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Corneal Tattooing (keratopigmentation) with new mineral micronised pigments to

restore cosmetic appearance in severely impaired eyes

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Running head: Corneal Tattooing

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#### **ABSTRACT**

**Aim:** To investigate keratopigmentation (KTP) with new mineral micronized pigments as a surgical alternative to improve cosmetic appearance in severely-impaired eyes.

**Methods:** 40 eyes underwent KTP alternatively to invasive cosmetic reconstructive surgery. Corneal staining with mineral micronized pigments was performed using either a intralamellar or superficial technique.

**Results:** One year postoperatively, all but two patients (95%) were satisfied. Pigmented eyes were improving patient's appearance. 8 cases needed a second KTP. 2 patients with preoperative corneal edema did not obtain an adequate cosmetic appearance due to progressive pigment clearance observed from 6 months postoperatively. 3 eyes with traumatic aniridia observed good cosmetic outcome and a significant reduction in glare.

**Conclusions:** KTP achieves good cosmetic results and is associated with high patient satisfaction, avoiding extensive and mutilating reconstructive surgery.

#### **INTRODUCTION**

Corneal tattooing has been used for cosmetic treatment of corneal opacities for centuries <sup>1,2</sup>. Galen (131-210 A.D.) is considered to be the first who pigmented the human cornea, using reduced copper sulphate to mask a corneal leukoma<sup>3,4,5</sup>. Afterwards, keratopigmentation (KTP) gained limited popularity due to a variety of reasons. Various chemical products such as Indian ink, metallic powders, organic colours, animal uveal pigment, Chinese ink, gold and platinum chloride and even soot were used. To obtain different shades, surgeons experimented with different combinations of such chemical products. The main problem which affected the outcome of previous keratopigmentation studies was the fading of the colours, which made the results to be inconsistent with time<sup>5</sup>. Probably because of these reasons, this technique to improve appearance of cosmetically disabled eyes<sup>5,6</sup> and even sighted eyes<sup>7</sup>, KTP has been used only occasionally and a very few scientific reports on its effectivity and stability are available. <sup>8,9,10</sup>.

Cosmetic contact lenses, enucleation or evisceration with orbital prothesis are the most frequently used methods to improve aesthetic appearance in cosmetically unacceptable, disabled eyes<sup>11,12,13</sup>. However, disabled eyes frequently have contact lens intolerance<sup>11</sup>, and prostheses often cause inflammation and infection<sup>14</sup>. Penetrating keratoplasty (PK) has risks of infection and graft rejection and its use for cosmetic purposes is ethically unacceptable in many parts of the world due to the worldwide shortage of corneal donors.

Our study aims to investigate the potential of corneal tattooing to improve ocular cosmetic appearance using new, micronized mineral pigments in cases of severely impaired eyes and to demostrate the safety, medium term durability and to investigate its potential as an alternative to invasive reconstructive surgery for the cosmetic correction of disabled eyes. To the best of our knowledge, this is the largest modern report on KTP performed for cosmetic purposes in a consecutive group of human eyes, since 1936<sup>16</sup>. This project is also, to the best

of our knowlegde, the first study in which micronised mineral pigments were used for this purpose.

#### **METHODS**

# Study design

Prospective, interventional, consecutive, non randomized, non-comparative series of cases.

#### **Patients**

Forty eyes of 40 patients, 18 women (45%) and 22 men (55%) underwent KTP for defigurating corneal opacities or severe leukoma and total aniridia (Table 1) as an alternative to invasive reconstructive cosmetic surgery. The mean patients age was  $50 \pm 19,98 (2 - 79)$  years. The tenets of Helsinki declaration (Tokyo 2004) were followed in this investigation. An adequate informed consent was required for this investigation. Since the treatments were performed as a compassive indication, no ethical committee approval was necessary for this study.

#### **Inclusion criteria**

Patients with significant cosmetic eye defect from differente causes (Table 1) causing severe corneal leukoma or complete aniridia were considered for this method as an alternative to evisceration and corneal prosthesis implant. All cases were intolerant to cosmetic contact lenses.

#### **Exclusion criteria**

Cases with chronically inflamed or painful eyes, extensive calcified corneal deposits and severe corneal neovascularization, either superficial or/and deep forma, were excluded from the study.

#### Methods

For this study a new set of mineral micronized pigments (Registration No. DGFPS 84-PH, Spanish Ministry of Health, 2001) consisting of Isopropyl alcohol 40%, water 10%, glycerin 20%, titanium dioxide C47-051 10-30%, iron oxide C33-123 20-30%, indigold C37-038 15-30%, 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 were used. Different pigment combinations were used to match the fellow eye in this study. Associated problems such as strabismus or high intraocular pressure were treated, in most cases, at the moment of KTP. Peribulbar anesthesia was used in all cases. In cases of strabismus, adequate recession/resection resctus muscle technique were used according to the angle of the deviation in primary positional gaze. High IOP cases (superior to 30mmHg with topical medication) were treated with one or two sessions of trans-scleral diode laser cyclophotocoagulation.

