• Review Article •

An updated comprehensive review on keratopigmentation

Hassan Hashemi[1], *Ali Hadavandkhani*[2], *Mehdi Khabazkhoob*[3]

[1]Noor Ophthalmology Research Center, Noor Eye Hospital, Tehran 1983963113, Iran
[2]Noor Research Center for Ophthalmic Epidemiology, Noor Eye Hospital, Tehran 1968653111, Iran
[3]Department of Medical Surgical Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran 1983969411, Iran
Correspondence to: Hassan Hashemi. Noor Ophthalmology Research Center, Noor Eye Hospital, Tehran 1983963113, Iran. hhashemi@noorvision.com
Received: 2025-04-10 Accepted: 2025-07-28

Abstract

● This study aimed to differentiate between the therapeutic and purely cosmetic aspects of keratopigmentation by examining the results of previous studies. Corneal opacity, corneal leukoma, and iris abnormalities represent the primary reasons for keratopigmentation in therapeutic settings. In therapeutic contexts, the most commonly reported adverse effects included inflammation, foreign body sensation, light sensitivity, reduced intraocular pressure, and neovascularization. The side effects most frequently noted in purely cosmetic applications were photophobia and ectasia. In therapeutic scenarios, patients who experience pre-operative vision impairment often report not only the absence of visual loss post-procedure but also an enhancement in visual acuity, accompanied by alleviation of symptoms such as glare. In purely cosmetic procedures, visual acuity tends to remain stable. Research indicates that dissatisfaction with keratopigmentation results is more prevalent in studies aimed at therapeutic interventions compared to cosmetic enhancements. Furthermore, instances of discoloration and fading are more frequently observed in therapeutic cases than in cosmetic ones, including the need for retouching. The use of keratopigmentation in both therapeutic and cosmetic settings produces positive and acceptable results, especially in cosmetic applications. Nevertheless, complications are more commonly observed in therapeutic situations, which underscores the importance of candidate selection for keratopigmentation procedures.

● **KEYWORDS:** keratopigmentation; corneal leukoma; cosmetic; iris abnormality; corneal opacity

DOI:10.18240/ijo.2025.11.22

Citation: Hashemi H, Hadavandkhani A, Khabazkhoob M. An updated comprehensive review on keratopigmentation. *Int J Ophthalmol* 2025;18(11):2183-2194

INTRODUCTION

The alteration of eye color *via* tattooing and cosmetic iris implants was originally developed for therapeutic purposes, addressing conditions such as iris abnormalities, corneal scarring, leukocoria, strabismic diplopia, and Urrets-Zavalia syndrome. Nevertheless, studies have revealed that this method, particularly using cosmetic iris implants, carries significant risks, including uveitis, hyphema, cataracts, and corneal endothelial cell damage; these adverse effects have the potential to result in vision loss[1]. Subsequent methods introduced, including laser depigmentation surgery, were also associated with significant complications, including ciliary muscle hemorrhage and mild anterior chamber reaction[2].

The femtosecond laser-assisted keratopigmentation method was first introduced by Alio *et al*[3] in 2010 to address pathological conditions. Later, in 2015, Ferrari and Morin[4] applied this technique exclusively for cosmetic reasons in a 49-year-old patient. In this minimally invasive technique, the pigment is administered *via* a layered pocket within the cornea, typically at a depth of approximately 225 microns. A significant focus of the existing research has been on evaluating the outcomes of this surgical procedure, particularly concerning its complications and the level of patient satisfaction[5-11]. The complications associated with this technique are reported to be fewer than those linked to earlier methods of altering eye color. Various studies have identified limited complications, including toxic reactions to the pigment, epithelial defects, and corneal melting. In certain specific and pathological instances, keratopigmentation can provide satisfactory cosmetic outcomes, thereby eliminating the need for reconstructive surgery[12-13]. The limited complications linked to this technique, when compared to other methods for changing eye color, have generated considerable interest in this surgical procedure for purely aesthetic purposes, extending beyond pathological cases to normal individuals. Research in this area has predominantly concentrated on assessing patient satisfaction and investigating some specific complications[5-8,14-17].

The application of the keratopigmentation method for changing eye color has been the subject of numerous studies since 2010[3-10,12-32]. Nonetheless, discrepancies across various studies, the advent of newer surgical techniques and pigments, the growing expertise of ophthalmologists due to ongoing developments, and the rising popularity of this procedure have prompted us to undertake this review study. Review articles have already been published on this topic[2,27,33-34]; however, certain elements, including the rationale for referral, pigments, complications, indications and contraindications, visual outcomes, patient satisfaction, and treatment efficacy, have not been thoroughly explored. On the other hand, due to the limited number of studies[4-5,8-9,25] focusing on keratopigmentation for purely cosmetic purposes, a consensus regarding its various dimensions in these instances remains elusive. In this review, we aimed to differentiate between the therapeutic and purely cosmetic aspects of keratopigmentation by examining the results of previous studies, hoping that this may provide additional valuable insights for surgeons.

Method of Literature Search This research, conducted in 2025, adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A comprehensive literature search was carried out across four major databases PubMed, Google Scholar, Scopus, and Science Direct using the following keywords: “keratopigmentation”, “change eye color”, “cosmetic iris implants”, “corneal tattooing”, “tattooing the cornea”, and “apparent color of the eye”.

Following the initial search, all retrieved articles were imported into EndNote (V.21) reference management software to identify and remove duplicates. Key data from each eligible study including author names, publication year, reported complications, type of pigment or ink, inclusion and exclusion criteria, surgical technique, visual outcomes, patient satisfaction, efficacy and the stated rationale for keratopigmentation were systematically extracted for detailed analysis.

The evaluation process was independently performed by two researchers, Khabazkhoob M and Hadavandkhani A. Any disagreements between them were resolved through consultation with a third reviewer, Hashemi H.

