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ARTICLE

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Scleral sutured aniridia intraocular lens (Morcher®): indications and long-term outcomes

Rabia Bourkiza[1,4], Georgios Vakros[1,4]✉, Sonali Tarafdar[2], Elizabeth Yang[1] and David G. Charteris[1,3]

BACKGROUND/OBJECTIVE: To evaluate the outcomes of trans-scleral sutured posterior chamber black diaphragm intraocular lens (BDIOL) (Morcher®) implantations over 11 years.

SUBJECTS/METHODS: Retrospective case-series of patients, who underwent BDIOL implantation, identified from electronic patient records system from 2006 to 2016, Moorfields Eye Hospital. Demographics, pre/post-operative, final best-corrected visual acuity (BCVA), diagnosis, symptomatic improvement, intraoperative and postoperative complications immediate or late were collected and analysed to relate outcomes to surgical indication.

RESULTS: Forty eyes of 38 patients (F:M 1:2.8) underwent BDIOL implantation with a mean surgical age of 46.6 years and follow-up of 44.5 months (range of 8–132 months). Indications included 23(57%) ocular trauma, 7(17%) congenital aniridia, 7(17%) iatrogenic lens and/or iris loss, and 3(7%) infectious keratitis. Mean preoperative BCVA was 1.64 logMAR and mean final postoperative BCVA was 0.94 logMAR with an average improvement in BCVA of 0.23 logMAR, equivalent to 1.5 lines of Snellen visual acuity. Visual results varied according to indications. Infectious cause patients had the greatest vision improvement (−0.7 logMAR), followed by trauma (−0.3 logMAR), and 25% of these achieved vision of 0.3 logMAR (6/12 in Snellen acuity) or better. Conversely, the aniridia group had the least improvement (worsened vision of 0.01 logMAR), 17 patients (42%) reported subjective improvement.

CONCLUSION: BDIOLs achieve reasonably good visual outcomes in eyes with complex vision threatening pathology. No significant intra-operative complications are documented and most post-operative complications are related to the pre-existing pathology. Post – trauma and iatrogenic aniridia have better outcomes compared to congenital aniridia.

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INTRODUCTION

Partial or complete aniridia is a debilitating condition due to photophobia and visual disturbance as well as the aesthetic appearance of the eye. Aniridia can be either congenital such as in cases of *PAX6* mutations or acquired related to iatrogenic or exogenous trauma or infections. The lens-iris diaphragm is pivotal to visual function and its absence leads to spherical and chromatic aberrations significantly affecting vision. This results in debilitating glare, decreased depth of focus, and photophobia, with overall decrease in the quality of vision and life [1, 2]. For the symptomatic and cosmetic treatment of aniridia multiple treatment options are available including coloured contact lenses, corneal tattooing, iridoplasty, foldable or non-foldable artificial iris implants and intraocular lenses with coloured diaphragm. The latter is an intervention of choice in cases with co-existing aphakia or cataract, hence repairing both issues in potentially one surgical procedure [3]. In the late 1950s, Choyce designed anterior chamber fixated implants in several colours in order to address such issue, though long-term clinical results were not reported [4]. In 1991, Morcher® GmbH developed a posterior chamber, black diaphragm intraocular lens (BDIOL) and since its successful launch in 1994 by Sundmacher [5], it has been widely used for such indications.

Evidence of outcome and complication rates of BDIOL for the various indications has been reported though limited by absence of long-term data. Detailed case series are therefore necessary to inform patient selection and advise patients on likely outcomes long term. Our study reports on a large group of ethnically diverse patients who underwent implantation of BDIOL over an 11-year period. The objective was to evaluate the visual outcome of such lenses as well as any related short- and long-term issues.

METHODS

Demographics

Thirty-eight consecutive patients (40 eyes) who underwent insertion of a BDIOL at Moorfields Eye Hospital NHS Foundation Trust London, UK from 1st January 2006 to 31st December 2016 were identified retrospectively from the electronic patient record OpenEyes™ (Apperta Foundation CIC, Sunderland, England). Inclusion criteria were: patients who underwent all types of Morcher® aniridia implant and had at least 6 months follow up. Patients with less than 6 months follow up and Morcher® complete or partial aniridia rings or diplopia implants were excluded from the study.

[1]Department of Vitreoretinal Surgery, Moorfields Eye Hospital, 162 City Road, London EC1V 2PD, UK. [2]Department of Ophthalmology, Ninewells hospital, James Arrott drive, Dundee DD2 1SG, UK. [3]NIHR Biomedical Research Centre at Moorfields Eye Hospital and University College London Institute of Ophthalmology, London EC1V 2PD, UK. [4]These authors contributed equally: Rabia Bourkiza, Georgios Vakros. ✉email: g.vakros@nhs.net

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Table 1. Demographics of patients categorised by different indications for Morcher® IOL implantation, and mean length of follow up.

