Review Article

Small incision lenticule extraction: a review

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Abstract

Small incision lenticule extraction (SMILE) is a new type of keratorefractive surgery and is gaining popularity in Hong Kong and worldwide. This article aims to provide a brief introduction to SMILE, including the surgical steps, common intraoperative difficulties, and a literature review on its visual, refractive, and safety outcomes.

Key words: Myopia; Refractive surgical procedures

Introduction

The increased prevalence of myopia has increased the demand for refractive surgery to correct myopia. Small incision lenticule extraction (SMILE) has gained popularity since its first prospective study in 2010.[1] This article aims to give an overview of the SMILE procedure, highlight some intraoperative tips, discuss its advantages and limitations, and review the literature about its efficacy and safety.

Evolution of refractive surgery

Laser-assisted *in-situ* keratomileusis (LASIK) has been the most popular method of keratorefractive surgery in the past decade. It involves creation of a corneal flap, followed by stromal ablation with excimer laser. It has proven safety, visual, and refractive outcomes with almost immediate visual recovery. Nonetheless, creation of the flap is associated with the risk of early flap-related complications and post-LASIK dry eyes. The procedure also weakens the biomechanical strength of the cornea and may lead to late complications including regression and postoperative ectasia.

Femtosecond laser and related techniques

Femtosecond laser is characterized by ultrafast pulses of light at a duration of 10^{-15} seconds. A laser beam is focused at a precise depth within the cornea. At the point of focus, brief bursts of energy convert the local tissue into a plasma state, vaporizing a small volume of tissue. This process is called photodisruption. Femtosecond laser creates a tissue plane with extremely limited collateral damage.[2] The use of femtosecond laser in refractive surgery has gone through different generations.[3] It was first used in LASIK flap creation in replacement of microkeratome, giving rise to femtosecond laser-assisted LASIK. With further development, stromal ablation is avoided, and instead an intrastromal lenticule is cut and removed from the cornea. This is known collectively as refractive lenticule extraction. The first to emerge was femotosecond lenticule extraction (FLEX). It involved creating a corneal flap and an intrastromal lenticule using a femtosecond laser. The lenticule was then extracted after lifting the corneal flap. Later on, SMILE was developed in which the lenticule was extracted via a small arcuate incision without the need for a corneal flap.

SMILE procedure

SMILE distinguishes itself from LASIK by avoiding the need to create a flap. In essence, it involves creation of an intrastromal lenticule and peripheral incisions using

femtosecond laser, followed by dissection and removal of the stromal lenticule (**Figure**).

Docking and femtosecond laser incisions

The first step of SMILE femtosecond laser is docking and incision. Achieving an accurate centration of the eye is quintessential to the success of SMILE. The eye is placed under the laser platform and the curved contact glass, and the surgeon looks at the eye via a surgical microscope. A green indicator light can be seen via the microscope and should be placed at the centre of the pupil. To ensure proper centration, the patient fixates on an internal target light coming from the treatment pack, while the surgeon adjusts the position of the operative table and hence the patient's eye, a process termed docking. The surgeon then moves the table up so that the cornea is partly applanated onto the contact glass. Once the centration is confirmed, the surgeon applies negative suction to keep the eye in place. Femtosecond incisions can then be initiated.

Creation of intrastromal lenticule

There are four femtosecond laser incisions that create the intralamellar lenticule. The first incision creates the posterior plane of the lenticule. The laser passes from the periphery to the center in a spiral fashion, a maneuver that minimizes the time during which the central cornea is affected. The second incision creates the side-cut at 90° perpendicular to the anterior cap along its periphery. The third incision creates the anterior cap of the lenticule by passing the laser from the center to the periphery in a spiral manner, completing the carving of the intralamellar lenticule. The fourth incision is a small incision of 2 to 5mm along the circumference of the anterior cap to enable extraction of the lenticule.

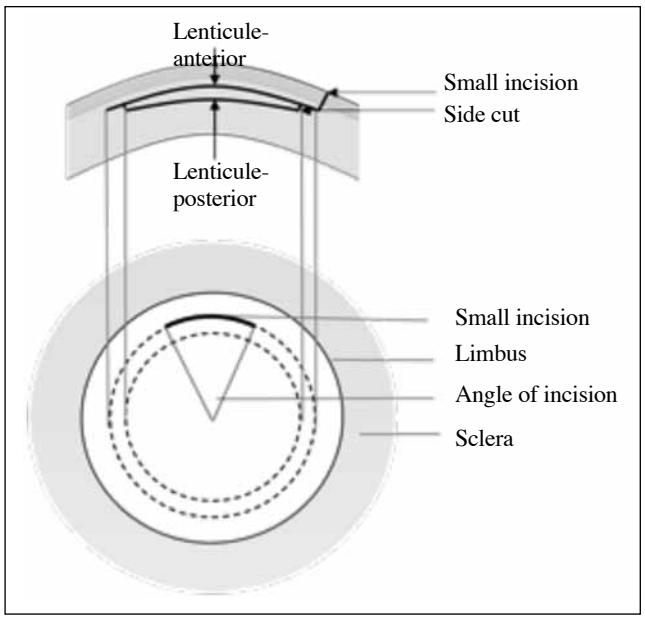

Figure. Schematic diagram illustrating small incision lenticule extraction.

