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Authors

Date, Rishabh C
Olson, Michael D
Shah, Manali
et al.

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Outcomes of a modified capsular tension ring with a single black occluder paddle for eyes with congenital and acquired iris defects: Report 2

Rishabh C. Date, MD, Michael D. Olson, OD, PhD, Manali Shah, MS, Samuel Masket, MD, Kevin M. Miller, MD

PURPOSE: To evaluate the safety and efficacy of Morcher 96F iris diaphragm implantation to manage small defects of the human iris.

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

DESIGN: Prospective nonrandomized interventional case series.

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

RESULTS: Sixteen patients had CTR implantation. There was a statistically significant improvement in the median CDVA of 2.5 Snellen lines ($P < .01$), with 4 patients having minor decreases in CDVA for reasons unrelated to the device. There were no intraoperative complications. Three adverse events were reported: 1 ocular hypertension, 1 postoperative retinal detachment, and 1 25-degree rotation of the CTR. There were 4 secondary surgical interventions. There was a statistically significant improvement in the median CDVA with glare of 8 Snellen lines ($P < .01$), but 2 patients had a decrease in CDVA with glare for reasons unrelated to the device. There were statistically significant improvements in the median daytime and nighttime glare symptom scores of 5 points and 4 points, respectively (both $P < .01$). There was no change in cosmesis for most patients.

CONCLUSION: Iris diaphragm CTR implantation was relatively safe and effective at reducing light and glare sensitivity in eyes with small iris defects.

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Defects involving the partial or total absence of the human iris can produce debilitating light and glare sensitivity for affected patients and associated significant quality-of-life implications. The iris functions as a diaphragm or aperture to regulate the amount of light entering the eye. It also aids in fine-tuning depth of focus and decreasing spherical and other aberrations arising from the peripheral cornea and lens. Symptoms associated with iris defects include photophobia,

glare, decreased visual acuity, reduced visual quality, and poor contrast sensitivity. There are also cosmetic concerns, especially in individuals with light-blue irises.

Aniridia, which is the partial or complete absence of iris tissue, is occasionally present at birth. In our clinical experience, however, it is more often one of the sequels of ocular injury. When caused by trauma, there is often associated anterior segment disruption and

damage to adjacent structures, thus compounding the impact on vision. Iris defects can also occur without the loss of iris stromal tissue that is characteristic of aniridia. Examples of nonaniridic iris injury include traumatic mydriasis, traumatic iridotomy, and iris pigment epithelial loss.

For decades, iris defects were managed with dark sunglasses, colored or artificial pupil contact lenses, iris suturing, or corneal tattooing. More recently, however, iris prostheses have gained popularity. A 2-piece black iris-reconstruction intraocular lens (IOL) was first used in Germany in 1994 by Sundmacher et al.^{1,2} This device contained a clear poly(methyl methacrylate) (PMMA) IOL with a black PMMA annulus. A modified PMMA capsular tension ring (CTR) was subsequently developed by Volker Rasch, MD, and Kenneth J. Rosenthal, MD, and manufactured by Morcher GmbH. This device has a single black occluder extending radially inward from the ring. This CTR can be inserted through a smaller incision than an iris-reconstruction IOL and placed permanently within the capsular bag.

Morcher iris diaphragms have been implanted in many patients to date.³⁻¹⁰ Modifications of the original iris diaphragm IOL include segmental prosthetic irises such as the Morcher 96F used in this study (Figure 1), which is a modified CTR with a single black occluder segment extending 90 degrees around the ring.^{3,7,11,12} The primary advantage of this modification is that it allows for implantation through a small incision when the capsular bag is intact. Long-term follow-up evaluating the safety and efficacy of these iris prostheses generally has been favorable,^{3,5,8,12-14} although few clinical trials have been performed recently in the United States. Morcher artificial iris diaphragms are no longer available under the compassionate-use exemption through the U.S. Food and Drug Administration (FDA).

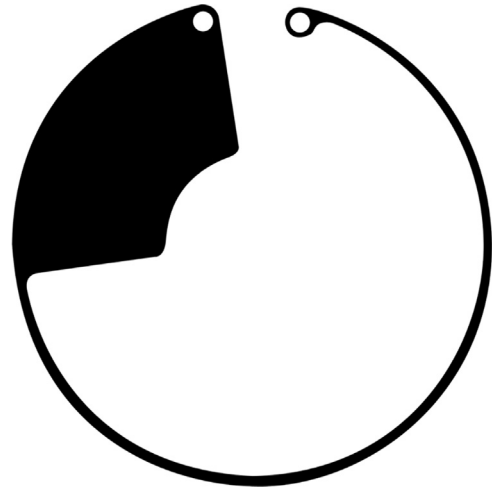


Figure 1. The black modified CTR with a single 90-degree occluder paddle used in this study.

Two of the authors (K.M.M., M.D.O.) obtained an investigational device exemption (IDE) from the FDA in 2003 and began a clinical trial of several Morcher iris diaphragms. K.M.M. is currently the only surgeon in the United States who is authorized to implant these devices. The trial for use of this device was approved for 70 patients; the 70th patient was enrolled in late 2012. An interim report (report 1³) of the first 13 patients was published in 2008. The current report (report 2) focuses specifically on the safety and efficacy of the Morcher 96F CTR, which is a 0.15 mm thick CTR with a 90-degree segmental occluder manufactured from clinical-quality, ultraviolet light-filtering, opaque PMMA. It is intended for the correction of small sectoral iris defects, although multiple rings can be implanted to cover larger defects, and is designed for implantation in the capsular bag. Data for the 16 patients who had implantation of the 96F model and followed to 1 year are presented.

