Review Article

Refractive lenticule extraction small incision lenticule extraction: A new refractive surgery paradigm

Sri Ganesh, Sheetal Brar, Raghavender Reddy Arra

Small incision lenticule extraction (SMILE), a variant of refractive lenticule extraction technology is becoming increasingly popular, as a flapless and minimally invasive form of laser vision correction (LVC) for the treatment of myopia and myopic astigmatism. This review aims at summarizing the principles, surgical technique, and clinical outcomes in terms of visual and refractive results, safety, efficacy, postoperative dry eye, aberrations, and biomechanics of SMILE and its comparison with other conventional techniques of LVC, such as laser *in situ* keratomileusis (LASIK) and photorefractive keratectomy (PRK). Recent advancements in the laser frequency and energy delivery patterns, instrumentation, and surgical techniques have shown significant improvement in the visual recovery and outcomes after SMILE, compared to the initial results published by Sekundo and Shah *et al*. Most of the recently published literature on long-term outcomes of SMILE shows excellent stability of the procedure, especially for higher myopia. In terms of the postoperative dry eye, SMILE shows a clear advantage over LASIK as numerous studies have shown significant differences about the Schirmer's, Tear film break up time, corneal sensitivity, and corneal nerve regeneration to be better following SMILE compared to LASIK. There is some evidence that since the Bowman's membrane (BM) and the anterior lamellae remain intact after SMILE, this may be a potential advantage for corneal biomechanics over LASIK and PRK where the BM is either severed or ablated, respectively, however, the data on biomechanics are inconclusive at present. Overall, this procedure has proved to be promising, delivering equivalent, or better visual and refractive results to LASIK and providing clear advantage in terms of being a flapless, minimally invasive procedure with minimal pain and postoperative discomfort thus offering high patient satisfaction.

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Refractive surgery through laser vision correction (LVC) has evolved significantly within the past few decades. From the first generation techniques involving surface ablation to Laser *in situ* keratomileusis (LASIK), refractive surgery has now become intrastromal with the advent of refractive lenticule extraction (ReLEx) technology.[1] This procedure when performed through a small incision (2–4 mm) was described as small incision lenticule extraction (SMILE), which is essentially a bladeless, flapless and minimally invasive technique compared to LASIK, where a corneal flap is created using either a blade or a femtolaser.[2] In this review, we aim at providing an overview on SMILE, discussing the concepts, techniques, outcomes, recent advances, and future considerations of this relatively newer technology, which has now become an acceptable modality of myopia correction.

Historical Background

It was way back in 1999 when a precursor to modern ReLEx was first described, using a picosecond laser to carve an intrastromal lenticule that could be manually removed after lifting the flap.[3,4] Later in 1998 and 2003, femtosecond lasers were used to perform intrastromal lenticule creation in rabbit and partially sighted human eyes, respectively, which improved the precision of lenticule creation, however, these initial studies were not followed up with further clinical trials.[5,6]

In 2007, following the introduction of the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany),[7] the femtosecond lenticule extraction (FLEx) procedure was reintroduced, which enabled the removal of an intrastromal lenticule from under a flap. The initial 6-month results of the first 10 fully seeing eyes treated were published in 2008[1] and subsequently further studies[8,9] showed that the refractive results were comparable to those observed in LASIK. The next stage following FLEx was a new procedure called SMILE. This procedure involves the creation of a small 2–4 mm incision, through which a dissector can be introduced to separate the lenticular interfaces and allows the lenticule to be removed through the same incision [Fig. 1]. In this way, the need for creation of a large corneal flap is eliminated. Following the results of the initial prospective trials,[2,10] there is now a large body of publications about the SMILE procedure.

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Principles and Surgical Technique

To accomplish the SMILE procedure, first the patient's eye needs to be docked to the curved contact glass of the femtosecond laser. As the cornea touches the contact glass, a meniscus of tear film appears, and the patient is able to see the fixation target which appears as a green flashing light, clearly because the vergence of the fixation beam is focused according to the patient's refraction.[11]

At this point, the patient is instructed to look directly at the green light which essentially infers that the centration in SMILE is patient controlled and is fixed on the visual axis of the eye.[12] Once the centration is confirmed, the suction is activated to fixate the eye in this position. After adequate suction is established, the patient is instructed to hold still, and not to follow the green light if it shifts or to search for it when it disappears. The centration can also be confirmed by the surgeon using the infrared light, after which the laser is fired. The patient is able to maintain fixation once the suction is activated, and during initial stage of laser delivery due to a much lower intraocular pressure (IOP), as compared to other femtolaser systems.[13] The lower IOP is mainly attributed to the corneal suction and curved contact glass present in the VisuMax femtosecond laser system.

