Journal of Education, Health and Sport. 2026;88:69004
eISSN 2391-8306.

https://doi.org/10.12775/JEHS.2026.88.69004

Journal of Education, Health and Sport. eISSN 2450-3118

Journal Home Page
https://apcz.umk.pl/JEHS/index

ŻAK, Sandra, RUZIK, Alicja, PRZEBIERADŁO, Patrycja, RĘDZINIAK, Patrycja, RAJS, Monika, GAJ-HUNTER, Antonina Magdalena, KOWALSKA, Monika, ŻUREK, Katarzyna, STOLARSKA, Kaja, and TERPIŁOWSKA, Sandra. The Safety and Outcomes of Keratopigmentation as a Cosmetic Eye Color Change Procedure. Journal of Education, Health and Sport. 2026;88:69004. eISSN 2391-8306.
https://doi.org/10.12775/JEHS.2026.88.69004

The journal has had 40 points in Minister of Science and Higher Education of Poland parametric evaluation. Annex to the announcement of the Minister of Education and Science of 05.01.2024 No. 32318. Has a Journal's Unique Identifier: 201159. Scientific disciplines assigned: Physical culture sciences (Field of medical and health sciences); Health Sciences (Field of medical and health sciences).
Punkty Ministerialne 40 punktów. Załącznik do komunikatu Ministra Nauki i Szkolnictwa Wyższego z dnia 05.01.2024 Lp. 32318. Posiada Unikatowy Identyfikator Czasopisma: 201159. Przypisane dyscypliny naukowe: Nauki o kulturze fizycznej (Dziedzina nauk medycznych i nauk o zdrowiu); Nauki o zdrowiu (Dziedzina nauk medycznych i nauk o zdrowiu).
The authors declare that there is no conflict of interests regarding the publication of this paper.
Received: 15.02.2026. Revised: 01.03.2026. Accepted: 02.03.2026. Published: 05.03.2026.

The Safety and Outcomes of Keratopigmentation as a Cosmetic Eye Color Change Procedure

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Abstract

We review the articles discussing the rationale for performing keratopigmentation (KTP) for purely aesthetic purposes and the safety considerations associated with this method. Originally developed for therapeutic purposes, such as iris defects and corneal opacities, KTP has recently gained popularity as a permanent cosmetic method for changing eye color. Advances in femtosecond-assisted techniques and the use of micronized mineral pigments have enhanced the precision of the procedure and its biocompatibility, contributing to high patient satisfaction rates.

Published data, mainly in the form of case reports and small case series, suggest that cosmetic KTP is generally well tolerated. The most commonly reported adverse effects are mild and reversible. Functional parameters typically remain stable, although reductions in contrast sensitivity and mild endothelial cell loss have been reported. Corrective procedures are often necessary, and repeated interventions may increase the risk of complications.

Given the limited long-term evidence and the ethical considerations of performing irreversible surgery on healthy eyes, cosmetic KTP should be approached with caution, ensuring thorough patient counseling and careful candidate selection.

Keywords Keratopigmentation, Eye color change, Cornea, Pigments

Introduction

The earliest historical description of corneal tattooing comes from Galen (131–210 AD), who used reduced copper sulfate to mask corneal opacities [1,2]. During such procedures, other pigments were also employed, including metal powders, gold and platinum chlorides, Indian and Chinese inks, organic dyes, soot, and animal-derived pigments [3–5]. Another reference dates to 450 AD, when Aetius described a method involving cauterization of the cornea followed by application of dye to conceal opacities [3,6]. The technique was not mentioned again until 1869, when Louis von Wecker introduced a corneal tattooing method utilizing cocaine anesthesia, application of Indian ink, and insertion of pigment into the cornea using a grooved needle [7]. In subsequent years, Taylor modified the technique by replacing a single needle with a bundle of needles, thereby increasing precision [7]. In 1901, Nieden developed a needle based on the mechanism of a fountain pen, inspired by Edison's electric pen [6,8]. Armagnac, in turn, used a funnel attached to the cornea at three points, through which Chinese ink was delivered. The pigment was applied using a needle, which enabled the creation of a regular, pupil-like shape [3,6].

Currently, the most thoroughly investigated technique for eye color change, and one that has recently been developed with an acceptable safety and efficacy profile, is keratopigmentation (KTP). Other, more controversial approaches have also been described, including cosmetic iris implant surgery and laser-assisted iris depigmentation [9].

