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Good Reasons to SMILE

Latest clinical experiences with minimally invasive, flapless surgery

SMILE: Beyond PRK and LASIK

The 3rd generation of laser vision correction.

BY WALTER SEKUNDO, MD

In the 1960s, José Ignacio Barraquer, MD, envisioned performing laser keratomileusis without a corneal flap.[1] Now, 50 years later, this dream is within reach (Figure 1). After extensive animal research and initial operations on blind and partially seeing eyes, Marcus Blum, MD, and I performed the first refractive lenticule extraction surgery in March 2006. The initial surgical procedure, femtosecond lenticule extraction, or FLEx, required a corneal flap. The procedure matured into small incision lenticule extraction, or SMILE, a minimally invasive technique that was commercially introduced in 2011.

CAPTURING THE MARKET

It has been a pleasure to watch refractive lenticule extraction develop in the past 9 years. ZEISS is currently the only company to offer ReLEx SMILE, and there are more than 100 peer-reviewed articles and one international textbook dedicated to the technique. The procedure also attracts great attention at international meetings and conferences, highlighting the potential of the SMILE concept with the latest study results.

Over the course of development of this technique, many efforts have been made to improve the SMILE procedure and make it an appealing refractive surgery alternative for surgeons and patients alike. For instance, in 2009, the repetition rate of the VisuMax femtosecond laser (ZEISS) changed from 200 to 500 kHz. Also, an enhanced standard setting definition has led to shorter treatment times and quicker visual recovery, and a helpful graphical user interface guides the surgeon through situations of suction loss. Better surgical tools have also become available, and several studies comparing SMILE with femtosecond LASIK have shown comparable or better mid-term outcomes after SMILE.

There is room for further development and improvement in SMILE, as the concept has not yet reached its limits. In the near future, it may be possible to treat hyperopia and presbyopia with SMILE and, further down the road, to implant and re-implant SMILE lenticules for various refractive and therapeutic reasons. These are just examples of what might be possible in the future with the refractive lenticule extraction technique.

CONCLUSION

Reflecting on what has been accomplished in the past 9 years with SMILE, it is easy to see that the procedure has matured from an exploratory concept into an established commercial procedure. It has reached the market as the 3rd generation in laser vision correction, and I am convinced that we are far beyond the feasibility stage. SMILE will coexist with excimer laser technologies for some time, but it will eventually surpass them because minimally invasive surgical techniques are the wave of the future. ■

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1. Interview with Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO, on the benefits of ReLEx SMILE; 2012.

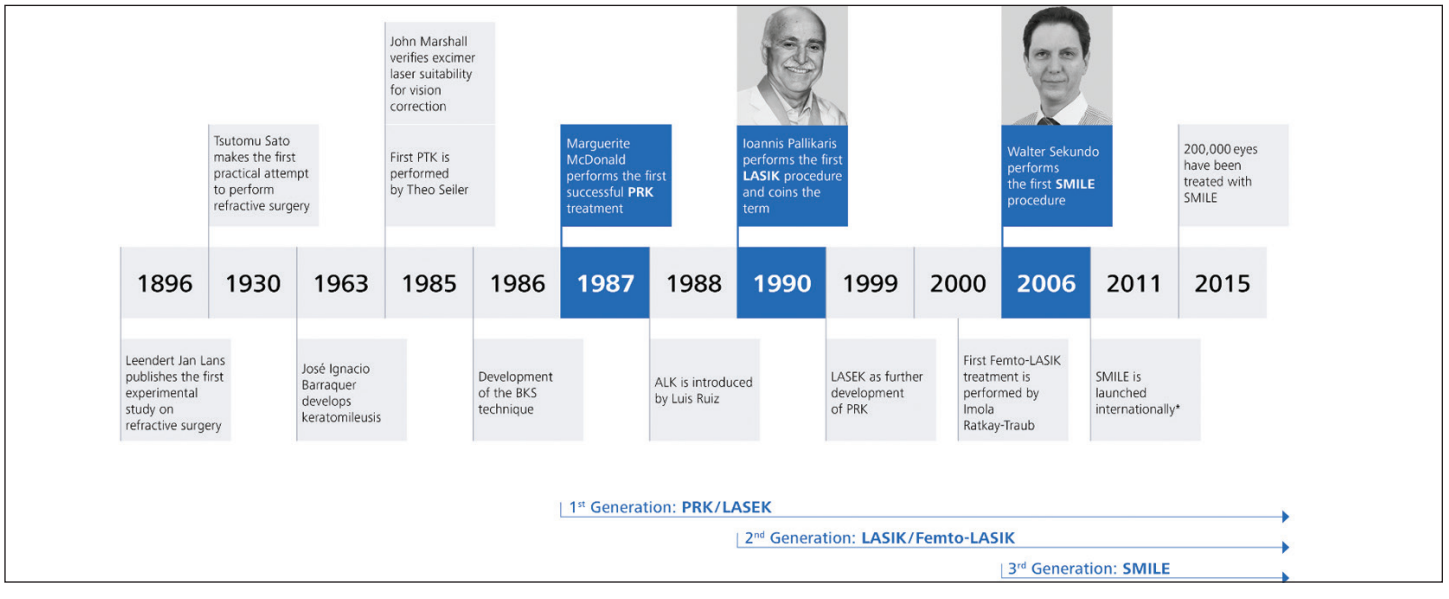

Figure 1. Laser vision correction through the years, beginning with PRK and LASEK and leading to SMILE.

ReLEx SMILE in 2015

With similar refractive outcomes to LASIK, SMILE also boasts superior biomechanics and faster recovery of dry eye symptoms and corneal nerve reinnervation.

BY DAN Z. REINSTEIN, MD, MA(CANTAB), FRCSC, DABO, FRCOPHTH, FEBO

Since the introduction of femtosecond lasers in refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can be removed in one piece manually. In 2006, Sekundo et al performed femtosecond lenticule extraction, or FLEx, to achieve a refractive correction with manual removal of a lenticule after lifting a corneal flap, circumventing the need for photoablation by an excimer laser. Thereafter, small incision lenticule extraction, or SMILE, was developed. Today, this all-femtosecond, minimally invasive, flapless procedure has the potential to revolutionize corneal refractive surgery.*

Recent reports have demonstrated that the visual and refractive outcomes after SMILE are similar to LASIK outcomes, and other studies recognize the need for a nomogram to adjust for an undercorrection of astigmatism. With more than 200,000 SMILE procedures performed worldwide and more than 600 surgeons performing it regularly, the SMILE procedure is gaining popularity. Additionally, the feasibility of SMILE has been shown in studies on the surface quality of the lenticules, wound healing and inflammation, lack of impact on the corneal endothelium, and the accuracy of the lenticule thickness parameters.

TWO DISTINCT ADVANTAGES

The safety of SMILE and LASIK are also similar, and our recent publication has shown that there is no issue in using SMILE to treat low myopia. In terms of safety, SMILE also offers two advantages over LASIK, of which one is relevant to the most common complication of laser vision correction (dry eye symptoms) and the other the most serious complication (ectasia due to decreased biomechanical strength). This is because SMILE uses a minimally invasive pocket incision technique, resulting in maximal retention of anterior corneal innervation and structural integrity.

Dry eye symptoms. Although the trunk nerves ascending into the epithelial layer within the diameter of the cap are severed in SMILE, those that either ascend outside the cap diameter or are anterior to the cap interface are spared. A number of studies have demonstrated a lower reduction and faster recovery of corneal sensitivity after SMILE than LASIK, with recovery to baseline achieved within 3 to 6 months after SMILE compared with 6 to 12 months after LASIK. Some studies have also used confocal microscopy to demonstrate a lower decrease in subbasal nerve fiber density after SMILE than LASIK.

Biomechanical strength. The other major advantage of SMILE is that the anterior stroma above the lenticule remains uncut (except in the location of the small incision), unlike in LASIK where anterior stromal lamellae are severed by the creation of the flap. Because the vertical sidecut of a flap is responsible for almost all changes in strain and because the anterior corneal stroma is the strongest part of the stroma, SMILE must leave the cornea with greater biomechanical strength than LASIK for the same amount of tissue removal. Using a mathematical model based on the nonlinearity of tensile strength through the stroma, we have shown that SMILE also leaves greater biomechanical strength than PRK for the same amount of tissue removal, as PRK involves ablating within the strongest anterior stroma.

Surgeons are accustomed to calculating the residual stromal thickness in LASIK as the amount of stromal tissue left under the flap. Therefore, one's instinct is to apply this rule to SMILE. However, for the reasons given above, the actual residual stromal thickness in SMILE should be calculated as the total uncut stroma (ie, the stroma above and below the lenticule).

