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# Outcomes of implantation of modified capsule tension rings with multiple black occluder paddles for eyes with congenital and acquired iris defects: Report 3

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**PURPOSE:** To evaluate the safety and efficacy of Morcher 50F iris diaphragm implantation to manage moderate to large defects of the human iris.

**SETTING:** Stein Eye Institute, UCLA, Los Angeles, California, USA.

**DESIGN:** Prospective nonrandomized interventional case series.

**METHODS:** The demographic, preoperative, and postoperative data of patients who had implantation of modified capsular tension rings and followed to 1 year were reviewed. Safety measures included loss of corrected distance visual acuity (CDVA), surgical complications, adverse events, and secondary surgical interventions. Efficacy measures included CDVA with glare, daytime and nighttime glare symptom scores, and subjective cosmesis scores.

**RESULTS:** The study comprised 12 patients. The median CDVA was 20/70 before surgery and 20/20 after surgery. There were no lost lines of CDVA and no intraoperative complications. The most common postoperative complication was posterior capsule opacification. Two adverse events were unrelated to the device. Four patients had secondary surgical interventions, the most common of which was laser capsulotomy. The median CDVA with glare improved from less than 20/400 before surgery to 20/50 after surgery. One patient worsened. The median subjective daytime glare symptom score improved from 9 to 3 on a 10-point scale ( $P = .001$ ). The median nighttime subjective glare symptom score improved from 8 to 2 ( $P = .001$ ). The subjective cosmetic appearance of the eye stayed the same or improved for all patients ( $P = .031$ ).

**CONCLUSION:** Iris diaphragm implantation was relatively safe and effective for reducing light and glare sensitivity in eyes with iris defects when combined with cataract extraction and intraocular lens implantation.

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Problems associated with iris defects include photophobia, glare sensitivity, decreased visual acuity, reduced visual quality, and impaired contrast sensitivity. In addition, affected patients often have psychological trauma from the cosmetic defect, especially those with light-blue or hazel irises. For decades, practitioners have managed iris defects with tinted glasses, colored or artificial pupil contact lenses, iris sutures, or corneal tattooing. Recently, however, iris prostheses

have become available in limited markets around the world.<sup>1–9</sup> They are manufactured by Morcher GmbH, Ophtec BV, and HumanOptics AG at this time.

Morcher iris diaphragms have been implanted for more 2 decades. They come in the following 2 basic forms: iris-reconstruction lenses, also known as aniridia implants,<sup>10–19</sup> and modified capsular tension rings (CTRs), also known as aniridia rings.<sup>20–22</sup> Iris reconstruction lenses are typically used when an eye is

aphakic; however, they can be implanted at the time of cataract surgery or during an intraocular lens (IOL) exchange if the zonular fibers are lax or damaged. Aniridia rings are typically implanted at the time of cataract surgery and are placed within the confines of the capsular bag. Morcher also has a limited number of rings that are intended for placement in the ciliary sulcus. Single case reports<sup>20,23</sup> and small series reports<sup>12-18,21,24-27</sup> evaluating the long-term safety and efficacy of Morcher iris prostheses have in general been favorable, although few clinical trials have been performed. Morcher artificial iris devices are no longer available in the United States through the U.S. Food and Drug Administration's (FDA) compassionate-use device exemption pathway. They are Conformité Européenne (CE) marked for implantation in Europe, however.

Two of the authors (K.M.M., M.D.O.) of this study obtained an investigational device exemption from the FDA in 2003 and began a clinical trial of several Morcher iris diaphragms. The trial was approved for 70 patients; the 70th patient was enrolled in late 2012. An interim report (report 1) of the first 13 patients was published in 2008.<sup>28</sup> A second report (report 2) detailed the outcomes of 16 patients who had implantation of the Morcher 96F modified CTR.<sup>29</sup>

This report (report 3) focuses specifically on the safety and efficacy of the Morcher 50F device, which is a 0.15 mm thick CTR with 8 segmental occluder paddles manufactured from clinical-quality ultraviolet light-filtering opaque poly(methyl methacrylate) (PMMA) (Figure 1). Two rings must be implanted in the capsular bag to create a 4.0 mm artificial pupil. The 50F CTR is intended for the correction of relatively large defects that cannot be managed by 1 or 2 Morcher 96F rings. Data for the 12 patients who had implantation of 2 50F rings and followed to 1 year are presented.

