

## ORIGINAL ARTICLE

## COMPARISON OF VISUAL ACUITY RESULTS AFTER FEMTOSECOND LASER-ASSISTED IN SITU KERATOMILEUSIS (FS-LASIK) AND SMALL INCISION LENTICULE EXTRACTION (SMILE)

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### ABSTRACT

**Introduction:** Two of the most popular refractive surgery methods currently used are Femtosecond Laser-Assisted In Situ Keratomileusis (FS-LASIK) which creates a flap using femtosecond laser and stromal ablation using excimer laser, and Small Incision Lenticule Extraction (SMILE), a flapless procedure in which a lenticule is extracted through a small incision. The aim of this study is to compare the visual acuity results of FS-LASIK and SMILE.

**Methods:** This is a descriptive cross-sectional study. Data were collected from the medical record of patients who underwent FS-LASIK or SMILE procedure at Cicendo Eye Hospital, the national eye centre, in 2022. Patients were followed up at 1 day, 1 week, and 1 month postoperatively and visual acuity outcomes between the two procedures were compared.

**Results:** A slightly higher percentage of eyes in FS-LASIK (46.6%) achieved a UCVA of 1.0 at 1 day postoperatively compared to SMILE (45.5%). At 1 week and 1 month, SMILE showed superior results with 83% and 94.6% of eyes achieving a UCVA of 1.0, meanwhile FS-LASIK had 72.2% and 86.2%. Residual refractive error at 1 month had a median of -0.6146 and -0.3125 in the FS-LASIK and SMILE groups.

**Conclusion:** This study found better UCVA results in the FS-LASIK group compared to the SMILE group at 1 day postoperatively. Meanwhile, UCVA at 1 week and 1 month postoperatively, showed superior results in the SMILE group. Residual refractive error at 1 month postoperatively also showed better results in SMILE than FS-LASIK.

**Keywords:** visual acuity, FS LASIK, SMILE

### INTRODUCTION

Refractive surgery is a procedure used to correct refractive errors, alleviating the need for glasses or contact lenses. Techniques and methods in this field are constantly evolving along with technology. Two of the most popular procedure currently used are Femtosecond Laser-Assisted In Situ Keratomileusis (FS-LASIK) and Small Incision Lenticule Extraction (SMILE). LASIK is a procedure that creates a corneal flap, followed by stromal ablation to alter the shape of the cornea. The use of femtosecond laser in FS-LASIK creates higher accuracy and precision in corneal flap creation compared to a microkeratome blade, used in LASIK, resulting in lower risk of complications. Refractive lenticule extraction is a more recently developed method which uses femtosecond laser to create an intrastromal lenticule to then be extracted.

Specifically in SMILE, the lenticule is extracted through a small incision, created by the same femtosecond laser. This flapless procedure results in a more biomechanically stable cornea, less anterior corneal innervation disruption causing less dry eye symptoms, as well as absence of flap-related complications.<sup>1-3</sup>

Both FS-LASIK and SMILE have been found to have excellent outcomes in terms of safety, efficacy, and predictability.<sup>4-6</sup> Although both procedures have similar outcomes, results regarding which procedure were superior to the other in terms of uncorrected visual acuity (UCVA) vary between certain postoperative timestamps. In a study conducted by T. Liu et al., FS-LASIK was shown to have better UCVA results at the very early stage of recovery, specifically at 2 hours and 4 hours postoperatively, although both results were similar and satisfactory at 24 hours. Results have varied the most between studies regarding the 24 hour timestamp, in which SMILE was shown to have better results in a study done by Ganesh et al., whereas according to M. Liu et al., FS-LASIK were superior. In the same study done by M. Liu et al., results at 1 week, 1, 3, and 6 months postoperatively had no statistically significant difference. Ganesh et al., also found UCVA results between the two procedures to be similar at 3 months postoperatively, although SMILE was still superior with less postoperative symptoms.<sup>5-7</sup>

Since the aim of refractive surgery is to improve a patient's refractive status, visual acuity becomes an extremely important parameter to assess as it is highly associated with patient satisfaction.<sup>8</sup> Minimal studies comparing the results of FS-LASIK and SMILE have been done in Indonesia. This study was conducted in Cicendo Eye Hospital as the National Eye Center of Indonesia, to compare the visual acuity results after FS-LASIK and SMILE.

