Implantation of a small-aperture intraocular lens and a partial aniridia implant in eyes with traumatic iris defects

Hyeck-Soo Son, Timur Yildirim, Ramin Khoramnia, Grzegorz Labuz, Christian Mayer, Gerd U. Auffarth*

David J. Apple International Laboratory for Ocular Pathology and International Vision Correction Research Centre (IVCRC), Department of Ophthalmology, University of Heidelberg, Heidelberg, Germany

ARTICLE INFO

Keywords:
- Traumatic iris defect
- Small aperture IOL
- Partial aniridia implant

ABSTRACT

Purpose: To report the clinical outcomes after implantation of a small-aperture intraocular lens (IOL) and a partial aniridia ring in three patients with traumatic iris defects.

Observations: The corrected distance visual acuity (CDVA), irregular astigmatism, and glare improved in all patients. In one patient, the monocular defocus curve showed a visual acuity (VA) of 0.30 logMAR or better from 1.0 to −1.5 D, and the halo size and intensity were 5 and 10 (on a scale from 0 to 100), respectively, and the glare size and intensity were 23 and 16 (on a scale from 0 to 100), respectively.

Conclusions and importance: The pinhole effect of the small-aperture IOL helped considerably decrease irregular astigmatism and improve visual acuity. The partial aniridia implant also contributed to the reduction of the glare symptoms, while allowing a sufficient fundus assessment. The combined implantation of the small-aperture IOL and the partial aniridia device, therefore, presents an effective option for improvement of the visual symptoms in patients with traumatic iris defects.

1. Introduction

Ocular injury resulting in a traumatic iris defect is not uncommon and patients present with reduced visual acuity, glare, photophobia, and bothersome cosmetic appearance. Depending on the severity of the injury, its management can be quite challenging.

Currently, there are various types of treatment options available. For patients who show contact lens tolerance, colored contact lens wear may lead to temporary relief of the symptoms. Corneal tattooing has also been reported to improve both cosmetic appearance and visual impairment; however, this method is associated with potential complications such as granulomatous keratitis, iridocyclitis, and persistent epithelial defects. Surgical management may offer more long-term benefits. While small sectorial defects can be repaired by sutures, larger injuries require implantation of artificial iris prostheses for surgical iris reconstruction.

If cataract surgery is also planned, the choice of IOL is particularly difficult in such patients. Simply implanting a monofocal IOL may not sufficiently alleviate the photophobic symptoms induced by aniridia. Furthermore, surgeons are generally reluctant to implant toric or multifocal IOLs due to the irregularity of the corneal astigmatism and potential presence of capsular bag defects.

Recently, a novel small-aperture intraocular lens (IOL) IC-8 (Acufocus, Inc., Irvine, CA) has been introduced to the market. Its optical principle is based on the corneal KAMRA® inlay, which utilizes the pinhole effect to prevent unfocused peripheral light rays from reaching the retina. In the case of ametropia, a pinhole lens not only reduces the size of the retinal blur spot, thereby improving the visual resolution, but also minimize the sensitivity to light. In this study, we report three cases in which this small-aperture technology was used in combination with a partial aniridia ring (Type 96G, Morcher GmbH, Stuttgart, Germany) to address the iris tissue defect and its related symptoms.

* Corresponding author. International Vision Correction Research Centre (IVCRC), Dept. of Ophthalmology, Univ. of Heidelberg, INF 400, 69120, Heidelberg, Germany.

E-mail addresses: HyeckSoo.Son@med.uni-heidelberg.de (H.-S. Son), Timur.Yildirim@med.uni-heidelberg.de (T. Yildirim), Ramin.Khoramnia@med.uni-heidelberg.de (R. Khoramnia), Grzegorz.Labuz@med.uni-heidelberg.de (G. Labuz), Christian.Mayer@med.uni-heidelberg.de (C. Mayer), Gerd.Auffarth@med.uni-heidelberg.de (G.U. Auffarth).

