

Preliminary assessment of the safety and effectiveness of artificial iris implantation

Si-Yi Wang¹, Mi-Mi Liu², Xi-Le Li², Chao-Xiang Ge², Wei Chen¹, Zhen-Quan Zhao¹

¹National Clinical Research Center for Ocular Diseases, Eye Hospital, Wenzhou Medical University, Wenzhou 325027, Zhejiang Province, China

²Hainan Boao International Optometry and Ophthalmology Hospital, Qionghai 571442, Hainan Province, China

Correspondence to: Wei Chen and Zhen-Quan Zhao. National Clinical Research Center for Ocular Diseases, Eye Hospital, Wenzhou Medical University, Wenzhou 325027, Zhejiang Province, China. chenwei@eye.ac.cn; zzquan2004@126.com

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Abstract

• **AIM:** To preliminary explore the safety and effectiveness of artificial iris implantation.

• **METHODS:** Fourteen patients with iris defects who underwent artificial iris implantation at Hainan Boao Super Hospital from June 2020 to September 2021 were retrospectively analyzed for safety and effectiveness of the surgery by comparing the preoperative and postoperative best-corrected visual acuity (BCVA), intraocular pressure (IOP), corneal endothelial cell density (ECD), ocular axial length (AL), anterior chamber depth (ACD), patient satisfaction of photophobia and appearance improvement, and postoperative complications.

• **RESULTS:** The mean age was 37.21±14.85 (7-60)y, including 13 males and 1 female. The mean follow-up period was 4.64±2.32 (1-10)mo. The mean AL was 24.00±1.06 (21.68-25.58) mm. The postoperative mean anterior chamber depth measured was 4.07±0.75 (2.61-5.07) mm. The mean BCVA was 0.69±0.65 logMAR preoperatively and 0.46±0.60 logMAR at the last follow-up time ($P=0.36$). There was no significant differences in the IOP preoperative and postoperative (14.14±3.10 and 13.65±3.08 mm Hg, respectively, $P=0.69$). The preoperative ECD was 1674.09±566.11 per 1 mm², and the postoperative ECD was 1439.45±425.15 per 1 mm² ($P=0.21$). No obvious corneal opacity or corneal decompensation was observed in all patients. The preoperative and postoperative photophobia scores were 8.50±1.55 and 4.50±1.94, respectively ($P<0.05$), and the preoperative and postoperative appearance defect scores were 6.58±2.98 and 2.75±1.69,

respectively ($P<0.05$). Among the 14 patients, one had artificial iris displacement, two had a transient IOP rise after treatment of antiglaucomatous eyedrops. No complications were observed during surgery.

• **CONCLUSION:** The novel artificial iris material is safe, which can significantly improve the appearance defects and photophobia, improve the postoperative visual acuity to a certain extent. This surgery had a high patient satisfaction rate with few and controllable postoperative complications. At the same time, the artificial iris, with its diverse configurations, variable colors, arbitrary cutting, and various surgical procedures, fully realizes personalized treatment, which solves the clinical problem of iris defect.

• **KEYWORDS:** artificial iris; iris defect; eye trauma; pupil reconstruction

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INTRODUCTION

Iris defects are usually caused by trauma, but can also be seen in congenital, iridocorneal endothelial syndrome, and iatrogenic injuries. Iris defect not only affects aesthetics, but also leads to a decline in visual quality including vision loss, photophobia, glare, and declines in contrast sensitivity. Small iris defects can be repaired by sutures^[1-3]. Large defects need to be repaired by implanting the iris-intraocular lens septum, capsular tension ring-based prosthetic iris device, or by wearing colored contact lenses or sunglasses to improve the visual quality^[4-6]. But the material of previous implants is hard and requires larger incisions for implantation.

Artificial iris (HumanOptics ArtificialIris®, Human-Optics, Erlangen, Germany) is a foldable biocompatible silicone prosthesis, which was approved by the United States Food and Drug Administration (FDA) in May 2018. It has a 3.35 mm pupil, a total diameter of 12.8 mm, and a thickness ranging from 0.4 mm (the edge of the pupil) to 0.25 mm (the periphery). Due to the soft material, the artificial iris can be easily cut with scissors or trephine, and be implanted into the eye through a small

incision^[7]. The artificial iris can be placed either in the capsular bag or ciliary sulcus, or fixed to the sclera or residual iris by sutures. Artificial iris can be divided into two types: fibrous and non-fibrous. At the same time, the color of the artificial iris can also be customized according to the fellow eye or the residual iris, which will restore the appearance to the greatest extent. Recent research has delineated a novel type of retinomorphonic neuron, which emulates the structure and function of biological retinal neurons, employed for artificial vision and iris regulation. Findings suggest that this bioinspired neural morphology of artificial iris achieves automatic modulation of incoming light levels by leveraging the intensity information of light through electrochromic devices^[8].

