

Original Article

Comparing the Clinical Outcome of Transepithelial and Conventional Photorefractive Keratectomy in Correction of Moderate Myopia

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Abstract

Purpose: To compare the clinical outcomes of one-step transepithelial photorefractive keratectomy (tPRK) with those of conventional photorefractive keratectomy (PRK) in correction of moderate myopia.

Patients and Methods: In this prospective, randomized case-control study consecutive patients with moderate myopia were randomly assigned to undergo either one-step tPRK or conventional PRK using the Schwind Amaris excimer laser system at Vanak Eye Surgery Center, Tehran, Iran, from May to December 2020. Outcome measures included one and three months post-surgical uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), sphere, cylinder, spherical equivalent (SE), intraocular pressure, haze, and levels of pain and discomfort.

Results: One hundred and twenty eyes from 60 consecutive patients were evaluated. No statistically significant differences were observed in mean UCVA, BCVA, or SE at one and three months postoperatively. One month postoperatively, the mean haze was significantly lower in the tPRK group compared to the PRK group ($P < 0.001$), but this difference was not observed at three months. Patients undergoing tPRK experienced significantly less pain ($P = 0.027$) and discomfort ($P < 0.001$) one day postoperatively. No differences between the two groups regarding postoperative intraocular pressure were observed.

Conclusion: The findings of the present study suggest that the tPRK method is associated with reduced early postoperative pain and discomfort at day one as well as less corneal haze at one month postoperatively, compared to the conventional PRK method. There were no significant differences between the two methods in terms of postoperative intraocular pressure, UCVA, BCVA, or SE.

Keywords: Photorefractive Keratectomy; Transepithelial; Myopia; Haze; Pain; Discomfort.

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Introduction

The use of excimer laser in corneal refractive surgery has seen significant advancements in recent years. Initially beginning with a limited range of animal experiments, it has now evolved to a point where millions of surgeries are performed annually^{1,2}. Photorefractive keratectomy (PRK) was the pioneering laser technique in refractive surgery, initially limited to mild to moderate myopia³. Later, methods like laser-assisted in situ keratomileusis (LASIK) gained popularity, largely due to the reduced incidence of complications such as stromal haze, postoperative pain, and delayed vision improvement associated with the PRK method^{4,5}. Today, while LASIK is the most common refractive surgery method, PRK remains a viable alternative for correcting mild to moderate myopia or hyperopia in certain cases, particularly due to concerns about flap-related complications and postoperative ectasia in LASIK procedures⁵⁻⁷. PRK is also preferred over LASIK for patients with conditions like epithelial basement membrane dystrophy (EBMD) or thin corneas^{8,9}.

In conventional PRK, the corneal epithelium is manually removed using methods like diluted ethanol or a rotating brush before photorefractive ablation. Transepithelial photorefractive keratectomy (tPRK) offers an alternative approach, combining laser epithelial removal with stromal ablation in a single step, without any surgical equipment making contact with the cornea¹⁰⁻¹³. This approach is theorized to result in reduced postoperative pain, shorter epithelial healing times, and less postoperative dry eye^{13,14}.

Several studies have compared postoperative results between PRK and tPRK, including aspects like haze, visual and refractive outcomes¹¹⁻²⁴. However, fewer studies have focused on the association between surgical

method and patient-reported outcomes such as postoperative pain and discomfort, with some yielding contradictory results^{11,12,14-16,18,19,21}. This study aims to compare visual and refractive outcomes, postoperative haze, as well as pain scores and patient satisfaction between conventional PRK and tPRK methods.

Patients and Methods

This randomized clinical trial involved 120 eyes from 60 consecutive patients with moderate myopia, who were referred to Vanak Eye Surgery Center, Tehran, Iran, between May and December 2020. The protocol received approval from the ethics committee at Shahid Beheshti University of Medical Sciences, also located in Tehran, Iran (approval number: IR.SBMU.MSP.REC.1398. 228). All participants provided written informed consent prior to their involvement in the study. The inclusion criteria specified participants aged 20 to 40 years, with moderate myopia ranging from 3 to 4.6 diopters, a corrected visual acuity of 10/10, and a post-surgery stromal tissue thickness of over 380 μm . The exclusion criteria encompassed systemic diseases that could impede corneal wound healing, such as collagen and vascular diseases or diabetes mellitus, along with a history of eye surgery, diseases affecting the anterior and posterior segments of the eye, corneal dystrophy, retinal diseases, glaucoma, dry eye, previous eye trauma, irregular astigmatism, suspected keratoconus, and periods of pregnancy or lactation.

