Aus der Klinik für Augenheilkunde
der Heinrich-Heine-Universität Düsseldorf
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# Refraktive Ergebnisse der photorefraktiven Keratektomie (PRK) im Vergleich zwischen trans-PRK und phototherapeutischer Keratektomie (PTK)-PRK zur Korrektur von Myopie und myopem Astigmatismus

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*Meiner Familie und meinem Bruder, die mir auf diesem Weg stets zur Seite standen*

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# Zusammenfassung

Die refraktive Chirurgie zählt zu den am häufigsten durchgeführten medizinischen Eingriffen. Zu den prominentesten Vertretern zählen die photorefraktive Keratektomie (PRK), die Laser-in-situ-Keratomileusis (LASIK) sowie die Small Incision Lenticule Extraction (SMILE). Die PRK eignet sich insbesondere für Patienten mit dünnen Hornhäuten, hohen Ametropien oder rezidivierenden Hornhauterosionen als bevorzugte Behandlungsmethode zur Korrektur vorhandener Fehlsichtigkeiten. Aktuell stehen neuere Operationstechniken der PRK zur Verfügung, wobei man einzeitige Verfahren (tPRK) von den klassischen zweizeitigen Verfahren unterscheidet. Im Rahmen des tPRK-Verfahrens erfolgt eine simultane Abtragung von Hornhautepithel und -stroma. Die phototherapeutische Keratektomie (PTK) ermöglicht die Abtragung pathologischer Hornhautschichten, wodurch eine Wiederherstellung der Hornhauttransparenz und -regularität erzielt werden kann. Eine Kombination beider Verfahren (PTK-PRK) umfasst zunächst die Abtragung des Hornhautepithels mittels PTK, gefolgt von der refraktiven Ablation des Hornhautstromas mittels PRK. Im Rahmen dieser retrospektiven Studie wurden die refraktiven Ergebnisse nach tPRK und PTK-PRK bei der Korrektur von Myopie und myopem Astigmatismus miteinander verglichen. Bislang existiert lediglich eine geringe Anzahl an Publikationen zum kombinierten PTK-PRK-Verfahren als alternative Behandlungsmethode zur gängigen Praxis, insbesondere im Kontext der refraktiven Chirurgie. In dieser Studie wurden 154 Augen von 86 Patienten eingeschlossen. Die Gruppe A wurde einer tPRK-Behandlung mit dem Amaris750-Laser unterzogen, während die Gruppe B eine PTK-PRK-Behandlung mit dem MEL90-Laser erhielt. Im Rahmen der vorliegenden Untersuchung wurden die Vorhersagbarkeit, Effektivität, Sicherheit sowie Änderungen der Wellenfrontaberrationen analysiert. Die Auswertung hat ergeben, dass sich die beiden Gruppen hinsichtlich der untersuchten Parameter nicht signifikant unterscheiden ($p > 0,05$). In Gruppe A wiesen alle Augen eine Abweichung von höchstens ±0,50 Dioptrien vom angestrebten Zielwert auf, während dies bei 95,7 % der Augen in Gruppe B der Fall war. Hinsichtlich der Effektivität und Sicherheit wiesen beide Gruppen jeweils einen Index von 1,0 auf. Es wurden keine Komplikationen beobachtet. Sowohl das tPRK- als auch das PTK-PRK-Verfahren führten zu sicheren und effektiven refraktiven Resultaten bei der Korrektur von Myopie und myopem Astigmatismus. Daher stellt die Kombination aus PTK und PRK eine innovative und vielversprechende Alternative zur etablierten tPRK-Methode dar, da sie eine schonende refraktive Hornhautchirurgie mit einer klassischen Excimer-Laserplattform ermöglicht.

## Summary

Refractive surgery is one of the most frequently performed medical procedures. The most prominent examples include photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK) and small incision lenticule extraction (SMILE). PRK is particularly indicated for patients with thin corneas, high ametropia, or recurrent corneal erosions, as it is the preferred treatment method for correcting existing visual defects. Newer PRK surgical techniques are currently available, whereby a distinction is made between single-stage procedures (tPRK) and the classic two-stage procedures. In the tPRK procedure, the corneal epithelium and stroma are removed simultaneously. Phototherapeutic keratectomy (PTK) enables the ablation of pathological corneal layers, thereby restoring corneal transparency and regularity. A combination of both procedures (PTK-PRK) initially involves the ablation of the corneal epithelium using PTK, followed by refractive ablation of the corneal stroma using PRK. This retrospective study aimed to compare the refractive outcomes following tPRK and PTK-PRK in the correction of myopia and myopic astigmatism. To date, only a limited number of publications have evaluated the combined PTK-PRK procedure as an alternative treatment method to standard practice, particularly in the context of refractive surgery. The present study included 154 eyes from 86 patients. Group A underwent treatment with the Amaris 750 laser for tPRK, while Group B underwent PTK-PRK treatment with the MEL90 laser. The present study aimed to analyze the predictability, efficacy, safety, and changes in wavefront aberrations. The evaluation demonstrated that there was no statistically significant difference between the two groups regarding the parameters examined ($p > 0.05$). In Group A, all eyes exhibited a maximum deviation of ±0.50 diopters from the target value, whereas this was observed in 95.7% of eyes in Group B. Regarding efficacy and safety, both groups demonstrated an index of 1.0. No complications were noted. Both the tPRK and PTK-PRK procedures resulted in safe and effective refractive outcomes in the correction of myopia and myopic astigmatism. Therefore, the combination of PTK and PRK represents an innovative and promising alternative to the established tPRK method, as it enables safe refractive corneal surgery with a classic excimer laser platform.

