Review Article

Small Incision Lenticule Extraction: A review on current concepts and recent advances

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Abstract

The past few decades have seen a significant advancement in the field of refractive surgery. Laser in situ keratomileusis (LASIK) and its variant, femtosecond LASIK (FS-LASIK) although form the bulk of refractive procedures performed worldwide, is not free from complications, including flap-related complications, postoperative dry eye, denervation of corneal nerves, and biomechanical instability leading to potential corneal ectasia. Small incision lenticule extraction (SMILE) is minimally invasive bladeless technique which circumvents the creation of flap, thereby avoiding flap associated complications seen with LASIK. This review summarizes the current practices and recent innovative advances in SMILE.

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Introduction

More than 35 million eyes have undergone excimer laser vision correction worldwide, with Laser in situ keratomileusis (LASIK) forming the bulk of these procedures.[1] Considering the increasing demand, refractive surgeries have evolved significantly within the past few decades. The first generation techniques involved surface ablation and LASIK, however refractive surgery has now progressed to an intrastromal procedure with the advent of refractive lenticule extraction (ReLEx) technology. Refractive lenticule extraction marks a paradigm shift in the field of refractive surgery from the conventional flap-based corneal ablative procedures to flap-less extraction of FS- laser created intrastromal lenticules. ReLEx when performed through a small incision (2–4 mm) is described as small incision lenticule extraction (SMILE). SMILE is an intrastromal keratomileusis technique that requires a single femtosecond laser, to create a 3 dimensional lenticule that is extracted through a small corneal incision ranging from 2–4 mm. It circumvents creation of a corneal flap and there is preservation of the anterior-most stromal lamella and Bowman's layer, excluding the region of the incision.[2] It has been shown to be comparable to FS- LASIK in terms of safety, efficacy, and predictability. Moreover, it has the advantages of better ocular surface stability and biomechanical strength compared to FS- LASIK.[3,4]

Historical background

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, however, significant manual dissection was required leading to an irregular surface.[5] Following the introduction of the VisuMax femtosecond laser [Carl Zeiss Meditec, Jena, Germany (Figure 1)] in 2007, the intrastromal lenticule method was reintroduced in a procedure called Femtosecond Lenticule Extraction (FLEx).[6] In the initial studies, the refractive results were similar to those observed LASIK, but visual recovery time was longer due to the lack of optimization in energy parameters, further refinements have led to much improved visual recovery times.[7,8] Following the successful implementation of FLEx, a new procedure called Small Incision Lenticule Extraction (SMILE) was developed. SMILE was first performed by Sekundo et al[9] in 2008 using 2 opposing 5.0 mm entry incisions at the 12 o'clock and 6 o'clock positions. Eventually, incisional quantity and magnitude were decreased, transitioning from a bi-incisional to a mono-incisional approach with a concurrent incision size decrease to 2.0 mm.

Figure 1: *VisuMax Laser System*

Role of SMILE in correction of myopia and myopic astigmatism

SMILE received US Food and Drug Administration (FDA) approval in 2016 and the current change in FDA approval (2018) states that SMILE is approved for the treatment of myopia from −1 D to −10 D and astigmatism 0.75 to −3.0 D, a maximum of total prescription (nearsightedness plus half of the astigmatism) of no more than -10.00 diopters in power; and stable nearsightedness and astigmatism that has changed by no more than 0.50 diopter in power in the year before surgery.[10]

SMILE has become accepted as an effective means of correcting myopic astigmatism with a high safety profile and a good clinical outcome. However, undercorrection of high cylinders has been reported. Various studies have documented an overall undercorrection of approximately 15%.[11,12] Most of the observed undercorrection was dependent on the magnitude of the attempted cylinder correction and was similar in WTR astigmatism and ATR astigmatism. Undercorrection of astigmatism is a well-known difficulty, not only in SMILE, but also in LASIK. Cyclotorsion, which occurs when the patient goes from a standing to a supine position, has been reported to be a major contributor to keratorefractive undercorrection, and uncorrected torsion as small as 4 degrees will induce a 14% undercorrection. At present, cyclotorsion control is not available in the Visumax platform.[13]

