Excimer Laser Photorefractive Keratectomy on High Myopia

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Abstrak

Penelitian retrospektif ini bertujuan untuk menyimpulkan hasil keratektomi fotorefraktif (KRF) laser excimer pada miopia tinggi. KRF laser excimer dikerjakan dengan cara zona ablasi tunggal dengan maksimal ablasi untuk koreksi 15 dioptri. Cara ini telah dilakukan pada 55 mata dengan miopia tinggi dari -10,00 hingga -24,50 D (dioptri); grup I: 49 mata dengan miopia -10,00 hingga -15,00 D, rerata -11,70 simpang baku (sb) 1,53; goup II: 6 mata dengan miopia -16,00 hingga -24,50 D. Pemeriksaan dilakukan pada akhir bulan ke 3, 6, 12, 18 dan 24 sesudah operasi. Hasil: pengamatan setelah 3 bulan pada grup I menunjukkan rerata refraksi subjektif -0,20 (sb 2,14); pada 6 bulan pasca operasi -0,60 (sb 1,53); pada 12 bulan -1,30 (sb 0,96); pada 18 bulan -1,11 (sb 1,64) dan 12 bulan -0,76 (sb 1,34). Pada grup II hasil sangat bervariasi. Haze terdapat pada 14 mata (25%). Kesimpulan : KRF untuk miopia tinggi adalah efektif untuk menurunkan miopia. Pada miopia lebih dari 15,00 D hasil sangat bervariasi. Regresi terdapat pada pengamatan lebih lama.

Abstract

Purpose: Retrospective study to summarize the results of excimer laser photorefractive keratectomy (PRK) on high myopia. Method: Excimer laser PRK was performed using a Telco excimer laser unit using standard program setting, single diameter ablation zone and set on maximal correction (15 D). This treatment was performed on 55 eyes with high myopia ranging from -10.00 to -24.50 diopters (D); group I: 49 eyes ranging from -10.00 to -15.00 D, mean -11.70 D; group II: 9 eyes ranging from -16.00 to -24.50 D. The follow up were done at the end of the 3rd, 6th, 12th, 18th and 24th month respectively. Results: 3 months after PRK the mean spherical equivalent correction (SEQ) was -0.20 D (sd 2.14); 6, 12, 18 and 24 months after PRK it was -0.60 D (sd 1.53); -1.30 D (sd 0.96); -1.11 D (sd 1.64); -0.76 (sd 1.34) respectively. In group II the results showed great variations. Haze were noted on 14 eyes (25%). Conclusion:PRK was effective to reduce myopia. Myopia of more than -15.00 D showed variable results. Regressions were noted in longer follow up.

Keywords : mean spherical equivalent correction, haze, regression

The development of keratorefractive surgery increased dramatically in the last decade. The improvement in equipment, surgical technique and results of surgery enhances public need and awareness as well its marketing. Patients seek surgical treatment as an alternative instead of glasses and contact lenses.

The excimer laser photorefractive keratectomy (excimer laser PRK) was rapidly used as a developing new technology to correct myopia since Trokel et al¹ introduced excimer laser in 1983. Many researches have been done to see the effect of excimer laser PRK on animal cornea²⁻⁸ as well as on human cornea.⁹⁻¹¹ Previous reports¹²⁻¹⁵ demonstrated the efficacy of excimer laser in the treatment of low and high myopia, and corneal scars. Recently some excimer laser instru-

Department of Ophthalmology, Faculty of Medicine, University of Indonesia/Dr. Cipto Mangunkusumo Hospital, Jakarta, Indonesia ments have been approved by the FDA for phototherapeutic keratectomy (PTK) and photorefractive keratectomy (PRK) to correct myopia. However, the depth of ablation in excimer laser PRK on high myopia has many problems in regression, and wound healing process of the epithelium and corneal stroma.¹⁴

This study is a retrospective study and aims to summarize the results of excimer laser PRK on high myopia with 24 months follow up.

