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Corneal tattooing (keratopigmentation) with new mineral micronised pigments to restore cosmetic appearance in severely impaired eyes

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ABSTRACT

Aim To investigate keratopigmentation (KTP) with new mineral micronised pigments as a surgical alternative to improve cosmetic appearance in severely impaired eyes.

Methods 40 eyes underwent KTP alternatively to invasive cosmetic reconstructive surgery. Corneal staining with mineral micronised pigments was performed using an intralamellar or superficial technique.

Results One year postoperatively, all but two patients (95%) were satisfied. Pigmented eyes were improving patient's appearance. Eight cases needed a second KTP. Two patients with preoperative corneal oedema did not obtain an adequate cosmetic appearance due to progressive pigment clearance observed from 6 months postoperatively. Three eyes with traumatic aniridia observed good cosmetic outcome and a significant reduction in glare.

Conclusions KTP achieves good cosmetic results and is associated with high patient satisfaction, avoiding extensive and mutilating reconstructive surgery.

INTRODUCTION

Corneal tattooing has been used for cosmetic treatment of corneal opacities for centuries.^{1,2} Galen (AD 131–210) is considered to be the first to pigment the human cornea, using reduced copper sulfate to mask a corneal leucoma.^{3–5} Afterwards, keratopigmentation (KTP) gained limited popularity due to a variety of reasons. Various chemical products such as Indian ink, metallic powders, organic colours, animal uveal pigment, Chinese ink, gold and platinum chloride and even soot were used. To obtain different shades, surgeons experimented with different combinations of such chemical products. The main problem affecting the outcome of previous KTP studies was the fading of colours, which made the results inconsistent over time.⁵ Probably because of these reasons, in using this technique to improve the appearance of cosmetically disabled eyes^{5,6} and even normal-sight eyes,⁷ KTP has been used only occasionally, and very few scientific reports on its effectivity and stability are available.^{8–10}

Cosmetic contact lenses, enucleation or evisceration with orbital prosthesis are the most frequently used methods to improve the aesthetic appearance in cosmetically unacceptable, disabled eyes.^{11–13} However, disabled eyes frequently have contact lens intolerance,¹¹ and prostheses often cause inflammation and infection.¹⁴ Penetrating keratoplasty (PK) carries risks of infection and graft rejection, and its use for cosmetic purposes is ethically unacceptable in many parts of the world due to the worldwide shortage of corneal donors.

Our study aims to investigate the potential of corneal tattooing to improve ocular cosmetic appearance using new, micronised mineral pigments in cases of severely impaired eyes; to demonstrate the safety and medium-term durability; and to investigate its potential as an alternative to invasive reconstructive surgery for the cosmetic correction of disabled eyes. To the best of our knowledge, this is the largest modern report on KTP performed for cosmetic purposes in a consecutive group of human eyes, since 1936.¹⁵ This project is also, to the best of our knowledge, the first study in which micronised mineral pigments were used for this purpose.

METHODS

Study design

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

Patients

Forty eyes of 40 patients, 18 women (45%) and 22 men (55%), underwent KTP for disfiguring corneal opacities or severe leucoma and total aniridia (table 1) as an alternative to invasive reconstructive cosmetic surgery. The mean patient age was 50 ± 19.98 (2–79) years. The tenets of Helsinki declaration (Tokyo 2004) were followed in this investigation. Informed consent was required for this investigation. Since the treatments were performed as a compassionate indication, no ethical committee approval was necessary for this study.

Inclusion criteria

Patients with significant cosmetic eye defect from different causes (table 1) causing severe corneal leucoma or complete aniridia were considered for this method as an alternative to evisceration and corneal prosthesis implantation. All cases were intolerant to cosmetic contact lenses.

Exclusion criteria

Cases with chronically inflamed or painful eyes, extensive calcified corneal deposits and severe corneal neovascularisation, superficial and/or deep forma, were excluded from the study.