Rationale for keratopigmentation Keratopigmentation is performed for several reasons, which can be classified into three primary categories: 1) Cosmetic enhancement: Individuals may wish to change their eye color for personal or social reasons, often in the absence of any underlying medical issues or symptoms. 2) Aesthetic concerns related to specific corneal and iris conditions, such as leukoma, heterochromia, and corectopia, may motivate individuals to pursue keratopigmentation. 3) Visual disturbances, including photophobia, glare, and monocular diplopia, as well as large iridotomy or iridectomy[28], provide further rationale for this intervention.

An examination of earlier research indicates that corneal opacity and corneal leukoma have historically been major issues prompting individuals to pursue keratopigmentation, making them prevalent motivations for seeking this treatment[6-7,10,27,32,35]. Table 1[3,5-10,12-15,18,21-22,24-26,29,32,35-43] presents the reasons for referral as identified in various studies. Additionally, prior investigations have demonstrated that keratopigmentation is utilized in certain cases involving corneal opacity who are unable to tolerate cosmetic contact lenses.

Following corneal opacification, individuals presenting with iris-related issues, which encompass a diverse array of conditions such as iris atrophy and aniridia[3,12-13,18,29], as well as those with iris malformations and albinism[12], are potential candidates for this surgical intervention. Moreover, the presence of post-surgical scars and other types of scarring also serves as a motivation for patients to seek keratopigmentation. Keratopigmentation is used as a treatment option to relieve photophobia or monocular diplopia resulting from peripheral iridotomies[29], aniridia, and other iris defects[3,12-13,18,29]. Enhancement of visual function for functional purposes has also been documented through its therapeutic effect to alleviate visual disorders resulting from significant disability glare in individuals with iris anomalies, including aniridia, iris coloboma, and extensive iridectomies[29]. Furthermore, individuals who have undergone successful vitreoretinal surgery may continue to encounter significant visual disturbances[29], including diplopia, dysphotopsia, or photophobia; consequently, keratopigmentation surgery may be recommended in such cases[29].

Pigment or ink in therapeutic-cosmetic keratopigmentation surgery The choice of ink or pigment in corneal tattooing is crucial. The first generation of inks consists of materials identical to those utilized in skin tattooing. These inks possess inherent limitations stemming from their incompatibility with corneal tissue. An intermediate solution, second-generation inks were developed; however, research indicates that these inks often demonstrate suboptimal effectiveness[5,44]. In contrast, third-generation inks have been specifically formulated for ocular tattooing, promising improved compatibility with corneal tissue and enhanced overall performance.

In the initial stages of keratopigmentation, two distinct categories of dyes were employed. The first category comprised chemical dyes, such as gold and platinum chloride, while the second involved carbon. The process of carbon impregnation proved to be more complex and labor-intensive compared to chemical tattooing; however, it offered greater durability than chemical dyes. As the field evolved,

Table 1 Summary of other study

First author	Publication year	Sample size	Age (y)	Complication	The rationale for keratopigmentation
Hashemian[36]	2025	85 eyes of 85 patients	14–77	Photophobia (28.2%), tearing (23.5%), pain (8.2%) dry eye (5.8%), delayed epithelial healing (2.3%), microbial keratitis (1.1%)	Corneal scarring or iris abnormalities
Trindade[37]	2025	8 eyes of 8 patients	-	Without complications	Cosmetic therapeutic
Yilmaz[32]	2023	42 individuals	49.4	Without complications—complications may arise if the dye reaches the optic nerve	Aesthetic purposes Corneal leukoma
Mohan[10]	2023	463 individuals	NR	Tearing, foreign body sensation, redness, discomfort, pain	Corneal opacity
Alió[18]	2011	One patient	23	Discomfort, conjunctival redness	Iris disorders
Bandivadekar[24]	2018	3 individuals	10, 16, 20	Mild irritation, foreign body sensation, mild changes in keratometry, subconjunctival hemorrhage	Limbal dermoid
Alio[13]	2012	One patient	33	Without complications	Severe visual function disability, cosmetic appearance, Urrets-Zavalia syndrome and incapacitating photophobia, glare, and decreased VA
Jabbour[38]	2019	19 eyes	53	Mild eye irritation	Dysphotopsia after to laser peripheral iridotomies (LPI)
Karslioglu[7]	2020	16 individuals	30.5±12.06 (16 to 53)	Mild pigment reduction, pigment leakage	Cosmetic and corneal and scleral thinning and prosthetic contact lens intolerance, patient with band keratopathy and microphthalmus and nystagmus and poor contact lens fit.
Chao[29]	2022	One patient	66	Foreign body sensation, pigment fading.	Intractable photophobia secondary to traumatic aniridia
Balgos[6]	2020	72 individuals	5–83	Conjunctival staining, corneal microperforations	Combination of therapeutic KTP and strabismus surgery to enhance the cosmesis of the eyes for people with squint and corneal opacity
Bafna[35]	2021	5 individuals	25–35	Without complications	Pterygium surgery along with corneal tattooing for combined cosmetic rehabilitation in eyes with corneal opacity and pterygium or pseudo-pterygium
Ricardo[21]	2015	2 individuals	73 and 54	Without complications	Treatment of functional visual disabilities caused by peripheral iridectomies
Agarwal[39]	2021	3 individuals	29.31±15.46 (8–56)	Without complications	Unilaterally disfiguring corneal scar and nil visual prognosis
Camerati[26]	2020	2 individuals	64 and 55	Without complications	Photophobia and aesthetic complaints after Boston type 1 keratoprosthesis (Kpro I) implantation
Alio[12]	2011	11 individuals	23–59	Significant glare	Severe visual dysfunction secondary to unilateral essential iris atrophy due to the presence of iridocorneal endothelial syndrome. The patient presented with complaints of photophobia and monocular diplopia in the affected eye.
Alio[3]	2010	40 individuals	50±19.98 (2–79)	Without complications	To improve cosmetic appearance in severely impaired eyes (disfiguring corneal opacities or severe leucoma and total aniridia)
Alio[15]	2018	204 individuals	NR	Complications were divided into two categories: organic (45%) and functional (55%). Functional complications included: light sensitivity (49%), visual field limitations (4%), MRI changes (2%). Organic complications included: color change (19%), pigment fading (19%), neovascularization (7%)	Therapeutic and cosmetic reasons
Goldberg[40]	2018	One woman	63	An unintentional KTP following blepharopigmentation surgery, with no effect on VA	Normal inadvertent corneal pigmentation as a complication of cosmetic eyelid tattooing or blepharopigmentation
Rodriguez[14]	2017	40 rabbits	NR	No intraoperative complications. Mild to moderate conjunctival hyperemia and transient corneal epithelial defect	Normal rabbits/experimental study
Amesty[22]	2016	14 rabbits	NR	Without complications or local toxicity	To study the tolerance and biocompatibility of mineral pigments for corneal pigmentation
Alafaleq[9]	2023	42 participants	37.6	Pain (81%), dry eye (76%), glare (56%), redness of the eye (67%), tingling (71%), halos (no reports)	Purely cosmetic
D'Oria[8]	2021	40 patients	34±11 (21–63)	Pigment dispersion at the LASIK flap junction, hypersensitivity to light (30%), color change (7.5%), complaints of pigment fading (5%), visual field limitations (2.5%), bilateral progressive corneal ectasia, and cataracts	Purely cosmetic
Alió[5]	2016	7 patients	40 (27–63)	Without complications	Purely cosmetic
Ferrari[25]	2018	One woman	21	No signs of leakage, pigment dispersion, inflammation, or any other adverse effects on the cornea were observed.	Purely cosmetic
Nouzovská[41]	2024	5 cases (10 eyes)	21–40	Decreased vision, progressive myopia, irregular astigmatism, increased corneal curvature, corneal ectasia, photophobia, irritation	Purely cosmetic
Uddin[42]	2025	1	NR	Corneal ulceration	Purely cosmetic
Alio[43]	2025	166 eyes	24–50	Without complications	Purely cosmetic

