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Intraocular Lens Case Designs

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Abstract

IOLAB Corporation makes two types of intraocular lenses for the replacement of cataracts: one from polymethyl methacrylate (PMMA) and a newer one from silicone. IOLAB ships the lens to the doctor in a two-piece case made from polycarbonate. At a price of $0.53 per case, IOLAB spends about $270,000 per year on lens cases (based on 1994 purchases of 500,000 cases).

IOLAB asked us to reduce the cost of the existing lens case and to design a new case to protect and fold the silicone lens. We designed three items:

1. ***A lens case which will hold all of IOLAB's 108 PMMA lens models. The initial investment in tooling for the new universal case will be less than $60,000 and the estimated cost will be $0.30 per case, a 43% reduction in the cost of the case (annual savings of $140,000). The payback period will be less than one year.***
2. ***A lens case which will fold and protect the silicone lens.***
3. ***An injection molded part which attaches to the existing case and helps the doctor fold the silicone lens.***

Client Information

IOLAB makes and sells products for cataract surgeries, including intraocular lenses, micro-surgical equipment and instruments, and AmVisc (a viscoelastic material). IOLAB is the third largest producer of intraocular lenses in the U.S. Chiron Vision purchased IOLAB from Johnson & Johnson in April, 1995.

Problem Definition

IOLAB asked us to reduce the cost of the existing intraocular lens case and to design a new case to fold and protect silicone lenses.

Proof of Need

a. PMMA lens case

The current lens case, consisting of a base and a cap, costs $0.53. Other costs include the costs of ordering, storing, and documenting the ten different bases and two different caps.

IOLAB ordered 500,000 lens cases in 1994 at a total cost of $270,000. For the next five years, IOLAB estimates case purchases of 600,000 per year.

b. Silicone lens case

IOLAB forecasts that the new silicone lenses will continue to increase in market share and will account for 50% of the total intraocular lens market by 1997. To encourage doctors to buy IOLAB's lenses, IOLAB needs to make the lens easier to fold. IOLAB's competitors already have lens cases which help the surgeon fold the lens and IOLAB does not.

Analysis of the Problem

a. Cataracts

Cataracts are a common disorder for people over 40. A cataract results when the normally clear lens in the eye becomes cloudy, usually from a natural deterioration of the lens caused by aging. This clouding obscures the vision of the patient and surgery must be performed to restore the patient's sight. Cataract surgery involves destruction of the clouded lens with ultrasound, removal of the lens debris using a vacuum, and insertion of an intraocular lens. This surgery is performed in about fifteen minutes and the patient goes home with clear vision and minimal pain.

b. Intraocular lenses

An intraocular lens (see Figure 1) is a small diameter optic (5-7 mm) with haptics, or loops, protruding from the side of the lens. The haptics center the lens in the eye.

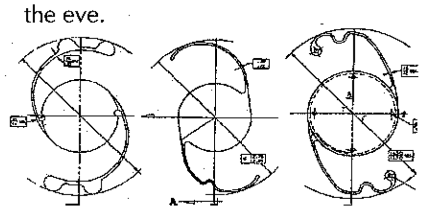

Figure 1: Three IOLAB lenses

IOLAB makes lenses from two types of materials: silicone and polymethyl methacrylate (PMMA). Silicone lenses have two advantages over PMMA lenses:

1. silicone lenses do not break as easily as PMMA lenses, and
2. a flexible silicone lens of the same optic diameter as a PMMA lens can be folded in half like a taco. The folded lens can be inserted into the eye where the lens unfolds and regains its original shape. A folded silicone lens requires an incision of only 3-4 mm, instead of the 5-7 mm needed to insert an unfolded PMMA lens. Small incisions (< 4 mm) do not require stitches and lead to fewer post-surgical complications and faster patient recoveries.

c. Current lens case

Both the PMMA and the silicone lenses are packaged in the same case. The current case is made from polycarbonate and consists of a base and cap (see Figure 2:A and Figure 2:B). Plastic pins inside the base keep the lens from sliding in the case thus preventing scratches on the optics and broken haptics.

IOLAB uses ten different bases and two different caps. Nine bases are for PMMA lenses and the tenth base is for silicone lenses. The bases are designed around the diameter of the lens optic and the caps are designed for different lens diopters.

