

Single Step Transepithelial Photorefractive Keratotomy in Treatment of Moderate and High Myopia Six Months Outcome

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Abstract

Background: In this study the efficacy and safety of single step transepithelial PRK is evaluated on moderate and high myopia. The outcome of the procedure is compared like SER, residual astigmatism, HOAs and haze.

Aim of Study: Trans PRK is a laser-assisted method for epithelial removal, was introduced as an alternative to conventional PRK which is based on mechanical debridement of the corneal epithelium.

Patients and Methods: Patients were divided into two groups moderate and high myopia both groups were chosen based on inclusion criteria. Patients were operated using the same laser machine. The parameters and software were slandered for the two groups. The machine was programed for laser ablation of the corneal epithelium which was calculated as standard 50-60 micron followed by laser ablation of the stroma based on refractive errors and stromal thickness all were in single step. The postoperative regimen for the two groups was the same and the follow-up period start from day one till the sixth month.

Results: Forty eye in each group in high myopia group patients gain one line are 25% while in moderate myopia group patients gain one line are 42% and 12.5% for two lines. The UDVA by the sixth month was 15% 20/25, 65% 20/20, and 20% 20/16 while in moderate myopia it was 2.5% 20/25, 50% 20/20, 30% 20/16 and 17.5% 20/12.5. The residual errors for high myopia were $75\% \pm 0.50$ and $100\% \pm 1.00$ while in moderate myopia $82.5\% \pm 0.50$ and $100\% \pm 1.00$. the residual astigmatism was $35\% \pm 0.25$ and $100\% \pm 0.50$ in high myopia while it was $52.5\% \pm 0.25$ and $100\% \pm 0.50$ in moderate myopia.

Conclusion: Transepithelial photorefractive keratotomy is a safe and effective procedure in treating moderate and high myopia considering the postoperative recovery period and haze.

Key Words: Photorefractive keratotomy – Phototherapeutic keratectomy – Smart pulse technology – Spherical equivalent refraction – Mitomycin C – Higher order aberrations.

Introduction

TRANSEPIHELIAL photorefractive keratectomy (tPRK) was introduced in late 1990s to avoid

flap related complications and ectasia after laser in situ keratomileusis (LASIK). Variable results were reported using different laser platforms. All were based on large-beam ablation. In studies of these platforms, epithelial removal was performed in a phototherapeutic keratectomy (PTK) mode, giving a smoother corneal surface than that achieved with mechanical debridement of the corneal epithelium. However, because of the curvature of the cornea, the energy of the incident laser beam on the corneal periphery is reduced as a result of the oblique incidence of laser rays on the periphery and the longer distance the beam travel. This leads to some loss of laser energy, resulting in uneven epithelial removal and, subsequently, irregular epithelial healing [1-4].

Initially, Trans PRK was a two components surgery in which the corneal epithelium was removed first and then the corneal stroma was ablated. The unique feature of single step tPRK technique is that it removes the corneal epithelium and ablates the stroma in one step with one ablation profile. The advantages of tPRK include flapless surgery, minimal trauma to the eyes there is no mechanical scraping of the corneal epithelium and without flap-related complications [5].

Trans PRK (SCHWIND Eye-Tech-Solutions GmbH and Co KG, Kleinostheim, Germany) has been widely used in the field of refractive surgery since its release. This technique combines both epithelial ablation and stroma ablation. The laser beam ablates the corneal epithelium at a depth of $55\mu\text{m}$ at the center and $65\mu\text{m}$ at the periphery of the cornea. Several previous studies have shown that transepithelial ablation shortens the operative time and reduces early postoperative pain, haze formation, and the epithelial healing period [6,7].

