ORIGINAL

Photorefractive keratectomy in Hyperopia: Refractive outcomes and Patients' satisfaction

Queratectomía fotorrefractiva en hipermetropía: Resultados refractivos y satisfacción de los pacientes

Saman Mohammadzadehsaliani[1] , Neda Kargar Dehnavi[2] , Alireza Nouralishahi[3] , Hadis Kheradjoo[4]

1. MD Ophthalmology Department, Buraimi Hospital, Buraimi, Oman
2. MD, Ophthalmoloy Department, Shafa Hospital, Isfahan University of Medical Sciences, Isfahan, Iran,
3. Isfahan Eye Research Center, Isfahan University of Medical sciences, Iran; KIMS Health Hospital, Oman.
4. MD, Laboratory Department, Buraimi Hospital, Buraimi, Oman.

Corresponding author
Hadis Kheradjoo
E-mail: hadiskheradjoo@gmail.com

Abstract

Background: This study was aimed to describe the factors that influence on refractive outcomes and patients' satisfaction after hyperopic photorefractive keratectomy (PRK).

Methods: 80 patients including 133 eyes undergoing primary PRK with a refractive target of emmetropia were assessed in this study. Patients underwent refractometry and Ophthalmologic examinations before and after operation. Refractive outcomes and patients' satisfaction, as the main studied variables, were assessed in patients. Liner and logistic regression were use the relation between satisfaction, predictability (- 0.5D POST OP SE≤ 0.5 D) as an indicator of refractive outcome, efficacy index and safety index, both as the indicators of visual outcome, with other studied variables.

Results: The mean of uncorrected visual acuity (UCVA) (log MAR before operation was 0.47 and after that was 0.07 (P-value=0.0001). The mean of postoperative best corrected visual acuity (BCVA) was not significantly different from preoperative. The mean of defocus equivalent was 1.35 ±0.94 before operation and 0.22 ±0.49 after operation. The mean of safety and efficacy were 1.01 and 0.91, respectively. Mean of patients' satisfaction score was 41.41 ±2.6 of 52 (Total Score). About predictability, 72.2% of studied eyes had post op SE within ±0.5 D of the intended refraction. Preoperative BCVA, index of success of astigmatism surgery and absolute angle of error were correlated variables to predict safety and efficacy index. Corneal haze was significantly correlated to predict patients' satisfaction score. Preoperative UCVA was significantly correlated to predictability.

Conclusion: Our findings suggest that PRK is a safe, predictable, and effective with good patients' satisfaction way of correcting of refractive error in hyperopic patients.

Key words: Photorefractive Keratectomy, Hyperopia, Refractive Outcome, Satisfaction.

Resumen

Antecedentes: El objetivo de este estudio es describir los factores que influyen en los resultados refractivos y la satisfacción de los pacientes después de la queratectomía fotorrefractiva (PRK) para hipermetropía.

Métodos: En este estudio se evaluaron 80 pacientes que incluían 133 ojos sometidos a PRK primaria con un objetivo refractivo de emetropía. Los pacientes se sometieron a una refractometría y a exámenes oftalmológicos antes y después de la operación. Se evaluaron los resultados refractivos y la satisfacción de los pacientes como principales variables de estudio. Se utilizó la regresión lineal y logística para establecer la relación entre la satisfacción y la predictibilidad (- 0,5D POST OP SE≤ 0,5 D) como indicadores del resultado refractive y el índice de eficacia y el índice de seguridad, ambos como indicadores del resultado visual.

Resultados: La media de no correcta agudeza visual corregida (UCVA) (log MAR antes de la operación fue de 0,47 y después de ella de 0,07 (valor P=0,0001). La media de mejor agudeza visual corregida (MAVC) postoperatoria no fue significativamente diferente de la preoperatoria. La media del equivalente de desenfoque fue de 1,35 ±0,94 antes de la operación y de 0,22 ±0,49 después. La media de seguridad y eficacia fue de 1,01 y 0,91, respectivamente. La media de la puntuación de satisfacción de los pacientes fue de 41,41 ±2,6 de 52 (puntuación total). En cuanto a la predictibilidad, el 72,2% de los ojos estudiados tuvieron una SE postoperatoria dentro de ±0,5 D de la refracción prevista. La AVC preoperatoria, el índice de éxito de la cirugía de astigmatismo y el ángulo de error absoluto fueron variables correlacionadas para predecir el índice de seguridad y eficacia. La turbidez corneal se correlacionó significativamente para predecir la puntuación de satisfacción de los pacientes. La UCVA preoperatoria se correlacionó significativamente con la predictibilidad.