MEASURING BIOMECHANICAL DIFFERENCES

Efforts to measure the biomechanical difference have been mixed; however, this is probably due to the difficulty of measuring it in vivo. In two of five studies with the Ocular Response Analyzer (Reichert), corneal hysteresis (CH) and corneal resistance factor (CRF) were slightly greater after SMILE than LASIK; the other three showed no difference in CH or CRF between the procedures. However, it is likely that CH and CRF are not ideal parameters for measuring corneal biomechanics given that many studies show little or no change in them after CXL. Similar results have been reported using the CorVis ST tonometer (Oculus Optikgeräte).

Further evidence for biomechanical differences is that there is less induction of spherical aberration after SMILE compared with LASIK. In a recent study, we found that SMILE, although minimally aspheric, produced a similar induction in spherical aberration to the highly aspherically optimized Laser Blended Vision profile. However, as the ablation depth was lower for SMILE, the optical zone could be increased, thereby inducing less spherical aberration for equivalent tissue removal and improving optical quality. These results are similar to other published studies showing that SMILE induced less aberrations than LASIK and that aberration induction was similar.

ADDRESSING THE CONCERNS

The main disadvantage of SMILE is the slightly slower visual recovery experienced by some patients compared with LASIK. Although day 1 visual acuity is on average slightly lower than LASIK, the use of different energy and spot spacing settings seem to improve the delay in visual recovery. The difference in UCVA is now more like 1 or 2 lines on postoperative day 1, equalizing by 2 to 3 weeks postoperatively.

One group has described microdistortions in the Bowman layer after SMILE. However, there were no clinically significant corneal striae at the slit-lamp and the microdistortions did not impact

visual acuity or quality and decreased over time. We have found that central microdistortions can be minimized by appropriate centrifugal cap distension immediately following the procedure.

Some have expressed a concern with the absence of eye tracking in the SMILE procedure. However, studies have shown that centration is straightforward and the patient essentially autocentrates the lenticule to the visual axis. The centration of SMILE has been shown to be similar to that achieved with LASIK using a modern eye tracker.

CONCLUSION

The visual and refractive outcomes of SMILE, a minimally invasive method for corneal refractive surgery, are similar to LASIK, and there is increasing evidence of the benefits of SMILE over LASIK. By leaving the anterior stroma intact, SMILE boasts superior biomechanics and faster recovery of dry eye symptoms and corneal nerve reinnervation compared with LASIK. Progress is also being made on extending the SMILE technique to hyperopia with encouraging results. ■

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* Editor's Note: The basis of this article was taken from: Moshirfar M, McCaughey MV, Reinstein DZ, et al. Small-incision lenticule extraction. *J Cataract Refract Surg.* 2015;41(3):652-665. For a full listing of references used to compile the article above, please refer to the journal article.

Update on SMILE for Hyperopia

The 6.3-mm optical zone and 2-mm transition zone of the SMILE treatment appear to produce significantly better results than previous FLEx treatments for hyperopia.

BY DAN Z. REINSTEIN, MD, MA(CANTAB), FRCSC, DABO, FRCOPHTH, FEBO

Treating hyperopia with the ReLEx technique was first investigated in 2010 in the form of femtosecond lenticule extraction, or FLEx. The initial study, published in 2013,[1] confirmed that lenticule extraction could be achieved. Although outcomes were promising, some eyes experienced a loss of BCVA and a large degree of regression most likely due to the treatment's small transition zone.

Subsequently, characteristics of the lenticule geometry were redesigned,[2,3] including the change to a larger 2-mm transition zone. Initial results in nine eyes using the new parameters of ReLEx FLEx, presented at the ESCRS meeting in 2014,[4] showed that these changes had succeeded in achieving larger optical zones and greater refractive stability. We are running a parallel study with Kishore Pradhan, MD, at the Tilganga Institute of Ophthalmology in Nepal. Treatments are now performed as small incision lenticule extraction, or SMILE, and 3-month data is available for 36 eyes.[5] The geometry of the SMILE parameters used in the study included a 6.3-mm optical zone and a 2-mm transition zone (Figure 1).

In our experience, ReLEx SMILE for hyperopia has been similar to myopic SMILE, with straightforward lenticule plane dissection and little resistance. Identifying the edges of the lenticule is slightly easier than in myopic lenticule dissections due to the thicker edge geometry of the hyperopic lenticule in comparison to the thin edge in myopia. All lenticules were successfully extracted and confirmed as being whole immediately after removal by inspection under the microscope.

Size and centration of the optical zones was assessed by overlaying paracentral rings and a central grid onto the tangential curvature difference maps of the Atlas corneal topographer (ZEISS). We then repeated the analysis in a LASIK control group matched for hyperopia using 6.5- and 7-mm optical zones.[2,3]

The centration offset of the optical zone was equal in all groups (0.30 ±0.17 mm in the 6.3-mm SMILE group, 0.31 ±0.24 mm in the 7-mm LASIK group, and 0.33 ±0.16 mm in the 6.5-mm LASIK group; $P>.73$). This demonstrated that the centration in hyperopic SMILE was equivalent to LASIK despite the fact that SMILE does not use an eye tracker.

The mean achieved effective optical zone diameter for 6.3-mm SMILE (5.08 ±0.30) was larger than both 6.5-mm (4.58 ±0.24) and

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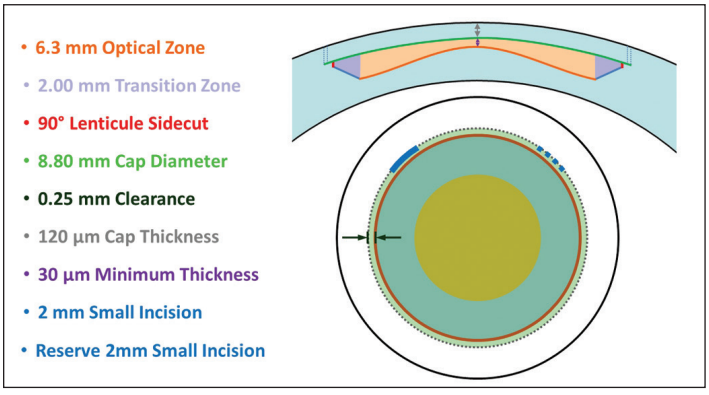


Figure 1. Geometry of lenticule parameters for the hyperopic SMILE treatment.

SMILE at the Edges

A summary of the procedure's potential in high and low myopia.

BY THIERRY CHAZALON, MD; AND JOAQUIN FERNANDEZ, MD

SMILE for High Myopia

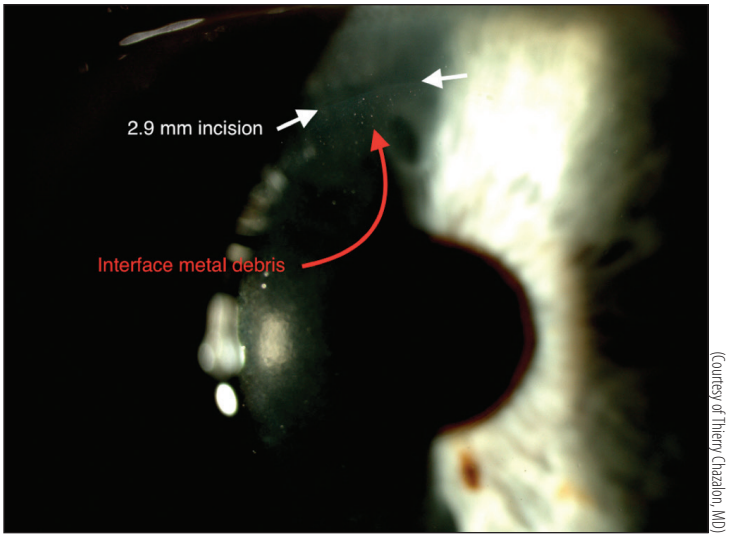
By Thierry Chazalon, MD

SMILE is not only suitable for low and moderate myopia but also for high myopia, as it supposedly only minimally alters the biomechanical properties of the cornea. Additionally, this flapless laser vision correction method has the potential to reduce the complications intrinsic to LASIK, including striae, corneal folds, flap dislocation, dry eye, and epithelial ingrowth.

SUITABLE FOR HIGH MYOPIA

One benefit of SMILE compared with LASIK is that SMILE reduces the amount of tissue alteration produced by the procedure. Marcony et al[1] showed that, with LASIK, a percentage of tissue altered (PTA) of 40% or less was a major risk factor for ectasia. *(Editor's note: The PTA is the sum of the flap thickness and stromal photoablation thickness in relation to the preoperative corneal thickness.)* Because flapless techniques can reduce tissue alteration by 90 to 100 µm, postoperative ectasia is less likely.

The location of the lenticule in SMILE is also beneficial and one reason why treatments are possible in highly myopic eyes. Using in vitro measurements, Randleman et al[2] showed that the anterior surface of the cornea (40% of the cornea) was twice as resistant as the posterior surface (60% of the cornea). Furthermore, using a mathematical model, Reinstein et al[3] calculated that the corneal resistance is best preserved when the lenticule cut is made deeper in the stroma. At the same postsurgery corneal resistance, 100 µm more can be removed with SMILE than it can with LASIK—translating to nearly 8.00 D with a 6.5-mm optical zone. In other words, higher degrees of myopia (and thinner corneas) can be treated with SMILE. For the time being, however, care should be taken to stay within the conventional LASIK safety parameters.



