ARTIFICIAL COSMETIC IRIS – POTENTIAL RISK OF VISUAL IMPAIRMENT. A CASE REPORT

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SUMMARY

In this paper, the authors present a case report of a 46–year–old patient with decompensated pigmentary glaucoma and anterior uveitis after unilateral implantation of a BrightOcular artificial cosmetic iris (Stellar Devices, New York, USA). Postoperatively, there was a decrease of endothelial cells (ECD) down to 1216 cells/mm^2, a uveal reaction in the anterior chamber and a significant decompensation of intraocular pressure (IOP). During the first examination at our clinic, the explantation of the artificial cosmetic iris was indicated. However, despite all warnings, the patient repeatedly refused this procedure. The patient later decided to undergo the artificial cosmetic iris explantation due to persistent elevation of IOP with intense eye pain. The cosmetic iris implant was removed almost five months after its implantation. Postoperatively, the anterior uveitis resolved, but there was a further decrease in ECD of 130 cells/mm^2 and also an increase in IOP, despite maximal antiglaucoma therapy. Nearly one month after removal of the artificial cosmetic iris, the patient underwent implantation of the Express P50 drainage shunt (Alcon Inc, Fort Worth, TX, USA). After the drainage procedure, IOP was normalized and remained within physiological limits during the first year after surgery. Thereafter, there was a recurrence of elevated IOP, which subsided to normal, after initiation of a combination of two antiglaucoma therapies. Four years after surgery the eye was quiescent, ECD stationary, the optic nerve head was stable, and the visual field remained within the physiological norm. This case report highlights a potentially harmful procedure that is presented as a relatively safe alternative for an iris colour change, representing a deceptive marketing strategy for companies trading in these implants.

Key words: artificial cosmetic iris, BrightOcular, pigmentary glaucoma, anterior uveitis

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INTRODUCTION

From an anatomical point of view, the iris forms the anterior part of the uveal tract which affects the pupil size regulating the amount of light reaching the retina [1,2]. Iris defects, such as post-traumatic or iatrogenic aniridia and colobomas, can cause not only cosmetic but also functional defects, such as decreased vision due to marked glare or loss of contrast sensitivity [3]. Implantation of an iris prosthesis in the posterior chamber of the eye has been shown to be a safe and effective method of reducing photophobia in a variety of ocular pathologies including aniridia, ocular albinism, and traumatic iris defects [4,5].

On the other hand, in recent years, cosmetic iris implants have appeared for implantation in the anterior chamber in phakic individuals who want to change the colour of their iris [6].

Although these artificial cosmetic iris implants have not received a European Declaration of Conformity (CE) for the European market and have not been approved by the Food and Drug Administration (FDA) for the US market, some online promotions for these cosmetic implants contain misleading claims of US patent approval [7,8]. Moreover, commercial companies trading in these implants present them as being almost without side effects, thus misleading potential clients with an

incorrect safety analysis, comparing them with already approved anterior chamber intraocular lenses (AC IOLs) [9,10]. Due to the fact that, in most economically developed countries with well-functioning legislation and clear regulatory mechanisms, these implants have not been approved, those interested in these procedures travel abroad to countries where these implants are not regulated. In addition to Panama, iris discolouration with an artificial cosmetic implant is currently performed in Mexico, Costa Rica, Albania, Tunisia, Turkey, Morocco, Iran, Lebanon, Jordan, Syria, China and India, and the cost of these procedures, as reported on the websites of providers, ranges from approximately $6 000 to $10 000 [11,12].

