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Flexible silicone artificial iris in cases of aniridia and iris deficiencies

Iris artificiel en silicone flexible pour aniridies et déficiences iriennes

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Synopsis: The new flexible silicone artificial iris is a good option in cases of aniridia and iris deficiencies. The cosmetic result is outstanding. Elevated IOP is the main problem.

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But: Evaluer un nouvel iris artificiel en silicone flexible en cas d'aniridie ou de déficience irienne

Lieu: Centre Hospitalier National d'Ophtalmologie, Hôpital des Quinze-Vingts, Paris, France.

Type d'étude: Etude retrospective étudiant le résultat cosmétique, la photophobie, la densité endothéliale et la pression intraoculaire.

Méthodes: Des patients, atteints de déficiences iriennes se plaignant de photophobie ou d'un problème esthétique et nécessitant une chirurgie de cataracte, ont reçu le nouvel iris artificiel en silicone flexible

Resultats: Quinze yeux de 14 patients ont été évalués. L'âge moyen était de 49.5 années (+/- 18.5). 50 % étaient aphaques, 22.4 % pseudophaques et 28.6 % phaques. L'étiologie était un traumatisme (57.1 %), un traumatisme chirurgical (28.6 %) ou une aniridie congénitale (14.3 %). A 3 mois postopératoire, sur une échelle de 0 à 10, la photophobie subjective moyenne s'est améliorée de 5.2 points ($P = .002$) et le résultat esthétique de 4.7 points ($P = .001$). La perte endothéliale était de 16 % ($P = .001$). Entre 3 mois et 1 an postopératoire il n'y avait plus de perte endothéliale significative ($P = .320$). L'élévation de la pression intraoculaire était la complication principale (35.7 %). Deux patients souffrant d'un glaucome pré-existant ont nécessité une cyclodestruction. L'iris artificiel a dû être retiré pour un patient du fait d'une pression élevée et d'une douleur associée à une inflammation chronique. Les symptômes ont disparus après l'ablation de l'iris artificiel.

Conclusion: L'implantation du nouvel iris artificiel est une bonne solution du fait de ses résultats esthétiques probants. Cependant, les patients atteints de glaucome pré-existant ne

sont pas de bons candidats. Les patients doivent être prévenus de la nécessité d'une possible explantation

Mots clés : iris artificiel, aniridie, déficience irienne

Purpose: To evaluate a customized silicone flexible artificial iris in cases of aniridia or iris deficiencies.

Setting: Centre Hospitalier National d'Ophtalmologie, Hôpital des Quinze-Vingts, Paris, France.

Design: Retrospective case series investigating cosmetic result, photophobia, endothelial cell density and intraocular pressure.

Methods: Patients with iris deficiencies requiring cataract surgery or correction of aphakia, or pseudophakic patients, complaining of photophobia or cosmetic disturbances were implanted with the new flexible artificial iris.

Results: Fifteen eyes of 14 patients were evaluated. Mean age was: 49.5 (+/- 18.5). 50 % were aphakic, 22.4 % pseudophakic and 28.6 % phakic. Etiology was trauma (57.1 %), previous surgical trauma (28.6 %) and congenital aniridia (14.3 %). Three months postoperatively, the mean subjective photophobia score improved by 5.2 points ($P = .002$) and the mean cosmesis score by 4.7 points ($P = .001$) on a 0 to 10 scale. Mean endothelial cell loss was 16 % ($P = .001$). There was no further statistically significant endothelial cell loss between the 3-month follow-up and the 1-year follow-up visit ($P = .320$). Elevated intraocular pressure was the main complication (35.7 %). Two patients with pre-existing glaucoma required cyclodestructive procedures. The artificial iris was removed in one eye because of chronic pain, elevated intraocular pressure and inflammation that resolved rapidly after removal.

Conclusion: Implantation of the customized artificial iris is a very good option because of its outstanding cosmetic result. However, patients with pre-existing glaucoma are not good

candidates. Patients should also be warned of possible chronic inflammation necessitating explantation.