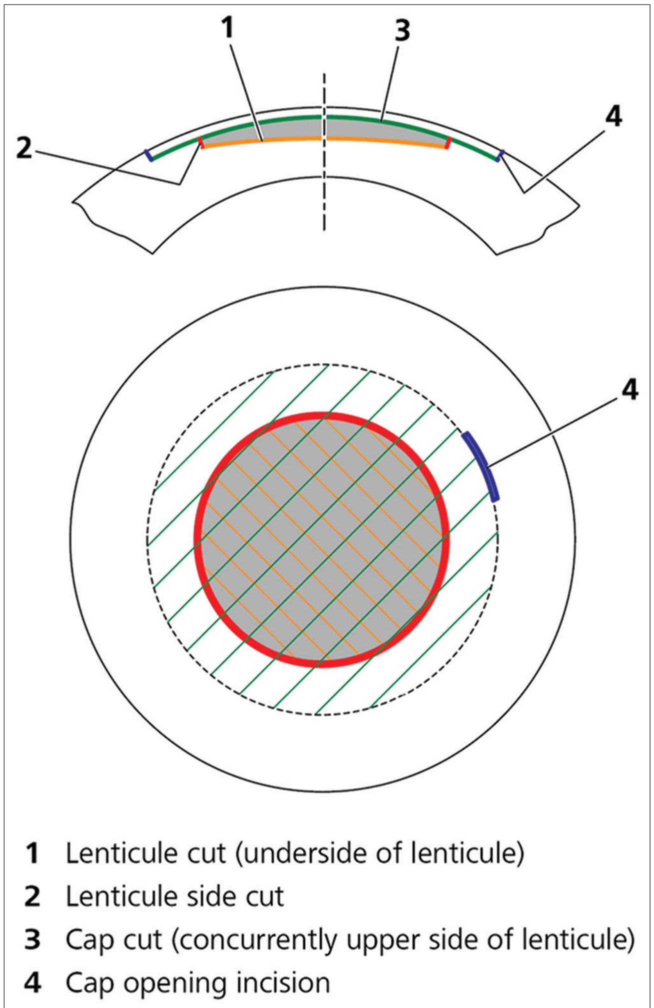

Figure 1: The lenticule cut (1) is performed (the underside of the lenticule), followed by the lenticule sidecuts (2). Next, the cap interface (3) is created (the upper side of the lenticule), and finally a 2–3 mm small incision (4) is created superotemporally. The lenticule interfaces are dissected using a flap separator and the lenticule is extracted manually, all via the small incision (Reproduced after permission from Prof Dan Reinstein)

The laser first creates the lower interface of the intrastromal lenticule in a spiral in pattern (out-to-in direction), followed by a 360° sidecut, followed by creation of the upper interface in a spiral out pattern (in-to-out direction), known as the cap, and finally, a 2–4 mm access incision (usually superior or superotemporal) that connects the cap interface to the corneal surface [Fig. 1]. Total suction time is approximately 25–35 s (depending on the mode used) and is independent of refractive error treated.

For removal of the lenticule, the small incision is opened and the upper and lower interfaces of the lenticule are identified to define the tissue planes. The upper interface is usually separated first using a blunt dissector, the movement of the instrument being in a windshield wiper like fashion with the fulcrum at the center of the incision. Various instruments have been developed for interface separation, the recent designs having a blunt circular tip.[14] The lower layer is then dissected in a similar fashion. During separation, the eye may be stabilized with a fixation forceps to have better control while separating the surgical planes. Once both interfaces are separated, and the lenticule is free, it is grasped with a pair of micro-forceps and extracted or can be directly scooped out from within the pocket using the latest versions of the lenticule separating dissectors. At the end of the procedure, some surgeons prefer to flush/wash the interface with saline while others do not perform this step for the concerns of corneal hydration and introduction of infection. In our experience, minimal washing of the interface with balanced salt solution leads to better visual outcomes on postoperative day 1, possibly due to clearing of the Bowman's membrane folds which occur due to sudden collapse of anterior corneal layers and surgical manipulations. This was observed in a contralateral eye study, where one eye received interface wash, while the fellow eye interface was not washed after extraction of the lenticule. Although the visual and refractive results were comparable at 2 weeks, the 1st day uncorrected distance visual acuity (UDVA) and contrast sensitivity was significantly better in the eyes receiving the wash versus the eyes which did not receive the wash.[15]

We recently described a new method of lenticule management called "lenticuloschisis," a no-dissection technique in which the lenticule is gently peeled off the stroma in a rhexis like pattern without performing actual dissection of the planes using any dissector.[16] The technique may offer better quality of vision immediate postoperative due to minimum manipulation of the tissues compared to the conventional dissection technique, as the interface seen on first postoperative day showed less roughness, irregularity compared to the dissection technique [Fig. 2]. However, we emphasized that the prerequisites such as optimized energy levels, ideal bubble pattern, myopia >3D and good experience in conventional technique of lenticule dissection must be fulfilled before attempting this technique.

