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Safety and efficacy of custom foldable silicone artificial iris implantation: A prospective compassionate-use case series

Running title: Custom artificial iris implantation

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ABSTRACT

Purpose: To assess the preliminary safety and efficacy of custom silicone artificial iris implantation.

Setting: Stein Eye Institute.

Design: Prospective consecutive case series.

Methods: Review of medical records of patients implanted with the artificial iris and followed for 1 year. Safety measures included corrected distance visual acuity (CDVA), intraocular pressure (IOP), endothelial cell count (ECC), surgical complications, secondary interventions, and adverse events (AEs). Efficacy measures included CDVA with glare, subjective daytime and nighttime glare graded from 0 to 10 (very significant), and subjective cosmetic appearance graded from 0 to 10 (very satisfied).

Results: Twenty eyes (19 patients) were implanted. Safety data were mixed. CDVA improved in 13 eyes and worsened in 6. ECC decreased from 1918 ± 870 to 1405 ± 705 cells/mm^2 ($P = 0.02$). Eight eyes experienced postoperative complications. There were 4 IOP elevations, 2 corneal decompensations, 1 case of cystoid macular edema, and 1 device dislocation. Four eyes underwent secondary surgical interventions including 2 AEs (1 glaucoma surgery, 1 device dislocation). Efficacy outcomes were excellent. CDVA with glare improved from 1.5 ± 0.6 to 0.7 ± 0.8 logMAR ($P < 0.01$). Mean subjective daytime glare decreased from 8.9 ± 1.8 to 2.7 ± 2.6 ($P < 0.01$) and nighttime glare decreased from 7.9 ±

1.8 to 2.5 ± 2.7 ($P < 0.01$). Mean cosmesis improved from 2.2 ± 1.6 to 8.8 ± 2.1 ($P < 0.01$).

Conclusion: Custom artificial iris implantation was moderately risky but very effective at reducing light and glare sensitivity and improving ocular cosmesis.

INTRODUCTION

Patients with large congenital or acquired iris defects usually experience visual impairment, light and glare sensitivity, and the emotional consequences of having a deformed body part.[1] Moreover, a history of prior surgeries and an abundance of ocular comorbidities can lead to other ocular health and psychological issues. Eyes with iris defects often have problems such as corneal scarring, corneal edema, lens issues, glaucoma, and retinal pathology.[2] Clinical presentations are heterogenous and multifaceted, requiring a personalized approach to each affected patient.[3] Non-surgical treatment options included sunglasses, artificial pupil contact lenses, and patching. Surgical options include iris suturing, corneal tattooing, and the implantation of various iris prostheses placed either in the capsular bag as partial or total aniridia rings or in the sulcus as aniridia diaphragms or aniridia implants.[4] Some of these approaches are associated with a high rate of postoperative complications and most are associated with unimpressive cosmetic results.[4]

The CustomFlex Artificial Iris (HumanOptics AG, Erlangen, Germany) is a foldable biocompatible silicone prosthesis that was approved by the United States Food and Drug Administration (US FDA) in May 2018. This custom artificial iris is designed for implantation into aphakic or pseudophakic eyes, including those that will undergo simultaneous cataract surgery. It has a 3.35 mm pupil, an overall diameter of 12.8 mm, and a thickness that varies from 0.4 mm at the pupil margin to 0.25 mm in the periphery. The front side is hand-painted and customized for each

patient based on a clinical photograph of the fellow eye, if normal. A sample is shown in Figure 1. If a patient has bilateral iris defects or is monocular, a photograph of any eye can be used as the template. The back of the iris is black and opaque. The device is not intended for implantation for cosmetic reasons alone. It can be injected through a sub-3.2 mm clear corneal incision using a variety of lens injectors or it can be inserted through a larger incision with or without an intraocular lens (IOL) sutured to it.[5] It comes in fiber-free and fiber-containing models. The fiber-free model can be passively fixated within the capsular bag or ciliary sulcus. The fiber-containing model can be suture-fixated to an IOL, the sclera, or residual iris tissue. At this time, the device is not manufactured with an integrated optic. The functional outcomes and complications of custom artificial iris implantation have been published in a few reports, mostly European and retrospective.[6-12] The aim of this prospective, consecutive surgical case series is to report our experience in the United States with custom artificial iris implantation in eyes with large iris. These eyes were implanted before the FDA clinical trial was initiated. Our results were then compared to previously published series.

