Outcome of PRK and LASIK for the Initial 100 Cases at Kirkuk City

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Abstract:

Background: Despite that LASIK showed faster visual recovery after the operation, there was no considerable variation in the visual results between LASIK and PRK with long term- follow up.

Aim of study: To assess the outcome of photorefractive keratectomy (PRK) and laser (or laser-assisted) *in situ* keratomileusis (LASIK) for the initial 100 cases in the same center at Kirkuk city.

Patients and Methods: This clinical study was designed as a prospective, 6-month clinical study. A total 198 eyes of 100 patients entered the study cohort: 141 randomized to LASIK and 57 to PRK. All patients received a one-pass, multizone excimer laser ablation as part of either PRK or LASIK procedure using the Alcon Allegretto excimer laser. The preoperative manifest spherical equivalent ranged from -9.25 diopters (D) to +5.0 D for the LASIK group and -4.50 D to -0.6 D for the PRK group.

Results: At 6 months after surgery, 43 (75.4%) and 10 (17.5%) eyes in the PRK group achieved UCVA of 6/6 and 6/12 or better respectively, while after LASIK, 63 (44.6%) and 71 (50.3 %) eyes achieved UCVA of 6/6 and 6/12 or better, respectively. After PRK 56 (98.2%) eyes were within 1.0 D of attempted correction compared to 132 (92.7%) eyes in the LASIK group. At 6 months postoperatively, most of the eyes (85 eyes in the LASIK group and 43 eyes in the PRK group) achieved UCVA line similar to the preoperative BCVA line. No significant complications at operation were seen in any PRK cases. For LASIK-treated eyes, five eyes (3.5%) had intraoperative flap complications, four incomplete flaps and one button hole. All these cases were treated with PRK after one month. All incomplete flap cases got final UCVA of 6/6, while buttonhole flap case achieved final UCVA of 6/18.

Conclusions: The essential outcomes of both LASIK and PRK in this study show no significant differences in efficacy at 6-months follow-up. Both LASIK and PRK seems to be relatively effective and safe procedure for myopia and hypermetropia. PRK has the advantage of easier surgery without corneal flap complications, while LASIK offers the advantages of minimal discomfort and faster visual rehabilitation.

Keywords: Myopia, Hypermetropia, Uncorrected visual acuity, Best corrected visual acuity, Refraction.

Introduction:

For achieving initial kerato-refractive operations, the appropriate setting is debatable [1, 2]. The intraoperative complications with PRK are rare, while complications associated with the making of a corneal flap during LASIK may be associated with inappropriate visual results [3, 4]. With LASIK an increased prevalence of flap-related complications were documented between both novices [5] and experienced ophthalmic surgeons. The corneal flap complications have a range from (4.8%) to (6.0%) during the early surgeries and decreased to < (1.0%) after achieving number of operations exceeding 500 cases [6, 7, 8]. For the higher percentage of the corneal flap

complications that may occur during the initial surgeries and their potential for inducing irreversible reduction of vision in otherwise normal individual, the residency programs were unwilling to give "hands-on" LASIK surgeries. Recently, the better micro-keratome design has upgraded the safety associated with LASIK surgery [9], even as utilized by relatively less experienced ophthalmologist [5, 10]. Also, the safety of corneal flap making has risen with the use of the femtosecond laser [11, 12].

The 193 NM argon-fluoride (ArF) excimer laser treats refractive error by ablating the anterior corneal stroma to create a new radius of curvature. Two major refractive surgical techniques use excimer laser ablation. In surface ablation techniques, including photorefractive keratectomy (PRK), the Bowman layer is exposed either by debriding the epithelium through various methods or by loosening and moving, but attempting to preserve, the epithelium. In LASIK, the excimer laser ablation is performed under a lamellar flap that is created with either a mechanical microkeratome or a femtosecond laser [13].

Surface ablation procedures were initially performed as PRK, the sculpting of the deepithelialized corneal stroma to alter refractive power, and they underwent extensive preclinical investigation before being applied to sighted human eyes. Results of early animal studies provided evidence of relatively normal wound healing in laser-ablated corneas [13].