## **METHODS**

This comparative study was approved by Padjadjaran University Research Ethics Committee and Cicendo Eye Hospital Research Ethics Committee. Data were collected from the medical record of patients who underwent FS-LASIK or SMILE from January 1st to December 31st of 2022 in Cicendo Eye Hospital, a tertiary referral hospital as well as the national eye center. Subjects were selected using total population sampling method. The inclusion criteria were patients with preoperative best corrected visual acuity (BCVA) equivalent to 1.0, ages 18 to 40 years old, and patients who came in for check-ups at 1 day, 1 week, and 1 month postoperatively unless UCVA results have reached 1.0. Subjects predicted to have residual refractive error during preoperative consultation, or those who underwent an enhancement procedure sooner than 1 month after the primary procedure were excluded.

Statistical analyses were performed with Microsoft® Excel 16.66.1 and IBM SPSS Statistics. Normality was tested using the Kolmogorov–Smirnov test and the Shapiro Wilk test. Mean  $\pm$  standard deviation (SD) was used for quantitative variables that were normally distributed and median (minimum-maximum) was used for quantitative variables that were not normally distributed.

## RESULTS

A total of 291 subjects (490 eyes) fit the criteria of this study, in which 226 subjects underwent FS-LASIK, 64 subjects underwent SMILE, and one subject underwent both procedures in different eyes. Therefore, 378 eyes underwent FS-LASIK and 112 eyes underwent SMILE. Preoperative data consisting of age, sex, and laterality are summarized in table 1. The median age for the FS-LASIK group was 19 and for the SMILE group was 20. In the FS-LASIK group, 153 patients were male (68%) and 73 were female (32%), while in the SMILE group, 27 patients were male (42%) and 37 were female (58%). Seventy-five patients in the FS-LASIK group only had 1 eye that fit the research criteria, while in 151 patients, both eyes fit the criteria. In the SMILE group, 17 patients had 1 eye that fit the criteria, and 47 patients had both eyes that fit the criteria.

**Table 1. Preoperative Patient Data**

Variable	FS-LASIK (n= 226)	SMILE (n= 64)	FS LASIK & SMILE (n= 1)
<b>Age (years)</b>			
Median (Min-max)	19 (18–38)	20 (18–39)	22
<b>Sex</b>			
Male (%)	153 (68%)	27 (42%)	0 (0%)
Female (%)	73 (32%)	37 (58%)	1 (100%)
<b>Laterality</b>			
1 eye (%)	75 (33%)	17 (27%)	0 (0%)
2 eyes (%)	151 (67%)	47 (73%)	1 (100%)

FS-LASIK = femtosecond laser-assisted in situ keratomileusis, SMILE = small incision lenticule extraction

Preoperative refractive status of all eyes are summarized in table 2. Preoperative UCVA values were categorized according to the World Health Organization (WHO) classification of vision impairment.<sup>9</sup> Most eyes in the FS-LASIK group had UCVA of <6/60-3/60, with 161 (42.6%) eyes, and UCVA of <6/18-6/60 with 99 (26.2%) eyes. Meanwhile, the vast majority of eyes in the SMILE group, 82 (73.2%) eyes, had had UCVA of <6/60-3/60. Eyes were also categorized based on preoperative spherical equivalent (SE) values (sum of the sphere power and half of the cylinder power) like those of a study conducted by Althomali.<sup>10</sup> Myopia was considered as a SE of less than 0, further categorized as low ( $\geq -0.50$  diopters (D) and  $< -3.00$  D), moderate ( $\geq -3.00$  D and  $< -6.00$  D) and high ( $\geq -6.00$  D). Hyperopia was considered as

