Keratopigmentation to Change the Apparent Color of the Human Eye: A Novel Indication for Corneal Tattooing

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Background: Recently developed surgical techniques of keratopigmentation, assisted by femtosecond laser technology, using adequately developed micronized mineral pigments, have been reported to be efficient and conveniently safe as they are not associated with significant sight-threatening complications for changing the apparent color of the eye in cases of cosmetic therapeutic and functional keratopigmentation. We report the use of intrastromal keratopigmentation for electively changing the apparent color of the eyes, for purely cosmetic reasons.

Methods: In a case series, 7 patients underwent purely cosmetic keratopigmentation to change the apparent color of the eye. The indication was compassionate and the procedure was conducted under the tenets of the Helsinki Declaration. Superficial automated keratopigmentation, manual intralamellar keratopigmentation, and femtosecond-assisted keratopigmentation were used. In this study cosmetic outcome, patient satisfaction, visual outcomes, stability of pigmentation, and presence of any related complications are reported.

Results: In this study 42.8% were females, with a mean age of 40 years (27–63). In 4 patients, pigment retouch was done to improve the cosmetic outcome. Results were monitored by an independent observer with follow-up ranging from 6 months to 2.5 years. All patients expressed high satisfaction with the cosmetic outcomes, with no complications and stable visual acuity during the period of follow-up.

Conclusions: As a novel indication, purely cosmetic keratopigmentation demonstrated stable pigmentation with no visual disability, high patient satisfaction, and favorable outcomes in all patients. Elective keratopigmentation seems to be a viable and convenient modality for changing the apparent color of the eye in selected cases.

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Keratopigmentation (KTP), or corneal tattooing, has been used as a method to change the apparent color of the eye, and improve the cosmetic appearance in eyes with leukomas or other disfiguring problems, and also in cases with functional visual disability such as colobomas and fixed dilated symptomatic pupils.[1] The concept is to improve the corneal opacity appearance through surgery delivering pigments into the corneal stroma.[2] Potential risks of inadequately selected pigments may include toxic reaction of the pigments, color fading and changes, under- or overpigmentation, and especially not matching pigmentation with the color of the normal eye because of the limitation in pigments' spectrum.[3–5]

In the past decade, major improvements have been accomplished in this concept using state-of-the-art technologies, either through surgical techniques or pigments, which markedly increased the safety and stability and improved the cosmetic outcome.[6] In previous reports, we have described the use of a new generation of corneal pigments with new surgical approaches applied for 2 indications: the first is the cosmetic therapeutic, indicated to improve the cosmetic appearance of disfiguring problems in nonseeing eyes, whether due to congenital, traumatic, or other ocular pathologies.[6] The second is the functional therapeutic, to treat debilitating visual symptoms such as light scattering, photophobia, or incapacitating diplopia, caused by cases of iris defects, such as posttraumatic aniridia or iris coloboma.[7–11] The use of KTP in these indications waives the need for other more complex or risky surgical procedures such as evisceration, enucleation, or penetrating keratoplasty, and the frequent problem of poor tolerance to using cosmetic colored contact lenses.

The good outcomes found, the high safety profile with lack of toxicity, tolerance to pigments of modern KTP found in our investigations, and positive patient satisfaction[8–10] encouraged us to seek a novel indication, which is elective cosmetic KTP in adequately selected patients who wish to change the color of their eyes to acquire a much desired cosmetic appearance. We report the outcomes of our first 7 cases of purely cosmetic KTP.

METHODS

Study Design

This study is a consecutive series of cases of elective KTP for purely cosmetic reasons with follow-up ranging from 6 months to 2.5 years.

All patients signed consent in accordance with the tenets of Declaration of Helsinki. Investigative review board and ethics committee approval was obtained at VISSUM Corporation, Alicante, Spain; Resbiomed Ophthalmology Center, Sofia, Bulgaria; and Beverly Hills Center, Kuwait.

Inclusion/Exclusion Criteria

Study included patients asking to change their eye color for purely cosmetic reasons, with no visual disabilities.