Conclusión: Nuestros hallazgos sugieren que la PRK es una forma segura, predecible y eficaz, con buena satisfacción de los pacientes, de corregir el error refractivo en pacientes hipermétropes.

Palabras clave: Queratectomía fotorrefractiva; Hipermetropía; Resultado refractivo; Satisfacción.

Introduction

Photorefractive keratectomy (PRK) is a laser surgical correction technique of refractive error first introduced in the mid-1980s as the preferred method to correct mild to moderate myopia[3] and in the mid-1990s it was used to correct hyperopia[2]. Although PRK is considered as safe and effective method in correction of refractive errors, it soon was replaced by other methods due to pain and discomfort in the first few days after surgery corneal stromal haze, relatively long time for corneal epithelium healing and visual recovery. LASIK was introduced as the preferred laser surgical method for refractive errors correction due to less post-operative pain and discomfort, rapid healing of corneal epithelium, fairly well vision on the first day after surgery, faster stability of refractive error and removal of haze[13].

Today PRK has become prevalent internationally and also in Iran as a safe, secure and efficient method because of lower visual threatening complication (less than 1%), improved surgical techniques and laser machines. However, PRK, like any other surgical procedure, may have some complications which should be aware by the surgeon and patient, especially that candidates of refractive surgery are not required to perform refractive surgery and surgery will not remove or reduce the threat to their vision[9]. For minimizing complications, the surgeon should not be involved in PRK operation without previous experience.

Although most of these surgical operations are with low complications, post-operative complains, lack of complete refractive error correction, treatment costs and etc. are factors which cause dissatisfaction of patients. Since surgical correction of hyperopia has high prevalence, and on the other hand, a few comprehensive study has been done on details of PRK surgeries in Hyperopic patients and the factors influencing patient satisfaction, conducting current study seems necessary for determining PRK operation results on Hyperopic patients and the factors influencing patient satisfaction after Photorefractive Keratectomy.

Materials and methods

It is an analytical descriptive study conducted in 2013-14 in Isfahan Feyz Medical Educational Center. Statistical population included Hyperopic patients undergoing Photorefractive Keratectomy using Technolas 217 Z100 admitted to the center. Needed sample size in this study was estimated using sample size estimation formula for prevalence studies considering confidence level 95% ($Z1-a/2 = 1.96$), and prevalence of Hyperopia was estimated at about 30 percent. And error level was considered as 0.05 and sample size was estimated as 80.

Patients undergoing Hyperopic eye correction surgeries using Photorefractive Keratectomy (PRK) method were selected and following taking consent of patients for participation in the study. topographic status of patients eyes was investigated using Pentacam prior to surgery. These patients underwent Ophthalmologic examinations and refractometry before and after operation in order to detect post operative corneal haziness. Then, questionnaire form for operation was given to the patients and they were trained regarding its completion. General information and demographic information of patients was collected in attachment of questionnaire form. Finally, changes were analyzed. The safety index was calculated as the postoperative Best corrected visual acuity (BCVA) the preoperative BCVA, while the efficacy index was calculated as the postoperative uncorrected visual acuity (UCVA) the preoperative BCVA.

Data analysis
Obtained information was analyzed using SPSS 22 software. Significance level was set as less than 0.05.

Results

Table I shows the characteristics of studied patients. The mean age of respondents was 33.98 years (range: 20-59). Of the 80 studied patients, 56.25% were male and 43.75% were female. Most of subjects reported fine vision. independency for their occupation. The mean of UCVA (log MAR) before operation was 0.47 and after that was 0.07 (P-value = 0.0001) which is shown in **figure 1**.

Table I: Characteristics of studied patients.