# Abkürzungsverzeichnis

| | |
|---|---|
| **LASIK** | Laser-in-situ-Keratomileusis |
| **PRK** | Photorefraktive Keratektomie |
| **tPRK** | Transepitheliale Photorefraktive Keratektomie |
| **SMILE** | Small Incision Lenticule Extraction |

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# 1 Einleitung

## 1.1 Refraktiv-Chirurgische Verfahren

In den vergangenen Jahren konnten im Bereich der refraktiven Chirurgie bedeutende Fortschritte bei der Behandlung von Brechungsanomalien des Auges, wie Kurzsichtigkeit (Myopie), Weitsichtigkeit (Hyperopie) und Hornhautverkrümmung (Astigmatismus), erzielt werden. In diesem Kontext haben sich verschiedene laserbasierte Operationstechniken als äußerst präzise und effektive Therapieoptionen etabliert (Kim et al., 2019).

Zu den gängigen Verfahren zählen unter anderem die photorefraktive Keratektomie (PRK) sowie die laser in-situ-Keratomileusis (LASIK) und die Small Incision Lenticule Extraction (SMILE). Diese Methoden ermöglichen eine gezielte Modifikation der Hornhautkrümmung, wodurch eine Korrektur der Lichtbrechung des Auges erzielt werden kann.

Bei den meisten refraktiv-chirurgischen Eingriffen findet der Excimer-Laser Anwendung, ein ultravioletter Gaslaser, der primär für die Ablation von Hornhautgewebe verwendet wird. Die Emission von Licht mit einer Wellenlänge von 193 nm ermöglicht dem Excimer-Laser eine präzise Abtragung des Hornhautstromas bei minimaler thermischer Schädigung des umliegenden Gewebes. Die hohe Energiedichte führt zu einer Photoablation, bei der die molekularen Bindungen des Gewebes aufgebrochen werden, ohne dass es zu einer signifikanten Erwärmung kommt.

Die Auswahl des geeigneten refraktiv-chirurgischen Verfahrens basiert auf diversen Kriterien, darunter die spezifische Refraktionsanomalie, die Hornhautdicke und -beschaffenheit sowie individuelle Patientenmerkmale. Gegenwärtig sind Forschungsarbeiten darauf ausgerichtet, die genannten Methoden hinsichtlich Präzision, Sicherheit und langfristiger postoperativer Ergebnisse zu optimieren.

## 1.2 Transepitheliale photorefraktive Keratektomie (tPRK)

Die konventionelle PRK ist ein etabliertes Verfahren der refraktiven Hornhautchirurgie bei dem zunächst das Hornhautepithel mechanisch oder chemisch entfernt wird, bevor der Excimer-Laser zur präzisen Ablation des darunterliegenden Stromas eingesetzt wird. Diese Methode hat sich als effektiv erwiesen, allerdings sind mit ihr

potenzielle Nachteile wie postoperative Schmerzen und eine verlängerte Heilungsphase verbunden (Way et al., 2024).

In den vergangenen Jahren hat sich die transepitheliale photorefraktive Keratektomie (tPRK) als vielversprechende Weiterentwicklung der konventionellen PRK etabliert. Die tPRK basiert auf einem einzeitigen Ansatz, bei dem die Ablation der Hornhautoberfläche unmittelbar erfolgt, ohne dass zuvor eine separate Abtragung des Hornhautepithels erforderlich ist.

Die direkte Ablation des Stromas ohne vorherige Epithelentfernung kann zu einer regelmäßigen Beschleunigung der Wundheilung führen. Als Vorteile sind insbesondere reduzierte Raten von postoperativen Hornhauttrübungen (Haze) und geringere postoperative Schmerzen zu nennen. Die tPRK erlaubt zudem eine präzisere Anpassung der Ablationsparameter, da die Hornhautoberfläche weniger Unregelmäßigkeiten aufweist als nach mechanischer oder chemischer Epithelentfernung (Alasbali, 2022).

## 1.3 Phototherapeutische Keratektomie (PTK)

Die phototherapeutische Keratektomie (PTK) ist ein spezialisiertes hornhautchirurgisches Verfahren, welches sich von rein refraktiven Eingriffen wie der photorefraktiven Keratektomie (PRK) oder der Laser-in-situ-Keratomileusis (LASIK) unterscheidet. Während die PTK primär auf die selektive Abtragung irregulärer oder pathologischer Strukturen der Hornhautoberfläche abzielt, fokussieren sich refraktive Verfahren auf die Korrektur von Fehlsichtigkeiten (Nagpal et al., 2020).

Die PTK nutzt die präzise Ablationsfähigkeit des Excimer-Lasers, um beispielsweise Hornhauttrübungen zu entfernen, Narbengewebe abzutragen oder unregelmäßige Epithelverhältnisse zu glätten. Die gezielte Ablation führt zu einer Re-Konturierung der Hornhautoberfläche, wodurch sich die Hornhauttransparenz erhöhen und die Sehschärfe verbessern kann.

Die Kombination von PTK und PRK (PTK-PRK) stellt einen vielversprechenden Ansatz dar, da hierbei die laser-gestützte Abtragung des Hornhautepithels mittels PTK mit der refraktiven Korrektur der PRK vereint wird. Im Anschluss an die Abtragung des Hornhautepithels erfolgt eine PRK-Excimer-Laserablation zur Korrektur des refraktiven Fehlers im Hornhautstroma (Tangmonkongvoragul et al., 2021).

Dadurch kann die initiale PTK-Behandlung eine glattere und regelmäßigere Hornhautoberfläche als Ausgangspunkt für die refraktive Korrektur schaffen im Vergleich zur mechanischen Abtragung, wie sie bei der konventionellen PRK zum Einsatz kommt.

## 1.4 Evidenzlage

Die bisherige Evidenzlage zeigt, dass die PTK-PRK-Technik eine potenzielle Alternative zur tPRK darstellen könnte. Es wird postuliert, dass die vorgeschaltete PTK-Ablation durch Optimierung der Hornhautoberfläche die Vorhersagbarkeit und Präzision der anschließenden refraktiven Behandlung verbessern könnte. Obwohl diese Ansätze vielversprechend erscheinen, weist der aktuelle Forschungsstand signifikante Limitationen auf. Um eine abschließende Bewertung ihrer klinischen Ergebnisse zu ermöglichen, wären systematische Vergleichsuntersuchungen zwischen beiden Methoden erforderlich. Zudem fokussierten sich die bisherigen Studien primär auf bestimmte Excimerlaser-Plattformen, wodurch die Übertragbarkeit der Ergebnisse auf andere Systeme limitiert ist. Die Ergebnisse der vorliegenden Studien legen nahe, dass die PTK-PRK-Methode ähnliche Erfolge zeigen können wie die etablierte tPRK (Abdel-Radi et al., 2023; Tangmonkongvoragul et al., 2021).

