### **PRK – PHOTO REFRACTIVE KERATECTOMY IN CORRECTION OF MYOPIA: HOW USEFUL IS IT?**

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#### HOW TO CITE THIS ARTICLE:

Chitra Pande, Vikas Mahatme, Atul Borkar, Sudha Sutaria, Nikhilesh Wairagade. "PRK – Photo Refractive Keratectomy in Correction of Myopia: How Useful is it?". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 22, March 16; Page: 3890-3896, DOI: 10.14260/jemds/2015/559

**ABSTRACT:** The study comprised of retrospective and prospective evaluation of 30 eyes treated with PRK – Photo Refractive Keratectomy at Mahatme Eye Bank Eye Hospital, Nagpur India. Our results show that PRK is less safe, less effective and less predictable procedure in correcting high and extreme myopia and myopic astigmatism.

**KEYWORDS:** Myopia, refractive surgery, Photo Refractive Keratectomy - PRK, keratome, hansatome, spherical equivalent (SE) refraction, BSCVA (Best surgically corrected visual acuity), UCVA (Uncorrected visual acuity), corneal haze, astigmatism.

**INTRODUCTION:** PRK stands for Photo Refractive Keratectomy. PRK was the first type of laser eye surgery for vision correction and is the predecessor to the popular LASIK procedure. First PRK procedure was performed in 1987 by Dr. Theo Seiler,<sup>1</sup> then at the Free University Medical Center in Berlin, Germany. The main difference between PRK and LASIK is that in LASIK surgery a thin, hinged flap is created on the cornea to access the treatment area, whereas in PRK the cornea's entire epithelial (outer) layer is removed to expose the area and no flap is created. PRK is still commonly performed and offers advantages over LASIK for some patients.

PRK advantages includes less depth of laser treatment than LASIK, suitable for patients with a thin cornea, no risk of corneal flap complications and reduced risk of compromised corneal thickness. The disadvantages of PRK are slower recovery than LASIK, best vision takes longer to obtain, increased risk of post-surgery infection, inflammation and haze and more eye discomfort during early PRK recovery, compared with recovery after LASIK surgery.<sup>2</sup> Unlike LASIK, in PRK corneal flap is not created. Instead, the outer layer of the cornea is removed to expose an area for a laser to reshape. This makes PRK a better choice for people whose eyes meet certain criteria, such as having thin corneas or chronically dry eyes. The most significant differences between PRK and LASIK are the initial discomfort and the speed of visual recovery. Recovery from PRK takes a little longer than from LASIK because the outer layer of the cornea needs time to heal.

The present study aimed at finding out efficacy, safety, predictability and visual outcome of PRK in high myopia.

**MATERIALS AND METHODS:** A retrospective and prospective non comparative single surgeon study was done on 30 eyes of 20 patients; 8 men and 12 women; using photo refractive keratectomy (PRK) as a primary procedure to correct myopia and myopic astigmatism. The study was conducted at Mahatme Eye Bank Eye Hospital, Nagpur, India in 2004 after ethics committee approval. Patients with high myopia in whom LASIK was not possible were selected for this study.

#### **INCLUSION CRITERIA:**

- 1. Age 18 to 45 years.
- 2. Normal anterior segment.
- 3. Stable refractive error for more than 6 months.
- 4. Normal videokeratography i. e. not showing evidence of ectatic disease.

#### **EXCLUSION CRITERIA:**

- 1. Unstable refraction.
- 2. Corneal thinning disease.
- 3. Presence of ectasia or any other corneal pathology.
- 4. Past history of corneal surgery like refractive surgery or penetrating keratoplsty.
- 5. Central corneal vascularization.
- 6. Glaucoma.
- 7. Small palpebral aperture.
- 8. Sunken eyes.
- 9. Monoocular patients.
- 10. Patients with lid problems like blepheritis.
- 11. Deep amblyopia.
- 12. Retinal pathology markedly limiting visual performance.
- 13. Presence of bleb after glaucoma filtering surgery.
- 14. Systemic or ocular vascular disease.
- 15. Autoimmune diseases as they might affect wound healing.
- 16. Pregnancy and immunocompromised states.

**Counseling of Patients:** This has significance as unrealistic expectations are the most common causes of dissatisfaction after refractive surgery. Care was taken to make patient understand that no refractive surgery is perfect and it may not be possible to achieve same quality of vision as with spectacles or contact lenses in all the cases.