Role of SMILE in hyperopia

Use of small-incision lenticule extraction and femtosecond lenticule extraction for correction of hyperopia is currently under investigation. The first study evaluating femtosecond lenticule extraction for the correction of hyperopia obtained unsatisfactory results, with significant postoperative regression.[14] However in a recent prospective study of vertex-centered hyperopic SMILE using the VisuMax femtosecond laser it was found that For eyes targeted for emmetropia (n = 36), uncorrected distance visual acuity was 20/40 or better in 89%. Spherical equivalent refraction relative to target was -0.17 ± 0.85 D (range: -2.20 to +3.00 D), with 59% within ±0.50 D and 76% within ±1.00 D. It concluded that refractive and visual outcomes 3 months after SMILE for hyperopia were promising, given the high degree of hyperopia corrected and relatively reduced CDVA in this population. Undercorrection of more than 1.00 D in 5 eyes might be partly explained by latent hyperopia in these young patients.[15]

The pre-operative assessment and patient selection in SMILE is similar to that of flap-based refractive surgeries. For SMILE, the percentage tissue altered (PTA) is calculated as (lenticule thickness + cap thickness)/central corneal thickness, and a value of more than 40% is suggestive of an increased risk of ectasia.[16] The absolute and relative contraindications to smile are illustrated in (Table 1).

Table 1: Absolute and relative contraindications to SMILE

Absolute Contraindications	Relative Contraindications
• Corneal ectasia (keratoconus, Pellucid marginal degeneration) • Unstable refractive error • Ocular surface and tear film disorders • Pregnancy and breastfeeding • One-eyed patient • Uncontrolled glaucoma or uveitis	• Age ≤21 years • Mild/treated ocular surface disorders • Epithelial and basement membrane corneal dystrophies • Systemic immunodeficiency • Past ocular herpes infection • Autoimmune disorders

Surgical steps

Preoperative preparation

An informed consent should be obtained before starting the procedure. Topical antibiotics may be instilled in both eyes in the pre-operative period. Topical proparacaine 0.5% is instilled in both eyes to provide topical anaesthesia.

Docking

First the patient's eye needs to be docked to the curved contact glass of the FS 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. The centering is checked, and suction is activated. 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 suction pressure generated by the VisuMax laser system is approximately 35 mmHg. Total suction time is approximately 25–35 s (depending on the mode used).

Femtosecond laser application

Conventionally, the treatment parameters are set at an anterior cap depth of 120 μm (range, 100–160 μm) with a side cut width ranging from 2 to 5 mm and minimum lenticule thickness at edge of 15 μm (range 10–30 μm). A 6.0-mm optical zone is selected with no transition zone for spherical errors and 0.10-mm transition zone for astigmatism. The cap diameter is set to 1 mm larger than the lenticule diameter. The pulse energy is set between 100 and 160 nJ. A 500-kHz FS laser is used to create the intrastromal lenticule. The lenticule cut is created first in an outside-in manner, followed by the lenticule side cut and cap cut in an inside-out manner. The cap side cut is created last.

Lenticule dissection

After FS laser delivery, a uniform bubble layer is observed in the corneal stroma. 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. The lower layer is then dissected in a similar fashion (Figure 2).

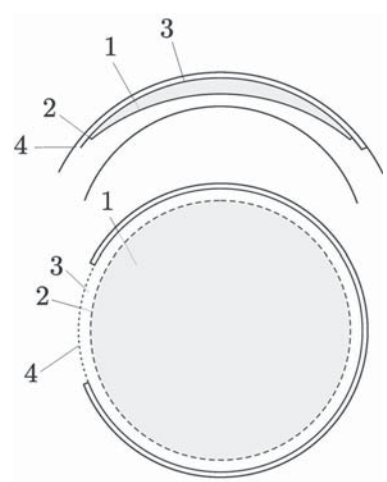

Figure 2: *Cross Section of the Various Cleavage Planes Created During Femtosecond Laser Lenticule Extraction*

Lenticule extraction

The separated lenticule is extracted via the side-cut incision using a microforceps. After extraction, the lenticule must be examined for its completeness. The interface may be irrigated with a balanced salt solution (BSS). The cap is smoothed over the residual stromal bed with the help of merocel sponges or a blunt instrument (Figure 3).

Lenticuloschisis[17]: 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 has been described. 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.

Intra-operative complications and their management

SMILE has a longer learning curve than other refractive surgeries, and may be associated with a number of complications. Early recognition and management of complications is essential to ensure good refractive results.