The technical parameters for these laser-generated incisions have not been standardized. Based on our clinical experience, we recommend a cap thickness of 120 μm, cap diameter of 7.5 mm, lenticule diameter of 6.5 mm with a transition zone of 0.1 mm, cut energy of 1.4 nJ, and spot and tracking distance of 2.0-3.0 μm.[4]

Manual extraction of the lenticule

Following the femtosecond laser incisions, the suction to keep the eye in place can be removed, and the stromal lenticule is ready to be extracted. The surgeon inserts a spatula into the side-cut to dissect residual lenticular appendages along the anterior plane and then the posterior plane. When the anterior plane is dissected, the edge of the posterior surface cannot be seen; the contrary is true when the posterior plane is dissected. This difference in appearance helps the surgeon to ensure dissection at the correct surface. Once the dissection is completed and no appendages are left, the lenticule can be extracted with a pair of forceps. A segment of residual corneal tissue anterior to the lenticule becomes largely disconnected from the remainder of the cornea; this segment is known as the cap. Care should be taken not to damage it. Some surgeons may irrigate the intralamellar space, some not. Finally the edge of the side-cut is repositioned with a brush.

Postoperatively, topical steroid, antibiotics, and lubricating eyedrops are prescribed for several weeks.

Indications and contraindications

SMILE is appropriate for most patients who are fit for refractive corneal surgeries. Its use in correcting myopia and myopic astigmatism has been established.[5-7] Based on our experience, the optimal range of spherical and cylinder is -0.75 D to -10 D and < -5 D, respectively. Keratometry should fall within 38-48 D. Nonetheless, its applicability in correcting hypermetropia remains to be investigated. Other inclusion criteria include age 18 years or above, stable refraction, transparent cornea with no history of keratitis or scar, normal topography, and corneal thickness > 480 μm. SMILE is contraindicated in those with previous intraocular surgery, ocular co-morbidities or autoimmune connective tissue disorders.

Common difficulties for surgeons

Many refractive surgeons experienced with LASIK may hesitate to switch to SMILE due to the learning curve. We discuss a few common intraoperative difficulties and provide some management tips.

Maintaining centration

Without proper centration, the accuracy of laser-based incisions is compromised. To achieve better centration during docking, the patient should be instructed to keep fixating on the light until suction is applied. Patients with more severe astigmatism or a larger angle Kappa may need further adjustment. Negative suction maintains the eye position

once centration is achieved. The strength of suction needs to be carefully adjusted; a lower suction allows the patient to fixate on the light throughout the procedure. The size of the suction ring depends on the size of the globe and baseline refractive error. In general, a small ring size is recommended for myopia correction in Chinese, whereas a medium ring size can be used for astigmatism correction. The connecting tubes should be placed at the patient's temporal side. Suction loss may occur even when suction is properly achieved in the first instance. To prevent this, the surgeon should avoid putting the conjunctiva under suction. Excess liquid and conjunctival discharge should be wiped away in time, and environmental interference minimized. In case instability is noticed, the surgeon should re-apply suction. If suction loss occurs, the surgeon can choose to continue with SMILE, convert to LASIK or FLEX, or reschedule the operation.

Locating and extracting the lenticule

Locating the lenticule is readily achievable when the following steps are attended to. The lenticule should not be too thin. Blunt instruments should be used to dissect the lenticule from within the cornea, first along the periphery of the anterior surface. The surgeon should search for the edge of the lenticule using the gas bubble as a guide. The side cuts should be carefully identified. Should the lenticule not be extracted, the surgeon can use a shorter and sharper instrument to accurately identify the edge. Slit lamp or anterior segment optical coherence tomography may be used in difficult cases. If lenticular extraction remains non-feasible despite extensive searching, the incisions need to be closed and the operation rescheduled. Alternatively, the surgeon can convert to the FLEX procedure.

The lenticule may be difficult to extract if it is not properly created. This may arise from incorrect setting of laser parameters, incomplete side cut, or unstable laser performance. Either too high or too low energy is problematic; in the former, an opaque bubble layer forms in the cornea, whereas in the latter the spot distance and track distance increase. Whatever the cause, difficulty in extraction can be overcome using careful blunt dissection. Laser parameters should be adjusted to produce useful cuts. Incomplete side cuts can be managed using scissors or special equipment.

During its extraction, the lenticule may be torn or left behind, causing residual lenticular tissue. This may occur when the cornea has a pre-existing defect, such as scarring, when laser energy was inappropriately high causing an opaque bubble layer around the lenticule or when the lenticule is too thin or when the patient is not cooperative. To prevent these, patients with corneal scars should be screened out during a preoperative assessment. In those with low refraction, the cap thickness should be increased. Gentle maneuvers to ensure complete clearance of the anterior and posterior lamellar plane are essential. The lenticule should be gently grasped with forceps. Should tearing occur, a careful dissection should be performed. All residual lenticular tissue should be removed. Small strips of tissue at the periphery may be observed, but those in the optical zone must be removed.