When planning the treatment, the following parameters need to be selected by the surgeon: cap thickness, cap diameter, cap side cut angle, refractive correction, lenticule

Table 1: Visual and refractive outcomes, safety and predictability of some recent studies performed on Small Incision Lenticule Extraction

Study	Number of eyes and follow-up	Spherical equivalent		Eyes within ±0.50 D (%)	Postoperative UDVA (LogMAR)	UDVA 20/20 or better postoperative (%)	Loss of 2 lines in CDVA (%)
		Preoperative (D)	Postoperative (D)				
Sekundo *et al.*[2]	91 6 months	−4.75±1.56	−0.01±0.49	80	-	84	1.1
Shah *et al.*[10]	51 6 months	−4.87±2.16	+0.03±0.30	91	-	67	0.0
Hjortdal *et al.*[19]	670 3 months	−7.19±1.30	−0.25±0.44	80	-	61	2.4
Kamiya *et al.*[18]	26 6 months	−4.21±1.63	+0.01	100	−0.15±0.10	96	0.0
Ganesh and Gupta[20]	50 3 months	−4.95±2.09	−0.14±0.28	-	-	96	0.0
Ağca *et al.*[21]	40 1 year	−4.03±1.61	−0.33±0.25	95	0.02±0.06	65	0.0
Pedersen *et al.*[22]	87 3 years	−7.30±1.40	−0.40±0.60	78	0.03±0.19	72	0.0
Blum *et al.*[23]	56 5 years	Range (−4.89-−4.97)	−0.375	48.2	0.01	-	0.0
Han *et al.*[24]	47 4 years	−6.30±1.47	−0.09±0.39	89	−0.04±0.06	92	0.0
Yıldırım *et al.*[25]	45 2 years	−7.10±0.95	−0.30±0.50	92	0.03±0.07	86	0.0

UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, LogMAR: Logarithm of the minimum angle of resolution

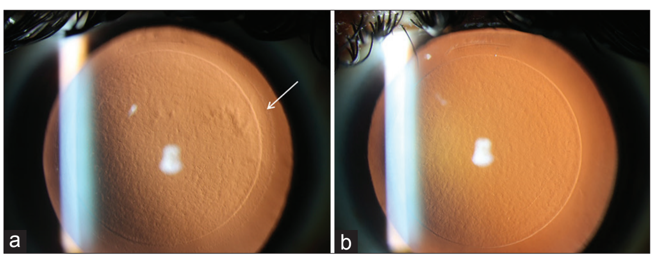

Figure 2: Clinical pictures of corneal interface in retroillumination after dilatation, on 1st day postoperation in a patient who underwent small incision lenticule extraction with conventional dissection technique in the right eye (a) and lenticuloschisis (b) in the contralateral eye by the same surgeon in the same sitting for similar degree of myopia (−4.00 D both eyes). The corneal interface showed more roughness in the eye with dissection and showed prominence of the cap edge (white arrow) (a), whereas it was smoother in the lenticuloschisis eye (b). Patient also reported better clarity with the eye with lenticuloschisis. (Reproduced after permission from Journal of Refractive Surgery)

diameter (optical zone), lenticule side cut angle, minimum lenticule thickness, and the fluence levels required to accomplish each step of the lenticule creation. The treatment planning would depend on the age, refractive error, scotopic pupil size, and the residual bed thickness and does not differ from the planning in LASIK.

Visual and Refractive Outcomes

Currently, ReLEx SMILE corrects myopia from up to −10.00 D, myopic astigmatism up to −5.00 D and a spherical equivalent (SE) of up to −12.5D.[17,18] Till date, sufficient data have been published, reporting the short- and long-term visual and refractive outcomes of SMILE across all degrees of myopia. Some of the major studies reporting these outcomes have been summarized in Table 1.[2,10,18-25]

Recently published long-term studies support SMILE to be an effective, stable, and safe procedure for the treatment of myopia and myopic astigmatism. Han *et al*. investigated 4 years refractive outcomes, wavefront aberrations and quality of life after SMILE for moderate-to-high myopia (mean SE - 6.30 ± 1.47 D) and concluded that SMILE provides a predictable and stable correction of moderate-to-high myopia, as no significant changes of SE occurred among postoperative follow-ups at months 1, 3, 6 and years 1, 2, 4.[24] Similarly, Blum *et al*. in their study, did not find any significant change to the 6-month data, 5-year postoperatively. Thirty-two of the 56 eyes had gained 1–2 Snellen lines and no eye lost 2 or more lines. A mild regression of 0.48 D was observed over a period of 5 years.[23] This was also observed by Wu *et al*., who compared the stability of SMILE in high myopia (SE >6D) versus low-to-moderate myopia (SE <6D), and found significant regression in the high myopia group.[26] This may be attributed either to the epithelial changes or progression of myopia in high myopic individuals. Epithelial changes in particular may contribute to significant changes in refraction, as reported by our group. We studied the behavior of epithelium after SMILE in low, moderate, and high myopia groups and noted statistically significant epithelial hypertrophy in all groups at 3 months, which was also clinically significant in high myopia group.[27] Hence, it was recommended that surgeons specific nomograms must be derived based on the initial refractive outcomes to compensate for potential regression, especially in highly myopic individuals.