Suction loss:

The suction pressure during lenticule creation with the Visumax platform is lower than observed with other platforms and microkeratomes, whereas the duration of FS laser application is longer (25–28 seconds), which predisposes to suction loss. Certain risk factors predisposing to this complication include narrow eyelid fissure, forcible lid squeezing, smaller corneal diameter, large cap diameter and higher amounts of cylinder.[18,19]

The management of suction loss depends on the stage at which suction is lost:

- Before completion of 10% of lenticule cut: The SMILE procedure may be re-started in the same sitting. The VisuMax femtosecond laser machine has an inbuilt repair module that allows the continuation of SMILE procedure after re-docking in cases where the suction is lost during lenticule side cut, cap cut, or cap side cut.
- >10% of lenticule cut: The procedure needs to be abandoned, and a re-treatment with LASIK or Photorefractive keratectomy (PRK) may be planned in the same sitting or at a later date.

Opaque bubble layer (OBL):

Each laser pulse generates a cavitation bubble, which rapidly expands to assist in tissue separation, and then collapses. When the remaining gas bubbles created during this process cannot dissipate and coalesce at the stromal interface, the transient opacity remaining is called OBL.[20] OBL can be observed in cases with too high or too low laser energy settings and may lead to delayed visual recovery. The main risk factors for OBL are thick corneas and thin lenticules (low correction).

- The management of an area with OBL includes dissection with gentle lamellar movements to release adhesions.
- Optimal energy settings can help to prevent OBL.
- Li et al. suggest that increasing cap thickness may reduce the risk of OBL in cases of low correction.[21]

Black spots:

It occurs because of adherence of water droplets or meibomian secretions onto the interface between the suction cone and cornea, acting as a barrier to the laser pulses.[20]

- This may be prevented by adequately wetting the cornea before docking and avoiding any debris on the ocular surface as well as the contact lens.
- In case debris is noted in the interface after docking, suction should be released and a repeat docking should be attempted after cleaning the interface and irrigating the ocular surface.
- It is suggested that one should abort the procedure in cases of large black spots or when they reach the pupillary axis.[20]

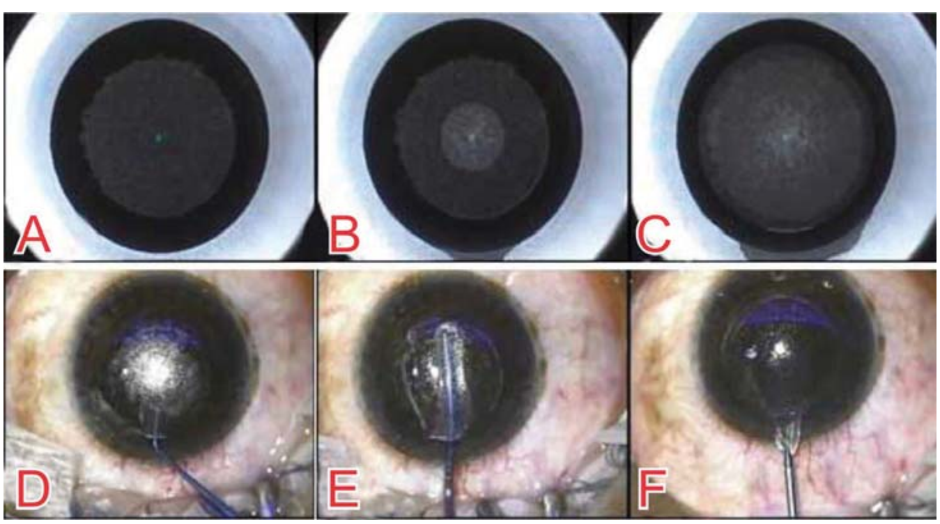

Figure 3: *Surgical steps of SMILE procedure: Femtolaser assisted (A) posterior tissue disruption plane or lenticule cut (B) anterior tissue disruption plane or flap cut (C) Superior flap side cut incision. Manual (D) delineation of planes (E) dissection of planes (F) lenticule removal*

Cap perforation and incisional tear:
Inadvertent handling of the instrument when facing tissue resistance during anterior plane dissection may lead to cap perforation or incisional tear.[22] Incisional tear risk is greater when the incision is smaller than 2.0 mm.