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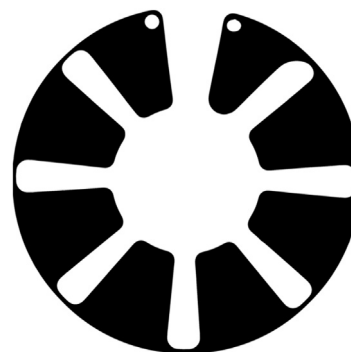
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**Figure 1.** The black modified CTR with 8 occluder paddles. Two devices must be implanted in the capsular bag to reconstruct an iris with a 4.0 mm pupil.

## PATIENTS AND METHODS

The University of California Los Angeles (UCLA) Institutional Review Board (IRB) approved this prospective single-site nonrandomized interventional trial in 2002 and has renewed it each year since. The FDA granted permission for device implantation in 20 patients initially and then expanded the study to include up to 70 patients. Information can be found at the U.S. National Institutes of Health Clinical Trials site<sup>A</sup> using the keyword *Morcher*. Devices the FDA has allowed for implantation include the 96F, 96S, 50D, 50F, and 67B. The current report focuses on the safety and efficacy of the 50F modified CTR for eyes with iris defects that cannot be managed satisfactorily by suture techniques or by implantation of a single 96F ring.

Patients were recruited from the first author's UCLA practice. All surgeries were performed between 2003 and 2013. Inclusion criteria included (1) age 18 years or older at the time of enrollment, (2) congenital or acquired iris defect with significant light and/or glare sensitivity, contrast loss, blurred vision, and/or multiplopia, (3) the presence of a visually significant cataract in the eye with the iris defect, and (4) willingness to comply with all study protocol requirements. Exclusion criteria included (1) asymptomatic individuals, (2) those with clear crystalline lenses, (3) iris defects small enough to be closed with sutures or covered by 1 96F ring, (4) symptoms that could be treated adequately with tinted glasses or contact lenses, (5) active ocular infection or inflammation, (6) advanced corneal decompensation, (7) allergy or intolerance to postoperative medications, and (8) pregnant or lactating women. All procedures were performed at the time of cataract extraction and IOL implantation. The 2 50F devices were implanted in the capsular bag, usually anterior to the IOL, to create an artificial pupil with a 4.0 mm diameter. Implantation of these rings in a torn capsular bag or the ciliary sulcus is contraindicated.

Patients were examined preoperatively and postoperatively at 1 day, 2 weeks, 3 months, 6 months, and 1 year. They were seen at other times as needed. Many patients continued to be followed beyond the study as regular patients. At each postoperative visit, patients were evaluated for the status of their iris implants and IOL.

Safety was ascertained by any decrease in corrected distance visual acuity (CDVA) as well as by surgical complications, adverse events, and secondary surgical interventions. The CDVA was measured using a Snellen eye chart.

Efficacy was evaluated by objective measurement of Snellen CDVA with glare and subjective assessment of daytime and nighttime glare symptoms. Each patient also subjectively evaluated the cosmetic appearance of his or her study eye.

The CDVA with glare was measured in a phoropter or trial lens frame with a transilluminator light held 6 to 12 inches in front and slightly to the side of the study eye in 4 sequential quadrants, recording the lowest visual acuity thus obtained. Daytime and nighttime glare symptoms and cosmesis were ascertained by a study coordinator and rated on a simple scale of 0 (no problem) to 10 (significant problem) preoperatively and 3 months postoperatively. At the 3-month examination, patients were reminded of their preoperative scores so that they could accurately report interval changes.