CASE REPORT

At the beginning of January 2016, a 46-year-old healthy patient sought immediate treatment from our clinic for pain, redness and photophobia of the right eye (RE). The ophthalmological anamnesis showed that almost a month earlier (12/2015), she had undergone unilateral (RE) implantation of the BrightOcular® artificial cosmetic iris (Stellar Devices, New York, USA) in Tunisia under general anaesthesia. The surgery on the second eye was planned for a later date, due to the patient's misgivings. The patient underwent immediate postoperative follow-up in Tunisia, where antibiotic therapy (tobramycin/dexamethasone eye drops five times a day) was used. Almost 2 weeks after implantation of the artificial cosmetic iris, due to pain and pressure in her RE, the patient paid an emergency visit to an ophthalmologist in Switzerland, where she was on vacation. There, an increase in intraocular pressure (IOP) of the RE was found at 56 mmHg and subsequently at 60 mmHg. A local antiglaucoma therapy (latanoprost eye drops once a day and 250 mg acetazolamide tbl. 1–0–0) was prescribed. However, the patient subsequently discontinued local antiglaucoma therapy due to poor tolerability after only a few days of application. She only used the 250 mg acetazolamide tbl. 1–0–0, including on the day of her first visit to our clinic. The initial best corrected visual acuity (BCVA) of the RE was 6/6 with correction -0.5-1.0/110˚, and BCVA of the left eye (LE) was 6/6 with correction -0.5/70˚. The IOP measured by Goldmann applanation tonometry (Zeiss AT 020, Carl Zeiss Meditec AG, Germany) was 17 mmHg for the RE and 18 mmHg for the LE. Biomicroscopically, an image of acute anterior uveitis of the RE was seen, with the appearance of precipitates on the endothelium, the presence of inflammatory cells (1+) in the anterior chamber and a blue artificial cosmetic iris implant visible in front of the iris (Figure 1). Gonioscopic examination of the RE showed the presence of an artificial cosmetic iris implant in the iridocorneal angle, rich trabecular meshwork pigmentation, and pigment dispersion above the Schwalbe line (Figure 2). Due to the presence of the iris implant, it was not possible to identify other structures in the iridocorneal angle of the RE, so we supplemented the visualisation of the iridocorneal angle with an examination with a Scheimpflug camera (Pentacam HR, Oculus Optikgerate GmbH, Germany), in which we measured the width of the iridocorneal angle of the RE to 40.9 degrees and of the LE to 37.3 degrees (Figure 3). In the left eye, the finding was both biomicroscopically and gonioscopically pathology-free. We also performed optical coherence tomography of the macula of both eyes (OCT, Cirrus HD-OCT 4000, Carl Zeiss Meditec AG, Germany), which was free of pathological findings. We supplemented the examination with photo documentation of the retina and the optic nerve head of both eyes, in which no fundamental pathology was found (the optic nerve head was pink in colour, with C/D 0.5 and neuroretinal rim preserved). However, Heidelberg retinal tomography (HRT II, Heidelberg Engineering GmbH, Germany) showed a decrease in the neuroretinal rim of the RE optic nerve head, in the lower nasal quadrant. No similar pathology was found in the LE. A perimetric examination of the RE (central threshold test 30–2, Humphrey HFA3, model 840, Carl Zeiss Meditec AG, Germany) showed no visual field loss. The corneal endothelial cell density (ECD) was measured, using a specular microscope (CEM-350 NIDEK CO., LTD., Japan). Comparatively, the ECD value of the RE was almost 50% lower than that of the non-operated eye and amounted to 1216 cells/mm^2 (Figure 4).

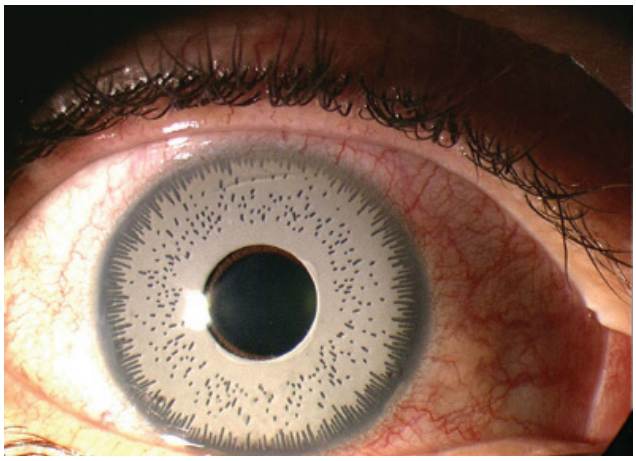

Figure 1. Image of the anterior segment of the right eye, showing the artificial cosmetic iris BrightOcular® (Stellar Devices, New York, USA)