The corneal biomechanics are less affected in trans PRK than other refractive procedures, including femtosecond lasik and Small Incision Lenticule

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Extraction (SMILE), also it allows safe and simple reoperation [8]. Moreover, Trans PRK using Smart Pulse Technology (SPT) provides significant accelerated healing and visual rehabilitation than without SPT [9]. Myopia is the most common refractive disorder. It is predicted that myopia and high myopia account for 49.8% and 9.8% of the world's population by 2050 respectively [10]. Patients with high myopia are those with spherical equivalent refraction more than -6.00 D and less than -9.00 D, while extreme myopia usually refer to those patients SER more than -9.00 D. LASIK is a safe procedure with predictable results for low to high myopia correction, but the outcomes for extreme myopia is not satisfactory. FS-LASIK has been developed rapidly for high myopia correction with high accuracy and predictability in flap thickness creation. The adequate correction of refractive errors more than -9.00 D SER. Is a big challenge regarding corneal biomechanics and ectasia [11,12]. This prospective clinical study evaluated the visual acuity, refractive error and efficacy, safety, corneal haze, epithelial healing and HOAs outcomes of Trans PRK in moderate and high myopic eyes with up to -1.75 astigmatism.

Patients and Methods

This prospective interventional case controlled study enrolled patients with myopia. The patients divided into two groups based on their refractive errors. The moderate myopia group includes 20 patients with 40 eyes which include patients with refractive spherical equivalents between -3.00 D and -6.00 D and the high myopia group which includes 20 patients with 40 eyes with SER more than -6.00 D. The cylinder in both groups range from 0.0 to -1.75 D. The study performed in the specialized eye center between 2017 and 2018. All patients informed about the details of surgery, postoperative medications and follow-up program. Written informed consent was obtained before surgery from all patients. The study adhered to the Tenets of the Declaration of Helsinki.

Inclusion criteria:

The inclusion criteria were moderate myopia -3.00 to -6.00 D and high myopia > -6.00 D [spherical equivalent fraction (SER) [13]. Age more than 18 years with stable refraction for at least one year. All patients should have cornea with residual stromal bed $280\mu\text{m}$ [14]. All patient should complete six month follow up after surgery. All patient should have preoperative CDVA of 20/20. Emmetropia was the target of the study. All patients should have informed consent.

Exclusion criteria:

Exclusion criteria included anisometropia, amblyopia, one eye patients, corneal dystrophy, forme-fruste keratoconus, pellucidmarginal degeneration, severe dry eye syndrome and previous corneal or intraocular surgery. Patients with cataract, diabetic retinopathy, maculopathy and retinopathy, eye lid disorders, glaucoma, any systemic diseases affect the ocular tissue all are excluded from the study.

Full detailed examinations performed for all patients preoperative and at postoperative, one day, one week, 1 month, 3 months and 6 months. Preoperative examinations included the uncorrected and corrected distance visual acuity (UDVA) and (CDVA), manifest and cycloplegic refraction, slit-lamp examination (Haag-Streit, Köniz, Switzerland), slit-lamp biomicroscopy, fundus examination, corneal epithelium assessment by fluorescein staining, tear breakuptime, Schirmer I test, intraocular pressure measurement (noncontact tonometer; NT-530, NCT Nidek Co., Ltd., Aichi, Japan), central corneal thickness(CCT) using ultrasound pachymetry (UP-1000; Nidek), Corneal wave front aberrations were measured using the Keratron Scout (Optikon 2000, Rome, Italy), and Scheimpflug-based corneal topography (Pentacam HR, Oculus, Wetzlar, Germany). All patients instructed to discontinue contact lens wearing three weeks before assessment and before the procedure. Visual acuity was measured at 6 M with a Snellen chart and converted to the log MAR scale for statistical analysis. Both groups were operated using the single step transepithelial PRK SCHWIND Amaris 500E excimer laser platform(SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany). The ablation algorithm was calculated using ORK-CAM software. This software module, based on a spherical ablation profile, automatically considers the ablation volume of the epithelium, the ablation plan utilized $55\mu\text{m}$ centrally, and $65\mu\text{m}$ peripherally. It takes into account the difference in epithelial thickness between the center and the periphery of the cornea and delivers different ablation energies to the epithelium and the stroma. The program provides an even laser energy on the entire corneal surface.