METHODS

The data was collected from the Jakarta Eye Center from March 1993 through August 1994. During this period 55 eyes were treated for high myopia (range -10.00 to -24.50 D). The data was divided into two groups. Group I consisted of 49 eyes having the following characters: preoperative mean spherical equivalent was -11.70 (sd 1.53, range -10.00 to -15.00 D); preoperative mean best corrected visual acuity

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was 0.8 (range 0.6 to 1.0). Group II consisted of 6 eyes having the following characters: myopia ranged from -16.00 to 24.50 D; preoperative best corrected visual acuity ranged from 0.3 to 0.7. The mean age was 31 years with a range of 20 to 43 years. Prior to excimer laser procedures all patients were informed about the predictable results of PRK on high myopia, its course and complications. All patients had routine preoperative examination including: pachymetry, visual acuity, refraction, tonometry, keratometry, slitlamp examination and corneal topography. Preoperative pachymetric examination should show more than 500 micron. Patients with the sign of keratoconus were excluded.

PRK procedures were performed with a 193 nm argon fluoride Telco excimer laser unit (Lion's Eye Institute Perth Australia). After instillation of topical anesthesia (0.5 % tetracaine), delineation of the treatment area using a 7.0 mm diameter alcohol-paper was done for 30 second, then the epithelium was removed with a spatula. During the procedure, the patient was asked to fixate his/her sight on the fixation light within the operating microscope. The two HeNe beams were focused to the central of the surface of the cornea with the pupil as the guideline. The maximum ablation was set to correct 15.00 D which was equal to 150 micron ablation depth using a single 5.6 mm ablation diameter.

Topical antibiotic (0.5 % chloramphenicol) eye drop was administered four times a day until the epithelium healed. Disposable contact lens was placed if the epithelium did not heal within 4 days.

Topical 0.1 % fluoromethalone in combination with neomycine (FML Neo) treatment was started four times a day after the epithelium had completely healed and tapered off over three months.

Post operative evaluation including evaluation on visual acuity, refraction, tonometry, slitlamp and topography were done at the first day through the third day, the end of the first week, second week, first month, third month, sixth month, twelfth month, eighteenth month and twenty fourth month respectively. The corneal haze was classified as grade 0, +0.5, +1, +2, and +3. Grade 0 means no haze, +0.5 means very mild subepithelial haze that is visible with retro illumination light and without visual disturbance; +1 means subepithelial traces or reticular haze, visible with direct light without functional disturbance; +2 means subepithelial, reticular or punctuate opacity with direct light causing functional disturbance; +3 means stromal scarring with direct light, causing reduced visual acuity.¹⁴

RESULTS

The majority patients had already re-epithelized within 72 hours. Only two eyes (1%) showed incomplete re-epithelization and treated with bandage soft contact lenses. Patients had lexperienced pain and tearing since the first through the third day and they feeled discomfort before the epithelium had completely healed. There was no infection in any cases.

Group I

Forty-nine eyes in group I have been followed up for three months. The preoperative mean spherical equivalent was -11.70 (sd 1.53, range -10.00 to -15.00D). The mean spherical equivalent refraction after treatment was -0.20 D (sd 2.14, range + 6.50 D to -7.00 D); mean visual acuity 0.8 (range 0.2 to 1.0); mean intraocular pressure 15.3 mmHg (sd 2.3). Three eyes showed scar (haze +2), seven eyes showed haze +1 and four eyes showed haze + 0.5 (Table1).

 Table 1. The results of PRK on 49 eyes in group I at 3-month follow up

Pre ope	rative	3-month follow up					
mean	visus	mean seq	visus	Haze grade			
			VISUS	0	+0.5	+1	+2
-11.70	0.8	-0.20	0.8	35	4	7	3

seq = spherical equivalent correction

Forty-nine eyes in group I have been followed up for six months. The preoperative mean spherical equivalent was -11.70 D (sd 1.53, range -10.00 to -15.00). The mean spherical equivalent refraction after treatment was -0.60 D (sd 0.19, range +0.70 to -5.00 D); mean visual acuity 0.8 (range 0.3 to 1.0); mean intraocular pressure 14.8 mmHg (sd 1.9). Three eyes lost one line of snellen chart best corrected visual acuity and showed corneal scar (haze +2), seven eyes showed haze +1 and four eyes showed haze + 0.5 (Table 2).