Mit modernen Excimerlaserplattformen wie dem MEL90-Laser lassen sich möglicherweise neue Optimierungspotenziale für eine rein laserbasierte PRK-Methode erschließen. Die technologischen Fortschritte in diesem Bereich eröffnen die Möglichkeit, die Effizienz und Präzision existierender Verfahren weiter zu steigern und dadurch weitere Behandlungsmöglichkeiten anzubieten.

## 1.5 Ziele der Arbeit

Die vorliegende retrospektive klinische Vergleichsstudie hat zum Ziel, die refraktiven Ergebnisse nach tPRK und PTK-PRK unter Verwendung des MEL90-Lasers bei der Behandlung von Myopie und myopem Astigmatismus gegenüberzustellen. Das übergeordnete Ziel besteht in der Evaluierung der Eignung der PTK-PRK-Kombination als potenzielle Alternative zur etablierten tPRK-Methode sowie in der Generierung evidenzbasierter Erkenntnisse für die klinische Praxis.

Im Rahmen dieser Untersuchung erfolgt eine Analyse spezifischer Zielparameter, insbesondere der refraktiven Ergebnisse, der Sicherheit der Eingriffe und der Veränderungen

der Wellenfrontaberrationen, um eine Bewertung des Einflusses der Behandlungen auf die optische Qualität des Auges zu ermöglichen. Aufgrund der Resultate früherer Studien zur PTK-PRK-Methode wird die Hypothese aufgestellt, dass diese Technik ähnlich sichere und effektive refraktive Resultate erzeugt wie die tPRK.

## 1.6 Ethikvotum

Die Durchführung dieser Studie wurde von der zuständigen Ethikkommission geprüft und genehmigt (Studien-ID 2022-1980). Alle Studienteilnehmer wurden über die Zielsetzung, den Ablauf sowie mögliche Risiken der Untersuchung informiert und haben ihre schriftliche Einwilligung erteilt.

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ORIGINAL PAPER

# Refractive results of photorefractive keratectomy comparing trans-PRK and PTK–PRK for correction of myopia and myopic astigmatism

**Ahmed Saad · Amr Saad · Andreas Frings**

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**Abstract**
*Purpose* To compare refractive outcomes after transepithelial photorefractive keratectomy (*t*PRK) and combined phototherapeutic keratectomy (PTK–PRK) procedure using two different excimer laser platforms for correction of myopia and myopic astigmatism.
*Methods* In this retrospective multicenter study, we compared the results of two different PRK methods. The first group received a *t*PRK treatment with the Amaris750 excimer laser (Schwind eye-tech solutions). The second group received a combined PTK–PRK treatment with the MEL90 excimer laser (Carl Zeiss). Only healthy eyes with no previous surgery and a spherical equivalent (SE) of −1 to −8 diopters (*D*) were included. Preoperative spherical equivalent (SE), age, and sex were matched among the two groups. All treatments were performed by the same surgeon in different clinics. This study was approved by the local Ethics Committee (No. 2022–1980).
*Results* We included 154 eyes of 86 patients in our study. There was no difference in predictability of SE between the two groups. Efficacy and safety indices were equally high in both groups. Similarly, no significant differences were seen in change of higher order aberrations (HOA) between the two groups ($p > 0.05$). No complications occurred.
*Conclusion* Both investigated methods provide safe and effective refractive results. The combination of PTK with PRK may be a suitable option to the already used one-step *t*PRK for the correction of myopia.

**Keywords** Refractive surgery · Photorefractive keratectomy · Phototherapeutic keratectomy · Myopia

## Introduction

Refractive surgery is one of the most commonly performed procedures in medicine. The field of refractive surgery has evolved rapidly in recent years. Several surgical treatment options are now available, including photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK), and small incision lenticule extraction (SMILE). Nevertheless, PRK remains a popular method for correcting refractive errors, especially in eyes with thin corneas, high refractive errors, or recurrent corneal erosions [1, 2].

PRK can be performed in different ways. Either as a single-step procedure, in which the corneal

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epithelium and stroma are ablated simultaneously with an excimer laser, called transepithelial PRK (tPRK), or as a two-stage procedure, in which it is possible to distinguish between the mechanical, alcohol-assisted, or laser-assisted method of epithelial ablation. The introduction of *t*PRK in the 1990s aimed to avoid complications associated with epithelial debridement [3] and showed at least non-inferior results compared to two-step PRK [4]. However, there are only a few devices currently available in the market for the single-step PRK (e.g., SCHWIND Amaris and Alcon Wave Light). Representative of this procedure is the Amaris750 excimer laser. Therefore, the two-step method is still used by surgeons who do not have access to these laser platforms.

Basically, the two-stage procedure, consisting of mechanical epithelial and subsequent stromal ablation, is used in PRK treatment with the MEL90 excimer laser platform (Carl Zeiss Meditec). Excimer lasers like this are also used for PTK in other indications (e.g., degenerative diseases of the cornea) [5, 6]. Therefore, the sequential combination of PTK followed by PRK represents an option for non-contact laser correction with the MEL90.