Methods

For this study, a new set of mineral micronised pigments (Registration No DGFPS 84-PH, Spanish Ministry of Health, 2001) consisting of isopropyl alcohol 40%, water 10%, glycerine 20%, titanium dioxide C47-051 10–30%, iron oxide C33-123 20–30%, indigold C37-038 15–30%,

Table 1 Cosmetic keratopigmentation clinical conditions of the patients and simulated pupil size

Clinical diagnosis	No of eyes	Vision	Cosmetic complaint	Simulated pupil size (mm)
Traumatic OD	12	Counting fingers 10 cm to HM	Total leucoma	4
Traumatic aniridia	3	20/40	Asymmetrical cosmetic appearance and disabling glare in affected eye	5
Blindness retinopathy of prematurity	2	Amaurosis	Severe corectopia	3
Longstanding retinal detachment	12	NLP	Leucoma	4
			Phthisis bulbi	4
Chemical burn with phthisis bulbi	7	Amaurosis	Amyloidotic corneal degeneration	4
Absolute glaucoma	3	HM	Corneal leucoma	4
Congenital Sclerocornea	1	NLP	Leucoma microphthalmus	3

HM, hand movement; NLP, no light perception; RD, retinal detachment.

dianisidine-acetoacetanilide 20%, trans red oxide 20%, green L-9361 20%, yellow YT-858D 20%, blue 639-4433 20%, blackish, yellow-brownish, bluish and greenish were used. Different pigment combinations were used to match the fellow eye in this study. Associated problems such as strabismus or high intraocular pressure were treated, in most cases, at the moment of KTP. Peribulbar anaesthesia was used in all cases. In cases of strabismus, adequate recession/resection rectus muscle techniques were used according to the angle of the deviation in primary positional gaze. High IOP cases (superior to 30 mm Hg with topical medication) were treated with one or two sessions of trans-scleral diode laser cyclophotocoagulation.

Surgical techniques

KTP was performed by only one surgeon following two different approaches:

Intralamellar corneal staining (ICS)

The centre of the cornea was marked with a calliper and the pupil size diameter determined by an RK optic zone marker of 3, 3.5, 4 or 4.5 mm (Katena, New York) (see figure 1A–I).

Free-hand incisions were performed with a diamond blade radially from the limbus to the border of the marked pupil to match the low mesopic pupil diameter of the healthy eye, estimated with a Holladay gauge or an infrared pupillometer of 4 mm (Procyon, Bausch & Lomb Surgical, Rochester, New York).

To draw the pupil, an arcuate incision out from the radial incisions was made at the level of the circumference of the pupil limit, avoiding contact with the radial incisions. From this arcuate incision, a dissection of the central cornea up to the defined limits of the pupil was made, approximately 50% of the total corneal thickness. Then, the pupil was stained by injecting 0.1 cm³ of the adequate black colour pigment.

From radial incisions, the cornea was dissected intralamellarly and circularly with a microcrescent knife (Sharpoint, Surgical Specialties Corporation, Reading, Pennsylvania). Three or four incisions were usually necessary, and the dissection was made until the dissector reached the nearest incision on both sides. Finally, the whole cornea was dissected from the periphery to the corneal pupil. The adequate colour was injected with a 30-gauge cannula in the rest of the peripheral dissected cornea. If

the colour was lighter than the contralateral eye, then the colour was darkened, by applying a small amount of black stain on the previous pigment in an irregular fashion, for a better reproduction of the iris crests until the adequate colour was achieved. For KTP itself, no stitches were used in any case. Re-treatments were performed when needed, using the previously formed corneal dissection planes and increasing the staining if necessary.

Superficial corneal staining (SCS)

When the corneal opacity was too superficial or the scar was directly over the corneal surface, intralamellar staining was not sufficient to provide an adequate cosmetic appearance, and so superficial staining was performed as follows: a drop of the adequate stain was put on the cornea surface, and then micro-punctures were performed down to the superficial layers of the stroma with a 30-gauge needle. At this level, the bevel of the 30-gauge needle was facing inferiorly towards the cornea in order to increase the penetration of the dye.

The manoeuvre was repeated, until the adequate amount of micronised stain was introduced into the superficial cornea to achieve an acceptable cosmetic appearance. Once the staining was finished, the superficial cornea was thoroughly washed to eliminate the stained epithelium.

The surgical technique which we have used in the majority of cases was ICS—28 patients (70%) versus SCS—eight patients (20%). In four cases (10%) we have performed combined ICS and SCS procedures (table 2).