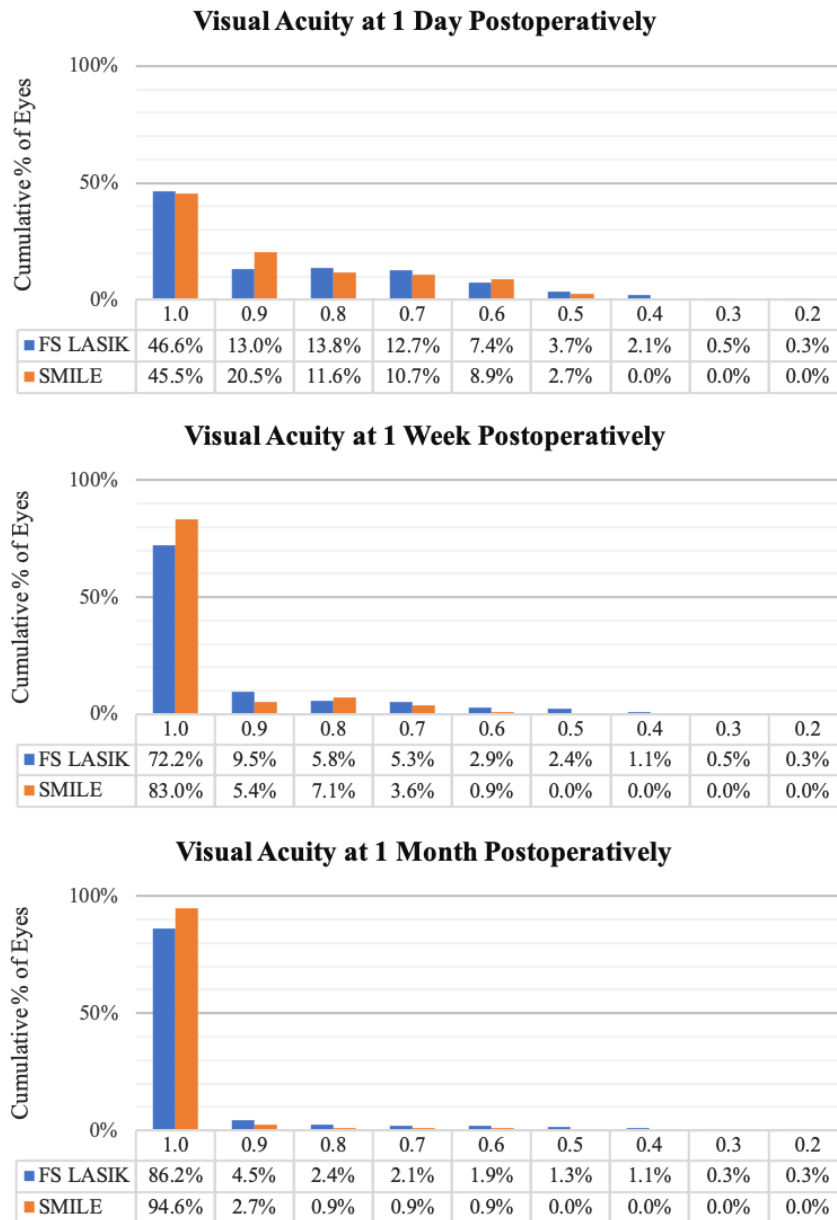
a SE of higher than 0, further categorized as low to moderate ( $\geq +0.50$  D and  $< +3.00$  D) and high ( $\geq +3.00$  D) hyperopia. The majority of the eyes in the FS-LASIK group, 205 (54.2%), were categorized as low myopia, while half of the eyes in the SMILE group were categorized as moderate myopia. The median spherical equivalent was -2.75 and -3.81 in the FS-LASIK and SMILE groups. The range in myopic spherical values were -0.25 up to -11.50 in the FS-LASIK group and -1.00 up to -8.00 in the SMILE group, hyperopic spherical values were +0.50 to +2.00 in the FS-LASIK group while SMILE had no hyperopic eyes, and cylindrical values were -0.25 up to -4.50 in the FS-LASIK group and -0.25 and -2.25 in the SMILE group.

**Table 2. Preoperative Refractive Status**

Variable	FS-LASIK (n= 378 eyes) (%)	SMILE (n= 112 eyes) (%)
<b>UCVA</b>		
$\geq 6/12$	50 (13.2%)	3 (2.7%)
$< 6/12-6/18$	29 (7.7%)	0 (0%)
$< 6/18-6/60$	99 (26.2%)	17 (15.2%)
$< 6/60-3/60$	161 (42.6%)	82 (73.2%)
$< 3/60$	39 (10.3%)	10 (8.9%)
<b>Myopia</b>		
Low	205 (54.2%)	39 (34.8%)
Moderate	104 (27.5%)	56 (50%)
High	68 (18%)	17 (15.2%)
<b>Hyperopia</b>		
Low to Moderate	1 (0.3%)	0 (0%)
High	0 (0%)	0 (0%)
<b>SE (D)</b>		
Median (Min-Max)	-2.75 (-11.75-1.38)	-3.8125 (-8.88-1.13)