The CDVA and CDVA with glare were compared preoperatively to 1 year postoperatively. Because a small number of patients were enrolled into the 50F arm of the study and many of the acuity values were not numeric, median acuity values were used to assess group changes in visual acuity. Glare symptoms and cosmesis scores were compared preoperatively to 3 months postoperatively. Preoperative to postoperative statistical comparisons were performed using the Wilcoxon signed-rank test.

## RESULTS

The study comprised 12 patients (9 men, 3 women) ranging in age from 32 to 83 years. Table 1 shows demographic data, the etiology of the iris defect, the preoperative condition of the study eye, and the IOL information for each patient. Iris defects varied in circumferential extent from 90 to 360 degrees, and most were caused by ocular trauma. Six patients had ocular comorbidities that were potentially vision limiting.

### Case Reports

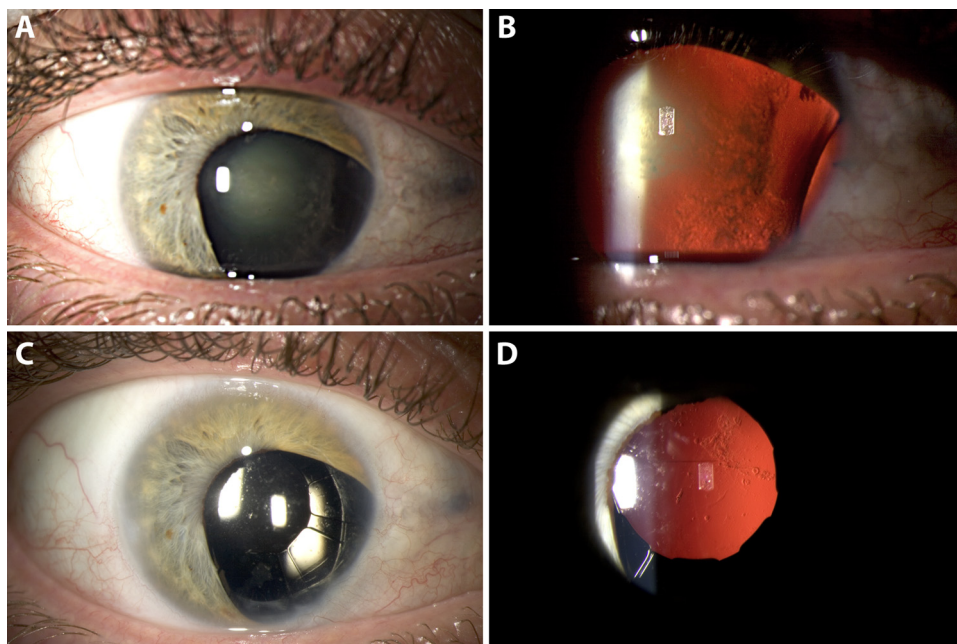
The following detailed descriptions of 3 study patients show the typical preoperative pathologies and surgical outcomes after iris diaphragm implantation.

**Case 1** Patient 8 was a 48-year-old man at the time of iris diaphragm implantation (CTR) in the right eye (Figure 2). He fell against a sprinkler in his yard at 7 years of age, rupturing his globe and causing iris

