Residual Iris Retraction Syndrome After Artificial Iris Implantation

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• PURPOSE: To evaluate the effect of an artificial iris implant on the remnant iris.
• DESIGN: Interventional case series.
• METHODS: Setting: Single center. Patient Population: Forty-two consecutive patients. Observation Procedures: Morphologic evaluation over 24 ± 14 months. Main Outcome Measures: Remnant pupillary aperture, iris color, visual acuity, intraocular pressure, and endothelial cell count.
• RESULTS: In 7 of 42 cases (16.7%), the residual iris aperture dilated from 36.6 ± 15.4 mm^2 preoperatively to 61.1 ± 12.5 mm^2 1 year postoperatively (66.9% increase). In 5 of 7 affected eyes the artificial iris had been implanted into the ciliary sulcus; in 2 eyes it had been sutured to the sclera. Four of the 7 patients presented with remarkable complications: 2 eyes needed glaucoma shunt surgeries owing to pigment dispersion; 1 suffered from recurrent bleedings; and in 1 case artificial iris explantation was performed owing to chronic inflammation. Anterior chamber depth and angle, endothelial cell count, and visual acuity did not change in this cohort. Changes in color were not observed in the remnant iris.
• CONCLUSIONS: The implantation of an artificial iris prosthesis can lead to a residual iris retraction syndrome. It is likely that residual iris is trapped in the fissure between the artificial iris and the anterior chamber angle, preventing further pupil constriction. Another possibility could be a constriction or atrophy of the residual iris. A scleral-sutured implant and an implantation in the capsular bag were both found to prevent the iris retraction. The study group number is inadequate to allow statistical comparison of these different implantation methods. As the use of artificial irises increases, we may expect more patients with iris retraction syndrome in the future. (Am J Ophthalmol 2019;199:159–166. © 2018 Elsevier Inc. All rights reserved.)

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IRIS DEFECTS CAN SEVERELY IMPAIR A PATIENT'S VISION, chiefly as a result of heightened sensitivity to glare. The patients can also have concerns about the cosmetic appearance of the eye. In addition, these eyes often show further pathology: corneal and scleral scarring, aphakia, retinal changes, and glaucoma. The Artificial*Iris* (HumanOptics AG, Erlangen, Germany), a thin, foldable prosthetic iris made of silicone, seems to offer a promising option in the surgical treatment of large iris defects. The manufacturer offers a variety of colors in its implants, which the surgeon can match with the patient's natural iris color. The standard size of the implant is 12.8 mm, which the surgeon can alter using a trephine to match the patient's natural iris size. In 2011 the device gained CE approval, and FDA approval followed in 2018. Recently, several surgeons have presented a variety of cases of pupil and iris reconstruction using this new implant.[1–5] Different methods of implantation are described[6]; it may be implanted in the capsular bag or in the ciliary sulcus, where it may (or may not) be sutured to the sclera. To date, there have been only a few reports about the effect of the prosthesis on the residual iris.[2,7] In a relatively large cohort of 42 patients, we observed and described anatomic changes that developed during a postimplantation period of at least 2 years. We also identified a previously unrecognized late complication of artificial iris implantation with the HumanOptics device.

METHODS

AT THE EYE CLINIC OF THE TECHNICAL UNIVERSITY OF Munich, 50 Artificial*Iris* silicone iris prostheses were implanted between June 2011 and December 2016. The main indication for surgery was intense sensitivity to glare. Secondary reasons were the patients' concerns about cosmetic appearance and decreased visual acuity. We analyzed the morphologic changes of the residual iris 24 ± 14 months after surgical reconstruction (at least 1 year of follow-up). Six patients suffered from complete aniridia and 2 received a sector-shaped implant. Because any change in the remaining iris tissue cannot be observed in such cases, they were excluded from this study. In the 42 remaining eyes we evaluated the influence of the artificial iris prosthesis on the residual iris. We assessed the anatomy of the remnant iris:

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TABLE. Data in Chronological Order of 7 Patients Exhibiting Residual Iris Retraction Syndrome After Artificial*Iris* Implantation

