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Research Article

Transepithelial Photorefractive Keratectomy: Refractive Outcome

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Abstract

Background: To assess the refractive outcomes of transepithelial photorefractive keratectomy (TransPRK) using aspheric ablation profile.

Methods: This retrospective study comprised 24 eyes which had uneventful Aberration-Free single- step transepithelial PRK (TransPRK) ablation profile using Amaris excimer laser system 750 S (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany). The study included myopic eyes with or without astigmatism with a mean manifest Refraction Spherical Equivalent (MRSE) of -3.35 D ± 1.57 (range from -1.00 to -6.00). Postoperative follow-up was at least 12 months included UDVA, CDVA and slit-lamp examination. postoperative haze were analyzed and subjective pain evaluation was recorded.

Results: The procedure significantly reduced the MRSE and cylinder post operatively (95% were ± 0.50D and 100% ± 1.00D), with stability of refraction and UDVA over the follow up period (up to 12 months) after surgery. No eye lost any line of the CDVA which reflects excellent safety profile of the procedure on the other hand one eye (5%) gained one line and one eye (5%) even gained 2 lines. Fast epithelial healing with no haze/clinically insignificant haze formation. There were no significant complications during or after the procedure.

Conclusion: Transepithelial photorefractive keratectomy (TPRK) for Myopia/myopic astigmatic shows predictable, effective and safe refractive outcomes that were stable through 12 months. Longer follow up period is required to detect any further refractive changes.

Keywords: *Transepithelial Photorefractive Keratectomy (TPRK); Manifest Refraction Spherical Equivalent (MRSE); Ablation Profile*

Introduction

Corneal refractive surgery laser treatments have several modalities, the oldest one is surface ablation in the form of photorefractive keratectomy (PRK) [1,2]. with the advent of laser- in situ keratomileusis (LASIK) which offered a painless spherocylindrical error correction with fast visual recovery and no clinically significant haze, the popularity of surface ablation has declined [3]. however, LASIK in patients with high myopia or with thin cornea might jeopardize the corneal stability, increasing the risk of postoperative iatrogenic ectasia [4]. Moreover, a surface ablation treatment has several advantages with no risk of flap complications (buttonhole, striae, DL, etc.) [5].

Several advanced surface ablation techniques are available, an alcohol-assisted technique was proposed in 2003 called laser-assisted subepithelial keratectomy (LASEK) [6]. Epithelial laser in situ keratomileusis (Epi-LASIK) is another method that uses a device similar to a microkeratome (called epi-keratome) with a blunt oscillating blade that slides just underneath the epithelium in order to create an epithelial flap that can be repositioned back after ablation over the stromal bed [7].

In the late 1990s, transepithelial photorefractive keratectomy was introduced where removal of the epithelium is performed with excimer laser phototherapeutic keratectomy (PTK) followed by PRK of the stroma. This 2-step technique did not gain much popularity due to the prolonged surgery time with the older relatively slow generation of excimer lasers which could lead to excessive dehydration of the stroma, increased pain, and a lack of accuracy nomograms [8].

Recently a new modality, a single- step transepithelial PRK (TransPRK) allows removing the epithelium and stroma in a single step with one ablation profile, has been described. Epithelial removal in this technique takes place using a population-based epithelial profile instead of the uniform PTK epithelial removal. with this fast single step technique, smoother corneal stroma bed, faster re-epithelization along with lower incidence of post-operative haze is expected [9].

Aim of the Study

The aim of this study is to evaluate visual recovery time, corneal epithelial healing and post-operative pain and stromal haze after TransPRK.

Material and Methods

Setting and study design

This retrospective study comprised 24 eyes of 12 Egyptian patients (8 females and 4 males) who had uneventful Aberration-Free single- step transepithelial PRK (TransPRK) ablation profile using Amaris excimer laser system 750 S (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany), between February 2012 and September 2015 in International Eye Hospital, Cairo, Egypt.

