

Control-matched comparison of refractive and visual outcomes between small incision lenticule extraction and femtosecond laser-assisted LASIK

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Purpose: This retrospective case-matched study aimed to compare visual and refractive outcomes between small incision lenticule extraction (SMILE) and LASIK.

Patients and methods: Patients who underwent SMILE (34 eyes of 23 patients) or LASIK (34 eyes of 24 patients) were enrolled and matched according to preoperative manifest refractive spherical equivalents. The mean preoperative manifest refractive spherical equivalent was -4.69 ± 0.6 and -4.67 ± 0.64 D in the SMILE and LASIK groups, respectively. The safety, efficacy, and predictability were compared 3 months after surgery. Changes in corneal refractive power from the center to peripheral points and their maintenance ratios were analyzed and compared between the two groups.

Results: In the SMILE and LASIK groups, 82.4% and 85.3% of patients, respectively, achieved 20/13 or better uncorrected distance visual acuity ($p=1.00$). There were no eyes that lost two or more lines of corrected distance visual acuity in either group. The maintenance ratios of corneal refractive power changes at the peripheral points in the SMILE group were significantly higher than those in the LASIK group ($p<0.05$).

Conclusion: Both groups achieved similar high efficacy and safety. SMILE surgery resulted in higher refractive power correction in the peripheral cornea than LASIK surgery.

Keywords: small incision lenticule extraction, LASIK, corneal refractive power, refractive power correction efficiency, corneal topography

Introduction

LASIK was developed by Pallikaris et al in 1990¹ and has been widely performed in many countries. Previous studies have confirmed the safety and efficacy of LASIK surgery.²⁻¹² On the other hand, small incision lenticule extraction (SMILE) was developed as a refractive surgery without the use of excimer laser in 2008. Shah et al¹³ and Sekundo et al¹⁴ reported early results with SMILE, and confirmed that it was a highly safe and effective refractive surgical technique.

Generally, in LASIK surgery, a corneal flap is created; excimer laser ablation is then performed on the corneal stromal layer under the flap.¹⁵ Although excimer laser can accurately ablate the central part of the cornea, ablation efficiency is reduced at the peripheral cornea.^{13,16} In contrast, the SMILE surgery corrects refractive error using a femtosecond laser, in which a lenticule is created and extracted from a small incision in the cornea. Because femtosecond lasers can accurately create corneal incisions at specified depths, SMILE surgery is expected to achieve accurate refractive corrections, even at the peripheral cornea.^{13,17}

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In the current study, we performed a matched comparison analysis of the visual and refractive outcomes between SMILE and LASIK. Additionally, we compared changes in central and peripheral corneal refractive power between SMILE and LASIK using corneal topography.

To our knowledge, this is the first study to use a matched comparison method to evaluate the visual/refractive outcomes and changes in corneal refractive power after adjusting optical zone size between SMILE and LASIK.

Patients and methods

Patients

This matched comparison study included a total of 68 eyes of 47 patients who underwent SMILE or LASIK surgery for myopia and astigmatism correction between August 2012 and December 2015 at Nagoya Eye Clinic (Nagoya, Japan). Consecutive patients who underwent SMILE were selected and subsequently matched with LASIK patients, based on a preoperative manifest refractive spherical equivalent (SE) difference of within ± 0.5 D for each pair. Investigators were blinded to postoperative refractive and visual outcomes when the patients were matched. Ultimately, the patients who underwent SMILE (34 eyes of 23 patients; mean age 32.2 ± 6.8 years) and LASIK (34 eyes of 24 patients; mean age 29.9 ± 6.8 years) were enrolled in the study.

Table 1 summarizes the demographic information of patients in each group. The preoperative manifest refractive sphere was -4.52 ± 0.54 and -4.45 ± 0.61 D in the SMILE and LASIK groups, respectively. The preoperative manifest refractive cylinder was -0.33 ± 0.38 and -0.45 ± 0.44 D in the SMILE and LASIK groups, respectively. With the exception

of planned ablation depth, there were no significant differences among parameters between the two groups.

The study was approved by the Institutional Review Board of the Nagoya Eye Clinic and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients after explanation of the nature and possible outcomes of the study.