Case Number (Corresponding Figure)	Sex; Age	Eye	Year of Implantation	BCVA (logMAR)		IOP (mm Hg)		Anterior Chamber Angle (Degrees)		Endothelial Cell Count		AC Depth (mm)	
				Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
1 (Fig. 2, 3rd row)	M; 73	OD	2012	0.4	0.1	13	10	n/a	66.9	n/a	1351	n/a	4.3
2 (Fig. 2, 2nd row)	F; 47	OD	2012	0	1.3	10	20	n/a	28.3	n/a	n/a	n/a	3.73
3 (Fig. 2, 5th row)	F; 48	OD	2012	1.7	1.4	18	17	n/a	30.3	n/a	2488	2.71	3.05
4 (Fig 1)	M; 58	OD	2013	1	0.5	14	12	65.3	32.9	1718	1637	4.4	4.49
5 (Fig. 2, 1st row)	M; 66	OS	2013	0.1	0	16	18	48.5	29.6	1595	964	3.62	3.81
6 (Fig. 2, 4th row)	M; 41	OS	2014	0.7	0.7	14	16	24.1	36.6	1168	n/a	3.96	4.58
7 (Fig. 2, Last row)	M; 58	OS	2015	0.3	0.1	18	16	32.9	75	2660	2611	3.27	4.13

AC = anterior chamber; AI = artificial iris; BCVA = best-corrected visual acuity; IOP = intraocular pressure; ME = macular edema; n/a = data not applicable owing to morphologic alterations or owing to the impossibility of data acquisition (eg, scars, compliance); UBM = ultrasound biomicroscopy.

Data provided preoperatively and at least 3 months postoperatively.

its shape, color, and brightness. In all cases, preoperative residual iris motility was not notable or remarkable.

Informed consent was obtained from all participants. The study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the Institutional Review Board. The implant was fixed in the ciliary sulcus without sutures in pseudophakic eyes (n = 20), implanted in the capsular bag in combination with an intraocular lens (IOL) (n = 3), or sutured to the sclera with or without an attached IOL (n = 19).[8] In cases where sutures were used, an embedded fiber meshwork implant was used. The prosthesis is not designed for implantation in the anterior chamber.

In each case the required artificial iris diameter was determined by measuring the white-to-white (WTW) diameter first horizontally, then vertically, and then averaged. Afterward, the artificial iris was trimmed with a trephine, if necessary. Proper sizing of the implant is important to achieve precise centration of the pupil postoperatively. In our case series, we used a diameter that was slightly smaller than the ciliary sulcus (approximately the WTW minus 0.5 mm). The manufacturer, HumanOptics AG, requires all surgeons to pass an online certification course regarding proper handling of the artificial iris device. In all cases, at least 2 iridectomies were made in the prosthesis, except that it was implanted in the capsular bag. A detailed description of the methods used for implantation has been published elsewhere.[6]

All eyes were screened by photographic analysis for morphologic and color changes. Documentation was done with photography (Canon SLR including 100 mm Macro-Objective, Canon, Tokyo, Japan and Digi Pro 3 HD slit lamp, Bon SL-75, Bon Optic, Lubeck, Germany), gonioscopy, anterior segment SD-OCT (Heidelberg Engineering GmbH, Heidelberg, Germany), Pentacam (OCULUS Optikgeräte GmbH, Wetzlar, Germany), and ultrasound biomicroscopy. Endothelial cell counts were performed with an endothelial cell biomicroscope (CellChek XL, Konan Medical Inc., Irvine, USA). Each examination was repeated until good image quality was achieved using an automatic mode. Afterward, the images were checked for plausibility. In cases of poor image quality and/or corneal alterations after trauma, the endothelial cell count was conducted manually. Best-corrected visual acuity (BCVA) was tested with the chart monitor TCP-2000 (Tomey GmbH, Nuremberg, Germany). Intraocular pressure (IOP) was acquired using standard Goldmann applanation tonometry. The residual pupillary aperture was photographed and measured in square millimeters (mm^2) preoperatively, at 1–2 days postoperatively, and at 6 and ≥12 months postoperatively using the HEYEX EyeExplorer (Heidelberg Engineering GmbH, Heidelberg, Germany).

RESULTS

IN 7 OF 42 EYES (16.7%) WE DETECTED A RETRACTION SYNdrome of the patient's residual iris after implantation of the artificial iris prosthesis (Table). A continuous enlargement of the original pupillary aperture was noted during the follow-up in these patients. None of them complained about disturbing symptoms, especially pain, cosmetic alterations, or visual disturbances owing to the dilated residual iris.

Five of the affected patients were male and 2 female; mean age was 55.9 ± 1.3 years; and 3 were right and 4 were left eyes (Figures 1–3). Preoperatively, the BCVA was 0.6 ± 0.59 logMAR, IOP 14.71 ± 2.9 mm Hg, endothelial cell count 1785 ± 629 cells/mm^2, anterior chamber depth 3.6 ± 0.65 mm, and anterior chamber angle 42.7 ±18.13 degrees.