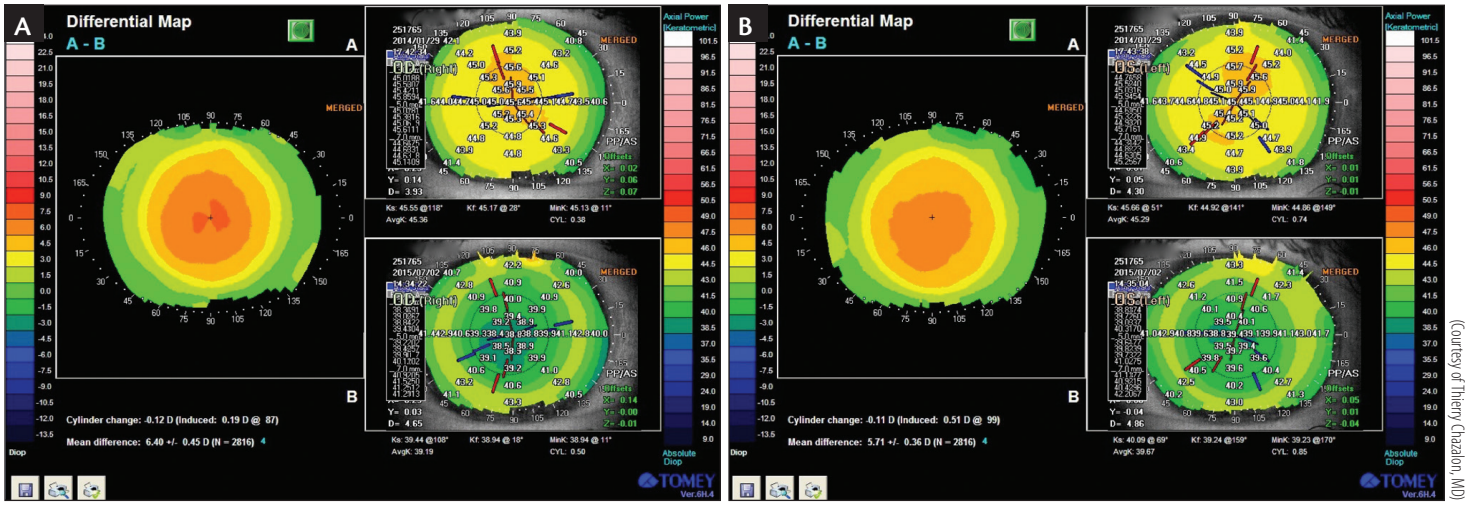
(Courtesy of Thierry Chazalon, MD)

Figure 1. Metal debris are noticeable at the slit lamp.

ZEISS has set the following ranges for SMILE in high myopia: The first incision (posterior or refractive cut) must leave at least 250 µm of residual posterior stroma and endothelium; the second incision (anterior or cap cut), must be between a minimum of 100 µm and a maximum of 160 µm of the surface.

CASE REPORT

In January 2014, a 42-year-old man presented to our clinic for refractive correction. He had a stable refraction for more than



(Courtesy of Thierry Chazalon, MD)

Figure 2. At 16-month follow-up, the mean difference at vertex distance was 8.00 ±0.56 D in the patient's right eye (A) and 7.13 ±0.45 D in his left (B).

TABLE 1. PREOPERATIVE MEASUREMENTS

- Keratometry: OD: 44.75 20°, 45.25 110° / OS: 44.75 150°, 45.50 6°
- Refraction (subjective): OD: -10.25 / OS : -8.75 -0.50 X 110°
- BCVA: OD: 20/20-25 / OS: 20 /20-25
- Cycloplegia (subjective): OD: -9.75 / OS: -8.00 -0.50 X 110°
- Anterior and posterior segment normals
- Orthoptic: Stereoscopic vision and weak fusion: O-X'4, D4-C8, D'12-C'16
- Endothelial cell density (cells/mm²): 2,663 / 2,584
- Topography: TMS-5: Pachymetry (µm): OD: 530 / OS: 527
  - Normal anterior and posterior surfaces
  - Anterior Chamber Depth from endothelium (mm) : 3.12 / 3.10

5 years and did not wear contact lenses. His preoperative data are found in Table 1. Although a Visian ICL (STAAR Surgical) would have provided the patient with a good result, we felt that the anterior chamber depth was not deep enough for this option. Also, the patient's steep keratometry is a positive point for laser vision correction. LASIK with the MEL 80 (ZEISS) would be possible using an aspheric ablation profile and an optical zone diameter of 5.75 mm; however, we opted for SMILE because it has a wider effective optical zone and can provide better accuracy and stability of the refractive results.

Because of the patient's age, we chose to use the cycloplegic subjective refraction, and we usually add 0.75 D to the measured subjective refraction for highly myopic patients (-8.00 D and above). We explained to the patient that slight undercorrection in the right eye should provide him with better near vision.

SURGERY

The procedure was performed in March 2014; the lenticule thickness was slightly different between eyes (148 µm in the right and 146 µm in the left). Due to the thickness of the lenticules, in both eyes we reduced the diameter from the standard 6.5 mm to 6.2 mm, and we moved the cap cut anteriorly from 140 µm (our standard) to 130 µm from the surface. To account for the increase of against-the-rule cylinder over time, we added 0.25 D to the intended refraction in the left eye.

On the first postoperative day, the patient's binocular UCVA was 20/20-25, with normal interfaces. However, at the slit lamp, metal debris was noticeable in the interface of right eye (first operated), just behind the incision (Figure 1). We believed this was due to a bad single-use manipulator. At the 2-month follow-up, the patient reported observing some halos at night, but his UCVA was 20/20-25 in his right eye and 20/20 in his left. By the 16-month visit (Figure 2), as in usual healing after SMILE, the incidence of halos had decreased and was mentioned by the patient only when asked about them. His binocular UCVA was 20/20 (OD: 20/20-25; OS: 20/20-25), and he only needed spectacle correction (-0.25 D) when driving at night.

CONCLUSION

We believe that SMILE is a safe, effective, predictable, and stable procedure for correcting myopia and myopic astigmatism, especially in high myopia. Patients are happy with SMILE because the procedure is bilateral, painless, and fast. Even if there is slight blur immediately after surgery due to corneal edema, patients often describe their visual acuity by the next day as "life-changing."

With the treatment range of up to -10.00 D of myopia and possible future expansion, SMILE represents and interesting alternative to a phakic IOL.

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SMILE for Low Myopia

By Joaquín Fernández, MD

Questions about the efficacy and safety of SMILE in low myopia have been raised, especially compared with those of LASIK.[1,2]

However, the reproducibility of the VisuMax femtosecond laser (ZEISS) in creating thinner lenticules has been reported to be between 4.4 and 9 µm,[3,4] indicating that no problem with laser precision should be expected. Moreover, Reinstein et al demonstrated that safety and efficacy of SMILE for low myopia (range, -1.03 to -3.50 D) is comparable with the efficacy of LASIK for low myopia.[5]

Our results[6] agree with Reinstein's work. In our study, no statistically significant differences in terms of safety, efficacy, and predictability were found between low (-1.00 to -3.00 D), moderate (-3.25 to -5.00 D), and high myopic (-5.25 to -7.00 D) patients treated with SMILE.

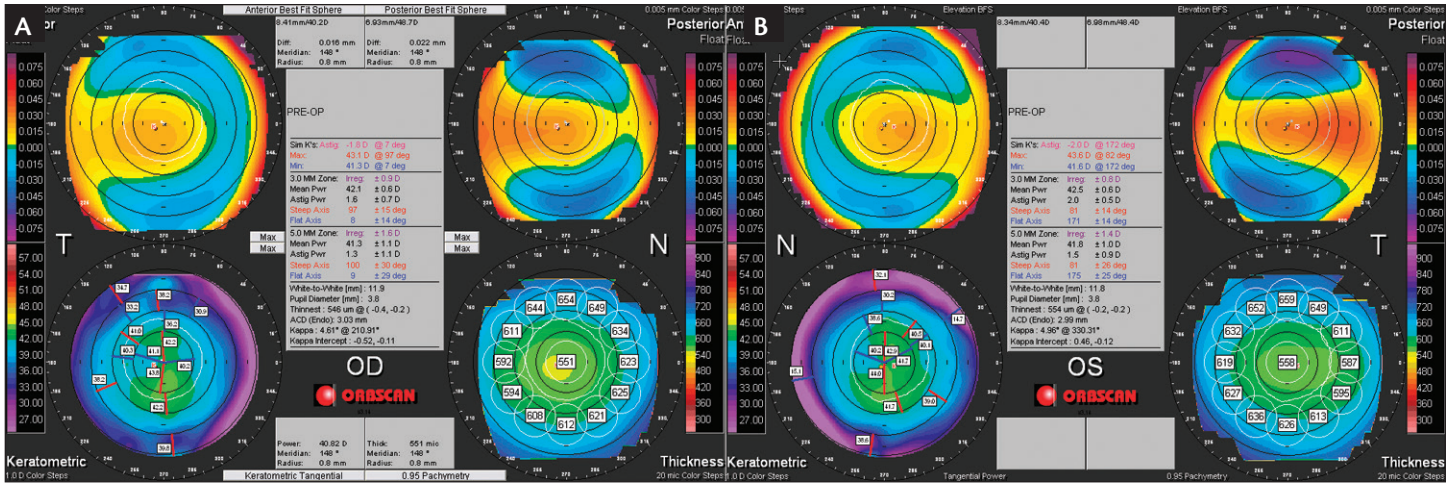
Another concern with SMILE for low myopia is in handling the thin lenticule; however, to date, I have not experienced breaking or tearing of the lenticule in these cases. In fact, even though it has been suggested to increase the lenticule diameter in any low myopia cases over -1.00 D in order to increase the thickness of the lenticule, I do not follow this protocol and have not experienced any complications.