There are numerous studies comparing the results of SMILE with LASIK procedure.[28-31] Zhang *et al*. performed a systematic review and meta-analysis of 11 studies comparing SMILE with LASIK and found no significant difference between the two procedures in terms of final refractive SE, the proportion of eyes losing one or more lines of corrected distance visual acuity (CDVA), or the proportion of eyes achieving an UDVA of 20/20 or better and percentage of eyes within ± 1.00 diopter of the target values.[32] A recent study compared the 2-year visual and refractive outcomes between SMILE and wavefront-guided LASIK. The accuracy was significantly better in SMILE group with 100% eyes achieving postoperative SE within ± 0.5D versus 73% eyes in the LASIK group. Moreover, a significant correlation was seen between myopic regression and the changes in the keratometric readings from 3 months to 2 years after LASIK, but not after SMILE, thus concluding that SMILE offers better refractive outcomes than wavefront-guided LASIK during a 2-year follow-up for the correction of myopia and myopic astigmatism.[29]

Studies comparing the outcomes of SMILE, with another flapless procedure photorefractive keratectomy (PRK) or surface ablation,[33,34] have also shown comparable results with both procedures in terms of visual outcomes and refractive predictability for low myopia. However, in our comparison study, SMILE showed better safety compared to PRK group, in which 4 eyes lost 1 line of CDVA due to haze and better patient satisfaction due to minimal postoperative discomfort and significantly less higher order aberration (HOA) induction resulting in superior quality of vision. Our results were better compared to Yildrim *et al*. for low myopia, possibly due to 10% nomogram application, use of large optical zones and increase in peripheral lenticule thickness to facilitate its safe extraction.[34]

The results on efficacy of SMILE shown above depend significantly on the precision of the lenticule creation by the femtosecond laser. Reinstein *et al*. used VHF digital ultrasound to measure the accuracy of the thickness of the SMILE lenticule[35] and found that the readout central lenticule depth was 8.2 μm thicker on average than the Artemis measured stromal thickness change. This difference was partially explained by alignment errors between the pre- and postoperative scans and partly by central stromal expansion caused by biomechanical changes occurring after SMILE.[36,37]

Safety of Small Incision Lenticule Extraction

SMILE is generally a safe procedure, the risk of occurrence of visually significant complications being extremely low in experienced hands. However, some complications may occur especially during the learning phase of the procedure. Ivarsen *et al*.[38] in a large population analysis of 1800 eyes, reported the incidence of intra- and post-operative complications following SMILE. During the procedure, a small percentage of eyes had epithelial abrasions (6%), small incision tears (1.8%), difficult lenticule extraction (1.9%), cap perforation (0.22%), and major tear (0.06%); however, none of these patients suffered from late visual consequences. Incidence of intraoperative suction loss was 0.8% (14 eyes). Postoperative complications included trace haze (8%), interface inflammation secondary to central abrasion (0.3%), and minor interface infiltrates (0.3%), which affected CDVA in only one case at 3 months. Irregular corneal topography reducing CDVA or ghost images at 3 months, occurred in 1% of eyes (18 eyes), requiring topography-guided custom ablation,[39] which was effective in improving irregular astigmatism.

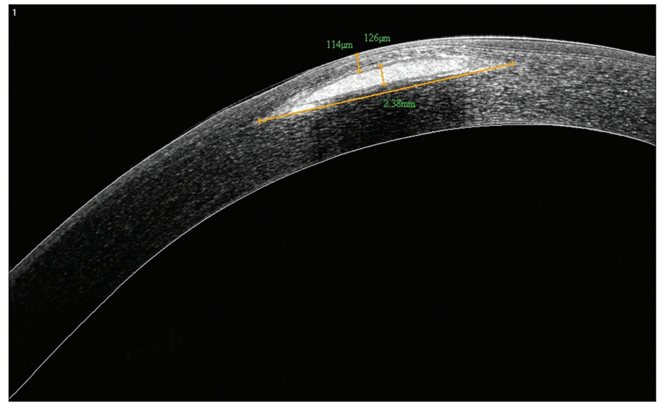

Figure 3: Anterior segment Optical Coherence Tomography of an eye showing retained lenticular fragment following a failed primary small incision lenticule extraction procedure

Another complication unique to SMILE is a lenticule remnant being left in the interface due to inadvertent tearing of the lenticule causing irregular astigmatism [Fig. 3].[40] Transepithelial phototherapeutic keratectomy (PTK) was shown to be an effective treatment option for correcting irregular astigmatism;[41] however, in our opinion, such cases should be reevaluated using topography, anterior segment optical coherence tomography (AS-OCT) and clinical photography to assess the location of the lenticule remnant. Surgical exploration of the corneal pocket for removal of the remnants under slit illumination of the VisuMax laser may be a better option to restore the vision and a topography-guided PRK/PTK procedure may then be unnecessary. In our experience, it may be possible to extract such retained pieces of lenticules as late as 9 months of the failed primary SMILE procedure.

