

CLINICAL STUDY TO EVALUATE THE VISUAL OUTCOME AND PATIENT COMFORT IN LASIK AND PHOTOREFRACTIVE KERATECTOMY IN LOW-TO-MODERATE MYOPIC ASTIGMATISM PATIENTS

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ABSTRACT

BACKGROUND

To evaluate visual outcomes following LASIK and Photorefractive Keratectomy (PRK) in low-to-moderate myopia and/or myopic astigmatism in age and refractive error matched eyes.

MATERIALS AND METHODS

Of a total 30 patients aged ≥ 21 years, 20 (40 eyes) underwent LASIK and 10 (20 eyes) underwent PRK for low-to-moderate myopia or myopic astigmatism. LASIK was performed with the Alcon wave light 500 and PRK with the alcohol application for epithelial removal. All ablations were performed using the same excimer laser system. One surgeon operated all patients by using an excimer laser (Alcon wave light 500 system). Age and refractive error matched patients were divided in two groups. Preoperative and one year postoperative uncorrected visual acuity, best corrected visual acuity and manifest refractions were recorded to compare the outcomes of both the procedures. Outcome measures to assess the patient comfort levels in both groups include postoperative pain and quality of vision. Other outcome measures to assess the wound healing includes intraoperative complications, corneal haze and corneal reepithelialisation.

RESULTS

Sixty eyes of 30 patients were found matched regarding age and refractive error. In PRK group, among 10 patients, 5 (50%) were males and 5 (50%) were females, whereas in Lasik group, males were 12 (60%) and 8 (40%) were female patients. Mean preoperative MRSE was -4.06 ± 1.00 Dioptres (D) for LASIK versus -4.50 ± 1.25 D for PRK. Complete flap healing was achieved by postoperative day 4 in 86.9% of LASIK eyes versus complete reepithelialisation in 92.4% of PRK eyes. Using Fisher exact test, a significantly higher percentage of LASIK eyes compared to PRK eyes achieved 20/15 or better at 1 month (35.8% vs. 17.8%, $P=0.031$), 3 months (69.3% vs. 49.3%, $P=0.004$), 6 months (79.1% vs. 59.9%, $P<0.001$) and 12 months (85.9% vs. 61.9%, $P=0.002$). A change in MRSE >0.50 D occurred in 12.4% of LASIK eyes within the 3- and 12-month interval versus 25.7% of PRK eyes ($P=0.04$). Patients in both groups were happy regarding their visual outcome.

CONCLUSION

LASIK showed superior refractive efficacy and stability for low-to-moderate myopia with RBT (residual bed thickness) >320 microns. PRK shows better results in thinner corneas (RBT 280-320 microns). Both treatments were safe and comparable except in terms of pain and haze formation in selective PRK cases.

KEYWORDS

LASIK, PRK, MRSE, Myopic Astigmatism.

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BACKGROUND

Majority of the spectacle or contact lens wearers desire to see clearly without glasses or contact lenses. With the availability of excimer laser for the correction of myopic refractive errors, this dream seems to come true. Keratorefractive procedures are well established and have become more acceptable in the recent years among the people suffering from refractive errors. Photorefractive Keratectomy (PRK) and Laser-Assisted in Situ Keratomileusis

(LASIK) are among the commonly performed procedures.^{1,2} Photorefractive Keratectomy (PRK) has stood the test of time as a safe and simple procedure to correct low-to-moderate levels of myopia and astigmatism.^{2,3} Equally good results are achieved with use of an Amoils rotating brush, Paton spatula, 20% alcohol or laser to remove the epithelium.^{4,5} PRK is also considered a better option for patients with thin corneas, recurrent erosions or work/sport-related predisposition to trauma or in patients for whom fitting a suction ring could have adverse consequences such as those with glaucoma or retinal pathology.^{6,7} However, visual recovery is relatively slow and patients can experience postoperative discomfort/pain and haze.^{8,9} PRK is a simpler and easy to learn technique, whereas LASIK is more complicated and has a steep learning curve. It involves creation of corneal flap, application of laser and repositioning of flap exactly back to its place.^{10,11} Use of microkeratome makes this procedure more expensive. Cost of the procedure is the main concern of most of the patients in third world countries.^{12,13}

The purpose of this study is to evaluate the visual outcome and patient comfort levels of both PRK and LASIK in age and refractive error matched eyes.

