

Decade - long journey with small incision lenticule extraction: The learnings

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Over the past decade, small incision lenticule extraction (SMILE) has revolutionized the field of keratorefractive surgery. With the promise of superior corneal biomechanics and reduced postoperative dry eye, SMILE afforded a distinct advantage over flap-based procedures. Our evolving understanding of the surgical technique and management of its unique complications has further enhanced the outcomes. This review will highlight specific pearls on various preoperative and intraoperative principles allowing optimization of outcomes with SMILE.

Key words: Myopia, small incision lenticule extraction, SMILE, refractive surgery

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Small incision lenticule extraction (SMILE) marks a paradigm shift in the field of keratorefractive procedures. The procedure entails the application of femtosecond laser that delivers sequential corneal cuts to fashion an intrastromal lenticule. The lenticule is subsequently dissected free from the surrounding stroma and removed to offer a myopic correction. The last decade has seen a constant evolution in our understanding of SMILE, and the manuscript will focus on various preoperative and intraoperative principles allowing optimization of outcomes.

Patient Selection Criteria and Treatment Parameters

Currently, ReLEx SMILE is available as a treatment modality for myopic correction of up to -10 dioptres (D) and an astigmatic correction of up to -5.0D, with a maximum spherical equivalent correction of -12.5D. The procedure is at present not commercially available for hyperopic treatment.

Patients greater than 18 years of age with a refractive stability over at least 1 year and normal corneal tomography are ideal candidates. Preoperative corneal pachymetry of greater than 500 microns at the thinnest point and calculated postoperative residual stromal bed exceeding 280 microns are additional preferred practice patterns.^[1]

Importance of minimum lenticule thickness

In eyes with low myopia undergoing SMILE correction, the minimal lenticule thickness should be increased to 30 microns (traditionally fixed at 15 microns for moderate to high myopic correction). As this portion of the lenticule is

parallel to both the anterior and posterior corneal surface, no refractive effect is induced. This allows the formation of a relatively thick lenticule with subsequent ease in surgical delamination and extraction, especially for novice surgeons. Additionally, the femtosecond laser delivery includes a spiral-in pattern for the posterior lenticule cut followed by a spiral-out delivery forming the anterior lenticule cut. In thinner lenticular tissue, the posteriorly formed cavitation bubbles may distort the central lenticule prior to anterior laser delivery with subsequent alteration in desired lenticular shape and suboptimal visual outcomes. Therefore, increasing minimum lenticule thickness can help decrease the extent of lenticular distortion.

Astigmatism correction with SMILE

Although the treatment of myopic astigmatism with successful visual outcomes has been reported following SMILE, certain limitations exist with the current software. The machine does not allow treatment of pure cylindrical errors and a minimal coexisting spherical power of -0.50D is warranted for treatment planning. One of the potential drawbacks of the VisuMax femtosecond laser is the absence of an active cyclotorsion compensation mechanism for astigmatic correction. Intraoperative cyclotorsion greater than 2° can induce under correction and corneal aberrations especially in high astigmatism.

Ganesh and co-workers were the first to demonstrate the advantages of manual cyclotorsion compensation in SMILE,

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with significantly better outcomes in eyes with astigmatism greater than $-1.50D$ and cyclotorsion more than 5 degrees.^[2] However, the lack of a control arm and the application of a nomogram with 10% over correction were potential limitations of the study. Chen and co-workers demonstrated significantly better postoperative CDVA following cyclotorsion compensation vis-à-vis no compensation in a cohort of 84 eyes.^[3] However, low degrees of mean cyclotorsion ranging from 1.6° to 1.8° were included in the study. Xu and colleagues demonstrated no significant advantage of cyclotorsion compensation in moderate to low myopia of around $-1.50D$ cylinder.^[4]

The manual corneal markings for measuring cyclotorsion should be carried out on a relative dry surface to prevent the spread of ink. Additionally, the use of triple centration method would afford greater accuracy in comparison to two markings at the 0° and 180° horizontal axis. The markings should be placed at the 7 mm corneal diameter zone as against limbal markings which could prove technically challenging to make. However, the efficacy of manual markings for cyclotorsion compensation still remains controversial. The thickness of the marking itself would correspond to a few degrees thereby limiting the accuracy. Moreover, the dissection under the markings requires greater effort secondary to a slight obstruction of femtosecond laser delivery and suboptimal tissue photo disruption. The development of an inbuilt compensation mechanism would afford greater predictability and allow us to truly assess the benefits of cyclotorsion compensation, if any.