CASE REPORT

The following case study shows that SMILE is suitable to treat low myopia.

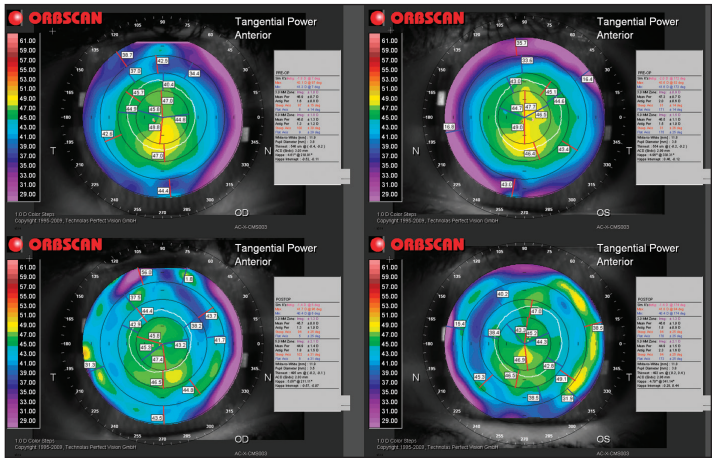
A 30-year-old woman seeking refractive correction presented with distance UCVAs of 20/32 and 20/40 in her right and left eyes, respectively. Manifest refraction was -0.50 -1.00 X 10° in her right eye and -0.75 -1.25 X 175° in her left, and distance BCVA was 20/20 in both eyes.

Preoperative corneal topography (Figure 3) showed less than



(Courtesy of Joaquín Fernández, MD)

Figure 3. Orbscan quad map for refractive surgery screening in the patient's right (A) and left (B) eyes.



(Courtesy of Joaquín Fernández, MD)

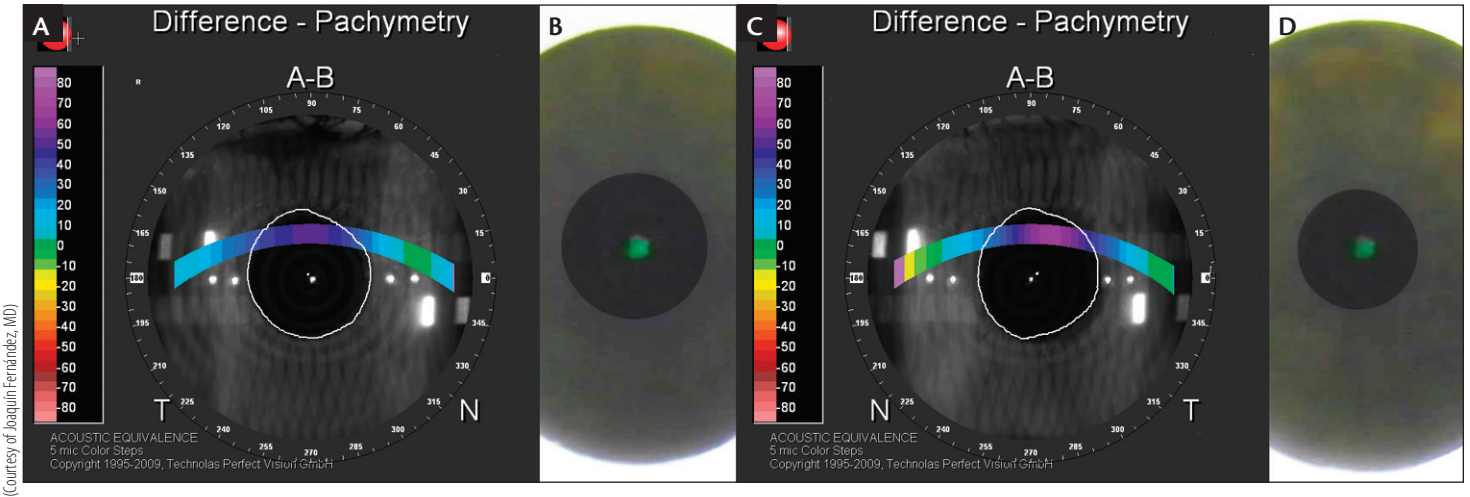
Figure 4. Pre (top) and 17-month postoperative (bottom) tangential powers.

-2.00 D of with-the-rule corneal astigmatism in both eyes, central corneal thicknesses of more than 550 µm, and no elevation pattern contraindications for SMILE. We programmed the VisuMax laser with the following treatment parameters: optical zone of 6.5 mm, cap diameter of 7.6 mm, cap thickness of 120 µm, and incision size of 2 mm.

The patient had a distance UCVA of 20/20 within 48 hours postoperatively. Objective refraction was measured at 3, 6, and 17 months (Table 2), and manifest refraction was considered as emmetropia (monocular distance UCVA of 20/20) in all the postoperative visits.

In order to collect long-term data, the patient was examined 17 months after the procedure, and pre- and 17-month postoperative tangential corneal topographies are show in Figure 4. The preoperative patterns show slight asymmetrical bow ties; that could be the reason why the postoperative patterns show a slight asymmetry in the pupil center (more evident in the left eye), as the treatment of astigmatism with laser ablation is considered symmetrical.

As some authors have questioned the reliability of corneal thickness measurements taken before and after SMILE,[1] we used thickness profiles from different pachymetry maps in order to understand approximately where the lenticule should be centered (Figure 5). Our intent was to center it on the pupil. In this case, good centration was obtained in the patient's right eye, which had a thinner lenticule than the left (47 vs 54 µm).



(Courtesy of Joaquín Fernández, MD)

Figure 5. Preoperative thickness difference (A) and image capture after cone suction (B) and postoperative thickness difference (C) and image capture after cone suction (D). Image capture was conducted with a circular black mask in order to delineate the exact position of the pupil.

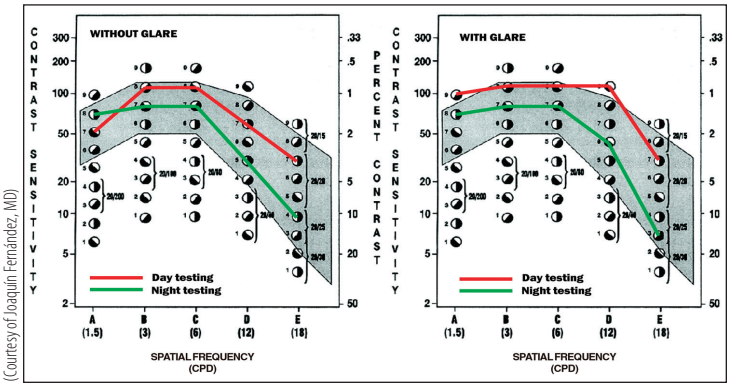
TABLE 2. OBJECTIVE REFRACTION

Time	Objective Refraction		Monocular UDVA (OD and OS)	Binocular UDVA
	RE	LE		
3 months	0.25 -0.50 X11°	-0.50 X 167°	20/20	20/20
6 months	-0.25	-0.50 X 177°	20/20	20/20
17 months	-0.25 -0.50 X 4°	0.25 -0.75 X 163°	20/20	20/16

RE = right eye; LE = left eye; UDVA = distance UCVA; OD = right eye; OS = left eye

TABLE 3. ABERRATIONS OF LEFT AND RIGHT EYES

		Right Eye		Left Eye	
Index	Higher-Order Aberration	Preoperative (D)	17-month postoperative (D)	Preoperative (D)	17-month postoperative (D)
Z33	Vertical trefoil	-0.15	-0.21	-0.01	-0.14
Z31	Vertical coma	0.16	0.37	0.14	0.33
Z31	Horizontal coma	0.10	0.04	-0.12	-0.07
Z33	Horizontal trefoil	0.06	0.06	0.2	0.25
Z44	Quadrafoil	0.04	0.05	-0.005	-0.002
Z42	Astigmatism	0.01	0.03	-0.003	-0.06
Z40	Spherical aberration	0.08	0.18	0.09	0.12
Z42	Astigmatism	-0.001	0.11	0.000	0.11
Z44	Quadrafoil	-0.07	-0.11	-0.02	-0.13



(Courtesy of Joaquín Fernández, MD)

Figure 6. Binocular contrast sensitivity function without correction at different testing conditions.

