Superficial Keratopigmentation: An Alternative Solution for Patients With Cosmetically or Functionally Impaired Eyes

Olena Al-Shymali, MD,† Alejandra E. Rodriguez, PhD,‡§ Maria A. Amesty, MD, PhD,¶ and Jorge L. Alio, MD, PhD, FEBO‖**

Purpose: To report the use of different superficial keratopigmentation (KTP) techniques for restoring or enhancing cosmetic appearance of eyes impaired for several reasons.

Methods: This is a retrospective, consecutive, noncomparative interventional series of cases, in which 136 cosmetically disabled eyes (due to different corneal abnormalities) of 130 patients were included. A total of 222 procedures of superficial manual KTP and superficial automated KTP were performed. The procedures were divided into 2 groups: first and second-stage procedures. The patients' cosmetic appearance and satisfaction were evaluated and graded as excellent, good, or poor.

Results: A total of 222 procedures were performed, 57.2% were superficial automated KTP, 22.5% were superficial manual KTP, and 20.3% included the combination of superficial KTP with other KTP techniques. Six procedures were purely cosmetic, 16 therapeutic functional, and 200 therapeutic cosmetic. Superficial KTP, as a second-stage procedure, was performed in 13 eyes that were previously pigmented by intrastromal techniques. Superficial KTP as an initial indication (first-stage procedure) alone or in combination with another KTP technique in the same surgery was performed in 123 eyes, in which 44.7% of them were reoperated once or more. Best-corrected visual acuity changed insignificantly, and the intraocular pressure decreased significantly in all the studied groups. No intraoperative complications were observed, 11.2% of eyes with a follow-up time of more than 3 months developed postoperative complications. Most of the patients (98.5%) were satisfied.

Conclusions: The modern superficial KTP procedure provides the possibility to improve the cosmetic appearance of impaired eyes, as an alternative to evisceration, enucleation, prosthetic contact lenses, or keratoplasty.

Key Words: superficial keratopigmentation, superficial automated keratopigmentation, keratopigmentation, pigments, corneal leukomas, cosmetic therapeutic keratopigmentation, functional therapeutic keratopigmentation, disfigured eyes, impaired eyes

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Management of permanent corneal opacities of any origin is challenging. Patients with such disfigured eyes have negative psychological well-being, and cosmetic reconstruction is necessary in these cases. Management choices are limited to prosthetic contact lenses, keratoplasty, evisceration, enucleation, or, more recently, keratopigmentation (KTP).[1–4]

Leukomatous corneas are pathological and frequently are intolerant of contact lenses or external prosthesis because of fitting, discomfort sensation, or an irregular corneal surface.[5,6] Keratoplasty can be used in patients in cases in which vision improvement is expected and the risk of rejection is minimal. Mutilating reconstructive surgeries such as evisceration and enucleation are more traumatic procedures and are associated with different prosthesis-related problems.[7–9]

KTP has shown to be an alternative solution for those patients.[10,11] Recently, different surgical techniques[1] for various purposes[2,10,12–15] have been described using new mineral micronized pigments.[16] Permanent superficial corneal opacities cannot be dissimulated using only intrastromal techniques described earlier.[1] Thus, superficial KTP is a choice for patients with disfigured blind eyes because it may help to mask the corneal opacities, leukomas, and neovascularization.

Our previous experimental work reported has demonstrated the safety and feasibility of superficial KTP as a conservative and precise alternative for these leukomatous corneas.[3] In our recent study, we described the complications encountered in all our patients who underwent KTP using its different techniques.[17] Several reports were made by our group describing the different techniques of KTP including superficial and intrastromal. However, in this clinical study, we analyzed, for the first time, the largest series of cases with

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From the *Research and Development Department, VISSUM Innovation, Alicante, Spain; †Department of Cornea, Cataract and Refractive Surgery, VISSUM Corporation, Alicante, Spain; ‡Research and Development Department, VISSUM Innovation, Alicante, Spain; §Cornea and Ocular Surface Department, VISSUM Corporation, Alicante, Spain; ¶Ocular, Plastic, Reconstructive, Lacrimal and Orbital Surgery Department, VISSUM Corporation, Alicante, Spain; ‖Division of Ophthalmology, School of Medicine, Universidad Miguel Hernández, Alicante, Spain; and **Cornea, Cataract and Refractive Surgery Department, VISSUM Corporation, Alicante, Spain.

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Correspondence: Jorge L. Alio, MD, PhD, FEBO, VISSUM Alicante, Calle Cabañal 1, Alicante 03016, Spain (e-mail: jlalio@vissum.com).

the longest follow-up treated by superficial manual (SMK) or superficial automated keratopigmentation (SAK) using systematically and specifically studied mineral micronized pigments developed for corneal pigmentation.

