The Artisan aphakia intraocular lens in the paediatric eye
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CHAPTER 6

LONG-TERM FOLLOW-UP OF THE CORNEAL ENDOTHELIUM AFTER ARTISAN LENS IMPLANTATION FOR UNILATERAL TRAUMATIC AND UNILATERAL CONGENITAL CATARACT IN CHILDREN: TWO CASE SERIES

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Abstract

Purpose. To retrospectively estimate the long-term corneal endothelial cell loss in children after perforating corneal trauma and implantation of an iris-fixated anterior-chamber intraocular lens (IOL), either the Artisan aphakia lens or the Artisan Iris Reconstruction IOL, and to compare this corneal endothelial cell loss to that in children who received an Artisan aphakia lens to correct aphakia after cataract extraction for unilateral congenital cataract.

Methods. A retrospective study was performed, evaluating the charts and endothelial photographs of six patients with unilateral traumatic cataract, with a mean age at IOL implantation of 9.5 years (range, 5.8-12.8 years) and a mean follow-up after IOL implantation of 10.5 years (range, 8.0-14.7 years), and of three children who were operated on for unilateral congenital cataract at a mean age of 2.7 years and who received an Artisan aphakia IOL, with a mean follow-up after IOL implantation of 9.5 years (range, 4.7-14.5 years). Parameters that were studied were central endothelial cell density (CECD) in both the operated and the normal eye at the last follow-up visit, percentage of cell loss in the operated eye compared with the normal eye, and length and location of the corneal scar in the injured eye.

Results. In the traumatic cataract group, CECD was, on average, 41% (range, 22%-58%) lower in the operated eye ($1.647 \pm 322$ [SD] cells/mm$^2$) than the normal eye ($2.799 \pm 133$ cells/mm$^2$). A significant negative linear correlation was found between the length of the corneal perforation scar and CECD. In the congenital cataract group, no statistical difference in CECD was found between the operated ($3.323 \pm 410$ cells/mm$^2$) and the unoperated ($3.165 \pm 205$ cells/mm$^2$) eye.

Conclusions. Endothelial cell loss 10.5 years after iris-fixated IOL implantation for traumatic cataract was substantial and related to the length of the corneal scar of the original trauma. In children operated on for congenital cataract, no difference was found in CECD in the operated and unoperated eyes 9.5 years after Artisan aphakia IOL implantation.
INTRODUCTION

For the surgical correction of traumatic aphakia, several options are available. One of these is the Artisan aphakia intraocular lens (Ophtec, Groningen, the Netherlands). Despite more than ten years of favourable clinical experience with this intraocular lens (IOL) in the Netherlands and elsewhere, very few studies on the use of the Artisan lens for this indication have been published\textsuperscript{1-4}. In phakic eyes, uncertainty exists on the long-term safety of this iris-fixated anterior-chamber lens to the corneal endothelium\textsuperscript{7-11}. Because several studies have shown that endothelial cell loss after intraocular surgery continues at a higher rate than the normal age-related cell loss rate\textsuperscript{12,13}, safety with regard to the corneal endothelium is even more important in the paediatric age group than in adult patients. Only a few studies have been published on the corneal endothelium after IOL implantation in children, and only three of these were published in the last ten years\textsuperscript{14-20}. For this reason, we performed a retrospective follow-up study on the corneal endothelium in children with monocular traumatic aphakia, corrected with an Artisan lens. We compared the endothelial cell parameters in the injured eye to those in the normal eye of the same patient and correlated the amount of cell loss in the injured eye compared with the normal eye to the length of the scar of the original traumatic corneal perforation. We also compared these results with endothelial cell counts in children with an Artisan aphakia lens in only one eye after cataract extraction for monocular congenital cataract, without a history of trauma.

