Complications of cosmetic iris implants: French series of 87 eyes

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ARTICLE

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Purpose: Iris intraocular implants were developed to manage congenital or traumatic iris defects. However, they are also used to change the color of patient eyes. The aim of this retrospective series was to report complications in patients managed in France after cosmetic implantation.

Setting: Ophthalmological institutions and private ophthalmologists in France.

Design: Multicenter retrospective observational study.

Methods: Questionnaires were sent to all ophthalmology departments in university hospitals and to private ophthalmologists. This questionnaire listed demographic and clinical data for each implanted eye with a focus on safety, the description of ocular complications (corneal edema, endothelial cell loss, increased intraocular pressure, and intraocular inflammation), and the therapeutic management implemented.

Results: Forty-four questionnaires (87 eyes) were collected, and ultimately, 33 questionnaires (65 eyes) were considered complete and analyzed. Two types of implants were identified. Of the 65 eyes analyzed, only 5 eyes (7.7%) did not experience any complication and 60 eyes (92.3%) had at least 1 complication. The most commonly reported complication was corneal decompensation (78.5%). The diagnosis of glaucoma was made in over half (52.3%) of the cases. Explantation was needed in 81.5% of cases. The mean final visual acuity was 0.45 ± 0.08 logarithm of the minimum angle of resolution (logMAR) (0 to 2 logMAR).

Conclusions: Several ocular complications with a decreased mean visual acuity were described in a young healthy population. In addition, patient information on the safety of this procedure appeared insufficient.

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Online Video

Different iris implants have been developed since the first implantation of an intraocular lens (IOL) for managing iris defects by Choyce in 1956.[1,2] They are intended to correct congenital (coloboma, ocular albinism, etc.) or traumatic iris defects to reduce glare and light sensitivity.[3–5] Some recent studies in the literature have reported an esthetical use of iris IOLs in young patients without ophthalmologic history to change the color of their eyes.[6,7]

Two medical devices are used cosmetically, without Conformité Européenne (CE) marking or U.S. Food and Drug Administration (FDA) approval. The NewColorIris implant (Kahn Medical Devices), patented in 2006,[8] is a silicone

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implant 11.0 mm to 13.0 mm in diameter with a pupillary aperture of 3.5 mm and a thickness of 0.16 mm. To hold it in place in the anterior segment, 6 rounded flaps are present at the periphery. The BrightOcular (Stellar Devices LLC), patented in 2012,[9] presents slightly different characteristics (11.5 to 13.5 mm in diameter and 0.16 to 0.18 mm in thickness). It is held in place by 5 peripheral triangular flaps. Finally, its posterior face presents grooves to theoretically allow an easier flow of the aqueous humor.[10]

A recent literature review has reported a significant number of ocular complications in patients in Panama who underwent an esthetic procedure with these implants.[11] In this study, we reported the French experience based on a single questionnaire of patients managed in 2017 after esthetic implantation performed mostly abroad, with a focus on safety.

METHODS

This was a multicenter, retrospective, observational study based on data collection through a questionnaire sent to the French College of Academic Ophthalmologists and to ophthalmologists who were members of the Société de l'Association Française des Implants et de la Chirurgie Réfractive. This questionnaire collected demographic and clinical data of patients implanted for esthetic purposes. Anonymized identification data (date of birth, sex, first 3 letters of the last name, and first names) allowed for excluding patients who consulted several ophthalmologists. Implantation data were collected (age at the time of implantation, locations, date, type of implant used, and associated surgical procedures). The other data analyzed were visual acuity (VA) at the time of the first and last consultations in France, endothelial cell density by specular microscopy, maximal intraocular pressure (IOP), number of IOP-lowering treatments if used, presence of anterior chamber inflammation, date of the first complication, type of complication (corneal edema, intraocular inflammation, high IOP, cataract, or retinal complications), and surgical procedures performed (explantation, keratoplasty, filtering surgery, and cataract surgery). Comments were also allowed to provide information on the patients, especially on the follow-up difficulties. Only the questionnaires containing identification data and with 80% of information completed were selected for the analysis to present the most accurate data possible.