Five of the 7 implants were fiber mesh–free devices. Two to 4 prophylactic peripheral iridectomies were performed. The implant diameter was 12.0 ± 0.6 mm: 1 implant was

TABLE. Continued

Gonioscopy of the Remnant Iris Tissue	UBM Data	Number of Peripheral Iridectomies	Trephined Implant Diameter (mm)	Implantation Technique[6]	AI With Embedded Fiber Mesh	Decentration of the AI (mm)	Comments
Seems retracted, not pinched	Compressed in the angle	2	12.8 (original)	Sutureless ciliary sulcus	No	0.94	Combination of slight rotation and decentration; revision not successful
Retracted and pinched by the AI	Iris not clearly visible	2	12.5	Sutureless ciliary sulcus	No	0.15	Chronic inflammation with ME; explantation after 1 year
Displaced behind the AI	Iris not clearly visible	2	12.0	Sutureless ciliary sulcus	No	0.34	Glaucoma with need for shunt surgery
Retracted in the anterior chamber angle	Pushed together in angle	2	12.0	Sutureless ciliary sulcus	No	0.5	Uncomplicated course
Retracted and compressed in the angle	n/a	3	11.0	Sutureless ciliary sulcus	No	0.04	Massive pigment dispersion with need for glaucoma shunt surgeries
Retracted and pinched (reduced image quality)	Thickened in the angle	4	12.0	IOL + AI separately sutured to the sclera	Yes	0.11	Recurrent bleeding in anterior chamber, conservative glaucoma treatment, spontaneous recovery
Retracted residual iris tissue without signs of incarceration	n/a	2	12.0	"Sandwich" technique: IOL sutured to the AI, then sutured to the sclera	Yes	0.26	Uncomplicated course

used in its original size (12.8 mm), 1 was punched to a diameter of 12.5 mm, 4 to 12.0 mm, and 1 to 11.0 mm. Scanning electron microscopy of the trephinized iris showed a variety of smooth to sharp edges and protruding fibers (Figure 4).

Five of 7 implants were positioned in the ciliary sulcus without suture fixation in the eyes that were pseudophakic prior to surgery. In the other 2 cases, the implant had been sutured to the sclera in the ciliary sulcus. There was no implantation in the capsular bag in any of the 7 affected cases.

The mean pupillary aperture in these 7 cases was 36.6 ± 15.4 mm^2 preoperatively. At 2 ± 1 days after surgery, the residual iris pupil aperture was 42.9 ± 16.7 mm^2. The postoperative pupil aperture formed by the iris implant measured exactly 8.8 mm^2 and stayed stable. At 6 months postoperatively, the mean pupillary aperture of the residual iris was 51.2 ± 16.6 mm^2 and after 1 year it was 61.1 ± 12.5 mm^2 (Figure 5). Overall, 1 year after artificial iris implantation the residual pupillary aperture had increased by 24.5 mm^2 (66.9% increase).

At the last follow-up visit, the BCVA was 0.6 ± 0.57 logMAR, IOP 16.9 ± 6.7 mm Hg, endothelial cell count 1810 ± 717 cells/mm^2, anterior chamber depth 4.0 ± 0.53 mm, and anterior chamber angle 42.8 ± 19.56 degrees. Decentration of the implant (distance between the center of the newly formed pupil and the corneal anatomic center) was 0.33 ± 0.3 mm. Changes in color and brightness of the remnant iris could not be found in any of the cases.

Clinically, the residual iris "disappeared" almost completely and was only detectable by gonioscopy or ultrasound biomicroscopy (UBM; Figures 1 and 6) in the anterior chamber angle. The use of pupil-constricting agents (eg, pilocarpine and acetylcholine) did not alter the integrity of the remnant iris.

In 6 of the 7 cases, there was no detectable rotation of the artificial iris. In the 1 case in which the implantation technique had been suture-free and where the artificial iris had been embedded in the ciliary sulcus (Figure 2, Third row), a combination of slight rotation and decentration was observed. Chronic inflammation was not detected at any time point in the follow-up of this single case.

Four of 7 patients with the residual iris retraction showed severe complications: the retraction can lead from a partial to a complete angle closure and, consequently, highly raised IOP. The IOP could be well controlled with local antiglaucomatous eye drops. Two of these patients needed glaucoma shunt surgeries owing to pigment dispersion associated with glaucoma (Figure 2, First row and Fifth row). One patient suffered from recurrent bleeding into the anterior chamber with temporarily raised IOP (Figure 2, Fourth row).