Variables	
Age (year)	33.98 ± 10.1
Gender (Male/Female)	45(56.25)/35(43.75)

Education
    Under diploma
    Diploma
    Academic
	
	 19(23.75)
	 46 (57.5)
	 15 (18.75)

Occupation
    Fine Vision Independent
    Fine Vision Indifferent
    Fine Vision Dependent
	
	 57 (71.25)
	 14 (17.5)
	 9 (11.25)

Preoperative UCVA	0.47 ± 0.19
Postoperative UCVA	0.07 ± 0.07
Preoperative BCVA	0.02 ± 0.04
Postoperative BCVA	0.02 ± 0.03
Preoperative Defocus Equivalent	1.35 ± 0.94
Postoperative Defocus Equivalent	0.22 ± 0.49
Surgically Induced Astigmatism	2.51 ± 1.51
Index of Success of Astigmatism Surgery	0.29 ± 0.37
Magnitude of Error	- 0.35 ± 0.56
Absolute Angle of Error	5.55 ± 14.69
Arithmetic Angle of Error	- 1.43 ± 15.64
Corneal haze	47(35.3)
Data presented as mean ± SD, or number (%)	

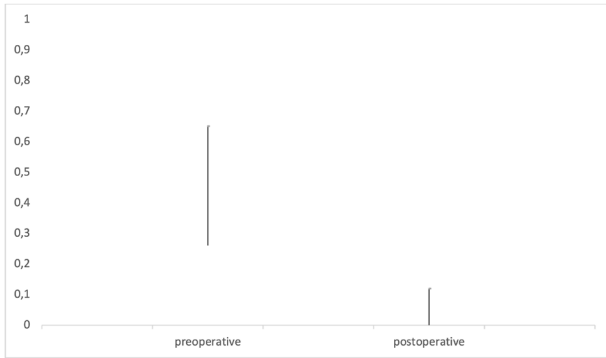**Figure 1:** Pre and post operative UCVA (P-value < 0.0001).

Table II shows results of safety index, efficacy index, predictability and patients' satisfaction in studied patients. As shown the mean of safety index was 1.01. The mean of efficacy index was 0.91. Also the mean of patients' satisfaction score in studied patients was 41.41 with SD, 2.6 of 52 as the total score. For predictability, SE of 96 of the 133 studied eyes (72.2%) were within ±0.5 D of the intended refraction and 37 eyes (27.8%) show SE out of ±0.5 D of the intended refraction (**Figure 1**).

Table II: Safety index, Efficacy index, Predictability, Patients Satisfaction in 133 eyes of 80 studied patients.

Variables	
Safety index	1.01 ±0.13
Efficacy Index	0.91 ±0.17
Predictability	
post op SE within ± 0.5 diopter post op SE out of ± 0.5 diopter	96(72.2) 37(27.8)
Patients Satisfaction	4.41 ±2.6
Data presented as mean ± SD, or number (%)	

To assess the correlation between safety index and studied variables, liner regression was used. Safety index was significantly correlated with preoperative BCVA (β. -1.25; 95% CI, 1.383 to -1.117; P-value = 0.000), surgically induced astigmatism (β.- 0.017; 95% CI, -0.031 to -0.002; P-value = 0.026), index of success of astigmatism surgery (β. -0.201; 95% CI, -0.25 to -0.152; P-value = 0.000), and absolute angle of error (β, 0.004; 95% CI, 0.002 to 0.005; P- value 0.000). (See **table III**). There was no significant correlation between safety index and other studied variables.

Table III shows results of the correlation between efficacy index and studied variables.

The results of the current study showed that there was no significant correlation between studied variables with patients' satisfaction score and just the corneal haze was the only variable that was significantly correlated with patients' satisfaction score (β. 1.741; 95% CI, -0.731 to 0.749; P-value= 0.011).

Table III: Safety index, Efficacy index, Predictability, Patients Satisfaction in 133 eyes of 80 studied patients.

Variables	B	95% CI	Standardized β	P-value
Age (year)	0.000	-0.003 to 0.003	-0.007	0.939
Gender (male)	0.01	-0.034 to 0.055	0.03	0.648
Education	0.29	-0.016 to 0.073	0.108	0.201
Occupation	0.004	-0.032 to 0.039	0.015	0.836
Corneal haze	-0.057	-0.12 to 0.005	-0.159	0.071
Preoperative UCVA	0.112	-0.015 to 0.239	0.123	0.083
Preoperative BCVA	-1.089	-1.345 to -0.832	-0.554	0.000
Preoperative spherical equivalent	0.017	-0.006 to 0.039	0.152	0.14
Surgically Induced Astigmatism	-0.025	-0.053 to -0.003	-0.217	0.76
Index of Success of Astigmatism surgery	-0.272	-0.366 to -0.177	-0.587	0.000
Absolute Angle of Error	0.004	0.002 to 0.007	0.324	0.002
Arithmetic Angle of Error	-0.001	-0.003 to 0.001	-0.081	0.204

The correlation between predictability as categorical dependent variable and other studied variables, logistic regression was used and results are shown in **table IV**.

