



EVALUATION OF EFFICACY AND CLINICAL SAFETY PROFILE OF KERATO-PIGMENTATION DONE WITH AN AUTOMATED TATTOOING MACHINE

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ABSTRACT

Corneal tattooing or keratopigmentation (KTP) is a surgical procedure used for functional and cosmetic correction of corneal scar. This study aims to evaluate the efficacy and safety profile of superficial KTP done with presterilized gamma irradiated derma ink and an automated micropuncture device - Digital PMU & MTS system.

Material and method – KTP was performed for 25 eyes of 24 patients of superficial or deep corneal opacity with no perception of light. Out of 25 eyes, 16 had corneal scar following penetrating corneal injury 5 had corneal opacity following healed keratitis, 2 had post-therapeutic failed graft and one eye each of Band shaped keratopathy (BSK) with corneal opacity and corneal opacity with absolute glaucoma. Follow up was done on postoperative day 1, 5, 2week and then monthly. Patients were evaluated for intraoperative and postoperative complications, stability of dye and on a subjective scale of satisfaction (an imaginary score with totally unsatisfied as score 1, satisfied – 2, happy – 3 and extremely happy as score 4).

Results – Intraoperative bleed was reported in 2 of the patients. Postoperative complications included nonhealing epithelial defect (12%), inconsistent colouring (20%), colour fading (16%). Secondary surgical procedure performed were temporary tarsorrhaphy (4%) and repeat KTP (16%). 44% patient graded their experience as happy, 48% as satisfactory and 8% as totally unsatisfactory.

Conclusion – Superficial automated KTP using Digital PMU & MTS system and derma ink a relatively simple procedure with no significant intraoperative or postoperative complication. The histological safety of dye and the efficacy of this system needs to be evaluated in larger number of patients.

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INTRODUCTION

Management of corneal disfigurement involves various non-surgical and surgical procedures. The available options are cosmetic contact lenses, corneal tattooing, lamellar or full thickness keratoplasty, enucleation or evisceration with ocular implants and prosthesis. Keratoplasty is a complex procedure with its inherent risk and complication and is commonly reserved for eyes with potency of better visual acuity. Different ocular mutilating reconstructive surgeries as enucleation and evisceration are associated with magnitude of symptoms related to both anophthalmic socket and prosthesis.^{1,2}

Corneal tattooing or keratopigmentation (KTP) has been in clinical application since Galen (131-210 A.D.) used reduced copper sulphate to mask a corneal leukoma.³The automated method of corneal impregnation involves machine driven introduction of colour pigment in anterior corneal stroma. The aim of this study is to evaluate the efficacy and clinical safety profile of keratopigmentation done with presterilized gamma

irradiated derma ink and handheld automated Digital PMU & MTS system in first 25 eyes.

MATERIALS AND METHODS

It was a hospital based prospective, nonrandomized, noncomparative interventional study conducted after approval from departmental research committee. All cases of KTP were done by a single surgeon Dr Singh M between November 2018 and March 2020. A written consent was taken from every patient after a proper explanation about the procedure, associated complications and result.

Inclusion and exclusion criteria

Patients with superficial or deep corneal opacity with no perception of light and nil visual prognosis were included in this study.

Patients with inflamed ocular surface, severe dry eye, anterior staphyloma, phthisis bulbi, corneal thinning and patients with unrealistic expectations were excluded from study.

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The study involved 25 eyes of corneal opacity of 24 patients between 10 year to 43 years of age. 17 of them were female and 7 were male. 16 of the 25 eyes had corneal scar following penetrating corneal injury. 5 eyes had corneal opacity following healed keratitis, including 3 cases of childhood measles keratitis. There were 2 cases of post-therapeutic failed graft and one case each of Band shaped keratopathy (BSK) with corneal opacity following retinal surgery and corneal opacity with absolute glaucoma. A detailed slit lamp evaluation was done to assess the ocular surface and status of cornea. Eyes with corneal thinning on slit lamp evaluation were deferred from this procedure.

Tattooing machine and pigment – The automated device used in this study is a commercially available dermatological tattooing machine, the Digital PMU & MTS system (Model : ZX1511) marketed and manufactured by a Chinese company. It consists of a console, handpiece with disposable needle and a foot plate (Figure 1). When attached with a power supply there is an antero-posterior vibration of needle, the depth of which can be adjusted with the attached rotator of handpiece.

The corneal pigment used in this study was presterilized with gamma irradiation and is approved for dermal tattooing. The method of application and the safety of this machine for KTP was first reported by Dr Pradhan A⁴ and has been published as a case report by Madhivanan N.⁵

Surgical procedure

All the surgeries were performed under local anaesthesia (topical or peribulbar), in operation theatre under full aseptic precaution. Corneal epithelium was removed from the site of KTP with 15 no blade, colour pigment of brown and black was smeared and mixed over the surface and was propelled into the superficial cornea by making micropuncture with automated handpiece. Repeated application of pigments insured the desired intraoperative final cosmesis. Any other surgical procedure required for the patient (EDTA calcium chelation for BSK) was also carried out in the same sitting. Bandage contact lens (BCL) was applied at the end of surgery. The postoperative regimen included topical antibiotic, cycloplegic, steroid and lubricating eye drops.