In 1 case, explantation of the iris implant was necessary owing to chronic inflammation and elevated IOP (Figure 2, Second row).

The 1 case with an implant sutured to the sclera showed no complications (Figure 2, Last row).

To date, 3 retraction syndromes were detected in patients treated in 2012 (3/7 = 42.9%). Two patients have had surgery in 2013 (2/10 = 20.0%), 1 in 2014 (1/11 = 9.1%), another 1 in 2015 (1/14 = 7.1%), and none in 2016. In all detected cases neither patients nor the treating ophthalmologists noticed the remnant iris retraction syndrome. Nevertheless, the alterations were clearly visible in the photographic comparisons.

DISCUSSION

WE DESCRIBE A PREVIOUSLY UNRECOGNIZED LATE complication of artificial iris implantation with the Artificial*Iris* device: *R*esidual *I*ris retraction *S*yndrome (RITS), which is an unforeseeable event after artificial

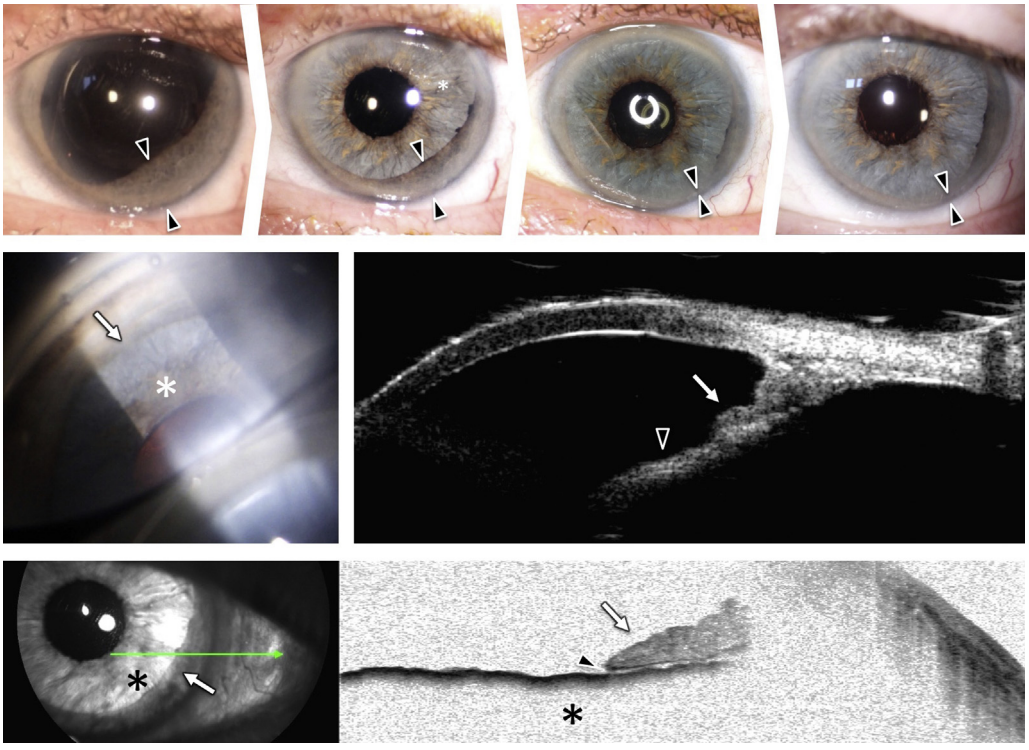

FIGURE 1. Residual iris retraction syndrome. (Top row) Left image shows preoperative situation with partial traumatic aniridia; subsequent images show the results at the postoperative follow-up visits (1 day, 6 months, and 18 months after artificial iris implantation). (Middle left) Gonioscopy, (Middle right) ultrasound biomicroscopy, and (Bottom) optical coherence tomography findings: The patient's residual iris is pushed and wrinkled in the angle and ciliary sulcus. The residual iris is not located below the implant but gathered in the gap between the prosthesis and the sclera.

iris implantation that is late onset—detectable during a long postoperative follow-up period. RITS is manifest by progressive enlargement of the pupil and retraction of the residual iris.

In 7 patients treated with an artificial iris, we detected morphologic changes in the residual iris. It appears as a very slow dilation of the residual pupil. The residual iris requires a long time (months to years) for these changes to develop. Given the slow onset of the condition and the increasing use of Artificial*Iris* devices, we may expect to see more cases of RITS in the future.