PATIENTS AND METHODS

This prospective, nonrandomized, interventional, compassionate-use case series was approved by the institutional review board (IRB) at University of California, Los Angeles (IRB #11-002964). Patients were recruited from the practice of the senior author (KMM), who performed all

of the procedures. Compassionate use device exemptions were obtained from the US FDA for each patient implanted. Consent for surgery and the collection and analysis of perioperative clinical metrics were obtained from each patient. Data collection was compliant with the Health Insurance Portability and Accountability Act (HIPAA) and all research adhered to the tenets of the Declaration of Helsinki. Most patients gave separate written permission to have their own full-face photographs used in educational presentations and publications, such as this one. All procedures were performed at the Stein Eye Institute between March 30, 2010 and March 1, 2015. Patient enrollment ceased when the FDA stopped issuing compassionate use device exemptions just prior to the launch of the formal FDA clinical trial.

To be included in the study, patients had to be 18 years or older at the time of enrollment and have a congenital or acquired iris defect, significant light and glare disability, contrast loss, photophobia, blurry vision, and dissatisfaction with non-surgical options. Exclusion criteria included small iris defects, symptoms that could easily be treated with contact lenses or tinted glasses, the presence of a clear crystalline lens, or active ocular infection or inflammation.

Subjective measurements

Corrected distance visual acuity (CDVA) with glare was measured in a trial lens frame or phoropter with a transilluminator light held 6 to 12 inches in front and slightly to the side of the study eye in four sequential

quadrants. The lowest Snellen visual acuity obtained in the process was recorded. Glare and cosmesis symptoms were assessed by a questionnaire before surgery and 3 months afterwards. Subjective daytime and nighttime glare were assessed by asking patients to rate their symptoms on a scale of 0 (none) to 10 (very significant). Cosmesis was graded on a scale of 0 (very dissatisfied) to 10 (very satisfied). Patients were reminded of their preoperative scores at the 3-month postoperative evaluation so that interval changes could be assessed accurately.

Surgical technique

Short surgeries were performed under local anesthesia using an orbital injection technique. Longer or more difficult procedures were performed under general anesthesia. All iris devices implanted in this study were fiber-free and most were not trephined. When the horizontal diameter of the cornea was less than about 11.8 mm, the iris was trephined to the horizontal white-to-white measurement plus 1.0 or 1.2 mm. There are no widely accepted sizing criteria at this time and the manufacturer does not make specific recommendations. Our desire was to make the implant fit snugly in the sulcus to keep it stable during saccadic eye movements and to block all incoming light from coming around its periphery. If we identified any evidence of vault after implantation, we planned to remove the iris and trephine it to a smaller diameter. Device explantation and trephination occurred 1 time during this series, in an eye with a very complex ocular history. During the first 5 procedures, a single

iridectomy was fashioned at the outer edge of the implant using a 2-mm skin punch. This was done to eliminate the risk of pupillary block. The iridectomy was abandoned for all subsequent surgeries as it was deemed unnecessary. The irises were either inserted with forceps or tri-folded, placed in a PSCST cartridge (Abbott Medical Optics, subsequently Johnson & Johnson Vision, Santa Ana, California), and injected using a Silver Series injector (Abbott Medical Optics) through a 3.0-mm clear corneal incision. Additional procedures such as penetrating keratoplasty (PK), cataract extraction, iridoplasty, glaucoma tube shunt revision, IOL removal or implantation, and anterior vitrectomy were performed as needed.