The popularity of PRK decreased in the late 1990s, when LASIK began to be performed because of LASIK's faster recovery of vision and decreased postoperative discomfort. Although more LASIK than surface ablation procedures are still performed, the number of surface ablations has increased in recent years. PRK remains an especially attractive alternative for specific indications, including irregular or thin corneas; epithelial basement membrane disease (often-called map-dot-fingerprint dystrophy); previous corneal surgery, such as penetrating keratoplasty and radial keratotomy; and treatment of any LASIK flap complications, such as incomplete or buttonholed flaps. Surface ablation eliminates the potential for stromal flap - related complications and may have a decreased incidence of postoperative dry eye. Corneal haze, the major risk of PRK, decreased markedly with the use of adjunctive mitomycin C; subsequently, the use of PRK for higher levels of myopia has increased [13].

The term keratomileusis comes from the Greek words for "cornea" (kerato) and "to carve"n (mileusis). Laser in situ keratomileusis, which combines keratomileusis with excimer laser stromal ablation, is currently the most frequently performed keratorefractive procedures because of its safety, efficacy, quick recovery of vision, and minimal patient discomfort. LASIK combines 2 refractive technologies: excimer laser stromal ablation and creation of a stromal flap [13].

The aim of the study:

To assess the outcome of PRK and LASIK for the initial 100 cases in the same center at Kirkuk city.

1. Patients and Methods:

1.1 Study Design:

This clinical study was designed as a prospective, 6-month, randomized clinical study intended to evaluate the safety and efficacy of PRK and LASIK for the treatment of myopia and

hypermetropia for the initial 100 cases which were performed by the same surgeon. Informed consent was taken from all patients. Assessment outcomes were based on a comparison of preoperative and postoperative values in conjunction with analysis of adverse events and complications.

1.2- Inclusion criteria:

All patients included in the study were 19 years or older and had refractive spherical equivalent (SE) between -9.25 D to +5.0 D for the LASIK group and -4.50 D to -0.6 D for the PRK group, with the purpose of achieving BCVA. The least observational time of 6 months after surgery was needed for involvement in the statistical analysis.

1.3-Exclusion criteria:

Eyes with previous surgery, functionally monocular, previous or current ocular disease, including keratoconus and systemic disease that may influence wound healing were not involved in the study.

2. Patient Enrollment (preoperative assessment):

Every patient had a central corneal thickness analysis, manifest and cycloplegic refraction, along with corneal curvature analysis on Pentacam-Oculus. Prior to performing the surgery, all cases were reviewed by the same senior refractive surgeon to confirm suitability for refractive surgery. The benefits and drawbacks of LASIK and PRK were fully explained to the patients.

3. Surgical Technique:

Photorefractive keratectomy (PRK) is performed with the excimer laser, which can accurately ablate corneal tissue to an exact depth with minimal disruption of surrounding tissue. Myopia is treated by ablating the central anterior corneal surface so that it becomes flatter. Hypermetropia is treated by ablation of the periphery so that the center becomes steeper.

Technique

- The visual axis is marked and the corneal epithelium removed.
- The patient fixates on the aiming beam of the laser.
- The laser is applied to ablate only Bowman layer and anterior stroma. This usually takes 30–60 seconds.
- A therapeutic contact lens was put and removed after 5 days.

For LASIK, the excimer laser is used to reshape the corneal stroma exposed by the creation of a superficial flap; the flap remains attached by a hinge to facilitate accurate and secure repositioning. To decrease the risk of subsequent ectasia, a residual corneal base at least 300 μm thick was remained after ablation.

Technique:

- A suction ring centered on the cornea is applied to the globe; this raises the intraocular pressure substantially.
- The ring stabilizes the eye and provides the guide track for a mechanical microkeratome, which is advanced across the cornea to create a thin flap.
- The flap is reflected and the bed reshaped, followed by flap repositioning.

The corneal flap was done with the Moria LSK2 Carriazo- Barraquer manual microkeratom for all LASIK patients. In all cases, a superiorhinged flaps were done. For PRK, the de-epitheliazation was performed by

mechanical debridement and the mitomycin C (0.02%) was put at the end of the operation for 15 seconds.

