



Clinical Alert: Ocular Complications of Cosmetic Anterior Chamber Iris Implants

Issued by ASCRS, ESCRS, APACRS, ALACCSA-R/LASCRS

Unregulated cosmetic iris implants being inserted outside the United States and European Union are causing severe ocular complications in many patients.

Unlike functional artificial iris devices, which are designed to be placed in the capsular bag or ciliary sulcus of pseudophakic eyes (*i.e.*, Morcher, HumanOptics, Ophtec), “color changing” iris implants are being placed into the anterior chamber of young phakic patients, over a healthy iris, and in direct contact with angle structures.

Two case series^{i,ii} and several case reports^{iii,iv,v} have described severe and irreversible complications of these implants, even following explantation. The most frequent problems include corneal decompensation, sectoral iris atrophy, glaucoma, cataract, and uveitis. Many of the patients in the two case series required secondary surgeries including corneal transplantation, glaucoma tube shunt implantation, iris repair (in some instances necessitating a HumanOptics sulcus artificial iris implant^{vi}), and cataract surgery. These complications develop months to years after cosmetic iris implantation.

The American Society of Cataract and Refractive Surgery (ASCRS), the European Society of Cataract and Refractive Surgeons (ESCRS), the Asia-Pacific Association of Cataract & Refractive Surgeons (APACRS), and Asociación latinoamericana de Cirujanos de Catarata Segmento Anterior y Refractiva/Latin American Society of Cataract and Refractive Surgeons (ALACCSA-R/LASCRS) strongly advise against the implantation of any anterior chamber cosmetic iris implants that have not been subject to rigorous regulatory approval and thoroughly studied in appropriate clinical trials.

Cosmetic anterior chamber iris implants are not Food and Drug Administration (FDA) approved in the United States, nor are they Conformité Européenne (CE) marked in Europe. Additionally, no clinical trials are underway to study their safety or efficacy. The only publications to date describe their devastating complications.

History:

The original cosmetic iris implant was inserted in Panama from 2006 to 2010. More recently, a similar device has been implanted in at least 10 countries outside of the United States and Europe.ⁱ There are no safety studies or regulatory approvals for these implants to date. Internet promotion for these cosmetic implants includes misleading claims of a US patent approval and being made of “ophthalmic grade silicone.”

Recently, entertainment celebrities have travelled internationally to obtain these cosmetic color implants and general media coverage has incorrectly deemed the unapproved implant and procedure as simply “controversial.”

Management of cosmetic color changing iris implants:

Patients will occasionally present to ophthalmology practices in the United States and Europe for “clearance” before travelling abroad for surgery. It is incumbent on any eye care provider who sees these patients to educate them on the dangers associated with these unapproved implants and strongly discourage surgery.

Regarding patients who come for consultation after cosmetic iris implantation, close periodic monitoring for early signs of complications is warranted. Prompt explantation of implants is recommended at the earliest sign of corneal endothelial cell loss, corneal edema, prolonged iritis, ocular hypertension, cataract, or pupil ovalization, which may be difficult to detect behind an implant. Following primary explantation, these eyes should be treated for elevated intraocular pressure and inflammation. Secondary interventions can be planned, as indicated. Because of time and money these patients invest, and because of their desire for a new cosmetic appearance, some are hesitant to have the implants removed despite being educated on the risks.

The rate of complications with cosmetic iris implants is unknown; but, as with historical closed-loop angle-supported implants, complications are expected to increase with time.

Conclusion:

Cosmetic anterior chamber iris implants represent a health hazard for unsuspecting patients. The ASCRS, ESCRS, APACRS, and ALACCSA-R/LASCRS strongly advise against this surgical procedure until appropriate clinical trials have been performed that yield long-term safety data, and regulatory approvals have been obtained.

ⁱ. Mansour AM, Ahmed IIK, Eadie B, et al. Iritis, glaucoma and corneal decompensation associated with BrightOcular cosmetic iris implant. Br J Ophthalmol 2015; 0:1-4

ⁱⁱ. Hoguet A, Ritterband D, Koplin R, et al. Serious ocular complications of cosmetic iris implants in 14 eyes. J Cataract Refract Surg 2012; 38;387-393

- iii. Arjmand, P Gooi P, Ahmed II. Surgical technique for explantation of cosmetic anterior chamber iris implants. J Cataract Refract Surg 2015; 41(1); 18-22
- iv. Shweikh Y, Ameen S Mearza A. Complications secondary to cosmetic artificial iris anterior chamber implants: a case report. BMC Ophthalmology 2015; 15;97; 1-4
- v. Sikder S, Davis SW, Patel VP, et al. Complications and management of NewColorIris implantation in phakic eyes. J Refract Surg. 2011;27 (4): 239-40
- vi. <https://www.youtube.com/watch?v=ZCloJN5iCuw&feature=youtu.be&a> accessed on 9/12/16