Cosmetic Iris Implants

AAO Council Advisory Recommendation

Sponsor: American Glaucoma Society (AGS)

Co-Sponsors:
American Society of Cataract and Refractive Surgery (ASCRS)
Contact Lens Association of Ophthalmologists (CLAO)
New York State Ophthalmological Society (NYSOS)

Problem Statement

Intraocular iris implants have been marketed for the purpose of cosmetic alteration of iris color. These implants have not been approved by the US Food and Drug Administration (FDA), yet they are being currently implanted in Americans traveling to Panama for the surgery. Case reports in the scientific literature have reported a number of vision threatening complications resulting from implantation of these cosmetic devices. Given the significant risk to patients, the American Academy of Ophthalmology (AAO) should take the position that eye care professionals should strongly discourage its use for cosmetic reasons.

Summary of Facts and Background Information

Newer silicone anterior chamber implants such as the NewColorIris (Kahn Medical Devices, Panama City, Panama) were initially developed for the treatment of oculocutaneous albinism (Kahn DA; poster presentation at the American Academy of Ophthalmology Annual Meeting 2006). However, this implant has been subsequently marketed and advertised on the Internet as a cosmetic procedure for individuals who wish to change their eye/iris color (http://newcoloriris.com).

The NewColorIris is a US patented, single-piece, silicone implant that is surgically implanted into the anterior chamber under topical anesthesia. The implant is surgically folded and inserted through a corneal keratome incision and then unfolded and situated on the anterior iris surface. These implants have been manufactured and placed in patients in Panama since 2006, and there is growing interest on the internet regarding its cosmetic applicability.
The procedure is being described on informational websites without much medical review. For example, an article on eHow.com (‘New Iris Color Surgery’) states, “The surgery is considered safe because it utilized technology that is similar to the procedure used for treating cataracts.” (http://www.ehow.com/about_6531585_new-iris-color-surgery.html).

An increasing scientific literature has described serious post-operative complications and elevated intraocular pressure (IOP) associated with the NewColorIris cosmetic implant.¹⁻⁵ These include reduced vision, hyphema, uncontrolled IOP and glaucoma, uveitis, cataract, corneal decompensation, bullous keratopathy, and bilateral central retinal vein occlusion and secondary neovascular glaucoma. In these reported cases, surgical explantation of the implants was required. However, in one patient, surgical explantation of the cosmetic iris implants resulted in significant surgical aniridia in both eyes.⁵

References:

Possible Solutions

A.) The AAO should work with the Food and Drug Administration (FDA) to educate the public and health care community on the risks of cosmetic iris implant surgery.
B.) The AAO should work with the Federal Trade Commission (FTC) to monitor the quality and balance of information provided on the internet pertaining to these cosmetic iris implants (e.g. manufacturer website).
C.) The AAO should work with the Centers for Disease Control and Prevention (CDC) to educate the public and health care community regarding the risks of cosmetic iris implant surgery as pertaining to international medical tourism.

D.) The AAO should contact the manufacturer to express its significant concern regarding the marketing of these implants for cosmetic and non-medical reasons.

E.) The AGS and other sponsoring subspecialty societies (CLAO) should work with AAO to develop media materials to educate the public and health care community regarding the risks of cosmetic iris implant surgery.

F.) The AAO should enlist the support of educational/service organizations (e.g. Prevent Blindness America) to educate the public and health care community regarding the risks of cosmetic iris implant surgery.

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