ARTICLE

Safety and efficacy of black iris diaphragm intraocular lens implantation in eyes with large iris defects: Report 4

Kevin M. Miller, MD, Alan Kuo, MD, Michael D. Olson, OD, PhD, Samuel Masket, MD

Purpose: To assess the safety and efficacy of Morcher 67B black iris diaphragm intraocular lens (IOL) implantation for managing large iris defects and aphakia.

Setting: Stein Eye Institute, UCLA, Los Angeles, California, USA.

Design: Prospective case series.

Methods: The demographic, preoperative, and postoperative data on patients implanted with a black iris diaphragm IOL 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: Thirty-one eyes of 31 patients were implanted. There was a 7-line improvement in median Snellen CDVA ($P < .001$). Four eyes worsened more than 1 line. There was 1 minor intraoperative complication. Twenty-one eyes experienced postoperative complications, most of which were related to preexisting ocular comorbidities. Three adverse events included cystoid macular edema, corneal graft dehiscence, and uveitis with ocular hypertension. There were 12 secondary surgical interventions. The CDVA with glare improved 6 Snellen lines ($P < .0001$). The mean subjective glare symptoms improved 4.94 points on a 0 to 10 scale during the day ($P < .0001$) and 3.61 points at night ($P < .0001$). The mean cosmesis score improved 2.23 points ($P < .0001$) on the same scale.

Conclusion: Black iris diaphragm IOL implantation in aphakic eyes with large iris defects and significant ocular comorbidity was found to be relatively safe and very effective at improving CDVA and reducing light and glare sensitivity.

J Cataract Refract Surg 2018; 44:686–700 © 2018 ASCRS and ESCRS

Iris defects can be congenital or acquired and can vary greatly in extent within these groups. Congenital defects run the spectrum from small colobomas to complete aniridia. Most congenital iris defects are associated with other ocular comorbidities. Acquired defects can result from blunt or penetrating trauma, surgical trauma, intraocular pressure spikes, intraocular inflammation, and a variety of rare progressive disorders such as iridocorneal endothelial syndrome. Blunt trauma typically produces mydriasis or iridodialysis without actual iris tissue loss. Penetrating injuries and surgical trauma are usually associated with iris tissue loss and a variety of comorbidities involving the anterior and posterior segments and periocular tissues.

Iris reconstruction lenses, also known as aniridia implants, are designed to correct aphakia and large iris defects simultaneously. The first devices were designed by Peter Choyce in the late 1950s.[1] These implants were produced in blue, green, and brown colors and were designed for fixation within the anterior chamber. There are no reports of long-term clinical results with these early designs. In 1991, Morcher GmbH developed a poly(methyl methacrylate) intraocular lens (IOL) with a black artificial iris diaphragm that was intended for implantation in the posterior chamber. The manufacturer subsequently produced many other black iris diaphragm IOLs, several of which were shown in 1994 by Sundmacher et al.[2] to hold promise. In the years since, numerous additional case series[3–34] and several single case reports[7,35–41] from all over the world have shown the benefits and challenges associated with black iris diaphragm IOL implantation. Several excellent reviews of artificial iris devices are available.[42–44]

Morcher implants are Conformité Européenne marked and available in Europe under the Active Implantable

Submitted: February 4, 2018 | Final revision submitted: March 22, 2018 | Accepted: March 29, 2018

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

Supported in part by grants from the Carl & Roberta Deutsch Foundation, Santa Monica, California; grants from the Hazen Polsky Foundation, New York, New York; a UCLA Faculty Senate Grant; and the Paul J. Vicari endowed cataract research fund at UCLA.

Corresponding author: Kevin M. Miller, MD, Stein Eye Institute, 300 Stein Plaza, UCLA, Los Angeles, California, 90095-7000, USA. Email: miller@jsei.ucla.edu.

0886-3350/$ - see frontmatter
https://doi.org/10.1016/j.jcrs.2018.03.033

Medical Device Directive. In the United States, they were previously available on a compassionate use basis through the U.S. Food and Drug Administration (FDA). In 2003, 2 of the authors (K.M.M., M.D.O.) were granted an investigational device exemption from the FDA to study several Morcher iris diaphragm models in a prospective clinical trial involving 20 patients. This number was subsequently expanded to 70 patients. Models studied in the trial included the 96F, 96S, 50D, and 50F modified capsular tension rings (CTRs) with black occluder paddles and the 67B black iris diaphragm IOL. The institutional review board of the University of California Los Angeles approved this prospective single-site nonrandomized interventional trial in 2002 and has renewed it every year since. Information about the clinical trial can be found at ClinicalTrials.gov.[A]

An interim report on 13 patients implanted with the 50D, 50F, 96S, and 96F modified CTRs was published 2008.[45] These devices were found to be generally safe and effective at reducing light and glare sensitivity. Subsequent reports have documented favorable outcomes for the cohorts of patients implanted with 96F and 50F modified CTRs.[46,47] Technical difficulties associated with implantation of 50D and 96S models caused the surgeon in the study (K.M.M.) to stop implanting these 2 devices.[48]

The Morcher 67B is a modified IOL with a 3.0 mm pupil, 10.0 mm iris black iris diaphragm, and 12.5 mm haptics with suture fixation eyelets (Figure 1). The device has a central clear optic that is manufactured in 0.5 diopter (D) increments from 10.0 to 30.0 D and has an extended range option. Implantation requires an incision of at least 10.0 mm. This report focuses on the safety and efficacy of 67B implantation in eyes with large iris defects.

