Keratopigmentation (corneal tattooing) for the management of visual disabilities of the eye related to iris defects

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ABSTRACT

Aim To investigate the functional and cosmetic outcomes of keratopigmentation (KTP) in cases of moderate to severe visual dysfunctions owing to different iris disorders.

Methods 11 eyes with moderate to severe visual disabilities related to iris defects underwent KTP for functional and cosmetic restoration using micronised mineral pigments and assisted with modern technologies such as femtosecond laser and new automated keratopigmentation instruments for the intrastromal and superficial application of the pigments.

Results Following the KTP surgery, the visual-function-related symptoms improved in all cases, from significant improvement to total elimination. Eight patients were asymptomatic after the surgery. In two patients, minimal non-disabling symptoms remained after surgery. One patient with traumatic aniridia complained of significant residual glare at the 3-month postoperative visit and was reoperated to reduce the simulated pupil to 4 mm. The cosmetic outcomes were analysed and classified as excellent in eight patients and good in three.

Conclusion KTP using new micronised mineral pigments and new surgical protocols has proven in this series to be an effective surgical technique for the management of moderate to severe visual dysfunctions related to iris defects.

INTRODUCTION

Keratopigmentation (KTP) has been practised for cosmetic purposes for many years,[1–5] but only recently some scientific reports have confirmed successful outcomes with KTP using modern micronised mineral pigments[1] rather than with other now obsolete and usually transitory and potentially toxic methods of corneal staining.[6] However, the use of KTP has rarely been reported for the functional correction of visual and light disabilities such as monocular diplopia, severe glare or photophobia caused by total or partial iris defects.[7–10]

Since the initial use of this technique,[3 7] very few scientific papers published on the use of KTP have dealt with the subject of cosmetic eye disabilities.[1–5] The use of KTP for visual functional purposes has been very scarce and limited to only a few case reports.[7–9] Such reports indicate the potential role that KTP may have in the management of visual dysfunctions related to iris defects such as traumatic aniridia, either total or partial, large iris defects and colobomas, iridodialysis, iris atrophies consecutive to trauma or anterior segment surgery, inadequately performed peripheral iridectomies and even congenital defects such as albinism or essential iris atrophy. KTP could be highly beneficial in these difficult cases, as it is a less invasive technique than intraocular procedures[11 12] and may provide advantages for the practical surgeon owing to its reduced cost and potential accessibility.

In this study, we report, to the best of our knowledge, the first systematic clinical series of cases with 11 patients affected by different degrees of functional light disabilities caused by moderate to severe iris defects. The purpose of this study is to demonstrate that KTP practised with new micronised mineral pigments and assisted with modern surgical technologies such as femtosecond laser and new automated keratopigmentation instruments for the intrastromal or superficial application of the pigments may be a very effective and relatively simple alternative in the treatment of moderate to severe visual disabilities related to iris defects.

PATIENTS AND METHODS

The purpose of this study is to investigate the functional and cosmetic benefit obtained by KTP in cases of moderate to severe visual dysfunctions owing to different iris disorders. For this purpose, different original micronised mineral pigments and new specific KTP techniques have been used, including manual intralamellar keratopigmentation (MIK), femtosecond assisted keratopigmentation (FAK) and superficial automated keratopigmentation (SAK).

Study design

Prospective, interventional, consecutive, non-randomised, non-comparative series of cases.

Patients

Eleven eyes of 11 patients, six women and five men, underwent KTP for moderate to severe visual function disabilities related to different types of iris defects and pupil abnormalities.

The tenets of Helsinki declaration (Tokyo 2004) were followed in this study. Adequate informed consent was signed for each patient for this investigation. Ethical Board Committee approval was obtained for the study.

Selection of patients: inclusion and exclusion criteria

Only patients with functional visual disorders related to different types of iris defects were included in this investigation (table 1). In all cases, the iris defect resulted in moderate to serious visual impairment. The selected cases included traumatic aniridia, large iris defects and colobomas, iridodialysis, iris atrophies, symptomatic peripheral iridectomy and congenital or evolutive iris defects. In all