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 every year since. The trial was originally approved by the FDA for implantation of 20 patients with various Morcher devices but was expanded after the first 20 were implanted to include 70 patients. Devices implanted in the larger study have included the 96F, 96S, 50D, 50F, and 67B. This study evaluated the safety and efficacy of the 96F modified CTR in eyes with small iris defects that could not be managed satisfactorily by suture techniques because of their size or geometry or because of patient preference for an unsutured approach.

All patients were recruited from the author's (K.M.M.) UCLA practice or referred by other ophthalmologists and optometrists. The same surgeon performed all implantations between 2003 and 2013. Inclusion criteria included

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From the Jules Stein Eye Institute and the Department of Ophthalmology, David Geffen School of Medicine at UCLA, Los Angeles, California, USA.

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Corresponding author: Kevin M. Miller, MD, Stein Eye Institute, Edie and Lew Wasserman Building, 300 Stein Plaza, UCLA, Los Angeles, California 90095-7000, USA. E-mail: miller@jsei.ucla.edu.

age 18 years or older at the time of enrollment, congenital or acquired iris defect with significant light and/or glare sensitivity, contrast loss, blurred vision, and/or multiplopia, aphakia, pseudophakia or the presence of a visually significant cataract in the eye with the iris defect, and willingness to comply with all study protocol requirements. Exclusion criteria included asymptomatic individuals, clear crystalline lenses, iris defects small enough to be closed with sutures, symptoms that could be treated adequately with modified glasses or contact lenses, active ocular infection or inflammation, advanced corneal decompensation, or allergy or intolerance to postoperative medications.

One or 2 Morcher 96F devices were implanted depending on the size of the iris defect. All procedures were performed with simultaneous or antecedent IOL placement in the capsular bag. The CTRs were implanted in the capsular bag and anterior to the IOL in every case. Implantation is contraindicated in the ciliary sulcus space or within a torn capsular bag.

Patients were examined preoperatively and postoperatively at 1 day, 2 weeks, 3 and 6 months, and 1 year. They were seen at other times as needed. All patients continue to be followed beyond the study as regular patients. At each postoperative visit, patients were evaluated for the status of their iris implant and IOL. Safety was evaluated by any decrease in corrected distance visual acuity (CDVA) as well as by adverse events, surgical complications, and secondary surgical interventions. The CDVA was measured on a Snellen chart. Efficacy was evaluated by objective measurement of CDVA with glare and by subjective assessment of daytime and nighttime glare symptoms. The cosmetic appearance of the eye was assessed subjectively. 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 scored using a simple rating of 0 (no problem) to 10 (significant problem) preoperatively and 3 months postoperatively. A study coordinator obtained these scores. At the 3-month examination, patients were reminded of their preoperative scores.

The CDVA and CDVA with glare were compared preoperatively with the values 1 year postoperatively with Snellen acuities converted to logMAR values for analysis. Visual acuity of hand motions was converted to 20/20000, and visual acuity of counting fingers (CF) was converted to 20/400 for the purpose of this study as described by Holladay.¹⁵ Glare symptoms and cosmesis scores were compared preoperatively to 3 months postoperatively. All data analyses were performed using the Wilcoxon signed-rank test.

RESULTS

Overall, 16 eyes of 16 patients in the larger Morcher trial were managed with 96F iris diaphragm implantation. Patient demographics, preoperative data, and device information are shown in Table 1. The patients consisted of 10 men and 6 women ranging in age from 39 to 76 years. Four patients had previous implantation of posterior chamber IOLs and the other 12 had visually significant cataracts. Patient 64, who was pseudophakic, had a significant manifest

refractive error at the time of enrollment. He had IOL exchange and implantation of the iris diaphragm device. Ocular trauma was the most common cause of the iris defects in this substudy, with 8 patients suffering from surgical trauma and 6 from penetrating or blunt trauma. Only 2 had congenital iris defects. Both of the congenital patients were afflicted with colobomas of the iris and choroid. The number of devices implanted in each patient depended primarily on the size of the iris defect. Three patients received 2 devices; the rest received 1 device each, for a total of 19 devices.

Case Examples

Three study patients are described in some detail because they demonstrate typical preoperative pathologies and surgical outcomes after iris diaphragm implantation.

Patient 22 was a 61-year-old woman at the time of the modified CTR implantation (Figure 2). She had an iridocyclectomy for an iris spindle-cell melanoma of her right eye. She developed chronic cystoid macular edema (CME) postoperatively and a visually significant cataract. Her CDVA and CDVA with glare before cataract surgery were 20/50⁻² and CF at 10 feet, respectively. Two modified CTRs were implanted because of the size of her iris defect. Three months after surgery, her CDVA and CDVA with glare were 20/20⁻² and 20/40, respectively. About a year after cataract surgery, she had a laser posterior capsulotomy and blepharoptosis repair. Over the next several years, she received injections of bevacizumab and triamcinolone to treat chronic CME. Four years after cataract surgery, she had Ahmed glaucoma tube shunt implantation to treat corticosteroid-induced ocular hypertension.