Surgical techniques

A 500 kHz femtosecond laser system (VisuMax; Carl Zeiss Meditec, Jena, Germany) was used for surgical refractive corrections in patients in the SMILE group. The femtosecond laser parameters were as follows: cap thickness, 120 μm ; diameter of cap cut, 7.5 mm; and posterior lenticule diameter, 6.5 mm. In the LASIK group as well, flaps were created using a 500 kHz VisuMax femtosecond laser system. The target flap thickness was 80 μm and a hinge was created at the superior position in all cases. An excimer laser (MEL80, Carl Zeiss Meditec) was used for tissue ablation. The MEL80 parameters were as follows: diameter of optical zone, 6.0 mm and diameter of transition zone, 8.2 mm. The Aberration Smart Ablation and wavefront-guided program with data obtained using the WASCA aberrometer (Carl Zeiss Meditec) were applied to all patients.

Preoperative examinations

Preoperative examination included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), manifest refraction, corneal thickness (Orbscan II; Bausch & Lomb, Rochester, NY, USA), corneal topography (TMS-4; Tomey, Nagoya, Japan), and corneal refractive power.

Postoperative examination

Postoperative examination included UDVA, CDVA, manifest refraction, corneal topography, and corneal refractive power 3 months postoperatively.

Comparison of refractive power correction efficiency

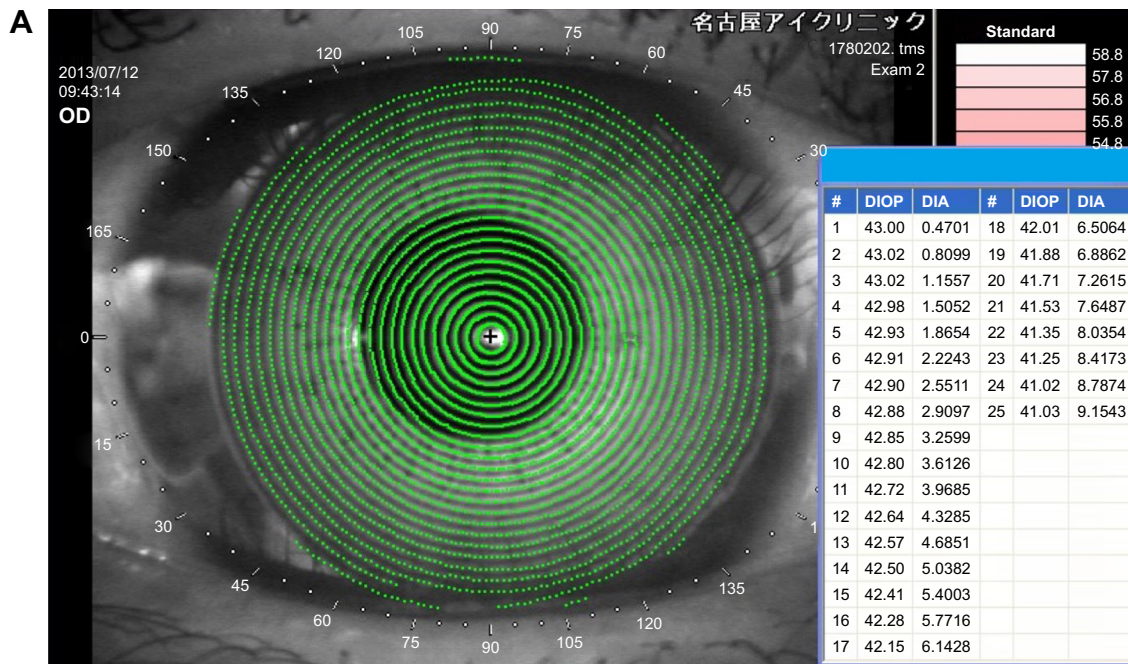
Initially, the “reference” point in both the SMILE and LASIK groups was defined as a position located at 0.5 mm from the measurement center. Because the diameter of the optical zone was different between the SMILE and LASIK groups (SMILE, 6.5 mm; LASIK, 6.0 mm), the diameter of the optical zone was divided into 10 segments, each named 1st–10th from the center to the peripheral cornea.

