Two Cases of Cosmetic Iris Implant Explantation Secondary to Uveitis, Glaucoma, and Corneal Decompensation

Cosmetic alteration of the iris color has long intrigued individuals. This has been accomplished with cosmetic contact lenses and most recently with intraocular artificial iris implants. We report 2 cases of uveitis, glaucoma, and corneal decompensation in women who underwent bilateral simultaneous implantation of a non–US Food and Drug Administration–approved cosmetic iris implant (NewColorIris). This device is a plate-styled colored silicone prosthesis designed for placement in the anterior chamber. Both patients had traveled to Panama City, Panama, to undergo the elective procedure. After surgery, both developed variants of an ocular complex comprising uveitis, glaucoma, and corneal decompensation and requiring explantation of the cosmetic iris implants. Various in situ and extirpated imaging techniques demonstrate implant placement, size, and surface characteristics that likely contributed to the ocular complications in these 2 cases.

Report of Cases. Case 1. Three weeks after bilateral NewColorIris implantation, a 28-year-old Brazilian woman had bilateral anterior segment inflammation, intraocular pressure elevation, and discomfort (Figure 1A). Anterior segment optical coherence tomography (OCT) showed close approximation of the inserted iris prosthesis to the corneal endothelium and anatomical angle (Figure 1B). Endothelial specular microscopy performed at that time revealed marked endothelial cell loss, with cell counts of 1533/ mm² OD and 1215/mm² OS (Figure 1C and D). The iris implants were removed 1 week later after a short course of topical steroids and brimonidine tartrate.

Case 2. One year after bilateral NewColorIris implantation, a 29-year-old American woman had blurred vision and right eye pain (Figure 2A). At the initial visit, her intraocular pressure was 54 mm Hg OD and 30 mm Hg OS. The right eye demonstrated marked corneal decompensation and an associated visual acuity
reduction to 20/400. After treatment with topical glaucoma medications, endothelial cell counts were found to be 2392/mm² OD and 1357/mm² OS. Central corneal thickness measured 547 µm OD and 553 µm OS. Anterior segment OCT demonstrated crowding of the anatomical angles bilaterally by the cosmetic iris implant’s edge (Figure 2B). Following explantation, gonioscopic examination revealed broad peripheral anterior synechiae, nearly 360° OU. Subsequently, she developed severe, acute, secondary angle-closure glaucoma in both eyes, necessitating urgent trabeculectomies. In addition, her left cornea decompensated and she recently underwent a combined penetrating keratoplasty and cataract extraction. Currently, she is re-

Figure 2. Findings in case 2. A, Cosmetic iris implant. B, Anterior segment optical coherence tomographic image demonstrating the cosmetic iris implant’s close approximation to the patient’s anatomical angle as well as in direct contact with the anterior surface of the iris.

Figure 3. Microscopy findings. A, Light microscopy photomicrograph of the explanted device (original magnification ×5). B, Scanning electron microscopy photomicrograph of the anterior surface of the explant with irregular surfaces in the area of color pigmentation (original magnification ×500). C, Scanning electron microscopy photomicrograph of the posterior surface of the explant demonstrating a rough surface (original magnification ×1000). D, Light microscopy photomicrograph demonstrating irregular edge characteristics of the explant (original magnification ×100).
ceiving maintenance therapy with multiple topical agents for control of the intraocular pressure in her left eye.

**Analysis of Explanted NewColorIris Implant.** Analysis using both light and scanning electron microscopy of one of the explanted NewColorIris devices shows surface and edge characteristics that deviate significantly from the appearance of other currently US Food and Drug Administration–approved anterior chamber implants on scanning electron microscopy. Specifically, the posterior surface of the NewColorIris implant has an irregular surface architecture and the edge has a very rough, nearly serrated appearance on close examination (**Figure 3**). These morphologic features support our contention that the surface characteristics of the NewColorIris contributed to ocular inflammation, secondary glaucoma, and endothelial cell loss in both patients. The edge profile appears to have been particularly deleterious to patient 2 due to direct apposition of the device against the angle structures as demonstrated by OCT.

**Comment.** These 2 cases add to a growing body of literature regarding profound anterior segment damage, including uveitis, glaucoma, and corneal decompensation, secondary to NewColorIris implantation. While not approved by the US Food and Drug Administration for implantation in the United States, the NewColorIris poses a very real risk to patients willing to travel abroad to have it implanted. As we have demonstrated by anterior segment OCT and light and scanning electron microscopy, the NewColorIris device has intraocular positioning and surface characteristics that likely contribute to its poor tolerance in the anterior chamber of some patients. Specifically, if the device is undersized relative to the anterior chamber, it may not sit properly and can then contact the corneal endothelium (as in case 1). Alternatively, it can cause direct damage to angle structures in those with less generously sized anterior segments, which can lead to glaucomatous angle changes such as synchiae. This was particularly evident in case 2, in which profound angle damage was inflicted in the setting of an implant that was shown by OCT to be directly apposing the angle structures prior to its explantation. It is our feeling that the surface characteristics of the implant, particularly its relative surface irregularity compared with other better-tolerated anterior segment implants, were responsible for significant ocular inflammation in both patients in this series. The medical literature demonstrates that inappropriately sized anterior chamber implants deleteriously affect corneal endothelial cell counts and angle structures, as shown in the analysis of phakic intraocular lens tolerance. Although implant design and positioning issues strongly influenced these outcomes, the biocompatibility of the material and chemical coloring of the NewColorIris device may have also contributed to these complications; however, we were unable to confirm this.

Scientific data on the safety of this device are lacking in the published literature. Therefore, given its lack of adequate clinical testing and a growing body of literature describing potentially vision-threatening complications related to its implantation, we advise patients to avoid undergoing implantation of the NewColorIris prosthesis. Additionally, eye care professionals should warn patients interested in this procedure of these potential complications. Other iris devices have proven very safe and effective, and patients requiring noncosmetic iris reconstruction may consider using other posterior chamber and secured iris reconstructive devices such as those from Morcher, Ophtec, and HumanOptics (ArtificialIris). Finally, those who have already undergone cosmetic iris implantation should be closely monitored for complications, and explantation of the iris prosthesis should be undertaken at the earliest sign of ocular intolerance.

**Effect of Peripapillary Vitreous Opacity on Retinal Nerve Fiber Layer Thickness Measurement Using Optical Coherence Tomography**

Optical coherence tomography (OCT) is a widely used technique for the measurement of retinal nerve fiber layer (RNFL) thickness. It emits a light from the light source to the retina or reference mirror and measures RNFL thickness by detecting the different reflectivities of retinal structures. Therefore, any media opacity in the cornea, lens, or vitreous body can affect OCT measurement. However, little is known about the effect of vitreous opacity on RNFL thickness measurement. Vitreous opacity associated with age-related posterior vitreous detachment is a commonly found abnormality. In aged eyes with posterior vitreous detachment, a vitre-