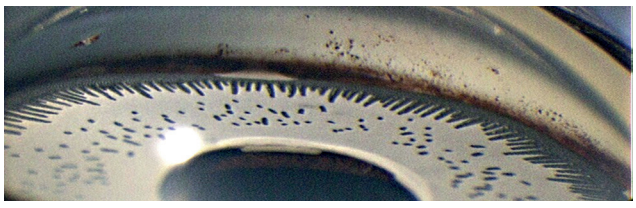

Figure 2. Gonioscopic image of the right eye with the artificial cosmetic iris placed in the iridocorneal angle

Based on the results of the examination, we diagnosed secondary pigmentary glaucoma with acute induced anterior uveitis of the RE after implantation of a cosmetic artificial iris. At the first examination, we started topical therapy with dexamethasone eye drops every 2 hours, a short-acting mydriatic (tropicamide) twice a day, dorzolamide hydrochloride/timolol maleate twice a day and discontinued oral therapy with acetazolamide. Over the next almost 3 months of follow-up, the BCVA remained stable (6/6). The uveal reaction subsided significantly, but there was significant fluctuation and decompensation of IOP in the RE (from 19 to 52 mmHg), despite the maximum antiglaucoma therapy that the patient tolerated – brinzolamide/brimonidine tartrate three times a day, timolol maleate twice a day, acetazolamide tbl. 1–1–1. The explantation of the artificial cosmetic iris was recommended in January 2016, due to the decompensation of IOP, but the patient refused the procedure and signed an informed refusal due to a planned trip abroad for 1 month. After returning from abroad, due to significant RE pain with IOP 52 mmHg, the patient agreed to the explantation of the artificial iris. The procedure was performed under local anaesthesia in April 2016 and was without complications.

Perioperatively, after the removal of the iris implant, we found a plegic, broad, non-rounded pupil and an atrophic iris pigment epithelium (Figure 5). Gonioscopically, a significant dispersion of pigment and anterior synechia was evident, especially in the lower and nasal part of the iridocorneal angle (Figure 6). On the first postoperative day, the uncorrected visual acuity (UCVA) of the RE was 6/9 and it did not improve with refractive correction. The IOP of the RE was 30 mmHg and we did not notice any significant worsening of uveal reaction in the anterior segment. Immediately after the operation, as a result of decompression retinopathy, several intraretinal haemorrhages developed peripapillary and in the periphery of the retina, which were gradually absorbed during the first month after surgery (Figure 7). Postoperatively, antiglaucoma therapy (brinzolamide/brimonidine tartrate eye drops twice a day), as well as antibiotic

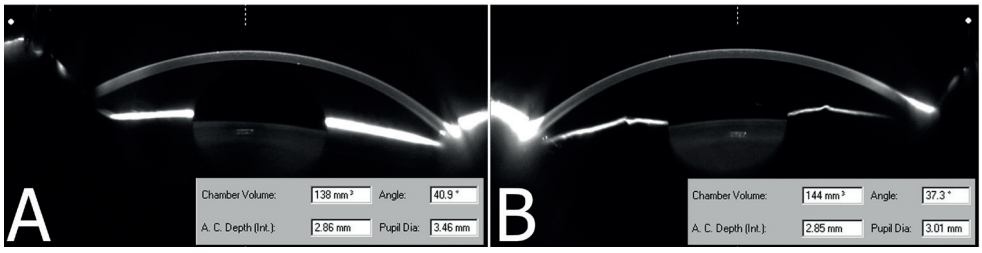

Figure 3. Image of the anterior segment of the eye and the measurement of the iridocorneal angle using a Scheimpflug camera: Figure A shows the artificial cosmetic iris implant, and Figure B shows the physiological appearance of the anterior chamber.

