

Iris Prosthesis/ IOL Implantation

Concomitant defects in the capsulozonular complex and the iris, although common, demand the deployment of specialized techniques and implantable devices for their correction.

BY KENNETH J. ROSENTHAL, MD, FACS

Iris defects occur in a variety of conditions, including congenital aniridia, coloboma, iridocorneal endothelial syndrome, Axenfeld-Rieger syndrome, trauma (surgical and nonsurgical), uveitis, and idiopathic postoperative mydriasis. Many patients have coexisting zonular and capsular abnormalities.¹ Patients with iris and capsular defects present surgical challenges because (1) the anterior segment may destabilize after cataract removal and (2) the implantation of a traditional IOL may cause the patient significant glare, photophobia, and polyopsia. In addition, patients with thin or transparent irides, such as in ocular albinism, chronic inflammation (eg, herpetic uveitis), or trauma may have an exquisite and debilitating sensitivity to light.

The implantation of a masking artificial iris implant can potentially reduce glare and improve patients' visual function. Such devices may also mask the optical aberrations prevalent in the peripheral cornea and eliminate visual competition between focused and unfocused images.

SURGICAL APPROACH

Iris Defect Repair Options

Because every iris defect is unique, the surgical approach must be tailored to the specific situation. Primary repair of an iris defect by means of techniques such as iris sphincterotomy, synechialysis, iris suturing, and cerclage may be adequate in some patients and should be considered before an

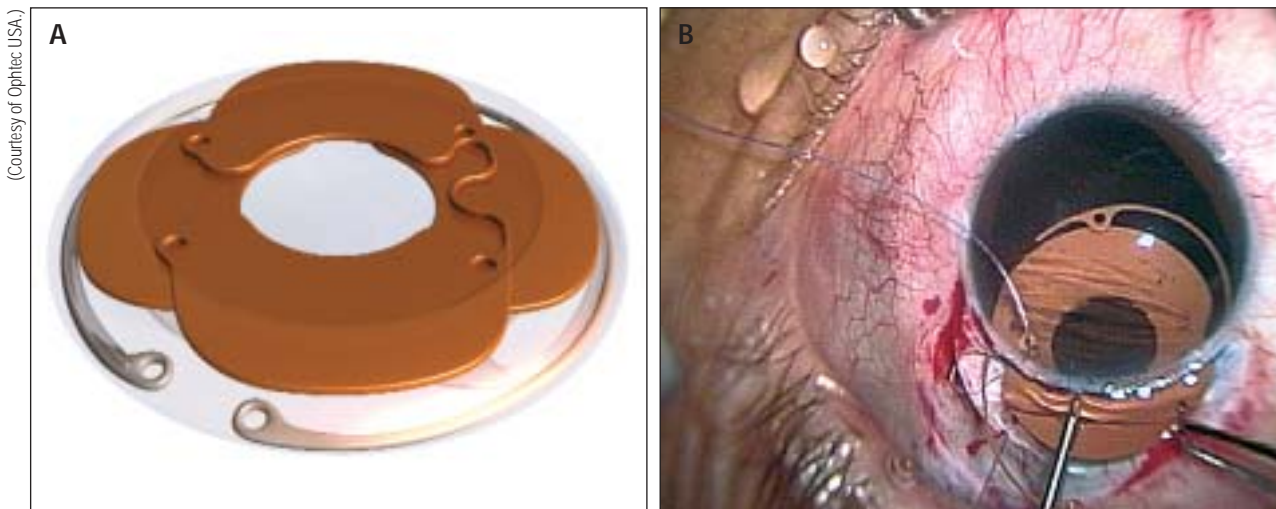


Figure 1. The Ophtec Iris prosthetic device is available in multiple colors, including black, brown, green, and blue. The modular Iris Prosthetic System, shown here, is for use in intact capsular bags with or without zonular support (A). The surgical insertion of the Ophtec Model 311 requires a 10- to 11-mm incision (B).