MATERIALS AND METHODS

This single center retrospective analysis of the patient's records was done who attended the clinic for followup. These patients had refractive surgery procedure (either PRK or LASIK) from June 2015 to December 2016 and have completed one year of follow up. All patients signed an

informed consent. The study included 60 consecutive eyes of 30 patients with myopia or myopic astigmatism (Manifest Refraction Spherical Equivalent (MRSE) -1.0 to -5.0 dioptres (D)). The 60 eyes included in this study are a subset of the total myopic population that met the following parameters: spherical equivalent (SE) -1.00 to -6.00 D with a cylinder of 0 to -2.00 D; not had previous ocular surgery and elected to undergo LASIK/PRK surgery. Eyes with a larger SE and/or astigmatism, previous ocular or refractive surgery, other ocular pathology, as well as those undergoing retreatment were excluded from the analysis.

Patients were divided in two groups (PRK patients group A and LASIK patients group B) and only age and refractive error matched patients were included in the study. Selected age range was 20 to 25 years, mean refractive error between -1.5 D and -5 D and astigmatism in the range -0.75 D to -2.25 D were included in the study. Exclusion criteria for surgery included CCT by pachymetry less than 475 microns, patients with less than 270 microns of calculated (after deducting the flap thickness for both groups respectively) residual bed depth and/or topographies suggestive of keratoconus or other corneal abnormalities. All the patients were subjected to following postoperative measures, which includes monocular distance visual acuity (i.e., Uncorrected Distance Visual Acuity (UDVA) and Corrected Distance Visual Acuity (CDVA)) by Snellen charts, external ocular examination, slit-lamp microscopy based haze scoring and corneal topography by Pentacam were recorded at baseline and at intervals of 1, 3, 6 and 12 months postoperative period.