The Ethics Committee of the French Society of Ophthalmology approved the study (IRB 00008855 Société Française d'Ophtalmologie IRB#1). It was conducted in accordance with the law on data protection (no. 2004-801, August 6, 2004).

The statistical analysis was performed using IBM SPSS Statistics for Windows software (version 22.0, IBM Corp.). Data are presented as means with standard deviations and the minimum and maximum values. The difference between the initial VA and the final VA (end of follow-up) was analyzed using a *t* test for paired values. The significance threshold used was .05.

RESULTS

Forty-four questionnaires were collected, and 11 questionnaires were excluded because the reported data were either redundant or insufficient. Finally, 33 questionnaires from 33 different patients (65 eyes) were analyzed.

Patient Characteristics

The patient mean age at the time of implantation was 34.2 ± 10.9 years (Table 1). The youngest and oldest patients were

Table 1. Comparative reports of complications after cosmetic iris implantation.

	Current Study (n = 65)	Galvis et al.[11] (n = 128)
Age, yrs (range)	34.2 ± 10.9 (19–57)	32.6 (19–65)
Implantation location (eyes, n)	Tunisia (37)	Panama (78)
	France (8)	Lebanon (12)
	India (6)	India (9)
	Dubai (2)	Turkey (7)
	Egypt (2)	Tunisia (6)
	Lebanon (2)	Jordan (4)
	Panama (2)	Mexico (2)
	Turkey (2)	France (2)
	2 NA eyes	8 NA eyes
Complication rate at first consultation (eyes, n)	92.3% (60)	91.4% (117)
Implant type	10	86
NewColorIris	12	39
BrighOcular	43 NA	3 NA
Complication rate (eyes, n)	92.3% (60)	91.4% (117)
Explantation rate (eyes, n)	81.5% (53)	68.8% (88)
Final VA	0.45 ± 0.08 logMAR	9.3% VA <20/200
	25.4% VA >1 logMAR	
Corneal complication (eyes, n)	78.5% (51)	33.6% (43)
Mean endothelial density	1484.9 ± 126 cells/mm^2	1224 ± 571 cells/mm^2
Keratoplasty (eyes, n)	20% (13)	20.3% (29)
Mean maximal IOP	26.1 ± 1.6 mm Hg	40 mm Hg
Glaucoma (eyes, n)	52.3% (34)	46.1% (59)
Glaucoma surgery (eyes, n)	23.1% (15)	22.7% (29)
Cataract (eyes, n)	15.4% (10)	14.8% (19)
Inflammation (eyes, n)	38.5% (25)	30.5% (39)

IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; NA = not available; VA = visual acuity

19 and 57 years old, respectively. Most patients were women ([26/33 78.8%]). No patient had a history of significant ocular disease other than refractive errors. No information about potential procedure-related complications was provided to 31 (93.4%) of 33 patients. Only 1 patient had unilateral surgery; all others had bilateral surgery on the same day. Some patients had iris implant combined with other refractive procedures such as laser in situ keratomileusis or photorefractive keratectomy laser (4 eyes) or phacoemulsification (6 eyes including 2 eyes with the implantation of multifocal implants).

The implant brand was identified in 22 eyes (33.9%), of which 10 eyes were implanted with NewColorIris and 12 with BrightOcular. Table 1 reports the country where procedures were performed; more than half of the procedures were performed in Europe and the north of Africa (37 eyes in Tunisia [56.9%], 8 eyes in France [12.3%], and 2 eyes in Egypt [3.1%]). In 2 patients, the origin of the implantation was not specified in the questionnaire. One patient underwent revision surgery with a second implantation and change of the first implants because she was not satisfied by the initial esthetic outcome.

Patients were implanted between July 2005 and May 2017. The mean time before the first consultation with an ophthalmologist in France was 1.5 ± 0.3 years. At the time of this first consultation, 92.3% of eyes had at least 1 complication and some patients had several complications. Only 5 eyes did not experience any complication; their implantations were performed recently, 84.4 ± 38.3 days before consultation.