Patients were divided into two groups. The first group consisted of 22 patients (55%) who underwent only KTP. The second group contained patients who underwent KTP and additional procedures, such as: strabismus surgery (11 patients, 27.5%), injections of silicone to the vitreous due to severe hypotonia (two patients, 5%), upper lid blepharoplasty (one patient, 2.5%), marginal tarsorrhaphy (one patient, 2.5%), cyclodiode laser coagulation (two patients, 5%), phacoemulsification with intraocular lens implantation (one patient, 2.5%) and phacoemulsification with IOL implantation and trabeculectomy (one patient, 2.5%). Postoperative treatment included patching of the eye on the first day, a topical dexamethasone (Maxidex, Alcon, Barcelona) one drop four times a day for 2 weeks from the second day and an antibiotic, tobramycin (Tobradex, Alcon, Barcelona) one drop twice a day for 5 days.

Follow-up and main outcome measures

For this study, the follow-up period was 1 year after the surgery. The patients were examined on the first postoperative day, and then 1 week, 1 month, 3 months, 6 months and 1 year after the surgery by an independent observer. All but three patients completed the entire follow-up period. One patient was followed for 6 months, and two patients were revised for the last time 3 months after the surgery (mean follow-up 11.4 months).

The main outcome measures were: observer's opinion about patient's appearance, patient's satisfaction and complications of the procedure. Improvement in cosmetic appearance and patient satisfaction were evaluated at each visit following adequate evaluation protocols (table 3).

Outcome evaluation

The observers graded the cosmetic improvement of the case as poor, good and excellent as shown in table 1. Patients' satisfaction after surgery was graded as unhappy or poor, happy or good and very happy or excellent. Patients were also asked if they would consider having this surgery again. All outcome data refer to the 1-year follow-up visit.