Although the refractive error decreased postoperatively, providing great binocular distance UCVA (20/16), the presence of higher-order aberrations (HOAs) increased in both eyes, especially vertical coma, which went from a mean in both eyes of 0.15 ±0.01 µm preoperatively to 0.35 ±0.01 µm at 17 months postoperatively and spherical aberration, which went from a mean of 0.09 ±0.01 µm preoperatively to 0.15 ±0.04 µm at 17 months postoperatively (Table 3).

The increase in spherical aberration is considered inside the normal range after any myopic laser refractive surgery, and the vertical coma is expected considering the asymmetric astigmatism that can be seen in the preoperative corneal topography in Figure 4. Contrast sensitivity function (CSF) was measured in day and night conditions and with and without glare (Figure 6). Despite the slight increase in HOAs, the CSF was inside the normal range in all the measured conditions, thereby providing the patient with good visual performance.

CONCLUSION

This SMILE case is one of 583 we have performed successfully in our clinic since September 2013. In our experience, we have not seen any statistically significant difference to LASIK results in terms of safety, efficacy, and predictability in low, moderate, and high myopia.[6] Therefore, SMILE is our procedure of choice to treat the entire range of myopia. The most important indicator to us is that patient satisfaction after SMILE is exceptionally high. For instance, the patient described above was asked to rate her satisfaction with the procedure on a scale of 0 to 10 (10 being the best score), and not only did she score it as a 10, but she indicated that she would recommend SMILE to her family and friends. ■

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Options for Retreatment After SMILE

Although SMILE has many advantages over LASIK, some challenges remain to be addressed, including management of residual refractive errors. In this article, a panel of surgeons discusses three options for retreatment.

BY RAINER WILTFANG, MD; OSAMA IBRAHIM, MD; MOONES ABDALLA, MD; AND RUPAL SHAH, MD

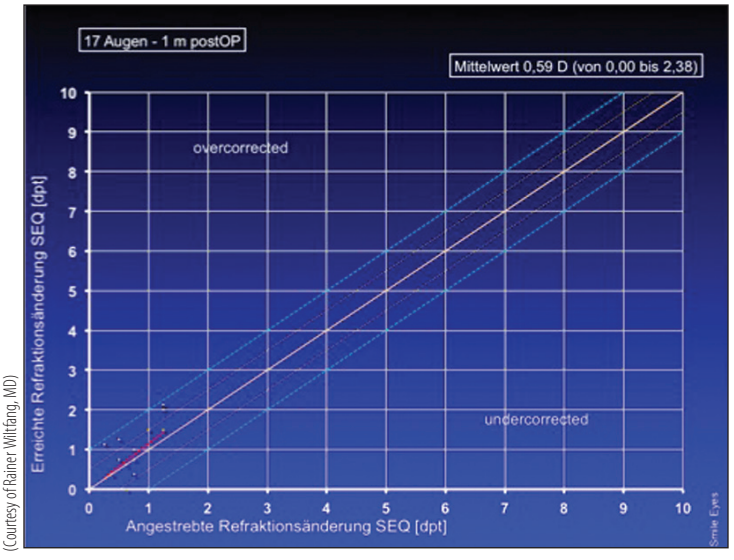
LASEK With the MEL 90 Excimer Laser

By Rainer Wiltfang, MD

I have performed approximately 2,000 small incision lenticule extraction, or SMILE, procedures in the past 4 years. Of these, only 28 have required a refractive enhancement. With such a low enhancement rate (1.4%), I have come to rely mainly on LASEK to correct the majority of these residual refractive errors (Figure 1). I have also used LASIK in two patients with residual hyperopia.

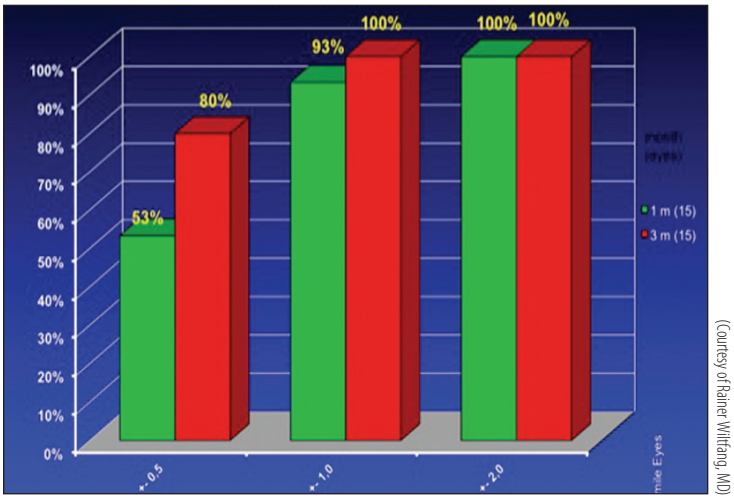
At the moment, we are still discussing what is the best method for retreatment after SMILE. However, in comparison to a flap-based surgical enhancement technique, LASEK maintains all of the advantages of the original SMILE procedure, including enhanced biomechanical stability and a lower incidence of postoperative dry eye. LASEK also eliminates the burden of risks associated with hitting the original SMILE interface during LASIK flap creation and, because the epithelium is removed during LASEK, there is no need to account for epithelial thickness in the touch-up.

When counseling patients about refractive surgery, I share all surgical options: LASEK/PRK, LASIK, and SMILE. I then explain the advantages of the flapless SMILE procedure, in that it combines



(Courtesy of Rainer Wiltfang, MD)

Figure 1. Predictability of LASEK enhancement at 1-month postoperative.



(Courtesy of Rainer Wiltfang, MD)

Figure 2. Refractive outcomes at 1 and 3 months after LASEK enhancement.

the advantages of LASEK/PRK and LASIK and has greater biomechanical stability than any of these. The only drawbacks are that LASEK and other surface ablation retreatments are more painful procedures and have slower visual recovery that, in some patients, can take between 4 weeks and 3 months. Haze is also a consideration when using LASEK, especially as an enhancement to SMILE. I generally can see a difference between treating a virgin eye with LASEK and doing a touch-up LASEK after SMILE. Possible reasons could be that visual recovery takes longer.

Even with these things in mind, I still consider LASEK to be the best option for retreatment because it maintains all of the advantages of the SMILE procedure. This includes the fact that I do not have to create a flap and I do not have to account for epithelial thickness when planning the retreatment. I am happy with the predictability of the procedure, and by 3 months postoperative my patients are happy with their results (Figures 1 and 2).

In the future, other options—such as performing a second SMILE procedure—may be possible, but in the meantime, we will continue to trust the majority of our enhancements to LASEK.

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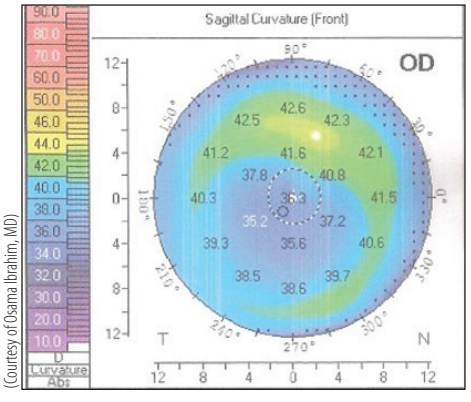
Topography- and Wavefront-Guided PRK

By Osama Ibrahim, MD; and Moones Abdalla, MD

Among the options to correct refractive errors and, less commonly, surgically induced errors after SMILE is topography- and wavefront-guided PRK. We prefer surface ablation to LASIK because it avoids the need for flap creation, thereby preserving the advantages of SMILE.

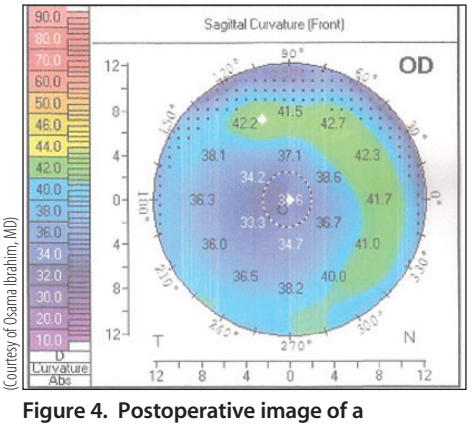
The disadvantages of PRK include delayed visual recovery and postoperative pain and discomfort; however, they can be explained to the patient and subsequently managed appropriately. We also prefer PRK to LASEK because it avoids the use of alcohol and its unforeseeable complications.

