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ORIGINAL RESEARCH ARTICLE

Short-term outcomes of small-incision lenticule extraction (SMILE) for low, medium, and high myopia

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ABSTRACT

Purpose: To determine the safety, efficacy, and predictability of small-incision lenticule extraction at 6-month follow-up, depending on the level of the myopic refractive error. The surgeries were performed by a surgeon new to this technique.

Methods: Seventy-one subjects with a mean age of 31.86 ± 5.57 years were included in this retrospective observational study. Subjects were divided into 3 groups depending on the preoperative spherical equivalent (SE): low group from -1.00 D to -3.00 D, medium from -3.25 D to -5.00 D, and high from -5.25 D to -7.00 D. Manifest refraction, corrected distance visual acuity (CDVA), and uncorrected distance visual acuity (UDVA) were measured before surgery and at 6 months after the treatment.

Results: In total, 1.4% of the eyes lost 1 line of CDVA after the procedure, whereas 95.8% remained unchanged and 2.8% gained 1 line. A significant undercorrection ($p = 0.031$) was found in the high myopia group (median -0.50 D), whereas the low and medium groups remained near to emmetropia. In terms of efficacy, no statistically significant intergroup differences for postoperative UDVA ($p = 0.282$) were found. The vector analysis also showed undercorrection of the preoperative cylinder, even though the standard deviations decreased from 0.9 D in the x axis and 0.7 D in the y axis to 0.24 D and 0.27 D, respectively.

Conclusions: Small-incision lenticule extraction might be a safe, effective, and predictable procedure even for inexperienced surgeons. No differences in efficacy were found among myopia levels even though undercorrections were found for SE and cylinder in high myopia.

Keywords: Myopia, Refractive surgery, Small-incision lenticule extraction, SMILE

Introduction

Small-incision lenticule extraction (SMILE) has demonstrated similar or better visual and refractive outcomes compared to traditional laser-assisted in situ keratomileusis (LASIK) in the treatment of myopia, with the additional advantage of using only a laser system for the entire procedure (1, 2). Furthermore, some studies have shown better results with this technique in optical quality than femtosecond LASIK (FS-LASIK), with lower induction of higher-order aberrations (3, 4). However, some authors suggest that SMILE has poorer visual recovery rates than LASIK (5), with considerable differences in uncorrected distance visual acuity (UDVA) achieved between 1 day and 3 months (6). It has been hypothesized that laser parameters might affect visual recovery (7, 8), but other recent studies have not found early postoperative interface scatter or delay in visual recovery (9) or have reported similar percentage for 20/20 or better at 1 day (89%) in comparison to 1 month (91%) with SMILE (10). Although longer studies at 3, 6, and 12 months show that SMILE is a safe, effective, and predictable procedure (11, 12), most are based on data from experienced SMILE surgeons with personalized nomograms (10) and either do not state whether the surgeon had previous experience with SMILE before the study (12) or analyze the results independently of the degree of refractive error (13, 14). The aim of this study was to analyze the outcomes with SMILE at 6 months postoperatively depending on the level of myopia for the first 71 consecutive patients of an inexperienced surgeon.

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Methods

Patients and examinations

One random eye of the first 71 consecutive patients treated with SMILE between September 2013 and January

2014 at Qvision (Department of Ophthalmology, Virgen del Mar Hospital) were included in this retrospective observational study. Patients underwent a complete preoperative eye examination including objective and subjective refraction performed by optometrists, Goldmann intraocular pressure, aberrometry, pupil size, and corneal topography with Orbscan II and Zywave systems (both from Bausch and Lomb, Rochester, NY, USA), slit-lamp evaluation, and funduscopy. Postoperative visit at 6 months included UDVA, corrected distance visual acuity (CDVA), manifest refraction, and slit-lamp examination to evaluate the integrity of the anterior segment. Visual acuities (VAs) were measured with a LCD wall screen in decimal notation scale and converted to Snellen for reporting in standardized graphs.

