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Article *in* Journal of Ophthalmic & Vision Research · October 2016

DOI: 10.4103/2008-322X.194070

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Transepithelial Photorefractive Keratectomy for Low to Moderate Myopia in Comparison with Conventional Photorefractive Keratectomy

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Running Title: tPRK and PRK in Myopia

Financial Disclosure: None of the authors have a financial or proprietary interest in any material or method

Abstract

Purpose: To compare the effectiveness, safety and stability of the results of transepithelial photorefractive keratectomy (tPRK) with conventional photorefractive keratectomy (PRK) for low to moderate myopia.

Methods: In this prospective non-randomized case-control study, patients with low to moderate myopia were assigned to the tPRK group (case group) or the PRK group (control group). In the tPRK group, eyes were treated using the Amaris excimer laser(SCHWIND eye-tech-solutions GmbH & Co. KG · Germany). Outcome measures included post-operative pain using McGill Pain Questionnaire , epithelial healing time, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest refraction, and safety and efficacy indexes which were compared between the study groups.

Results: Three hundred forty eyes of 170 patients were enrolled in this study. Each study group comprised of 170 eyes of 85 patients. The study groups were balanced in terms of baseline refractive error and BCVA (P=0.6 and P = 0.8, respectively). There was a significant difference between the two groups regarding the postoperative pain scores in favor of the tPRK group (P=0.04). The tPRK group had a shorter epithelial healing time than the conventional PRK group postoperatively (P= 0.01). Mean UCVA was significantly better in the case group than in the control group at the postoperative month 2 (P =0.01). Regarding the safety and efficacy indexes, the tPRK group had better results than the conventional PRK group (P < 0.01 for both comparisons).

Conclusion: tPRK seems to be superior to conventional PRK for treatment of low to moderate myopia in terms of postoperative pain, epithelial healing time, visual recovery and safety and efficacy indexes. .

Keywords: Conventional Photorefractive Keratectomy, Transepithelial Photorefractive Keratectomy, Myopia

Introduction

Photorefractive keratectomy (PRK) has commonly been used as an effective, safe and reasonable method for treatment of patients with low to moderate myopia since 1983[1-6]. Moreover, PRK is appropriate for subjects with refractive errors who are not eligible candidates for laser in situ keratomileusis (LASIK) due to thin corneas, subtle topographic irregularities and epithelial basement membrane disease, [7-8]. Corneal haze, epithelial healing irregularity and pain are known adverse effects of PRK [9-10]. Transepithelial PRK using Amaris excimer laser is a modified and alternative method for conventional PRK [11]. The unique feature of this technique is that it can be applied as one -step, no-touch surgery using the transepithelial PRK nomogram of the Amaris laser [12].

To the best our knowledge, there are few studies on the outcomes of transepithelial PRK [12-13]. Our previous experience with these tools differed from published literature. Herein, we compared the outcomes of transepithelial PRK with those of conventional PRK with respect to the postoperative pain, healing time and visual acuity recovery.

Methods

In this prospective, non-randomized, controlled trial, patients with mild to moderate myopia with or without astigmatism who underwent photorefractive keratectomy (PRK) between January

2013 and May 2013 were enrolled. Patients were divided into two groups; the case group for whom transepthelial PRK was performed and the age-matched control group who received conventional alcohol-assisted PRK. Mild myopia was defined as a spherical equivalent refraction of −0.50 to −3.00 D in at least one eye and moderate myopia as a spherical equivalent refraction between −3.25 and −6.00 D in at least one eye [14]. The study protocol was approved by the institutional review board and signed informed consent was obtained from all patients. Patients were excluded if they failed to meet any of the above inclusion criteria or for the following reasons : unstable standard cycloplegic refraction, preoperative best corrected visual acuity (BCVA) less than 20/20, eyes unsuitable for PRK based on preoperative assessment of ocular topography e.g. corneal dystrophy with topographic irregularity, pellucid marginal degeneration, forme fruste keratoconus, corneal warpage, severe dry eye syndrome, previous corneal or intraocular surgery, history of current eyelid disease, or any form of keratitis. Patients were requested to discontinue contact lens wear for a minimum of 4 days (soft lenses) or a minimum of 3 weeks (gas-permeable lenses) prior to the preoperative evaluation.