MATERIALS AND METHODS

Study Design

This is a retrospective, consecutive, noncomparative interventional series of cases conducted at VISSUM Ophthalmology Institute (Alicante, Spain) between 2003 and 2017. Ethical Board Committee approval was obtained for this retrospective study. All patients signed adequate informed consent in accordance with the tenets of the Declaration of Helsinki (Fortaleza, Brazil, October 2013).

Statistics

Patient's data and clinical data were gathered and organized in a Microsoft Office Excel file. The data were analyzed using SPSS for Windows software (version 18.0, SPSS, Inc).

Patients

A total of 222 consecutive surgeries using superficial KTP were performed in 136 eyes of 130 patients by the same experienced surgeon (J.L.A.). Superficial KTP, SMK, or SAK, was indicated as 1) therapeutic cosmetic, as it is done in corneas that had pathologies leading to the cosmetic impairment of the eye, 2) therapeutic functional, done in eyes with pathologies that alter the visual function like iris colobomas, or 3) purely cosmetic procedure, done in healthy patients who wish to change their apparent eye color.

Inclusion/Exclusion Criteria

Patients with cosmetically disabled eyes related to any corneal abnormality were candidates for superficial KTP. The exclusion criteria were any active ocular inflammation, chronic corneal epithelial defects and ulcers, corneal dellen, severe dry eye syndrome, and extremely thin corneas (<300 μm). Patients who underwent only intrastromal KTP with no superficial techniques were excluded from the study.

Surgical Techniques

KTP techniques are divided into superficial and intrastromal ones. The superficial KTP is divided into superficial manual keratopigmentation (SMK) and superficial automated keratopigmentation (SAK). The intrastromal technique is divided into manual intrastromal keratopigmentation (MIK) and femtosecond laser-assisted intrastromal keratopigmentation (FIK).

1-Superficial Manual Keratopigmentation

This technique was used at the beginning of KTP surgeries, before the development of the new automated puncture device. For this purpose, a 25-G sterile needle was used by repeatedly puncturing the area of the cornea, in which KTP was needed and a drop of pigment had been previously deposited.[2]

2-Superficial Automated Keratopigmentation

SAK was performed using the Vissum Eye MP System device, Madrid, Spain (Apl. No. 2.949.539) provided by Blue Green Medical, Spain (Fig. 1). Automatic micropunctures were performed penetrating the epithelium and superficial layers of the stroma to an approximate depth of 120 μm from the corneal surface.[18] The penetration depth of the needles was regulated by a trundle located in the distal part of the handpiece (Fig. 1). We used different tips, with different numbers of needles, depending on the area that was going to be treated. For the iris simulation, we used a tip with several needles (No. 3 or No. 5), (Blue Green Medical, Spain), and for the limbus area or pupil simulation, we used the tip with only one needle (Nº1) (Fig. 1).

3-Manual Intrastromal Keratopigmentation

Radial incision at 12 o'clock was performed using a calibrated diamond blade up to 40% to 50% of the corneal thickness. Afterward, through this incision, the cornea was dissected intrastromally in a lamellar and circular way at the same depth with a helicoidal dissector, avoiding the pupil area. Surgical instruments specially designed for KTP were used. The adequate pigment, previously prepared and loaded into a 1-mL syringe, was injected with a 27-gauge flat cannula into the dissected corneal tunnel.[2]

FIGURE 1. Superficial automated keratopigmentation device Vissum Eye MP system, Madrid, Spain (Apl. No. 2.949.539), provided by Blue Green Medical, Spain. (Left) The body of the device to which a handpiece is attached (right top). The distal part of the handpiece has a trundle (right center) that regulates the penetration depth of the needles. (Right bottom) Disposable tip that contains different numbers of needles depending on the area that will be pigmented.

