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Trans advanced surface laser ablation outcomes using SmartPulseTechnology for hyperopia

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Abstract

To evaluate the safety and efficacy of Transepithelial photorefractive keratectomy (TransPRK) for hyperopia using SmartPulseTechnology (SPT). The study included 108 eyes (56 patients) with hyperopia (0.50 to 7.25 diopters [D]), with or without astigmatism (0.00 to-3.00 D), who underwent single-step transepithelial PRK with Amaris 500 -Hz excimer laser (SCHWIND eye technology) solutions, Kleinostheim, Germany). Two groups were formed as hypermetropia below three and above 3. A 6-month follow-up was performed. Preoperative and postoperative visual acuity, preoperative and postoperative manifest refraction, and postoperative corneal hase were compared. Postoperative uncorrected visual acuity (UCVA) was 0.006 ± 0.018 logmar in group 1 and 0.022±0.034 logmar in group 2. When the groups were compared, there was a statistically significant difference between preoperative and postoperative UCVA. (p<0.01) The mean preoperative spherical equivalent value was 2.47±1.01 and 5.75±1.32 diopters, respectively. The mean postoperative spherical equivalent value was 0.16±0.24 and 0.32±0.27 diopters, respectively. No corneal hase was found in both group in the 6th postoperative month. There was no difference between the groups in the postoperative spherical equivalent. (p=0.374) TransPRK using SPT is promising in achieving the target refractive value in low and moderate hyperopia. This method allows patients to everyday-quickly return to normal life due to the rapid recovery process and low corneal damage rate.

Keywords: Transepithelial photorefractive keratectomy, hyperopia, surface laser ablation, SmartPulseTechnology

Introduction

The first laser procedure to correct vision defects was performed about 30 years ago. Initial studies using Photorefractive Keratectomy (PRK) aimed to correct low and moderate myopia [1-3]. PRK is a reputable technique for rectifying vision anomalies, and it's among the top surgical methods for laser-based eye correction. Complications that can occur during mechanical debridement in the PRK procedure and flap-related problems in Laser-assisted in situ keratomileusis (LASIK) have rekindled interest in alternative surface ablation techniques [4].

Transepithelial PRK, a laser-assisted removal of the epithelium, was introduced in the 1990s. After this method was introduced, various clinical studies and results have been reported [5,6]. The theory suggests that in PRK, delivering lower laser energy to the cornea's outer curve than its center leads to inconsistent depth of ablation and uneven stripping of the epithelium, contributing to less-than-ideal outcomes [7,8].

Recently, studies have been conducted on single-stage stromal ablation of transepithelial PRK with promising results. In these studies, epithelial removal was achieved using a depth of ablation based on a population-based epithelial thickness profile to adjust the energy delivered to the corneal center and periphery. Additionally, it has been hypothesized that it may reduce stromal dehydration [9,10]. A revolutionary software tool called "smart-pulse technology" was introduced in 2017 to expand the possibilities of the Amaris single-step platform.

The smart-pulse laser technology algorithm uses pulse technology software to reduce stromal bed abnormalities on the

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immediate operating surface. A more uniform corneal stromal surface is believed to facilitate quicker healing and prompt epithelial regrowth. Research indicates that transepithelial PRK is both reliable and effective for treating myopia. While correcting myopic refractive error, the corneal center is flattened; on the contrary, it is straightened in hyperopia. As a result, higher refractive regression and unpredictability of residual refractive error can occur [11,12]. Therefore, there are reservations about hyperopia refractive error. This study aimed to share the 6-month results of our patients with hyperopia who underwent transepithelial PRK using Smart Pulse Technology (SPT).

Material and Methods

In the study, patients who underwent transepithelial PRK using SPT between December 2018 and February 2020 in a single center and followed up for at least six months then were retrospectively analyzed. Informed consent was obtained from all patients. Ethics committee approval was obtained from the Fırat University Faculty of Medicine with the number 2022/6-34, by the principles of the Declaration of Helsinki.

Patients with mild to moderate astigmatism or hyperopia who were stable at least 12 months before the procedure were included in our study. The patients were intervened after taking a break from contact lenses for more than one month.

Patients meeting the following conditions were excluded from the study;

Coexisting Eye Disorders: We excluded individuals who were afflicted with eye conditions such as glaucoma or dry eye.

Ongoing Inflammation: Individuals demonstrating current inflammatory symptoms affecting the eye's front segment or surface were not considered.

Existing Systemic Illnesses: Any participant with diagnosed systemic medical conditions was deemed ineligible for the study.

Incomplete Correction from Previous Surgery: Patients who had not achieved optimal refractive correction in a prior surgery were removed from the study sample.

Retinal or Corneal Issues: Those with known retinal diseases or corneal ectasia were not considered eligible participants.