The initial VA was 0.62 ± 0.09 logarithm of the minimum angle of resolution (logMAR) (0 to 2 logMAR).

Complications and Management

Corneal Complications Edematous endothelial decompensation was present in 51 (78.5%) of 65 eyes (Table 1 and Figure 1, A). Specular microscopy was performed in 51 eyes (78.4%). The result was uninterpretable in 6 eyes due to corneal edema. The mean initial endothelial density was 1484.9 ± 126 cells/mm^2.

Keratoplasty was performed in 13 (20%) of 65 eyes. Eleven eyes had Descemet membrane endothelial keratoplasty, and 2 eyes (of 1 patient) had bilateral penetrating keratoplasty (Figure 1, B).

IOP-Related Complications The mean maximal IOP during the follow-up was 26.1 ± 1.6 mm Hg (8.0 to 50.0 mm Hg). Maximal ocular hypertension higher than 21 mm Hg was reported in 54.1% of patients. Initiating IOP-lowering treatment was needed in 39 (60%) of 65 eyes. Eleven eyes received a fixed dual therapy, 3 eyes received triple therapy, 15 eyes received quadritherapy, and 4 eyes received systemic treatment in addition to quadritherapy. Filtering surgery was needed in 15 eyes (23.1%). Finally, the diagnosis of glaucoma defined by a structural and functional impairment was reported in 34 eyes (52.3%). The examination of the iridocorneal angle showed a contact between the flaps of the implant and the angle (Figure 2).

Cataracts Six of the 65 eyes underwent lens surgery associated with the initial cosmetic iris implantation.

During follow-up, 10 eyes (15.4%) underwent cataract surgery. Two patients experienced unilateral retinal detachment after their cataract surgery.

Since their initial implantation (1.5 years), nearly a quarter of patients (16/65) with a mean age of 34.2 years were pseudophakic.

Intraocular Inflammation Signs of anterior uveitis were reported in 25 eyes (38.5%) and of posterior inflammation (pseudophakic cystoid macular edema [CME], CME without cataract surgery, and epiretinal membrane) in 6 eyes (9.2%) (Figure 3). One patient with CME subsequently developed bilateral macular atrophy responsible for a decrease in VA.

Iris Peripheral iridocorneal synechiae were reported in six eyes (9.2%), and 2 eyes had a corectopia. One eye had a nevus that was only discovered after explantation.

Explantation Of all eyes, 53 (81.5%) had explantation, of which 51 eyes had a complication and 2 eyes were explanted preventively (Figure 4). The other patients refused explantation (12 eyes, 6 patients). Explantation was performed on average 2.3 ± 0.4 years after implantation (Supplemental Digital Content, Video 1, http://links.lww.com/JRS/A9).

At the end of the follow-up, the mean VA was 0.45 ± 0.08 logMAR (0 to 2 logMAR) and the improvement in VA was statistically significant (P = .007); however, the VA did not reach the theoretical VA corresponding to this age range. Only half (33/65) of the patients had a VA at 0 logMAR at the end of their follow-up. At the end of this follow-up, 16 of the 33 patients presented a binocular VA less than 0.3 logMAR, which was not compatible with driving in France, and 8 patients presented criteria of blindness (binocular VA less than 1 logMAR).

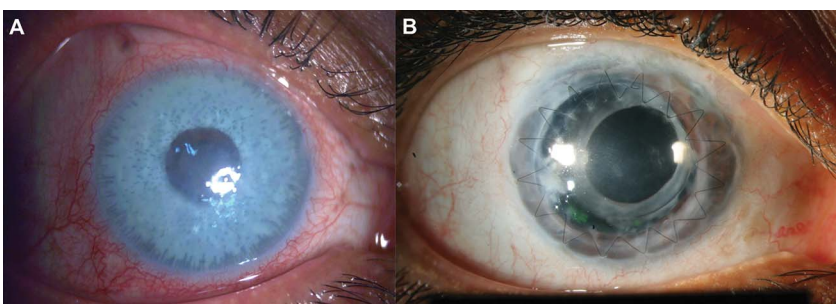

Figure 1. *A:* Corneal decompensation in an eye with a BrightOcular cosmetic implant (Courtesy of Dr. A. Robinet-Perrin, Bordeaux, France). *B:* Penetrating keratoplasty for managing decompensation, this eye underwent a cataract surgery after the implantation and before the penetrating keratoplasty (Courtesy of Prof. M. Muraine, Rouen, France.).