Since the application of artificial iris, there have been many relevant researches abroad^[9-13], but China still lacks relevant reports. This study is the first the analysis of the application of artificial iris in the Chinese population. The purpose is to analyze the safety and effectiveness of artificial iris implantation, so as to provide a reference for clinical practice.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved by the Ethics Committee of Hainan Boao International Optometry and Ophthalmology Hospital and performed in accordance with the tenets of the Declaration of Helsinki. Written informed consents were obtained from all participants.

Participants Fourteen patients (14 eyes) with iris defect who underwent artificial iris implantation in Hainan Boao International Optometry and Ophthalmology Hospital from June 2020 to September 2021 were retrospectively analyzed.

Patients' pre- and postoperative data including best corrected vision acuity (BCVA), intraocular pressure (IOP), and corneal endothelial cell density (ECD), ocular axial length (AL), anterior chamber depth (ACD) were compared. BCVA was measured using a fractional visual acuity chart and converted into logMAR visual acuity, where postoperative visual acuity increased by 2 or more lines was considered as improved, decreased by 2 or more lines was considered as worsened, and visual acuity changes within 2 lines were considered as stable. IOP was measured with a non-contact tonometer. ECD was measured by corneal endothelial biomicroscopy. AL was measured with IOL Master-500. ACD was measured with ultrasound biomicroscopy (UBM). Anterior segment photography recorded the anterior segment before and after surgery. Photophobia symptoms and aesthetic appearance improvement were self-rated by patients: 0 being no photophobia/no cosmetic defect, and 10 being severe photophobia/marked appearance defect.

All operations in this study were performed by one surgeon. Based on the status of the iris defect, lens, and capsule, different surgical methods were used: 1) iris defect with

lens integrity: phacoemulsification combined with capsular tension rings and intraocular lens implantation and artificial iris (without mesh) implanted in the capsular bag; 2) focal iris defect with adequate capsule support: three-piece intraocular lens implanted in the capsular bag with artificial iris (without mesh) implanted in the ciliary sulcus; 3) large iris defects with adequate capsule support: three-piece intraocular lens implanted in the capsular bag with artificial iris (without mesh/with mesh) scleral suture fixation; 4) aniridia and capsule defect: scleral suturing of the intraocular lens and artificial iris (without mesh/with mesh), respectively or the artificial iris-intraocular lens complex.

In this study, SPSS 22.0 was used for statistical analysis, and *t*-test was used to analyze the difference between pre- and postoperative results. $P < 0.05$ was considered statistically significant.

RESULTS

Among 14 patients 13 were males and 1 female, the mean age was 37.21 ± 14.85 (7-60)y, and the mean follow-up time was 4.64 ± 2.32 (1-10)mo. The cause of iris defect was trauma in all patients. The mean period of time from injury to surgery was 11.5 ± 13.49 (5-24)mo, and the mean number of operations before artificial iris surgery was 2.07 ± 0.96 (1-4). The mean AL was 24.00 ± 1.06 (21.68-25.58) mm. Given that our patient cohort predominantly consists of individuals without crystalline lenses and with extensive iris defects, preoperative ACD measurements were not taken, the postoperative mean ACD measured was 4.07 ± 0.75 (2.61-5.07) mm. Nine patients were aphakic, three were pseudophakic, and two were phakic. In terms of surgical methods, phacoemulsification combined with artificial iris implantation in the capsular bag in 2 cases, artificial iris scleral fixation in 3 cases, artificial iris scleral suture fixation after intraocular lens implantation in 1 case, and artificial iris-intraocular lens complex scleral suture fixation in 8 cases. Basic information of the study subjects was summarized in Table 1.