URLs: http://www.ivcrc.com, http://www.djapplelab.com (G.U. Auffarth).

https://doi.org/10.1016/j.ajoc.2020.100673
Received 15 July 2019; Received in revised form 20 November 2019; Accepted 14 March 2020
Available online 17 March 2020

2451-9936/ © 2020 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/BY-NC-ND/4.0/).
1.1. Findings

1.1.1. Surgical technique – cases 1–3

The surgical procedure was standardized in all patients. After skin disinfection and placement of the lid speculum, two paracenteses were performed at 7 and 11 o’clock. As recommended by the manufacturer of the IC-8 IOL, a 2.4 mm wide corneal incision was made. In our study, the incisions were performed on-axis to have a positive influence on the astigmatism-reducing effect. A dispersive ophthalmic viscoelastic device (OVD) (Viscoat, Alcon, Fort Worth, TX, USA) was inserted into the anterior chamber and capsulorhexis was performed, followed by hydrodissection, hydrodelineation, and phacoemulsification of the lens. After polishing and injecting a cohesive OVD (Healon GV, Johnson & Johnson, Santa Ana, CA, USA) into the capsular bag, the corneal incision was enlarged to 4.5 mm to allow the implantation of the iris-segment capsular tension ring (CTR), which was carefully inserted into the accoring iris quadrant. Then, the small-aperture IC-8 IOL, which requires a 3.5 mm wide corneal incision according to the manufacturer, was implanted underneath the iris device and centered in the optical axis. The remnant OVD was removed and the two paracenteses were hydrated. Cefuroxime was injected intracameral. The corneal incision was sutured using 10–0 nylon sutures.

In this study, all surgeries were performed without any intraoperative or postoperative complications.

1.1.2. Case 1

A 63-year-old man was seen in consultation with our clinic complaining of increasing glare sensitivity in his left eye. The patient reported a history of a nail injury on the affected eye 49 years ago. He had previously been treated with an iris-print contact lens; however, he did not “tolerate it very well” and thus sought for a second opinion.

The slit-lamp examination of the anterior segment revealed a corneal scar at 12 o’clock, traumatic cataract and partial aniridia reaching from 6 to 12 o’clock (Fig. 1A). The right eye showed no pathological findings. Fundoscopy findings as well as the optical coherence tomography (OCT) measurements were unremarkable in both eyes. Corrected distance visual acuity (CDVA) was 0.50 logMAR with a manifest refraction (MR) of −0.75 diopeters sphere (DS)/−1.00 diopeters cylinder (DC) x 56° on the left eye, and 0.00 logMAR with a MR of −0.75 DS/−1.50 DC x 46° on the right eye.

In this patient, the IC-8 IOL with a power of 26.0 D (target refraction of −0.31 D) was implanted. Twenty-one months after the surgery, the patient had an uncorrected distance visual acuity (UDVA) of 0.31 D and a CDVA of 0.10 logMAR with a MR of +0.50 DS/-1.00 DC x 160°. The defocus curve is shown in Fig. 4. The patient reported a subjective improvement of visual acuity and perception of little to no glare sensitivity. Despite having remnant partial aniridia in the superonasal quadrant (Fig. 1B), the patient perceived little to no halos and glare anymore, with halo size and intensity values of 5 and 10 (on a scale from 0 to 100), respectively, and glare size and intensity values of 23 and 16 (on a scale from 0 to 100), respectively (Fig. 5).

1.1.3. Case 2

A 56-year-old male, who suffered a car accident in 1981 with a traumatic injury to the left eye, presented to our clinic complaining of intolerable sensitivity to glare. Due to the perforating nature of the injury, the left eye had undergone a penetrating keratoplasty directly following the incident. He reported that his attempts to reduce the photophobic symptoms by wearing sunglasses during daytime were futile.

In the slit-lamp examination, the affected eye showed a clear corneal graft, partial aniridia from 9 to 1 o’clock, and a corticonuclear cataract (Fig. 2A). The right eye showed a LASIK flap that had been performed just a year ago. The retinal assessment including the OCT scan showed no pathology in both eyes. The UDVA of the left eye was 2.00 logMAR and the CDVA was 0.80 logMAR with a MR of +3.00 DS/-12.00 DC x 76°. The UDVA on the right eye was 0.04 logMAR.

As the patient had high levels of astigmatism and as the previous ocular history made it extremely difficult to perform an accurate biometry, we implanted an IC-8 IOL with a power of 15.5 D and a target refraction of −3.66 D, taking into account the fact that this IOL has been shown to possess high tolerability to astigmatic defocus. Two months after the surgery (Fig. 2B), the left eye showed an UDVA of 1.00 logMAR and a CDVA of 0.52 logMAR with a MR of +2.00 DS/-7.75 DC x 40°. While the patient reported subjective improvement in vision, he was particularly content with the significant reduction in glare sensitivity.