Table 1 Summary of clinical data of 11 patients with functional visual disorders

No	Sex	Age (years)	Diagnosis	Visual complain	Keratopigmentation technique	Visual acuity preoperatively	Visual acuity postoperatively	Follow-up (months)
1	F	32	Traumatic aniridia	Photophobia	MIK	0.7	0.7	12
2	M	29	Intractable diplopia	Double vision	MIK	1.0	0.8	12
3	F	36	Peripheral iridotomy	Photophobia	MIK	1.0	1.0	12
4	F	23	Irido corneal endothelial syndrome	Photophobia monocular diplopia	FAK	0.8	1.2	6
5	F	58	Traumatic aniridia	Photophobia	MIK+SAK	0.3	0.5	12
6	F	59	Traumatic aniridia	Glare	MIK	0.4	0.4	12
7	M	30	Traumatic coloboma	Debilitating glare	MIK	0.9	0.9	12
8	M	43	Traumatic aniridia and corectopia	Glare	MIK	0.4	0.5	12
9	M	33	Traumatic iris atrophy and coloboma	Photophobia	MIK	0.8	0.8	12
10	M	33	Atrophic, dilated and areflexic iris	Photophobia	FAK+SAK	0.1	0.1	3
11	F	36	Traumatic aniridia	Incapacitating glare and polyopia	MIK	0.5	0.5	12

FAK, femtosecond assisted keratopigmentation; MIK, manual intralamellar keratopigmentation; SAK, superficial automated keratopigmentation.

these cases, other conservative measures, including cosmetic contact lenses, were previously tried without success.

Cases with chronic intraocular or ocular surface inflammation, painful eyes, corneal opacities or cases with very limited visual potential were excluded from the investigation. Before and after the surgery, an adequate evaluation protocol was used to quantify both the functional and the cosmetic disability changes perceived by the patients following KTP (table 2). The cosmetic appearance was also adequately evaluated by an ophthalmological examiner before and after the KTP procedure (table 2).

Keratopigmentation surgery

Pigments

For this study, mineral micronised pigments (Salvador Cordoba SL, Madrid, Spain) were used (Spanish Ministry of Health Registration No 280-PE and 281-PE).

All KTP procedures were performed by the same experienced surgeon (JLA). Different techniques were used depending on the case. The postoperative follow-up visits were performed by a different independent observer at VISSUM Corporation, Alicante, Spain.

Surgical techniques

Manual intralamellar keratopigmentation

The centre of the cornea was marked with a calliper and the pupil size diameter determined by an optic zone marker of 3, 3.5, 4 or 4.5 mm (Pupil KTP markers set, Epsilon, Irvine, California). Radial incisions were performed from the limits of the mark, one or two free-hand, with a diamond blade calibrated at 40–50% of the pachymetric value measured with ultrasonic pachymetry. The marked pupil matched the low mesopic pupil diameter of the contralateral eye, estimated with a Holladay gauge or an infrared pupillometer (Procyon, Bausch & Lomb Surgical, Rochester, New York).

From such radial incisions, the cornea was dissected intralamellarly and circularly at the same depth with a corneal dissector (KTP corneal spiral dissector, Epsilon, Irvine, California). The number of incisions and size of dissection were variable depending on the condition and defect size of the iris. The appropriate colour, previously prepared for the purpose, was injected with a 27-gauge flat cannula into the dissected corneal areas until the adequate colour of the simulated iris was achieved.

1-B femtosecond assisted keratopigmentation

Two patients from the 11 were treated with KTP assisted by femtosecond laser FAK. Total circular tunnels of 9.5 mm external and 4.5 mm internal diameters and one superior 90° radial 4 mm incision were performed 250 μm from the corneal surface with a 60 kHz femtosecond laser, with an energy of 2 μJ (IntraLase, Irvine, California). The adequate eye colour used in each case was injected through one superior incision.

Table 2 Visual disability and cosmetic evaluation before and after surgery

No	Diagnosis	Visual disability (preop)	Visual disability (postop)	Cosmetic observer evaluation (postop)	Cosmetic patient satisfaction (postop)
1	Traumatic aniridia	3	0	3	3
2	Intractable diplopia	3	0	3	3
3	Peripheral Iridotomy	3	0	3	2
4	Irido corneal endothelial syndrome	4	0	3	3
5	Traumatic aniridia	4	1	2	2
6	Traumatic aniridia	2	0	3	2
7	Traumatic coloboma	2	0	2	3
8	Traumatic aniridia and corectopia	3	1	2	3
9	Traumatic iris atrophy and coloboma	2	0	3	3
10	Atrophic, dilated and areflexic iris	4	2	3	3
11	Traumatic aniridia	2	0	3	3

