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ARTICLE

Complications of cosmetic iris implants: a French series of 87 eyes

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Purpose: Iris intraocular implants have initially been developed for managing congenital or traumatic iris defects. However, some ophthalmologists also use them 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: This study was based on sending questionnaires 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 were collected, corresponding to 87 eyes, 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 one complication. The most commonly reported complication was corneal decompensation (78.5%). The diagnosis of glaucoma was made in more than 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: This retrospective study is the largest series conducted to date. Several ocular complications were described in a young healthy population with a decreased mean visual acuity. 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 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 literature data have reported an esthetical use of iris intraocular implants by some ophthalmologists in young patients without ophthalmologic history to change the color of their eyes.[6,7]

Two medical devices are used in this indication in the absence of CE marking or FDA approval. The NewColorIris implant (Kahn Medical Devices), patented in AU2

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2006 (US patent 2006#7025781 2B),[8] is a silicone implant of 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, six rounded flaps are present at the periphery. The second more recent implant, BrightOcular (Stellar Devices LLC), patented in 2012 (US patent 2012#8197540),[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 five peripheral triangular flaps. Finally, its posterior face presents grooves to theoretically allow an easier flow of the aqueous humor.[10]

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

MATERIALS AND 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 three 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). Free 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.

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, concerning 65 eyes, were analyzed.

Table 1. Comparative reports of complications after cosmetic iris implantation

	French report (n = 65)	Galvis et al.[11] review (n = 128)
Age	34.2 ± 10.9 years (19–57 years)	32.6 years (19–65 years)
Implantation location	37 eyes in Tunisia	78 eyes in Panama
	8 eyes in France	12 eyes in Lebanon
	6 eyes in India	9 eyes in India
	2 eyes in Dubai	7 eyes in Turkey
	2 eyes in Egypt	6 eyes in Tunisia
	2 eyes in Lebanon	4 eyes in Jordan
	2 eyes in Panama	2 eyes in Mexico
	2 eyes in Turkey	2 eyes in France
	2 NC eyes	8 NC eyes
Complication rate at the time of the first consultation	92.3% (60 eyes)	91.4% (117 eyes)
Implant type	10 NewColorIris	86 NewColorIris
	12 BrightOcular	39 BrightOcular
	43 NC	3 NC
Complication rate	92.3% (60 eyes)	91.4% (117 eyes)
Explantation rate	81.5% (53 eyes)	68.8% (88 eyes)
Final VA	0.45 ± 0.08 logMAR	9.3% VA <20/200
	25.4% VA >1 logMAR	
Corneal complication	78.5% (51 eyes)	33.6% (43 eyes)
Mean endothelial density	1,484.9 ± 126 cells/mm^2	1,224 ± 571 cells/mm^2
Keratoplasty	20% (13 eyes)	20.3% (29 eyes)
Mean maximal IOP	26.1 ± 1.6 mm Hg	40 mm Hg
Glaucoma	52.3% (34 eyes)	46.1% (59 eyes)
Glaucoma surgery	23.1% (15 eyes)	22.7% (29 eyes)
Cataract	15.4% (10 eyes)	14.8% (19 eyes)
Inflammation	38.5% (25 eyes)	30.5% (39 eyes)

IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; VA = visual acuity

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 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 one patient underwent unilateral surgery, and all others underwent bilateral surgery on the same day. Some patients underwent procedures combined with other refractive procedures such as laser in situ keratomileusis or photorefractive keratectomy laser (four eyes) or phacoemulsification (six eyes including two 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 (Kahn Medical Devices, Corp) and 12 with BrightOcular (Stellar Devices LLC). 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]. In two 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 one complication, and in some patients, several complications could be associated. Only 5 eyes did not experience any complication, as their implantation was 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 six 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 underwent Descemet membrane endothelial keratoplasty, and two eyes (one patient) underwent 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 the follow-up in France, 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 two eyes had a corectopia. One eye had a nevus that was only discovered after explantation.