On the one hand, the *t*PRK method has been proven many times as a safe and effective way to treat myopia [7]. On the other hand, the PTK−PRK procedure seems to show stable results, as demonstrated previously by two groups [8, 9] with the EX500 laser (Alcon Laboratories). Also, older publications indicate that the PTK−PRK combination is an effective treatment [10, 11]. However, only one of the previous works compared the PTK−PRK method with the *t*PRK and none of them evaluated the two-stage PTK−PRK method using the MEL90 excimer laser. This retrospective data analysis aims to compare these two approaches (*t*PRK vs. PTK−PRK) in terms of postoperative outcomes. Here, the standard target parameters of visual acuity, efficacy, and safety indices are considered and analyzed [12]. Hereby, we want to make an important contribution to this novel modified PRK application with the MEL90 and offer users of this excimer laser more evidence for individual therapy decisions. It is interesting to ask whether these two methods differ significantly. To the best of our knowledge, there is very little work on PTK−PRK procedures using MEL90, especially in the field of refractive surgery. Thus, further research on this issue is necessary to provide proper evidence for this alternative method.

## Methods

In this retrospective study, we compare data from 154 eyes of 86 patients, treated at the same private practices. This study was approved by the local research ethics committee (No. 2022−1980) and complies with the Declaration of Helsinki. Our study is registered in the German Clinical Trials Register, DRKS (DRKS−ID: DRKS00030977). All patients gave informed consent for the use of their routinely collected data for research purposes. In addition, all patients were older than 18 years and none had any ocular disease, previous ocular surgery or trauma, or general disorders affecting the eye. Patients with any systemic diseases that might affect the eye were excluded from surgery. We included only eyes with a spherical equivalent (SE) of −1 to −8 diopters (*D*).

For comparison, we formed two groups. Group A patients received conventional *t*PRK treatment with Amaris750. Group B patients underwent refractive surgery using the combined PTK−PRK method using the MEL90 laser. To avoid sampling bias, we randomly select the 154 eyes (86 patients) from a larger cohort (approximately 197 eyes) using the random number function of Excel (Microsoft Excel 2017, Microsoft®). To reduce any bias caused by different preoperative refractive errors and thus different ablation depths, all groups were matched regarding the preoperative SE.

All patients were examined before surgery according to a standard protocol. Visual acuity in terms of subjective refraction, including uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), was collected within 2 weeks before and 6 months after surgery. We also obtained topographic data using Schwind Anterior Segment Analyzers (Peramis and Sirius, Schwind eye−tech solutions) for *t*PRK patients and the TMS−5 Scheimpflug tomograph (Tomey) and WASCA aberrometer (Carl Zeiss) for PTK−PRK patients all at an optical zone (OZ) of 6.5 mm. For treatment planning, we used the *K* values of the respective topography device as well as those of an auto-refractometer/keratometer (Nidek).

All operations were performed by the same surgeon using two different laser platforms with a repetition rate of 500-Hz for the MEL90 and 750-Hz for the Amaris 750. For all treatments, topical anesthesia (Oxybuprocaine, Conjuncain EDO® 0.4 mg/mL, Bausch & Lomb) was used. Patients were asked to focus their gaze on the fixation light to center the ablation zone. Group A patients underwent a single stage tPRK procedure in which the excimer laser simultaneously reshapes the corneal epithelium and stroma to correct the refractive error. Patients in group *B* first received PTK treatment for epithelial ablation, with a depth of 50 µm and diameter of 8mm. Following this, refractive ablation of the stroma was performed using the PRK mode, without any further modifications. Our own ablation nomogram was utilized for this step, and no wavefront-guided mode was employed. It is important to acknowledge that the SCHWIND Amaris750 incorporates an aspherical epithelium ablation, taking into consideration the impact of keratometry and the associated higher energy loss in the periphery. In contrast, the MEL−90 does not account for peripheral energy loss. Regardless of the method employed, all refractive ablations were consistently performed with an OZ of 6.5 mm and a transition zone of 1.5 mm. Mitomycin C (MMC, 0.02%) was applied for 15–30 s (sec), depending on ablation depth. For corrections up to −4 *D*, MMC was applied for 20 s, while durations of 45 s were employed for corrections exceeding −4 *D*.

At the end of the procedure, all eyes got a therapeutic contact lens for 5 days, as well as preservative-free eyedrops of ofloxacin (Floxal EDO®, Bausch & Lomb) and dexamethasone (Dexa EDO®, Bausch & Lomb). Postoperative care included the application of Nepafenac eyedrops (0.1%, Nevanac®, Novartis) for 5 days, as well as hyaluronan (Hylo−Comod®, Ursapharm) eyedrops and dexamethasone (Dexa EDO®, Bausch & Lomb) eyedrops for 6 weeks.

Statistical analysis was performed using R Core Team software (R Foundation for Statistical Computing 2021). Refractive results are represented as standard graphs for reporting outcomes in refractive surgery [12], which show the efficacy, safety, predictability, and accuracy of each treatment. The efficacy index (EI) describes the ratio between postoperative UDVA and preoperative CDVA, whereas the safety index (SI) describes the ratio between postoperative CDVA and preoperative CDVA. Predictability is evaluated as the proportion of eyes achieving a postoperative SE within ± 0.50 *D* of targeted visual acuity and was analyzed using the least squares method. The differences in percent (%) of eyes within 0.50 *D* between the groups were tested with Fisher's exact test.

The differences in pre- and postoperative parameters were tested using either the independent *t*−test or Mann–Whitney test, based on whether the assumptions of parametric test were satisfied. Normality was tested with Shapiro–Wilk test, homogeneity of variances with Levene test, and outliers, if any, were identified using the box plot method. The changes within the groups were tested with either Wilcoxon signed rank test or paired *t* test. And the differences in changes were tested with either Mann–Whitney test or independent *t* test.

## Results

In this study, we evaluated the refractive outcomes of 154 eyes of 86 patients. Both treatment groups (*t*PRK and PTK−PRK) were matched in terms of preoperative refraction, age, and sex to achieve more accurate analysis. The mean age in both treatment groups was 35 years. No complications occurred postoperatively.