Exclusion: Patients with nonseeing eyes or poor vision, with disfiguring pathologies related to cornea or lens, were excluded. Patients with functional visual disabilities related to iris pathologies, abnormal corneal topographies, thin corneas, dermatological disorders such as atopy, and ocular surface diseases or dry eye and patients with reported sensitivities were also excluded. Mentally disabled patients were excluded as per the initial personal clinical interview, performed by the principal investigator of the study (J.L.A.).

Main Outcomes

The main outcomes are the cosmetic evaluation of pigmentation pattern, patient satisfaction, and pigment stability on successive follow-ups; corneal problems of any type observed at slit lamp biomicroscopy during the follow-ups; and changes in vision or corneal topographic maps. All these were evaluated by an independent medical observer along with the follow-up under the supervision of the local ethical committee.

Surgical Technique

Three main surgical techniques have been lately described for KTP. Superficial automated KTP that uses a micropuncture device while applying different parameters in terms of power and depth and that uses different tips according to each individual case, to deliver the pigments to the superficial layers of the cornea, especially in cases with deep and dense corneal opacities or in fine-touching the details of the iris pattern; manual intralamellar KTP that uses a diamond knife to create incisions to the depth of nearly 40% to 50% of the pachymetric corneal thickness, and a special set of helicoidal dissectors, to create intrastromal tunnels in a circular fashion; and finally, the femtosecond-assisted keratopigmentation (FAK) creates many unified and accurate tunnels at customized varying depths and dimensions, according to the surgeon's preferences and the requirements of each individual case.

Before completion of surgery clinical examination of the anterior segment and fundus was done. The time-domain Visante optical coherence tomography (Carl Zeiss Meditec AG) was used to evaluate the local corneal thickness and tomography in the different areas of the cornea; the pachymetry values were also obtained, to decide the appropriate lamellar depth of the femtosecond tunnels. The white-to-white horizontal and vertical diameters were measured using a caliper to determine the diameter of the lamellar dissection.

All surgeries were performed by a single surgeon (J.L.A.); 3 cases were performed at the VISSUM Corporation, Alicante, Spain; 2 cases at the Resbiomed Ophthalmology Center, Sofia, Bulgaria; and 2 cases at the Beverly Hills Center in Kuwait. The procedure was conducted under topical anesthesia (proparacaine hydrochloride 0.5%). In 4 cases, intrastromal tunnels were created using a 60-kHz femtosecond laser (IntraLase AMO, Irvine, CA), while in the third and fourth cases, VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) was used to create the tunnel. The tunnel depth ranged between 300 and 350 μm from the surface with pupil diameter set to an inner diameter of 5.5 mm and an outer diameter of 9.5 mm. The energy was set at 2 μJ, with a vertical incision at the 6-o'clock position. Opening the intralamellar femtosecond tunnel and widening it to the external limits of the cornea to reach the limbus was done by a lamellar dissector (KTP corneal dissector; Epsilon, Irvine, CA). Customized mineral micronized pigments were prepared matching the color desired by the patient and tested at the wet laboratory a few days before the surgery to ensure matching of the color. During surgery the pigments were injected with a 27-gauge cannula into the deeper tunnel through the 6-o'clock incision; some touch-ups were performed with the superficial technique.

The micronized mineral pigments of different colors (Blue Green Company, Spain) are composed of varying amounts of isopropyl alcohol, water, glycerin, and micronized pigments found in the positive list of allowed colorants in cosmetics by the Ministry of Health in accordance with Annex IV of European Regulation of Cosmetics.

Postoperative treatment was a combination of topical antibiotics (Oflox 0.3%, Exocin; Alcon), and steroid (dexamethasone 0.1% Maxidex; Allergan) for 2 weeks, using standardized postoperative instructions.

Follow-up was done by an independent medical observer other than the surgeon to evaluate the change in visual acuity, refraction, topographic pattern after pigmentation, visual symptoms, and complications. The observers graded the cosmetic improvement of the case as poor, good, or excellent. 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 6- to 30-month follow-up.