4. Postoperative Management:

After operation, in the PRK group eyes, prednisolone acetate (1%), ofloxacin and artificial tear drops 4 to 6 times daily and oral vitamin C were applied up to 1 month and in addition to diclofenac and tramadol orally were used for the first few days. In the LASIK cases, prednisolone acetate (1%) and ofloxacin were administered 4 to 6 times daily for 2 weeks and then discontinued, but the artificial tear drop was used for 2 to 3 months.

Postoperative examination schedule was done for all cases after one day, one week and one, three and six months.

5. Outcome Measures:

The main outcome measures were uncorrected visual acuity (UCVA), refraction; best corrected visual acuity (BCVA), adverse events, operative and postoperative complications and subjective satisfaction and symptoms.

6. Statistical Analysis:

Excel spreadsheet is used for analysis of the data that were extracted from each chart. Analysis of differences between the two procedures in the comparative approximation of preoperative BCVA (best corrected visual acuity) to postoperative UDVA (uncorrected distance visual acuity) was performed by converting Snellen's acuity to log MAR. For independent samples, t test and Mann Whitnney test was utilized to calculate P values. A P value <0.05 was considered statistically significant.

7. Results:

Preoperative characteristics:

In this study 198 eyes of 100 patients had surgery. 57 eyes were operated with PRK surgery and 141 with LASIK. The mean age was 29.6 years (21 – 45 years) in the LASIK cases and 26 years (19 – 36 years) in the PRK cases. 48 cases were female and 26 were male in the LASIK group; 12 were female and 14 were male in the PRK group. (Graph1). Most patients underwent bilateral surgery, but 2 cases underwent unilateral surgery.

The preoperative average central corneal thickness (CCT) was 541.7 microns in the LSIK group and 532.9 microns in the PRK group with an overall average being 537.3 microns. The patients having thinner corneas and calculation of residual posterior corneal thickness of less than 300 microns after LASIK surgery being considered for PRK.

UCVA (Uncorrected Visual Acuity):

Visual outcomes of LASIK and PRK at 6 months following surgery are summarized in table 1 and 2.In the LASIK group, the preoperative UCVA in most cases (119 eyes) were worse than 6/12, while 6 months after the operation this level was achieved in 134 eyes. In the PRK group, the preoperative UCVA in most cases (54 cases) were worse than 6/12, while 6 months after the operation this level was achieved in 56 patients.

By comparing the pre-operative BCVA with 6 month post-operative UCVA, we found (34%) of eyes achieved a BCVA of 6/6 or better pre-operatively, while (44.6%) of eyes achieved UCVA with that level post-operatively and (56%) of eyes had 6/12- < 6/6 pre-operatively, and (50.3%) got this level post-operatively in the LASIK group. In the PRK group, we found (80.7%) of eyes achieved a BCVA of 6/6 or better pre-operatively, while (75.4%) of eyes achieved UCVA with that level at 6

months post-operatively and (17.5%) of eyes had 6/12- < 6/6 pre-operatively, and (22.8%) got this level post-operatively.

Refractive error:

Refractive error distribution before and after the operation are summarized in the table 3 and 4. In the LASIK group, preoperatively most of the eyes were myopic with spherical equivalent -2.1 _ -6.0 D in (56%) and (16.3%) of eyes were with -6.1 _ -10.0 D and only 20 eyes were hypermetropic with SE range +1.1_ +6.0; while postoperatively the SE range of 0.0_+1.0 D was achieved in (53%) of eyes and SE range of -0.10D _ -1.0 D was achieved 39.7 of the eyes. In the PRK group, all patients were myopic with SE range -1.10_-2.0 D at 49.1% and SE range of -2.10_ -6.0 D at (47.3%), while postoperatively the SE range 0_+1.0 D was achieved in (49.1%) of eyes and the SE range of -0.1D _ -1.0 D was also achieved in (49.1%) of eyes.

Postoperative UCVA line versus Preoperative BCVA line:

At 6 months postoperatively, most of the eyes (85 eyes in the LASIK group and 43 eyes in the PRK group) achieved UCVA line similar to the preoperative BCVA line. While improvement of Postoperative UCVA versus Preoperative BCVA line by 1 line were achieved in 36 eyes of LASIK group and 4 eyes in the PRK group, but 2 lines improvement was noted in 10 eyes of LASIK group and one eye on PRK group. One eye in the LASIK group could get 4 lines improvement. Loss of the Postoperative UCVA line versus the Preoperative BCVA line with one line was noted in 7 eyes of LASIK group and 6 eyes of PRK group, and by 2 lines was noted in two eyes of LASIK group and three eyes of PRK group. Nobody got impairment more than two lines. These worsening were due to under correction. Despite these mild worsening of VA lines, most of the patients were satisfied postoperatively with their vision (Graph 2 and 3).