	All eyes	Trauma	Iatrogenic	Aniridia	Infectious (Fusarium keratitis)
Number of eyes	40	23	7	7	3
Mean age (years)	46.6	41.7	62.9	41.9	57.3
Male	30 (75%)	22 (96%)	3 (43%)	4 (57%)	1 (33%)
Female	10 (25%)	1 (4%)	4 (57%)	3 (43%)	2 (67%)
Mean follow up (months)	44.5	38.7	36.9	68.9	48
Ethnicity					
Caucasian	32	17	5	7	3
Asian	4	3	1	0	0
Afro-Caribbean	2	1	1	0	0
Other	2	2	0	0	0

Data were extracted on patients' demographics (age, gender, ethnicity), surgical indication (congenital, trauma, biopsy or laboratory proven infection, iatrogenic), and visual outcomes (logMAR best corrected visual acuity; BCVA) at 3 months, 6 months, 12 months and at final follow up. Details of all past, concurrent, and subsequent surgical procedures, intra-operative, post-operative complications, long term sequelae of the surgical intervention, the IOL model, power, estimated refraction and symptom improvement as reported by the patients were also included.

Surgical technique

Four models of BDIOLs were used in the cohort; Morcher® 67(total diameter 12.5 mm, optical diameter 3.5 mm), 67 G (total diameter 12.5 mm, optical diameter 5.0 mm), 67 F (total diameter 13.5 mm, optical diameter 5.0 mm) and 68 (total diameter 12.5 mm, optical diameter 4.5 mm). All lenses were secured in the eye by suturing to the sclera. The surgeries were performed both by anterior and posterior segment surgeons. All primary surgeons were consultant grade and some variation to the technique was noted (scleral flaps or Hoffman pockets [6], cow hitch at the eyelet of the lens or suture passed through eyelet). Superior and inferior conjunctival peritomies were performed 180 degrees apart, with matching partial thickness scleral flaps. These were marked with callipers 2 mm from the limbus. A large corneal 3-step incision was performed depending on the size of the IOL model used (8–9 mm for 67 model, 11–12 mm for 67 G, 67 F, 68 models). A 10-0 prolene suture was passed through the superior IOL haptic eyelet to the superior pocket and inferior eyelet to the inferior sclera with handshake technique. The IOL was inserted, and the sutures tied. The scleral flaps were either sutured with 10-0 vicryl or glued. In all surgeries, the corneal incision was closed with 10-0 nylon and the conjunctiva was closed with 8-0 vicryl. All patients received intracameral cefuroxime and subconjunctival dexamethasone. Concurrent surgeries were also performed as needed; pars plana vitrectomy with or without fragmetome was performed in cases of dropped nucleus or IOL, cataract surgery if phakic, iridectomy/membranectomy for iris remnants or scar tissue, penetrating keratoplasty for corneal failure. Finally, anterior vitrectomy was performed in cases of non-vitrectomised eyes if there were evidence of vitreous prolapse due to posterior capsular rupture or pre-existing vitreous prolapse in traumatic cases. An anterior chamber maintainer was used at the operating surgeon's discretion.

All patients received intensive topical dexamethasone 0.1% eyedrops (2-hourly) and titrated according to the response and chloramphenicol 0.5% four times a day for 2 weeks. In addition, we used topical ketorolac 0.5% three times a day for the cases of cystoid macular oedema until it resolved. This was diagnosed and monitored clinically combined with the use of ocular coherence tomography (OCT). Patients continued any pre-operative eyedrops for ocular surface or glaucoma and were also started on topical anti-hypertensives if high intraocular pressure was identified at any of the post-operative visits. The surgical team followed up the patients and if any input was needed for any other post-operative complications, the appropriate subspecialty was involved at the primary surgical team's discretion.

This study followed the tenets of the Declaration of Helsinki and the treatment chosen was part of the standard care. This study was approved by the local Clinical Governance and Audit committee. All subjects consented for clinical information and all the photos taken or used.

