Real-world Comparison of StreamLight™ transepithelial PRK and Conventional PRK With Regard to Refractive Outcome, Wound Healing, Pain Intensity and Visual Recovery Time

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Research Article

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Abstract

Purpose

To compare clinical outcomes of single-step transepithelial photorefractive keratectomy (tPRK) and conventional photorefractive keratectomy (PRK) regarding refractive outcome, visual acuity, wound healing, pain intensity and visual recovery time.

Methods

In this prospective clinical observational study 200 eyes of 100 consecutive patients with mild to moderate myopia with or without mild astigmatism were included. One hundred eyes each were treated with StreamLight™ tPRK or conventional PRK with the WaveLight® EX500 excimer laser. Visual acuity (Decimal) was assessed preoperatively and at day 4, 7 and 6 weeks postoperatively. Wound healing (hours between surgery and complete epithelial closure) was monitored at the slit lamp. Subjective pain intensity level was evaluated by a numeric pain rating scale (0 – 15) at day 4.

Results

Visual recovery was significantly faster in the tPRK group. At days 4 and 7, the mean monocular UCDVA was significantly better in the tPRK group than in the PRK group (p < 0.001). Four days after surgery 72% of eyes in the tPRK group but no eye in the PRK had an UCDVA of 0.7 or better. At six weeks postoperatively, UCDVA of 1.0 or better was achieved in both groups. Complete epithelial wound closure was achieved significantly faster in the tPRK group (p < 0.0001) and maximum pain level within the first 4 days after surgery was significantly lower in the tPRK group (p < 0.0001). No patient had lost a line of BCVA and no complications or adverse effects were observed.

Conclusion

Both treatments offer a safe and effective correction of low to moderate myopia with and without astigmatism. However, StreamLight™ tPRK offers faster visual recovery and epithelial healing and is associated with less pain as compared to conventional PRK. It can therefore be considered a good treatment option for patients who refuse or are not eligible for Femto-LASIK, but at the same time demand a faster and more comfortable recovery time than conventional PRK can offer.

Introduction

The introduction of single-step transepithelial photorefractive keratectomy (tPRK) procedures in recent years has led to a renaissance of surface ablation treatments in refractive surgery. Since decades, photorefractive keratectomy (PRK) is a well-established and safe surface ablation technique to correct low to moderate myopia and astigmatism [1, 2]. Moreover, it is also suitable for patients who reject or are not eligible for laser in situ keratomileusis (LASIK), e.g. due to thin corneas or subtle topographic irregularities [3, 4]. Refractive outcomes after PRK are good and complications like corneal haze are rare.
However, a long visual rehabilitation period and considerable postoperative pain deter many patients from opting for PRK [7, 8]. Since a few years "no-touch" single-step tPRK procedures are available from various manufacturers and have proven to be effective and safe [9 - 10]. StreamLight™ is a novel, one-step tPRK procedure in which the epithelium is first removed by phototherapeutic keratectomy (PTK) immediately followed by PRK in a single procedure using the Wavelight EX500 excimer laser. Due to newly calculated nomograms, size and location of the PTK treatment zone are automatically aligned with the PRK ablation profile and centration is only required once in StreamLight™ procedure. Moreover, a multidimensional eye tracker is active throughout the complete procedure.

The purpose of our prospective observational study was to evaluate the clinical outcomes of StreamLight™ tPRK in daily clinical practice and compare them to those of conventional PRK regarding refractive outcome, visual acuity, wound healing, pain intensity and visual recovery time.

Methods

Study design and patients

This is a prospective clinical observational study including 200 eyes of 100 consecutive patients with mild to moderate myopia (-2.0 D to -6.0 D spherical equivalent) and mild (0.0 D to -2.5 D) astigmatism who underwent conventional PRK or tPRK at the Augenlaserzentrum Neu-Ulm, Germany between January and December 2019. After comprehensive information about risks and benefits of the two surgical techniques, patients were free to choose one of the two procedures. All patients provided a signed informed consent form for data collection, evaluation and publication. The research has been carried in accordance with the Declaration of Helsinki. All methods were performed in accordance with the relevant guidelines and regulations, although ethical approval was not required and deemed unnecessary according to national regulations of the Bavarian Medical Association (Bayerische Landesärztekammer (BLÄK) Ethikomission (ethics committee), Mühlbaurstraße 16, 81677 München), which states that study projects with anonymized data are not subject to consultation. All patients provided a signed informed consent form for data collection and consent to participate in this study with data evaluation and publication.