Biomechanical advantage of SMILE and its clinical implications

SMILE offers a biomechanical advantage over Laser in-situ Keratomileusis (LASIK) as the stronger anterior and peripheral collagen fibers are left relatively intact. Additionally, vertical cuts have a greater biomechanical effect in comparison to horizontal cuts, with greater weakening for deeper incisions. As LASIK entails vertical side cuts of a larger area, the corneal strain induced is greater in comparison to SMILE.^[5-8]

Due to stronger biomechanics, it was assumed that eyes with borderline corneal tomography contraindicated for LASIK may demonstrate safe outcomes following SMILE. However, numerous reports of ectasia following SMILE with preoperative normal tomography have been published since.^[9-11] Therefore, a greater understanding of the biomechanical changes post SMILE is warranted, and till then preoperative criteria for patient selection should be as stringent as LASIK.

Optimizing the SMILE Procedure

SMILE procedure consists of three distinct steps including initial docking with precise centration, verification and maintenance of suction during femtosecond laser delivery and surgical extraction of the formed lenticule.

Pearls for Predocking preparation

The procedure is carried out under topical anaesthesia. Excessive instillation of anaesthetic may result in loosening of epithelial tissue with subsequent formation of dark spots and should be avoided. The patient's eye is aligned under the contact interface using the joystick attached to the movable

bed. A proper head position is achieved by tilting the patient's head medially to avoid nasal contact with the cone of the contact glass interface. The chin must also be tilted upwards or downwards in a manner that the cornea is in the centre of the palpebral fissure and maximum exposure to the contact glass interface is available. Novice surgeons should refrain from operating on patients with narrow palpebral fissure or deep set eyes in the initial cases. A moist corneal surface is recommended to prevent formation of dark spots. However, excessive fluid from the conjunctival cul-de-sac should be wiped dry with a sponge to prevent suction loss. Moreover, multiple attempts at docking should be avoided as debris and dried tear secretions may collect onto the under surface of the contact interface, and interfere with subsequent femtosecond laser delivery resulting in uncut areas of tissue. Wiping the contact interface under surface prior to redocking attempts is recommended.

Obtaining optimal suction and laser delivery

Following proper centration, suction is initiated to hold the cornea against the contact glass interface. Femtosecond laser pulses with a typical pulse energy of 120–170 nJ are delivered with a pulse repetition rate of 500 KHz. Typical spot distance between each pulse is 2–5 microns. The pattern of the opaque bubble layer (OBL) should be noted and the energy settings should be reduced in cases of dense OBL with subsequent dissection difficulties. Thicker corneas and thinner lenticules predispose to the formation of OBL and should be avoided during the initial learning curve of the surgeon.^[12] It is important to note that the energy parameters need to be optimized for each individual machine and this can enhance ease of dissection as well as result in faster visual recovery. Shetty and co-workers demonstrated a positive correlation between corneal deformation and ease of lenticule removal, thereby allowing customization of energy parameters.^[13]

The femtosecond laser creates four sequential tissue disruption planes. The posterior lenticule cut is the refractive cut (from periphery to centre) followed by transition zone at the edge of the refractive zone (for spherocylindrical correction and is usually 0.1 mm). The diameter of the posterior lenticule surface is determined by the optical zone. This is followed by the vertical edge cut along the perimeter of the lenticule. The anterior lenticule surface (from centre to periphery) extends about 0.5–1 mm beyond the posterior lenticule surface followed by the peripheral corneal incision for lenticule access and extraction. The incision is generally created superiorly or superotemporally to preserve the nasal and temporal nerve arcades and to provide surgical convenience.

Lenticule delineation and removal

The formed lenticule is separated from the surrounding stroma and extracted to offer a refractive correction. The anterior and posterior channels should be created in opposite directions to avoid incorrect delineation. Following lenticule delineation, the anterior lenticule plane is dissected from the overlying cap using a blunt spatula. While dissecting the posterior plane, small peripheral areas should be left undissected superiorly (towards the corneal side cut) to provide counter traction and avoid lenticule from folding over.

Various methods to enhance delineation of correct planes have been described.^[14-16]

The stop sign sign describes the resistance noted at the junction between the dissected and undissected halves of both the planes, interfering with subsequent lateral movement of the instrument [Fig. 1].^[17] The resistance is demonstrated at both the anterior and posterior lenticular plane. This allows ideal dissection of the lenticule from the overlying cap and underlying stroma thereby reducing complications arising from incorrect tissue dissection.

Following dissection, the lenticule is extracted using toothed forceps. In cases of stromal adhesions, a circumferential pull allows lenticule separation without tears or residual fragments. The extracted lenticule should be spread over the corneal surface to ascertain complete removal, especially during dissection difficulties and for beginner surgeons.

