ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 02 | February - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

"COMPARISON BETWEEN VISUAL AND CLINICAL OUTCOMES OF FEMTOSECOND LASER IN SITU KERATOMILEUSIS AND PHOTOREFRACTIVE KERATECTOMY IN TREATMENT OF MYOPIA WITH ASTIGMATISM AT A TERTIARY CARE HOSPITAL"

Ophthalomology

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ABSTRACT

Purpose: The aim of this study is to compare the visual outcomes, contrast sensitivity and stereoacuity changes between Femtosecond Laser Assisted In Situ Keratomileusis and Photorefractive Keratectomy in correction of myopia with astigmatism. **Study Design:** Hospital based, randomized, open labelled prospective interventional study. **Materials And Method:** The study included healthy subjects aged 21-40 years with myopic astigmatism and healthy corneas meeting the inclusion criteria of our study who attended routine ophthalmology out-patient department. Informed consent was taken from all the selected patients and they were randomized to undergo Photorefractive Keratectomy & Femtosecond Laser Assisted In Situ Keratomileusis. Post operatively they were followed up at Day 1, 1 week, 1 month, 3 month and 6 months and changes in UCVA, Contrast Sensitivity, Stereopsis and Intraocular Pressure were noted. **Results:** In our study it was found that the UCVA was found to be better in FsLASIK patients initially compared to PRK group at Postoperative Day 1 (p-value =0.029) , 1 week (p-value= 0.028) & 1 month (p-value=0.046) compared to PRK. However, at the end of 6 months similar UCVA was achieved with both modalities. Intraocular pressure though was found to be higher in FsLASIK compared to PRK (p-value= 0.005) at postoperative Day 1 at later follow ups no significant difference was found. There was no statistically significant difference in the post-operative Stereoacuity & Contrast Sensitivity between both the groups. **Conclusion:** It can be concluded that both PRK & FsLASIK give similar visual outcomes eventually however FsLASIK gives better visual outcomes more rapidly. Stereoacuity improves with both the modalities but is again improved sooner with FsLASIK. Contrast Sensitivity is unaffected by both the surgeries. However, the study comprised of a small sample size and hence further study might be required on larger scale.

KEYWORDS

Myopic astigmatism, PRK, FsLASIK, Visual outcomes, Stereopsis

Recent studies and WHO reports indicate that refractive errors are the first cause of visual impairment and the second cause of visual loss worldwide[1]. Globally, myopia is the leading cause of distance refractive error. In 2010, an estimated 1.9 billion people had myopia, and 70 million of them (2.8%) had high myopia. These numbers are projected to rise to 52% and 10%, respectively, by 2050[2]. Currently corrective laser refractive surgeries are the most used method to correct various types and degree of refractive errors.

Photorefractive keratectomy (PRK) is the original laser vision correction procedure which involves surface ablation, in which after removal of epithelial layer of cornea, corneal stroma is ablated to change the refractive power[3]. Laser in situ keratomileusis (LASIK) combines Excimer laser stromal ablation and stromal flap creation. In FS LASIK procedure, femtosecond laser is used to create corneal flaps. FS LASIK is more preferred nowadays due to quicker recovery time, less patient discomfort and reduced incidence of intraoperative complications. Despite their advantages, femtosecond lasers are used in only a few centres at present[4]. However, in recent years, the application of PRK has increased, due to its preference for specific indications including irregular or thin corneas, epithelial basement membrane disease and previous corneal surgery, decreased incidence of flap-related complications and postoperative dry eye[5].

In this study, we therefore aim to compare the visual and clinical outcomes between the patients undergoing treatment with the above two modalities in treatment of myopia with astigmatism.

