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The artificial iris – Analysis of various implantation techniques after ocular trauma

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Purpose: The aim of this study is to analyze the outcome of various techniques for a custom-made iris prosthesis implantation as part of reconstructive anterior segment surgery following traumatic aniridia. **Methods:** This retrospective interventional study was done for 6 eyes that received an artificial iris as secondary reconstructive measure for photophobia and unsatisfactory vision following initial globe repair. Different implantation techniques were employed. These included simple sulcus implantation, implantation of a composite (iris prosthesis with attached intraocular lens) implant, and combinations with phacoemulsification, vitrectomy, and penetrating keratoplasty. **Results:** In all cases, the artificial iris was implanted successfully. In the follow-up period (1–48 months), postoperative complications included rhegmatogenous retinal detachment, prolonged intraocular inflammation, and corneal transplant decompensation due to graft rejection. There was no case of secondary glaucoma. Complications could be managed successfully. All patients showed improved best-corrected visual acuity and were satisfied with functional and cosmetic results. **Conclusion:** This case series highlights the different implantation techniques for reconstruction of the anterior segment after ocular trauma. The versatility of the custom-made iris implant accounts for a wide range of applications and the foldable material reduces the need for large incisions in the already traumatized eye.

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Traumatic iris defects may cause severe ocular discomfort after blunt or penetrating injury to the eye.[1,2] In complex cases, they can be associated with other pathologies such as corneal scars, traumatic cataract, glaucoma, and posterior segment complications. Often these eyes have to undergo more than one surgery until final rehabilitation is achieved.[3,4] In cases with insufficient iris tissue for primary repair, an iris prosthetic device can be implanted to reduce photophobia and improve visual acuity.[1]

The device used in our series is the Artificial Iris Customflex® (henceforth referred to as AI, Human Optics, Erlangen, Germany). The implant is not for cosmetic eye color change but a prosthesis for functional ocular rehabilitation. It is a purely posterior chamber device and not to be implanted in phakic eyes.

In this article, we would like to introduce some implantation techniques of this device in various challenging cases.

Methods

In our retrospective interventional study, six patients with ocular injuries and subtotal or total iris loss were operated on with the implantation of an AI to reconstruct the anterior segment. Main indications for iris reconstruction were photophobia and reduced vision. Ethics Committe approval has been obtained and granted EKNZ August 3rd 2017. Number 2017-00937.

The AI by Human Optics, Germany, has been in use since 2002 and has been approved by the United States Food and Drug Administration (FDA).[5,6] It is made of a silicone elastomer with a smooth black posterior surface and a customizable anterior colored surface with pigments integrated into the silicone. Its structure mimics that of the natural iris. Photographs of the healthy eye serve as template to match the color and give the maximum possible cosmesis. It is also available in certain standard colors (e.g. four different shades of brown). The implant can be reinforced with a polymer mesh, giving it more rigidity and stability for suture fixation.

The implant is intraoperatively trephined to the appropriate size using corneal trephines and taking the white-to-white diameter as reference. It can be placed into the capsular bag or into the sulcus if there is enough support. In cases without sufficient support, suture fixation can be done. Sutures described for fixation involve 10-0 nylon, 9-0 polypropylene, and 8-0 GoreTex®. The pupil diameter is 3.35 mm. As the AI is made of silicone, it can be folded and implanted through a small clear corneal incision, reducing the intraoperative trauma to the eye.

Included in this study were three male and three female

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patients between 24 and 78 years of age. All eyes were posttraumatic, three following penetrating injury, two following blunt injuries with globe rupture, and one following blunt injury without globe rupture.

The follow-up period ranged between 1 month and 4 years.

Patient 1 (D.H.), a 69-year-old male, had undergone wound repair following globe rupture elsewhere. Seven months after the event he underwent phacoemulsification with intraocular lens (IOL) implantation and 23-gauge pars plana vitrectomy (23g PPV) along with simple AI implantation into the sulcus [Fig. 1].

