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EARLY VISUAL OUTCOMES POST SMALL INCISION LENTICULE EXTRACT AND ITS ASSOCIATION WITH CONTRAST SENSITIVITY

Ophthalomology

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ABSTRACT

Objective: To evaluate the impact of Small Incision Lenticule Extraction (SMILE) on visual acuity and contrast sensitivity in mild to moderate myopia. **Methods:** This prospective interventional study included 11 subjects (21 eyes) aged 21–38 years, with an average age of 26.91 ± 4.68 years. Preoperative and postoperative uncorrected (UDVA) and corrected distance visual acuity (CDVA), as well as contrast sensitivity, were assessed at baseline, 1 day, 1 week, 1 month, and 3 months post-surgery. **Results:** Preoperative UDVA ranged from 0.60 to 1.77 (mean 1.04 ± 0.29). Postoperative UDVA improved significantly by day 1 (-0.10 to 0.20, mean 0.02 ± 0.08, p=0.001) and remained stable throughout follow-up. At 3 months, UDVA was 0.00 ± 0.10. Contrast sensitivity consistently measured 0.80 across all time points, showing no change (SD=0.00). **Conclusion:** SMILE significantly improves visual acuity without affecting contrast sensitivity in patients with mild to moderate myopia.

KEYWORDS

INTRODUCTION

Refractive errors are among the most prevalent eye conditions, impacting individuals across all age groups. They are recognized as a significant public health concern. According to recent research and reports by the World Health Organization (WHO), refractive errors are the leading cause of visual impairment globally and the second most common cause of vision loss. Approximately 43% of all visual impairments are linked to refractive errors.[1] Myopia is a major global health problem and I one of the most common ocular comorbidities in the world. The global cases of myopia are on a steady increase and it is estimated that the number of myopia cases will encompass half of the world's population by the year 2050.[2]

Refractive surgery has evolved greatly over the years, form archaic corneal incision surgery to excimer laser based to the currently used minimally invasive femtosecond lased based techniques such as FS-Lasik and Small incision lenticule extraction (SMILE).[4]

Refractive Lenticule Extraction (ReLEx) represents a significant advancement in corneal refractive surgery. Small incision lenticule extraction is a flap less corneal refractive surgery which Yields equivalent outcomes to LASIK. Furthermore, the absence of a corneal flap minimizes the risk of nerve transection, significantly reducing postoperative discomfort and the incidence of dry eye, while facilitating faster visual and functional recovery.[4] RelEx SMILE is known to correct a myopic error ranging up to -10 D and an astigmatism till -5.00 D. It is seen to be effective in correction of refractive error with a spherical equivalent of almost -12.5D.[5,6]

An important observation is the improvement in contrast sensitivity following SMILE surgery, as demonstrated by measurements obtained using the CSV-1000 test.[7]

This study evaluates the early visual outcomes and contrast sensitivity of SMILE in mild to moderate myopia when performed by the same experience surgeon.

MATERIALS AND METHODS

Following ethics committee approval, eligible patients providing informed consent will undergo a comprehensive ophthalmic evaluation. This prospective study assesses 21 eyes with mild-to-moderate myopia after SMILE surgery over a 3-month follow-up.

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. Patient willing to give informed consent (Annexure 1).
2. Patients above 18 years of age of either sex.
3. Patients with a corrected visual acuity of 20/25 or better
4. Patients with a stable refractive error (< 0.50 D of refractive error change in the past 2 years) and no contact lens use 2 weeks prior to preoperative examination.

Exclusion Criteria:

1. Patients with keratoconus or suspicion of keratoconus.
2. Patients with Severe dry eye
3. Patients with a corneal scar
4. Patients with a history of herpetic keratitis
5. Patients with cataract, glaucoma, retinal pathology, ocular surgery
6. Patients with any systemic disease.

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

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

Objectives Of The Study:

To evaluate the outcomes of visual acuity on patients with mild to moderate myopia undergoing small incision lenticule extraction.

