Explantation of BrightOcular cosmetic iris implant and goniosynechialysis: A case report

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A 48-year-old lady presented with bilateral symptomatic uveitis. She had bilateral cosmetic iris implantation 4 years ago. She underwent bilateral cosmetic iris explantation and goniosynechialysis to open up areas of angle compromise. This patient presented before significant angle compromise. This case report also serves to highlight the serious potential risks associated with cosmetic iris implantation. Patients with cosmetic iris implants should be warned of the potential complications and advised explantation at the earliest.

Key words: BrightOcular, cosmetic iris implant, explantation, goniosynechialysis

Iris implants were classically used in the management of symptomatic aniridia, coloboma and ocular albinism. However, in the last decade, they have gained popularity in the form of cosmetic colored implants for those who wish to change their iris color. The two main implants available are NewColorIris (Kahn Medical Devices, Panama City, Panama) and BrightOcular (Stellar Devices, New York, USA).

We describe a case of bilateral recurrent uveitis and anterior chamber angle compromise following cosmetic iris implantation. This case also serves to highlight the complications associated with a surgical procedure advertised as safe and popular.[1]

Case Report

A 48-year-old lady presented to the clinic with recurrent redness and pain in both eyes for the last 3 years. She was using loteprednol etabonate 0.5% four times a day in both eyes at presentation. She had bilateral ptosis surgeries and cosmetic iris implantation 3 to 4 years prior, respectively. On examination, her best corrected visual acuities (BCVA) were 20/30 OD and 20/30 OS. Corneas were clear. Anterior chamber had 1+ cells and bilateral greyish green cosmetic iris implants bilaterally [Fig. 1]. Gonioscopic view was partly obscured by the implants; however, the trabecular meshwork and the scleral spur were visualized for at least 180 degrees in both eyes. Early cataracts with a few pigmentary deposits on the anterior capsules were noted. The intraocular pressures (IOP) were 14 mmHg in both eyes. Fundus examination was unremarkable with a cup-to-disc ratio of 0.4 in both eyes. After a detailed discussion regarding the potential complications that could be caused by the implants, such as corneal decompensation, recurrent iritis and glaucoma, the patient decided to have them explanted.

She underwent bilateral explantation of the iris implants and goniosynechialysis. Both eyes were separately cleaned and draped for the procedure. The implants were first cut into three pieces using intraocular microscissors. Subsequently, the pieces were gently teased from the angle and removed through a 3-mm corneal wound [Fig. 2]. The implants were not adherent to the iris. Iris atrophy was noted bilaterally, and pupil distortion was noted bilaterally, though more on the right. On intraoperative gonioscopy, peripheral anterior synechiae (PAS) were present for approximately 80 degrees in each eye. Goniosynechialysis was performed using micrograspers, opening up the angles and partly restoring the shape of the pupils [Fig. 3].

Postoperatively, the patient was started on the following eye drops: Difluprednate ophthalmic emulsion 0.05% thrice a day, loteprednol etabonate 0.5% twice a day and moxifloxacin hydrochloride 0.5% thrice a day; the steroids were gradually tapered and stopped. There was no hyphema postoperatively. She was noted to have bilateral slowly progressing immature cataracts. Although the angle opened up more after goniosynechialysis, we noted that there were some areas of residual PAS on follow-up [Fig. 4]. The BCVA at the last follow-up 9 months postoperatively was 20/40 in each eye. The IOP was 12 in each eye on no anti-glaucoma medication. Her cup-to-disc ratio continued to be 0.4.

Discussion

The cosmetic iris implants are associated with numerous complications, such as glaucoma, uveitis, cataract and corneal decompensation.[2-5] Patients can present as late as four years after implantation with complications.[6]

NewColorIris cosmetic iris implantations were initially performed in Panama. BrightOcular, a newer implant, introduced modifications intended to improve the safety of the procedure. The main design improvement was the patented posterior grooves, which theoretically allow continuous flow of aqueous between the implant and the iris and minimal iris chafing, thus preventing iris atrophy and elevated intraocular

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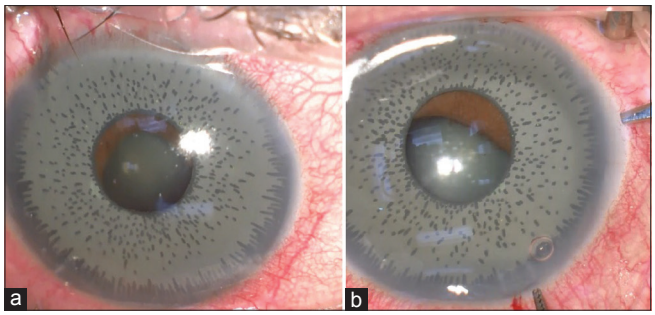