In this study, the roles of surgeon and the individual conducting preoperative and postoperative examinations were distinctly separate. The examiner was not informed about the specific surgical procedure performed on each patient.

Upon admission, baseline characteristics including gender, age, and medical history were recorded for each patient. Preoperative examinations involved assessing corrected and uncorrected visual acuity, slit lamp examination, indirect ophthalmoscopy, corneal haze measurement, intraocular pressure measurement using non-contact tonometry (Topcon non-contact tonometer, CT-11 P, Tokyo, Japan), eye pain assessment (utilizing the Wong Baker scale after patients were trained in using the scale consistently), and discomfort level (using a scale from 0 to 5, where 0 indicates no discomfort and 5 indicates severe discomfort). All these measurements were repeated at one- and three-month postoperative follow-ups. Additionally, pain and discomfort scores were also recorded one day after surgery.

Corneal haze in the study was graded according to the scale developed by Kim et al.,²⁴ ranging from 0, representing a clear cornea, to 4, indicating significant opacity. A grade of 1 signified mild, faint reticular haze visible only under broad tangential illumination; 2 denoted opacity faintly visible under direct focal illumination and clear under narrow slit illumination; 3 referred to opacity easily visible under direct focal illumination, obscuring iris detail to some extent; and 4 indicated opacity visible without the need for a slit lamp. Pain severity was assessed using the Wong-Baker scale, which spans from 0 (no pain) to 10 (the worst pain ever experienced). The feeling of discomfort was quantified by asking patients to rate their discomfort on a scale from 0 (no discomfort) to 5 (severe discomfort).

Surgical Methods

The one-step transepithelial photorefractive keratectomy (tPRK) and conventional PRK procedures were both conducted using

the Schwind Amaris excimer laser system. Patients were randomly assigned to either the case group (undergoing tPRK) or the control group (undergoing conventional PRK) using a random number table.

In the conventional PRK method, the epithelial tissue was prepared for removal by exposing the area to 20 % alcohol for 15 seconds. Mitomycin was applied in cases where more than 65 μm of tissue needed removal, with the application duration being 10 seconds for each myopic diopter. Following this, the eye surface was thoroughly rinsed. The one-step tPRK, on the other hand, was performed using the same laser system but without mechanical debridement of the epithelium.

For both methods, a soft lens was placed on the eye post-operation and removed after five days. No eye drops were administered immediately after the surgery. However, if the patient experienced pain, ketorolac drops were given every eight hours for 24 to 48 hours post-surgery. Chloramphenicol eye drops were prescribed every eight hours for the initial five days. Betamethasone eye drops were used following a specific tapering schedule over a period of 25 days. Additionally, Vitamin C (one gram daily) was administered for the first five days. Artificial tears were prescribed as needed for symptoms like foreign body sensation or burning in the eyes. Patients were also advised to wear sunglasses during the postoperative period.

Patients were scheduled to return for an initial evaluation and measurement of relevant parameters 24 hours post-surgery. A follow-up visit for re-examination and lens removal was arranged for five days post-operation. Subsequent visits were scheduled at the end of the first and third months for further assessments and data collection related to the study.

Statistical Analysis

The results of the study were presented as means \pm standard deviations (SD) for quantitative variables and summarized by frequency (percentage) for categorical variables. Continuous variables were compared between the two groups using either the t-test or the Mann-Whitney test. The latter was employed in cases where the data did not appear to be normally distributed or when the assumption of equal variance was not met across the study groups. Additionally, changes within groups were evaluated using either a paired t-test or the Wilcoxon signed-rank test, depending on the same criteria.

