Review Article

A to Z of ReLEx SMILE: All you need to know

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Abstract

ReLEx SMILE (Refractive lenticule exchange - Small incision lenticule extraction) is a new generation of laser vision correction, performed using the Visumax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) for the correction of myopia and myopic astigmatism. It ensures greater biomechanical stability, lesser chances of dry eyes and predictable visual and refractive outcomes, making it the procedure of choice for myopic corrections. This article explains in detail regarding the pre-operative work up, steps of the surgical procedure, laser parameters, intra-operative complications such as suction loss, opaque bubble layer, dark spots, cap tear, lenticular adhesion and post-operative complications such as interface haze, interface debris, diffuse lamellar keratitis etc. and their management. The learning curve of SMILE being steeper than that of LASIK, well experienced surgeon and a well co-operative patient would ensure better surgical outcomes, minimising the complications. It also briefly explains about the options available for enhancement post SMILE.

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Introduction

The first report of refractive intrastromal lenticule extraction was published in 1996 with the use of picosecond (10^{-12}) lasers.[1] Femtosecond laser assisted refractive lenticule extraction procedure using the Intralase machine (Abott Medicals Optics, USA) was published years later in 2003.[2] Femtosecond laser offers a unique edge over other lasers as it has better precision and less collateral damage. This technique was perfected and the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) was developed, which delivers fixed patterns of femtosecond laser pulses to create an intrastromal refractive lenticule at a particular depth along with side cuts at desired positions and works by the principle of photo-disruption.

SMILE (Small Incision Lenticule Extraction) is the most advanced refractive surgery for the correction of myopia and myopic astigmatism, with a high level of safety, efficacy and precision.Unlike LASIK, SMILE is a bladeless procedure with a small incision of 2-4mm, with lesser incidence of symptomatic dry eyes post surgery because of better preservation of corneal innervation.[3,4,5] Due to the pattern of arrangement of the corneal lamellae, a vertical cut causes more loss of tensile strength than a parallel cut. The vertical cut in LASIK is almost 270 degrees, while the side cut in SMILE is only 40 degrees causing lesser disturbance of corneal biomechanics and thereby providing better biomechanical stability.[6,7]

Pre Operative Evaluation

- Uncorrected distance visual acuity (UCVA), corrected distance visual acuity (CDVA) and vision with pinhole
- Manifest and cycloplegic refraction
- Intraocular pressure measurement by Non contact tonometry
- Slit lamp biomicroscopy
- Dilated fundus examination
- Dry eye assessment (Schirmer's I and II)
- Topography with Pentacam
- Aberrometry
- Specular microscopy
- Anterior segment OCT (if available)

Pre Operative Counselling

Patient is adequately counselled about the procedure and an informed consent is taken. Topical anaesthetic drops (proparacaine 0.5%) are instilled to both the eyes. Excessive use of topical anaesthetic is avoided as it may loosen the epithelium and in-turn affect the femtosecond laser delivery resulting in black spots and thus difficult dissection.

Surgical Procedure

It involves 4 important steps - Docking, femtosecond laser delivery, lenticule dissection and lenticule extraction.

a. Docking

The patient is made to lie down supine on the operating table. The docking cone is attached to the femtosecond laser delivery system. Selection of the cone depends on the corneal white-to-white diameter (Figure 1, 2). The eye

Figure 1: *Suction cone*

Figure 2: *Under surface of the Suction cone*

to be operated is positioned under the cone and patient is asked to fixate on the green blinking light (Figure 3). The bed is moved up till the curved contact glass interface applanates the corneal surface (Figure 4). Excess saline in the conjunctival sac is removed. Once the contact lens touches the cornea, a meniscus tear film appears and the fixation light becomes clearly visible to the patient. Care is taken to make sure that it is purely a corneal suction and that there is no conjunctival tissue prolapse into the cone. The patient is asked to focus on the green light and suction is activated

