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One-year Outcomes of Photorefractive Keratectomy and Factors Influencing Its Efficacy

Fotorefraktif Keratektomide Birinci Yıl Sonuçlarımız ve Başarıyı Etkileyen Faktörler

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Öz

Fotorefraktif keratektominin (FRK) bir yıllık sonuçlarını değerlendirmek ve etkinliğini etkileyen faktörleri araştırmak için retrospektif bir çalışma yürüttük. Ocak 2021 ile Ocak 2023 tarihleri arasında miyopik, hipermetropik ve/veya astigmatik kırma kusurları nedeniyle FRK uygulanan 18-40 yaş arası 98 hastanın 196 gözünün tıbbi kayıtları ve ameliyat sonrası birinci yıldaki sonuçları çalışmaya dahil edildi. Ameliyat sonrası birinci yıldaki sferik eşdeğer (SE) ölçümünün ± 0.50 D içinde olması başarılı olarak kabul edilmiştir. Yaş, cinsiyet, ameliyat öncesi kornea kalınlığı, görme keskinliği, kırma kusurunun tipi ve büyüklüğü, astigmatizma tipi ve ortalama keratometri gibi başarıyı etkileyebilecek potansiyel faktörlerin başarıya etkisi araştırıldı. Tüm FRK ameliyatları aynı cerrah tarafından, WaveLight® EX 500 cihazı kullanılarak alkol destekli epitel soyma yöntemiyle gerçekleştirilmiştir. Ameliyat sonrası birinci yıl vizitinde, hastaların %80.1'inde ± 0.50 D içinde SE elde edildi. İntraoperatif veya postoperatif komplikasyon gözlenmedi. Ameliyat öncesi kornea kalınlığının FRK'nın birinci yıl sonuçlarını etkileyebilecek tek faktör olduğu saptandı. Çoklu model sonuçlarının analizi, ameliyat öncesi pakimetri değerindeki bir birimlik düşüşün başarı olasılığını 1.021 (1/0.979) kat artırdığını göstermiştir (p=0.001). Diğer bağımsız değişkenlerin başarı olasılığı üzerinde istatistiksel olarak anlamlı bir etkisi saptanmamıştır. (p>0.05).

Anahtar Kelimeler: Cerrahi Sonuç, Fotorefraktif Keratektomi, Refraktif Cerrahi

Abstract

We conducted a retrospective study to evaluate the one-year outcomes of photorefractive keratectomy (PRK) and investigate the factors affecting its efficacy, The medical records of 196 eyes of 98 patients aged 18-40 years who underwent PRK between January 2021 and January 2023 for myopic, hypermetropic, and/or astigmatic refractive errors, and follow-up examinations in the first postoperative year were included. Outcome measures included intraoperative and postoperative complications and objective refraction spherical equivalent (SE) at the postoperative 1st year visit. A one-year postoperative measurement of SE within ± 0.50 D was considered successful. Potential factors that may influence success, including age, sex, preoperative corneal thickness, visual acuity, refractive error type and magnitude, astigmatism type, and mean keratometry (Kmean) were investigated. All PRK surgeries were performed by the same surgeon, utilizing alcohol-assisted epithelial removal using a WaveLight® EX 500 device. At the first year visit, 80.1% of patients achieved SE within ± 0.50 D. No intraoperative or postoperative complications were observed. Preoperative corneal thickness was identified as the sole factor affecting PRK outcomes. Analysis of the multiple model results indicated that a one-unit decrease in the preoperative pachymetry value increased the probability of success by a factor of 1.021 (1/0.979) (p=0.001). The other independent variables did not exhibit a statistically significant effect on the probability of success (p>0.05).

Keywords: Surgical Outcomes, Photorefractive Keratectomy, Refractive Surgery

Introduction

Numerous individuals opt for refractive surgery as an alternative to wearing glasses or contact lenses, and outcomes have demonstrated significant improvement over the past decade (1). Althought laser in situ keratomileusis (LASIK) has emerged as the predominant technique, it is not without potential complications, including corneal ectasia, diffused lamellar keratitis epithelial ingrowth, and flap-related issues (2). Conversely, photorefractive keratectomy (PRK) is a well-established procedure that has been utilized for over two decades and presents a lower risk of complications owing to its flapless nature (3). Moreover, PRK may be more appropriate for certain individuals who are not optimal candidates for LASIK, such as those with thin corneas, corneal epithelial patologies, or those at risk of flap instability issues, including security force personnel and contact sports participants (4,5).