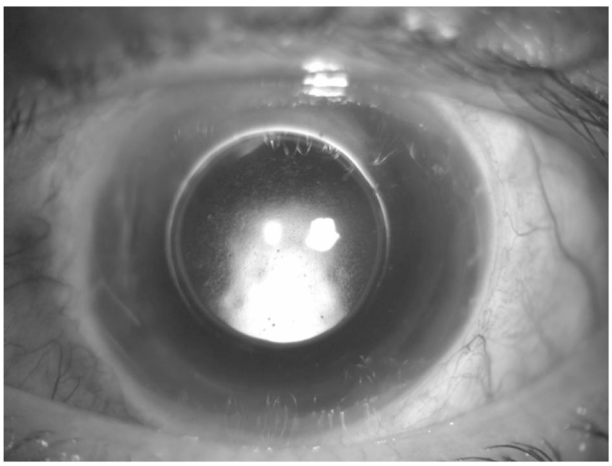

Fig. 1 Post-operative image of Morcher® 67 G IOL implant in a patient with congenital aniridia with a 5.0 mm optic.

Statistical analysis

We analysed the differences in outcomes and complications between the four main indications for Morcher® IOL implantation: trauma, iatrogenic iris/lens loss, congenital aniridia, and infectious keratitis. The one-way ANOVA test was used to compare differences in logMAR BCVA between these four categories of patients. A P value of 0.05 or less was considered statistically significant. Statistical analysis was performed using GraphPad Prism version 8.00 for Windows (GraphPad Software, La Jolla California USA, www.graphpad.com).

RESULTS

Our search results yielded 40 eyes of 38 patients over the 11-year period from 2006 to 2016 (Table 1). Mean follow up was 44.5 months with a range of 8 to 132 months. The average age was 46.6 ± 14 years (range: 20–75 years). Overall, there was Caucasian ethnicity and male predominance of 80% and 75% respectively. The largest proportion of these surgical indications was trauma (23 eyes, 57%) followed by iatrogenic loss of lens and/or iris (7 eyes, 17%), then congenital aniridia (7 eyes, 17%) (Fig. 1), and lastly acquired iris damage from fusarium keratitis, which we classed under "infectious" indications (3 eyes, 7%).

Examples of iatrogenic indications include iris removal for melanoma (1 eye), corneal graft dehiscence with iris prolapse (1 eye), Uretts-Zavalia syndrome (1 eye), complicated cataract (1 eye), tilted intraocular lens with iris coloboma (1 eye), iridectomy for glaucoma (2 eyes), with and without anterior segment ischaemia.

The mean overall preoperative and postoperative BCVA was 1.64 and 0.94 logMAR respectively, with an average improvement in BCVA of 0.23 logMAR, equivalent to 1.5 lines with Snellen visual

Table 2. Summary of pre-operative and subsequent changes in best-corrected visual acuity (VA), categorised by surgical indications for Morcher® IOL implantation.

	All patients	Trauma	Iatrogenic	Aniridia	Infectious (Fusarium keratitis)	*P* value
Mean pre-operative VA	1.64	1.73	1.55	1.46	1.54	0.51
Mean post-operative VA at 3 months	0.71	0.61	0.58	1.04	1.04	0.18
Mean post-operative VA at 6 months	0.76	0.66	0.72	1.02	0.91	0.68
Mean post-operative VA at 12 months	0.86	0.71	0.84	1.16	1.19	0.56
Final mean post-operative VA	0.94	0.81	0.9	1.24	1.13	0.79
Mean change in VA from pre-operative to 6 months	−0.48	−0.63	−0.06	−0.22	−0.91	0.10
Mean change in VA from pre-operative to final	−0.23	−0.30	−0.03	0.01	−0.70	0.67
Proportion of patients who achieved 6/12 Snellen or better	8/40 (20%)	6/23 (26%)	1/7 (14%)	1 /7 (14%)	0	–
Proportion of patients with visual stability or improvement	25/40 (62%)	15/23 (65%)	4/7 (57%)	4/7 (57%)	2/3	
Proportion of patients with documented subjective symptom improvement	17/40 (42%)	8/23 (35%)	3/7 (42%)	5/7 (71%)	1/3	–

Best-corrected visual acuity values are recorded in log MAR. *P* values from the one-way ANOVA test for comparison of mean VA between the four groups, whereby $p < 0.05$ is considered significantly different.

Table 3. Summary of complications grouped by indications for Morcher® IOL implants.