Challenges Unique to SMILE

Although the absence of flap creation allows certain advantages over earlier techniques, it brings with it challenges unique to the procedure. Incisional abrasion or epithelial sloughing are visually insignificant complications associated with SMILE.^[18,19] Subsequent discussion entails management of complications associated with potentially suboptimal visual outcomes.

Caveats for management of suction loss

A longer duration of suction in SMILE vis-à-vis LASIK increases the risk of suction loss. Moreover, the dock is more gentle, secondary to corneal suction and lower rise in pressure. Ocular conditions including narrow palpebral fissure, excessive tearing, and poor fixation are other predisposing factors. Immediate redocking using the same contact interface, cleaning the under surface of the interface prior to redock, and counselling the patient regarding the disappearance of the “green blinking light” are important caveats to improve outcomes. Redundant conjunctiva should be swept away from the limbus using a merocel sponge. Solid speculum as against a wire lid speculum should be used in cases of conjunctival prolapse.

Management of suction loss is unique to SMILE and has a longer learning curve as it differs depending on the stage of suction loss. If suction loss occurs during the posterior lenticule cut (more than 10% complete), the surgeon should convert to a femtosecond LASIK. The only limitation is as SMILE is usually performed with a small cone, the flap diameter cannot extend beyond 7.9 mm and therefore centration of the flap over the pupil becomes important, especially in astigmatic correction. The depth of the femtosecond flap is independent of the initial SMILE procedure and can be fashioned at a more superficial plane.

SMILE procedure can be completed when suction loss occurs following posterior lenticule cut. The major challenge here is to achieve the same centration of the subsequent dock as the initial cut in the presence of an OBL. In case of dense OBL, it may even be worthwhile waiting till it clears to allow better visibility and centration of the dock and subsequent laser delivery. Additionally, when suction loss occurs during side cut, a reduction in the side cut diameter by 0.2–0.4 mm is required to ensure it falls within the lenticule that has been created.

In the rare instance of impending suction loss secondary to superiorly encroaching conjunctiva, it would be preferable to

release suction and redock than to continue with laser delivery, as this could result in an unformed corneal side cut. In such an eventuality, sharp instruments may be required to open out the incision and perform subsequent lenticule dissection. The use of CIRCLE software has been described as a rescue tool in conditions where access to the formed lenticule is not possible.^[20] This allows the conversion of the cap into a flap following which the underlying lenticule can be peeled of akin to a FLEx procedure.

Incorrect dissection

Incorrect tissue plane identification can result in primary separation of the posterior lenticule surface, resulting in its adherence to the overlying cap. The challenge now is to achieve an anterior dissection. A sharp-tipped instrument or micro forceps can be used to create a small area of separation, and subsequently the lenticule can be dissected from the surrounding stroma. The lenticulerrhexis and lenticuloschisis techniques entail peeling the lenticule from the surrounding stroma without prior dissection and should be avoided by beginner surgeons.^[21,22] The use of balanced saline solution in the interface has been demonstrated with the lenticule irrigation and hydroexpression procedures.^[23,24] Intraoperative anterior segment optical coherence tomography (ASOCT) affords direct visualization. However, it is limited by the increased cost and surgical time.^[25]

Management of retained lenticule fragments

Retained lenticule fragment is a unique complication of SMILE and is commonly associated with thinner lenticules (thickness lower than 50 microns), suboptimal laser disruption secondary to inadequate OBL or interface debris, and inadequate surgical experience.^[26] Larger or central fragments with resultant corneal surface irregularities mandate a surgical exploration for their removal.

Anterior segment OCT is a useful tool to delineate the lenticule remnants and can also demonstrate localised discrepancy in pachymetry [Fig. 2]. A simple retro illumination examination with pupillary dilatation on slit-lamp bio microscopy will help in clearly delineating remnant tags that can be removed to restore a smooth interface [Fig. 3].^[27]

Currently described intraoperative modalities to delineate lenticule remnants include ASOCT and CIRCLE software.^[28,29] However, the incurred cost and restricted availability limit their widespread use. The instillation of diluted triamcinolone acetonide in the intrastromal pocket has been successfully demonstrated [Fig. 4].^[30] Potential advantages include easy availability, low cost, and application in eyes with thin lenticules or reduced visibility secondary to haze or edema.