The mean preoperative Manifest Refraction Spherical Equivalent (MRSE) of -3.35 D ± 1.57 (range from -1.00 to -6.00). The mean age of the patients was 27.71 ± 8.24 (ranging from 18 to 49 years). Other baseline preoperative values are listed in table 1. All treatments were performed by the author.

Baseline preoperative values				
Characteristics	**Mean**	**SD**	**Min**	**Max**
Age	27.71	8.24	18	49
Mean preop (MRSE) (D)	-3.35	1.57	-6.00	-1.00
Central pachymetry (µm)	533	44.31	574	492
Mean keratometry (D)	44.31	1.21	42.1	45.82
Mesopic Pupil diameter (mm)	3.1	0.7	2.6	4.1
Total Ablation zone (mm)	8.42	0.43	8.07	9.05
Max Ablation Depth (µm)	107.23	26.14	72	151

Table 1: *Baseline characteristics and surgical parameters of 24 myopic eyes undergoing TransPRK.*

Selection criteria

Inclusion criteria included patients over 18 years old with preoperative stable refraction for at least one year, normal corneal tomography with expected postoperative flat K reading not less than 38D, and postoperative residual stromal bed not less than 350 µm and postoperative follow-up of at least 12 months.

Exclusion criteria included: Patients with preoperative corrected distance visual acuity (CDVA) of worse than 20/30, amblyopic patients, patients with a history of previous ocular surgeries, herpetic eye infection, or corneal dystrophies. Patients with other ocular conditions e.g. uveal or retinal diseases, and glaucoma patients were also excluded.

Preoperative examination and follow-up

The preoperative examination included measuring uncorrected distance visual acuity (UDVA), (CDVA), manifest and cycloplegic refractions; full ophthalmological examination included slitlamp biomicroscopy, Goldmann applanation tonometry, and full fundus evaluation.

Corneal topography and corneal wavefront measurements were done using the Keratron Scout (Optikon 2000, Rome, Italy), Scheimpflug-based imaging system (Pentacam, Oculus Optikgeräte GmbH) were also performed in all cases. Ablation profile calculations were done using ORK-CAM software. The aberration free ablation profile was selected, which is basically an aspherical ablation profile, with TransPRK mode.

Since the epithelium does not have a uniform thickness all over the cornea, the ablation profile considers the ablation thickness of the epithelium 55 μm centrally, and 65 μm peripherally for an 8 mm ablation zone, this data was generated from population model It also delivers different ablation energies to the epithelium and stroma.

With this approach, the area of epithelial removal corresponds directly to the area of the intended ablation, so only the necessary amount of epithelium is removed.

Postoperative follow-up examinations were conducted at 1 day, 3 days/(5 days if needed), 1 week, 1 month, 3 months, 6 months, and 1 year.

Surgical technique

Prior to the surgery, topical benoxinate hydrochloride 0.4% (Benox, Epico, Inc., Cairo, Egypt) was instilled into the eyes. The periocular area and closed eyelids were then scrubbed with Povidone-iodine (10%) and draped, A lid speculum was used to open the eyelid. The other eye was occluded and covered.

Before starting the Excimer laser application a standardized wet sponge application; a Merocel sponge (Medtronic Inc., Minneapolis, MN, USA) dipped in balanced salt solution (BSS) was applied with three slow painting movements on the corneal surface to avoid uneven wetting that could lead to uneven irregular ablation.

Laser delivery was performed immediately afterward, Mean planned maximum ablation depth was 107.23 μm (SD: 26.14; range: 72 - 151 μm) including the epithelium thickness which is by software default 55 μm in the center. Optical zone was set to 6.50 mm in all cases with variable transitional zone calculated by the software.

