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SMILE VERSUS FS-LASIK IN MYOPIC PATIENTS AND THE IMPACT IN UCVA AND TEAR FILM STABILITY

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ABSTRACT

This study aimed to assess and compare the effects on uncorrected visual acuity (UCVA) and tear film stability of two refractive surgical techniques used in myopic patients: femtosecond laser-assisted in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE). Two groups, the FS-LASIK group (200 patients) and the SMILE group (200 patients), were randomly assigned to comprise the 400 myopic patients treated at our facility. At various postoperative intervals, we compared the groups' UCVA, tear breakup time (BUT), Schirmer's test (Sit), and corneal higher-order aberrations (HOAs). With no statistically significant differences ($P > 0.05$), the UCVA at preoperative, 2 weeks, 1 month, and 3 months postoperatively was comparable between the two groups. But at one and three months after surgery, the SMILE group outperformed the FS-LASIK group in terms of BUT, Sit values, and HOAs ($P < 0.05$). While both procedures were equally effective in terms of UCVA and visual function, SMILE showed superior overall maintenance of tear film stability and elimination of higher-order aberrations of the cornea.

KEYWORDS: UCVA, HOAs, BUT.

INTRODUCTION

One type of refractive error known as myopia occurs when incoming parallel light is focused in front of the retina while the eye is at rest. This causes blurry retinal pictures, which can cause symptoms such asthenopia and poor distance vision. Occlusion, distortion, and double vision worsen as myopia progresses, further weakening the ocular fundus and resulting in permanent vision loss. Advances in medical technology have served to extend this surgical option and varieties for the correction of myopia (Li et al., 2021).

Therefore, because to individual heterogeneity, the efficacy of different myopia correction techniques may vary. The femtosecond laser tiny incision lenticule extraction is one of the least invasive of these procedures since it doesn't involve making a corneal flap and allows for a quick recovery for the patient. Another common corneal refractive procedure is femtosecond laser-assisted in situ keratomileusis (FS-LASIK), which is performed with accuracy, ease of use, and quick recovery (Fu et al., 2021).

The most recent LASIK technique, called Sub-Bowman's Keratomileusis, creates corneal flaps that are 90–100 µm thick and include Descemet's membrane and a tiny portion of the stroma underneath. This makes the procedure supportively accessible to a broad spectrum of patients with stable results. In order to determine how SMILE and FS-LASIK alter structural ocular function and visual acuity, the current study will compare their clinical results in treating myopia. The findings will make it possible to comprehend these processes and offer insightful information about how to best enhance surgical myopia therapies (Mehta & Fuest, 2021).

PATIENTS AND METHODS

Patient Selection

400 patients diagnosed with myopia were enrolled at our hospital. The diagnostic criteria adhered to established guidelines for myopia. Inclusion criteria required patients to be between 18 and 40 years old, exhibit symptoms of asthenopia and impaired distance vision, and have complete baseline data. Additionally, eligibility was confined to patients with myopia less than −10.00D, astigmatism less than −6.00D, corneal curvature between 40–46D, and a pupil diameter within 6 mm. Informed consent was voluntarily provided by all participants and their families.

Table 1: Baseline Characteristics Comparison (Mean ± SD, n)

Group	Number of Subjects	Age (years)	Operative Eye (mm)	Intraocular Pressure (mmHg)	Gender Composition (%)
		Range	Mean ± SD	Range	Mean ± SD
SMILE	200	18–39	28.59 ± 4.12	361–400	380.52 ± 8.23
FS-LASIK	200	18–40	29.01 ± 4.56	358–400	379.04 ± 8.01
X²/F	-	2.040	2.160	2.690	3.054
P Value	-	0.131	0.116	0.069	1.217

Exclusion criteria included patients with corneas too thin to meet surgical requirements, significant structural abnormalities of the eye such as eyelid defects or deformations, other severe ophthalmic conditions like cataracts or glaucoma, autoimmune disorders, history of serious infectious diseases, or individuals with mental health issues, language barriers, or low levels of cooperation.

Grouping
Two groups of patients were randomly assigned: 200 cases were treated with SMILE in the SMILE group, and 200 cases were treated with FS-LASIK in the FS-LASIK group. Age, treated eye, intraocular pressure, and gender composition were among the baseline parameters that did not significantly differ across the groups (P>0.05) (Table 1). The Helsinki Declaration was strictly adhered to during the study protocol's execution, and the Medical Ethics Committee gave its approval.