Explantation Of all the eyes, 53 (81.5%) underwent 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

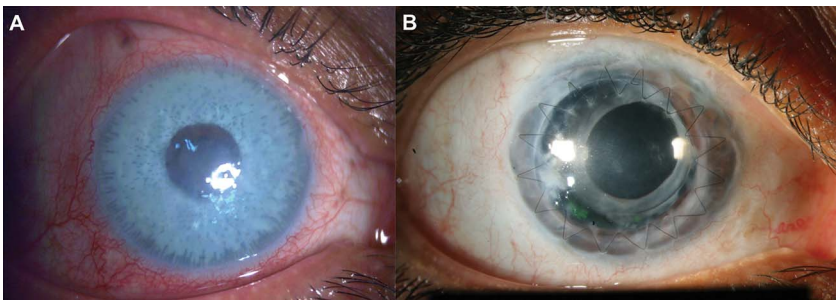

Figure 1. A: Corneal decompensation in an eye with a BrightOcular cosmetic implant (Courtesy of Dr. A. Robinet-Perrin, Bordeaux, France.). B: Penetrating keratoplasty for managing decompensation, this eye underwent a cataract surgery after the implantation and before the penetrating keratoplasty (Courtesy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

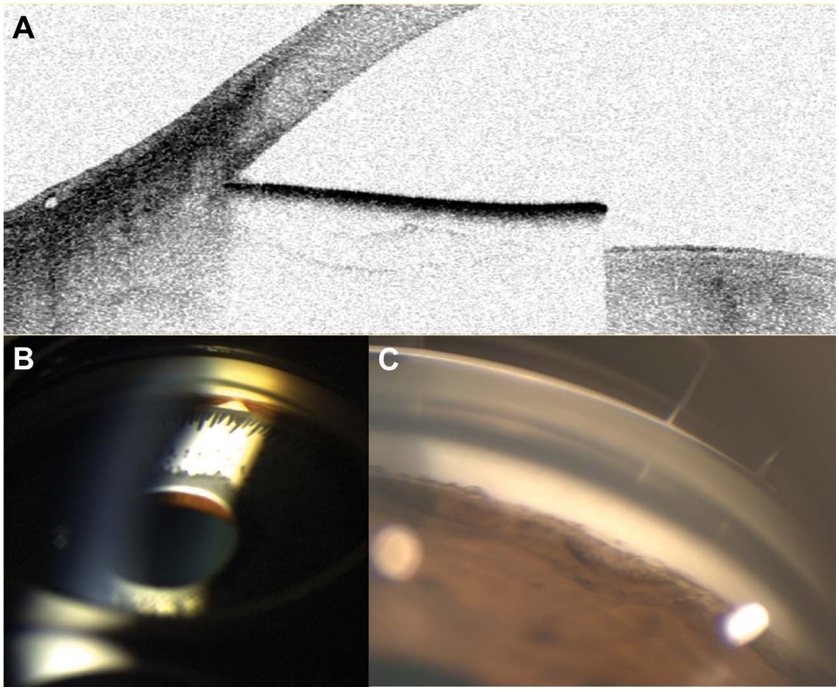

Figure 2. Angular flaps of the anterior segment implant on optical coherence tomography (*A*) and on gonioscopy (*B*) showing a contact between the flaps of the implant and the apex of the angle. C: In this eye, the mentioned contact between the implant and the iridocorneal angle caused synechiae and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

logMAR, which was not compatible with light vehicle driving in France, and 8 patients presented criteria of blindness (binocular VA less than 1 logMAR).

DISCUSSION

We report here a series of patients managed in France after iris implant cosmetic 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 eight 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, it should be noted that 92.3% of eyes examined had at least one complication after a relatively short mean postoperative period of 1.5 ± 0.3 years. This figure is similar to that reported in the literature review 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 such serious complications and cause the loss of the best-corrected 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 diseases and who had probably an initial normal VA. In more than half of the patients (16 of the 33 patients), 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% of patients in our series did not receive any information from their surgeon). The various websites on which these implants are proposed compare them to surgical procedures in which intraocular lenses are implanted (including cataract surgery).[11] These implants have no CE marking or FDA approval. Although there is a specific standard (ISO 11979) governing the production of intraocular implants (anterior and posterior intraocular lenses) as well as the rules of their clinical assessment, only the manufacturing information according to the ISO 13485 standards (international standards of quality management systems for industries manufacturing medical devices) is given by websites. However, obtaining the CE marking is