Table 1 Preoperative patient demographic information

Characteristic	SMILE (n=34)	LASIK (n=34)	p-value
Age (years)	32.2 \pm 6.8	29.9 \pm 6.8	0.172
Male/female (n/n)	13/10	10/14	0.387
UDVA (logMAR)	1.18 \pm 0.12	1.24 \pm 0.15	0.089
CDVA (logMAR)	-0.17 \pm 0.02	-0.18 \pm 0.00	0.325
Refractive sphere (D)	-4.52 \pm 0.54	-4.45 \pm 0.61	0.086
Refractive cylinder (D)	-0.33 \pm 0.38	-0.45 \pm 0.44	0.199
Spherical equivalent (D)	-4.69 \pm 0.6	-4.67 \pm 0.64	0.750
Mean keratometric value (D)	42.96 \pm 1.07	43.00 \pm 1.65	0.319
Central corneal thickness (μm)	564.6 \pm 20.2	557.0 \pm 25.44	0.183
Planned ablation depth (μm)	96.97 \pm 12.34	104.03 \pm 10.26	<0.0001

Notes: Data presented as mean \pm SD, unless otherwise indicated. All parameters except planned ablation depth did not show any significant differences.

Abbreviations: CDVA, corrected distance visual acuity; SMILE, small incision lenticule extraction; UDVA, uncorrected distance visual acuity.



B

Analysis point (th)	Analysis diameter	
	SMILE (mm)	LASIK (mm)
0	0.5	0.5
1	0.7	0.6
2	1.3	1.2
3	2	1.8
4	2.6	2.4
5	3.3	3
6	3.9	3.6
7	4.6	4.2
8	5.2	4.8
9	5.9	5.4
10	6.5	6

Figure 1 Representative image of corneal topography and analysis points in SMILE and LASIK groups.

Notes: Corneal refractive power at each analysis diameter (0th–10th) was estimated using corneal refractive power on 25 mire rings (A). Initially, the “reference” area in both the SMILE and LASIK groups was defined as the position located at 0.5 mm from measurement center. Because the diameter of the optical zone between SMILE and LASIK groups is different (SMILE 6.5 mm, LASIK 6.0 mm), a diameter of optical zone was divided into 10 and each analysis point was named 1st–10th from the center to the periphery. The analysis diameter was rounded up to the first decimal place and is shown in (B).

Abbreviation: SMILE, small incision lenticule extraction.

The analysis diameter was rounded up to the first decimal place. The anterior corneal refractive power at each of the selected analysis points (0th–10th; Figure 1B) was calculated using results obtained with the TMS-4 topographer. Briefly, based on the refractive power and diameter of each Mire ring (Figure 1A), a linear regression equation was created in each case. Then, the refractive power at a specific point (0th–10th) in the LASIK and SMILE groups (Figure 1B) was calculated from the equation. The differences in corneal refractive power were then calculated at each point before and after surgery in both the groups. The change at the 0th analysis

point was defined as the “reference”. The maintenance ratio of the corneal refractive power changes was calculated using the following equation:

$$\text{Maintenance ratio} = \frac{\text{Corneal refractive power change at each analysis point}}{\text{Corneal refractive power change at 0th analysis point (reference point)}}$$

The maintenance ratio obtained was compared between the SMILE and LASIK groups.

Statistical analyses

The chi-squared test was applied to compare the sex ratios between the two groups. Spearman's rank correlation was used to analyze correlations between refractive power correction efficiency and analysis diameters. Fisher's exact test was performed to compare the ratios of postoperative distribution of refractive power, UDVA, and CDVA between the two groups. Paired *t*-test was applied to compare age, preoperative UDVA, CDVA, central corneal thickness, planned ablation depth, postoperative refractive power correction efficiency at each analysis point, preoperative and postoperative manifest refractive sphere, manifest refractive cylinder, SE, and mean K. A *p*-value <5% was considered to be statistically significant.

Results

Comparison of efficacy of refractive surgery

In the SMILE and LASIK groups, 82.35% and 85.3% of patients, respectively, achieved 20/13 or better UDVA

(*p*=1.00). All patients in both groups exhibited UDVA 20/20 or better (Figure 2A).