Small Incision Lenticule Extraction and Ectasia

Till date, of the approximately 750,000 SMILE procedures performed worldwide, only 7 eyes of ectasia have been reported.[42] However, on detailed analysis, it was found that these eyes which developed keratectasia were either diagnosed or undiagnosed cases forme fruste keratoconus[42-45] or had an unreliable preoperative topography scan.[46] Although data support that SMILE may cause less corneal weakening compared to LASIK, one should be cautious while planning SMILE, especially in borderline cases, until there is conclusive evidence to prove the biomechanical advantage of SMILE over LASIK.

Small Incision Lenticule Extraction and Astigmatism

Chernyak in their study evaluating the cyclotorsional eye motion between wavefront measurement and excimer laser refractive surgery found that a rotation of 5° or more can induce significant undercorrection of astigmatism, which was more noticeable as the degree of astigmatism increased.[47]

In ReLEx SMILE procedure, the potential sources of torsional errors could be static cyclotorsion due to change in position from upright to supine, application of suction, speculum insertion, and squeezing of the eye during docking, and hence, it may be important to compensate for these cyclotorsional errors especially in higher degrees of astigmatism. Studies aiming at evaluating the outcomes of astigmatism correction comparing LASIK with SMILE showed superior outcomes with LASIK.[28,48,49] Furthermore, studies by Kunert *et al*. and Sekundo *et al*. showed a significant undercorrection of astigmatism with both FLEx and SMILE procedures respectively.[2,50] The probable explanation of these results could be the lack of an active eye-tracking software in the VisuMax femto laser system. Since no definite method of cyclotorsion compensation exists for ReLEX SMILE, this may also be considered a potential limitation of this procedure at present.

Previous studies on LASIK suggested that manual markings were equally safe and effective as the automated dynamic eye trackers for cyclotorsion compensation during the surgery.[51] Based on these observations, our group attempted to investigate the feasibility of manual compensation of the intraoperative torsional error using limbal markings as a guide, in patients with significant myopic astigmatism undergoing ReLEx SMILE. Fig. 4 shows the method of intraoperative cyclotorsion compensation followed in our study.

In our prospective study, manual compensation of cyclotorsion error resulted in favorable outcomes in patients with myopic astigmatism treated with ReLEx SMILE. Results were analyzed by categorizing the data into two groups of low (−0.75–−1.50D) and high (>−1.51D) astigmatism. It was observed that the predictability and accuracy of cylinder correction were better in eyes with high astigmatism compared to low astigmatism.[52] Based on the results of this study,

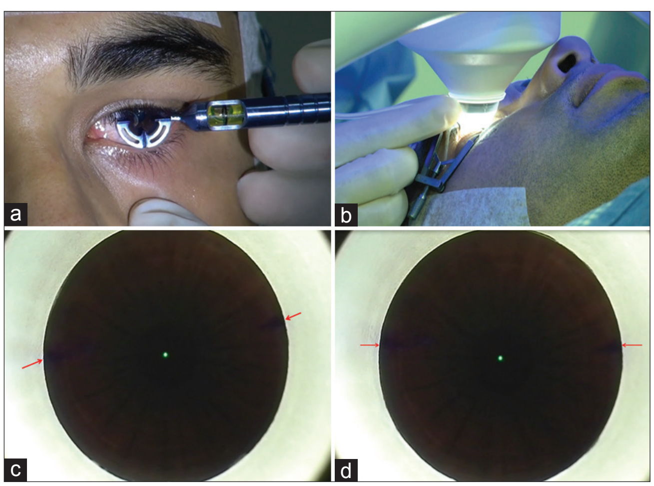

Figure 4: (a) Preoperative limbal marking with the Ganesh bubble marker (Epsilon Surgical, Chino, CA, USA). This instrument uses three marks on the limbus at 0°, 90°, and 180°, extending 2 mm toward the center of the cornea, which are easy to visualize while the eye is being docked. (b) Method of manual cyclotorsion compensation by a gentle rotation of the cone while holding the same at the attachment of the tube to the cone. (c) Position of the limbal marks (red arrows) under suction "ON" condition without cyclotorsion compensation before starting the laser, showing approximately 12° of cyclotorsion. (d) Final position of the limbal marks after manual compensation of the cyclotorsion error (alignment with the horizontal axis of the eyepiece reticule). Delivery of the laser follows this (reproduced after permission from Journal of Refractive Surgery)

preoperative limbal marking for all eyes with astigmatism of 1.5 D or more and manual compensation of cyclotorsion was recommended.

Visual Recovery after Small Incision Lenticule Extraction

Visual recovery following SMILE has been shown to be relatively slower when compared to LASIK. Agca *et al*. evaluated the light intensity of the corneal backscatter in the anterior stroma following SMILE and LASIK using *in vivo* confocal microscopy.[53] They found the backscattered light intensity to be higher for SMILE than LASIK in the first 3 months after surgery due to the extracellular matrix and activated keratocytes and this was linked to the slower visual recovery observed after SMILE. The authors postulated possible causes as the greater femtosecond energy delivered to the cornea in SMILE, due to two femtosecond lamellar cut surfaces (as opposed to one surface by an excimer laser), and the increased surgical maneuvers required in SMILE.

