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Implantation of a black diaphragm intraocular lens in ten cases of post-traumatic aniridia

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PURPOSE. *To retrospectively review the safety and efficacy of black-diaphragm intraocular lenses (IOL) implanted for the treatment of post-traumatic aniridia.*

METHODS. *Ten patients (mean age 48 years, range 21-75) were implanted with a black-diaphragm posterior chamber IOL (Morcher GmbH, model 67F) for correction of post-traumatic aniridia associated with cataract or aphakia. This IOL, in poly(methylmethacrylate), consists of an opaque diaphragm surrounding the transparent optic, and was inserted through a 10-mm scleral tunnel (seven eyes) or through the corneal trephination in cases of simultaneous penetrating keratoplasty (three eyes), and in-the-sulcus implanted, transsclerally sutured (six eyes) or on capsular support (four eyes). Mean follow-up was 33.4 months (range 12-52).*

RESULTS. *Best-corrected visual acuity (BCVA) improved in eight eyes and remained unchanged in two. Glare and photophobia decreased in all patients. Intraoperatively, ciliary sulcus bleeding occurred in two cases and haptic rupture during lens insertion in one. Postoperatively, persistent intraocular inflammation was seen in four eyes, secondary glaucoma in four eyes, transient hyphema and/or hemovitreous in four, IOL decentration in two, and post-traumatic haptic detachment in one eye.*

CONCLUSIONS. *Although in our experience the haptics still seem weak and the diaphragm diameter too large, implantation of the black-diaphragm IOL type 67 F appeared sufficiently safe and provided satisfactory functional results for correction of post-traumatic aniridia combined with cataract or aphakia, improving BCVA and reducing glare and photophobia in most patients, though clearly more cases and longer follow-up are needed to assess its clinical performance properly. (Eur J Ophthalmol 2003; 13: 62-8)*

KEY WORDS. *Aniridia, Cataract, Aphakia, Intraocular lens implantation, Black diaphragm intraocular lens, Eye injuries*

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INTRODUCTION

An intact iris diaphragm is essential for normal visual function because it reduces spherical and chromatic aberrations arising from the lens and increases the depth of focus (1); its partial or complete absence, a condition called aniridia, may induce glare and photophobia (2, 3). Aniridia may be congenital or occur after a severe ocular trauma.

Post-traumatic aniridia is usually accompanied by severe anterior segment disruption and may be associated with corneal scarring, traumatic cataract, secondary glaucoma, vitreous prolapse, cystoid macular edema and retinal detachment (3). Consequently, treatment aimed at improving visual acuity may include, if necessary, reconstruction of the iris diaphragm, cataract extraction with intraocular lens (IOL) implantation, glaucoma surgery, penetrating keratoplasty, and vit-

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reo-retinal surgery (2, 3).

Many approaches have been tried to compensate for the lack of the iris diaphragm, including eyelid surgery, iridoplasty, colored contact lenses, corneal tattooing (4). In 1964 Choyce (5) described the implantation of colored diaphragm IOLs in the anterior chamber of phakic and aphakic eyes with traumatic aniridia, but this surgical procedure may have several drawbacks such as insufficient iris support for the IOL and possible surgical damage of the endothelium and of the drainage angle. In 1991 a newly designed posterior chamber IOL consisting of an opaque diaphragm surrounding the optical lens was proposed by Reinhard et al for correction of congenital and traumatic aniridia (6, 7).

We describe our experience in a series of ten cases of post-traumatic aniridia with cataract or aphakia, in which a black-diaphragm posterior chamber IOL was implanted.

Fig. 1 - *Model 67 F of the black-diaphragm aniridia IOL (Morcher GmbH), with a diaphragm diameter of 10.0 mm, optic diameter 5.0 mm, and haptic diameter 13.5 mm.*

PATIENTS AND METHODS

Ten patients had monolateral implantation of a black-diaphragm posterior chamber IOL (Morcher GmbH, model 67 F) for correction of post-traumatic aniridia associated with cataract or aphakia. Their basic preoperative data are shown in Table I. All patients were men; their mean age at the time of surgery was 48.8 years (ranging from 21 to 75 years). Three had previous penetrating eye injuries and seven had a contusive ocular trauma.

In all cases a full examination was done preoperatively, one week, one and three months after surgery, and then at three-month intervals; this included best-corrected visual acuity (BCVA), biomicroscopy, applanation tonometry, fundus exploration and subjective assessment of discomfort, glare and photophobia.