The preoperative and postoperative BCVA of the patients were 0.69 ± 0.65 and 0.46 ± 0.60 , respectively ($P = 0.36$). Among them, 6 patients had improved visual acuity, 7 patients had stable visual acuity, and 1 patient had worsened postoperative visual acuity. The preoperative and postoperative mean intraocular pressures were 14.14 ± 3.10 and 13.65 ± 3.08 mm Hg, respectively ($P = 0.69$). Eleven patients had ECD before and after operation, which were 1674.09 ± 566.11 and 1439.45 ± 425.15 per mm^2 , respectively ($P = 0.21$), two patients could not detect ECD due to corneal scar, and one patient did not undergo ECD examination before operation. Twelve of 14 patients participated in the scoring of photophobia and appearance changes before and after surgery. The photophobia scores preoperative and postoperative were 8.50 ± 1.55 and 4.50 ± 1.94 ,

Table 1 Basic information of the study subjects

Items	Data
No. of subjects	14
Age, y	37.21±14.85
Gender	
Male	13
Female	1
Iris defects cause, traumatic	14
AL, mm	24.00±1.06
Postoperative ACD, mm	4.07±0.75
Time between diagnosis and surgery, mo	11.5±13.49
Follow-up time, mo	4.64±2.32
Surgeries before artificial iris implant, times	2.07±0.96

SD: Standard deviation; AL: Axial length; ACD: Anterior chamber depth.

respectively ($P<0.05$), and the appearance defect scores were 6.58 ± 2.98 and 2.75 ± 1.69 , respectively ($P<0.05$). The preoperative and postoperative clinical information of the patients was summarized in Tables 2 and 3, Figure 1.

Among the 14 patients in this study, one patient had artificial iris dislocation after surgery, and underwent artificial iris reposition. Two patients had transient IOP increase after operation, after using antiglaucomatic medications, their IOP gradually stabilized and became normal at the last follow-up. During the follow-up period, no retinal detachment, intraocular hemorrhage, macular edema and other complications were found in all patients. No intraoperative complications occurred in all patients.

DISCUSSION

The management of artificial iris in patients with aniridia or iris defect represents a major advance^[14]. This study is the first for analyzing the safety and efficacy of the artificial iris implantation in China.

In our study, postoperative BCVA improved compared with preoperative ones, which may be related to pupillary reconstruction, reduced glare, increased depth-of-field, and increased contrast sensitivity^[15-16]. Previous articles had reported the same results^[12,17]. However, Bonnet and Miller^[18] showed that 30% of the cases had different degrees of visual acuity loss at 1y after surgery, which may relate to the preoperative ocular disease, such as glaucoma and corneal endothelial decompensation, repeated intraocular hemorrhage, etc. In our cases, one patient had decreased postoperative visual acuity, and this patient had corneal scarring due to trauma, and corneal scarring may have contributed to the decreased visual acuity. Therefore, patients should be fully informed before surgery that their preoperative comorbidities may continue to develop after surgery, may limit visual recovery and cause potential postoperative complications.

In previous reports, IOP increased in some patients after

Table 2 Clinical information

Items	Preoperative	Postoperative	P ^a
BCVA (logMAR)	0.69±0.65	0.46±0.60	0.36
IOP (mm Hg)	14.14±3.10	13.65±3.08	0.69
ECD (per mm ²)	1674.09±566.11	1439.45±425.15	0.21
Photophobia scores	8.50±1.55	4.50±1.94	<0.05
Appearance defect scores	6.58±2.98	2.75±1.69	<0.05

^aPaired *t* test. *P* value relates to the difference between preoperative and postoperative results. BCVA: Best-corrected visual acuity; IOP: Intraocular pressure; ECD: Corneal endothelial cell density.

artificial iris surgery, and the incidence was about 8.8%-21.9%^[12-13,18], and the proportion of glaucoma requiring surgical treatment was 3.9%-9%^[7,13,17]. Rickmann *et al*^[17] found that all postoperative glaucoma cases were those implanted with fibrous mesh artificial iris. It was proposed that after the fibrous mesh artificial iris was cut by trephine, sharp polymer fibers may expose from the cutting edge which may stimulate the surrounding tissue and cause glaucoma. Among the cases reported by Mayer *et al*^[13], one patient developed glaucoma due to pigment dissemination syndrome, which may also be related to the stimulation of the pigmented membrane by the artificial iris. Therefore, the application of artificial iris without mesh or a slightly reduced size of a tailored artificial iris may be beneficial in reducing the incidence of glaucoma. Figueiredo and Snyder^[19], in a follow-up study of patients with congenital aniridia who underwent artificial iris implantation for over 6mo, discovered that 26.6% of patients without preoperative glaucoma diagnosis developed glaucoma postoperatively, and 53.1% of glaucoma cases progressed. However, this study lacked a control group, making it inconclusive whether elevated IOP is associated with artificial iris implantation. In our cases, there was no significant change in IOP before and after surgery. Two patients had transient IOP increase postoperative, and the IOP returned to normal after antiglaucomatic medicals treatment. The UBM of these 2 patients was analyzed, and the artificial iris was in contact with the residual iris in 1 patient. The increase in IOP in this patient may be related to the transient inflammatory reactions caused by the artificial iris stimulation to the surrounding tissue. The other patient, preoperative UBM showed partial angle closure, which may be caused by trauma. Long-term changes in IOP still need further observation.