Patient 2 (C.S.), a 56-year-old male, had a penetrating injury with primary corneal suturing and iris resection done elsewhere. One month later, phacoemulsification with IOL implantation into the capsular bag along with 23g PPV was performed for traumatic cataract. Artificial iris implantation with suture fixation (10-0 nylon) was done 3 months after the initial trauma for subtotal traumatic aniridia [Fig. 2].

Patient 3 (S.W.), a 78-year-old female, had sustained a globe rupture with complete loss of iris and lens. Nine months after the initial wound repair, done elsewhere, an AI-IOL composite implant was placed with suture fixation (10-0 nylon) through a clear corneal approach [Fig. 3].

Patient 4 (G.M.), a 23-year-old female, sustained a severe globe contusion with iris destruction and lens-subluxation and underwent phacoemulsification without IOL-implantation, iris suturing, and anterior vitrectomy. After 7 months, she underwent 23g PPV with implantation of a retropupillary iris claw lens into the iris remnants. After another contusion to the eye 5 years later, the iris claw lens dislocated into the vitreous and was removed via 23g PPV. In order to partially correct the corneal astigmatism of 6 diopters (D), a toric, single-piece acrylic sclera-fixated Carlevale® IOL was implanted along with a suture-fixated (9-0 polypropylene) AI iris prosthesis [Fig. 4].

Patient 5 (B.K.), a 47-year-old female, had a penetrating hammer-chisel type injury with a metallic intraocular foreign body (IOFB). Primary wound repair along with lens aspiration, 23g PPV, and removal of IOFB was performed. She subsequently developed a retinal detachment (RD), which was managed with encircling band, Re-PPV, and silicone oil endotamponade. Two years after the initial event, anterior segment reconstruction was performed with implantation of a suture fixated (10-0 nylon) AI with attached posterior chamber IOL and penetrating keratoplasty (PK).

Patient 6 (A.A.), a 80-year-old male, had sustained a penetrating injury with intraorbital foreign body at age 53. He was known to have primary open angle glaucoma (POAG) with a significant optic atrophy and presented to us with dense cataract and significant glare due to traumatic aniridia. Phacoemulsification with IOL implantation was done 30 years after the initial event, and an artificial iris implantation was performed as a secondary procedure a month after cataract surgery.

Results

Patient 1: Postoperative inflammation was prolonged and could be managed with topical steroids, which were gradually tapered over 1 year. Preoperative best-corrected visual acuity (BCVA) was 6/30, which improved to 6/7.5 at the last follow-up 4 years after surgery. Intraocular pressure was always within normal limits.

Patient 2 developed RD with proliferative vitreoretinopathy approximately 1 month following artificial iris implantation. Typically, 23g PPV with gas-endotamponade was performed successfully with the implant in place. At last follow-up (3 years), he was very satisfied with the result. Visual acuity had improved from 6/18 before AI implantation to 6/6 postoperatively.

Patient 3: Immediate postoperative visual acuity was 6/60 (preoperative 6/120). Due to progression of her preexisting age-related macular degeneration, there was subsequent decrease in BCVA to count fingers.

Patient 4: The preoperative BCVA improved from 6/15 (refraction: +14.0/-6.0/10°) to 6/6 (refraction: +1.0/-2.25/23°) with reduction of photophobia. There were no complications and the patient was very satisfied. The preoperative astigmatism was corrected to a significant degree by the toric IOL.

Patient 5 had the most prolonged course. After anterior segment reconstruction, there was graft rejection of the corneal transplant with subsequent corneal decompensation for which human leucocyte antigen-typed revision PK was done 3 years after the initial PK. Her BCVA improved from 6/95 prior to anterior segment reconstruction to 6/60 4 years later. At the last follow-up, she was under treatment with topical steroids and cyclosporine. Poor visual outcome was also due to a macular scar resulting from the initial impact of the IOFB on the retina.

Patient 6: Preoperative BCVA (perception of hand movement) did not improve after surgery due to the glaucomatous optic atrophy, but the patient was very satisfied with the marked decrease in photophobia and improvement in cosmesis. He developed mild chronic iritis and is currently under treatment with topical steroids.