Table IV: Correlation between predictability and studied variables by logistic regression.

Variables	B (SE)	OR	95% CI OR	P-value
Age (year)	0.027 (0.34)	1. 028	0.962 to 1.098	0.416
Gender (male)	-0.152 (0.476)	0.859	0.338 to 2.182	0.749
Education	-0.198 (0.445)	0.82	0.343 to 1.964	0.656
Occupation	0.369 (0.354)	1.447	0.723 to 2.894	0.297
Corneal haze	1.2 (0.67)	3.321	0.894 to 12.341	0.073
Preoperative UCVA	-3.476 (1.63)	0.031	0.001 to 0.754	0.033
Preoperative BCVA	-2.682 (2.528)	0.068	0.000 to 9.7	0.289
Preoperative spherical equivalent	-2.282 (2.25)	0.754	0.462 to 1.232	0.26
Surgically Induced Astigmatism	-0.158 (0.303)	0.854	0.471 to 1.547	0.602
Index of Success of Astigmatism surgery	-3.008 (2.03)	21.933	0.41 to 1172.162	0.128
Magnitude of Error	0.186 (0.528)	1.204	0.428 to 3.389	0.725
Absolute Angle of Error	-3.079 (0.052)	0.924	0.835 to 1.024	0.131
Arithmetic Angle of Error	1.017 (0.024)	1.017	0.97 to 1.066	0.486

Discussion

The results of our study suggest that PRK is a safe, predictable, and effective with good patients' satisfaction way of correcting of hyperopia. The mean preoperative SE in the Stidham et al. study[12] was 7.36 D and postoperative was 2.10 D. in Pacella et al. study[7], the mean preoperative SE was 3.50 D and postoperative SE after one year was

- 0.01 D. In Nucci et al. study[5] postoperative SE was 3.70 D. In other study preoperative mean of SE after PRK was 2.38 D[4]. The mean of defocus equivalent was 1.35 ±0.94 before operation and 0.22 ±0.49 after operation. The differences between these findings can be explain by number of studied patients and follow-up period, sample size in our study was more than other reported studies and we measured SE 6 months after operation whereas other studies reported SE after one year follow-up. Also, predictability in our study was 72.2% of studied patients that means they had postoperative SE within ±0.50 D, and 37.8% of our patients had postoperative SE out of ±0.50 D. Similarly, in Moore et al study[4] 91% of eyes were within ±0.50 D of the intended correction and in Autrata et al. study[1] 57% of PRK eyes were within ±0.5 D of the intended refraction. Predictability in Sia et al. study[11] in PRK at 1 month was 68.5%, and at 12 months postoperatively was 92.5%.

In the present study safety was evaluated by changes in BCVA, observed after operation. The mean of safety index in our study was 1.01 with SD of 0.13, which was similar to Autrata et al. study[1] who reported 1.069 for safety index 2 years after PRK, also the safety index in Moore et al. study[4] reported 0.995 one year after PRK. The PRK safety index in children reported by Paysse et al.[8] was 1.24. The safety index Sia et al.[11] after 1 month and one year follow-up were 0.61 and 1.29, respectively. As shown, despite the differences between follow-up periods the mean of safety index in our study is similar to previous reports. Therefore, according to these findings PRK in the treatment of hyperopic seems to be safe after two years of follow-up.

Efficacy was evaluated by UCVA after operation, the mean of Efficacy index in our study postoperatively was 0.91. In agreement with our results the efficacy index in Moore et al. study[4] at 12 months follow-up was 0.92. And in Autrata et al. study[1] after 12 months follow-up was 0.953. The PRK efficacy index in Paysse et al. study[8] was 1.12. The efficacy index after 1 month and one year follow-up reported in Sia et al.[11] were 0.39 and 0.67, respectively. So, these findings showed that PRK in the treatment of hyperopic seems to be effective.

It has been asserted that higher age groups may make PRK corrections less predictable[10]. Data from our study, presented here, would seem to agree with previously two published data by Moore et al.[4] with 12-month follow-up and O'Brart et al.[6] with 7.5 years follow-up[6,8], who also found no evidence of hyperopic shift or late regression after PRK in hyperopic patients with age advancing. Though, in the present study data were collected only 6 month after PRK and patient did not followed for more time.

Conclusion

PRK has good safety and efficacy index with high rate of predictability and present it as a satisfactory way to correct of hyperopic patients' refractive error.

Conflict of Interest
The authors declare that no competing interests exist.

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