Although PRK is considered a safe refractive surgical procedure, it presents two primary disadvantages compared to LASIK and small incision lenticule extraction (SMILE). The first disadvantage is ocular discomfort during the initial postoperative period and the second is delayed visual rehabilitation (6). However, recent advancements have contributed to the renewed popularity of PRK and mitigated its disadvantages. These advancements include improvements in excimer laser technology, modifications to ablation profiles, utilization of mitomycin C (MMC), application of bandage contact lenses, implementation of pupil tracking systems, the elimination of cyclotorsion effects, and development of transepithelial technique (T-PRK) (7). Despite being the first laser assisted refractive surgery procedure to be used, the results of PRK are still being compared with those of

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LASIK and SMILE and are the subject of many studies (8-11).

The objective of this investigation was to present the postoperative PRK outcomes at 12 months and examine the factors influencing its efficacy.

Material and Method

The study was approved by Samsun Ondokuz Mayıs University Ethics Committee (Date: 31.10.2024, Decision no:B.30.2.ODM.0.20.08/589-629). The study was executed in compliance with the principles outlined in the Declaration of Helsinki. The medical records of 600 eyes of 300 patients aged 18–40 years who underwent PRK at our institution between January 2021 and January 2023, seeking vision correction for myopic, astigmatic, hyperopic or myopic-astigmatic refractive errors, were analyzed. The medical records of 196 eyes of 98 patients who underwent follow-up examinations during the first year and adhered to the prescribed medication regimens for the initial 1 month were included in the study. The medical records of patients who did not undergo follow-up examinations in the first year and those who underwent ocular surgical procedures other than refractive surgery (cataract, vitrectomy, glaucoma surgery, etc.) during this 1-year period were excluded from this study.

The patients underwent a comprehensive ophthalmologic examination, which included visual acuity assessment, corneal topography, pachymetry, intraocular pressure measurement, and fundoscopy, conducted by the same physician (KY) prior to the PRK procedure. The patients' refractive errors were determined through cycloplegic refractions obtained 45 min after the administration of 1% cyclopentolate drops, applied thrice at 5-minute intervals. Surgical intervention was planned with a postoperative target value of 0 diopter.

Those with a spherical value ≤ -0.50 D and minus cylindrical value ≥ -0.25 D were considered myopic; those with a spherical value ≤ -0.50 D and minus cylindrical value ≤ -0.50 D were considered myopic-astigmatic. Those with a spherical value ≥+1.00 D and minus cylindrical value ≥ -0.25 D were considered hyperopic; those with a spherical value ≥+1.00 D and minus cylindrical value ≤ -0.50 D were considered hyperopic-astigmatic. Patients with spherical refractive error between -0.50 and +1.00 and minus cylindrical value ≤-0.50 D were considered as astigmatism only. Types of astigmatism were defined based on the minus astigmatism axis of the eye: with the rule (WTR; cylinder axis 0° to 30° or 150° to 180°), against the rule (ATR; cylinder axis 60° to 120°) and oblique (OBL; cylinder axis 31° to 59° or 121° to 149°). A WaveLight® EX 500 (Alcon Inc. Ft Worth, Texas, USA) device was used for the excimer laser photorefractive keratectomy.

Surgical Procedure

All the PRK procedures were performed by the same surgeon (KY). Local anesthetic topical proparacaine 0.5% (Alcaine®, Alcon, Belgium) drops were applied twice in both eyes 10 minutes apart before the excimer laser. After surgical field disinfection, draping, and blepharostat application, 20% alcohol was instilled into the central cornea in an 8.5 mm ring. Following a 15-second application period, the alcohol was rinsed with 30 mL of balanced salt solution (BSS). Subsequently, the epithelium was mechanically debrided by using a standard hockey stick-shaped blade. After excimer laser photorefractive keratectomy, the corneal stroma was treated with mitomycin-C at a concentration of 0.02% for 30 s, and the eye was irrigated with 30 cc of BSS. Subsequently, a 0.5% drop of moxifloxacin (Vigamox®; Alcon Laboratories, Inc, Texas, USA) was instilled directly onto the cornea. At the end of the procedure, bandage contact lens was applied to both eyes of the patients as a bandage contact lens. Postoperative medication regimen consisted of loteprednol 0.5% (Lotemax®, Bausch&Lomb Inc. USA) five times a day in both eyes, moxifloxacin 0.5% (Vigamox®; Alcon Laboratories, Inc ,Texas, USA) five times a day in both eyes, and preservative-free artificial tears containing 0.15% sodium hyaluronate (Eyestil®; SIFI, Italy) eight times a day. On the 5th day, the bandage contact lenses were removed by the physician who performed the procedure (KY).