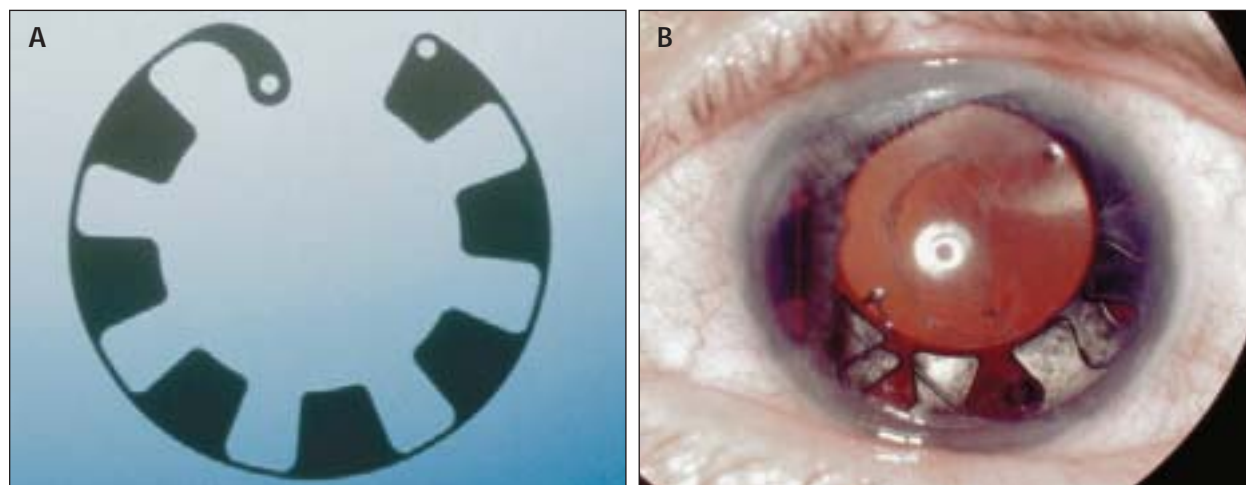


Figure 2. The Rasch Rosenthal Iris Diaphragm ring (A) can be inserted through a 4-mm incision (B).

iris prosthetic implant. However, these other forms of repair may be neither possible nor sufficient in eyes with more extensive iris defects. Overly aggressive iris suturing techniques should be avoided with these cases, because the iris tissue is almost universally abnormal and there is a risk of iatrogenic iridodialysis and hemorrhage, as well as of sequential iris atrophy in areas under tension from suturing. Furthermore, with some iris defects, such as those associated with iridocorneal endothelial syndrome, or in eyes with comorbid conditions, such as retinal abnormalities or glaucoma, the overall success of the procedure may ultimately be compromised by the progression of the disease.

PROSTHETIC IRIS DEVICES

For eyes that have iris defects too extensive for simple repair, a small selection of implantable iris prosthetic devices have been developed that will aid the surgeon in compensating for the deformed or imperfectly functioning iris. Two companies produce these devices on a customized basis. As a participant in the FDA clinical trials for an implant manufactured by Ophtec BV (Groningen, the Netherlands), I have had the opportunity to place a number of these implants.² Similar devices are available from Morcher GmbH (Stuttgart, Germany), but they are not FDA-approved and require individual compassionate use exemptions from the FDA. The Morcher implant is available in black only and is made of a rather brittle material. The Ophtec devices are available in multiple colors (Figure 1).

In 1991, Rainer Sundmacher, MD, of Düsseldorf, Germany,³ developed a PMMA IOL surrounded by an opaque black segment that serves as an artificial iris diaphragm for implantation in patients with iris defects. Peter Choyce, MD, developed and implanted similar designs

as early as the 1950s.⁴ In patients with absent or inadequate capsular support, this lens is quite useful, although the black optic carrier measures up to 10 mm in diameter (and encompasses varying optic sizes), thus requiring a large incision. Thomas Reinhard, MD, of Düsseldorf, Germany,³ has shown that these devices provide good visual rehabilitation, although they have been associated with a greater amount of postoperative inflammation and a higher incidence of postoperative pressure elevation when compared to standard extracapsular surgery. This problem may relate to the disruption of the blood-aqueous barrier, although it should be pointed out that many of these eyes have other serious defects as well. Robert Osher, MD, and Scott Burke, MD, of Cincinnati have demonstrated similarly favorable results.⁵

STUDY PROGRESSION

Preliminary results of the ongoing Ophtec Iris Prosthetic implant study have been strongly favorable to date.⁶ There have been no reported surgical, postoperative or optical complications caused by the device, and there has been no substantial difference in inflammatory response compared with that expected from traditional extracapsular surgery (the device requires an incision larger than 10 mm). All patients reported a subjective improvement in visual quality as well as a reduction in glare and ghosting or other undesired images.

Volker Rasch, MD, of Potsdam, Germany, and I invented a series of aniridia and coloboma aperture rings (Morcher GmbH) designed to be implanted in an intact capsular bag, with or without zonular instability and with a separately implanted IOL (Figure 2).⁷ A similar device is available from Ophtec USA (Boca Raton, FL). Because these devices incorporate the properties of a capsular tension ring, they can be used to treat partial