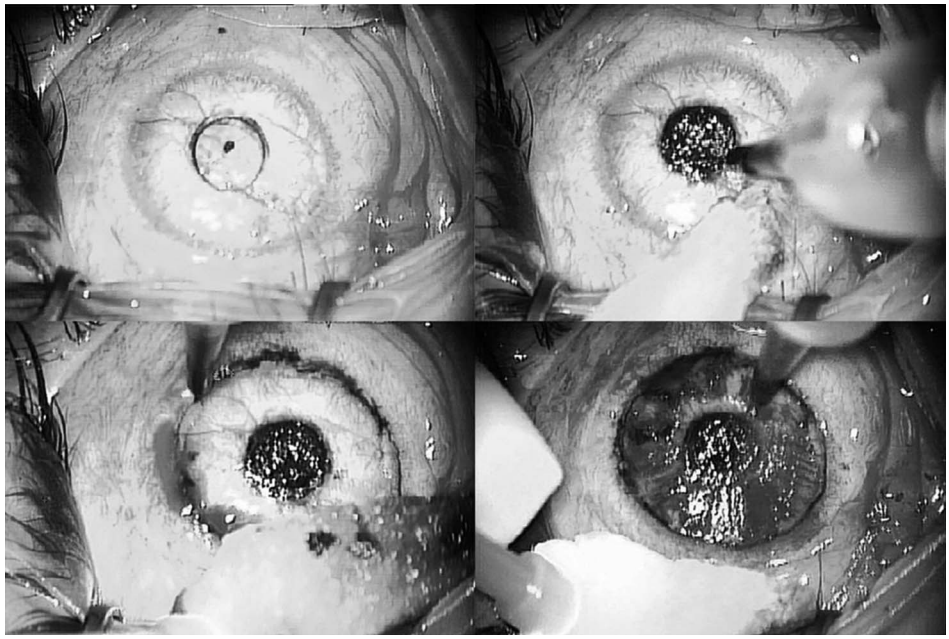

FIGURE 2. Superficial automated keratopigmentation. (Top left) The center of the cornea was marked with a calliper, and the pupil size was determined by an RK optical zone marker (Katena), and afterward, black pigments are introduced to simulate the pupil (top right). The same black color is used to pigment the limbus circumferentially (bottom left), and finally a customized pigment that matches the fellow eye is used to simulate the iris (bottom right).

4-Femtosecond Laser-Assisted Intrastromal Keratopigmentation

In our previous publications, we used to refer to this technique with the abbreviation FAK, but to avoid confusion, we have changed it in this article to FIK. For this technique, a 60-kHz IntraLase femtosecond laser was used to create a circular tunnel of 9.5 mm external and 5.3 internal diameters and one superior 90-degree radial 4-mm incision, at 50% depth of the thinnest cornea, however, never less than 250 μm depth. The tunnel was opened, and the pigments were injected through the superior incision using a 27-gauge flat cannula.[4]

Retouch

Retouch is a reintervention of KTP and can be done using any of the 4 KTP techniques described above. If retouch was done in any of the intrastromal techniques, no new tunnels were made. The tunnel made in the primary surgery (either manually or using the femtosecond laser) was opened and the pigments injected into it.

Surgical Procedure

For both procedures, SMK and SAK, ocular topical double anesthetic (tetracaine 0.1% and oxybuprocaine 0.4%, Colircusi; Alcon Cusi S.A., Barcelona, Spain) was used before and during surgery. Peribulbar anesthetic (Mepivacaine Braun 2%, Braun Medical, Barcelona, Spain) was used when the area to be pigmented was extensive, as in cases of total leukoma.

The center of the cornea was marked with a calliper and the pupil size determined by an RK optical zone marker (Katena, NY) (Fig. 2, top left). The epithelium was preserved, and micropunctures were performed to inject the pigments into the superficial layers of the stroma. The pigments have a liquid consistency, they are hydrosoluble, they tend to spread easily, and should be washed out from the corneal surface from time to time. Pupil simulation was performed using only black pigment. The pigment was injected inside the area marked with the optical zone marker of a specific diameter depending on the size of the mesopic pupil of the fellow eye (Fig. 2, top right). In cases in which the limbus had

TABLE 1. Indications for Superficial Keratopigmentation

Eyes	Pathology
Therapeutic cosmetic procedure	
52 (38.2%)	Total or partial corneal leukomas: traumas, infections, opacification of the donor–recipient borders in eyes with previous keratoplasties
28 (20.6%)	Chronic corneal edema: after several unsuccessful keratoplasties, cataract or phakic IOLs surgeries, congenital glaucoma, ocular infections, or Fuchs dystrophy
21 (15.4%)	Phthisis bulbi
17 (12.5%)	Corneal calcification and leukomas of different levels
1 (0.7%)	Sclerocornea
1 (0.7%)	Blind eye: transparent cornea, paralytic mydriasis with white cataract due to trauma
1 (0.7%)	Blind eye: transparent cornea, no pupil with the iris pulled backward because of trauma
Therapeutic functional procedure	
6 (4.4%)	Partial or complete aniridia as a consequence of trauma
2 (1.5%)	Severe photophobia by albinism
1 (0.7%)	Progressive iris cyst
Purely cosmetic procedure	
6 (4.4%)	To enhance the color of the eyes in 3 patients previously pigmented with the femtosecond laser-assisted intrastromal technique for eye color change

to be pigmented, black pigments were introduced circumferentially in the limbal area (Fig. 2, bottom left). Afterward, pigments were injected repeatedly until the adequate amount was deposited in the superficial stroma to achieve the desired color and shape of the iris (Fig. 2, bottom right). This pigmented area was centrally delimited by the previously pigmented pupil and peripherally by the limbus. Finally, a therapeutic contact lens was applied to the cornea.