The optical zone (OZ) ranged from 6.0 to 7.0mm for all patients based on scotopic pupillary diameter measurement by wave front, SER and pachymetry. One drop of topical anesthesia (proparacaine 0.50%) was applied to the eye twice with two minutes interval before starting surgery. Diluted povidone iodine was applied on the lashes and eyelids, a closed loop lidspeculum was placed, and

the single step Trans-PRK ablative surgery was performed.

The laser treatment was centered on the pupillary axis, the static cyclotorsion control program used during surgery. After laser ablation, MMC 0.02% was applied for 30 seconds in all cases [15]. Large amount of cold balanced salt solution (BSS) used to wash the bed. A soft contact lens with high water content and high gas permeability was used to the eye 3-4 day till complete healing of the corneal epithelium [16]. One drop of topical antibiotic, one drop topical steroids, and one drop of preservative free lubricant eye drops were applied. The postoperative regimen of medications was as follow, gatifloxacin 0.3% four times daily for one week, 0.1 % fluorometholone drops were initiated four times a day after epithelial healing and contact lens removal, the drops were tapered gradually over the following three months. Preservative free lubricant eye drops used five times a day for six months and systemic nonsteroidal anti-inflammatory tablets once daily for the day of surgery and the first postoperative day. Corneal haze was graded according to a study by Fantès et al.as follows: 0 = no haze; 0.50 = trace haze on obliqueillumination; 1 = corneal cloudiness not interfering with the visibility of fine iris details; 2 = mild dimness of fine iris details; 3 = moderate obliteration of iris details,4 = details of the lens and iris not discernible. All patients examined at first postoperative day, one week, one month, three months and six months postoperatively. Safety of the procedure was defined as the percentage of eyes losing more than 2 lines of BCVA.

The safety index is defined as the ratio of postoperative CDVA/preoperative CDVA. The efficacy index is defined as the ratio of postoperative UDVA/preoperative CDVA [17,18].

Statistical analysis:

Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data was summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann-Whitney test. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. *p*-values less than 0.05 were considered statistically significant.

Results

The mean age for high myopia was 23.05±2.36 and 22.25±3.02 for moderate myopia. The preoperative SER was -6.46±3.18 D and -4.07±2.39 D for moderate myopia. The preoperative CCT for high myopia was 511.85±13.23 micron and 486.12±6.13 for moderate myopia. The preoperative HOAs were 0.44±0.03 while the postoperative HOAs were 0.92±0.09 for the high myopia and 0.43±0.04 and 0.61±0.04 for moderate myopia. The mean postoperative UDVA was 0.16±0.07, 0.04±0.05 and -0.01±0.06 one month ,three months and six months for high myopia and 0.09±0.09, -0.02±0.09 and -0.06±0.08 Log MAR. The percentage of 20/20 and more in one month was 0% and 40% in high and moderate myopia respectively. It was 57.5% and 75% in three months and finally it was 85% and 97.5% respectively. The incidence of haze was 15% in high myopia and 7.5% in moderate myopia. 25% of high myopia gains one line of UDVA while 42.5% gain one line and 12.5% gain two lines of UDVA in moderate myopia. In high myopia group 12.5% lost one line of preoperative CDVA while it was 2.5% in moderate myopia.

Table (1): Comparison between groups.