Severe Astigmatism and Keratoconus: Patients with high levels of astigmatism (greater than 3.00 D) or diagnosed with keratoconus were also excluded.

In the preoperative evaluation, the patients' age, gender, which eyes were intervened, uncorrected visual acuity, manifest spherical and cylindrical values, and presence of aberration were evaluated. In the postoperative period, uncorrected visual acuity, spherical and cylindrical values, and the presence of abnormality were assessed.

Local anesthetic drops were applied to perform the ablation procedure, then the periorbital area was cleaned with 10% povidone-iodine, draped, and speculum placed. A salt solution that was balanced was irrigated into the eyes. No procedure other than the integrated device system was used to remove the epithelium. Epithelium thichness were calculated according to the smartsurface nomograms. All ablations were performed with integrated CAM software with the Amaris 500-Hz excimer laser (SCHWIND eye-tech-solutions, GmbH, Kleinostheim, Germany).

The ablation profile was centered on the corneal vertex for eyes with a pupillary offset (distance between the pupil center and corneal vertex) larger than 0.2 mm. A pupil-centered profile was employed for all other eyes. In a single, continuous session, the excimer laser was used to carry out an aspheric aberration neutrally tuned profile that single-handedly removed both the epithelium and the stroma. With further adjustment of the differential ablation rate in the epithelium compared to the stroma, the population-based epithelium thickness profile ablation plan uses 55 m centrally and 65 m peripherally, distributing uniform laser energy across the whole corneal surface. The optical zone was from 6.7 to 7.5 mm. The smartsurface program calculates the optical zone for every patient individually. Two surgeons (MKK/SA) carried out all procedures. Standard procedure for all patients is to apply 0.02% mitomycin C (MMC)-soaked and squeezed sponge over the stromal bed for 10 to 20 seconds following ablation. A 100 mL solution of cold, balanced salt water was used to rinse the eye. Then a soft bandage contact lens was put on. The applied optical zone's mean standard deviation (SD) across all treated eyes was 7±0.22 mm overall. The postoperative medication; Dexamethasone Drop 3 times a day (Dexa-sine® Alcon Laboratories, Inc, Fort Worth, TX, USA), moxifloxacin (Vigamox® Alcon Laboratories, Inc, Fort Worth, TX, USA) four times a day, and 3% trehalose (Thealoz®, Laboratoires Théa, Clermont-Ferrand, France) six times a day was administered. After the operation, we used therapeutical contact lenses in all eyes for five days. We used Moxifloxacin for 14 days, dexamethasone for 21 days, and sodium hyaluronate and trehalose drops for 1 month. All patients were advised to use UV-450-blocker sunglasses for all outdoor activity. During clinical practice, topical steroidal agents and anti-glaucoma drugs can often be used together to treat refractive regression. However, in this study, anti-glaucoma drugs were not used to prevent posterior surface protrusion as hyperopia treatment was performed during refractive regression [13].

Following surgery, patients were checked on the first and third postoperative days, as well as every day after that until the epithelium had fully recovered. unless they have recovered by the third day. After a week, a month, three months, and six months, the patients were examined. Using a slit-lamp examination, we monitored the epithelium recovery during the initial follow-ups. Once the wound was fully healed, the recovery period was noted, and BCL was then withdrawn. For corneal clarity and the development of corneal postoperative haze anterior segment examination was performed. The anterior segment examination was performed to assess corneal clarity and postoperative haze

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developments. After the surgery, follow-up appointments were set for 1, 3, and 6 months later. According to the previously mentioned system [14], follow-up exams included CDVA, UDVA manifest refraction, and corneal haze grading using a slit lamp [14]. Low hyperopia (hyperopia 3.00 D) and moderate hyperopia (hyperopia>3.00 D) are the two categories into which we divided the eyes. To determine the variations between pre- and post-surgery results, we applied the paired Student's t-test or the Wilcoxon test when appropriate. The Mann-Whitney U test or the group t-test was employed, depending on the circumstance, to compare the variations between the two groups. It was agreed that a P value of 0.05 or less was statistically significant. All analyses were performed using SPSS software (version 23; IBM Corporation, Armonk, NY).

Statistical method

The package application SPSS 27.0 was used to analyze the data. In the descriptive statistics of the data, the mean, standard deviation, median (min-max), frequency, and percentage values were used. The Shapiro-Wilk Test was used to assess the variability of the variables. Quantitative data between two independent groups were analyzed using the Independent Samples t-Test and Mann-Whitney U Test. To ascertain the correlation between two independent variables, Pearson and Spearman's correlation analysis were used. The significance threshold of 0.05 was approved.