 Table 2.
 The results of PRK on 49 eyes in group I at 6-month follow up

Pre ope	rative		6-month follow up					
mean	visus	mean seq	visus		grade	de		
	(10ub		VISUS	0	+0.5	+1	+2	
-11.70	0.8	-0.60	0.8	35	4	7	3	

seq = spherical equivalent correction

Forty-four eyes out of forty nine eyes in group I were able to be assessed at the end of the twelfth month. Preoperative mean spherical equivalent was -11.65 (sd 1.54, range -10.00 to -15.00 D). The mean spherical equivalent refraction after treatment was -1.30 D (sd 0.96, range +1.00 to -5.00 D). Mean visual acuity 0.8 (range 0.5 to 1.0). Mean intraocular pressure 14.2 mm Hg (sd 1.7). Three eyes lost one line of snellen chart best corrected visual acuity and showed significant corneal scar (haze + 2), five eyes showed haze +1 and four eyes had haze + 0.5 (Table 3).

Table 3. The results of PRK on 44 eyes in group I at 12-month follow up

Pre operative			12-month follow up					
				Haze grade				
mean	visus	mean seq	visus	0	+0.5	+1	+2	
-11.65	0.8	-1.30	0.8	32	4	5	3	

seq = spherical equivalent correction

Twenty-eight out of forty nine eyes in group I were able to be assessed at the end of the eighteenth month. Preoperative mean spherical equivalent was -11.86 (sd 1.71, range -10.00 to -15.00 D). The mean spherical equivalent refraction after treatment was -1.11 D (sd 1.64, range +0.75 to -5.00 D). Mean visual acuity 0.8 (range 0.6 to 1.0). Mean intraocular pressure 13.9 mmHg (sd 1.6). Two eyes lost one line of snellen chart best corrected visual acuity and showed significant corneal scar (haze +2), four eyes showed haze +1 and one eye showed haze + 0.5. (Table 4).

Seventeen eyes out of forty nine eyes in group I were able to be assessed at the end of the twenty-fourth month. Preoperative mean spherical equivalent was -12.32 D (sd 0.48, range -10.00 to -15.00 D). The mean spherical equivalent refraction after treatment was -0.76 D (sd 1.34, range +0.75 to -5.00 D). Mean visual acuity 0.8 (range 0.6 to 1.0). Mean intraocular pressure 14.1 mmHg (sd 1.6). One eye showed significant corneal scar (haze+2) and lost one line of snellen chart best corrected visual acuity, one eye showed haze +1 and one eye showed haze + 0.5 (Table 5).

Table 4. The results of PRK on 28 eyes in group I at18-month follow up

Pre operative			18-month follow up					
				Haze grad			e	
mean	visus	mean seq	visus	0	+0.5	+1	+2	
-11.86	0.8	-1.11	0.8	21	-1	4	2	

eq = spherical equivalent correction

Table 5. The results of PRK on 17 eyes in group I at24-month follow up

Pre operative			24-month follow up						
hu biya biya		-153-40		Haze grade					
mean	visus	mean seq	visus	0	+0.5	+1	+2		
-12.32	0.8	-0.76	0.8	14	- 1	1	1		

seq = spherical equivalent correction

Group II

The individual results of PRK with maximal correction of 15 D on 6 eyes in group II were showed in table 6. The results showed that the majority cases were still under corrected. Only one eye was over corrected. We found haze +0.5 on 3 eyes and haze +3 on one eye. The retreatment was not performed, because the pachymetry of those eyes was less than 400 microns.