All patients had an extensive iris defect and reported severe photophobia and glare; six were aphakic, two pseudophakic and three had post-traumatic cataract; three had a secondary glaucoma well controlled by medical therapy.

The surgical details are summarized in Table II. All surgery was performed by the same surgeon between March 1997 and September 2000. In all cases a complete reconstruction of the anterior segment was required, with vitreo-retinal surgery if necessary. Anesthesia consisted of a peribulbar injection of 5 mL of a 1:1 mixture of lidocaine 2% and bupivacaine hydrochloride 0.5% (Marcaine).

In all cases a black-diaphragm posterior chamber IOL (Morcher GmbH, Stuttgart, Germany) model 67 F was implanted (Fig. 1): this IOL consists of two parts both made of poly(methylmethacrylate) (PMMA), the optical zone surrounded by the black diaphragm, clipped together. Model 67 F has a biconvex clear PMMA central optic of 5.0 mm diameter, a peripheral black PMMA diaphragm from 5.0 to 10.0 mm in diameter, overall length of 13.5 mm and one hole on each haptic (Fig. 1).

The black-diaphragm IOLs were always implanted in the ciliary sulcus, by trans-scleral fixation following a personal inside-out three-point fixation technique in six cases, on capsular support in two and, in the other two eyes one haptic was trans-sclerally fixated while the other was placed in front of residual capsular structures.

When present, the cataractous lens was removed by phacoemulsification (two cases); in the two

TABLE I - PREOPERATIVE DATA

Pt	Sex	Age (years)	Eye	Original ocular problem	Previous surgery	BCVA	Glare	Iris defect (sector)	Lens status	IOP elevation pre-op	IOP controlled	Associated pathology
D.E.	M	34	right	non-penetrating ocular trauma	lensectomy, VPPV for RD repair	0.3	++	extensive	aphakic	-	-	-
A.G.	M	75	left	non-penetrating ocular trauma	phacoemulsification, in-the-bag, IOL Implant	0.5	+++	superior	pseudophakic	-	-	IOL tilt and dislocation
R.G.	M	28	right	penetrating sclero-corneal injury	glass foreign body removal, penetrating injury repair, ECCE+IOL in the sulcus	FC	+++	superior	pseudophakic	-	-	corneal leukoma IOL dislocation tractional CME
P.R.	M	45	right	penetrating cornel injury	penetrating injury repair, lensectomy, VPPV for RD repair, penetrating keratoplasty	LP	+++	extensive	aphakic	-	-	corneal graft perforation
V.L.	M	21	left	post-traumatic corneal wound diastase in PK for keratoconus	corneal wound repair, lensectomy, VPPV for RD repair	0.5	+++	extensive	aphakic	-	-	macular pucker
B.D.	M	53	left	non-penetrating ocular trauma	none	FC	+++	extensive	aphakic	-		post-traumatic aphakia, AMD
D.S.	M	74	left	non-penetrating ocular trauma	none	0.7	++	sup-nasal	lens subluxation	+	medically	lens subluxation secondary glaucoma
L.O.	M	74	left	non-penetrating ocular trauma	ICCE	0.1	+++	sup-temporal	aphakic	+	medically	secondary glaucoma chronic aphakic CME
M.B.	M	46	right	non-penetrating ocular trauma	none	0.3	++	inferior	phakic	-	-	traumatic cataract
P.A.	M	38	right	penetrating corneal injury	penetrating injury repair, lensectomy	FC	+++	extensive	aphakic	+	medically	corneal leukoma secondary glaucoma

PK = Penetrating keratoplasty; VPPV = Via pars plana vitrectomy; RD = Retinal detachment; ECCE = Extracapsular catarat extraction; ICCE = Intracapsular cataract extraction; BVCA = Best corrected Visual acuity; FC = Finger counting; LP = Light perception; CME = Cystoid macular edema; AMD = Age-related macular degeneration

pseudophakic patients the IOL was explanted and replaced with a black-diaphragm IOL. Simultaneous penetrating keratoplasty (PK), anterior vitrectomy (AV) and pars plana posterior vitrectomy (VPPV) were done respectively in three, seven and four eyes. In cases of simultaneous PK, the IOL was inserted through the corneal trephination; in the other eyes, the IOL was inserted through a 10-mm scleral tunnel, then closed with a continuous 10-0 nylon suture.