The anatomic changes vary from slight remnant iris dilation up to a sectorial or complete retraction ("completely invisible"). The residual iris tends to disappear almost completely and irreversibly and is detectable only by gonioscopy or UBM. These examinations can detect the remaining iris in the anterior chamber angle. The difficulty of visualizing these hidden structures makes it difficult to find the cause of the retraction.

Despite the ocular complications, all affected patients reported satisfaction with the implant. The newly formed pupillary aperture compensates for these problems.

• **CAUSATIVE HYPOTHESES:** Causative hypotheses are described in detail herein.

Friction and Incarceration of the Remnant Iris. One possible reason for the iris retraction could be a persisting slight dilation of the pupil at low light conditions. Also, the residual iris could be still capable of moving slightly in cases of persisting post-traumatic mydriasis. It cannot be ruled out that the patient had received pupil-dilating agents from other ophthalmologists who had seen the patient. In both instances, friction of the residual iris on the artificial iris could have led to iris retraction. The outer rim of the prosthesis has a relatively sharp edge when trephined to the correct diameter prior to implantation. The increasingly dilating pupil could be incarcerated in the fissure between the artificial iris and the ciliary sulcus or anterior chamber angle. Consequently, the pupil cannot constrict further.

Support for this hypothesis comes from our observation that there was no alteration detectable in iris tissue when the iris prosthesis had been implanted in the capsular bag and the lens capsule covers the trephined edge.

Constriction of the Remnant Iris. There could be an ongoing spastic retraction of the residual iris. The musculus sphincter pupillae is discontinued after the trauma, but the radial fibers of the musculus dilatator pupillae can still contract, resulting in an imbalance in the relative strength of these muscles. This imbalance leads to a more dilated pupil.