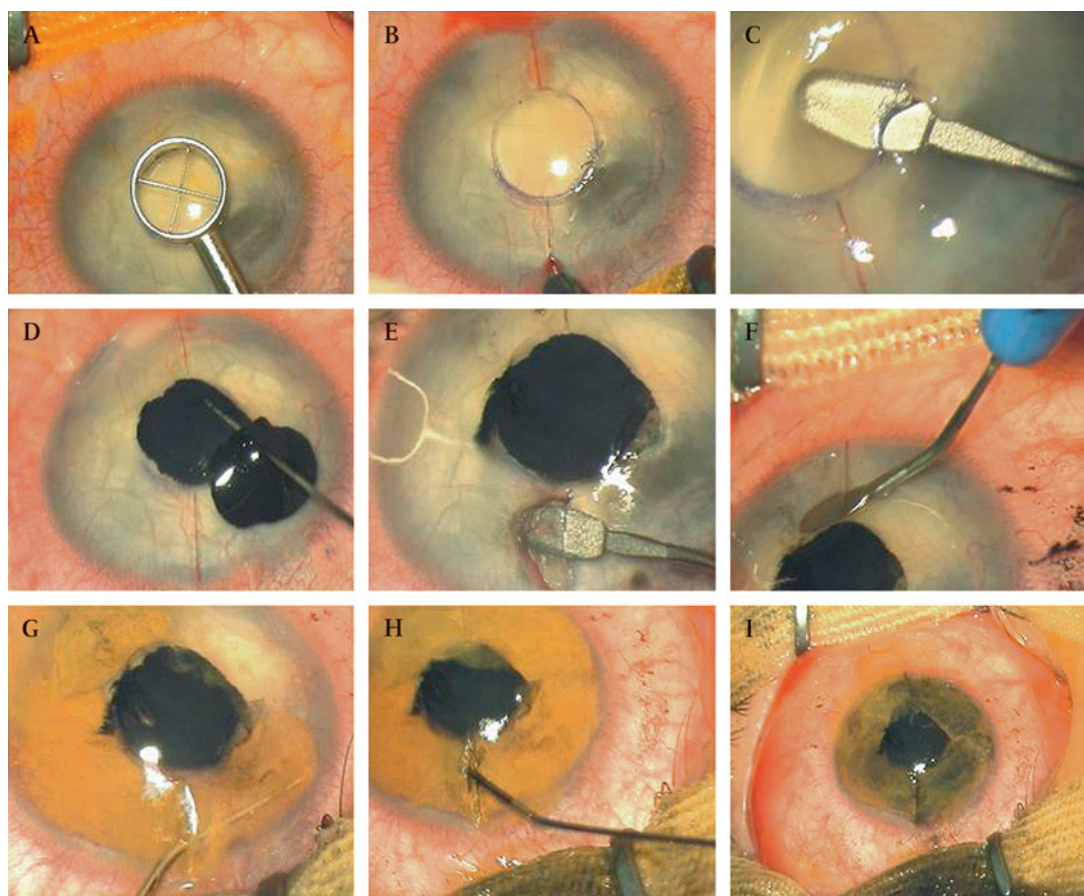


Figure 1 Intralamellar corneal staining (ICS). (A) Pupil diameter of 4 mm previously estimated following the low mesopic pupil and marked with an RK optic marker. (B) 3–4 incisions with a prephased diamond ring of 1 mm. (C) Cornea dissected intralamellary with a micro crescent knife (Sharpoint). (D) Pupil stained with the adequate dark colour (0.1 cm³) with a 30-gauge cannula. (E) Dissection of peripheral cornea top side. (F) Dissection of peripheral cornea bottom side. (G) Colouring peripheral cornea in an irregular format to recreate better the iris crests. (H) Mixing black and yellow-brown colours to give the right colour for the fellow eye. (I) Final result of the corneal tattooing.

RESULTS

The pre- and postoperative clinical situation and surgical technique (ICS, SCS) of the 40 eyes of the 40 patients included in this report are shown in tables 1, 2. Table 3 shows the level of patients' satisfaction after surgery.

In 95% of cases of KTP, a brownish-black colour was used and a bluish-green colour for 5% of the cases. Pupil diameters were different, 4 mm being the most frequent (table 1). In 10 cases of KTP by ICS, KTP was performed in two consecutive stages (retattooing) to adjust the cosmetic results to the needs of the case and the patient's expectations. An example is shown in figure 3A–C. In the first stage, the iris was reconstructed applying

blue pigment. In the second stage of surgery, a brownish pigment was applied to better match the shades of the fellow eye.

The cosmetic results and postoperative ocular cosmetic symmetry (table 3), as analysed by an independent observer, were classified as excellent in 27 cases, good in 10 cases and poor in three cases. All except three of our patients stated they would

Table 2 Cosmetic keratopigmentation: reoperations and associated surgeries

Surgical technique	No of patients	Retattooing	Other associated surgeries
Intralamellar cornea staining	26	10	1 upper lid blepharoplasty 9 strabismus 1 intraocular lensimplantation 1 intraocular lensimplantation with trabeculectomy
Superficial corneal staining	08	0	2 strabismus 1 marginal tarsorrhaphy
Combined intralamellar and superficial staining procedures	06	0	2 silicon oil tamponades 2 diode cyclocoagulation

Table 3 Cosmetic keratopigmentation observer's objective assessment of the cosmetic appearance and patient's satisfaction

	No of patients
Observer's evaluation	
Poor: unacceptable aesthetic aspect or very different to the fellow eye	03
Good: symmetrical aspect compared with the fellow eye and very acceptable cosmetically	10
Excellent: excellent aspect cosmetically and excellent symmetry compared with the fellow eye	27
Patient's satisfaction	
Unhappy or poor	03
Happy or very good*	10
Very happy or excellent	27
Would repeat surgery	
Yes	37
No	03

*All three patients with traumatic aniridia and disabling glare reported a very significant decrease in glare in the keratopigmented eye.

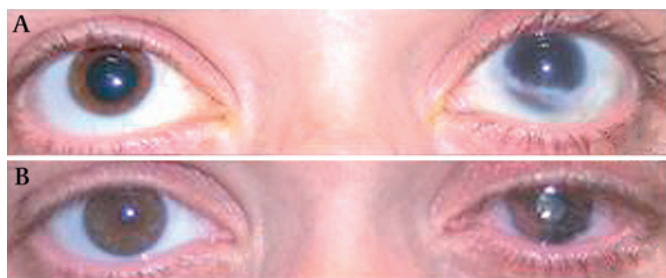


Figure 2 Pre- and postoperative appearances of selected patients. (A) Preoperative appearance of the left eye (LE). (B) Results 1 year after iris appearance reconstruction and pupil simulation.

repeat the surgery. Patients' subjective opinions about the results achieved are shown in table 3.