LASIK: Laser *in situ* keratomileusis; NR: Not reported; KTP: Keratopigmentation; VA: Visual acuity.

additional organic dyes, along with Indian ink and Chinese ink, were incorporated into keratopigmentation techniques[44]. Micronized mineral pigments were introduced and utilized for the first time in the keratopigmentation procedure in 2010[3]. These mineral pigments exhibit greater stability. The process of micritization, which reduces the particle size to 2.5 microns or smaller, enhances sterilization, diminishes corneal sensitivity, and lowers the foreign body reaction associated with pigments inserted in the corneal stroma[5]. Furthermore, a significant benefit of micronized mineral pigments is the extensive variety of colors they offer[7,22].

Ultrastructural analysis of metallic and nonmetallic pigments reveals that metallic pigments induce a greater degree of cellular damage, leading to an increased accumulation of cellular debris within the corneal extracellular matrix. Consequently, it is to be expected that metallic tattoos are more prone to harbor extracellular pigment compared to their nonmetallic counterparts. In the study conducted by Amesty *et al*[22], histological analysis revealed the presence of pigment granules within keratocytes when non-metallic pigments were utilized, unlike the findings in patients who received treatment with metallic pigments. It has been established that keratocytes possess the ability to retain non-metallic dye particles within their cell membranes for extended periods. Corneal fibroblasts can internalize injected ink particles through endocytosis within 3 to 4d, with the capacity to store these particles for a minimum of 6mo[22]. The outcomes reported were notably positive. The safety of these pigments has been established through animal studies[14,19]. One animal study indicated that non-metallic compounds exhibited superior performance compared to those containing iron[22].

While most studies have not identified any notable differences in efficacy and satisfaction among various inks, a report by Alio *et al*[3] indicated that iron oxide inks yielded the lowest levels of satisfaction. Consequently, one might infer that using iron oxide should be avoided. Nevertheless, this inference cannot be deemed entirely definitive, as numerous factors can affect the performance of an ink. In general, applying micronized mineral pigments has been associated with favorable cosmetic outcomes in most research findings[14-15,19].

The initial documentation regarding the application of micronized mineral pigments emerged from Alio *et al*'s[3] study, which involved 40 eyes affected by severe corneal opacities, leukoma, and aniridia. In this investigation, the pigments utilized were characterized by the following specifications (Registration No DGFPS 84-PH, Spanish Ministry of Health, 2001): consisting of isopropyl alcohol 40%, water 10%, glycerine 20%, titanium dioxide C47-051 10e30%, iron oxide C33-123 20e30%, indigold C37-038 15e30% dianisidine-acetoacetanilide 20%, trans red oxide 20%, green L-9361 20%, yellow YT-858D 20%, blue 639-4433 20%, blackish, yellow-brownish, bluish and greenish.

This study[3] demonstrated that 95% of patients, except two individuals, expressed satisfaction with the pigments one year post-surgery. Eight patients necessitated a repeated keratopigmentation procedure, while two patients who presented with preoperative corneal edema were unable to attain satisfactory aesthetic outcomes due to pigment clearance occurring six months after the surgery. Additionally, three eyes affected by traumatic aniridia exhibited notable cosmetic enhancement and a significant decrease in glare, leading to an overall assessment of satisfactory results.

In a separate study, Alio *et al*[12] conducted keratopigmentation on 11 eyes exhibiting iris-related visual disturbances, utilizing mineral micronized pigments (Salvador Cordoba SL, Madrid, Spain; Spanish Ministry of Health Registration No 280-PE and 281-PE). The findings indicated that eight patients experienced no symptoms following the procedure, while two patients reported minimal, non-disabling symptoms post-surgery. Notably, one patient with traumatic aniridia expressed significant residual glare during the three-month follow-up and subsequently underwent a reoperation aimed at reducing the simulated pupil size to 4 mm. The cosmetic outcomes were rated as excellent for eight patients and good for three patients.

Another study conducted by Alio *et al*[15] involved 234 eyes from 204 individuals who underwent either cosmetic-therapeutic or purely cosmetic surgical procedures. This research employed various keratopigmentation techniques alongside different generations of pigments. The findings indicated that using third-generation pigments is associated with reduced color alteration and fading. Furthermore, the study demonstrated that utilizing a new generation of pigments, specifically micronized mineral pigments, which possess CE mark certification (Conformité Européenne), is linked to improved outcomes and a lower incidence of complications.

