Long-term outcomes of patients with artificial iris implants

Iris defects can arise from a number of causes including trauma, congenital abnormalities, and iatrogenic complications.[1] Deformities in the pupil or iris can lead to decreased visual acuity and contrast sensitivity, increased glare, and a loss in depth of focus.[2] While minor defects in the iris may be managed with surgical suturing,[3] larger defects causing visual symptoms require surgical management with artificial iris implants.[4] Patients with conditions such as aniridia and major iris colobomas are indicated for artificial iris implants, while patients with smaller defects seen in chronic traumatic or uveitis-induced mydriasis require reconstructive suturing techniques[5] Numerous iris implants are approved by Health Canada that vary in composition, design, and implantation site.[1] These prosthetic iris devices can broadly be categorized as either iris–lens diaphragms, endocapsular capsular tension rings, or customized artificial irises.[1] The HumanOptics artificial iris implant (HumanOptics AG, Erlangen, Germany) is a foldable custom iris prosthetic composed of silicone.

Studies have shown that the artificial implants can have improved visual outcomes and good cosmetic results but also may have negative complications such as cataract formation, glaucoma, pigment dispersion, darkening of the iris, and retinal detachment.[2] A recent systemic review conducted by Romano et al.[6] revealed that artificial iris implants are associated with improved visual acuity and reductions in glare and photophobia, with the most prevalent complication being postoperative glaucoma secondary to the prosthetic implantation. This complication was seen among various prosthesis types, with a prevalence of around 27% and a mechanism still poorly understood. The review by Romano et al.[6] also documents a slightly higher rate of postoperative complications in iris–lens diagram prostheses compared with artificial iris implants that is likely attributed to the minimally invasive technique and smaller incision size. Despite the widespread use of this procedure, there is limited literature discussing the long-term implications of artificial iris implants. In particular, there is minimal research on the HumanOptics artificial iris implant. As such, increased knowledge and information are needed to adequately understand the potential outcomes and complications associated with this treatment modality. The goal of this study was to investigate the long-term stability and overall outcome of HumanOptics artificial iris implantation in patients with iris defects.

This study was conducted as a retrospective noncomparative case series of patients under the care of an ophthalmologist (H.N.K.) in Victoria, British Columbia. The project protocol was approved by the Clinical Research Ethics Boards at the University of British Columbia (H21-02785), and the study was conducted in accordance with the tenets of the Declaration of Helsinki.

Analysis was done on patients seen between December 1, 2000, and November 1, 2021. Patients included in the study were those with a diagnosis of iris defect who received the HumanOptics silicone iris implant. Our exclusion criteria included patients who did not meet the clinical features of an iris defect, those with an iris defect but no artificial iris implant, and those who received an implant other than HumanOptics silicone iris implant. The artificial iris used was the custom HumanOptics silicone prosthesis. The dimensions of this implant include a 3.5 mm pupil, 12.8 mm overall diameter, and a thickness gradient that is 0.4 mm at the pupillary margin and decreases to 0.25 mm at the periphery.[7]

Following standard cataract extraction and intraocular lens implantation, initial paracentesis incisions were made in the inferotemporal and superotemporal locations. Xylocaine 1% without epinephrine and Healon viscoelastic (Abbot Medical Optics, Santa Ana, Calif.) were instilled into the anterior chamber. A 2.75 mm keratome was used to perform a nearly clear corneal incision temporally. Following intraocular lens implantation, the artificial iris was trephined to the manufacturer's specification. It was rolled into an intraocular lens injector cartridge and delivered into the anterior chamber under Healon viscoelastic protection. The implant was placed into the ciliary sulcus using a Sinsky IOL Hook (Surtex Instruments, New Malden, United Kingdom) and was positioned posterior to the iris remnant. The implant was rotated into position and confirmed to be well centred. All segments of the prosthetic iris were confirmed to be posterior to the patient's native iris tissue. This approach does not require suturing. Healon was irrigated and replaced with BSS Sterile Irrigating Solution (Alcon Medical Company, Geneva, Switzerland). The wound was secured and sealed with BSS with a 30-gauge needle cannula. Vancomycin 1 mg was instilled into the anterior chamber. The wounds again were examined and noted to be secure with stable intraocular pressure. This method of surgery was conducted on all eyes having concurrent cataract extraction; in the pseudophakic eye, the procedure was performed using similar incisions.