The cornea was then cooled with 20 mL chilled BSS. After drying the stroma with a dry sponge MMC (0.02%) (Kyowa-hakko Co. Ltd., Tokyo, Japan) was applied in all cases for 20 seconds using Corneal Light Shield with 8mm diameter- Lint free PVA, then the cornea, conjunctiva (including fornices) and lid margins were copiously irrigated with BSS. One drop of topical Prednisolone acetate (1%) (Pred Forte, Allergan, Inc., Irvine, CA, USA) and one drop of moxifloxacin (0.5%) (Vigamox 0.5%; Alcon Laboratories Inc., Fort Worth, Texas) were subsequently instilled, and a high-oxygen-content (50%) soft contact lens (Acuvue Oasys, Johnson and Johnson) bandage contact lens was inserted and left in place until total epithelial healing. Postoperatively, all eyes received topical moxifloxacin (0.5%) qid for 1 week, Prednisolone acetate (1%) drops qid tapered over 3 weeks, and artificial teardrops (Refresh Tears, Allergan, Irvine, CA, USA) qid for 3 months.

Oral nonsteroidal anti-inflammatory drug in the form of Diclofenac Potassium 50 mg (Cataflam; Novartis, Stein, Switzerland) up to 3 times/day if needed was prescribed in the early postoperative period and oral Ascorbic acid (vitamin C) 1 gm/day for one month was also prescribed.

Ethics

This study was approved by the Institutional Review Board and adhered to the tenets of the Declaration of Helsinki.

Analyses

Statistical analysis and graphs were done with standard spreadsheet software program using Microsoft Excel 2013 (Microsoft Corporation, Seattle, WA, USA).

Availability of data and materials' statement: The datasets analysed during this study are available in the International Eye Hospital, Cairo, Egypt.

Results

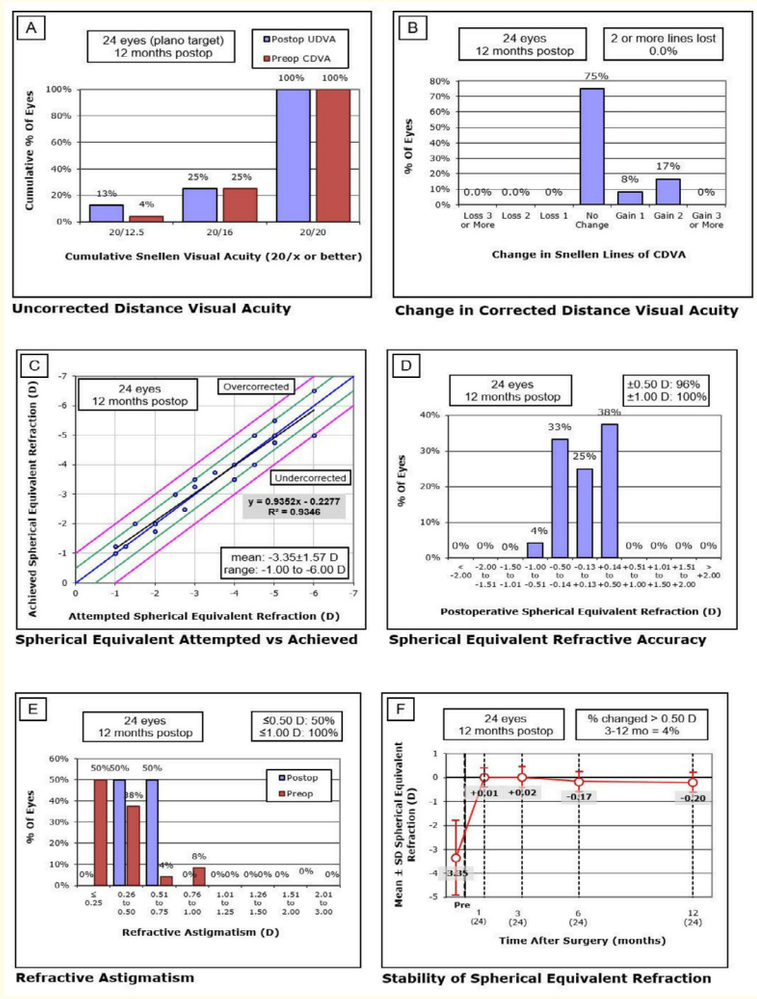
TransPRK were easily performed with no intraoperative or early post-operative complications in any of the patients. All cases had a follow-up of at least 12 months after the treatment.