# Surgical techniques

KTP was performed by only one surgeon following two different approaches:

Intralamellar corneal staining (ICS) (see figures 1A-I)

The centre of the cornea was marked with a calliper and the pupil size diameter determined by an RK optic zone marker of 3, 3.5, 4 or 4.5 mm (Katena, New York, USA).

Free hand incisions were performed with a diamond blade radially from the limbus to the border of the marked pupil to match the low mesopic pupil diameter of the healthy eye, estimated with a Holladay gauge or an infrared pupillometer of 4mm. (Procyon, Bausch & Lomb surgical, Rochester, New York, USA).

To draw the pupil, an arcuate incision out from the radial incisions was performed at the level of the circumference of the pupil limit, avoiding contact with the radial incisions. From this arcuate incision, a dissection of the central cornea up to the defined limits of the pupil was

made, approximately 50% of the total corneal thickness. Then, the pupil was stained by injecting 0.1cc of the adequate black colour pigment.

From radial incisions the cornea was dissected intralamellarly and circularly with a microcrescent knife (Sharpoint, Surgical Specialties Corporation, Reading, PA; USA). 3 or 4 incisions were usually necessary and the dissection was made until the dissector reached the nearest incision on both sides. Finally, the whole cornea was dissected from the periphery to the corneal pupil. The adequate colour was injected with a 30 gauge cannula in the rest of the peripheral dissected cornea. If the colour was lighter than the contralateral eye, then the colour was darkened applying a small amount of black stain on the previous pigment in an irregular fashion, for a better reproduction of the iris crests until the adequate colour was achieved. For KTP itself no stitches were used in any case. Retreatments were performed when needed, using the previously formed corneal dissection planes, and increasing the staining if necessary.

#### Superficial corneal staining(SCS)

When the corneal opacity was too superficial or the scar was directly over the corneal surface, intralamellar staining was not sufficient to provide an adequate cosmetic appearance, therefore, superficial staining was performed as follows: a drop of the adequate stain was put on the cornea surface and then micropunctures were performed down to the superficial layers of the stroma with a 30 gauge needle. At this level, the bevel of the 30 gauge needle was facing inferiorly towards the cornea in order to increase the penetration of the dye.

The manoeuvre was repeated, until the adequate amount of micronized stain was introduced into the superficial cornea to achieve an acceptable cosmetic appearance. Once the staining was finished, the superficial cornea was thoroughly washed to eliminate the stained epithelium.

The surgical technique which we have used in the majority of cases was ICS - 28 patients (70%) vs SCS - 8 patients (20%). In 4 cases (10%) we have performed combined ICS AND SCS procedures (Table 3).

Patients were divided into two groups. The first group consisted of 22 patients (55%) who underwent only KTP. The second group contained patients who underwent KTP and additional procedures, such as: strabismus surgery(11 patients, 27,5%), injections of silicone to the vitreous due to severe hypotomia (2 patients, 5%), upper lid blepharoplasty (1 patient, 2,5%), marginal tarsorraphy (1 patient, 2,5%), cyclodiode laser coagulation (2 patients, 5%), phacoemulsyfication with IOL implantation (1 patient, 2,5%) and phacoemulsyfication with IOL implantation and trabeculectomy (1 patient, 2,5%). Postoperative treatment included patching of the eye the first day, a topical dexamethasone (Maxidex, Alcon, Barcelona, Spain) 1 drop 4 times a day for 2 weeks from the second day and an antibiotic – tobramycin (Tobradex, Alcon, Barcelona, Spain) 1 drop twice a day for five days.

#### Follow up and main outcome measures

For this study, the follow up period was 1 year after the surgery. The patients were examined on the first post-operative day, and then one week, one month, three months, six months and one year after the surgery by an independent observer. All but 3 patients completed the entire follow-up period. One patient was followed for 6 months and 2 patients were revised for the last time three months after the surgery (mean follow-up was 11.4 months).

Main outcome measures were: observer's opinion about patient's appearance, patient's satisfaction and complications of the procedure. Improvement in cosmetic appearance and patient satisfaction were evaluated at each visit following adequate evaluation protocols (Table 2).

#### **Outcome evaluation**

The observers graded the cosmetic improvement of the case as poor, good and excellent as shown in Table 1. 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 refers to the 1 year follow up visit.

#### RESULTS

The pre and postoperative clinical situation and surgical technique (ICS, SCS) of the 40 eyes of the 40 patients included in this report are shown in Table 1 and 2. Table 3 shows the level of patients' satisfaction after surgery.

