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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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 Artificial Iris Implant, 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 6 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 3 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 ± 322 [SD] cells/mm^2) than the normal eye (2.799 ± 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 ± 410 cells/mm^2) and the unoperated (3.165 ± 205 cells/mm^2) eye.

Conclusion: 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.

Key Words: corneal endothelium, traumatic cataract, children, cataract surgery, intraocular lens

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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 10 years of favorable 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.[1–6] In phakic eyes, uncertainty exists on the long-term safety of this iris-fixated anterior-chamber lens to the corneal endothelium.[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,[12,13] safety with regard to the corneal endothelium is even more important in the pediatric age group than in adult patients. Only a few studies have been published on the corneal endothelium after IOL implantation in children, and only 3 of these were published in the last 10 years.[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 1 eye after cataract extraction for monocular congenital cataract, without a history of trauma.

MATERIALS AND METHODS

We retrospectively studied the charts of 10 patients, 3 girls and 7 boys, who were operated on for unilateral penetrating ocular injury requiring cataract extraction under

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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 10 eyes underwent cataract extraction (CE) through irrigation and aspiration at the time of surgical repair of the corneal laceration. Five of 10 patients received a standard Artisan aphakia lens: 1 patient during the primary surgical procedure and in the remaining 4 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.[1,2,4–9] The other 5 patients received an individually designed iris-fixated Artisan lens with a colored iris diaphragm to treat photophobia caused by traumatic partial aniridia or traumatic mydriasis and aphakia: the custom-made Artificial Iris Implant. In 6 of these 10 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 Artificial Iris Implant 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 Fig. 1 for an example of an eye with an Artisan Artificial Iris Implant). Both the standard aphakia IOL and the artificial iris implant are made of polymethyl methacrylate (PMMA) material; the standard aphakia IOL is totally transparent, and in the Artificial Iris Implant, the central optic part is transparent. For the peripheral part, a choice can be made between 4 colors: 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 Artificial Iris Implants 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 Artificial Iris Implant 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 noncontact 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 1 of the authors (M.T.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 3 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 Fig. 2 for an example of an eye of a child with a standard Artisan aphakia IOL). All patients were operated on by the same surgeon (N.G.).

TABLE 1. Patient Characteristics

Patient	Sex	Eye	Type of Artisan Aphakia Lens	Age at CE (yr)	Interval Between CE and IOL Implantation (yr)	Follow-Up Period After IOL Implantation (yr)	Location of Scar (Central or Not Central)	BSCVA	Other Procedures Besides IOL Implantation
1	M	OS	Standard aphakia	5.6	0.2	14.7	Not central	20/100	RD surgery (4 times)
2	M	OS	Standard aphakia	8.8	0.8	8.5	Central	20/30	YAG laser of vitreous strand
3	F	OD	Standard aphakia	10.3	0	8.0	Not central	20/100	No
4	M	OS	Custom-made with colored artificial iris	7.7	5.1	12.5	Not central	20/30	No
5	M	OS	Custom-made with colored artificial iris	6.3	2.9	10.6	Not central	20/200	No
6	M	OS	Custom-made with colored artificial iris	6.9	2.8	8.3	Not central	20/100	IOL refixation (after partial dislocation due to blunt trauma)
Mean ± SD				7.6 ± 1.7	2.0 ± 2.0	10.5 ± 2.7			

F, female; M, male; CE, cataract extraction; IOL, intraocular lens; BSCVA, best spectacle-corrected visual acuity; RD, retinal detachment; HM, hand motion.

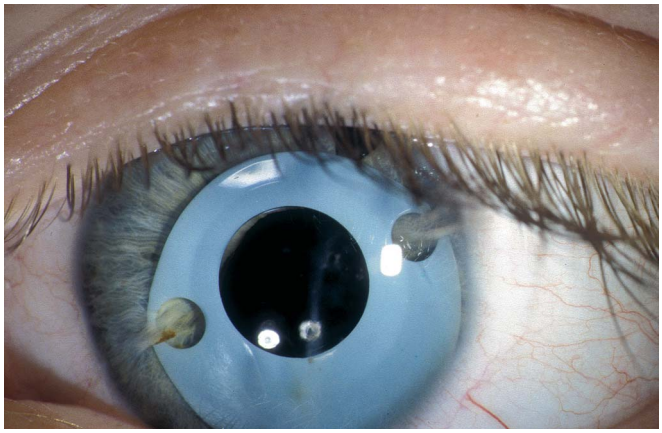

FIGURE 1. Example of an eye with an Artisan artificial iris implant: left eye of patient 4.

