

Visual and refractive outcomes after SMILE vs FS-LASIK: a paired-eye study

Resultados visuales y refractivos posterior a SMILE versus FS-LASIK: estudio de ojos pareados

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Abstract

Objective: To compare visual acuity, refraction, Schirmer test, tear break-up time (TBUT), esthesiometry, optical quality, higher order aberrations and posterior corneal elevation measurements before and after small-incision lenticule extraction (SMILE) and femtosecond laser-assisted in situ keratomileusis (FS-LASIK). **Method:** Paired eye, randomized, cohort study. Follow-up was performed at days 1 and 7, and at months 1, 3, 6 and 12. **Results:** Forty-two eyes were enrolled in the study. Over time, a difference in posterior corneal elevation was statistically significant ($p < 0.01$) with a greater change in patients treated with SMILE. There was no difference in corrected distance visual acuity and uncorrected distance visual acuity and cylinder between the two techniques; however, there was a statistical significant difference in spherical error and spherical equivalent ($p < 0.01$). There was no difference between the eyes with FS-LASIK and SMILE in the assessment regarding the TBUT, the Schirmer test and esthesiometry. **Conclusions:** SMILE showed more changes in the posterior elevation with a progressive backward shift throughout time during follow-up. SMILE and FS-LASIK provides similar results in myopic patients regarding visual acuity, refraction, Schirmer test, TBUT and esthesiometry.

Keywords: SMILE. FS-LASIK. Myopia. Refractive surgery. Cornea. Aberrometry.

Resumen

Objetivo: Comparar la agudeza visual, la refracción, la prueba de Schirmer, el tiempo de ruptura lagrimal (TBUT), la estesiometría, la calidad óptica, las aberraciones de alto orden y las medidas de elevación corneal posterior antes y después de la extracción de lenticula por pequeña incisión (SMILE) y de queratomileusis in situ asistida por láser femtosegundo (FS-LASIK). **Método:** Estudio de cohorte, aleatorizado, de ojo pareados. El seguimiento se realizó en los días 1 y 7, y en los meses 1, 3, 6 y 12. **Resultados:** Se incluyeron 42 ojos en el estudio. Con el tiempo, la diferencia en la elevación posterior de la córnea fue estadísticamente significativa ($p < 0.01$), con un cambio mayor en los pacientes tratados con SMILE. No se observaron diferencias en la agudeza visual con corrección y agudeza visual sin corrección y el cilindro entre las dos técnicas; sin embargo, el error esférico y el equivalente esférico tuvieron una diferencia estadísticamente significativa ($p < 0.01$). No se halló diferencia con respecto al TBUT, la prueba de Schirmer ni la estesiometría. **Conclusiones:** SMILE mostró más cambios en la elevación posterior, con un desplazamiento posterior progresivo a lo largo del seguimiento. SMILE y FS-LASIK brindan resultados similares en pacientes miopes en cuanto a agudeza visual, refracción, prueba de Schirmer, TBUT y estesiometría.

Palabras clave: SMILE. FS-LASIK. Miopía. Cirugía refractiva. Córnea. Aberrometría.

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Introduction

Femtosecond laser-assisted in situ keratomileusis (FS-LASIK) is a blade-free procedure that has become the treatment of choice for refractive errors like myopia. The main advantages of creating flaps with the femtosecond laser compared to the standard technique, which uses a microkeratome, include a thinner and more uniform flap thickness from center to periphery and greater precision and predictability^{1,2}. However, dry eye and biomechanical corneal abnormalities remain significant concerns. Excimer laser refractive surgery alters the biomechanical resistance of the cornea by surgically removing tissue³. Furthermore, it requires the use of two laser platforms, which increases the time and cost of the procedure.

Small-incision lenticule extraction (SMILE) is a flapless procedure in which a refractive intra-stromal lenticule is manually dissected and removed through a small incision at the periphery of the cornea. This technique reduces the risk of flap-related complications and decreases the effects on corneal hysteresis⁴⁻⁶. Potential biomechanical advantages of SMILE have been proposed based on the non-linearity of the stromal tensile force⁷. Additionally, it theoretically reduces the area of the sub-basal nerve plexus, making the corneal sensitivity and dry eye less affected.

The aim of this study is to compare visual acuity, refraction, Schirmer test, tear break-up time (TBUT), esthesiometry, optical quality, higher-order aberrations (HOA), and posterior corneal elevation measurements before and after performing the SMILE and FS-LASIK procedures on each eye, respectively. Patient follow-up was conducted on days 1 and 7, and months 1, 6, and 12 postoperatively.

Method

We conducted a cohort study at a single center, with a convenience-selected population. The eye pairs of the patients were randomized using version 4.0.2 of the R statistical program (R Core Team, Vienna, Austria) for SMILE in one eye and FS-LASIK in the other eye, for myopia or myopic astigmatism, between January 2012 and December 2013 at *Instituto de Oftalmología Conde de Valenciana* (Mexico City).