Table 1 compares the preoperative descriptive data of the two groups and the total cohort. In addition to SE values, coma, trefoil, and spherical aberration (SA) and higher order aberrations (HOA) are also listed. There is no significant difference between the two groups regarding all parameters ($p > 0.05$). Table 2 shows the same parameters 6 months postoperatively for the two groups and the complete cohort. Again, there is no significant difference between the two groups ($p > 0.05$). Table 3 summarizes the differences in pre- and postoperative parameters within the two groups and between the groups, respectively. The postoperative change in sphere, cylinder, and SE was highly significant in the two groups ($p < 0.001$). However, the differences in changes between the two groups were not statistically significant in all other parameters.

Figure 1 presents four standard graphs reporting the refractive outcome of the two surgical methods in comparison. Regarding efficacy, which is postoperative UDVA in relation to preoperative CDVA, both surgical methods showed equally high results with no

**Table 1** Preoperative descriptive data (subjective refraction and higher order aberrations)

| Parameter | *t*PRK (*N* = 77) | PTK–PRK (*N* = 77) | Total (*N* = 154) | *p* value |
|---|---|---|---|---|
| Manifest sphere (*D*) | | | | *W* = 2995, *p* = 0.913, *r* = −0.009[a] |
| Range | −1.25, −7.50 | −1.50, −7.50 | −1.25, −7.50 | |
| Mean (SD) | −4.31 (1.77) | −4.29 (1.75) | −4.30 (1.76) | |
| Median (*Q*1, *Q*3) | −4.00 (−2.75, −6.25) | −4.25 (−3.00, −6.00) | −4.00 (−3.00, −6.00) | |
| Manifest cylinder (*D*) | | | | *W* = 2908, *p* = 0.836, *r* = −0.017[a] |
| Range | −1.75, 0.00 | −1.75, 0.00 | −1.75, 0.00 | |
| Mean (SD) | −0.45 (0.41) | −0.45 (0.45) | −0.45 (0.43) | |
| Median (*Q*1, *Q*3) | −0.25 (−0.75, −0.20) | −0.25 (−0.75, 0.00) | −0.25 (−0.75, 0.00) | |
| Manifest spherical equivalent (*D*) | | | | *W* = 2984.5, *p* = 0.944, *r* = −0.006[a] |
| Range | −1.00, −7.38 | −1.25, −7.00 | −1.00, −7.38 | |
| Mean (SD) | −4.09 (1.81) | −4.06 (1.78) | −4.08 (1.79) | |
| Median (*Q*1, *Q*3) | −3.88 (−2.62, −5.88) | −4.00 (−2.75, −5.88) | −3.88 (−2.62, −5.88) | |
| Coma | | | | W = 2867, *p* = 0.726, *r* = −0.028[a] |
| Range | 0.01, 0.47 | 0.00, 0.51 | 0.00, 0.51 | |
| Mean (SD) | 0.11 (0.07) | 0.12 (0.08) | 0.11 (0.07) | |
| Median (*Q*1, *Q*3) | 0.10 (0.06, 0.14) | 0.11 (0.06, 0.15) | 0.11 (0.06, 0.15) | |
| Tefoil | | | | W = 2601, *p* = 0.189, *r* = −0.106[a] |
| Range | 0.01, 0.28 | 0.01, 0.28 | 0.01, 0.28 | |
| Mean (SD) | 0.11 (0.07) | 0.12 (0.06) | 0.11 (0.06) | |
| Median (*Q*1, *Q*3) | 0.09 (0.06, 0.14) | 0.11 (0.08, 0.15) | 0.10 (0.06, 0.15) | |
| Spherical aberration | | | | *t* (150.9) = 0.11, *p* = 0.916, *r* = 0.009[b] |
| Range | −0.13, 0.18 | −0.11, 0.21 | −0.13, 0.21 | |
| Mean (SD) | 0.07 (0.06) | 0.07 (0.06) | 0.07 (0.06) | |
| Median (*Q*1, *Q*3) | 0.08 (0.02, 0.12) | 0.07 (0.02, 0.10) | 0.07 (0.02, 0.11) | |
| Higher order aberration | | | | W = 2783, *p* = 0.513, *r* = −0.053[a] |
| Range | 0.11, 0.65 | 0.11, 0.72 | 0.11, 0.72 | |
| Mean (SD) | 0.23 (0.08) | 0.24 (0.09) | 0.23 (0.09) | |
| Median (*Q*1, *Q*3) | 0.21 (0.18, 0.27) | 0.22 (0.18, 0.29) | 0.21 (0.18, 0.28) | |

[a] Mann–Whitney test, [b] Independent *t* test, *D* diopter, *SD* standard deviation, *Q*1 first quartile, *Q*3 third quartile

loss in Snellen lines (Fig. 1A). Binocular visual acuity (VA) of all patients was 20/20 (Snellen acuity). Similar results can be shown in terms of safety, which describes the postoperative CDVA in relation to preoperative CDVA (Fig. 1B). Therefore, the safety and efficacy indices (SI and EI) were 1.0 for both treatment groups. It is important to note that these visual results were obtained binocular for a more realistic examination of the visual outcome. To calculate predictability, the attempted SE is set in relation to the achieved SE. Here, 100% of eyes in Group A and 95.7% in Group B achieved the attempted SE target within a range of ±0.50 D (Fig. 1C). There were no differences in predictability between the groups as shown by the Fisher's exact test ($p = 0.245$). The accuracy, indicating the proportion of eyes with a SE within ±0.50 *D* of the target, is presented in Fig. 1D. All eyes were within this target range, except 4% of eyes in the PTK–PRK group, which were between −1.00 and −0.50 *D*, postoperatively.