The patients were scheduled for follow-up examinations at 1, 3 and 6 months and 1 year postoperatively. The quantities and keratometric values measured after PRK were documented. Patients with objective refractive error of SE ≤ ±0.50 D were classified as emmetropic and successful in the first postoperative year. In the cohort that did not achieve emmetropia, potential factors influencing the outcome were investigated by analyzing correlations between age, gender, preoperative corneal thickness, amoun and type of refraction, and mean keratometry, preoperative visual acuity.

Statistical analysis

Data were analyzed using SPSS (version 23.0; IBM, Inc., Chicago, IL, USA). First, the data distribution was evaluated using the Kolmogorov–Smirnov test. Normally distributed data were expressed as mean ± standard deviation, and non-normally distributed data were expressed as median and maximum–minimum values. Categorical data were expressed as numbers and percentages. The effect of the independent variables on the probability of success was analyzed using univariate and multiple models with binary logistic regression.

Results

The mean age of the 98 patients (54 males, 44 females) included in the study was 28.11±6.16 years. Of the 196 eyes operated, 35 (17.9%) exhibited myopia, 11 (5.6%) astigmatism, 147 (75%) myopic astigmatism, and 3 (1.5%) hyperopic-astigmatic refractive errors. The mean preoperative SE was -3.14±1.61 D, with flattest keratometry values (K1) of 42.74±1.58 D, steepest keratometry values (K2) of 43.97±1.59 D, mean keratometric value (Kmean) of 43.36±1.55 D, and preoperative corneal thickness of 529.92±33.79 microns. The median best corrected visual acuity was 1.00 (range: 0.5-1.0). The demographic data are presented in Table 1 and 2.

Table 1. Preoperative characteristics of patients.

Factor	Minimum	Maximum	Mean	Std. deviation
Age	18	40	28.11	6.16
Sphere	-6.75	2	-2.56	1.63
Astigmatism	-4.25	0	-1.16	0.98
SE	-7.5	0.62	-3.14	1.61
Visual Acuity	0.5	1	0.97	0.09
K1	39.5	47.5	42.74	1.59
K2	40	48.25	43.98	1.59
K mean	39.87	47.87	43.36	1.55
Pachymetry	424	613	529	33.79

Table 2. Preoperative characteristics of patients.

Factor	Frequency (n)	Percent (%)
Male	44	44.9
Female	54	55.1
Myopia	35	17.9
Astigmatism	11	5.6
Myopia and Astigmatism	147	75
Hypermetropia and Astigmatism	3	1.5
Astigmatism Type		
With the rule	124	77
Against the rule	21	13
Oblique	16	9,9

The obtained success rate (SE ≤ ±0.50 D) was 80.1% at 12 months. No intraoperative or postoperative complications were observed, and corneal haze that resolved with medical treatment was not considered a complication. None of the patients required surgical intervention for haze management. At 12 months postoperatively, 157 of 196 eyes (80.1%) achieved a spherical equivalent (SE) of ≤±0.50 D, which was considered successful. None of the patients required retreatment during the first year of follow-up.

The effect of the independent variables on the probability of success was analyzed using univariate and multiple models with binary logistic regression. The univariate model revealed that a one-unit decrease in the preoperative pachmetry value increased the probability of success by a factor of 1.019 (1/0.981) (p=0.001). The other independent variables did not demonstrate a statistically significant effect on probability of success (p>0.05). Analysis of the multiple model results indicated that a one-unit decrease in the preoperative pachmetry value increased the probability of success by a factor of 1.021 (1/0.979) (p=0.001). Similarly, the other independent variables did not exhibit a statistically significant effect on the probability of success (p>0.05). Table 3 presents the results of the regression analysis.

