

# Keratopigmentation with micronised mineral pigments: complications and outcomes in a series of 234 eyes

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## ABSTRACT

**Aim** To report the complications observed in a consecutive large series of cases treated with keratopigmentation (KTP).

**Methods** KTP was performed in 234 eyes of 204 patients for therapeutic and cosmetic reasons. From them, 50 eyes of 29 patients suffered complications. Different KTP techniques and three generations of pigments (GP) were used. The follow-up period ranged from 4 months to 12 years. Light sensitivity (LS), visual field (VF) limitations and MRI alterations were considered functional complications. Organic complications were described as change in colour, colour fading and neovascularisation.

**Results** The percentage of complications was 12.82%. Most patients complained of LS (49%), then colour fading and change in colour (19%). Neovascularisation, VF limitations and MRI complications constituted 7%, 4% and 2%, respectively. Organic complications were observed with the previous GP but resolved with the latest third GP with CE mark certification (Conformité Européene). Although LS remained with the corneal-specific pigments, it gradually disappeared in most of the patients (81.81%) 6 months postoperatively.

**Conclusion** To the best of our knowledge this is the first time a study systematically and comprehensively approaches and reports KTP complications. KTP with third GP provides better results and fewer complications than previous ones. It is a modern, minimally invasive technique that helps solve several functional ocular problems and improves cosmetic appearance of the patients. Dermatological pigments should not be used as they lead to complications; instead pigments specifically tested for the eye in terms of toxicity and teratogenicity should be used.

## INTRODUCTION

Corneal pigmentation, in spite of its recent development, has been practised for centuries. Keratopigmentation (KTP) or corneal tattooing has been used for cosmetic purposes and for restoring eyes with functional disabilities. It has been applied in eyes with iris loss, atrophy or trauma to correct glare, photophobia and monocular diplopia<sup>1-10</sup> and in eyes with aniridia or iris coloboma to disable light scattering and photophobia.<sup>7 10-12</sup> This procedure has been proposed and used also as a purely cosmetic ophthalmological surgical procedure for the elective change of the apparent colour of the eye.<sup>13</sup>

Nowadays, KTP practice has been limited due to several factors such as the use of non-studied, non-standardised pigments and poorly systematised surgical techniques.<sup>1</sup> This phenomenon has been surmounted as we have described in previous reports regarding modern surgical approaches, and the use of new corneal micronised mineral pigments,<sup>13 14</sup> that have been tested in different experimental studies with very good results from clinical, histopathological and immunological perspectives.<sup>1 15 16</sup>

KTP uses pigments that could have local toxicity, local tissue damage and could be the subject of chemical reactivity with corneas, such as change in colour, neovascularisation, melting and colour fading. The aim of this study is to systematically and comprehensively approach for the first time and report the complications observed in a consecutive large series of cases treated with KTP in its different modalities and with three generations of pigments (GP).

## METHODS

### Study design

This is a retrospective, consecutive, non-comparative series of cases study.

All patients signed an informed consent in accordance with the tenets of Declaration of Helsinki (Fortaleza, Brazil, October 2013). Ethical board committee approval was obtained for this retrospective study.

### Patients

A total of 234 consecutive eyes of 204 patients operated with KTP following the same protocol and performed by the same surgeon were included. Of these, 50 eyes of 29 patients suffered complications. KTP was applied for cosmetic therapeutic, functional therapeutic or purely for cosmetic reasons.

### Surgical techniques

The following KTP techniques were used: superficial automated keratopigmentation (SAK),<sup>6</sup> femto-second-assisted keratopigmentation (FAK) using a single tunnel technique<sup>4 6 13</sup> or a double tunnel technique<sup>5</sup> and manual intralamellar keratopigmentation (MIK).<sup>6 14-16</sup>

Some eyes were treated with a combination of more than one technique (table 1). Sixteen eyes were treated with SAK, 45 eyes were treated with FAK and 3 eyes were treated with MIK. An overall of 14 eyes were reoperated due to different reasons.