Statistical Analysis:

Statistical analysis was performed using SPSS version 21 (IBM, NY, USA). Data were entered in Excel, with descriptive statistics (mean, standard deviation, frequency, proportions) calculated. Independent t-tests compared group parameters, with significance set at 5%

RESULTS:

The study included a sample of 11 subjects (21 eyes) whose ages ranged from a minimum of 21 years to a maximum of 38 years. The average age of the subjects was 26.91 years, with a standard deviation of 4.679 years. At baseline, UCVA ranged from 0.60 to 1.77, with a mean of 1.04 and a standard deviation of 0.29. The mean UCVA significantly improved by the first day post-operation, ranging from -0.10 to 0.20, with a mean of 0.02 and a standard deviation of 0.08. This improvement was sustained throughout the follow-up periods, with mean UCVA values of 0.04 (S.D. = 0.09) at one week, 0.00 (S.D. =

0.09) at one month, and (S.D. = 0.10) at three months post-operation. The p-value of 0.001 indicates that the changes in UCVA over time were statistically significant. At all-time points—baseline, post- op day 1, post-op one-week, post-op one month, and post-op three months—contrast sensitivity consistently measured at 0.80, with no variation (standard deviation of 0.00) across all subjects. This uniformity indicates that there was no change in contrast sensitivity throughout the study period.

Table 1: Comparison Of Ucva At Different Time Line

UCVA	N	Minimum	Maximum	Mean	S.D	p value
Baseline	21	.60	1.77	1.04	0.29	0.001*
Post Op Day 1	21	-.10	.20	0.02	0.08	
Post Op 1 week	21	-.10	.20	0.04	0.09	
Post Op 1 Month	21	-.20	.20	0.00	0.09	
Post Op 3 Months	21	-.2	.2	0.00	0.10	

DISCUSSION

Small incision lenticule extraction (SMILE) is an innovative one-step refractive technique using a femtosecond laser to correct myopia and myopic astigmatism.[8] It is a novel refractive surgery procedure that uses a femtosecond laser to extract a stromal lenticule via a small side cut, eliminating the need for a corneal flap.[8]

Small Incision Lenticule Extraction (SMILE) was first performed in 2007 by Sekundo et al.,[9] and has evolved into a flapless procedure surgery in which a femtosecond laser creates an intrastromal lenticule, which is then manually retrieved through a small corneal incision made peripherally.[10]

Our study consisted of a small sample size of 11 subjects (21 eyes), wherein the mean ± S.D age of the subjects was found to be 26.91 ± 4.68 years; with an age range of 21- 38 years. Almost similar results were reported by Xia et al.,[11] who found the mean age to be 26.77 years with a range of 18 – 38 years, which was also in agreement with Shah et al., [37] who reported the mean age of 26.0 ± 5.55 years UCVA improved significantly post-SMILE, dropping from 1.04 ± 0.29 preoperatively to 0.02 ± 0.08 on day 1, stabilizing at 0.00 ± 0.09 by three months (p=0.001). Kamiya et al.[12] similarly reported long-term improvement, with LogMAR UDVA improving significantly from preoperative levels to -0.16 ± 0.11 at one year.

We further assessed the Best Corrected Visual Acuity (BCVA) amongst our study subjects which was found to be in the range from -0.10 to 0.20, with a mean ± S.D of 0.010 ± 0.069.Xia K et al.,[13] in their study; had mean CDVA of −0.03 ± 0.06 (range, −0.1 to −0.1) which changed to −0.06 ± 0.07 (range: −0.2 to 0) log MAR after a 4-year postoperative follow- up visit The Spherical Equivalent (SE) was also recorded in our study, which was found in the range of -6.38 to -1.38, with a mean ± S.D of -4.202 ± 1.419.Almost similar results were reported by Kamiya K, et al.,[12] wherein they reported the Spherical Equivalent (SE) range of from -8.25 to -1.25, with a mean of -4.11 ± 1.73, which was also agreed upon by Shah et al.,[14] who reported the mean ± S.D Spherical Equivalent of -4.87±2.16, as well as by Sekundo et al.,[9] with the mean ± S.D Spherical Equivalent being -4.75±1.56.

The study assessed contrast sensitivity at various time intervals from baseline through three months post-operation using repeated measures ANOVA in a sample of 21 subjects. At all-time points—baseline, post-op day 1, post-op one-week, post-op one month, and post-op three months—contrast sensitivity consistently measured at 0.80, with no variation (standard deviation of 0.00) across all subjects. This uniformity indicates that there was no change in contrast sensitivity throughout the study period. Therefore, the lack of variability suggests that the contrast sensitivity remained constant and was unaffected by the operation.

Our study had shortcomings such as limited sample size, single-centric study, only short term follows up, limited resources as well as lack of randomization and universal assessment.

Therefore, for future studies, we advocate a large, multi-centric randomized study designed to eliminate such shortcomings and reduce any known/unknown bias and provide more reliable, clear data with respect to the same.

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