To date, research has focused predominantly on the therapeutic use of KTP in patients with ocular disorders such as iris defects [10,11], corneal scarring [7,12], leukocoria [13], diplopia [12], photophobia, and Urrets-Zavalia syndrome [14]. Recent refinements in surgical techniques, together with advances in the development of micronized pigments, have led to increasing interest in the use of KTP for purely aesthetic purposes driven by patient's personal desire to change their iris color [15].

In this review, we provide an analysis of the available evidence on the application of KTP in procedures aimed at cosmetic iris color modification, with particular emphasis on the safety profile of the technique.

Discussion

1. Contemporary surgical techniques in keratopigmentation

Currently surgical techniques for KTP can be divided into two principal categories: superficial and intrastromal [9].

Intrastromal KTP techniques may be performed either manually or with the aid of a femtosecond laser [9].

The intrastromal technique preserves the integrity of the corneal basement membrane. If this membrane is disrupted—regardless of whether the injury is mechanical or chemical —patients may develop recurrent corneal epithelial erosions [16,17]. Compared with other KTP methods, the intrastromal technique provides greater precision, more rapid wound healing, and a more homogeneous distribution of the pigment. In addition, because the corneal surface remains intact, the pigment is not exposed to washout by the tear film [17].

Femtosecond-assisted keratopigmentation (FAK) is the recommended and most frequently employed technique in cases of cosmetic KTP. The use of a femtosecond laser enables the precise creation of corneal stromal tunnels. Prior to the procedure, corneal thickness must be measured to allow accurate planning of tunnel depth according to the patient's individual requirements. Two variants of this technique have been described: creation of a single tunnel or creation of two intrastromal tunnels [10,14]. In the single-tunnel method, the femtosecond laser creates a circular stromal channel, into which the pigment is introduced using a flat cannula [10]. The two-tunnel technique involves the formation of two intrastromal channels: a deeper tunnel filled with a darker pigment simulating the iris pigment epithelium, and a more superficial tunnel filled with a lighter pigment corresponding to the intended iris color [14].

FAK provides opportunities for customization, offers enhanced precision and ease of execution, reduces postoperative pain, and facilitates faster wound healing compared with other KTP techniques [10,18].

A more recent variant of this approach is femtosecond laser-assisted annular keratopigmentation (FLAAK). This procedure consists of creating an annular intrastromal tunnel with a femtosecond laser, performing stromal dissection using a specialized circular spatula, and subsequently introducing micronized mineral pigment [19].

Manual intralamellar keratopigmentation (MIK) involves delivering pigment into the anterior corneal stroma via an intrastromal pocket. Radial incisions are made at approximately 40–50% stromal depth, extending from the limbus to the boundary of the predetermined pupil diameter. Subsequently, intralamellar and peripheral corneal stroma dissection is performed using a crescent microscalpel and spiral intrastromal corneal dissectors. Once the stromal tunnel is fashioned, pigment is injected using a cannula of appropriate diameter [9].

Superficial KTP can be performed using two approaches. Manual superficial KTP is based on multiple punctures of the corneal surface with a needle to introduce pigment. More recently, superficial automated keratopigmentation (SAK) has become the preferred technique. Through automated micro-puncturing with individualized adjustment of depth and power, SAK enables a more uniform pigment distribution [11,20]. It is most often employed in challenging cases involving deep, dense corneal opacities or for achieving fine iris-pattern detailing. It is not recommended as a first-line treatment for patients seeking purely cosmetic eye color change [9].

2. Pigments

Initially, two main categories of dyes were used in KTP. The first comprised chemical agents, including gold and platinum chloride [21]. The second consisted of carbon-based pigments. Carbon staining was more technically demanding and time-consuming than chemical tattooing, yet its effects were more durable. Subsequently, additional organic dyes—such as India ink and Chinese ink—were introduced into clinical use [22].

At present, micronized mineral pigments represent the preferred option and were first implemented in clinical practice in 2010 [23]. Reducing the particle size of the pigment minimizes the risk of foreign-body sensation and decreases the likelihood of immunologic activation [24–27]. An additional advantage is the availability of a broad color palette, enabling precise customization of the aesthetic outcome to meet the patient's individual expectations [24]. Third-generation pigments are now available, manufactured in accordance with European (CE) standards and containing, among other components, lactic acid, propanediol, and mineral pigments with defined color indices (BIOTIC Phocea, France). Both composition and shade are selected individually, often aided by computer-generated simulations performed on patient photographs [28].