The time of reconstructive surgery after initial trauma repair ranged from 3 months to 30 years. At the time of surgery, three patients were aphakic, two were pseudophakic, and one eye presented with a nuclear cataract, which was operated in the same sitting. The number of surgeries the eyes underwent for the initial trauma and complications thereof ranged between one and four.

Simple sulcus implantation between the iris remnant and the IOL was possible in two of the six cases. In four eyes, the AI had to be sutured into the sulcus due to inadequate anterior and/or posterior support. In two of these cases, a three-piece IOL was first sutured to the posterior surface of the implant with 10-0 nylon and then introduced into the eye as a lens–iris composite implant.

The implantation of the AI was combined with phacoemulsification and pars plana vitrectomy in one case. In four other patients, vitrectomy had been carried out prior to AI implantation because of vitreous hemorrhage (two eyes), RD (one eye), and in one case at the time of implantation of a retropupillary iris claw lens. In one eye, a simultaneous PK was performed due to central corneal scars.

The results are summarized in Table 1.

Discussion

This cross-sectional study highlights the different implantation techniques and versatility of the AI implant.

Traumatic aniridia can lead to decreased visual acuity because of glare and spherical aberration.[2] Different types of iris prostheses have been introduced so far to improve the results of reconstructive surgery. There are capsular tension ring-based prosthetic segments which have been described in