Pre- and postoperative pictures of three patients from this study are shown. Figures 2A,B and 6A,B show the aspect before and 1 year after the iris and pupil reconstruction performed in a 30-year-old female with a history of ocular trauma on the left eye (LE) with only light perception.

Figure 3A shows a 55-year-old patient with total aniridia and aphakia due to ocular trauma before anterior segment reconstruction including a sulcus-sutured intraocular lens. To more accurately match the bluish colour of the LE, initially, the pigmentation for iris reconstruction was performed using only blue pigment (figure 3B) and completed with a secondary pigmentation to improve cosmesis of the LE (figures 3C and 6C).

Figure 4A,B shows pre- and 1-year postoperative images of a 65-year-old male patient affected by multiple retinal detachments resulting in complete blindness corneal leucoma and strabismus. Severe restrictions to ocular motility prevented an adequate alienation of the axial axis. For partial iris reconstruction, three different pigments were used to mimic the appearance of the LE.

A 44-year-old female patient with a history of childhood ocular trauma leading to partial iris atrophy (figure 5A) underwent corneal KTP for sectoral iris simulation. Figure 5B shows the appearance of the patient 1 year after surgery. Figure 6D shows in detail the sectoral iris simulation under slit-lamp examination.

There were no cases of inflammatory reactions or side-effects associated with KTP procedures such as pain, foreign-body

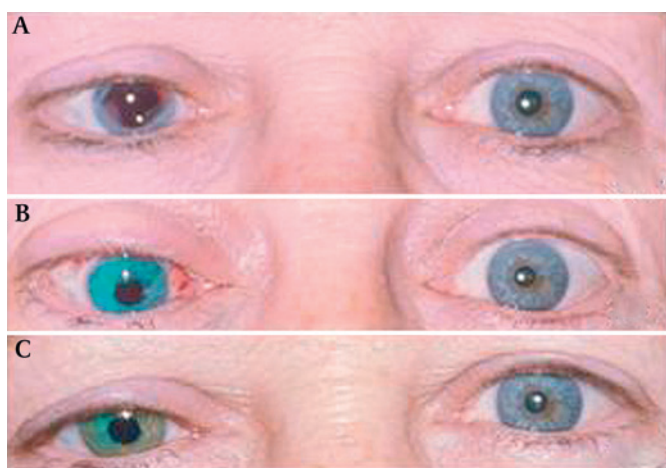


Figure 3 Pre- and postoperative appearances of selected patients. (A) Preoperative appearance before anterior segment reconstruction including a sulcus-sutured intraocular lens. (B) First pigmentation using only blue pigment. (C) Second pigmentation to better match the appearance of the LE.



Figure 4 Pre- and postoperative appearances of selected patients. (A) Preoperative aspect of a patient with partial iris atrophy secondary to childhood ocular trauma. (B) Appearance of the patient 1 year after sectoral iris simulation.

reaction, corneal de-epithelisation or colour loss throughout the study. Only three patients reported not being satisfied with the cosmetic results, although they have not experienced any complications associated with KTP.

DISCUSSION

Today, the preferred treatment for a patient with a blind and cosmetically severely impaired eye is the use of cosmetic contact lenses, which often are not well tolerated by patients. Another alternative is the use of external prosthesis, which in some cases causes chronic inflammation, ocular surface erosion and frequently discomfort. PK with all the well-known limitations and risks is also occasionally used in cases of injured eyes. Finally, evisceration and enucleation and prosthesis adaptation are mutilating procedures that are used in the most severe or intractable cases.^{11–14}