A significant decrease in ECD was observed in the articles of Mayer *et al*^[12], Bonnet and Miller^[18]. Ayres *et al*^[20] conducted a one-year postoperative observation of 447 eyes implanted with artificial iris. At 6 and 12mo postoperatively, the overall study population showed average percentage changes in ECD of 0.84% and -6.36%, with median changes of -5.33% and -7.18%, respectively. These rates of change were significantly lower than the reported 13.9% ECD loss rate in combined

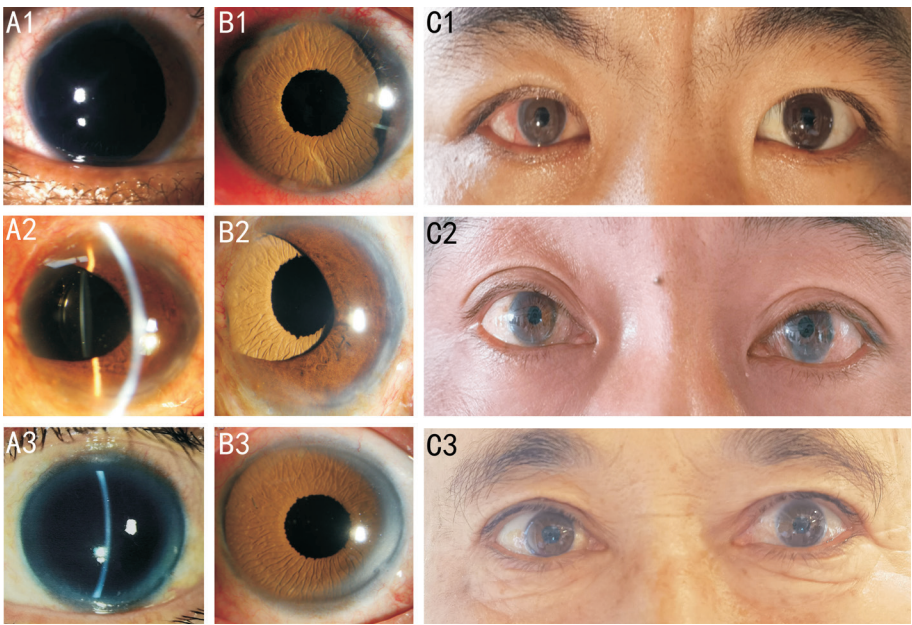


Figure 1 Anterior segment photograph before and after surgery in 3 patients A: Preoperative photograph; B: Postoperative photograph; C: Local appearance after the operation.

Table 3 Clinical information of each patient

Patients	BCVA (logMAR)		IOP (mm Hg)		ECD/mm ²	
	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
1	0.52	0.52	14.0	12.9	1367	2111
2	0.00	0.00	19.5	9.6	NA (not detect)	1691
3	0.15	0.05	18.8	20.4	2399	2399
4	0.22	0.10	11.1	8.2	1159	887
5	1.00	0.80	8.8	12.1	2594	1335
6	0.60	0.05	18.0	12.1	1307	1220
7	0.40	0.10	11.3	12.7	1392	1283
8	2.80	0.22	14.0	11.1	1435	1110
9	0.70	0.70	17.0	19	NA (cornel scar)	NA (cornel scar)
10	0.80	0.05	12.4	15.6	2356	1321
11	0.80	2.30	11.7	14	NA (cornel scar)	NA (cornel scar)
12	1.00	0.70	13.1	15.8	754	1135
13	0.40	0.30	15.7	15.6	2113	1498
14	0.30	0.22	12.5	17.6	1539	1535

NA: Not applicable; BCVA: Best-corrected visual acuity; IOP: Intraocular pressure; ECD: Corneal endothelial cell density.