Standard postoperative medication consisted of desamethasone and ofloxacin eyedrops four times a day for the first week and then in progressively decreasing doses for another three weeks. The mean follow-up was 33.4 months (range from 12 to 52 months).

TABLE II - SURGICAL DATA

Pt	IOL type	IOL fixation	Haptic position	Lens or IOL extraction	Corneal graft	AV	VPPV	Intra-op complications
D.E.	67 F	10 mm scleral tunnel/ transscleral fixation	ciliary sulcus	-	-	-	-	-
A.G.	67 F	10 mm scleral tunnel/ transscleral fixation-capsular remnants	ciliary sulcus, in part on capsular support	IOL explantation	-	-	-	-
R.G.	67 F	via 8.0 mm corneal trephination in comb. with PK/ capsular support	ciliary sulcus on capsular support	IOL explantation	allograft 8.0 mm	+	+	-
P.R.	67 F	via 8.5 mm corneal trephination in comb. with PK/ transscleral fixation	ciliary sulcus	-	allograft 8.5 mm	+	-	ciliary sulcus bleeding
V.L.	67 F	10 mm scleral tunnel/ transscleral fixation	ciliary sulcus	-	-	+	+	-
B.D.	67 F	10 mm scleral tunnel/ transscleral fixation	ciliary sulcus	cortical remnants aspiration	-	+	+	ciliary sulcus bleeding IOL haptic rupture
D.S.	67 F	10 mm scleral funnel/ transscleral fixation-capsular remnants	ciliary sulcus, in part on capsular support	phacoemulsification	-	+	-	-
L.O.	67 F	10 mm scleral tunnel/ transscleral fixation	ciliary sulcus	-	-	+	+	-
M.B.	67 F	10 mm scleral tunnel/ capsular support	ciliary sulcus on capsular support	phacoemulsification	-	-	-	-
P.A.	67 F	via 8,5 mm corneal trephination in comb. with PK/ transscleral fixation	ciliary sulcus	cortical remnants aspiration	allograft 8.5 mm	+	-	-

PK = Penetrating keratoplasty; AV = Anterior vitrectomy; VPPV = Via pars plana vitrectomy

RESULTS

Intraoperatively there were two cases of transient ciliary sulcus bleeding during the IOL trans-scleral fixation; one case of rupture of a haptic occurred during the lens insertion that required the substitution and re-implantation of a black-diaphragm IOL (Tab. II). The postoperative data are listed in Table III and refer to the last visit available.

BCVA improved postoperatively in eight eyes and remained unchanged in two. Discomfort, glare and photophobia diminished subjectively in all cases, and disappeared in four patients.

The black-diaphragm IOL centration was excellent

TABLE III - POSTOPERATIVE DATA

Pt	Follow-up (months)	BCVA pre-op	BCVA post-op	Glare pre-op	Glare post-op	IOL position	IOP elevation pre-op	IOP elevation post-op	IOP elevation controlled	Post-op complications
D.E.	12	0.3	1.0	++	-	excellent	-	-	-	-
A.G.	15	0.5	0.7	+++	-	excellent	-	-	-	-
R.G.	23	FC	0.1	+++	++	superior decentration	-	+	surgically by trabeculectomy	persistent iritis secondary glaucoma IOL decentration IOL haptic rupture
P.R.	28	LP	LP	+++	+	excellent	-	-	-	persistent iritis transient vitreous hemorrhage
V.L.	37	0.5	0.5	+++	++	inferior decentration	-	-	-	IOL decentration transient hyphema and vitreous hemorrhage
B.D.	52	FC	0.05	+++	+	excellent	-	-	-	persistent iritis transient vitreous hemorrhage
D.S.	50	0.7	0.9	++	-	excellent	+	+	medically	secondary glaucoma
L.O.	42	0.1	0.2	+++	++	excellent	+	+	medically	transient hyphema secondary glaucoma
M.B.	41	0.3	0.9	++	-	excellent	-	-	-	-
P.A.	34	FC	0.5	+++	+	excellent	+	+	medically	persistent iritis secondary glaucoma

BCVA = Best corrected visual acuity; FC = Finger counting; LP = Light perception

in eight eyes; one IOL appeared slightly decentered superiorly and one was marked luxated inferiorly and required surgical repositioning. Slight intraocular inflammation persisted in four eyes but disappeared within at most three months using topical steroids.