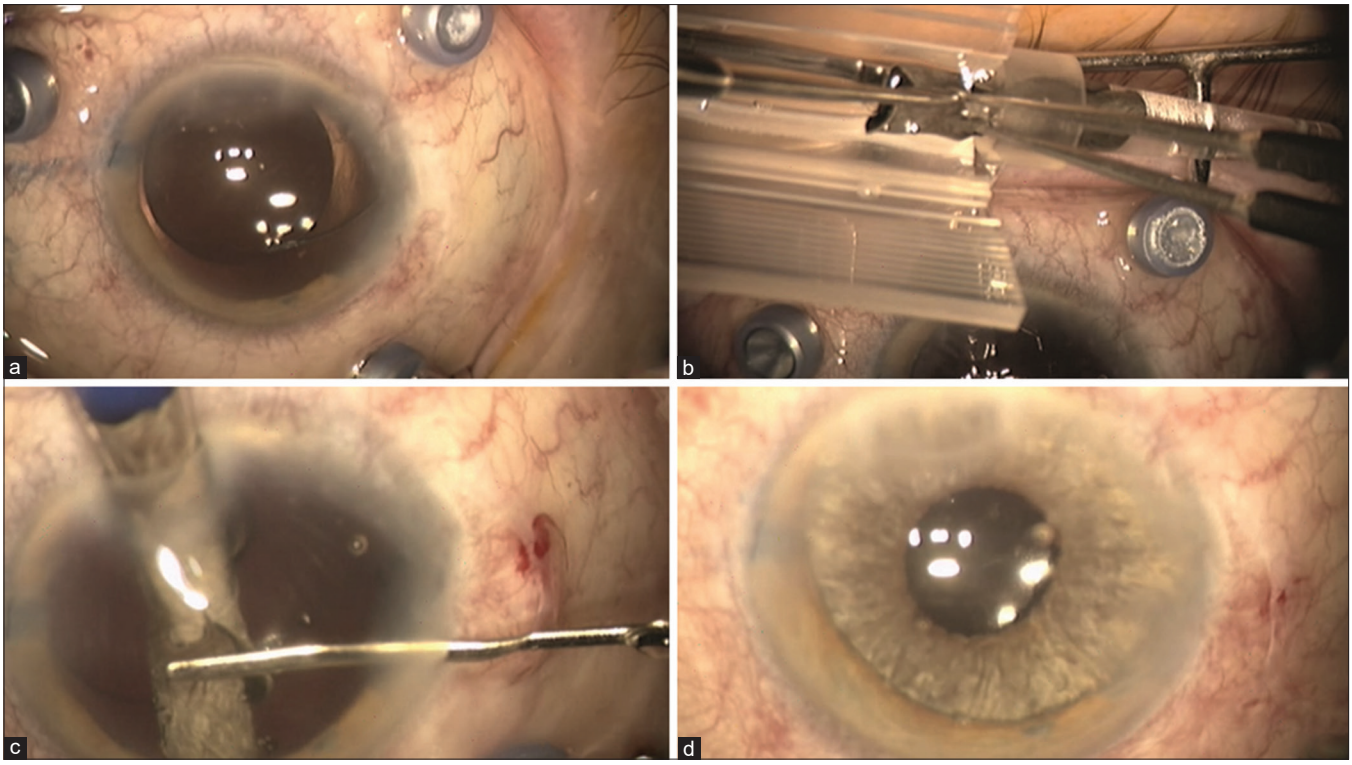

Figure 1: Patient 4 (D.H.): (a) At the end of phacoemulsification and pars plana vitrectomy: Pseudophakia, 160º aniridia, the remaining iris tissue is mydriatic. Slight decentration of the IOL (in the capsular bag), (b) Prepared implant is placed into a standard cartridge, (c) Injection of the implant into the sulcus with a second instrument held anteriorly for protection of the corneal endothelium, and (d) Implant in place, residual recipient-iris tissue is visible anterior to the implant as crescent from 3 to 10 o'clock position. No additional suture fixation was required due to adequate anterior and posterior support. Patient 6 (A.A.) underwent a similar procedure

