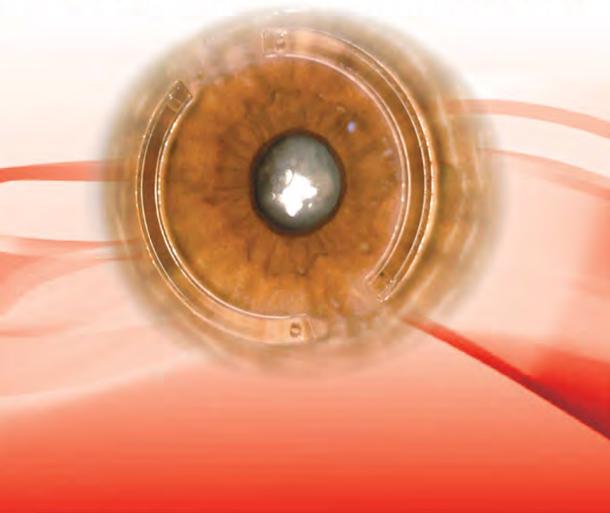
Gems of Ophthalmology CORNEA & SCLERA



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SMILE versus LASIK

Jorge L Alio, Mohamed El Bahrawy

RECENT EVOLUTION OF LASER REFRACTIVE SURGERY OF THE CORNEA

The concepts of modern refractive surgery witnessed its breakthrough when Professor Jose I Barraquer described his coined technique of keratomileusis in 1949, setting the foundation for all following innovations in this field. The name 'excimer laser' came as an abbreviation of 'excited dimer', introduced by the Russian, Nikolay Basov, in 1970 using a xenon dimer gas. A few years later, the argon-fluoride excimer laser was developed and was first tried on an organic tissue by IBM scientists. The introduction of excimer laser to be used in the human eye was done by Stephen Trokel as a precise and safe tool of corneal shaping, these concepts later defined the refractive techniques which are widely used now, when Marguerite McDonald under the supervision of Steve Kaufmann, performed the most commonly used epithelium removal technique photorefractive keratectomy (PRK). Peyman, presented the first patency using excimer laser as a corneal refractive tool, and it was accepted in June 1989 (personal correspondence Gholam Peyman). Following Ioannis Pallikaris, among others, introduced the most widely used and commonly accepted technique of laser in situ keratomileusis (LASIK) in 1990.1 Laser refractive surgery has been performed for decades, and there have been tremendous advancements in terms of technique and technology, making it increasingly precise and highly predictable. ² LASIK is currently the most common laser refractive procedure for the treatment of myopia—its advantages include early postoperative improvement in visual acuity and minimal postoperative patient discomfort. Although LASIK patients report 95% satisfaction, a spectrum of complicated side effects can negatively impact results.3

Femtosecond laser technology was first developed by Dr. Kurtz at the University of Michigan in the early 1990s⁴ and was rapidly adopted in the surgical field of ophthalmology. Femtosecond lasers emit light pulses of short duration (10–15 seconds) at 1,053 nm wavelength that cause photo-disruption of the tissue with minimum collateral damage.⁵ The femtosecond laser has revolutionized corneal and refractive surgery with respect to its increased safety, precision and predictability over traditional microkeratomes. Advantages of bladeless femtosecond-assisted LASIK (FS-LASIK) over conventional microkeratome-assisted LASIK (MK-LASIK) include reduced dry eye symptomatology, reduced risk of flap button hole or free-cap formation.^{6,7}

Ever since femtosecond lasers were first introduced into refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can then be manually removed as a single piece thereby circumventing the need for incremental photoablation by an excimer laser. A precursor to modern refractive lenticule extraction (ReLEx) was first described in 1996 using a picosecond laser to generate an intrastromal lenticule that was removed manually after lifting the flap;^{8,9} however, significant manual dissection was required leading to an irregular surface. The switch to femtosecond improved the precision¹⁰ and studies were performed in rabbit eyes in 1998¹¹ and in partially sighted eyes in 2003, 12 but these initial studies were not followed up with further clinical trials. Following the introduction of the VisuMax® femtosecond laser (Carl Zeiss Meditec, Jena, Germany) in 2007, 13 the intrastromal lenticule method was reintroduced in a procedure called femtosecond lenticule extraction (FLEx). The 6-month results of the first 10 fully seeing eyes treated were published in 2008¹⁴ and results of a larger population have since been reported. 15,16 The refractive results were similar to those observed in LASIK, but visual recovery time was longer due to the lack of optimization in energy parameters and scan modes; further refinements have led to much improved visual recovery times.¹⁷ Following the successful implementation of FLEx, a new procedure called small-incision lenticule extraction (SMILE) was developed. This procedure involves passing a dissector through a small 2-3 mm incision to separate the lenticular interfaces and allow the lenticule to be removed, thus eliminating the need to create a flap. The SMILE procedure is now gaining popularity following the results of the first prospective trials. 18-29