Inclusion criteria were patients undergoing 6-month follow-up after the procedure with preoperative spherical equivalent (SE) between -1 D and -7 D and astigmatism under 3.5 D, stable myopia for at least 1 year before surgery, and CDVA of 20/25 or better. Exclusion criteria were pregnancy at time of surgery or follow-up, a preoperative central corneal thickness of less than 480 µm, an expected postoperative residual stromal bed of less than 250 µm, topographic map compatible with subclinical keratoconus or other ectatic corneal disorder, and any other ocular disease for which laser refractive surgery procedures are not indicated (15). The procedure was explained to all the patients who signed the preoperative informed consent, and the study complied with the tenets of the Declaration of Helsinki.

Surgical procedure

Optical principles and general description of the SMILE procedure have been widely described (16); however, some particular laser settings or surgical maneuvers can vary depending on the surgeon. The particular laser settings and maneuvers for this study are detailed below. Before suction, centration was accepted when the ring of the applanation zone was concentric with the margin of the cone and near to the pupil center (14). Suction was then applied, and a slight rotation of the applanation cone was made to compensate for cyclotorsion in cases of high astigmatism with markings, taking as reference the horizontal lines seen through the microscope.

The photodisruptive procedure follows the next sequence: the laser creates the lower lenticular interface from center to periphery; this is the lenticule diameter or optical zone, which was set to 6.5 mm. A transition zone with a side cut angle of 90° follows the optical zone cut for intersecting the upper lenticular interface. The laser creates the cap of 7.6 mm of diameter, 1.1 mm larger than the optical zone, in such a way that the lenticule is confined below the cap. The depth or cap thickness was set to 140 µm and the laser software computes the lenticule thickness depending on the refractive error, but a minimum thickness of 15 µm was configured. Finally, the incision at the extreme of the cap, 2 mm of width, is created with a side cut angle of 30° for extracting the lenticule close to 12 o'clock position. A graphical description for understanding each one of these parameters has been detailed by other authors (17).

Laser configuration parameters were as follows: repetition rate of 500 kHz, spot distance of 4.50 µm for the lenticule and 2 µm for its border, and pulse energy of level 30 in the software, which corresponds to approximately 150 nJ (9). The target refractive error correction was directly inserted in the software without applying any nomogram. After laser treatment, the patient was moved to the surgical microscope for the second part of the procedure, which involves the following: (1) delineating front and back lenticule surfaces; (2) surface separation using the standard lamellar corneal surgical technique of moving the instrument back and forth using a blunt circular tip (Femto Double-Ended instrument [G-33954], Carl Zeiss Meditec AG, Jena, Germany) starting with the complete dissection of the front cap and following with the dissection of the posterior lenticule surface; (3) lenticule extraction with forceps (Lenticule Forceps [G-33961], Carl Zeiss Meditec AG); (4) corneal surface pressure from center to periphery using a dry microspear and drying the incision with the same. Finally, all patients received 2 drops of tobramycin (3 mg) and dexamethasone (1 mg) combination at the end of the procedure.

The same surgeon (J.F.) performed all the SMILE treatments with the VisuMax femtosecond laser system (Carl Zeiss Meditec AG). It is important to note that this sample corresponded with the first consecutive SMILE cases of this surgeon, including results from the early phase of the learning curve. All patients were treated with 2 drops of topical anesthesia (oxybuprocaine hydrochloride 0.4%) at 5 minutes and 2 further drops 1 minute before surgery. In patients requiring astigmatism correction over 1.50 D, corneal reference marks were made before surgery at the 3-o'clock and 9-o'clock meridians with the patient standing up.