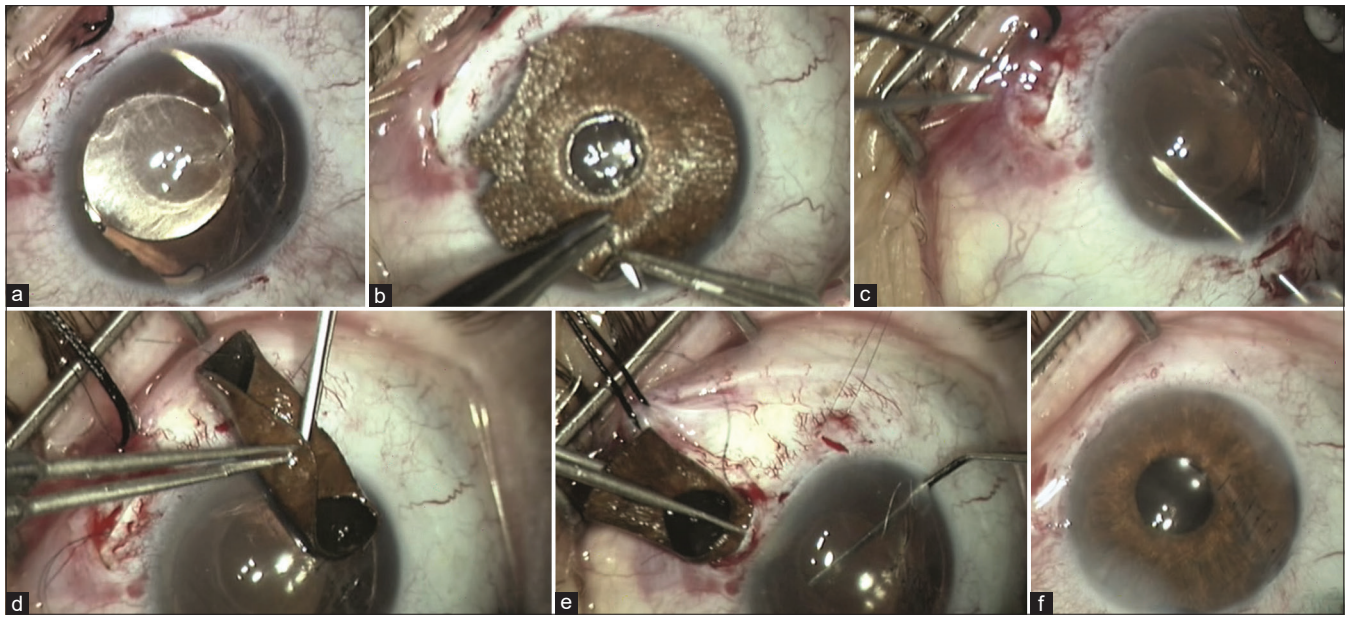

Figure 2: Patient 3 (C.S.): (a) Pseudophakia, complete aniridia, slight decentration of the IOL (in the capsular bag), (b) Placement of 10-0 Nylon suture to the implant, and (c) The sutures are preplaced into the eye before introduction of the implant. For this, the suture is introduced into a 27g needle, which is inserted into the eye at 1.5 mm from the limbus and into a scleral tunnel, (d) The implant is rolled between two forceps and (e) introduced into the eye via a 3 mm sclero-corneal incision. (f) implant in place. Suture fixation was carried out due to missing anterior support (no residual iris tissue) in the recipient

Table 1: Postoperative results in our cohort. Visual acuity was guarded in three cases because of associated pathologies

Patient	Pre-OP BCVA	Post-OP BCVA (time post-OP)	Complication	Associated pathology for guarded visual prognosis
1 (D.H)	6/30	6/7.5 (4 years)	Prolonged inflammation	
2 (C.S.)	6/18	6/6 (3 years)	Retinal detachment	
3 (S.W.)	6/120	6/60 (2 weeks), CF (4 years)	None	ARMD
4 (G.M.)	6/15	6/6 (1 month)	None	
5 (B.K.)	CF	6/60 (4 years)	Graft rejection	Keratoplasty, macular scar
6 (A.A.)	HM	HM (2 years)	None	Glaucomatous optic atrophy

BCVA - best-corrected visual acuity (Snellen's), CF - counting fingers, HM - hand movement, ARMD - age-related macular degeneration

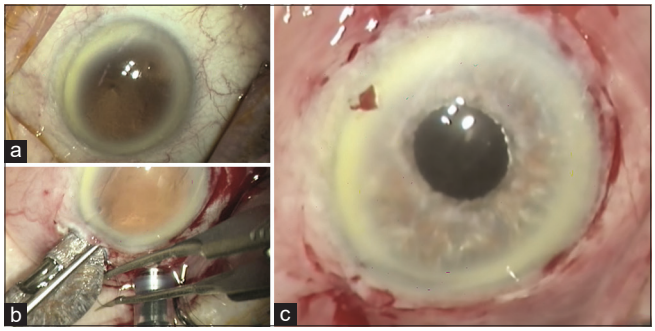

Figure 3: Patient 5 (S.W.): (a) Aphakia, complete aniridia, (b)10-0 nylon sutures have been preplaced into the eye; prepared implant (Customflex®/IOL composite) is folded and introduced into the eye via a 5 mm sclero-corneal incision (the IOL was sutured to the posterior surface of the implant with 10-0 Nylon), (c) Implant in place. Suture fixation was carried out due to missing anterior and posterior support (no capsular bag, no residual iris tissue) in the recipient

