

## Double-pass Excimer Laser Photorefractive Keratectomy: Treatment in 62 Eyes with High Myopia

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To evaluate the efficacy and safety of Excimer Laser Photorefractive Keratectomy (PRK) on the correction of high myopia, we performed planned double-pass PRK procedure at the same session on 62 eyes of 55 patients with myopia ranging from  $-6.30\text{D}$  to  $-15.25\text{D}$  (mean,  $-9.94\text{D}$ ). In the first pass, a myopic correction of  $-6.00\text{D}$  with a 4.5 millimeter ablation zone was performed, and immediately after, a second correction of remaining myopia with a 5.0 millimeter ablation zone was performed. Attempted correction ranged from  $-6.30\text{D}$  to  $-9.50\text{D}$  (mean,  $-8.70\text{D}$ ). The eyes were divided into two groups which were  $-10.50\text{D}$  or less (group A), and higher than  $-10.50\text{D}$  (group B). All the eyes received topical corticosteroid therapy postoperatively.

One year after double-pass PRK, uncorrected visual acuity in group A and B improved to 20/40 or better in 84.0%, and 73.3% of the eyes and to 20/30 or better in 75.0% and 33.3% of the eyes respectively. The mean refractive errors at 12 months after PRK were  $-0.3 \pm 1.6\text{D}$  in group A, and  $-1.5 \pm 2.1\text{D}$  in group B. The percent of achieved correction within  $\pm 1.0\text{D}$  were 70.8% in group A, and 46.7% in group B 12 months after surgery. The epithelium healed by three days and there were no corneal erosions. Corneal haze (Grade 2 or more) was seen in 9.0% in group A and 36.4% in group B at 12 months after PRK.

A planned double-pass PRK is a promising approach to correct high myopia (up to  $-10.50\text{D}$ ), but long-term follow up will be required.

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**Key words:** excimer laser, high myopia, photorefractive keratectomy

### INTRODUCTION

Photorefractive keratectomy (PRK) using the argon fluoride excimer laser is now an efficient and

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safe procedure for correcting low to moderate myopia. Because higher myopic correction needs a deeper corneal ablation, it may cause more corneal opacity, greater regression and poorer visual acuity after PRK,<sup>1</sup> and have higher possibilities of intraocular pressure rise due to the prolonged use of corticosteroids. In addition, individual variations in response to the PRK are more marked in patient with high myopia.<sup>2</sup> There have been a few reports showing the results of the double-pass correction of high myopia over than  $-6.00\text{D}$  using Summit excimer laser system.<sup>3-5</sup> The purpose of this study is

to present the data of effectiveness and stability of PRK in 62 high myopic eyes which underwent double-pass PRK.

## PATIENTS AND METHODS

All the treatment were performed with a Excimer Laser (Excimer UV 200LA, Summit Technology, Inc., Waltham, MA) between May 1992 to February 1994. The study population included 31 women and 24 men (62 eyes) with ages ranging from 20 to 49 years (mean, 27.3). The preoperative myopia ranged from  $-6.30\text{D}$  to  $-15.25\text{D}$  (mean  $\pm$  SD,  $-9.94 \pm 2.08\text{D}$ ) (Fig. 1). Patients younger than 20 years, or patients with corneal abnormalities such as subclinical keratoconus, dry eyes, blepharitis, and any ocular or other pertinent systemic disease were excluded. Informed consent was obtained from all patients after a thorough explanation of the procedure and its known risks.

Before every operation, homogeneity and ablation rate were calibrated with a polaroid film. Pilocarpine 2% and proparacaine hydrochloride 0.5% were instilled 30 minutes before treatment. After lid speculum was inserted, central corneal epithelium was mechanically removed with Beaver blade within the central 7 mm of the cornea, followed by careful cleaning with microspongy to dry the surface. The top center of the cornea was focused using He-Ne beam, while the patient fixated on the green target light and then, the excimer laser was performed.