Pigments

Three generations of selected micronized mineral pigments were used for this study. Pigments of the first-generation were originally used for dermopigmentation. Those of the second-generation were selected pigments that showed good results in the previous stage and were adapted to be used in eyes. Those of the third-generation were specific corneal, CE mark certificated pigments (Blue Green Company, Spain). In accordance with the Ministry of Health and the Annex IV of European Regulation of Cosmetics, the CE mark pigments are composed of different amounts of lactic acid, propanediol, and micronized mineral pigments (CI: 77,007, 77,491, 77,499, 77,492, 77,288, and 77,891).

Postoperative Treatment

Postoperative treatment included topical antibiotic tobramycin 0.3% plus dexamethasone 0.1% (Tobradex; Alcon, Barcelona, Spain) 1 drop 4 times a day for 1 week.

Patient examination was done in the following postoperative periods: day 1, week 1, month 1, month 3, month 6, and year 1. Photographs were taken at each visit to detect any change in the appearance of the eyes treated. The anterior segment examination also included the presence or absence of conjunctival injection, corneal haze, corneal neovascularization, and corneal infiltrates.

Main Outcome Measures

Main outcome measures were evaluated using previously described protocols.[2] An independent observer evaluated the patients' cosmetic appearance, which was graded as excellent (excellent symmetry with the fellow eye and excellent cosmetic aspect), good (symmetrical and acceptable aesthetic aspect), or poor (asymmetrical and unacceptable cosmetic aspect). Patients' satisfaction was assessed and graded as excellent or very happy, good or happy, and poor or unhappy. Additionally, patients were asked whether they would repeat surgery or not.

RESULTS

This study included 136 eyes of 130 patients treated with superficial KTP. Mean age of the patients was 41 years (minimum of 1 and maximum of 83). The 1-year-old child had sclerocornea and was pigmented to enhance the cosmetic appearance of his eye. There were 71 right eyes, 53 left eyes, and in 6 patients both eyes were operated.

The mean follow-up time (FUT) was 2.4 years with a range from a few days to more than 14 years. Seventy patients (53.8%) had an FUT more than 1 year. Fourteen patients (10.8%) had an FUT less than 1 year, 17 (13.1%) less than 6 months, 12 (9.2%) less than 3 months, 9 (6.9%) less than 1 month, and only 8 patients (6.2%) had an FUT less than 1 week. These dropouts that could not come for further examinations were assessed by a telephone conversation to evaluate their satisfaction.

Indications

Superficial keratopigmentation was indicated as a therapeutic cosmetic, therapeutic functional, or purely cosmetic procedure depending on the patient's ocular pathology (Table 1).

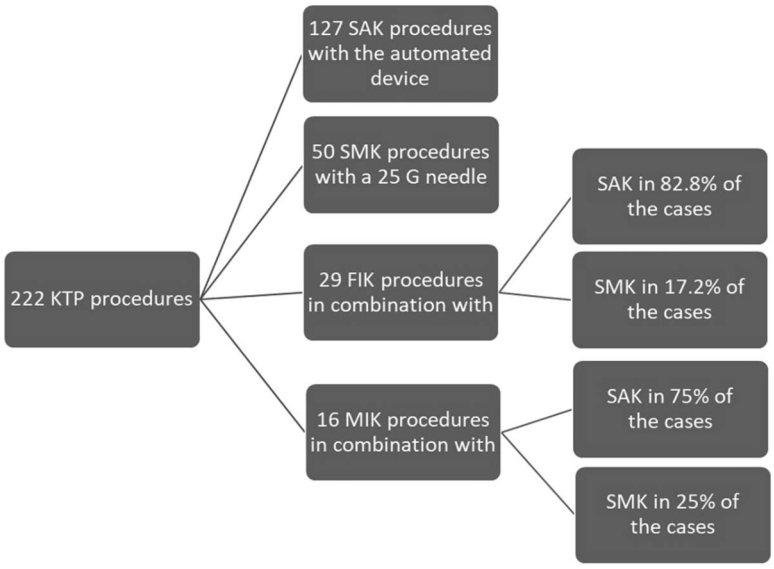

FIGURE 3. Division of the total number of procedures with the different keratopigmentation techniques.