SMILE OUTCOME

Since the development of the SMILE technique, the exciting new concept of the flapless nature of the technology, namely the *3rd generation laser refractive surgery*, has driven many authors to approach it and report the results of SMILE outcomes alone or in comparison with LASIK.

In a study we conducted, we compared the outcomes of a matched cases of SMILE versus 6th generation excimer laser LASIK patient, where the cases

Comparison		SMILE (%)	FS-LASIK (%)
	20/20 or more	93.75	92.18
	20/25 or more	100	96.87
	20/40 or more	100	100
Efficacy	No loss of lines	96.87	93.43
	Lost more than 2 lines	0	0
	Gained lines	18.75 (1 line)	18.64 (1–3 lines)
Predictability	% of cases	84.43	86.25
	±0.5 D		
	% of cases	100	100
	±1.0 D		100

Table 4.1: Refractive outcome of comparative study between SMILE and LASIK.

SMILE: Small-incision lenticule extraction; LASIK: Laser assisted in situ keratomileusis; FS-LASIK: Femtosecond-assisted LASIK.

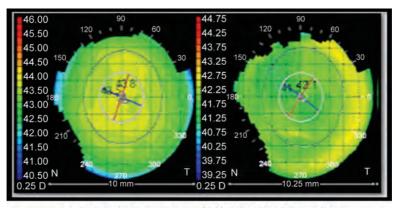
were matched by age, gender and spherical equivalent. In the SMILE group; 50% females, 34 years (23:49), -4.59 diopters (-2.125:8.37), the LASIK group; matching SMILE/FLEx cases: of same gender, age (± 1 year), spherical equivalent (± 0.5 D). The study included 16 eyes in each group, and we reported both SMILE and LASIK had comparable results in terms of safety, efficacy and predictability, in follow-up of 6 months duration (Table 4.1).

Many other authors reported similar outcomes, still with a disadvantage of slower refractive recovery in SMILE patients, which is currently witnessing significant improvements due to the development of different energy and spot spacing setting. 17,21 Kim et al. reported that age may be a predictor that influenced visual outcome, as outcomes were better in younger patients of his study sample but its effect appeared clinically insignificant.²² SMILE surgery was effective and safe in correcting low-to-moderate astigmatism, and stable refractive outcomes were observed at the long-term follow-up. The preoperative cylinder ranged from -2.75 D to -0.25 D (average of -0.90 ± 0.68 D), and the mean postoperative cylinder values were -0.24 ± 0.29 D, -0.24 ± 0.29 D and -0.20 ± 0.27 D at 1 month, 6 months and 12 months, respectively.²³

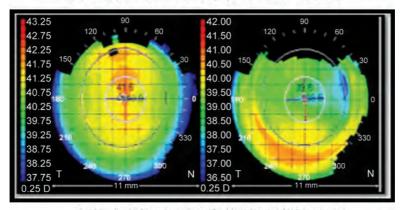
On the other side, topographic changes and aberrometric changes were significantly lower in SMILE patients compared with LASIK patients whether in mild-to-moderate myopia or high myopia as reported by results of our study (Figs. 4.1A and B and 4.2A and B).

ADVANTAGES OF SMILE IN CASES OF DRY EYE AND OCULAR SURFACE DISEASE

The flapless nature of SMILE will preserve the important anterior corneal phase, this will preserve the natural integrity of corneal nerves, which will significantly influence the ocular surface and tear film stability (Fig. 4.3).