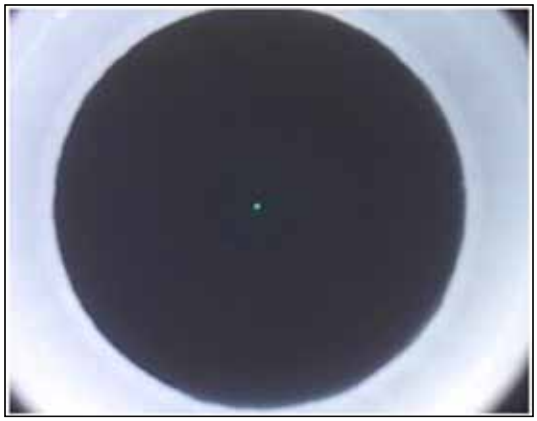

Figure 3: *Fixation light*

Figure 4: *Docking*

(Figure 5). The treatment is centred on the coaxial corneal light reflex (CCLR) and the centration is confirmed using the infrared light. The suction achieved is gentle and the maximum suction pressure generated by the VisuMax laser system is approximately 30-35 mmHg.[8] In cases where there is significant preoperative astigmatism (>0.75D), manual compensation for cyclotorsion may be performed by gently rotating the cone after activation of suction and aligning it to 0°-180° axis.[9]

b. Femtosecond Laser Delivery

The VisuMax laser system delivers femtosecond laser pulses at a wavelength of 1,043 nm and frequency of 500 kHz to create an intrastromal refractive lenticule.8 The posterior surface of the lenticule is created first in a spiral in fashion followed by the creation of side-cut and then the anterior cap creation occurs in a spiral out fashion. Finally a 2 – 4 mm incision is created superiorly.[10] (Figure. 6, 7, 8, 9)

Figure 5: *Suction bar indicating the level of suction*

Figure 6: *Stage of lenticule creation*

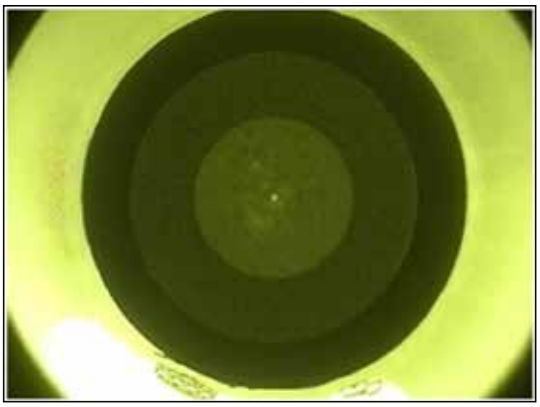

Figure 7: *Completion of lenticule side cut and beginning of cap formation*

Figure 8: *Completion of anterior cap formation*

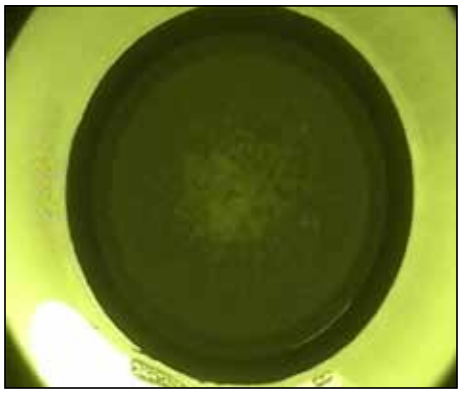

Figure 9: *Incision creation*

Conventionally, the treatment parameters are set at an anterior cap depth of 120 μm (range 100–160 μm) and minimum lenticule thickness at edge of 15 μm (ranging from 10– 30μm), optical zone ranging from 6.0 – 7.0 mm 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. Total suction time is approximately 25–35 seconds (depending on the mode used). Laser parameters in various treatment modes are as shown in the table below (Table 1).[11]

Table 1: Laser Parameters In Various Treatment Modes

Laser Parameters	Expert Mode	Standard Mode	Fast Mode
Pulse energy	140–200 nJ	130 nJ	170 nJ
Energy offset(1 offset = 5 nJ)	28–40	26	34
Track distance (μm)	Lenticule and cap: 4.50	Lenticule and cap: 3.00	Lenticule and cap: 4.50
	Lenticule side and cap side cut: 2.00	Lenticule side and cap side cut: 2.00	Lenticule and cap side cuts: 2.00
Spot distance (μm)	Lenticule and cap: 4.50	Lenticule and cap: 3.00	Lenticule and cap: 4.50
	Lenticule side and cap side cut: 2.00	Lenticule side and cap side cut: 2.00	Lenticule side and cap side cut: 2.00

c. Lenticule Dissection

The incision is opened and the edge of the lenticule is identified by delineating the anterior and posterior planes (Figure.10, 11). The anterior lenticular plane is separated from the overlying cap by blunt lamellar dissection, followed by the posterior plane dissection. A small peripheral area is left un-dissected till the end to provide counter-traction during posterior plane dissection and to prevent the lenticule from folding on to one side.

