

Transepithelial photorefractive keratectomy mode using SCHWIND –ESIRIS excimer laser: initial clinical results

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Abstract

- **AIM:** To evaluate postoperative pain, uncorrected visual acuity (UCVA), and cornea haze value after transepithelial photorefractive keratectomy (T-PRK) performed with aspherical ablation profile using SCHWIND ESIRIS excimer laser.

- **METHODS:** Retrospective case series. Fifty-nine eyes (32 patients) with myopia associated with or without astigmatism underwent phototherapeutic keratectomy (PTK) followed by photorefractive keratectomy (PRK) which performed by Optimized Refractive Keratectomy (ORK)-CAM software based on aspherical ablation profile using SCHWIND ESIRIS excimer laser. Postoperative pain scale was measured on a questionnaire through five levels. Haze was graded by five grades, and UCVA, manifest refraction spherical equivalent (MRSE) were analyzed.

- **RESULTS:** Mean pain level was (1.37± 0.613) (range: 1 to 3), the mean time picking out the soft contact lens was (6.22± 1.73) days, at 3 months, UCVA was 1.0 for 40 eyes (67.8%), 0.5 for all eyes (100.0%). The UCVA was significantly less than the preoperative best spectacle corrected visual acuity (BSCVA) ($t=-2.84$, $P=0.006$), haze value was (0.27± 0.25), no patients had a haze grade up to 2. Mean MRSE was (0.76± 0.96) diopter(D) by 3 months.

- **CONCLUSION:** The outcomes from this study show that using the SCHWIND ESIRIS aspherical ablation profile for transepithelial PRK has a good visual result. The primary advantage is related to a spherical ablation profile, automatically considers the ablation volume of the stroma and the accurate and smooth removal of the epithelium with PTK. Additional studies are needed to determine long-term outcomes.

- **KEYWORDS:** myopia surgery; transepithelial photorefractive keratectomy; phototherapeutic keratectomy

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INTRODUCTION

Even though laser *in situ* keratomileusis (LASIK) is the most popular mode in the refractive surgery ^[1], the followed potential intraoperative or postoperative flap complications, cornea ectasia, *etc.* can affect the vision seriously. Thus, in this respect, the surface ablation is safer for there is no flap involved and reserve more cornea thickness. So more and more surface ablation techniques were studied in order to reduce the incidence of postoperative pain, cornea haze and other related complications. Current surface ablation includes epithelial LASIK (epi-LASIK), laser-assisted subepithelial keratectomy (LASEK), mechanical epithelial removal photorefractive keratectomy (M-PRK) or transepithelial photorefractive keratectomy (T-PRK).

Since the late 1990s, a surface ablation technique was introduced using the phototherapeutic keratectomy (PTK) mode to remove the epithelium and followed by ametropic laser (transepithelial PRK, T-PRK) ^[2,3], and then variable clinical results were reported using different laser platforms^[4-6]. To our knowledge, however, no report on transepithelial PRK performed with aspherical ablation profile using SCHWIND ESIRIS excimer laser have been published.

In this retrospective study, we reported postoperative pain, uncorrected visual acuity (UCVA) and haze value using

transepithelial PRK performed with aspheric ablation profile by SCHWIND ESIRIS excimer laser's ORK-CAM software (SCHWIND eye-tech solutions, Kleinostheim, Germany).

MATERIALS AND METHODS

Subjects The medical records of all cases with a diagnosis of myopia associated with or without astigmatism at Eye Laser Department, Liuzhou Eye Hospital, between September 2010 and July 2011, were reviewed. All the cases were performed by one ophthalmologist (Dr. Guang-Sheng Chen) and had complete data. All the patients were excluded from keratoconus, intraocular or outer eye diseases, collagenosis and autoimmune diseases.

