



Bilateral Artificial Iris implantation in patients with bilateral iris defects

Christian Steffen Mayer^{a,1}, Isabella Diana Baur^{a,1}, Julia Storr^b, Ramin Khoramnia^{a,**}

^a Department of Ophthalmology, University of Heidelberg, Heidelberg, Germany

^b Ophthalmology Clinic and Polyclinic, Technical University of Munich, Munich, Germany

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ABSTRACT

Purpose: Binocular traumatic or atraumatic iris defects can lead to an increased sensitivity to glare and cosmetic disfigurement. Surgical iris reconstruction is one approach to alleviate these problems. We report the clinical outcomes after medically indicated bilateral implantation of an Artificial Iris prosthesis in three patients with binocular iris defects with different etiologies.

Observations: All three patients underwent binocular CUSTOMFLEX ArtificialIris (AI) (HumanOptics AG, Erlangen, Germany) implantation with simultaneous cataract surgery. Corrected distance visual acuity (CDVA), manifest refraction, Contrast sensitivity, endothelial cell density and subjective visual impairment as well as subjective cosmetic disfigurement were measured pre- and postoperatively. CDVA remained stable or improved in all three patients. We observed an increase in contrast sensitivity and reduction of glare sensitivity in two patients. All patients reported satisfaction with the cosmetical result after the implantation.

Conclusions and importance: The bilateral Artificial Iris implantation is an effective therapeutic option to reduce glare sensitivity and to achieve an aesthetically pleasing result also in selected patients with binocular traumatic or atraumatic iris defects.

1. Introduction

Patients with monocular iris defects often report photophobia and glare sensitivity and suffer from severe visual impairment and cosmetic disfigurement.¹ Such complaints can be even more pronounced in patients with rare bilateral iris defects.

Conservative therapeutic options include wearing sunglasses for temporary relief or iris print contact lenses. These tinted contact lenses can effectively reduce the visual symptoms and provide an aesthetically pleasing solution,² but some patients are intolerant to contact lens wear or are unable to handle them. Furthermore, contact lenses require regular cleaning or need to be exchanged and this generates ongoing costs. Corneal tattooing can also be performed in patients with iris defects,³ but there are several risks associated with this procedure, such as micro-perforation or recurring corneal erosions. Inhomogeneous or fading pigmentation have also been reported.⁴ A study examining corneal tattooing in 147 disfigured eyes found a complication rate of 12%, with most complications leading to repeat surgery.⁵ The goal of corneal tattooing is to achieve a good aesthetic outcome, but the problem of glare usually remains, because such tattoos are not completely

lightproof.

Surgical iris reconstruction with an Artificial Iris implant is another therapeutic option that may be advantageous in the long term.²⁵ The silicone prosthesis is handcrafted to match the color of the patient's remaining iris tissue and it can be implanted using various techniques¹ depending on the comorbidities present. The implantation of an Artificial Iris prosthesis has shown good functional and aesthetic results in patients with monocular iris defects.⁶ In this case series, we report about our experience in patients who underwent binocular implantation of the CUSTOMFLEX ArtificialIris (AI, Fig. 1) (HumanOptics AG, Erlangen, Germany).

2. Materials and methods

2.1. Surgical technique

The surgical techniques to implant an AI are varied and have been described in detail elsewhere.^{1,7,8} The three patients in this present case series had surgery in both eyes with a delay of 2–8 weeks under general anesthesia, performed by one surgeon (CM): phacoemulsification with

** Corresponding author. Universitätsaugenlinik Heidelberg, Im Neuenheimer Feld 400, 69120, Heidelberg, Germany.

E-mail address: Ramin.Khoramnia@med.uni-heidelberg.de (R. Khoramnia).

¹ Isabella Baur and Christian Mayer contributed equally to this paper.

