



COMPARATIVE STUDY OF CLINICAL OUTCOMES OF FEMTO SECOND- LASER ASSISTED IN SITU KERATOMILEUSIS VS SMILE SURGERY IN TREATMENT OF MYOPIA WITH ASTIGMATISM

Ophthalmology

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ABSTRACT

Background: Refractive surgeries are one of the most common operations performed globally. Refractive surgical options include laser corneal surgeries such as photorefractive keratectomy, laser assisted keratomileusis, laser assisted subepithelial keratectomy and refractive lenticule extraction. **Methodology:** In this Hospital based prospective, interventional, comparative study, conducted at Regional Institute of Ophthalmology, Minto Ophthalmic Hospital during the study period from August 2022 to January 2024. 24 patients (48 eyes) with myopia and astigmatism were included. patients were randomized into 2 groups wherein 24 eyes underwent Small incision lenticule extraction and 24 eyes underwent Femtosecond Laser Assisted In Situ Keratomileusis. **Results & Conclusion :** The mean age was 26 .33 in the SMILE and 26 in the FS LASIK group. Mean BCVA at the of 6 months was -0.006 and 0.052 respectively which was statistically significant. IOP also showed a significance difference between the groups though it was within normal limits. There was no significant difference in terms of contrast sensitivity and stereoacuity between the groups.

KEYWORDS

SMILE-Small Incision Lenticule Extraction

INTRODUCTION

Refractive errors are the most common ocular problem affecting all age groups. They are considered as public health challenge. Recent studies and WHO reports indicate that refractive errors are the first cause of visual impairment and the second cause of visual loss worldwide as 43% of visual impairments are attributed to refractive errors(1).Myopia is the most common eye disorder worldwide, affecting up to more than 80% in some Asian population(2).

Refractive surgeries are one of the most common operations performed globally(3).Refractive surgical options include laser corneal surgeries such as photorefractive keratectomy, laser assisted keratomileusis, laser-assisted subepithelial keratectomy and refractive lenticule extraction.

Laser in situ keratomileusis (LASIK) is a popular refractive procedure(4).A flap is first created with a microkeratome or a femtosecond laser, after which an excimer laser is used to ablate the cornea stromal bed(5).

Small-incision lenticule extraction was subsequently introduced in 2011, where the stromal lenticule is extracted through a small 2 to 4 mm arcuate corneal incision(6). Refractive lenticule extraction surgery confers few advantages over LASIK, it only requires a single laser machine(7), has lowered total laser energy requirements(8,9), avoids flap related complications such as dry eyes, cornea neurotroph, postoperative discomfort(10).

This study is conducted to evaluate and compare the clinical outcome between SMILE and Femto Second Laser-assisted in situ keratomileusis in terms of visual acuity, Contrastsensitivity and stereoacuity.

METHODS:

After obtaining approval and clearance from the institutional ethics committee, the patients fulfilling the inclusion criteria will be enrolled for the study after obtaining written informed consent. A detailed ophthalmic evaluation including visual acuity (uncorrected and best corrected), refraction, keratometry, slit lamp bio microscopy, indirect ophthalmoscopy, corneal topography and corneal pachymetry will be done. In this prospective, comparative, interventional series, 48 eyes of myopia with astigmatism will be randomized to undergo Femto second laser assisted in situ keratomileusis and SMILE surgery

Patient Selection: Patients aged above of 21 years and less than 40 years; best spectacle corrected visual acuity (BSCVA) ≥ 0.8 (20/25) patients having myopia with astigmatism

Inclusion Criteria:

1. Patients aged above of 21 years and less than 40 years; best spectacle corrected visual acuity (BSCVA) ≥ 0.8 (20/25) patients

having myopia with astigmatism

2. Spherical myopia up to -10 D and myopic astigmatism up to -5 D cylinder.
3. The central corneal thickness should be more than 500 mm and the calculated residual stromal bed >250 mm.
4. Patients having stable refraction, defined as $< 0.5D$ change within 6 months before the operation

Exclusion Criteria:

1. Subjects not willing to give informed consent.
2. Patients with a calculated residual stromal depth < 250 mm.
3. Evidence of ocular diseases like meibomian gland diseases, herpetic keratitis.
4. Concomitant ocular autoimmune diseases.
5. Concomitant systemic autoimmune diseases.
6. Patients with thyroid eye disorder.
7. Any pathologies of cornea like corneal dystrophies, any corneal opacity, h/o ocular trauma or surgery within optical zone.
8. Patients who have undergone any previous ocular laser therapy including refractive surgery.
9. History of dry eye.

Study Protocol

Study Design: Hospital based, randomized, open labelled prospective interventional study.

Study Period: August 2022 to January 2024

Place Of Study: Department of Ophthalmology, RIO Minto Ophthalmic Hospital

Table- Comparison of the mean parameters (post-op 6 months) between the groups using independent sample t test

Post-op (6 months)	Groups	N	Minimum	Maximum	Mean	S. D	Mean diff	P value
UCVA	Group A	24	-0.079	.170	-.006	.066	-0.057	0.011*
	Group B	24	0.000	.170	.052	.080		
CS	Group A	24	.80	.80	.800	.000	0.00	1.00
	Group B	24	.80	.80	.800	.000		
IOP	Group A	24	11.0	16.0	13.965	1.226	1.15	0.005*
	Group B	24	11.0	16.0	12.813	1.402		
Stereoacuity	Group A	12	12.5	100.0	44.167	30.372	9.62	0.441
	Group B	12	12.5	120.0	34.542	29.742		

Instruments used:

1. Snellen's visual acuity chart.
2. Slit lamp bio microscopy.
3. Autorefraction.
4. Auto keratometry.
5. Intraocular pressure measurement with the Goldmann

- applanation tonometer.
- Indirect ophthalmoscopy for fundus examination
 - Uncorrected (UDVA) and corrected (CDVA) distance visual acuities as well as objective and subjective refractions.
 - Corneal topography- Pentacam.