The iris was passively fixated in the ciliary sulcus if capsular support was deemed adequate. Otherwise, it was secured to the sclera by suturing the iris to an IOL with 10-0 Prolene and suturing the IOL to the sclera with 9-0 Prolene. We used 10-0 Prolene to suture the devices together as this had been our suture of choice for iris repair and we had had no problems with it over many years. We used 9-0 Prolene rather than Gore-Tex to suture lenses to the sclera because, according to the manufacturer, Gore-Tex is not intended for ophthalmic use. The surgeon avoided the fiber-containing model early in his experience, fearing it would be too stiff to be in contact with uveal tissue. He experienced no problems with cheese wiring when suturing a fiber-free iris device to an IOL, but he was careful not to tie the sutures too tightly. No device in this series was implanted inside the capsular bag or sutured directly to the sclera. Additional fixation techniques were adopted in the subsequent FDA clinical trial.

Postoperative management

Routine postoperative treatment consisted of moxifloxacin 0.5% ophthalmic solution administered 4 times per day for one week and prednisolone acetate 1% ophthalmic suspension administered 4 times per day for one month. Topical corticosteroids were tapered beyond 1 month by 1 drop per week if there was any residual inflammation at the 1-month examination. In cases of concomitant penetrating keratoplasty, the topical corticosteroid regimen was modified as deemed necessary by either the senior surgeon (KMM) or the cornea specialist. Glaucoma drops were continued or added if necessary, based on intraocular pressure (IOP) measurements.

Data collection

Data recorded included demographic information, the preoperative state of the eye including the status of the lens, and surgical details. Safety measures included loss of CDVA, intraoperative and postoperative complications, adverse events, secondary surgical interventions, IOP measurements, and endothelial cell counts (ECC) before and after surgery. Efficacy measures included Snellen CDVA with glare, subjective evaluation of daytime and nighttime glare symptoms scores, and subjective evaluation of cosmetic results. Device centration was another efficacy outcome, measured by the senior surgeon at a slit-lamp biomicroscope using the 3.35 mm artificial pupil as an intraocular ruler. After enrollment,

patients were examined 2 weeks before surgery and 1 day, 2 weeks, and 1, 3, 6, and 12 months after surgery. Additional examinations were scheduled as needed.

Custom artificial iris color matching, centration, and sizing were assessed at the 1-year follow-up examination.

Statistical analyses

All statistical analyses were performed using Excel 2019 for Mac (Microsoft Corp., Redmond, Washington) with XLSTAT software version 2018.55292 (Addinsoft, Paris, France). For statistical analysis, CDVA and CDVA with glare were converted to the base 10 log of the minimum angle of resolution (logMAR). Parametric (paired *t*-test) and non-parametric (Wilcoxon signed-rank test) analyses were performed. A P value of 0.05 or less was considered statistically significant.

RESULTS

Twenty-two patients (24 eyes) signed consent forms. Three patients (3 eyes) changed their minds after being consented and 1 patient who was implanted in 1 eye was blocked from proceeding with second eye surgery because the FDA stopped issuing compassionate use device exemptions. The second eye was implanted in the formal FDA study some time later. Thus, 20 eyes of 19 patients were implanted with a custom artificial iris, 1 patient bilaterally. Sixteen surgeries were performed under general anesthesia. Four were performed under local anesthesia. All patients were

pseudophakic following surgery and every patient returned for every scheduled examination during the 1-year follow-up interval.