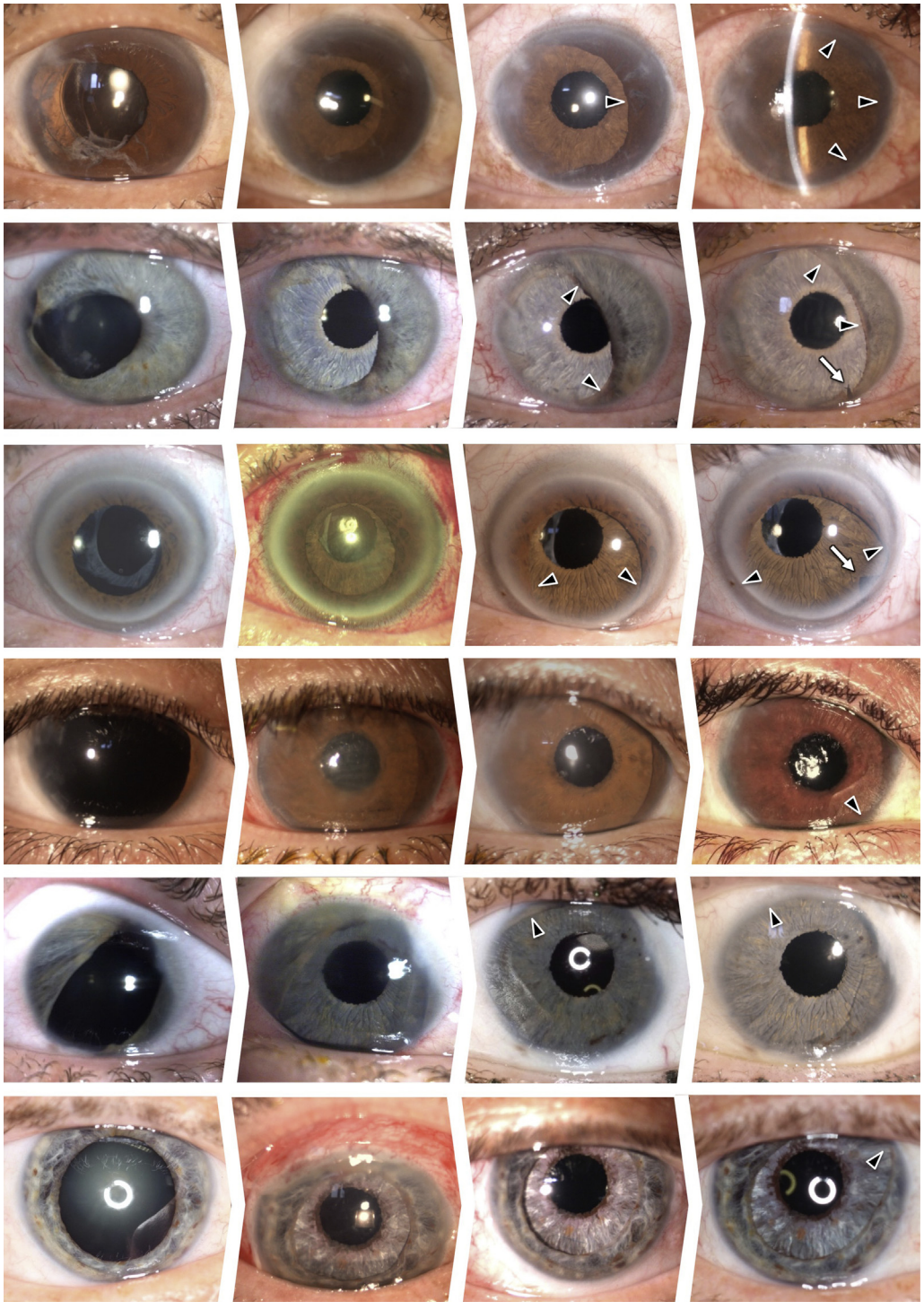

FIGURE 2. Six eyes observed with a retraction syndrome of the residual iris (1 patient in each row; right to left: preoperative, at postoperative day 1–2, after 6 months, and after 1 year): Arrowheads designate margin of the residual iris. White arrow indicates iridectomy. The opening of the residual iris differs from mild (Rows 4–6) to a complete dilation (Top row).

Atrophy and/or Fibrosis of the Remnant Iris Tissue. The residual iris tissue may become atrophic and dissolve, at least in part. On the other hand, examinations with spectral-domain optical coherence tomography and ultrasound could still detect remnants of the iris tissue. Unfortunately, histologic specimens could not be obtained to prove this hypothesis. It may be that some patients' irides after a trauma would become atrophic without the

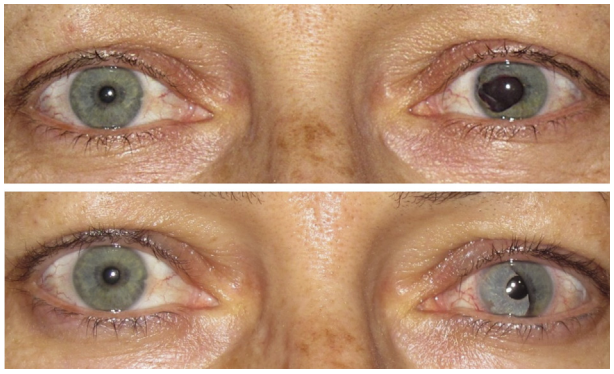

FIGURE 3. Preoperative (Top) and postoperative (Bottom) findings after artificial iris implantation in the left eye. Same patient as in Figure 2, Second row.

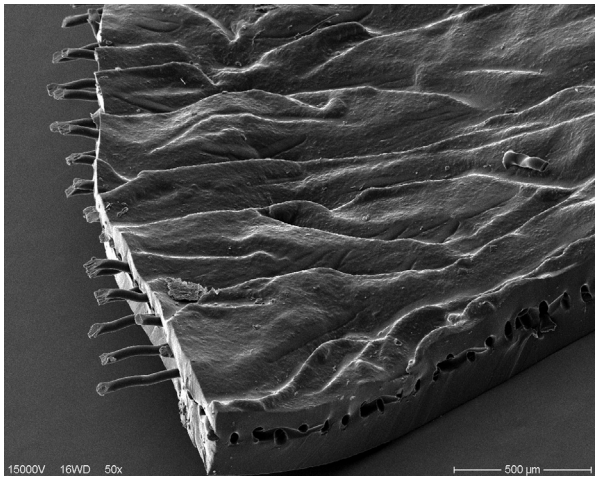

FIGURE 4. Electron microscope image of the trephined edge of an artificial iris with embedded fiber meshwork. Protruded fibers can be seen at the outer rim of the implant while the trephined silicone tissue edge is clean cut. The surface of the prosthesis shows a 3-dimensional texture.

implantation of an artificial iris. We could not find reports to support this hypothesis, but it cannot be ruled out.

Irritation of Surrounding Tissue Owing to Adjustments of the Implant. All the implants in our series had at least 2 peripheral iridectomies. Some required trephination. The corners created by the peripheral iridectomies or arcuate punch-outs can create a sharp rim that does not occur with trephination alone. Five of the 7 patients were treated with artificial irides that did not contain the fiber meshwork, only silicone, ruling out the former as a likely cause for the clinical observation of iris retraction. However, it is possible that the ciliary sulcus tolerates some IOL materials better than other materials.