Statistical significance was determined by a P value of less than 0.05. For statistical analysis, the study utilized SPSS software, version 23.0 (IBM, Armonk, New York). The calculation of the sample size was based on postoperative pain as reported by Fadlallah et al.,¹² who compared postoperative pain after tPRK and conventional PRK methods.

Results

In this study, 60 patients (120 eyes) were enrolled, with 30 patients in each group. The mean age of patients in the PRK and tPRK groups was 28.93 ± 7.18 years and 26.20 ± 6.02 years, respectively ($P = 0.115$). The male-to-female ratio was 43.3 % to 56.7 %

($P = 0.279$) (Table 1). Table 2 in the study presents a comparison of patients' vision between the two groups, as well as the changes observed before and after surgery within each group. According to this table, the change in patients' vision (UCVA, BCVA) at one and three months postoperatively was significant in both groups compared to their preoperative values. The rate of UCVA change was similar between the two groups at one month ($P = 0.19$) and three months ($P = 0.13$) postoperatively. There was no significant difference observed in the mean UCVA between the two groups at either one or three months postoperatively. Similarly, the mean BCVA did not show a significant difference between the groups at one month ($P = 0.572$) and three months ($P = 0.741$) postoperatively.

As indicated in table 3, there was a statistically significant difference in the mean sphere at one month postoperatively ($P = 0.029$). However, at three months postoperatively, this difference was not significant. Additionally, there was no significant difference in the mean cylinder and axis between the two groups of patients at both one and three months postoperatively. The mean Spherical Equivalent (SE) at one and three months postoperative follow-ups improved significantly in both groups compared to preoperative readings, as shown in table 4. At the one-month follow-up, the mean SE change was 3.68 ± 1 diopters in the

Table 1: Demographic characteristics of patients entering the study

| Variable | | Total | Group | | P value |
|----------|--------|------------------|------------------|-----------------|---------|
| | | | PRK | tPRK | |
| Sex | Male | 21 (35.0 %) | 13 (43.3 %) | 8 (26.7 %) | 0.279* |
| | Female | 39 (65. %) | 17 (56.7 %) | 22 (73.3 %) | |
| Age | | 27.57 ± 6.71 | 28.93 ± 7.18 | 26.2 ± 6.02 | 0.115** |
| | | 26 (20,40) | 27 (20,40) | 25 (20,40) | |

*Based on Chi-square test

** Based on t-test

Table 2: Comparison of visual acuity between the tPRK and PRK methods

| Visual Acuity (LogMAR) | Group | | P value* |
|--------------------------------|---------------|---------------|----------|
| | PRK | tPRK | |
| Preoperative UCVA | 0.5 ± 0.3 | 0.54 ± 0.39 | 0.28 |
| One month postoperative UCVA | 0.05 ± 0.09 | 0.03 ± 0.08 | 0.172 |
| Change | - 0.45 ± 0.33 | - 0.61 ± 0.42 | 0.019 |
| P-within** | < 0.001 | < 0.001 | |
| Three month postoperative UCVA | 0.03 ± 0.06 | 0.02 ± 0.05 | 0.809 |
| Change | - 0.47 ± 0.31 | - 0.52 ± 0.41 | 0.13 |
| P-within** | < 0.001 | < 0.001 | |
| Preoperative BCVA | 0 ± 0 | 0 ± 0 | — |
| One month postoperative BCVA | 0.03 ± 0.07 | 0.02 ± 0.05 | 0.572 |
| Change | 0.03 ± 0.07 | 0.02 ± 0.05 | 0.572 |
| P-within** | 0.004 | 0.004 | |
| Three month postoperative BCVA | 0.01 ± 0.03 | 0.01 ± 0.03 | 0.741 |
| Change | 0.01 ± 0.03 | 0.01 ± 0.03 | 0.741 |
| P-within** | 0.017 | 0.009 | |

* Based on Mann-Whitney test

** Based on Wilcoxon signed-rank test

UCVA: Uncorrected Visual Acuity

BCVA: Best Corrected Visual Acuity

PRK group and 3.92 ± 0.92 diopters in the tPRK group, indicating a significantly higher improvement in the tPRK group ($P = 0.032$). However, there was no statistically significant difference in the mean SE between the two groups at one month. Similarly, no significant difference in mean SE was observed between the two groups at the three-month postoperative visit.