Comparison of safety of refractive surgery

In the SMILE and LASIK groups, 97.06% and 100% of patients, respectively, achieved 20/13 or better CDVA (*p*=1.00). All patients in both groups exhibited 20/20 or better CDVA (Figure 2B). There were no eyes that lost two or more lines of CDVA in either group (Figure 3).

Comparison of predictability of refractive surgery

Postoperative manifest refractive sphere 3 months after surgery was $+0.17\pm 0.41$ and $+0.32\pm 0.34$ D in the SMILE and LASIK groups, respectively. There were no significant differences between the two groups (*p*=0.155). Postoperative manifest cylinder 3 months after surgery was -0.13 ± 0.25 and -0.15 ± 0.26 D in the SMILE and LASIK groups, respectively. There were no significant differences between the two groups (*p*=0.829; Table 2).

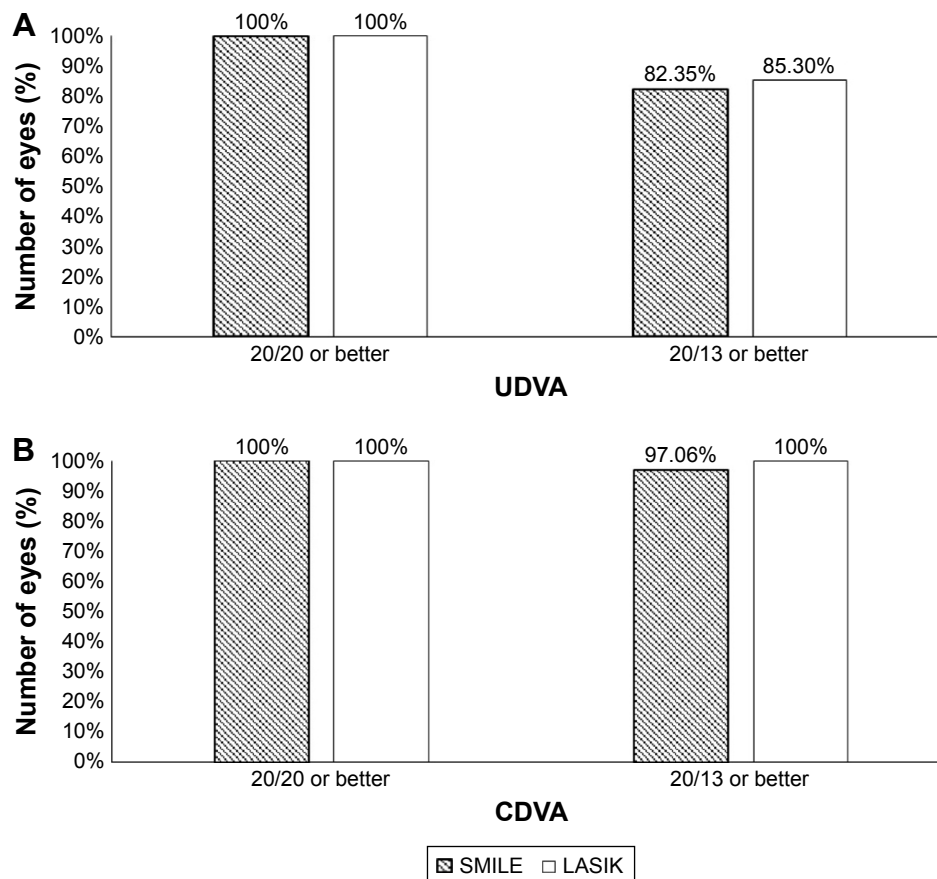


Figure 2 Visual outcomes in SMILE and LASIK groups.

Notes: There were no significant differences between the two groups regarding the ratio of UDVA 20/20 or better, or 20/13 or better (*p*=1.00) (A). Similarly, there were no significant differences between the two groups with regards to the ratio of CDVA 20/20 or better, or 20/13 or better (*p*=1.00) (B).

Abbreviations: CDVA, corrected distance visual acuity; SMILE, small incision lenticule extraction; UDVA, uncorrected distance visual acuity.