Surgical Methods
The patient in the SMILE group underwent SMILE surgery while in a supine position. Using 4 g/L oxybuprocaine hydrochloride eye drops (Shiga Plant, Santen Pharmaceutical Co. Ltd., Japan, Spec. 20 ml: 80 mg/box), surface anesthetic was applied, and a lid speculum was used to hold the eyelids open. Using a comprehensive femtosecond laser refractive surgery equipment (VisuMax, Carl Zeiss, Germany), the eye was repaired using negative pressure suction after being centrally positioned under microscopic guidance. With a side cutting angle of 90°, an incision width of 2 mm, a lens diameter of 6.0–6.5 mm, and a desired corneal flap thickness of 120–130 µm, the laser was calibrated at 500 kHz and 130 nJ energy. Following pre-scanning of the corneal layer, a balanced solution was dripped onto the corneal stromal bed, and the corneal stromal lenticule was sliced and retrieved via a microincision.

Under comparable surface anesthetic, FS-LASIK was performed on patients in the supine position for the FS-LASIK group. A femtosecond laser system with the following settings was used to construct a corneal flap: 185 nJ laser energy, 90–110 µm flap thickness, 7.9–8.5 mm flap diameter, and 4.10 mm flap width. Using an excimer laser (VISX STAR S4, Nuctech, USA) operating at 250 kHz, corneal stromal cutting was finished. The flap was then repositioned, dried, and eye shielding was applied.

Following surgery, both groups were given standard postoperative care, which included sodium vitrate eye drops (URSAPHARM Arzneimittel GmbH, Germany. Registration No. H20150150, size 0.1% preservative-free, 10 ml/box) and tobramycin dexamethasone eye drops (Hangzhou Guoguang Pharmaceutical Co. Ltd., State Pharmacopoeia H20073641, Spec. 5 ml: 15 mg: 5 mg/box), which were given four times a day for seven days.

Observation Metrics
Uncorrected visual acuity (UCVA) was evaluated across all three groups preoperatively and at 2 weeks, 1 month, and 3 months postoperatively using a standard visual acuity chart. UCVA ≥1.0 in the surgical eye was deemed normal, and the mean UCVA was recorded.

Tear film stability was assessed using tear breakup time (BUT) and the Schirmer I test (Sit) preoperatively and at 1 and 3 months postoperatively. BUT was measured by placing fluorescein-impregnated filter paper in the lower conjunctival sac, with the patient blinking 3–5 times before removal. The time from the last blink to the appearance of a dry spot was noted, and the mean value from three measurements was recorded. For the Sit, filter paper strips were placed at the lower eyelid margin, and after 5 minutes, the degree of wetness was recorded.

Corneal high-order aberrations (HOAs) were measured with a wavefront aberration analyzer (OPD-SCAN) preoperatively and at 1 and 3 months postoperatively, with the mean value from two measurements recorded.

Statistical Analysis
Data were analyzed using Statistical Product and Service Solutions (SPSS) version 23.0 (IBM, Armonk, NY, USA). For measurement data following a normal distribution, an independent sample t-test was used for between-group comparisons, with results expressed as ($\bar{x} \pm s$). Categorical data were analyzed using the chi-square test and expressed as rates (%). A P-value of <0.05 was considered statistically significant.

RESULTS

UCVA in the two Groups
The UCVA values across the two groups were comparable before surgery, as well as at 2 weeks, 1 month, and 3 months postoperatively, with no statistically significant differences observed ($P > 0.05$) (see Table 2).

Table 2: UCVA Comparison Among the Two Groups (Mean ± SD, LogMAR)

Group	Number of Subjects	Pre-op UCVA	2 Weeks Post-op	1 Month Post-op	3 Months Post-op
SMILE	200	0.57 ± 0.12	0.91 ± 0.22	1.01 ± 0.24	1.03 ± 0.25
FS-LASIK	200	0.58 ± 0.14	0.95 ± 0.25	1.02 ± 0.22	1.01 ± 0.23
F	-	0.950	1.420	0.380	0.450
P value	-	0.386	0.242	0.686	0.638

Intimal Stability Among the two Groups

The BUT and Sit values were similar across the two groups preoperatively, with no statistically significant differences (P > 0.05). However, the SMILE group exhibited higher BUT and Sit values compared to the FS-LASIK at 1 and 3 months postoperatively, with statistically significant differences (P < 0.05) (see Table 3).

Table 3: Intimal Stability Comparison Among the two Groups (Mean ± SD).

Group	Number of Subjects	BUT (seconds)	Sit (mm/5 min)
		Pre-op	1 Month Post-op
SMILE	200	9.14 ± 2.11	5.23 ± 1.21
FS-LASIK	200	9.17 ± 2.14	4.86 ± 1.25
F	-	0.040	5.360
P value	-	0.961	0.005

Corneal Higher-Order Aberrations (HOAs) in the two Groups

The corneal higher-order aberrations (HOAs) were similar across the two groups preoperatively, with no statistically significant differences (P > 0.05). However, the SMILE group showed higher HOAs at 1 and 3 months postoperatively compared to the FS-LASIK , with statistically significant differences (P < 0.05) (see Table 4).