Preoperative evaluation consisted of uncorrected visual acuity for both – distance and near; best spectacle corrected visual acuity, manifest and cycloplegic refraction, ocular dominance, keratometry, applanation tonometry, scotopic pupillary size, tear film break up time, blinking rate, Schirmer test when necessary, pachymetry, slitlamp examination and computerized video keratography. In all patients, fundus photography was done using indirect ophthalmoscopy for screening the peripheral retina in order to rule out associated retinal pathology that might predispose to retinal detachment. A suspicious lesion was treated with laser or cryotherapy and in those patients surgery was postponed for 8 to 12 weeks.

Specialized Instruments: These included Hansatome, Microkeratome, Laser delivery system, Barraquer tonometer, Videokeratography, Pachymeter.

Surgical Procedure: Procedures done under topical anaesthesia, De-epithelization was done using 15 No. disposable blade after marking central 7. 5mm cornea with trephine. The laser ablation was done according to pre-programmed calculations depending on refractive error. In 21 patients, full correction was done while in 9 patients, under-correction was done. A multizone, multipass ablation was done in 9 patients; 3 ablation zones of 5.0 mm, 5.5 mm and 6mm were used.

In remaining 21 patients, mono zonal ablation was done. Before and after laser ablation, cornea was flooded with ice chilled balanced salt solution for 30 seconds. Mitomycin (0.02%) solution was applied to ablated area with the help of merocoele sponge for 1 minute. The area was thoroughly washed with balanced salt solution again. UV protecting bandage soft contact lens was placed over cornea. The bandage contact lens was removed 3 to 4 days postoperatively. If re-epithelization was not yet complete, bandage contact lens was replaced by a new one.

**OBSERVATIONS:** Data was analyzed on Microsoft excel using Kruskal Wallis test with Dunn's multiple comparison test. P value less than 0. 05 was considered as clinically significant.

Table 1 shows demography of patients.

Parameter	Patients		
Total No. of patients	20		
Bilateral cases	10(50%)		
Unilateral cases	10(50%)		
Women	12(60%)		
Men	8(40%)		
Total number of eyes	30		
Right eye	17(56.66%)		
Left eye	13(43.33%)		
Mean Age	25. 3 +/- 5. 478 years (Range 20 to 37 yrs)		
Table 1: Demographics of 20 patients in study group			

The mean preoperative SE was -14.99 +/- 4.722 (Range -7.0 to -26.0) and mean preoperative cylinder was -1.617 +/- 1.208 (range -1 to -4). Preoperatively the mean UCVA was 0.032+/- 0.214 (0.01 to 0.10 i. e.1/60 to 6/60) and mean BCVA was 0.556 +/- 0.246 (range 0.25 to 1.0 i. e. 6/24 to 6/6).

The mean follow up was 13.1 months (range 9 to 18 months).

The eyes were divided in two groups. Group A of 21 eyes in whom emmetropia was planned. Group B of eyes in whom under-correction was the target.

**Group A:** Preoperative mean UCVA was 0.036+/-0.023 (range 0.02 to 0.10 i. e. 1/60 to 6/60). Mean BCVA was 0.605+/-0.253 (range 0.1 to 1.0 i. e. 6/60 to 6/6). Preoperative mean Spherical equivalent (SE) was -12.64+/-2.997 (range -7 to -17) and mean preoperative astigmatism was -1.529+/-1.199 (range -1 to -4).

**Group B:** Mean preoperative UCVA was 0.021 + - 0.007 (range 0.01 to 0.03 i. e. CF<sup>1</sup>/<sub>2</sub> m to 2/60). Mean BSCVA was 0.442 + -0.196 (range 0.17 to 0.66 i. e. 6/36 to 6/9). Preoperative mean Spherical equivalent (SE) was -21.47 + -3.178 (range -17 to -26) and mean preoperative astigmatism was -1.83 + -1.275 (range -1.5 to -4). The mean attempted correction was -17.33 + -1.516 (range -14.5 to -19).

UCVA: Uncorrected visual acuity.

J of Evolution of Med and Dent Sci/ eISSN- 2278-4802, pISSN- 2278-4748/ Vol. 4/ Issue 22/ Mar 16, 2015 Page 3892

**Group A:** 1 month postoperatively, the mean UCVA was 0.3519 +/- 0.158 (range 0.08 to 0.66 i.e. 5/60 to 6/9); P <0.001. After 1 year, mean UCVA was 0.162 +/- 0.158 (range 0.02 to 0.66 i. e. 1/60 to 6/9); P<0.01. At 1 month, 7 eyes (33.3%) had UCVA of 6/12 or better and in 12 eyes (57.14%) have UCVA of 6/18 or better. At 1 year, 2 eyes (9.52%) had UCVA of 6/12 or better and in 3 eyes (14.28%) had UCVA of 6/18 or better.