Pigments in patients undergoing purely cosmetic keratopigmentation surgery In 2016, Alió *et al*[5] released a report detailing the outcomes of keratopigmentation conducted solely for cosmetic purposes. This investigation utilized micronized mineral pigments (Blue Green Company, Spain). Over a follow-up duration ranging from 6mo to 2.5y, the findings indicated that applying these pigments was linked to a significant degree of patient satisfaction. It is important to mention that retouching procedures were carried out for four patients; however, no complications were reported throughout the follow-up period.

In a 2021 study involving 40 participants, D'Oria *et al*[8] conducted cosmetic keratopigmentation on 79 healthy eyes. The research utilized a third-generation pigment characterized by the following attributes:

CE mark certificated pigments (Blue Green Company, Spain) are composed of different amounts of lactic acid, propanediol, and micronized mineral pigments.

The findings from this study demonstrated a high level of patient satisfaction alongside favorable cosmetic outcomes, leading D'Oria *et al*[8] to advocate for this technique as a safe and effective approach for altering eye color.

In 2018, Ferrari and van Haselen[25] employed Neoris®-Biotic pigment (Paris, France) for a patient undergoing a purely cosmetic keratopigmentation procedure. The findings indicated that both the surgical intervention and the pigment were deemed safe and effective during a follow-up conducted six months post-operation. In 2023, Alafaleq *et al*[9] conducted a study assessing the satisfaction, safety, and efficacy of the procedure utilizing micronized mineral pigment (Biotic Phocéa, Marseille, France) in a cohort of 42 patients. The results demonstrated a favorable safety profile and high levels of patient satisfaction, with an average follow-up period of 13.4mo after the surgery, although some patients reported experiencing visual symptoms and pain.

In general, several articles have discussed the significance of the pigments employed in various applications. It has been noted that while mineral pigments maintain their color stability over time, they may lead to negative outcomes, including photophobia and a delay in the epithelial cell regeneration. Conversely, although traditional plant pigments utilized in skin tattooing are prone to long-term fading, contemporary plant pigments exhibit enhanced durability and resist discoloration. Organic complications are predominantly associated with first- and second-generation pigments[27]. In contrast, keratopigmentation demonstrates greater efficacy in enhancing aesthetic outcomes when utilizing third-generation pigments[27]. Previous research has indicated that micronized mineral pigments yield favorable cosmetic results while exhibiting corneal tolerance and biocompatibility[14]. Furthermore, key attributes of these pigments include their resistance to prolonged light exposure and the maintenance of the cornea's transparent and avascular properties.

The predominant long-term effect noted was pigment fading, necessitating repeated keratopigmentation[15]. This fading was particularly prevalent with vibrant pigments like green and blue. While these pigments are generally well accepted, certain iron-based compounds may contribute to infrequent instances of oxidation[9], potentially resulting in discoloration as time progresses. Consequently, a new generation of pigments (the third generation) is now being embraced as a solution to this issue[31].

Patient selection in therapeutic-cosmetic keratopigmentation surgery The selection of appropriate surgical candidates is a critical consideration in keratopigmentation. Prior research has considered the inclusion and exclusion criteria that are essential for identifying suitable candidates for keratopigmentation. Ocular conditions that may qualify for this surgical approach include corneal opacities and leukomas, extensive peripheral iridectomies[32], patients with significant corneal scarring that are not suitable for keratoplasty, off-center corneal opacities that do not necessitate keratoplasty, as well as anterior or posterior lens or capsular opacities in blind eyes[3,10,12]. Additionally, the presence of non-anatomical light sources leading to monocular diplopia, deformities in blind eyes or those with no potential for vision restoration (such as in cases of posterior segment diseases), and eyes exhibiting corneal-iris scarring are also relevant considerations[10,12,21].

Furthermore, certain secondary conditions may be suitable for this surgical intervention. These include photophobia resulting from iris complications due to trauma[29], iris coloboma[18], and individuals experiencing glare symptoms linked to iris loss or atrophy, as seen in conditions such as Chandler's syndrome[18], essential iris atrophy[18], and Cogan-Reese syndrome, all of which fall under the category of iridocorneal endothelial syndrome (ICE). Other conditions that may warrant consideration for surgery include limbal dermoids, intractable diplopia[13], Urrets-Zavalia syndrome[9], albinism, leukocoria, and similar cases, particularly in patients who cannot tolerate cosmetic contact lenses[3].

Careful consideration of the exclusion criteria in the patient selection process can effectively mitigate the risk of severe complications, including those that could potentially result in blindness. The exclusion criteria and contraindications can be categorized into three primary groups: 1) ocular issues; 2) corneal issues; 3) systemic and individual issues.

Ocular issues encompass a range of conditions such as severe dry eye syndrome[16,31], eyelid abnormalities[10], glaucoma[31], ocular pain, ocular inflammation and infections. Corneal issues comprise significant corneal vascularization[3,26], extensive calcium deposits within the cornea[3,26], corneal ulcers or dellen[32], epithelial defects, corneal thickness below 300 microns [5,8,10,16,32], endothelial dysfunction[13], persistent severe corneal edema[13], and central corneal opacity, which may allow for potential vision improvement following keratoplasty[10]. These conditions are considered absolute contraindications in specific cases, requiring thorough evaluation during preoperative assessments. Systemic and individual issues include inflammation and infection[3,8,12,45], unreasonable expectations regarding surgical outcomes particularly in purely cosmetic procedures[26], diabetes[31], certain dermatological conditions[5], significant systemic disorders[25,46].

Patient selection in purely cosmetic keratopigmentation surgery In studies focused exclusively on cosmetic

procedures, the inclusion criteria for surgical intervention are predicated on the patient's desire for a permanent alteration of eye color, provided that the individual does not suffer from any visual impairments. Notably, age is not specified as a criterion in the current literature, with the youngest participant being 21 years old[25] and the oldest participant being 63 years old[5] across all examined studies. In Alió *et al*'s[5] study, a psychological profiling assessment was conducted for certain patients to rule out the possibility of psychodynamic imbalances and obsessive behaviors.