Statistical analysis

Even though both eyes from each patient were operated and measured before SMILE surgery and at 6 months, a random eye per subject was included in the statistical analysis because of the high concordance shown in the preoperative SE between eyes (ICC 0.92, $p<0.001$; 95% confidence interval 0.87, 0.95) (18). If one of both eyes of the patient presented a complication, the patient was excluded from the randomization and the contralateral eye was included in the statistical analysis, but the complication was included in the safety section. The randomization was performed with a MATLAB function (The Mathworks Inc., Natick, MA, USA) that filtered randomly the data of one eye for each patient. Eyes were divided into 3 groups depending on the preoperative SE. Thirty eyes (42.3%) were included in the low group, from -1.00 D to -3.00 D, 31 (43.7%) in the medium, from -3.25 D to -5.00 D, and 10 (14.1%) in the high, from -5.25 D to -7.00 D. Decimal VAs were converted to logMAR for assessing the differences between groups (19), and were later reconverted to Snellen for reporting results to follow the standard graphs reporting results (20). Visual acuity of 0.9 decimal was considered as 20/25 for plotting the standard graphs (20), but its value was maintained after conversion to logMAR for statistical purposes.

Nonparametric statistical methods were used due to nonnormal distribution of study variables. The Wilcoxon signed rank test was used to evaluate the differences between preoperative CDVA and postoperative UDVA. A Kruskal-Wallis H test was run to determine if there were differences in some dependent variables among low, medium, and high myopic

groups. Pairwise comparisons were done with a Bonferroni correction for multiple comparisons. Statistical analyses were performed using SPSS (v20; SPSS Inc., Chicago, IL, USA), and significance was set at p<0.05. Standard graphics (20, 21) were generated using Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA) and our own MATLAB library was used for vector analyses.

Results

Seventy-one consecutive myopic eyes of 71 patients, mean age 31.86 ± 5.57 SD (range 21-43 years), were included in the sample. Table I provides the preoperative data of these patients stratified depending on their refractive error level.

Safety

In total, 95.8% (68 eyes) had unchanged CDVA, 1.4% (1 eye) lost 1 line, and 2.8% (2 eyes) gained 1 line. The eye that lost 1 line belonged to the low myopic group, whereas eyes that gained 1 line belonged to the high myopic group. There were no eyes with CDVA worse than 20/40 for the subgroup of eyes with CDVA of 20/20 or better preoperatively. No eye showed an increase in manifest refractive astigmatism of 2.00 D over preoperative refraction. One eye had a suction loss during the surgical procedure, which was not included in the sample for reporting refractive results. The suction happened during the lower lenticular interface creation and SMILE was reapplied on the same day. This eye posteriorly developed epithelial ingrowth, corneal folds, and irregular astigmatism that were solved with photorefractive keratectomy (PRK), achieving UDVA of 20/25 and CDVA of 20/20.

Predictability

The slope (0.9475) of the linear regression model (p<0.001) relating achieved and intended SE confirmed the slight trend to undercorrection, especially for high myopic eyes (Fig. 1). More detailed information about predictability is shown in Figure 2, where it can be seen that more than half of the subjects (52%) were close to emmetropia, and 26% achieved an SE between -0.50 D and -0.14 D. The undercorrection was more evident in the high myopic group, with 70% of eyes achieving SE between -1.00 D and -0.14 D.