	T-PRK HIGH MYOPIA					T-PRK MODERAT MYOPIA					<i>p</i> -value
	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	
Age	23.05	2.36	23.00	19.00	27.00	22.25	3.02	22.50	18.00	27.00	0.181
PREOP CCT	511.85	13.23	511.00	487.00	535.00	486.12	6.13	486.00	470.00	501.00	<0.001
PREOP SER	-6.46	3.18	-7.00	-9.00	7.00	-4.07	2.39	-4.75	-5.75	5.50	<0.001
PREOP ASTIGMATISM	-1.24	0.38	-1.37	-1.75	-0.50	-1.16	0.52	-1.37	-1.75	0.00	0.775
PREOP HOAs	0.44	0.03	0.43	0.36	0.50	0.43	0.04	0.43	0.35	0.49	0.163
PREOP CDVA	0.00	0.00	0.00	0.00	0.00	-0.01	0.03	0.00	-0.10	0.00	0.041
UDVA 1M	0.16	0.07	0.10	0.10	0.30	0.09	0.09	0.10	0.00	0.30	<0.001
UDVA 3M	0.04	0.05	0.00	-0.10	0.10	-0.02	0.09	0.00	-0.20	0.10	0.003
UDVA 6M	-0.01	0.06	0.00	-0.10	0.10	-0.06	0.08	0.00	-0.20	0.10	0.001
POST SER	0.08	0.62	0.50	-1.00	1.00	-0.12	0.50	-0.25	-0.75	0.75	0.192
POST ASTIGM	0.41	0.12	0.50	0.25	0.50	0.33	0.21	0.25	-0.25	0.50	0.075
POSTOP HOAs	0.92	0.09	0.90	0.83	1.21	0.61	0.04	0.61	0.50	0.69	<0.001
POST CDVA	-0.01	0.06	0.00	-0.10	0.10	-0.07	0.07	-0.10	-0.20	0.00	0.002

Table (2): Residual error two groups.

	T-PRK HIGH MYOPIA		T-PRK MODERAT MYOPIA	
	Count	%	Count	%
RESIDUAL ERROR:				
-1.00 TO -0.50	4	10.0	3	7.5
-0.50 TO -0.14	14	35.0	23	57.5
-0.13 TO +0.13	0	0.0	0	0.0
+0.14 TO +0.50	16	40.0	10	25.0
+0.50 TO +1	6	15.0	4	10.0

Table (3): UDVA, CDVA, Astigmatism two groups.

	T-PRK HIGH MYOPIA		T-PRK MODERAT MYOPIA		<i>p</i> -value
	Count	%	Count	%	
Gender:					
M	24	60.0	22	55.0	0.651
F	16	40.0	18	45.0	
HAZE:					
Yes	6	15.0	3	7.5	0.481
No	34	85.0	37	92.5	
GAIN ONE:					
Yes	10	25.0	17	42.5	0.098
No	30	75.0	23	57.5	
GAIN TWO:					
Yes	0	0.0	5	12.5	0.055
No	40	100.0	35	87.5	
LOST ONE:					
Yes	5	12.5	1	2.5	0.201
No	35	87.5	39	97.5	
PREOP CDVA:					
20/16	0	0.0	4	10.0	0.116
20/20	40	100.0	36	90.0	
UDVA 1 M:					
20/20	0	0.0	16	40.0	<0.001
20/25	23	57.5	15	37.5	
20/32	12	30.0	6	15.0	
20/40	5	12.5	3	7.5	
UDVA 3M:					
20/12.5	0	0.0	2	5.0	0.001
20/16	1	2.5	12	30.0	
20/20	22	55.0	16	40.0	
20/25	17	42.5	10	25.0	
UDVA 6M:					
20/12.5	0	0.0	7	17.5	0.005
20/16	8	20.0	12	30.0	
20/20	26	65.0	20	50.0	
20/25	6	15.0	1	2.5	
POST CDVA:					
20/12.5	0	0.0	6	15.0	0.002
20/16	11	27.5	15	37.5	
20/20	23	57.5	19	47.5	
20/25	6	15.0	0	0.0	
POST ASTIGM:					
-0.25	0	0.0	3	7.5	0.090
0.25	14	35.0	18	45.0	
0.50	26	65.0	19	47.5	

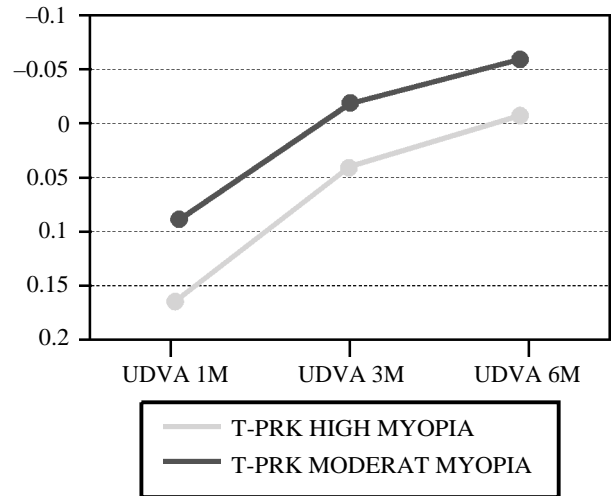


Fig. (1): Comparison of UDVA two groups.

