration of the final design installed on the eye. The lid is made transparent to show underlying parts.

Figure 3: Device with lid open; internal parts are coloured for clarity.
Adjustment

After seeing the results of the first surgery and device installation, the surgeon can make additional adjustments with the patient having only a local anesthetic administered. A 3mm incision in the conjunctiva allows the surgeon to access the device. After opening the lid, the doctor can move the catch into the desired location with tweezers. The lid is snapped closed and the conjunctiva sutured shut to complete the procedure. An animation of the installation and adjustment of the device is shown in Figure 6.

![Animation showing device installation and adjustment. The conjunctiva is hidden for clarity.](image)

Manufacturing and Materials

As mentioned previously, the hard polymer chosen is PEEK Optima. It is a biocompatible and sterilizable plastic made by Invibio, and has a long history of successful implantation. It also has the strength required for this application, with a yield strength of 100MPa and fatigue strength of 60MPa. PEEK was selected over PMMA—specified previously—for its superior strength and fatigue behaviour.

The silicone selected is Nusil MED-4850. It is a translucent, 50A durometer elastomer with a tensile strength of 9.7MPa. MED-4850 is suitable for permanent implantation and can bond to PEEK during the thermal overmolding process. If there are adhesion issues, Nusil MED-160 primer applied to the PEEK part will ensure a solid bond.

![Exploded view of device for material identification. The base, catch, and lid (left) are made from hard white PEEK Optima, while the base coating and top muscle clamp (right) are made from translucent Nusil MED-4850 silicone.](image)