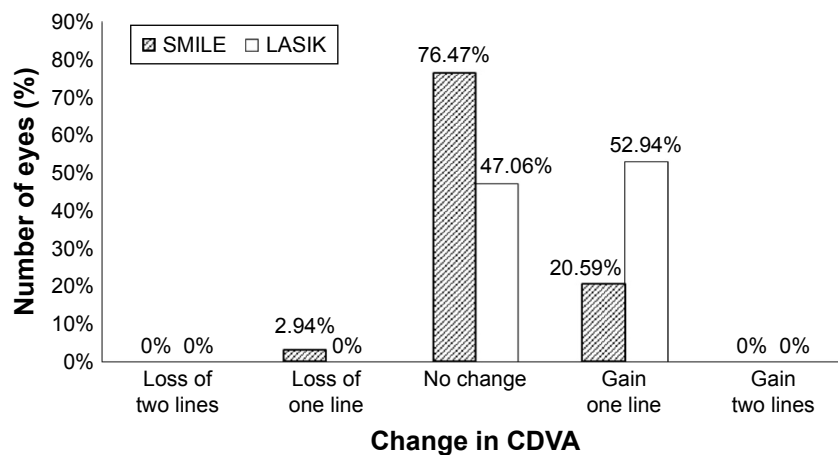


Figure 3 Distribution of the change in Snellen lines of CDVA.

Note: No eyes lost two or more lines of CDVA in either group.

Abbreviations: CDVA, corrected distance visual acuity; SMILE, small incision lenticule extraction.

Ratio corrected within ± 0.5 D of target refraction was 85.29% and 88.24% in the SMILE and LASIK groups, respectively; this was not significantly different ($p=1.00$; Figure 4A–C). All cases in both groups were corrected to within ± 1.00 D of target refraction.

Comparison of refractive power correction efficiency

The average maintenance ratios of refractive power changes at the 1st to the 10th point of the cornea are shown in Figure 5. There were no significant differences in the maintenance ratios between the two groups at the 7th or inner analysis points. However, the maintenance ratios at the 8th to 10th analysis points in the SMILE group (8th, $83.71\% \pm 8.44\%$; 9th, $74.03\% \pm 7.9\%$; and 10th, $63.25\% \pm 8.06\%$) were significantly higher than those in the LASIK group (8th, $79.86\% \pm 5.83\%$; 9th, $70.44\% \pm 6.11\%$; and 10th, $57.7\% \pm 6.37\%$; the p -values being 8th, $p=0.0346$; 9th, $p=0.0392$; and 10th, $p=0.0016$). In addition, subtraction of maintenance ratio of LASIK from SMILE revealed that the difference in maintenance ratios between the SMILE and LASIK groups increased at the peripheral points of the cornea ($r=0.91$, $p=0.0003$; Figure 6).

Table 2 Comparison of postoperative refractive outcomes between SMILE and LASIK groups

Outcome	SMILE	LASIK	p -value
Refractive sphere (D)	0.17 ± 0.41	0.32 ± 0.34	0.155
Refractive cylinder (D)	-0.13 ± 0.25	-0.15 ± 0.26	0.829
Spherical equivalent (D)	0.1 ± 0.38	0.25 ± 0.32	0.117
Mean keratometric value (D)	39.12 ± 1.2	39.17 ± 1.3	0.852

Notes: Data presented as mean \pm SD, unless otherwise indicated. There were no significant differences in any refractive parameters between the two groups.

Abbreviation: SMILE, small incision lenticule extraction.

Discussion

The current study found no significant differences in postoperative UDVA and CDVA between the SMILE and LASIK groups, which is consistent with several previous reports.^{15,18–20} However, Ganesh and Gupta²¹ reported that their SMILE group achieved a higher rate of UCVA (20/20 or better) than the LASIK group. In our study, all patients in both groups achieved UDVA and CDVA 20/20 or better at 3 months after surgery. The discrepancies with our investigation may be due to study design or the number of cases included. In our study, no cases lost two or more lines of CDVA in either group. Our results confirm that both LASIK and SMILE are highly effective and safe as corneal laser refractive surgical techniques.

Similarly, significant differences were not found in the postoperative refractive sphere, refractive cylinder, and prediction accuracy between SMILE and LASIK groups in our study. A comparative study by Lin et al¹⁸ reported no differences in postoperative SEs between the SMILE and LASIK groups. Although Ganesh and Gupta²¹ found that the postoperative SEs in their SMILE group were smaller than those in the LASIK group, the differences between the two groups were small.