Yao *et al*. described microdistortions in Bowman's layer after SMILE identified by OCT, but with no clinically significant corneal striae at the slit lamp.[54] However, these microdistortions did not have an impact on visual acuity or quality in the long term. Central microdistortions can be minimized by distending the cap immediately at the end of the procedure as described by Dan *et al*.[11] We, however, postulate that it may also be the irregularity or roughness of the interface, resulting in the relatively slower visual recovery after SMILE. We conducted a prospective study to visualize interface healing after SMILE using dilated clinical photography on postoperative day 1, 2 weeks, and 3 months, and observed that the interface was visibly rough immediately post-SMILE, and took 3 months or longer for complete clarity. These changes in the interface were positively correlated with UDVA, contrast sensitivity and aberrations up to the last follow-up (unpublished data).

Small Incision Lenticule Extraction and Higher Order Aberrations

Few studies have compared the induction of HOAs between SMILE and LASIK.[20,21,55] Ağca *et al*., using a 6-mm diameter analysis zone, found the induction of total higher-order root mean square (increase by 0.14 µm) and spherical aberration (increase by 0.07 µm, OSA notation) to be similar between SMILE and LASIK.[21] We also observed an increase in the HOAs after both SMILE and LASIK, however, the HOAs were significantly lower at 3 months in SMILE group.[20] The possible reason for lower induced aberrations could be an optimized aspheric lenticule profile and absence of fluence projection errors in the periphery in SMILE, as compared to LASIK or PRK where there is peripheral loss of energy due to cosine effect.[33]

Small Incision Lenticule Extraction and Postoperative Dry Eye

There are numerous studies published which demonstrate a clear advantage of SMILE over LASIK for postoperative dry eye as the corneal nerves remain largely preserved in SMILE except for the area of small incision. Table 2 shows

Table 2: Summary of major meta-analysis of Small Incision Lenticule Extraction versus laser *in situ* keratomilieusis and their outcomes

Author (year)	Number of studies compared	Follow-up visits	Procedures compared and number of eyes	Outcomes compared at various follow-ups	Results
Kobashi *et al*. (2017)[56]	5 prospective	1 and 6 months	SMILE FS-LASIK	Schirmer's test score	No significant difference
				TBUT	Significantly higher in SMILE
				OSDI score	Significantly lower in SMILE
				Tear osmolarity	No significant difference found between groups
				Corneal sensitivity	Significantly higher in SMILE
				Corneal sub-basal nerve density	Significantly higher in SMILE
Shen *et al*. (2016)[57]	5 prospective 1 RCT	1, 3 and 6 months	SMILE (291) FS-LASIK (277)	Schirmer's 1 test	No significant difference at any time point
				Tear film osmolarity	No significant difference at any time point
				TBUT	Significantly worse in FS-LASIK at all-time points
				OSDI score	Significantly worse in FS-LASIK at all-time points
He *et al*. (2015)[58]	5 studies	1 week, 1, 3 and 6 months	SMILE (174) FS-LASIK (189)	Central corneal sensitivity	Significantly worse at 1 week, 1 and 3 months in FS-LASIK group No significant difference at 6 months
Cai *et al*. (2017)[30]	8 studies	1 week, 1 and 3 months	SMILE (386) FS-LASIK (386)	OSDI score	Significantly lower in SMILE
				TBUT	Significantly better in SMILE
				Schirmer's test	No significant difference at any time point
				Corneal sensitivity	Significantly higher in SMILE at 1 and 3 months, no difference at 6 months
Shen *et al*. (2016)[59]	9 prospective 3 RCT	3 and 6 months	SMILE (567) FS-LASIK (509)	OSDI score	Significantly impaired in FS-LASIK
				Corneal sensitivity	Significantly higher in SMILE

SMILE: Small Incision Lenticule Extraction, FS-LASIK: Femtosecond assisted laser *in situ* keratomilieusis, RCT: Randomised control trial, TBUT: Tear film break-up time, OSDI: Ocular surface disease index score

the summary of important meta-analysis studies[30,56-59] comparing ocular dryness parameters between SMILE and LASIK. The study comparing SMILE with LASIK demonstrated significantly high tear osmolarity in LASIK group at 3 months compared to SMILE.[20] Furthermore, other dry eye parameters such as the tear film break-up time, Schirmers 1 and 2 were significantly worse in LASIK group suggesting better tear film and ocular surface health following SMILE. In the study by Reinstein *et al*. including 156 eyes, corneal sensation was reduced in the early postoperative period after SMILE, but recovered to baseline in 76% of eyes by 3 months and in 89% of eyes by 6 months.[60] Demirok *et al*. performed a contralateral eye study comparing central corneal sensation after LASIK and SMILE found that the mean central corneal sensation was reduced after both SMILE and LASIK at 1 week, 1 month, and 3 months, however, it was statistically significantly higher in the SMILE group at all-time points.[61]