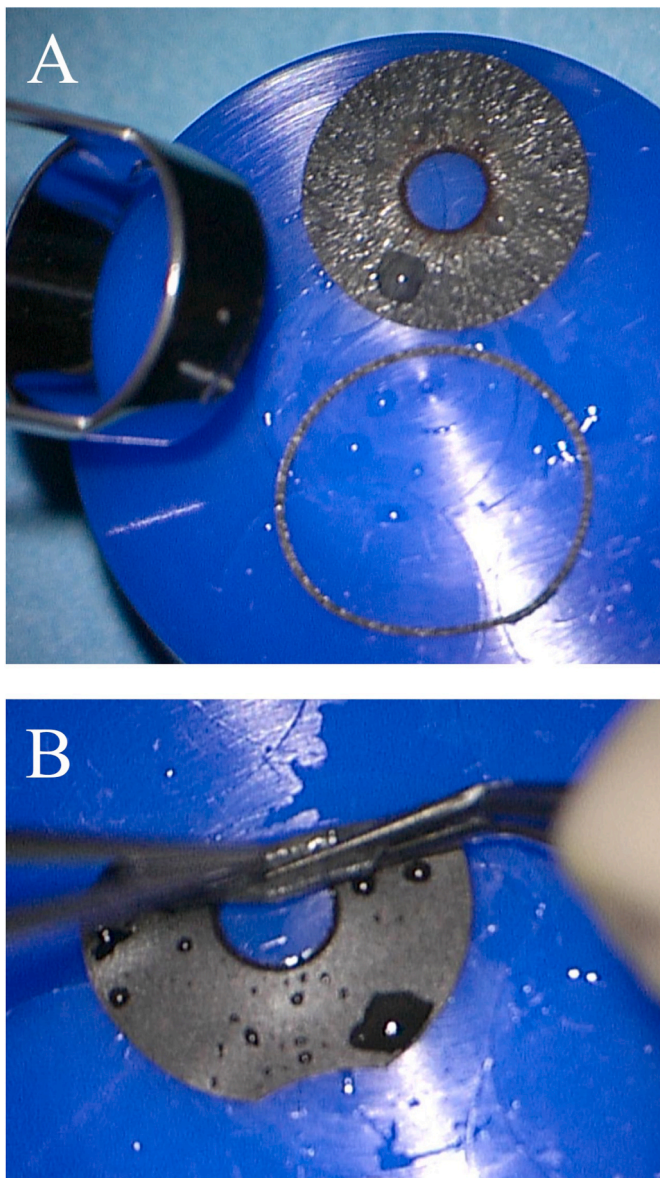


Fig. 1. Artificial Iris Customflex (HumanOptics, Erlangen, Germany) after trephination. A) Anterior View. B) Posterior view of a partially folded device.

subsequent IOL implantation into the capsular bag as well as an AI implantation. The same model of intraocular lens (MC6125AS-Y, HumanOptics, Erlangen, Germany) was implanted in all patients. The AI was trimmed to a size slightly smaller than the white-to-white value or the expected capsular bag diameter. In both eyes of one patient (case 1), the AI was ultimately implanted into the ciliary sulcus after intraoperative problems with the centration of the device in the capsular bag. The AI implants were prepared with prophylactic iridectomies to reduce the risk of IOP elevation, as the AI was placed in the sulcus in this case. In two patients (case 2 and 3) the AI was implanted into the capsular bag. In these cases, a capsular tension ring was used to prevent capsular shrinking, as this might cause a position change or tilting of the AI. In all cases, an AI without embedded fiber was used. All surgeries were performed without significant complications.

2.2. Follow-up

The follow-up time ranged from 11 to 14 months post-surgery. Postoperative assessment was performed at 3 months post-surgery.

Corrected distance visual acuity (CDVA) and manifest refraction, as well as contrast sensitivity and endothelial cell density, were determined pre- and postoperatively. Contrast sensitivity was measured using a Pelli Robson Chart. Furthermore, the patients were asked to rate their sensitivity to glare and the discontent with their eyes' appearance on a numerical scale from 1 to 10, with 1 standing for low and 10 standing for high severity. This assessment was done preoperatively and postoperatively. At the postoperative follow-up, patients were asked to additionally rate their overall satisfaction with the result on a numerical scale from 1 to 10 with 1 standing for very low satisfaction and 10 standing for maximum satisfaction. Patients were also asked if they would undergo the same procedure again if they had the choice.