Keratitis following SMILE

Infectious keratitis management in SMILE could be challenging secondary to limited topical penetration in deep-seated infiltrates and difficulty in obtaining tissue for microbiological analysis. The interface provides a conduit for deeper administration of medication especially topical antifungals.^[31]

Sterile infiltrate

A high degree of clinical suspicion is required in cases of sterile infiltrate. Clinical presentation includes an intact overlying epithelium, clear intervening zone up to limbus and absence of anterior chamber reaction. Administration of steroids and

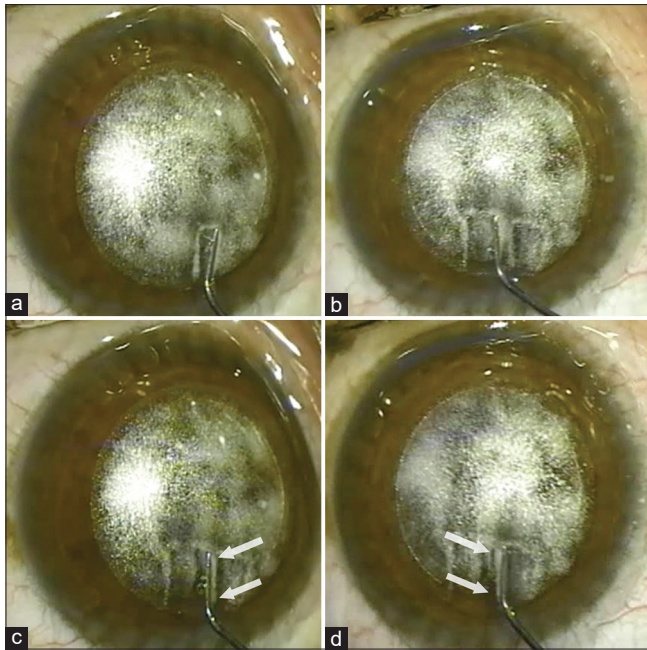


Figure 1: Stop sign – Anterior plane delineated on the right side (a) followed by posterior separation on the left (b). Stop sign at junction of dissected and undissected halves between the two planes. This provides resistance to lateral movement of instrument (left to right) in the posterior (c, arrows) and (right to left) anterior plane (d, arrows)

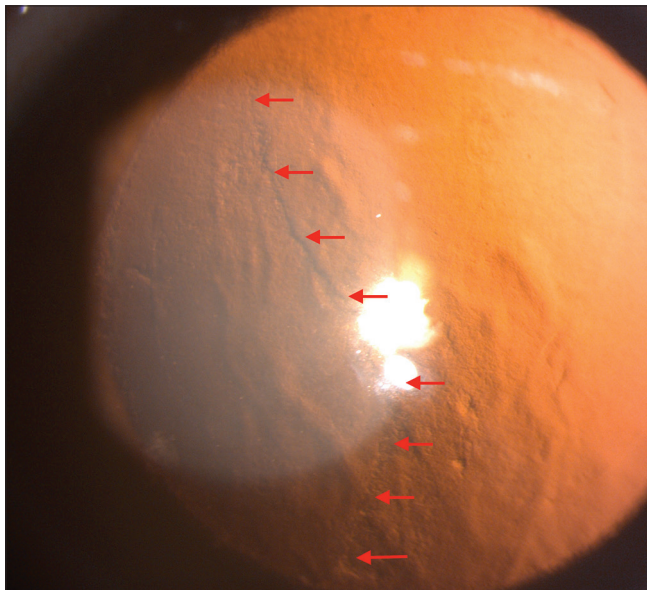


Figure 3: Slit-lamp biomicroscopy delineating retained lenticule edges (arrows) on dilated retroillumination examination

prophylactic topical antibiotics allows resolution with optimal visual outcomes.^[32]

Visual Outcomes

Visual outcomes following SMILE and femtosecond LASIK are comparable in terms of safety and efficacy. The aberration profile in SMILE especially spherical aberration is significantly better in comparison to LASIK.^[33,34]

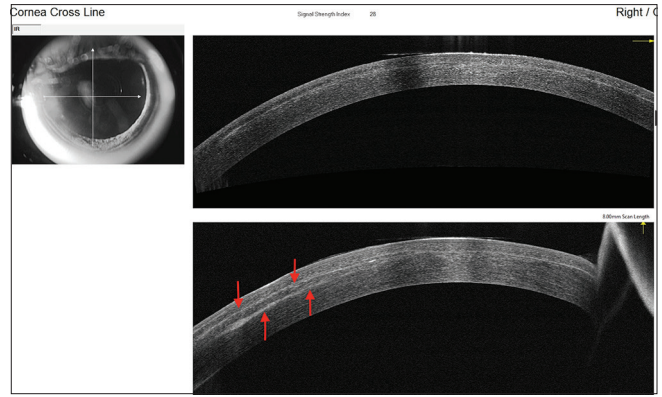


Figure 2: Anterior segment optical coherence tomography demonstrating retained lenticule fragment temporally (arrows)