MATERIALS AND METHODS

We retrospectively studied the charts of ten patients, three girls and seven boys, who were operated on for unilateral penetrating ocular injury requiring cataract extraction under the age of 14 years and who also underwent Artisan lens implantation, either at the time of the primary surgery or as a secondary procedure. All ten eyes underwent cataract extraction (CE) through irrigation and aspiration at the time of surgical repair of the corneal laceration. Five of ten patients received a standard Artisan aphakia lens: one patient during the primary surgical procedure and in the remaining four as a secondary procedure. Surgical technique of implantation of an aphakia Artisan IOL is similar to the technique in phakic Artisan IOL implantation and has been described elsewhere\textsuperscript{1,2,4,9}. The other five patients received an individually designed iris-fixated Artisan lens with a coloured iris diaphragm to treat photophobia caused by traumatic partial aniridia or traumatic mydriasis and aphakia: the custom-made Artisan Iris Reconstruction IOL. In six of these ten patients with unilateral traumatic cataract, photographs of the central corneal endothelium were available of both eyes: these patients were included in the study. Clinical results and complications in these patients are described in Table 1.
The Artisan Iris Reconstruction IOL was designed using an anterior-segment photograph of the affected eye and information from the surgeon indicating the preferred location of the “claws” because atrophic iris tissue is not suitable as fixation site (see Figure 1 for an example of an eye with an Artisan Iris Reconstruction IOL). Both the standard aphakia IOL and the Iris Reconstruction IOL are made of polymethylmethacrylate (PMMA) material; the standard aphakia IOL is totally transparent, and in the Iris Reconstruction IOL, the central optic part is transparent. For the peripheral part, a choice can be made between four colours: black, blue, green, and brown. The pigment is molecularly bound in the PMMA. The size of all Artisan aphakia IOLs used in patients in this study was 5 × 8.5 mm, 5 mm being the diameter of the optic. The smallest diameter of the Artisan Iris Reconstruction IOL varied from 6 to 8.5 mm; the largest diameter was 8.5 mm. Diameter of the optic was 4 mm. All IOLs were implanted through a corneoscleral incision with a size corresponding to the smallest diameter of the IOL. The claws each were fixated (or “inclavated”) by grasping a piece of midperipheral iris and pulling it into the claw by special toothed forceps or by using a bent needle to push some iris tissue into the claw. The forceps or bent needle was introduced into the eye through separate side ports and not through the main incision. Healon was used in all cases. No additional iris sutures were used. Implanting the Artisan Iris Reconstruction IOL requires more skill than implanting a standard Artisan aphakia IOL because it is mandatory to avoid excessive manipulation of the iris in these already severely damaged eyes and to avoid atrophic parts of the iris in placing the claws.

The endothelial photographs were made with a non-contact auto-focus SP2000P specular microscope (Topcon Corp., Tokyo, Japan), after an average follow-up period of 10.5 years after IOL implantation. All images were analyzed using Imagenet 2000 software (Topcon Corp.). Using this program, the cell borders were corrected interactively by one of the authors (M.Th.P.O.) before endothelial cell parameters were computed.

We wanted to know whether the size and location (central or not central) of the corneal laceration was related to the amount of endothelial cell loss in these eyes. The size of the corneal scar had been measured in all eyes at a follow-up visit by aligning the slit beam of the slit lamp to the corneal scar and using the slit length indication on the Haag Streit BQ slit lamp (Bern, Switzerland) to estimate the size of the scar. The location of the scar was documented by drawings in the charts, and in most cases, was documented by anterior-segment photography as well.

We also wanted to find out whether the endothelial cell loss should be attributed to the presence of the Artisan lens or to the original trauma and the subsequent repair surgery, including lens aspiration. Therefore, we retrospectively examined the endothelial photographs of three children who were operated on for unilateral congenital cataract in our clinic at a mean age of 2.7 years and received an Artisan aphakia lens, with a mean follow-up of 9.5 years after lens implantation (see Figure 2 for an example of an eye of a child with a standard Artisan aphakia IOL). All patients were operated on by the same
Figure 1. Example of an eye with an Artisan Iris Reconstruction IOL: left eye of patient 4.