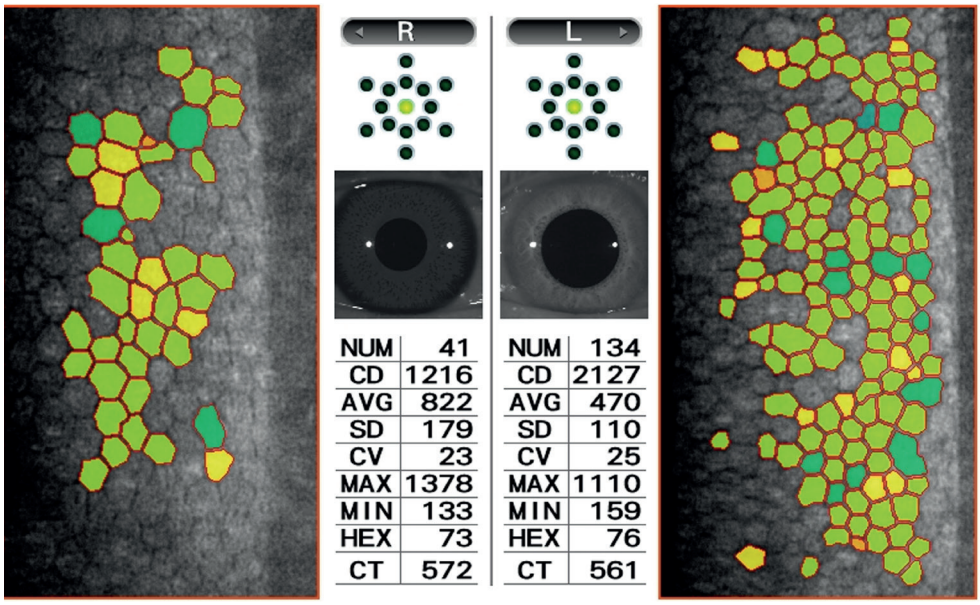

Figure 4. Specular microscope measurements of endothelial cells of both eyes (CEM-350 NIDEK CO., LTD.)

therapy (levofloxacin hemihydrate eye drops five times a day) and corticosteroid therapy (dexamethasone eye drops five times a day) was used for 1 week. Subsequently, in the second and third weeks after surgery, corticosteroid therapy was reduced to fluorometholone acetate eye drops four times and twice a day, respectively. In the third postoperative week, there was a further decrease in ECD of almost 130 cells/mm^2 and decompensation of IOP in the RE to 52 mmHg, despite local and systemic antiglaucoma therapy with brinzolamide/brimonidine tartrate eye drops three times a day, latanoprost/timolol maleate once a day, acetazolamide 250 mg tbl. 1–1–1. Subjectively, the patient reported photophobia, blurred vision in the RE (especially in the morning), pressure and headache, retrobulbar pain and subsequently in the temporal area, but without signs of pain in the right eye. Due to the decompensation of secondary pigmentary glaucoma of the RE, an antiglaucoma operation with implantation of the Express P50 drainage shunt (Alcon Inc, Fort Worth, TX, USA) under local anaesthesia was performed in May 2016. On the first day after surgery, the RE UCVA was 6/9, stenopeic,