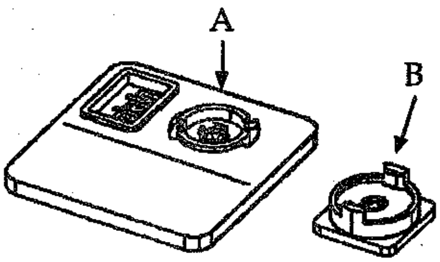

Figure 2: IOLAB lens case

The following complaints about the case have been voiced by IOLAB employees and a doctor:

1. the case is difficult to open,
2. the lenses stick to the cap when the case is opened,
3. the lenses are difficult to remove from the case, and
4. the lenses arrive with damaged optics and broken haptics.

d. Ideas for cost reduction

After looking at a breakdown of the molding costs of the case, we saw three area for cost reduction:

1. change the manufacturing process,
2. change the case material, and
3. reduce the number of different bases and caps.

The best option is to build a universal case - a case which can hold any of IOLAB's PMMA lenses (seeTable 1).

Universal Case Design

Any lens case must

1. be sterilizable by Ethylene Oxide (EtO),
2. be translucent,
3. be easy to use,
4. remain intact during shipping,
5. protect the lens, and
6. fit in the existing secondary packaging.

We designed a lens case which holds the lens in place with pressure on the top and bottom surfaces of the lens optic (see Figure 3). A rubber spring in the bottom of the case adjusts to the center thickness of the lens. The exterior of the case looks like a contact lens case and is about the same size as IOLAB's current lens case. The base and cap are connected by a flexible strap; the cap folds over to cover the base. The manufacturing, material, and assembly costs will total about \$0.30, twenty cents less than the price of the current lens case.

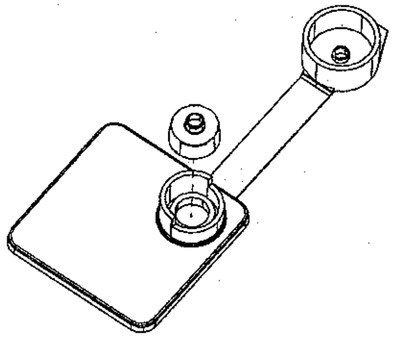

Figure 3: Lens case assembly

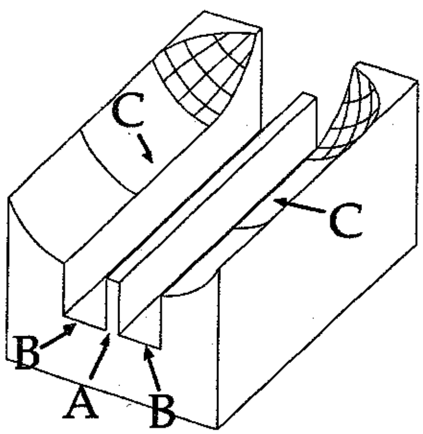

Figure 4: Folding assistant

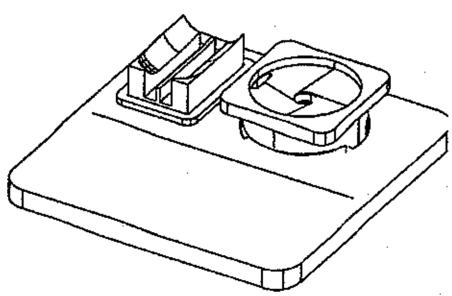

Figure 5: Folding assistant in well

Silicone Case Designs

Folding the silicone lens for insertion into the eye requires two pairs of forceps and manual dexterity. IOLAB asked us for cases which

1. fold the lens,
2. protect the lens from damage,
3. secure the lens in place,
4. allow inspection of the optic,
5. work with IOLAB's injector system, and
6. do not infringe on any patents.

We designed seven lens cases. The two best are the folding assistant (see Figure 4) and the dual-flex injector (see Figure 7). The folding assistant snaps into the well of the existing case and allows the surgeon to fold the lens with one pair of forceps. The dual-flex

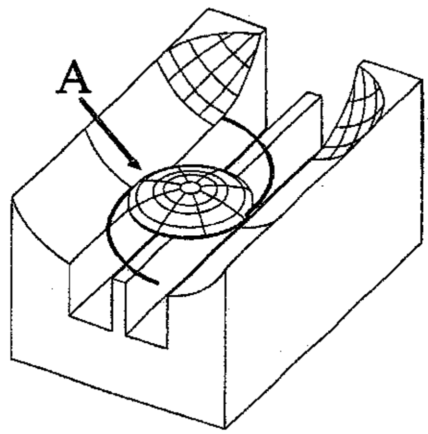

Figure 6: Folding assistant with lens

injector folds the lens and pushes the lens out of the case where the folded lens can be grabbed with one pair of forceps or the lens can be placed directly into an injector system (mechanical device for easier insertion of the lens into the eye).