1.1.4. Case 3

A 78-year-old male presented to our clinic complaining of extreme photophobia, epiphora, and worsening visual acuity. He had suffered a perforating ocular injury with a glass shard on his left eye 50 years ago and now wished for a treatment that could relieve his visual symptoms.

The slit-lamp examination of the affected eye revealed a peripheral corneal scar at 6 o’clock, a partial aniridia from 5 to 7 o’clock, and a corticonuclear cataract (Fig. 3A). The fellow eye was pseudophakic and did not show any signs of traumatic injury. Both eyes had unremarkable retinal findings. The UDVA of the left eye was 1.00 logMAR and the CDVA was 0.36 logMAR with a MR of −3.50 DS/−2.00 DC x 10°. The UDVA of the right eye was 0.02 logMAR.

In this patient, the IC-8 IOL with a power of 23.0 D and a target refraction of −0.54 D was implanted. At four-days postoperative follow-up examination (Fig. 3B), the UDVA of the left eye was 0.30 logMAR and the CDVA was 0.20 logMAR with a MR of −0.75 DS in the left eye. The patient expressed high satisfaction with the overall results, reporting that he no longer experiences any glare symptoms. As the patient lives far away from the clinic, however, he wished to have the subsequent postoperative examinations at the private ophthalmologist’s practice near his home.

2. Discussion

Treating eyes that suffered a traumatic injury may be quite challenging. Often times, multiple ocular components are affected,
requiring a comprehensive and individualized treatment. Corneal scarring or opacity can lead to irregular astigmatism, cause stray light, and impede visualization during surgery. Iris defects such as irregular pupil or traumatic mydriasis can reduce the visual quality by inducing higher-order optical aberrations. If the injury also resulted in a traumatic cataract that requires treatment, the accuracy and reliability of IOL power calculation may be undermined by the corneal irregularities.

Previous studies reported clinical results after implementation of different techniques to address the traumatic iris defects. In this study, we report the visual outcomes after implantation of the small-aperture extended-depth-of-focus (EDOF) IOL in combination with a sectorial aniridia ring in patients with iris defects secondary to trauma.

The concept of the small-aperture IOL is based on the well-established optical principles of a pinhole. A small, central pinhole reduces the effective pupil size, thereby leading to a decrease in the size of the blur circle projected on the retina and an increase in the depth of focus. Ogle et al. studied the relationship between the pupil size and the depth of focus and found an inverse relationship between the two, with a 2-mm pupil size showing a much larger depth of focus compared to an 8-mm pupil. Furthermore, a pupil size of less than 2-mm leads to a rapid increase in the depth of focus. By blocking the peripheral cone of rays from entering the eye, a pinhole is also less susceptible to the effects of optical aberrations, presenting a suitable management option for cases of paracentral corneal scarring or irregular astigmatism.

Consequently, the small-aperture IC-8 IOL presents a good treatment option to phakic patients with a traumatic ocular injury as its mask with a central 1.36-mm aperture provides an EDOF effect and high tolerance to the problems associated with optical aberrations and corneal irregularities. Ang measured the IC-8 IOL’s levels of tolerability to astigmatic defocus and observed a visual acuity of 20/25 or better even at 1.50 D cylinder defocus. Schultz et al. treated a 17-year-old patient with large paracentral corneal scars, iris defect, and aphakia by implanting the small-aperture lens and described an improvement in the visual acuity and a significant reduction in photopic phenomena 6 months after surgery.

Due to its unique optical design, concerns may be raised regarding its potential hindrance to the performance of clinical fundoscopy, which is particularly of interest as an ocular trauma may potentially lead to long-term retinal complications. However, in accordance with the previous studies that reported unproblematic retinal assessments with KAMRA inlays, Empey et al. showed how vitreoretinal surgeries could also be performed with good visibility with the IC-8 IOL. In our patients the fundus assessment was also possible with a partial aniridia ring, as discussed in more detail below.