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**Table 1** The data and complications encountered by patients after KTP

P	G/A	E	Operation	Tech	PG	Colour	Change in colour	NVC	LS	Colour fade	VF limitations	MRI alterations	FUT
1	W/38	L	FT	MIK; SAK	Second	Black and light brown	X	X		X			9 y
2	W/42	R	FT	MIK	Second	Brown	X	X		X			6 y
3	W/46	L	CT	SAK	Second	Brown	X	X					4 y
4	M/41	R	FT	FAK double tunnel; SAK	Second	Black and brown	X			X			6 y
5	W/28	L	FT	FAK double tunnel	Second	Black and brown	X			X			6 y
6	M/29	B	FT	FAK double tunnel	Third	Black and blue	X		X	X			10 m
7	W/66	R	FT	MIK; SAK	First	Blue and grey	X	X		X			12 y
8	M/21	R	CT	FAK; SAK	Second	Black and brown	X			X			4 y
9	M/35	B	PC	FAK	Third	Green			X		X		4 m
10	W/71	R	CT	SAK	Third	Indian ink; brown and black						X	10 m
11	M/46	B	PC	FAK	Second	Blue			X	X			1 y
12	W/33	B	PC	FAK	Second	Blue			X				20 m
13	M/63	B	PC	FAK	Third	Brown			X				19 m
14	M/58	B	PC	FAK	Third	Blue			X				4 m
15	W/26	B	PC	FAK	Third	Blue			X				4 m
16	M/38	B	PC	FAK	Third	Blue			X				9 m
17	M/21	B	PC	FAK	Third	Brown			X				4 m
18	W/22	B	PC	FAK	Second	Blue			X				3 y
19	W/31	B	PC	FAK	Second	Green			X				4 m

B, both eyes; CT, cosmetic therapeutic; E, eye; FAK, femtosecond-assisted keratopigmentation; FT, functional therapeutic; FUT, follow-up time; G/A, gender/age; L, left eye; LS, light sensitivity; M, man; m, month; MIK, manual intralaminar keratopigmentation; MRI, magnetic resonance imaging; NVC, neovascularisation of the cornea; P, patient; PC, purely cosmetic; PG, pigment generator; R, right eye; SAK, superficial automated keratopigmentation; Tech, technique; VF, visual field; W, woman; y, year.

## Pigments

Three different and consecutive GPs were used for the purpose of this investigation. In the process of applying and evolution of KTP, pigments that did not offer good cosmetic appearance or faded were either chemically modified or abolished for future use. The first generation was dermatological pigments. The second-generation were selected pigments that showed good results in the previous stage but eventually were replaced by specific corneal, third-generation, CE mark (Conformité Européenne) certificated pigments. In accordance with the Ministry of Health and the Annex IV of European Regulation of Cosmetics (Biochromaeyes, Blue Green Company, Spain), the CE mark pigments are black, green, brown and light brown and are composed of different amounts of lactic acid, propanediol and micronised pigments (CI: 77007, 77491, 77499, 77492, 77288 and 77891) found in the register of permitted colourants in cosmetics.

## Follow-up

The follow-up time (FUT) ranged from 4 months to 13 years. From 204 patients operated, 97 patients had FUT less than 6 months, 22 patients had a FUT of 6–12 months, 29 patients had a FUT of 1–3 years, 30 patients had a FUT of 3–6 years, 16 patients had a FUT of 6–10 years and 10 patients had a FUT of more than 10 years. We described the complications that appeared during the FUT mentioned. Evaluation of the visual acuity, refraction, keratotopography, visual field (VF), cosmetic appearance, patient's satisfaction and a slit lamp examination were done by an independent observer 1 week, 1 month, 3 months and 6 months after the surgery. Patient satisfaction was graded as poor, good and excellent, following a previously described protocol.<sup>6</sup> Dropouts were considered patients with FUT less than 1 year if pigmented with first GP, less than 6 months with second GP and less than 4 months with third GP. Dropouts were handled by calling each one and inviting them to the clinic for an evaluation. Patients that could not come were asked over the phone about their satisfaction.

## Complications

Complications were divided into organic and functional. Light sensitivity (LS), VF limitations and MRI alterations were considered functional complications. Organic complications were described as change in colour, colour fading and neovascularisation.

## RESULTS

Fifty eyes (21.37%) of 29 patients (14.22%), 14 men and 15 women, with a mean age of 38 years (21–71) showed one or more the above-mentioned complications and were included in this study.