Visual disability (pre-postoperative): 0, no symptoms; 1, minimal: not disabling, perform normal life; 2, moderate: disabling and bothersome; 3, important: disabling, unable to perform daily activities without occluding eye; 4, very important: very disabling, unable to keep the eye opened and driving at night is difficult. Cosmetic observer's evaluation (postoperative): 1, poor: unacceptable aesthetic aspect or very different to the fellow eye; 2, good: symmetrical aspect compared with the fellow eye and very acceptable cosmetically; 3, excellent: excellent aspect cosmetically and excellent symmetry compared with the fellow eye. Cosmetic patient's satisfaction (postoperative): 1, unhappy or poor; 2, happy or very good; 3, very happy or excellent.

1-C superficial automated keratopigmentation

Some cases underwent superficial corneal staining when the intralamellar staining was not sufficient to provide an adequate cosmetic appearance. In these cases, superficial corneal staining was performed using a punctural device prototype (Vissum Eye MP System, Madrid, Spain; Apl No 2.949.539). Different parameters and tips were used according to each individual case.

Automatic micropunctures were performed down to the superficial layers of the stroma to an approximate depth of 120 μm from the corneal surface. The manoeuvre was repeated until the adequate amount of micronised pigment was visually presented in the superficial cornea to achieve an acceptable cosmetic appearance. The penetration depth of the needles was controlled by adjusting the axial length of the needle used. This adjustment is performed by the fine calibration of the needle penetration length, increasing or decreasing the vibration speed and period of the vibration of the tip.

Postoperative treatments

Postoperative topical therapy included topical antibiotic eye-drops (Ofloxacin 0.3%, Exocin, Alcon, Forth Worth, Texas) four times daily and a steroid (Dexamethasone 0.1%, Maxidex, Allergan, Irvine, California) for 2 weeks. Cyclopentolate 1% (Colircusi Ciclopleji co, Alcon Cusí, Barcelona, Spain) drops were used every 8 h for the initial postoperative.

Follow-up and main outcome measures

A follow-up period of 12 months after the surgery was performed. The patients were examined on the first post-operative day, and then 1 week, 1 month, 3 months, 6 months and 1 year after surgery by an independent observer. All but two patients completed the entire follow-up period. One patient was followed up for 6 months, and one patient was revised for the last time 3 months after the surgery.

The main outcome measures of the study were a subjective improvement in the functional visual disabilities related to the iris defect and patient's and observer's cosmetic satisfaction.

RESULTS

Eleven eyes of 11 patients, six women and five men, with a mean age of 37 years were included in this study.

In table 1 the data of the patients included in the study are shown. Five patients had traumatic aniridia either total or partial, two patients traumatic coloboma, one patient symptomatic peripheral iridectomy, one patient atrophic and fixed dilated iris, one patient severe iridocorneal endothelial syndrome with irregular pupil and polycoria, and one patient intractable monocular diplopia.

Following the KTP surgery, the visual-function-related symptoms improved in all cases, from a significant improvement to total elimination of symptoms. No patient lost any line of visual acuity, and no significant complications such as inflammation or pain were observed in any patient during the follow-up period.

Table 2 shows the evaluation protocol for the postoperative functional symptoms of the 11 patients. The cosmetic appearance was qualified as good to very good by all patients.

Eight patients were asymptomatic after the surgery. In two patients, minimal non-disabling symptoms remained after surgery. One patient with total traumatic aniridia complained of significant residual glare at the 3-month postoperative visit and was reoperated to reduce the simulated pupil to 4 mm.

The cosmetic results as analysed by an independent observer were classified as excellent in eight patients and good in three. No patient was considered as having poor or unacceptable aesthetic appearance (table 2). Such results correlated well with the patient's subjective opinion on the cosmetic outcome. In all cases after the surgery, the examiner was able to explore the angle and examine the peripheral retina.