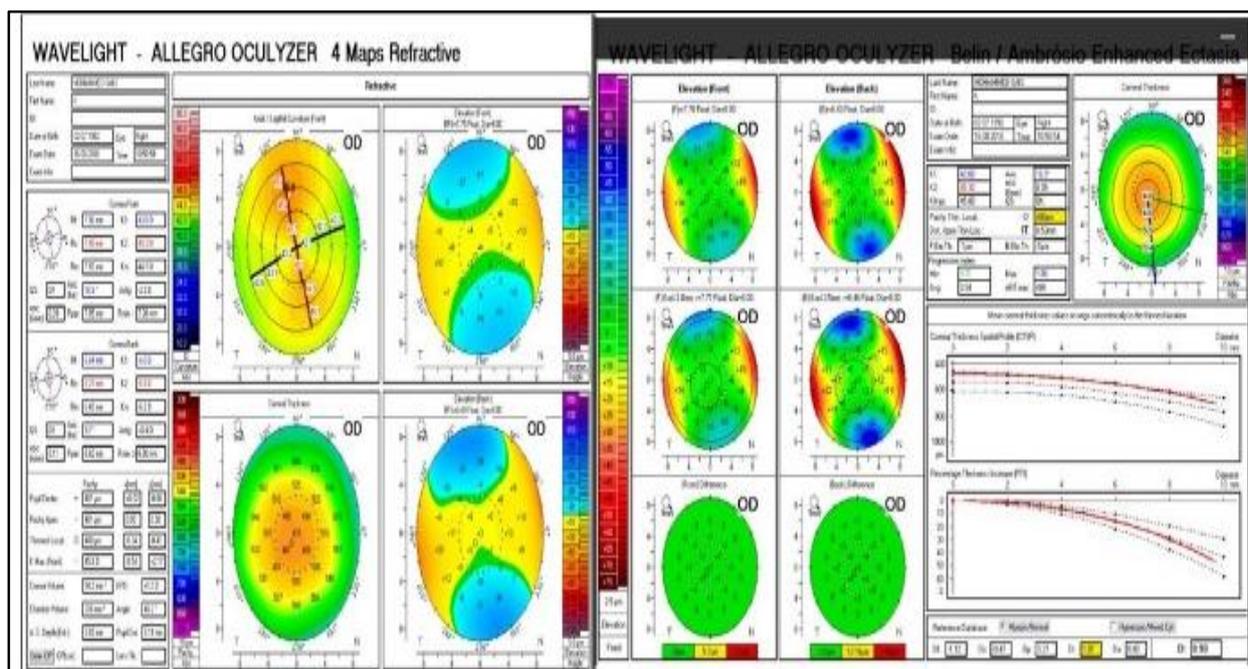


Figure 1. Pentacam Corneal Topography Showing Corneal Thickness, Front and Back Elevation of Myopic Patient for PRK Workup

Scoring of Haze levels were done using slit-lamp microscopy with starting (0 to 4) based upon direct illumination and the visibility of underlying iris structures. The scores include, 0=no haze; 0.5=visible only by tangential illumination; 1=trace haze seen with difficulty under direct illumination; 2=moderate haze (possible to observe iris in detail); 3=marked haze (difficult to observe iris in detail); and 4=severe haze (not possible to observe iris in detail).

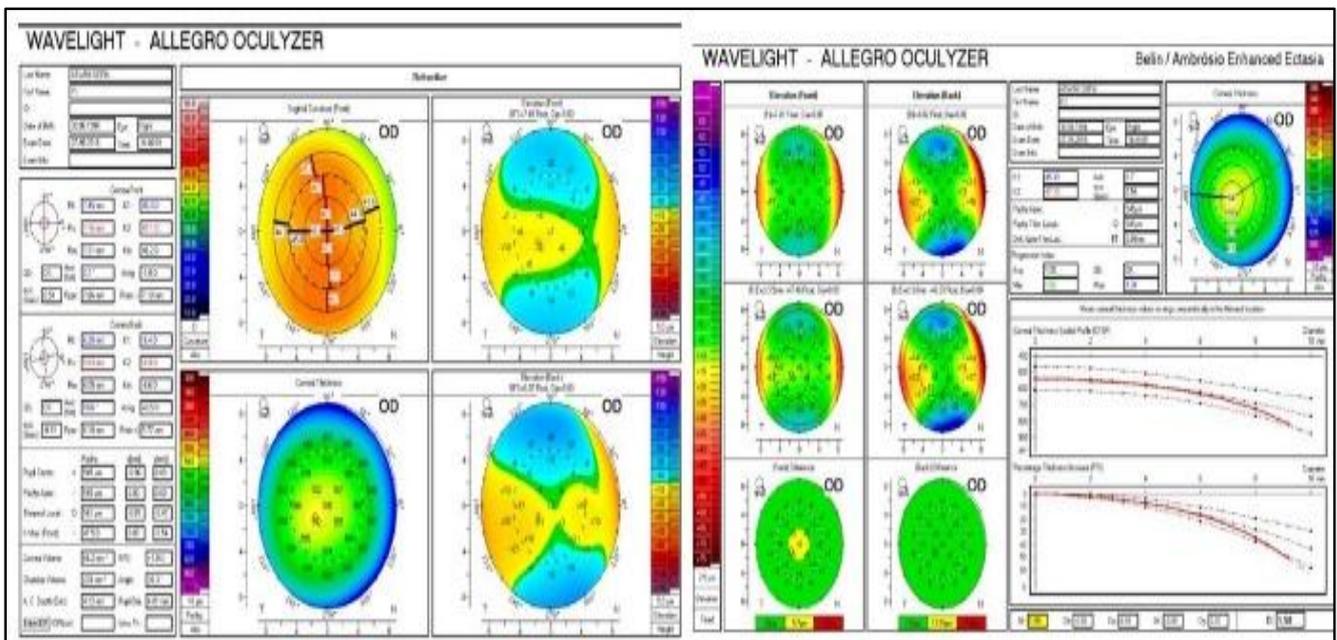


Figure 1a. Pentacam Corneal Topography Showing Corneal Thickness, Front and Back Elevation of Myopic Patient for LASIK Workup