Gas Bubble Escape Sign (GBE)

The GBE sign refers to the escape of gas bubbles on delineation of the lenticular planes, followed by an immediate improvement in the clarity of the interface (Figure 12, 13, 14). A study by Ganesh et al. showed that GBE sign indicates an optimized laser energy pattern, which may

Figure 10: *Delineation of the anterior plane*

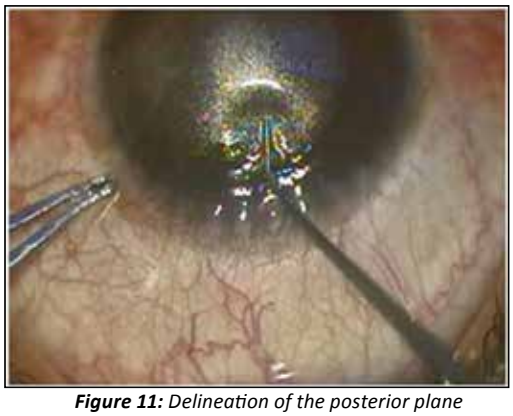

Figure 11: *Delineation of the posterior plane*

Figure 12: *Gas bubble escape sign*

Figure 13: *Before the escape of gas bubbles*

Figure 14: *Increase in the clarity of the interface after the escape of gas bubbles*

Figure 15: *Extraction of separated lenticule using lenticule forceps*

ease the lenticular dissection and thus provide better quality of vision in the immediate post-operative period.[12]

d. Lenticule Extraction

After making sure that the lenticule is well separated and is free from all sides, it is extracted through the small incision using a microforceps. After extraction, the lenticule is spread out over the surface of the cornea and is examined for its completeness (Figure 15)

Currently, ReLEx SMILE corrects myopia of up to −10.00 D, myopic astigmatism up to −5.00 D and a spherical equivalent (SE) of up to −12.5 D.[13,14]

Visual Recovery After Smile

Although visual outcomes have been good after SMILE, visual recovery is relatively slower compared to LASIK. The backscattered light intensity is seen to be higher in SMILE due to the activated keratocytes, extracellular matrix and irregularity of the interface which may be attributed to the slower visual recovery.[15]

Post-Operative Dryness

Reinstein et al. found that corneal sensation was reduced in the early postoperative period after SMILE, but recovered to baseline in 89% of the eyes by 6 months.[16]

Intraoperative Complications

1. Suction Loss

Risk factors: Deep set eyes, narrow palpebral fissure, excessive eyelid squeezing, flat keratometric power, loose corneal epithelium, excessive reflex tearing, patient's inability to maintain fixation or follow instructions.[17,18]

Patient should be well counselled pre-operatively to fixate on the green light and avoid any eye movements or head movements. A self-retaining speculum should be inserted to ensure adequate exposure. Excess fluid in the conjunctival sac should be cleared before docking. The presence of a fluid meniscus in the periphery after docking is a sign of imminent suction loss and it is advisable to release the suction and re-dock in such cases to prevent intra-operative complications. The management of suction loss depends on the stage at which it occurs. If it occurs at the stage where more than 10% of lenticule has been formed, SMILE procedure is abandoned and is converted to LASIK. However, at all other stages re-docking can be done and can proceed with SMILE by reducing the lenticule diameter and cap diameter by 0.2-0.4mm.

2. Vertical Gas Breakthrough

This may occur if there is a focal break or a scar in the bowman's layer and in cases of epithelial basement membrane dystrophy.[19,20] Gas bubbles created during cap/ lenticule creation can track through anterior corneal scars onto the surface of cornea. These bubbles can block the successive laser pulses leading to incomplete lenticule creation in the area of gas bubble and thus causing difficult dissection intra-operatively and can also lead to the formation of a buttonhole which can cause post-operative complications such as epithelial in-growth and scarring.[21] Surface ablative procedures can be considered for the correction of refractive error at a later date after ensuring complete healing of the buttonhole.[22]

3. Opaque Bubble Layer (OBL)

OBL is formed when excess of gas and water bubbles get trapped between the stromal lamellae, unable to pass uniformly through the lamellar interface, which in turn makes the lenticular dissection difficult (Figure 16). It can