FS-LASIK = femtosecond laser-assisted in situ keratomileusis, SMILE = small incision lenticule extraction, UCVA = uncorrected visual acuity, SE= spherical equivalent

Postoperative UCVA were recorded in both groups and summarized in figure 1. Visual acuity values were written in decimal notations, as written on the medical records. At 1 day postoperatively, 176 (46.6%) eyes in the FS-LASIK group and 51 (45.5%) eyes in the SMILE group achieved a UCVA of 1.0. At 1 week postoperatively, 273 (72.2%) eyes in the FS-LASIK group and 93 (83%) eyes in the SMILE group achieved a UCVA of 1.0. At 1 month postoperatively, 326 (86.2%) eyes in the FS-LASIK group and 106 (94.6%) eyes in the SMILE group achieved a UCVA of 1.0.



**Figure 1. Uncorrected Visual Acuity Results at 1 Day, 1 Week, and 1 Month Postoperatively in FS-LASIK and SMILE**

Postoperative refractive status of all eyes at 1 month postoperatively in terms of residual refractive error (RRE) are summarized in table 3. RRE were recorded according to the spherical equivalent (SE) value of the lenses needed to correct the eyes that had yet to achieve a postoperative UCVA of 1.0. Although, there were 4 eyes and 2 eyes in the FS-LASIK and SMILE group that did not achieve a postoperative UCVA of 1.0 yet had no record of lens correction at 1 month postoperatively, which resulted in 48 and 4 eyes in the FS-LASIK and SMILE groups that had RRE. The mean and median of RRE in both groups are presented on the table. As previously mentioned, myopia is defined as having a SE of  $\geq -0.50$  D and hyperopia as a SE of  $\geq +0.50$  D, which will help to determine whether any eyes are still or no

longer defined as such postoperatively. In the FS-LASIK group there were 25 eyes with a RRE of  $\geq -0.50$  D and none  $\geq +0.50$  D. Whereas in the SMILE group, there were no eyes with an RRE of  $\geq -0.50$  D or  $\geq +0.50$  D. BCVA values were recorded according to the best visual acuity achieved with lenses at 1 month postoperatively. Sixteen (4.2%) eyes and 3 (2.7%) eyes in the FS-LASIK and SMILE groups did not achieve a BCVA of 1.0.

**Table 3. Postoperative Refractive Status**

Variable	FS-LASIK (n= 48 eyes)	SMILE (n= 4 eyes)
<i>Residual Refractive Error</i>		
+ 0.5 - - 0.5 D	23 (47.9%)	4 (100%)
Mean $\pm$ SD (D)	-0.6146 $\pm$ 0.3608	-0.1563 $\pm$ 0.3590
Median (Min-Max) (D)	-0.625 (-1.63-0.25)	-0.3125 (-0.38-0.38)

FS-LASIK = femtosecond laser-assisted in situ keratomileusis, SMILE = small incision lenticule extraction, UCVA = uncorrected visual acuity, SE= spherical equivalent

## DISCUSSION

The goal of refractive surgery is to improve the visual ability of patients with ametropia and restore normal vision without the help of glasses nor contact lenses. In corneal refractive surgery, adjustment of the shape and thickness of the cornea is what alters the refractive power of the eyes. FS-LASIK and SMILE are two of the most popular corneal refractive surgery methods currently used. Both procedures differ in their techniques, as FS-LASIK creates a flap using femtosecond laser and stromal ablation using excimer laser, while SMILE is a flapless procedure in which a lenticule is formed and extracted through a small incision, both created by the same femtosecond laser.