Results

108 eyes of 56 patients (35 men and 21 women) were included in the study. The mean±SD age of patients was 29.04±6.6 years. All of the eyes were primary hyperopia (range: 0.50 to 7.25 D), with or without (0.00 to -7.25 D) astigmatism, undergoing transepithelial PRK. Thirty-nine eyes (36.11%) had hyperopia more significant than 3.00 D.

Preoperative uncorrected visual acuity (UCVA) was 0.56±0.23 logmar in the hyperopia group with less than 3 D (group 1) and 0.89±0.22 logmar in the group with a higher than 3 D (group 2). When the groups were compared, there was a statistically significant difference between preoperative UCVA. ($p<0.01$) Postoperative UCVA was 0.006±0.018 logmar in group 1 and 0.022±0.034 logmar in group 2. When the groups were compared, there was a statistically significant difference between postoperative UCVA (<0.01).

The mean preoperative spherical value was 1.409±0.73 and 4.73±0.92 diopters, and the mean postoperative spherical value was 0.06±0.19 and 0.25±0.28 diopters, respectively. There was a statistically significant difference between postoperative and preoperative spherical values when both groups were compared ($p<0.05$).

The preoperative cylindrical values of both groups were -2.12±1.23 and -2.21±1.66 diopters, respectively. When the preoperative cylindrical values were compared, there was no statistically significant difference between the groups. ($p=0.669$) The postoperative cylindrical values of both groups were -0.2±0.23 and -0.14±0.35 diopters, respectively. When the postoperative cylindrical values were compared, there was a statistically significant difference between the groups. ($p=0.014$)

The mean preoperative spherical equivalent value was 2.47±1.01 and 5.75±1.32 diopters, respectively. The mean postoperative spherical equivalent value was 0.16±0.24 and 0.32±0.27 diopters, respectively. When both groups were compared, there was a statistically significant difference between preoperative spherical equivalent values. ($p<0.05$) However, there was no difference between the groups in postoperative spherical equivalent. ($p=0.374$) By the 6-month follow-up visit, 100% in group 1 and 95% in group 2 were within ±0.50 D of the targeted spherical equivalent. ($p=0.068$) If targeted spherical equivalent increased to ±1.00 D, 100% in group 1 and 98% in group 2 were within aimed post operative borders.

When aberrations were compared, there was a statistical difference between the two groups in the preoperative period. ($p=0.028$) After applying trans-PRK to both groups, there is a statistical difference between aberration. ($p=0.018$) These results suggest that patients whom have below 3 diopters benefited more in terms of aberation. Mitomycin-c was used in 59 patients in group 1 and 35 patients in group 2. There was no statistical difference between the groups. ($p=0.529$) No corneal hase was found in both groups at the 6th postoperative month. Table 1 summarizes all the data.

Table 1. Clinical and demographic characteristic of the patients by groups with statistical analysis

	Group 1 n: 69 eyes	Group 2 n:39 eyes	p values
Preoperative UCVA* (logmar)	0.56±0.23	0.89±0.22	**p<0.01**
Postoperative UCVA* (logmar)	0.006±0.018	0.022 ± 0.034	**p<0.01**
Mean preoperative spherical value	1.409±0.73	4.73±0.92	**p<0.01**
Mean postoperative spherical value	0.06±0.19	0.25±0.28	**p=0.008**
Mean preoperative cylindrical values	-2.12±1.23	-2.21±1.66	p=0.669
Mean postoperative cylindrical values	-0.2±0.23	-0.14±0.35	**p=0.014**
Mean preoperative spherical equivalent	2.47±1.01	5.75±1.32	**p<0.01**
Mean postoperative spherical equivalent	0.16±0.24	0.32±0.27	p=0.374
Preoperative aberration (y/n)	47/22	34/5	**p=0.028**
Postoperative aberration (y/n)	2/67	7/32 p=0.018	**p=0.018**
Rate of patients targeted 0.50 diopters at 6th month	100%	95%	p=0.068

Bold font indicates statistical significance, *UCVA: uncorrected visial acuity, Mann–Whitney U-test was used in the calculations