Summary of some clinical cases

- A 30-year-old male patient complained of debilitating glare and poor vision related to traumatic iris defects. An anterior-chamber pseudophakic intraocular lens (IOL) had been implanted previously to solve the problem of traumatic aphakia. An iris coloboma loss of 4 h was observed (figure 1A). MIK was performed, and the patient reported a very significant decrease in glare and improvement in vision quality in the keratopigmented eye (figure 1B–D). A refractive change of 1.5 D was observed as permanent in this patient and stable during the follow-up.
- A 36-year-old female patient was referred to our clinic due to epithelial iris cyst which developed following phakic IOL implantation. Two attempts of intracyst mitomycin injection were unsuccessful (figure 2A). Sector iridectomy and iris suturing of the peripheral pupil edges were performed. The patient was complaining of polyopia and incapacitating glare, and was unable to function with this eye probably especially at night while driving (figure 2B). Sectorial KTP with adequate mineral micronised pigment was selected and prepared.

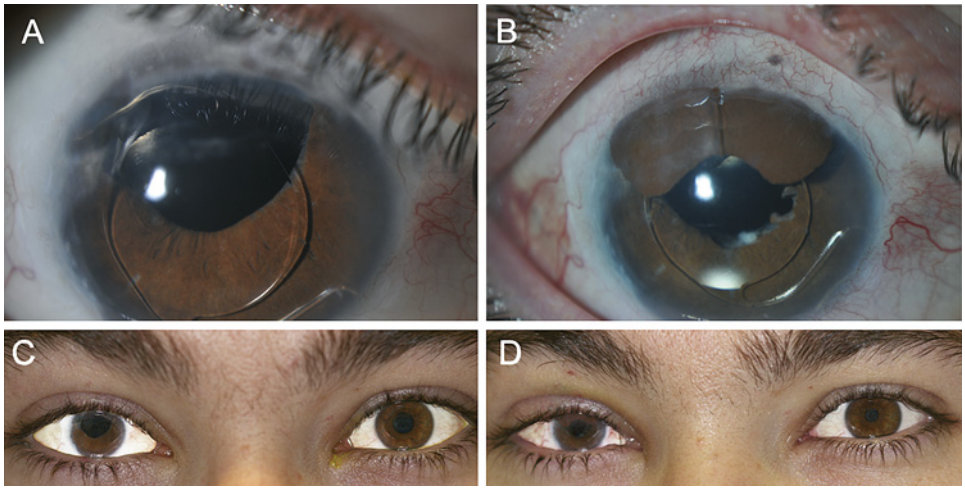

Figure 1 Pre- and postoperative slit-lamp examination of selected patients. (A, C) Preoperative aspect of the patient complaining of debilitating glare owing to traumatic coloboma. (B, D) Postoperative appearance after restoration of the iris defect with manual intralamellar keratopigmentation. A significant decrease in glare was reported by the patient.