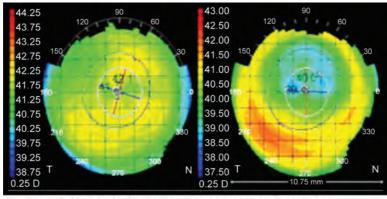
(A) -2.25D: (Left) Preoperative; (Right) After SMILE correction



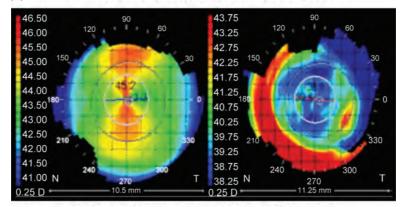
-2.00D: (Left) Preoperative; (Right) After LASIK correction
 Figs. 4.1A and B: Topographical changes in moderate myopia.

SMILE: Small-incision lenticule extraction: LASIK: Laser assisted in situ keratomileusis.

Central corneal sensitivity exhibited a small decrease and a faster recovery after the SMILE procedure compared to FS-LASIK during the first 3 postoperative months. Corneal sensitivity after SMILE and FS-LASIK was similar at 6 months after surgery.²⁴ Qiu et al. in a longitudinal retrospective study studied 97 consecutive patients (194 eyes) who underwent SMILE for myopia. Parameters evaluated included: subjective dry eye symptoms (dryness, foreign body sensation and photophobia), tear film breakup time (TBUT), Schirmer's test without anesthesia, tear meniscus height (TMH) and corneal fluorescein staining. Each parameter was evaluated before, and subsequently at 1 day, 1 week, 1 month and 3 months after surgery. The results showed that compared with preoperative data, dryness was noted to be significantly increased at 1 week and 1 month postoperatively (<0.01). Symptoms of photophobia and foreign body sensation demonstrated significant differences at 1 day and 1 week as compared with preoperative scores respectively (<0.01). These values were decreased at 1 month and 3 months postsurgery (>0.05). Conversely the corneal staining scores were higher than the preoperative data at 1 day, 1 week and 1 month (<0.01), but were close to



-8.00D: (Left) Preoperative; (Right) After SMILE correction (A)



(B) -9.25D: (Left) Preoperative; (Right) After FLEx correction

Figs. 4.2A and B: Topographical changes in high myopia.

SMILE: Small-incision lenticule extraction: FLEx: Femtosecond lenticule extraction.

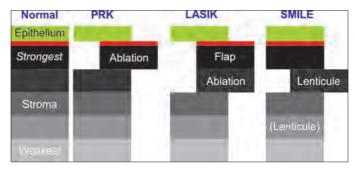


Fig. 4.3: Effect of different refractive procedures on the anterior corneal surface.

PRK: Photorefractive keratectomy; LASIK: Laser assisted in situ keratomileusis; SMILE: Small-incision lenticule extraction.

the preoperative level at 3 months postoperatively. There was a significant decrease in TMH at 1 week and 1 month (<0.01), but the value was close to the preoperative level at 3 months postoperatively (=0.16). The examination outcomes of ST were significantly increased at 1 day then reduced at 1 week

after surgery (<0.01). Each value subsequently returned to the baseline value at 1 month and 3 months (>0.05). TBUT was significantly decreased at all postoperative time points (<0.01). It is reported that SMILE resulted in mild dry eye symptoms, tear film instability and ocular surface damages; however, these complications can recover in a short period of time.²⁵ This was confirmed when compared with FS-LASIK by Li et al. as he reported that SMILE surgeries resulted in a short-term increase in dry eye symptoms, tear film instability and loss of corneal sensitivity. Furthermore, SMILE surgeries have superiority over FS-LASIK in lower risk of postoperative corneal staining and less reduction of corneal sensation.²⁶

TEAR INFLAMMATORY MEDIATORS IN SMILE

In a study by Gao et al., tears were collected and analyzed for interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF- α), nerve growth factor (NGF) and intercellular adhesion molecule-1 (ICAM-1) levels using multiplex magnetic beads. All measurements were preformed preoperatively and 1 day, 1 week, 1 month and 3 months postoperatively. They reported that in the early postoperative period, ReLEx SMILE results in milder ocular surface changes than FS-LASIK. Furthermore, the tear inflammatory mediators IL-6 and NGF may play a crucial role in the ocular surface healing process following ReLEx SMILE and FS-LASIK.²⁷ SMILE induces less keratocyte apoptosis, proliferation and inflammation compared with femtosecond laser LASIK.²⁸

BIOMECHANICAL PROPERTIES OF THE CORNEA IN SMILE

Randleman et al. suggested that the cohesive tensile strength of the stroma is based on how the stromal lamellae are held together, which decreases from anterior to posterior within the central corneal region. They used a mathematical model to predict that the postoperative tensile strength would be higher after SMILE than both LASIK and PRK, given the fact that the strongest anterior lamellar layer remains intact, enabling it to correct higher levels of myopia with a better safety profile. In our investigation, we studied biomechanical corneal properties by comparing targeted versus obtained radius of curvature (Fig. 4.4).