In the double-pass PRK procedure, we first attempted to correct  $-6.00\text{D}$  with 4.5 millimeter

ablation zone. The second pass was performed immediately to correct the remaining myopia with a larger 5.0 millimeter ablation zone to minimize expected halos and glare sensitivity. Preoperative spherical equivalent in diopters was corrected to the corneal plane. There was a period of about 25 seconds between the first and second ablations. The maximal attempted correction was  $-9.50\text{D}$ . The eyes were divided into two groups. The myopes with  $-10.50\text{D}$  or less were assigned to group A (mean  $\pm$  SD,  $-8.60 \pm 1.03\text{D}$ ) in which emmetropia was the purpose of ablation, and the myopes higher than  $-10.50\text{D}$  to group B (mean  $\pm$  SD,  $-12.10 \pm 1.35\text{D}$ ). Ablation depth ranged from 57.75 to 88.25  $\mu\text{m}$ . The average ablation rate was 0.25  $\mu\text{m}/\text{pulse}$  and fluence was internally maintained at 180  $\text{mJ}/\text{cm}^2$  with a repetition rate of 10Hz.

Examinations were performed before surgery and postoperatively at one day, one week, and one, three, six, nine, and twelve months. Pre- and postoperative ocular examinations included visual acuity, both uncorrected and best corrected, cycloplegic refraction, K-reading, slit lamp examination, intraocular pressure measurement, specular microscopy, pachometry, and posterior segment examination. Postoperative corneal haze was graded by three examiners using the gradation scheme described by Fantes et al.<sup>6</sup>

Following ablation, topical 0.3% ofloxacin eyedrop and erythromycin ointment were instilled and the eyes were pressure patched until reepithelialization. After the epithelium healed completely, topical fluorometholone eye drops were instilled eight times a day for the first two months which was longer than single-pass, and gradually tapered over the next 5 months. In eleven eyes that had significant scarring and regression, the topical fluorometholone therapy was once again initiated and then tapered. Follow up period ranged from 6 to 24 months (mean, 11.9 months).

## RESULTS

The epithelium was healed by day 2 or 3 (mean  $\pm$  SD,  $2.80 \pm 0.54$ ), and no cases of recurrent corneal erosion or infectious keratitis were observed. Three months postoperatively, haze of grade 2 or 3 was observed in 29.0% in group A, and 17.4% in group

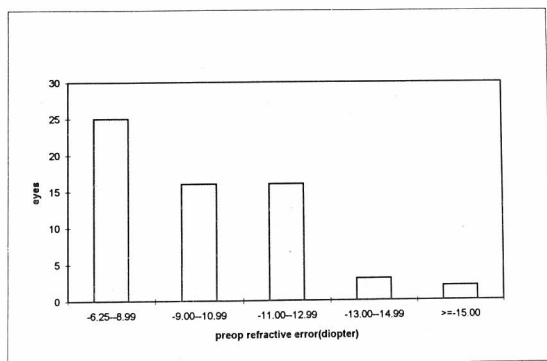
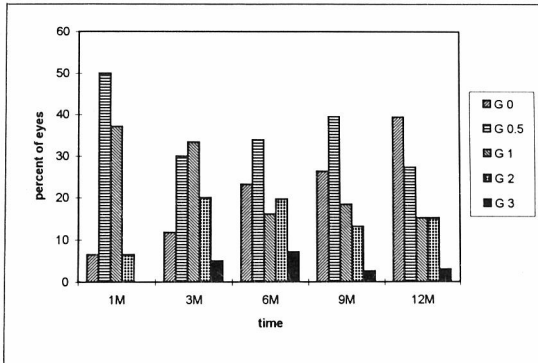


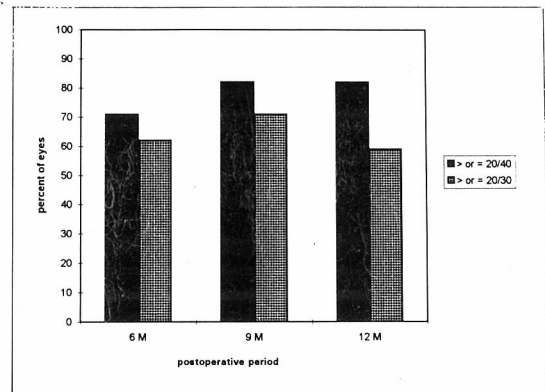
Fig. 1. Distribution of preoperative refractive errors.