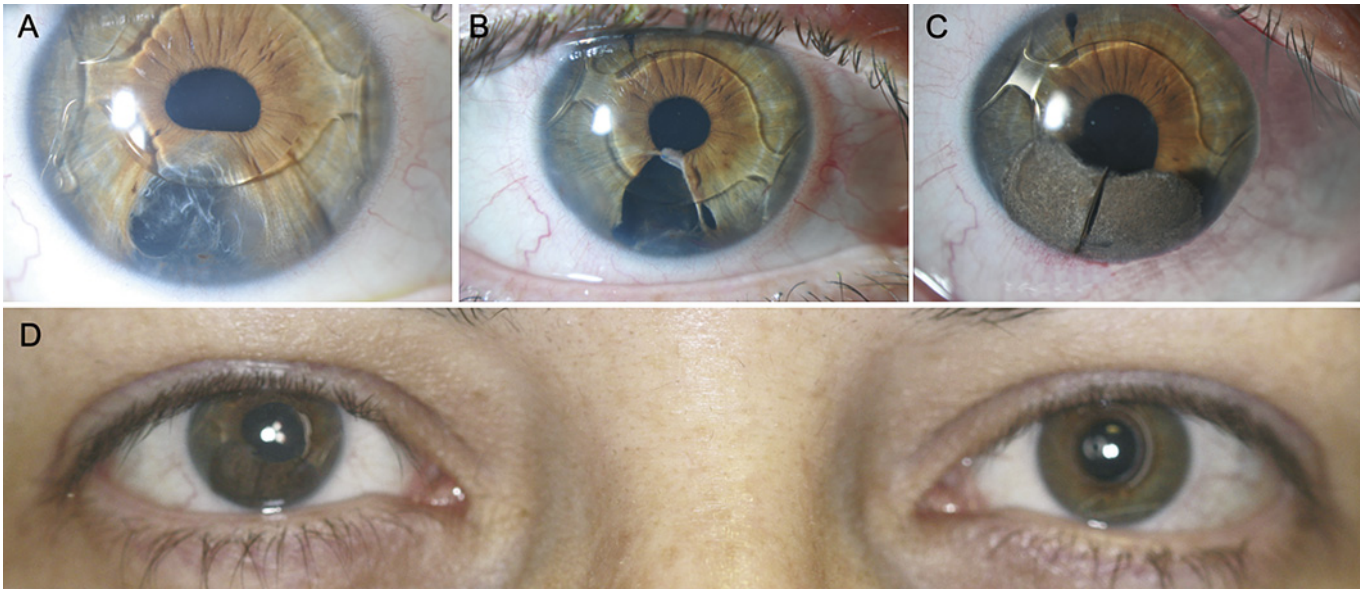

Figure 2 Patient's iris defect secondary to epithelial iris cyst in her right eye. (A) Aspect of the eye after two unsuccessful attempts of intracyst mitomycin injection. (B) Aspect of the eye after sectorial iridectomy and iris suturing of the peripheral pupil edges. The patient complained of polyopia and incapacitating glare. (C, D) Postoperative aspect of the patient after manual intralamellar keratopigmentation.

Radial 4.5 mm incision at the centre down to the inferior limbus was performed. The cornea was dissected using a lamellar dissector (KTP corneal spiral dissector, Epsilon). Mixed pigments were introduced using 27 G cannula. Following the procedure, total elimination of the symptoms was achieved, and an excellent cosmetic result was reported both by the patient and by the observer (figure 2C,D).

- A 33-year-old man was referred to our clinic with history of trauma in his left eye due to a work accident. The patient showed an atrophic fixed dilated iris. This eye had been previously implanted with a phakic angle supported IOL owing to myopic anisometropia. The patient was suffering from severe photophobia and decreased vision (figure 3A). A complete corneal iris simulation was performed with FAK, and completed with SAK to achieve the adequate cosmetic appearance. Total disappearance of the photophobia and improvement in vision with a very good cosmetic appearance were achieved (figure 3B–D).
- A 36-year-old female patient was suffering from monocular diplopia at night following the implantation of a posterior chamber phakic IOL (ICL Saar, Monrovia, California) to correct high myopia. An inadequately performed peripheral iridotomy was the cause of the symptoms. A MIK procedure was indicated at the area of the iridectomy. Total disappearance of the symptoms were achieved at the postoperative (figure 4).

DISCUSSION

Although several series using KTP for cosmetic purpose in blind eyes with leucomas have been reported,[1–5] only a few clinical cases have been described concerning the use of KTP for correction of visual disability of the eye related to iris and pupil defects.[7–10] These defects may result in intolerable glare and photophobia, which may effectively impair visual function. To the best of our knowledge, this is the first systematic, interventional, consecutive study using KTP as a surgical tool for the management of functional visual problems related to iris defects. We have used different surgical techniques for this purpose, including femtosecond, new surgical KTP instruments and automated punctural techniques.