Demographics and surgical details

Demographic information, the preoperative status of the eye, and surgical details are shown in Supplemental Table 1. Mean age at the time of surgery was 50.5 ± 16.6 years. The most common etiology of iris defect was blunt trauma without globe rupture (35%) followed by surgically-induced mydriasis (30%). The mean number of clock hours of iris involvement was 8.0 ± 4.5 and the mean preoperative pupil diameter was 9.3 ± 1.3 mm. The median number of preoperative ocular comorbidities was 2.4 (range 1 to 7). The most common comorbidity was vitreoretinal pathology (12 eyes, including 7 who were status post retinal detachment repair), followed by corneal scarring (10 eyes), and glaucoma (4 eyes). Eight eyes were aphakic, 8 eyes were pseudophakic, and 4 eyes had cataract at the time of iris implantation. Four eyes underwent simultaneous PK at time of artificial iris implantation. It was not possible to determine the model of IOL implanted in every pseudophakic eye. The custom artificial iris was passively fixated in the ciliary sulcus of 9 eyes. An IOL and artificial iris were sutured to each other and the IOL was sutured to the sclera in 11 eyes.

Clinical examples

Three patients are described in detail to demonstrate typical preoperative ocular comorbidities and clinical results of custom artificial iris implantation.

Subject #1 was 53 years old at the time of custom artificial iris implantation. His right eye was injured while playing flag football at age 27. A player from the opposing team accidentally hit him in his right eye while running toward him, with a sharp downward blow from the side of his hand. The injury resulted in a hyphema, traumatic mydriasis, and premature cataract. He was enrolled in a Morcher iris diaphragm compassionate use clinical trial that the senior author was conducting at the time. The plan was to remove the cataract and implant a posterior chamber IOL and two Morcher 50F modified capsule tension rings inside the capsular bag to construct a black artificial iris. Intraoperatively, an occlusion break surge occurred while removing the cataract. The surge resulted in a capsule tear, which precluded implantation of the 50F ring devices. An anterior vitrectomy was performed instead; an AQ2010V (STAAR Surgical, Monrovia, California) 3-piece IOL was placed in the ciliary sulcus; and the surgery was concluded. The patient’s uncorrected distance visual acuity (UDVA) was 20/20 (logMAR 0.0) postoperatively, but he remained light and glare sensitive as he had been preoperatively. The senior author subsequently learned about the availability in Europe of the HumanOptics artificial iris and he contacted the patient. The patient expressed a desire to be implanted and a compassionate use device exemption was obtained from the FDA. Figure 2a shows his preoperative

appearance. The device was inserted with forceps through a 3.8-mm peripheral corneal incision and passively fixated in the ciliary sulcus in front of the previously implanted 3-piece IOL. The artificial iris eliminated his light and glare sensitivity and left his UDVA unchanged. Figure 2b shows his appearance 3 months after surgery.

Subject #2 was 57 years old at the time of custom artificial iris implantation. She accidentally poked herself in her left eye while playing with scissors when she was 2 years old. The injury resulted in a penetrating corneal laceration, iris tissue loss, corectopia, and traumatic cataract. She underwent 2 surgeries to close the laceration and later had bilateral strabismus surgery. Cataract extraction with toric IOL implantation was performed when she was 57 years old. Following cataract surgery, she lost her ability to drive at night despite UDVA of 20/20 because of severe photophobia and glare sensitivity. She remarked that every light at night had a wide streak through it. Figure 3a shows her preoperative appearance. Because she was pseudophakic and had strong zonules, her artificial iris was passively fixated in the ciliary sulcus. Her CDVA improved from 0.30 to 0.10 logMAR and her CDVA with glare improved from 1.30 to - 0.12 logMAR. Her IOP remained stable in normal range as did her ECC (1858 to 1903 cells/mm^2). Figure 3b shows her appearance 3 months after surgery.