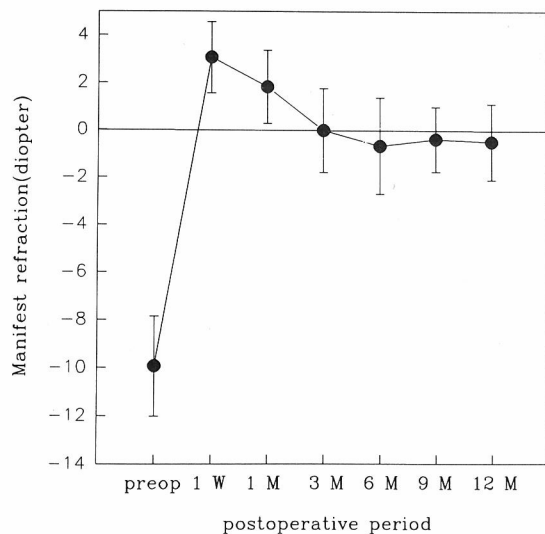
**Fig. 2.** The percent of corneal haze score at different time interval after double-pass PRK.

B. The degree of haze decreased gradually with time so that haze of grade 2 or more was noted in 9.0% in group A, but increased to 36.4% in group B (Fig. 2). The mean uncorrected visual acuity was 0.1 preoperatively, and improved to 0.8 in group A, 0.6 in group B at twelve months after (Table 1). Uncorrected visual acuity improved to 20/40 or better in 84.0% of the eyes in group A, and 73.3% in group B, and to 20/30 or better in 75.0% in group A, and 33.3% of the eyes in group B one year after surgery (Fig. 3). Best corrected visual acuity decreased more than 2 lines in 4.7% only in group B 12 months after surgery.

One week after double-pass PRK, the mean refraction showed initial hyperopic shift (mean  $\pm$  SD,  $+3.10 \pm 1.62$ D in group A,  $+2.90 \pm 1.37$ D in group B), of which amount decreased with time. At twelve months, the mean postoperative refraction was  $-0.30 \pm 1.61$ D in group A, and  $-1.50 \pm 2.07$ D in group B (Fig. 4). The postoperative refraction within  $\pm 1.0$ D of emmetropia was achieved in 70.8% in group A, and 46.7% in group B at postoperative 12 months. Undercorrection below  $-1.0$ D in group A and B were developed in 20.8%, and 53.3% respectively, and overcorrection above  $+1.0$ D in 8.4%, and 0% respectively at twelve



**Fig. 3.** The percent of mean uncorrected visual acuity better than 20/40 or 20/30 after double-pass PRK.



**Fig. 4.** The changes in the mean refractive error after double-pass PRK.

months after PRK (Table 2). Because maximal attempted correction was  $-9.50$ D even in the higher myopes than  $-9.50$ D, the overall incidence of undercorrection seemed to be high in group B.

**Table 1.** Uncorrected visual acuity after double-pass PRK (mean  $\pm$  SD)

	preoperative	6 months	postoperative 9 months	12 months
group A	0.10 $\pm$ 0.10	0.80 $\pm$ 0.31	0.80 $\pm$ 0.23	0.80 $\pm$ 0.24
group B	0.10 $\pm$ 0.08	0.60 $\pm$ 0.31	0.60 $\pm$ 0.26	0.60 $\pm$ 0.22
total	0.10 $\pm$ 0.09	0.69 $\pm$ 0.31	0.73 $\pm$ 0.27	0.75 $\pm$ 0.26

**Table 2.** The percent of manifest refraction within  $\pm 1.0$  diopter, undercorrection, and overcorrection after double-pass PRK

group	6 months		postoperative 9 months		12 months	
	A	B	A	B	A	B
N	35	23	25	19	24	15
within $\pm 1.0$ D	68.6	56.5	76.0	63.2	70.8	46.7
undercorrection ( $> 1.0$ D)	20.0	39.1	20.0	36.8	20.8	53.3
overcorrection ( $> 1.0$ D)	11.4	4.4	4.0	0.0	8.4	0.0

group A:  $> -6$ D and  $\leq -10.50$ D, group B:  $> -10.50$ D, N: number of eyes

The mean keratometric flattening was 5.13D from a preoperative mean of 42.24D to postoperative mean of 37.10D at twelve months. Significant corneal flattening was observed at 1 week (mean  $\pm$  SD,  $36.30 \pm 0.53$ D in group A,  $36.0 \pm 0.17$ D in group B) and thereafter the degree of flattening decreased slightly (Fig. 5).