**Group B:** Under-correction was the target. The mean UCVA at 1 month was 0.245 +/- 0.133 (range 0.1 to 0.5 i.e. 6/60 to 6/12); P <0.001.After 1 year, mean UCVA was 0.06 +/- 0.025 (range 0.02 to 0.1 i.e. 1/60 to 6/60); P value not significant. At 1 month, 3 eyes (33.3%) had UCVA of 6/18 or better while at 1 year, no eye had UCVA of 6/18 or better.

**BSCVA:** Best spectacle corrected visual acuity.

**Group A:** 1 month postoperatively, the BSCVA was 0.631+/-0.199 (range 0.02 to 1.0 i.e. 6/24 to 6/6); P value not significant. At 1 year, the BSCVA was 0.510 +/- 0.236 (range 0.1 to 1.0 i.e. 6/60 to 6/6).

**Group B:** 1 month postoperatively, the BSCVA was 0.458+/-0.197 (range 0.17 to 0.66 i.e.6/36to 6/9). At 1 year, the BSCVA was 0.378+/-0.190 (range 0.1 to 0.66 i.e.6/60 to 6/9); P value not significant.

In both the groups together, 14 eyes (46.66%) had maintained preoperative BCVA. 5 eyes (16.66%) had improved BCVA. 11 eyes (36.66%) had loss of preoperative BCVA; out of which 2 eyes (6.66%) had 1 line loss; 8 eyes (26.66%) had 2 line loss while 1 eye (9.33%) had more than 2 lines loss in BSCVA.

**SER:** Spherical Equivalent Refraction.

**Group A:** At 1 month postoperatively, the mean SE refraction was -1.077+/-1.43 (range +1.5 to -5); P < 0.001. At 1 month 13 eyes (69.9%) had SE within +/- 1.00 while at 1 year, only 3 eyes (14.2%) had SE within +/- 1.00 correction.

**Group B:** At 1 month postoperatively the mean SE was -2.167 +/- 2.562 (range +1.5 to -5.5); P<0.001. At 1 year, the mean SE was -7.417 +/- 2.781 (range -3.5 to -11); P<0.05.0nly 1 eye (11.1%) had SER within +1.0 at 1 month; then no eye had SE within +/- 1.00 at 1 year.

The mean regression from 1 month to 1 year taking all patients together was -3.546 (+0.5 to - 12.5). In Group A, it was -3.03 mean (range +0.5 to -8.75) while in group B, it was -5.25 mean (range - 1 to -12.5).

#### Astigmatism:

**Group A:** Mean cylinder at 1 month postoperatively was -0.5 +/- 0.684 (range +1 to -1.75). At 1 year it was -1.025 +/- 0.79 (range -0.5 to -3); P value not significant.

**Group B:** Mean cylinder at 1 month postoperatively was -0.777 +/- 0.265 (range +0.5 to -2); P<0.05.At 1 year it was – 1.5 +/- 0.829 (range -1 to -3); P value not significant.

**Safety Index:** Ratio of mean postoperative BCVA to mean preoperative BCVA was 0.842 in Group A and 0.855 in Group B.

**Efficacy Index:** Ratio of mean postoperative UCVA at 1 year to mean preoperative UCVA was 0.267 in group A and 0. 135 in Group B.

#### **Complications:**

**Haze:** Grade I haze was noticed in 36. 66%; Grade II haze in 43.33%; Grade III in 3. 33% and Grade IV in 3.33%.

**Pain<sup>3</sup>:** All the patients complained of significant pain and photophobia for 3–4 days which got reduced by 1<sup>st</sup> week in most of the cases.

Criteria	Preoperative	1 Month Postop	1 Year Postop
SE Refraction	-12.64 +/- 2.997 (range -7 to -17)	-1.077 +/- 1.43	-4.1 +/- 2.855
		(range +1. 5 to -5)	(range - 0. 25 to -11)
		P < 0.001	P < 0.001
Cylinder	1.529 +/- 1.199 (range -1 to -4)	-0.5 +/- 0.684	-1.025 +/- 0.79
		(range +1 to -1.75)	(range -0. 5 to -3)
		P < 0.01	P - NS
UCVA	0.036 +/- 0.023 (range 0.02 to 0.10)	0.3519 +/- 0.158	0.162 +/- 0.158
		(range 0. 08 to 0.66)	(range 0. 02 to 0.66)
		P < 0.001	P < 0.01
BSCVA	0.605 +/- 0.253 (range 0. 1 to 1.0	0.631 +/- 0.199	0.510 +/- 0.236
		(range 0.02 to 1.0)	(range 0. 1 to 1.0)
	(1 alige 0. 1 to 1.0	P - NS	P – NS

Table 2 and 3 show all the observations in tabulated form.