The percentage of complications among all the KTP procedures in our KTP practice between 2002 and 2016 was 12.82%. Of which 45% were organic and 55% were functional complications. The vision of the patients who underwent cosmetic therapeutic KTP did not change after the procedure as it ranged from total blindness to light perception with no colour perception and no hope for any improvement. We had no loss of vision in any case of patients with purely cosmetic KTP and their 20/20 visual acuity remained the same. In the therapeutic functional patients, the vision remained unchanged postoperatively and ranged from 20/200 and 20/20, except in one case (patient 5). This patient had an iridocorneal endothelial syndrome, and the best corrected visual acuity decreased from 20/22 to 20/27 2 years after the surgery. Some patients had more than one complication. For a

**Table 2** The division of the complications according to the technique used.

KTP technique	Complications
SAK	Change in colour, neovascularisation, MRI alterations
MIK	Change in colour, neovascularisation, colour fading
FAK double tunnel	Change in colour, colour fading, light sensitivity
FAK single tunnel	Light sensitivity, VF limitations, colour fading

FAK, femtosecond-assisted keratopigmentation; KTP, keratopigmentation; MIK, manual intralamellar keratopigmentation; SAK, superficial automated keratopigmentation; VF, visual field.

better understanding of the cases, the data and the outcomes are summarised in [table 1](#). Six patients had functional therapeutic and three had cosmetic therapeutic KTP. Twenty patients had purely cosmetic KTP, of which 10 encountered difficulties ([table 1](#)). The other 10 had LS in the first weeks after the operation but disappeared during the first month. Patients' satisfaction was assessed; three patients showed poor, five patients showed good and 21 patients reported excellent.

From the 234 eyes, 23.93% were pigmented with first generation, 31.62% with second and 44.44% with third GPs. The mean FUT of patients pigmented with first GP was 6 years (SD 4.18 (range 0.014–13.35)), with second GP FUT was 1.7 years (SD 2 (range 0.003–6.22)) and with third GP FUT was 0.37 years (SD 0.42 (range 0.003–2.03)). Change in colour is an organic complication reported in nine eyes, one of which was pigmented with first, six eyes with the second and two eyes with the third GP. The mean time for KTP to change colour in these patients was 4.6 years (SD 3.65 (range 0.17–12)). Neovascularisation was noticed in three eyes pigmented with second GP after 3.33 years (SD 1.26 (range 2–4.5)). The organic complication, colour fading, was observed in seven eyes pigmented with second GP and two eyes with third GP. Colour fading was noted after a mean time of 1.53 years (SD 1.84 (range 0.0055–4)). MRI alteration is a functional complication encountered in one eye pigmented with third GP 2 months postoperatively. VF limitations were found in both eyes of one patient pigmented with third GP 2 months after KTP. LS was the most frequent complication that occurred the next day postoperatively and was observed in 23

eyes, pigmented as following: one eye with first GP, eight eyes with second GP and 14 eyes with third GP. [Table 2](#) shows the complications encountered in each KTP technique used.

All patients were examined, and the percentage of each complication was established ([figure 1](#)). From the pie chart, it is clear that the majority of patients complained of LS (49%), after colour fading and change in colour (19% each). Neovascularisation, VF limitations and MRI complications constituted 7%, 4% and 2%, respectively.