The safety of micronized mineral pigments in KTP has been confirmed in several experimental animal studies. Histopathological and clinical assessments have demonstrated that these pigments do not diffuse within the cornea, do not induce color alteration, and do not provoke inflammation or neovascularization [20,24,26,29].

In the clinical study by Alió et al. (2010), KTP using micronized mineral pigments yielded favorable cosmetic outcomes without major intraoperative complications. After one year of follow-up, most patients reported high satisfaction with the aesthetic results, and only a few required retreatments [23].

Further development and refinement in this field remain necessary [15].

3. Other Methods for Cosmetic Eye Color Change

Other methods enabling permanent alteration of eye color for cosmetic purposes include iris implant surgery and laser iris depigmentation [9].

Iris implant surgery is associated with severe complications, such as corneal endothelial cell decompensation, uveitis, bullous keratopathy, glaucoma, and elevated intraocular pressure (IOP) [30–32]. None of the available implants have received CE marking or approval from the Food and Drug Administration (FDA). Despite the substantial risks—including the potential for irreversible vision loss—this procedure continues to be performed in certain countries. It should, however, be strongly discouraged. Given that it remains in use, clinicians must be adequately prepared to manage the possible intraoperative and postoperative complications [33–35].

Laser iris depigmentation involves the removal of pigment from the anterior iris stroma using a 532-nm Nd:YAG laser. This technique is associated with several complications, including iris perforation due to excessive depigmentation, pigmentary glaucoma, and laser-induced maculopathy [36–39]. Its effectiveness is also limited—particularly in patients with dark irises, in whom the color change remains minimal even after multiple treatment sessions and is often noticeable only in bright sunlight. Moreover, the procedure does not allow for targeted selection of the desired eye color; for example, it cannot convert blue irises to green. Depigmentation merely reveals the natural gray stromal fibers of the iris, leading many dissatisfied patients to subsequently seek additional KTP [40].

4. Application of KTP – Outcomes and Complications

Alió et al. were the first to report outcomes of cosmetic KTP in 2016, presenting a case series of seven patients who underwent the procedure for elective eye color change. During surgery,

the SAK, MIK, and FAK techniques were employed. Over a follow-up period ranging from 6 months to 2.5 years, no procedure-related complications were observed. The authors demonstrated excellent stability of the pigmentation pattern, absence of pigment toxicity, and no changes in visual acuity or astigmatism. In four patients, pigment touch-ups were performed to enhance the cosmetic outcome. All patients reported a high level of satisfaction with the cosmetic results [25].

Another report on cosmetic KTP was a case study of a 21-year-old female patient described by Ferrari et al. in 2018. The procedure was performed using the FLAAK technique. Pigment was introduced into a corneal channel created with a femtosecond laser at a depth of 225 µm. The surgical procedure was uneventful. One day postoperatively, the patient reported no pain and described the eye color change as "natural." No postoperative photophobia was reported. At the 8-month follow-up examination, a 3% decrease in endothelial cell density was observed in the left eye. Refraction, visual acuity, pachymetry, and IOP remained stable preoperatively and at follow-up visits conducted 3 and 8 months postoperatively. Furthermore, optical coherence tomography (OCT) pachymetry performed 8 months after surgery confirmed stable pigment localization at a depth of 225 µm, with no evidence of pigment leakage or diffusion within the cornea; therefore, no color correction was required. No signs of inflammation were detected throughout the entire follow-up period. At both 3- and 8-month follow-up visits, the patient reported no adverse effects related to the procedure and expressed satisfaction with the result. It should be noted that this study assessed only short- and mid-term outcomes, which are insufficient for a comprehensive evaluation of procedural safety [15].