**Table 2** Postoperative descriptive data (subjective refraction and higher order aberrations)

| Parameter | *t*PRK (*N* = 77) | PTK–PRK (*N* = 77) | Total (*N* = 154) | *p* value |
|---|---|---|---|---|
| Manifest sphere (*D*) | | | | $W = 3201.5$, $p < 0.001$, $r = -0.287$[a] |
| Range | −0.50, 0.25 | −0.50, 0.25 | −0.50, 0.25 | |
| Mean (SD) | −0.08 (0.18) | −0.19 (0.20) | −0.14 (0.19) | |
| Median (*Q*1, *Q*3) | 0.00 (−0.25, 0.00) | −0.25 (−0.25, 0.00) | 0.00 (−0.25, 0.00) | |
| Manifest cylinder (*D*) | | | | $W = 2490.5$, $p = 0.376$, $r = -0.076$[a] |
| Range | −0.25, 0.00 | −0.50, 0.00 | −0.50, 0.00 | |
| Mean (SD) | −0.11 (0.13) | −0.14 (0.16) | −0.13 (0.14) | |
| Median (*Q*1, *Q*3) | 0.00 (−0.25, 0.00) | 0.00 (−0.25, 0.00) | 0.00 (−0.25, 0.00) | |
| Manifest spherical Equivalent (*D*) | | | | $W = 3202.5$, $p < 0.001$, $r = -0.340$[a] |
| Range | −0.50, 0.25 | −0.62, 0.25 | −0.62, 0.25 | |
| Mean (SD) | −0.13 (0.16) | −0.26 (0.19) | −0.20 (0.19) | |
| Median (*Q*1, *Q*3) | −0.12 (−0.25, −0.06) | −0.25 (−0.38, −0.12) | −0.25 (−0.25, −0.12) | |
| Coma | | | | $W = 2631$, $p = 0.897$, $r = -0.011$[a] |
| Range | 0.00, 0.45 | 0.02, 0.53 | 0.00, 0.53 | |
| Mean (SD) | 0.13 (0.08) | 0.14 (0.09) | 0.14 (0.08) | |
| Median (*Q*1, *Q*3) | 0.12 (0.08, 0.18) | 0.12 (0.08, 0.18) | 0.12 (0.08, 0.18) | |
| Tefoil | | | | $W = 2536$, $p = 0.616$, $r = -0.042$[a] |
| Range | 0.02, 0.28 | 0.02, 0.35 | 0.02, 0.35 | |
| Mean (SD) | 0.10 (0.06) | 0.10 (0.06) | 0.10 (0.06) | |
| Median (*Q*1, *Q*3) | 0.09 (0.05, 0.13) | 0.09 (0.06, 0.14) | 0.09 (0.06, 0.14) | |
| Spherical aberration | | | | $t\,(143.4) = -0.06$, $p = 0.949$, $r = 0.005$[b] |
| Range | −0.15, 0.22 | −0.17, 0.23 | −0.17, 0.23 | |
| Mean (SD) | 0.04 (0.08) | 0.05 (0.08) | 0.05 (0.08) | |
| Median (*Q*1, *Q*3) | 0.04 (−0.01, 0.10) | 0.04 (0.00, 0.10) | 0.04 (−0.01, 0.10) | |
| Higher order aberration | | | | $W = 2380$, $p = 0.266$, $r = -0.092$[a] |
| Range | 0.12, 0.57 | 0.11, 0.52 | 0.11, 0.57 | |
| Mean (SD) | 0.24 (0.08) | 0.26 (0.09) | 0.25 (0.09) | |
| Median (*Q*1, *Q*3) | 0.23 (0.19, 0.27) | 0.23 (0.19, 0.32) | 0.23 (0.19, 0.29) | |

[a] Mann–Whitney test, [b] Independent *t* test, *D* diopter, *SD* standard deviation, *Q*1 first quartile, *Q*3 third quartile

## Discussion

PRK is still highly valued today, either as a first treatment for eyes with thin corneas, high refractive error, or as a retreatment after a previous refractive intervention [13]. Therefore, studies investigating different PRK methods are still important. Our data show high efficacy and safety indices for both treatment modalities, *t*PRK and PTK–PRK, without significant differences.

Previous studies have already provided numerous proofs of the high efficacy and safety of the *t*PRK method. Alasmari et al. demonstrated a good refractive outcome with *t*PRK in mild myopia correction [14]. Furthermore, two meta-analyses underline these promising results [7, 15] in addition to several comparative studies [16–18].

Regarding the comparison of the two laser ablation methods, two- and one-step PRK, there seems to be no significant difference in refractive outcomes

**Table 3** Tests for changes after treatment

| | *t*PTK† | PTK−PRK* | PTK−PRK vs. tPTK‡ |
|---|---|---|---|
| Manifest sphere (*D*) | <0.001[b*] | <0.001[b*] | 0.848[c] |
| Manifest cylinder (*D*) | <0.001[b*] | <0.001[b*] | 0.174[c] |
| Manifest spherical equivalent (*D*) | <0.001[b*] | <0.001[b*] | 0.953[c] |
| Coma | 0.080[b] | 0.038[a] | 0.681[c] |
| Tefoil | 0.087[a] | 0.247[a] | 0.662[d] |
| Spherical aberration | 0.021[b] | 0.029[b] | 0.950[c] |
| Higher order aberration | 0.140[a] | 0.385[a] | 0.521[d] |

*a* Paired *t* test, *b* Wilcoxon signed rank test, *c* Mann–Whitney test, *d* Two−sample *t* test, * Tests changes within PTK−PRK, † Tests changes within *t*PTK, ‡ Tests differences in changes between PTK−PRK and *t*PTK

expressed in the standard parameters of efficacy, safety, and predictability [19]. However, in highly myopic eyes (> −6.00 D), *t*PRK appears to be more effective than the conventional PRK methods [20]. One disadvantage of conventional PRK is the uneven dehydration of the stroma caused either by mechanical- or alcohol-assisted debridement of the corneal epithelium [15]. In contrast, *t*PRK allows for a more consistent corneal ablation, resulting not only in stable refractive outcomes, but also in less pain and haze formation over time [21]. Controversial results may be caused by the different surgical regimens in terms of MMC use or the follow-up period [3].