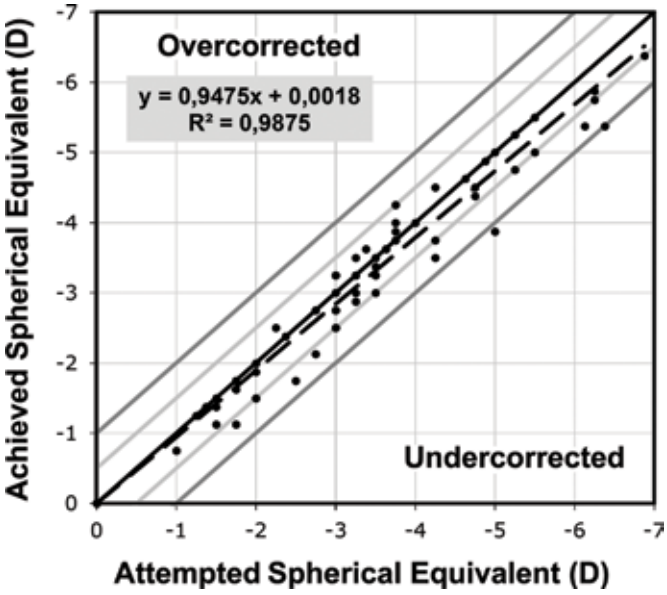

Fig. 1 - Linear regression model for predictability. The scatterplot shows undercorrection with the increase in attempted spherical equivalent.

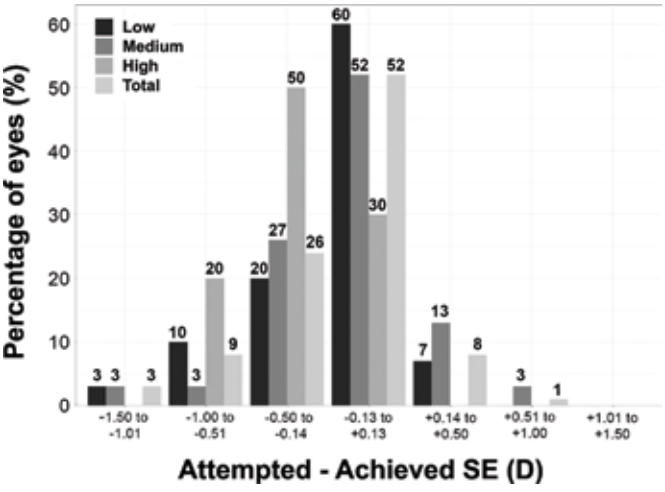

Fig. 2 - Predictability for all eyes, and for eyes from the low, middle, and high spherical equivalent (SE) groups.

TABLE I - Preoperative descriptive analysis of the sample by refractive error

Parameters	Low (n = 31)		Medium (n = 30)		High (n = 10)	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median (range)
Age, y	32.20 (5.25)	33.50 (25, 43)	31.58 (5.64)	31.00 (22, 43)	28.70 (5.38)	28.00 (21, 36)
UDVA, logMAR	0.72 (0.26)	0.7 (0.3, 1.3)	1.04 (0.18)	1.0 (0.7, 1.3)	1.33 (0.26)	1.3 (1.0, 2.0)
CDVA, logMAR	-0.02 (0.04)	0.0 (-0.1, 0.0)	0.02 (0.03)	0.0 (-0.1, 0.0)	0.00 (0.05)	0.0 (-0.1, 0.0)
Manifest SE, D	-2.07 (0.58)	-2.00 (-3.00, -1.00)	-3.86 (0.57)	-3.75 (-5.00, -3.25)	-5.86 (0.58)	-5.81 (-6.88, -5.25)

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.

Indeed, the median SE was 0 D for low and medium myopic groups and -0.50 D for the high myopic group; the difference was statistically significant, p = 0.031. We also found statistically significant differences in postoperative SE between the medium (40.95) and high myopic groups (22.20) (p = 0.026), but not between the low (35.48) and high or medium myopic groups (Tab. II). The percentages of eyes with SE within ±0.50 D were 87%, 92%, 80%, and 86% for low, medium, and high myopic groups and the total sample, respectively, and 97%, 98%, 100%, and 97% of eyes were within ±1.00 D.

Efficacy

A postoperative UDVA of 20/20 or better was achieved by 67% and 74% of eyes in the low and medium myopic groups, respectively. However, the percentage for this level of UDVA for the high myopic group was 50%. We found that 100% of eyes in the high myopic group had UDVA of 20/25, whereas for this level the percentage was 97% for the low and medium myopic groups (Fig. 3). Median was close to 20/20 for all groups (Tab. II), and no statistically significant differences were found among them, p = 0.282. Median differences in CDVA between groups were not statistically significant, p = 0.232 (Tab. II).

