Preventing Posterior Capsular Opacification With an Endocapsular Equator Ring in a Young Human Eye

2-Year Follow-Up

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Objective: To report the results of a specially designed closed ring with a square edge (endocapsular equator ring) in a young patient to prevent posterior capsular opacification.

Methods: One eye of a 22-year-old atopic patient underwent endocapsular equator ring implantation with a 1-piece polymethylmethacrylate intraocular lens immediately after phacoemulsification at Hara Eye Hospital on January 10, 2003. The solid flexible silicone ring has an outer diameter of 9.0 mm, is 1.0 mm wide and 1.0 mm thick, and has a square edge. The loops of the intraocular lens are fixed in the inner groove of the ring. The contralateral control eye underwent phacoemulsification and implantation with a conventional intraocular lens implantation. The Hayashi method was used to determine the posterior capsular opacification score.

Results: The ring retained the transparency of the entire posterior capsule. Two years postoperatively, the posterior capsular opacification score in the central area was 3.75 in the ring eye and 15.25 in the control eye, which underwent Nd:YAG laser capsulotomy 2.5 years postoperatively.

Conclusion: An endocapsular equator ring effectively prevents posterior capsular opacification in a young patient with atopic cataracts.

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A trial of a new device in human eyes should be performed carefully. For this reason, we selected 1 young patient with atopic cataract for a pilot study. We also believe that the postoperative follow-up of 2 years is sufficient to reach a definitive conclusion about the efficacy of the ring. Our ultimate goal is to implant this ring into both
eyes of most patients with cataract. However, because this was a pilot study, the ring was used in only 1 eye; the contralateral eye implanted with only a conventional IOL served as a control. Although this study included only 1 eye, reporting the results is meaningful before we proceed to a multicenter trial of human cataracts.

METHODS

The patient was a 22-year-old man with atopic cataracts in both eyes and atopic dermatitis over his entire body. There were no other ocular abnormalities besides the cataracts. The preoperative best-corrected visual acuity (logarithm of the minimum angle of resolution) was 0.7 in the right eye and 0.5 in the left eye.

STRUCTURE OF THE RING

The closed ring, which is made of flexible silicone, is 1.0 mm wide and 1.0 mm thick. The outer diameter is 9.0 mm. There is a groove on the inner surface of the ring for IOL loop fixation (Figure 1). The ring weighs 22.62 mg in air and 20.48 mg in water. This ring and the IOL for the other ocular abnormalities besides the cataracts. The preoperative best-corrected visual acuity (logarithm of the minimum angle of resolution) was 0.7 in the right eye and 0.5 in the left eye.

The ring weighs 22.62 mg in air and 20.48 mg in water. This ring and the IOL for the ring were constructed by Morcher GmbH, Stuttgart, Germany, for this pilot study based on our design.

PREOPERATIVE AND POSTOPERATIVE EXAMINATIONS

In both eyes, the visual acuity, intraocular pressure, values of anterior chamber laser-flare-cell metry, and the PCO score based on the Hayashi method were recorded in the central 1 mm and peripheral 2 to 3 mm from the pupillary center.

SURGICAL PROCEDURE

On January 10, 2003, the right eye underwent phacoemulsification and ring-IOL implantation. Five days later, the left eye underwent a conventional phacoemulsification and IOL implantation. The IOL used in the control eye was a 1-piece hard PMMA IOL with a 6.0-mm optic and a total length of 12.5 mm (ES-23; Menicon Co, Nagoya, Japan). At Hara Eye Hospital, soft IOLs generally are used in patients older than 50 years and hard PMMA IOLs are used for patients younger than 50 years because the hard PMMA IOLs have a longer history in the eye than the soft IOLs. Because no currently available IOL could be fixed securely in the groove in the ring, a specially made, hard, 1-piece PMMA IOL with a 5.5-mm optic and a total length of 12.9 mm was used. (At present, an acrylic soft IOL is also used.)

Most preoperative and postoperative steps were identical to those during a standard cataract IOL surgery. After anesthesia was induced using 4% lidocaine hydrochloride eye drops, the cataract was removed by phacoemulsification through a 3.2-mm scleral incision 2 mm from the limbus with a fornix-based conjunctival flap. The ring was implanted into the bag through the same incision using a conventional soft IOL injector. After the scleral incision was enlarged to 6.0 mm, the hard IOL was implanted, and the loops were fixed in the inner groove of the ring. The insertion of the loops into the inner groove of the ring was easily confirmed by direct observation. Conjunctival flap was sealed by wet field bipolar coagulator. No sutures were used to close the scleral incision.

Preoperatively, the procedure was fully explained to the patient verbally and by documentation. Also, he was informed that the procedure was experimental and was to be performed in a human eye for the first time. The effects and possible complications also were explained in the same manner. The patient provided written informed consent. This procedure was approved by the ethics committee in our hospital.

RESULTS

The postoperative course in the control eye was uneventful. Iritis developed in the eye implanted with the ring on day 1 postoperatively but was managed by oral prednisolone starting at 30 mg a day. The dosage was reduced according to the recovery of the iritis and discontinued by the tenth postoperative day. The iritis resolved completely without residual abnormalities such as iris synechiae deposits on the IOL surface and high intraocular pressure.