MATERIALS & METHODS:

Study Population:

The study includes patients diagnosed as myopia with astigmatism who attended the outpatient department of our tertiary centre. The patients satisfying the below mentioned criteria were included:

- Patient willing to give informed consent
- Age: 21-40 years
- Patients of either sex
- Spherical myopia up to -10D and myopic astigmatism up to -5 D cyl
- Best spectacle corrected visual acuity (BSCVA) ≥0.8 (20/25)
- Central corneal thickness > 500 µm and the calculated residual stromal bed > 250 µm.
- Patients having stable refraction, defined as < 0.5D change within 6 months before the operation

Ophthalmologic Examination:

All enrolled patients underwent a complete ophthalmic examination and had no ocular disease except myopia with astigmatism. Preoperative examinations included uncorrected distance visual acuity (UCVA), corrected distance visual acuity (BCVA) both measured with Snellen chart, Automated refraction, Slit lamp biomicroscopy, specular microscopy (Tomey EM-3000), corneal topography (Pentacam Oculus) and dilated fundoscopy examination (Annexure 2-3). 40 eyes with myopia with astigmatism with central corneal thickness > 500 µm underwent simple randomization for division into PRK and FS-LASIK groups.

Surgical Intervention:

The surgery was performed by using the ZEISS MEL 90 ArF excimer laser (Carl Zeiss, Meditec AG, Jena, Germany) for PRK and ZEISS VisuMax (Carl Zeiss, Meditec AG, Jena, Germany) for Femto-LASIK.The patients in both the groups were then compared postoperatively on the basis of visual and refractive status which will be assessed by obtaining visual acuity, refraction, keratometry. Patients were followed up on post op day 1, 1 week, 1month, 3 months and 6 months.

Statistical Analysis:

The data collected will be analysed statistically using descriptive statistics namely mean, standard deviation, percentage wherever applicable.

- Appropriate parametric and non-parametric tests will be used
- Chi square test will be used to compare the clinical and visual outcomes in the two groups.

RESULTS

In PRK Group age range was 21.0-36.0 yrs with a mean age of 26.10+/-4.51 yrs while the FsLASIK group had an age range of 22.0-36.0, with a mean score of 26.20+/-3.97 yrs. Overall, 60% of the participants were female, and 40% were male. Best corrected visual acuity (BCVA) showed negligible differences between groups, with a mean difference of -0.002 and a p-value of 0.96.For RE, Mean astigmatism was 0.985+/-0.646 (PRK) & 1.955+/-1.038(FsLASIK), with a mean difference of -0.97 and a significant p-value of 0.022. For LE, Mean astigmatism was 1.00+/-0.52 (PRK) & 1.64+/-0.75(FsLASIK) had with a mean difference of -0.64 and a significant p-value of 0.039.At postoperative Day 1 (TABLE 1), right eye UCVA was 0.210+/- 0.095 (FsLASIK) & 0.076+/- 0.152 (PRK) with a p-value =0.029 indicating statistically significant difference. Similarly, there was a statistically significant difference between UCVA of both groups at 1-week (p-value= 0.028) & 1 month (p-value=0.046). However, at 6 months there

was no statistically significant for UCVA (p-value of 0.646)(TABLE 2) (FIGURE 1).For LE, at 6 months UCVA was 0.038+/-0.114(PRK) and 0.036+/-0.138 (FsLASIK) with a p-value of 0.972, indicating no statistically significant difference (FIGURE 2). At 6 months, Stereoacuity did not show a statistically significant difference between the groups with a mean of 47.450+/- 35.798 (PRK) & 37.700 +/- 31.718 (FsLASIK), yielding a mean difference of 9.75 and a p-value of 0.527.Upon comparison of Pre-operative & 6-month post-operative stereoacuity, there was no statistically significant difference in both the groups with a p-Value of 0.667 in PRK group & p-value of 0.527 for FsLASIK group. At Postoperative Day 1**,** Intraocular pressure (IOP) showed a significant difference, with mean of 12.460+/-1.153 (PRK) & 15.000+/-2.261(FsLASIK) resulting in a mean difference of -2.54 and a p-value of 0.005. However, at all remaining follow ups there was no statistically significant difference between the IOPs of the two groups (All p-values > 0.05).Contrast sensitivity was identical for both groups pre & post operatively which was 0.800 with no variation and a p-value of 1.00.