Lenticular mis-dissection, retained lenticule or a lenticular tear:
Partially retained lenticule fragments may be encountered after forceful extraction of an incompletely dissected lenticule. A torn lenticule during extraction can arise from situations prone to difficulty during lenticule dissection.

- The retained lenticules may be extracted in the same sitting with a microforceps after dissecting it from the surrounding stroma. Prompt removal of lenticule fragments can help restore visual acuity and achieve optimal outcomes.[23]
- Completely retained lenticule: In such cases, the circle pattern of VisuMax laser may be performed, which allows the surgeon to raise a flap and then extract the refractive lenticule similar to FLEx
- Customized surface ablation may be attempted in cases where the lenticule fragments cannot be successfully removed.

Intra-operative signs to prevent and identify lenticule mis-dissection

Meniscus sign:
The "meniscus sign" described by Titiyal[24] et al helps to identify the lenticule edge. After FS laser application, a "double ring" is visible signifying the diameter of cap cut (outer ring) and lenticule cut (inner ring). The lenticule edge is identified at the beginning of delineating the anterior and posterior lamellar planes in two different directions. The "meniscus sign" is created by slightly pushing the lenticule edge away from the surgeon during creation of the posterior lamellar channel to create a gap between the inner ring (diameter of lenticule cut) and the lenticule edge. The lenticule edge assumes a frilled wavy appearance, and the "meniscus sign" is observed as a gap between the lenticule edge and the inner ring. The advantage of identifying the "meniscus sign" at the beginning of the surgery is a primary prevention of lenticule mis-dissection.

Shimmer sign:
The shimmer sign given by Shetty et al[25] presents as a bright reflex around the dissecting instrument in cases with lenticule mis-dissection wherein the posterior plane is dissected first. This reflex is not visible during dissection of anterior plane and helps to identify the correct plane of dissection.

White ring sign:
The "white ring sign" described by Jacob et al[26] refers to the light reflex from the lenticular side cut that may be better observed using oblique external illumination in darker irides. The position of the white ring relative to the instrument is useful in identifying the dissection plane, as the white ring is posterior to the instrument during anterior plane dissection and anterior to the instrument during posterior plane dissection. Observing this sign during SMILE can be useful in preventing as well as detecting lenticule mis-dissection.

Retreatment and enhancement

It has been reported that a post-surgical enhancement may be required in 2.7%–4% cases with primary undercorrection, overcorrection, or regression.[27] Also, in cases with irregular astigmatism as a result of intraoperative complications enhancement may be needed. The surgical modalities available for or re-treatment include surface ablation and thin-flap LASIK and a repeat SMILE is not advisable owing to the risk of creating multiple dissection planes. 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.[28]

SMILE versus LASIK

Efficacy and safety:
Numerous studies have compared the efficacy of SMILE with LASIK procedure (Table 2).[29,30,31] A recent study compared the 2-year 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, thus concluding that SMILE offers better refractive outcomes than wavefront-guided LASIK for the correction of myopia and myopic astigmatism.[29] However, in a meta-analysis of 11 studies comparing SMILE with LASIK no significant difference was found between the two procedures in terms of final refractive spherical error or the proportion of eyes achieving an UDVA of 20/20 or better.[31]

Table 2: SMILE vs LASIK

	Advantages	Disadvantages
LASIK	Established and extensively investigated Can correct myopia, hyperopia and astigmatism	Creation of a 20mm flap (with a blade/ femtosecond laser) Flap-related complications Limited range of correction More glare, halos and higher order aberrations More dry eye Two laser platforms
SMILE	Blade-less and flapless minimally invasive (2mm incision) Less severe denervation and dry eye More suitable for thin corneas Fewer higher order aberrations Single laser platform reducing procedural time Improved mechanical stability of postsurgical cornea	Steep learning curve Limited range of correction Uncertainty of enhancement strategy

Higher-order aberrations (HOAs):
SMILE has exhibited significant reductions in induced spherical aberration, compared with FS-LASIK in various studies.[13,33] However, in one study higher vertical coma was shown in SMILE than wave front guided FS-LASIK and the authors concluded that this might be a potentially impact factor for patients' vision under certain lighting conditions.[34]