Outcome measures of overall success of the surgical operation were based on corrected distance visual acuity (CDVA, logMAR), intraocular pressure, complications, and subjective symptoms (i.e., changes in the levels of pain and comfort), and cosmetic outcome. Data were reported as mean ± standard deviation. IBM SPSS Statistics version 22.0 (IBM Inc, Armonk, NY) was used for statistical analysis.

Four patients (5 eyes total), 3 males and 1 female, with a median age of 68.5 years (range, 33–89 years) were enrolled in the study. Of the 4 patients, 3 had surgical implantation in 1 eye, and 1 patient had implants in both eyes, for a total of 5 eyes (Table 1). Two patients had traumatic

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Table 1—Summary of patient demographics, surgery, and results

Patient no.	Age, y	Sex	Diagnosis	Preoperative CDVA, logMAR	Preoperative IOP, logMAR	Procedure	Follow-up, mos	Postoperative CDVA, logMAR	Postoperative IOP, mm Hg	Latest CDVA, logMAR	Latest IOP, mm Hg	Additional comments
1	71	M	Traumatic aniridia	OS 20/50	OS 19	Left artificial iris implantation	90.4	OS 20/40	OS 28	OS 20/150	OS 19	End-stage glaucoma (traumatic angle recession from original blast injury)
2	89	F	Temporal sector iridectomy	OD 20/40	OD 10	Right artificial iris implantation	94.0	OD 20/70	OD 21	OD 20/60	OD 12	Two years later had right pseudophakic bullous keratopathy and subsequent Descemet stripping endothelial keratopathy
3	66	M	Traumatic aniridia	OS 20/25	OS 11	Left artificial iris implantation	7.1	OS 20/30	OS 10	OS 20/25	OS 11	—
4	33	M	Congenital aniridia	OD 20/100 OS 20/60	OD 12 OS 12	Bilateral artificial iris implantation	34.4	OD 20/40 OS 20/40	OD 22 OS 16	OD 20/30 OS 20/25	OD 22 OS 15	Repositioning done 34 weeks postoperatively due to pigment dispersion from excessive artificial iris–iris contact; required SLT following persistently raised IOP OD

CDVA, corrected distance visual acuity; IOP, intraocular pressure; SLT, selective laser trabeculoplasty

iridodialysis, 1 had a temporal sector iridectomy following complicated cataract surgery and choroidal effusion, and the final patient had congenital aniridia. The mean follow-up time was 56.5 ± 42.8 months, with the longest follow-up being 94.0 months from surgery.

For the 5 eyes of 4 different patients, the median preoperative CDVA was 0.50 logMAR, and the median latest postoperative visual acuity was 0.18 logMAR. Two eyes had an improvement of 0.52 and 0.38 logMAR, 1 eye remained unchanged, and 3 eyes had a decrease in CDVA of 0.48 and 0.18 logMAR.

The median preoperative intraocular pressure (IOP) of patients was 12.0 mm Hg. Postoperatively (within 1 week), the median IOP was noted to be 16.0 mm Hg, and at the latest follow-up, the median IOP was 15.0 mm Hg. Three of the 5 eyes (60%) had an average increase in IOP of 2, 3, and 10 mm Hg from baseline at the latest follow-up. A 51.60% increase was noted in IOP from preoperative values to the first postoperative visit and was found to be 23.40% at the final postoperative visit. Three eyes were noted to be affected by glaucoma prior to surgery (2 associated with aniridia and 1 with traumatic angle recession).