Key words: artificial iris, aniridia, iris deficiencies

Aniridia and iris deficiencies can be congenital or acquired. They are often associated with other important ocular comorbidities. Acquired defects result from trauma, intraocular pressure (IOP) spikes (Urrets-Zavalía syndrome), intraocular inflammation or less frequently iridocorneal-endothelial syndrome. Both congenital and acquired pathologies result in iris deficiencies due to partial or total loss of iris tissue or simply mydriasis. Iris deficiencies cause cosmetic impairment, photophobia and decreased visual acuity. Cosmetic impairment and photophobia can be very debilitating. It is thus important to consider iris repair when planning cataract surgery, correction of aphakia or in disturbed pseudophakic patients. In cases of large iris defects when pupilloplasty is not possible, modified capsule tension rings (Morcher 50 F, 50 C and 96 C) or aniridia implants (Ophtec 311 brown, green and blue) and Morcher black 67 F and 67 G) were until recently the only possible options¹⁻¹¹. The cosmetic result with these different devices is correct when the color of the fellow eye is black or brown but poor in cases of blue or green eyes. Furthermore, in cases of aphakia, it is necessary to enlarge the corneal incision to 9 or 10 mm. A relative new option for treatment is the use of a custom-made flexible silicone iris (Human Optics ArtificialIris[®] or CustomFlex[®] in the United States) that enables insertion through a small incision. To date, few studies have been published about this new option¹². This article reports our experience.

I. PATIENTS AND METHODS

This is a retrospective case series. The study was performed in conformance with the tenets of the Declaration of Helsinki. The Human Optics Artificial Iris[®] has received Conformité Européenne marking. No board approval was required. It is not to be mistaken with the

esthetical artificial irises NewColorIris[®] and BrightOcular[®] used to change the color of a normal eye. They have not received the Conformité Européenne approval and should not be used because they often lead to very serious complications. All surgeries were performed by the same experienced surgeon (SR). Inclusion criteria were:

- age: 18 years and older
- congenital or acquired iris deficiencies with no possibility of pupilloplasty correction
- necessity of cataract surgery, aphakia correction (after failure of contact lens wear) or pseudophakic patients complaining of disturbing photophobia or cosmetic appearance.

Patients with ocular inflammation, retinal detachment dating less than 6 months or corneal epithelial disease (a common feature in some congenital aniridia) were excluded. Glaucoma patients with controlled intraocular pressure were not excluded.

All the patients had a complete preoperative examination. All eyes had a preoperative endothelial cell count (ECC), except case 7 and 10 because of corneal scarring and corneal decompensation respectively. Each patient was asked to subjectively assess his/her cosmetic appearance pre and postoperatively on a scale of 0 (very unsatisfied) to 10 (very satisfied) and his/her photophobia (0 = no photophobia to 10 = intolerable photophobia).

Follow-up was 1 day, 10 days, 1 month, 3 months, 1 year postoperatively.

Surgical technique. The artificial iris (AI) was customized by Human Optics (Erlangen, Germany) for each patient based on the photographic documentation of the fellow eye. The AI is made of flexible silicone and has an overall diameter of 12.8 mm and a central pupil aperture of 3.35 mm. It comes in two versions: without fiber ('fiber-free') or with an embedded polymer fiber meshwork to prevent suture migration through the silicone ('with-fiber'). The manufacturer recommends ordering the 'with-fiber' version when the AI is to be scleral-sutured. However, if needed, the 'fiber-free' version can be cautiously sutured. The advantage of the 'fiber-free' AI is increased flexibility. Two AI are delivered for each patient

and it is possible to order both versions for the same patient. The AI must be cut with a trephine to the right dimension before insertion into the eye. In cases of an associated cataract surgery, a 'fiber-free' artificial iris downsized to 9 mm was planned to be placed in the capsular bag except for one patient with a subluxated lens where it was decided to scleral-suture a 'with-fiber' AI in the ciliary sulcus. In cases of pseudophakia or aphakia the trephine diameter was horizontal White-To-White (WTW) distance - 1 mm and an iridectomy was made in the upper part of the AI. In cases of aphakia, the IOL (Alcon SN 60 WF) was to be sewn to the back of the AI and the resulting IOL-iris prosthesis complex was to be scleral-sutured in the ciliary sulcus behind the iris remnants using a double-arm 9-0 polypropylene as described by Sptizer¹³ and Mayer¹⁴. In cases of pseudophakia the AI was planned to be placed in the sulcus behind remnants of the iris tissue or to be scleral-sutured in the sulcus if the remnants were not considered sufficient.

One patient had a combined penetrating keratoplasty (PKP).

The iris was implanted through a small incision using either a forceps (4 mm) or an injector (Viscojet Mediceal 2.2 mm)

Statistical analysis. Descriptive statistics were presented as numbers (%) for qualitative variables and as median (minimum-maximum) for quantitative variables. To compare evolution of photophobia and cosmesis score and endothelial cell, the Wilcoxon signed-rank test was used. All tests were bilateral (cut-off 5%) and R version 3.5 (<http://www.R-project.org>) was used for the statistical analyses. A *P* value of less than 0.05 was considered statistically significant.