For accurate correction of astigmatism, accurate alignment of the cylinder axis is essential. A previous study showed that iris registration system was effective in performing accurate astigmatism correction in LASIK.²² Because the current SMILE procedure does not have an iris registration system, we evaluated astigmatism correction separately. In our study, we found that there was no significant difference in postoperative manifest cylinder between the two groups. Ivarsen and Hjortdal²³ reported that cylinder correction in SMILE was 87% per D (low astigmatism) and 84% per D

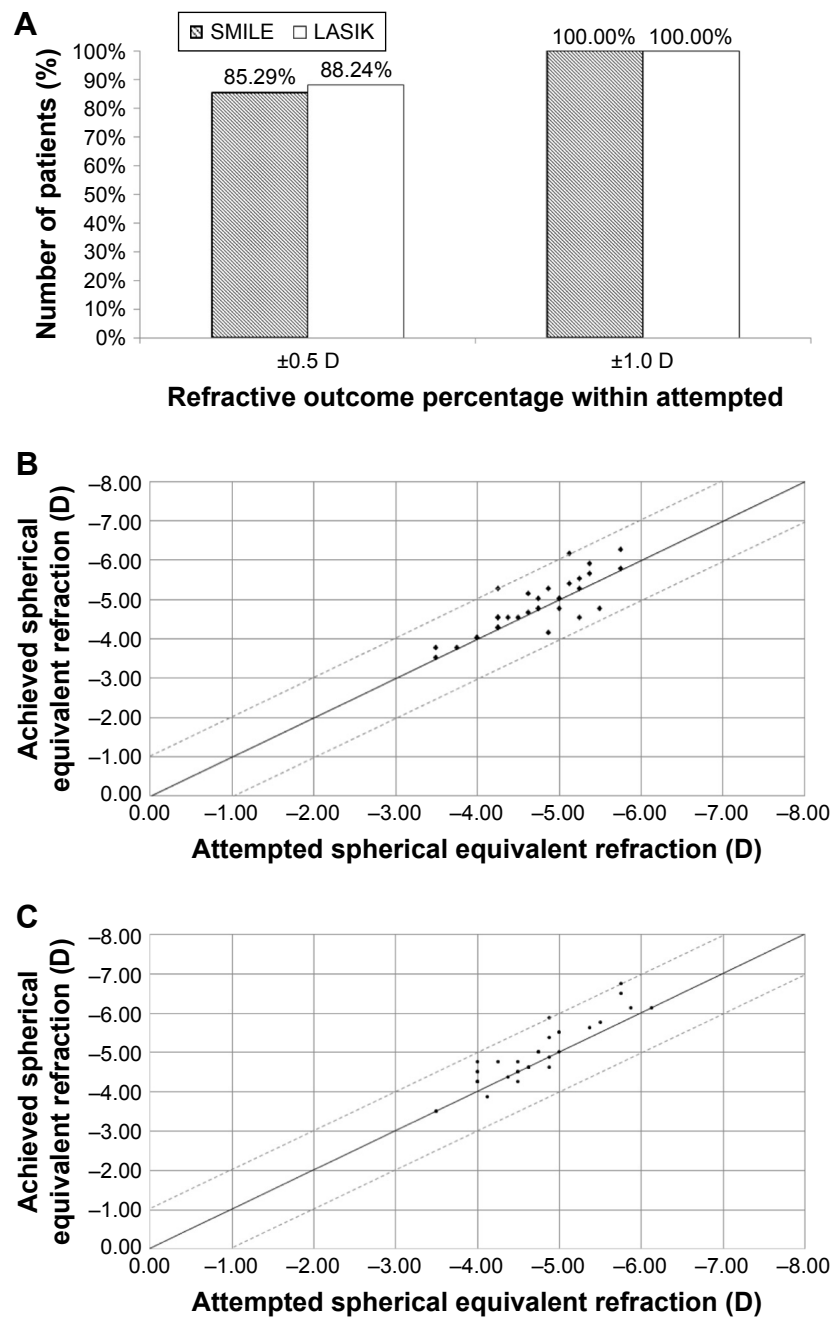


Figure 4 Comparison of the predictability between the SMILE and LASIK groups.