Research on keratopigmentation aimed at altering eye color for purely cosmetic reasons has identified several factors that discourage the procedure. These include visual impairments, although refractive errors have not been specifically addressed and do not appear to be a disqualifying factor. Other contraindications encompass corneal opacities and diseases, functional visual impairments associated with iris and lens conditions, abnormal corneal topography, thin corneas, ocular surface disorders, dry eye syndrome, an endothelial cell count below 2500, chronic inflammatory diseases of the ocular surface, glaucoma, vitreous and retinal disorders, keratoconus, dermatological conditions such as atopy, mental health issues, and cataracts[5,8]. Overall, the findings suggest that individuals seeking keratopigmentation for cosmetic reasons should be free from any ocular pathology.

Surgical technique in therapeutic-cosmetic keratopigmentation surgery The surgical technique employed in corneal tattooing is of paramount importance. A critical criterion for categorizing keratopigmentation procedures is the site of pigment deposition, as this can significantly influence the procedure's efficacy, potential complications, and overall technique. It is essential to recognize that the selection of the surgical approach is contingent upon the intended outcome, whether it is solely cosmetic or encompasses both cosmetic and therapeutic objectives. Furthermore, in cases of corneal scarring and varying degrees of corneal opacity, the method chosen will be determined by the specific location of the scar and the extent of the opacity.

Surgical techniques for keratopigmentation can be categorized into two primary approaches: intralamellar corneal staining (ICS) and superficial corneal staining (SCS). The ICS encompasses two specific methods: 1) manual intrastromal keratopigmentation (MIK); 2) femtosecond assisted keratopigmentation (FAK)[44].

In the intralamellar technique, the absence of direct contact between the ink with the tear film and the corneal surface, as well as the non-invasion of the basement membrane particularly in traumatic cases—results in a reduced risk, enhanced precision, greater ease during the procedure, and improved recovery outcomes[7]. Liu *et al*[20] has indicated that the intralamellar method offers several advantages over the superficial technique, including reduced sensitivity, quicker recovery times, more rapid action, and a more uniform color distribution. In a 2016 animal study conducted by Amesty *et al*[22], it was observed that tunneling into the stroma necessitates a reduced amount of dye, minimizes disruption to the corneal structure, and may lower the likelihood of corneal perforation[20] in individuals with thinner corneas.

A review of literature indicates that intrastromal keratopigmentation yields superior outcomes; however, in instances of corneal scars that are not amenable to this technique, more superficial methods of keratopigmentation may be necessary. The deep keratopigmentation method, which utilizes a femtosecond laser, presents numerous benefits, such as increased accuracy, diminished risk, a simplified procedure, and a quicker recovery time[13]. These advantages likely contribute to the widespread adoption of this technique in clinical settings. Literature indicates that femtosecond technology is predominantly employed except in situations where the device is inaccessible or when complications such as elevated intraocular pressure, retinal issues, or significant corneal irregularities and opacities are present.

The SCS includes two main methods for keratopigmentation: superficial manual keratopigmentation (SMK) and superficial automated keratopigmentation (SAK)[44]. Another method involves the use of superficial tattoos, which entails the introduction of pigment into the upper layers of the epithelium and stroma. Although this technique can effectively address corneal surface opacities, it carries certain risks and limitations, including the possibility of increased tearing, corneal instability, and diminished color retention due to the rapid renewal of epithelial tissue. Presently, most procedures favor the deep ICS method, except in cases where the corneal surface is opaque. In these cases, the MIK technique is utilized. The SAK method employs tattoo machines and is typically used for superficial procedures, except in cases of very small opacities. The SMK is specifically designated for extremely small opacities.

Surgical technique in purely cosmetic keratopigmentation surgery The range of surgical techniques employed in cases where keratopigmentation is conducted solely for aesthetic purposes is narrower compared to those utilized for therapeutic interventions. The predominant method documented in research is femtosecond-assisted keratopigmentation, as demonstrated by Alió *et al*[5] and D'Oria *et al*[8]. Additionally, a novel approach known as femtosecond laser-assisted annular keratopigmentation has recently emerged, with applications reported by Alafaleq *et al*[9] and Ferrari and van Haselen[25]. In both techniques, a tunnel is initially formed

using a femtosecond laser, extending from a diameter slightly larger than the pupil (typically between 5 and 5.5 mm) to a diameter of 9.5 mm. Subsequently, this tunnel is widened using a specialized spatula, extending it to a distance of half to one millimeter from the limbus, after which the pigment is introduced into the tunnel. A significant distinction of the Annular method, which represents a more recent advancement compared to earlier approaches like manual intralamellar keratopigmentation, lies in the pigment insertion technique employed. In the femtosecond laser-assisted annular keratopigmentation method, the channel is enlarged with a circular spatula for pigment insertion, whereas in prior methods, pigments were injected into the tunnel using a 27-gauge needle.

Complications in therapeutic-cosmetic keratopigmentation surgery An analysis of the literature indicates that the complications associated with keratopigmentation can be categorized into both short-term and long-term effects. The majority of studies focusing on the outcomes of keratopigmentation have primarily documented short-term complications. Notably, inflammation has emerged as the most frequently reported short-term complication, as evidenced by multiple studies[3,9,15,32,46]. Following inflammation, foreign body sensation[10,20,29], pain and photophobia[5,8,15,32,36] were identified as the next most prevalent complications. Additionally, various pathological ocular complications have been noted, including intraocular pressure decline[47-48], microbial infections[36], conjunctival hyperemia[13,18], subconjunctival hemorrhage[24], corneal edema[15], conjunctival inflammation[26]. Patients have also reported experiencing symptoms such as itching, discomfort, and tearing[10,36]. Long-term complications identified in various studies were similar to short-term complications, such as foreign body sensation and photophobia, yet tended to persist over an extended period. Among the most significant long-term complications documented in therapeutic cases are neovascularization[15], rust formation, corneal thinning, irregular corneal steepening, and induced astigmatism[38].