Table 6. Individual data of the results of PRK on Group II at 3, 6, 12, 18 and 24-month follow up

Pre	op	3 mo	nths	6 mo	nths	12 mo	onths	18 moi	nths	24 mo	nths	haze
D	v	D	v	D	v	D	v	D	V	D	v	1.000
-24.50	0.4	- 9.00	0.3	-10.00	0.4	-10.00	0.4	-10.00	0.4	-10.00	0.4	+0.5
-22.00	0.3	-11.00	0.3	-11.00	0.3	-11.00	0.3	-11.00	0.3	-11.00	0.3	+0.5
-20.00	0.4	-12.00	0.4	-13.00	0.5							+0.5
-18.00	0.4	- 1.75	0.7	- 1.75	0.7	- 1.75	0.7	- 1.75	0.7	- 1.75	0.7	
17.00	0.6	+ 3.75	0.7	+ 2.00	0.7							
-16.00	0.7	-12.00	- 0.5	-11.00 =	0.5		0.5	-11.00	0.5	-11.00	0.5	+3

V = visual acuity, D = myopia in diopter

Correlation between haze and best corrected visual acuity

Two eyes showed delayed epithelium healing and were treated with disposable contact lenses. One eye lost two snellen lines best corrected visual acuity after the treatment and it had significant stromal scarring (haze +3) in group II (table 6), 3 eyes lost one line best corrected visual acuity and showed corneal scar (haze +2) in group I and 7 eyes showed haze +1 with the same best corrected visual acuity before and after treatment. Forty six eyes had same best corrected visual acuity before and after treatment. Four eyes gained three lines and one eye gained two lines of best corrected visual acuity after treatment.

Astigmatism correction

The correction of astigmatism in group I: pre-operative mean cylinder was -1.27 (sd 0.91, range 0 to 3.00 D), at 3-month follow up it was -1.03 (sd 0.87, range 0 to -3.50 D). In group II with maximal spherical equivalent correction 15.00 D: pre-operative mean cylinder was -1.50 (sd 1.23, range 0 to 3.00 D), at 3-month follow up it was -1.33 (sd 0.98, range 0 to - 2.50 D) (table 7).

Table 7. Corre	ection of astigm	natism at 3-mor	th follow up
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Gre	oup I	Group II			
Pre op mean cylinder	Post op mean cylinder	Pre op mean cylinder	Post op mean cylinder		
-1.27 ± 0.91	-1.03 ± 0.87	-1.50 ± 1.23	-1.33 ± 0.98		

DISCUSSION

The success of refractive corneal surgery should fullfil the following criteria: effective and predictable result, long term stability, safety and patient's satisfaction. The recent reports of PRK on high myopia showed a large variation on results and regression.^{16,17} Technology improvement in homogeneity of the beam, better calibration, technique of ablation using multiple ablation zones has improved the surgical outcome and minimized the complication rate in high myopia.¹⁷

Efficacy

The results of group I showed that the mean best corrected visual acuity was similar between preoperative and postoperative at any time of follow up. Mean spherical equivalent refraction showed some regression on the mean spherical correction which was -0.20 D at 3-month, -0.60 D at 6-month, -1.30 at 12-month. -1.11 at 18-month and -.076 at 24-month follow up respectively; the overall range was +6.5 to -7D and haze was +0.5 to +2 according to the regression level (Table 1 to 5). I found that the refractive results of patients with preoperative myopia of more than 15 D were undercorrected (Table 6). It is agreed that the upper limit of PRK on high myopia is still unknown, but the retreatment was not performed because the pachymetry was less than 400 microns. The procedure in retreatment consists of initial photorefractive keratectomy to eliminate the epithelium, corneal scar or haze and subsequent photorefractive keratectomy of determined power to correct the residual myopia.¹⁸ Retreatment and first treatment in high myopia might require more than 150 microns ablation depth. The ablation depth require more than 100 micron stromal removal depending on the corneal scar, epithelium thickness and correction of the residual myopia. Prof Jose Barraquer, a pioneer in keratomeulisis suggested that stromal removal should not exceed 150 microns (30 % of the corneal thickness) to avoid corneal ectasia. Patients with high myopia of more than -15.00 D showed unpredictable results (Table 6). PRK on high myopia have two major problems: corneal wound healing and regression. Thus the clear lens extraction with intraocular lens implantation or Lasik (laser assisted in situ keratomeulisis) procedure was strongly suggested. Phototherapeutic keratectomy (PTK) is suggested to eliminate subepithelial scar (haze) to improve visual acuity.