Complications	All (n = 40)	Trauma (n = 23)	Iatrogenic (n = 7)	Aniridia (n = 7)	Infectious (n = 3) (Fusarium keratitis)
Glaucoma:	14 (35%)	7 (30%)	4 (57%)	2 (28%)	1 (33%)
Corneal decompensation and/or scarring	14 (35%)	6 (26%)	3 (42%)	5 (71%)	0
Graft failure:	4 (10%)	1 (4%)	1 (14%)	0 (no prior or concurrent grafts)	2 (67%)
Significant astigmatism:	4 (10%)	3 (7%)	1 (14%)	0	0
Microbial keratitis:	3 (7%)	0	1 (14%)	1 (14%)	1 (recurrence of fusarium) (33%)
CMO:	2 (5%)	1 (4%)	1 (14%)	0	0
None	1 (2%)	1 (4%)	0	0	0
Others:		1 exposed implant and scleritis (4%) 1 photophobia (4%) 1 macula hole (4%) 1 retinal detachment (4%) 1 persistent epithelial defect (4%)	1 retinal fold	0	0

acuity (Table 2). It is noted that not all patients had BCVAs recorded at all time points of 3, 6, and 12 months, which accounts for the varying average visual acuities at these points, but all patients did have a final BCVA recorded. Amongst the four different groups, we found that the infectious cause patients had the greatest level of vision improvement (−0.7 logMAR), followed by trauma (−0.3 logMAR), and a quarter of these achieved vision of 0.3 log Mar (6/12 in Snellen acuity) or better. Conversely, the aniridia group had the least improvement (worsened vision of 0.01 logMAR), which likely reflects this group's inherent aberrant visual function (for example, glaucoma, optic nerve or macula dysfunction, corneal stem cell deficiency). However, these differences in visions and changes in vision between the four groups are not statistically significant, which may be a reflection of small numbers in each category. Despite that, our patients reported symptomatic improvement of visual acuity and glare (17 had documented subjective visual improvement, 42%).

Post-operative complications (Table 3) included glaucoma/ocular hypertension requiring treatment (14 eyes), which was most prevalent in eyes with iatrogenic aniridia (4 out of 7 eyes), corneal decompensation or scarring (14 eyes), graft failure (4 eyes), intolerable astigmatism/anisometropia requiring further surgery (4 eyes), microbial keratitis (3 eyes), chronic cystoid macular oedema (2 eyes) and retinal detachment (1 eye). Four out of the 7 eyes with aniridia developed both glaucoma and corneal opacity post operatively, and none of them underwent prior corneal grafts. Table 4 provides details of glaucoma occurrence in each category.

DISCUSSION

This study is unique in that it presents the long-term outcomes of BDIOL implantation in a large cohort of eyes for various indications, not limited to congenital aniridia and/or trauma.

Table 4. Glaucoma occurrence grouped by onset and indications for Morcher® IOL implants.

	All (n = 40)	Trauma (n = 23)	Iatrogenic (n = 7)	Aniridia (n = 7)	Infectious (n = 3)
Pre-existing glaucoma	4	0	0	2	2
Pre-existing ocular hypertension	2	2	0	0	0
Post-operative glaucoma	14	7	4	2	1
Post-operative ocular hypertension	2	2	0	0	0

Our results compare favourably in terms of visual outcome and complication rates to other series, most of which reporting outcomes of fewer patients with shorter follow up [7]. One previous case series has reported a larger cohort, but it was limited to acquired cases, with a follow up of 2.1 years [8]. We have demonstrated that BDIOL implantation is a safe and effective surgical intervention in inherently complex eyes with aniridia.

In our series with a mean follow up of nearly four years, the mean BCVA at the final visit was 0.23 LogMAR better than pre-operatively. This was in keeping with previously published studies [7–9], indicating that BDIOL is generally a successful intervention for these cases. Specifically, those with the largest improvement were noted to be in the infectious group (mean change −0.7 logMAR) followed by the trauma group (mean change −0.3 logMAR). Evidence of the outcomes of BDIOL in fungal cases is scarce and is limited to case reports [10]. As such, it is difficult to draw conclusions from our 3 cases in this series. Our results also compare favourably to other studies that included or reported exclusively on traumatic causes of aniridia [11].

In our analysis of the congenital aniridia group, we found that the mean change in BCVA was slightly worse in comparison to the other groups. This is in agreement with data from previous studies [12–14] which showed that BCVA improvement, in congenital aniridic eyes that had BDIOLs implantation, was less than the improvement of trauma patients. On the other hand, data from smaller cohorts did not exhibit the same conclusions most likely due to their small case numbers [15–17]. This variability of outcomes in patients with congenital aniridia reflects the different severity of this clinical syndrome and that the co-morbidities that these patients develop (glaucoma, limbal stem cell deficiency and foveal hypoplasia) influence the visual acuity.