A comprehensive analysis of various studies indicates that the complications associated with keratopigmentation are influenced by the specific surgical technique employed. Techniques involving anterior stromal puncture present a heightened risk of corneal perforation, particularly when non-calibrated sharp instruments are utilized. Accurately assessing the residual bed thickness and the depth of needle insertion poses challenges, especially in cases where dermoids have been excised, as the residual bed tends to be thinner than that of normal corneas. Conversely, the surface tattooing following epithelial debridement, is characterized by its less invasive nature and does not introduce an additional risk of perforation post-dermoid removal. The commonly employed techniques for corneal tattooing in cases of pathological conditions are transepithelial intrastromal micropuncture, tattooing after epithelial debridement, and the intrastromal lamellar pocket technique. However, these procedures are associated with a range of complications, including intraoperative microperforations, pigment heterogeneity, and progressive pigment fading. At present, the main strategies adopted for therapeutic purposes are summarized in two methods: ISC and SCS.

Complications arising from these procedures are typically categorized into intraoperative and postoperative according to their time of onset. Intraoperative complications primarily include perforation, corneal infections, epithelial erosion, leakage of dye into the conjunctival space or anterior chamber, as well as any technical errors that may occur during the surgery. Conversely, late complications may manifest as photosensitivity, inconsistent staining, pigment loss, uveitis, corneal edema, conjunctivitis, epithelial defects, and visual field defects. Table 1 presents the complications outlined in various studies.

Complications in purely cosmetic keratopigmentation surgery An examination of research focused on cases where eye color change was undertaken exclusively for aesthetic purposes indicates that, overall, the incidence of pathological complications is lower in these patients compared to those undergoing therapeutic procedures. Alió *et al*[5] documented an absence of complications in a study involving seven cases, while Alafaleq *et al*[9] noted no complications in a cohort of sixty eyes. Moreover, Ferrari *et al*[4,25] reported no complications in two separate case reports. Alió *et al*'s[5] research indicated that within the framework of the FAK method, mild photophobia and light sensitivity were reported in seven patients between two weeks and three months post-surgery, with the use of sunglasses providing relief. Similarly, D'Oria *et al*'s[8] study involving 79 eyes from 40 individuals utilizing the FAK method revealed that light sensitivity emerged as the predominant complication during the initial month, affecting 30% of the subjects. Additionally, changes in color and color fading were noted in 7.5% and 5% of the eyes, respectively, although these findings might be more appropriately categorized under efficacy rather than complications. D'Oria *et al*[8] also identified a limitation in the visual field in one case. Furthermore, he documented ectasia in a patient with a prior LASIK procedure who subsequently underwent CXL, as well as pigment dispersion in the flap area of two patients with a LASIK history at the time of surgery.

Alafaleq *et al*[9] in a subsequent report utilizing the femtosecond laser assisted annular keratopigmentation technique (FLAAK) method, observed that among 42 patients,

34 (81%) experienced pain, 32 (76%) reported dry eyes, 23 (56%) noted glare, 28 (67%) experienced redness, and 30 (71%) reported tingling sensations following the procedure. Notably, no instances of visual halos were documented among the patients. The findings revealed that a significant proportion of these complications, including pain, tingling, glare, and redness, resolved within 48h for 50% of the patients. Furthermore, the median duration of these complications for those who continued to experience them beyond 48h was recorded as 7d.

Uddin et al. reported a case of severe corneal ulceration following a purely cosmetic keratopigmentation procedure[42]. Additionally, another study documented endothelial cell depletion caused by Alio *et al*[43].

Nouzovská *et al*[41] documented a study involving five patients who underwent keratopigmentation for aesthetic reasons, all exhibiting no pathological abnormalities in vision or corneal topography prior to the intervention. Post-procedure, however, they experienced either ectasia or alterations in corneal topography. Notably, in one patient, while ectasia was absent, keratometric changes were observed. Additionally, three out of the five patients underwent epi-off corneal cross-linking. Importantly, the findings from the studies indicate that significant corneal pathological complications, such as neovascularization, and intraoperative issues like corneal perforation, were not observed in cases performed for cosmetic purposes.

Visual outcomes in therapeutic-cosmetic keratopigmentation surgery Most studies that documented the outcomes of keratopigmentation were primarily conducted for aesthetic purposes rather than for vision correction, often in the context of corneal or iris abnormalities. Consequently, the reporting of visual outcomes in therapeutic studies remains sparse. The majority of these investigations indicated no significant alterations in visual acuity. In cases where the tattooing was performed for therapeutic reasons, there was a minimal decrease in vision, whereas patients who underwent the procedure to alleviate halos and glare associated with pathological conditions experienced an improvement in postoperative vision[5,15,21].

Yin and Walter[17] conducted a study involving 18 patients with a history of iris-related problems, revealing that an average of 60mo post-keratopigmentation surgery, all participants experienced significant improvements in visual symptoms. Furthermore, 94% of the eyes that underwent the procedure demonstrated improved corrected vision[17]. Specifically, 42% of the eyes exhibited an increase of two lines in visual acuity, while another 42% showed an increase of one line, and 10% achieved an increase of three lines[17]. In a separate report by Alio *et al*[12], 11 cases were analyzed, with three cases showing an increase of one to two lines in visual acuity, while the remaining cases maintained stable visual acuity. Notably, one case experienced a loss of one line in visual acuity.

In individuals experiencing post-laser peripheral iridotomy dysphotopsias[23], therapeutic keratopigmentation was found to alleviate symptoms and enhance visual clarity[23]. A case study involving two patients with prior unsuccessful corneal transplants, who were candidates for Kpro implants, revealed visual acuity levels of approximately 20/150 and 20/200, alongside a reduction in photophobia and glare, ultimately contributing to improved patient comfort[26].

In individuals with strabismus[6], it is important to recognize that the simultaneous performance of keratopigmentation and strabismus surgery within a single surgical intervention enhances aesthetic outcomes and may reduce the necessity for additional surgical procedures. This approach has been associated with improved visual acuity in patients compared to those who only undergo strabismus surgery, as well as superior strabismus control.