In 95% of the cases of KTP a brownish-black colour was used and a bluish-green for 5% of the cases. Pupil diameters were different, 4 mm being the most frequent (Table 1). In 10 cases of keratopigmentation by ICS keratopigmentation was perofrmed in two consecutive stages (retattooing) to adjust the cosmetic results to the needs of the case and the patient's expectations. An example is showed in figure 3A-C. In a first stage, the iris was reconstructed applying blue pigment. In a second surgery, brownish pigment was applied to better match the shades of the fellow eye.

The cosmetic results and postoperative ocular cosmetic symmetry (Table 3), as analyzed by an independent observer were classified as excellent in 27 cases, good in 10 cases and poor in 3 cases. All except three of our patients stated they would repeat the surgery again. Patients' subjective opinions about the results achieved are shown in Table 3.

We show pre- and post-operatory pictures of 3 patients from this study. Figures 2A-B and 6A-B show the aspect before and 1 year after the iris and pupil reconstruction performed in a 30 years-old (y/o) female with a history of ocular trauma on LE with only light perception.

Figure 3A shows a 55-y/o patient with total aniridia and aphakia due to ocular trauma before anterior segment reconstruction including a sulcus-sutured intraocular lens. To more accurately match the bluish colour of the LE, initially, the pigmentation for iris reconstruction

was performed using only blue pigment (figure 3B) and completed with a secondary pigmentation to improve cosmesis of the LE (figure 3C, 6C).

Figures 4A and 4B present pre- and 1 year-postoperative images of a 65y/o male patient affected by multiple retinal detachments resulting in complete blindness corneal leukoma and strabismus. Severe restricctions to ocular motility prevented an adecuate alineation of the axial axis. For partial iris reconstruction three different pigments were used to mimmic the appearance of the LE.

A 44 y/o female patient with a history of childhood ocular trauma leading to partial iris atrophy (figure 5A) underwent corneal keratopigmentation for sectorial iris simulation. Figure 5B displays the appearance of the patient 1 year after surgery. Fig 6D shows in detail the sectorial iris simulation under slit lamp examination.

There were no cases of inflammatory reactions or side-efects associated with KTP procedures such as pain, foreign body reaction, corneal de-epithelization or colour loss thoughout the study. Only three patients reported being not satisfied with the cosmetic results although they have not experienced any complications associated with keratopigmentation.

# **DISCUSSION**

Today, the preferred treatment for a patient with a blind and cosmetically severely impaired eye is the use of cosmetic contact lenses, which often are not well tolerated by patients. Another alternative is the use of external prothesis which in some cases causes chronic inflammation, ocular surface erosion and frequently discomfort. PK with all the well known limitations and risks is also occasionally used in cases of injured eyes. Finally, evisceration and enucleation and prosthesis adaptation are mutilating procedures that are used in the most severe or intractable cases<sup>11-14</sup>.

Two different methods of KTP were described during the last century. One of them was a chemical dye with gold or platinum chloride, a simple technique, mainly used in central

Europe<sup>1,2</sup>. Another method was a carbon impregnation. Chemical tattooing was easier and quicker than the carbon impregnation, but it faded more rapidly than non-metallic tattooing<sup>16</sup>. Later, India ink, Chinese ink, lamp black, and other organic dyes were used<sup>16</sup> but the final results were not satisfactory because fading still occurred with the need to frequently repeat the procedure<sup>10</sup>.

To the best of our knowledge, this is the first report on the practice of KTP with mineral micronized pigments and the first report on the use of intrastromal KTP with stable results in the largest serie reported since 1936<sup>15</sup>. We have also reported the combined use of the two surgical approaches: dying the anterior corneal surface (SCS) and introducing the pigment directly into the corneal stroma (ICS). Previous investigations have proven the good corneal tolerance to KTP performed with other dyes<sup>17,18,19</sup> even though granulomatous keratitis was reported in one case<sup>20</sup> which demonstrates that long term follow up and studies such as those carried out using the confocal microscope should be made to finally establish the tolerance and stability of new dyes used for KTP <sup>19</sup>.

According to our findings, the ICS itself is more advantageous than SCS as it provides a more homogeneous aspect of the pigmented area, surgery is faster, the patient showed a faster and less symptomatic postoperative recovery, the corneal surface is untouched and the staining is not exposed to tearfilm.

KTP was also succesfully associated to other types of surgeries in combinations that targeted different complications associated to cosmetic disabling problem. One limitation of KTP was corneal edema, which caused a partial clearance of the pigments at one year of aurgery. Most probably, the fluctuating condition of corneal edema may not be a good indication of KTP and probably is the cause of previous failures with other pigments previously used.KTP as shown in this study has revealed as a potentially useful tool in the management of traumatic aniridia and traumatic coloboma.