Patient 10 was a 64-year-old man at the time of CTR implantation (Figure 3). He had scleral buckling, pars plana vitrectomy, and intraocular gas injection for treatment of a macula-on retinal detachment in his right eye. Immediately after surgery, he was found to have an irregularly enlarged pupil. He subsequently developed a visually significant cataract and had cataract surgery with the implantation of a single CTR. His CDVA and CDVA with glare before cataract surgery were 20/400 and 20/125, respectively. Three months after surgery, his CDVA and CDVA with glare were 20/40⁻² and 20/125, and he had a visually significant opacity of the posterior capsule. One year after cataract surgery and 3 months after a laser capsulotomy, his CDVA and CDVA with glare were 20/20⁺² and 20/30, respectively.

Patient 62 was a 43-year-old woman at the time of the modified CTR implantation (Figure 4). She had been highly hyperopic all of her life and had multiple

Table 1. Demographic and other information.

Overall Study No.	CTR (n)	Age (Y)	Race	Sex	Eye	Etiology of Iris Defect	Lens Status	Ocular Comorbidities	Intraocular Lens Model	No. of Implants
5	1	76	White	M	L	Penetrating trauma	Cataract	None	Staar AQ2010V	1
6	2	59	Indian	M	L	Penetrating trauma	Cataract	Peripheral corneal scar, status after corneal laceration repair, anterior synechiae	Alcon SN60AT	1
10	3	64	White	M	R	Surgical trauma	Cataract	Status after retinal detachment repair, dry eye	Alcon SN60AT	1
13	4	71	White	F	L	Surgical trauma	Cataract	Narrow-angle glaucoma	Alcon SN60WF	1
22	5	61	White	F	R	Surgical trauma	Cataract	None	Alcon SN60WF	2
41	6	48	White	F	R	Penetrating trauma	Cataract	None	Alcon SN6AT5	1
42	7	73	White	F	R	Congenital defect	Cataract	None	Alcon SN6AT5	1
49	8	71	White	F	R	Surgical trauma	PC IOL	Corneal edema	Previously implanted	1
50	9	39	White	M	L	Congenital defect	Cataract	None	Alcon SN60WF	1
52	10	68	White	M	L	Surgical trauma	Cataract	Fuchs endothelial corneal dystrophy, status after corneal transplantation	Alcon SN60WF	1
56	11	43	White	M	R	Blunt trauma	Cataract	Zonular dehiscence in the area of the iris defect	Alcon SN60WF	1
58	12	65	Other	M	R	Penetrating trauma	Cataract	Anterior synechiae	Alcon SN60WF	2
62	13	43	White	F	R	Surgical trauma	PC IOL	Narrow-angle configuration, dry eye	Previously implanted	1
64	14	59	White	M	R	Surgical trauma	PC IOL	None	Alcon SN60WF (IOL exchange)	1
65	15	50	White	M	L	Surgical trauma	PC IOL	Status after macular hole closure	Previously implanted	1
66	16	42	Middle Eastern	M	L	Penetrating trauma	Cataract	Absent zonules in superonasal quadrant	Alcon SN60WF	2

CTR = capsular tension ring; IOL = intraocular lens; PC IOL = posterior chamber intraocular lens

strabismus surgeries as a child. She had a laser iridotomy in both eyes for narrow angle configuration. Cataract surgery in the right eye was complicated by iris prolapse through the phacoemulsification incision, loss of iris pigment epithelium, and postoperative photophobia and glare sensitivity from iris transillumination. Her CDVA and CDVA with glare were 20/15 and 20/30⁻², respectively, after cataract surgery. She had subsequent surgery to reopen the capsular bag and implant an iris diaphragm. The occluder paddle was aligned with the iris pigment epithelial defect, eliminating the transillumination. A small amount of glare sensitivity remained that could

be attributed to posterior capsule opacification (PCO). Her CDVA and CDVA with glare after surgery were 20/15⁻² and 20/15, respectively. A laser posterior capsulotomy was performed 14 months after CTR implantation, resulting in elimination of glare sensitivity.

Several patients had ocular comorbidities that had the potential to negatively affect the final CDVA or predispose to postoperative complications. Three patients had corneal defects, including 1 with a corneal scar after a repaired corneal laceration, 1 with corneal edema, and 1 with a history of Fuchs corneal endothelial dystrophy treated by corneal transplantation. Two patients had anterior synechiae, 1 had narrow-angle