Note: All cases in SMILE (A) and LASIK (B) groups were accurately corrected to within ± 1.00 D, and there were no differences in the ratio of correction to within ± 0.5 D between the two groups (C).

Abbreviation: SMILE, small incision lenticule extraction.

(high astigmatism). Furthermore, Pedersen et al²⁴ reported that cylinder correction in SMILE was 89% per D at 1 year postoperatively. Based on the results from previous reports and our current analysis, we conclude that SMILE does not have limitations for astigmatism correction, even without an iris registration system.

In the current study, we found that the refractive power correction efficiency in the SMILE group was better than the LASIK group in the outer 70% area of the optical zone.

Gyldenkerne et al²⁵ also compared corneal shape changes between SMILE and LASIK groups. They found that the corneal sagittal curvature in the SMILE group was constant within the central 4 mm diameter, while the LASIK group showed a gradual steepening with increasing diameter. However, they compared different optical zones between the two groups. Some cases in the SMILE group had a larger diameter than the cases in the LASIK group. Since we were interested in the detailed refractive power correction at the peripheral

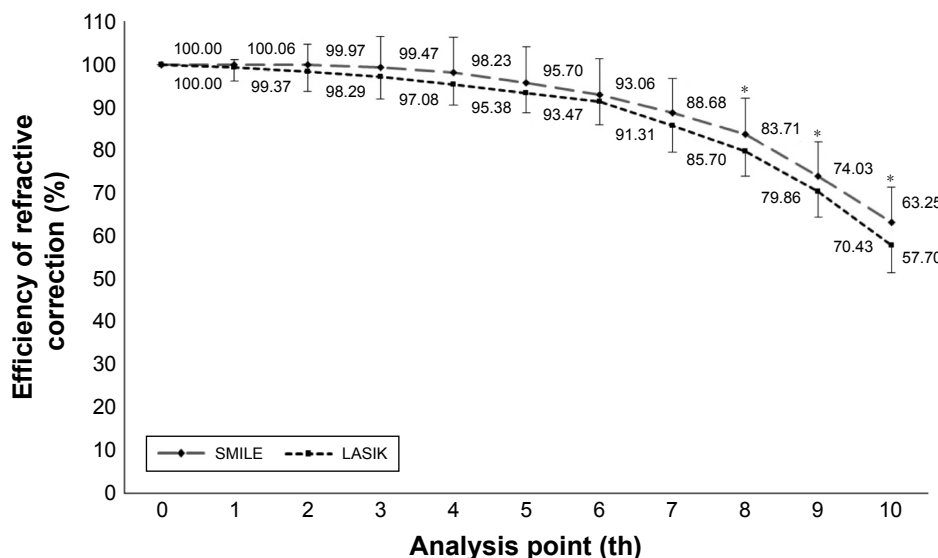


Figure 5 Changes in the refractive power correction efficiency (1st–10th analysis diameter).
Notes: The maintenance ratios at the 8th–10th analysis points in the SMILE group (8th, 83.71%±8.44%; 9th, 74.03%±7.9%; 10th, 63.25%±8.06%) were significantly higher than those in the LASIK group (79.86%±5.83%, 70.43%±6.11%, and 57.7%±6.37%, respectively; *p*-values being 8th, *p*=0.0346, 9th, *p*=0.0392, 10th, *p*=0.0016). **p*<0.05.
Abbreviation: SMILE, small incision lenticule extraction.

cornea, we divided the optical zone into 10 regions and measured the refractive power correction efficiency at each diameter. Moreover, to compare the refractive correction efficiency between the two groups in an equitable manner, we compared the same region between the two groups.

Lin et al¹⁸ compared higher-order aberrations (HOAs) between SMILE and LASIK groups and found that spherical, coma, and total HOAs were significantly lower in the SMILE group than in the LASIK group. Another study also compared HOAs and contrast sensitivity between the two groups and found that postoperative HOAs were significantly lower and contrast sensitivity was significantly better in the SMILE group compared with the LASIK group.²¹ Because increased

HOA is a known cause of night vision disturbances such as glare, halos, and decreased contrast sensitivity,^{26–30} we speculate that corneal refractive power changes at the peripheral cornea may have affected these differences between the LASIK and SMILE groups.