Biomechanical strength:
SMILE being a flap-less surgery minimizes corneal nerve disruption and therefore, has a theoretical advantage over LASIK (Figure 4). It provides a greater degree of residual corneal stability and corneal sensation postoperatively. Measurement of total stromal tensile strength comparing LASIK, PRK, SMILE, theoretically anticipated a greater amount of postoperative tensile strength with SMILE. According to the corneal hysteresis (CH) and corneal resistance factor (CRF) value measured with ocular response analyzer (ORA), corneal biomechanical strength has been shown to be preserved significantly better after SMILE than LASIK. Furthermore, it has been found that the difference was greater after postoperative 12 months. This might indicate wound healing is better after SMLE.[35]

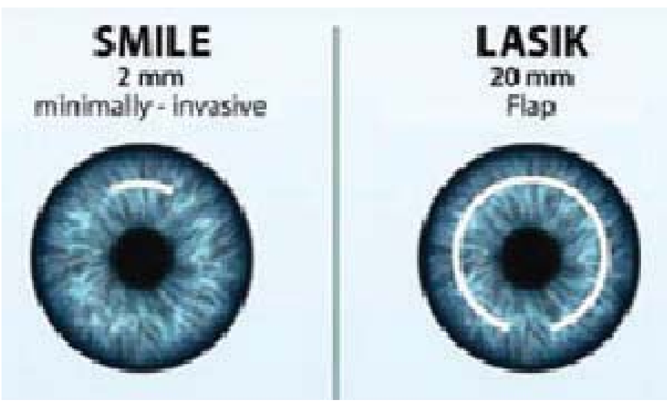

Figure 4: *SMILE vs LASIK*

Additional uses of smile lenticule

Tailored stromal expansion with refractive lenticule for cross linking the ultrathin cornea – Sachdev Technique[36]
Traditional corneal collagen crosslinking (CXL) requires a minimal stromal thickness of 400 microns for the procedure to be carried out safely and effectively in case of keratoconus. However patients with advanced forms of keratoconus often have thinner corneas, thus making the disease not amenable to traditional CXL.
We described a technique recently where using refractive lenticule, the thickness of the cornea is increased in the most physiological manner by adding stromal tissue whose biological and absorptive properties are the same as that of the cornea to be treated. Refractive lenticules of variable thickness can be obtained. Placement of the central lenticule over the apex of the cone enables us to augment the corneal thickness where required while sparing the remaining stroma to be cross linked normally (Figure 5, 6).

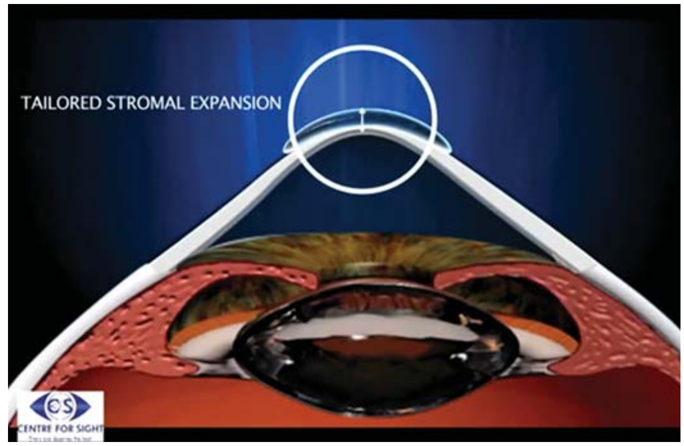

Figure 5: *Tailored stromal expansion*

Figure 6: *Augmentation of stromal thickness by placement of lenticule over stromal bed following epithelial debridement*

Femtosecond laser intrastromal lenticular implantation for hyperopia (FILI)[37]
Cryopreserved stromal lenticules obtained following SMILE for myopic correction are placed in a femtosecond created intrastromal pocket for the treatment of hyperopia.
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 higher-order aberrations.

Conclusion

SMILE is an effective, stable, and safe procedure for the treatment of myopia and myopic astigmatism and is therefore being increasingly preferred over conventional flap-based procedures. Patient selection is essential to achieve optimal visual outcomes. The technique is surgically demanding and novice surgeons should avoid cases with low magnitude of refractive errors, high astigmatism or difficult orbital anatomy. Identification of the lenticule edge and the correct dissection planes are the most crucial steps of surgery.

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