Figure 1: Intraoperative pictures of the iris implants before explantation. The right (a) and left (b) pupils are displaced inferiorly

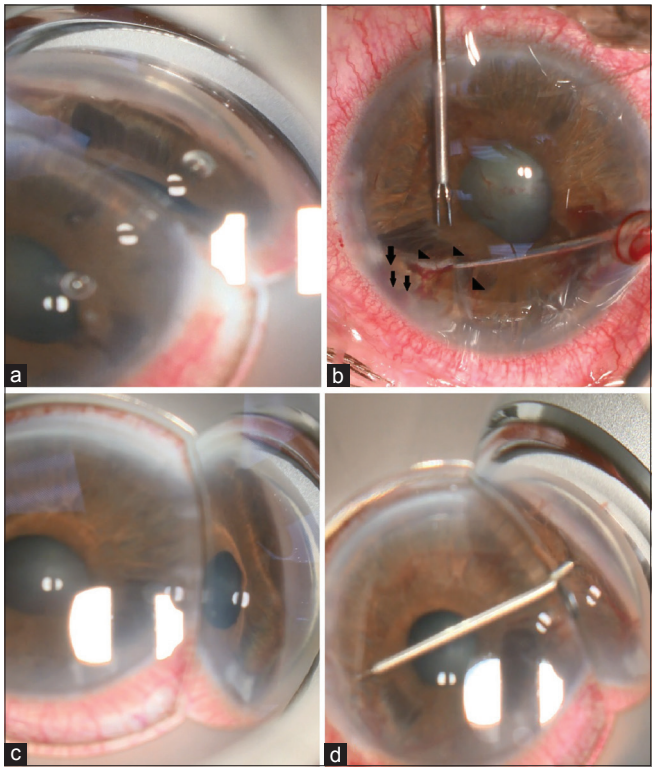

Figure 3: Goniosynechialysis. (a) Iris atrophy and peripheral anterior synechiae seen on intraoperative gonioscopy in the left eye. (b) After using microgaspers to separate the iris tissue from the angle, a second instrument is used to separate the membranous adhesion (black arrowheads) from the angle, taking care not to cause an iridodialysis. Minimal bleeding from the angle is seen (black arrows). (c) Localized area of peripheral anterior synechia seen on intraoperative gonioscopy in the right eye. (d) Iris tissue divided from the angle using microgaspers

pressure. The implant comes in different sizes: Diameter 11.5-13.5 mm, five rounded triangular edges 0.12 to 0.14 mm thick and 0.8-1.0 mm long, thickness 0.3-0.5 mm.[7]

This medical grade silicone device is not approved by the United States Food and Drug Administration and cannot be used legally in the USA and Europe. However, it is being implanted in Albania, China, Costa Rica, India, Jordan, Lebanon, Mexico, Syria, Tunisia and Turkey.[7,8]

Although BrightOcular implant is an improvement compared to NewColorIris in principle, it is far from safe, given the serious nature of the complications reported, such as glaucoma, uveitis, and corneal decompensation.[7-9] The