Objectives Of The Study:

- To compare the visual outcome between Femto second Laser-assisted in situ keratomileusis and SMILE in correction of myopia with astigmatism.
- To compare changes in contrast sensitivity, stereoacuity between Femto second Laser-assisted in situ keratomileusis and SMILE in correction of myopia with astigmatism.

Sample Size Estimation:

Formula used for sample size calculation

$$n = \frac{Z_{\alpha/2}^2 \cdot P_1(1-P_1) + Z_{\beta}^2 \cdot P_2(1-P_2)}{(P_1 - P_2)^2}$$

Where,

- P_1 = Proportion in the first group
- P_2 = Proportion in the second group
- α = Significance level
- β = Power

Statistical Analysis:

SPSS (Statistical Package for Social Sciences) version 21. (IBM SPSS statistics [IBM corporation: NY, USA]) was used to perform the statistical analysis

- Data was entered in the excel spread sheet.
- Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables.
- Inferential statistics like
- Independent sample t test was applied to compare the quantitative parameters between the groups.
- The level of significance is set at 5%

RESULTS

The mean age was 26.33 in the SMILE and 26 in the FS LASIK group. Mean BCVA at the of 6 months was -0.006 and 0.052 respectively which was statistically significant. IOP also showed a significance difference between the groups though it was within normal limits. There was no significant difference in terms of contrast sensitivity and stereoacuity between the groups.

DISCUSSION:

Refractive errors are the most common ocular problem affecting all age groups. They are considered as public health challenge. Refractive surgical options include laser corneal surgeries such as photorefractive keratectomy, laser assisted keratomileusis, laser-assisted subepithelial keratectomy and refractive lenticule extraction. Femto second Laser in situ keratomileusis (Fs LASIK) is a popular refractive procedure. A flap is first created with femtosecond laser, after which an excimer laser is used to ablate the cornea stromal bed. Small-incision lenticule extraction was subsequently introduced in 2011, where the stromal lenticule is extracted through a small 2 to 4 mm arcuate corneal incision.

In this prospective, comparative, interventional study 48 eyes of 24 patients with myopia and astigmatism were randomized into 2 groups to undergo FsLASIK and SMILE at Regional Institute of Ophthalmology, Minto Ophthalmic Hospital from August 2022 to January 2024.

On post op 1 week Group A had a mean of -1.72 (S.D. = 3.33), while Group B had a mean of -1.46 (S.D. = 3.20), resulting in a mean difference of -0.257 (p = 0.796), indicating no significant difference. On one month post op Group A had a mean of -0.70 (S.D. = 2.33) and Group B had a mean of 0.04 (S.D. = 0.08), resulting in a mean difference of -0.74 (p = 0.131), indicating no significant difference. On 3 months post op Group A had a mean of -0.02 (S.D. = 0.08), while Group B had a mean of 0.04 (S.D. = 0.07), resulting in a mean difference of -0.054, which was statistically significant (p = 0.02). 6 months post op Group A had a mean of -0.006 (S.D. = 0.066) compared to Group B's mean of 0.052 (S.D. = 0.080), resulting in a mean

difference of -0.057, which was statistically significant (p = 0.011*).

Intraocular pressure (IOP) had a mean of 15.39 (S.D. = 2.57) in Group A and 16.62 (S.D. = 1.91) in Group B, with a mean difference of -1.22 (p = 0.073) pre-operatively. Intraocular pressure (IOP) showed a significant difference, with Group A having a mean of 15.59 (S.D. = 2.14) compared to Group B's 13.30 (S.D. = 1.33), resulting in a mean difference of 2.28 (p = 0.001) at 6 months postoperative period. There was a tendency for increase in IOP in Group A compared to Group B in postoperative period.

Stereoacuity for Group A was 120.68 (S.D. = 141.33) and Group B was 41.96 (S.D. = 21.52), with a mean difference of 78.72 (p = 0.07). Group A had a mean of 44.167 (S.D. = 30.372) compared to Group B's 34.542 (S.D. = 29.742), resulting in a mean difference of 9.62 (p = 0.441), indicating no significant difference at 6 months postoperative period. In our study there was significant difference in the stereoacuity among the groups pre and postoperatively but there was no significant difference between the groups.

In a study conducted by Marianne et al, Visual outcomes of F-LASIK appear to be slightly better than SMILE during the first month after surgery but stabilized at 3 months postoperatively. There were significant differences between the mean UCVA at 1 month follow-up. At 3 months, 71.5% of SMILE and 86.8% of F-LASIK groups achieved 20/20 or better vision.

Where as in a study conducted by Hua Li et al IOP underestimation after SMILE or FS-LASIK was related to corneal biomechanics as well as preoperative IOP and flat keratometry. IOP after SMILE seem to remain more stable

CONCLUSION:

Both SMILE and FS LASIK are safe and efficacious in treatment of myopia up to -10D and astigmatism up to -5D. However visual outcomes after SMILE was better when compared to FS LASIK at 6 months post operative period. There was no significant difference in contrast sensitivity post operatively in both the groups. There was a tendency for increase in IOP after SMILE compared to FS LASIK. No significance difference was noted in stereoacuity between SMILE and FS LASIK, however there was improvement in stereoacuity post procedure owing to pre operative SE.

However larger sample size is required to establish a significant difference between the procedures.

Strength And Limitations

- The sample size is small. Hence, a larger multi-centric study over a larger duration of period is necessary to establish a significant difference between the procedures
- Lack of long term follow-up to assess future ophthalmological sequelae.

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