All patients qualified for surface ablation according to the German standards for surface ablation of the German Committee of Refractive Surgery (Kommission Refraktive Chirurgie) [12].

Exclusion criteria were unstable refraction, severe ocular surface disease, corneal epithelial pathology, keratoconus, any posterior segment pathology or any previous intraocular or corneal surgery. All patients were advised to discontinue contact lens wear for a minimum of 3 weeks prior to preoperative examination and treatment.

Pre- and postoperative assessments
Preoperatively, all patients underwent a complete eye examination including uncorrected distance visual acuity (UCDVA) and best corrected distance visual acuity (BCDVA) assessment, manifest refraction, autokeratometry, intraocular pressure measurement, and slit lamp examination to evaluate the anterior segment and the fundus. Visual acuity (at 5 m, decimal) and manifest refraction measurements as well as corneal topography assessment by Allegro Topolyzer-Vario (WaveLight, Erlangen, Germany) and Scheimpflug tomography examination by Allegro Oculyzer II (WaveLight, Erlangen, Germany) were performed by one experienced optometrist.

Postoperatively, slit lamp examinations were performed by one ophthalmologist at day 1, 2, 3, 4, 7, and 6 weeks after surgery. Monocular UCDVA was measured on day 4, 7 and 6 weeks postoperatively. Manifest refraction and binocular BCDVA were assessed at 6 weeks after surgery. Moreover, patients evaluated their subjective maximum pain intensity level within the first four days after surgery on a numeric pain rating scale (0-15) which was completed by the patients themselves. Accordingly, pain could be rated as low (1-5), high (6-10) or very high (11-15). Wound healing was followed during daily slit lamp examinations until day 4.

Surgical procedures

All surgical procedures were performed bilaterally at the same day, with the right eye being treated first by one single surgeon (HCG). The wavefront-optimized (WFO) ablation profile was planned using the standard planning software including WaveLight nomograms and was based on manifest refraction. In StreamLight™ procedures, a newly calculated shot matrix enables an equal ablation of the epithelium over the treatment zone (7mm for myopia and 9 mm for mixed myopic astigmatism).

In both groups standard wavefront optimization laser ablation profiles with a refractive ablation zone of 6.5 mm in all cases were applied and the use of Mitomycin C was avoided according to the recommendations of the German Committee of Refractive Surgery [12].

The standard preoperative procedure for both procedures was the same. Topical proparacaine hydrochloride 0.5% (Alcaine; Alcon Laboratories, Inc., Fort Worth, TX, USA) eye drops were instilled twice directly before surgery. In the PRK group, de-epithelialization was performed with a 9 mm rotating brush (Amoils Rotary Epithelial Scrubber, Innovative Excimer Solutions, Inc., Toronto, Canada) and remaining epithelial cells were removed using a dry PVA eye spear. Subsequently, PRK laser ablation was carried out followed by 1 minute of corneal and conjunctival cooling with ice-cold BSS administered with a syringe. In the tPRK group, conjunctiva and cornea were pre-cooled with ice-cold BSS from a syringe for 30 seconds. After removing excessive liquid from the conjunctiva and cornea with a dry PVA eye spear, de-epithelialization was performed using the StreamLight™ PTK mode for 22 - 30 seconds depending on preexisting astigmatism. StreamLight™ allows to individually determine the epithelial ablation depth between 45 µm and 65 µm after epithelial mapping. In our daily practice we usually work with an epithelial ablation depth of 55 µm. After the PTK mode, the cornea was checked and any remaining epithelial cells were removed mechanically with a dry PVA eye spear. After an interruption of around 10
seconds to cool down the cornea, PRK laser ablation was applied followed by 1-minute cooling of the cornea and conjunctiva with ice-cold BSS administered with a syringe. Following both laser procedures preservative-free Ofloxacin and corticosteroid eye drops were instilled, a pre-cooled soft bandage contact lens (Acuvue ®; Johnson and Johnson Vision Care, Inc., Jacksonville, USA) was placed on the cornea and preservative-free eye drops containing 0,15 % sodium hyaluronate were applied. The soft bandage contact lens was removed 4 days after surgery in both groups. Patients were advised to continue three times daily with preservative-free corticosteroid eye drops for 4 weeks and to regularly use preservative-free 0,15 % sodium hyaluronate eye drops at least 5 times per day.

Statistical analysis

Results are expressed as mean ± standard deviation. Data were analyzed using Statview 5.01 software for Windows (Abacus Concepts, Inc., Berkeley, California). For determining statistical significance between both groups, the non-parametric Mann-Whitney U test and the t-Test for independent samples were performed (p < 0.05 considered statistically significant).