Surgical Techniques

One surgeon operated all patients by using the same excimer laser machine (Alcon wave light 500). Preoperatively, all patients given moxifloxacin, a fourth-generation fluoroquinolone four times a day as topical antibiotic prophylaxis and to promote epithelial healing, 500 mg vitamin C given orally twice per day for 1 week prior to the procedure. For topical anaesthesia, two drops of 0.5% proparacaine hydrochloride were administered and to reduce the anxiety, 1 mg lorazepam OD given orally just before the surgery. 10% povidone applied to the eyelid and eyelashes for achieving a sepsis. In PRK,¹⁴ an 8 mm epithelial trephine was used to score the epithelium and then warm 20% alcohol was applied for 40 seconds using an 8.5 mm well, followed by removal of excess alcohol by Meroceel surgical sponge and saline irrigation. The loosened epithelium was separated using hockey stick knife and the epithelial debris thoroughly cleaned from the ablation zone.

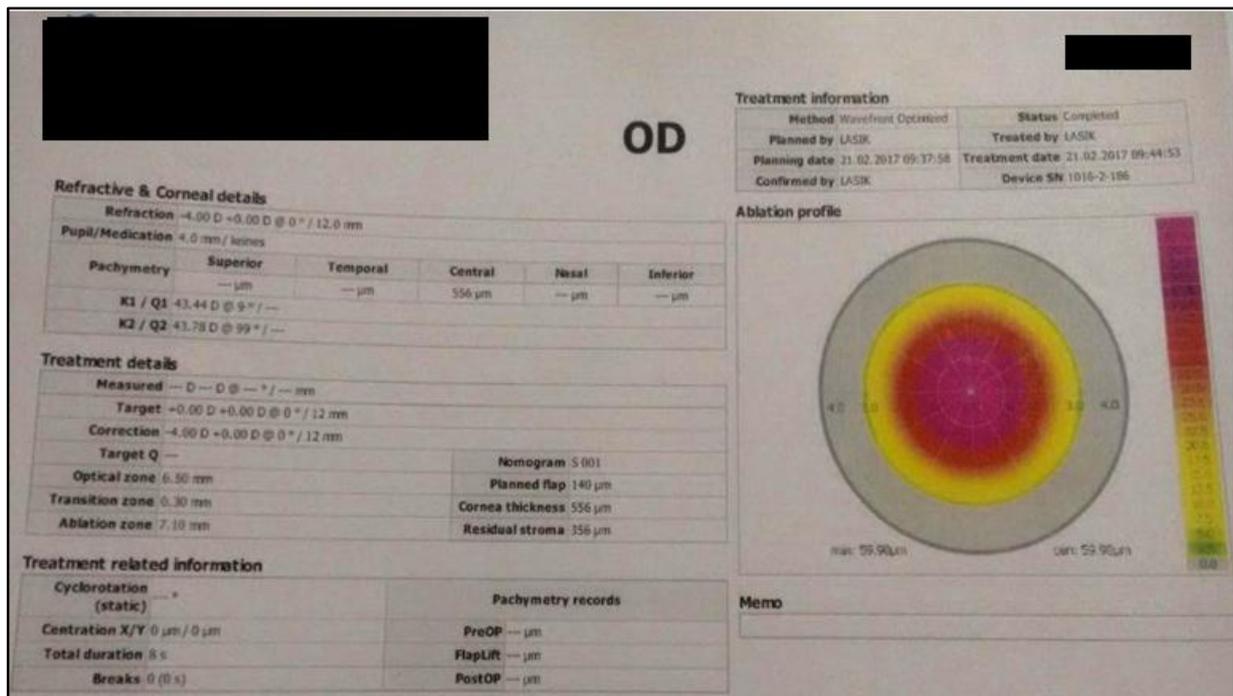


Figure 2. Post LASIK Ablation Profile in Patient with CCT- 556 mic

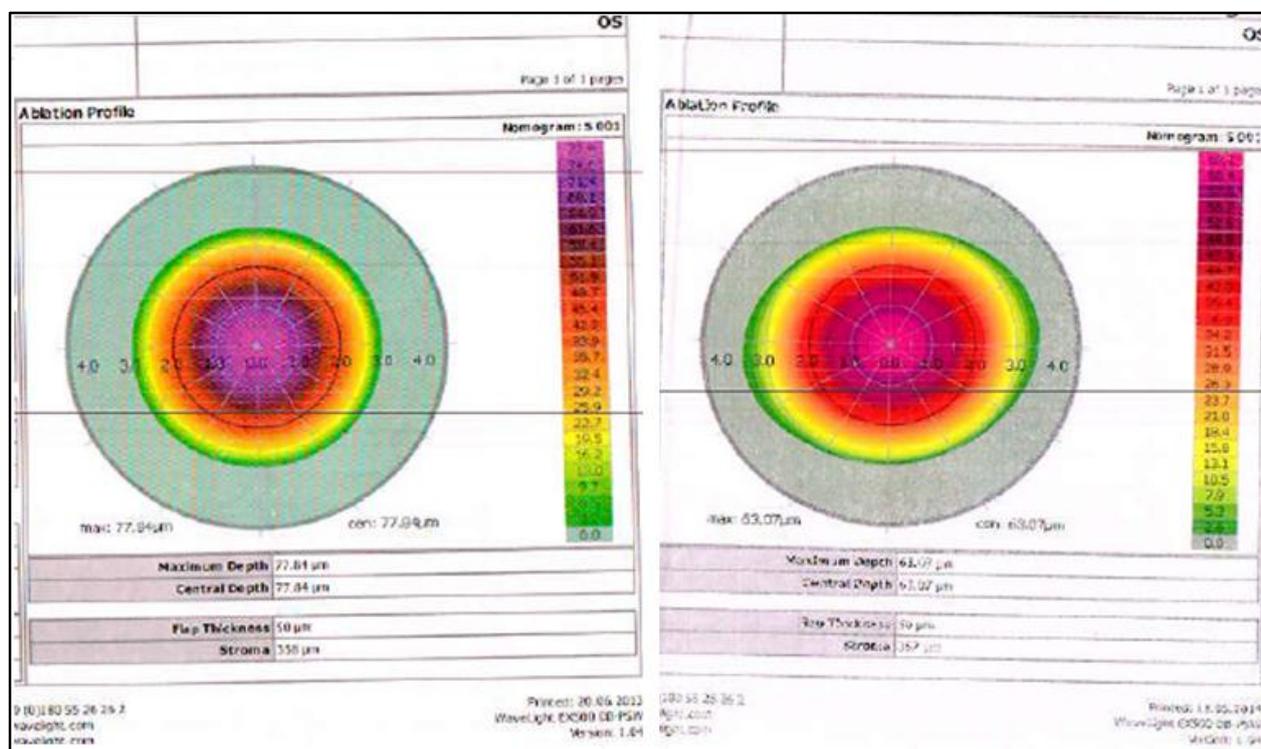


Figure 3. Shows Post LASIK Ablation Profile in Patients with Myopic and Myopic Astigmatism

Mitomycin C (MMC) 0.02% solution was applied with a Merocel surgical sponge for 30 seconds for all ablations exceeding 80 μm depth and/or cylinders -2.0 D, followed by cool balanced salt solution irrigation to reduce the chance of haze formation.^{15,16} Depending on the procedure, the epithelial flap was either replaced or removed. The patients were fitted with a -0.50 D bandage contact lens with base curve of 8.6, until the epithelium healed (3-7 days).^{17,18,19} Postoperatively, a nonsteroidal anti-inflammatory drop, ketorolac 0.5% was used at the time of surgery and continued four times a day for the first 24 hours. A solution of dilute tetracaine in artificial tears was given for use on an as needed basis to mitigate ocular discomfort. In addition, fluorometholone ophthalmic suspension 0.1% four times a day was prescribed in a tapering fashion over the ensuing three months.^{20,21} Oral vitamin C (500 mg twice per day), which was started a week before surgery was continued twice a day for 1 week after surgery. Patients were encouraged to use ocular lubricants for the first two months and later if required.