Inclusion criteria were patients aged 21 years or older with a normal ophthalmologic examination, a stable refractive error for at least 1 year, overt spherical refraction from 1 to 10 diopters (D), manifest cylinder

from 0 to 5 D, and spherical equivalent < 8 D. Patients had to be good candidates for laser vision correction, with a similar refractive error in both eyes (difference < 0.5 D), preoperative pachymetry > 500 μm , and estimated residual stromal bed thickness > 300 μm .

Exclusion criteria were a family history of keratoconus or evidence of corneal diseases or other eye conditions.

All patients underwent a complete ophthalmologic examination before surgery to ensure a normal cornea and anterior segment. Measurements included spherical and cylindrical error, spherical equivalent, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure, simulated keratometry, posterior keratometry, pachymetry, optical quality, HOA, and posterior corneal elevation.

Patients were masked as to which procedure was performed on each eye. After data collection, this information was unmasked along with the randomization list for statistical analysis.

Follow-up was conducted on days 1 and 7, and months 1, 3, 6, and 12 postoperatively.

Schirmer test

The non-anesthetic test to assess tear secretion was performed by inserting a 30 mm strip (Tear Flow Test Strips, AMCON Laboratories, Missouri, USA) into the inferior fornix at the junction of the middle and lateral third of the lower eyelid margin. The strips remained in this position for 5 minutes with the eyes closed. The degree of wetting was then measured according to the scale provided by the manufacturer.

Tear break-up time

A fluorescein-stained strip (BIO GLO, HUG Pharmaceuticals, California, USA) was placed and moistened with saline solution in the inferior conjunctival sac, and the patient was asked to blink several times. On slit-lamp biomicroscopy with a cobalt blue filter, the time before the first tear film break after a complete blink was observed and recorded as the TBUT. The mean of 3 measurements was calculated.

Corneal esthesiometry

It was measured with a Cochet-Bonnet esthesiometer (Luneau, Paris, France). The instrument was

advanced perpendicular to the central surface of the cornea until contact was made. A positive response was considered if the patient felt the nylon monofilament. Corneal sensitivity was examined three times with each filament length, and the length was sequentially reduced in 5 mm steps. Two positive responses out of three attempts were considered a positive result for each filament length. The corneal sensitivity threshold was considered the result with the longest filament.

Corneal topography

Performed with a Scheimpflug camera and a topographer with Placido disk technology (Sirius; Costruzioni Strumenti Oftalmici, Florence, Italy). Measurements included corneal thickness, simulated keratometry, central 3 mm keratometry, posterior keratometry, HOA, optical quality, and posterior corneal elevation.

Surgical technique

Both procedures were performed under topical anesthesia, after placing standard sterile fields and inserting a blepharostat. Each procedure was performed using the established and described technique⁸.

SMILE

The patient's eye was placed under the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany). The bed was moved to the treatment position under a curved contact lens illuminated for suction. Once proper centration was achieved, the surgeon initiated automatic suction. The laser was activated for photodissection in the following sequence: first, the posterior surface of the refractive lenticule was formed (spirally inward), followed by the anterior surface (spirally outward), and then a small 2-5 mm incision along the circumference of the anterior lenticule surface was made to allow for its extraction.

In all cases, the intended depth of the anterior lenticule surface was 110 μm , with a diameter of 8 mm. Once the femtosecond cutting procedure was completed, the lenticule was dissected, separated through the lateral opening incision (4.0 mm), and manually extracted.

FS-LASIK

The corneal flap was created using the VisuMax femtosecond laser platform (Carl Zeiss Meditec AG, Jena, Germany). The energy of each pulse was set at 140 nJ. The pulse distance was 3 μm for the lamellar flap and 2 μm for the side cut. The side cut was set at 90°, and the flap diameter was fixed at 8.0 mm for all patients. After creating the flap (at a depth of 110 μm), the patient was moved to a Mel-80 excimer laser platform (Carl Zeiss Meditec AG, Jena, Germany) for photoablation. The residual stromal bed was washed with balanced saline solution, and the flap was repositioned.

The postoperative regimen consisted of moxifloxacin drops (Vigamoxi® 0.5%, Alcon, Mexico City, Mexico) every 4 hours for 10 days, fluorometholone (Flumetol® 0.1%, Sophia, Jalisco, Mexico) every 4 hours with a tapering schedule for 3 weeks, and hyaluronic acid 0.4% (Lagricel®, Sophia, Jalisco, Mexico) as needed. Subsequently, only lubricating drops were applied for up to 3 months.

Sample size

The group size of 21 and 21 eyes achieves 7% power to detect non-inferiority using a unilateral independent samples t-test. The non-inferiority margin is 0.0. The true difference between the means should be 0.0. The significance level (alpha) of the test is 0.050. The data are drawn from populations with standard deviations of 0.3 and 0.4.

Statistical analysis

The mean and standard deviation of visual acuity, refraction, Schirmer test, TBUT, esthesiometry, optical quality, HOA, and posterior corneal elevation were determined before and during the follow-up of the SMILE and FS-LASIK surgical procedures.