Results

Demographic and baseline characteristics are displayed in Table 1. There was no statistically significant difference regarding demographic and baseline characteristics between the two groups (p > 0.05).

Table 1: Demographics and baseline characteristics

|                | PRK (n=100 eyes of 50 patients) | tPRK (n=100 eyes of 50 patients) |
|----------------|---------------------------------|----------------------------------|
| **Age (years), mean ± SD** | 27.2 ± 3.3                      | 27.7 ± 3.4                       |
| **Gender, n**  |                                 |                                  |
| Male           | 16                              | 20                               |
| Female         | 34                              | 30                               |
| **Refractive error (D), mean ± SD** | -3.24 ± 1.20                   | -2.77 ± 1.00                     |
| Sphere         | -0.71 ± 0.65                    | -0.64 ± 0.58                     |
| Cylinder       |                                 |                                  |
| **BCDVA (decimal), mean ± SD** | 1.17 ± 0.18                    | 1.11 ± 0.15                      |

BCDVA, best corrected distance visual acuity; D, diopter; UCDVA, uncorrected distance visual acuity; PRK, photorefractive keratectomy; tPRK, transepithelial photokeratectomy. SD, standard deviation.

Postoperative results are summarized in Table 2. Visual rehabilitation was achieved significantly faster in the tPRK group. At days 4 and 7, the mean monocular UCDVA (decimal) was significantly better in the
tPRK group than in the PRK group (p < 0.001), while six weeks after surgery both groups had achieved a comparable mean UCDVA of better than 1.0 (p > 0.05) (Fig 1). Four days after surgery 72% of eyes in the tPRK group had a UCDVA of 0.7 or more, while no eye in the PRK group reached that level. Up to one week postoperatively, the proportion of eyes with an UCDVA of 0.7 had further increased to 89% in the tPRK group and to 34% in the PRK group. BCDVA was similar in both groups six weeks after surgery and no patient had lost a line of preoperative BCDVA. The levels of accuracy of refractive correction were high, with no statistically significant difference between both groups regarding mean spherical equivalent off target at six weeks postoperatively (p > 0.05) (Fig. 2). The achieved SE was within 1.0 D of the intended SE for all treated eyes and within ± 0.5 D for 84% of eyes in the PRK group and within -0.25 D and + 0.5 D for 82% of eyes in the tPRK group.

Table 2: Postoperative results

|                               | PRK (n=100 eyes) | tPRK (n=100 eyes) | P value |
|-------------------------------|------------------|-------------------|---------|
| **UCDVA (decimal), mean ± SD**|                  |                   |         |
| Day 4                         | 0.53 ± 0.09      | 0.62 ± 0.17       | < 0.001 |
| Day 7                         | 0.63 ± 0.08      | 0.74 ± 0.18       | < 0.001 |
| 6 weeks                       | 1.1 ± 0.07       | 1.1 ± 0.07        | > 0.05  |
| **BCDVA (decimal), mean ± SD**|                  |                   |         |
| 6 weeks                       | 1.21 ± 0.16      | 1.18 ± 0.15       | > 0.05  |
| **Refractive error (D), mean ± SD, 6 weeks**| |                   |         |
| Sphere                        | - 0.23 ± 0.14    | - 0.21 ± 0.21     | > 0.12  |
| Cylinder                      | 0.12 ± 0.28      | 0.03 ± 0.21       |         |
| **Spherical equivalent off target** |                |                   |         |
| Pain Score* (0-15), mean ± SD | 10.8 ± 1.44      | 5.4 ± 2.84        | < 0.0001|
| **Epithelial healing time (hours), mean ± SD**| |                   |         |
|                               | 59.10 ± 6.79     | 45.76 ± 9.46      | < 0.0001|

BCDVA, best corrected distance visual acuity; D, diopter; UCDVA, uncorrected distance visual acuity; PRK, photorefractive keratectomy; tPRK, transepithelial photokeratectomy. SD, standard deviation.

Epithelial wound healing was achieved significantly faster in the tPRK group. Complete wound closure was observed in the tPRK group after in mean 45.76 ± 9.46 hours, whereas it took in mean 59.10 ± 6.79 hours in the PRK group (p < 0.0001) (Fig. 3). Maximum pain level within the first 4 days after surgery revealed significantly less pain in the tPRK group compared to the PRK group (p < 0.0001) (Fig 4). No
patient developed a postoperative corneal haze during the observation period and no other adverse effects or complications were observed.