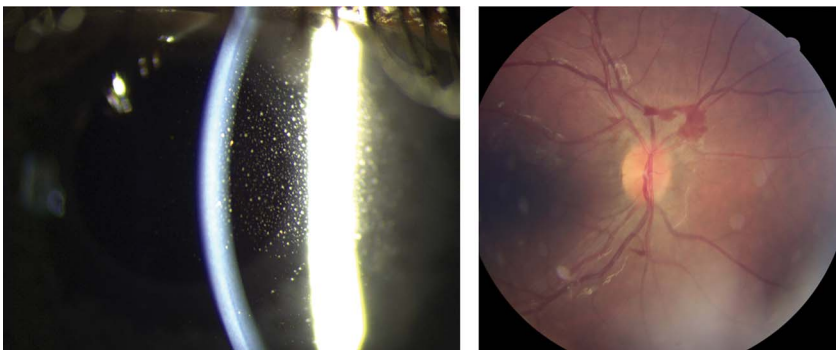

Figure 3. Anterior uveitis and posterior complications in a patient with a cosmetic implant (Courtesy of Dr. A. Hay, Nancy, France.). The patient presented peripapillary hemorrhages with a papillary edema on the left eye and an anterior uveitis on the right eye.

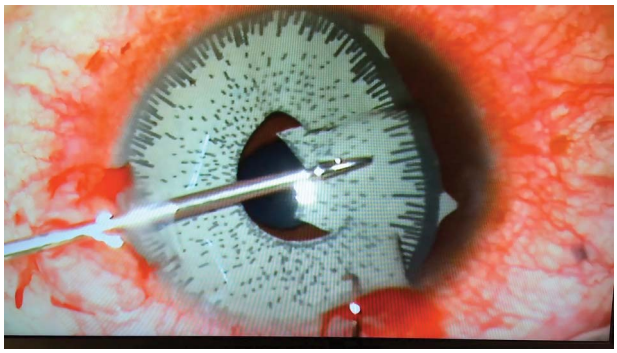

Figure 4. Surgical image of the explantation procedure of a BrightOcular cosmetic implant (Courtesy of Prof. Muraine, Rouen, France.).

yet another certification step, which is essential for guaranteeing the safety of medical devices. Despite the absence of CE marking, some patients underwent this procedure in Europe (eight implants, 12.3% of cases implanted in France), without being able to identify how the cosmetic iris implant was ordered (internet?).

In our series, one patient who underwent such a procedure had an iris nevus that was discovered only after explantation. The implant made its observation and follow-up impossible, so that if signs of malignancy appeared, they would not be discovered. In one 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 only with 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 various case studies and, in particular, the review by Galvis et al.[11] as well as our series 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 one 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 one of five cases of implanted patients in this series.

Ocular hypertension was also common. In our series, 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 aggravate IOP increase.[17] This hypertension is difficult to control even after explantation. Indeed, in our series, although IOP-lowering treatment was initiated, more than two local treatments were needed in more than half of the cases (22/39 eyes). The use of filtering surgery was reported in nearly a quarter of patients, and this result is comparable with that reported by Galvis et al.[11] [29/128 eyes (22.7%)].

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 two 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 may also be invasive, and different techniques are proposed to reduce this trauma.[16,18] Explantation was performed in 81.5% of patients because several patients refused this eventuality. 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.

Note finally that among our patients, there were surprising professions for this kind of behavior: lawyer, company head, and even physician. Most patients were poorly observant or even adepts of medical nomadism. This was confirmed through the cross-identification of patients in the questionnaires.

Our study has some limitations that are mainly related to the small number of cases in our series and to its retrospective design. This is nevertheless the largest series published to our knowledge because few data are really available apart from isolated cases and a review compiling them. 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 may pose less risk than the NewColorIris implant.[19] Scanning electron microscopy showed surface irregularities in the NewColorIris implant, and these irregularities may contribute to uveitis and trabecular meshwork damage.[20] BrightOcular with the patented grooves may have partially corrected some of the problems inherent with NewColorIris.[10]

The strengths of our series are the use of a single questionnaire sent to ophthalmologists specialized in the anterior segment that helped to identify nomadic patients who were therefore included only once. We also excluded almost one of five questionnaires (18%) to ensure a satisfactory response completeness rate (>80%).

This French questionnaire–based study provides European data that are consistent with those published in the review by Galvis et al.,[11] which mainly concerns the American continent. It confirms the dangerousness of these cosmetic implants that may be vision-threatening and lead to disability. The management of complications may require several surgical procedures, and the follow-up is made difficult because of the poor compliance of the 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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000 Complications of cosmetic iris implants: a French series of 87 eyes

Some ophthalmologists use iris implants for cosmetics purposes, but complications are frequent. In this series, 92.3% of eyes had at least one complication. More than 80% need an explantation.

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