Methods All procedures were performed using the SCHWIND ESIRIS excimer laser; transepithelial removal was performed using PTK mode of the excimer laser with a diameter of 7.0-9.0mm and a depth of 45-52mm, depending on surgeon preference. The epithelia removal was controlled by monitoring the disappearance of blue fluorescence. And the ametropic laser was performed using PRK by ORK-CAM software based on aspheric ablation profile. A 330-Hz infrared eye tracker centered on the pupil was used for both PTK and PRK ablations. Mitomycin-C (MMC) 0.02% was used for 15-30 seconds according to the preoperative manifest refraction spherical equivalent (MRSE).

At the end of laser ablation, a high-oxygen-content (>50%) silicone hydrogel soft contact lens was placed over the cornea, followed by one drop each of a Levofloxacin 0.3%, a Tobramycin dexamethasone, and a diclofenac sodium ophthalmic solution 0.1%. Patients were given diclofenac sodium ophthalmic solution 0.1% 4 times a day for 3 days; Tobramycin dexamethasone drops 4 times a day for 1 week followed by fluorometholone 0.1% three times daily for 1 month and twice daily in the second month, and then reduced the usage according to the cornea haze and intraocular pressure. Preservative-free artificial tears were supplied 6 times daily for at least 1 month. The soft contact lenses were picked out on 4-7 days postoperative, due to the patient's follow-up time and the epithelial healing.

Postoperative pain level was measured on a questionnaire. Level 1 = minimal or no pain; level 2 = mild pain; level 3 = moderate pain; level 4=severe pain, and level 5=described as unbearable pain [7]. Corneal haze was graded based upon an article by Fantes *et al* [8], the grading was as follows: 0= no haze; 0.5= trace haze on oblique illumination; 1= corneal cloudiness not interfering with the visibility of fine iris details; 2=mild effacement of fine iris details; 3 and 4= details of the lens and iris not discernible. At each follow-up visit (at 1 day, 1 week, 1 month, and 3 months), UCVA, MRSE, and corneal transparency were assessed.

Statistical Analysis Decimal visual acuities were converted to the logarithm of minimal angle of resolution

(LogMAR) scores for the purposes of statistical analysis. The patients' preoperative and postoperative UCVA; preoperative best spectacle corrected visual acuity (BSCVA) and final postoperative UCVA; the mean MRSE at the different time postoperative was analyzed using the paired Student's *t* test. The haze value and constituent ratio were used to compare the differences between current study and the relative literature performed by independent sample's *t* test and Chi-square test respectively. $P < 0.05$ was considered statistically significant.

RESULTS

Thirty-two patients 59 eyes were included for our study. Mean patient age was (24.6±4.3) years (range 19 to 38 years). Preoperative UCVA was (1.01±0.21)(LogMAR scores); BSCVA was (-0.03±0.06) (LogMAR scores) and mean MRSE was (-6.62±2.2)D (range: -2.62 to -10.75D). Mean preoperative central corneal thickness was (505±31.3)µm, mean simulated keratometry readings was (44.49±1.17)D. Mean pain level was (1.37±0.613) (range: 1 to 3). Mean time picking out the soft contact lens was (6.22±1.73) days. At 1 month, UCVA was 0.5 for 58 eyes (98.3%), and 1.0 for 23 eyes (39.0%). At 3 months, UCVA reached 0.5 for all eyes (100.0%), 1.0 for 40 eyes (67.8%), the UCVA was statistically significantly less than the preoperative BSCVA ($t = -2.84$, $P < 0.05$).

At 1 month postoperative, the mean MRSE was (1.01±1.02) D, reducing to (0.76±0.96)D at 3 months. The haze value was (0.4±0.23) at 1 month, reduced to (0.27±0.25) at 3 months and there are 27 eyes (45.8%) completely recovering to cornea transparency. No patients had a haze grade up to 2.

