Initial Supervised Refractive Surgical Experience: Outcome of PRK and LASIK

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Abstract: ***Aim of this paper is to compare the visual outcome in supervised PRK and LASIK surgery. Materials and methods used are Retrospective review of cases performed with Technolas 217 Z platform between July 1, 2009 and June 30, 2010. Inclusion criteria were spherical equivalent of -0.50 to -09.50 diopters (D), refractive mean astigmatic error of -3.00 D, intention to provide full distance correction, and minimum 3-month postoperative follow-up after initial ablation RESULTS: A total of 114 cases performed by 3 different surgeons met the inclusion criteria; 55 eyes underwent PRK and 59 eyes had LASIK. After initial treatment, mean uncorrected distance visual acuity (UDVA) at 3 months after PRK was log MAR 0.032(0.097) and after LASIK was 0.017(0.06). PRK was associated with a significantly better approximation between preoperative Best corrected distance visual acuity (BCVA) and postoperative UDVA (log MAR 0.002 vs. 0.0322; P=0.005). Percentage of eyes that achieved UDVA of 20/20 or better was (89% vs. 92.3%). There were no statistically significant differences between PRK and LASIK cases with respect to complication rates. The mean surgical time taken was 10.15 minutes for LASIK and 11.12 minutes for PRK (P=0.089). In this paper, Supervised PRK was associated with equal visual outcome and surgical time as compared to LASIK.***

Keywords: LASIK, PRK, Supervised, Surgical, Refractive Outcome

1. Introduction

The optimal setting for performing initial refractive surgical procedures is controversial [1], [2]. Although surgical complications with photorefractive keratectomy (PRK) are rare, the creation of a corneal flap during LASIK may be associated with intra- and postoperative complications, which may compromise visual outcome [3]-[5].

With LASIK an increased prevalence of flap-related complications was documented among both novice [6] and experienced ophthalmic surgeons [7]-[9] during the surgical experience, with flap complications ranging from 4.8% to 6.0% during the early learning curve and declining to <1.0% after completion of more than 500 procedures. Until recently, residency programs were reluctant to provide “hands-on” LASIK experience due to the increased prevalence of microkeratome-related flap complications that may occur during the learning curve and their potential for inducing irreversible loss of vision in otherwise healthy eyes. Fortunately, improved microkeratome design has improved the safety associated with flap creation [10], even when used by relatively inexperienced surgeons [6],[11]. The introduction of the femtosecond laser has further increased the safety profile of LASIK flap creation [12]-[14]. Furthermore, several studies have documented recent refractive surgical results and safety profiles among anterior segment subspecialty fellows who receive their initial refractive experience in a well-structured, supervised environment immediately after completion of an accredited residency [6],[11]. In a series of 755 consecutive eyes treated by 2 fellows, Bowers et al [11] reported that 99.4% of eyes achieved uncorrected distance visual acuity (UDVA) of 20/40 or better and 77.2% of eyes were 20/20 or better. In a series of 500 consecutive eyes treated by 10 fellows, Al-Swailem and Wagoner [6] reported that 94.6% of eyes had uncorrected vision that was within 2 lines of preoperative corrected distance visual acuity (CDVA) and only 2.0% of eyes lost more than 1 line of CDVA.

Currently, providing familiarity to both the theoretical and practical aspects of refractive surgery is becoming an increasingly important component of training programs. Today, junior refractive surgeons receive hands-on refractive surgical experience in both PRK and LASIK treatment techniques. In the present study, we report the results of supervised refractive surgical experience during the initial learning years after the introduction of Zyoptix technology at our institution.

2. Materials and Methods

After obtaining approval of the Institutional Review Board, the charts of patients who had refractive Surgery performed by ophthalmologists in their learning curve between July 1, 2009 and June 30, 2010 were retrospectively reviewed.