**Table 1.** Demographic and other information.

Overall Study #	Rings (n)	Age (Y)	Race/Ethnicity	Sex/Eye	Etiology of Iris Defect	Lens Status	Ocular Comorbidities	Intraocular Lens	
								Model	Power (D)
7	1	56	White	M/R	Surgical trauma	Cataract	Status post RD repair, OHT, neurotrophic cornea, exotropia	Alcon MA60AC	+13.0
8	2	48	White	M/R	Penetrating trauma	Cataract	None	Alcon SA60AT	+25.0
11	3	32	Persian	M/R	Blunt trauma	Cataract	Commotio retinae, central scotoma, blepharoptosis	Alcon SN60WF	+18.0
12	4	83	Hispanic	M/R	Blunt trauma with rupture	Cataract	Posttraumatic filtration bleb	Alcon SN60WF	+19.5
18	5	58	White	M/R	Surgical trauma	Cataract	Blepharoptosis	Alcon SN60WF	+19.5
19	6	48	White	F/R	Congenital defect	Cataract	Limbal stem cell deficiency, corneal vascularization and haze, glaucoma, sensory nystagmus, exotropia	Alcon SN60WF	+28.0
31	7	42	White	M/R	Penetrating trauma	Cataract	Corneal scar	Alcon SN60WF	+11.5
35	8	61	White	F/L	Penetrating trauma	Cataract	Corneal scar, blepharoptosis	Alcon SN60WF	+18.5
37	9	61	White	M/R	Penetrating trauma	Cataract	Corneal scar, posterior synechiae, blepharoptosis	Alcon SN60WF	+15.0
44	10	79	White	M/L	Blunt trauma	Cataract	None	Alcon SN60WF	+18.5
47	11	72	White	F/L	Surgical trauma	Cataract	Post LASIK, post trabeculectomy with large iridectomy, posterior synechiae	Alcon SN60WF	
48	12	52	White	M/R	Congenital defect	Cataract	OHT	Alcon SN60WF	+21.0

LASIK = laser in situ keratomileusis; OHT = ocular hypertension; RD = retinal detachment

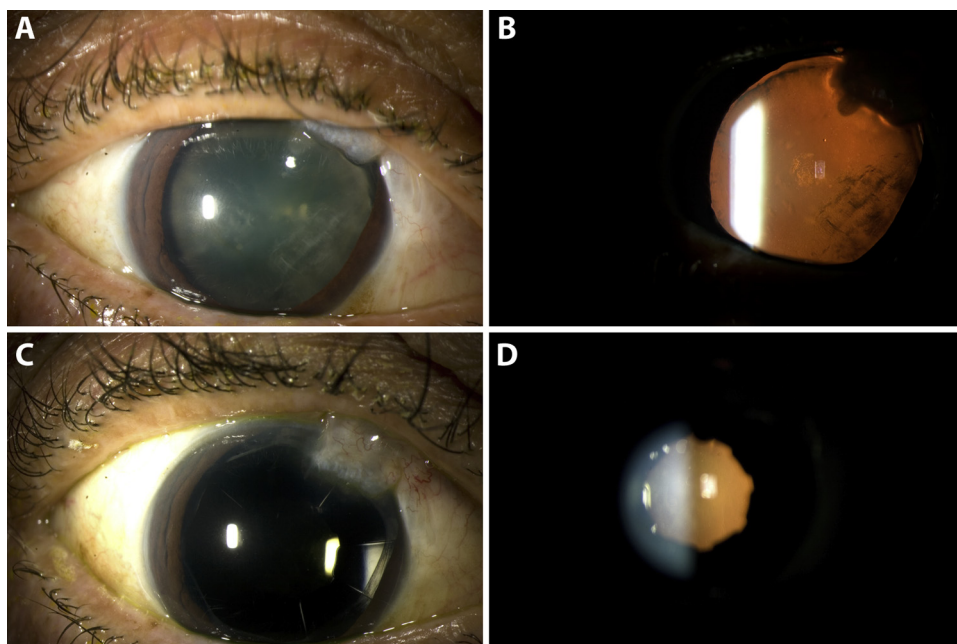


**Figure 2.** This 48-year-old man had repair of an open injury involving his right eye at 7 years of age. *A* and *B*: The preoperative appearance of his eye in direct and retroillumination. *C* and *D*: The appearance of the same eye after cataract surgery and the implantation of 2 modified CTRs.

prolapse. The prolapsed iris was excised at the time of the primary injury repair. Although the crystalline lens was retained, the patient developed a posttraumatic cataract several decades later. At the time of presentation to the study investigators, the CDVA in the right eye was  $20/60^{-2}$  and CDVA with glare was worse than  $20/300$  with a mixed nuclear, cortical, and posterior subcapsular cataract. Two CTRs were implanted because of the size of the defect. Three months after cataract surgery, the CDVA and the CDVA with glare were  $20/15$ . One year after surgery, the CDVA remained

$20/15$  with and without glare. He had no postoperative complications or secondary surgical interventions.