To compare the means of the mentioned parameters, paired Student's t-test was used for each procedure, and unpaired Student's t-test was used to compare both procedures. A multiple linear regression analysis was conducted independently for SMILE and FS-LASIK to estimate the desired vs the obtained spherical equivalent, and the results are given as regression coefficients (beta) and standard errors. All analyses were performed with Stata/MP 13.1 (Stata Corporation, Texas, USA).

Results

A total of 42 eyes from 21 patients were included; 21 eyes underwent SMILE, and 21 eyes underwent FS-LASIK. The mean age of the patients was 28.3 ± 4.57 years (range: 21 to 31), and 66% of the eyes belonged to female patients. All patients had a mean follow-up of 16.5 ± 3.1 months (range, 13 to 19). No surgical complications were documented, and no eye was diagnosed with corneal ectasia during the follow-up. Pre- and postoperative refractive characteristics are shown in Tables 1 and 2, respectively.

Figure 1 shows the refractive outcomes of the eyes that underwent SMILE at the 12-month follow-up. The mean preoperative UDVA was logMAR 1.39 (Snellen 20/490) and postoperative was logMAR 0.05 (Snellen 20/22) ($p < 0.001$); at the 12-month follow-up, 95% had a UDVA of 20/25 or better (Fig. 1A). The mean preoperative and postoperative CDVA was logMAR -0.006 (Snellen 20/19) and logMAR -0.036 (Snellen 20/18), respectively ($p > 0.001$). In terms of safety, 16 eyes maintained the same CDVA in the postoperative period, and 5 eyes gained 1 line of vision vs preoperative (Fig. 1B). A safety index of 3.0 was achieved.

A strong correlation was found between the desired and obtained spherical equivalent ($R^2 = 0.99941$) (Fig. 1C). The mean preoperative spherical equivalent was -5.49 D, and postoperative, -0.45 D ($p < 0.001$). A total of 90% of the eyes undergoing SMILE had a spherical equivalent of ± 0.50 D, and all eyes in this group remained within ± 1.00 D (Fig. 1D). The pre- and postoperative refractive astigmatism was -1.45 D and -0.66 D, respectively ($p < 0.001$); all eyes had final astigmatism ≤ 1.00 D (Fig. 1E). In long-term follow-up, only 4% of the eyes had a change in spherical equivalent of 0.50 D or more (Fig. 1F).

Figure 2 shows the refractive outcomes of the eyes that underwent FS-LASIK at the 12-month follow-up. In this group, the pre- and postoperative UDVA were logMAR 1.36 (Snellen 20/458) and logMAR 0.07 (20/23), respectively ($p < 0.001$); at the 12-month follow-up, 90% had a UDVA of 20/25 or better (Fig. 2A). The mean pre- and postoperative CDVA was logMAR -0.006 (Snellen 20/19) and logMAR -0.03 (Snellen 20/18) ($p < 0.001$). In terms of safety, 17 eyes maintained the same CDVA in the postoperative period, and 4 eyes gained 1 line of vision (Fig. 2B). Similarly, a safety index of 3.0 was achieved.

A good correlation was found between the desired and obtained spherical equivalent ($R^2 = 0.99762$) (Fig. 2C). The pre- and postoperative spherical

Table 1. Preoperative Refractive Characteristics in Eyes Undergoing SMILE and FS-LASIK

Refractive Characteristic	SMILE (Mean $\pm$ SD)	FS-LASIK (Mean $\pm$ SD)	p
Overt Spherical Equivalent (D)	-4.49 ± 2.23	-4.47 ± 3.85	> 0.05
Spherical Error (D)	-5.49 ± 2.23	-5.40 ± 2.26	> 0.05
Cylindrical Error (D)	-1.45 ± 1.08	-1.17 ± 1.28	> 0.05
LogMAR UDVA	1.37 ± 0.32	1.35 ± 0.36	> 0.05
LogMAR CDVA	-0.006 ± 0.02	-0.006 ± 0.02	> 0.05

CDVA: corrected distant visual acuity; D: diopters; SD: standard deviation; LogMAR: logarithm of the minimum angle of resolution; UDVA: uncorrected distant visual acuity.

Table 2. Postoperative Refractive Characteristics in Eyes Undergoing SMILE and FS-LASIK 12 Months After Surgery

Refractive Characteristic	SMILE (Mean $\pm$ SD)	FS-LASIK (Mean $\pm$ SD)	p
Manifest Spherical Equivalent (D)	-0.45 ± 0.50	0.20 ± 0.65	< 0.01
Spherical Error (D)	-0.06 ± 0.56	0.24 ± 0.64	< 0.01
Cylindrical Error (D)	-0.66 ± 0.54	-0.64 ± 0.30	> 0.05
LogMAR UDVA	0.04 ± 0.09	0.03 ± 0.79	> 0.05
LogMAR CDVA	-0.36 ± 0.56	-0.30 ± 0.53	> 0.05

CDVA: corrected distant visual acuity; D: diopters; SD: standard deviation; LogMAR: logarithm of the minimum angle of resolution; UDVA: uncorrected distant visual acuity.

equivalent were -4.77 D and 0.245 D, respectively ($p < 0.001$). A postoperative spherical equivalent of ± 0.50 D was achieved in 76% of the eyes, and ± 1.00 D in 90% of the eyes undergoing FS-LASIK (Fig. 2D). The mean preoperative and postoperative refractive astigmatism was -4.47 D and -0.20 D, respectively ($p < 0.001$), with final astigmatism ≤ 1.00 D in 95% of the eyes (Fig. 2E). By the end of the follow-up, the spherical equivalent changed by 0.50 D or more in 15% of the eyes (Fig. 2F).