All patients had a complete preoperative eye examination including uncorrected visual acuity (UCVA) and BCVA assessment,, manifest and cycloplegic refraction, slit-lamp biomicroscopy (Carl Zeiss ,Germany) to evaluate the anterior segment and the fundus, and applanation tonometry.

All surgical procedures were performed by a single surgeon (MN). After povidone iodine scrub was applied on the lashes and eyelids, a closed-loop lid speculum equipped with suction was placed. One drop of proparacaine 0.5% was instilled in the eye. In the case group, laser ablative surgery was performed in a single step using the transepithelial PRK nomogram (Amaris laser's ORK-CAM software, SCHWIND eye-tech-solutions, Kleinostheim, Germany).

In the control group, 17% ethyl alcohol in an 8-9 mm well was placed on the cornea for 15

seconds. Cornea was irrigated using balanced salt solution and dry polyvinyl alcohol sponge (Merocel) was used to peel off the epithelium. Subsequently, laser ablation was done in both groups using ablation profile of the laser's software. The optical zone varied between 6.5 mm and 7mm in both groups, and the transition zone was calculated based on the patient's age, refractive error, and K readings using the nomogram. Then, mitomycin C 0.02% was applied on the ablated stroma in corneas with an ablation depth of more than 30 µm. The duration of mitomycin C application was approximately 35 seconds.

After laser ablation, a high-water-content bandage contact lens Senofilcon A (Acuvue) was placed on the cornea and topical antibiotic and corticosteroid eye drops were instilled. Postoperatively, patients received betamethasone and chloramphenicol eye drops four times a day and preservative-free artificial tears every two hours. Chloramphenicol eye drops were discontinued after one week but betamethasone eye drops were tapered off over 4 to 6 weeks.

Patients were followed up daily until the corneal epithelium completely healed. Epithelial healing was assessed daily at the slit lamp, with fluorescein staining when needed. The therapeutic contact lens was removed once there was no epithelial defect.

Postoperatively, visual acuity (expressed in logMAR) and refractive outcomes were analyzed at months 2 and 6. Furthermore, an examiner who was masked to the type of surgery performed postoperative examinations including manifest refraction and slitlamp examination. .Moreover, a masked nurse interviewed the patients to record the pain score they had experienced at postoperative day 1 using a 5-point Present Pain Intensity (PPI) scale of the standard long-form

McGill Pain Questionnaire (LF-MPQ). Accordingly, pain severity was scored as follows: 1=mild, 2=discomforting, 3=distressing, 4=horrible, 5=excruciating. . Corneal haze was graded according to a study by Fantes *et al* [21], 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 dimness of fine iris details; 3= moderate obliteration of iris details, 4 = details of the lens and iris not discernible.

Safety of the procedure was defined as the percentage of eyes losing more than 2 lines of BCVA. Safety index was considered as mean postoperative BCVA/ mean preoperative BCVA ratio. Efficacy was defined as the percentage of the eyes achieving a UCVA of 0.50 LogMAR (20/40) or better postoperatively. Efficacy index was defined as mean postoperative UCVA/ mean preoperative BCVA ratio. [15-16]

Statistical analysis was performed using SPSS software (version 18.0, SPSS, Inc, IBM, Chicago, IL, USA.). An unpaired t test was used to compare the mean spherical equivalent (SE) refraction. The postoperative data were analyzed using Mann-Whitney tests to compare the epithelial healing time and postoperative pain scores between the study groups. Probability values less than 0.05 were considered as significant..

Results

Three hundred and forty eyes of 170 patients were enrolled in the study. The study groups included 170 eyes of 85 patients each. The case group included 31 (36.5%) male and 54 (63.5%) female subjects with a mean age of 28 ±7 (range, 19–51) years. The control group consisted of 28 (33%) male and 57 (67%) female patients, with a mean age of 28.3±7 (range, 19-50) years. Mean preoperative spherical equivalent

refraction was -3.06±1.5 diopters (D) in the case group and -2.9±1.9 D in the control group.