**Case 2** Patient 12 was an 83-year-old man at the time of CTR implantation (**Figure 3**). He sustained blunt trauma and a superonasal globe rupture in the right eye 30 years earlier from a metal crowbar used to change a tire. At the time of presentation to the study investigators, he had a superonasal bleb from the initial repair and a permanently dilated pupil with iris loss superonasally. The CDVA was  $20/25^{+1}$  in



**Figure 3.** This 83-year-old man suffered a blunt open-globe injury to his right eye 30 years previously. *A* and *B*: The appearance of the eye in direct and retroillumination before surgery. *C* and *D*: The appearance of the same eye after cataract extraction and the implantation of 2 modified CTRs.

the right eye; the CDVA with glare was worse than 20/400 with a mixed nuclear and cortical cataract. Two CTRs were implanted because of the size of the defect. Three months after cataract surgery, the CDVA was 20/15<sup>-2</sup> and the CDVA with glare was 20/25. One year after surgery, the CDVA was 20/15<sup>-2</sup>. He had no postoperative complications or secondary surgical interventions.

**Case 3** Patient 48 was a 52-year-old man at the time of CTR implantation (Figure 4). He was born with incomplete aniridia manifesting as polycoria in both eyes. He had a visually significant 3+ nuclear cataract in the right eye, reducing the CDVA to 20/40<sup>+2</sup> and the CDVA with glare to worse than 20/400. Two CTRs were implanted because of the sizes of the defects. Three months after surgery, the CDVA was 20/15<sup>-1</sup> and the CDVA with glare was 20/20. At the 12-month postoperative examination, the CDVA was 20/15. He had no postoperative complications or secondary surgical interventions.

### Safety

Table 2 shows the safety outcomes. There was improvement in the median CDVA from 20/70 before surgery to 20/20 after surgery. No patient lost visual acuity. In addition, there were no intraoperative complications. The most common postoperative complication was posterior capsule opacification (PCO). Four patients experienced secondary surgical interventions, of which the most common was laser capsulotomy. Two adverse events were reported to the IRB. Patient 18 had a pars plana vitrectomy for removal of retained

lens material that escaped posteriorly through a break in the zonular fibers. Patient 19 had congenital aniridia and experienced corneal decompensation and glaucoma from underlying disease. She had keratoprosthesis surgery and Ahmed glaucoma seton implantation with satisfactory results.