Epithelial removal after SMILE, either mechanically or by alcohol in LASEK, reveals irregularities in the Bowman layer that resemble mud cracks or fingerprints. Therefore, our technique for PRK enhancement is to remove the epithelium by a 7-mm diameter and 50-µm depth PTK, followed by a 6- to 6.5-mm excimer laser ablation depending on the refractive error and cap thickness; this method avoids penetrating the SMILE cap. (We use this technique in cases with our current standard cap thickness of 120 µm; other retreatments for lower cap thickness are converted into LASIK with the CIRCLE technique, which is described in the next contribution by Rupal Shah, MD.) Next, chilled balanced saline solution is applied, followed by 0.02% mitomycin C for 30 seconds to avoid postoperative haze. A bandage contact lens is placed and a combination of antibiotics and steroids are prescribed. Pain medications are given for 2 days, and the contact lens is removed once epithelialization is complete.



(Courtesy of Osama Ibrahim, MD)

Figure 3. Mild inferior decentration was noticeable in this case.



(Courtesy of Osama Ibrahim, MD)

Figure 4. Postoperative image of a topography-guided PRK.

We have performed SMILE in more than 5,000 eyes; retreatments were performed in less than 30 (0.6%). Of these, nine (six patients) required surface ablation because of small residual errors and cap thicknesses greater than 120 µm. Of them, five eyes underwent conventional PRK, three underwent topography-guided PRK to correct associated decentration (Figures 3 and 4), and one eye underwent wavefront-guided PRK. The mean post-SMILE, pre-PRK spherical equivalent (SEQ) in these cases was -1.65 D (range, -1.00 to 2.75 D), and the mean astigmatism was -1.12 D (range, -0.75 to 2.00 D). After the enhancement, the mean SEQ was -0.15 D (range, 0.75 to -0.75 D) and all but one eye had achieved epithelial healing by day 4 postoperatively. In the remaining eye, epithelial healing was reached by day 7. This eye also had mild haze that persisted for 5 month before it resolved completely. No other complications were reported.

In our experience, PRK is an effective modality to treat mild post-SMILE refractive errors (up to -3.00 D). While preserving the advantages of flapless SMILE, our technique is safe and predictable and patient satisfaction, despite the postoperative discomfort, is high.

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Osama Ibrahim, MD, is a Professor of Ophthalmology at Alexandria University, Roaya Vision Correction Center, Alexandria, Egypt. Dr. Ibrahim states that he is a consultant to Carl Zeiss Meditec. He may be reached at ibrosama@gmail.com.

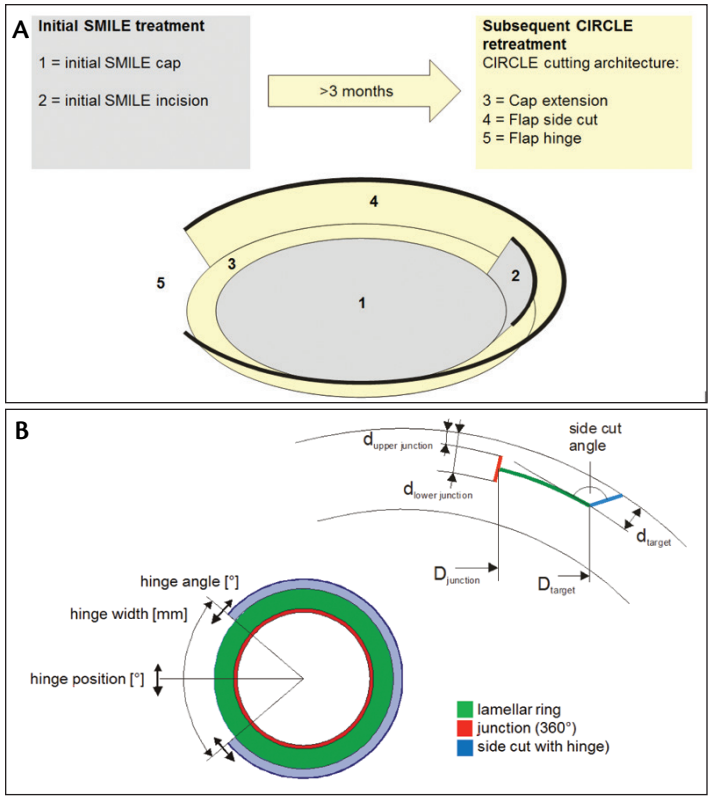
Enhancing SMILE With the CIRCLE Procedure

By Rupal Shah, MD

In our clinics, fewer than 1% of patients who undergo SMILE need, or ask for, enhancements. The rate is slightly higher in highly myopic patients, at approximately 4%.

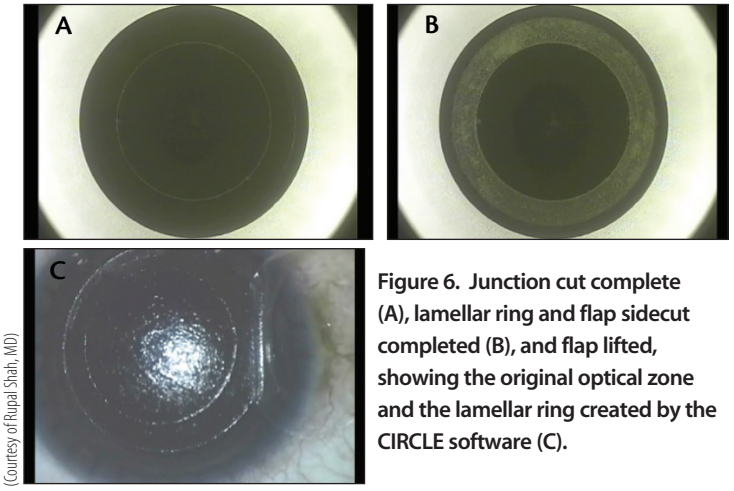
Although surface ablation is a viable option for enhancements, my preferred technique is the CIRCLE procedure. Available as standard software with the VisuMax femtosecond laser (ZEISS), CIRCLE is designed to create three cuts: (1) an incision plane, encircling the original cap cut as a lamellar ring; (2) a sidecut with hinge around the new incision plane; and (3) a junction cut, allowing the original cap and the new incision plane to be part of one larger surface (Figure 5). This creates a corneal flap, which can be lifted in the usual fashion and the excimer laser ablation applied to correct the residual refractive error. The advantage of this method is that, compared with PRK and LASEK, there is less patient discomfort and quicker visual recovery. The procedure is similar to LASIK, and therefore one drawback is that the benefits of SMILE—flaplessness and minimally invasiveness—cannot be maintained.

I prefer to use CIRCLE because my standard SMILE technique is to use a very thin cap thickness (80–100 µm), which perfectly converts into a flap. To illustrate one case, Patient UA (refraction, -8.00 -1.25 X 170º and BCVA, 0.9) underwent SMILE in August 2011. The cap diameter was 6.75 mm and the cap thickness was set at



(Courtesy of Rupal Shah, MD)

Figure 5. Diagrams (A,B) of the SMILE procedure and subsequent CIRCLE retreatment.



(Courtesy of Rupal Shah, MD)

Figure 6. Junction cut complete (A), lamellar ring and flap sidecut completed (B), and flap lifted, showing the original optical zone and the lamellar ring created by the CIRCLE software (C).

90 µm. A 6-mm optical zone was selected. At 1 year postoperatively, the patient had a residual refractive error of -0.75 D, with a UCVA of 0.5 and a BCVA of 0.9. He underwent CIRCLE enhancement, with an 8.5-mm flap diameter, and a CIRCLE pattern D (which creates the flap thickness at the same level as the original cap thickness), followed by the correction of the refractive error with the MEL 80 excimer laser (ZEISS). One year later, his refractive error was only -0.25 D, with an UCVA of 0.9 (Figure 6). ■

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(Reinstein, continued from page 4)

7-mm LASIK (4.87 ±0.26). Optical zone size was also analyzed using axial curvature maps; the diameter measured significantly larger in all groups (Figure 2). The relatively larger optical zone (SMILE vs LASIK) also had a positive influence on induced spherical aberration, whereby the 6.3-mm SMILE treatment (Z (4.0) -0.53 ±0.25 µm) induced a similar amount of spherical aberration to the 7-mm LASIK treatment (Z (4.0) -0.47 ±0.19 µm; *P*=.324) and less than the 6.5-mm LASIK treatment (Z (4.0) -0.76 ±0.18 µm; *P*<.01).