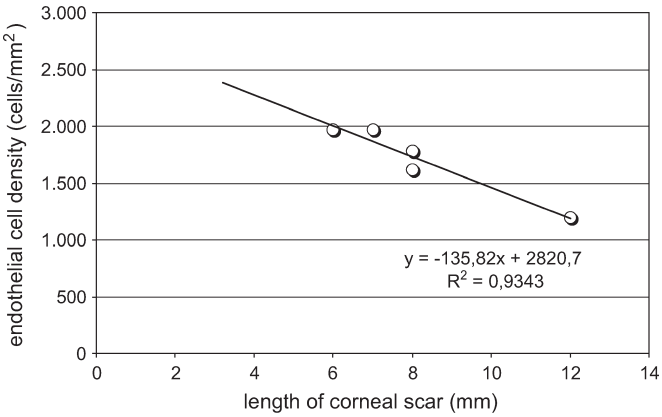

FIGURE 3. Central endothelial cell density and length of corneal scar.

Endothelial cell loss was estimated by comparing central endothelial cell density (CECD) of the operated eye with CECD of the normal, nonoperated 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 unoperated 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 6 of 10 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 6 patients can be found in Table 1. In 3 other patients of the total group of 10 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, 3 years after the original trauma.

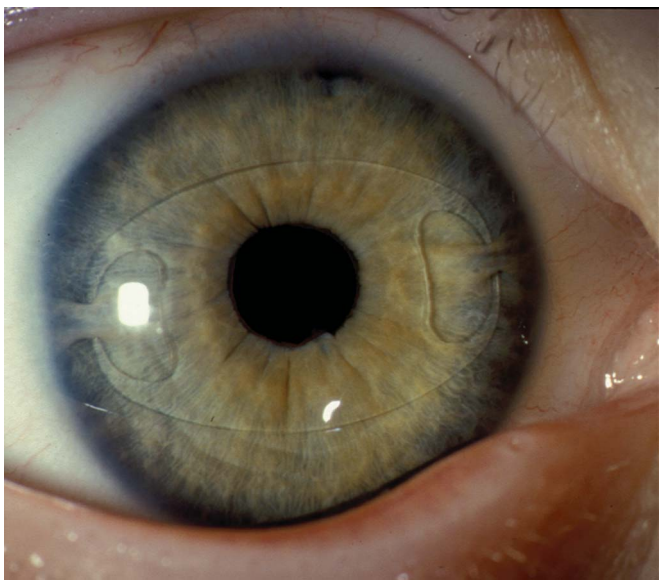

FIGURE 2. Typical appearance of an eye with the standard Artisan aphakia IOL.

The 6 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 Implant lens (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 1 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 al.[21] In the remaining 5 eyes, a strong negative correlation between endothelial cell density and length of the corneal scar was found (Fig. 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 nonoperated 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 unoperated eyes in all groups.

DISCUSSION

In the management of pediatric 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

TABLE 2. Endothelial Cell Parameters

	Patients Operated on for Unilateral Congenital Cataract		Patients Operated on for Traumatic Cataract	
	Operated eye	Unoperated eye	Operated eye	Unoperated eye
N	3	3	6	6
Mean age on date of IOL implantation (yr)	2.7	NA	9.5	NA
Mean follow-up time (yr)	9.5	NA	10.5	NA
Range (yr)	4.7–14.5	NA	8.0–14.7	NA
Mean endothelial cell density (cells/mm^2)	3.323	3.165	1.647*	2.799
Range	2.875–3.679	2.980–3.386	1.197–1.967	2.542–2.894
SD	410	205	322	133
Mean % cell loss, compared with unoperated eye	−6	NA	41	NA
Range	−23 to 15	NA	22–58	NA
Coefficient of variation of cell size	27	26	29	25
% Hexagonal cells	74	73	70	64

*Cell density difference between operated and unoperated eye is statistically significant ($P \leq 0.005$, Student t test).
IOL, intraocular lens; NA, not applicable.

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 10 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,[21] 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 3 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 1 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 5 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[22] measured cell loss in 7 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 2 years. Churchill et al[19] measured endothelial cell loss compared with the other eye in 3 children with relatively small corneal perforations (eg, caused by a pin) and traumatic cataract after a mean follow-up of 9 years and found a mean cell loss of 30%. Kora et al[15] found a mean cell loss of 44% in 5 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 8 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 Artificial Iris Implant, because a larger corneoscleral incision is usually necessary for implantation of this device.

In 1 of 4 children of whom endothelial photographs were not available, the cornea developed calcific band keratopathy 3 years after artificial iris 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 1 eye, but without perforating injury, was not available. In the group of 3 children that were operated on for congenital cataract and received an Artisan aphakia IOL, cell densities in the unoperated 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.[23,24] Mean cell density in the operated eyes in the patients in the congenital cataract group was not different from that in the unoperated 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.[13,25–27] In children, Basti et al[14] 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 6 to 9 months, and Kora et al[15] found a mean cell loss

of 6% after a mean follow-up of 4 years after implantation of a posterior-chamber IOL in 6 eyes of children with congenital cataract, operated on at a mean age of 11.3 years. Lifshitz et al[20] recently reported on the corneal endothelium of 2 children, 4 and 12 years of age, after Artisan aphakia IOL implantation after lens extraction for a subluxated lens. After a follow-up of 8 months, they also did not find any endothelial cell loss in the operated eyes compared with the unoperated 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.[28] 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.

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