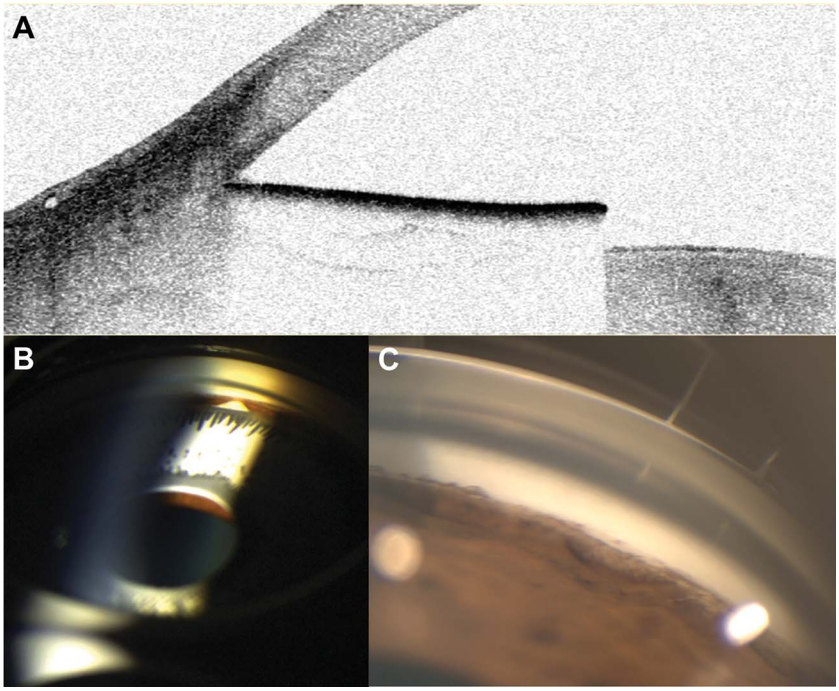

Figure 2. Angular flaps of the anterior segment implant on optical coherence tomography (*A*) and on gonioscopy *B:* showing a contact between the flaps of the implant and the apex of the angle. In this eye, the contact between the implant and the iridocorneal angle caused synechiae and pigment deposition (C) (Courtesy of Dr. E. Landman, Paris, France (*A*) and Dr. A. Hay, Nancy, France (*B* and *C*).).

DISCUSSION

We report here a series of patients managed in France after cosmetic iris implantation. These implants were diverted from their original use for esthetic purposes. To our knowledge, this is the largest series published to date. A review of the literature conducted by Galvis et al.[11] has reported a total of 128 cases in 8 countries (Table 1).

Our series did not allow for determining the incidence of complications following this procedure because the total number of implanted French patients is not known. However, 92.3% of eyes examined had at least 1 complication after a relatively short mean postoperative period of 1.5 ± 0.3 years. This figure is similar to that reported by Galvis et al.[11] In this review, the complication rate is estimated in 117 (91.4%) of 128 eyes. This esthetic procedure can be responsible for serious complications and cause loss of VA in patients. A final decrease in VA was observed in more than half of the patients in our series (the mean VA at the end of the management: 0.45 ± 0.08 logMAR). In 25.4% of cases, the final VA was less than 1 logMAR in these young active patients who had no significant history of ocular disease and who likely had an initial normal VA. In more than half of the patients (16 of 33), the binocular VA was not compatible with driving according to the French law.