3. Findings

3.1. Case 1 (Fig. 2)

A woman in her fifties presented with intense glare and cosmetically disturbing anisocoria and decentration of the pupil (Fig. 2A–C). She reported a history of bilateral iritis. The patient had not been treated for her symptoms before. The patient rated both the visual impairment resulting from glare and the discontent with her eye's appearance with the maximum value of 10 on the numerical scale. The slit lamp examination revealed an anisocoria of 1.2 mm (L > R) and iris transillumination defects on both eyes, as well as a beginning bilateral subcapsular cataract. The fundus examination was without pathological findings in both eyes. CDVA was 0.00 logMAR with a manifest refraction (MR) of -2.5 diopters sphere (DS)/ -1.0 diopters cylinder (DC) $\times 93^\circ$ on the right eye and 0.00 logMAR with a MR of -3.25 DS on the left eye. Preoperative contrast sensitivity was 1.35 log units on both eyes.

A MC6125AS-Y IOL (HumanOptics) with a power of $+22.00$ D was implanted in both eyes. The target refraction was -2.82 D for the right eye and -3.44 D for the left eye. The AI diameter was 12.0 mm for both eyes. On the left eye, the AI was first implanted into the capsular bag together with the IOL. The patient at first was not satisfied with the cosmetic result. A slight decentration of the new pupil was visible because the diameter chosen for the trephined implant had been too small. The AI was explanted in a second surgery a few days later, and the stand-by AI was implanted into the ciliary sulcus. One week later, the IOL was implanted in the capsular bag of the fellow eye, while the AI was implanted into the ciliary sulcus.

Fourteen months after surgery, the CDVA was 0.00 logMAR on both eyes, with an MR of -3.25 DS on the right eye and an MR of -3.75 DS on the left eye. Contrast sensitivity values were 1.5 log units for the right eye and 1.35 log units for the left eye. The endothelial cell density (CD) had slightly decreased from 3145 to 3049 on the right eye and from 3135 to 2924 on the left eye. The patient reported a considerable reduction in glare sensitivity and was very satisfied with the cosmetic result (Fig. 2D–F). Subjective visual impairment due to glare and subjective discontent with her eye's appearance were now both 1 on the 10-point numerical scale. The online supplementary video shows the surgical procedure of this patient's right eye.

3.2. Case 2 (Fig. 3)

A male patient in his seventies presented with unclear persistent mydriasis with severe photophobia and decreased visual acuity (Fig. 3A–C). The reason for the bilateral permanent mydriasis remained unclear as the patient could not remember any trauma. The patient had not been treated for his complaints so far. He rated the visual impairment resulting from glare with 10 and surprisingly the discontent with his eye's appearance only with 2 on the 10-point numeric scale. In the slit lamp examination, both eyes showed a permanent mydriasis and cataract. Both eyes showed no retinal pathologies. CDVA was 1.00 logMAR on the right eye, with an MR of $+5.0$ DS/ -2.75 DC $\times 3^\circ$, and 0.70 logMAR on the left eye, with an MR of $+3.75$ DS/ -2.0 DC $\times 175^\circ$.