RESULTS

In all 7 cases reported, 42.8% were females, with an average age of 40 years (27–63 years); we found that cosmetic outcomes were very satisfactory, for both the patients and the surgeon, in spite of the need for pigment retouch in some cases to improve the outcome, in 3 cases upon patients' request and in 1 case upon recommendation by the surgeon. The procedure did not affect the visual acuity or

refraction of any of the patients, and no complications or any corneal or ocular surface tissue problems were observed on evaluation by the medical observer or reported by the patients in the study during the postoperative follow-up. The postoperative topographic patterns revealed a rather curious aspect (Fig. 1), that is, there was a normal central pattern corresponding to the pigment-free papillary area, while there was blockage of the topographic mapping in the pigmented area. Moreover, none of the patients reported any change in the quality of vision or photic phenomena after the initial 4 weeks of follow-up. In all patients only transient mild to moderate photophobia or moderate light sensitivity was reported ranging from 2 weeks to a maximum of 3 months, for which sunglasses were effectively used until the resolution of symptoms.

Case 1

A 27-year-old female patient, with dark brown eyes, using cosmetic contact lenses on a regular basis, and for personal considerations, was asking for a permanent procedure to change the color of her eyes and get rid of the need to use contact lenses. She had been wearing cosmetic blue contact lenses for over 10 years and her personal image was