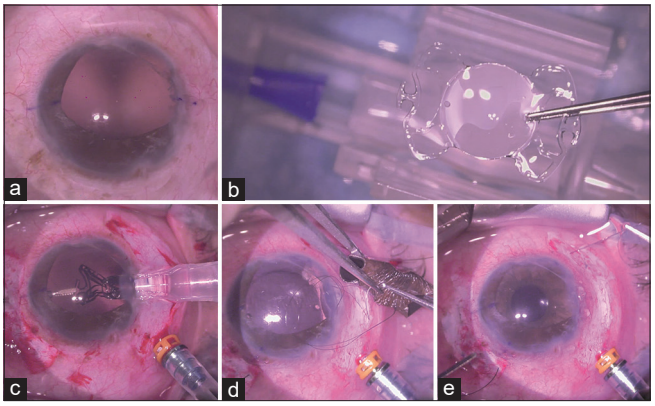

Figure 4: Patient 1 (G.M.): (a) Aphakia, partial aniridia, and traumatic mydriasis, markings for externalization of toric IOL done at 0° and 180°. (b) Toric Carlevale® IOL placed into the shooter, (c) IOL injected into the eye through 2.3 mm clear corneal incision and leading haptic externalized with a 23g forceps introduced through sclerotomy, (d) Customflex® implant with preplaced 9-0 Nylon sutures introduced into the eye, and (e) At the end of the surgery.Suture fixation was carried out because of inadequate support anteriorly (180° peripheral iris loss). A knotless technique using intrascleral Z-sutures was used so that no additional scleral pockets were needed

detail and full prosthetic implants with or without an optic for the correction of associated aphakia.[7] The main disadvantages of these are the large incision needed for implantation and the lack of adequate cosmesis with a black colored device.[8,9]

There are two foldable colored, silicone-based iris implants available:

Bright ocular iris implants® were developed for cosmetic change of iris color in normal eyes. The implantation was therefore in phakic eyes into the anterior chamber, which resulted in disastrous complications such as secondary glaucoma and uveitis.[10-13] However, there have been some case reports detailing posterior chamber implantation in pseudophakic and aphakic eyes for reconstructive purposes with good results.[14]

In our study, we have used the AI in cases with partial and complete aniridia as well as in pseudo- and aphakia.[15-18]

All our patients benefitted from the procedure. Four patients showed improvement in BCVA as well as in reduction of glare. In two patients, the visual acuity did not improve because of ocular comorbidity. Some case series have demonstrated visual improvement after iris reconstruction, whereas others could not demonstrate improvement in visual acuity.[19-21]

We performed a simple AI implantation into the sulcus (without suture fixation) in two cases. In both cases, the implantation was done via a clear corneal incision and with a standard IOL-shooter (cases 1 and 6). Anterior support was considered adequate if peripheral iris remnant was present for at least 7–8 clock hours. Posterior support was considered adequate if the capsular bag was intact or if there was a stable sulcus-fixated IOL (case 4). Suture fixation to the sclera was required in four cases due to inadequate anterior and/or posterior support.

Prior to the implantation, the patients had already undergone between one and four surgeries (mean 2.2 ± 1.2). Three patients were aphakic, two pseudophakic, and one had a cataract.

In two of the six cases, a composite implant (iris + IOL) was placed for correction of coexisting aphakia from trauma (one eye) or previous surgery (one eye). Composite implants can be obtained with suturing the IOL to the posterior surface of the AI implant or a haptic tuck.[15,16] We sutured the IOL onto the implant.

In case 4, aphakia was simultaneously corrected with placement of a toric sclera-fixated IOL (Carlevale® IOL, Soleko, Italy). To the best of our knowledge, this is the first case report of a toric Carlevale-IOL® combined with an iris prosthesis.

Aphakia correction can also be obtained with standard sclera-fixated IOLs, for which various techniques have been described, most notably the sutured IOL and forms of intrascleral haptic fixation (e.g. glued IOL, Yamane technique).[17] One case describes the placement of an artificial iris in an eye with an anterior chamber iris claw lens in place.[22]