Table 1: Comparison Of The Mean Parameters (post Operative Day 1) Between The Groups Using Independent Sample T Test

Side	Parameters	Groups	N	Minimum	Maximum	Mean	S.D.	Mean diff	p value
Right	UCVA	Group 1	10	0.00	.30	.210	.095	0.134	0.029*
		Group 2	10	-.10	.30	.076	.152		
	CS	Group 1	10	.8	.8	.800	.000	0.00	1.00
		Group 2	10	.8	.8	.800	.000		
	IOP	Group 1	10	11.0	14.0	12.460	1.153	-2.54	0.005*
		Group 2	10	12.0	18.0	15.000	2.261		
Left	UCVA	Group 1	10	0.00	.30	.162	.123	0.096	0.151
		Group 2	10	-.10	.30	.066	.160		
	CS	Group 1	10	.8	.8	.800	.000	0.00	1.00
		Group 2	10	.8	.8	.800	.000		
	IOP	Group 1	10	9.0	15.0	13.120	1.861	-2.23	0.039*
		Group 2	10	10.5	19.0	15.350	2.572		
Stereoacuity		Group 1	10	32.0	480.0	103.000	141.695	54.80	0.242
		Group 2	10	32.0	100.0	48.200	21.545		

*significant

Table 2: Comparison Of The Mean Parameters (post Operative 6 Months) Between The Groups Using Independent Sample T Test

Side	Parameters	Groups	N	Minimum	Maximum	Mean	S.D.	Mean diff	p value
Right	UCVA	Group 1	10	-.10	.30	.038	.114	0.022	0.646
		Group 2	10	-.10	.18	.016	.096		
	CS	Group 1	10	.8	.8	.800	.000	0.00	1.00
		Group 2	10	.8	.8	.800	.000		
	IOP	Group 1	10	11.0	16.0	13.300	1.337	0.420	0.533
		Group 2	10	11.0	16.0	12.880	1.602		
Left	UCVA	Group 1	10	-.10	.30	.038	.114	0.002	0.972
		Group 2	10	-.10	.30	.036	.138		
	CS	Group 1	10	.8	.8	.800	.000	0.00	1.00
		Group 2	10	.8	.8	.800	.000		
	IOP	Group 1	10	11.0	15.3	13.920	1.204	1.13	0.067
		Group 2	10	11.0	15.5	12.790	1.382		
Stereoacuity		Group 1	10	12.5	120.0	47.450	35.798	9.75	0.527
		Group 2	10	20.0	120.0	37.700	31.718		