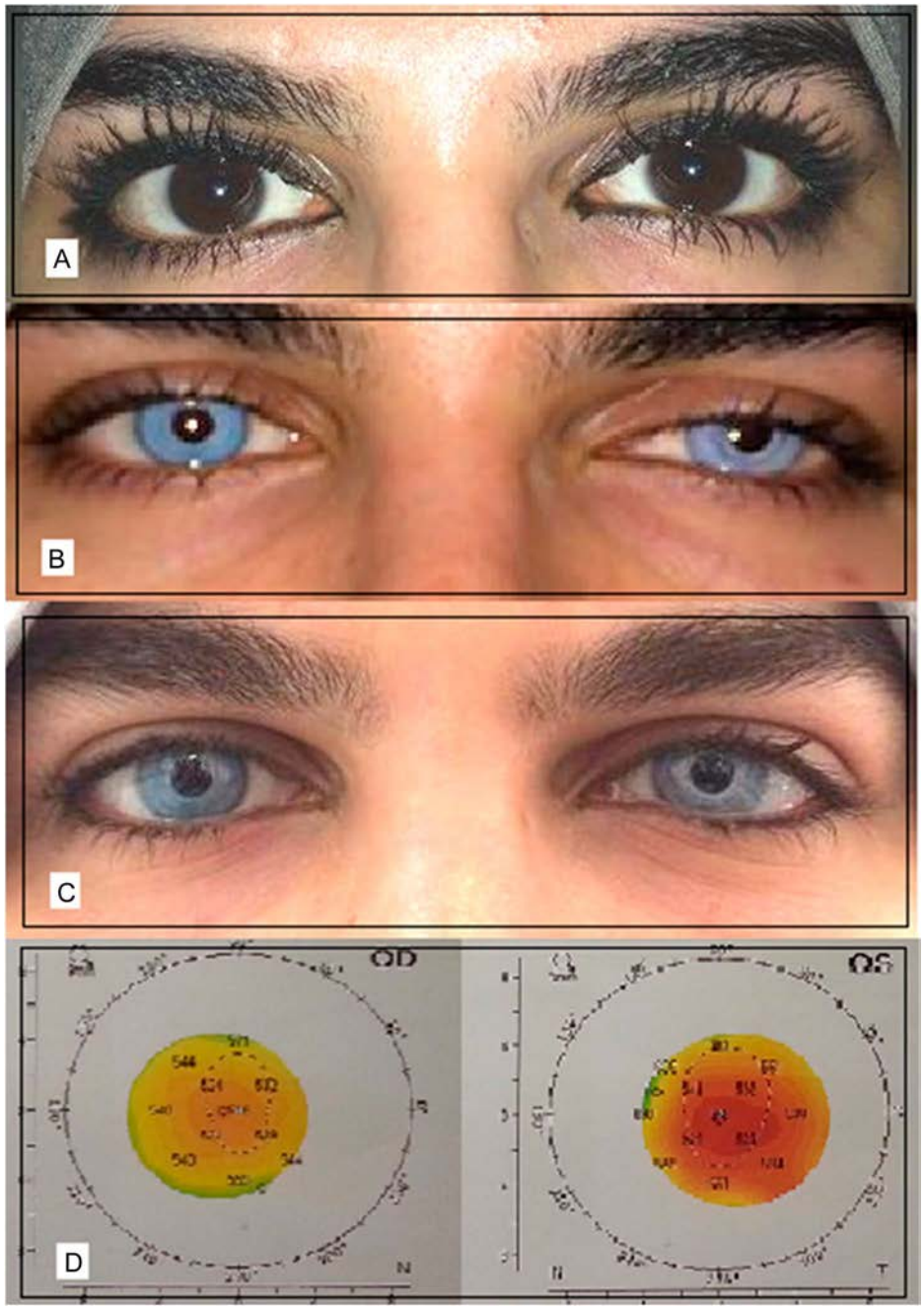

FIGURE 1. Cosmetic outcomes of case 1. A, Original dark color of the patient's eyes. B, Light blue color after first KTP. C, One-year follow-up of the more natural gray–blue color. D, Postpigmentation topographic results.

related to this eye color; she wanted to keep this as a permanent color of her eyes to get married. She was offered KTP as an alternative solution for her problem. Preoperative examination revealed completely normal eyes bilaterally, with no history of surgery or trauma, and uncorrected visual acuity (UCVA) was 1.0 (decimal) in both eyes. Our biochemistry team prepared the customized color pigments and conducted a preoperative wet laboratory color experiment, to test the targeted pigmentation color. The patient underwent FAK using blue pigment (VEMP 605; Blue Green Company). On her first follow-up, the patient did not express any complaint or visual disabilities, with stable visual acuity in both eyes; she was very satisfied with the result. On cosmetic evaluation, the surgeon noticed that the blue color was a bit light for the skin tone, giving her an artificial look, and he advised the patient about undergoing a color retouch to adjust it to a more natural color. Pigment enhancement was done using black pigment (VEMP 110; Blue Green Company) to delineate the pupil and limbus, with personalized grayish blue pigment to modify the iris color. Photophobia in this patient lasted for 3 months with gradual improvement until complete relief of the symptom. At 2.5 years' follow-up, pigmentation pattern was stable with no signs of visual acuity, UCVA 1.0; topographic study showed peripheral block of the imaging by the pigment, but with normal central mapping in both eyes. The patient was highly satisfied with her new more natural appearance (Fig. 1).

Case 2

A 30-year-old female patient regularly used green color cosmetic lenses for more than 10 years, and was asking for a permanent solution to simulate her contact lens color because she was becoming intolerant to the contact lenses. Owing to her job, it was important for her to keep her eye color as her personal image was related to it. She was advised about the use of cosmetic KTP, to deliver her desired cosmetic look. Preoperative examination was normal in both eyes, with a UCVA visual acuity of 1.0 (decimal) bilaterally. An adequately produced customized pigment to match the desired color elected by the patient was produced. The patient underwent FAK using a customized green mixed with light gray (VEMP500; Blue Green Company) pigment. On postoperative follow-up, the patient reported moderate photosensitivity for 3 weeks with stable visual acuity. Although the cosmetic appearance was more natural than the originally desired cosmetic contact lens pattern, the patient was not completely satisfied with the results and requested for a pigment enhancement. The second touch-up was performed using bluish pigment (VEMP 604; Blue Green Company), to create a pattern closer to that of the desired contact lens, but with a more natural appearance. At the 2-year follow-up, the patient was satisfied with the cosmetic result and examination revealed stable corneas and visual acuity in both eyes. A final minimal touch-up using superficial technique to apply some yellow pigment dots, according to a decision made by the patient and seconded by the surgeon for further improvement of the cosmetic appearance, was performed (Fig. 2). The postoperative topographic study in the patient showed no change in the central 5 mm with blockage of the topographic pattern at the peripheral cornea with UCVA 1.0.

Case 3

A 46-year-old male patient complaining of difference between the colors of his eyes since birth was asking for a permanent solution for this problem. Examination revealed congenital iris heterochromia; the right eye was light blue with a sector of brown and the left eye was brown. His UCVA was 0.7, whereas best corrected visual acuity (BCVA) was 1.0 (decimal) bilaterally, with no history of trauma or surgery. When advised about the option of purely cosmetic KTP as a permanent solution for his complain, the patient agreed to the option and requested to change his right blue eye to brown. FAK was performed using a mix of brown (VEMP 201; Blue Green Company) and black (VEMP 110; Blue Green Company) pigments. Photophobia was transient for only 2 weeks. At 1-year follow-up, the patient expressed very high satisfaction with the cosmetic result, and examination revealed no signs of ocular toxicity or change in BCVA 1.0 (Fig. 3).