TABLE 2. Preoperative and Postoperative Best-Corrected Visual Acuity and Intraocular Pressure in Patients Who Underwent Superficial Keratopigmentation for Different Indications

Indication	No of Eyes	Subgroup	% of Eyes	BCVA Preop	BCVA Postop	*P*	IOP Preop	IOP Postop	*P*
Purely cosmetic KTP	6	NA	100	20/20	20/20	NA	15	14	NA
Therapeutic functional KTP	9	NA	100	20/60	20/70	0.172	17.2	14.1	0.167
Therapeutic cosmetic KTP	121	Sighted eyes	14	20/62	20/44	0.674	19.4	14.4	0.028
		Low/no vision eyes	2.1	CF < 1 m	CF < 1 m	NA	13.8	10.6	0.02
			7.5	HM	HM	NA			
			13	PL	PL	NA			
			63.4	NPL	NPL	NA			

BCVA postop, postoperative best-corrected visual acuity; BCVA preop, preoperative best-corrected visual acuity; CF < 1 m, counting fingers on a distance less than 1 m; HM, hands movements; IOP postop, postoperative intraocular pressure; IOP preop, preoperative intraocular pressure; NA, not applicable; No, number; NPL, no perception of light; PL, perception of light.

Because most of the patients had blind, decompensated eyes, they showed other pathologies that were treated on the same day of KTP or after KTP within an interval of 3 months maximum. Some patients had the combination of 2 or 3 procedures. From 136 eyes, 53 of them had a strabismus correction, 18 blind glaucomatous eyes had cyclodiode laser treatment to relieve pain, 15 eyes underwent ptosis surgery, 1 eye had surgery for nystagmus, and 8 eyes had pupilloplasty. The latter included 4 patients with a history of trauma and iris rupture or dilated fixed pupil. However, the pupilloplasty itself did not resolve the problem of photophobia completely, so KTP was performed. Two patients had penetrating keratoplasty and deformed iris, in which pupilloplasty was performed, and KTP was performed to pigment the opacified donor–recipient borders. One patient had a penetrating trauma with severe corectopia that was corrected with pupilloplasty and a partial corneal scar that was masked using KTP. Another patient had a progressive iris cyst that was primarily corrected with pupilloplasty and after the severe progression with KTP. All patients with corneal calcification were treated with 2% EDTA.

The total number of KTP procedures performed including first surgery and the subsequent retouches was 222 procedures (Fig. 3). Six of the procedures were indicated for purely cosmetic reasons, 16 were therapeutic functional, and 200 were therapeutic cosmetic procedures.

The procedures were divided into 2 groups: first-stage and second-stage. The former included patients who underwent superficial KTP as an initial indication alone or combined with another KTP technique in the same surgery. The latter included patients who underwent superficial KTP as a second stage after a certain time after initial KTP was performed using intrastromal techniques.

Second-Stage Procedures

Thirteen eyes of 11 patients were included. Four eyes were previously pigmented with MIK and as a second-stage; 2 of them had SAK and the other 2 had SMK. Nine eyes had FIK in the past, afterward 5 of them had SAK, and 4 had SMK as a second-stage procedure.

The indications were distributed as follows: 7 eyes (53.9%) were cosmetic therapeutic, 2 eyes (15.4%) were functional therapeutic, and 4 eyes (30.8%) were purely cosmetic.

The mean interval between the initial procedure and the second superficial KTP procedure was 1.7 years with a range of 0.1 and 6.3 years. The FUT ranged from 2 days to 9.3 years (mean, 2.4 years).

First-Stage Procedures

Superficial KTP as an initial procedure was performed in 123 eyes of 119 patients, in which SAK was performed in 62 eyes (50.4%) and SMK in 23 eyes (18.7%); 25 eyes (20.3%) underwent a combination of FIK with either superficial techniques (SAK in 20 eyes and SMK in 5 eyes); 13 eyes (10.6%) had MIK combined with either superficial techniques (SAK in 10 eyes and SMK in 3 eyes). The indications were distributed as follows: 114 eyes (92.7%) were cosmetic therapeutic, 7 eyes (5.7%) were functional therapeutic, and 2 eyes (1.6%) were purely cosmetic.

Sixty-eight eyes (55.3%) were operated once and did not require more interventions. Overall, 55 eyes (44.7%) were reoperated, whereas 31 eyes (25.2%) had 1 retouch, 19 eyes (15.4%) had 2 retouches, 3 eyes (2.4%) had 3 retouches, and 2 eyes (1.6%) had 4 retouches.