Table 4: Comparison of Corneal Higher-Order Aberrations (HOAs) Among the two Groups (Mean ± SD)

Group	Number of Subjects	Pre-op HOAs	1 Month Post-op	3 Months Post-op
SMILE	200	0.28 ± 0.08	0.96 ± 0.11	0.97 ± 0.14
FS-LASIK	200	0.27 ± 0.06	0.48 ± 0.84	0.47 ± 0.10
F	-	1.340	23.420	40.320
P value	-	0.262	0.001	1.1

DISCUSSION

Myopia, a prevalent eye condition, is influenced by both genetic and environmental factors. Although the exact etiology of myopia remains still unknown, genetic predisposition has always been flagged off, wherein environmental factors like reading continuously and having inadequate lighting raise the likelihood of developing myopia, according to Zhao et al. (2021). Moreover, micronutrient deficiencies and nutritional imbalance, continuous exposure to electronic devices, have been strongly linked with the cause of myopia. These findings underscore the priority for preventive measures and for therapy in individuals exposed to these risk factors (Xu et al., 2017).

The traditional method of managing myopia has been through the use of corrective eyeglasses. A prescription eyeglass, if used appropriately, would help to relieve the symptoms of eye strain and improve visual acuity by correcting the refractive status of the eye. However, conventional eyewear and pharmacological treatments are inefficient in most cases of the disorder, and in most instances, one or the other fails to provide a definite cure. Corneal refractive surgery and intraocular lens implantation are surgical interventions that have shown better prospects of success. This is underscored by the increasing number of myopic patients coming for surgical treatment, so it is particularly important to select a suitable surgical way in line with the condition of the patient, diagnosis, budget for the treatment, and available conditions of surgical equipment. Not only will it increase surgical efficacy but also contribute to a positive doctor-patient relationship. (Yin et al., 2021).

This study compared the procedures of SMILE and FS-LASIK in detail. According to the results, the UCVA was similar in both groups at different postoperative periods of two weeks, one month, and three months after surgery with P > 0.05 in all cases. The results suggested that both surgical modalities were effective in improving UCVA and in alleviating the symptoms associated with myopic patients involving impairment of distance vision. Results from all these techniques have a similarity that can be explained by their common platform of laser-based corneal refractive surgery. Some of the advantages of laser are quick treatment time, high precision, very less interference with surrounding tissues, and minimal damage to adjacent organs (Yin et al., 2021). The cornea provides most of the refractive power of the eye, and coupled with the refractive power in the lens, it focuses parallel light onto the retina, ensuring that an image formed is clear (Qian et al., 2020).

Corneal refractive surgery recovers the normal corneal refractive power in myopic patients by modifying the thickness and shape of the cornea, hence improving acuity of vision and facilitating the process of restoring normal vision. The results of this study proved that, in terms of surgical efficacy, the SMILE procedure was superior to the FS-LASIK one in maintaining tear film stability and improving corneal higher-order aberrations—as manifested by better BUT, Sit values, and corneal higher-order aberration scores at both the one- and three-month follow-ups after surgery (P<0.05). This can be attributed to the flapless technique of SMILE—a strategy involving simply the creation of a corneal stromal lenticule by a laser. This minimally invasive strategy reduces possible tissue and nerve damage during surgery (Guo et al., 2019).

On the other hand, both types of FS-LASIK necessitate that a corneal flap be made. The formation of the corneal flap during laser ablation may inadvertently damage the sensory nerve fibers within the cornea. This can break the nerve reflex arc, which regulates tear secretion and the blink reflex, thereby diminishing both and subsequently causing dry eye symptoms after surgery. This means less surgical trauma with regard to FS-LASIK and SMILE, better preservation of the cornea's biomechanical properties, and minimize aberration changes caused by the flap, hence improving postoperative visual recovery. In support of previous studies by Yu et al. (2019), this study confirms that SMILE is better in improving the corneal aberrations in myopic patients. However, the study was a single-centered one and included a small sample; therefore, further studies including multicenter studies, randomized and double-blind studies with large samples are necessary for the validation of such findings.

CONCLUSION

In summary, SMILE, FS-LASIK, all had appropriate surgical outcomes for the treatment of myopia, by which the uncorrected visual acuity can be effectively enhanced and normal visual function restored. However, SMILE performed better in terms of maintaining tear film stability and reducing corneal higher-order aberrations.

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