Mid- and long-term outcomes of cosmetic KTP, with follow-up ranging from 29 to 69 months, were reported by D'Oria et al. in 2021. The procedures were performed on 79 healthy eyes of 40 individuals using micronized mineral pigments with the FAK technique (39 patients) and the SAK technique (1 patient). Among intraoperative complications, two patients experienced pigment dispersion at the site of previous Laser-Assisted In Situ Keratomileusis (LASIK) surgery. The most common postoperative complication, reported by twelve patients (30%), was increased light sensitivity, which resolved spontaneously within one month after surgery. Other reported complications included pigment color change (7.5% of patients), color fading (5%), and visual field limitations in cases with a pupil diameter of 4.5 mm (2.5%). Reoperation was required in as many as 28 eyes (35.4%); among these, seven eyes (8.9%) underwent two color

corrections, and four eyes (5.1%) required three color corrections. Within 6 months postoperatively, one patient (2.5%) with a history of LASIK developed bilateral progressive corneal ectasia, which was successfully treated with standard epithelium-off corneal cross-linking (CXL). The authors advise against performing KTP in post-LASIK patients. No significant deviations were observed in corneal topography, pachymetry, refraction, or visual acuity after KTP. A transient early hyperopic shift normalized spontaneously. Overall, 92.5% of patients reported high satisfaction with the procedure, and all patients stated that they would undergo the surgery again [28].

In 2023, Alafaleq et al. conducted a study evaluating the safety profile and patient experience of 42 individuals undergoing eye color correction after KTP using a novel FLAAK technique. Patients reported procedure-related symptoms using a questionnaire. The most common perioperative and postoperative symptoms were pain (81%), dry eye (76%), tingling sensation (71%), redness (67%), and glare (56%). No patient reported visual halos. The duration of these symptoms was also assessed. Pain, tingling, glare, and ocular redness resolved within 48 hours postoperatively in approximately 50% of patients, while dry eye symptoms resolved within this timeframe in 22% of patients. Among those with persistent symptoms, the median duration was 7 days. Notably, prolonged adverse effects lasting several months were documented. Two patients experienced pain lasting 120 and 270 days, respectively, and one patient reported tingling persisting for 60 days. Ultimately, all reported symptoms resolved in all patients. Importantly, all patients in the study group required color correction, accounting for 53% of individuals who underwent the primary procedure. Patient satisfaction was assessed on a scale from 0 to 10, with a mean score of 8.1 (SD 1.6). Improvement in well-being after surgery was reported by 85% of patients, while two patients reported no improvement [19].

In 2025, Alió et al. published results from a large case series including 166 eyes of 83 patients who underwent therapeutic KTP between 2021 and 2023. The procedure was performed using the FAK technique with Biochromaeyes pigment (BIOTIC Phocea, France). Clinical evaluations were conducted immediately after the intervention and at 3, 6, and 12 months of follow-up. Analysis of functional parameters revealed no statistically significant changes in visual acuity or visual field at 12 months postoperatively ($p > 0.05$). Importantly, patients did not report subjective peripheral visual field loss. Changes in IOP were not statistically significant, which the authors attribute to the extraocular nature of the KTP procedure. No

statistically significant effect on the total higher-order aberrations was observed at 12 months, despite minor transient changes at earlier follow-up visits. However, a decrease in corneal endothelial cell density was observed at 12 months postoperatively, with mean values declining from 2393.29 ± 123.69 cells/mm² preoperatively to 2308.58 ± 126.64 cells/mm² postoperatively, corresponding to an approximate 3% loss [41]. This finding is consistent with earlier observations reported by Ferrari et al [15]. The study also demonstrated a statistically significant reduction in contrast sensitivity after surgery, likely related to reduced light transmission through the neo-pupil. Despite this decrease, measured values remained within clinically normal limits [41]. According to previous reports, reduced contrast sensitivity may be associated with decreased quantity and quality of the tear film [42]. Patient satisfaction was assessed using five general questions administered both by telephone and during the final visit, with responses recorded on a five-point scale ranging from "very satisfied" to "very dissatisfied." High satisfaction with the procedure was reported by 84.33% of patients, while 13.25% expressed a neutral opinion, most related to insufficient attention to pigment color selection. No procedure-specific complications such as inflammation, infection, uveitis, corneal perforation, neovascularization, elevated IOP, retinal complications, or pigment fading requiring retouching were observed during follow-up. Two patients underwent reintervention solely for pigment color change, unrelated to pigment degradation or matting. In two patients, pronounced photophobia and dry eye symptoms persisted for approximately four months and resolved following pharmacological treatment [41].

Analysis of the available clinical data suggests that cosmetic KTP may be well tolerated in carefully selected patients. Most reported complications are mild and reversible, including pain, dryness, tingling, redness, and glare. Furthermore, the procedure is associated with a high level of patient satisfaction, reported in 84–100% of cases. Most functional ocular parameters—such as visual acuity, visual field, IOP and corneal topography—remain stable following the procedure. However, transient changes in contrast sensitivity and a reduction in corneal endothelial cell density have been observed [15, 19, 25, 28, 41]. A summary of clinical studies on cosmetic KTP is presented in Table 1.