Subject #19 was 59 years old at the time of custom artificial iris implantation. She had undergone radial keratotomy many years earlier. Ten months before presentation, she was driving a motor vehicle with

faulty brakes. When the brakes completely failed, she jumped from the vehicle and the left side of her face hit a rock. The trauma fractured her left orbit and ruptured her left globe along 3 radial scars in the cornea, resulting in iris and crystalline lens expulsion and retinal detachment. The globe rupture was repaired the same day and surgery to repair the retinal detachment was performed some time shortly thereafter. She was left aphakic. Figure 4a shows her preoperative appearance. During the surgery to implant the custom artificial iris, a simultaneous PK was performed. The iris was sutured to a 14.5 D CR70BU (Alcon Laboratories, Fort Worth, Texas) IOL and the haptics of the IOL were sutured to the sclera after corneal trephination. Five days after, cyanoacrylate tissue adhesive and a bandage contact lens were applied to treat an aqueous leak at the intersection of a radial keratotomy incision and the corneal transplant wound. By the 1-year postoperative examination, her CDVA had improved from 1.2 to 0.3 logMAR and her CDVA with glare improved from 2.3 to 0.5 logMAR. Her IOP remained stable in normal range throughout the follow-up interval. Figure 4b shows her appearance 3 months after surgery.

Safety outcomes

Safety outcomes are shown in Table 1. Three months postoperatively, there was no significant change in mean CDVA (0.9 ± 0.7 logMAR before surgery versus 0.6 ± 0.8 logMAR after surgery, $P = 0.05$). By the 1-year postoperative examination, CDVA improved in 12 eyes (60%), but worsened in 6 eyes (30%). There was a single intraoperative

complication in a very sick eye with end-stage glaucoma that had experienced multiple prior intraocular hemorrhages and was being considered for evisceration. The complication was a recurrent choroidal hemorrhage associated with anterior segment bleeding. The custom artificial iris was implanted in the ciliary sulcus in this eye. The visual acuity was bare light perception before surgery and no light perception several months after surgery. Four eyes (20%) had corneal epithelial irregularity, which was not considered a complication. One eye developed corneal endothelial decompensation requiring a Descemet stripping endothelial keratoplasty (DSEK) before the 1-year follow up examination and the one patient mentioned above had a persistent but improving choroidal hemorrhage.

Nine eyes (45%) experienced 1 or more complications during the first year that were not present as preoperative comorbidities. The most common postoperative complication was ocular hypertension (4 eyes, 20%). There was no statistically significant difference in mean IOP between the preoperative and 3-month postoperative examinations (11.8 ± 4.2 mmHg versus 16.1 ± 5.2 mmHg, $P = 0.06$). One eye developed mild cystoid macular edema that resolved on topical therapy. Four eyes underwent secondary surgical interventions. Of these, 1 eye experienced a corneal graft leak that was repaired by cyanoacrylate tissue adhesive and bandage contact lens placement (subject #16). One patient underwent a DSEK (subject #18). One eye underwent glaucoma tube shunt implantation (subject #17). Lastly, 1 eye underwent a pars plana

vitrectomy and IOL exchange when the passively fixated artificial iris slipped posteriorly through a break in the zonules 4 weeks after surgery (subject #3). It was the surgeon's subjective call at the time of surgery that the patient's zonules were strong enough to support passive sulcus fixation of the artificial iris. That decision shaved 60 minutes off the surgery and considerable intraocular trauma that would have been associated with suture placement. However, the judgement call proved to be wrong and the devices dislocated postoperatively. The replacement IOL and artificial iris were sutured to the sclera. The last 2 procedures were reported to the IRB as adverse events in accordance with UCLA guidelines. No cases of prolonged postoperative inflammation were noted.

There was a statistically significant decline in mean ECC (1918 ± 870 cells/mm^2 before surgery versus 1405 ± 705 cells/mm^2 three months after surgery, $P = 0.02$). Endothelial cell counts could not be obtained in eyes with extensive corneal edema or scarring. For the 13 eyes in which an ECC could be obtained before and after surgery and excluding eyes that underwent concurrent PK, the average ECC loss was 28%. Suture of the IOL was not associated with an increased loss in ECC ($P = 0.65$).

Most of the safety events we encountered were monophasic and treatable with additional surgery or medical therapy. None were ongoing or chronic, as might be expected if uncontrolled IOP or intraocular inflammation had been present.