In addition, our study reports a lack of information provided to patients; 93.4% did not receive any information from their surgeon. The websites for these implants compare them to surgical procedures where IOLs are implanted (ie, cataract surgery).[11] These implants have no CE marking or FDA approval. Although there is a specific ISO standard (11979) governing the production of IOLs (anterior and posterior) and their clinical assessment, only the manufacturing standards (ISO 13485) are provided on the websites. However, obtaining CE marking is yet another certification step, which is essential for guaranteeing the safety of medical devices. Despite the absence of CE marking, some patients in Europe had implants inserted (8 eyes [12.3%])12.3% of cases implanted in France), without being able to identify from where cosmetic iris implant was ordered.

In our series, 1 patient had an iris nevus that was discovered only after explantation. The implant made its observation and

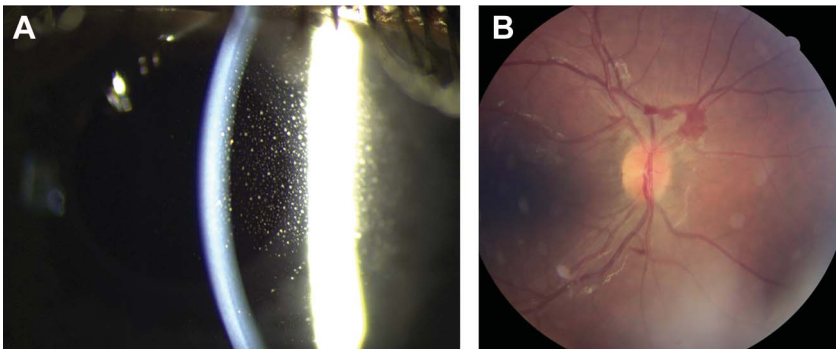

Figure 3. Anterior uveitis and posterior complications in an eye with a cosmetic implant (Courtesy of Dr. A. Hay, Nancy, France). The patient presented peripapillary hemorrhages with a papillary edema on the left eye and an anterior uveitis on the right eye.

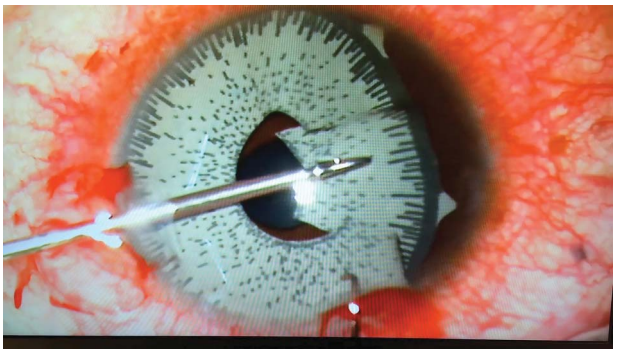

Figure 4. Surgical image of the explantation procedure of a BrightOcular cosmetic implant (Courtesy of Prof. Muraine, Rouen, France.).

follow-up impossible, so that if signs of malignancy appeared, they would not be discovered. In 1 patient, implant exchange involving a new bilateral procedure was reported for esthetic dissatisfaction, which exposed the patient to the risks of a second intraocular surgery for only cosmetic purposes. Galvis et al.[11] described severe iris atrophy in 3.9% of the eyes; our questionnaire was not designed for this information.

Our series reports a balanced distribution between the two different implants currently used. Data on material tolerance and implant stability in the anterior segment are limited.[12] But the case studies reviewed by Galvis et al.[11] and this study are consistent in reporting many complications related to this procedure. Despite these data, patients in our series had almost no postoperative follow-up after surgery in other countries and all but 1 underwent bilateral implantation on the same day despite the potential risk for infection. No cases of endophthalmitis were reported.