No intraoperative complications were noted in any of the patients. One patient had repositioning of an implant that was done 34 weeks after the initial surgery due to pigment dispersion from excessive artificial iris—iris contact. The horizontal corneal diameter (white-to-white) measurements of this patient were found to be 15.4 mm OD and 10.4 mm OS. The larger OD white-to-white value allowed for hypermobility and iridodonesis due to a less ideal implant fit. Congenital glaucoma in this patient, secondary to aniridia, likely led to buphthalmos and increased corneal diameter. The repositioning was performed under local anaesthesia with viscoelastic and a Sinsky hook. The implant was rotated, and all sectors were kept posterior to the rudimentary iris stump. One patient had a right pseudophakic bullous keratopathy and subsequent Descemet stripping endothelial keratopathy.

In terms of subjective symptoms, considerable reductions in glare, pain, and irritation were noted in all except 1 patient. This patient described a gritty sensation postoperatively, and over time, the patient further described light sensitivity, soreness, and irritation. A pronounced cosmetic improvement was noticed in all patients based on patient feedback and analysis of the surgeon Figure 1.

The use of a custom artificial iris implant plays a valuable role in the current management of patients with total or partial iris defects. This procedure can be done without sutures with small surgical incisions that allow for quick visual recovery. With a mean follow-up time of 4.7 years, to our knowledge, our study is the longest investigation of visual outcomes in HumanOptics artificial iris implants to date.

Mavrikakis et al.[4] noted an 80% reduction in glare following artificial iris implantation, and our study also achieved this same percentage reduction. An improved cosmetic outcome was noted in all patients, which was

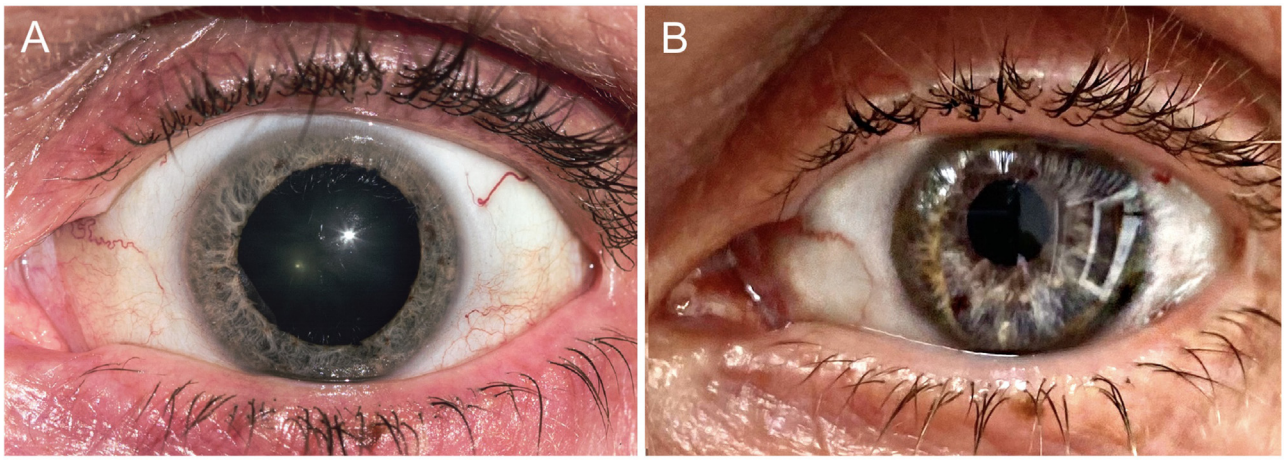

Fig. 1—Preoperative (A) and latest follow-up postoperative (B) images following artificial iris implantation.

amplified by the HumanOptics implant, which is custom crafted for the patient and matches the fellow iris. As such, with patients noting decreases in glare and light sensitivity and positive cosmetic improvements, generally there was very high patient satisfaction.