Figure 2. Typical appearance of an eye with the standard Artisan aphakia IOL.
<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Eye</th>
<th>Type of Artisan</th>
<th>Aphakia Lens</th>
<th>Age at CE (yr)</th>
<th>Interval between CE and IOL Implantation (yr)</th>
<th>Follow-up Period after IOL Implantation (yr)</th>
<th>Location of Scar (central or not)</th>
<th>BSCVA</th>
<th>Other Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>0</td>
<td>Standard IOL</td>
<td>20/200</td>
<td>0</td>
<td>10.5 ± 2.7</td>
<td>7.6 ± 1.7</td>
<td>not central</td>
<td>20/100</td>
<td>RD surgery (4 times)</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>0</td>
<td>Standard IOL</td>
<td>20/30</td>
<td>0</td>
<td>8.8 ± 0</td>
<td>10.5 ± 2.7</td>
<td>central</td>
<td>20/30</td>
<td>no</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>0</td>
<td>Standard IOL</td>
<td>20/100</td>
<td>0</td>
<td>8.5 ± 0</td>
<td>10.5 ± 2.7</td>
<td>not central</td>
<td>20/100</td>
<td>no</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>0</td>
<td>Iris Reconstruction</td>
<td>IOL</td>
<td>20/30</td>
<td>7.7 ± 0</td>
<td>10.5 ± 2.7</td>
<td>not central</td>
<td>20/30</td>
<td>IOL reposition (after partial dislocation due to blunt trauma)</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>0</td>
<td>Iris Reconstruction</td>
<td>IOL</td>
<td>20/200</td>
<td>6.3 ± 0</td>
<td>10.5 ± 2.7</td>
<td>not central</td>
<td>20/200</td>
<td>no</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>0</td>
<td>Iris Reconstruction</td>
<td>IOL</td>
<td>20/100</td>
<td>6.9 ± 0</td>
<td>10.5 ± 2.7</td>
<td>not central</td>
<td>20/100</td>
<td>no</td>
</tr>
</tbody>
</table>

Table 1. Patient characteristics

F, female; M, male; CE, cataract extraction; IOL, intraocular lens; BSCVA, best spectacle corrected visual acuity; HM, hand motion.
Endothelial cell loss was estimated by comparing central endothelial cell density (CECD) of the operated eye with CECD of the normal, non-operated eye at the last follow-up visit.

For statistical analysis, the paired Student t test was used to compare endothelial cell densities and parameters between the operated and non-operated eyes in each group. To find a possible correlation between length of the corneal perforation and corneal cell loss, we performed linear regression analysis.

RESULTS

In six of ten patients with an Artisan lens for traumatic aphakia, endothelial photographs were made at the last follow-up visit, with a mean follow-up period of 10.5 years after lens implantation. Details of these six patients can be found in Table 1. In three other patients of the total group of ten patients, the cornea of the operated eye was clear at the last follow-up visit, with a mean follow-up period of 10.8 years after IOL implantation, except for the corneal scar resulting from the trauma, but endothelial photographs were not taken. In the remaining patient, endothelial photographs could not be made because of the development of calcific band keratopathy, three years after the original trauma.

The six eyes with an Artisan lens for traumatic aphakia and a clear cornea, in which endothelial photography was performed at the last follow-up visit, showed a substantially lower endothelial cell count than the normal fellow eyes. These trauma eyes had a substantial mean endothelial cell loss of 41% (range, 22%-58%) compared with the normal fellow eye. At the last follow-up visit, no significant difference was found in mean endothelial cell loss (compared with the normal eye) between the eyes with a custom-made Artisan Iris Reconstruction IOL (42%) and the eyes with a standard Artisan aphakia lens (40%).

Endothelial cell loss was related to the size of the wound. For the calculation of a possible correlation between size of the corneal laceration and central endothelial cell density, we excluded one eye with a central corneal perforation and a central endothelial cell density of 1349 (cell loss of 53%), because a lower cell density next to the site of the perforation than away from the perforation was observed by Kletzky et al21. In the remaining five eyes, a strong negative correlation between endothelial cell density and length of the corneal scar was found (Figure 3).

In the eyes operated on for unilateral congenital cataract, no significant endothelial cell loss was found when the operated eyes were compared with the non-operated fellow eyes (Table 2). The endothelial morphologic parameters, coefficient of variation of cell size, and percentage of hexagonal cells showed no statistical difference between the operated and non-operated eyes in all groups.
**Discussion**

In the management of paediatric traumatic aphakia, several treatment options exist in the absence of adequate capsular support: the use of a contact lens, an angle-supported anterior-chamber IOL, a sulcus-sutured lens, and the Artisan lens. The Artisan lens is an iris-fixated lens that recently received US Food and Drug Administration (FDA) approval for the correction of high ametropia in the phakic eye. In the Netherlands and elsewhere, an iris-fixated lens of similar design has been widely and successfully used for more than ten years for the correction of aphakia in the absence of capsular support. This is the first long-term follow-up study on the impact on the corneal endothelium of this lens for this indication in children.