Case 4

A 48-year-old male patient had a history of right eye blunt ocular trauma, nearly 7 years ago, which caused a change in his originally brown iris color to a light blue color; his visual acuity was affected by the trauma due to a posttraumatic macular lesion, with a UCVA of 0.4 and BCVA of 0.5 (decimal) in this eye. He wanted a cosmetic solution to restore the color of his eye because the traumatic heterochromia was causing him some social and professional limitations. He was advised about the option of purely cosmetic KTP to improve the general look of his eye. FAK was performed using a mix of brown pigments (VEMP 201; Blue Green Company). Photophobia was transient for a period of 3 weeks. At the 1-year follow-up, the patient expressed his satisfaction with the result and how it improved his social and professional life. UCVA and BCVA were stable, 0.5, and the eye did not demonstrate any postoperative complications. A final touch-up was done to darken the color a little bit. The photograph of this case is not available for public use because the patient denied permission to use it for the purpose of scientific publication.

Case 5

A 32-year-old male patient with very light blue eyes, not happy with his appearance, wished to change it for personal reasons related to the social environment where he had to perform his labor activities to a brown color, which was more adequate for him. Based on his background knowledge about the possibility of changing the apparent color of the eye through purely cosmetic KTP, and after initial clinical examination, which revealed a UCVA visual acuity of 1.0 (decimal) bilaterally, as well as normal anterior segment and fundus examination, he requested this surgical solution. KTP was conducted by the femtosecond-assisted technique using