Efficacy outcomes

Efficacy outcomes are reported in Table 2. The mean CDVA with glare before surgery was 1.5 ± 0.6 logMAR, improving to 0.7 ± 0.8 logMAR 1 year after surgery ($P < 0.01$). By 3 months after surgery, mean subjective daytime glare improved 6.2 points (from 8.9 ± 1.8 to 2.7 ± 2.6, $P < 0.01$). Mean subjective nighttime glare improved 5.4 points (from 7.9 ± 1.8 to 2.5 ± 2.7, $P < 0.01$).

Aesthetic outcomes are shown in Table 3. The mean cosmesis score improved 6.7 points by 3 months after surgery (from 2.2 ± 1.6 to 8.8 ± 2.1, $P < 0.01$). One patient did not appreciate any change. In no instance was worse cosmesis score recorded. The custom artificial iris was centered well in 16 eyes (80%) and decentered by approximately 1 mm in 4 eyes (20%). The decentrations were in the nasal, superior, inferior, and inferotemporal directions.

DISCUSSION

We report the outcomes of a prospective consecutive series of patients who were implanted with a HumanOptics custom artificial iris before the start of the US FDA clinical trial. We demonstrated that this device is effective at reducing light and glare sensitivity and improving the cosmetic appearance of eyes with large iris defects. Safety outcomes were mixed and postoperative problems were common. Subsequent problems were usually related to preoperative comorbidities and/or the surgery required to implant the device rather than the device itself. Most of the complications were treatable by additional surgery or topical medications.

At the time of this report, an extensive literature review identified 11 published studies that are summarized in Supplemental Table 2. The first publication was in 2012.[6] It was a retrospective review of 4 eyes that experienced positive cosmetic and visual outcomes under attentive postoperative management. Until 2016, all subsequent publications were small retrospective case series.[8,10,13,14] Mayer et al. published the first prospective series of 32 eyes that were followed for an average of 13.6 months. Their most recent report, which increased the count to 51 eyes, is the largest published series.[2] The authors described good cosmetic and functional results with a significant reduction in glare and light sensitivity and high patient satisfaction. Transient high IOP, corneal decompensation, and cystoid macular edema were common complications.[2,15]

Most of the eyes in our compassionate use series had extensive iris defects. This was quantified by a high average preoperative pupil diameter and a high number of clock hours of iris involvement. In addition, most eyes had extensive ocular comorbidities, widely responsible for low preoperative CDVAs and limited visual potential. Pre-existing glaucoma was a frequent ocular comorbidity, as reported elsewhere.[16] However, besides transiently elevated IOP, medically treated in 3 eyes and surgically treated in 1 eye, we did not observe any significant changes in IOP 1 year following surgery. These results that are consistent with an earlier long term report, in which new onset glaucoma varied from 0% to 9%.[11] Thus, the relationship between device implantation and glaucoma is unclear and

may be related to the initial injury or subsequent operations; nevertheless, IOP should be monitored on a regular basis.[2]

Loss of CDVA was the primary safety outcome of this study. While we didn't observe a significant change in mean CDVA 1 year following surgery, 30% of eyes experienced some degree of vision loss. This high percentage is likely explained by the high prevalence of preoperative comorbidities that were present in study eyes. In 4 eyes, corneal epitheliopathy or superficial punctate keratopathy limited visual acuity results. One eye that was particularly sick had a history of multiple prior intraocular hemorrhages and end-stage glaucoma with only a small temporal island of vision remaining. During the surgery to implant the iris, she experienced another hemorrhage that extinguished her last remaining visual field and led to no light perception vision. She was delighted with the result despite the complication as her personal goal was primarily cosmetic. Finally, 1 eye experienced endothelial corneal decompensation and underwent a DSEK before the 1-year postoperative examination. This patient had a very low ECC preoperatively and was counseled regarding the high likelihood of corneal decompensation but preferred to proceed with artificial iris implantation as a stand-alone procedure regardless. Clearly, the limitations and potential complications of surgery must be discussed thoroughly, and patients should be aware that their preoperative comorbidities may progress after surgery and limit visual recovery.[15]