There was no statistically significant difference in the baseline manifest refraction between the two groups (P =0.62). Mean preoperative BCVA (LogMAR) was 0.01±0.05 (≃ 20/20 Snellen) in the case group and 0.00 ±0.04 (≃ 20/20 Snellen) in the control group (P =0.81).

Table 1 and figure 1 show the postoperative results. The mean time to complete epithelial healing was significantly shorter in the case group (2.90 ±0.42 days) as compared to the control group (3.30 ± 0.72 days) (P value =0.01). The mean subjective postoperative pain score at 24 hours was significantly lower in the case group compared to the control group (P value= 0.04).

After two months, the mean UCVA was significantly better in the case group than in the control group (P < 0.01), while there was no statistically significant difference between the two groups in UCVA at postoperative month 6 (Table 1). The majority of eyes had mild corneal stromal haze and only one patient had a haze grade 3 in the conventional PRK group (Table 1).

In the case group, spherical refraction decreased from -3.06±1.5D to -0.09±0.2D and cylindrical refraction decreased from -0.98±1.1D to -0.09±0.2D postoperatively. In the control group, spherical refraction decreased from -2.9±1.9D to -0.05±0.10D and cylindrical refraction changed from -1.2±1.2D to -0.01±0.08D after surgery.. There were significant differences in the mean spherical and cylindrical refraction between the two groups postoperatively (p < 0.05).

Moreover, two months post-operation was associated with a higher percentage of UCVA within ± 2 lines of the preoperative BCVA (97.6% vs 88.2%) (Table2). Mean efficacy index was 0.20 ± 0.16 in the transepithelial PRK group and 0.13 ± 0.9 in the conventional PRK group (p < 0.01). Mean safety index was 1.36 ± 0.11 in the transepithelial PRK group and 0.98 ± 0.22 in the conventional PRK group (p<0.05). Despite this significant difference, the safety index approached 1.00 in the control group postoperatively, indicating that the visual outcome was

satisfactory in this group. None of the patients were lost to follow up. . There were no early postoperative complications such as infection or recurrent erosion.

Discussion

The present study assessed the visual outcomes and safety of transepithelial PRK versus conventional PRK for low to moderate myopia. We found that transepithelial PRK was better than conventional PRK regarding epithelial healing time, postoperative pain, safety and efficacy indexes and visual acuity recovery.

In a recent study comparing transepithelial PRK and conventional PRK, the average period to complete healing was 2.5 days in the transepithelial group versus 3.7 days in conventional PRK [12]. Similarly in the current study, the epithelial healing period was shorter in the case group than in the control group. It could be due to the difference in the epithelial denuding area and the ablation area between the two groups; in tPRK, the epithelial removal size was equal to the ablation size in our study, whereas in conventional PRK, the epithelial removal size was more than the ablation size that could defer re-epithelialization.(data not shown in table).

Patients' perception of pain was another indicator for better postoperative outcome in the transepthelial PRK group in the present study. Fadlallah et al [12] found lower difference of pain

score in tPRK method compared to conventional PRK. However, the pain score in their study was lower than what we found in our study. The major reason for the higher pain score in our study is the fact that we checked pain on the first postoperative day, while they reported pain score 48 hours postoperatively.

The rate of visual recovery was investigated and compared between the study groups. Fadlallah et al [12] reported significantly better UCVA in the tPRK group than in the PRK (P=0.01) and LASIK (P=0.008) groups. We found similar results as the tPRK group was superior to the conventional PRK group regarding UCVA at postoperative month 2. Lee et al[19] reported 27 patients who had laser epithelial keratomileusis (LASEK) in one eye and conventional PRK in the other eye for low to moderate myopia. Mean UCVA 3 months after PRK was 20/25 or better in 56% of patients. In our study, we noticed the UCCA of ≥20/25 in 84.7% of patients in the control group two months after PRK. It may be concluded that better visual acuity and faster visual recovery after transepithelial PRK in the present study was seemingly due to the absence of epithelial removal in this group.