The comparison of results from Figure 3 (UDVA) with the percentage of subjects with preoperative CDVA of 20/20 or better (Fig. 4) revealed that 17% of eyes achieved 1 line of UDVA less than the preoperative VA obtained with spectacles (CDVA). This was more remarkable in the low myopic group, where this percentage decreased from 97% to 67% (30% of decrease), whereas in the medium and high myopic groups this percentage only decreased from 81% to 74% (7%) and from 60% to 50% (10%), respectively. Of the 71 operated eyes, a decline from preoperative CDVA to postoperative UDVA was found in 21 eyes, 4 eyes presented improvement, and 46 eyes maintained the same VA. Even though the median was 20/20 for preoperative CDVA and postoperative UDVA, the Wilcoxon signed rank test showed statistically significant differences among both VA values, p<0.0005. The mean and standard deviation was -0.01 ± 0.04 for preoperative CDVA and 0.03 ± 0.06 for postoperative UDVA, the difference being less than 1 line of VA. Differences in postoperative UDVA minus preoperative CDVA among low, medium, and high myopic groups were not statistically significant, p = 0.099 (Tab. II).

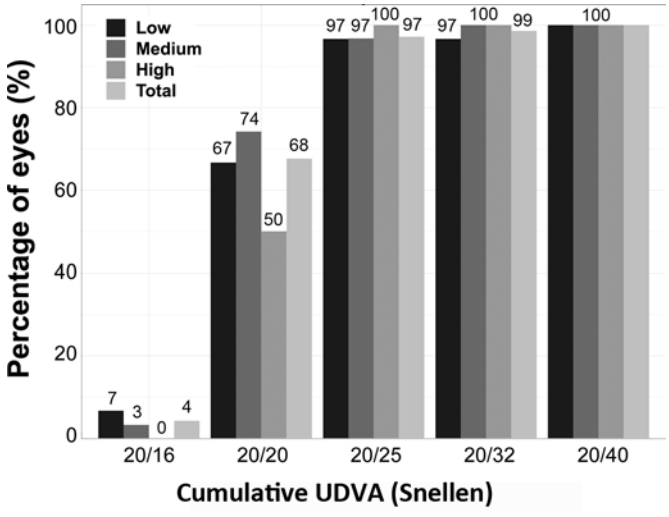

Fig. 3 - Cumulative percentage of eyes with different post-small-incision lenticule extraction levels of uncorrected distance visual acuity (UDVA), by refractive error group.

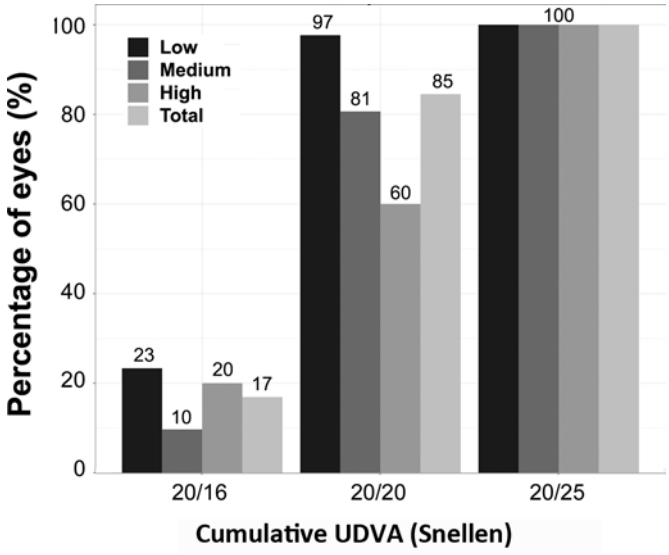

Fig. 4 - Cumulative percentage of eyes with different pre-small-incision lenticule extraction levels of corrected distance visual acuity (CDVA), by refractive error group.