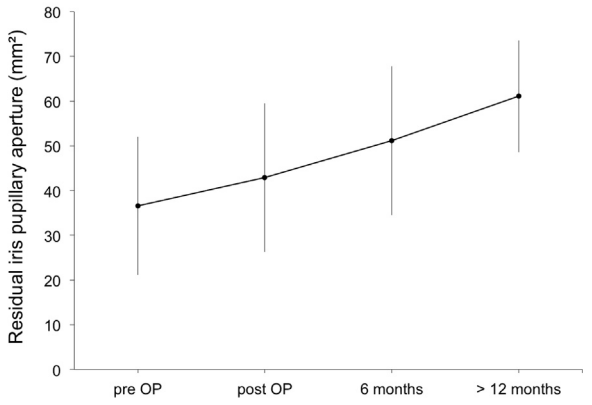

FIGURE 5. Development of the residual pupillary aperture (mm^2) after artificial iris implantation in individual patients (Cases 1–7) preoperatively and 1–2 days, 6 months, and more than 1 year after surgery.

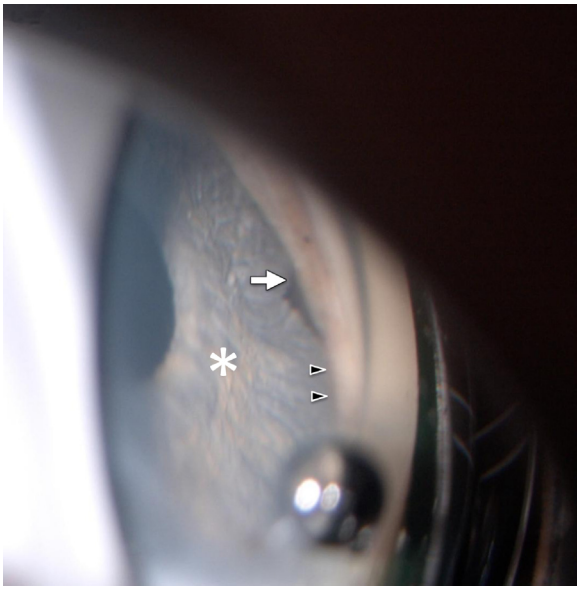

FIGURE 6. Gonisocopy image 1 year after artificial iris implantation; same eye as in Figure 2, Row 5. The implant (asterisk) is slightly tilted with parts posterior and parts anterior to the scleral spur (arrows). The residual iris cannot be seen. Peripheral iridectomy touching the sclera (arrowhead).

• PROPOSAL FOR PROPHYLAXIS AND SOLUTIONS: The use of miotic agents to constrict the residual iris had no effect.

In 1 eye we performed a revision surgery (Figure 2, Third row); because of a slight decentration of the new pupil we tried to mobilize the residual and the artificial iris in order to achieve centration. However, the residual iris was stuck in the ciliary sulcus, so that even a revision surgery was not successful in terms of a recentration of the implant.

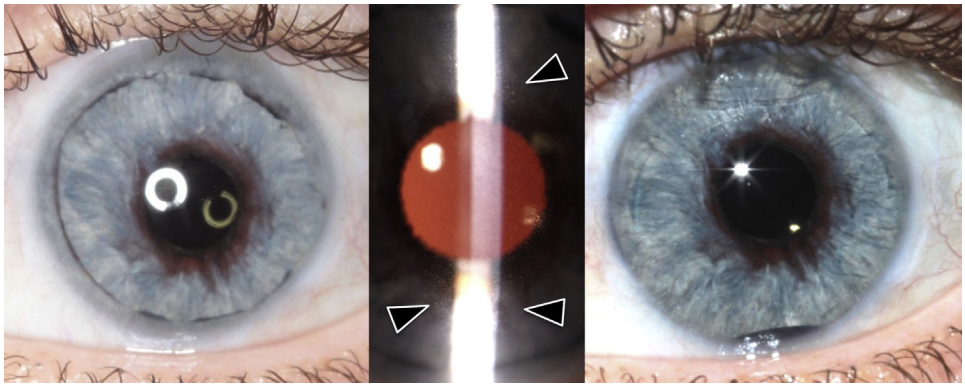

FIGURE 7. (Left) A 30-year-old man suffering from persistent mydriasis and pigmentary dispersion glaucoma but not from residual iris retraction syndrome after blunt trauma. (Middle, arrowheads) Extensive pigmentary dispersion after artificial iris implantation. In this patient the artificial iris had been sutured to the sclera. (Right) Pigmentary dispersion stopped after successfully removing all the remnant iris.