Table 2: Visual Acuity & Refractive data of patients undergoing PRK – Group A

Criteria	Preoperative	1 Month Postop	1 Year Postop		
SE Refraction	-21.47 +/- 3.178	-2.167 +/- 2.562	-7.417 +/- 2.781		
		(range +1.5 to -5.5)	(range -3.5 to -11)		
		P < 0.001	P < 0.05		
Cylinder	-1.83 +/- 1.275 (range -1.5 to -4)	-0.777 +/- 0.265	- 1.5 +/- 0.829		
		(range +0.5 to -2)	(range -1 to -3)		
		P < 0.05	P - NS		
UCVA	0.021 +/- 0.007 (range 0.01 to 0.03	0.245 +/- 0.133	0.06 +/- 0.025		
		(range 0.1 to 0.5)	(range 0.02 to 0.1)		
		P<0.001	P- NS		
BSCVA	0.442 +/- 0.196 (range 0.17 to 0.66	0.458 +/- 0.197	0.378 +/- 0.190		
		(range 0.17 to 0.66)	(range 0.1 to 0.66)		
		P - NS	P – NS		
Table 3: Visual Acuity & Refractive data of patients undergoing PRK – Group B					

**DISCUSSION:** In our series, we studied role of PRK in treating high myopia along with use of Mitomycin C. we divided patients in 2 groups – Group A with myopia SE mean -12.64 +/- 2.997 (-7 to -17) in whom full correction was done and Group B with mean SE -21.47 +/- 2.178 (-17 to -26) in whom under-correction was done. In all patients, mytomycin c was applied for 1 min in the ablated area.

The UCVA was better than 6/12 in 33.3% eyes at 3 months while in only 9.52% of eyes at 1 year in Group A. also change in BCVA values were not significant statistically at 1 month or 1 year. In Group B, only 9.52% eyes had UCVA of 6/12 or better at 1 month, while no eyes had 6/12 or better vision at 1 year, which can be due to under-correction planned. Changes in BCVA values were not statistically significant at 1 month or 1 year.

36.66% eyes had loss of preoperative BCVA. About 30% of eyes had 2 or more line loss of BCVA. About 50% eyes had visually significant haze at 1 year.

Though the visual acuity results were better at 1 month, it slowly reduced due to large myopic regression as well as sub-epithelial haze formation. Also there was a loss of BCVA. The myopic regression was more in group B with higher myopia (mean -5.25; range -1 to -12.5) than that in group A (mean -3.03; range +0.5 to -8.25) with lower myopia.

The efficacy index was found to be low in both the groups; 0.267 in Group A and 0.135 in Group B. Also safety index was 0.842 in Group A and 0.855 in Group B. So also was the predictability which was found low in both the groups.

The prophylactic use of diluted mitomycin C solution is known to produce lower haze rates, better UCVA and BCVA results.<sup>4</sup> We did not have a control group to compare in our study.

The cylindrical correction which was apparent at 1 month was not statistically significant at 1 year.

William D K<sup>5</sup> in a series of PRK in high myopia, treated 88 eyes with SE refractive correction ranging from -12 to -22 with 12 months follow up. He reports 14% eyes with loss of 2 or more lines of BCVA. UCVA of 6/12 or better was not reported. Our results were similar to this study. Our results also matched with study by Salz J I, Maguen E, Nesburn AB et al<sup>6</sup> and study by Rajan Madhavan.<sup>7</sup>

With high corrections, the stromal wound healing after PRK can lead to haze formation in high percentage of cases. Haze is probably the major complication of PRK because not only does the loss of transparency results in visual loss, also stromal reaction induce refractive regression and increase corneal surface irregularity.<sup>8</sup> To add to this there is slower visual recovery and discomfort during the immediate postoperative period.

**CONCLUSION:** Photorefractive keratectomy – PRK is less predictable, less effective and less safe to correct high and extreme myopia. Though there is early visual recovery, there is later fall in both UCVA and BCVA due to central corneal haze and myopic regression. Regression is found to be more in higher myopic range.

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> Date of Submission: 21/02/2015. Date of Peer Review: 23/02/2015. Date of Acceptance: 04/03/2015. Date of Publishing: 16/03/2015.