1. Folding assistant

The folding assistant is an injection molded part (see Figure 4) which snaps into the irrigation well of the current lens case (see Figure 5). The folding assistant allows the surgeon to fold the lens with only one pair of forceps.

The folding assistant has a ridge in the middle (see Figure 4:A), two grooves on either side of the ridge (see Figure 4:B), and two ledges that support the edges of the lens (see Figure 4:C). After removing the lens from the base, the surgeon places the lens on the folding assistant. The lens is placed on the ridge along the 6 and 12 o'clock axis of the optic (see Figure 6). The side edges of the optic lie on the ledges. The surgeon places the forceps on the edges of the optic and pushes the edges down into the grooves of the folding assistant. The grooves allow the lens to be folded over the ridge. The surgeon then lifts the folded lens out from the groove with the pair of forceps.

We made two folding assistants: one from aluminum and the other from polypropylene.

Advantages:

a. attachment for current case,
b. one piece - no moving parts,
c. one pair of forceps folds lens,
d. successful tests, and
e. low cost (about $0.11 per case).

2. Dual-flex injector

This case has two sliders (see Figure 7:A) and a flexible, curved plastic piece (see Figure 7:B). Grooves cut in the tips of the two sliders hold the lens (see Figure 7:C). The flexible piece is folded and sits between the two sliders. Pushing the sliders along tracks in the outer shell squeezes the edges of the lens together and folds the lens. The sliders also compress the flexible plastic piece causing the piece to extend vertically. When the lens is almost completely folded, the flexible piece is extended far enough to push the lens out of the case. To prevent the lens from folding the wrong way, the soft, curved plastic piece is positioned a short distance below the lens. If the lens folds down, the plastic piece forces the lens to bend correctly.

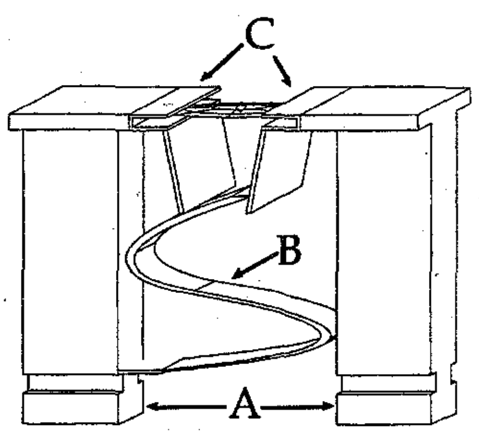

Figure 7: Dual-flex injector (outer shell not shown)

Advantages:

1. one motion to fold and eject lens,
2. injector compatible,
3. no forceps required, and
4. in-case inspection of lens optic.

Tools and Methods

We used I-DEAS Master Series by SDRC on Hewlett Packard computers to make drawings and to do finite element analyses of the existing case.

To design the rubber spring inside the new case, we considered two situations:

1. the pressure on the lens when the lens and case are in static equilibrium (to prevent excessive deformation of the lens from creep, the pressure cannot exceed 203 psig), and the maximum pressure on the lens and the maximum displacement of the lens caused by an impact (the pressure cannot exceed 10,500 psig, the compressive yield strength of PMMA).

Recommendations

We recommend IOLAB:

1. build the PMMA lens case,
2. develop the dual-flex injector case, and
3. build and sell the folding assistant as an addition to the existing case or as a separate piece which can be reused by the doctor.
4. IOLAB is now evaluating these recommendations.

Economic Evaluation

IOLAB requires a payback period less than three years and a discounted cash flow rate of return greater than 15%.

Table 1 summarizes the savings for each of our cost reduction ideas. A universal case is the best option.

Acknowledgments

We would like to thank Professors Joe King and Phil Cha at Harvey Mudd College for their assistance with the case designs and David S. Howard and Dr. Charles S. Sherwood at IOLAB for their guidance.

Idea	Payback Period	Discounted Cash Flow Rate of Return	Annual Savings
retool molds	3 years, 8 months	26%	$140,000
universal case	< 1 year	230%	$140,000

Table1: Comparison of cost reduction ideas