Table 3 shows the pre- and postoperative topographic measurements of both groups, including pachymetry, simulated keratometry, central 3 mm keratometry, and posterior keratometry. The only statistically significant difference was in postoperative pachymetry, which was lower in the SMILE vs the FS-LASIK group.

On day 1 postoperative, there was no statistically significant difference ($p > 0.58$) in posterior corneal elevation between SMILE and FS-LASIK eyes;

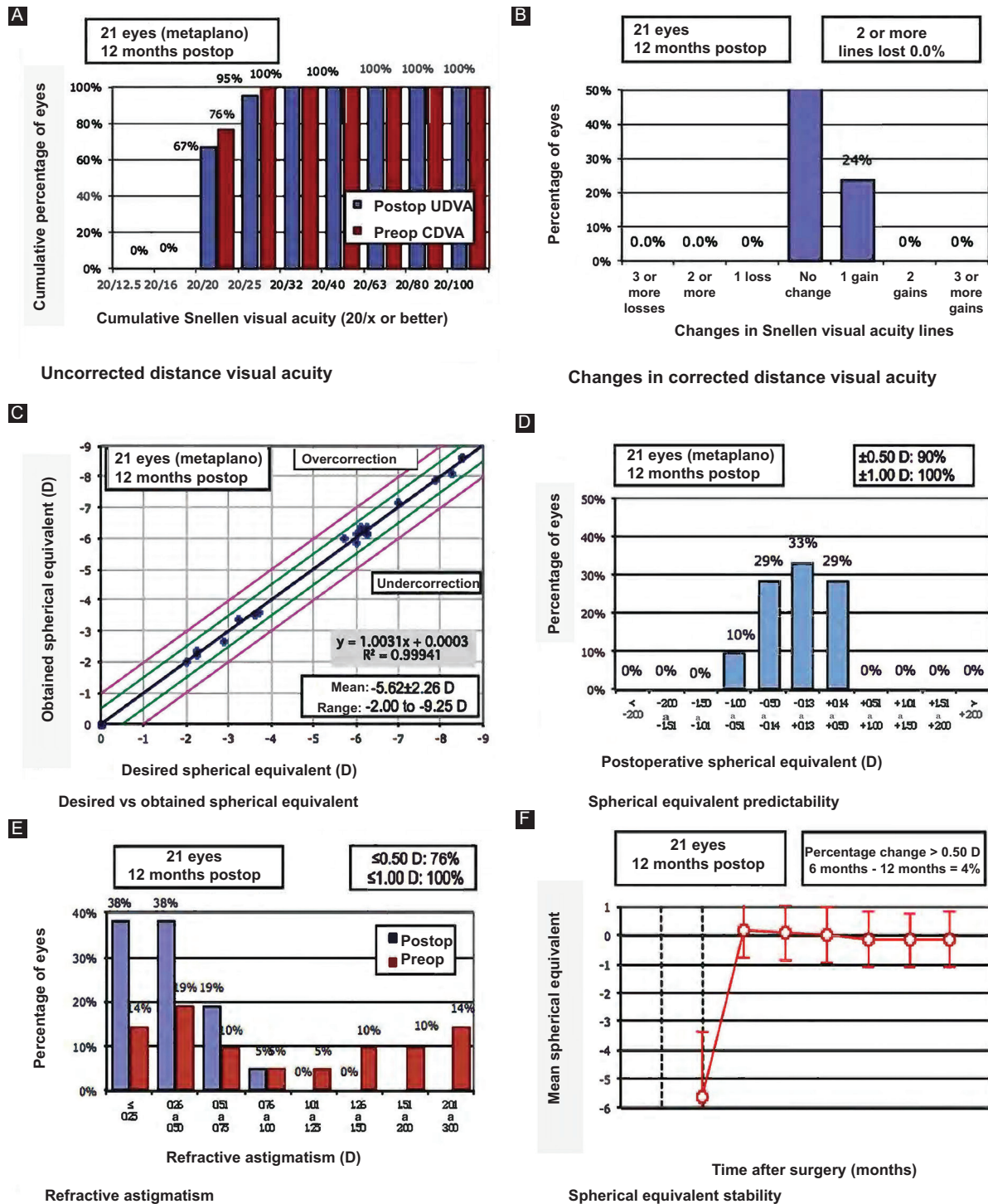


Figure 1. Refractive outcomes of eyes undergoing SMILE at the 12-months follow-up. These graphs provide detailed information on the accuracy, predictability, safety, and efficacy of the procedure. **A:** cumulative uncorrected distant visual acuity graph. Results indicate that 70% of eyes achieved 20/20 vision, 95% reached 20/25, and 100% achieved 20/30. **B:** safety graph. The analysis