In this study, UCVA at 1 day postoperatively showed a slightly higher percentage in the FS-LASIK group (46.6%) than in the SMILE group (45.5%). Previous studies have also shown that FS-LASIK tend to have better visual acuity results in the early postoperative phase, such as the study conducted by T. Liu et al. and M. Liu et al.<sup>5,7</sup> This is caused by the difference in the healing response in both procedures which creates muddiness of the refractive media associated with the formation of interface haze during the SMILE procedure.<sup>7</sup> Another reason suggested by Agca et al were the surgical maneuvers in SMILE that are more challenging than those of FS-LASIK, such as the creation of two lamellar cuts (superficial and deep) rather one flap cut and an increased number of surgical steps needed to separate the lenticule. In terms of the effects of the laser treatment, the total energy applied to the corneal stroma in SMILE is also higher compared to the stroma in FS-LASIK. These differences may contribute to the varying inflammatory response.<sup>11</sup>

UCVA results at 1 week and 1 month postoperatively in this study showed superior results in the SMILE group. These results align with those of a study conducted by Ganesh et

al., in which 96% of eyes in SMILE achieved a UCVA of 20/20 or better meanwhile FS-LASIK had only 88%, and Lin et al. in which 85% of eyes in SMILE achieved a UCVA of 20/20 or better meanwhile FS-LASIK had only 84%.<sup>4,6</sup> Although in those studies, UCVA results were recorded at 3 months, which are different to this study. In a systemic review conducted by Guo et al., corneal biomechanical strength in SMILE was preserved significantly better than in FS-LASIK.<sup>12</sup> This was thought to be caused by the fact that the SMILE procedure only makes a small incision, rather than a flap, which creates preservation of stronger anterior corneal lamellae. As a result, the recovery effect of a patient's visual ability is further improved and is a contributing factor to the superior results of SMILE in this study.<sup>1,13</sup>

Regarding residual refractive error, this study also showed better results in the SMILE group which were similar to those of a study conducted by Ganesh et al. This was believed to be caused by an intraoperative difference between the two procedures that creates a variation in hydration, thus creates a possibility of under ablation or over ablation. The process of lifting the flap in FS-LASIK exposes the stroma, causing hydration changes before creating refractive correction with the excimer laser. Meanwhile, in SMILE, lenticule creation by the femtosecond laser is done before any disturbance of the stroma. As a result, SMILE is thought to have better predictability.<sup>6</sup> Although, at Cicendo Eye Hospital, the temperature and humidity of each operating rooms are controlled to minimize the possibility of this phenomenon. SMILE also showed better results in terms of BCVA, with less eyes achieving a postoperative BCVA of less than 1.0 at 1 month.

One case recorded in this study showed the results between FS-LASIK and SMILE done to the same patient in different eyes. The patient had originally come in to undergo SMILE on both eyes, although during the procedure, black spots developed in the left eye leading to the decision of the surgeon to postpone the procedure on that eye. There were no complications on the right eye. The patient came in 3 months later to undergo FS-LASIK on the left eye. The results were excellent in both eyes, which achieved a UCVA of 1.0 at one month postoperatively.

Six eyes in the FS-LASIK group had yet to achieve a UCVA of  $\geq 6/12$  at 1 month postoperatively. Three out of the six eyes had a BCVA value of 1.0, while the other 3 eyes had a BCVA value of 0.8, 0.6, and 0.4. Although, 2 out of the 3 eyes that had a BCVA value of less than 1.0 had a much more satisfactory result at 3 months postoperatively, which indicated a slower recovery. No intraoperative complications were reported in the six eyes. Another contributing factor to poorer results in the FS-LASIK group is due to the fact that two of the six eyes had high myopia preoperatively, one being the eye with the highest SE in this study. This

may also be another reason to the overall superiority of the SMILE results, in which more eyes, 68 (18%) eyes, had high myopia in FS-LASIK than in SMILE, which had 17 (15.2%) eyes. Eyes with a higher degree of ametropia are more likely to experience under correction and will require more time to reach refractive stability.<sup>1</sup>

This study had its limitations such as the difference in the number of subjects included from each group, in which more patients who came to Cicendo Eye Hospital chose to undergo FS-LASIK rather than SMILE. Duration of postoperative follow up in this study were also limited to 1 month as most patients did not come in for a follow up at 3 and 6 months or longer.

## CONCLUSION

In conclusion, this study found slightly better results of UCVA in FS-LASIK than SMILE at 1 day postoperatively. A more significant difference was found at 1 week and 1 month postoperatively, in which UCVA of the SMILE group showed superior results. Residual refractive error recorded at 1 month was also shown to be better in SMILE than FS-LASIK. In terms of BCVA, less eyes in the SMILE group had a loss of lines. For future studies, a prospective method should be considered with better control of confounding variables between the two groups, such as the degree or type of ametropia included in the study, surgeons operating on the procedures, as well as comparing data before and after both procedures.

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