Figure 16: *Opaque bubble layers (OBL)*

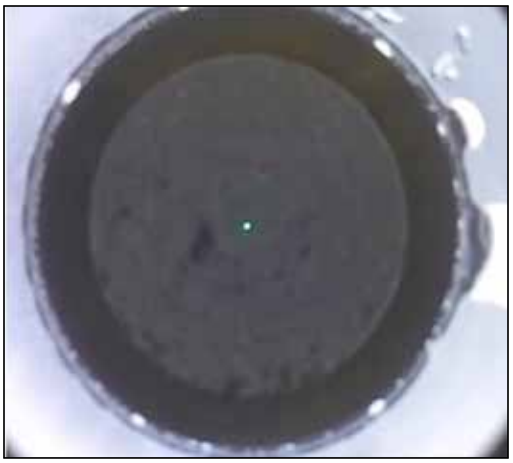

Figure 17 : *Dark spots*

Figure 18 : *Dark spots*

be observed in cases with too high or too low laser energy settings. Risk factors include thicker corneas and older patients with denser peripheral collagen that prevent the escape of gas bubbles.[23]

4. Dark Spots

Debris/meibomian secretions entrapped between the contact glass and the cornea causes incomplete laser delivery in that area resulting in the formation of dark spots and subsequent difficult dissection. (Figure 17, 18) Care should be taken to dissect the area gently to prevent lenticular tear.

5. Cap Lenticular Adhesion

It results from an inadvertent dissection of the posterior lenticular plane before separating the anterior surface from the overlying cap. Care should be taken to carefully delineate the anterior plane and dissect it completely to ensure complete separation of the cap from the underlying lenticule. Improper management of cap lenticular adhesion can lead to suboptimal visual outcomes with an increased incidence of cap tears, side-cut tears, retained lenticular fragments and iatrogenic damage to the corneal stroma.[24]

6. Epithelial Defects

Excessive use of topical anaesthetic drops can cause iatrogenic loosening of the epithelium, which in-turn can cause epithelial defect during lenticule dissection (Figure 19). This can be prevented by limiting the use of anaesthetic drops. A bandage contact lens is placed postoperatively till the epithelium heals.[25]

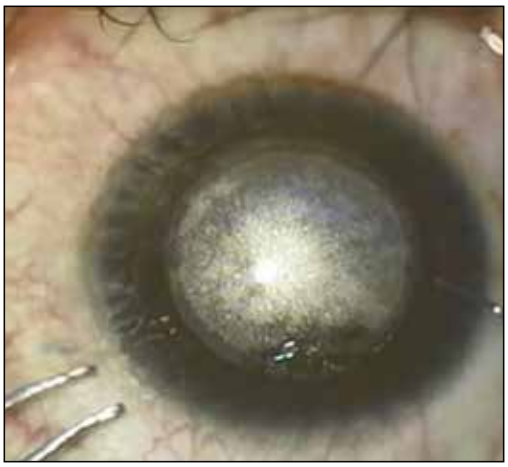

Figure 19 : *Epithelial defect near the incision site*

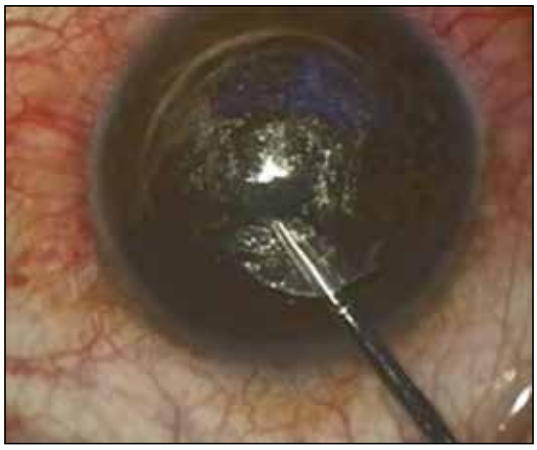

Figure 20 : *Cap tear*

Figure 21: *Lenticule tear during extraction*

7. Cap Tear

Cap tear can occur in the hands of an in-experienced surgeon, due to micro-adhesions and/or excessive intra-operative manipulation (Figure 20). Small tears usually heal well, whereas larger tears extending upto the visual axis can affect visual outcomes. It is advisable to place a bandage contact lens until the tear heals, in addition to frequent lubrication.