TABLE II - Postoperative analysis of eyes from the low, medium, and high myopic refractive groups and evaluation of median differences between preoperative CDVA and postoperative UDVA

Parameter	Low (n = 31)		Medium (n = 30)		High (n = 10)		
	Median (min, max)	Mean (SD)	Median (min, max)	Mean (SD)	Median (min, max)	Mean (SD)	p value[a]
UDVA, logMAR	0.0 (-0.1, 0.3)	0.03 (0.07)	0.0 (-0.1, 0.2)	0.02 (0.05)	0.0 (0.0, 0.1)	0.03 (0.04)	0.282
CDVA, logMAR	0.0 (-0.1, 0.0)	-0.02 (0.04)	0.0 (-0.1, 0.0)	0.0 (0.03)	0.0 (-0.1, 0.0)	-0.02 (0.03)	0.232
Manifest SE, D	0.00 (-1.63, 0.25)	-0.20 (0.37)	0.00 (-1.13, 0.50)	-0.10 (0.32)	-0.50 (-1.00, 0.00)	-0.41 (0.33)	0.031
Pre CDVA –post UDVA	0 (0, 0.5)	-0.05 (0.07)	0 (-0.1, 0.3)	-0.02 (0.05)	0 (-0.1, 0.4)	-0.03 (0.08)	0.099

[a] Kruskal-Wallis H test.
CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.