Endothelial cell counts were another major safety measure. Changes in ECC were significant, as has been noted by others.[7] Accordingly, patients with large iris defects should be counseled about the high probability they will need subsequent lamellar or penetrating corneal surgery. Beyond 3 months, the ECC was not systematically evaluated in this study without clinical suspicion of corneal deterioration. Indeed, ECC loss is more likely related to the surgery to implant an iris device than to the device itself. Rickmann and colleagues did not specifically measure ECC loss in their series of 34 patients, but did not report undue corneal decompensation after a mean follow-up of 50 months.[11] More than the implantation itself, concomitant procedures such as anterior vitrectomy, capsulotomy, or peripheral synechiae lysis that were frequent in our series could explain the high rate of endothelial cell loss observed.[16] Regardless, eyes that have already suffered significant ECC loss from initial trauma or antecedent surgery may experience ongoing cell loss and careful follow up is mandatory.

Perioperative complications and adverse events were additional safety measures. Four eyes underwent secondary surgical procedures and the 1 eye mentioned previously suffered a recurrent choroidal hemorrhage. This patient had experienced 8 prior surgeries, including 2 laser in situ keratomileusis enhancements, 2 pars plana vitrectomies, and 1 cyclo-destructive procedure. Her visual potential was known to be low and her surgical risk was high. The patient was nevertheless hoping to improve her aesthetic appearance. Notwithstanding the complication, she

was satisfied with her postoperative cosmetic appearance and the final surgical result.

Accurate sizing of the device remains empirical. We chose to go larger than some authors and prefer not to trephine unless we must. However, the sizing evaluation is subjective and different authors size the device differently.[5] The use of anterior-segment optical coherence tomography or ultrasound biometry may be useful adjuncts for evaluating the position of the artificial iris with respect to the ciliary body.[15]

Postoperative retinal examination was easily performed through the artificial pupil but was limited in cases of corneal opacification or edema. As with the Boston type 1 keratoprosthesis and its limited pupillary aperture, the use of wide-field imaging might be useful and remains to be evaluated.[17]

Overall, custom artificial iris implantation was highly successful at reducing light and glare sensitivity in this study. It was also effective at improving ocular cosmesis. Longer follow-up is needed to confirm these good results, especially as “iris retraction syndrome” with changes in residual iris color has recently been described.[18]

In conclusion, with appropriate informed consent regarding the potential risks and benefits of surgery, custom artificial iris implantation was sufficiently safe, given the availability of remedies for subsequent medical and surgical problems, and very effective, offering excellent visual and cosmetic outcomes compared to other artificial iris devices available commercially.[4, 19]

WHAT WAS KNOWN

- The CustomFlex Artificial Iris from HumanOptics is a custom-made foldable silicone iris implant that can be used for the repair of large congenital or acquired iris defects.
- The device was approved by the United States Food and Drug Administration in May 2018.
- There are a limited number of publications that document clinical results and complications.

WHAT THIS PAPER ADDS

- In this prospective compassionate-use clinical trial, the custom artificial iris was found to be very effective at reducing light and glare sensitivity and improving cosmetic appearance.
- Safety outcomes were acceptable given the extensive preexisting ocular comorbidities present in affected eyes.
- Transient high intraocular pressure was the most frequent postoperative complication.

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FIGURE LEGENDS

Figure 1. This is an example of a brown custom artificial iris device.

Figure 2. Composite before (2a) and after (2b) photographs of subject #1. The artificial iris in this case was passively fixated in the ciliary sulcus.

Figure 3. Composite before (3a) and after (3b) photographs of subject #2. The artificial iris in this case was passively fixated in the ciliary sulcus.

Figure 4. Composite before (4a) and after (4b) photographs of subject #16. The artificial iris was sutured to the haptics of the IOL and the IOL was sutured to the sclera.

X