Elevated IOP following surgery has been documented as one of the most common postoperative complication of patients following iris implantation.[1] In our study, 3 of 5 eyes (60%) had persistently elevated pressures that were 23.4% higher than preoperative values at the latest follow-up. However, it is important to note that 3 eyes were previously affected by glaucoma before surgery, which may have contributed to these higher pressures. It is postulated that elevations in IOP from iris implants are a result of aqueous flow obstruction or compression of the trabecular meshwork.[1] For 1 patient with preexisting glaucoma, pigment release was noted in the right eye that was believed to be secondary to artificial iris—iris contact. The average corneal horizontal diameter (white-to-white) has been shown in studies to be 11.77 ± 0.37 mm with a range of 11.04 to 12.50 mm (±2 SDs).[8] The measurement of this patient revealed 15.4 mm OD. As such, the considerably larger white-to-white measurement may have allowed for iridodonesis due to a less than ideal fit of the artificial iris and led to subsequent pigment disruption. Repositioning of the implant was done, but elevated IOP remained from the previous pigment dispersion. Because the patient was on maximum medical therapy with glaucoma drops, repeat selective laser trabeculoplasty was done, which helped to slightly reduce the IOP. No other patients were found to require glaucoma surgery because of the implants. The other patient noted to have persistent IOP elevations (due to original blast injury and traumatic angle recession) was managed medically by adjusting glaucoma medications to 2 combination drops (brimonidine/brinzolamide and trovoprost/timolol), and this provided marginal improvement.

Although 3 eyes were found to have a decrease in visual acuity, it is important to recognize the underlying cause of the iris defect as well at the longstanding comorbidities of the eyes involved. Two of our patients had progressive glaucoma, and 1 patient had a right pseudophakic bullous keratopathy (PBK) and subsequent Descemet stripping endothelial keratopathy. The patient with PBK had a history of cataract extraction complicated by a choroidal effusion and iris prolapse. The procedure was interrupted, and partial iridectomy was performed where the iris could not be reposited, and the eye was left aphakic. Subsequent iris implantation may have contributed but was not the only factor in the development of PBK.

Our study was limited by the small sample size and limitations of data collection inherent to retrospective case series. This prevented an analysis of which patient population benefits the most from these implants. With all surgeries conducted by a single surgeon, alternative surgical techniques are not explored, which may have led to different visual outcomes. Additionally, no data were collected using specular microscopy to evaluate for long-term endothelial cell loss following surgery. However, it has been noted that iris—lens diaphragm prostheses are associated with higher rates of endothelial cell loss when compared with artificial iris implants.[6] A more formal method for evaluating patient glare and pain levels also could be used in future studies.

In summary, HumanOptics artificial iris implants were found to be a viable long-term option for patients with iris defects that provide good cosmetic outcomes, decrease glare, and generally have high patient satisfaction. However, in

certain patients, elevated IOPs persisted years later, so this potential complication should be taken into consideration when selecting suitable candidates.

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References

1. Srinivasan S, Ting DSJ, Snyder ME, Prasad S, Koch HR. Prosthetic iris devices. Can J Ophthalmol 2014;49:6–17.
2. Rickmann A, Szurman P, Januschowski K, et al. Long-term results after artificial iris implantation in patients with aniridia. Graefes Arch Clin Exp Ophthalmol 2016;254:1419–24.
3. Tsao SW, Holz HA. Iris mattress suture: a technique for sectoral iris defect repair. Br J Ophthalmol 2015;99:305–7.
4. Mavrikakis I, Mavrikakis EM, Syam PP, et al. Surgical management of iris defects with prosthetic iris devices. Eye (Lond) 2005;19:205–9.
5. Koch KR, Heindl LM, Cursiefen C, Koch HR. Artificial iris devices: benefits, limitations, and management of complications. J Cataract Refract Surg 2014;40:376–82.
6. Romano D, Bremond-Gignac D, Barbany M, et al. Artificial iris implantation in congenital aniridia: a systematic review. Surv Ophthalmol Nov 2022 [Epub ahead of print]. doi: 10.1016/j.survophthal.2022.11.001.
7. Bonnet C, Miller KM. Safety and efficacy of custom foldable silicone artificial iris implantation: prospective compassionate-use case series. J Cataract Refract Surg. 2020;46:893–901.
8. Rüfer F, Schröder A, Erb C. White-to-white corneal diameter: normal values in healthy humans obtained with the Orbscan II topography system. Cornea 2005;24:259–61.

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