PATIENTS AND METHODS

This was a prospective nonrandomized interventional clinical trial. Patients were recruited from the first author's UCLA practice. All surgeries were performed during the 10 years between 2003 and 2013. Inclusion criteria included (1) age 18 years or older at the time of enrollment; (2) a congenital or acquired iris defect causing significant light and/or glare sensitivity, contrast loss, blurred vision, and/or multiplopia; (3) the presence of a visually significant cataract, aphakia, or pseudophakia 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 addressed by Morcher 50D, 50F, 96S, or 96F modified CTRs; (4) symptoms that could be treated adequately with tinted glasses or contact lenses; (5) active ocular infection or inflammation; (6) allergy or intolerance to postoperative medications; and (7) pregnant or lactating women. Surgeries variably included penetrating keratoplasty (PKP), cataract extraction, IOL removal, and anterior vitrectomy. A Morcher 67B device was never implanted as a standalone procedure. It was always combined with some other medically necessary procedure. The device was either passively fixated in the ciliary sulcus or fixated to the sclera using 9-0 polypropylene (Prolene) sutures.

After enrollment, patients were examined preoperatively and 1 day, 2 weeks, 3 months, 6 months, and 1 year postoperatively. They were seen at other times as necessary. Most patients continue to be followed beyond the study as regular patients of the practice.

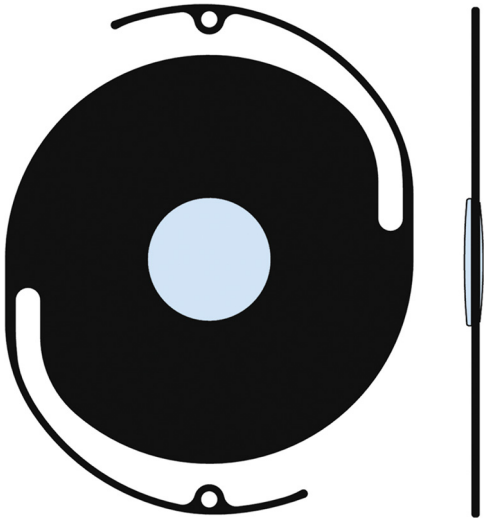

Figure 1. The black iris diaphragm IOL that was studied in this clinical trial (IOL = intraocular lens).

Safety was ascertained by any decrease in Snellen corrected distance visual acuity (CDVA) and by surgical complications, adverse events, or secondary surgical interventions. Endothelial cell loss was measured as well. The CDVA was assessed using a Snellen eye chart. Efficacy was evaluated by measuring Snellen CDVA with glare and through subjective assessment of daytime and nighttime glare symptoms.

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 were determined by questionnaire. A study coordinator instructed patients to rate their glare symptoms on a scale of 0 (very slight) to 10 (very significant) before surgery and 3 months after surgery. At the 3-month postoperative examination, patients were reminded of their preoperative scores for more accurate reporting of interval changes.

Each patient provided a subjective assessment of the cosmetic appearance of the study eye before surgery and 3 months after surgery. Grading was done on the same 0 (very unsatisfied) to 10 (very satisfied) scale. Again, patients were reminded of their preoperative scores. Iris reconstruction lens centration was estimated at the slitlamp biomicroscope at the 1-year postoperative examination.

The CDVA and CDVA with glare were compared preoperatively and 1 year postoperatively. Because there were many nonnumeric CDVA values (eg, light perception, hand motion [HM], counting fingers [CF]), or some patients could only be measured as worse than 20/400, median and range of acuity values were calculated and presented as summary statistics for preoperative and postoperative visual acuity. The statistically significant change in visual acuity was assessed qualitatively using the sign test, which ignores the magnitude of the change. The statistically significant change in all other efficacy outcomes was evaluated quantitatively using the Wilcoxon signed-rank test. The difference in proportions between 2 groups was compared using the Fisher exact test. All statistical analyses were performed using SAS software (version 9.4, SAS Institute, Inc.), and a P value of less than 0.05 was considered statistically significant.

RESULTS

Thirty-one patients had black iris diaphragm IOL implantation. Thirty of 31 patients completed all study visits. Patient 17 failed to return for the 12-month postoperative