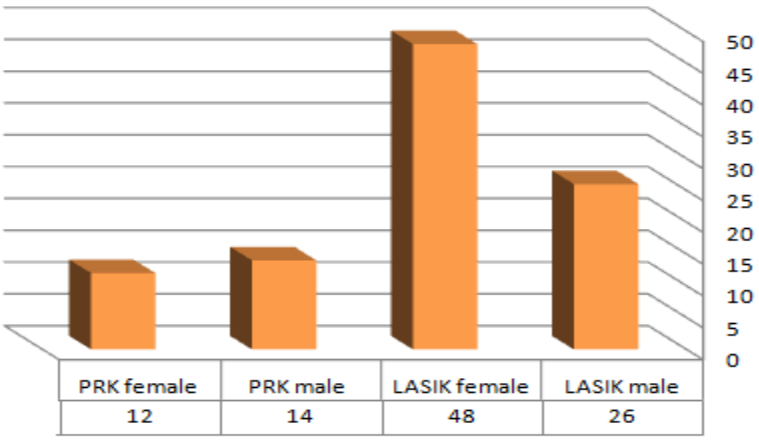

Figure (1): Gender Distribution in study.

Table (1): Visual outcome of patients who underwent LASIK: No. (%) of eyes.

VA	Preoperative UCVA	Preoperative BCVA	Postoperative UCVA
6/6 or better		48 (34)	63 (44.6)
6/12 - < 6/6	9 (6.3)	79 (56)	71 (50.3)
6/18 - < 6/12	13 (9.2)	14 (9.9)	7 (4.9)
6/60 - < 6/18	55 (39)		
3/60 - < 6/60	56 (39.7)		
1/60 - < 3/60	8 (5.6)		

Table (2): Visual outcome of patients who underwent PRK: No. (%) of eyes.

VA	Preoperative UCVA	Preoperative BCVA	Postoperative UCVA
6/6 or better		46 (8o.7)	43 (75.4)
6/12 - < 6/6	3 (5.2)	10 (17.5)	13 (22.8)
6/18 - < 6/12	13 (22.8)	1 (1.7)	1 (1.7)
6/60 - < 6/18	36 (61.1)		
3/60 - < 6/60	5 (8.7)		

Table (3): Refractive error distribution before and after operation for the LASIK group: No. (%) of eyes.

Refractive errors	Preoperative	Postoperative
+2.1_ +6.0	12 (8.5)	1 (0.7)
+1.1 _+2.0	7 (4.9)	4 (2.8)
0 _ +1.0	1 (0.7)	76 (53)
-0.1 _ -1.0	6 (4.2)	56 (39.7)
-1.1 _ -2.0	13 (9.2)	4 (2.8)
-2.1 _ -6.0	79 (56)	
-6.1 – 10.0	23 (16.3)	

Table (4): Refractive error distribution before and after operation for the PRK group: No. (%) of eyes.

Refractive errors	Preoperative	Postoperative
+1.1 _+2.0		1 (1.7)
0 _ +1.0		28 (49.1)
-0.1 _ -1.0	2 (3.5)	28 (49.1)
-1.1 _ -2.0	28 (49.1)	
-2.1 _ -6.0	27 (47.3)	

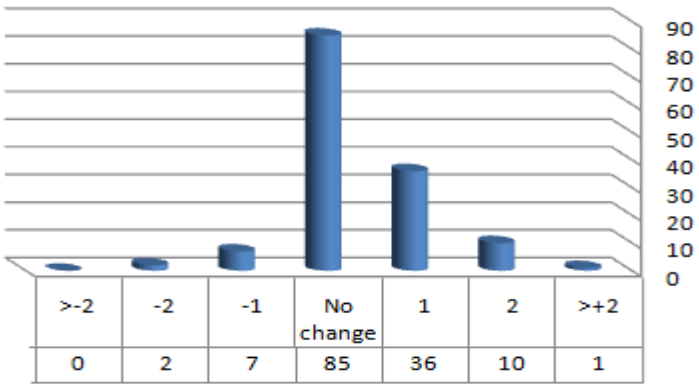

Figure (2): Changes in Best spectacle corrected visual acuity for LASIK group.