Table. Preoperative and Postoperative Patient Data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>With Ring</th>
<th>Without Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraocular pressure, mm Hg</td>
<td>14</td>
<td>16</td>
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<tr>
<td>Anterior chamber flare, photon counts/mm² per second</td>
<td>7.4</td>
<td>9.9</td>
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<tr>
<td>Corneal endothelial cell density, cells/mm²</td>
<td>3648</td>
<td>3760</td>
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<tr>
<td>2-y Postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best-corrected visual acuity, logMAR</td>
<td>1.2</td>
<td>1.0</td>
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<tr>
<td>Intraocular pressure, mmHg</td>
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<td>14</td>
</tr>
<tr>
<td>Anterior chamber flare, photon counts/mm² per second</td>
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<td>Corneal endothelial cell density, cells/mm²</td>
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<td>Endothelial cell loss, %</td>
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<tr>
<td>Central PCO value</td>
<td>3.75</td>
<td>15.25</td>
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<tr>
<td>Peripheral PCO value</td>
<td>5.38</td>
<td>12.3</td>
</tr>
</tbody>
</table>

Abbreviations: logMAR, logarithm of the minimum angle of resolution; PCO, posterior capsular opacification.
pressure. Transient iritis did not increase the PCO rate. The results are shown in the Table.

What is noteworthy is the prominent difference in PCO. The eye implanted with the ring retained posterior capsular transparency 2 years after implantation (Figure 2). The PCO score in the central area was 3.75 in the eye with the ring and 15.25 in the control eye; in the periphery, the scores were 5.37 and 12.3, respectively. The results showed that the ring can retain posterior capsular transparency over the entire posterior capsule. To be stressed also is that there was no contact between the IOL optic and the clear posterior capsule. The PCO continued to increase in the control eye (Figure 3), and Nd:YAG laser capsulotomy had to be performed 2.5 years after surgery.

Figure 2. Postoperative posterior capsular opacification (PCO). Postoperative time was 2 years. In the eye with the ring, the ring and the intraocular lens (IOL) remain in the correct position and the posterior capsule is clear over an area wider than the IOL optic. There is no contact between the ring and the iris and ciliary body. The IOL optic does not contact the posterior capsule. There is no PCO. TI indicates transillumination image; SI, Scheimpflug image.

Figure 3. In the eye without a ring, there is considerable posterior capsular opacification. Postoperative time was 2.5 years.
We have accumulated acceptable results with the current ring in rabbit and monkey eyes.10,11 The current results proved the same efficacy in a human eye for the first time. The ring can prevent PCO in an area wider than the IOL optic. The IOL optic did not contact the posterior capsule. If the IOL is combined with the ring, further development of the material, the design of the IOL optic edge, and the loops will be less important. The values of corneal endothelial cell loss and anterior chamber flare were within acceptable ranges. If we select a soft IOL, the entire procedure can be performed through a 3.2-mm corneal limbal incision without sutures.

The wide, clear, posterior capsule facilitates easy observation of the fundus. Although dense PCO can be treated by capsulotomy, several complications have been reported, including reopening of macular holes after Nd:YAG laser capsulotomy.10 Therefore, the ideal situation is to prevent PCO over the wide area without breaking the posterior capsule. The ring will not prevent PCO in all cases. In the future, some eyes will require Nd:YAG laser capsulotomy. There is a potential for dislocation of the ring and IOL after capsulotomy. It can cause serious complications. Capsulotomies in the initial cases have to be performed at a small rate and followed up carefully. Although this is not yet proved, it seems logical that postoperative IOL exchange can be performed more easily without damaging the capsule than the conventional method without the ring.

There are 2 potential applications of the procedure. The first is the use of the IOL in pediatric eyes; the IOL can be exchanged accordingly with patient growth. The second is implantation in highly myopic eyes, in which correct IOL power calculation is difficult. After subsequent easy IOL exchange, the exact refraction can be obtained.

In the closed-ring surgery, the size of the ring is important. If the ring is larger than the capsule, the ring cannot be inserted into the capsule. Violent insertion will cause a fatal accident. If the ring was smaller than the capsule, in the rabbit eye, the ring stability was good.10 In the current human eye, the ring with a 9.0 mm outer diameter caused a postoperative iritis. However, after changing the diameter to 9.5 mm, iritis did not occur in any subsequent cases. In the current case, transient ring rotation in the capsule might cause iritis. Regarding the ring size, at least for the Japanese adult patients, 9.0 mm is small and 9.5 mm is ideal. If it is bigger than 9.5 mm, direct observation of the ring becomes difficult. The ring size for the pediatric patients should be discussed further.

The 2-year follow-up period is sufficiently long to demonstrate the effectiveness of the ring in a young atopic eye. The results from more cases, including a 9.5-mm ring with longer follow-up periods, are to be reported in other articles. However, the results of the current case are meaningful enough to be reported as a pilot study to spur further development of IOL surgery for PCO prevention and easy IOL exchange. The commercially available IOLs could not be fixed in the ring without deforming the IOL or the circular ring shape. Therefore, we used a specially designed IOL. However, this problem will be resolved in the future when the ring becomes widely available.

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REFERENCES