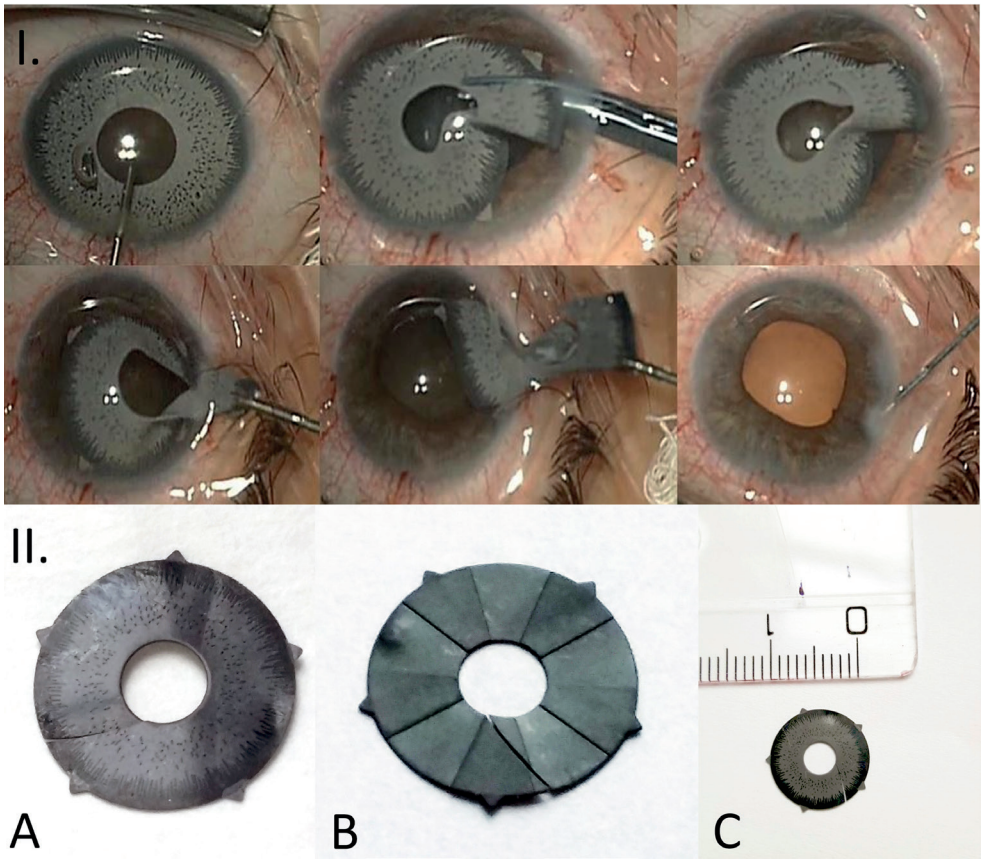

Figure 5. Image of explantation of the artificial cosmetic iris of the right eye (I.) and of the artificial cosmetic iris implant after explantation (II.): anterior side (A), posterior side (B) and implant size (C)

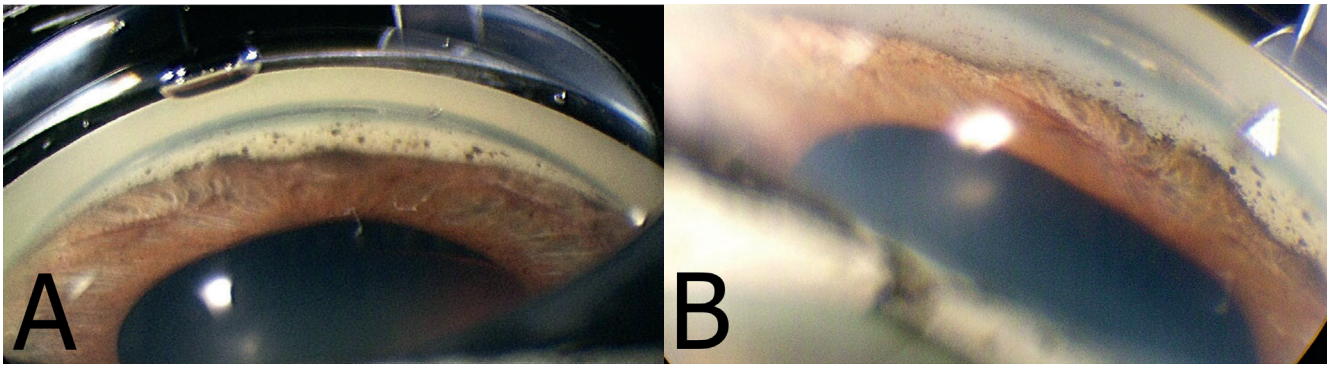

Figure 6. Gonioscopic photograph of the right eye, showing marked pigment dispersion and anterior synechia in the iridocorneal angle

and was not further improved by refractive correction. IOP was 10 mmHg, and the anterior segment was calm. However, there was another smaller loss of endothelial cells to 996 cells/mm^2. Due to the increased filtration of the Express implant, a shallowing of the anterior chamber occurred. For subsequent deepening of the anterior chamber, we used a slight compression of the upper lid with a bandage for two days after the operation.