Postoperative ocular hypertension was present in four eyes and was controlled medically in three cases and surgically (trabeculectomy) in one. In four eyes a transient hyphema and/or vitreous hemorrhage was seen after IOL trans-scleral fixation.

There was one case of postoperative rupture of the IOL haptic (specifically, after trabeculectomy, during the manual massage on the filtration bleb), requiring explantation of the black-diaphragm IOL and its substitution with a normal trans-scleral-fixated IOL.

DISCUSSION

The black-diaphragm IOL, proposed in 1991 by Reinhard and coauthors for the correction of congenital and post-traumatic aniridia, is a posterior chamber IOL consisting of an opaque diaphragm surrounding the transparent optic (6, 7). In cases of congenital aniridia a cataract is often associated and in post-traumatic aniridia the anterior segment is usually severely disrupted with concomitant aphakia or post-traumatic cataract, so the black-diaphragm IOL offers an opportunity to correct the iris deficiency simultaneously with the lens opacification or aphakia.

Short-term results with the first black-diaphragm IOL prototypes (types 67, 67 A-D), published in 1994 (6, 7), were encouraging but difficulties were reported in inserting the IOL because of its large overall and diaphragm diameters and the fragility of the haptics; postoperative persistent low-grade intraocular inflammation and several cases of secondary glaucoma were also described (6, 8). Subsequent technical modifications produced slightly smaller and more resilient IOL models (types 67 E-G), that provided better results with fewer postoperative complications (9).

We started implanting black-diaphragm posterior chamber IOLs in cases of post-traumatic aniridia combined with cataract or aphakia in 1997. For in-the-sulcus lens implantation we considered the model 67 F was more indicated because of its overall diameter of 13.5 mm; in fact, the more recent 67 G model, with a smaller overall diameter of 12.5 mm, could theoretically tilt or dislocate if implanted in the ciliary sulcus. As far we know, there are no other published reports concerning specifically the model 67 F.

Our postoperative outcomes appear encouraging and comparable to those obtained by other authors using the 67 G model (9). Most of our patients had an improvement in BCVA and all reported a reduction of subjective glare and photophobia postoperatively. These results are definitely satisfactory considering that, in most of our cases, the aniridia was associated with other disorders that can severely limit postoperative visual function, and most of our patients had had multiple previous surgery.

Still discussed in the literature (8, 9), the effect of the black-diaphragm IOLs on glare and photophobia was satisfactory but unpredictable in our experience, suggesting the multifactorial etiology of dysphotopsia.

In two cases the IOL was not correctly centered, and because the black- diaphragm IOL has a relatively small (5.0 mm diameter) clear optic, small degrees of decentration are more noticeable. Accurate centering of the IOL in cases such as those presented here is made more difficult by the lack of a central pupil to provide a reference for the optic axis and by distortions caused by corneal scarring.

Intra- and postoperative complications associated with the trans-scleral fixation, such as the ciliary sulcus bleeding with transient hypema and/or vitreal hemorrhage, occurred with the same frequency as for other trans-scleral fixation procedures (10). As reported by other authors (6, 7, 11), the most frequent postoperative complications were persistent intraocular inflammation and secondary glaucoma, that seem to be related much more to the extensive post-traumatic disruption of the anterior segment seen in all cases and to the in-the-sulcus IOL implantation procedure (10), especially with the trans-scleral fixation technique (12), than to the characteristics of the black-diaphragm IOLs. Anyway, in our series, this postoperative iritis disappeared in not more than three months using topical steroids, and the postoperative ocular hypertension was always controlled by medical or surgical treatments.

In spite of technical improvements, we found the black-diaphragm IOLs were still too brittle, with two cases of haptic fracture, and too big, requiring a wide surgical incision for the implant, causing high postoperative induced astigmatism. The fragility of the black

PMMA was already known (6-8) and cases of aniridia IOL haptic fracture have been published (13).

In conclusion, in our experience the black-diaphragm IOL type 67 F provided satisfactory functional results in the treatment of post-traumatic aniridia combined with cataract or aphakia, improving BCVA in most of our patients and reducing discomfort, glare and photophobia.

Persistent mild postoperative inflammation and secondary glaucoma have been described with other models of these lenses (6, 8), but were not common in our series and responded to treatment.

Even if their haptics still seem weak and the diaphragm diameter too big, implantation of the black-diaphragm IOLs appeared sufficiently safe, but a larger number of patients and longer follow-up are obviously necessary to assess their clinical performance properly.

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