**Discussion**

To the best of my knowledge, this is the first study to evaluate the clinical results of StreamLight™ tPRK based on Alcon/Wavelight ablation profile in patients with mild to moderate myopia with and without mild astigmatism compared to conventional PRK. The new StreamLight™ method requires only three parameters to calculate the WFO ablation profile: manifest refraction, optical zone and epithelial depth. This helps to reduce possible sources of error in the calculation of the ablation profile, especially in everyday hospital routine, and to implement efficient workflows and a very convenient calculation of the ablation profile.

The two patient groups examined in our study were comparable in terms of preoperative characteristics and reflect the typical patient population seeking for refractive correction. The key findings of our study are that both treatments provide safe and effective refractive correction, but StreamLight™ tPRK is superior to conventional PRK in terms of epithelial healing, postoperative pain and visual recovery time. This considerably increases comfort and may contribute to greater patient satisfaction with tPRK treatment.

The main reason for accelerated epithelial healing and reduced pain in the tPRK group could be the smaller epithelial defect. In conventional PRK the epithelial removal zone is larger than the ablation zone, which might delay re-epithelialisation, whereas in StreamLight™, the size of the epithelial removal zone matches the size of the ablation zone. This might contribute to a faster re-epithelisation. In addition, also the PTK treated stromal bed can have provided the ideal basis for a fast and firmly adherent re-epithelialisation. The shorter epithelial healing time after tPRK observed in our study has been shown in other clinical studies evaluating tPRK treatments performed with other nomograms and other laser systems. Fadlallah et al observed an average period to complete healing of 2.5 days in the tPRK group versus 3.7 days in the conventional PRK group while Naderi et al reported 2.9 days and 3.3 days respectively [11, 13]. Although these results were obtained in different studies and therefore cannot be directly compared, it still has to be noted that in our study complete closure of the epithelium after StreamLight™ tPRK was achieved in average after 46 hours, i.e. in less than two days. Another factor that may have contributed to faster wound healing after tPRK is significantly less pain. One of the most frequent complications after PRK is pain [14]. However, pain and wound healing are closely related and form a vicious circle: when there is pain, more inflammatory parameters are released through the tear film and the conjunctiva, which is thought to slow down wound healing. In addition, pain contributes to patients squeezing their eyes more often, which in turn mechanically impairs the newly forming epithelial cell layer. In order to minimize post-operative pain, our conventional PRK procedure includes the avoidance of alcohol for epithelial removal, direct cooling of the cornea after ablation and the use of a bandage contact lens. Nevertheless, StreamLight™ tPRK patients still experienced significantly less pain.
during the early postoperative period compared to PRK patients. In mean, the pain score of tPRK patients was 5.4, only half as high as the PRK patients' pain score of 10.8. This is in line with the results from other clinical studies on tPRK, indicating that postoperative pain after tPRK is lower compared to conventional PRK [10, 11, 13].

According to our patients, one of the main reasons for their high satisfaction with the Streamlight™ tPRK, in addition to the accelerated wound healing and significant pain reduction, was the rapid visual rehabilitation. Although patients in both groups achieve a very good mean UCDVA of over 1.0 after 6 weeks, visual acuity in the tPRK group is significantly better from day 4. Almost three-quarters of all tPRK eyes but none of the PRK eyes achieved an UCDVA of 0.7 or better four days postoperatively. For patients, this is a crucial visual threshold, because permission for car driving is only given from a UCDVA of 0.7 in Germany [15]. Moreover, the rapid visual recovery after StreamLight™ tPRK can - combined with clever planning of the procedure close to the weekend - help to ensure that patients only have to take one day off work. Especially for the mostly young, employed patients this is another a very important aspect to choose this procedure.

Our study has limitations that should be addressed. First, the rate of epithelial healing was not objectively assessed by an image analysis software. Secondly, a longer follow-up period is required to fully assess the development of visual acuity and refractive stability. However, the six-week follow-up period chosen in our study allows a proper evaluation visual recovery time, pain sensation and wound healing.

Overall, this study provides important insights from daily clinic routine with this novel tPRK method. Our results show that StreamLight™ tPRK is a safe and effective treatment option for the correction of low to moderate myopia, offering faster visual recovery and epithelial healing compared to conventional PRK, with less pain. It can therefore be considered a good treatment option especially for patients who refuse or are not eligible for Femto-Lasik, but at the same time demand a faster and more comfortable recovery time than conventional PRK can offer. To confirm these results, further prospective, randomized studies with longer follow-ups are required to evaluate the efficacy and safety of this procedure in more detail.