shows that 100% of eyes maintained or improved their uncorrected distant visual acuity after surgery, with no losses observed. **C:** spherical equivalent predictability graph. A good correlation was found between the desired and obtained spherical equivalent ($R^2 = 0.99941$). These results highlight the predictability of the procedure, showing reliable performance in achieving the expected refractive outcomes. **D:** spherical equivalent predictability graph. A total of 90% of eyes were within ± 0.50 D, and 100% were within ± 1.00 D of the postoperative spherical equivalent. **E:** astigmatism predictability graph. All eyes had final astigmatism ≤ 1.00 D. **F:** spherical equivalent stability graph. At long-term follow-up, only 4% of eyes showed a change of 0.50 D or more in spherical equivalent.

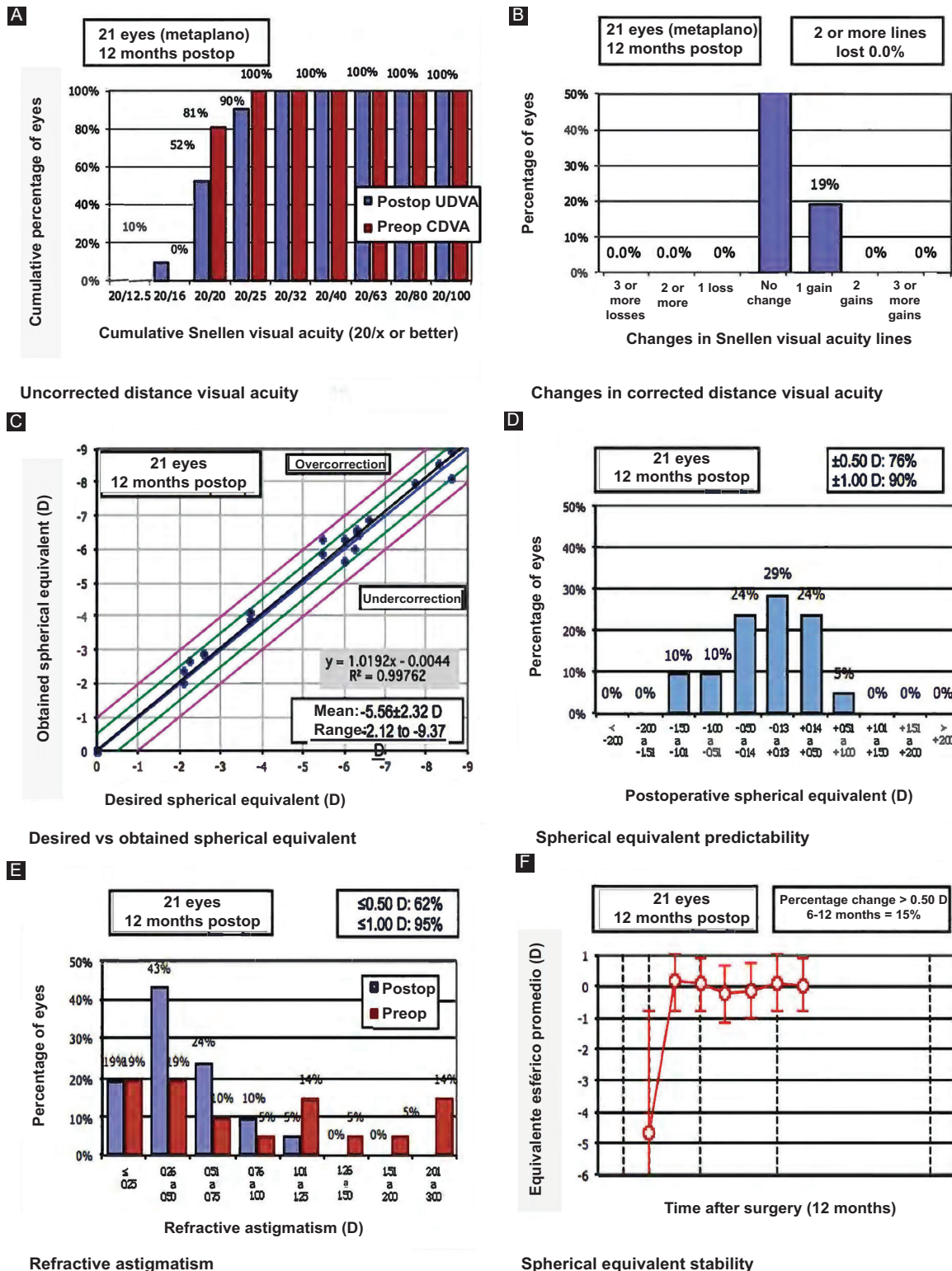
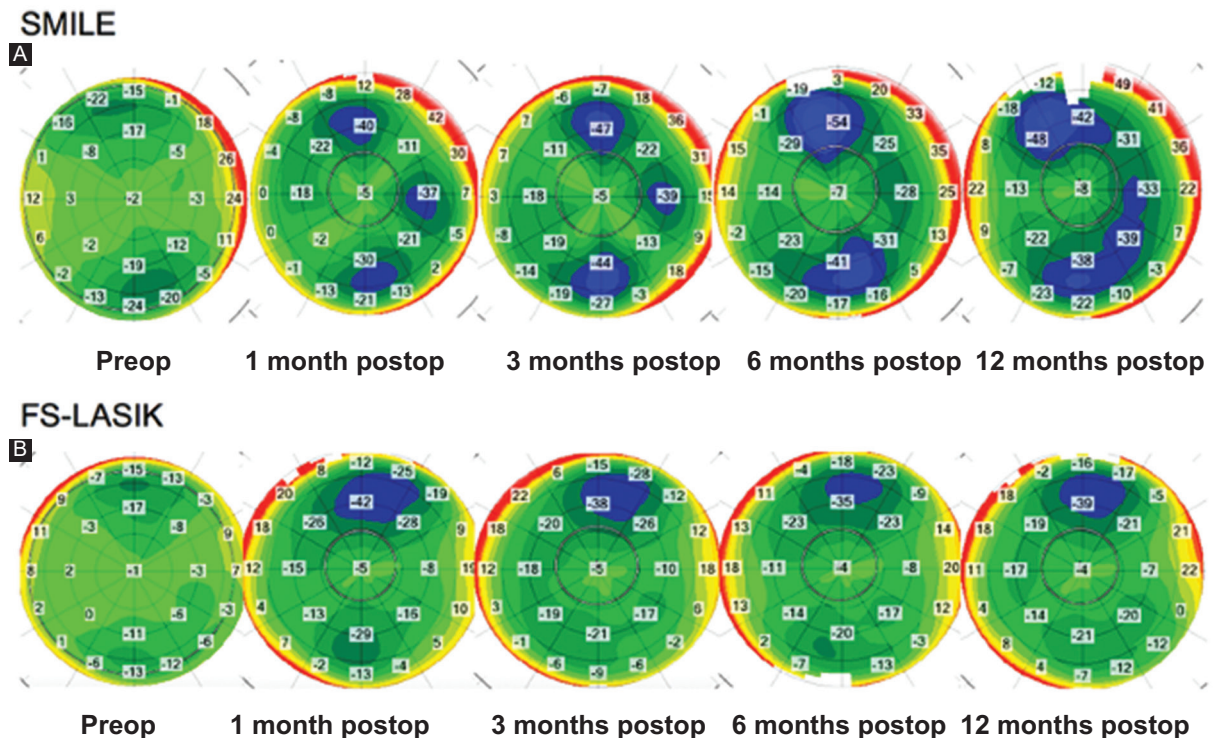