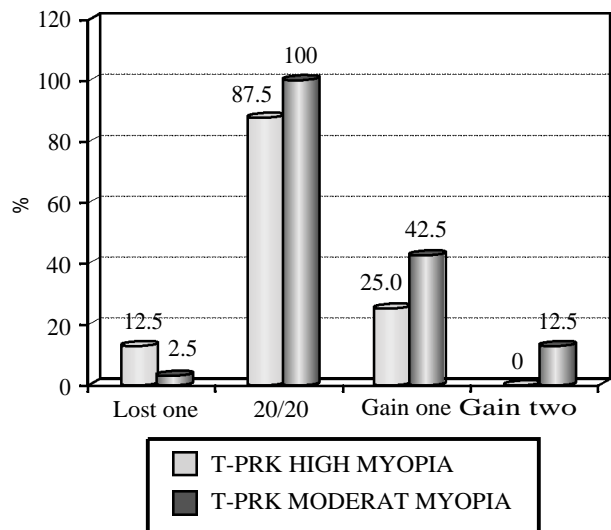


Fig. (2): Gain and lost lines two group.

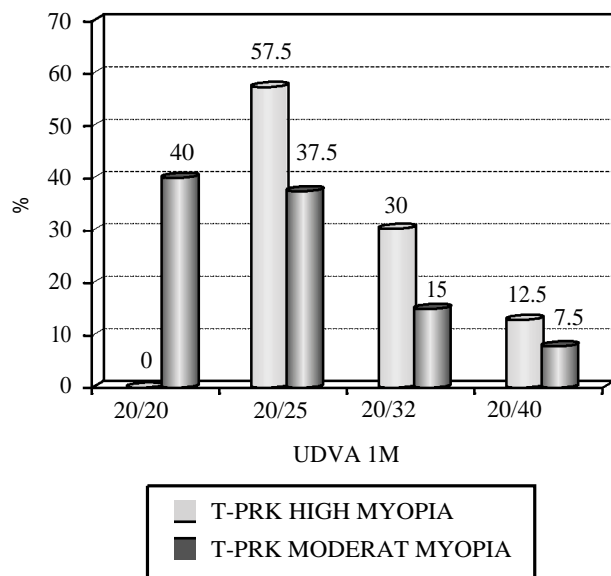


Fig. (3): UDVA one month two groups.

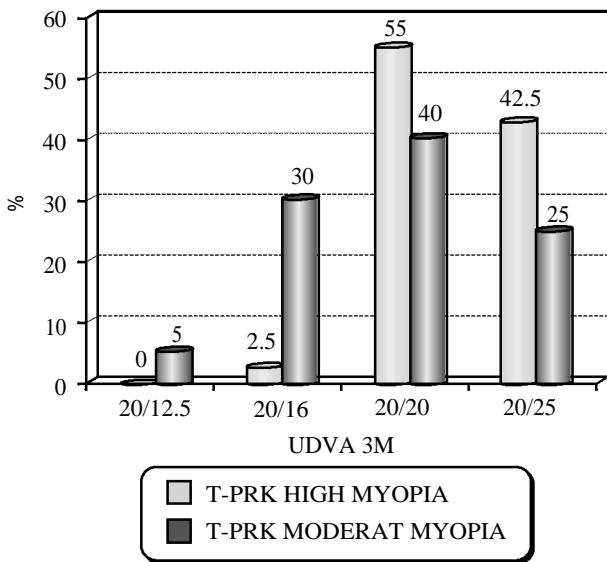


Fig. (4): UDVA three months two groups.