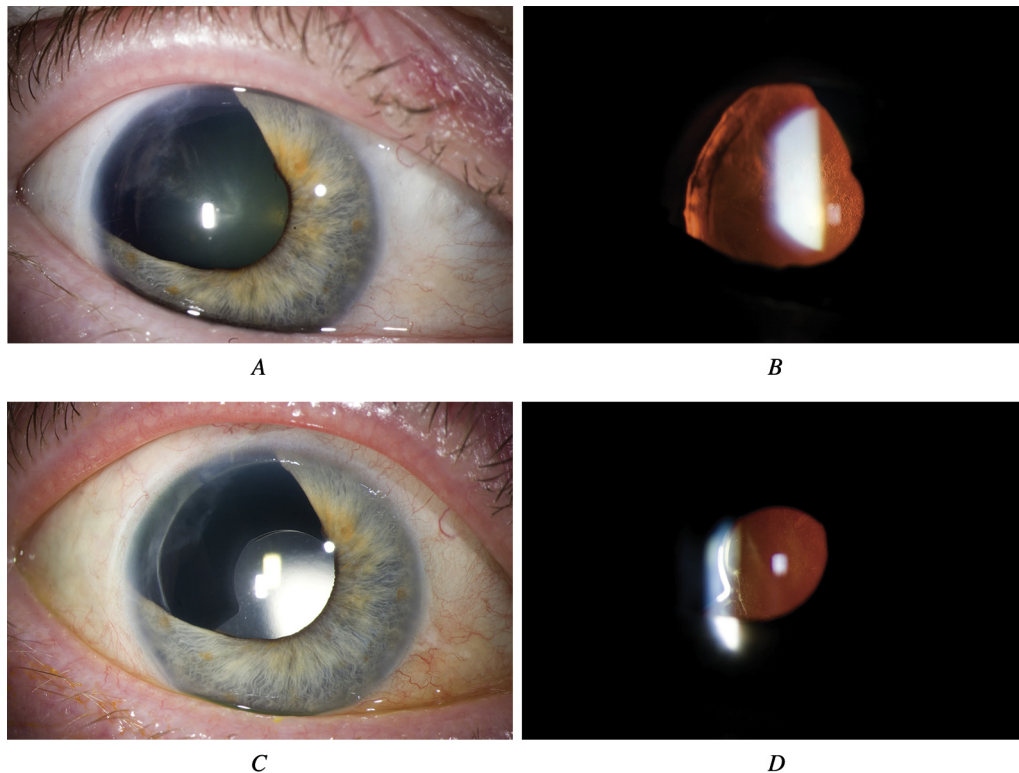


Figure 2. This 61-year-old woman had an iridocyclectomy for an iris spindle-cell melanoma of her right eye. *A* and *B* show the preoperative appearance of the eye in direct and retroillumination. *C* and *D* show the appearance of the eye after cataract surgery and implantation of 2 modified CTRs.

glaucoma, 1 had a history of retinal detachment and dry eye, and 1 had zonular dehiscence over the area of the iris defect.

Safety Outcomes

Safety outcomes for the modified CTR are shown in Table 2. Two patients (12.5%) lost CDVA by 1 year after surgery. The first (patient 49) had a 1 Snellen line decrease in CDVA from 20/20⁻² to 20/25⁻². She had preoperative corneal edema and CME from prior trauma and cataract surgery and was ultimately found to have changes consistent with age-related macular degeneration (AMD) at an examination 14 months after surgery. Her 1-line loss of CDVA was not considered attributable to the modified CTR. The second (patient 65) experienced a 2 Snellen line decrease from 20/15⁻² to 20/25 that was attributable to PCO. He experienced an improvement in CDVA to 20/15 and a reduction in glare symptoms after laser posterior capsulotomy. Two other patients (patients 62 and 64) had insignificant 1- to 2-letter decreases but also had PCO. Their CDVA improved after neodymium:YAG (Nd:YAG) laser capsulotomy. In all, there was only a 1-line loss of CDVA in 1 patient, which was not

attributable to the modified CTR implantation. On the other hand, there was a statistically significant improvement in the median CDVA of 2.5 Snellen lines in all patients ($P < .01$), including those who were already pseudophakic.

There were no intraoperative complications. Six patients had postoperative complications, 2 of which were device-related. The most common postoperative complication was elevated intraocular pressure (IOP), which occurred in 3 patients. Two of the patients were taking corticosteroids for CME before the start of the study. One of the patients (patient 22) was successfully treated with a glaucoma medication, and the other patient (patient 56) was managed by a medication change for his CME. An adverse event report was filed with the IRB in the latter case. The third patient (patient 58) with elevated IOP had a history of anterior synechiae. The modified CTR rotated after implantation in 2 patients. Patient 50 had a 15-degree rotation but did not complain of decreased visual acuity or glare symptoms and his iris defect was still well covered, so no additional surgery was performed. The other patient (patient 41) had a 25-degree rotation and was taken back to the operating room 1 week postoperatively for repositioning of the occluder paddle to