Steroid-induced transient increase of intraocular pressure was observed in 13.2% in group A, and 21.7% in group B at 3 months after PRK. In these cases, steroid dosage was reduced or discontinued and beta blocker was administered, which led to the control of IOP at 12 months except one eye. This eye received trabeculectomy because of progressive

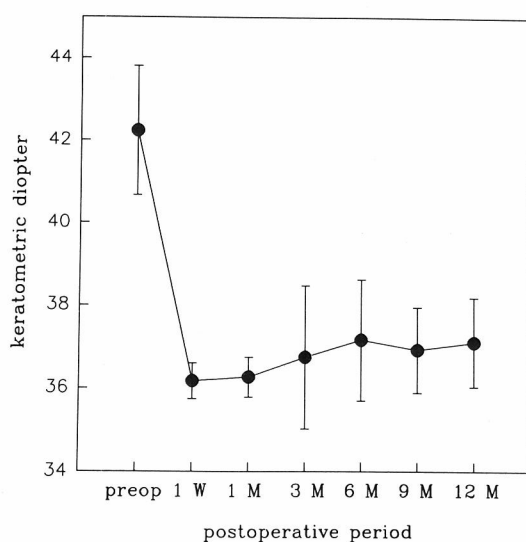
glaucomatous optic nerve damage despite maximum tolerable medical therapy.

Most patients felt discomfort and pain, which did not last beyond the third day. Night halos was a common subjective symptom but the intensity of halos appeared to decrease with time. For the first month after surgery, most patients reported foreign body sensation from time to time. No patient complained of fluctuation of vision except night halos.

## DISCUSSION

Clinical studies have been reported on the correction of high myopia with excimer laser PRK and have showed some problems in its efficacy, predictability, and safety.<sup>2,3</sup> In a preliminary series of patients who underwent excimer laser PRK, McDonald et al.<sup>7</sup> reported significant regression by 3 months in patients with myopia between  $-5.0$  and  $-9.0$ D. Gartry et al.,<sup>2</sup> using the Summit machine, reported a mean regression of 4.9D in a group of 20 eyes in which correction of 7.0D of high myopia was attempted. Sedaravic et al.<sup>1</sup> have reported limited success in patients with myopia over  $-10.0$ D. Of these patients, regressions of 2.0 to 6.0D were common and 25% of patients had significant corneal haze.

The major objectives of this study were to examine the safety and efficacy of simultaneous two-step excimer laser PRK in high myopic eyes. Safety was documented by epithelial healing, corneal clarity scores, and severity of complications. In our study, the epithelium was generally healed within three days. No corneal epithelial complications such

**Fig. 5.** The changes in the mean keratometric value after double-pass PRK.

as recurrent erosion, nonhealing epithelial defects, and corneal ulcers were seen in high myopic eyes with two-step PRK. However, in corrections of myopia greater than  $-6.0\text{D}$ , scarring and undercorrection may occur more frequently.

In this study, mild haze (grade 0-1) was detected in 91.0% in group A, and 63.6% in group B at 12 months. Haze more than or equal to grade 2 was seen in 9.0% in group A, and 36.4% in group B. This rate was similar to Shimizu et al.'s report,<sup>8</sup> but higher compared to the data of one-step PRK<sup>9</sup> and other reports.<sup>10,11</sup> Seiler et al.<sup>10</sup> reported 8.8% of scarring in high myopia greater than  $-6.0\text{D}$  and others<sup>11</sup> reported 10.5% in  $-6.0\text{D}$  to  $-10.0\text{D}$  of myopia and 26.0% in myopia greater than  $-10.0\text{D}$ .