Laser-assisted epithelial removal, as used in PTK, is a less traumatic technique which provides a smoother ablation profile by reducing the postoperative fibroblast hyperplasia and increasing the epithelial adherence [22, 23]. Published data on the novel PRK method we studied, which consists of PTK treatment followed by PRK, are very scarce. The few available studies have been published on combined PTK−PRK treatment for myopic eyes with corneal scars or other opacities [24]. In addition, this combination is also used to correct complications from previous refractive treatments [25]. This is the first study comparing the *t*PRK technique using the Amaris750 with PTK−PRK performed with MEL90. Tangmonkongvoragul et al. demonstrated good refractive results of the PTK−PRK method for treating mild myopia with the EX500 excimer laser [8]. A recently published study also confirmed the efficacy of PTK−PRK surgery compared to *t*PRK treatment [9]. These results are consistent with our findings. This two-step procedure has some similarities with the *t*PRK, as it is a non-contact laser treatment. Nevertheless, Abdel−Radi et al. demonstrated a faster recovery time in *t*PRK eyes compared with PTK−PRK patients, which they attributed to a shorter surgical time and thus more precise alignment between the epithelial and stromal ablation with respect to their contraction. They concluded that *t*PRK surgery is superior to PTK−PRK regarding visual outcome. The faster recovery of this single-step technique is known from previous studies, which compared *t*PRK to mechanical two-step PRK [16]. Regarding HOA, we found no significant differences between the two groups. However, it is worth mentioning that an aspheric PTK theoretically produces different aberrations than a PTK-based epithelial ablation without aspheric correction, where less energy reaches the peripheral cornea. This may have clinical relevance under scotopic lighting conditions.

The use of MMC in refractive surgery is frequently discussed. While some authors promise stable results without MMC [26], others recommend its use to avoid postoperative complications such as haze and scarring [27]. Some also suggest the use of MMC after PTK treatment [28]. We have used MMC for all our treatments with no postoperative complications in the follow-up period, which is in line with previous works. Abdel−Radi et al. reported minimal haze formation (grade 1) even after MMC application [9]. However, they used a different laser platform, which makes comparison difficult.

A limitation of our study is the short follow-up period, which may have led us to overlook potential postoperative complications. However, from our experience, we know that the use of MMC prevents haze formation in almost all PRK cases, which can be one of the biggest issues after PRK. Further limitations may be the small group size and the lack of comparison data of other study groups using

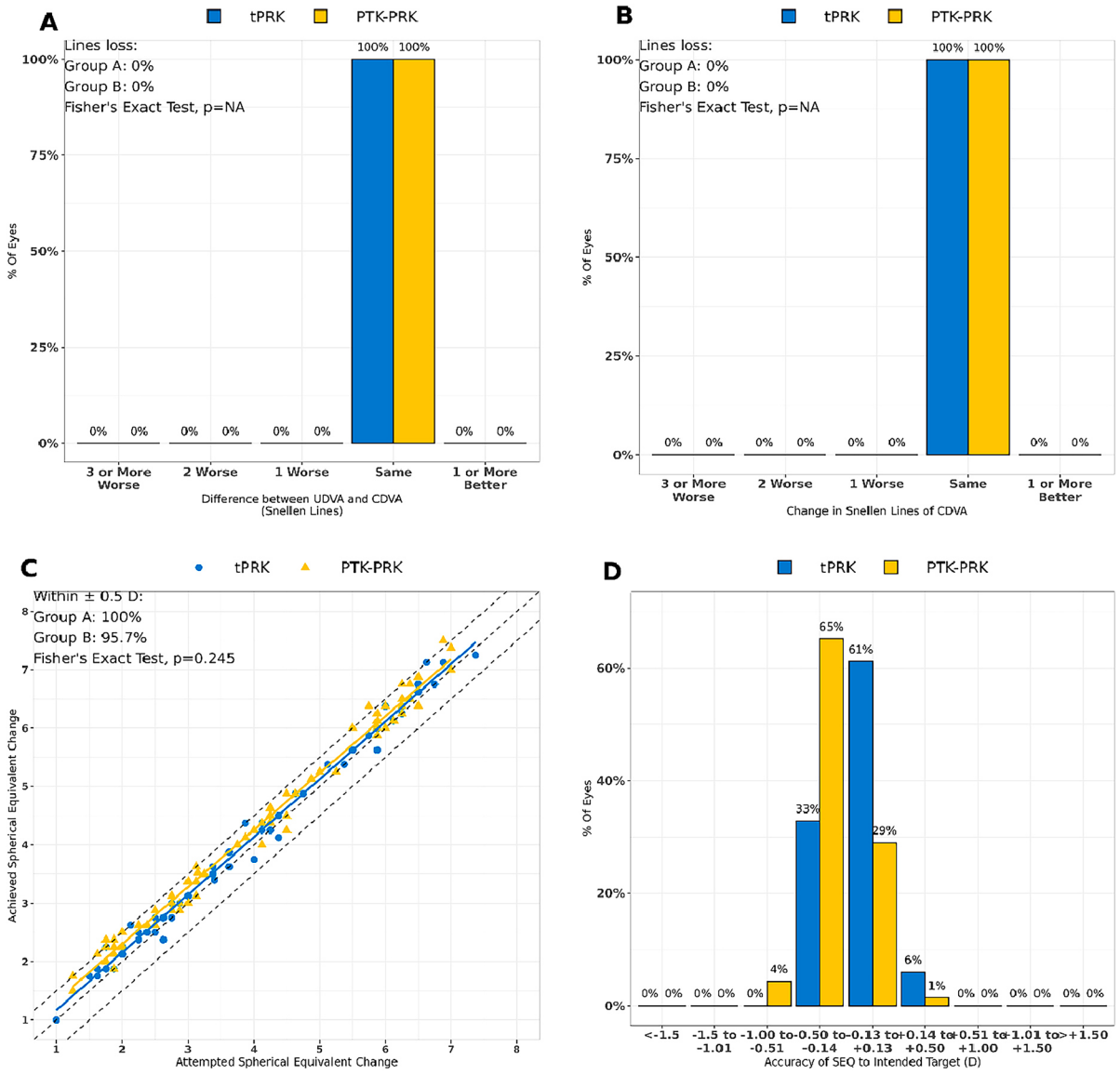


**Fig. 1** Standard graphs reporting visual outcomes for Groups A and B: **A** Efficacy graph, **B** Safety graph, **C** Precision graph, **D** Accuracy graph; *t*PRK: transepithelial photorefractive keratectomy, PTK–PRK: combined phototherapeutic keratectomy and photorefractive keratectomy, UDVA: uncorrected distance visual acuity, CDVA: corrected distance visual acuity, SEQ: spherical equivalent

the same laser platforms. Additionally, due to differences in equipment availability at the respective practice locations, different devices were utilized for topographic measurements in the two groups, potentially introducing a bias. However, we made concerted efforts to alleviate this potential influence by ensuring consistent optical zone settings across all employed devices.