Li *et al*. found that the decrease in subbasal nerve fiber density was less severe in the first 3 months after SMILE than after LASIK.[62] Vestergaard *et al*. also demonstrated that the decrease in corneal nerves was greater after LASIK compared with SMILE at 6 months.[63]

The other factor that explains some of the variation in results is the cap thickness that was used in the different studies; thinner cap thicknesses (100–110 μm) will create lenticule more anteriorly and so would be expected to have a greater impact on the subbasal corneal nerve plexus than using thicker caps (135 μm and above).[11]

Small Incision Lenticule Extraction and Corneal Biomechanics

In 2008, Randleman *et al*. measured the tensile strength of strips of stromal lamellae cut from different depths within the cornea and found a strong negative correlation between stromal depth and tensile strength. They observed that the anterior 40% of the central corneal stroma was the strongest region of the cornea, whereas the posterior 60% of the stroma was at least 50% weaker.[64] The absence of a flap in SMILE, and the fact that the anterior-most stromal lamellae remain intact after the procedure (except for the region of the small

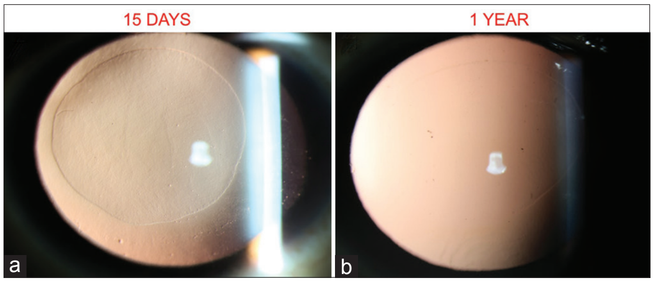

Figure 5: Clinical Photographs of an eye at 15 days (a) and 1 year (b) following FILI for + 4.5 D of hyperopia showing well centered and clear lenticule at the last follow-up

incision), in contrast to both LASIK and PRK, where the anterior stromal lamellae are severed by the excimer laser ablation and additionally by flap creation in LASIK, may indirectly suggest that SMILE must leave the cornea with greater biomechanical strength than both LASIK and PRK. Reinstein *et al*. have suggested that the actual residual stromal thickness in SMILE should be calculated as the stromal thickness below the posterior lenticule interface plus the stromal component of the overlying cap (between the anterior lenticule interface and the epithelium) since the anterior stromal lamellae have not been cut.[11] Some studies have evaluated corneal biomechanics after SMILE and compared them with LASIK and PRK.[65-69] Wang *et al*., when comparing SMILE with LASIK for myopia <−6.00 D, using the ocular response analyzer (ORA) observed that the corneal hysteresis, corneal resistance factor, p1area, and p2area decrease was less after SMILE.[65] In another study, they found that changes in the cornea's viscoelastic properties were less after lenticule extraction than after LASIK.[66] Similar results were observed when Chen *et al*. (2016) and Dou *et al*. compared the biomechanical effects of SMILE and LASEK, and found that both procedures alter corneal biomechanical strength postoperatively. However, the changes induced by SMILE were more predictable and SMILE had less effect on corneal biomechanics than LASEK, possibly due to preservation of the stiffer anterior stroma.[67,68] On the contrary, Kamiya *et al*. did not find statistically significant differences between the biomechanical changes between SMILE and LASIK procedures at any time postoperative using ORA, concluding that the presence or absence of flap lifting does not significantly affect biomechanical parameters.[69] In view of these conflicting results and the absence of an ideal tool to measure corneal biomechanics, it appears that data are still inconclusive to establish a definite biomechanical advantage of SMILE over excimer-based treatments at the moment.

Retreatment Options

There are a number of different options for performing retreatments after SMILE, the decision largely depends on the preference of the surgeon. PRK as a retreatment option is simple to perform, however, theoretically may be associated with increased risk of haze. Recently, Siedlecki and coworkers in their retrospective study of 1,963 SMILE procedures, where they enhanced 43 eyes (2.2%) with surface ablation along with the intraoperative application of mitomycin C, concluded that this modality seems to be a safe and effective method of secondary enhancement after SMILE. However, due to a usually low residual myopia, the aspherically optimized profile (ASA) profile was not recommended in these cases as it may lead to overcorrection.[70]

If a thin cap thickness (100–110 μm) had been used, then a femtosecond laser can be used to create a side cut only to convert the cap into a flap, although this limits the optical zone that can be used. The VisuMax laser also offers a special software referred to as "Circle software" to convert the cap into a flap with a larger diameter than the original cap.[71] If the cap thickness was thicker, then a thin flap LASIK procedure can be performed. The limiting factor for this option is whether a new LASIK interface can be safely created (a) without crossing the existing cap interface and (b) avoiding the creation of a cryptic buttonhole by the interface crossing into the epithelium (particularly as the epithelium will have thickened after the SMILE procedure). Ideally, a direct measurement of the existing cap interface and epithelial thickness must be performed before the retreatment using an AS-OCT or VHF ultrasound.[11] Recently, Donate and Thaëron showed the feasibility of performing another SMILE procedure below the existing interface.[72]