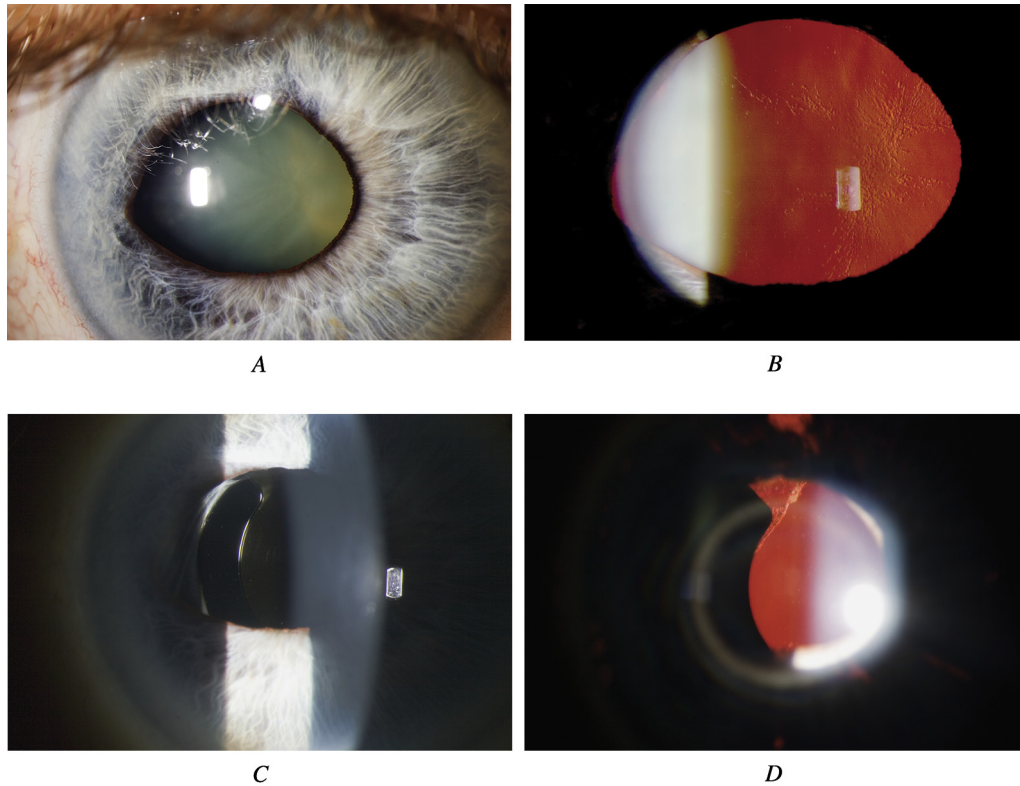


Figure 3. This 64-year-old man had scleral buckling, pars plana vitrectomy, and intraocular gas injection for treatment of a macula-on retinal detachment in his right eye. *A* and *B* show the appearance of the eye in direct and retroillumination before surgery. *C* and *D* show the appearance of the eye after cataract extraction and implantation of a modified CTR.

the appropriate meridian, after which it remained in place. An adverse event report was filed in this case. Patient 56 developed a macula-off rhegmatogenous retinal detachment, which was managed by pars plana vitrectomy and scleral buckling. An adverse event report was filed for this event as well as his IOP rise, as mentioned previously. This patient had preoperative zonular dehiscence secondary to a penetrating injury. His CDVA at the 1-year follow-up was 20/40⁺². Finally, patient 6 complained of glare sensitivity, and he developed a crescent-shaped negative dysphotopsia in the inferotemporal field of the eye with the CTR. This patient had implantation of an SN60AT IOL, a square-edge acrylic IOL that is known to cause negative dysphotopsia in a small percentage of cataract surgery patients. However, this did not affect his CDVA, which was 20/15 at the 1-year follow-up examination. None of the patients who had cataract surgery before modified CTR implantation experienced intraoperative or postoperative complications.

Altogether, there were 6 postoperative complications, 3 adverse event filings, and 4 secondary surgical interventions during the 1-year follow-up required by the study protocol. Two of the 4 secondary surgical interventions were laser capsulotomies. Several

additional laser capsulotomies were performed more than 1 year after surgery.

Efficacy Outcomes

Efficacy outcomes for modified CTR implantation are shown in Table 3. The change in CDVA with glare was statistically significant ($P < .01$), with a median CDVA with glare improvement of 8 Snellen lines. All but 2 patients (patients 6 and 64) had an improvement in CDVA with glare; both of these patients were found to have PCO, and they subsequently had Nd:YAG laser capsulotomies. Patient 6 had a decrease from 20/40⁻² to less than 20/400 at the 1-year follow-up, but all follow-up examinations preceding 1 year showed a CDVA with glare of 20/15. After Nd:YAG laser posterior capsulotomy at 14 months, his pre-capsulotomy visual acuity was restored.

Daytime and nighttime glare improved significantly by a median of 5 points ($P < .01$) and 4 points ($P < .01$), respectively, on glare symptom grading. Both daytime and nighttime glare improved from median preoperative values of 9 to median postoperative values of 4. Almost every patient showed an improvement in the glare symptom score. Patient 10 had an