Particular caution should be exercised in patients with a history of LASIK, in whom serious complications such as corneal ectasia have been reported [28]. In addition, pigment retouching

was frequently required [19, 25, 28, 41] and repeated interventions may increase the risk of adverse events.

The American Academy of Ophthalmology (AAO) in 2024 has issued an official statement regarding purely cosmetic eye color–changing procedures, warning against potential health risks associated with techniques currently promoted on social media, including iris implant surgery and laser-assisted corneal pigmentation. The AAO highlights the risk of severe complications such as corneal damage leading to opacification, deformation, fluid leakage, and vision loss; photophobia; allergic reactions to pigments resulting in inflammation, uveitis, or ocular neovascularization; bacterial or fungal infections causing corneal scarring and visual impairment; uneven pigment distribution; intraocular pigment leakage; and color fading [43].

Accordingly, cosmetic KTP procedures should be approached with caution and performed only after comprehensive patient counseling regarding potential risks. The decision to proceed must take into account ethical considerations and patient safety, in line with the recommendations of the AAO [43].

Conclusions

In recent years, there has been growing interest in KTP performed for purely aesthetic purposes. Although this procedure is gaining popularity among patients seeking a permanent change in iris color, its application raises concerns within the medical community. These concerns stem both from the limited availability of solid scientific evidence and from doubts regarding the justification of surgical intervention in a healthy visual organ for cosmetic reasons alone.

The current state of knowledge is largely based on case reports, small case series, and studies conducted on relatively limited patient cohorts, which significantly restricts the ability to draw definitive clinical conclusions.

In light of the available evidence and the AAO position, the routine use of KTP solely for aesthetic purposes, without therapeutic indication, should be critically reconsidered in clinical practice due to the potential risk of complications that may threaten ocular health and visual function. Despite reports of potential efficacy and high patient satisfaction, current evidence does not allow for a definitive assessment of the long-term safety of this procedure.

At the same time, it should be emphasized that further prospective studies conducted under strictly controlled conditions, involving appropriately selected patient cohorts and adhering to rigorous ethical standards and fully informed consent, are essential to reliably evaluate the

safety profile, durability of cosmetic outcomes, and the impact of KTP on visual function. The acquisition of such data is a prerequisite for any future consideration of the acceptability of this procedure in ophthalmic practice.

Disclosure section

Funding Statement: This research received no external funding.

Institutional Review Board Statement: Not applicable

Informed Consent Statement: Not applicable

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflict of Interest Statement: The authors declare no conflicts of interest.

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Table 1. Summary of clinical studies on cosmetic keratopigmentation: techniques, complications, and patient satisfaction.

Study (author, year)	Study Type	Cohort (F, M, number of participants)	Technique	Perioperative symptoms	Postoperative complications	Patient satisfaction
Alió et al. (2016) (25)	Prospective cohort study	7 (3F, 4M)	SAK, MIK, FAK	None	None / Brak	100% - high satisfaction
Ferrari et al. (2018) (15)	Case report	1 (F)	FLAAK	None	None / Brak	100% - high satisfaction
D'Oria et al. (2021) (28)	Prospective multicenter study	40 (79 eyes)	SAK, FAK	Intraoperative pigment dispersion in prior LASIK area	- Light sensitivity (30%, reversible) - Pigment color change (7.5%) - Fading (5%) - Visual field limitations with 4.5 mm pupil (2.5%) - Corneal ectasia (2.5%), (1 post-LASIK patient, treated with CXL)	92.5% - high satisfaction; 35.4% required pigment touch-ups
Alafaleq et al. (2023) (19)	Cross-sectional, questionnaire study	42 (27F,15M)	FLAAK	- Pain (81%) - Dry eyes (76%) - Tingling (71%) - Redness (67%) - Glare (56%)	Temporary symptoms: – pain up to 270 days – tingling up to 60 days	Average 8.1/10, 85% reported improved well-being
Alió et al. (2025) (41)	Prospective sequential, non-randomized study	83 (166 eyes)	FAK	- Light sensitivity (2 patients, 4 months) - Dry eye symptoms (2 patients, 4 months)	- Endothelial cell loss (~3% after 12 months) - Reduced contrast sensitivity	84.33% high, 13.25% neutral