Research into visual field outcomes has been conducted in several studies, revealing that visual field restrictions can occur as a complication, albeit infrequently. Alio *et al*[15] documented visual field limitations in 4% of 50 eyes that experienced complications, attributing these issues to the selection of a 5 mm pupil diameter; such limitations were not observed in patients where the diameter was increased to 5.3 mm.

Visual outcomes in purely cosmetic keratopigmentation surgery The current body of literature regarding visual outcomes in individuals who have undergone keratopigmentation for cosmetic reasons is markedly limited. A major shortcoming of these investigations is the lack of assessment of visual acuity or visual fields, even though some visual symptoms have been recorded. Research by Alió *et al*[5] and D'Oria *et al*[8] demonstrated that visual acuity remained unchanged post-keratopigmentation. Furthermore, Alió *et al*'s[5] research found that patients did not report any alterations in quality of vision or photic phenomena four weeks subsequent to the procedure.

Ferrari documented a case involving a 21-year-old female patient who exhibited no alterations in vision or visual field[25]. Additionally, he noted that a 49-year-old individual who underwent annular keratopigmentation to change eye color experienced no changes in vision or visual field three months post-operation[4]. D'Oria *et al*[8] indicated that among 40 patients who had surgery with a 4.5-mm pupil size, one individual did experience visual field restriction. Furthermore, Alafaleq *et al*'s[9] study involving 42 patients revealed that while none reported halos, 56% did experience glare.

In the study conducted by Alafaleq *et al*[31] in 2023, a group of 30 patients (60 eyes) underwent pure FAK cosmetic surgery, with a pupil diameter of 5 mm. Follow-up evaluations at six

months post-surgery indicated that routine ophthalmological assessments showed no abnormalities, and the ability to perform examinations remained unaffected. However, the measurement of endothelial cell density in the peripheral cornea was not feasible due to staining of the corneal stroma. Furthermore, a 30-degree visual field test was administered, which revealed no impairments, and no difficulties were observed during this evaluation.

Patient satisfaction in therapeutic-cosmetic keratopigmentation surgery Surgeons engaged in keratopigmentation acknowledge that, in addition to objective success metrics, subjective outcomes are of considerable significance. Importantly, patient satisfaction with the results of the procedure is often regarded as the most vital element. A review of pertinent studies reveals that a considerable number of patients expressed total satisfaction with the keratopigmentation procedure. Balgos *et al*[6] and Al-Shymali *et al*[16] reported the highest levels of patient satisfaction among the studies reviewed, with Al-Shymali *et al*[16] indicating that 98.5% of the 130 patients who underwent surgery rated their outcomes as good or excellent. Similarly, Balgos *et al*[6] found that all 72 patients included in their study expressed satisfaction with the cosmetic results of the surgery. One of the pioneering studies in this area was conducted by Alio *et al*[3] in 2010, which involved 40 patients with severely impaired eyes. This research revealed that 95% of participants were satisfied with their outcomes, with only three individuals expressing dissatisfaction regarding the cosmetic results, despite the absence of any complications associated with keratopigmentation.

In the study conducted by Karslioglu *et al*[7] patient satisfaction was evaluated using a questionnaire that employed a scoring system ranging from 0 to 5. The findings indicated that all participants achieved a score of 3 or above, with 13 out of 16 individuals attaining a score of 4 or higher. Similarly, in the study by Liu *et al*[20] among 32 patients presenting with various pathologies, 28 reported excellent satisfaction levels, while 4 indicated very good satisfaction. Furthermore, Mohan *et al*'s[10] study revealed that over 90% of the 463 patients suffering from corneal opacity expressed good to excellent satisfaction. This particular study utilized micronized organic pigment for keratopigmentation, employing two distinct techniques: the intrastromal pocket technique and the intrastromal needle puncture technique. In a separate investigation involving 11 eyes exhibiting significant visual impairment, Alio *et al*[12] reported that 8 individuals achieved a satisfaction score of 3, while 3 individuals received a score of 2. This indicates that all 11 participants were satisfied with the surgical procedure.

The findings imply that keratopigmentation for therapeutic-cosmetic purposes is typically linked to elevated levels of patient satisfaction, a trend corroborated by the majority of research in this area. Nonetheless, a minor fraction of patients may not achieve their desired outcomes, potentially attributable to various factors, including underlying ocular conditions or differing expectations regarding the results.

Hashemian *et al*[36] reported that in patients with corneal scarring or iris abnormalities who underwent keratopigmentation using SAK, femtosecond laser-assisted intrastromal keratopigmentation (FIK), or a combination of both techniques, cosmetic satisfaction was achieved in 73.9% of the SAK group, 86% of the FIK group, and 100% of the combined SAK+FIK group three weeks after surgery.

It has been demonstrated that patients with corneal leucoma often experience severe depression. Changing eye color not only improves visual symptoms but also alleviates psychological distress related to appearance and enhances overall quality of life[49]. Trindade *et al*[37] reported that out of eight eyes treated, seven showed a significant improvement in eye color, accompanied by an increase in the patients' quality of life.

Patient satisfaction in purely cosmetic keratopigmentation surgery Patient satisfaction in purely cosmetic procedures represents a significant and subjective factor. As previously discussed, in therapeutic scenarios, the use of keratopigmentation has been associated with enhanced aesthetic outcomes, leading patients to express satisfaction with their surgical experiences, even when complications arose. Conversely, attaining patient satisfaction in purely cosmetic procedures appears to be more challenging. Alió *et al*'s[5] report on seven patients indicated that they experienced a high level of satisfaction with the results. Furthermore, the report highlighted that surgeon also reported a high degree of satisfaction with the surgical outcomes. Importantly, the other outcomes evaluated in this study were favorable, and no serious complications were documented among the patients. D'Oria *et al*[8] conducted a study involving 40 patients, revealing that 92.5% expressed satisfaction with the surgical outcomes six months post-surgery, and all participants indicated a willingness to undergo the procedure again. This is while this study also acknowledged significant complications, with 35.4% of the eyes requiring reoperation. In a separate study, Alafaleq *et al*[9] assessed 42 patients and found that their average satisfaction rating was 8.1 on a scale from 0 to 10, which they categorized as excellent. Furthermore, the author reported an average improvement in patient well-being of 2.8 on a scale from 0 to 4, with 36 patients (85%) acknowledging a sense of overall enhancement in their condition.