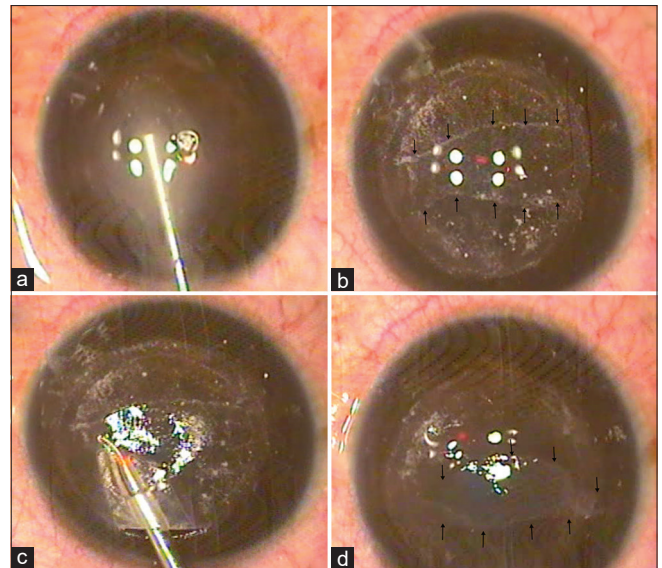


Figure 4: Diluted triamcinolone acetonide (1 mg/0.1 ml) injected in the intrastromal pocket (a). Lenticule edges clearly delineated following staining with triamcinolone crystals (b). Remnant delineated from surrounding stroma and subsequently extracted using micro forceps (c). Fragment spread on corneal surface demonstrating complete removal (d)

Postoperative Recovery after SMILE

Visual recovery following SMILE demonstrated variable outcomes in the earlier cohorts. Application of higher energy levels in these studies could be a possible explanation, with faster recovery seen following energy optimization.^[35,36] Lower early postoperative inflammation with SMILE vis-à-vis LASIK allows faster healing and reduced wound modulation. This would allow earlier stabilization of refractive outcomes.

Moreover, dissection difficulties secondary to excessive OBL, poor laser delivery, or improper technique can induce micro distortions and interface inflammation, delaying recovery. This however reduces over time and plateaus after a period of 3 months. Improvement in laser parameters and standardization of dissection techniques have now enabled visual recovery in SMILE to be comparable to that of LASIK.

As the extent of cut along the anterior cornea is minimal in SMILE compared to LASIK, the transection of corneal nerves is also limited. This leads to faster recovery of corneal sensation, lesser dry eye symptoms, quicker stabilization of the tear film, and therefore the overall subjective comfort post SMILE procedure is superior in comparison to flap-based procedures.^[37,38]

Enhancement following SMILE

Enhancement following SMILE secondary to under correction or regression is required in 2.7-4% of the eyes.^[39,40] With a mean latency period of 10 months, 71% of the retreatments are performed within the first month. Risk factors include increased age greater than 35 years, preoperative spherical error and astigmatism more than 6.0D and 3.0D, respectively, and intraoperative suction loss.^[41] Surface ablation, thin flap LASIK, SMILE on SMILE and the use of CIRCLE software have been described as enhancement techniques.^[42]

Although surface ablation offers a flap free approach and preserves the advantages of the primary procedure, postoperative pain and risk of haze formation are potential limitations. A greater speed of visual recovery following CIRCLE vis-à-vis surface ablation has been noted, although results at 3 months were comparable.^[43]

CIRCLE software allows the conversion of the cap into a flap, which can be subsequently raised to ablate the underlying stroma. The creation of a lamellar ring outside the optical zone allows further extension of retreatment area.^[44] To facilitate surgical manipulation, the outer diameter should be programmed to extend beyond the SMILE interface while the inner diameter should be smaller than the lenticule. Additionally, the flap orientation should be such that the hinge does not overlap the SMILE side cut.^[45]

LASIK following SMILE requires the surgeon to fashion a thick cap of around 160 microns in the primary SMILE procedure.^[46] However, the biomechanical weakening induced would be greater in comparison to PRK or CIRCLE software.

Conclusion

In conclusion, over the last decade, SMILE has revolutionized the field of refractive surgery. Our evolving understanding of the technology, the technique and unique complications have further helped in optimizing outcomes. The advantage of a flap-free procedure with superior biomechanics, faster wound healing, and improved patient comfort has set SMILE apart as the procedure of choice.

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Conflicts of interest

There are no conflicts of interest.

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