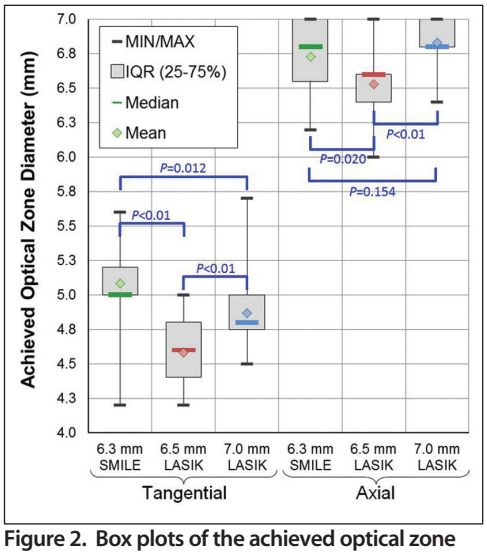

Figure 2. Box plots of the achieved optical zone diameter based on both the tangential and axial curvature difference maps for 6.3-mm SMILE and 6.5- and 7-mm LASIK.

SUMMARY

The 6.3-mm optical zone and 2-mm transition zone of the SMILE treatment appear to produce significantly better results than previous FLEx treatments for hyperopia.[4] The superior optical zone results in SMILE versus LASIK might be due to eliminating fluence projection errors[6] and truncation errors. Analysis of a larger cohort of sighted eyes will allow us to investigate refractive stability and visual outcomes. However, the improved optical zone achieved in the current study suggests that refractive stability will be comparable to and possibly better than LASIK. Additionally, it would be expected that SMILE's other advantages over LASIK, including reduced dry eye symptoms and biomechanical response, will also be found. ■

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Tips for Keeping Your Refractive Business Current

SMILE can help one to run a successful refractive center.

BY PAVEL STODULKA, MD, PHD

I have witnessed firsthand the importance of keeping a refractive practice up-to-date. As the first surgeon in the Czech Republic to offer LASIK and femtosecond LASIK (femto-LASIK), I understand the importance of offering the latest techniques and treatments to my patients. Therefore, in the past few years, I have closely watched the development of small incision lenticule extraction, or SMILE, the latest innovation in laser refractive surgery, in the hopes of one day offering it to my patients.

After listening to presentations, reading articles, and talking to my colleagues about SMILE, I decided to do a wet lab in 2012 to gain initial experience with the procedure. I was intrigued by the easy handling of the lenticule, but I waited to incorporate the technique into my practice. Meanwhile, published studies showed that postoperative results were similar to those of LASIK, and this made me eager to incorporate SMILE into my clinic. I finally started offering this procedure in my clinic in 2014.

Figure 1. The VisuMax femtosecond laser, as set up in one of the Gemini Eye Clinics facilities.

THE PATIENT PERSPECTIVE

In my experience, patients generally like to have different surgical options to choose from. With the popularity of social media, patients nowadays are well informed about the latest developments in refractive surgery and search actively for information on these procedures. Therefore, I have found that many of my patients have heard of and are interested in SMILE. The concept of minimally invasive surgery is familiar to them, thanks to other surgical procedures like endoscopic abdominal and joint surgery.

Patients come to our clinic already understanding that SMILE requires much less cutting on the corneal surface than LASIK, but I take time to explain the procedure's clinical benefits. I also share that the patient interface of the VisuMax femtosecond laser (ZEISS; Figure 1) attaches by vacuum to the cornea, and not to the conjunctiva like all the other refractive femtosecond lasers, meaning they should feel little or no discomfort and the risk of conjunctival bleeding is minimal.

Patients also like the idea of using only one laser for the entire procedure. We like it, too, because it increases our efficiency in the operating room and shortens the procedure time, as there is no need to transfer the patient from the femtosecond laser to the excimer laser.

THE SURGEON PERSPECTIVE

I enjoy performing SMILE because it is a change from my typical daily surgical routine. I have truly enjoyed learning how to perform SMILE, and I like the using the femtosecond laser to create the lenticule (https://youtu.be/chhzaEAZGzY). During my learning curve, the procedure took longer than a standard LASIK case; however, after gaining experience with the technique, a typical SMILE procedure takes about 3 minutes.

Based on my experience with SMILE, I have developed several surgical instruments with Rumex International. The set, consisting of the Stodulka ReLEx SMILE double spatula (for opening the incision and dissecting the lenticule) and Stodulka forceps, support lenticule extraction through a 2-mm incision (https://youtu.be/Kyqll6niXQc; Figure 2).

WHEN TO OFFER SMILE

Our primary indication for SMILE is myopia and myopic

(Continued on page 14)

SMILE: A Perfect Choice for High-Volume Clinics

About 80% of eligible patients in one high-volume center select this procedure.

BY JONG HO LEE, MD

The Seoul/Busan BalGeunSeSang Eye Clinic was the first laser vision correction center to open in South Korea. Since 1997, we have performed more than 330,000 refractive surgery procedures, continually aiming to offer patients the latest techniques and technologies our field has to offer. We currently have 12 operating rooms (Figure 1) and 50 consulting rooms, and we employee 200 staff members—among them 16 surgeons.

As a leader in refractive surgery in South Korea, we were eager to gain early experience with refractive lenticule extraction using the VisuMax femtosecond laser platform (ZEISS) and had plans to one day add it to the procedures we offered at our centers. Therefore, in 2012, I performed several femtosecond lenticule extraction, or FLEx, procedures, the initial ReLEx femtosecond lenticule extraction technique. However, I did not officially start performing ReLEx in our clinic until August 2013, after the latest generation of the procedure, ReLEx small incision lenticule extraction, or SMILE, was commercially introduced. In the meantime, I had devoted much energy into researching results, ultimately deciding to wait until the procedure had more time to mature. I felt the time was right when SMILE became available as new clinical procedure, as I believed it would be the ideal solution to providing even more patients with safe, effective, and accurate laser vision correction.

Figure 1. One of the operating rooms at Busan BalGeunSeSang Eye Clinic.

IMPLEMENTING THE PROCEDURE

Since we acquired the VisuMax femtosecond laser in 2009, many of our surgeons are highly skilled in its use. This, in my opinion, was one of the driving factors for implementing SMILE in our clinic. Shortly after I had gained meaningful experience with SMILE, I trained eight additional surgeons to perform the

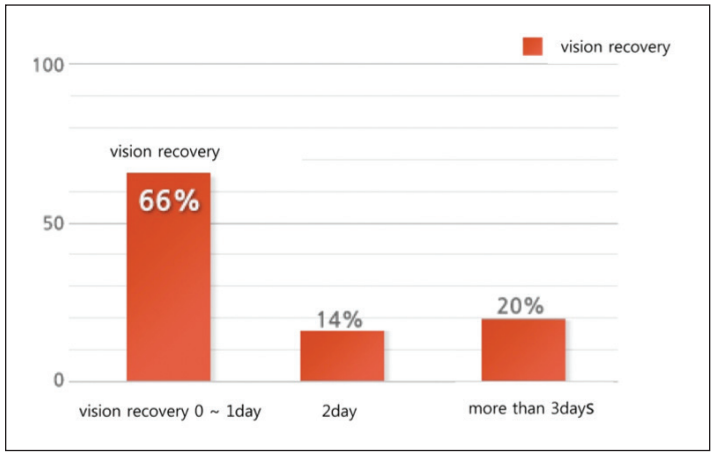

Figure 2. About 66% of patients reported visual recovery within 1 day of the procedure.

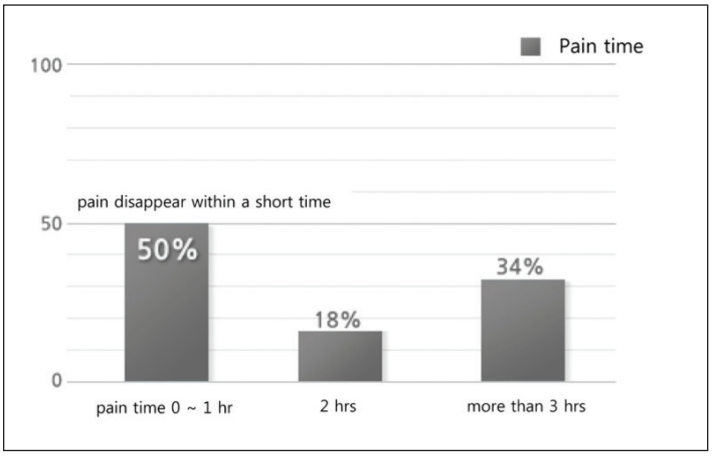

Figure 3. About 50% of patients reported the absence of pain within 1 hour after surgery.

procedure, bringing the number of surgeons in our center well versed in the SMILE technique to nine. Shortly thereafter, Carl Zeiss Meditec awarded us with the ReLEx SMILE Award for Superior Expertise in Korean Ophthalmology.

Since August 2013, our center has completed 11,000 refractive surgery procedures. Although LASIK still accounts for the majority, the number of SMILE procedures is on the rise, and we fully expect these to exceed LASIK procedures in the near future. The first reason is that, in our experience and in accordance with results shared at academic conferences and symposia, SMILE is safer than PRK, LASIK, and LASEK and patients need less time to recover. In our clinic, 66% of patients who have undergone SMILE reported good recovery of vision on the day of the procedure (Figure 2).