Postoperatively, the patient applied tobramycin/dexamethasone eye drops five times a day for 2 weeks, followed by 2 weeks of fluorometholone acetate in a reduced dose. During the first year after antiglaucoma surgery, the RE was calm, IOP of the RE without antiglaucoma therapy was in the range of 16–19 mmHg and the optic nerve head, including the perimeter, was stable. In June 2017, we recorded an elevation of IOP in the RE to 28 mmHg and therefore antiglaucoma therapy (brimonidine tartrate twice a day and dorzolamide hydrochloride twice a day) was prescribed again. Since 2018, intraocular pressure has been within normal limits and without major fluctuations, due to the combined antiglaucoma therapy (brimonidine tartrate and dorzolamide hydrochloride). At the last check-up in April 2020, the UCVA of the RE was 6/6, IOP was 16 mmHg, ECD 809 cells/mm^2, the eye was calm (Figure 8), the optic nerve head was stable and the visual field remained within the norm.

DISCUSSION

Congenital or acquired iris pathology can cause a

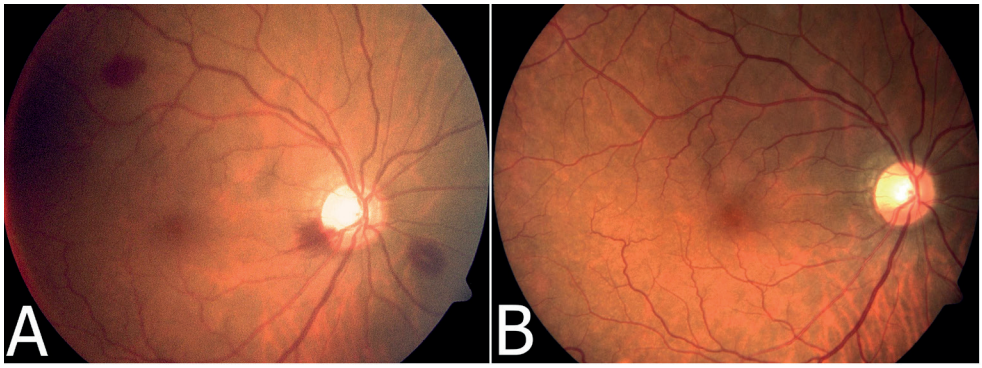

Figure 7. Photo-documentation of the retina of the right eye immediately after explantation of the artificial iris, showing intraretinal haemorrhage peripapillary and in the periphery of the retina (A), and subsequent absorption of haemorrhage (B)

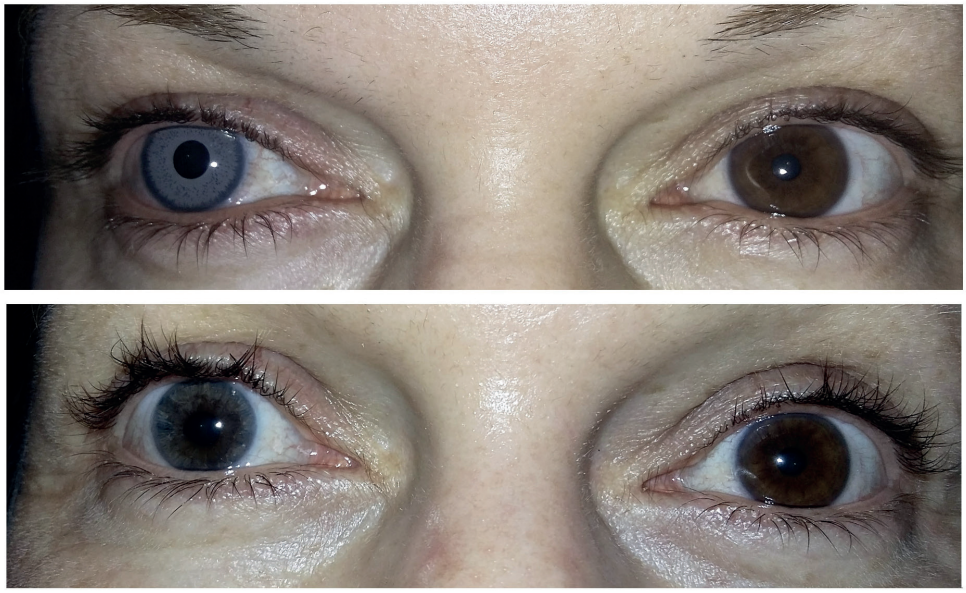

Figure 8. Photo-documentation of the patient before (upper image) and four years after the explantation of the artificial cosmetic iris (lower image). The lower image (i.e. in the fourth year after the explantation of the artificial cosmetic iris implant) shows a calm anterior segment of the eye and also a significant progressive atrophy of the pigment layer of the peripheral part of the iris, as compared to the condition immediately after surgery