The results of correction on astigmatic myopia with pre-operative astigmatism maximum of -3.00 D is still unsatisfactory (table 7). Some patients showed postreatment induced astigmatism maximum of -2.50 D. Therefore centration of the ablation is very critical in PRK for high myopia. Photorefractive keratectomy (PRK) to correct myopia uses a circular beam of varying diameter. A cylindrical ablation can be achieved by using a slit shaped or an elliptical beam. All procedures to correct myopic astigmatism use the elliptical beam program in the Telco excimer laser unit. The procedure was called photoastigmatic refractive keratectomy (PARK).¹⁹

Predictability

The predictability of correction in the two groups was showed in the scatter diagram (Figures 1 and 2).

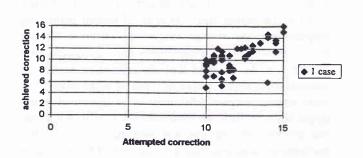


Figure 1. Attempted and achieved spherical correction in myopia of 10 to 15 D

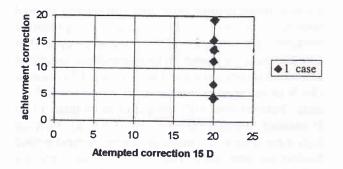


Figure 2. Attempted and achieved spherical correction in myopia of more than 15 D

The scattergrams showed that the majority cases were undercorrected. The lower myopia was less undercorrected compared to the higher myopia.

Safety and stability

The intensity of haze had an effect on the extent of regression.¹⁴ The results of this study showed minimal regressions when 5.6 mm single ablation technique of PRK was used. Regressions have been observed in high myopia from the beginning of excimer laser PRK.^{20,21} The smoothness and integrity of the corneal healing depends on the quality of the beam of the excimer laser unit and the degree of intended correction of myopia and/ or diameter of ablation zone.

The ablation depth is the main factor in regression after PRK in myopia. Larger ablation zone increases the ablation depth of tissue removal. However, larger ablation zone may cause gradual change of the slope at the edge of the wound. This phenomena will cause less initial epithelial migration and hyperplasia.²² In smaller ablation zone there will be less tissue removal, but this was not effective to reduce high degree myopia. Small ablation zone will result in a steep slope and will stimulate epithelial migration and hyperplasia, thus resulting regression. Scanning with tapered transition zone produces a smoother edge curvature and it reduces haze and regression.²⁰ The usage of topical steroid after PRK is controversial. The majority surgeons use topical steroid as a routine treatment, but some investigators reported an equal good visual outcome of treatment without topical steroid or any other anti inflammatory regimens.²³

Based on this study, corneal wound healing did not pose many problems. There were only two eyes which showed delayed re-epithelization and were treated using bandage contact lenses. The single 5.6 mm diameter ablation zone and the quality of the beam used in the excimer laser unit was effective in producing smooth and integrated corneal wound healing.

Patient's satisfaction

The mean best corrected visual acuity were similar before and after treatment in group I (Table 1 to 5) and group II. There were very view of patients who had lost Snellen line best corrected visual acuity. In group I three eyes with haze +2 lost one line best corrected visual acuity, where as in group II one eye with haze +3 lost two lines best corrected visual acuity (Table 6). All patients with haze more than +1 showed regression. The majority patients showed no changes in mean best corrected visual acuity between preoperative and postoperative. Some patients gained 2 to 3 lines best corrected visual acuity.

CONCLUSION

Excimer laser PRK using single ablation zone with maximal 15.00 D correction is safe and effective to reduce myopia. The majority cases were still undercorrected. In lower degree myopia it showed less undercorrection and regression compared to higher myopia. Myopia of more than 15 D showed variable results. Long term observation is needed.

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