The Artisan aphakia intraocular lens in the paediatric eye
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Chapter 5

Implantation of the Artisan® Iris Reconstruction Intraocular lens in five children with aphakia and partial aniridia caused by perforating ocular trauma

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ABSTRACT

Purpose. To describe the long-term clinical results of the implantation of the Artisan Iris Reconstruction intraocular lens (IOL) in five eyes of five children for aphakia and partial aniridia attributable to penetrating ocular trauma.

Methods. The charts of five children were retrospectively reviewed. The nature and the extent of injury; age at IOL implantation; visual, refractive, and cosmetic outcome; endothelial cell density; and complications and subsequent surgical interventions were evaluated.

Results. Mean follow-up period was 8.9 years (range, 4.9–12.4). Mean age at implantation of the Artisan Iris Reconstruction IOL was 9.5 years (range, 7.7–12.7). Visual acuity improved in two of five eyes, remained stable in two of five eyes and decreased in one of five eyes. Complaints of photophobia were reduced, and a satisfactory cosmetic outcome was achieved in three of five patients. The mean spherical equivalent refractive error at last follow-up was -4.0 dioptres. Mean endothelial cell loss when compared with the healthy fellow eye was 42%. Two cases were complicated by partial luxation of the IOL, one case by persistent anterior uveitis and secondary glaucoma. One eye developed a retinal detachment.

Conclusions. The Artisan Iris Reconstruction IOL is a treatment option for the treatment of aniridia and aphakia due to penetrating ocular trauma in children. We emphasise the high-risk characteristics of the eyes treated and the importance of careful patient selection in the outcome of the implantation of the Artisan Iris Reconstruction IOL.
INTRODUCTION

An intact iris diaphragm is important for accurate visual function. Symptoms of traumatic aniridia include a decreased visual function, incapacitating glare, photophobia, and concerns about cosmetic appearance. Several treatment options to overcome these problems have been described and include iridoplasty, coloured contact lenses, corneal tattooing, and IOLs of various designs. Some iris defects may be too large to repair with the use of suturing. Coloured contact lenses may not be tolerated, and the reduction of complaints caused by glare may be insufficient. Corneal tattooing causes a permanent opacity, which reduces the visibility of the posterior segment. In addition, long-term stability is unpredictable. In traumatic aniridia, the eye’s anterior segment is severely injured, which frequently is associated with cataract or aphakia. Implantation of an IOL with an iris prosthesis offers the physician the opportunity to correct the iris defect and aphakia simultaneously.

We present the long-term clinical outcome of the implantation of the Artisan® Iris Reconstruction IOL (Ophtec, Groningen, the Netherlands) in five eyes (of five children) with aphakia and partial aniridia caused by penetrating ocular trauma, with a mean follow-up period of 8.9 years (range, 4.9-12.4 years). The Artisan Iris Reconstruction IOL was designed for anterior segment reconstruction of eyes in which asymmetric iris damage has occurred. The Artisan Iris Reconstruction IOL is a tailor-made polymethylmethacrylate (PMMA) IOL with a coloured iris diaphragm to treat aphakia as well as photophobia. These lenses are available in various dioptic powers and colours (brown, blue, green, and black).

SUBJECTS AND METHODS

Five children with aphakic eyes and partial aniridia caused by previous penetrating ocular trauma received an Artisan Iris Reconstruction IOL in our clinic between 1987 and 1997. The charts of these five children were retrospectively reviewed. The nature and the extent of the injury; the age at IOL implantation; the visual, refractive and cosmetic outcome; and the complications and subsequent surgical interventions were retrospectively evaluated.

Images of the corneal endothelium with a noncontact, auto-focus specular microscope (Topcon Corporation, Tokyo, Japan) were available in three of five patients (cases 1, 2, and 4). The endothelial cell counts of the operated traumatic eye were compared with the endothelial cell counts of the healthy fellow eye. We presumed that the endothelial cell counts of the two eyes of one person are equal (100%) when there is no history of any surgery or trauma. The number of endothelial cells in the operated traumatic eye was divided by the number of endothelial cells in the healthy fellow eye and subtracted.
from 100% to obtain the estimated percentage of cell loss of the operated eye compared with the healthy fellow eye.

The lenses we used, were tailor-made using photographic documentation of the traumatic and the fellow eye. Pictures were sent to the Ophtec Laboratories, where the lens was designed. There, the size and claw position to the damaged iris was adjusted and the best matching from the four possible colours was chosen (Figure 1).