We do not recommended a prophylactic suture of the artificial iris implant to the remnant iris tissue in order to prevent dislocation, because a secure fixation cannot be achieved in the weakened remnant iris tissue.

There seems to be greater risk of iris retraction when the artificial iris is implanted in the ciliary sulcus without suture fixation to the sclera (5 vs 2 cases).

IOL implantation can lead to uveitis-glaucoma-hyphema (UGH) syndrome. This could be a reason why 2 patients had (pigmentary) glaucoma, eventually owing to friction of the residual iris with the implant. Comparable findings are described in cases with the implantation of an IOL into the ciliary sulcus[9–11] and in the capsular bag,[12] and with transscleral secondary IOL fixation.[13] Therefore, it might be beneficial to completely remove the remnant iris to prevent pigmentary dispersion and reduce the likelihood of secondary glaucoma when considering patients for surgical treatment with an artificial iris. Stability of the artificial iris should not be affected if it is either inserted in the capsular bag or sutured to the sclera. We already successfully performed a complete removal of remnant iris in a patient (Figure 7) suffering from severe pigmentary dispersion, but not from RITS. In this patient the artificial iris has been sutured to the sclera. We suppose that the pigment dispersion comes from the residual iris tissue. Pigment dispersion could also be caused by contact with the internal sulcus or the ciliary body. Unfortunately, UBM in these cases was not able to answer this question owing to insufficient resolution and difficult visualization.

The implantation of a sulcus-fixated artificial iris is somewhat comparable to a condition after piggy-back IOL implantation. In these cases, UGH syndrome, but no effect on the (residual) iris, was described.[14] The iris retraction syndrome was not observed in secondary sulcus IOL implantations; especially, this phenomenon was not reported in the use of supplementary IOLs, which are specifically designed for implantation in the sulcus, when there is already an IOL in the capsular bag. The superior behavior of these IOLs could be attributable to the softer surface and convex IOL design, and it may be of importance that IOLs such as the Sulcoflex are made of hydrophilic acrylic, which has more uveal biocompatibility than silicone elastomer.[15]

Although supplementary silicone sulcus IOLs have been infrequently reported as inducing iris chafe and UGH, the incidence is very low compared with our current findings. Interestingly, these IOLs are generally thicker (about 1.0 mm) than the artificial iris (0.25 mm). Reviewing the literature on supplementary IOLs does not reveal any cases of RITS. Also, phakic posterior chamber IOLs have not been associated with syndromes such as RITS or UGH. This suggests that the pathology may be related to the artificial iris physical dimensions, geometry, or the chemistry of the biomaterial.

Laser iridotomy was described as a successful prophylactic treatment in eyes with sulcus-fixated IOLs.[16] To prevent UGH syndrome and a pupillary block, a "peripheral iridectomy" was performed in all cases in the artificial iris implant by trephination prior to implantation.

The sharp edges and protruding fibers could cause residual iris irritation. These borders could be a causative factor in the pigment dispersion and UGH syndrome seen in this cohort. It seems possible that chronic movement and friction between the artificial iris and ciliary body may have been the reason for the recurrent bleeding or irritation of the residual iris tissue. After Case 9 (the point at which we checked the edges using electron microscopy), we began to always use single-use sharp trephines to achieve clean-cut edges. Because we adopted single-use trephines very early at our center and RITS was detected in patients treated after this change, we do not see a correlation.

A narrow anterior chamber is most likely not the reason for the residual iris retraction syndrome; anterior chamber depth and angle are similar preoperatively and

postoperatively. Nevertheless, the iris retraction syndrome occurred in the reported cases. Laser iridoplasty was successful in UGH syndrome[16] but is not feasible in an artificial iris made of silicone.

The implantation of an iris prosthesis can lead to a maximal dilation of the residual iris with angle closure and a consecutive increase of IOP. Therefore, it is necessary to inform the patient, as well as the surgeon, accordingly prior to surgery.

In conclusion, a retraction of the residual iris can be observed after implantation of an artificial iris. A scleral fixation of the prosthesis with sutures or implantation in the capsular bag (including a capsular tension ring) seems to be a safer procedure that avoids residual iris retraction syndrome: the sutures hold the artificial iris in a relatively posterior position, away from the residual iris. An artificial iris implanted in the capsular bag does not have direct contact with the residual iris. Both surgical techniques create results with less friction between the residual iris and the artificial iris. However, our study group number is inadequate to allow statistical comparison of these different methods of implant placement.

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