DISCUSSION

PTK mode in removing the epithelium produces minimal trauma and performs the debridement in a relatively brief and standardized interval reduces concern about stromal fluidity. It also provides a more smoothly basement surface for the followed PRK ablation which can promote the adherency and transmigration of epithelia and decrease hyperplasia of fibroblast in ground substance, thus improves the recovery of the visual acuity theoretically. However, as the difference from the laser device, the surgery parameter, and the procedure preoperative or postoperative as well as the surgery doctor's experience and so on, it carries on this surgery the clinical result also to be different [3-5].

Our preliminary research has got fairly good visual outcomes. Compared with Clinch *et al* [2] study (Summit Technology, Inc., Waltham, MA) on transepithelial PRK, we had a significantly higher proportion of UCVA of 1.0 at both 1 month ($P = 0.002$) and 3 months ($P < 0.001$, Table 1). There was no significant difference in haze value at 1 month ($P > 0.05$), but significant reduced haze value was present ($P < 0.05$) at 3 months (Table 2). Furthermore, we had a significantly higher MRSE preoperative (-6.62±2.2)D than

Table 1 Postoperative uncorrected visual acuity using the different platforms

Postoperative ncorrected visual acuity	Number of eyes(n)		X ²	P
	¹ Present study	² Clinch <i>et al</i> 's study		
1 month				
≥1.0	23/59(39%)	22/123(17.9%)	9.535	0.002
≥0.8	47/59(79.7%)	44/123 (35.8%)	30.722	<0.001
≥0.5	58/59(98.3%)	103/123 (83.7%)	8.287	0.004
3 months				
≥1.0	40/59(67.8%)	39/107(36.4%)	14.984	<0.001
≥0.8	56/59(94.9%)	65/107(60.7%)	22.469	<0.001
≥0.5	59/59(100%)	97/107 (90.7%)	4.333	0.037

¹Platform: Schwind Esiris excimer laser (Schwind eye-tech-solutions, Kleinostheim, Germany)

²Platform: Summit Omnimed excimer laser (Summit Technology, Inc., Waltham, MA).

Table 2 Manifest refraction spherical equivalent and haze value using different platform

	¹ Presented study	² Clinch <i>et al</i> study	t	P
MRSE (n)				
Preoperative	-6.62±2.2 (59)	-4.69± 2.00 (132)	5.98	<0.001
1 month after surgery	1.01±1.02 (59)	0.16 ±0.83(123)	6.07	<0.001
3 months after surgery	0.76±0.96 (59)	0.02±0.76(107)	5.44	<0.001
Haze value (n)				
1 month after surgery	0.4±0.23 (59)	0.41±0.22(123)	0.28	>0.05
3 months after surgery	0.27±0.25 (59)	0.37±0.27(107)	2.34	<0.01

MRSE: manifest refraction spherical equivalent;

¹Platform: Schwind Esiris excimer laser (Schwind eye-tech-solutions, Kleinostheim, Germany)

²Platform: Summit Omnimed excimer laser (Summit Technology, Inc., Waltham, MA).

the latter [(-4.69± 2.00)D, $P < 0.001$, Table 2), which confirmed with the point. The first reason may be because of the curvature of the cornea, the thickness of the center corneal epithelium is thinner than the periphery^[9], energy of the incident laser beam on the corneal periphery will be inequable and oblique incidence. This leads to uneven epithelial removal and subsequently, irregular healing. And the irregularities in the ablation can also affect the quality of vision^[10]. While aspherical ablation profile takes into account the keratometry reading to compensate for the loss of efficiency at the periphery and delivers different ablation energies to the stroma after de-epithelization with PTK^[11]. The aspherical ablation profile retains preoperative higher-order aberration measurements of an eye but targets to maintain these higher-order aberrations to preoperative levels automatically considers the ablation volume of the stroma^[12]. Thus makes it possible to have a better visual result, a more regular healing and less haze. The aspheric ablation profile is safe, efficacious, and predictable in the surface ablation^[12].