2.1 Inclusion criteria

Statistical analysis included all eyes with refractive spherical equivalent (SE) between -0.50 and -09.50 diopters (D) and refractive mean astigmatism -3.00 D that were treated with the intention of achieving full distance correction. A minimum follow-up period of 3 months after initial treatment (or after retreatment) was required for inclusion in statistical analysis.

2.2 Exclusion criteria

Eyes with previous refractive, corneal, or anterior procedures were not included in statistical analysis.

3. Patient Enrollment

Participants in the Supervised Refractive Surgery Program were evaluated by the operating ophthalmologists posted in the Cornea and Refractive surgery Department for suitability for refractive intervention. Every patient had manifest and cycloplegic refraction, Central corneal thickness (CCT) analysis along with corneal curvature analysis on Orbscan as well as Zyoptix analysis done, after which the patients were provided with different treatment choices. Generally, the ZYOPTIX treatment choice that most closely approximated the cycloplegic refraction was utilized. Prior to scheduling the refractive surgery, each case was reviewed by a senior refractive surgery faculty member to confirm suitability for refractive intervention. During the informed consent process, all patients were informed that the refractive procedure would be performed by a resident surgeon with faculty supervision. The advantages and disadvantages of PRK and LASIK were fully discussed. Patients without specific contraindications for LASIK were given the choice of undergoing PRK or LASIK. Patients with specific contraindications for LASIK who did not wish to have PRK were excluded. There was no specific requirement for a surgeon to perform a fixed percentage of PRK or LASIK procedures, nor was there a requirement regarding the sequence for which the procedures had to be done during each surgeon's training experience.

4. Surgical Training

All participating ophthalmologist in the Supervised Refractive Surgery Program were either D.O/M.S/DNB qualified surgeons. All surgeons had completed a formalized ophthalmology wet lab curriculum and had anterior segment surgical experience of at least 1000 cataract procedures prior to performing refractive surgery. Before their first refractive surgical procedure, each surgeon attended a series of didactic lectures covering the basics of refractive surgery, which was delivered as part of the cornea and external disease basic science lecture series. In addition, each surgeon attended at least two of the CME instruction courses, which included didactic lectures and a wet lab experience that was supervised by experienced refractive surgeons. These sessions included training in LASIK flap creation with several manual microkeratome; Epithelial debridement for PRK was done with ethyl alcohol/mechanical debridement as well as the technical application of excimer laser ablations.

5. Surgical Technique and Postoperative Management

All refractive ablations were performed with the Technolas 217 Z platform using the ZYOPTIX program. All cases were supervised by two fellowship-trained cornea and refractive surgery specialists who had more than 10 years of laser refractive surgical experience.

All cases of LASIK, flap construction was performed with the Moria LSK2 Carriazo- Barraquer manual microkeratome (Moria SA, Antony, France). Superior hinged flaps were used in all eyes. For PRK, the epithelium was removed by mechanical or alcohol debridement, depending on the preference of the supervising attending ophthalmologist. For PRK of myopic refractive errors of 6.00 D, a 12-second application of mitomycin C 0.02% was performed at the conclusion of the procedure. Mitomycin C was not used in any LASIK cases. Postoperative follow-up visits were scheduled for all patients after 1day, 1 week and 1 and 3 months. All eyes were treated for 1 week with prednisolone acetate and prophylactic topical antibiotics four to six times daily. Photorefractive keratectomy eyes were tapered off topical steroids over a 2- to 8-week period. LASIK treated eyes were tapered off topical steroids over a 1- to 3-week period. At 3-month follow-up, retreatment was offered to patients if all of the following criteria were met: 1) subjective dissatisfaction with visual outcome; 2) residual myopic refractive error of >0.50 D or astigmatic error of >_0.50 D; 3) improvement of 1 or more lines of visual acuity with the updated refraction; 4) subjective appreciation of the level of improvement offered by the updated refraction; and 5) informed consent of the patient after explanation of the risks and benefits of retreatment.