Figure 2. Refractive outcomes of eyes undergoing FS-LASIK at the 12-months follow-up. These graphs provide detailed information on the accuracy, predictability, safety, and efficacy of the procedure. **A:** cumulative uncorrected distant visual acuity graph. Results indicate that 90% had uncorrected distant visual acuity of 20/25 or better. **B:** safety graph. The analysis shows that 17 eyes maintained the same uncorrected distant visual acuity post-surgery, and 4 eyes gained 1 line after surgery, with no losses observed. **C:** spherical equivalent predictability graph. A good correlation was found between the desired and obtained spherical equivalent ($R^2 = 0.99762$). These results highlight the predictability of the procedure, showing reliable performance in achieving the expected refractive outcomes. **D:** spherical equivalent predictability graph. A total of 76% of eyes were within ± 0.50 D, and 90% of eyes were within ± 1.00 D of postoperative spherical equivalent. **E:** astigmatism predictability graph. A total of 95% of eyes had final astigmatism ≤ 1.00 D. **F:** spherical equivalent stability graph. At the end of follow-up, 15% of eyes showed a change of 0.50 D or more in spherical equivalent.

Table 3. Pre- and Postoperative Topographic Measurements: Comparison Between the 2 Techniques

Measurement	Preoperative (Mean $\pm$ SD)		p	Postoperative (Mean $\pm$ SD)		p
	SMILE	FS-LASIK		SMILE	FS-LASIK	
Pachymetry (μm)	522.0 $\pm$ 17.6	521.0 $\pm$ 17.4	> 0.05	414.8 $\pm$ 43.44	449.6 $\pm$ 33.7	< 0.01
Simulated Keratometry (D)	43.81 $\pm$ 1.25	43.8 $\pm$ 1.31	> 0.05	39.37 $\pm$ 1.80	40.07 $\pm$ 1.6	> 0.05
Keratometry at 3 mm (D)	43.95 $\pm$ 1.23	43.9 $\pm$ 1.27	> 0.05	39.22 $\pm$ 1.92	39.89 $\pm$ 1.6	> 0.05
Posterior Keratometry (D)	-6.16 $\pm$ 0.19	-6.15 $\pm$ 0.2	> 0.05	-6.33 $\pm$ 0.60	-6.35 $\pm$ 0.25	> 0.05

D: Diopters; SD: Standard Deviation

**Figure 3.** Changes in posterior corneal elevation over time in 1 eye with SMILE (A) and 1 eye with FS-LASIK (B).

however, at the 12-month follow-up, logistic regression analysis showed a statistically significant depression in the posterior elevation map in SMILE eyes ($p < 0.01$) (Fig. 3).