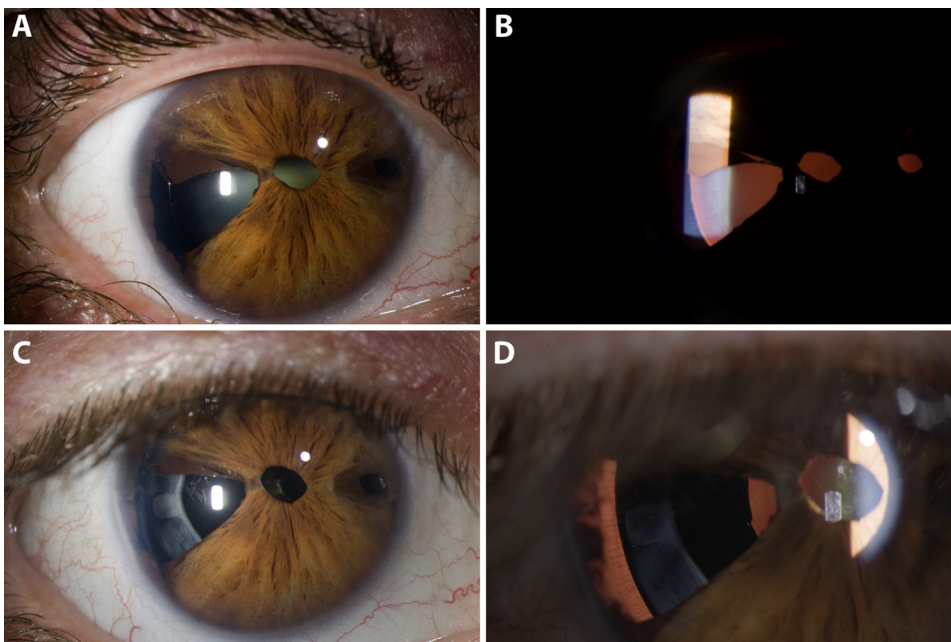
### Efficacy

Table 3 shows efficacy measures. There was an improvement in the median CDVA with glare from worse than 20/400 before surgery to 20/50 after surgery. The median subjective daytime glare symptom score improved from 9 before surgery to 3 after surgery ( $P = .001$ ). The median nighttime subjective glare symptom score improved from 8 before surgery to 2 after surgery ( $P = .001$ ). The results were inconsistent for 2 patients. Patient 7 had an improvement in CDVA with glare and the nighttime glare symptom score yet a 1-point worsening in the daytime symptom score. Patient 18 had worsening of CDVA with glare from counting fingers (CF) at 5 feet to hand motion (HM) yet an improvement in daytime and nighttime glare symptom scores.

Six patients reported an improvement in ocular cosmesis, and 6 patients reported no change ( $P = .031$ ). None reported a worsening of appearance.

### DISCUSSION

The Morcher 50F iris diaphragm is a modified CTR with 8 segmental occluder paddles made from black PMMA. Two devices must be implanted in the capsular bag to relieve the symptoms of light and



**Figure 4.** This 52-year-old man was born with incomplete aniridia manifesting as polycoria in both eyes. A and B: The appearance of the right eye in direct and retroillumination before surgery. C and D: The appearance of the same eye after cataract extraction and the implantation of 2 modified CTRs.

**Table 2.** Safety outcomes of CTR implantation.

Overall Study #	CDVA		Complications		Adverse Events	Secondary Surgical Interventions
	Preop	1 Y Postop	Intraop	Postop		
7	HM	20/125	None	PCO	N	Laser capsulotomy, silicone oil removal
8	20/60 <sup>-2</sup>	20/15 <sup>-1</sup>	None	None	N	None
11	20/160	20/100	None	PCO	N	Laser capsulotomy
12	20/25 <sup>+1</sup>	20/15 <sup>-2</sup>	None	None	N	None
18	CF 4 ft	CF 6 ft*	None	Retained lens fragment, PCO	Y	PPV, laser capsulotomy
19	CF 3 ft	20/200 <sup>†</sup>	None	Corneal decompensation, increased IOP	Y	Keratoprosthesis surgery, Ahmed glaucoma tube shunt
31	20/70	20/15 <sup>-1</sup>	None	None	N	None
35	20/60	20/20 <sup>+2</sup>	None	None	N	None
37	20/60	20/30 <sup>-1</sup>	None	None	N	None
44	20/400	20/15	None	None	N	None
47	20/50	20/20	None	None	N	None
48	20/40 <sup>+2</sup>	20/15	None	None	N	None

CDVA = corrected distance visual acuity; CF = counting fingers; HM = hand motion; IOP = intraocular pressure; PCO = posterior capsule opacification; PPV = pars plana vitrectomy  
 \*CDVA improved to 20/100 after a laser capsulotomy  
 †CDVA was achieved by keratoprosthesis surgery

glare sensitivity caused by moderate to large iris defects. The paddles of 1 ring must be aligned with the gaps on the other ring to create a complete black artificial iris that has no slits. Although used extensively in Europe and Asia, the FDA has not yet approved Morcher iris diaphragms for implantation in the U.S.