6. Outcome Measures

The main outcome measure was postoperative UDVA. Secondary outcome measures were refractive accuracy, stability, surgical time and complications. Comparisons were made between PRK and LASIK on the following parameters: 1) approximation of postoperative UDVA with preoperative BCVA; 2) percentage of eyes with postoperative UDVA that were 6/6 or better or 6/9 or better; 3) refractive accuracy and stability; 4) surgical time and 5) complications.

7. Statistical Analysis

Data were extracted from each chart and analyzed on an Excel spreadsheet (Microsoft Corp). Analysis of differences between the two procedures in the comparative approximation of postoperative UDVA to preoperative BCVA was performed by converting Snellen’s acuity to log MAR. Statistical comparisons were made using SPSS 17.0 software (SPSS Inc, Chicago, Illinois). Independent samples t test and Mann Whitney test was used to calculate P values. Analysis of the differences between the two procedures with respect to the other categorical variables was also performed similarly. Due to the relative inexperience of each training surgeon and the small number of procedures performed, each eye was considered to be at risk for a novice-related flap complication or variation in visual outcome due to differential ablation; therefore, the outcome of each eye was treated as an independent case and statistical event. A P value <0.5 was considered statistically significant.

8. Results

114 cases that met the inclusion criteria were performed by 3 different surgeons during the study period. 55 eyes had PRK and 59 eyes had LASIK (Graph 1). Most patients underwent bilateral surgery, but 3 cases underwent unilateral surgery (Graph 2).

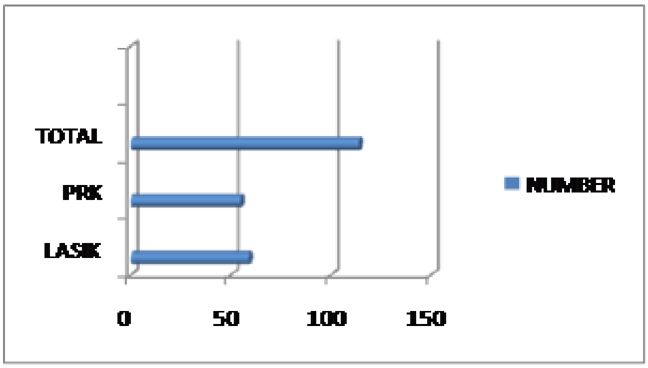

Figure 1: Study groups

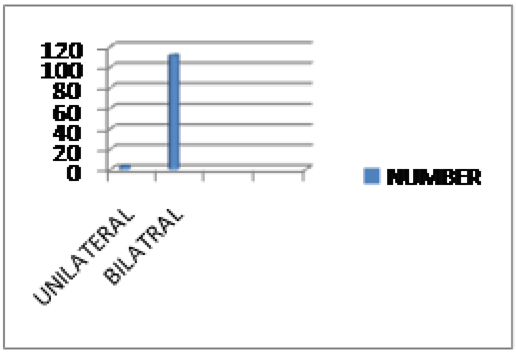

Figure 2: Laterality distribution

The selection of procedure type was elective in all eyes unless case was selected for PRK due to calculation of an inadequate residual posterior corneal thickness after LASIK. Mean (SD) of age is 24.2(4.4) years and the range is 18 – 42 years. No significant differences between groups regarding patient gender (Graph 3) and age.

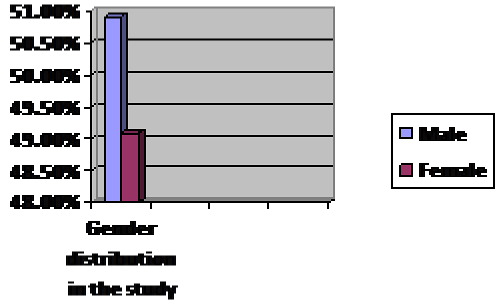

Figure 3: Gender Distribution in study

The preoperative average CCT was 540.37 in LSIK and 501.69 in PRK with overall average being 521.8 (Table 1).This difference was statistically significant; with patients having thinner corneas and calculation of an inadequate residual posterior corneal thickness after LASIK surgery being considered for PRK.