Newer Applications of Small Incision Lenticule Extraction

Small incision lenticule extraction XTRA

Recently in 2015, we published 1 year outcomes of SMILE XTRA technique, in which accelerated cross-linking is combined with SMILE for individuals with thinner corneas, borderline topography, and higher refractive errors.[73] In this technique, following the removal of lenticule, 0.25% riboflavin in saline is injected into the interface and allowed to diffuse for 60 s. Finally, the eye is exposed to UV-A radiation of 45 mW/cm^2 for 75 s through the cap. Total energy delivered is 3.4 J/cm^2. At the end of 1 year, mean SE was −0.24 ± 0.18 D and mean UDVA was 20/25 or better in all eyes. No eyes lost lines of (CDVA) and there were no complications such as haze, keratitis, ectasia, or regression. Based on the initial experience, it appears that SMILE Xtra may be a safe and feasible modality to prevent corneal ectasia in susceptible individuals. However, long-term effects on corneal stabilization following this procedure still need to be evaluated through better tools to measure corneal biomechanics.

Tissue Addition Procedures using Small Incision Lenticule Extraction Lenticules

The availability of a corneal lenticule as a by-product of SMILE, opens up the possibility of using the lenticule for other purposes. Jose Ignacio Barraquer in 1980 first described keyhole intrastromal form of keratophakia, in which a disc of donor corneal tissue is lathed to the appropriate refractive power and inserted into a manually created intrastromal pocket.[74] Similar technique of keratophakia using a SMILE lenticule and its implantation into a femto-enabled pocket created in a human subject was first reported by Pradhan *et al*. where a −10.00 D lenticule was inserted into a patient with +11.25 D of hyperopia and sensory exotropia.[75] In 2014, our group showed the feasibility of using cryopreserved SMILE lenticules in 9 eyes, for potential treatment of moderate-to-high hyperopia through a procedure called femtosecond intrastromal lenticule implantation (FILI).[76] In this procedure, a SMILE lenticule matched for the recipients refractive error was inserted into an intrastromal pocket created into the recipients cornea at a depth of 160 µm. At 6 months, all eyes showed significant improvement in UDVA and CDVA, with good predictability of correction within ±1.5 D. No eye developed infection, haze or immunological rejection [Fig. 5]. However, 2 eyes of one patient showed diffuse interface haze after 6 months, leading to loss in CDVA by one line, necessitating the explanation of the tissues. The patient underwent a repeat FILI procedure 3 months later, using fresh lenticules and remained stable with restoration of UCVA of 20/20 in both eyes until the end of 1 year, demonstrating the reversibility of the procedure (unpublished case report).

Later, in 2015, we showed the possibility of treating mild-to-moderate progressive keratoconus using the technique of FILI, where a doughnut-shaped lenticule was used for insertion into recipient's cornea.[77] This was then combined with accelerated cross-linking using 30 mW for 3.3 min, thus, delivering a total energy of 6.3 J to the cornea. Six months' outcomes in the initial 6 eyes showed significant improvement in uncorrected and corrected visual acuity with good stabilization of the cornea in all eyes treated. No eye showed the progression of keratoconus. We also reported the successful use of SMILE lenticules for sealing of partial thickness corneal defects and perforations.[78]

Hyperopic Small Incision Lenticule Extraction

SMILE for hyperopia is still under investigation. Recently Reinstein *et al*. performed a prospective study of 60 consecutive hyperopic SMILE procedures using the VisuMax femtosecond laser and matched LASIK procedures with the VisuMax and MEL 80 excimer lasers.[79] The lenticule profile used in hyperopic SMILE was different from myopic SMILE as large 7-mm optical zone with a 2-mm transition was used. They observed that the optical zone centration of hyperopic SMILE was similar to eye-tracker-centered hyperopic LASIK with the MEL 80 laser.[79] Preliminary results are encouraging, however, long-term data on the safety and efficacy of hyperopic SMILE are awaited until the software is available for commercial use.

Conclusion

The evolution of SMILE has introduced a new method for LVC. SMILE being a surgeon-based procedure involves a learning curve, which can be negotiated by ensuring good docking, optimizing energy levels, and gentle tissue handling. Outcomes may be further refined by developing surgeon-specific nomograms and manual cyclotorsion compensation. Although the outcomes of SMILE have been shown to be similar to LASIK in terms of safety and predictability, evidence is increasing that SMILE may be better than LASIK in terms of corneal biomechanics, postoperative dry eye and long-term stability of correction for high myopia.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest

Dr. Sri Ganesh is a consultant for Carl Zeiss Meditec, Germany and receives travel grants from the company.

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