Of the 55 eyes reoperated, 18 eyes (32.7%) had leukoma, 7 eyes (12.7%) had corneal leukoma and

TABLE 3. Observer's Evaluation and Patients' Satisfaction After Superficial Keratopigmentation Surgery

	No. of Patients	%
Observer's evaluation		
Excellent	90	69.2
Good	38	29.2
Poor	2	1.5
Patient's satisfaction		
Excellent	92	70.8
Good	36	27.7
Poor	2	1.5
Would repeat surgery		
Yes	128	98.5
No	2	1.5

FIGURE 4. Forty-six-year-old patient (top left) with strabismus, (top right) aniridia and a central corneal scar due to ocular trauma to his left eye. Therapeutic functional femtosecond laser-assisted intrastromal keratopigmentation was applied in combination with strabismus surgery. After 2 months, retouch with superficial automated keratopigmentation was performed. Postoperatively, (bottom left) the patient was satisfied with his cosmetic appearance and (bottom right) the left eye gained normal appearance. Best-corrected visual acuity remained stable, counting fingers at 2 m.

calcifications, 11 eyes (20%) presented with chronic corneal edema, 13 eyes (23.6%) had phthisis bulbi, and 6 eyes (10.9%) had transparent corneas but were keratopigmented because of different reasons: 3 had partial or total aniridia, 1 blind eye after ocular trauma with a transparent cornea, and 2 eyes of a patient with albinism.

Depending on the initial number of eyes presenting with each pathology, the frequency of retouches in each group was as follows: leukoma 34.6%, leukoma, and calcifications 41.2%, chronic corneal edema 39.3%, phthisis bulbi 61.9%, and in the group with transparent corneas 54.5%.

The mean time interval between the initial surgery and the first retouch was 0.6 years (0.01–6.1), between the first and second retouch was 2.6 years (0.03–11), between the second and third retouch was 1 year (0.3–2.9), and between the third and fourth retouch was 1.3 years (0.6–2.1).

Outcome Measures and Evaluation

Table 2 shows the preoperative and postoperative values of best-corrected visual acuity and intraocular pressure. We observed that the latter decreased significantly. This feature remains unexplained; however, we suggest that the procedure changes the corneal resistance and induces corneal irregularities and consequently the intraocular pressure (IOP) measures lower, but the actual intraocular pressure probably does not. The satisfied cosmetic results after observer's evaluation coincided with patients' satisfaction in 98.5% of the cases (Table 3).

Complications

Intraoperative

No perforations or problems related to the surgical procedure were observed in any case.

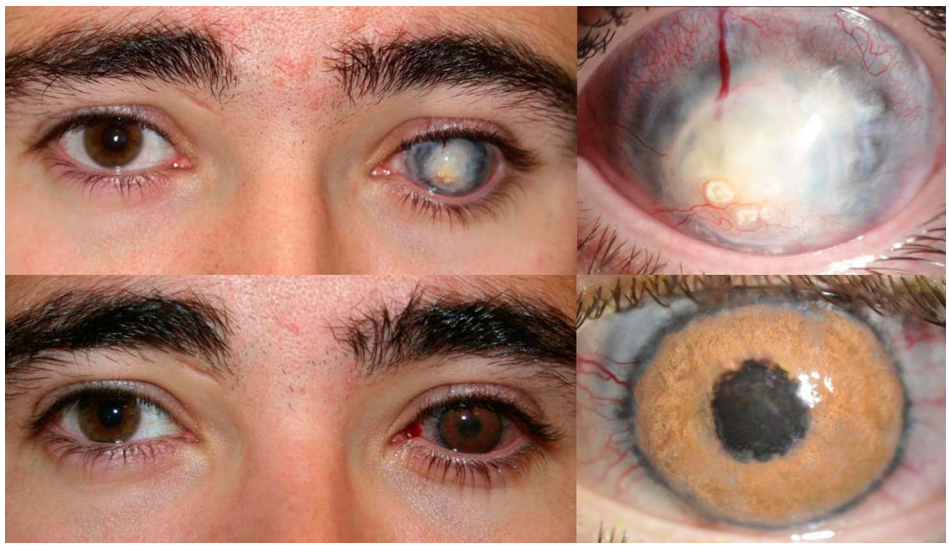

FIGURE 5. Twenty-eight-year-old patient with a history of trauma to his left eye. (Top left) The external evaluation showed a disfigured buphthalmic eye, (top right) and the slit-lamp evaluation revealed total corneal leukoma, neovascularization, and calcification. The patient had problems fitting a cosmetic contact lens. The IOP was extremely high, 75 mm Hg. Therapeutic cosmetic superficial automated keratopigmentation and transscleral cyclophotocoagulation were performed. The cosmetic appearance of the patient improved significantly (bottom left) with excellent appearance of the left eye (bottom right). The IOP reduced to 25 mm Hg.