The first author implanted 50D rings early in the study and found it difficult to align the paddles and gaps to eliminate slits through which light could enter. Even though the slits could be eliminated in the operating room after considerable effort in 1 patient, the rings rotated by the next day, necessitating a reoperation to reposition the rings. This prompted him to

**Table 3.** Efficacy outcomes of Morcher 50F modified capsule tension ring implantation.

Overall Study #	Snellen CDVA with Glare		Daytime Glare Score*		Nighttime Glare Score*		Cosmesis Score <sup>†</sup>	
	Preop	1 Y Postop	Preop	3 Mo Postop	Preop	3 Mo Postop	Preop	3 Mo Postop
8	<20/300	<20/15	8	0	7	2	8	10
11	HM	20/125	10	0	10	1	2	10
12	<20/400	20/25	9	2	6	2	5	5
18	CF 5'	HM	9	6	8	2	5	9
19	CF 2'	20/250 <sup>‡</sup>	10	8	8	6	2	5
31	<20/400	20/20 <sup>-2</sup>	10	0	10	0	4	4
35	<20/400	20/30	9	3	9	3	0	0
37	CF 4'	CF 10'	10	3	10	3	8	8
44	<20/400	20/25	7	4	5	4	5	5
47	20/150	20/25 <sup>+2</sup>	8	2	0	0	8	8
48	<20/400	20/50	8	2	10	9	5	6

CDVA = corrected distance visual acuity; CF = counting fingers; HM = hand motion  
 \*Scale 0 (no glare) to 10 (significant glare) on patient-completed questionnaire  
 †Scale 0 (poor cosmesis) to 10 (excellent cosmesis)  
 ‡Measured after keratoprosthesis surgery

consult the manufacturer to modify the 50D and make the occluder paddles wider and the devices more tolerant of misalignment. This is the genesis of the 50F ring. Although a few slits were noted between occluder paddles in the current series, they were uncommon.

The primary safety measure in this study was the change in CDVA. No patient lost visual acuity. All patients had an improvement in CDVA, as would be expected from cataract surgery. Secondary safety measures included surgical complications, adverse events, and secondary surgical interventions. The adverse events in 2 patients and the secondary surgical interventions in 4 patients were related to ocular comorbidities or the natural history of cataract surgery and not to the 50F devices or the surgery to implant them.

The primary efficacy measure in this study was the change in CDVA with glare. All but 1 patient had an improvement. The patient who lost CDVA with glare dropped from CF at 5 feet to HM, a marginal change. This same patient noted a marked improvement in subjective glare scores, making the CDVA with glare loss inconsistent. Secondary efficacy measures included the subjective assessment of daytime and nighttime glare symptoms. Daytime glare symptom scores improved for 11 of 12 patients. Nighttime glare symptom scores improved for all 12 patients.

Because a cataract was removed at the time of the CTR device implantation, we cannot attribute all the reduction in light and glare sensitivity to the artificial iris devices. The only way we could have determined their relative contribution would have been to perform cataract extraction with IOL implantation, make postoperative glare measurements after full recovery, then reoperate to implant the iris diaphragm devices. Ozturk et al.<sup>30</sup> reopened the capsular bag in 2 of their cases to implant Morcher iris diaphragm devices. It would have been neither practical nor ethical to do so in our study. These devices do an excellent job keeping incoming light from hitting the edge of an IOL. They fall short, however, in that they let light enter the eye peripheral to the capsule in any meridian where the iris is completely absent. It helps to have a small amount of residual peripheral iris for 360 degrees for best results.

The IOL was implanted behind the 50F rings in 11 of 12 patients. None of these patients experienced positive or negative dysphotopsias. A postoperative IOL exchange was considered likely for 1 patient; thus, his IOL was implanted in the sulcus and the rings were implanted in the capsular bag. He noted a negative temporal dysphotopsia from the square-edged IOL immediately after surgery. As a result of this single occurrence, we recommend that the IOL be placed behind the aniridia rings when possible.