Table 1: Preoperative Central Corneal Thickness Comparison Between the two study groups

CCT	*LASIK*	*PRK*	*Overall*	*p-value**	*Test*
Preoperative	540.37 (29.32)	501.69 (26.41)	521.8 (33.96)	<0.001	t-test

Table 2: Preoperative Spherical equivalent Comparison Between the two study groups

Spherical equivalent	*LASIK*	*PRK*	*Overall*	*p-value**	*Test*
Preoperative	-3.41 (2.06)	-2.55 (1.38)	-3.00 (1.82)	0	Mann-whitney U test

The overall mean spherical equivalent (Se = sphere + 1/2 cylinder) in the study was -3.00(1.82) (table 2). All cases in both the groups had myopia <-9.50 D and both groups were matched according to their refractive error before proceeding for surgery (graph 4).

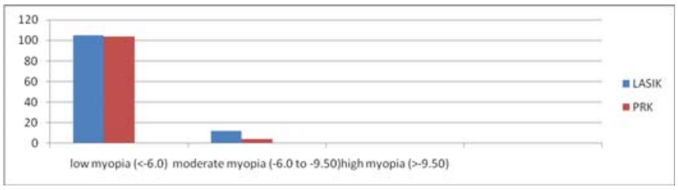

Figure 4: Refractive error distribution between the study groups

No significant intra operative complications were noted in any PRK eyes. There were no persistent epithelial defects beyond the first week, no persistent epitheliopathy beyond the fourth week, and no recurrent epithelial erosions. No eyes developed anterior stromal haze that was associated with >1 line loss of CDVA. For LASIK-treated eyes, two (2.2%) had intraoperative flap complications, one button hole and one flap repositioning. Both cases had final UCVA of 6/9 and BCVA of 6/6. One case had intraoperatively complete disk which was managed with Bandage Contact lens and had final UCVA 6/12 and

BCVA 6/6. Postoperative complications in PRK included one case of anterior uveitis which resolved with NSAIDS and one case of paracentral scarring. The paracentral scar developed final visual acuity of UCVA 6/9.4 cases (3.5%) developed subconjuctival hemorrhage postoperatively but did not affect their visual outcome. 2 cases of PRK developed stromal haze which resolved with topical steroids (table 3). No case was noted of interface haze or required flap relifting. No patients subjectively complained of moderate to severe dry eye symptoms or disturbing night vision symptoms.

Table 3: Complications in the study groups

Intra operative complications	*Frequency*	*Percent*
Button hole	01	00.87
Flap repositioning	01	00.87
Free cap	01	00.87
Total	03	

Postoperative complications	*Frequency*	*Percent*
Anterior uveitis	01	00.87
Paracentral scar	01	00.87
Subconjuctival hemorrhage (SCH) Left eye (LE)	03	02.63
SCH Right eye (RE)	02	01.75
Stromal haze	02	01.75
Total	09	

Table 4: Visual outcome of patients who underwent LASIK or PRK by training surgeons

	LASIK	*PRK*	*P value*
No of eyes	117	108	
Mean preop BCVA(logMAR)	0.0149	0.00	
Mean postop UCVA(logMAR)	0.0169	0.0322	
Difference	-0.002	- 0.0322	
P value	0.16	0.005	

Preop BCVA (%)	*LASIK*	*PRK*	*P value*
6/6 or better	92.3 %	100 %	0.007
6/9 or better	99.1 %	100 %	
6/12 or better	100 %	100 %	
Postop UCVA (%)			
6/6 or better	92.3 %	88.9 %	0.32
6/9 or better	97 %	93 %	0.29
6/12 or better	100 %	98.2 %	

Visual outcomes of PRK and LASIK at 3 months following initial treatment are summarized in table 4. After initial treatment Photorefractive keratectomy was associated with a significantly better approximation between preoperative CDVA and postoperative UDVA (P=0.005). There was high correlation between the preoperative BCVA and postop UCVA for both LASIK and PRK and the percentage of eyes which achieved UDVA that was 20/20 or better (P=0.32) or 20/30 or better (P=0.29) was not statistically significant between LASIK and PRK.. No eye lost > 1 line of CDVA after LASIK or PRK. The method of epithelial removal did not significantly affect visual outcome after PRK. None of the operated cases required retreatment according to the criteria set for resurgery at the beginning of the study.