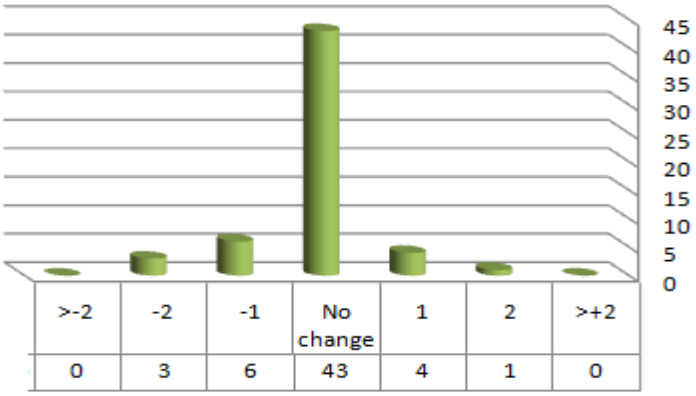

Figure (3): Changes in Best spectacle corrected visual acuity for PRK group.

Complications:

No significant operative complications were seen in any PRK cases. The persistent epithelial defect was noted in one eye, which was treated successfully. There were no recurrent epithelial erosion and no eyes developed significant anterior stromal haze.

For LASIK-treated eyes, five cases (3.5%) had intraoperative flap complications, four incomplete flaps and one buttonhole. All these cases were treated with PRK after one month. All incomplete flap cases were getting final UCVA of 6/6, while incomplete flap case achieved final UCVA of 6/18. Postoperative complications in PRK included one case of clinical non significant corneal haziness. In the LASIK group, one case developed clinically significant flap striae that are treated success fully by epithelial removal and flap relifting and repositioning with final UCVA of 6/6 partial. Diffuse lamellar keratitis (DLK) occurred in five cases and all of them were treated conservatively by frequent topical prednislone acetate except one which required flap relifting and washing. No case was noted to have interface haze. No other unanticipated adverse reactions such as corneal melting or perforation, corneal decompensation, microbial keratitis, retinal lesions or cataract were found in this study.

Subjective Assessments:

At each postoperative visit all patients were asked about their satisfaction. At 6months, most of the cases reported that they were very/extremely satisfied with the results of their surgery, despite minor under correction in some eyes.

8. Discussion:

During the last years, it has been suggested that LASIK may be more preferable than PRK, especially in high degrees of hypermetropia and mypia. The most suitable method that can compare these different procedures is the randomized controlled clinical trial.

Despite that LASIK showed faster visual recovery after the operation, this study showed that at 6 months of surgery, there was no considerable variation in the visual results between LASIK and PRK. Concerning to the long-term safeness of these two operations, the relative short follow-up and few complications in both operations prevent decisive conclusions; however, more investigations are suggested.

Efficiency of LASIK vs. PRK:

"Uncorrected visual acuity": Visual recovery was faster in the LASIK patients, due to unharmed epithelium, avoiding early healing stage of corneal surface in the PRK patients. Faster achieving of better UCVA seems to be one of the major advantages of the LASIK procedure. By the 1-month follow-up, however, the PRK group in general had caught up to the LASIK group. Also, it could be seen that there was a slightly better UCVA in the LASIK patients at 6 months; however this was not statistically important. In the PRK group, this was due to the higher number of under correction.

In analysis of myopic patients of -1.5 to -6.0 D with PRK [(14)], it has been found that older age was accompanied with less chance of attaining 6/12 or better UCVA. Also, in this study, a preoperative predictor of UCVA in the PRK-treated eye was the age of the patient, in contrast to the LASIK-treated eye in which the patient age is not an important factor. The explanation for that probably is the greater effect of wound healing, which may be affected by age of the patient, on results of PRK compared with LASIK. Also, in another study [(15)], it has been detected more irregular topographic patterns in PRK in comparison to the LASIK group. Age-related eye changes, such as macular and lenticular changes, may prevent an older age group to compensate for irregularities in the corneal topographies as in the younger age group and this may cause more compromised postsurgical UCVA with increasing age in PRK cases.