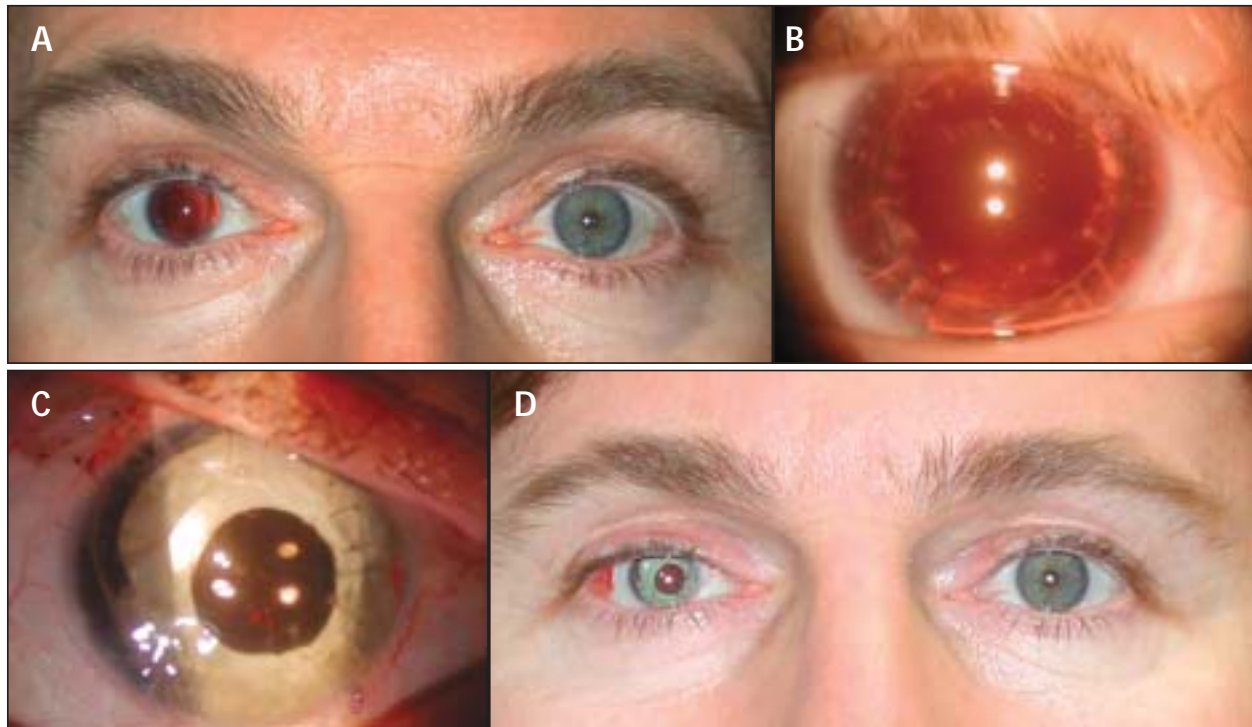


Figure 3. A 49-year-old male, status post 16-cut RK, suffered an expulsive injury to his right eye after being hit with a surfboard. Although the patient underwent corneal transplantation, a vitrectomy to remove retained lens material, and a repair of a retinal detachment, he was left aphakic and aniridic (A). The subsequent implantation of an Ophtec iris prosthesis improved his vision to 20/40 (B). The iris prosthetic implant (C) matched the color of the patient's fellow eye well (D).

capsular instability and iris defects (Figure 3). Michael Snyder, MD, of Cincinnati had suggested that I use a 6.5-mm IOL so that an overlap between the optic and haptic occurs, thereby reducing the potential for optical problems related to the IOL's edge. The devices available from Morcher are black in color, imparted by a proprietary alteration to the PMMA that renders the material very brittle. Therefore, it is necessary to implant the devices gently in order to avoid excessive flexing or torquing, and to have spare devices available in case of breakage. Because a common site of breakage is at the incision, but the ring can be dialed into the anterior chamber and then placed gently into the capsular bag. The Ophtec device is inserted similarly and in conjunction with a capsular tension ring, but it is more flexible and less prone to breakage.

Both companies also produce customized devices that cover only a sector of absent iris. These implants are suitable for the management of coloboma or partial defects such as those seen in iris and ciliary body coloboma or in trauma.

CONCLUSION

Capsular instability and iris abnormalities may coexist and remain daunting obstacles to surgical success both during

and after cataract surgery. The introduction of capsular fixation devices, which are configured with iris diaphragm attachments, represents a significant step toward improving surgical outcomes. ■

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1. Rosenthal KJ. The capsular ring, indications and surgery. Focal Point Module: *American Academy of Ophthalmology*. 2002;20:7.
2. Rosenthal KJ, Osher RH, ed. *Video Journal of Viscosurgery*. Pharmacia. 2002-2003;10.
3. Reinhard T, Engelhardt S, Sundmacher R. Black diaphragm aniridia intraocular lens for congenital aniridia: Long-term follow-up. *J Cataract Refract Surg*. 2000;26:375-381.
4. Choyce P. *Intra-Ocular Lenses and Implants*. London: H.K. Lewis; 1964: 21.
5. Osher RH, Burke SE. Cataract surgery combined with implantation of an artificial iris. *J Cataract Refract Surg*. 1999;25:1540-1547.
6. Rosenthal KJ. Artificial iris implants: update. Paper presented at: The AAO Annual Meeting; November 17, 2003; Anaheim, CA.
7. Rosenthal KJ. Sutureless phacotrabeculectomy and insertion of an iris diaphragm ring in a patient with the Axenfeld-Rieger Syndrome: first reported case. *Video Journal of Cataract and Refractive Surgery*. 1997;13(2).