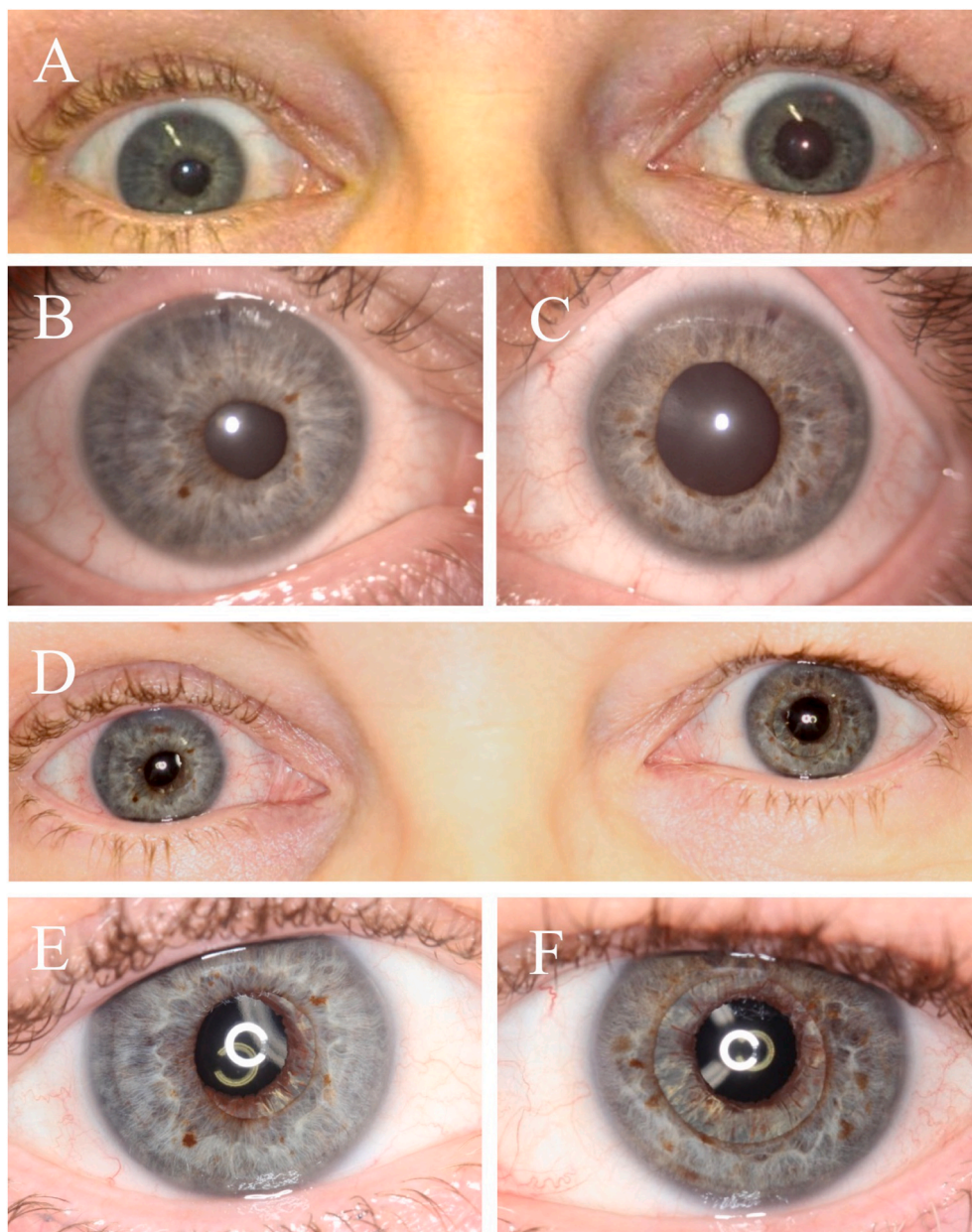


Fig. 2. Case number 1. A) Preoperative binocular photograph. B) Preoperative close-up photograph of the right eye. C) Preoperative close-up photograph of the left eye. D) Postoperative binocular photograph with ArtificialIris in both eyes. E) Postoperative close-up photograph with ArtificialIris in the right eye. F) Postoperative close-up photograph with ArtificialIris in the left eye.

Preoperative contrast sensitivity was 1.35 log units on both eyes.

An MC6125AS-Y IOL with a power of +23.0 D (target refraction +0.04 D) was implanted in the right eye, and an MC6125AS-Y IOL with an IOL power of +23.5 D (target refraction -0.14 D) was implanted in the left eye. The AI was trimmed to 9.0 mm diameter for both eyes.

11 months after the surgery, CDVA was 0.10 logMAR with a MR of +0.75 DS/-1.25 DC x 154° for the right eye, and 0.10 logMAR for the left eye. The manifest refraction was plano for the left eye. Contrast sensitivity had increased in both eyes to 1.5 log units. The endothelial cell count was stable on the right eye (3030 preoperatively vs. 3067 postoperatively) and had slightly decreased on the left eye (3030 preoperatively vs. 2817 post-surgery).

The patient expressed high satisfaction with the postoperative result (Fig. 3D-F). The subjective visual impairment from glare was reduced to 4 on the 10-point numerical scale, the discontent with his eye's appearance was 4 on the numerical scale.

3.3. Case 3 (Fig. 4)

A woman in her thirties presented with intolerable sensitivity to glare, having a history of binocular trauma 25 years earlier with a water jet. She had already tried iris print contact lenses but was not satisfied with them (Fig. 4D-E). Subjective visual impairment resulting from glare was rated with 10 and her discontentment with her eye's appearance she rated as 8. Slit lamp examination revealed bilateral traumatic mydriasis and cataract (Fig. 4 A to C). Funduscopy was unremarkable in both eyes. CDVA was 0.60 logMAR on the right eye, the MR was Plano. For the left eye, we found a CDVA of 0.20 logMAR with a MR of +1.5 DS/-3.0 DC x 0°. Contrast sensitivity was 1.95 log units for both eyes preoperatively.