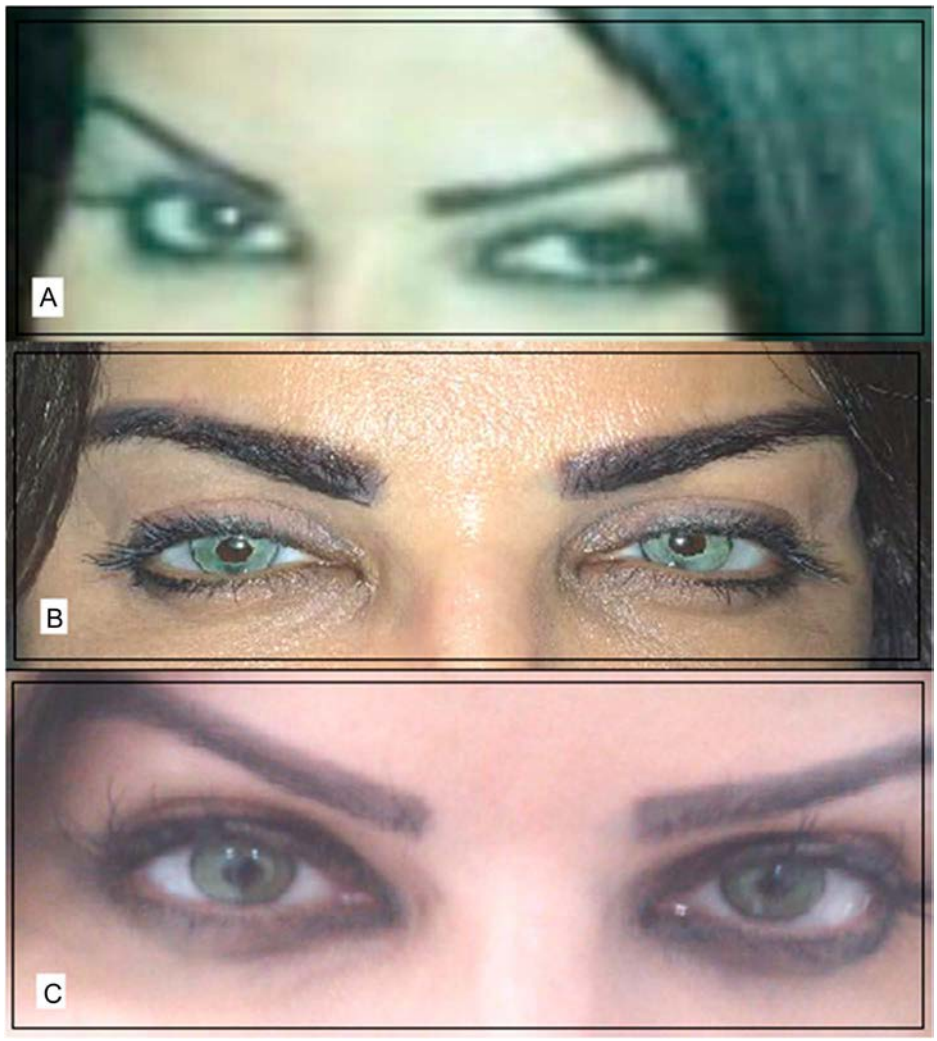

FIGURE 2. Cosmetic outcomes of case 2. A, Original dark color of the patient's eyes. B, Result of first KTP with more natural look than the originally desired look. C, One-year follow-up of the more natural green color.

a very light brown color just to darken his iris hue without losing the normal iris pattern of his eyes (VEP 201, Blue Green Company) with 20% concentration. Postoperative follow-up was clear except for the photophobia that lasted for a period of nearly 1 month. At 6-month follow-up the patient expressed satisfaction with his new look and stated that it provided him with a higher self-esteem with a stable UCVA of 1.0 (Fig. 4).

Case 6

A 32-year-old female patient had brown eyes and was a regular user of cosmetic contact lenses, which was no longer tolerated by her because of the chronic dry eye she was experiencing. As most of her social life was in an environment in which the color of her eyes was an important factor related to her personal image, she was seeking an adequate solution of her cosmetic image problem. She was advised about purely cosmetic KTP as an option. Preoperative examination revealed totally normal eyes with UCVA of 1.0 (decimal). KTP was conducted by the femtosecond-assisted technique and using blue pigment (VEMP 605; Blue Green Company). The postoperative examination revealed a very stable pattern and patient satisfaction with no need for enhancement at the 6-month follow-up; in this case the reported photophobia lasted for only 2 weeks (Fig. 5); the final UCVA was 1.0.

Case 7

A 63-year-old male patient, with blue eyes, who had gained recent knowledge about the availability of purely cosmetic KTP, requested for advice about the possibility of changing the apparent color of his eyes from light blue to a brown color matching the color of his son's eyes, for personal sentimental and social reasons related to the ethnicity of the family. His preoperative examination revealed normal eyes with UCVA of 0.8/0.9 (decimal) and BCVA of 0.9/0.9 for the right and left eyes, respectively. As standard in all cases the wet laboratory test was done to match the pigment for the iris color the patient provided. KTP was conducted by the femtosecond-assisted technique using brown pigment (VEMP 201; Blue Green Company) with a light concentration. At postoperative follow-up, in spite of not experiencing any symptoms, the patient requested a retouch to darken the color, which was conducted upon

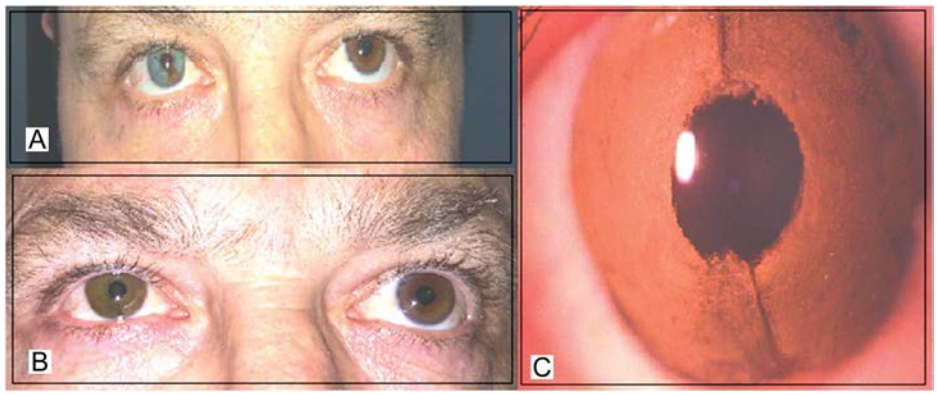

FIGURE 3. Cosmetic outcomes of case 3. A, Preoperative heterochromia with right blue and left brown eye. B, Postoperative cosmetic results at 1-year follow-up. C, Slit lamp microscopy of the brown pigmentation pattern after 6 months.