**Abbreviations**
Declarations

Ethics approval and consent to participate

Ethical approval was not required and deemed unnecessary according to national regulations of the Bavarian Medical Association (Bayerische Landesärztekammer (BLÄK) Ethikkommission (name of institutional review board, ethics committee), Mühlbaurstraße 16, 81677 München, Dr. med. Ulrike Artmeier-Brandt, E-Mail: u.artmeier-brandt@blaek.de Internet: www.blaek.de: “Study projects with anonymized data (no code list available, no personal reference can be established) are not subject to consultation”.

Link: http://ethikkommission.blaek.de/studien/sonstige-studien-15-bo/antragsunterlagen-primaerberatend

Patient consent to participate in this study:

All patients provided a signed informed consent form for data collection and consent to participate in this study with data evaluation and publication. The research has been carried out within an appropriate ethical framework in accordance with the Declaration of Helsinki

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to institutional policy but are available from the corresponding author on reasonable request.

Competing interests

The author has no financial or proprietary interest in any material or method mentioned.
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**Author contributions**

The author, Dr. Harald Gaeckle, was involved in data collection, performed data analysis and wrote the manuscript. The author has read and approved the final manuscript.

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**References**

1. Manasvee S. Kapadia, M.D., and Steven E. Wilson, M.D. One-Year Results of PRK in Low and moderate Myopia: Fewer Than 0.5% of Eyes Lose Two or More Lines of Vision. Cornea 2000;19:180-4.
2. McDonald MB, Liu JD, Byrd TJ, et al. Central photorefractive keratectomy for myopia: partially sighted and normally sighted eyes. Ophthalmology1991;98:1327–37.
3. Ambrósio R Jr, Wilson S. LASIK vs LASEK vs PRK: Advantages and indications. Semin Ophthalmol 2003;18:2-10.
4. Steiner R, Bafna S. Surgical correction of moderate myopia: Which method should you choose? II. PRK and LASIK are the treatments of choice. Surv Ophthalmol 1998;43:157-179.
5. Koshimizu J, Dhanuka R, Yamaguchi T. Ten-year follow-up of photorefractive keratectomy for myopia. Graefes Arch Clin Exp Ophthalmol 2010; 248: 1817– 1825.
6. Ang BCH, Foo RCM, Lim EWL, et al. Risk factors for early-onset corneal haze after photorefractive keratectomy in an Asian population: Outcomes from the Singapore Armed Forces Corneal Refractive Surgery Programme 2006 to 2013. J Cataract Refract Surg 2016;42:710-6.
7. Assouline M, Renard G, Arne JL, David T, et al. A prospective randomized trial of topical soluble 0.1% indomethacin versus 0.1% diclofenac versus placebo for the control of pain following excimer laser photorefractive keratectomy. J Ophthalmic Surg Lasers 1998;29:365-374.
8. McCarty CA, Garrett SK, Aldred GF, Taylor HR. Assessment of subjective pain following photorefractive keratectomy. Melbourne Excimer Laser Group. J Refract Surg 1996;12:365-369.
9. Jun et al. Comparison between Wavefront-optimized and corneal Wavefront-guided Transepithelial photorefractive keratectomy in moderate to high astigmatism. BMC Ophthalmology 2018; 18:154. https://doi.org/10.1186/s12886-018-0827-x
10. Adib-Moghaddam S, Soleyman-Jahi S, Moghaddam AS, et al. Efficacy and safety of transepithelial photorefractive keratectomy. J Cataract Refract Surg 2018; 44:1267–1279.
11. Naderi M, Jadidi K, Mosavi SA, Daneshi SA. Transepithelial Photorefractive Keratectomy for Low to Moderate Myopia in Comparison with Conventional Photorefractive Keratectomy. J Ophthalmic Vis Res 2016; 11: 358–362.
12. Kommission Refraktive Chirurgie (KRC). Bewertung und Qualitätssicherung refraktiv-chirurgischer Eingriffe durch die DOG und den BVA – KRC-Empfehlungen. Stand Februar 2019. 
https://www.aad.to/krc/qualit.pdf

13. Fadlallah A, Fahed D, Khalil K, Dunia I, Menassa J, El Rami H, et al. Transepithelial photorefractive keratectomy: Clinical results. J Cataract Refract Surg. 2011;37:1852–1857.

14. McCarty CA, Garrett SK, Aldred GF, Taylor HR. Assessment of subjective pain following photorefractive keratectomy. Melbourne Excimer Laser Group. J Refract Surg 1996; 12:365–369.

15. Lachenmayr B. Anforderungen an das Sehvermögen des Kraftfahrers. Dtsch Arztebl 2003; 100(10): A-624 / B-532 / C-503.