The IOL power of the implanted MC6125AS-Y IOL was +22.0 D for both eyes, with a target refraction of -0.35 for the right eye, and -0.48 D for the left eye respectively. The AI diameter was 10.0 mm for both

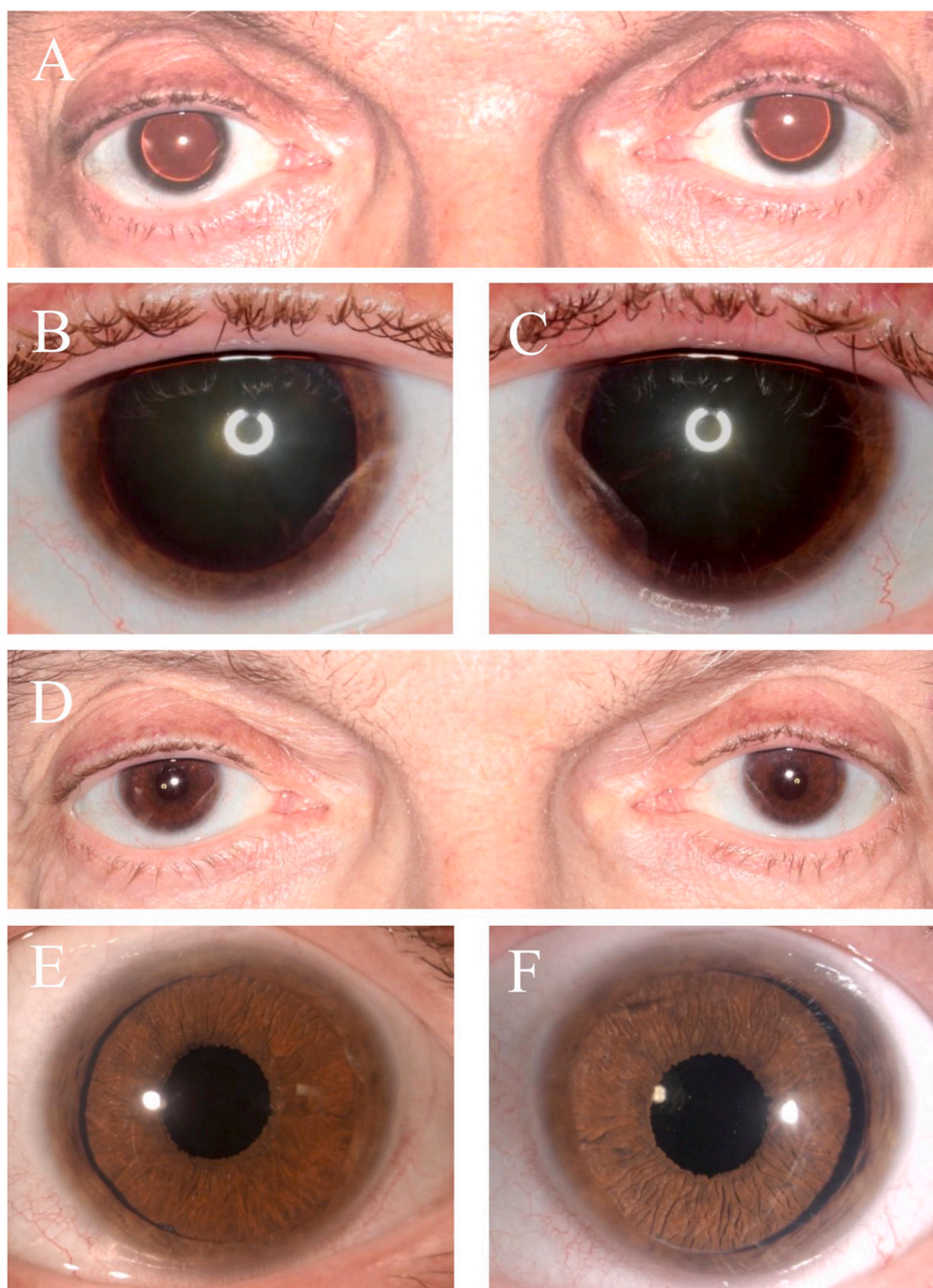


Fig. 3. Case number 2. A) Preoperative binocular photograph. B) Preoperative close-up photograph of the right eye. C) Preoperative close-up photograph of the left eye. D) Postoperative binocular photograph with ArtificialIris in both eyes. E) Postoperative close-up photograph with ArtificialIris in the right eye. F) Postoperative close-up photograph with ArtificialIris in the left eye.

eyes.