Re-epithelialization was complete at 3 days post-operatively in 20 eyes and at 5 days post-operatively in the remaining 4 eyes.

Postoperative pain improved after 2 to 3 days in all eyes.

Post-operative haze was not clinically significant in all cases after one month, no eye needed further continuation of steroids eye drops.

The refractive outcome is summarized in the following graphs A-F.



Efficacy

Regarding the efficacy of the procedure Graph A compared the Post-operative UDVA to the Preoperative CDVA, The post-operative UDVA was 20/20 or better in all eyes and 20/16 or better in 25% of the eyes (6 eyes) and 20/12.5 in 12.5% of the eyes (3 eyes). These results reflects excellent efficacy of the procedure.

Safety

Graph B represents the change in Snellen lines of post-operative CDVA at 12 months. no eye lost any line of CDVA while 8.3% of the eyes (2 eyes) gained one line of CDVA and 17% of the eyes (4 eyes) gained 2 lines of CDVA. These results reflects excellent safety of the procedure and even more line gain in 25% of the eyes (6 eyes).

Predictability

The scattergram in graph C represents the achieved post-operative Spherical Equivalent (SE) and attempted Spherical Equivalent (SE) at 12 months post-operatively and graph D shows the Post-operative SE in Diopters. 96% of eyes (23 eyes) were within ±0.5D of emmetropia and 100% of the eyes were within ±1.0D of emmetropia which reflects very good predictability of the TransPRK at 12 months postoperatively, No eyes needed further enhancement.

Although the postoperative SE of 4% of the eyes were more than ±0.5D and within ±1.0D, the UDVA reached 20/20 in these eyes.

Regarding astigmatic correction, graph E shows the correction of refractive astigmatism. 50% of the eyes (12 eyes) had less or equal to 0.5D of refractive astigmatism at 12 months post-operatively and 100% of the eyes had less or equal to 1.00D of refractive astigmatism at 12 months post-operatively.

Stability of refraction

Regarding the stability of the procedure, graph F shows that the target refractive correction was achieved after one month which remained more or less stable over the whole follow up period (12 Months) with negligible fluctuation.

Discussion

The concept of transepithelial PRK was reported to be an effective option for correction irregular astigmatism after keratoplasty, radial keratotomy [10,11] and also found to be a good option for treatment of LASIK flap complications [12].

Other studies showed variable results using transepithelial PRK in virgin corneas.

In one study by Clinch., *et al.* they reported that refractive results with mechanical removal of the epithelium (epi-LASIK) were superior to laser epithelium removal [8].

In another study by Lee., *et al.* they compared PRK, transPRK and alcohol assisted surface ablation (LASEK) using Visx Star S3. Postoperative pain, haze, and the postoperative CDVA were similar in the 3 groups. With transPRK, they reported a slight overcorrection and with LASEK they reported a slight under correction [13].

Another study by Ghadhfan., *et al.* they reported that transPRK provided slightly better visual outcomes than LASIK or LASEK in patients with low to moderate myopia and better visual outcomes than epi-LASIK, LASIK, and LASEK in eyes with high myopia [14].

Korkmaz., *et al.* compared Transepithelial PRK and LASEK for Myopia. This study included clinical and confocal microscopic assessment of both technique.

The epithelial healing time was almost one day longer after LASEK which was statistically significant ($P < 0.05$). however the mean subjective pain score on day 1 was significantly higher in transepithelial PRK than that in LASEK but After day 1, mean pain scores were similar. They also reported that at 6 months, 100% of eyes achieved 20/25 in both groups and more than 90% of eyes were within ±0.50D of emmetropia, these results remained stable at 12 months.