Discussion

This research showed that hyperopia (up to 7.25 D) could be effectively treated within 6 months using one-step combined transepithelial PRK. Within six months after-surgery, over 90% of the eyes treated achieved a refraction within±0.50 D of the intended outcome. During the follow-up period there was not any decrease in visual acuity or corneal hase observed. The first attempts to correct hypermetropia began when Lans examined thermokerato-plasty to increase the rabbit eyes corneal power as early as 1898. Thermokeratoplasty and other methods for treating hyperopia, such as radial keratotomy, hexagonal keratotomy, keratomileusis, keratophakia, epi-keratoplasty, and hyperopic automatic lamellar keratoplasty, have not, however, achieved satisfactory results due to low predictability, low stability, and reported significant regressions. Reports show that PRK and LASIK are good options for correcting mild to moderate hyperopia. However, due to considerable regression, poor predictability, and CDVA loss, the initial experience with hyperopia PRK and LASIK did not produce satisfactory outcomes [16,17]. This result was attributed to the smaller optic regions used in the studies and mis-centering of the treatment site. Small optical zones produce an abrupt transition between ablated and unablated areas, inducing aggressive tissue regeneration and regression [11]. Additionally, a high risk of decentration with small optical zonesresults from CDVA degeneration. This hypothesis was supported by other research utilizing bigger optical zones, and the outcomes were encouraging [18,19]. As a result, optical zones of 6.8 mm or greater were used in each of the procedures in our investigation.

High hyperopia has shown encouraging outcomes with clear lens extraction with intraocular lens implantation and phakic intraocular lens implantation, however it is important to be aware of the dangers associated with intraocular surgery complications. Recent studies with femtosecond-LASIK in hyperopic eyes have demonstrated better outcomes than hyperopic LASIK using a mechanical microkeratome [16,20]. Since its introduction in the early 1990s, transepithelial PRK has been utilized for refractive laser correction, and it has grown in popularity as a result of certain research [21,22]. Patients tolerate it well and find it to be both safe and highly effective [23]. By doing a smoothing PRK right away after the procedure, Vinciguerra et al. evaluated the decreasing stromal abnormalities and discussed the significance of a smooth postoperative corneal stromal bed [24,25]. In their experimental work on rabbits, Netto et al. used the excimer laser to inflict abnormalities at various depths in the corneal stroma. The findings of this investigation showed a significant correlation between stromal abnormalities and corneal clouding following PRK [26].

SmartPulseTechnology (SPT), a new Schwind Amaris laser platform software, reduces corneal irregularities after stromal ablation, enabling quicker corneal surface reepithelization and visual recovery, particularly in the first few days after treatment with a lower incidence of postoperative corneal haze.. To more accurately mimic the corneal shape, SPT employs a three-dimensional geometric model based on a fullerene structure. This method more accurately depicts the cornea's curvature, allowing the laser beam to safely ablate regions that are quite close to one another [27]. Vinciueraga et al.'s comparative experiments with 750 hz excimer laser and 1050 hz and spt software in myopic eyes indicated an improvement in uncorrected visual acuity at six months [28]. Because the reepithelialization period was quick and the risk of corneal hase was low, our study used SPT technology in all patients. Reepithelialization was finished in all of our patients by the third postoperative day. Additionally, none of our patients had any signs of corneal hase.

Adib-Moghaddam et al.'s study included 55 eyes with hyperopia, conducted at two centers using a single-stage transepithelial PRK system [29]. They shared their 12-month results in the study. In hyperopia with and without astigmatism, this 12-month trial showed the efficacy, predictability, and stability of single-step transepithelial PRK. In our research, transepithelial-PRK was performed using SPT on 108 eyes with and without hyperopia astigmatism in a single center. Despite the fact that our investigation was shorter in duration than Adib-Moghaddam et al.'s, it was found that refractive stability and predictability were high.

High levels of hyperopia are a challenge for excimer laser corneal refractive surgery. In comparison to myopic keratorefractive operations, the refractive and visual outcomes remain subpar. Although laser in situ keratomileusis (LASIK) is more frequently utilized, photorefractive keratectomy (PRK) and other surface treatments can also produce positive outcomes for hyperopia up to +4.5 dioptres (D). As the hyperopic correction rises, the predictability, safety, and refractive stability decrease. Recent studies using an 8 mm total ablation zone and 16 and 18 year follow-ups of hyperopic LASIK and hyperopic PRK demonstrated significant increases in hyperopic refractive error of 39% and 28%, respectively, compared to the error at one year [18,19].

There are some limitations in our study. First of all, our study was designed retrospectively. Secondly, we may have affected the formation of corneal haze due to the application of mitomycin-C to all cases. Another limitation is that it cannot be compared with different excimer laser methods and PRK without SPT mode [30].

Conclusion

Trans-PRK performed using SPT allows patients to return to everyday life quickly, as the recovery process is fast and the corneal hase rate is low. In addition, it is among the methods that can be safely preferred in suitable hyperopia patients, mainly due to its stability and satisfactory refractive results. However, comparative studies with other methods of longer duration are needed to evaluate the course of the efficacy.

Conflict of Interests
The authors declare that there is no conflict of interest in the study.

Financial Disclosure
The authors declare that they have received no financial support for the study.

Ethical Approval
Fırat University Non-Interventional Ethics Committee has obtained approval with the decision numbered 2022/06-34 dated 21.04.2022.

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