## CLINICAL CASES

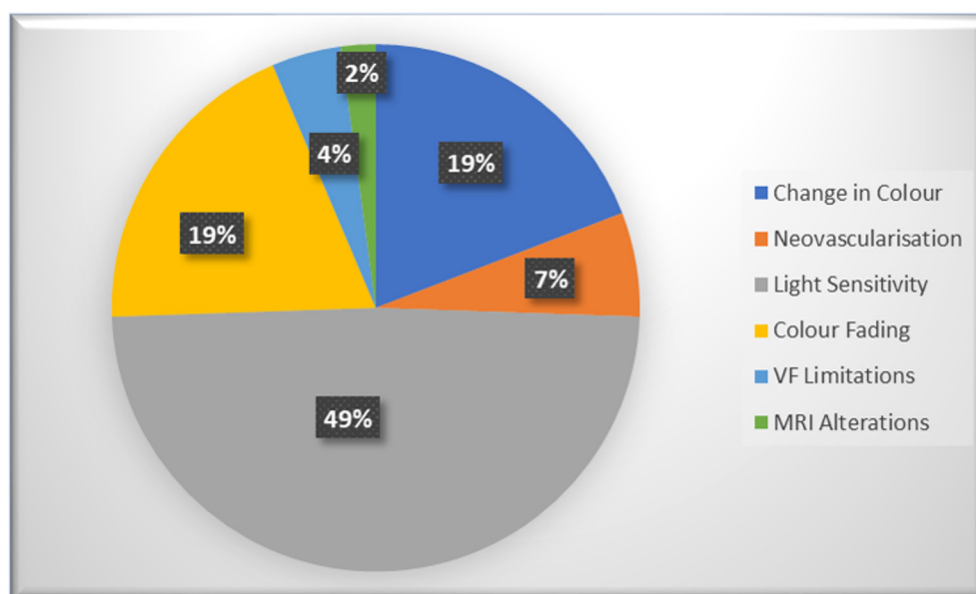
### Organic complications

#### Change in colour associated with neovascularisation

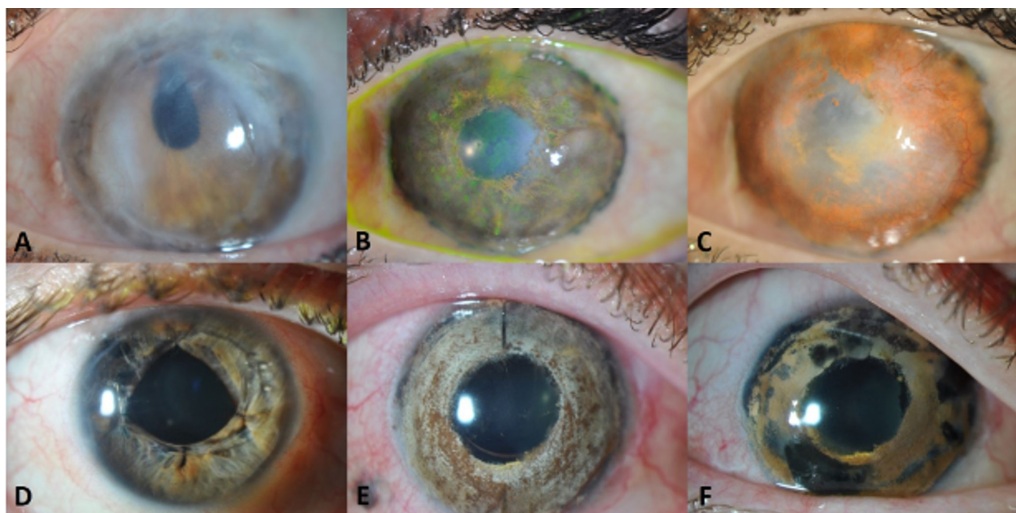
A 46-year-old woman was referred to our clinic with previous keratoplasties in her left eye due to herpetic keratitis. Examination showed corneal neovascularisation and opacification affecting the graft and the host cornea ([figure 2A](#)). It was agreed to perform SAK with brown colour. After 2 months, a retattoo was performed to the limbus with black pigment to enhance the cosmetic appearance ([figure 2B](#)). Subsequently, the patient was happy with the cosmetic appearance. At 3.5 years follow-up, the examination showed corneal oedema with deep and superficial neovascularisation and change of the pigment colour from brown to brownish red ([figure 2C](#)). The patient was advised for a retattoo.

#### Colour fading

A 41-year-old man addressed to our clinic after a labour trauma of his right eye. Severe photophobia was his main complaint despite the pupiloplasty done in advance ([figure 2D](#)). Examination showed a fixed dilated pupil and iris atrophy. After a short negative experience with cosmetic contact lenses, the patient decided to follow with KTP surgery. A FAK double tunnel technique was performed with black and brown pigments. The peripheral cornea in some areas was treated with SAK to create an optimal cosmetic effect ([figure 2E](#)). At the 4-year follow-up, fading of brown colour was noticed. In addition, a year later, an asymmetric distribution of the pigments and the appearance of the black colour from the deep tunnel were spotted ([figure 2F](#)).



**Figure 1** The portion and percentage of each complication in patients that underwent KTP. KTP, keratopigmentation; VF, visual field.



**Figure 2** (A) Preoperative left eye of patient 3. (B) Cosmetic appearance of the left eye of patient 3 after KTP. (C) Change in colour and neovascularisation 3.5 years postoperatively, patient 3. (D) Right eye after pupiloplasty of patient 4. (E) Cosmetic outcome after KTP of patient 4. (F) pigment fading and darken of the colour at 4-year follow-up, patient 4. KTP, keratopigmentation.