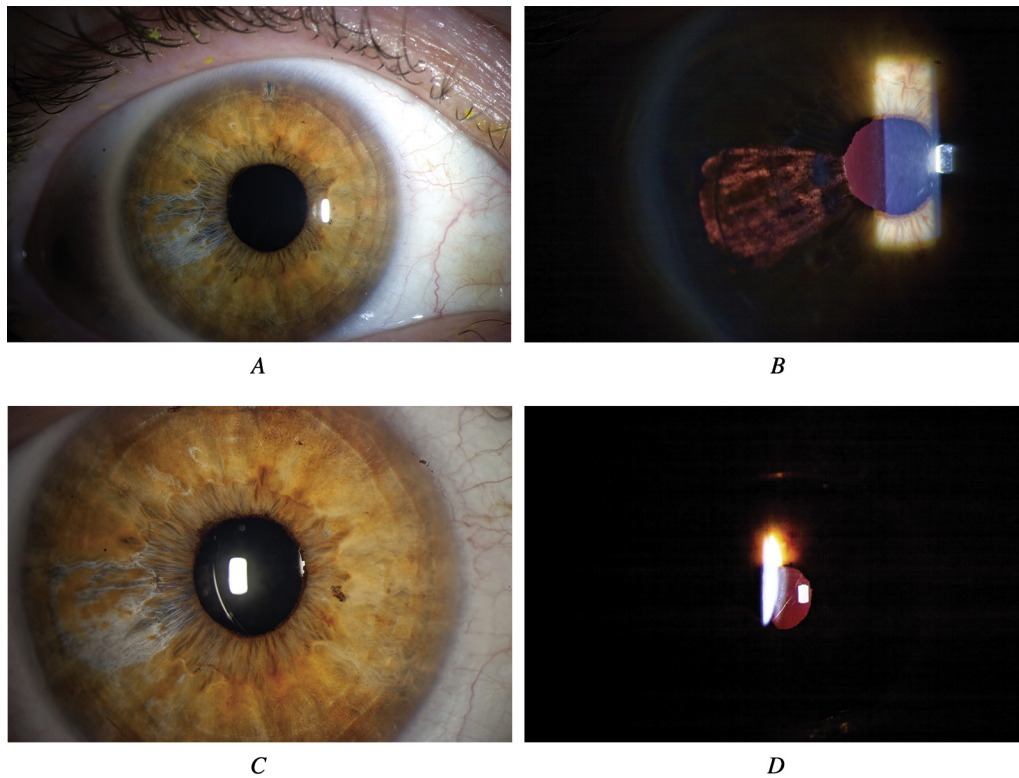


Figure 4. This 43-year-old woman's cataract surgery was complicated by iris prolapse through the phacoemulsification incision and postoperative photophobia and glare. *A* and *B* show the loss of iris pigment epithelium in direct and retro illumination shortly after cataract surgery. *C* and *D* show the appearance of the eye after secondary implantation of a modified CTR.

increase of 3 points for daytime glare symptoms and no change in nighttime glare symptoms, although he had a CDVA with glare improvement from 20/125 to 20/30 and a CDVA improvement from 20/400 to 20/20⁺. This patient reported significant dry eye preoperatively. Patient 62 reported an increase in nighttime glare symptoms of 1 point, although she noted this was not an accurate assessment of her glare symptoms as she was experiencing other unrelated ocular issues that were negatively affecting her vision at the time her glare symptoms were scored.

Because cataract removal alone can reduce glare sensitivity, it is difficult to ascertain from these aggregate results how much reduction in glare was achieved by the modified CTR implantation. Four patients (overall study patients 49, 62, 64, and 65) were implanted with the modified CTR after they were pseudophakic. These patients experienced CDVA with glare improvements of 5, 3, 0, and more than 10 lines, respectively; subjective daytime glare score improvements of 10, 6, 6, and 5; and subjective nighttime glare score improvements of 4, -1, 2, and 5. Patients 62 and 64 developed PCO, which may explain some of their inconsistent efficacy results, and both patients subsequently had laser capsulotomies. These limited data, while insufficient for statistical analysis, support

the hypothesis that implantation of the modified CTR independently reduces glare sensitivity beyond cataract surgery alone.

Overall, there was no statistically significant change in the subjective cosmetic appearance of eyes postoperatively, as one would expect with a black occluder device. Most patients reported no change in cosmetic appearance, but patient 13 reported a 5-point decrease from 9 to 4 and patient 5 reported a 9-point increase from 1 to 10. Patient 5 had significant iris reconstruction during his surgery. Patients 64 and 66 reported increases from 5 to 7 and from 3 to 7, respectively, although the reason for this improved subjective assessment is unclear.

DISCUSSION

The Morcher 96F iris diaphragm is a modified CTR with a 90-degree segmental occluder paddle that is made from black PMMA. It is intended for implantation in the capsular bag to relieve symptoms of light and glare sensitivity caused by small iris defects. Although used extensively in Europe and Asia, Morcher iris diaphragms are not FDA approved in the United States thus far and are no longer available by compassionate-use exemption. An IDE for this

Table 2. Safety outcomes of modified CTR implantation.

Overall Study No.	Preoperative CDVA	Postoperative CDVA*	Intraoperative Complications	Postoperative Complications	Adverse Events	Postoperative Interventions Within 1 Year
5	CF	20/70	None	None	N	None
6	20/25	20/15 ⁻²	None	Crescent-shaped dysphotopsia in the inferotemporal visual field	N	None
10	20/400	20/20 ⁺²	None	None	N	None
13	20/40 ⁻¹	20/20 ⁺²	None	None	N	None
22	20/50 ⁻²	20/25 ⁻¹	None	Increased IOP	N	Glaucoma medication
41	20/40 ⁺¹	20/15	None	25-degree counterclockwise rotation of the 96F ring	Y	Repositioned 1 week postoperatively
42	20/70 ⁺²	20/25 ⁺²	None	None	N	None
49	20/20 ⁻²	20/25 ⁻²	None	None	N	None
50	20/200	20/125	None	15-degree counterclockwise rotation of CTR (not visually significant)	N	None
52	20/70	20/40 ⁻²	None	None	N	None
56	20/60 ⁻²	20/40 ⁺²	None	Rhegmatogenous RD, increased IOP secondary to corticosteroid treatment of preoperative CME	Y	PPV and SB for retinal detachment, medication change for IOP control
58	20/40 ⁺²	20/20 ⁻¹	None	Increased IOP	N	Glaucoma medication
62	20/15	20/15 ⁻²	None	PCO	N	Laser capsulotomy
64	20/40	20/40 ⁻¹	None	PCO	N	Laser capsulotomy
65	20/15 ⁻²	20/25	None	None	N	None
66	20/200	20/30 ⁻¹	None	None	N	None