There are 2 orders in which an IOL can be implanted. We prefer to implant the IOL before the CTRs. Implantation of the first ring once the IOL is in the bag is relatively easy. The capsular bag must be fully inflated with an ophthalmic viscosurgical device (OVD) to facilitate dialing it. Implantation of the second ring is difficult because the capsulorhexis is hard to visualize after the first ring has been implanted. It helps to stain the anterior capsule with trypan blue before cataract extraction to facilitate visualization of the capsule. It also helps to inject an additional high-viscosity OVD over the first ring and use high magnification. It is easy to misdirect the second ring into the ciliary sulcus. The alternative order, one that we do not advocate, is to inject the foldable IOL through the 4.0 mm artificial pupil after the Morcher CTRs have been implanted. Done this way, it is much more difficult to fully deploy and center the IOL. When operating on eyes with congenital aniridia, one might consider staining the capsule with indocyanine green instead of trypan blue. Capsules in these eyes tend to be thin and friable, and indocyanine green does not reduce the elasticity of the capsule the way trypan blue does.<sup>31</sup>

Implantation of the 50F device requires a 4.0 mm incision. We made our incisions in the clear cornea and closed them with a single 10-0 nylon suture that was removed 1 to 2 weeks postoperatively. Rigid iris-reconstruction lenses from Morcher, such as the 67B, require a larger 10.0 to 11.0 mm incision for implantation.

The greatest fault of 50F device implantation, in our opinion, is that it does not improve the cosmetic appearance of eyes with iris defects. Because the enlarged pupil or iris defect is black preoperatively, the net effect of surgery is no change in cosmetic appearance. It was interesting to find that one half of the study patients thought their eye looked better after surgery. In our opinion, this was wishful thinking or an attempt by grateful study patients to make the surgeon feel better about his results. A device with color and texture to match a patient's native iris would be cosmetically advantageous but harder to produce given the wide variation in these attributes in clinical practice.

Iris defects seldom occur in isolation. Most of the time they travel with comorbidities related to underlying etiologies, whether congenital or acquired. To make matters more complex, patients may have had 1 or several eye surgeries by the time they present for care. Congenital iris defects are often associated with limbal stem cell deficiency, corneal pannus, epitheliopathy, deep stromal vessels, dry eye, secondary glaucoma, ciliary body and choroidal colobomas, visual field defects, foveal hypoplasia, reduced visual acuity,



and nystagmus. Acquired iris defects might be associated with corneal and scleral scars, endothelial failure, previous corneal transplantation, secondary glaucoma, capsule rupture, zonular dehiscence, traumatic cataract, aphakia, retinal detachment, epiretinal membranes, proliferative vitreoretinopathy, macular holes, macular scars, traumatic optic neuropathy, visual field defects, reduced visual potential, and strabismus. Cataract surgery in these settings is usually complex and subject to a greater likelihood of operative complications and secondary surgical interventions.

Alternatives to the 50F include other aniridia rings manufactured by Morcher, artificial iris segments and aniridia lens implants manufactured by Ophtec,<sup>32</sup> and a custom-made artificial iris made by HumanOptics.<sup>33–35</sup> Ophtec devices are manufactured in blue, green, and brown; however, they are flat and without texture. HumanOptics devices are custom painted to match the fellow normal eye, if there is one, and they have texture. All these devices are CE marked, although none is currently FDA approved. The HumanOptics artificial iris was in a U.S. phase 3 FDA clinical trial<sup>B</sup> at the time of this writing.

In summary, Morcher 50F device implantation, when combined with cataract extraction and IOL implantation, appears to be relatively safe and effective at relieving symptoms of light and glare sensitivity caused by moderate to large defects of the human iris.

#### WHAT WAS KNOWN

- Management of congenital and traumatic iris defects with iris diaphragms and iris reconstruction lenses has been reported extensively throughout Europe and Asia with successful results regarding safety and efficacy.
- There have been few studies evaluating these devices in the U.S. as they are not FDA approved and are no longer available through compassionate-use exemption.

#### WHAT THIS PAPER ADDS

- The iris diaphragm evaluated was implanted in the capsular bag at the time of cataract extraction and IOL implantation and safely and effectively improved the light and glare sensitivity of patients with moderate to large iris defects.

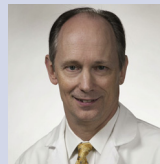
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