The patient developed postoperative macular edema on the right eye and was treated with an Ozurdex implant, which led to resolution of the edema. One year after surgery, CDVA in the right eye was 0.10 logMAR with an MR of +1.5 DS/−2.5 DC x10°, and CDVA in the left eye was 0.00 logMAR with an MR of +1.75 DS/−2.25 DC x 5°. Endothelial cell density of the right eye slightly decreased (from 2762 to 2445), whereas cell density remained stable for the left eye (2865 before surgery and 2959 postoperatively). Surprisingly, contrast sensitivity was reduced postoperatively to 1.65 log units in both eyes. The patient still rated visual impairment from glare with 10 on the 10-point numerical scale, although this could not be explained by clinical findings. Discontent

with her eye's appearance had decreased, however, with a postoperative value of 1. Fig. 4 F–H shows the postoperative result for both eyes of this case.

4. Discussion

In this case series, we report the clinical outcomes of three patients who underwent bilateral AI implantation for large traumatic or atraumatic iris defects.

In the cases discussed in this case series, the only comorbidity was cataract, and the eyes showed no active inflammation. Therefore, the AI could be implanted into the capsular bag in two cases and in the ciliary

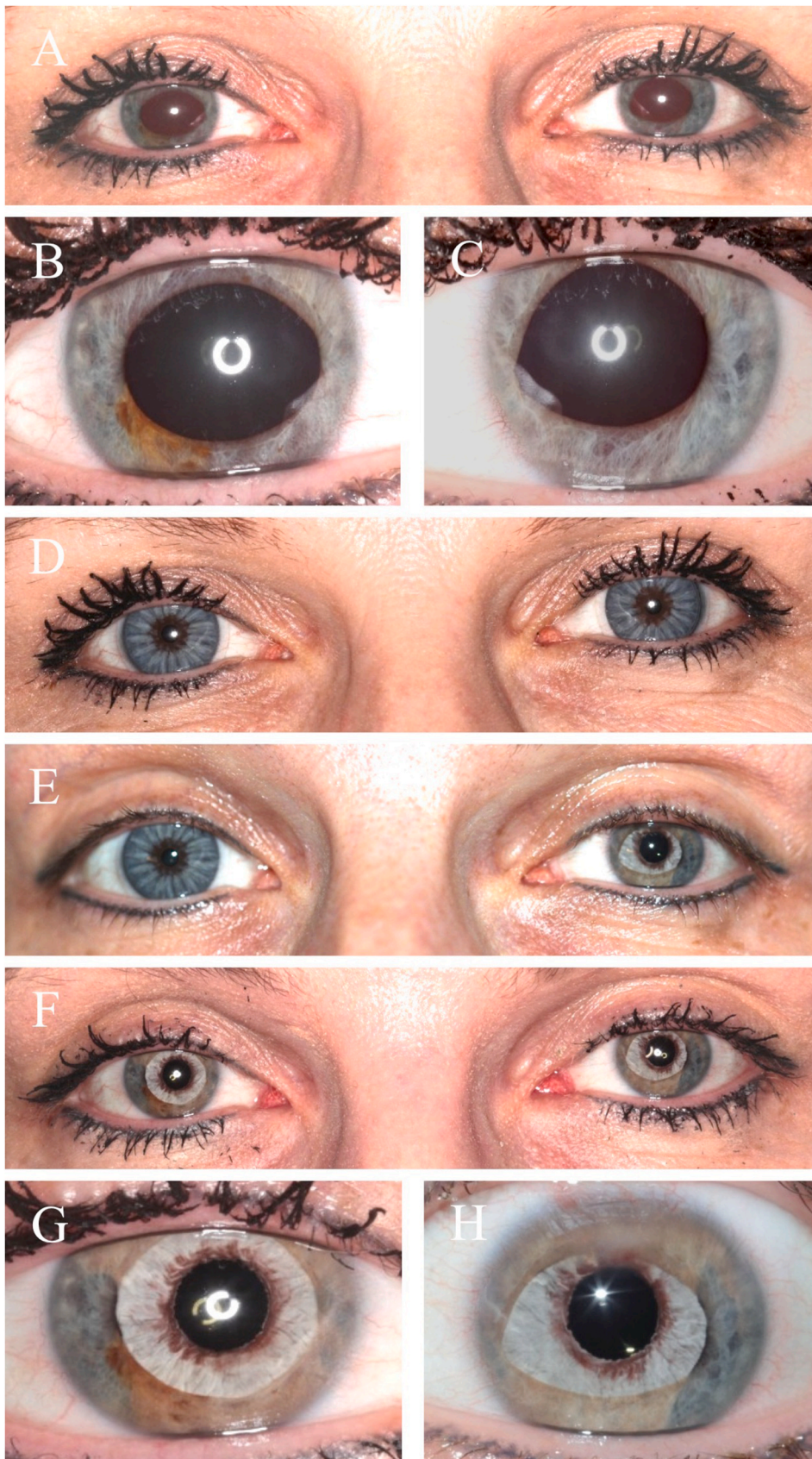


Fig. 4. Case number 3. A) Preoperative binocular photograph. B) Preoperative close-up photograph of the right eye. C) Preoperative close-up photograph of the left eye. D) Preoperative binocular photograph with iris-print contact lenses in both eyes. E) Binocular photograph with ArtificialIris in the right eye and ArtificialIris in the left eye. F) Postoperative binocular photograph with ArtificialIris in both eyes. G) Postoperative close-up photograph with ArtificialIris in the right eye. H) Postoperative close-up photograph with ArtificialIris in the left eye.

sulcus in one case. The implantation of both devices into the capsular bag is considered to be feasible and only rarely leads to complications. The creation of iridectomies is not necessary when using capsular fixation. However, we recommend implanting a capsular tension ring which will prevent capsular shrinkage since we presume that capsular shrinking may lead to tilting of the Artificial Iris.¹

To prevent IOP elevation after implanting the AI into the sulcus, we created peripheral iridectomies in each prosthesis before the implantation. We did not observe any IOP elevations requiring treatment in our patients. Endothelial cell density remained stable or decreased only slightly in all patients. CDVA remained stable or improved in all three patients. Photophobia was reduced in two patients, who also presented with improved contrast sensitivity. The discontent with the eyes' appearance decreased in two patients (case 1 and 2). We observed a very high patient satisfaction in all our described cases, with all patients stating that they would undergo the treatment again if they had the choice. However, one patient (Case 3) presented with persistent glare without any clinical explanation for this problem.