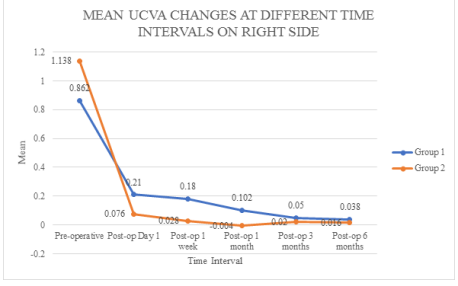

Figure 1: Mean Ucva Changes At Different Time Intervals On Right Side

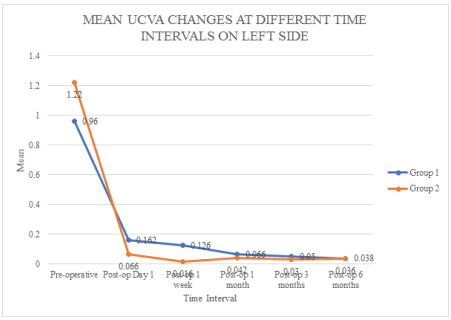

Figure 2: Mean UCVA changes at different time intervals on left side

DISCUSSION

In our study the mean age group in PRK was 26.10+/-4.51 yrs while it was 20+/-3.97 yrs in FsLASIK group. In Zhang et al. [6] the PRK group had a mean age of 25.6±6.1 & FsLASIK had a mean age of 23.9±5.5 (p-value= 0.161) which is similar to our results. The gender distribution difference between the two groups yielded a p-value of 0.361, indicating no statistically significant association in gender distribution between the two groups.In a similar study by Raad K Yacob et al [7], PRK group had 48.5% males & 51.5% females while LASIK group had 46.8% males & 53.2% females with a p-value of 0.46 which was similar to our study.Best corrected visual acuity (BCVA) showed negligible differences between groups, with a mean difference of -0.002 and a p-value of 0.96.For RE, Mean astigmatism was 0.985+/-0.646 (PRK) & 1.955+/-1.038(FsLASIK), with a mean difference of -0.97 and a significant p-value of 0.022. For LE, Mean astigmatism was 1.00+/-0.52 (PRK) & 1.64+/-0.75(FsLASIK) had with a mean difference of -0.64 and a significant p-value of 0.039.RE manifest refraction showed a larger variance with means of -3.46 (PRK) and -36.66 (FsLASIK) with a mean difference of 1.21 & a p-value of 0.131, indicating no statistically significant difference.LE manifest refraction means were -3.30 (PRK) and -4.51 (FsLASIK) with a mean difference of 33.2 and a p-value of 0.314, indicating no statistically significant difference. However in the study conducted by Gershoni et al[8] there was a statistically significant difference in spherical equivalent (SE) refraction prior to surgery with a mean of −3.43 ± 1.27 D (Trans-PRK) and −3.18 ± 1.34 D (FS-LASIK) (p < 0.001).For RE, at postoperative Day 1, UCVA was 0.210+/- 0.095 (FsLASIK) & 0.076+/- 0.152 (PRK) with a p-value =0.029 indicating statistically significant difference. Similarly, there was a statistically significant difference between UCVA of both groups at 1-week (p-value= 0.028) & 1 month (p-value=0.046). However, at 6 months there was no statistically significant for UCVA (p-value of 0.646).In Hashemi et al [9] however at 6 months after surgery, UDVA showed an improving trend, but it was better in the femto-LASIK group (P=0.026) which is contrary to our results.

Upon comparison of Pre-operative & 6-month post-operative stereoacuity, there was no statistically significant difference in both the groups with a p-Value of 0.667 in PRK group & p-value of 0.527 for FsLASIK group.

In a similar study conducted by Razmjoo et al [10] in patients undergoing LASIK surgery, stereoacuity remained unchanged in 58% of patients (P=0.007) which is similar to our findings.

However in contrast to above in a study conducted by Ghanavati et al [11] in patients undergoing PRK , the stereoacuities were recorded as 365.38 ± 112.65 s of arc and 343.51 ± 88.96 s of arc at 3 and 6 months, respectively. These differences were statistically significant (p < 0.001) and hence was inferred that stereoacuities declined post-surgery.We did not find any statistically significant difference between the IOPs of the two groups (All p-values > 0.05) except on postoperative day 1(p = 0.005). In a retrospective study done by Seith H.B[12], et al, there was no significant difference between IOPs of PRK & LASIK groups postoperatively (p=0.932) as also noted in our study.Contrast sensitivity was identical for both groups pre & post operatively which was 0.800 with no variation and a p-value of 1.00.

CONCLUSION

Astigmatism affects patients' visual acuity and contrast sensitivity at

all light levels. The total amount of astigmatism in the myopic eye is proportional to the degree of myopia. Both PRK & FsLASIK are efficacious safe surgical modalities for correction of myopic astigmatism in patients with spherical myopia up to -10D, myopic astigmatism up to -5 D cyl and the calculated residual stromal bed > 250 µm for minimal postoperative complications.

From this study it can be concluded that both PRK & FsLASIK give similar visual outcomes eventually however FsLASIK gives better visual outcomes more rapidly. Stereoacuity improves with both the modalities but is again improved sooner with FsLASIK. Contrast Sensitivity is unaffected by both the surgeries.

However, the study comprised of a small sample size and hence further study might be required on larger scale.

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