Patients were followed up on postoperative day 1, 5, 2week and then monthly. The minimum and the maximum follow up records available are for 6 month and 12 months respectively. On every follow up visit, clinical evaluation was done with slit lamp, clinical photography and on a subjective scale of satisfaction. Patient's satisfaction was graded between 1-4 (an imaginary score with totally unsatisfied as score 1, satisfied – 2, happy – 3 and extremely happy as score 4). The efficacy and postoperative complication, stability of KTP and satisfaction of patient.

RESULTS

This study involved 25 eyes of 24 patients. 17(70%) of them were female and 7(30%) were male. The result of this study was evaluated in terms of intraoperative and postoperative complications, stability of KTP with time and patient satisfaction graded between 1-4. Intraoperative complication – None of the patient had any significant intraoperative complication during surgery except for the minimal bleed in 2 of the vascularized corneal scars. This stopped with gauge pressure in one of the cases and needed electrocautry application in another. None of the cases had corneal

perforation. None of them had intraoperative migration of dye under conjunctiva or in anterior chamber.

Postoperative complication

All the patients had conjunctival congestion (Figure 2 and 3) and mild foreign body sensation in immediate postoperative phase which disappeared by day 7 in all except 3 cases. BCL was removed after epithelial healing.

There was a corneal epithelial defect in all the cases corresponding to KTP site which was healed at the end week 1 in all except 3 of the cases. Out of 3, 2 required hourly lubricating drop application and prolonged BCL application for 2 weeks, for complete epithelial healing. In one of the cases BCL was not stable and there was a persistent epithelial defect after 10 days of surgery. A temporary tarsorrhaphy was done in that case which lead to epithelial healing.

No evidence of prolonged surface inflammation, adverse reaction to dye, corneal ulcer, corneal melt, neovascularization, scarring, ocular surface inflammation or any other complication was noticed.

Stability of KTP

Inconsistent colouration was noticed in 5 of the eyes specially in eyes with irregular corneal scar at the end of month 1. The KTP colour fading (Figure 4) was seen in 4 out of 5 of these cases which needed repeat KTP procedure at the end of month 3.

Patient satisfaction

Out of 25 eyes, 11 graded this procedure as grade 3(happy), 12 as grade 2 (satisfied) and the other 2 as grade 1 (totally unsatisfied). These two patients included the patients with non-healing epithelial defect. None of the patients were extremely happy and the primary concern for all the patients was the stability of colour with time.