Bilateral iris defects are rather rare and there are only a few published case reports of bilateral AI implantation. Forlini et al. reported one case of bilateral traumatic aniridia who underwent simultaneous implantation of the CUSTOMFLEX ArtificialIris (HumanOptics AG, Erlangen, Germany) in both eyes with a good functional and aesthetic outcome.⁹ Fernández-López et al. reported a case of bilateral congenital aniridia, treated with bilateral CUSTOMFLEX ArtificialIris (HumanOptics AG, Erlangen, Germany) implantation. They observed a considerable reduction in photophobia and a very good cosmetic result.¹⁰

Although all our patients were satisfied with the final result, we did observe some unexpected problems. In Case 3, postoperative contrast sensitivity decreased and the sensitivity to glare could not be reduced. Reduced contrast sensitivity might be related to the development of a macular edema on one eye post-surgery. The reason for the persisting photophobia in this patient remains unclear, because there was no clinical explanation.

In one patient, the discontent with his eyes' appearance had increased from 2 preoperatively to 4 postoperatively. Interestingly, this was the only male patient in this case series. We had noticed before, that male patients tend to rate the discontent with the eyes' appearance lower, which is probably due to social stereotypes. We assume that social expectations had influenced the patient's preoperative assessment, as he expressed a high overall satisfaction with the result.

Our results are in good agreement with previously published cases of monocular AI implantations. It has already been shown that the AI implantation can effectively reduce photophobia.^{6,11-13} We reported that contrast sensitivity significantly increases after surgical iris reconstruction.⁶ The significant reduction in the pupillary aperture can explain both effects after the implantation.⁶

The AI implantation provides excellent aesthetic results^{6,11,12,14} and previous studies found a very high overall patient satisfaction.^{6,15} The AI is a silicone implant, which is customizable as it is hand painted, using a photograph as a template to match the look of the remaining iris tissue or the fellow eye. This requires, however, lengthy preparation before surgery. The importance of a good color-true photo has to be underlined, and the need to discuss the desired color result with the patient prior to surgery.