Discussion

The objective of this study was to report the one-year outcomes of PRK and examine the factors influencing its efficacy. In a cohort of 196 eyes from 98 patients, 80.1% achieved a SE ≤±0.50 diopters (deemed successful) in objective refraction measurements at 1 year postoperatively. Independent variables, including age, sex, preoperative magnitude of spherical equivalent, type of refractive error, magnitude and type of astigmatism, and mean keratometry value, did not significantly affect the success rate of PRK. However, each 1 micron decrease in preoperative pachymetry was associated with a 1.02-fold increase in the likelihood of success.

Previous studies have demonstrated that individuals over 40 years of age have an increased likelihood of retreatment for PRK (12,13). In our investigation, age was not identified as a factor influencing the success of PRK, because the study population comprised patients aged between 18 and 40 years. This outcome aligns with the findings reported in the literature. In the present study, sex was not identified as a factor affecting PRK outcomes, consistent with previous studies (14,15).

Table 3. Binary logistic results of probability of success.

Factor	Probability of success		Univariate		Multiple	
	Unsuccessful	Successful	OR (%95 CI)	p	OR (%95 CI)	p
Age	28.28±6.32	28.07±6.14	0.994 (0.939-1.053)	0.847	0.971 (0.911-1.035)	0.371
Male	16 (18.2)	72 (81.8)	1.218 (0.598-2.479)	0.587	1.432 (0.610-3.361)	0.410
Female	23 (21.3)	85 (78.7)				
Sphere	-2.49±1.92	-2.58±1.57	0.969 (0.781-1.202)	0.773	1.000 (0.792-1.280)	0.955
Astigmatism	-1.44±1.11	-1.09±0.95	1.384 (0.993-1.929)	0.055	1.529 (0.955-2.447)	0.077
SE	-3.21±1.91	-3.12±1.54	1.034 (0.833-1.283)	0.762		
Kmean	43.06±1.23	43.44±1.62	1.176 (0.93-1.487)	0.176	1.186 (0.895-1.572)	0.235
Pachymetry	546.15±32.96	525.89±32.88	0.981 (0.97-0.992)	**0.001**	0.979 (0.967-0.992)	**0.001**
Visual Acuity	0.95±0.11	0.98±0.09	16.215 (0.694-378.715)	0.083	2.301 (0.025-212.796	0.718

OR (%95 CI): Odds ratio (%95 confidence interval), SE: spherical equivalent

Levinger et al. examined the influence of keratometry on wavefront-optimized myopic PRK outcomes in patients aged 18-40 years with varying corneal steepness (16). The patients were stratified into three groups (each group comprised 650 patients with comparable baseline characteristics) based on the steepness of the cornea (flat <42 D; normal 42 to 46 D; and steep >46 D). No statistically significant differences were observed between flat, normal, and steep corneas in terms of safety and efficacy. The success rates (% SE ≤ ± 0.50) were comparable among the three groups (73.9% vs. 74.2% vs. 74.6%). Keratometry does not appear to be a factor influencing the efficacy of PRK, which is consistent with the results of current study, and our success rates align with those reported by Levinger et al.