Efficacy was documented by refraction and uncorrected visual acuity. In this study, correction within  $\pm 1.0\text{D}$  of emmetropia were achieved in 70.8% in group A at 12 months. This finding was higher than 61% in Machat and Tayfour's study<sup>12</sup> and 55% in Sher's study<sup>13</sup> in which patients had preoperative refractive errors of  $-4.0\text{D}$  to  $-12.0\text{D}$ . Undercorrection below  $-1.0\text{D}$  in this study was 20.8% in group A, and 53.3% in group B. This difference was because we tried to avoid deep ablation over  $100\text{ }\mu\text{m}$  in group B. The mean change of refraction was from preoperative spherical equivalent of  $-8.60 \pm 1.03\text{D}$  in group A, and  $-12.10 \pm 1.53\text{D}$  in group B to  $-0.30 \pm 1.61$  in group A, and  $-1.50 \pm 2.07\text{D}$  in group B at postoperative 12 months. This amount of myopic correction was slightly higher than the other study<sup>3</sup> (preoperative spherical equivalent of  $-8.94 \pm 1.86\text{D}$  to  $-2.10 \pm 1.25\text{D}$  at 12 months) which used the same instrument. Hyperopic shift in the early postoperative period was noted. This shift continued to decrease gradually up to three months, and then stabilized. The average regression amount at twelve months was 3.85D. This regression amount was slightly lesser than Gartry's study<sup>2</sup> (mean regression of 4.9D) which underwent 7.0D attempted correction of high myopia.

Visual acuity of 20/40 or better obtained in 84.0% in group A, and 20/30 or better obtained in 75.0% in group A which was slightly higher than those of other studies.<sup>3,12</sup> Only one patient lost 2 lines of best corrected visual acuity due to haze (grade 3) and irregular astigmatism.

Regression has been known due to hyperplastic thickening of the epithelium in the ablated area and new collagen deposition in the bed of ablation.<sup>7</sup> The possibility of individual variation in healing responses of the corneal stroma should be considered. Even though the same depth and diameter of ablation was used, the response of the stroma to laser ablation may be different in the wound healing. To minimize regression or scarring, we used topical fluorometholone eyedrops more frequently and longer than in cases of single-pass PRK. Tengroth et al.<sup>14</sup> have suggested that sudden refractive regression may be due in part to the changes in stromal hydration related to hyaluronic acid formation which can be restored by the use of corticosteroids. Topical dexamethasone treatment significantly decreased hyaluronic acid formation in rabbit corneas that have undergone excimer laser keratectomy.

The corneal haze is a result of the light scattering caused by newly synthesized collagen fibers and extracellular matrix which may cause greater interfibrillar spacing than normal. Tuft et al.<sup>15</sup> demonstrated that this new collagen formation diminished after topical corticosteroid treatment. With the use of long-term intensive topical corticosteroid therapy in our study, haze less than grade 1 was observed in the majority of the eyes. The corneal haze gradually diminished over time that seemed not to affect visual acuity significantly. The relationship between the formation of corneal haze and wound depth, edge profile, and zone diameter of ablation was also suggested.<sup>16,17</sup> Degree of corneal haze was greater after deep ablation. The greater ablation zone diameter and the smoother edge profile was, the less the haze developed. The smaller zone diameter was, the more haze was noted. In order to get shallower ablation depth and smoother edge profile as possible during double-pass procedure, we did not allow the ablation depth to exceed  $100\text{ }\mu\text{m}$ , and used smaller zone diameter ( $4.5\text{ mm}$ ) first, then  $5.0\text{ mm}$  in diameter of ablation zone.

With prolonged intensive topical corticosteroid therapy, we observed steroid induced ocular hypertension in 10 among 61 eyes at 3 months. Among these eyes, one eye, of which intraocular pressure was not controlled by maximal tolerable

medical treatment, received conventional trabeculectomy.

From our results, we think that simultaneous two-step PRK and heavy regimen of topical corticosteroid on high myopes up to -10.50D can be an efficient and safe procedure, but further careful investigation and long-term studies are needed to confirm the safety and the efficacy of the double-pass PRK in high myopes.

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