For details on colour, number of claws, and size of the IOLs, see Table 1.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Injury</th>
<th>Iris defect in clock position</th>
<th>Length of corneal scar (mm)</th>
<th>IOL color</th>
<th>Maximal lens diameter (mm)</th>
<th>Minimal lens diameter (mm)</th>
<th>Optic diameter (mm)</th>
<th>Number of claws</th>
<th>IOL power (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wooden stick</td>
<td>1</td>
<td>8</td>
<td>Blue</td>
<td>8.5</td>
<td>7.5</td>
<td>4.0</td>
<td>2</td>
<td>+22.0</td>
</tr>
<tr>
<td>2</td>
<td>Wooden stick</td>
<td>Traumatic mydriasis</td>
<td>12</td>
<td>Brown</td>
<td>8.5</td>
<td>8.5</td>
<td>4.0</td>
<td>3</td>
<td>+24.0</td>
</tr>
<tr>
<td>3</td>
<td>Pebble</td>
<td>4</td>
<td>8</td>
<td>Brown</td>
<td>7.0</td>
<td>5.0</td>
<td>3.0</td>
<td>2</td>
<td>+18.0</td>
</tr>
<tr>
<td>4</td>
<td>Pocket knife</td>
<td>4</td>
<td>6</td>
<td>Brown</td>
<td>7.5</td>
<td>6.0</td>
<td>4.0</td>
<td>3</td>
<td>+20.0</td>
</tr>
<tr>
<td>5</td>
<td>Glass splinter</td>
<td>5-6</td>
<td>12</td>
<td>Green</td>
<td>7.5</td>
<td>6.5</td>
<td>4.0</td>
<td>2</td>
<td>+21.0</td>
</tr>
</tbody>
</table>

Table 1. Injury and IOL characteristics. mm: millimetre; IOL: intraocular lens; D: dioptre.
Before implantation of the Artisan Iris Reconstruction IOL, the patients were contact lens intolerant (Cases 1, 2, and 4) and/or suffered from photophobia (Cases 2, 3, 4, and 5) and/or had concerns about their cosmetic appearance (Cases 1 and 5).

All implantation procedures were performed by one surgeon (NGM). Acetylcholine was administered preoperatively. The conjunctiva was opened at the superior limbus and the anterior chamber was approached through a corneoscleral incision. The size of the incision was adjusted to the smallest diameter of the custom-made implant, varying from 5 to 8.5 mm. Sodium hyaluronate (Healon, AMO, Santa Ana, CA, USA) was used to protect the corneal endothelium. The lens was inserted, rotated into the desired position, and attached to the remaining iris with a bent needle or an enclavation forceps (Ophtec) through limbal paracenteses. The location of the limbal paracenteses depended on the location of the claws of the custom-made implant. An iridectomy was made in selected cases to prevent pupillary block. The wound was closed with interrupted 10-0 nylon sutures. Subconjunctival Celestone (Schering-Plough, Madison, NJ, USA), and ChronoDose (Chrono Therapeutics, Inc., Trenton, NJ, USA), and gentamicin were administered. Postoperatively, all patients received topical steroid, antibiotic and mydriatic eye drops. The IOL power was calculated using the method described by Binkhorst and van der Heijde in 1976\textsuperscript{4,5}, with the use of ultrasound A-scan and keratometry of the traumatic eye and fellow eye. The IOL power ranged from 18 to 24D (Table 1).

**RESULTS**

All eyes had a perforating trauma from various objects. The length of the corneal scar varied from 6 mm to 12 mm, the iris injury from a traumatic mydriasis to a 5- to 6 o’clock defect. One green, one blue, and three brown lenses were implanted (for more IOL details, see Table 1).

The mean follow-up period was 8.9 years (range, 4.9-12.4). The mean age at implantation of the Artisan iris reconstruction IOLs was 9.5 years (range, 7.7-12.7). Information about patients’ sex and laterality appears in Table 2. Visual acuity improved in two of five eyes, remained stable in two eyes, and decreased from counting fingers to hand movements in one eye. The final best spectacle-corrected visual acuity is given in Table 3. The mean spherical equivalent refraction error at last follow-up was −4.0 D (range, −4.5 D to −3.25 D; Table 3).