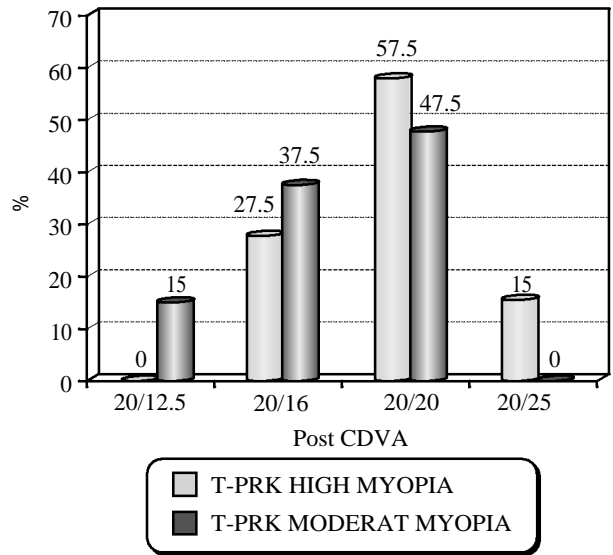


Fig. (7): Postoperative CDVA two groups.

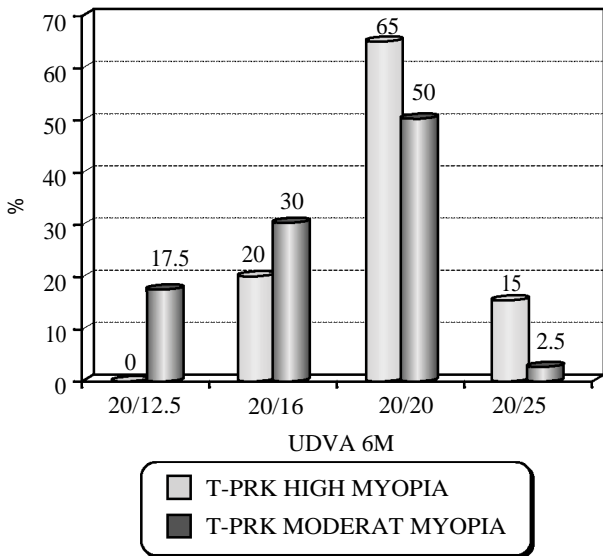


Fig. (5): UDVA six months two groups.

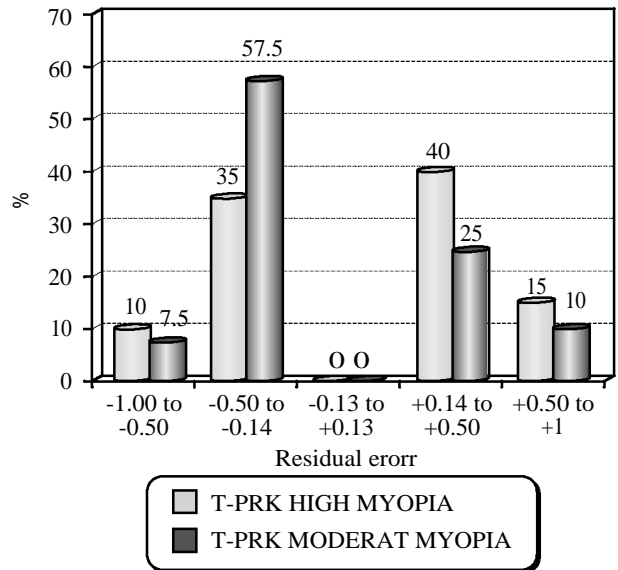


Fig. (8): Residual error two groups.

