Complications and Management of NewColorIris Implantation in Phakic Eyes

To the Editor:
Since 2004, the NewColorIris (Kahn Medical Devices, Panama City, Panama) silicone prosthesis has been implanted for cosmetic eye-color change in phakic eyes.1 These implants have been linked to sight-threatening complications including endothelial cell loss, corneal edema, elevated intraocular pressure (IOP), anterior chamber inflammation, decreased visual acuity, and cataract formation.2-5 The implant has not been approved by the US Food and Drug Administration and there are no published long-term safety data.

A 19-year-old man presented with complaints of subjective decreased vision in both eyes. Four months prior, he had bilateral blue NewColorIris implantation in Panama. Uncorrected distance visual acuity (UDVA) was 20/302 and IOP was 14 mmHg in both eyes. Gonioscopy revealed peripheral anterior synechiae in several quadrants with the implants lodged in the angles in both eyes. Flare as well as pigmented cells were visible on the angle structures and the surface of the implants. Explantation was scheduled after discussing the risks of cataract formation, glaucoma, cornea failure, and blindness without surgery. The patient requested the implants be removed bilaterally and consecutively for cosmetic reasons. Written informed consent was provided prior to surgery.

Removal of NewColorIris implants requires care to minimize corneal endothelium trauma. Anderson et al2 describe a process whereby a single 2.75-mm superotemporal incision is made in the cornea and the implant is removed en bloc. After reopening the original corneal incision and performing implant sphincterotomy, Hull et al4 perform an en bloc removal via a 5- to 6-mm incision. Garcia-Pous et al5 describe explantation through a 2.8-mm corneal incision, with no mention of manipulation of the iris implant. In our case, we cut the NewColorIris into three equal pieces by careful rotation in a viscoelastic-filled anterior chamber (Fig). This technique minimized trauma to the endothelium and further trauma on the iris and lens. By creating smaller segments, the iris implant could be removed through a 2.75-mm clear corneal temporal incision with less risk of lens contact during removal.

Postoperatively, topical steroid and antibiotic were prescribed. On postoperative day 1, the patient had UDVA of 20/302 in the right eye and 20/251 in the left eye. At 1-week follow-up, UDVA improved to 20/25 and 20/252 with an IOP of 12 and 15 mmHg in the right and left eyes, respectively. Unfortunately, he did not return for further follow-up.

To our knowledge, only 8 cases (16 eyes) of complications following NewColorIris cosmetic implantation surgery have been published prior to this letter.2-5 The only available long-term safety data are from the manufacturer, which studied 12 female patients (24 eyes) with a mean endothelial cell density loss of 2.6% after 8 months of follow-up.1 In this series, only 1 patient (2

Figure. Iris implant surgical removal, right eye. a) Initial segmentation through clear corneal incision and counter-clockwise rotation. b) Second segmentation 4 clock hours away from first segmentation. c) Removal of the first segment through the clear corneal incision with rotation of larger remaining piece. d) Third segmentation of the remaining implant. e) Removal of the second segment. f) Removal of the remaining implant segment through clear corneal incision.
eyes) required explantation due to uveitis and ocular hypertension.

Published cases in the literature, as well as this case, indicate that NewColorIris implantation for cosmetic eye-color change warrants caution. The current design causes sight-threatening complications including hyphema, IOP elevation, uveitis, and corneal decompensation, although the overall prevalence is unknown. Patients should therefore be informed of the risks including IOP management and/or urgent explantation.

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