his request. Photophobia lasted for 3 weeks. At the 6-month follow-up the patient was highly satisfied with the cosmetic and emotional effect of the new color of his eye and cosmetic evaluation revealed excellent pigmentation pattern with a BCVA of 0.9 bilaterally. The photograph of this case is not available for public use because the patient denied permission to use it for the purpose of scientific publication.

DISCUSSION

This is to the best of our knowledge the first study and report using a systematic approach for an elective change of the apparent color of the eyes; the reason to consider KTP is the vast scientifically proven background through studies and follow-ups concerning the pigments and surgical techniques.[5–8] Medicine as a discipline is considered with both the physical and psychological well-being of the patient, and one important aspect of this well-being is the establishment of a desired cosmetic appearance, including the color of the eyes, whether lighter or darker colors according to the patient's preferences. For that reason, many attempts have been made to either temporarily or permanently change the color of one's eyes. Cosmetic contact lenses may be considered a simple solution but still embedding risks such as corneal infection, abrasions or the induction of dry eye syndrome, and intolerance of the patient to its application.[12] Another approach suggested is the use of colored iris silicone diaphragm, which is an intraocular diaphragm implanted in front of the iris to mask its color, but it has many complications and risks, including risks of intraocular surgery including intraocular infection. Also, these devices induced chronic iritis due to continuous contact with the front of the iris.[13] With the recent advances in both the surgical modalities of KTP and pigments used, the safety and stability of the pigmentation has markedly improved, with excellent results in both cosmetic therapeutic and functional KTP and patients expressing high degrees of satisfaction with the cosmetic results of the surgery. A novel purely cosmetic KTP indication has been strongly suggested and presented as a more convenient method of delivering a permanent cosmetic change of the color of the eyes for selective patients asking for this option.

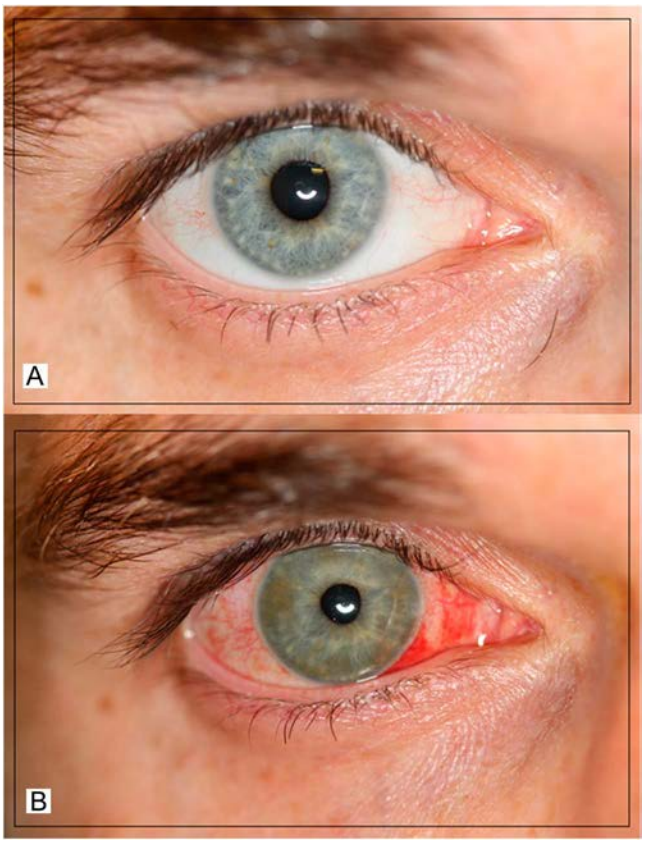

FIGURE 4. Cosmetic outcomes of case 5. A, Preoperative blue color of the iris. B, Change of the apparent iris color to brown.