Table 5: Time taken per patient in each study group

Astigmatic error	*LASIK (117 eyes)*		*PRK (108 eyes)*	
	Number of patients with refractive error	*Number of patients with zero refractive error*	*Number of patients with refractive error*	*Number of patients with zero refractive error*
Day1	0	117	0	108
1Month	02 (1.70%)	115	0	108
3Month	02 (1.70%)	115	0	108

Time	*LASIK*	*PRK*	*Overall*	*p-value**	*Test*
Time taken for surgery	10.15 (2.76)	11.12 (3.26)	10.62 (3.04)	0.089	t-test

The mean time taken for LASIK as well as PRK was not statistically significant (p=0.089) suggesting that supervision makes a surgeon faster in his refractive surgery which ever may be the type of surgery. The number of surgeries (both eyes) finishing in less than 15 minutes is 86.20% in LASIK and 79 % in PRK (table 5, Graph 5). Thus supervised surgery allows a surgeon to decrease surgical time and increase the number of cases operated in a given span of time.

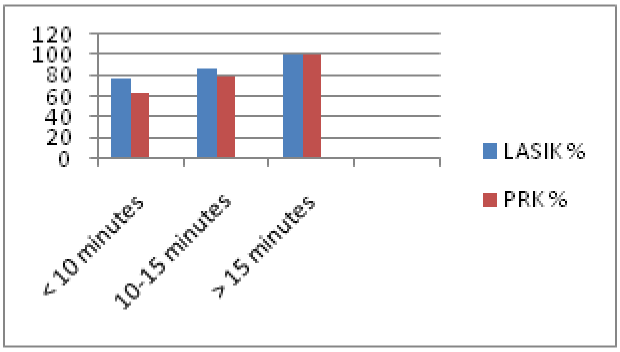

Figure 5: Comparison of surgical time between the two procedures

There was high stability of surgical correction demonstrated by the fact that only 1.70% patients who underwent LASIK had some amount of spherical or astigmatic error at 3 month review while 2.77% patients undergoing PRK had spherical error at 3 month review (table 6). None of these patients met with the criteria set for re surgery and so were not operated on again.

Table 6: Postoperative regression

Spherical error	*LASIK (117 eyes)*		*PRK (108 eyes)*	
	Number of patients with refractive error	*Number of patients with zero refractive error*	*Number of patients with refractive error*	*Number of patients with zero refractive error*
Day1	00	117	02 (1.85%)	106
1Month	02 (1.70%)	115	03 (2.77%)	105
3Month	02 (1.70%)	115	03 (2.77%)	105

9. Discussion

The excellent outcomes achieved by junior surgeons in the present study support the concept that the introductory experience to refractive surgery can be effectively and safely incorporated into a well-structured program that includes the key elements of 1) patient selection, recruitment and informed consent; 2) pre-surgical didactic lectures and "hands on" wet lab training; and 3) intraoperative and postoperative supervision by experienced refractive surgeons [15]. The recruitment of a well-educated patient base with the ability to give informed consent not only with respect to their ability to review the pertinent ophthalmic literature regarding the risks and benefits of refractive procedures, but to have an appropriate level of awareness is very important. The documented efficacy and safety profile of modern laser refractive surgery [13],[14], even in the hands of novice surgeons [6],[11], combined with the supervision of highly trained refractive surgeons, has made this an extremely successful program at our institution.