Corneal complications appear to be the most common.[11,13,14] They were related to edematous decompensation because of the loss of endothelial cells as shown by the reduced corneal density (1450 cells/mm^2) in this group of young patients with a mean age of 34 years. As it is known, in vivo mitosis of corneal endothelial cells in humans is very limited,[15] and therefore, any factor causing a persistent loss of these cells may eventually lead to irreversible corneal edema. This endothelial loss could be related to several factors: a mechanical loss secondary to the implantation procedure, an endothelial contact of the implant, a mechanism that has been reported with intraocular anterior chamber implants with angular support (the absence of customized sizing of iris implants makes this assumption plausible) worsened by implant irregularities,[6] and a biochemical toxicity of the material (shown by the presence in some cases of macrophages at the implant surface after explantation).[1] Their management required keratoplasty, especially endothelial keratoplasty, in 1 of 5 cases in this series.

Ocular hypertension was also common. More than half of the eyes showed signs of glaucomatous neuropathy. In some patients, gonioscopy revealed the presence of peripheral anterior synechiae that have previously been reported in the literature.[16] These synechiae develop as a result of the trauma related to the implant flaps. These flaps could also lead to direct trauma to the trabecular meshwork aggravating the resistance to the flow of the aqueous humor. Finally, the contact of the implant on the iris may lead to pigment dispersion, which in turn can increase the IOP.[17] This hypertension is difficult to control even after explantation. Indeed, in our series, although IOP-lowering treatment was initiated, more than 2 local treatments were needed in over half of the cases (22/39 eyes). The use of filtering surgery was reported in nearly a quarter of patients (29/128 eyes [22.7%]), and this result is comparable with that reported by Galvis et al.[11]

These implants could also be associated with posterior segment complications, including inflammation. They are probably underestimated because the analysis of the posterior segment remains difficult when the implants are positioned, because of the absence of pupillary dilation for the examination of the peripheral retina and also because of the lack of corneal transparency in some cases. We found 2 cases of retinal detachment after cataract surgery. This confirms the need for several surgical procedures in some patients during their postimplantation management, including after explantation (mean number of 2.4 ± 0.9 procedures per eye), as previously reported by Hoguet et al.[17]

During patient management, that is, 1.5 ± 0.3 years after implantation, all ophthalmologists proposed explantation for managing or preventing complications. This procedure might also be invasive, and different techniques are proposed to reduce this trauma.[16,18] Explantation was performed in 81.5% of patients; several patients refused explantation. It is worth noting that explantation was performed after a mean time of 2.3 ± 0.4 years after implantation, that is, almost 1 year elapsed between the first visit and this procedure. This stresses the difficulty to convince these patients to explant the device. They accept this procedure when complications are symptomatic. Among the patients in our study some had a high level of education (ie, lawyer). Most patients were poorly observant, and there were cases of medical nomadism confirmed by cross-identification of the questionnaires.

Our study has some limitations, mainly related to the small number of cases its retrospective design. The prevalence of complications cannot be analyzed because the total number of implantations remains unknown. The identification of the implant brand was possible only in 33.9% of cases. This low rate can bias the results. The BrightOcular implant might pose less risk than the NewColorIris implant.[19] Scanning electron microscopy showed surface irregularities in the NewColorIris implant, that might contribute to uveitis and trabecular meshwork damage.[20] BrightOcular has grooves that might have partially corrected the surface irregularities.[10]

The strength of our study was the use of a single questionnaire sent to anterior segment surgeons, which helped us to identify nomadic patients who were therefore included only once. We also excluded almost 1 of 5 questionnaires (18%) to ensure a satisfactory response completeness rate (>80%).

This study of French patients provides data from Europe that are consistent with those published by Galvis et al.,[11] of

which most data was from the Americas. Our study shows the risks of cosmetic implants, which might be vision-threatening and lead to disability. Management of the complications might require several surgical procedures, and the follow-up is difficult because of the poor compliance among these young, poorly informed patients.

WHAT WAS KNOWN

- Iris intraocular implants are used to correct iris defects, and some ophthalmologists use them for esthetical purposes. In these conditions, the implant causes different eye complications.

WHAT THIS PAPER ADDS

- The implants are used in the European Union without the CE mark or FDA approval.
- Complications lead to a decrease in visual acuity, to the extent of blindness in some patients, and loss of the professional or driving license.
- Follow-up of these patients remains difficult because of poor observance.

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