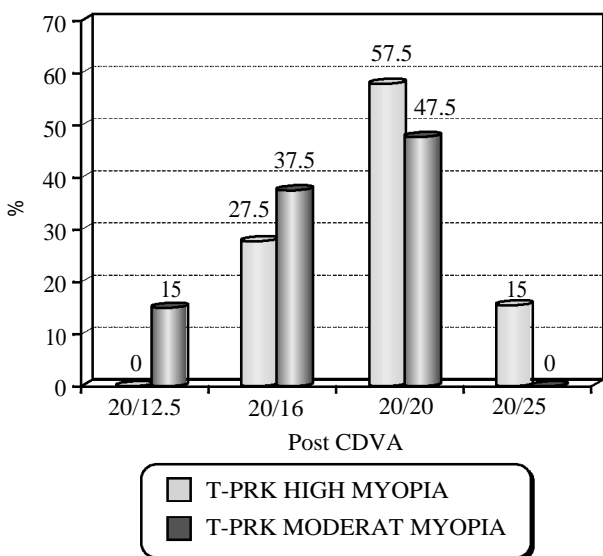


Fig. (6): Postoperative CDVA two groups.

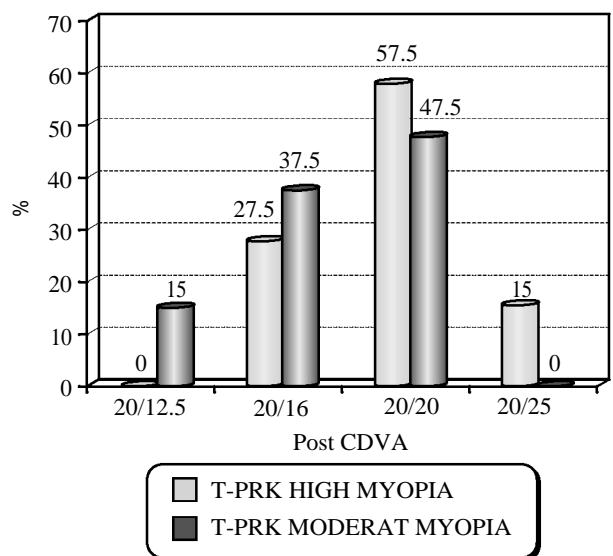


Fig. (9): Postoperative gain in CDVA.

Discussion

This study evaluates the outcome of single step transepithelial PRK on moderate and high myopia through six months. There is a significant improvement of postoperative UDVA, CDVA, and residual SER. In this study 97.5% of moderate myopia patients got a UDVA of 20/20 or better, however 100% of high myopia group got a UDVA of 20/25 and 85% of high myopia patients got a UDVA of 20/20 or better. The results of the study are much better than results recorded by previous study where The percentage was 77% and 88% in a previous studies of single step Trans PRK in high myopic eyes one year follow-up [19]. There was a significant difference in the UDVA between both groups the difference may be attributed to the high preoperative SER in high myopia group. Another reason could be relatively significant higher HOAs of the cornea postoperatively in high myopia compared to moderate myopia group.

The study results are comparable to the previous studies of Trans PRK [20,21,22]. Six months postoperative follow-up showed 82.5% of moderate myopia have $\pm 0.50D$ and 100% have $\pm 1.0D$ of the intended SE refraction, while 75% high myopia have $\pm 0.50D$ and 100% have $\pm 1.0D$ of the intended SE refraction. Aslanides et al. [19] found 91.4% and 97.1% were within $\pm 0.50D$ and $\pm 1.0D$ respectively while Antonios et al. [20] reported that 81.3% and 96.6% were within $\pm 0.50D$ and $\pm 1.0D$ in high myopia within 12 months postoperatively. There were slight regression in certain cases especially in high myopia groups. It is noticed that most of cases reach stability of refraction by the third month postoperatively. Corneal haze is one of the major side effect of TPRK, in high myopia group six eyes developed corneal haze, three of them were grade 1 and treated by frequent steroids and resolved completely by the first month while the other three cases were between grade two and three and resolved by the six month with frequent steroids. In moderate myopia group corneal haze were graded one to two and resolved by the first month with frequent steroid. MMC improves the results of the procedure as it reduces corneal haze postoperatively. MMC improves the stability of the visual outcome and SER during the follow-up time till six months [19,23]. MMC minimize the postoperative regression in high myopia, however the concentration and the applications time still a big challenge. More investigations about the optimum concentration and time of MMC are still needed in photoablation surgery [23,24]. Trans-PRK is lengthy procedure compared to conventional PRK and during the procedure the cornea is exposed to