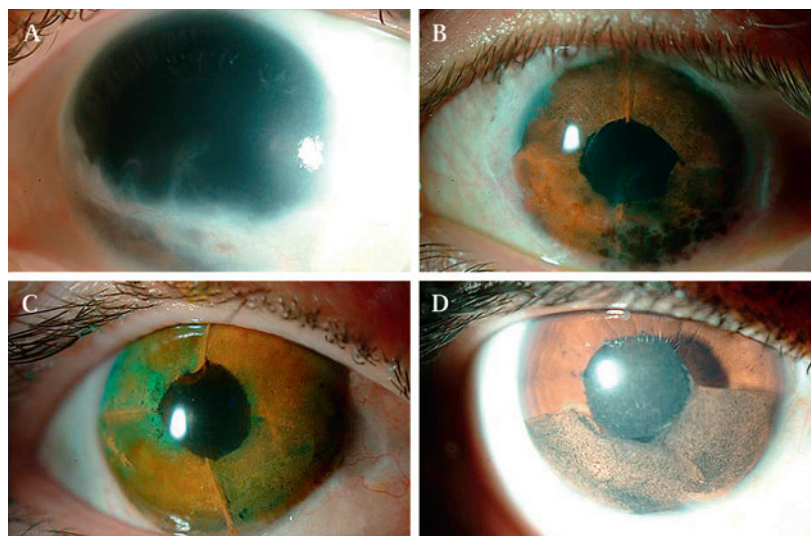
Two different methods of KTP were described during the last century. One of them was a chemical dye with gold or platinum chloride, a simple technique, mainly used in central Europe.^{1 2} Another method was carbon impregnation. Chemical tattooing was easier and quicker than carbon impregnation, but it faded more rapidly than non-metallic tattooing.¹⁵ Later, India ink, Chinese ink, lamp black and other organic dyes were used,¹⁵ but the final results were not satisfactory because fading still occurred with the need to repeat the procedure frequently.¹⁰

To the best of our knowledge, this is the first report on the practice of KTP with mineral micronised pigments and the first



Figure 5 Pre- and postoperative appearances of selected patients. (A) Preoperative aspect of patient with corneal leucoma and strabismus. (B) Results 1 year after strabismus surgery and partial iris reconstruction and colour simulation in LE.

Figure 6 Pre- and postoperative slit-lamp examination of selected patients. (A) Aspect of LE of the patient in figure 2A,B under a slit lamp before keratopigmentation. (B) Slit-lamp image of the cosmetic result achieved in LE of the patient in figure 2A,B 1 year after corneal pigmentation. (C) Detail of the sectoral iris simulation of the patient in figure 3A–C as seen with slit lamp. (D) Slit-lamp detail of the sectoral iris simulation of the patient in figure 5A,B.



report on the use of intrastromal KTP with stable results in the largest series reported since 1936.¹⁵ We have also reported the combined use of the two surgical approaches: dyeing the anterior corneal surface (SCS) and introducing the pigment directly into the corneal stroma (ICS). Previous investigations have proven the good corneal tolerance to KTP performed with other dyes,^{16–19} even though granulomatous keratitis was reported in one case,²⁰ which demonstrates that long-term follow-up and studies such as those carried out using the confocal microscope should be made to finally establish the tolerance and stability of new dyes used for KTP.¹⁹

According to our findings, the ICS itself is more advantageous than SCS, as it provides a more homogeneous aspect of the pigmented area, surgery is faster, the patient showed a faster and less symptomatic postoperative recovery, the corneal surface is untouched, and the staining is not exposed to the tear film.

KTP was also successfully associated with other types of surgeries in combinations that targeted different complications associated with cosmetic disabling problem. One limitation of KTP was corneal oedema, which caused a partial clearance of the pigments at 1 year of surgery. Most likely, the fluctuating condition of corneal oedema may not be a good indication of KTP and probably is the cause of previous failures with other pigments previously used. As shown in this study, KTP has been revealed as a potentially useful tool in the management of traumatic aniridia and traumatic coloboma.

In summary, KTP or corneal tattooing, using micronised mineral pigments, may be considered as an alternative for patients in whom evisceration or prosthesis implants would otherwise be used to improve their cosmetic appearance. Corneal tattooing can be a procedure for long-term or permanent correction of cosmetic eye deformities in patients who have cosmetically disabling corneal scars.

We can conclude that KTP used as described in this investigation achieves stable, satisfactory cosmetic results, during the follow-up of this study, with high patient satisfaction in corneal leukomas and aniridias and probably improving the patient's quality of life. According to the results of this clinical study, KTP is a safe surgical procedure that is easy to learn and perform, does not require expensive materials and avoids more extensive and invasive reconstructive ocular procedures. A further investigation of the stability of the pigments described is necessary for a better understanding of the long-term biological effects in the keratopigmented cornea of the micronised mineral pigments.

Contributors Design and conduct of the study (JLA); collection, management, analysis, and interpretation of the data (JLA, AWS, MM); preparation, review of the manuscript (JLA, AWS, BS).

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Competing interests None.

Patient consent Obtained.

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