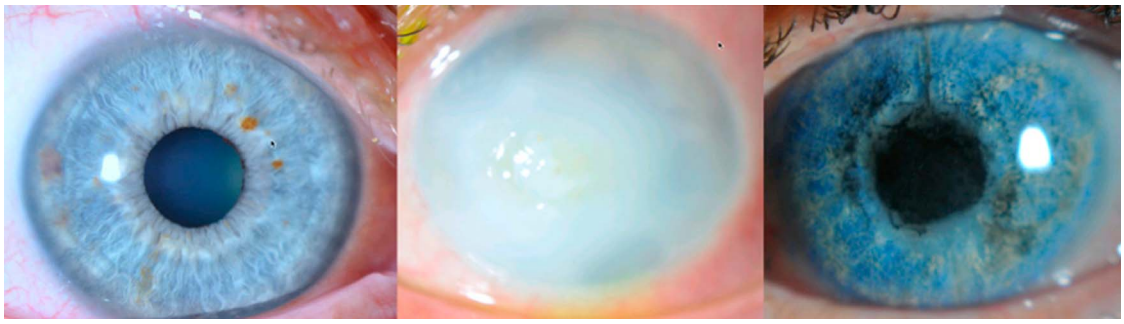

FIGURE 6. (Center) 55-year-old patient with a history of ocular trauma and total corneal leukoma of his left eye; therapeutic cosmetic superficial automated keratopigmentation was applied with blue and black pigments (right) and the color was adjusted according to the color of the fellow eye (left).

Postoperative

No chronic epithelial defects, ulcers, corneal dellen, ocular inflammation, uveitis, edema, visual field limitations, or photic phenomena were encountered in the eyes included in this study. Patients with an FUT less than 3 months: no early postoperative complications were encountered, except for 1 patient who was treated with SAK and experienced pain 2 months postoperatively while undergoing a magnetic resonance imaging head scan (see our recently published article[17]).

Patients with an FUT more than 3 months: 12 eyes (11.2%) developed postoperative complications. Some eyes had more than one complication. Change in color was seen in 6 eyes, neovascularization in 2 eyes, color fading in 7 eyes, and light sensitivity in 8 eyes. All these complications were studied in details and published in a previous report from our previous work.[17]

Summary of Some Clinical Cases

Figures 4–6 show the preoperative and postoperative appearance of some patients who underwent superficial KTP.

DISCUSSION

Recently, our team described different methods and techniques of KTP using consecutive generations of pigments.[1,2] During the learning and development curve, the third-generation CE mark pigments that had undergone histopathological and immunopathological studies are currently used for the purpose of pigmentation in human corneas.[16,19,20] KTP had been used for therapeutic cosmetic and functional reasons[2,4,21] and as a purely cosmetic technique.[15] In this study, we describe the superficial KTP in both of its modalities, manual and automated.

At first, superficial KTP was performed using a 25-gauge needle, and after the introduction of the automated KTP device, all superficial KTP procedures were automated. The same applied to the MIK technique that was mostly used before the debut of the femtosecond laser. Nowadays, the manual technique is very rarely applied and is used only in cases in which a small pocket has to be used to mask a small underlying defect or a peripheral iridotomy.

Most of the patients (98.5%) were satisfied with their cosmetic appearance although almost half of them (44.7%) needed a retouch. This can be a limitation of the KTP procedure in general. However, this opens a door for more research to improve the stability of pigments and the techniques.

In an attempt to analyze what kind of corneal pathology will most likely need retouch, we studied the frequency of retouches in each group of pathologies, and we found that patients with phthisis bulbi occupy the first place. However, these results should be considered with caution because these pathologies are rare and KTP surgery is also a relatively rare procedure. Therefore, we do not have a sufficient number of eyes in each group to properly compare them.

Different authors described the use of SMK for different cosmetic and functional indications such as iris coloboma (monocular diplopia), pseudopolycoria due to essential iris atrophy, band keratopathies, and corneal scars.[10,22,23] Beekhuis et al[24] reported MIK in a patient with photophobia due to posttraumatic aniridia.

Kim et al[11] described KTP using manual techniques, both superficial and intrastromal, for masking corneal opacities in a series of 147 eyes of 147 patients. They encountered complications such as fading of color, reopacification, and epithelial growth in 12% of the eyes. Most of the eyes required reoperation, unlike the results found in our series in which 44.7% of eyes were reoperated.

Eventually, with the development of new technologies (improved surgical techniques and pigments), the indications, observations, and complications of KTP will differ from those seen with older techniques and pigments. Keratopigmentation, in particular SAK, with micronized mineral pigments may be the solution for many patients with cosmetic or functional ocular deformities, especially if alternatives such as cosmetic lenses, evisceration, and implants or keratoplasties are not suitable procedures.