Table 5 presents the mean intraocular pressure (IOP). Compared to preoperative readings, there was a statistically significant reduction

in IOP at one and three-month postoperative follow-ups in both groups. However, there was no statistically significant difference in IOP reduction between the two groups of patients. Table 6 in the study details the corneal haze over the follow-up period. At one month post-surgery, the tPRK group exhibited significantly lower corneal haze compared to the PRK group ($P < 0.001$). However, this difference was not significant at the three-month postoperative evaluation ($P = 0.216$).

Regarding pain scores on the first day after

Table 3: Comparison of sphere, cylinder and axis between the tPRK and PRK methods

| Variable | Group | | P value* |
|-------------------------------------|----------------|----------------|----------|
| | PRK | tPRK | |
| Preoperative sphere | - 3.61 ± 0.7 | - 3.86 ± 0.81 | 0.079 |
| One month postoperative sphere | - 0.22 ± 0.52 | - 0.05 ± 0.28 | 0.029 |
| Change | 3.39 ± 0.93 | 3.81 ± 0.83 | 0.011 |
| P-within** | < 0.001 | < 0.001 | |
| Three months postoperative sphere | 0.01 ± 0.16 | - 0.07 ± 0.33 | 0.116 |
| Change | 3.64 ± 0.78 | 3.84 ± 0.81 | 0.169 |
| P-within** | < 0.001 | < 0.001 | |
| Preoperative Cylinder | - 0.86 ± 0.66 | - 0.96 ± 0.8 | 0.442 |
| One month postoperative cylinder | - 0.3 ± 0.36 | - 0.33 ± 0.45 | 0.645 |
| | 0.56 ± 0.75 | 0.63 ± 0.92 | 0.655 |
| | < 0.001 | < 0.001 | |
| Three months postoperative cylinder | - 0.1 ± 0.23 | - 0.14 ± 0.25 | 0.389 |
| | 0.77 ± 0.77 | 0.83 ± 0.77 | 0.633 |
| | < 0.001 | < 0.001 | |
| Preoperative axis | 113.14 ± 63.32 | 123.49 ± 65.68 | 0.421 |
| One month postoperative axis | 113.35 ± 66.38 | 102.03 ± 66.71 | 0.492 |
| | - 1.96 ± 71.56 | - 28.37 ± 85.3 | 0.223 |
| | 0.03 | < 0.001 | |
| Three months postoperative axis | 121 ± 65.98 | 93.27 ± 66.47 | 0.290 |
| | 30.5 ± 88.22 | - 18.5 ± 89.03 | 0.273 |
| | < 0.001 | < 0.001 | |

*Based on generalized estimating equation test

**Based on Paired T-test

surgery, the mean score was 7.6 ± 1.56 in the PRK group and 6.4 ± 1.52 in the tPRK group (Table 7). This suggests that patients undergoing tPRK experienced significantly

less pain than those in the PRK group ($P=0.027$). There was no significant difference in pain scores between the two groups at the one and three-month postoperative examinations.

Table 4: Comparison of spherical equivalent between the tPRK and PRK methods

| Variable | Group | | P value* |
|-------------------------------|---------------|---------------|----------|
| | PRK | tPRK | |
| Preoperative SE | - 4.04 ± 0.75 | - 4.34 ± 0.88 | 0.05 |
| One month postoperative SE | - 0.37 ± 0.62 | - 0.22 ± 0.36 | 0.103 |
| Change | 3.68 ± 1 | 4.12 ± 0.92 | 0.012 |
| P-within** | < 0.001 | < 0.001 | |
| Three months postoperative SE | - 0.04 ± 0.22 | - 0.14 ± 0.35 | 0.081 |
| Change | 4.02 ± 0.84 | 4.26 ± 0.88 | 0.138 |
| P-within** | < 0.001 | < 0.001 | |