At last follow-up, the iris reconstruction IOL was still in place in three patients (Cases 1, 2, and 4). They used sunglasses in the summer but did not report photophobia. These three patients also mentioned a satisfactory cosmetic outcome. Although initially the results were good (both cosmetic and regarding the photophobia) in Case 3, the IOL luxated spontaneously and was replaced by an Artisan aphakia IOL (Ophtec, Groningen,
Because of urgent surgery, no custom-made IOL was available at the time. In Case 5, the IOL was exchanged for an Artisan aphakia IOL because of a poor cosmetic result attributable to a difference in pupillary diameter and a difference in iris colour between the two eyes.

The endothelial cell density in three operated eyes (Cases 1, 2, and 4) ranged from 1197 to 1967 cells/mm$^2$ (mean, 1648 cells/mm$^2$) and in the fellow eye from 2773 to 2894 cells/mm$^2$ (mean, 2832 cells/mm$^2$). The mean endothelial cell loss, when compared with the nontraumatic, nonoperated fellow eye, was 42% (range, 29–58%) after a mean follow-up of 10.4 years (range, 8.2–12.4 years; Table 4). Comparable percentages of endothelial cell loss in paediatric eyes after traumatic cataract extraction and IOL implantation were reported by Kora et al.$^6$ and Sminia et al.$^7$.

In two patients (Cases 1 and 2), no complications were observed. In two patients (Case 3 and 4), one claw of the iris reconstruction IOL luxated. In Case 3, one claw of the IOL luxated 2.5 years after implantation. The claw could not be reattached. It was exchanged.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Eye</th>
<th>Age at CE (years)</th>
<th>Interval between CE and IOL implantation (years)</th>
<th>Follow-up period (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>OS</td>
<td>7.7</td>
<td>5.0</td>
<td>12.4</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>OS</td>
<td>6.2</td>
<td>2.9</td>
<td>10.6</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>OD</td>
<td>6.4</td>
<td>1.2</td>
<td>8.3</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>OS</td>
<td>6.9</td>
<td>2.8</td>
<td>8.2</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>OD</td>
<td>7.4</td>
<td>1.0</td>
<td>4.9</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td>6.9</td>
<td>2.6</td>
<td>8.9</td>
</tr>
</tbody>
</table>

Table 2. Patient characteristics. F: female; M: male; OD: right eye; OS: left eye; CE: cataract extraction; IOL: intraocular lens.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Preoperative BSCVA</th>
<th>Final BSCVA</th>
<th>Final SE (D)</th>
<th>Complications</th>
<th>Other procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20/80</td>
<td>20/30</td>
<td>-4.5</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>20/200</td>
<td>20/200</td>
<td>-3.25</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>20/400</td>
<td>20/400</td>
<td>-</td>
<td>luxation of claw, twice retinal detachment IOL exchange vitreoretinal surgery</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>20/200</td>
<td>20/100</td>
<td>-4.25</td>
<td>luxation of claw after blunt trauma</td>
<td>re-enclavation of claw</td>
</tr>
<tr>
<td>5</td>
<td>CF</td>
<td>HM</td>
<td>-</td>
<td>poor cosmetic result prolonged uveitis high IOP keratopathy</td>
<td>IOL exchange glaucoma surgery</td>
</tr>
</tbody>
</table>

for an Artisan aphakia IOL at the time of surgery. One claw of this Artisan aphakia IOL also luxated two years and three months later. As the result of poor patient compliance, the claw could not be replaced immediately. Three months later, a rhegmatogenous retinal detachment was diagnosed. The claw was reattached and, in the same surgical session, vitreoretinal surgery was performed. The patient underwent three additional vitreoretinal procedures, including injection with silicon oil. At last follow-up, 3.5 years later, the standard Artisan aphakia IOL was still in place and the retina was attached. In Case 4, one of the claws luxated four years after implantation as the result of a blunt trauma (ie, finger in the eye). The claw was reattached surgically, and the IOL remained in place at last follow-up, ie, four years later.

In one patient (Case 5), a persistent anterior uveitis and a raised intraocular pressure of up to 30 mm Hg occurred during the first postoperative year. This eye had the most severe initial anterior segment damage of all patients in this study, including a corneoscleral scar of 12 mm, extending into the sclera at both sides of the cornea. Because of difference in colour and pupil diameter between the iris reconstruction implant and the iris of the fellow eye, the cosmetic results were unsatisfactory in this patient. The Artisan Iris Reconstruction implant was exchanged for an Artisan aphakia IOL one year after implantation. At the same time goniotomy was performed. Finally, this eye developed calcific band keratopathy, which resulted in a decrease of the visual acuity. The intraocular pressure remained below 20 mm Hg without further treatment. The patient and her parents chose to not have further surgical treatment. At last follow-up, four years later, the Artisan aphakia IOL was still in place.