Regarding TBUT, the Schirmer test, and esthesiometry, no significant differences were observed between the 2 groups both preoperatively and at the 12-month follow-up (Table 4). A decrease in corneal sensitivity was observed with both techniques: in the FS-LASIK group, the decrease was from 5.76 ± 0.31 down to 4.79 ± 1.63 after treatment ($p = 0.032$), and in the SMILE group, it was from 5.797 ± 0.30 down to 5.11 ± 1.15 ($p = 0.038$).

Regarding optical quality, there was a higher increase in root mean square (RMS) within the first week of follow-up in the SMILE vs the FS-LASIK

group. At the 12-month follow-up, RMS decreased in both groups, with this decrease being statistically significant in the SMILE group. Additionally, an increase in point spread function was observed in both groups, but it was not statistically significant (Table 5).

Finally, a statistically significant decrease in wave-front error, HOA, and astigmatism was found in the SMILE group, while a statistically significant increase in trefoil and coma was found in the FS-LASIK group (Table 6).

Discussion

The femtosecond laser has revolutionized refractive surgery due to its high precision and its ability to make the procedure more reproducible. In this study, we

Table 4. Pre- and Postoperative Values of Tear Breakup Time, Schirmer Test, and Esthesiometry

Measurement	Preoperative (Mean $\pm$ SD)			Postoperative (Mean $\pm$ SD)		
	FS-LASIK	SMILE	p	FS-LASIK	SMILE	p
TBUT	10.9 $\pm$ 2.9	10.0 $\pm$ 2.2	> 0.05	8.7 $\pm$ 2.37	9.5 $\pm$ 2.8	0.151
Schirmer Test	19.3 $\pm$ 7.3	19.4 $\pm$ 7.5	> 0.05	21.6 $\pm$ 10.54	21.4 $\pm$ 11.0	0.474
Esthesiometry	5.7 $\pm$ 0.3	5.8 $\pm$ 0.3	> 0.05	5.9 $\pm$ 0.13	5.8 $\pm$ 0.2	0.231

SD: Standard Deviation; TBUT: Tear Breakup Time

compared 2 techniques, SMILE and FS-LASIK, in patients who underwent surgery in each eye.

Results regarding visual acuity and refractive characteristics did not differ between the 2 groups, except for the spherical equivalent, which was more favorable in the SMILE group ($p < 0.01$), and the spherical error, where the SMILE group tended to overcorrect, while the FS-LASIK group tended to undercorrect ($p < 0.01$). These results are similar to those reported by Kamiya et al.⁹ in a study where 1 eye underwent SMILE and the other lenticular extraction with femtosecond, and they found a trend toward better UDVA and a smaller spherical equivalent in SMILE eyes.

In a prospective, randomized study comparing SMILE and FS-LASIK, the UDVA on postoperative day 1 was higher in the FS-LASIK group, while no statistically significant difference was found at the 6-month follow-up. Similarly, no significant difference was found in terms of CDVA and mean spherical equivalent at the 6-month follow-up between both groups¹⁰. In a meta-analysis evaluating the clinical outcomes of SMILE and FS-LASIK for myopia correction, no significant difference in final spherical equivalent was found between both procedures¹¹.

When analyzing topographic measurements, there was a decrease in simulated keratometry and 3 mm central keratometry, with no statistically significant difference between the 2 groups. On the contrary, there was an increase in posterior keratometry with both procedures, which was statistically significant in the FS-LASIK group. An anterior shift in the posterior corneal surface has been reported in patients who underwent LASIK or FS-LASIK; however, some authors have rejected this finding^{3,12,13}. Corneal topography is the best index to evaluate the movement of the posterior corneal surface after LASIK^{14,15}. This anterior shift can be attributed to the amount of tissue ablated or the thickness of the residual stromal bed. Some studies have shown that progressive corneal deformation is greater when the residual stroma is less than 250 μm ^{16,17}.