REFERENCES

1. Alio JL, Rodriguez AE, Toffaha BT. Keratopigmentation (corneal tattooing) for the management of visual disabilities of the eye related to iris defects. *Br J Ophthalmol.* 2011;95:1397–1401.
2. Alio JL, Sirerol B, Walewska A, et al. Corneal tattooing (keratopigmentation) with new mineral micronised pigments to restore cosmetic appearance in severely impaired eyes. *Br J Ophthalmol.* 2010;94:245–249.
3. Rodriguez AE, Amesty MA, El Bahrawy M, et al. Superficial automated keratopigmentation for Iris and pupil simulation using micronized mineral

pigments and a new puncturing device: an experimental study. *Cornea.* 2017;36:1069–1075.
4. Rodriguez AE, Toffaha BT, Alio JL, et al. Femtosecond-assisted keratopigmentation for functional and cosmetic restoration in essential iris atrophy. *J Cataract Refract Surg.* 2011;37:1744–1747.
5. Yildirim N, Basmak H, Sahin A. Prosthetic contact lenses: adventure or miracle. *Eye Contact Lens.* 2006;32:102–103.
6. Masoudi S, Stapleton F, Willcox M. Contact lens-induced discomfort and protein changes in tears. *Optom Vis Sci.* 2016;93:955–962.
7. Bohman E, Roed Rassmusen ML, Kopp E. Pain and discomfort in the anophthalmic socket. *Curr Opin Ophthalmol.* 2014;25:455–460.
8. Hatamleh M, Abbariki M, Alqudah N, et al. Survey of ocular prosthetics rehabilitation in the United Kingdom, part 1: anophthalmic patients' aetiology, opinions, and attitudes. *J Craniofac Surg.* 2017;28:1293–1296.
9. Pine K, Sloan B, Stewart J, et al. A survey of prosthetic eye wearers to investigate mucoid discharge. *Clin Ophthalmol.* 2012;6:707–713.
10. Pitz S, Jahn R, Frisch L, et al. Corneal tattooing. An alternative treatment for disfigurating corneal scars. *Br J Ophthalmol.* 2002;86:397–399.
11. Kim C, Kim KH, Han YK, et al. Five-year results of corneal tattooing for cosmetic repair in disfigured eyes. *Cornea.* 2011;30:1135–1139.
12. Burris T, Holmes-Higgin D, Silvestrini T. Lamellar intrastromal corneal tattoo for treating iris defects (artificial iris). *Cornea.* 1998;17:169–173.
13. Laria C, Alio J, Pinero D. Intrastromal corneal tattooing as treatment in a case of intractable strabismic diplopia (double binocular vision). *Binocul Vis Strabismus Q.* 2010;25:238–242.
14. Liu X, Shen J, Zhou Q, et al. Personalised lamellar keratoplasty and keratopigmentation in Asian corneal leucoma patients. *Int J Clin Exp Med.* 2015;8:9446–9453.
15. Alio J, Rodriguez A, El Bahrawy M, et al. Keratopigmentation to change the apparent color of the human eye : a novel indication for corneal tattooing. *Cornea.* 2016;35:431–437.
16. Amesty MA, Alio JL, Rodriguez AE. Corneal tolerance to micronised mineral pigments for keratopigmentation. *Br J Ophthalmol.* 2014;98:1756–1760.
17. Alio J, Al-Shymali O, Amesty MA, et al. Keratopigmentation with micronised mineral pigments: complications and outcomes in a series of 234 eyes. *Br J Ophthalmol.* 2018;102(6):742–747.
18. Alio J, Amesty MA, Rodriguez AE. *Art and Science of Corneal Pigmentation: Text and Atlas*. New Delhi, India: Jaypee Brothers Medical Publishers; 2015.
19. Amesty MA, Rodriguez AE, Hernández E, et al. Tolerance of micronized mineral pigments for intrastromal keratopigmentation: a histopathology and immunopathology experimental study. *Cornea.* 2016;35:1199–1205.
20. Sirerol B, Walewska-Szafran A, Alio J, et al. Tolerance and biocompatibility of micronized black pigment for keratopigmentation simulated pupil reconstruction. *Cornea.* 2011;30:344–350.
21. Alio JL, Rodriguez AE, Toffaha BT, et al. Femtosecond-assisted keratopigmentation double tunnel technique in the management of a case of urrets-zavalia syndrome. *Cornea.* 2012;31:1071–1074.
22. Mannis MJ, Eghbali K, Schwab IR. Keratopigmentation: a review of corneal tattooing. *Cornea.* 1999;18:633–637.
23. Kobayashi A, Sugiyama K. In vivo confocal microscopy in a patient with keratopigmentation (corneal tattooing). *Cornea.* 2005;24:238–240.
24. Beekhuis WH, Drost BH, Van Der Velden EM, et al. A new treatment for photophobia in posttraumatic aniridia: a case report. *Cornea.* 1998;17:338–341.