number of complications, such as decreased visual acuity, glare, diplopia, and cosmetic defects. Deterioration of vision quality and depth of field is caused by both incorrect pupil photoreaction and spherical aberrations caused by a light beam passing through the peripheral part of the optical system [13]. Modern ophthalmology has found a solution for this problem in the form of iris prostheses, which are implanted in the anterior or posterior chamber of the eye (into the sulcus ciliaris or into the lens capsule) [14–20]. The use of iris implants significantly minimises photophobia and dysphotopsia and offers patients a satisfactory aesthetic result [18–21]. It has been shown that the safest way to implant these prostheses is to insert them in the posterior chamber of the eye, using custom-made prostheses [2,5,21]. The first anterior chamber iris prosthesis was implanted in 1956 by Dr. Choyce in the United Kingdom, in a patient with traumatic aniridia [17]. This prosthesis was made of rigid polymethyl methacrylate (PMMA) and was designed for implantation directly in the iridocorneal angle with three-point suture fixation (Rayner & Keeler Ltd.) [16–18]. Procedures of this type have caused secondary glaucoma or uveal irritation, so their use has been discontinued [18].

Subsequently, in 1991 Dr. Sundmacher was the first to implant an iris-lens diaphragm into the sulcus ciliaris (Iris diaphragm IOL, Morcher GMBH, Stuttgart, Germany) to treat congenital and traumatic aniridia [2,3,14,15,19]. This diaphragm, which consisted of an artificial intraocular lens with an integrated aperture, was made of black polymethyl methacrylate (PMMA) [14,15,18,19]. Although this iris-lens complex allowed the simultaneous correction of aniridia and aphakia, it was not an ideal solution, as its rigid structure required a larger corneal incision (150–180 °) for implantation [2]. Furthermore, it was not possible to choose an implant colour other than black, and therefore, a satisfactory cosmetic result was not always achieved [3].

A new generation of iris prostheses for therapeutic purposes has seen a low rate of complications, due to implantation in the posterior chamber and the use of modern materials for the production of these implants (biocompatible and foldable silicone) [4]. Compared to previous implants, the new generation has enabled safer implantation, thanks to a smaller corneal incision, and has also provided a greater choice of colours (Morcher, HumanOptics – Germany and Ophtec – Netherlands) [2,3,4]. Their implantation into the lens bag prevents mechanical irritation of the ciliary body and iridocorneal angle structures and thus significantly reduces the risk of secondary postoperative uveal reaction and elevated IOP [2].

In 2004, silicone anterior chamber implants called NewColorIris® (Kahn Medical Devices, Panama) appeared on the market in some countries, to improve the anatomical appearance of the iris of patients with congenital defects (e.g. oculocutaneous albinism) or post-traumatic iris defects [7,22–25]. It was a silicone, annular, one-piece implant with a diameter of 15 mm in a thickness of 0.16 mm, with a central opening for the pupil with a diameter of 3.50 mm and six anchor hinges placed in direct contact with the iris [22–24,26]. However, they were soon promoted as cosmetic anterior chamber implants, which were first introduced in practice in 2006 in Panama and targeted at individuals wishing to change the colour of the iris [11,25–28].

Subsequently, in 2012 a new generation of anterior chamber artificial cosmetic iris from BrightOcular® was patented, which was safer compared to the previous NewColorIris® model [8,10,29]. It is a one-piece, flexible and biocompatible silicone cosmetic implant with a thickness of 0.3–0.5 mm [11,29,30,32,33]. The primary modification of this implant was the choice of different sizes from 11.5 mm to 13.5 mm, according to the diameter of the cornea in the horizontal dimension (white to white) and of thickness from 0.3 to 0.5 mm [9,11,29,31–33]. The implant was equipped with posterior grooves, allowing better circulation of the aqueous humour with less friction between its surface and the iris [8,9,11,31,32]. The latest change in the design of implants was the addition of five rounded triangular handles around its circumference (0.12–0.14 mm thick and 0.8–1.0 mm long), designed for better fixation [9,11,32,34].