In summary, KTP or corneal tattooing, using micronized mineral pigments may be considered as an alternative for patients in whom evisceration or prosthesis implants would otherwise be used to improve their cosmetic appearance. Corneal tattooing can be a procedure for long term or permanent correction of cosmetic eye deformities in patients who have cosmetically disabling corneal scars.

We can conclude that KTP used as described in this investigation achieves during the follow up of this study, stable, satisfactory cosmetic results with high patient satisfaction in corneal leukomas and aniridias and probably improving the patient's quality of life. According to the results of this clinical study, KTP is a safe surgical procedure, easy to learn and to perform, that does not require expensive materials and it avoids more extensive and invasive reconstructive ocular procedures. Further investigation of the stability of the pigments described is necessary for a better understanding of the long term biological effects in the keratopigmented cornea of the micronized mineral pigments.

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# **TABLES**

Table 1 Cosmetic keratopigmentation clinical conditions of the patients and simulated pupil size

	Number			Simulated
Clinical diagnosis	of eyes	Vision	Cosmetic Complaint	pupil size
Traumatic OD	12	CF 10cm to HM	total leukoma	4mm
Traumatic Aniridia	3	20/40	asimetric cosmetic appearance and disabling glare in affected eye	5 mm
Blindness ROP	2	amaurosis	severe corectopia	3 mm
Long standing retinal detachment	12	NLP	leukoma phthisis bulbi	4 mm 4 mm
Chemical burn with phthisis bulbi	7	amaurosis	amyloidotic corneal degeneration	4 mm
Absolute glaucoma	3	НМ	corneal leukoma	4 mm
Congenital sclerocornea	1	NLP	leukoma microphthalmus	3 mm

ROP: Retinopathy of prematurity, RD: Retinal detachment; NLP: No light perception; HM: hand movements, CF: Counting fingers

Table 2 Cosmetic Keratopigmentation: reoperations and associated surgeries

	Number of		Other associated	
Surgical Technique	patients	Retattooing	Surgeries	
Intralamellar cornea staining	26	10	upper lid blepharoplasty  strabismus  lOL implantation  lOL implantation with trabeculectomy	
Superficial corneal staining	80	0	2 strabismus 1 marginal tarsorraphy	
Combined intralamellar and superficial staining procedures	06	0	2 sili con oil tamponades 2 diode cyclocoagulation	

**Table 3** Cosmetic keratopigmentation observer's objective assessment of the cosmetic appearance and patient's satisfation

3 0
0
10 27
3
0
.7
7

<sup>\*</sup> All the three patients with traumatic aniridia and disabling glare reported a very significant decrease in glare in the keratopigmented eye

# Legends to figures

# **Figures 1: Intralamellar Corneal Staining (ICS)**

- Figure 1A: pupil diameter of 4mm previously estimated following the low mesopic pupil was marked with an RK optic marker
- Figure 1B: 3-4 incisions with a prephased diamond ring of 1mm
- Figure 1C: cornea dissected intralamellary with a micro crescent knife (Sharpoint)
- Figure 1D: pupil stained with the adequate dark color (0.1cc) with a 30 gauge canula
- Figure 1E: dissection of peripheral cornea top side
- Figure 1F: dissection of peripheral cornea down side
- Figure 1G: coloring peripheral cornea in an irregular format to recreate better the iris crest
- Figure 1H: mixing black & yellow-brown colors to give the right color of the fellow eye
- Figure 1I: final result of the corneal tattooing

# Figures 2-5: Pre- and postoperative appearances of selected patients.

- Figure 2A: preoperative apperance of the LE.
- Figure 2B: results 1 year after iris appearance reconstruction and pupil simulation.
- Figure 3A: preoperative appearance before anterior segment reconstruction including a sulcus-sutured intraocular lens.
- Figure 3B: first pigmentation using only blue pigment.
- Figure 3C: a second pigmentation to better match the appearance of the LE.
- Figure 4A: preoperative aspect of patient with corneal leukoma and strabismus.
- Figure 4B: Results 1 year after strabismus surgery and partial iris reconstruction and colour simulation in LE.
- Figure 5A: Preoperative aspect of a patient with partial iris atrophy secondary to childhood ocular trauma.
- Figure 5B: appearance of the patient 1 year after sectorial iris simulation.

# Figure 6: Pre- and post-operative slit lamp examination of selected patients.

Figure 6A: aspect of LE under slit lamp before keratopigmentation.

Figure 6B: slit lamp image of the cosmetic result achieved in LE 1 year after corneal

pigmentation.

Figure 6C: detail of the sectorial iris simulation as seen with slit lamp.

Figure 6D: slit lamp detail of the sectorial iris simulation.