Previous studies have reported that LASIK surgery changed the prolate shape of the cornea to an oblate shape and, therefore, increased spherical aberrations after surgery.^{31–33} These changes are considered to be due to decreased ablation efficiency on the peripheral cornea in LASIK surgery. Generally, excimer laser is applied perpendicularly at the central cornea, but not at the peripheral cornea; therefore, ablation efficiency is reduced at the peripheral part of the

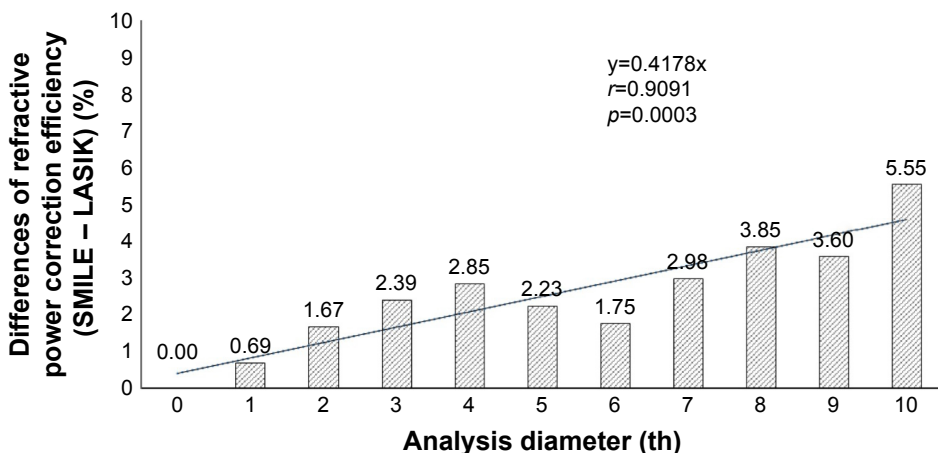


Figure 6 Changes in differences in refractive power correction efficiency (1st–10th analysis diameter) between SMILE and LASIK.
Note: The maintenance ratio in the LASIK group was subtracted from the maintenance ratio in SMILE, which revealed that the difference in maintenance ratios between the SMILE and LASIK groups was positively correlated with the number of analysis points (*r*=0.91, *p*=0.0003).
Abbreviation: SMILE, small incision lenticule extraction.

cornea.^{34,35} In addition, because excimer laser ablation is performed after the corneal flap is lifted, water content of the corneal stroma and humidity of the surgical suite could affect ablation efficiency.^{36,37} On the other hand, SMILE surgery is performed using a femtosecond laser. One of the advantages is that it can disrupt the corneal tissue accurately at the peripheral cornea.^{38–41} From this principle, SMILE surgery is expected to achieve high ablation efficiency, even at the peripheral cornea. Our results suggest that the difference in principles between SMILE and LASIK surgery affects the refractive power correction efficiency at the peripheral cornea.

The MEL80 Aberration Smart Ablation program was applied in all cases in this study. This program was designed to maintain the prolate shape of the cornea from -3 to -6 D of sphere correction.^{42,43} In addition, the wavefront-guided LASIK program was applied for all cases in the LASIK group; SMILE does not have such a program. If an aspheric lenticule or a wavefront-guided lenticule creation protocol was available for SMILE surgery, the difference between the SMILE and LASIK groups could potentially be larger.

The current study had several limitations, the first of which was its retrospective design. Prospective comparative studies are needed to evaluate refractive power correction efficiency. In addition, we did not measure HOAs and contrast sensitivity in the current study. Because peripheral corneal refractive power affects HOA and contrast sensitivity in dim light conditions, questionnaires regarding glare and halo should be used in future studies.

In conclusion, we found that both SMILE and LASIK were equally effective, safe, and highly predictable refractive surgical techniques. We demonstrated that SMILE surgery resulted in more accurate refractive error correction at the peripheral cornea than LASIK.

Acknowledgment

This study was orally presented at the Annual Meeting of the Japan Orthoptic Congress held in Osaka, October 15–16, 2016.

Disclosure

The authors report no conflicts of interest in this work.

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