**DISCUSSION**

In 2003 Hanumanthu et al. published the first case report on traumatic aniridia and aphakia treated with an Artisan Iris Reconstruction IOL, with encouraging results and a follow-up of 10 months. We report on the same implant in children, with a follow-up of at least 4.9 years. The Artisan aphakia IOL has a unique design in that it is attached to the midperipheral iris stroma by means of claws and therefore does not need angle
support, pupil fixation, or transscleral sutures. Sulcus-sutured IOLs are considered a more acceptable alternative for ciliary sulcus implantation of posterior chamber IOLs, in the absence of capsular support in children. However, in sulcus-sutured IOLs concerns exist about the risk of conjunctival and scleral erosion of scleral sutures leading to infection or endophthalmitis, IOL tilt, vitreous, or ciliary body hemorrhage, and secondary glaucoma. To the best of our knowledge, no data are available longer than three years after implantation of sulcus-fixated posterior chamber IOLs in children.

In the current literature, there are promising reports of black iris diaphragm posterior chamber IOLs for the treatment of congenital or traumatic aniridia in adults. In 1994 Sundmacher et al. first reported on black iris diaphragm aphakia IOL (Morcher GmbH) implantation for correction of traumatic and congenital aniridia. They encountered persistent low-grade anterior segment inflammation and secondary glaucoma. Thompson et al. reported a series of seven patients, using a modified design, smaller, black iris diaphragm aphakia IOL (Morcher GmbH) for traumatic aniridia. Of these cases, two developed secondary glaucoma requiring trabeculectomy. One case developed infectious endophthalmitis, and another case was complicated by persistent postoperative inflammation and a vitreous and anterior chamber hemorrhage. Burk et al. described Morcher artificial iris implants of various designs, some of which included IOL power integrated into the implant, for treating aniridia of various origin. In one of seven eyes, implanted with a single piece black diaphragm IOL, persistent uveitis was reported. In our study one case was complicated by prolonged postoperative anterior uveitis and secondary glaucoma. The glaucoma was surgically treated.

Pozdeyeva et al. report the results of a posterior chamber iris-lens diaphragm in 20 eyes of adult patients with aniridia and aphakia. Their most complicated cases were among six eyes in which transscleral sutures were used. They report one case of intraoperative vitreous hemorrhage, two cases of postoperative hyphema, one case of chronic low grade inflammation, and one case of cystoid macular edema. The mean follow-up in this series was six months.

In anterior chamber IOLs, as the Artisan Iris Reconstruction IOL, concern exists about corneal endothelial cell loss. In our series three of five eyes for which data were available showed a substantially lower endothelial cell count compared with the normal fellow eye. Photographs of the endothelium were obtained at last follow-up. Serial cell counts were not available. We recommend serial endothelial cell counts to detect possible progressive cell loss for further studies on the Artisan Iris Reconstruction IOL.

The Artisan Iris Reconstruction IOL can be used in the absence of capsular support with significant traumatic aniridia. This means that the IOL can be used for eyes with severe anterior segment injury. One should take into account that any eye in need for such repair has a history of extensive perforating trauma and a risk of late complications regardless of IOL implantation. Even for an experienced surgeon it can be difficult to judge the feasibility to attach the claws of the lens to the remaining iris tissue. In our
patient group, two claws luxated at least two years after implantation. One occurred spontaneously (Case 3); the other resulted from a blunt trauma (Case 4). In retrospect, we may conclude that most of the iris tissue in Case 3 was too atrophic for inclavation in the claws, leading to luxation of the Artisan Iris Reconstruction IOL. To reduce the risk of traumatic dislocation of the IOL, protective spectacle wear should be advised in contact sports.

Our long-term clinical outcome shows that the Artisan Iris Reconstruction IOL is a treatment option for the treatment of aniridia and aphakia caused by penetrating ocular trauma in children. The main problem in our patient group appeared to be the rate of complications. Partial luxation of the IOL occurred in two cases; one case was complicated by persistent anterior uveitis and secondary glaucoma; one eye developed a retinal detachment. We emphasize the high-risk characteristics of eyes treated with this IOL, due to the severe initial anterior segment trauma. Careful patient selection and the surgeon’s experience with patient selection and insertion of the IOL are considered important factors in the outcome of the implantation of the Artisan Iris Reconstruction IOL.
REFERENCES