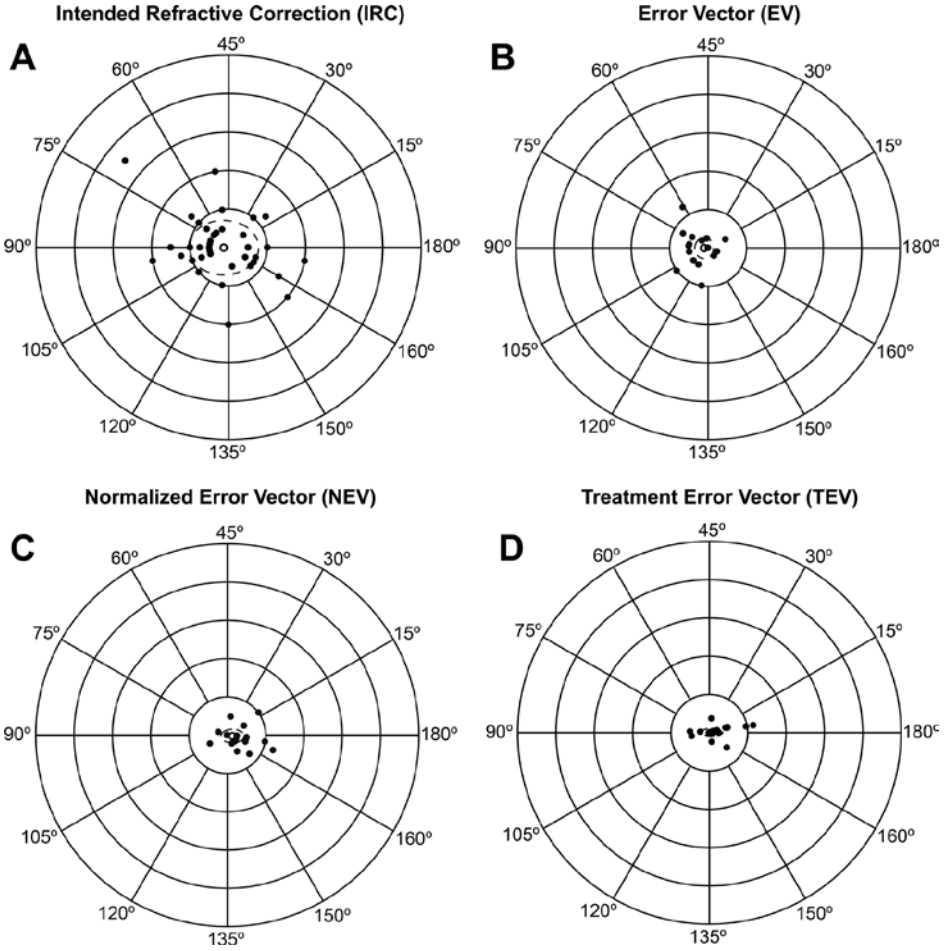

Fig. 5 - Each radial step represents an increase of 0.50 D from the center. (**A**) Intended refractive correction, which is the preoperative positive cylinder. (**B**) Error vector represents the residual refractive cylinder or postsurgery cylinder. (**C**) Normalized error vector and (**D**) treatment error vector represent the overcorrection at the right side of the vertical axis. Some computed points appear overlapped for low dioptric values of B, C, and D.

Vector analyses

Only eyes with preoperative astigmatism greater than zero were included in the vector analysis (n = 46). Figure 5A shows that the centroid coordinates (x, y) were near to 0 (-0.13, -0.01) for the intended refractive cylinder, and the standard deviation (radii of the ellipse) was higher in the horizontal axis SD_x = 0.9 D than in the vertical SD_y = 0.7 D. Therefore, the sample was evenly distributed between with the rule (WTR) and against the rule (ATR) astigmatisms, with less incidence of oblique astigmatism. Figure 5B shows the error vector or manifest cylinder after 6 months, showing how centroid coordinates were slightly close to 0 (-0.1, -0.01), although standard deviation decreased considerably to SD_x = 0.24 D and SD_y = 0.27 D. Furthermore, scatter at the left side of Figure 5B appeared to be greater than on the right side, suggesting an undercorrection of WTR or overcorrection of ATR. The normalized error vector in Figure 5C and treatment error vector in Figure 5D, with overcorrections on the left side and undercorrections on the right side, showed that an undercorrection was generally presented for the cylinder.

Discussion

We present the early outcomes of an inexperienced SMILE surgeon with previous experience in other laser refractive surgery techniques. One random eye from the first consecutive 71 subjects was included and analyzed depending on the refractive error level at 6-month follow-up.

Suction loss is one of the complications that have been reported with SMILE (22), but we only found 1 case, corresponding to the consecutive second surgery. Other complications of SMILE have been reported, such as incomplete femtosecond laser cutting (10), opaque bubble layer (23), infiltrates/keratitis or interface inflammation (24), abrasion at the incision, tears at the incision, cap perforation, haze, dry surface, epithelial islands at the incision, and fiber at the interface (25). However, we only found 1 eye with epithelial ingrowth and corneal folds. In terms of preoperative and postoperative CDVA, we found that SMILE was a safe procedure with only 1.4% of eyes losing 1 line of VA corresponding to the low myopic group. These results are slightly better than those reported by other authors (10, 26). As the percentage of eyes gaining 1 line of VA increased with the refractive error level, this improvement of postoperative CDVA may be due to the change in retinal image magnification after surgery compared to the use of spectacles in high myopic eyes (9, 12).

The first predictability results for SMILE at 6 months were reported by Shah et al (26). They found a mean SE of +0.03 ± 0.30 D, with 91% of subjects within ±0.50 D and 100% within ±1.00 D. They reported that refractive stability was achieved within 1 month, suggesting that predictability of SMILE would

be similar in studies with longer periods of follow-up. Subsequent studies at 3, 6, and 12 months have found that the percentage of subjects within ±0.50 D ranged from 77% to 100%, and within ±1.00 D from 94% to 100% depending on the study (5, 6). Our results are consistent with those reported in previous studies, with 86% of eyes with SE within ±0.50 D and 96% within ±1.00 D. Furthermore, we found a poorer predictability for refractive errors between -5.25 D and -7 D, with a median of -0.5 D for the postoperative SE in this group, while median SE was plano for low and medium refractive error groups. The undercorrection was associated with an increased refractive error, in which is consistent with the slope of the attempted versus achieved SE linear regression equation. This finding has been reported in other studies (11, 27).