Finally, our results show that the visual outcomes of PTK–PRK treatment are not significantly different from those of the *t*PRK method. Our aim of this analysis is to provide the refractive surgeon with evidence for an individual decision before PRK treatment. Two-stage PTK–PRK may be a suitable option for surgeons using the MEL90 excimer laser for the correction of myopia and astigmatism. Further

investigations with larger populations and longer follow-up are needed to proof the quality of the PTK–PRK method.

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**Declarations**

**Conflict of interests** The authors have no relevant financial or non-financial interests to disclose.

**Ethical approval** This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Heinrich Heine University in Düsseldorf (ID: 2022–1980).

**Consent to participate** Written informed consent was obtained from all individual participants included in the study.



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# 3 Diskussion

## 3.1 Einordnung der Ergebnisse in die Literatur

Die vorliegende Studie vergleicht die refraktiven Ergebnisse zweier unterschiedlicher PRK-Methoden, nämlich der tPRK und der Kombination aus PTK und PRK (PTK-PRK). In früheren Studien wurden beide Verfahren bereits separat untersucht und als sichere und effektive Behandlungsoptionen zur Korrektur von Fehlsichtigkeiten bzw. Hornhautpathologien, wie wiederkehrende Hornhauterosionen oder unregelmäßiger Astigmatismus, bewertet (Deshmukh et al., 2020; Wilson et al., 2017). Die Effektivität der tPRK-Behandlung wurde bereits in zahlreichen Publikationen nachgewiesen und zeigt sich unter anderem in teilweise überlegenen Resultaten hinsichtlich Genauigkeit und postoperativer Schmerzen (Adib-Moghaddam et al., 2018; Alasbali, 2022; Way et al., 2024).

Auch die Kombination der beiden Verfahren im Sinne einer PTK-PRK-Behandlung führt zu vielversprechenden klinischen Resultaten. In vorangehenden Studien wurden positive Ergebnisse sowohl bei gesunden als auch bei Patienten mit pathologischer Hornhaut, Narben oder vorbehandelten Augen nachgewiesen (Camellin and Arba Mosquera, 2010; Zhang et al., 2000). In beiden neueren Studien zu PTK-PRK-refraktiver Behandlung wurde der EX500-Excimer-Laser geprüft, wobei teilweise vergleichbare Ergebnisse zum etablierten tPRK-Verfahren erzielt wurden (Abdel-Radi et al., 2023; Tangmonkongvoragul et al., 2021).

Die Ergebnisse der aktuell vorliegenden Studie mit der MEL90-Excimerlaserplattform für die kombinierte PTK-PRK-Behandlung demonstrieren, dass beide Ansätze hinsichtlich der Vorhersagbarkeit, Effektivität und Sicherheit vergleichbare postoperative Ergebnisse liefern. Diese Befunde stehen im Einklang mit den Erkenntnissen früherer Studien, welche ebenfalls keine signifikanten Unterschiede zwischen tPRK und PTK-PRK nachweisen konnten. Die vorliegende Arbeit liefert daher wichtige zusätzliche Evidenz für diese alternative PRK-Methode und zeigt, dass PTK-PRK-Technik mit dem MEL90-Laser ähnliche Ergebnisse erzielt wie die tPRK mit dem Amaris750-Laser. Dies erweitert das Behandlungsspektrum und bietet Anwendern des MEL90-Systems eine weitere sinnvolle Option zur keratorefraktiven Korrektur von Myopie und myopem Astigmatismus.

## 3.2 Limitationen der Studie

Wie bei jeder klinischen Studie sind auch bei dieser Analyse gewisse Limitationen zu berücksichtigen. Trotz der statistischen Eignung der Stichproben in beiden Behandlungsgruppen ist die Anzahl der untersuchten Probanden relativ gering, sodass eine Verallgemeinerung der Ergebnisse nur eingeschränkt möglich ist. Eine größere Patientenzahl könnte möglicherweise zusätzliche, weniger offensichtliche Unterschiede zwischen den Verfahren aufdecken.

Ein weiterer limitierender Faktor ist der relativ kurze Nachbeobachtungszeitraum von sechs Monaten. Um die Stabilität der refraktiven Resultate über einen größeren Zeitraum beurteilen zu können, wären längerfristige Untersuchungen erforderlich. Während die präoperativen Charakteristika vergleichbar waren, lässt sich eine gewisse Verzerrung der Ergebnisse durch die ungenügende Randomisierung aufgrund des retrospektiven Studiendesigns nicht gänzlich ausschließen.

Schließlich wurden alle Operationen von einem einzelnen, erfahrenen Chirurgen durchgeführt. Eine Standardisierung der Methodik wurde somit gewährleistet, jedoch lässt sich eine Übertragbarkeit der Ergebnisse auf andere Anwender nicht ohne Weiteres verallgemeinern.

## 3.3 Schlussfolgerungen

Die Resultate der Studie legen nahe, dass sowohl die tPRK als auch die PTK-PRK sichere und effektive Methoden zur Korrektur von Myopie darstellen. Die Wahl der einen oder anderen Methode kann somit von der Verfügbarkeit der Laserplattform, der individuellen Präferenz des Operateurs sowie patientenbezogenen Faktoren abhängig gemacht werden.

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*Ahmed Saad*