CDVA = corrected distance visual acuity; CF = counting fingers; CME = cystoid macular edema; IOP = intraocular pressure; PCO = posterior capsule opacification; PPV = pars plana vitrectomy; RD = retinal detachment; SB = scleral buckle

*Measured 1 year postoperatively

study was obtained from the FDA by 2 of the authors (K.M.M., M.D.O.) in 2003 to evaluate the safety and efficacy of various Morcher devices. An interim report (report 1³) evaluating the outcomes of the Morcher 50D, 96F, and 96S devices was published in 2008, but the current report focuses specifically on the Morcher 96F.

The primary safety measure of this study was the change in CDVA. Four patients lost between 1 letter and 2 lines of visual acuity to problems unrelated to device implantation, with 3 patients experiencing improvements in CDVA after laser posterior capsulotomy. There was a statistically significant improvement in CDVA at the 1-year postoperative follow-up visit for the group as a whole. This was expected because most of the patients in the study had visually significant cataracts preoperatively and had cataract extraction with IOL implantation at the time of the modified CTR implantation. The 4 patients (patients 49, 62, 64, and 65) who did not experience an improvement in CDVA were those who had cataract extraction with posterior chamber IOL placement before they enrolled in the study. Patient 49, the one who lost acuity for reasons other than PCO, had preoperative

corneal edema and CME and shortly after the 1-year follow-up was found to have changes consistent with AMD. Her 1-line loss of CDVA was not attributable to the modified CTR.

Although most patients experienced improved CDVA, there were several who did not correct to 20/25 or better postoperatively. None of their outcomes were related to the modified CTR. Patients 5, 50, 64, and 66 were found to have PCO after cataract surgery and improved after Nd:YAG laser capsulotomy. Patient 52 had a history of Fuchs endothelial corneal dystrophy and corneal transplantation, and patient 56 had a complicated postoperative course with a macula-off retinal detachment, which was successfully repaired.

A theoretical concern with Morcher 96F implantation is low-grade toxicity from leakage of the black dye used in the manufacture of the device. Our FDA-approved protocol did not require the collection of corneal endothelial cell counts, fluorescein angiograms, or macular optical coherence tomograms. We obtained these studies only when indicated clinically—almost always for ongoing evaluation of problems present before device implantation. Anecdotally,

Table 3. Efficacy outcomes of modified CTR implantation.

Overall Study No.	Preoperative CDVA with Glare	Postoperative CDVA with Glare*	Preoperative Daytime Glare Score [†]	Postoperative Daytime Glare Score [†]	Preoperative Nighttime Glare Score [†]	Postoperative Nighttime Glare Score [†]	Preoperative Cosmesis Score [‡]	Postoperative Cosmesis Score [‡]
5	CF	20/200	9	4	9	3	1	10
6	20/40 ⁻²	<20/400 [§]	7	5	7	4	10	10
10	20/125	20/30	5	8	8	8	3	3
13	<20/400	20/20 ⁻²	10	1	9	7	9	4
22	CF	20/50	8	2	9	2	1	1
41	HM	20/25	10	5	9	4	9	9
42	<20/400	20/30	8	3	9	3	9	9
49	20/80	20/30 ⁺²	10	0	4	0	10	10
50	20/600	20/200	7	6	8	6	0	0
52	<20/400	20/60 ⁻²	8	4	5	2	9	9
56	20/400	20/50 ⁻²	10	0	10	2	10	10
58	20/400	20/20 ⁻¹	7	4	10	6	10	10
62	20/30 ⁻²	20/15	10	4	9	10	9	9
64	20/30 ⁻²	20/40	10	4	6	4	8	8
65	HM	20/30 ⁻²	10	5	9	4	5	7
66	20/400	20/60 ⁻¹	9	8	9	7	3	7

CDVA = Snellen corrected distance visual acuity; CF = counting fingers; HM = hand motions

*Measured 1 year postoperatively

[†]Measured 3 months postoperatively on a scale of 0 (no glare) to 10 (significant glare) on a subject-completed questionnaire

[‡]Rated by each subject 3 months postoperatively on a scale of 0 (poor cosmesis) to 10 (excellent cosmesis)

[§]Due to posterior capsule opacification (patient's CDVA with glare was 20/15 after laser posterior capsulotomy)

throughout the study we observed no clinical evidence of toxicity in any of our patients with a 96F CTR, nor have we found it in patients followed in other Morcher sub-studies. We have observed some patients for up to 10 years after implantation.