II. RESULTS

Fifteen eyes of 14 patients were enrolled from July 2017 to September 2019. Table 1 shows preoperative data of each patient. Because of intraoperative difficulty, one eye was excluded from the study (see below). Mean age was: 49.5 +/- 18.5. Seven eyes (50 %) were aphakic, 4 (28.6 %) phakic and 3 (21.4 %) pseudophakic. Two pseudophakic patients had a previous Ophtec 311 iris reconstruction and were not happy with the cosmetic result. The iris deficiencies etiologies were trauma (57.1 %), previous surgical trauma (28.6 %), and congenital (14.6 %).

Surgical technique. In phakic patients, the initial plan to place the AI in the bag was abandoned in 3 cases (cases 13, 14 and 15). In cases 13 and 14 the capsular bag appeared too fragile even after a ring implantation and we preferred placing the AI in the sulcus behind the remnants of iris tissue, without scleral fixation in case 13 and with scleral fixation in case 14. The former had to be repositioned and scleral-sutured 3 weeks after the initial surgery because of its migration forward in front of the remaining iris tissue causing sudden elevated IOP. In case 15, an Argentinian flag occurred during capsulorhexis and damaged the anterior capsule of the capsular bag. We could manage to implant the IOL in the damaged bag, but we decided to abandon the AI implantation in the bag or in the ciliary sulcus because of fear to cause further damage. The patient was excluded from the study. In aphakic patients, the IOL-AI complex was carefully and successfully scleral-sutured in the ciliary sulcus in all patients. In pseudophakic patients, the AI was simply placed without suture behind the iris remnants (case 12) or scleral-fixated after removal of the Ophtec lens (cases 1 and 6) as in the aphakic group. Table 2 lists complications and 3-month postoperative results. Increased IOP was observed in 5 eyes (35.7 %). Three of them had pre-existing controlled glaucoma prior to AI implantation. Two of these eyes demonstrated significantly elevated IOP and normalization was very difficult necessitating 2 cyclodestructions. One eye (case 6) demonstrated elevated IOP,

persisting ocular inflammation and chronic pain. Removing the AI was decided 2 months after initial surgery because no treatment was successful. The symptoms rapidly resolved after removal. As already mentioned, case 13 developed a delayed increased IOP related to the forward migration of the AI. The raised IOP resolved rapidly after repositioning and scleral fixation of the AI. Cases 7 and 11 did not recover a good visual acuity because of corneal scarring and macular degeneration (Berlin's edema) at the time of trauma. Due to pinhole effect and correction of the optical aberrations, best corrected distance visual acuity (CDVA) improved in case 2, 3, 13 and 14. Remarkably, case 2 (aphakic) recovered 20/20 without correction whereas her best-CDVA was 20/32 before surgery, and cases 13 and 14 (congenital aniridia associated with cataract surgery) recovered 20/40 whereas her best-CDVA was 20/100 few years ago before the presence of cataract (best-CDVA was 20/400 just before cataract surgery). Patients were highly satisfied with the cosmetic result. Mean cosmesis score improved by 4.7 points from 3.6 preoperatively to 8.3 after surgery ($P = .001$). A few representative examples are shown on Figure 1, 2 and 3. One AI was slightly decentered but the patient (case 4) did not think necessary to surgically re-center it. Photophobia has been dramatically reduced. Mean photophobia score improved 5.2 points from 5.9 preoperatively to 0.7 postoperatively ($P = .002$). Three months postoperatively, mean endothelial density loss was 16 % ($P = .001$). Case 13 experienced a severe 68 % loss of ECC due to the AI forward migration necessitating a secondary surgical intervention to scleral-fixate it. Table 3 compares the 3-month and 1-year endothelial cell density for the patients who attended, to date, their 1-year follow-up visit. There was no statistical difference ($P = .320$).

III DISCUSSION

Challenging surgical technique. In cases of cataract surgery, in-the-bag placement of the AI is the « gold standard » because it avoids uveal contact, but it is not always easy or possible. A large capsulorhexis, placement of a capsule tension ring before lens implantation, and staining the capsule can be helpful¹⁵. However, zonules and capsular bag are fragile in congenital aniridia^{3,4,16}. The risk is dislocation or tearing of the capsular bag when inserting the AI and it is sometimes safer to place the AI in the sulcus. We recommend to systematically order the ‘with-fiber’ and ‘fiber-free’ versions of AI for aniridia cataract surgery. In cases of sulcus placement, it is paramount to carefully place the AI in the posterior chamber behind the iris remnants to avoid irrecoverable rapid endothelial cell loss and trabecular impairment as frequently described with the devices (that should not be used) destined at changing iris colors and placed in front of the natural iris^{17,18}. It is also important to make sure that the tissue remnants will sufficiently « hold back » the AI and prevent its forward migration. In doubt it is best to scleral-fixate it.