There were no operative and postoperative complications recorded in the notes regarding the procedure. Data collected was preoperative manifest refraction and best corrected visual acuity and postoperative uncorrected visual acuity, manifest refraction and best corrected visual acuity.

RESULTS

In group A (PRK), 20 eyes of 10 patients whereas in group B (LASIK), 40 eyes of 20 patients completed one year follow-up.

In group A (PRK), 20 eyes (of 10 patients) and in group B (LASIK) 40 eyes (of 20 patients) met the inclusion criteria of age and preoperative refraction.

Group A (PRK) 10 (33%), Group B (LASIK) 20 (67%), Eyes- PRK (20), LASIK (40), Mean Age- PRK 23 years, LASIK 24 years.



Chart 1. Depicting Age Groups in the Study Population

Sex Distribution- Male PRK-(5) (50%), LASIK-(12) (60%), Female PRK- (5) (50%), LASIK-(8) (40%).

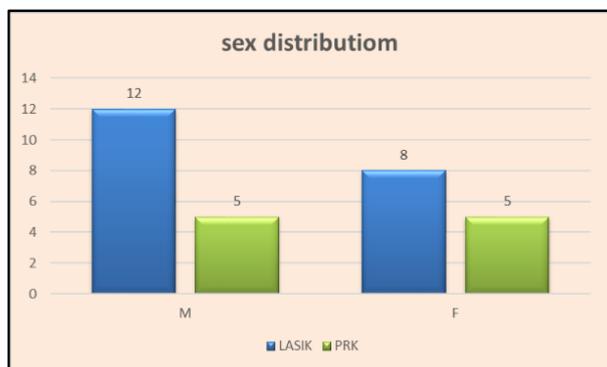


Chart 2. Sex Distribution in Both Groups

There were no significant differences in the preoperative variables between the groups including age and sex of the patients.

Preoperatively- MUCVA, MBCVA, etc.

Postoperatively- MUCVA, MBCVA, etc.

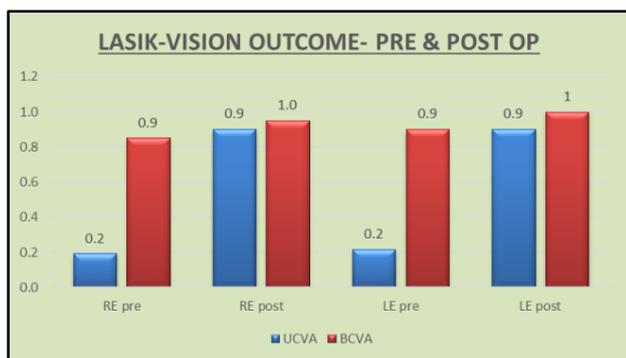


Chart 3. Pre and Postoperative Vision Outcome in LASIK

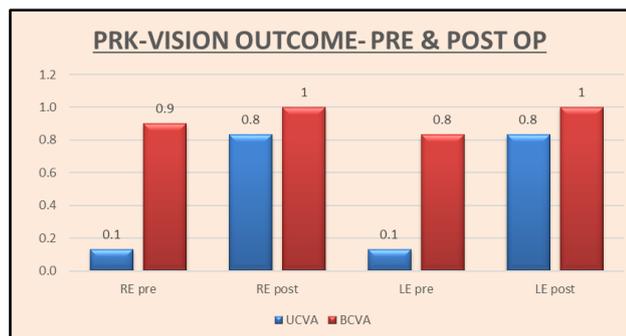


Chart 4. Pre and Postoperative Vision Outcome in PRK

MUCVA=Mean uncorrected visual acuity.