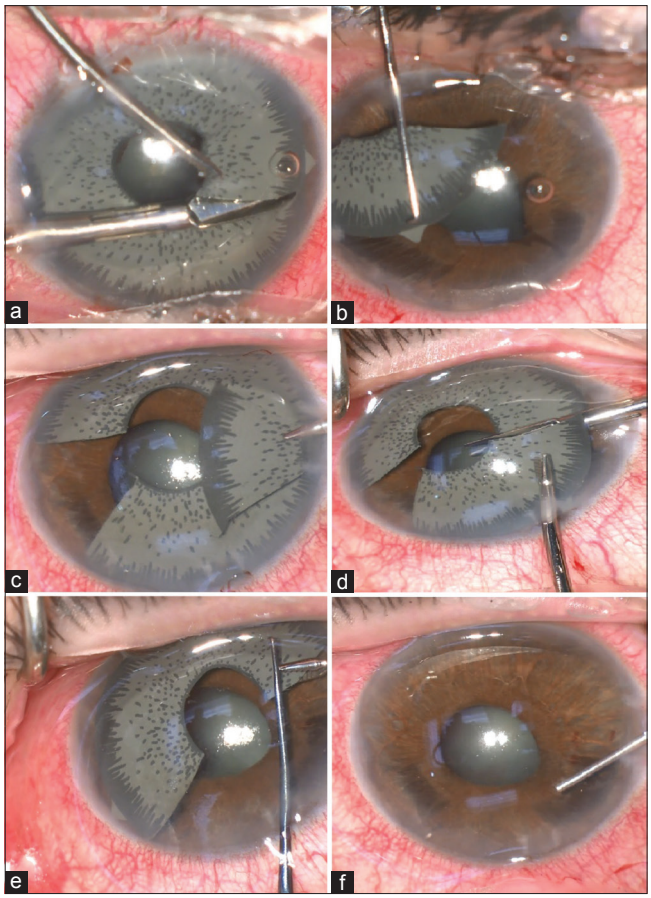

Figure 2: Piecemeal removal of the implant. (a and b) right eye; (c-f) left eye. a. Microscissors used to cut while micro-holding forceps is used to hold the implant. (b) Iris atrophy inferotemporally and inferonasally. Corneal endothelium is guarded by the second instrument while the implant piece is removed from the anterior chamber. Pupil appears distorted and pulled inferotemporally. (c and d) Iris implant cut into three pieces using micro-holding forceps and microscissors. Each piece is removed after cutting for better visualization and working space. (e) Use of second instrument to guard the corneal endothelium. (f) Patches of iris atrophy inferiorly. Pupil is less distorted

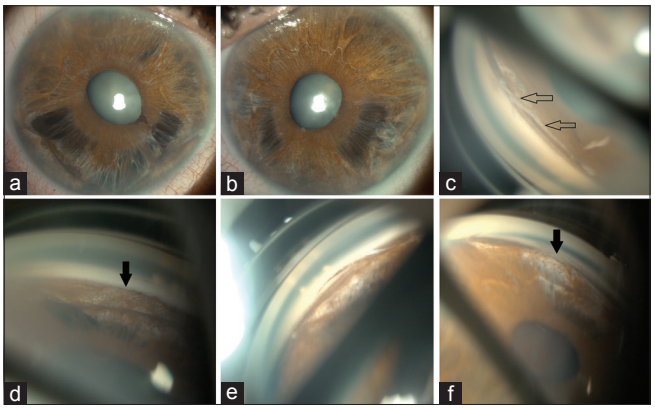

Figure 4: Postoperative images nine months after iris implant explantation. (a and b) Anterior segment photograph of the right and left eye, respectively, showing iris atrophy, mild pupil distortion and immature cataracts. (c and d) In the right eye, angles are mostly open. Two areas of peripheral anterior synechiae are seen: superonasally with membranous adhesion (black hollow arrows) and inferotemporally (black solid arrow). (e and f) In the left eye, angles are mostly open with one area of peripheral anterior synechia inferonasally (solid black arrow)

intraocular pressure was normal in our case as the areas of PAS were localized. The implant did not have any adhesions to the iris and was easy to explant. However, iris atrophy was visualized intraoperatively; this was likely secondary to iris chafing, which correlates with the persistent anterior uveitis noted preoperatively. Preoperative anterior segment optical coherence tomography or ultrasound biomicroscopy may provide more information on the status of the iris and angle hidden by the implant.

BrightOcular implants can be removed piecemeal after cutting the implant intraocularly using micrograspers and microscissors. It is prudent to use a second instrument to protect the corneal endothelium while removing the implant. Intraoperative gonioscopy can provide valuable information regarding angle anatomy, and should be routinely performed in similar cases. Intraoperative gonioscopy can also direct and assist in goniosynechialysis as needed. Goniosynechialysis involves division of iris tissue from the angle and opening up areas of angle compromise. This additional procedure has been reported to be useful in primary angle closure glaucoma.[10]

The rate of secondary glaucoma as a complication of the implant was as high as 43%. Nearly half of these eyes required surgical management for uncontrolled glaucoma. The final corrected distance visual acuity was 20/200 or worse in 15.1%, including one eye with no light perception. At least 20.3% of patients required keratoplasty. High complication rates as these are unacceptable for a cosmetic procedure.[5]

Those planning to have cosmetic iris implants should be made aware of the potential complications too. Those with implants should be advised for early explantation to prevent long-term sequelae. The goniosynechialysis can be attempted after explantation to open up compromised areas of the angle and restore the pupil shape.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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