Visual acuity. Visual acuity is usually not very relevant concerning aniridia studies because many patients have comorbidities that can affect the final visual outcome. However, because of pinhole effect and decreased optical aberrations, best-CDVA improvement is often observed as experienced by 4 patients (case 2, 3, 13 and 14) in our study.

Photophobia. The AI is very efficient at reducing photophobia. Photophobia can be very disturbing, and some patients report a profound life enhancement after their operation even without improvement of visual acuity. We consider photophobia in itself a very good indication. Most studies report a great improvement in the reduction of photophobia with the older devices^{2-5, 7-9, 16,19} or with this new device^{12, 20-23}.

Cosmetic appearance. At split lamp some color differences between the rest of the iris and the prosthesis may be detected but overall the match of the iris color between both eyes are excellent and most of the time relatives cannot tell the difference at conversational distance.

All the patients were overwhelmed by the cosmetic result especially young patients who were sometimes psychologically very disturbed by their preoperative cosmetic appearance. All studies ^{12,20-26} report an excellent cosmetic result with this new device when compared to older devices.

Endothelial density. Patients experienced a mean 16 % cell loss 3 months after the surgery. It is more than for a standard cataract surgery, but it is acceptable given the surgical challenge. One of our patients (Case 13) had a 68 % endothelial cell loss due to the AI forward migration. This case emphasizes the absolute necessity to perfectly place the AI in the sulcus and to prevent its migration. In our study, there was no significant loss between the 3-month and the 1-year ECC for the patients having attended, to date, their one-year follow -up visit. It seems to corroborate the long-term endothelial innocuity. However, larger and longer follow-up series are necessary to ascertain it.

Raised postoperative IOP was the main complication. It is a well-known complication with Morcher and Ophtec aniridia lenses placed in the sulcus ¹⁻⁸. This new device makes no exception. We observed significantly elevated IOP in 5 eyes (35.7 %) of which 3 had pre-existing glaucoma. Sptizer ²⁰ reports significantly increased IOP in 18 % of the eyes of which 50% had pre-existing glaucoma. Postoperative elevated IOP can sometimes be explained by a misplacement in the anterior chamber causing trabecular irritation and can be resolved by a better repositioning in the ciliary sulcus. It can also be explained by uveal tissue chafing which can cause elevated intraocular pressure but also chronic inflammation and ocular pain as observed in one of our patients. The only relieving treatment was AI removal. Pre and postoperative UBM could be helpful for a better AI sizing and positioning. We now currently use the smaller vertical WTW and not the longer horizontal WTW to determine the right diameter of the AI when inserted in the sulcus (trephine diameter: vertical WTW – 1 mm).

We consider postoperative IOP a major concern and patients with pre-existing glaucoma not good candidates.

There were no retinal detachment or vitreous hemorrhage in our series. If necessary, a vitrectomy through the pseudo 3.35 mm pupil is technically possible ²⁷.

In conclusion, the customized flexible artificial iris prosthesis offers an incomparable cosmetic result. Careful selection of patients and precise surgical technique are necessary. As with older devices, when placed in the sulcus, elevated IOP is the main complication and patients with pre-existing glaucoma may not be good candidates. Patients should also be warned of a possible chronic painful inflammation eventually requiring removal of the AI.

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Table 1. Preoperative data

Study Eye Number	Age and Sex	Etiology of Iris defect	Phakic status	Best CDVA	Ocular comorbidities	Photo Phobia Score	Cosmesis score	ECC (cells/mm ²)
1	F,37	trauma	pseudophakia (Ophtec311)	20/200	amblyopia	3	2	660
2	F,62	trauma	aphakia	20/32		6	3	2027
3	M,48	trauma	aphakia	20/32		4	3	2345
4	M,54	trauma	aphakia	20/70	glaucoma	6	2	600
5	M,32	trauma	cataract	20/400	subluxated lens	3	1	3412
6	M,40	trauma	pseudophakia (Ophtec311)	20/400	amblyopia glaucoma	3	4	1642
7	M,25	trauma	aphakia	20/400	corneal scarring, glaucoma	6	4	unable (corneal scar)
8	M,65	surgical trauma	aphakia	20/40	retinitis pigmentosa, monophthalmos	9	5	2615
9	F,47	surgical trauma	cataract	20/32	high myopia	6	3	2190
10	M,71	surgical trauma	aphakia	20/2000	corneal decompensation	5	5	unable (corneal edema)
11	M,84	trauma	aphakia	20/200	macular degeneration	9	5	2412
12	M,69	surgical trauma	pseudophakia	20/32		7	5	1200
13	F,29	congenital	cataract	20/400	nystagmus	8	4	2645
14	F,29	congenital	cataract	20/400	nystagmus	8	4	2522
15	M,30	congenital	cataract	20/2000	nystagmus	8	4	2250