Although excellent visual results were obtained with both PRK and LASIK, statistically superior outcomes were associated with the former if one accepts the approximation of preoperative CDVA and postoperative UDVA as the gold standard of success for refractive surgery. After initial treatment, eyes with PRK had mean postoperative UDVA that was almost identical to preoperative CDVA, which was better than eyes with LASIK ($p<0.005$). When comparing the percentage of eyes with postoperative UCVA 6/6 or 6/9 there is no statistical difference between LASIK and PRK. Among PRK eyes, the percentage of eyes that had final UDVA of 6/6 or 6/9 or better were 88.9% and 93 %, respectively, compared to preoperative CDVA while postoperative UDVA of 6/6 or 6/9 or better was achieved in 92.3% and 97%, respectively, of eyes after LASIK, compared to preoperative CDVA in 92.3% and 99.1% of eyes, respectively. Slightly better visual results among our training surgeons with PRK can potentially be explained on the basis of 1) issues related to the complexity of the LASIK procedure compared to technically simpler PRK, especially in the hands of novice surgeons; 2) iatrogenic or inherent difference in outcomes of surface versus bed ablations; or 3) a combination of these factors [15],[16]. Due to limited information in the literature regard15ing initial refractive experience of training refractive ophthalmologists, it is not possible to determine whether these findings are unique to our study or part of an emerging trend that suggests better outcomes may be achieved with PRK. In a larger series of refractive procedures performed by experienced refractive surgeons that were subjected to the same analysis, Ghadhfan et al [16] reported significantly better visual results with PRK compared to LASIK for the same parameters that were significant in the present study. Differences in their study were only present if epithelial removal was performed mechanically with a blade or excimer laser rather than with alcohol. This finding was not reproduced in the present study, perhaps due to the absence of postoperative epithelial wound healing complications in our alcohol-debrided eyes. Our study results also matched the study done on similar line by Michael D. Wagoner, MD et al [15].

Analysis of complications that occurred during or after LASIK suggests that the mere occurrence of such complications alone is insufficient to explain the differences in visual outcome that occurred in this study. Only 3 (2.56%) eyes experienced intraoperative microkeratome-related flap complications, a rate that is comparable to that previously reported in a similarly trained and supervised group of novice [6],[15] and experienced [16] surgeons using the same instrument. All (100%) eyes with flap-related complications retained a CDVA of 6/6 or better, with obtaining a final UDVA of 6/9 or better.

Statistically significant differences in the approximation of preoperative CDVA and postoperative UDVA in PRK cases cannot be explained exclusively on differences in the refractive accuracy of the procedures in spite of the percentage of eye receiving 6/6 or 6/9 or better was not statistically significant in LASIK and PRK .In the study by Ghadhfan et al [16], the disparate visual results between PRK and LASIK-treated eyes also occurred despite identical refractive outcomes between study groups, supporting a hypothesis of inherently better outcomes may be obtained with PRK. Irrespective of the reasons for the superior visual results that were observed after PRK, there is unequivocal evidence that during their initial refractive experience our supervised training surgeons provided better outcomes with a single PRK procedure than with initial LASIK treatment [15]. Although 100% of PRK-treated eyes experienced the typical postoperative morbidity associated with a transient epithelial defect, none of these eyes experienced subsequent complications or required additional intervention, and every eye achieved final UDVA that was identical or nearly identical to preoperative CDVA. Although none of the LASIK-treated eyes had any noteworthy postoperative discomfort, 2.56% eyes had intraoperative complications compared to nil intraoperative complications in PRK cases. In comparison of mean surgical time in spite of there being no statistical difference between LASIK and PRK every training surgeon stated that experienced supervision helped him perform the surgery faster and increase his number of surgeries in a given time frame.

10. Conclusion

At minimum, our observations suggest that every training/junior refractive surgeon (if not every refractive surgeon) should be familiar with the PRK technique before going to LASIK and experienced supervision in the initial learning curve helps to decrease complications, decreases surgical time and gives better postoperative result and that proper informed consent of every patient undergoing refractive surgery should include a frank discussion of the pros and cons of PRK and LASIK.

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