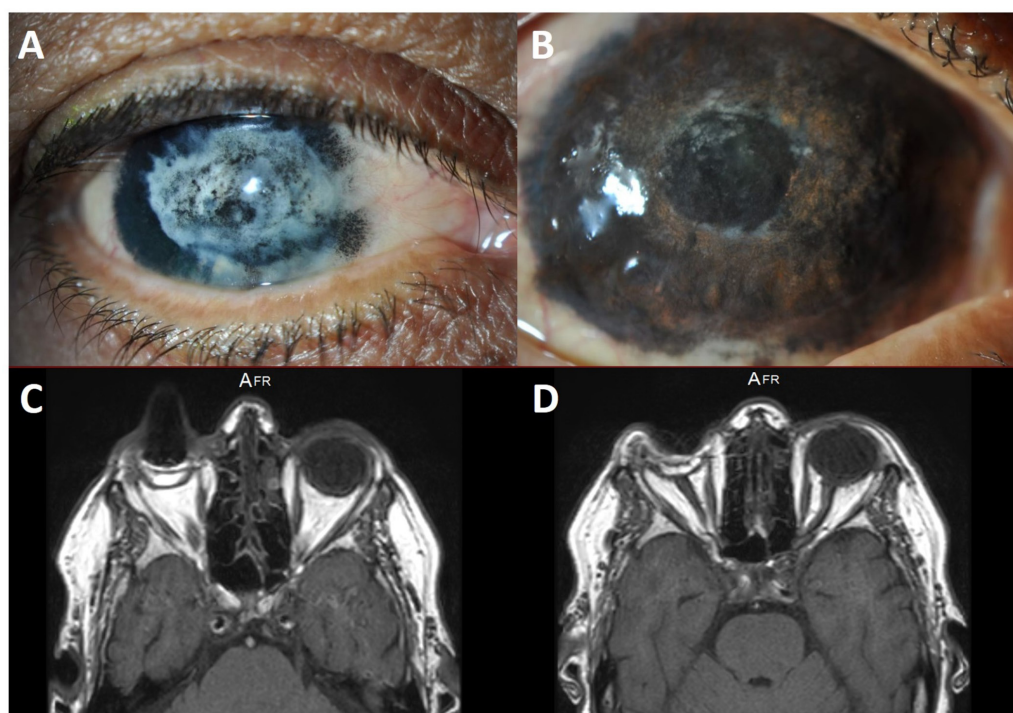
### Functional complications

#### VF limitations

A 35-year-old patient gained recent knowledge about the availability of purely cosmetic KTP. The patient was not satisfied with his appearance and wanted to change the colour of his eyes. FAK with green pigment was performed. The artificial pupil had a 5.0 mm diameter. At the 1-month follow-up, the patient complained of VF limitations. A central 24–2 Humphrey VF was made, and no VF limitations were detected. Afterwards, the 60–4 probe showed a constriction of the VF.

#### Complications while MRI

A 71-year-old woman desired to improve the cosmetic appearance of her right eye that was affected by an old trauma. The patient came with a previously pigmented right eye with Indian ink (figure 3A). SAK with brown and black pigments was applied. The patient was happy with the result (figure 3B). Two months later, the patient was urgently referred to us after unbearable pain in her right eye during a head MRI prescribed by another specialist. After revising the images, it was observed that the intraocular structures and the ocular globe were



**Figure 3** Patient 10. (A) Previously pigmented right eye with Indian ink. (B) Cosmetic outcome of the right eye after superficial automated KTP with black and brown pigments. (C and D) MIR images showing the distortion of the ocular globe. KTP, keratopigmentation.

smear, and no reliable data could be obtained from them (figure 3C,D).

### Light sensitivity

For the appropriate description of LS, we suggested a grading scale: grade 0: no LS reported by the patient; grade 1: (mild) LS with slightly discomfort that does not affect normal life activities, no need for sunglasses; grade 2: (moderate) sensitivity to light, inconvenient requiring wearing sunglasses when exposed outdoors; grade 3: (severe) difficulty with light that limits daily functioning despite wearing dark sunglasses; grade 4: (extremely severe) incapacitating LS; the patient cannot bear any light and has difficulty opening eyes in day light and indoors.

From 22 patients (two with functional therapeutic KTP and 20 with purely cosmetic KTP) encountering LS, 1 week after the operation, three patients had grade 4 LS, five patients had grade 3 LS, seven patients had grade 2 LS, six patients had grade 1 LS and one patient had grade 0 LS. The LS that continued to the 1-month follow-up was considered a complication and was observed in 12 patients: one patient with grade 4, three patients grade 3, four patients grade 2 and four patients grade 1. At the 3-month follow-up, one patient had grade 4 LS, three patients had grade 2 LS and one patient had grade 1 LS. One patient with albinism had grade 3 LS, and grade 1 LS was observed in three patients 6 months after the operation.