Cap perforation or abrasion at the side-cut incision can be problematic. The risk is higher when the cap is too thin or when the side-cut is too small. Gentle surgical technique and correct choice of instruments can prevent this, as well as ensuring the patient does not move the eye suddenly. Mild tears can be observed, but obvious tears need to be apposed to prevent epithelial ingrowth, which is readily achieved using a bandage contact lens.

Efficacy and safety

The efficacy of SMILE is defined by the percentage of eyes with good postoperative uncorrected distant visual acuity (UDVA).[8,9] In one SMILE study, 62% of eyes achieved UDVA ≥ 20/20, whereas 93% achieved ≥ 20/40.[8] The corresponding percentages for LASIK were 71% and 95%. In a study comparing SMILE with LASIK for 111 eyes, the two cohorts did not differ significantly in percentage of eyes with an UDVA of 20/20 or better at 1 and 3 months.[10] In addition, higher order aberrations and spherical aberrations were significantly lower in the SMILE cohort.[10] In terms of safety, most patients could maintain corrected distance visual acuity (CDVA), with a safety index (defined as postoperative CDVA / preoperative CDVA) between 1.0 and 1.1.[8,11] A loss of two lines or more was noted in only 0-2.3% of SMILE patients, compared with 0-2.4% for LASIK. High order aberrations and spherical aberrations were less common following SMILE than LASIK.[10,12-14] This was postulated to be related to the lack of flap creation in SMILE, as well as a more favorable healing response with femtosecond laser than with excimer laser.

With SMILE, a predictable correction in refractive outcome can be achieved. 79 to 92% of patients achieved within ± 0.5D of target refraction, compared with 80 to 90% for LASIK. For both procedures, >90% subjects could achieve within ± 1.0D of target refraction.[8,9] Refractive outcome was stable in long-term follow-up. Over 5 years, a regression of 0.48D was noted in SMILE patients, compared with 0.63-0.97D in LASIK patients.[15]

SMILE is proposed to cause less dry eye symptoms by preserving corneal sensation in the absence of flap creation. Evidence suggests that SMILE is associated with less denervation, accelerated healing of the ocular surface, and better corneal sensitivity.[16-19] Higher percentages of LASIK than SMILE patients are reported to have mild to moderate dry eyes 6 months postoperatively.[20]

Biomechanical stability is postulated to be stronger with SMILE, owing to preservation of the anterior corneal stroma. Mathematical modelling suggests that stromal tensile strength should be stronger with SMILE than LASIK.[21] Nonetheless, clinical results measured with Ocular Response Analyzer or CorVisST remain controversial.[9,22-26] A biomechanically stronger cornea should translate into less

regression and risk of ectasia in the long-term, although no such long-term data is available for SMILE yet.

A meta-analysis of 11 comparative studies involving 1101 eyes provides more insight into the efficacy and safety of SMILE in comparison with FS-LASIK.[27] The two procedures did not differ significantly in the mean postoperative refractive standard error, proportion of eyes losing one or more lines of CDVA, proportion of eyes achieving UDVA 20/20 or better, or proportion of eyes with postoperative refractions within ± 1.0 D of the target. At 6 months postoperatively, the SMILE group had significantly higher corneal sensitivity and longer tear break-up time. These results were in line with the impression derived from the findings of individual studies that SMILE and FS-LASIK were comparable in terms of safety and efficacy, with SMILE potentially superior in reducing dry eye symptoms.

We have also reported comparable efficacy and safety with SMILE.[4,28] For efficacy, UDVA was 20/20 or better in 48 to 80% of all subjects, and 20/40 or better in 93 to 100%. For safety, no patient had a loss of two or more lines of CDVA, and 93 to 99% had no loss of CDVA. For predictability, 94% achieved within ± 1.0D of target refraction. Correction of astigmatism was often inadequate in SMILE.[29,30] Our data showed that 87 to 96% of all subjects had correction of astigmatism within ±0.5D. Using vector analysis, we quantified a correction index of astigmatism by comparing surgical with target-induced astigmatism. The index was 0.81-1.00 for SMILE and 0.94-1.03 for LASIK, suggesting satisfactory correction of astigmatism for both procedures.[4,31] In terms of biomechanical stability, our experience suggests less reduction in corneal hysteresis, corneal resistance factor in SMILE.[26] We also observed a learning curve in our SMILE cases (unpublished data).

The most common complications of SMILE, in descending order, were peripheral corneal abrasion (5.5%), corneal haze (5.4%), early dry eye (3.2%), lenticule extraction difficulties (1.5%), tear at incision edge (1.5%), suction loss (1.0%), epithelial ingrowth (0.5%), irregular topography (0.5%), corneal microstriae (0.4%), and keratitis (0.3%).[29]

Conclusion

SMILE has good safety and efficacy comparable with LASIK. As a flapless procedure, it preserves more corneal sensation than LASIK and results in less postoperative dry eyes. It also has biomechanical advantages, although this remains to be proven in studies with longer follow-up and larger sample size.

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