Figure 1 – Automated keratopigmentation machine



Figure 2 Preoperative corneal opacity before corneal tattooing

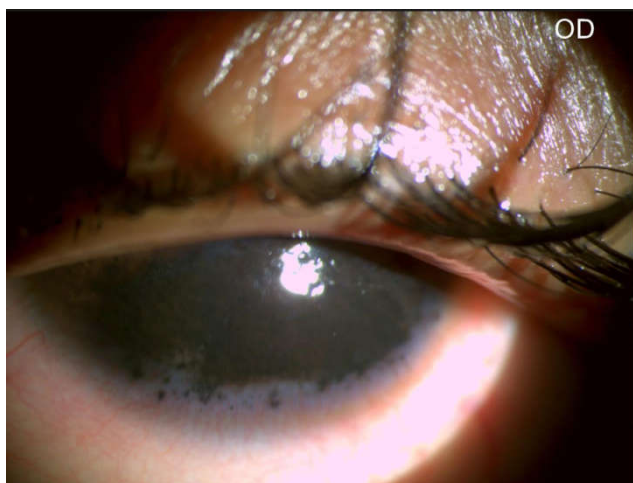


Figure 3 Postoperative day 1 photograph showing conjunctival congestion

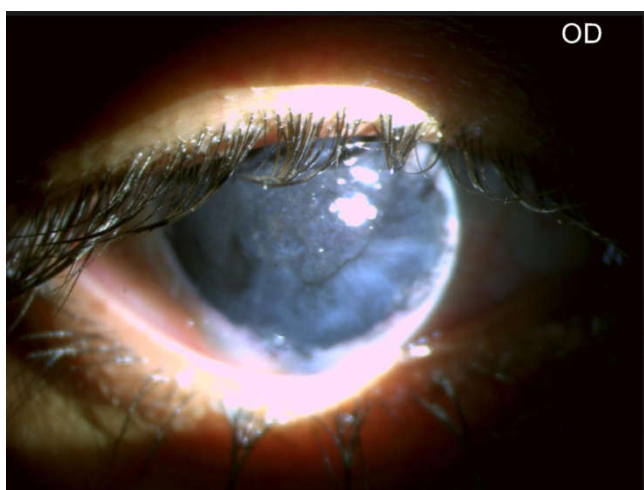


Figure 4 Fading of corneal pigments

Table 1 Result of automated keratopigmentation

Total number of eyes	25
Age of patient	10 – 43 years
Primary diagnosis	<ul style="list-style-type: none"> • 16/25(64%) - corneal scar following penetrating corneal injury. • 5/25(20%) - corneal opacity following healed keratitis, including 3 cases of childhood measles keratitis. • 2/25(8%) - post-therapeutic failed graft • 1/25(4%) - BSK corneal opacity following retinal surgery • 1/25(4%) -corneal opacity with absolute glaucoma.
Procedure	24/25 - Superficial automated KTP 1/25 – EDTA chelation + Superficial automated KTP
Intraoperative complication	2/25(8%) – Intraoperative bleed
Postoperative complication	3/25(12%) – Non-healing epithelial defect
Stability of KTP	5/25(20%) – Inconsistent colouration 4/25(16%) – Colour fading
Patient satisfaction	11/25(44%) - grade 3(happy) 12/25(48%) - grade 2 (satisfied) 2/25(8%) - grade 1 (totally unsatisfied)
Second procedure required	1/25(4%)– Temporary tarsorrhaphy 4/25(16%) – Repeat KTP

DISCUSSION

KTP has two important surgical indications – Functional – when it is performed for managing symptoms related to light scattering, excessive glare, diplopia etc and cosmetic – when it is performed for management of disfigured corneal scar. The

most significant criteria to define success of KTP is safety of colouring agent and stability of colour. Potential risks of inadequately selected pigments may include toxic reaction of the pigments, colour fading and changes, under- or over-pigmentation, and especially not matching pigmentation with the colour of the normal eye because of the limitation in pigments’ spectrum.⁶

There are multiple colouring agents which have been used for KTP like India ink, organic colours, metallic powder, animal uveal pigment, China ink, soot etc. Their superiority and advantage over one another are yet to be proved. There are different surgical ways of using these dyes in corneal tattooing like a simple staining procedure, an impregnation method or a lamellar (manual/automated) method. Lamellar method of corneal tattooing has been widely published. Panda et al in their report has published the advantages of lamellar method of KTP over surface staining⁷but reports also suggest that there is no optimal method of surgical technique for corneal tattooing.⁸ For impregnation method of corneal tattooing different instruments have been used like – direct injection of dye, spatulated needle and 26/30G needle for manual micropuncture over anterior corneal surface and automated micropuncture devices. Alsmman et al published their result of corneal tattooing by impregnating Rotring painting ink (Rotring Ink, Hamburg, Germany) by multiple transepithelial intrastromal injections on 53 blind eyes. They reported that 17% of eyes needed secondary injection for managing inconsistent or faded colour.⁹Pitz et al used a three edged spatula needle for impregnating commercially available drawing ink in 11 patients. In their study, one of the patient had intraoperative corneal perforation. They reported this technique to give a safe and stable result over a follow up period of 5 years.¹⁰

An animal study conducted on rabbit’s eye using an automated micropuncture device ((Vissum Eye MP System, Madrid, Spain) similar to our study and micronized mineral pigment reported excellent cosmetic appearance with no ocular surface inflammation 6 months after KTP. The histopathological report showed lack of inflammatory reaction and atypia and stability of pigments.¹¹Another large retrospective study by Al-Shymali O on KTP involving 136 eyes, used the same automated device. 57.2% of eyes underwent superficial automated KTP, 22.5% - superficial manual KTP and 20.3% - combination of superficial KTP with other KTP. The mean follow up duration of this study was 2.4years. There was no intraoperative or postoperative complication like chronic epithelial defect was reported. In their study 44.7% patient needed retouch in the form of repeat of KTP.¹²Kim et al in their 5 year follow up study of 147 eyes of superficial manual KTP using tissue marking dye reported long-term complications such as reopacification or increased opacity, fading of colour and epithelial growth in 12% of the tattooed eyes and most required reoperation.¹³ Our study although has been done using a different machine and ink, reports 16% percentage of patients requiring repeat KTP.

CONCLUSION

The available literature on KTP definitely shows a lack consensus regarding the technique, the machine and the corneal pigment. Our study suggests superficial automated Digital PMU & MTS system tattooing machine and derma ink is a relatively simple procedure with no significant intraoperative or postoperative complication. This gives a

satisfactory cosmetic correction. The stability of KTP in terms of colour fading is comparable to other published reports. The limitation of this study is its limited number of cases, lack of longer follow up records, no histopathological evidence to support the safety of this dermatological ink for cornea. The easy commercial availability of the dye and the machine, the simplicity of procedure and the satisfactory outcome of this procedure makes it a useful alternative technique of KTP.

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