Confocal microscopy showed that the keratocyte density was significantly lower in transepithelial PRK group than in LASEK group at 1 month and 3 months while more extracellular matrix deposition and activated keratocytes were observed in transepithelial PRK group than in LASEK group [15].

In all the above-cited studies, the laser epithelial removal part was performed using PTK based on an assumption that the entire epithelium has the same thickness.

By using very high-frequency digital ultrasonography (VHFUS), Reinstein., *et al.* studied the *in vivo* epithelial thickness in normal corneas and found that the mean epithelial thickness at the corneal vertex was 53.44 μm, and the average epithelial thickness map showed that the corneal epithelium was thicker inferiorly than superiorly (5.9 μm at the 3-mm radius), and thicker nasally than temporally (1.3 μm at the 3-mm radius) [16]. These results were quite similar to other data published by Kanellopoulos and Asimellis [17].

They used spectral-domain anterior-segment OCT (SD-OCT) and reported also epithelial non-uniformity. Urs., *et al.* compared epithelial thickness (ET) in maps obtained by the SD-OCT system with those obtained from the VHFUS and concluded that the obtained maps were highly correlated and did not show statistically significant differences [17].

All epithelial thickness mapping studies showed that there is a high inter-individual differences of the epithelial thickness. This variation could be a limiting factor for the efficacy, predictability, and safety of TransPRK ablation because if the central epithelial thickness is thinner than the default 55 μm, this will induce more ablation in the stroma, whereas in corneas with a normal thick epithelium the stromal ablation part of the TransPRK might start before total removal of the whole epithelial layers. It is noteworthy that the newer software has an option that allows for the actual epithelial thickness measurements entry.

There are two types of TransPRK technique. The older two-step one removes epithelium by phototherapeutic keratectomy (PTK) followed by PRK for stromal ablation to correct the refractive error. The newer one is single-step platform which simultaneously ablate surface and stroma. During single-step TransPRK, first the refractive part of the treatment, and then the epithelial profile is ablated. This sequence maximizes the smoothing effect of epithelium over stromal irregularities. Another advantage of this technique is being a fast treatment as it takes considerably less time than two-step PTK laser removal. This prevents stromal dehydration which might cause overcorrection. The excimer laser system used in this study (Schwind Amaris 750s) is equipped with Intelligent Thermal Effect Control which also prevents overheating of the stroma.

The clinical results of this study support other studies results regarding the efficacy, predictability, safety and stability of the procedure [9,18-22].

Using small beam fast flying spot excimer laser with intraoperative MMC (followed by immediate irrigation with chilled BSS), and postoperative vitamin C appears to effective at minimizing/preventing post-operative haze formation.

A recent study comparing TransPRK technique with the same laser system for low to moderate myopia with conventional PRK concluded that TransPRK appears to be superior to conventional PRK in terms of postoperative pain, epithelial healing time, visual recovery and safety and efficacy indexes [23].

The TransPRK has also been studied for high myopia and showed promising results and good post-operative quality of vision [24].

The technique was also useful in dealing with irregular refractive errors in post-RK patients when using topography-guided TransPRK [25].

There are several limitations of this study that include the small sample and lack of a control group.

The small size was due to that other recruited patients (15 patients/30 eyes) failed to complete the 12 months follow up period and they just appeared in the 6 months follow-up visit with very satisfactory refractive outcome so they skipped the 12 months visit and excluded from the study.

Conclusion

In conclusion, single-step TransPRK appears to be effective, predictable and safe in correction of myopia/myopic astigmatic. It shows also excellent stability over 12 months. Future studies on larger samples and longer follow up and further analysis are recommended.

Financial Disclosure

No author has a financial or proprietary interest in any material or method mentioned.

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