Intraoperatively, none of our patients experienced significant complications. Postoperatively, 36 patients (37 eyes) had complications, mostly related to their pre-existing conditions rather the IOL. One patient, who developed exposure of the suture causing scleritis and vitreous haemorrhage, had their implant removed 6 months later. One patient developed a macular hole, which was not present Intraoperatively. This patient underwent further vitrectomy with internal limiting membrane peeling for closure. A similar case had also been described by Miller et al. [7]. One patient developed a rhegmatogenous retinal detachment, successfully treated with vitrectomy and gas tamponade. Cystoid macular oedema was found in two patients: one had concurrent cataract surgery and the other had endothelial keratoplasty. Three patients developed microbial keratitis following the surgery, one of which was due to reactivation of the original fusarium keratitis, and the other two were deemed to be due to compromised ocular surface related to limbal stem cell failure. All three cases of keratitis resolved with medical treatment alone. Re-activation of fungal infections or re-infections in the context of poor ocular surface is known risk factors and has previously been described [18]. In addition to these complications, four patients had significant surgically induced astigmatism after the BDIOL implantation; also shown to be previously common with these lenses [7, 19]. The high astigmatism was not fully attributed to the BDIOL implantation as two out of the four patients had corneo-scleral laceration from previous globe ruptures, one had concurrent penetrating keratoplasty and one had an extracapsular cataract extraction wound due to complicated cataract surgery. All cases were subsequently treated with astigmatic keratotomies.

Glaucoma was a common problem in a significant proportion of patients, in keeping with other published series [7, 8, 11]. Fourteen out of the 40 eyes developed glaucoma post-operatively (35%), in addition to 6 eyes that had pre-existing glaucoma or ocular hypertension prior to the insertion of the Morcher® BDIOL (Table 4). The mechanism of secondary glaucoma in these patients is complex, however previous studies identified in patients who underwent Ultrasound Biomicroscopy (UBM) examination that part of the haptic was protruding in the anterior chamber angle influencing the function of it and/or adhesions forming [8, 11, 17]. We did not perform UBM in our study; however, the high glaucoma rates could be explained by the above mechanism. It is important to note that patients with limbal stem cell failure frequently have distorted limbal anatomy and accurate suture placement to ensure stable lens away from the anterior chamber may therefore be difficult [20].

Fourteen eyes developed corneal decompensation and/or scarring and 4 eyes developed corneal graft failure. BDIOL corneal decompensation or graft failure has been reported to be as high as 50% (Li et al.) in case series [11]. The possibility of bullous keratopathy from movements of the BDIOL has been postulated as both polymethyl methacrylate (PMMA) material and size of lens make it easy to move with the saccadic movements or nystagmus [21]. It has also been suggested that the movement of the lens can be reduced by additional retention sutures [22]. The complexity of these eyes means that the reduced endothelial cells count, and function are further compromised by any corneal insult, hence pre-op counselling is essential.

One important observation in our cohort is the absence of IOL dislocation due to suture breakage. Sutured IOLs have been used since the early 2000s [19]. Several studies have reported that the prolene suture breakages some years post operatively [23–25]. BDIOL dislocation due to suture breakage has consistently been reported at low levels [7, 8, 11]. The large IOL size, which encourages formation of peripheral synechiae, may explain this. Furthermore, UBM findings from Li et al. have demonstrated that synechiae do form between the loop haptic and remnants of iris especially with the anterior movement of the IOL, which stabilizes the lens even in an abnormal position and acts as an additional anchoring point [11].

A limitation of this study is the retrospective nature, making it difficult to obtain data on endothelial cell count and UBM findings. However, unlike most published BDIOL series, it included a large cohort of patients with long term follow up period and various indications, which provides evidence to inform case selection and surgical decision making and supports using these lenses in selected cases.

In conclusion implantation of the Morcher® BDIOL, though surgically challenging, remains one of the best options for visual rehabilitation in patients with iris loss, providing anatomical, functional, and aesthetic benefits in carefully selected cases. We observed better results in cases of traumatic and iatrogenic aniridia and less good outcomes in congenital aniridia.

SUMMARY

What was known before

- Morcher black diaphragm intraocular lenses has been used for more than 3 decades however no long term data have been available in an ethnically diverse population.

What this study adds

- Our study provides detailed long term safety data of Morcher black diaphragm intraocular lenses in an ethnically diverse population and evaluated the visual outcome as well as short and long term issues related to these lenses.

DATA AVAILABILITY

Data are available upon request to the corresponding author.

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AUTHOR CONTRIBUTIONS

RB. and G.V contributed equally in the following: Data acquisition and interpretation, drafting and revising the manuscript to its final version. GV is the corresponding author and responsible for the submission of the manuscript and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. DGC was responsible for conceptualisation and design of the study, critically revising and approved manuscript's final version for submission. EY was responsible for data collection, statistical analysis and interpretation. ST was responsible for proposal submission to local ethics committee and data collection.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

Correspondence and requests for materials should be addressed to Georgios Vakros.