In a study by Tananuvat et al., twelve-month outcomes of wavefront-optimized PRK for high myopic correction (≥ 6.0 D) were compared with those of low-to-moderate myopia (<6.0D) (17). Researchers have reported that PRK is safe and efficacious for low, moderate, and high myopia correction. In contrast, Mohammadi et al. asserted that preoperative SE > -5.0 D was associated with an elevated risk of retreatment (18). The discrepancy in results between these two studies may be attributed to the utilization of different laser systems (Alcon-Wavelight® EX500 vs Bausch&Lomb-Technolas® 217z100) in PRK. Consistent with the findings of Tananuvat et al., our investigation revealed that the preoperative SE amount was not a factor influencing success when employing the Alcon-Wavelight® EX500 device. Katz et al. compared the outcomes of LASIK and PRK in myopic patients with astigmatism > 3D and reported that both procedures demonstrated comparable success rates for high astigmatism at 2 and 6 months postoperatively (19). Stojanovic and Nitter compared LASIK and PRK results in myopic patients with < 4D astigmatism utilizing 200 Hz flying-spot technology LaserSight LSX excimer laser and concluded that both procedures were safe, effective, and predictable, with stable results at 6 and 12 months postoperatively (20). The present study's observation that the magnitude and type of preoperative astigmatism did not influence the efficacy of PRK at 12 months postoperatively is consistent with the findings of previous reports (19-23). Abdel-Radi et al. reported their twelve-month outcomes of single-step T-PRK for moderate hyperopia and hyperopic astigmatism (24). The study population comprised 48 eyes of 30 patients with moderate hyperopia or hyperopic astigmatism with a cycloplegic SE refraction between +2.0 and +4.5 D who underwent single-step StreamLight® T-PRK using Wavelight EX500 excimer laser. At 12 months, 38 eyes (79.1%) exhibited a postoperative cycloplegic cylinder of 0.5 D or less. Their success rate is comparable to that of our study, which predominantly consisted of myopic and/or astigmatic cases. Our study included only three hyperopic astigmatic eyes, all of which achieved less than 0.5 D at postoperative 12 months.

Roszkowska et al. conducted PRK in sixty-eight eyes of 18 subjects with bilateral refractive amblyopia and 32 subjects with unilateral anisometropic amblyopia (25). At twelve months post-intervention, 64.7% of eyes exhibited uncorrected visual acuity that was superior to or equivalent to the Preoperative BCVA. Furthermore, 82.4% of eyes demonstrated an improvement of one or more lines in BCVA. Notably, none of the eyes experienced a reduction in BCVA. The researchers concluded that excimer laser refractive surgery is a safe and efficacious modality for the treatment of ametropic and anisometropic amblyopia in adults. In a review by Alió, PRK, laser epithelial keratomileusis (LASEK) and LASIK were demonstrated to be safe and efficacious in pediatric refractive surgery for the treatment of amblyopia (26). In our study, we found that preoperative visual acuity (amblyopia or not) did not affect the success of PRK in the first year in an adult population, and none of our patients lost any line of visual acuity, which is consistent with the literature.

In this study, the preoperative corneal thickness was identified as the sole determinant of success. The findings suggest that PRK demonstrated a higher success rate in patients with thinner corneas. Conversely, previous studies have not established a correlation between corneal thickness and PRK success. For instance, Mohammadi et al. examined risk factors associated with regression and undercorrection in PRK using a Technolas 217z100 excimer laser (Bausch & Lomb, Rochester, NY, USA) in patients with myopia or myopic astigmatism refractive errors (15). Their analysis indicated that the preoperative corneal thickness was not a risk factor for postoperative regression or undertreatment. Similarly, a study by Pokroy et al. investigated the factors influencing myopic PRK retreatment in a large cohort with myopic and astigmatic conditions using a Wavelight Allegretto 200 Hz excimer laser (Alcon Laboratories, Inc.). This study found no correlation between preoperative corneal thickness and retreatment rates (18). Naderi et al. explored factors associated with refractive error regression after PRK surgery in hyperopic and myopic astigmatic cases using Technolas 217z100 (Bausch & Lomb) excimer laser device (27). Consistent with the current study, they reported a negative correlation between corneal thickness and regression rate in males. The discrepancy between the present findings and those of previous reports may be attributed to variations in laser systems, optic zones, ethnic differences, and refraction types or magnitudes within the study populations.

Conclusion

In conclusion, our results for alchol-assisted PRK with MMC showed favorable results at 1 year. No intraoperative or postoperative complications were noted. Age, sex, preoperative SE amount, astigmatism, keratometry, visual acuity, and refractive error type of the patients were not found to be factors influencing the outcomes at postoperative 1 year. Preoperative corneal thickness was the only factor affecting the success rate. PRK remains a good option among refractive surgery procedures.

Study Limitations: The limitations of this study include, retrospective design, relatively small sample size and lack of a sufficient number of hyperopic patients. Our results are most applicable to young myopic and/or astigmatic patients, and caution should be used in generalizing to older or hyperopic populations.

Conflict of interest statement

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Ethics Committee Approval: Ethical approval was obtained from the Samsun Ondokuz Mayıs University Clinical Research Ethics Committee (Date: 31.10.2024, Decision no:B.30.2.ODM.0.20.08/589-629).

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