The second reason is that patient satisfaction has been extremely high, which we believe is due in part to the fact that the procedure is minimally invasive and lasts only 10 minutes. In our clinic, by 1 week postoperative, 82% of patients who underwent SMILE reported mild pain (0 to 3 on a scale of 10). Additionally, 50% reported that the duration of pain was less than 1 hour (Figure 3). One unique element to our success with SMILE: We have developed a line of surgical tools to use in conjunction with SMILE to make the surgical procedure easier and achieve consistent excellent outcomes.

MARKETING

We believe it is important to inform patients of all their surgical options in the first consultation visit. Although we use PowerPoint presentations, video displays, and brochures to introduce each procedure to patients, we have found that the best method for patient education is one-on-one counseling.

All patients must receive a clear explanation of the advantages and disadvantages of each procedure. We also find that it is beneficial to share typical postoperative results with patients so that they can establish realistic expectations.

CONCLUSION

Among the patients undergoing preoperative examinations in our eye clinic, 50% are suitable for surgery. At this time, we are seeing a trend of about 80% choosing SMILE. Most patients decide for SMILE because, in comparison to other laser vision correction techniques, the chance for clear vision and a quicker return to everyday activities is almost immediate.

Currently, the most likely reason for not selecting SMILE is the cost of the procedure; however, in the near future and as procedural costs go down, the number of patients choosing SMILE over LASIK, LASEK, or PRK will steadily rise. This is because SMILE outperforms the other laser vision correction procedures we offer. Further, a more mature market will be conducive to increasing the range of SMILE treatments we can offer our patients. ■

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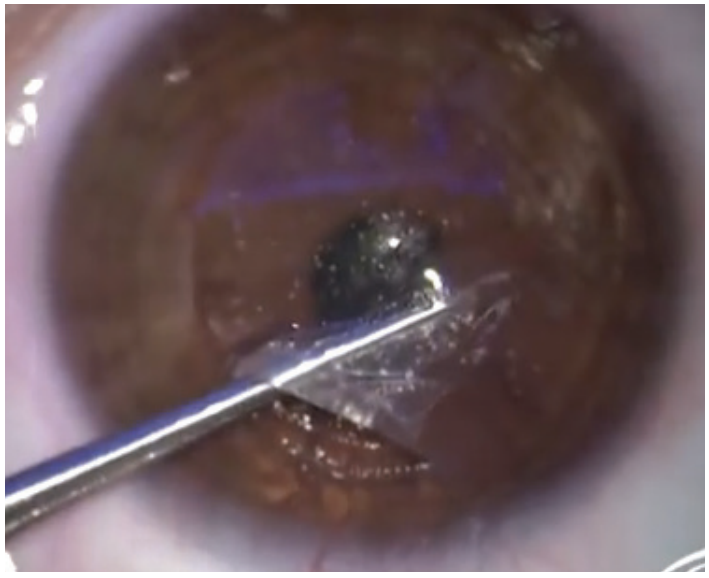

Figure 2. Lenticule extraction through a 2-mm incision.

(Stodulka, continued from page 12)

astigmatism from -4.00 to -10.00 D of spherical equivalent. For low myopia, we use femto-LASIK, and for myopia higher than -10.00 D we perform phakic IOL implantation. Another option for the treatment of high myopia is to combine SMILE with CXL. This can provide additional corneal stability above and beyond what the biomechanical advantages of SMILE already offer.

Since most of our patients fall into the category of moderate to high myopia (-4.00 to -10.00 D), SMILE fits nicely into our portfolio and has reached the market as the 3rd generation of laser vision correction after PRK and LASIK. We market SMILE as LASIK ReLEx SMILE because we do not want to pin LASIK as an old-fashioned and dangerous method as some of our competitors do. This harms the whole field of refractive surgery, and patients lose confidence in not only LASIK but in laser refractive surgery in general.

CONCLUSION

Thus far, our approach to SMILE has been successful. Patients are happy after surgery and generally share their experiences with other potential patients. Therefore, adding SMILE to our portfolio of refractive laser vision correction options was one of the best decisions I have ever made. Not only I can satisfy the demand of offering the latest refractive laser vision correction techniques, but my well-informed patients and I can both benefit from the advantages that SMILE offers.

Word-of-mouth advertising is our major source of new patients. Since the introduction of SMILE in my practice, I have been able to keep my practice volume constant despite the overall decrease of LASIK procedures in my country. ■

Pavel Stodulka, MD, PhD, is Chief Eye Surgeon, CEO of Gemini Eye Clinics, Czech Republic. Dr. Stodulka states that he has no financial interest in the products or companies mentioned. He may be reached at stodulka@lasik.cz.

The Benefits of Offering Multiple Procedures

In an average-volume clinic, allowing patients to choose between LASIK, PRK, and SMILE can help to increase surgical volume.

BY FRANCISCO POYALES-GALAN, MD

Our decision to acquire the VisuMax femtosecond laser (ZEISS) in September 2013 was based on the fact that we wanted to provide our patients with the latest laser refractive surgery techniques. Now, in addition to PRK and femtosecond LASIK (femto-LASIK), we are able to perform small incision lenticule extraction, or SMILE. In the past 2 years, 600 patients have chosen to undergo the flapless, minimally invasive technique.

We were eager to include SMILE in our surgical portfolio due to its numerous advantages. The biggest advantage is the absence of a corneal flap, thereby eliminating all flap-related complications such as striae, corneal folds, and free flaps. Likewise, the risks for epithelial ingrowth and diffuse lamellar keratitis are minimized. We have found that patients who play sports especially appreciate that SMILE is a flapless procedure. This is because most daily activities can be resumed almost immediately after surgery.

The second advantage of SMILE is that the technique is easy to learn. Both surgeons in our clinic who perform SMILE (Figure 1) felt comfortable performing it in a relatively short time. Great predictability of the refractive correction is another advantage it offers. This is especially true in higher myopic corrections (up to -10.00 D), where we have observed better outcomes than we typically do with PRK or LASIK. Because refractive results are so predictable after SMILE, our retreatment rate is very low (1.5%).

PRK, LASIK, OR SMILE?

We follow general standards in selecting the best surgical technique for each patient. We opt for PRK when the required refractive correction does not exceed -2.00 to -3.00 D of myopia. We also opt for PRK when the cornea is less than 500 µm thick.

Femto-LASIK is our procedure of choice for hyperopic and astigmatic errors of 3.00 D and above, and SMILE is our first choice for low (-2.00 to -3.00 D) and up to higher (-7.00 to -8.00 D) myopia, even in the presence of up to 3.00 or 4.00 D of astigmatism. Since this applies to most of our patients, 65% of our laser vision correction procedures are SMILE. Of course, every decision must be taken individually depending on the patient's visual requirements and expectations.

Although LASIK is the most prevalent surgical approach for myopic correction, quite a few patients ask for SMILE during their first visit. Additionally, as described above, we recommend the SMILE technique for any patient with moderate myopia and explain the advantages offered by a flapless surgery. Patients typically follow our advice, so we convert patients from LASIK to SMILE easily.

Figure 1. From left to right: Francisco Poyales-Galan, MD; Blanca Poyales, MD; and Ricardo Pérez, MD, in their operating room.

In the 4 years since the commercial introduction of SMILE, we have observed an increase in the level of patient awareness of the procedure. Some patients now explicitly ask for SMILE. Moreover, word-of-mouth referrals from happy patients are a considerable factor that helps to bring new patients to the clinic.

CONCLUSION

We are glad to have taken the steps necessary to offer our patients the broadest spectrum in laser vision correction. Now that we perform SMILE in our clinic, patients can choose to undergo the procedure that is best for them, including the latest laser vision correction technique. ■

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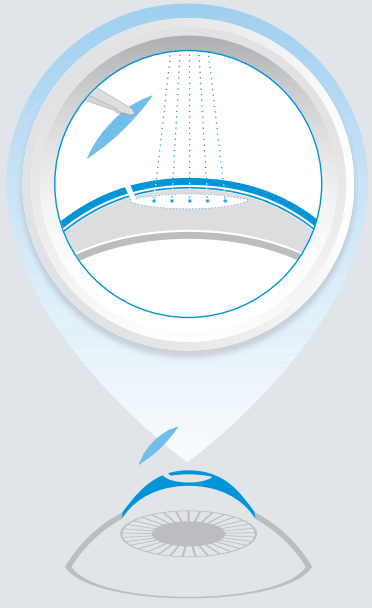
SMILE

3rd Generation
Laser Vision Correction



The future is minimally invasive!

Small incision lenticule extraction or SMILE represents the 3rd generation of laser vision correction beyond PRK and LASIK. As a minimally invasive, flapless procedure, SMILE is redefining refractive surgery as we know it.

SMILE combines the advantages of PRK and LASIK. Because there is no flap, there are also no flap-related complications, including less incidence of dry eye. Consequently, SMILE offers the potential for more biomechanical preservation and stability.

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