In our study, we also implanted a partial aniridia implant to minimize the glare disability. Currently, there are different types of iris implants available, each with its advantages and disadvantages. Aslam et al. implanted black diaphragm intraocular lenses (BDIs) with a central 5-mm diameter optic (67F, Morcher GmbH, Stuttgart, Germany) in patients with congenital and traumatic aniridia and observed that 80% of target eyes were within 2 D of predicted refraction, with significant improvement of the CDVA in the eyes with traumatic aniridia (40 eyes of 35 patients, 12-months to 6-years follow-up). However, this method resulted in a postoperative increase in the intraocular pressure (IOP) in 40% of patients immediately following the surgery. Similar complication had also been previously reported by another study, with chronic IOP elevation in 42% of patients after implantation of BDI lenses in patients with congenital aniridia (19 eyes of 14 patients, 12- to 84-months follow-up). The authors hypothesized that such an increase in the IOP may stem from the mechanical characteristics of the lens, as BDIs are much larger than a conventional IOL and has more rigid haptics, thereby possibly obstructing the aqueous flow.

Recently, a custom-made ARTIFICIALIRIS iris prosthesis (HumanOptics, Dr. Schmidt Intraocularlinsen GmbH, HumanOptics AG, Erlangen, Germany) has also been described as a promising alternative for functional and cosmetic treatment of iris defects. Its main advantages include flexibility, more appealing aesthetic recovery, and high versatility as it can be implanted in combination with an IOL, easily adapted in shape and size of the underlying iris defect, and implanted into either the capsular bag or the sulcus ciliaris. Mayer et al. investigated the clinical results after implantation of this iris prosthesis and observed significant improvement in glare symptoms and cosmetic appearance, significant increase in contrast sensitivity, as
well as high patient satisfaction (32 eyes of 32 patients, 12-months follow-up). However, this device also has some drawbacks, such as long preoperative planning required including color matching, challenging surgical technique that requires experience and dexterity, and lack of elongated depth of focus as it is sutured to a monofocal lens. Furthermore, it has been associated with complications, such as the residual iris retraction syndrome (RITS), which describes a gradual enlargement of the pupil size and retraction of the remnant iris that may lead to angle closure and IOP elevation.

The artificial iris device implanted in this study is a modified capsular tension ring with a segmental occluder that is intended for implantation into the capsular bag. Its poly (methyl methacrylate) material composition with ultraviolet light-absorbing properties serves to reduce the photophobic symptoms. While there are also other iris diaphragms available from the same manufacturer, such as model 96S that corrects iris defects of up to 180° or models 50D and 50F that can replace an entire iris, we implanted the 96G implant as the iris tissue defects were smaller and as these models would still allow for a posterior segment assessment. In Case 1, the partial aniridia ring was implanted infero-nasally to allow for a retinal assessment supero-nasally. Furthermore, the patient's upper eyelid also helps prevent the light rays from entering the eye. In Cases 2 and 3, clinical fundoscopy could be performed with ease in mydriasis through the areas around the IC-8 IOL and the partial aniridia ring.

Overall, all patients were satisfied with the postoperative outcomes, reporting subjective visual improvement and significant reduction in glare sensitivity. The implantation of the small-aperture IOL in combination with a partial anirida ring therefore presents an effective therapeutic option for management of traumatic iris defects in phakic patients. Further studies with larger sample size may be necessary to confirm its clinical efficacy.

**Patient consent**

Patient consent to publish this case series was not obtained. This report does not contain any information that could lead to identification of the patients. Retrospective review of this case series was done in accordance with the Declaration of Helsinki.

**Funding**

None.

**Authorship**

All authors attest that they meet the current ICMJE criteria for Authorship.

**Declaration of competing interest**

GUA and RK received research grants from AcuFocus. The following authors have no financial disclosures: HSS, TMY, GL, CM.
Acknowledgement

None.