MBCVA=Mean best corrected visual acuity.

Preoperatively, in group A (PRK), mean manifest spherical equivalent was $-4.5 D \pm 0.64 D$ (SD), (range -2 to -6 D), mean uncorrected Snellen's visual acuity was 0.1 and mean best corrected visual acuity was 0.85 (range 0.8 to 1.0).

Whereas, in group B (LASIK), mean manifest spherical equivalent was $-4.06 D \pm 0.61 D$ (SD), (range -2 to -6 D), mean uncorrected visual acuity was 0.1 and mean best corrected Snellen's visual acuity was 0.9 (range 0.6 to 1.0).

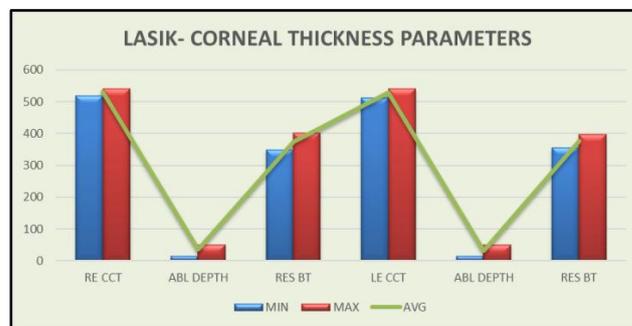


Chart 5. Corneal Thickness Parameters in LASIK Group

Central Corneal Thickness

In group A (PRK), mean CCT is 415 microns, (range 406-431 mic), mean ablation depth thickness achieved is 42 mic (range 35-50 mic) and the mean residual bed thickness is 293 mic (range 280-310 micron). Similarly, in group B (Lasik), mean CCT, mean ablation depth and mean residual bed thickness are 529 mic (range 516-542 mic), 35 mic (range 15-52 mic) and 375 microns (range 280-310 mic), respectively.

Uncorrected Distance Visual Acuity

Analysis of the total cohort at 1 year showed no statistically significant difference in the UDVA at the level of 20/20 or 20/15 between any of the procedures. Between 88% and 96% of patients in both treatment groups achieved UDVA of 20/20 or better, while the rates of UDVA of 20/15 or better ranged from 58% to 70%. In addition, analysis of low and moderate myopia groups revealed no statistically significant difference between the groups.

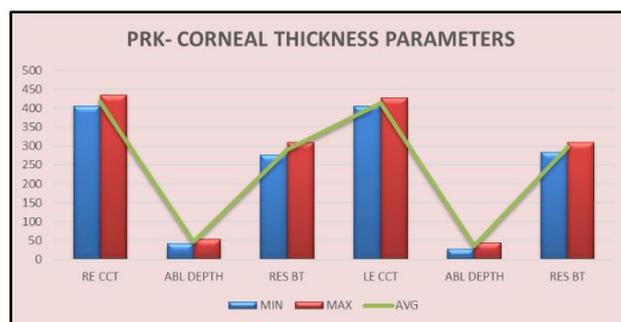


Chart 6. Corneal Thickness in PRK Group

Distance Corrected Visual Acuity

The proportion of eyes with preoperative CDVA of 20/20 (93%-100%) was similar between both treatment groups. Postoperatively, at 12 months, as expected, a greater proportion of eyes in the low myopia group (86%-100%) achieved a CDVA of 20/15 than in the moderate myopia group (40%-61%) with no significant difference (P >0.05) between any of the treatment groups.

Mean Manifest Refraction Spherical Equivalent (MRSE)-

MRSE was quite stable from 3 months to 1 year in both groups. At 3 months postoperative, all eyes showed an

under correction of <0.25 D. At the 1-year followup, mean MRSE across both groups ranged from -0.12 to -0.01 D with a very tight Standard Deviation (SD) MRSE did not change more than 60.25 D from 3 months to 1 year in 97% of eyes across the groups. This trend was consistent even when subanalysis was carried out for the different levels of myopia.