high amount of excimer laser especially in highly myopic eyes which induce thermal effect on corneal stroma which increases the postoperative haze and HOAs. In compensation to this process we used cold BSS to irrigate the cornea. A difference between the attempted and the achieved SE correction is noticed in both groups there is a significant results of over correction, which either due to long time of one step trans-PRK procedure which leads to dehydration and consequently overcorrection [5], or due to a thin corneal epithelium layers the percentage of patients from 0.50 to +1.00 D were 15% in high myopia and 10% in moderate myopia. The ablation profile is calculated estimating that the central epithelial thickness of a normal cornea is 55 and 65mm at 4mm from the center [20]. Since epithelial ablation algorithm is used for all eyes in T-PRK, regardless of the actual epithelial topometry, more stroma might be ablated than necessary in eyes with a thin epithelium, whereas in eyes with a thick epithelium the refractive part of the ablation might begin where there is still some pithelium left on the surface which is crucial issue in acurecy of the procedures. The mean safety index was greater than one in both moderate and high myopia, the safety index of moderate myopia was greater than high myopia group. In moderate myopia group 2.5% lost line of CDVA, 42.5% of eyes gain one lines and 12.5% of eyes gain two line. While in high myopia group 12.5% lost one line of CDVA and 25% gain one line of CDVA and the remaining have no changes in CDVA. Pain is another complains of TPRK, it usually last for 48 hours and there is need for pain killers and to avoid direct light exposure. Pain could be classified as mild, moderate and severe which is intolerable by some patients after surgery [25]. Serrao S et al. [26] founded that the safety index of the highly myopic eyes treated by PRK was 0.81 over a year postoperatively. The efficacy index was higher in moderate myopia than the high myopia group.

The postoperative UDVA improved in both groups but much more in the moderate myopia group. Corneal HOAs were evaluated, there was significant increase in HOAs in high myopia compared to moderate myopia group, however that increase still below 1.0. Many studies found that HOAs are related to night vision glare, shadows, halos and contrast sensitivity [27,28,29]. It could be due to delivery of uneven laser energy during ablation to different parts of the cornea which could change corneal sphericity. HOAs less than 1.0 had no noticeable effect on the clarity of retinal image, while blur could be seen with 1.0 to 1.5 μ m of wave front aberrations [28,30]. All eyes showed significant improvement of post-operative astig-

matism and the results are comparable to other studies [21]. All patient had contact lens removed by the third or the fourth postoperative day. There was no delayed epithelial healing and that was attributed to the uniform and smooth removal of epithelium during trans PRK [31]. Trans PRK is a safe procedure for treatment of myopia. No reported cases of ectasia. The procedure has advantages over other ablation procedures as it saves corneal stroma for ablation, better corneal biomechanics and easy redo surgery especially in high myopia with higher safety and efficacy index.

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استخدام تقنية تصحيح الابصار الضوئي خلال الخلايا السطحية للقرنية خطوة واحدة لعلاج قصر النظر

خلال هذه الدراسة الإكلينيكية تم تقسيم المرضى إلى مجموعتين أحدهما ذات قصر نظر عالي والأخرى متوسط وتم إجراء الفحوصات ما قبل العملية الجراحية وتم إجراء تصحيح الابصار بنفس القنتية المذكورة أعلاه لجميع المرضى وتمت مقارنة النتائج خلال ستة أشهر بعد الجراحة وتمت مقارنة النتائج من حيث قوة الابصار بدون نظارة نسبة التشويش البصري، نسبة ضعف الابصار بعد الجراحة ومعدلات انحراف القرنية وتبين أن التقنية ذات معدلات أمان عالية ويمكن الاعتماد عليها لتصحيح الابصار.