Overall, the Morcher 96F device appears to be relatively safe. The 1 postoperative complication that is clearly related to device implantation is rotation of the occluder paddle. Fortunately, it is easy to remedy. We found no evidence of corneal or macular toxicity that we would attribute to the device. It is clear that the device does not negatively affect CDVA. Most of the postoperative complications seen in this study were unrelated to the device and easily managed with medications or reoperation. It is important to note that most cases of partial or complete aniridia in this study were due to trauma. As such, there is likely to be concomitant injury to other anterior segment structures in these patients, leading to preoperative ocular comorbidity or predisposing to postoperative complications. It is important for surgeons to be aware of the mechanism of the iris injury in traumatic cases and how this might affect surgical and perioperative management.

The primary efficacy measures of the study were objective changes in CDVA with glare and subjective changes in daytime and nighttime glare measurements. There was a statistically significant improvement in all 3 of these measures after modified

CTR implantation. Only 2 patients (6 and 65) experienced a decrease in CDVA with glare; both had PCO that improved after laser posterior capsulotomy. All other patients improved to 20/30 or better postoperatively except for patients 5, 50, 52, and 56, probably for the same reasons discussed previously in regard to their CDVA measurements. Similarly, patients 22 and 66 only corrected to 20/50 and 20/40 postoperatively but were also found to have PCO and had subsequent laser capsulotomies.

Daytime and nighttime glare scores measured preoperatively and 3 months postoperatively improved in all but 2 patients. Both of these patients noted significant dry eye preoperatively and rated the dryness of their eyes as 8 or 9 out of 10, the highest scores in the study. Patient 62 also noted that she was experiencing several other unrelated problems at the time that were probably affecting her vision. Overall, Morcher 96F implantation proved to be effective in reducing glare and improving visual acuity in the presence of a glare source.

Cosmesis was evaluated subjectively, and there was no statistically significant impact of modified CTR implantation. This was expected because the device is black and difficult to distinguish from the preexisting irregular pupil or iris defect, thus having little to no impact on the external appearance of the eye. Patients who are candidates for artificial iris implantation who have cosmetic concerns with larger iris defects may

prefer the Ophtec 311 or the Humanoptics artificial iris device, which are colored or hand-painted to match the fellow iris.

There are some surgical pearls we can share as we have gained considerable experience implanting Morcher devices. First, the 96F ring should never be implanted in the ciliary sulcus. It is not sized for this space and probably would rotate or jiggle if placed there. It must be inserted in the capsular bag. We have not found the device to be particularly brittle, although we have heard verbal anecdotes to this effect. To date, we have not broken a single device during implantation. Next, it is best to place the IOL in the capsular bag before placing the modified CTR. The open-loop portion of the device should be implanted first, followed by the occluder. It is harder to advance the occluder paddle around the capsular bag than the open-loop portion. Placing the modified CTR in front of the IOL should reduce the incidence of subjective temporal scotomas or negative dysphotopias¹⁶ that arise from the square edge of an IOL, especially when the occluder paddle is oriented nasally. It should also reduce the prominence of third and fourth Purkinje images. If a toric IOL is used, the ring may catch the optic-haptic junction and spin the IOL. The IOL may have to be repositioned after the occluder has been aligned with the iris defect. Next, as with any CTR, the ring should be advanced into the capsule in the direction of greatest zonular weakness to avoid stressing weak zonular fibers further. Last, we found it easiest to guide the occluder portion of the device into the capsular bag by advancing it with a Sinsky hook that had been placed through a positioning hole on the occluder while exerting inward and downward pressure on the outer edge of the device with a Kuglen or iris push-pull hook inserted through a paracentesis.

Because the cornea has a larger diameter than the capsular bag, some light will enter the eye around the periphery of the Morcher 96F if there is no residual iris tissue near the iris root. Still, the benefit is much greater than would be realized if no device were implanted. Unlike other artificial iris devices, the small size of the Morcher 96F allows for a much smaller surgical incision, leading to quicker healing and decreased surgical trauma to an eye that probably has suffered significant trauma already. We usually place a single 10-0 nylon suture to close the incision. Multiple devices can be implanted to cover larger iris defects, but the procedure becomes more difficult when the second device is implanted because of the volume of devices already in the capsular bag. If more area must be covered than is possible with 2 Morcher 96F rings, 2 Morcher 50F rings should be considered instead. The 50F device has 8 occluder

paddles. It is possible to insert a 96F device into a pseudophakic eye, although this can be difficult if there is extensive capsule fibrosis. There are some minor aspects of the device that could be improved, such as the cosmesis of the implant, but overall the Morcher 96F has a proven beneficial role in the management of symptomatic congenital or traumatic aniridia and other defects of the iris.

In general, Morcher 96F device implantation is both safe and effective at relieving symptoms caused by small iris defects. The device is useful to prevent glare symptoms that might otherwise arise if the edge of an IOL were exposed to light coming in through an iris defect after implantation. Finally, the device is useful for treating small iris transillumination defects, such as those caused by iris prolapse through clear corneal incisions.

WHAT WAS KNOWN

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

WHAT THIS PAPER ADDS

- The modified CTR was used safely to improve light sensitivity and glare symptoms in eyes with small iris defects.

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First author:

Rishabh C. Date, MD

*David Geffen School of Medicine at
UCLA, Los Angeles, California, USA*