Some concerns over the cutting accuracy of the VisuMax or difficulties handling thinner lenticules have been pointed out (10). We usually increase the diameter of the optical zone for myopias under -1 D in order to increase the lenticule thickness to around 50 µm, but this was not done in this study because all patients were over -1 D of SE. Despite the thinner lenticule in the low myopic group, no problems occurred in handling or extracting it. Our efficacy results for the low myopic group contrast with those previously reported by Reinstein et al (10), who found, with their own nomogram, that 97% of eyes achieved UDVA of 20/20 at 3 months after SMILE. In our sample, only 67% achieved a UDVA of 20/20. It is important to note that these differences might be due to the fact that the Reinstein et al cohort had a cumulative percentage of preoperative CDVA (75%) of 20/16. This is considerably higher than ours (23%); therefore it is also understandable that the percentage of subjects with UDVA of 20/20 would be higher in their study because the preoperative CDVA was better.

The median change in VA from preoperative CDVA to postoperative UDVA was significant; nevertheless, it was less than 1 line of VA. Furthermore, no statistically significant differences in median VA change among the 3 groups were found, even though the percentage of subjects at 20/20 level decreased in a higher percentage (30%) in the low myopic group than in the medium (7%) and high myopic (10%) groups. This shows that SMILE might be as effective for low myopias as it is for medium and high myopias. It is important to note that 2 patients of the high myopic group and one of the low myopic group were treated successfully with PRK after this follow-up because they returned with complaints about their UDVA. However, some other patients of the high myopic group who presented UDVA less than 20/20 were not retreated with PRK if they were satisfied with their binocular vision.

Ivarsen and Hjortdal (28) reported a significant undercorrection of astigmatism as the intended refractive correction of the cylinder increased, which was similar to or better than FS-LASIK. This undercorrection has been also reported by Kunert et al (29), who found the centroid moved to the right of the vertical in the normalized error vector. In our study, we found that the correction of the cylinder is predictable with SMILE because the standard deviation was reduced from 0.9 D and 0.7 D to 0.24 D and 0.27 D. However, as the foregoing authors described in their studies, an undercorrection was shown in the normalized error vector since the data are predominantly moved to the right of the vertical (21).

Our research may have some limitations. We have only included myopic refractive SE refractions from -1 D to -7 D; however, SMILE has been awarded European conformity up to -10 D at the time of our study. Therefore, for comparison purposes in future studies that include myopias up to -10 D, the creation of a new level of very high myopia from -7.25 D to -10 D would be recommended. Furthermore, a poorly balanced sample was used, with only 10 eyes in the high myopia group, whereas the low and medium myopic groups had 30 and 31 eyes, respectively. A brief analysis of astigmatism has been included in terms of magnitude; nevertheless, it is important to note that studies centered on astigmatism results should be performed in terms of magnitude and angle of error (30). About cap thickness, it is important to note that it was set to 140 µm, which can vary between authors, but Güell et al (31) reported no differences in refractive result for lenticule thicknesses of 130, 140, 150, and 160 µm.

In summary, short-term outcomes of the SMILE technique for a novel surgeon were as safe, effective, and predictable as those previously reported in the literature for more experienced surgeons. Furthermore, no differences in the effectiveness of the procedure were found among low, medium, or high myopias. Future studies should include groups with myopias between -7.25 D and -10.00 D and the development of nomograms that improve the results obtained in this and previous studies.

Disclosures

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Conflict of interest: Dr. Fernández is a consultant for Carl Zeiss Meditec AG (Jena, Germany). The remaining authors have no financial or proprietary interest in the materials presented herein.

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