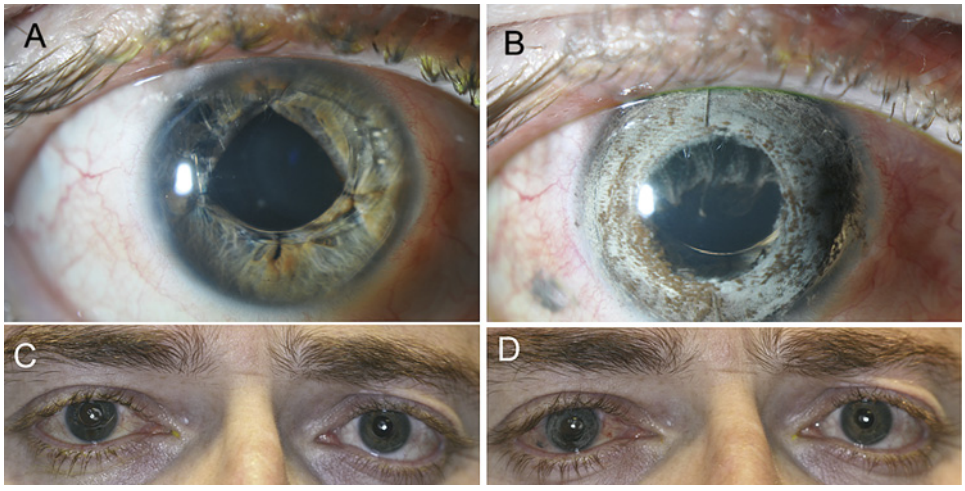

Figure 3 (A, C) Preoperative aspect of a patient complaining of severe photophobia owing to atrophic and dilated, areflexic iris caused by a trauma in his left eye. (B, D) Postoperative aspect of the same patient. A complete corneal iris simulation was performed with femtosecond assisted keratopigmentation and completed by superficial automated keratopigmentation. Total disappearance of the photophobia and improvement in vision was reported.

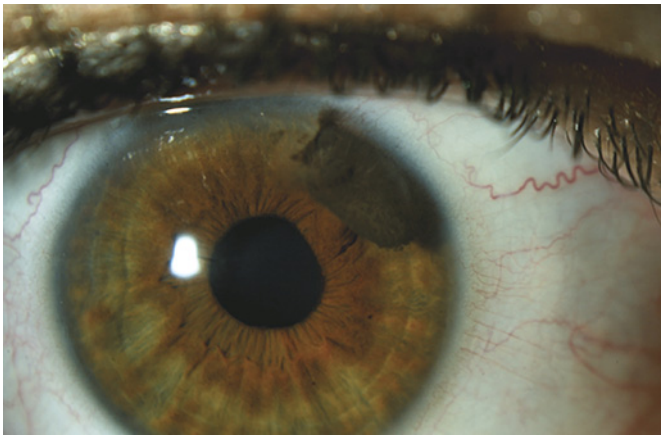

Figure 4 Postoperative slit-lamp examination of a patient suffering from monocular diplopia at night following the implantation of a posterior chamber phakic intraocular lens owing to an inadequately performed peripheral iridotomy. A manual intralamellar keratopigmentation procedure was indicated at the area of the iridectomy. Total disappearance of the symptoms was achieved.

Even though femtosecond lasers have been previously reported for KTP purposes,[13 14] femtosecond technology has never been used before for the purpose of KTP for visual functional disorders related to iris defects. Different intraocular alternatives have been described for the correction of iris defects, but they showed intraoperative or postoperative complications. Iris reconstruction should be considered as an invasive and difficult surgery, particularly when the defect is highly irregular and atrophied, and it might be impossible to obtain an adequate central and circular pupil. Prosthetic iris implantation and diaphragm intraocular lens have been reported as surgical solutions for iris defects.[11 12] However, these are not desirable choices, as the surgery is often technically challenging owing to the ocular abnormalities associated with traumatic iris defects requiring more aggressive surgery and lens or cataract removal.

The modern KTP techniques described here may allow the surgeon to obtain adequate cosmetic and functional outcomes with less invasiveness. The use of new adequately studied micronised mineral pigments with experimental evidence on their tolerance and toxicity[6] presents an additional advantage over other natural pigments because their particle size is reduced by micronising procedures. The small particle size diminishes the chance of developing a foreign-body reaction against the pigment intruding into the corneal stroma.[6] The new keratopigmentation technique through femtosecond technology allows the surgeon to plan different ways of customised corneal management through its flexible software which resulted in precise and uniform thickness of KTP. This later use of femtosecond laser in KTP had been mentioned as a novel technique[13 14] but still is not gaining in popularity owing to the relatively high expense of the femtosecond, which limits its availability in all ophthalmic hospitals. SAK may provide the surgeon with a better way of controlling the colour and the cosmetic appearance. MIK has also been shown to be effective in the solution of partial iris defects.

CONCLUSION

KTP using new micronised mineral pigments and new surgical protocols has proved in this series to be an effective surgical technique for correcting visual dysfunctions related to iris defects. KTP is minimally invasive and results in a significant decrease in the subjective glare and photophobia, and even in monocular diplopia in all cases. The cosmetic outcome was also very favourable. These techniques may allow the surgeon to correct the visual disabilities associated with iris defects in a new, more accessible way, thus avoiding more aggressive intraocular procedures.

Competing interests None.

Patient consent Obtained.

Ethics approval Ethics approval was provided by CEIC Vissum Corporation.

Contributors All authors were actively involved with the planning of the study, data acquisition and analysis, planning and writing the paper.

Provenance and peer review Not commissioned; externally peer reviewed.

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