Although improving CDVA is not the primary objective when implanting an Artificial Iris, it has been shown that CDVA increases in some cases,^{12,16,17,26} including two of the cases described, which is most likely due to simultaneous cataract surgery.

The aperture of the AI of 3.35 mm is not small enough to create a pinhole effect. Miller et al. examined the pinhole effect with different sizes of pinholes. They did not find a strong effect with a pupil size of 2.5 mm.¹⁸ Therefore it is unlikely that the even bigger aperture of the AI can create a pinhole effect that improves CDVA.

There are reports of complications associated with AI implantation, including CDVA decrease, hemorrhage of the remnant iris, elevated

intraocular pressure (IOP), AI dislocation or decentration, corneal decompensation, retinal detachment and macular edema.^{12,15,16}

As iris defects can be of various etiologies, including traumatic, post-uveitis or congenital, the patient collective is heterogenous. This is why the risk for complications varies among patients, depending on which comorbidities are present.

Cosmetic iris implants are associated with anterior uveitis.¹⁹ For sulcus or capsular bag fixated implants, there is no known association, therefore we considered the risk of a uveitis reactivation in case 1 to be rather low.

Patients with pre-existing glaucoma have a higher risk of IOP elevation after cataract surgery^{20,21} or vitrectomy.²² The same applies to patients with preexisting glaucoma after AI implantation.¹ In patients with a low endothelial cell density, the risk of corneal decompensation is increased and can lead to further surgical interventions.

In all cases, we used fiber-free models of the AI. Rickmann et al. found a higher complication rate in patients treated with AI with fiber. Sharp-edged fibers causing chronic irritation are a possible explanation for this finding.¹² This problem can be avoided completely in cases that do not require suturing of the AI, e.g., when implanting the AI into the capsular bag or sulcus of patients with enough capsule support.²⁷ In these cases, an AI without fiber can be used. In cases that require fixating the AI to the sclera however, an AI with fiber is desirable as it is more resistant to tearing while the implant is being sutured.

In patients with residual iris tissue, Rickmann et al. observed a darkening of the remaining iris.¹² The cause for this is unknown, but it can lead to a color mismatch between the AI and the natural iris tissue. Another complication associated with remaining iris tissue is the residual iris retraction syndrome (RITS).²³ In Patients with RITS, the original pupillary aperture gradually enlarges. The underlying pathomechanism is still unknown, but it has been reported that RITS can lead to severe complications like angle closure glaucoma and chronic inflammation.²³

Smaller iris defects and even traumatic mydriasis can be treated with iris sutures, but this requires enough iris tissue to achieve a round and well centered pupil and to avoid intraoperative iatrogenic iris damage.²⁴ The Ophtec Iris Prosthesis model C1/F1 can be implanted into the capsular bag and allows to correct aniridia and aphakia in one step, but the aesthetic results are not as good as with the individualized AI we used in our patients. There are also different capsular bag implants available from Morcher, like the type 50 implant. They are made of PMMA, a black and rather rigid material and therefore require larger incision sizes. To cover 360° two implants of this type have to be combined. The IC-8 intraocular lens (AcuFocus Inc., California, USA) is a small-aperture IOL enhancing the depth of focus. It can be an alternative therapeutic option in some cases, depending on the extent of the iris defect.^{28,29}

5. Conclusions

In summary, the bilateral implantation of an AI could eliminate photophobia and all patients who underwent bilateral treatment reported that they were very satisfied with the cosmetic and overall result. There are reports of different complications associated with the implantation of this iris prosthesis and the risk for these complications varies among patients depending on preexisting comorbidities, which highlights the importance of a careful assessment of the risks and benefits prior to surgery.

5.1. Patients consent

Full written consent has been obtained from the patients. The study was approved by the local Ethics Committee (Fakultät für Medizin, Ethikkommission, Technische Universität München, IRB no. 535/15 S) and performed in accordance with the tenets of the Declaration of Helsinki.

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Authorship

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

Declaration of competing interest

CM received travel grants and lecture fees from HumanOptics. The following authors have no financial disclosures: IDB, JS, RK.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.ajoc.2021.101108>.

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