Only a few studies have been published that include reports on endothelial cell loss after surgery for traumatic cataract after perforating ocular injuries. In a paper by Kletzky et al., mean endothelial cell loss in the injured eyes of 12 patients compared with the uninjured eyes was 58% near the wound versus 46% away from the wound. The age of the 12 patients was not mentioned, and follow-up ranged from three months to 3.4 years after repair of the corneal laceration and lensectomy. None of the patients received an IOL. The authors found a strong positive correlation between size of the corneal laceration and endothelial cell loss. In our study, we measured only central corneal endothelial cell parameters. Mean endothelial cell loss in the eyes with an Artisan lens compared with the uninjured eyes was on average 41%; in one eye with a central perforation, the cell loss was 53%, and in the remaining eyes, it was 38% on average, after a mean follow-up of 10.5 years. We also found a strong correlation between size of the corneal laceration and central endothelial cell density in the five eyes in which the scar was not in the center of the cornea. The eye with the highest endothelial cell loss (58%) also had the largest perforation: 12 mm (limbus to limbus). Roper-Hall et al.

![Figure 3. Central endothelial cell density and length of corneal scar.](image-url)
measured cell loss in seven patients that had lens surgery for traumatic cataract varying from 3.5% to 72.5% (mean, 32%) compared with the normal eye with a follow-up of approximately two years. Churchill et al. measured endothelial cell loss compared with the other eye in three children with relatively small corneal perforations (e.g., caused by a pin) and traumatic cataract after a mean follow-up of nine years and found a mean cell loss of 30%. Kora et al. found a mean cell loss of 44% in five eyes of children with traumatic cataract, mean age 9.9 years, with a mean follow-up of 6.8 years after implantation of a posterior-chamber IOL. One further patient in that study received an angle-supported anterior-chamber IOL at the age of 14 and showed 70% cell loss after eight years of follow-up.

We were surprised to find no difference in endothelial cell density between eyes with the Artisan aphakia IOL and eyes with the Artisan Iris Reconstruction IOL, because a larger corneoscleral incision is usually necessary for implantation of this device.

In one of four children of whom endothelial photographs were not available, the cornea developed calcific band keratopathy three years after Artisan Iris Reconstruction IOL implantation in an eye that experienced an extensive perforating trauma with a wound including the whole corneal diameter and extending into the sclera, iris, and lens. This eye also developed secondary glaucoma, necessitating surgical intervention. We speculate that this eye suffered from persistent low-grade inflammation, causing the calcific band keratopathy. Persistent low-grade inflammation is common after perforating
trauma and is, in our opinion, not related to this type of IOL.

Unfortunately, an age-matched group of patients with an Artisan aphakia IOL in one eye, but without perforating injury, was not available. In the group of three children that were operated on for congenital cataract and received an Artisan aphakia IOL, cell densities in the non-operated eyes were higher than in the uninjured eyes of patients in the trauma group. This finding is not surprising, given the difference in mean age (2.7 vs. 9.5 years) of the patients in both groups and the relatively large influence of age on cell density in children. Mean cell density in the operated eyes in the patients in the congenital cataract group was not different from that in the non-operated eyes. This finding is remarkable because, in adults, a cell loss of at least a few percent after cataract surgery is usual even with modern techniques. In children, Basti et al. found a mean cell loss of 6.5% in 18 eyes of children operated on for congenital cataract at a mean age of 9.3 years and a follow-up period of six to nine months, and Kora et al. found a mean cell loss of 6% after a mean follow-up of four years after implantation of a posterior-chamber IOL in six eyes of children with congenital cataract, operated on at a mean age of 11.3 years. Lifshitz et al. recently reported on the corneal endothelium of two children, 4 and 12 years of age, after Artisan aphakia IOL implantation after lens extraction for a subluxated lens. After a follow-up of eight months, they also did not find any endothelial cell loss in the operated eyes compared with the non-operated eyes. The corneal endothelium in children may be more resistant to surgical damage than the endothelium in adults. We feel that this finding needs confirmation in a larger group of patients, and it may not be applicable to phakic IOL implantation in children, where the distance of the IOL to the corneal endothelium is smaller because of the presence of the natural lens. However, we may conclude that the Artisan aphakia lens in any case does not seem to cause excessive endothelial cell loss compared with other studies of traumatic aphakia corrected with a contact lens or posterior-chamber IOL. The substantial cell loss in eyes after surgery for traumatic cataract seems to be caused primarily by damage caused by the perforating trauma and the repair surgery.
REFERENCES