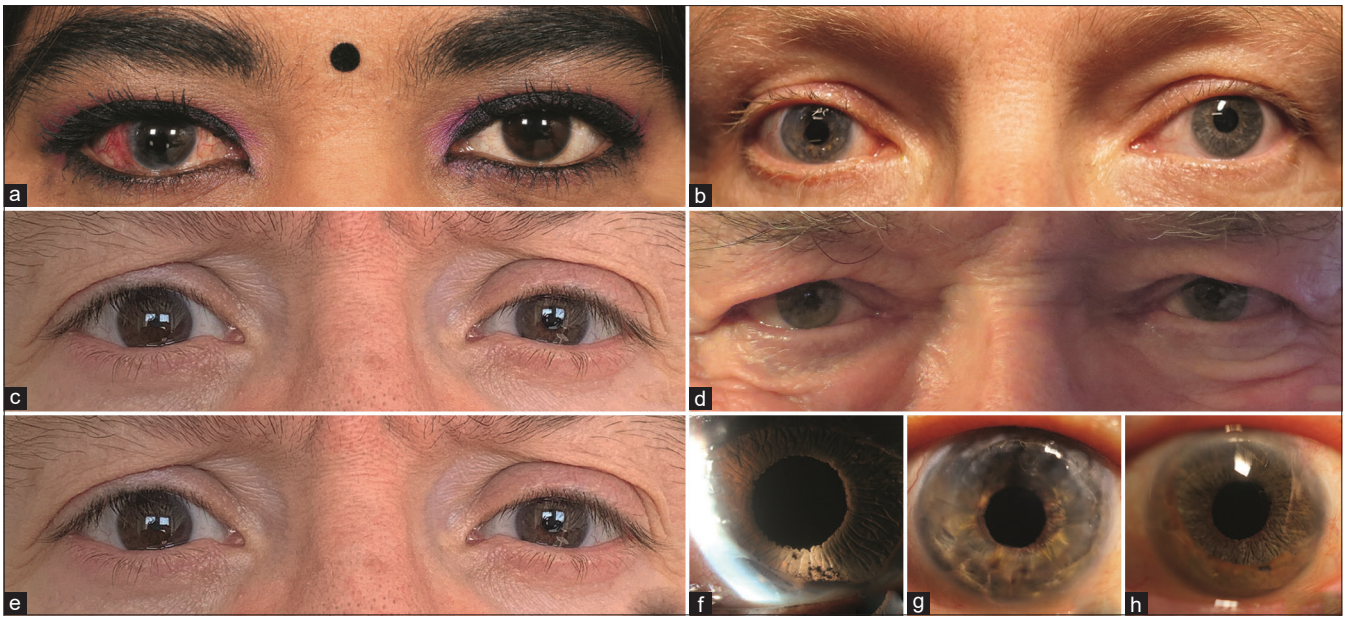

Figure 5: Postoperative pictures of patients 1–4 and 6 (a-e, pictures of case 5 not available), both eyes in straight gaze and the operated eye in detail of cases 1, 2, and 4 (f–h, respectively)

In combination with sclera-fixated IOLs, we prefer to suture the iris prothesis in two additional points to avoid decentration and subsequent irritation of the residual iris and ciliary body which might result in uveitis.

Postoperatively, patient 5 developed corneal graft rejection which ultimately led to the necessity of a graft exchange. Loss of endothelial cells following artificial iris implantation leading to corneal decompensation has been found to occur in 4–10% of cases.[17,23] Nevertheless, incidence for corneal graft rejection in high-risk cases such as posttrauma can be as high as 35% at 3 years.[24] Preoperative specular microscopic analysis may be a valuable adjunct to evaluate the corneal endothelial status prior to AI implantation, aiding in the assessment of possible postoperative complications.

One patient (case 2) developed RD 1 month following artificial iris implant. The surgery (23g PPV using a BIOM® viewing system with a 90-D lens) was done through the 3.35 mm "pupil" without difficulty. Visibility of the peripheral retina was not limited. This has been confirmed by other authors.[17] RD or peripheral retinal tears after AI implantation was described in 1% of cases in the large multicenter FDA approval study.[25] Because globe injury itself does predispose to this complication, no differentiation can be made between prosthesis-induced RD and trauma-induced RD.[26]

Two patients (cases 1 and 6) developed prolonged intraocular inflammation which was treated with topical steroids and nonsteroidal antiinflammatory agents. In other series, chronic iritis developed in 4% of cases and it has been shown that Customflex® implants with mesh can have sharp ragged edges, possibly leading to prolonged inflammation or cystoid macular edema. It is therefore advisable to use a sharp, single-use trephine to obtain smooth edges.[23,25,27] In our opinion, chronic or relapsing uveitis, especially in young patients, should be seen as a relative contraindication to implanting the device.