Efficacy in therapeutic-cosmetic keratopigmentation surgery Assessing the efficacy of corneal tattooing is a

critical component in the appraisal of this technique. This evaluation encompasses an analysis of the permanence of the alterations made and their enduring consequences. Various factors influence the success of corneal tattooing, including the specific dye utilized, the careful selection of suitable cases, the proficiency of the surgeon, as well as the type of laser and the techniques and instruments employed during the procedure.

The second- generation inks exhibited the most pronounced fading rates. This observation indicates that the choice of ink is crucial in determining the stability and durability of the outcomes. The predominant long-term effect noted was the pigment fading, which often necessitated re-keratopigmentation. Notably, the fading was more prevalent with the use of vibrant pigments, particularly those in the green and blue spectrum. Selecting an appropriate case for corneal tattooing is crucial. In instances such as corneal edema and phthisis bulbi, opting for lighter colors may result in accelerated fading of the tattoo. The proficiency of the surgeon executing the corneal tattoo significantly influences the outcome, impacting both the uniformity of the color and its longevity. Additionally, the passage of time is recognized as a critical element in the efficacy of corneal tattooing. Research indicates that the most substantial alterations in color are typically observed between two- and four-years post-procedure. In a particular study, a series of follow-up assessments were conducted at various time intervals, ranging from one day to one-year post-surgery. The findings revealed that the color appeared significantly darker the day following the procedure, subsequently lightening by the three-month mark. However, at the one-year follow-up, the color was noted to be darker again compared to the three-month assessment. These observations suggest that the alterations in color over time exhibit a complex and nonlinear pattern.

Various surgical techniques can significantly influence the efficacy of tattoo retention. In studies that documented the necessity for reoperation, the manual anterior stromal puncture (ASP) method exhibited an 80% rate of color recurrence, marking it as the method with the highest recurrence. Conversely, the intrastromal pocket technique (ISPT) method demonstrated no instances of recurrence, suggesting a high level of color stability associated with this approach. The combination of LK, ICS, and SCS yielded the lowest recurrence rate at 8.5%, indicating that these methods may be more favorable for achieving enduring results.

Alio *et al*[15] demonstrated that change in color was observed in 9 out of 50 eyes among a total of 234 eyes that experienced complications. Specifically, one case was linked to first-generation pigments, six cases to second-generation pigments, and two cases to third-generation pigments. Furthermore, he indicated that among the instances of color fading, seven were associated with second-generation pigments, while two were linked to third-generation pigments. Yilmaz and Oguz[32] found that color fading typically occurs within the first month post-surgery, noting that this phenomenon is more pronounced and occurs more rapidly in lighter colors. Al-Shymali *et al*[16] reported that changes in color were noted in 6 eyes, while 7 eyes exhibited color fading, within a sample of 136 eyes that underwent keratopigmentation surgery.

In Al-Shymali *et al*'s[16] study, it was found that 44.7% (55 eyes) necessitated retouching, with 31 eyes needing a single touch-up, 19 eyes requiring two touch-ups, 3 eyes needing three touch-ups, and 2 eyes requiring four touch-ups.

In Hashemian *et al*'s[36] study, 85 eyes underwent keratopigmentation surgery for corneal scarring or iris abnormalities. Of these, 36 were treated with FIK, 46 with SAK, and 3 with a combination of both techniques. The study showed that excellent or good cosmetic outcomes were reported by 91.4% of the SAK group, 91.5% of the FIK group, and 100% of the combined SAK+FIK group. Furthermore, 12 eyes from the SAK group and 5 from the FIK group required re-treatment due to color fading and cosmetic dissatisfaction.

Efficacy in purely cosmetic keratopigmentation surgery In a study involving patients who underwent keratopigmentation solely for cosmetic purposes, Alio observed stable pigmentation in seven individuals[5]. Although touch-up procedures were necessary for four patients—three at the request of patients and one recommended by the surgeon there were no reports of pigment leakage or fading. Conversely, D'Oria *et al*'s[8] findings indicated that the procedure was repeated in 35.4% of the eyes (28 eyes), with two color touch-ups conducted in seven eyes and three touch-ups in four eyes. He noted a color change in 7.5% of cases and color fading in 5%. Conversely, the Ferrari and van Haselen's study[25], which focused on a single case, reported no instances of fading or the need for corrections or touch-ups over an 8-month duration. This method was deemed effective, attributed to its color stability and the lack of visual and anatomical complications.

CONCLUSION

Applying keratopigmentation for altering eye color, whether for therapeutic or cosmetic purposes, yields highly satisfactory and acceptable outcomes. The growing adoption of this technique for eye color modification has contributed to the continuous enhancement of surgical methods and the pigments employed. Patients undergoing this procedure frequently report visual disturbances, including light sensitivity, glare, and halos, immediately following the operation. Nevertheless, the occurrence of significant complications in therapeutic scenarios underscores the necessity for careful candidate selection for keratopigmentation, with particular attention to pre-existing

conditions such as dry eyes and corneal thickness. Visual acuity and visual field remain largely unaffected, particularly in cases where the procedure is pursued solely for aesthetic reasons.

The current body of research regarding the efficacy and long-term complications of this technique in purely cosmetic applications is limited. Nevertheless, it can be suggested that individuals who wish to change their eye color, assuming they do not have any underlying psychological concerns, are likely to report high satisfaction levels following the procedure. This outcome is dependent on the utilization of third-generation and standard pigments, as well as the appropriate lasers and surgical tools employed by an experienced surgeon. However, to gain a comprehensive understanding of the long-term complications, the stability of pigment within the cornea, and any potential alterations in vision in purely cosmetic contexts, further extensive studies with extended follow-up durations are essential.

ACKNOWLEDGEMENTS

Foundation: Supported by Noor Ophthalmology Research Center.

Conflicts of Interest: Hashemi H, None; **Hadavandkhani A,** None; **Khabazkhoob M,** None.

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