## DISCUSSION

To the best of our knowledge, this is the first study that reports the complications of modern KTP technology using a systematic approach. Formerly, various non-studied chemical products and older techniques were used for KTP. In the second century Galen was the first to implement corneal tattooing using reduced copper sulfate to mask a corneal leukoma.<sup>10 12 16</sup> Products such as Indian ink, metallic powders, organic colours, animal uveal pigment, Chinese ink, gold and platinum chloride and even soot were used.<sup>3 16-19</sup>

Therefore, complications including fading of colour, incomplete coverage of the cornea opacity, poor cosmesis, reopacification and epithelial growth<sup>12 20 21</sup> were affecting the outcomes. Complications such as undesirable migration of pigment, hypopigmentation and hyperpigmentation, corneal perforation, microbial infection and uveitis were commented in the literature.<sup>22</sup>

New approaches in KTP surgery and new pigments have been used recently.<sup>1 16</sup> The tolerance and corneal stability of pigmentation has evidently refined, with great results in cosmetic/functional therapeutic and purely cosmetic KTP.<sup>4 6 13</sup> However, as all innovative concepts and techniques, KTP faced some complications. Some organic complications, such as change in colour, colour fading and neovascularisation, were observed with the previous GP; nevertheless those complications were resolved with the last third generation CE mark pigments. Though with the latter pigments, a functional complication, LS, was detected. The origin of LS experienced by the patients is not well understood.

Complications that followed KTP have multifactorial aetiology. The composition of the pigments, the technique and the injection depth, the ambient factors and their implications, most likely played a role. Based on our observations, one tunnel technique is preferable than the double tunnel technique, and deep corneal tunnels entail better outcomes than superficial intrastromal tunnels. In our opinion, washing out the pigments at the end of the operation decreases the risk of LS postoperatively. We believe that the VF limitations experienced by patient 9 were caused by the 5.0 mm

diameter of the artificial pupil. Subsequently, patients pigmented with a 5.3 mm diameter artificial pupil never demonstrated such difficulties. Further research should be conducted on the exact components of the pigments, their interactions with corneal tissue and their long-term effects on the cornea.

As far as we know changes in colour after KTP are not published, and the papers on this topic are limited to skin tattoos. Regarding this issue, inorganic pigments with iron oxide used for skin tattooing were darkened following Q-switched laser. The mechanism suggested implicates oxidation-reduction reactions of the ferric oxide to ferrous oxide that is black in colour.<sup>23</sup>

Many contradictions have been reported regarding the consequences of permanent dermatological tattoos during MRI. Weiss *et al* talked about the paramagnetic effect caused by heavy metals found in the pigment base of mascara and eyelining tattoos during MRI. That led to alteration of the local magnetic field in adjacent tissues and subsequently to distortion of images of the globes.<sup>24</sup> Nevertheless, Tope and Shellock reported that patients with permanent tattoo did not experience serious soft tissue reactions or adverse events during MRI imaging. Their conclusions were derived from a survey about the complications and adverse events in individuals with permanent tattoos who underwent MRI. Out of 135 subjects, one subject reported 'slight tingling' sensation and another one reported 'burning' sensation, that were transient.<sup>25</sup> Therefore, the exact factors causing the MRI artefacts found in patient 10 are unknown. However, we can suggest that the iron oxide found in the pigments can cause such globe image distortion.

Despite the complications encountered, most of the patients were satisfied with the final functional and cosmetic results. It is apparent that the specifically developed for corneal use third GP hold the risk of having functional complications, especially LS. Although in most of the patients (81.81%), the LS disappeared gradually by the sixth month postoperative. Organic complications, such as change in colour, neovascularisation and colour fading were mostly encountered with the first GP and especially the second GP. Hence, KTP with third GP holds minimal risks regarding visual acuity, refraction or ocular toxicity, but instead helps in solving several functional ocular problems and in improving the confidence and self-esteem of the patients with their cosmetic appearance. It would be considered a well-tolerated and safe enough technique to treat cosmetic and functional problems.

To conclude, modern KTP is a minimally invasive technique that improves the cosmetic appearance of patients. The complications shown in this study are most likely related to the learning curve that we followed in order to develop the adequate techniques and pigments.<sup>1</sup> More investigations and work in improving the pigments and techniques of KTP will probably lead to better outcomes and decrease complications as was demonstrated here.

**Contributors** All authors were actively involved with: planning of the study, data acquisition, analysis and writing and revising the drafts and the final version of the paper. All authors agree 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.

**Competing interests** None declared.

**Patient consent** Obtained.

**Ethics approval** Visum Alicante Spain.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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