These cosmetic silicone prostheses are first folded into an injector and then implanted into the anterior chamber, which is filled with viscoelastic material through a 2.8 mm or 3.2 mm corneal incision [23,33]. The implant is unfolded using an iris hook to protect the corneal endothelium from contact with the unfolding implant [33]. In the anterior chamber, the unfolded implant is placed directly on the iris [23,35].

Despite technical improvements in the BrightOcular artificial cosmetic implant, the incidence of serious complications (e.g. glaucoma, anterior uveitis, endothelial cell density decline, corneal decompensation and cataract development) is still high [11,29].

The incidence of a certain percentage of complications is reported for all types of iris implants, but the severity and incidence of complications is significantly higher for implants that are implanted in the anterior chamber [6,13,36–39]. The use of these implants, especially if they are indicated for purely cosmetic reasons, is very controversial. The most common complications reported in the literature are secondary glaucoma, corneal decompensation, iris atrophy, uveal reaction and cataract [6–11,13,22–29,31,32,36,38–42]. The resolution of these complications almost always requires explantation of the iris implant, possibly iris plastic surgery, filtering glaucoma surgery, corneal transplantation or cataract surgery.

Hoguet et al. recorded a high incidence of IOP decompensation in 2012 after implantation of cosmetic iris implants. This complication has been reported in up to 50% of patients [26].

In 2015, Mansour et al. published a series of 12 case

reports of patients after implantation of the BrightOcular artificial iris, reporting an increased incidence of glaucoma (58%), anterior uveitis (83%) and corneal decompensation (50%) [11].

Elevation of IOP connected with cosmetic iris implants is probably caused by direct mechanical irritation of the corneoscleral region by irregular edges and grooves on the implant, which create pressure on the trabecular meshwork, the Schlemm's canal and its collectors [41].

Other factors causing IOP decompensation include: trabeculitis due to chronic anterior uveitis, corticoid therapy used to treat the uveal reaction, pigment dispersion induced by direct contact between the iris and the implant, and pupillary block in the case of implantation without prior laser iridotomy [11,23].

Scanning electron microscopy performed on cosmetic iris implants revealed highly irregular edges that can come into contact with the natural iris itself. The abrasive effect of the cosmetic iris material and the constant contact between the implant grooves and the iris lead to chronic hypoxia, uveal irritation or pigment release and atrophy of the iris tissue [9,11,41].

The aetiology of postoperative complications from cosmetic iris implants is also explained by the larger size of the implant in relation to the anatomical dimensions of the eye and the permanent contact between the grooves of the implant and the iris [42]. Larger dimensions in implants lead to mechanical compression of the trabecular meshwork or endothelium and thus to their damage over time [38,42]. Permanent sectorial atrophy, the formation of iris tissue defects through the entire thickness, pupil deformation or cataract formation are all potential irreversible consequences, visible only after explantation of the artificial iris.

Implantation of cosmetic artificial irises in healthy, phakic patients causes serious eye complications that can pose a risk of irreversible damage to the eyes. Therefore, it is very important for professionals and patients to know both the immediate and long-term risks associated with these procedures, and it is necessary to alert patients to the importance of long-term eye monitoring, even after the explantation of these implants.

CONCLUSION

This case report highlights some of the long-term and vision-endangering consequences of the use of artificial cosmetic implants.

Based on the literature data and our specific case report, it can be stated that the implantation of an artificial cosmetic iris is at best high risk and in some cases a danger to the eyes. Although the use of these implants is not permitted in the countries of the European Union (EU), due to online advertising and the possibilities of medical tourism, we may encounter in our practice those who have undergone or intend to undergo this elective surgery in a location outside the EU. It is therefore appropriate to inform fellow professionals and possibly also the lay public about the possible risks, complications and their potential solutions. Due to the serious complications described above and the absence of sufficient evidence to demonstrate the safety or efficacy of these implants, the use of cosmetic iris implants cannot be recommended at present.

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