References

1. Mayer C, Tandogan T, Hoffmann AE, Khoramnia R. Artificial iris implantation in various iris defects and lens conditions. J Cataract Refract Surg. 2017;43(6):724–731.
2. Burger DS, London R. Soft opaque contact lenses in binocular vision problems. J Am Optom Assoc. 1993;64(3):176–180.
3. Reed JW. Corneal tattooing to reduce glare in cases of traumatic iris loss. Cornea. 1994;13(5):349–353.
4. Shafran A, Gupta P, Dogra MR, et al. Granulomatous keratitis following corneal tattooing. Indian J Ophthalmol. 2003;51(3):265–267.
5. Sharma A, Gupta P, Dogra MR, et al. Granulomatous keratitis following corneal tattooing. Indian J Ophthalmol. 2003;51(3):265–267.
6. Van der Velden, Samderubun EM, Kok JH. Dermatography as a modern treatment for coloring leucoma cornea. Cornea. 1994;13(4):349–353.
7. Tsao SW, Holz HA. Iris mattress suture: a technique for sectorial iris defect repair. Br J Ophthalmol. 2015;99(3):305–307.
8. Srinivasan S, Ting DS, Snyder ME, et al. Prosthetic iris devices. Can J Ophthalmol. 2014;49(1):6–17.
9. Mayer CS, Reznicek L, Hoﬀmann AE. Pupillary reconstruction and outcome after artiﬁcial iris implantation. Ophthalmology. 2016;123(5):1011–1018.
10. de Jong B, van der Meulen IJE, van Vliet JMJ, et al. Eﬀects of corneal scars and their treatment with rigid contact lenses on quality of vision. Eye Contact Lens. 2018 Sep;44(Suppl 1):S216–S220.
11. Ho YJ, Sun CC, Chen HC. Cataract surgery in patients with corneal opacities. BMC Ophthalmol. 2018;18(1):106.
12. Aslam SA, Wong SC, Ficker LA, et al. Implantation of the black diaphragm intraocular lens in congenital and traumatic aniridia. Ophthalmology. 2008;115(10):1705–1712.
13. Burk SE, Da Mata AF, Snyder ME, et al. Prosthetic iris implantation for congenital, traumatic, or functional iris deﬁciencies. J Cataract Refract Surg. 2001 Nov;27(11):1732–1740.
14. Reinhard T, Engelhardt S, Sundmacher R. Black diaphragm aniridia intraocular lens for congenital aniridia: long-term follow-up. J Cataract Refract Surg. 2000;26(3):375–381.
15. Olson MD, Masket S, Miller KM. Interim results of a compassionate-use clinical trial of Morcher iris diaphragm implantation: report 1. J Cataract Refract Surg. 2008;34:1674–1680.
16. Mayer CS, Hoﬀmann AE. [Surgical treatment with an artiﬁcial iris.] Ophthalmologe. 2015;112(10):865–868 [Article in German].
17. Mayer CS, Laubichler AE, Masif M, et al. Residual iris retraction syndrome after artiﬁcial iris implantation. Am J Ophthalmol. 2019;198:159–166.
18. Charama WN. Pinholes and pseudophoria: solution or sideshow? Ophthalmic Physiol Opt. 2019;39(1):1–10.
19. Ogle KN, Schwartz JT. Depth of focus of the human eye. J Opt Soc Am. 1959;49(3):273–280.
20. Duke Elder S, Abrams D. System of Ophthalmology Vol V: Ophthalmic Optics and Refraction. London: Kimpton; 1970:794–796.
21. Bennett AG. An historical review of optometric principles and techniques. Ophthalmic Physiol Optic. 1986;6:3–21.
22. Ang RE. Small-aperture intraocular lens tolerance to induced astigmatism. Clin Ophthalmol. 2018;12:1659–1664.
23. Dick HB, Piouellia M, Vukich J, et al. Prospective multicenter trial of a small-aperture intraocular lens in cataract surgery. J Cataract Refract Surg. 2017;43(7):956–968.
24. Yokota R, Koto T, Inoue M, et al. Ultra-wide-ﬁeld retinal images in an eye with a small-aperture corneal inlay. J Cataract Refract Surg. 2015;41(1):234–236.
25. Inoue M, Bissen-Miyajima H, Arai H, et al. Retinal images viewed through a small aperture corneal inlay. Acta Ophthalmol. 2014;92(2):e168–169.
26. Cañas-Llera P, Ruiz-Moreno JM, Aioi JL. Retinal imaging after corneal inlay implantation. J Cataract Refract Surg. 2011;37(9):1729–1731.
27. Empey G, Kuppermann B, Babbsbery SR, et al. Evaluation of vitrectomy and retinal surgery through a hydrophobic small aperture intraocular lens in New Zealand black rabbits. Invest Ophthalmol Vis Sci. 2015;56(7):2988.