CDVA : corrected distance visual acuity. Photophobia score from 0 (no photophobia) to 10 (intolerable photophobia). Cosmesis score from 0 (very unsatisfied) to 10 (very satisfied). ECC : endothelial cell count

Table 2. Three-month follow-up

Study Eye Number	Best-CDVA	AI placement	Photo Phobia score	Cosmesis score	ECC (cells/mm ²)	Complications
1	20/200	(IOL-AI) sulcus scleral-fixated	1	8	620	elevated IOP
2	20/20	(IOL-AI) sulcus scleral-fixated	0	9	1812	
3	20/25	(IOL-AI) sulcus scleral-fixated	1	9	2122	
4	20/2000	(IOL-AI) sulcus scleral-fixated	1	7	corneal edema	-elevated IOP -slight decentration of the AI -corneal decompensation
5	20/25	IOL in the bag AI sulcus scleral-fixated	0	10	3213	
6	20/400	(IOL-AI) sulcus scleral-fixated	3	4 (8 before AI removal)	1414	-elevated IOP -chronic pain and inflammation - AI removal at 2 months postop
7	20/400	(IOL-AI) sulcus scleral-fixated	2	6	preoperative corneal scar	elevated IOP
8	20/40	(IOL-AI) sulcus scleral-fixated	0	9	2412	
9	20/20	IOL and AI In the bag	0	9	1980	
10	20/200	(IOL-AI) sulcus scleral-fixated PKP	1	6	preoperative corneal edema	
11	20/200	(IOL-AI) sulcus scleral-fixated	1	9	2124	
12	20/32	Sulcus without suture	0	9	1020	
13	20/40	Sulcus without suture	0	9	842	AI migration and elevated IOP necessitating secondary surgical scleral fixation
14	20/40	Sulcus scleral-fixated	0	9	2350	
15		AI not inserted Excluded from the study			excluded from study	Intraoperative Argentinian flag. AI not inserted.

CDVA: corrected distance visual acuity. IOL: intraocular lens. AI: artificial iris. Photophobia score from 0 (no photophobia) to 10 (intolerable photophobia). Cosmesis score from 0 (very unsatisfied) to 10 (very satisfied). PKP: penetrating keratoplasty. IOP: intraocular pressure. ECC: endothelial cell count

Table 3. ECC change between 3-month and 1-year follow-up visit

Study Eye Number	3-month ECC (cells/mm ²)	1-year ECC (cells/mm ²)
1	620	628
2	1812	1814
3	2122	2112
4	corneal edema	corneal edema
5	3213	3215
6	1414	1412
7	preoperative corneal scar	
8	2412	2405
9	1980	1975

ECC: endothelial cell count

Figure 1. Case 2. Post traumatic aphakia and partial aniridia. IOL sewn to the artificial iris (AI) and then (IOL+AI) scleral-fixated. 20/20 postop without correction. A: preop, B: postop, C: UBM showing IOL and AI sulcus scleral-fixated, D: pre and postoperative appearance

Figure 2. Case 5. Post traumatic cataract with lens subluxation and iris tearing. IOL in the bag and artificial iris (AI) in the sulcus. A: preop, B: postop, C: UBM showing IOL in the bag and AI in the sulcus, D: pre and postoperative appearance

Figure 3. Case 9. Cataract and irreversible mydriasis after ICL placement for high myopia. IOL and artificial iris (AI) in the bag. A: preop, B: postop, C: UBM showing IOL and AI in the bag, D: pre and postoperative appearance



ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Stanislas	2. Surname (Last Name) Roman	3. Date 27-November-2020
4. Are you the corresponding author? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
5. Manuscript Title Flexible silicone artificial iris in cases of aniridia and iris deficiencies		
6. Manuscript Identifying Number (if you know it)		

Section 2. The Work Under Consideration for Publication

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Dr. Roman has nothing to disclose.

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4. Are you the corresponding author? Yes No Corresponding Author's Name
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Dr. BAUDOIN reports personal fees from alcon, personal fees from AERIE, personal fees from ALLERGAN, grants and personal fees from HORUS PHARMA, grants and personal fees from SANTEN, grants and personal fees from THEA, outside the submitted work;

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