cataract extraction and pars plana vitrectomy procedures^[21]. Other articles reported that the ECD damage after artificial iris surgery were 11.3%-16%^[22-23]. In our study, the postoperative ECD of the patients decreased compared with the preoperative ones, but without statistically significance, which may be related to the small number of cases. In our cases, the cause of the iris defects was ocular trauma and all had a history of intraocular surgery before artificial iris implantation. Both ocular trauma and intraocular surgery can lead to damage to the corneal endothelium, and artificial iris surgery may cause further damage to the corneal endothelium. Therefore, it is important to evaluate the corneal endothelium before surgery. During follow-up, the corneal transparency of the patients did

not change significantly, however, in other reports^[13], 9.8% of cases required surgical treatment of corneal opacity. Therefore, we still need long-term follow-up observation of the corneal status of the patients. Ang and Tan^[24] performed artificial iris implantation followed by Descemet membrane endothelial keratoplasty in five patients with bullous keratopathy and iris defects. During the 6-month to 1-year follow-up period, all grafts remained transparent at the final visit, with a decrease in mean central corneal thickness, suggesting favorable outcomes of repeat endothelial transplantation post artificial iris implantation. However, due to the small sample size and short follow-up duration, larger prospective studies are needed for further observation. Mayer *et al*^[25] conducted triple

surgery involving artificial iris, intraocular lens, and corneal transplantation in seven patients. Postoperative visual acuity improved, and IOP remained stable, indicating the safety and efficacy of triple surgery to some extent while reducing damage to the corneal margin from multiple surgeries. Nevertheless, due to the small sample size, short follow-up duration, and lack of measurements such as corneal endothelial cell counts, larger sample sizes and longer-term follow-up are still necessary.

According to self-score statistics, photophobia symptoms were significantly improved after artificial iris implantation and the postoperative appearance satisfaction was also significantly increased. In order to achieve the best cosmetic appearance, the artificial iris can be made separately with the colors according to the fellow eye^[26]. The pupil diameter of the artificial iris is 3.35 mm, which effectively reduces the pupil size^[12] and the amount of entering light, thereby reducing the clinical effect of photophobia symptoms. Mayer *et al*^[12] investigated patients' satisfaction with artificial iris surgery, and the results showed that patients were satisfied with postoperative photophobia and appearance improvement, and all patients expressed their willingness to undergo the same surgery. Khan *et al*^[27] conducted a mean follow-up of 56.5mo on 4 patients (5 eyes) who underwent artificial iris implantation. Among them, 80% of the eyes showed significant improvement in glare symptoms, with notable alleviation of pain and discomfort. While this study had a long observation period, its limitations include a relatively small sample size. Ayres *et al*^[20] using the NEI VFQ-25 scoring system, assessed patient symptoms at 12mo postoperatively and found a significant decrease in severe daytime photosensitivity by 59.7%, significant to severe nighttime photosensitivity reduced by 41.5%, significant to severe daytime glare reduced by 53.1%, and severe nighttime glare reduced by 48.5%. The overall score improved by 15.4 points, and through the Global Aesthetic Improvement Scale, 93.8% of patients showed cosmetic enhancement, indicating that artificial iris implantation yields favorable improvements in photophobia and glare symptoms, with excellent cosmetic outcomes.

During the follow-up, one patient had artificial iris displacement after surgery, and the artificial iris was incarcerated on the surface of the residual iris. According to previous reports^[13,20], artificial iris displacement and decentrations occurred in about 2.5%-5.9% and 1.8% of patients, respectively, ranging from 2d to several months after surgery. Mayer *et al*^[28] indicated that residual iris constriction syndrome may occur after artificial iris implantation, possibly because the residual iris is clamped in the gap between the artificial iris and the anterior chamber angle, preventing further pupillary shrinkage, another cause may be the shrinkage or atrophy of the residual iris, which leads to the displacement of the artificial iris. Considering

the possibility of the artificial iris incarcerated on the iris surface causing pigment dissemination, secondary glaucoma, and corneal endothelial damage, we performed artificial iris reposition surgery for this patient, and suture reinforcement was performed at the incarcerated iris position. During the follow-up time, the position is stable.

The literatures also report other postoperative complications, including macular cystoid edema, retinal detachment, chronic anterior chamber inflammation, corneal decompensation, autologous iris damage, central retinal vein occlusion, and cataracts^[20,29]. However, in our study, we did not observe the aforementioned complications, possibly due to our relatively small sample size and short follow-up duration. Additionally, our study did not involve artificial iris implantation in phakic eyes.

In conclusion, this study is the first on the artificial iris implantation in the China. The results showed that the operation has good efficacy and safety, artificial iris could significantly improve the appearance and reduce photophobia symptoms, and can improve the vision acuity to a certain extent. Patients were satisfied with this surgery, postoperative complications were fewer and controllable. However, there are still many limitations in our study. First, the sample size is small. Second, the observation and follow-up time is short, and long-term postoperative complications cannot be evaluated. Furthermore, since this study is retrospective in nature, additional randomized prospective studies are warranted to confirm these results.

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