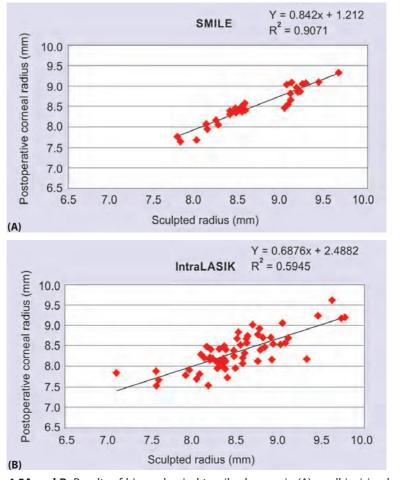
The mean values and standard deviation of the curvature change coefficient are: $[(Paired\ t\text{-}test)\ SMILE: -1.77 \pm 1.72\ (\%)\ ,\ FS\text{-}LASIK: -1.82 \pm 3.76\ (\%)],$ A good correlation for the linear fit: (Pearson Correlation) R = 0.95 for SMILE group; R = 0.85 for FLEx group. There are not statistically significant differences (P > 0.1) between two groups. However, the low-standard deviation of the SMILE group demonstrates a better predictability for this technique (Figs. 4.5A and B).

Other study used Sheimpflug-based noncontact tonometer, concluded that no significant modifications in biomechanical properties were observed

Coefficient of Biomechanical Response: - R_{post}: Post-surgical corneal radius (1 month after) - R_s: Surgical radius sculpted on corneal stroma by laser ablation (calculated) · C characterizes the change in corneal curvature due to biomechanical response of the corneal surface after the flap cut and relocation (LASIK) or lenticule cut and extraction (SMILE and FLEX) R_{post}>R_s Flattening (overcorrection) · Meaning: C>0 C<O R_{post}<R_s Steepening (undercorrection)

Fig. 4. 4: Mathematical model for calculation of corneal tensile properties.

LASIK: Laser assisted in situ keratomileusis; SMILE: Small-incision lenticule extraction; FLEx: Femtosecond lenticule extraction.



Figs. 4.5A and B: Results of biomechanical tensile changes in (A) small-incision lenticule extraction (SMILE) and (B) femtosecond-assisted LASIK (FS-LASIK).

after SMILE so this procedure could induce only minimal transient alterations of corneal biomechanics.²⁹ When correlating corneal biomechanical properties with the induced high-order aberrations. The preoperative chronic renal failure (CRF) was significantly correlated with the induced 3rd-6th-order higher-order aberrations (HOAs) and spherical aberration of the anterior surface and the total cornea after SMILE and FS-LASIK surgeries (P < 0.05), postoperatively. The CRF was significantly correlated with the induced vertical coma of the anterior and posterior surfaces and the total cornea after SMILE surgery (P < 0.05). There was a significant correlation between the CRF and the induced posterior corneal horizontal coma after FS-LASIK surgery (P = 0.013). This indicates that corneal biomechanics affect the surgically induced corneal HOAs after SMILE and FS-LASIK surgery, which may be meaningful for screening the patients preoperatively and optimizing the visual qualities postoperatively.³⁰ On the other hand in high-myopic patients, FS-LASIK demonstrated a greater increase in posterior corneal elevation than SMILE only at 12 months as well as a greater reduction of CRF than SMILE, but there were no significant difference between the two groups over time.31

CONFOCAL MICROSCOPY IN SMILE

In confocal microscopy study, the mean backscattered light intensity (LI) at all measured depths and the maximum backscattered LI were higher in the SMILE group than the FS-LASIK group at all postoperative visits. LI differences at 1-week, 1-month and 3-month visits were statistically significant (P < 0.05). LI differences at 6 months were not statistically significant. There was no difference in the number of refractive particles at the flap interface between the groups at any visit. It may be concluded that SMILE results in increased backscattered LI in the anterior stroma when compared with FS-LASIK.³² The decrease in subbasal nerve fiber density was less severe in the SMILE group than the FS-LASIK group in the first 3 months following the surgery. The subbasal nerve density was correlated with central corneal sensitivity.³³