Chart 7. MRSE in Both Pre and Postoperative among LASIK Group



Chart 8. MRSE in Both Pre and Postoperative among PRK Group

Preoperatively-MSE (SD).
 Postoperatively-MSE (SD).
 PRK -4.5 (±0.54) -0.64 (±0.54).
 Lasik -4.06 (±0.51) -0.45 (±0.7).
 MSE = mean spherical equivalent.
 SD = standard deviation.

Predictability

Predictability (achieved versus intended correction) of 61.0 D was found in 100% of eyes in both treatment groups.^{22,23}

Safety

On average, approximately 58% (range 47%-68%) of eyes in each group gained one line of CDVA and no eyes in any of the groups had lost had more than one line of CDVA at 12 months. The distance safety index (ratio of the mean postoperative CDVA/mean preoperative distance CDVA)^{24,25} was >1 in both treatment groups at 12 months.



Chart 9. Depicting Safety, Efficacy and Predictability in Both Groups

Efficacy

Efficacy index of a refractive procedure is reported as the ratio of the mean postoperative distance UDVA/preoperative distance CDVA.^{26,27} In our series, both groups were >1.0. The difference between groups was less than one line of postoperative visual acuity and was of no clinical significance.

Haze

Grading of haze severity^{28,29,30} showed that very few eyes (2%-7%) in PRK procedure groups had more than trace haze even at 1 month. At 12 months, haze was absent in nearly all eyes and there were no statistically significant differences between procedure groups.

Postoperatively, in group A (PRK), mean uncorrected Snellen’s visual acuity was 0.86 (range 0.8 to 1.0), mean manifest spherical equivalent was -0.64 (SD) ± 0.54 D (range +0.25 to -1.00 D) and mean best corrected Snellen’s visual acuity was 0.9 (range 0.8 to 1.0). Whereas, in group B (LASIK), mean uncorrected Snellen’s visual acuity was 0.9 (range 0.8 to 1.0), mean manifest spherical equivalent was -0.45 (SD) ± 0.7D (range +0.63 to -1.00 D) and mean best corrected Snellen’s visual acuity was 0.95 (range 0.9 to 1.0).

Complications

No intraoperative^{31,32} or early postoperative complications were detected. There were no infections and no stromal incursions. The corneal epithelial defect was healed in most of the eyes by day 7 (day 7 is our regular protocol for the third postoperative follow-up visit for patients undergoing refractive surgery. No patient had epithelial healing delay greater than 10 days. All corneas were clear. No patient had any loss in best corrected visual acuity. Patients had no complaint regarding vision except 2 in group A (PRK) and one in group B (LASIK) reported gritty sensations in eyes occasionally. All patients were happy regarding visual outcome.

DISCUSSION

The visual outcome of both PRK and LASIK is comparable in the given range of refractive error. All patients in both groups achieved satisfactory level of uncorrected vision.^{2,33} Health of the cornea after one year appears satisfactory in both groups. None of the patients reported any disturbances

of night vision. Stability of refraction in both groups is found not statistically different after one year post excimer laser treatment.^{34,35} Saragoussi D and Saragoussi J³⁵ reported similar kinds of results, though they reported occasional night vision symptoms, but 97.8% of the patients were satisfied with their vision. Efficacy outcomes were generally similar in the PRK and LASIK groups and both achieved good objective and subjective results after treatment, which was also reported by Neeracher B.³⁶ By careful selection of patients, desirable results can be achieved by photorefractive keratectomy in moderate degree of myopia with preservation of corneal health.^{3,37}

CONCLUSION

LASIK showed superior refractive efficacy and stability for moderate myopia with RBT (residual bed thickness) >320 microns. PRK shows better results in thinner corneas (RBT 280-320 microns). Both treatments were safe and comparable except in terms of pain and haze formation in selective PRK cases. For moderate degree of myopia, PRK is as effective as LASIK in low economic setups where patients cannot afford the cost of expensive procedures.

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