A very important issue is the quality of the pigments, as a cornerstone of both stability and safety, so as to withstand long exposure to the light and to preserve the avascular transparent nature of the cornea in this elective procedure. The pigments described before in our report are the third generation of biomedical pigments. The micronized mineral pigments used have an additional advantage over other natural pigments, because their particle sizes are reduced by processes of micronization. As small particles, 2.5 μm or smaller, the chance of developing a foreign body reaction against the pigment introduced into the corneal stroma is much lower than with bigger particles.[14,15]

In the cases we reported, the follow-ups were up to 2.5 years, showing stability of pigmentation pattern, delivering the natural look that the patient desires. Moreover, there were

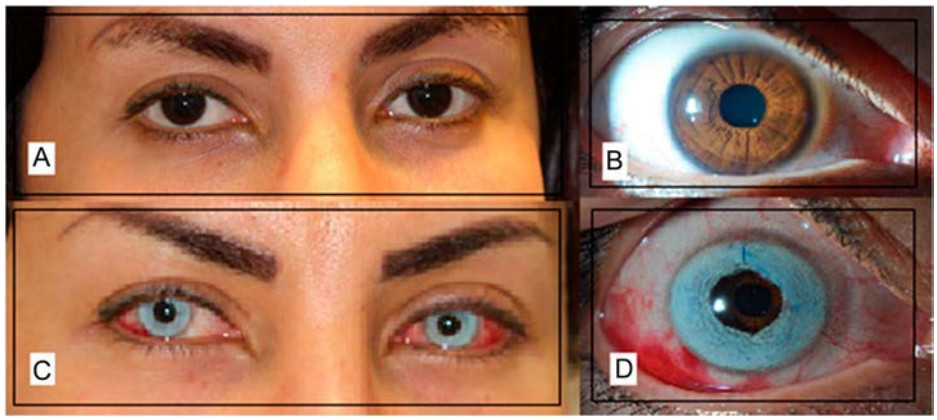

FIGURE 5. Cosmetic outcomes of case 6. A, Preoperative brown color of the iris. B, Preoperative slit lamp photography. C, Postoperative blue color of the eyes. D, Postoperative slit lamp photography.

no reported complications or ocular toxicity, and most importantly, there was visual stability; all patients had no change in both the UCVA and BCVA between preoperative assessment and successive postoperative follow-ups. The refraction was stable and the procedure did not induce an increase in astigmatism in any of the patients, also confirmed with topographic study (Fig. 1), in which the central 5 mm showed normal values, while as expected the pigment blocked the peripheral part of the cornea. The rather minimally invasive extraocular approach allows easy accessibility to enhancing the pigmentation pattern or color by retouching as indicated in some of the cases by either the patient or the surgeon.

The safety and stability of pigments used have been reported in animal and human models. Amesty et al, reported that with the use of micronized mineral pigments, no pigment diffusion or changes in color, inflammation, or neovascularization were detected in the eye treated, while histopathological examination confirmed the clinical observation regarding the absence of inflammation. Thus pigmented corneas showed a good cosmetic appearance without signs of ocular toxicity.[14–17] With the main future perspective of improving customization of colors and creating guidelines for standardization of surgical procedure and techniques, we believe that KTP will develop more potentiality in terms of cosmetic use of this novel surgical technique.

Similar to most innovative techniques, special consideration was given to ethical consideration, as patients underwent precise psychological interviews to determine the motive and the effect that this procedure will have on their lives; they where informed about the nature of the surgery and the possible complications. All patients of this series reported consistent reasons to support the indication of cosmetic KTP. The apparent pupil size diameter was set to an average of 5 to 5.5 mm, which is suitable for all intraocular surgeries. The lack of complications during the follow-up of the cases and the stability of the colors and corneal pigments chosen for the purpose are noteworthy.

As a conclusion we can state, based on the evidence of the outcomes here reported, that modern KTP using the state-of-the-art surgical techniques and adequately selected and well-investigated micronized mineral pigments seems to be a feasible surgical option for the elective change of the apparent color of the eye for purely cosmetic reasons, improving the confidence and self-esteem of the patient, with no observed ocular toxicity or visual disability. To the best of our knowledge this is the first report about the systematic use of KTP as an elective purely cosmetic ophthalmological surgical procedure.

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