Carones and co-authors [20] reported lower corneal haze at one month and better corneal regularity index at 3 months in eyes in which the epithelium was removed using 20% alcohol. Similar method was used in our study in the conventional PRK group. However, when the mean change in the postoperative UCVA was compared with the preoperative BCVA, a significant difference was noticed after tPRK compared with conventional PRK. These results suggest that for low to moderate myopia, tPRK may give slightly better overall visual outcomes than conventional PRK.

There was a significant difference between the safety index and efficacy index between the two groups at 2 months which showed superiority of tPRK group versus conventional PRK group in

short term period. Conversely, the conventional PRK group showed a slightly better UCVA than the tPRK group at 6 months. However, the difference was not statistically significant,however, it may be correlated with the remaining spherical equivalent especially in the tPRK group; provoking the unfavorable UCVA and making no prominent effect on long term postoperative visual acuity outcomes .

The current study had a few limitations. We evaluated pain intensity only on postoperative day one. Pain typically peaks during the first 24 hours after PRK surgery, and subsides after approximately 3 days, coinciding with corneal re-epithelialization [18]. Secondly, the size of epithelial defects and the rate of epithelial healing were not assessed by an image analysis software which could be more reliable. Thirdly, we did not randomize the patients into two groups; the type of the procedure was chosen based on the patient's preference(after detailed description of the methods and procedures) . The strengths of our study included a large sample size, stability of vision after six months and no reports pertaining adverse events in patient associated with any of the treatment methods .

In conclusion, this study highlighted the advantages of tPRK technique using Schwind Amaris nomogram over conventional PRK. Transepithelial PRK seems to be a safe and effective technique for the treatment of mild to moderate myopia. A randomized prospective study with a longer follow-up period is requiredto confirm the results of the current study.

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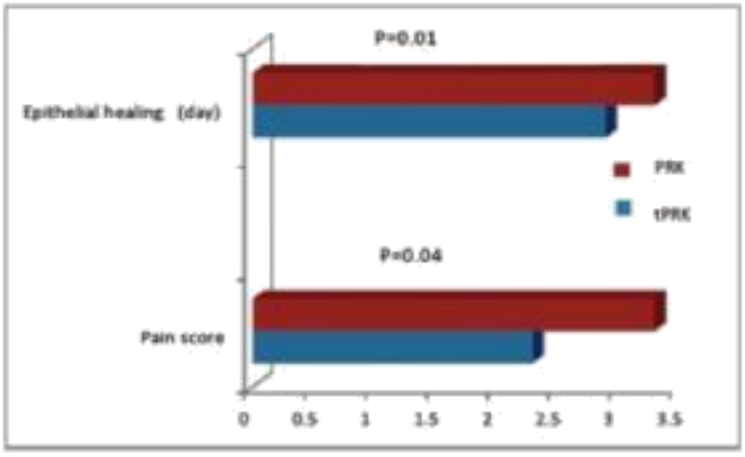

Figure 1.Corneal epithelial wound healing and pain score after photorefractive keratectomy using a conventional procedure (PRK) and transepithelial procedure (tPRK).

Table 1: Postoperative results of transepithelial PRK versus conventional PRK

Parameter	**tPRK**	**PRK**	***P* value**
Epithelial healing time(day) (Mean±SD)	2.90 ±0.42	3.30 ± 0.72	0.01
UCVA (2M) (log MAR) (Mean±SD)	0.001 ±0.04	0.002 ±0.08	0.01
UCVA (6M) (log MAR) (Mean±SD)	0.002 ±0.03	0.003 ±0.04	0.09
Pre BCVA vs Post UCVA After 2 M within ± 2 lines (%)	97.6	88.2	0.50
Sphere(Mean±SD)	-0.09±0.2	-0.05±0.10	0.02
Cylinder(Mean±SD)	-0.09±0.2	-0.01±0.08	0.01
Pain score (Mean±SD)	2.30± 0.56	3.3± 0.71	0.04
Corneal stromal haze	7(4.1%)	8(4.7%)	0.78

tPRK: Transepithelial photorefractive keratectomy : PRK: conventional photorefractive keratectomy UCVA:Uncorrected visual Acuity, BCVA:Best Corrected visual 344 Acuity , SD: standard deviation, logMAR: logarithm of minimum angle of resolution.