*Based on generalized estimating equation

**Based on Paired T-test

SE: Spherical Equivalent

The study also assessed the mean feeling of discomfort among patients. At the one day follow-up, the PRK group reported a mean discomfort score of 2.09 ± 0.94 , while the tPRK group reported a significantly lower score

of 0.03 ± 0.18 . This indicates that patients undergoing tPRK experienced considerably less discomfort on postoperative day 1 than those in the PRK group ($P < 0.001$). However, at the one and three-month postoperative

Table 5: Comparison of intraocular pressure between the tPRK and PRK methods

| IOP (mmHg) | | Group | | P value* |
|--------------------------------|------------|---------------|---------------|----------|
| | | PRK | tPRK | |
| Preoperative IOP | IOP | 15.27 ± 2.19 | 15.23 ± 2.45 | 0.937 |
| One month postoperative IOP | IOP | 13.83 ± 2.34 | 13.3 ± 2.15 | 0.197 |
| Change | Change.IOP | - 1.43 ± 3.22 | - 1.93 ± 3.45 | 0.414 |
| P-within** | | 0.001 | < 0.001 | |
| Three months postoperative IOP | IOP | 12.45 ± 1.54 | 12.96 ± 2.22 | 0.150 |
| Change | Change.IOP | - 2.88 ± 2.41 | - 2.29 ± 2.7 | 0.218 |
| P-within** | | < 0.001 | < 0.001 | |

* Based on t-test

** Based on paired t-test

IOP: Intraocular Pressure

Table 6: Comparison of corneal haze between the tPRK and PRK methods

| Variable | | Group | | P value* |
|--|------|-------------|-------------|----------|
| | | PRK | TPRK | |
| Corneal haze month one postoperative | 0.00 | 16 (26.7 %) | 40 (66.6 %) | < 0.001 |
| | 1.00 | 25 (41.6 %) | 14 (23.3 %) | |
| | 2.00 | 17 (28.3 %) | 6 (10.1 %) | |
| | 3.00 | 2 (3.3 %) | 0 (0.0 %) | |
| | 4.00 | 0 (0 %) | 0 (0.0 %) | |
| Corneal haze month three postoperative | 0.00 | 48 (80 %) | 42 (70 %) | 0.216 |
| | 1.00 | 10 (16.7 %) | 16 (26.7 %) | |
| | 2.00 | 2 (3.3 %) | 2 (3.3 %) | |

* Based on Mann-Whitney test

Table 7: Comparison of corneal pain score between the tPRK and PRK methods

| Pain Score | Group | | P value* |
|--------------------|-------------|-------------|----------|
| | PRK | TPRK | |
| Pain Score day 1 | 7.3 ± 1.56 | 6.4 ± 1.52 | 0.027 |
| Pain Score month 1 | 0.09 ± 0.94 | 0.03 ± 0.88 | 0.43 |
| Pain Score month 3 | 0.03 ± 0.64 | 0.06 ± 0.57 | 0.34 |

*Based on generalized estimating equation

exams, there was no significant difference in discomfort levels between the two groups.

Discussion

The present study compared UCVA at 1 and 3 month follow-ups with preoperative UCVA, and the results suggest a significant improvement post-surgery. The comparison of UCVA improvement between PRK and tPRK indicated similar rates of improvement at both

one month and three months postoperatively. Additionally, no significant difference in mean UCVA was observed between the two groups at these time points. This finding is consistent with Fadlallah et al.,¹² and Gharieb et al.,¹⁸ who also reported no significant difference in UCVA between tPRK and PRK at one and three months follow-up. In contrast Naderi et al.,¹¹ reported that the mean uncorrected visual acuity (UCVA) was significantly better in the tPRK group compared to the

PRK group at the two-month postoperative mark. Similarly, Bakhsh et al.,¹⁹ observed statistically significant better UCVA at 1 day, 1 week, and 1 month postoperatively for the tPRK group, with no significant differences noted at 3 and 6 months. Additionally, Celik et al.,²¹ reported significantly better UCVA for the tPRK group at one week postoperatively, but by the third month postoperatively, the UCVA levels were similar between the two groups. Alasbali's meta-analysis indicated a short-term advantage for tPRK in UCVA, but no long-term differences¹⁰. It appears that tPRK may offer a short-term advantage over PRK in terms of postoperative uncorrected visual acuity (UCVA) outcomes. However, this advantage seems to diminish in long-term follow-up.