8. Lenticule Tear

This occurs in an attempt to pull the lenticule without dissecting it completely from all sides, more so in cases of low myopic correction where the lenticule is very thin and can inadvertently tear during dissection or removal (Figure 21). Care should be taken to ensure complete dissection and separation of lenticule from all sides before pulling it out through the incision.

Post Operative Complications

1. Interface Haze

It may be observed in the immediate post-operative period due to suboptimal laser energy levels and in cases of difficult dissection due to OBL / sticky lenticule. It usually resolves well with topical steroids and cyclosporine eye drops without having an impact on the long term visual and refractive outcomes.[26]

2. Interface Debris

Lint fibres / debris on the instrument / meibomian secretions can be inadvertently introduced into the stromal pocket during lenticule dissection. (Figure 22) Interface wash is advisable in cases of excess intra-operative manipulation to wash out the debris if any. Minimal debris not involving the pupillary axis remains inert without affecting the visual and refractive outcomes.[27]

3. Diffuse Lamellar Keratitis (DLK)

It represents an acute inflammatory response characterised by accumulation of white granular cells in the interface. (Figure 23) Patient may present with discomfort, photophobia and blurring of vision. A definitive cause is unknown, although factors such as introduction of meibomian secretions, surgical debris into the interface have been attributed to this condition. The incidence of DLK following SMILE has been reported as between 0.04 and 1.6 percent.[28,29] Zhao et al. found that DLK was associated with larger lenticular diameter and thinner lenticules.24 The proximity of the larger diameter lenticules to the limbus and limbal vasculature may cause more inflammatory reaction. Thinner lenticules may represent a greater technical challenge increasing the intra-operative manipulation and thereby possible inflammatory response.[30] Mild cases are treated with intense topical steroids and severe cases with a combination of topical and oral steroids.

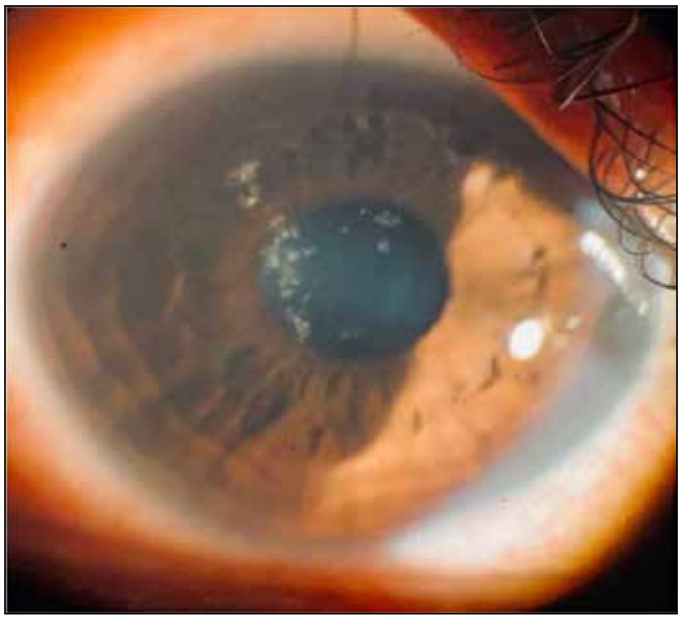

Figure 22: *Interface debris*

Figure 23: *Diffuse lamellar keratitis*

Post Smile Enhancement

The simplest way to perform an enhancement after SMILE is photorefractive keratectomy (PRK). An alternative to this is converting the SMILE cap into a flap and then ablating the stromal bed to correct the residual refractive error. A special software called the "Circle" (Carl Zeiss Meditec AG) has been developed to convert the original SMILE cap into a complete flap.[31]

Post Operative Treatment

Antibiotics (preferably Fluoroquinolones), Steroids (Prednisolone eye drops) in tapering dose and lubricants are used commonly. Cyclosporine 0.1% eye drops can also be added to prevent and treat interface haze.In patients who are steroid responders, low potent steroids along with pressure lowering agents are to be used.

Post Op Follow Up

Day 1, 1 week, 1 month, 3 months, 6 months and 1 yearly. On each follow up visits visual acuity (Uniocular and binocular), Intra ocular pressure and corneal interface clarity are looked at.

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