CORNEAL CAP PRECISION IN SMILE

There is a significant change in corneal deformation parameters following SMILE procedure. The changes may be caused predominantly by stromal lenticule extraction, while lenticule creation with femtosecond laser may not have an obvious effect on corneal deformation properties.³⁴ A study conducted investigating the morphology of SMILE cap using anterior segment optical coherence tomography reported that corneal caps of SMILE are predictable with good reproducibility, regularity and uniformity. Cap morphology might have a mild effect on refractive outcomes in the early stage, 35 and the predictability of cap thickness in SMILE surgery does not differ from the FS-LASIK flaps created using the same femtosecond laser platform.³⁶

ENHANCEMENTS AFTER SMILE SURGERY

One of the most important challenges facing SMILE technology is the enhancement methodology in postoperative refractive residuals. In a study enrolled 28 eyes of which 27 underwent the VisuMax[®] Circle pattern procedure for refractive enhancement, and 1 for residual lenticule extraction. In all cases (28 eyes), the lifting of the flap was possible, as planned. In all cases of refractive enhancement (27 eyes) by LASIK, the exposure of the stromal bed was sufficient for the necessary excimer laser ablation. No eyes lost two or more Snellen lines of corrected distance visual acuity (CDVA) and no procedure or flap related complications or serious adverse events occurred. This initial case series demonstrates that VisuMax[®] Circle pattern is efficacious and a suitable method to create a corneal flap for enhancement, following SMILE.37

INNOVATIVE INDICATIONS OF LASER LENTICULAR EXTRACTION

- The technique of cryopreservation of corneal lenticules extracted after small incision ReLEx SMILE and initial results of femtosecond laser intra*stromal lenticular implantation for hyperopia*: The technique seems to be a safe method of long-term storage of refractive lenticules extracted after ReLEx SMILE for use in allogeneic human subjects. It may potentially be a safe and effective alternative to excimer laser ablation for hyperopia because of the low risks of regression, haze, flap-related complications, postoperative dry eye and HOAs.³⁸
- ReLEx SMILE Xtra, SMILE with accelerated cross-linking; in patients with thin corneas and borderline topography: Based on the initial clinical outcome it appears that SMILE Xtra may be a safe and feasible modality to prevent corneal ectasia in susceptible individuals.³⁹ Also this has been investigated in forme fruste keratoconus and irregular corneas, combined SMILE and intrastromal corneal collagen crosslinking are a promising treatment option for patients for whom conventional laser refractive surgery is contraindicated.40
- Finally, a feasibility study reported that LASIK can be performed following lenticule reimplantation to create presbyopic monovision. The tissue responses elicited after performing LASIK on corneas that have undergone SMILE and subsequent lenticule reimplantation are similar to primary procedure.41

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Gems of Ophthalmology CORNEA & SCLERA

Salient Features

- · Corneal topography and corneal confocal microscopy
- LASIK, complications of LASIK and SMILE vs LASIK
- · Fungal, Acanthamoeba and herpetic keratitis
- · Corneal dystrophies and keratoconus
- · Advances in keratoplasty and keratoprosthesis
- · Dry eye and ocular surface reconstruction
- · Corneal changes in contact lens users
- · Episcleritis and scleritis.

HV Nema Ms has a distinguished academic career and is well-known for teaching, research and publications. He has served as a Consultant Editor/Advisory Editor to Indian Journal of Ophthalmology, Afro–Asian Journal of Ophthalmology and Indian Journal of Optometry. He has published more than 6 dozen papers in the national and international journals. He is an established author in the field of ophthalmology. *Ophthalmic Syndromes*



(Butterworth, London, UK, 1973) and *Textbook of Ophthalmology* (6th ed. 2012, Jaypee Brothers Medical Publishers, New Delhi, India) are some of his popular books. He has edited 13 volumes of *Recent Advances in Ophthalmology*, 3 editions of *Diagnostic Procedures in Ophthalmology* and *Eye in Systemic Disorders* (Wiley India) which were well-received by readers and favorably reviewed in Indian and international journals. He has delivered guest-lectures in many universities.

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