The previous researches on T-PRK mentioned that there is a slightly hypermetropic shift after operation^[2,6]. So in our T-PRK procedure, we set a fixed depth value range 45-52µm according to the preoperative cornea parameter, and in all cases stopped the ablation before the

autofluorescence disappeared, in other words, we'd better insufficiencies than overcorrection in de-epithelization intraoperative. Unfortunately, there was a significant hypermetropic shift meantime both at 1 month ($P < 0.001$) and 3 months ($P < 0.001$, Table 2), compared with Clinch *et al*^[2] study conversely. Though the reasons for hyperopic shift postoperative are not clear now, an explanation suggests that during PTK, some regions of the basal lamina and Bowman's layer may be unintentionally ablated for varying thickness of the corneal epithelium^[6]. Nevertheless, it is comparable to results to other studies that calculated the epithelial thickness using optical coherence tomography or confocal microscopy^[13, 14]. The other explanation was that each procedure needs two ablations. It takes time to switch the PTK mode to the PRK while the stroma is exposed during the operation. Thus increased the dehydration of the corneal stroma and induced overcorrection. Regretful to be that we do not record the time the operation taken, has no way to make the accurate contrast out. In future research, we need to record and shorter the operation time to decrease dehydration of the corneal stroma as far as possible.

In this study, we also found that although our cases had a better postoperative UCVA, they could not reach the preoperative BSCVA ($P < 0.05$). But this did not mean a failure result, a longer follow-up period (at least 6 months) is

ensured to comprehensively evaluate the visual outcome. These findings are a short-term study, the hyperopic condition didn't cause a change to the visual outcome and was to be acceptable yet. One of the reasons may be the lower haze value, because the evident conical haze can result in a decrease of BSCVA and refractive regression^[15]. The other reason may be the influence of accommodation caused by the different ages. The mean age in our study is 24.6 years which lower than Clinch *et al*^[2] (39.8 years). Amplitude of accommodation decline with increasing age. As the demand for accommodation postoperative is gradually increased following the increase in amplitude of accommodation. However, young patients (<30 years old) had a higher increase^[16], so the plasticity in accommodation is better in young patients than the older (>30 years old).

In Lee *et al*^[6] report, they found a progressive myopic shift in the remaining spherical equivalent in surface ablation groups up to 6 months postoperatively, which may cause unfavorable UCVA. For this reason, the initially hypermetropic transepithelial PRK group had a more favorable visual outcome. Our short-term studies were in the line with Lee *et al* study that at 1 month after transepithelial PRK, patients experienced a hypermetropic shift, emmetropic at 3 months; they also reported a reduction in the hyperopic shift within 6 months, with better UCVA in the transepithelial PRK group compared with the LASEK and mechanical PRK groups^[6]. The same, Ghadhfan *et al*^[5] reported transepithelial PRK (PTK mode; 7.0-9.0mm optical zone and 45-55 μ m of ablation) has a better visual outcome than epi-LASIK, LASIK, and LASEK using Nidek EC-5000 excimer laser in high myopia patients. Additionally, our study suggests that transepithelial PRK has the advantage of less pain, which is similar with other surface ablation techniques^[7].

Our study had several limitations: This short follow-up retrospective case was of a small sample, without making the grouping of the age and spherical equivalent refraction, and patient's wavefront aberrations, the contrast sensitivity and cornea topographic diagram changes had not been able simultaneously collected to integrate the observation. Despite these limitations, the outcomes from this pilot study suggest that using SCHWIND ESIRIS excimer laser for transepithelial PRK had a good visual result. Its primary advantage is related to a spherical ablation profile, automatically considers the ablation volume of the stroma and maintains the preoperative higher-order aberrations to as well as the accurate and smooth removal of the epithelium. We still need studies of larger sample sizes to investigate long-term results in various degrees of myopic and age's populations. Additional studies using confocal microscopy or optical coherence tomography required to determine the thickness of the epithelial layer. We also look

forward to an update of the laser equipment as well as shorten operating time in reducing refractive error after surgery.

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