We did not observe severe dislocation of the iris implant needing repeat surgery. The implant in case 4 is slightly decentered, but there is no functional deficit, and the patient is satisfied. The postoperative results can be seen in Fig. 5.

We also did not observe the development of glaucoma or pupillary block. The latter is prevented by fashioning multiple "iridectomies" in the implant. In the FDA approval study, 8% of patients showed elevated IOP, which was described as mainly due to preexisting conditions such as POAG. The authors found only one IOP-elevation (0.2%) to be implant related.[25] We would be conservative with the indication for an artificial iris in a known glaucoma case, but we would not see it as an absolute contraindication. The authors feel though that implantation in young patients with congenital or posttraumatic glaucoma should be used with extreme caution.

To date, none of the implants in our cohort had to be removed for postoperative complications.

The FDA certification study looked at one arm of pediatric patients who received the implant for congenital or traumatic aniridia as well as for anterior segment dysgenesis and found a similar implant-related risk profile as compared to the adult study population.[25] Nevertheless, we would recommend caution in these cases.

This case series highlights different implantation techniques for a custom-made silicone iris prosthesis and offers some insight into its possible uses in anterior segment reconstruction following severe trauma to the globe.

The indication for an iris prosthesis, independent of the device chosen, has to take the patient's symptoms, activities, age, and comorbidities of the eye into account. We have discussed several possible complications associated with a foldable silicone iris prosthesis in traumatic aniridia. These are largely caused by an additional foreign body in the eye, the surgery needed for implantation, the localization of the implant, and comorbidities due to the initial trauma.

Alternatives for an iris prosthesis are iris print contact lenses or tinted glasses if there is significant photophobia due to aniridia. These conservative measures avoid any

intraocular implantation and are a mainstay treatment in these cases. Nevertheless, tinted glasses my not be an acceptable alternative and in many cases long-term acceptance of iris print contact lenses is limited due to ocular surface irritation, the need for removing contact lenses on a daily basis, cost factors (depending on the health care system in place), and difficulty in handling contact lenses in elderly patients.

In general, the decision for or against an iris prosthesis should be done on an individual basis considering the alternatives. This thought process is applicable also when considering secondary IOL implantation. If the decision for an iris prosthesis has been made, we are of the opinion that a foldable device which can be implanted through a small incision might be a better alternative to rigid prostheses. There are iris prosthetic segments that can be inserted through a small incision, but often these can be implanted only into an intact capsular bag. In complete aniridia, there may be more than one implant needed in addition to the IOL, making the possibly unstable bag heavier. There are two foldable complete iris prostheses, one originally designed for changing eye color and available in ready-made colors, and the other, AI, which was used in our series. In our opinion, the latter provides superior cosmesis as it can be custom made for the eye color of the patient and mimics the iris structure.

Conclusion

The AI implant is a versatile iris prosthesis that can be utilized in partial or complete aniridia. The implant is used in pseudophakic or aphakic eyes strictly for placement in the posterior chamber for functional indications and not for cosmetic change of iris color.

In this case series, we demonstrate some implantation techniques (simple sulcus implantation, suture fixated, composite graft with posterior chamber IOL, open-sky implantation and combination with a toric sclera-fixated IOL) in six eyes with traumatic aniridia.

All patients benefitted from the surgery, most of them with improved visual acuity, and reduction in photophobia.

We also have to consider significant comorbidities in these traumatized eyes and a higher incidence of complications. There is definitely a learning curve, but we feel that the major plus points of the Customflex® remain the versatility, implantation via a small incision and superior cosmesis. It is therefore a valuable contribution to the armamentarium of anterior segment reconstruction and should be considered in traumatic aniridia.

Due to the small number of cases presented, we cannot draw any conclusions regarding the safety profile or efficacy of the implant. Since our main aim is descriptive, we feel that this fact does not limit the studies' statements.

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Conflicts of interest

There are no conflicts of interest

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