In spite of that both LASIK and PRK gave good visual outcomes, statistically better results were seen with the LASIK if one takes the approach of postoperative UCVA and preoperative BCVA as the main part of success for the operation.

When comparing the percentage of eyes with postoperative UCVA of 6/6 or 6/12 there is no statistical difference between LASIK and PRK. In the PRK cases, it had been found that (75.4%) and (98.2%) of eyes achieved final UCVA of6/6 or 6/12 or better, respectively, in comparison with presurgical BCVA (80% and 98.2%, respectively), while postoperative UCVA of 6/6 or 6/12 or better was achieved in (44.6%) and (94.9%), respectively, of LASIK-treated eyes, in comparison with BCVA (preoperative) at (34%) and (90%) of eyes, respectively. Slightly better visual outcomes among the PRK Patients in this study can be explained by: (1) relatively the more difficult surgical procedure of the LASIK in comparison with the technically easier PRK. (2) Inherent or iatrogenic variations in results of PRK (surface ablation) versus LASIK (bed ablation), or (3) a collection of the above factors [(15, 16)]. It is not reasonable to say if these results are specific to this study or an aspect of a trend that propose better results may be obtained with PRK, because of the finite informations in the literatures about the initial experience of training junior refractive ophthalmologists. In a larger groups of refractive operations that were done by expert ophthalmologists which were undergone same analysis, Ghadhfan et al [(16)] got considerably better visual outcomes in the PRK group in comparison to the LASIK group for the similar factors that were valuable in this study. The difference in their study was that the de-epithelialization done either mechanically or by the excimer laser instead of alcohol. This study results

also matched the study done on similar line by Michael D. Wagoner, MD, et al [15].

Analysis of the complications which happened during LASIK operation or after it shows that the appearance of such complications per se is not sufficient to clarify the visual results differences that took place in this study. Only 5 eyes (3.5%) experienced intraoperative microkeratome-related flap complications (four incomplete flap and one button hole), and this rate is analogous to that previously mentioned in a similarly supervised and trained beginner group [17, 15] and experienced [16] ophthalmologists using similar instruments. All these cases were treated with PRK after one month. All incomplete flap cases were getting final UCVA of 6/6, while incomplete flap case achieved final UCVA of 6/18.In the LASIK group, one case developed clinically significant flap striae that is treated successfully by epithelial removal and flap lifting and repositioning with final UCVA of 0.8. Diffuse lamellar keratitis (DLK) occurred in five cases and all of them were treated conservatively by frequent topical prednislone acetate except one which required flap lifting and washing

Statistically significant variations in the approach of presurgical BCVA and postsurgical UCVA in PRK cases cannot be clarified just on the differences in the refractive operation accuracy in spite of the percentage of eye receiving 6/6 or 6/12 or better was not statistically significant in LASIK and PRK. In the research by Ghadhfan et al [16], a thesis of inherently better results may be achieved with PRK supported by the various visual outcomes between LAISK and PRK - operated eyes had occurred in spite of the similar refractive results between the research groups.

Although (100%) of PRK-operated eyes complained from severe ocular discomfort due to evanescent corneal epithelial defect, nobody suffered from further complications or needed extra intervention, and all eyes got ultimate uncorrected visual acuity which was congruent or almost congruent to the preoperative best corrected visual acuity. In spite of the LASIK patients had no remarkable discomfort postoperatively, (3.5%) of the operated eyes had intraoperative complications compared to nil intraoperative complications in PRK cases.

Other operation side effects; epitheliazation was accomplished by 4 days in most cases after PRK, and there is no occurrence of persistent epithelial defect, sterile corneal ulceration, or infectious keratitis. As the epithelium was remained intact in LASIK surgery, the postoperative epithelial defect was not occurred in this study.

The corneal flap complications, however, are possible in LASIK surgery only. Incomplete flaps, thin flaps, and button hole flap were all seen in this study. However, all procedures ultimately were completed without adverse outcomes. Whether the advantages of early visual recovery and diminished corneal haze outweigh potential flap complications remains for further study.

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