No significant difference in postoperative best corrected visual acuity (BCVA) was observed between the tPRK and PRK groups, consistent with previous studies^{10,11,14,16,17,20,21}. Similarly, no significant difference was found in mean postoperative Spherical Equivalent (SE) between the two groups, aligning with other studies indicating similar long-term refractive outcomes for both methods^{13,14,16,17,19-22}.

The study found no statistically significant difference in postoperative intraocular pressure (IOP) between tPRK and PRK, which is in line with findings by Özülsen et al.,¹³ and Zarei-Ghanavati et al.,¹⁶.

In our study, we compared the formation of postoperative corneal haze between the tPRK and PRK methods. The results showed that corneal haze was significantly less severe one month postoperatively in patients who underwent tPRK compared to those who underwent PRK. However, this difference was not statistically significant at the three-month postoperative visit. Bakhsh et al.,¹⁹ reported a lower incidence of postoperative

corneal haze in the tPRK group compared to the PRK group at three distinct postoperative time points: 1 week, 1 month, and 3 months. They suggested that this difference might be attributed to factors like reduced keratocyte loss and apoptosis, the absence of alcohol-induced toxicity (which is present in alcohol-assisted mechanical debridement), and minimized epithelial injury due to the non-touch technique used in tPRK¹⁹. Similarly, Aslanides et al.,¹⁵ observed less corneal haze using the modified tPRK method compared to the PRK method at all time points from 1 to 6 months. However, many other studies have reported no statistically significant differences in postoperative corneal haze formation when comparing tPRK and PRK methods^{13,14,16,18,20,23}.

Given that tPRK typically results in a smaller corneal epithelial defect diameter, it is anticipated to facilitate faster healing and less pain shortly after surgery^{14,24,25}. However, the data on postoperative pain when comparing tPRK and PRK are not consistent across studies. Our findings indicated significantly less pain among tPRK patients on the first day after surgery, but this difference did not reach statistical significance at one and three months postoperatively. This trend of lower early postoperative pain in tPRK compared to PRK is in line with the majority of previous studies^{11,15,19,21,26}. Nonetheless, more recent research, specifically by Hashemi et al.,¹⁴ and Zarei-Ghanavati et al.,¹⁶ contradicts this, reporting significantly less pain on the first day after surgery with the PRK method as compared to tPRK.

Ultimately, we noted significantly lower discomfort in the tPRK group compared to the PRK group at the one month follow-up. However, there was no significant difference in discomfort observed between the two

groups at three months postoperatively. These results contrast with those reported by Hashemi et al.,¹⁴ and Zarei-Ghanavati et al.,¹⁶ who both found less discomfort among patients undergoing PRK compared to those undergoing tPRK on the first postoperative day. Differences in laser settings, epithelial healing time, or patient-reported pain scales might be the reason for these different results. In summary, while our results align with many previous studies in showing that tPRK and PRK are comparable in terms of improving visual outcomes, the comparison of postoperative pain and discomfort between these two methods remains inconclusive. This might be attributed to the lack of standard measurement protocols. We recommend further randomized, double-blind studies involving a greater number of participants and standardized methods for measuring postoperative pain and discomfort to obtain more definitive results. The present study has certain strengths, including being among the few studies that compare postoperative patient discomfort between the tPRK and PRK methods. However, it also has limitations, such as the relatively small number of participants and the absence of a comparison of corneal healing times between the two methods.

Conclusion

The findings of the present study suggest that the tPRK method is associated with reduced early postoperative pain and discomfort at day one as well as less corneal haze at one month postoperatively, compared to the conventional PRK method. There were no significant differences between the two methods in terms of postoperative intraocular pressure, UCVA, BCVA, or SE.

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Footnotes and Financial Disclosures

Conflict of interest:

The authors have no conflict of interest with the subject matter of the present manuscript.