Table 5. Optical Quality in the Follow-Up of SMILE and FS-LASIK

	SMILE (Mean $\pm$ SD)		FS-LASIK (Mean $\pm$ SD)	
	RMS	PSF	RMS	PSF
Preoperative	1.58 $\pm$ 0.83	0.09 $\pm$ 0.04	1.48 $\pm$ 0.80	0.10 $\pm$ 0.06
1 Week	1.78 $\pm$ 0.99	0.11 $\pm$ 0.03	1.25 $\pm$ 0.31	0.11 $\pm$ 0.03
1 Month	1.40 $\pm$ 0.38	0.10 $\pm$ 0.03	1.25 $\pm$ 0.52	0.12 $\pm$ 0.04
3 Months	1.31 $\pm$ 0.34	0.11 $\pm$ 0.03	1.21 $\pm$ 0.40	0.11 $\pm$ 0.03
6 Months	1.36 $\pm$ 0.51	0.12 $\pm$ 0.03	1.28 $\pm$ 0.53	0.13 $\pm$ 0.03
12 Months	1.27 $\pm$ 0.37	0.13 $\pm$ 0.04	1.22 $\pm$ 0.40	0.12 $\pm$ 0.03
p (Preoperative to 12 Months)	0.05	0.10	0.68	0.13

SD: Standard Deviation; PSF: Point Spread Function; RMS: Root Mean Square

Similarly, a statistically significant decrease in posterior corneal elevation was observed in SMILE patients. This group had a posterior corneal shift that remained stable during the follow-up. It has been reported that after SMILE, there are changes in the keratometric power of the posterior cornea¹⁸. Therefore, these patients may have a protective factor against iatrogenic ectasia or myopic regression, which are related to an increase in posterior corneal elevation³.

In the present study, similar values were found for TBUT, corneal sensitivity, and the Schirmer test in both groups after surgery. As in other studies, TBUT values decreased after surgery¹⁹. Some authors have reported advantages of the SMILE technique concerning dry eye and corneal sensitivity. Li et al.¹⁹ demonstrated that SMILE patients were less likely to have corneal staining vs FS-LASIK patients; similarly, SMILE is superior in terms of a smaller reduction in corneal sensitivity. It has been described that SMILE has a lesser impact on the ocular surface and corneal innervation vs LASIK, reducing the incidence of dry eye syndrome²⁰, which may be influenced by less

Table 6. Pre- and Postoperative Optical Aberrations in Eyes with SMILE and FS-LASIK: Comparison Between Both Techniques

	SMILE		p	F-LASIK		p
	Preoperative	Postoperative		Preoperative	Postoperative	
WFE	1.37 ± 0.77	1.02 ± 0.44	< 0.05	1.24 ± 0.77	1.04 ± 0.54	> 0.05
HOA	0.40 ± 0.47	0.57 ± 0.23	> 0.05	0.33 ± 0.07	0.65 ± 0.22	> 0.05
Astigmatism	1.24 ± 0.74	0.79 ± 0.41	< 0.01	1.17 ± 0.80	0.7 ± 0.63	> 0.05
Trefoil	0.17 ± 0.25	0.2 ± 0.19	> 0.05	0.12 ± 0.08	0.24 ± 0.12	< 0.05
Coma	0.22 ± 0.30	0.3 ± 0.18	> 0.05	0.20 ± 0.08	0.4 ± 0.22	< 0.05

HOA: Higher Order Aberrations; SD: Standard Deviation; WFE: Wavefront Error

apoptosis, proliferation, and inflammation of keratocytes^{21,22}. In a meta-analysis comparing both techniques, it was found that TBUT was longer in SMILE patients 1 and 6 months after surgery, and corneal sensitivity was higher 6 months after surgery¹¹.

In this study, a reduction in optical quality was observed during the early postoperative period in the SMILE group, with higher RMS, likely due to haze, which is consistent with other studies²³. However, there was an improvement over time.

A significant increase in trefoil and coma was found in the FS-LASIK group. It has been reported that there is an increase in anterior corneal aberrations after myopic LASIK by creating a flap, either with a mechanical microkeratome or with the femtosecond laser²⁴. No increase in aberrations was found after the SMILE procedure, although a slight decentration has been associated with induced coma²⁵. In general, postoperative HOAs are smaller after SMILE vs FS-LASIK^{25,26}.

This study has some limitations. The number of patients should be increased to obtain more precise results, and some analyses show a trend toward 1 of the 2 surgical procedures without reaching statistical significance, possibly due to the small sample size.

This study is the first paired-eye study in the Mexican and Latin American population, as only the Singapore National Eye Centre group has studies with this eye-pairing design in which, with the same sample of 70 patients, predictability and refractive results²⁷, optical zone functionality and centration²⁸, as well as visual quality from the patient's point of view²⁹, are analyzed.

In conclusion, SMILE and FS-LASIK provide similar results in myopic patients regarding visual acuity, refraction, Schirmer test, TBUT, and esthesiometry. SMILE showed more changes in posterior elevation, with a progressive backward shift over time during follow-up.

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Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed their workplace protocols regarding the publication of patient data.

Right to privacy and informed consent. The authors obtained approval from the Ethics Committee for the analysis and publication of clinically obtained data. Informed consent from patients was not required as this is a retrospective observational study.

Declaration on the use of artificial intelligence. The authors declare that they have not used any type of generative artificial intelligence in the drafting of this manuscript, nor for the creation of figures, graphics, tables, or their corresponding footnotes.

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