·Letter to the Editor·

# Analysis and management of intraoperative complications during small-incision lenticule extraction

*Pei-Jin Qiu, Ya-Bo Yang*

Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310009, Zhejiang Province, China

**Correspondence to:** Pei-Jin Qiu. Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310009, Zhejiang Province, China. qpeijin@zju.edu.cn

Received: 2016-03-20 Accepted: 2016-06-26

**DOI:10.18240/ijo.2016.11.27**

Qiu PJ, Yang YB. Analysis and management of intraoperative complications during small-incision lenticule extraction. *Int J Ophthalmol* 2016;9(11):1697-1700

**Dear Editor,**

I am Dr. Pei-Jin Qiu, from Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine in Hangzhou, Zhejiang Province, China. I write to present five cases of intraoperative complications during small-incision lenticule extraction (SMILE).

The advent of SMILE was literally a breakthrough, making the corneal refractive surgery enter the age of "knifelessness, flaplessness and minimal invasiveness" [1-4]. Nevertheless, the appearance of any novel surgical mode is necessarily accompanied by the occurrence of complications and SMILE is no exception.

We hereby report five cases of intraoperative complication during SMILE surgery with clinical findings, management and outcomes (Table 1). The VisuMax femtosecond laser system (VisuMax; Carl Zeiss Meditec, Inc.) was used for SMILE and the surgery was performed in the standard fashion [4-5]. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were measured by means of a Snellen chart.

**CASE 1**

A 26-year-old man had a preoperative refraction of -7.00-0.75×155 in the left eye, with a CDVA of 20/20. During the centering procedure, the patient's eyes kept moving due to excessive nervousness. The operator repeated docking until the third time when the suction was successfully established. During the laser scanning, it was found that at the first step of laser cutting (*i.e.* the creation of the posterior surface of lenticule) multiple black spots developed and were noted paracentrally in the left eye (Figure 1A). In this situation, the laser scanning did not stop and the procedure was performed according to the planned sequence. During the attempted separation of undersurface of lenticule, strong adhesion between the lenticule and stromal bed was noted, and the resistance was high. After multiple attempts, the lenticule was finally loosened and got extracted as a whole.

One day after the surgery, the patient had symptoms of mild irritation. Mild intrastromal edema was noted in the left cornea by the slit-lamp examinations; and the UDVA was 20/32 (20/32 with +1.75-1.00×80). After 3mo postoperatively, the patient's left cornea was transparent. At this stage, the UDVA remained 20/32 (20/25 with +1.50-0.50 ×85) and there was irregular and decentered topography (Figure 2). During subsequent follow-up examinations, there was no further improvement in the patient's UDVA, the manifest refraction and CDVA in the left eye.

**CASE 2**

A 30-year-old woman with myopia and myopic astigmatism in the left eye was due for SMILE surgery. The preoperative manifest refraction was -3.25-0.75 ×178 and the CDVA, 20/20. During the operation, it was found that white, dense plaques were generated at the third step of the laser scanning (*i.e.* the creation of the anterior surface of lenticule) (Figure 1B). In this situation, the surgery was continued and eventually completed smoothly.

One day after the surgery, the patient's cornea in the operative eye was completely transparent. The UDVA was 20/25, with -0.25 D; the CDVA was 20/20. Three months postoperatively, the UDVA was 20/20, the manifest refraction was plano -0.50×180, and the CDVA was 20/16. In the subsequent follow-up intervals, the UDVA, CDVA and the refraction remained stable.

**CASE 3**

An 18-year-old man had SMILE surgery for the correction of myopia and myopic astigmatism of -4.25-0.25 ×178 in the right eye. The CDVA was 20/20. During the femtosecond scan pass at the first step of procedure (*i.e.* the creation of the posterior surface of lenticule), it was observed that the patient suddenly moved his eyes due to nervousness, thereby inducing the separation of the contact glass from the cornea and generating suction loss (Figure 1C). The system indicated that the cut completion was >10% . After the patient's consent was obtained, the SMILE surgery was

**Table 1 Demographics and clinical manifestations of patients**

| Case | Age/gender | Eye | Preop. SE (D) | Complication | Time of occurrence | Immediate retreatment | Visual and refractive outcomes 3mo follow-up | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | UDVA | CDVA | SE (D) |
| 1 | 26/M | L | -7.38 | Black spots | Posterior lenticule cut | None | 20/32 | 20/25 | +1.25 |
| 2 | 30/F | L | -3.63 | OBL | Anterior lenticule cut | None | 20/20 | 20/16 | -0.25 |
| 3 | 18/M | R | -4.38 | Suction loss | Posterior lenticule cut >10% | FS-LASIK | 20/20 | 20/20 | +0.25 |
| 4 | 20/M | L | -3.25 | Incomplete laser incision opening | Cap opening incision | Manual keratotomy | 20/20 | 20/20 | -0.25 |
| 5 | 23/F | R | -6.25 | Suction loss | Anterior lenticule cut | SMILE | 20/20 | 20/20 | -0.50 |

SMILE: Small-incision lenticule extraction; Preop.: Pre-operative; SE: Spherical equivalent; FS-LASIK: Femtosecond laser assisted laser *in situ* keratomileusis; UDVA: Uncorrected distance visual acuity; CDVA: corrected distance visual acuity; OBL: Opaque bubble layer.

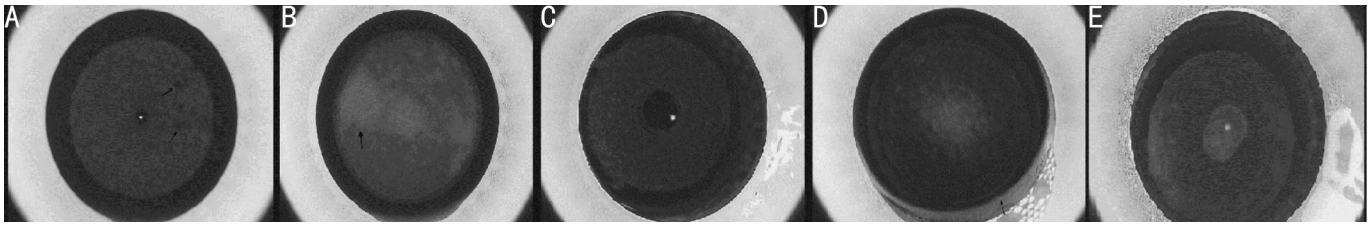


**Figure 1 The intraoperative findings** A: Black spots (black arrows) occurred during the posterior lenticule cut; B: An opaque bubble layer (OBL) (black arrow) developed during the anterior lenticule cut; C: Suction loss after the cut completion of the posterior lenticule was >10%; D: Incomplete corneal incision opening (black arrow) developed during SMILE; E: Suction loss during the creation of the anterior lenticule.

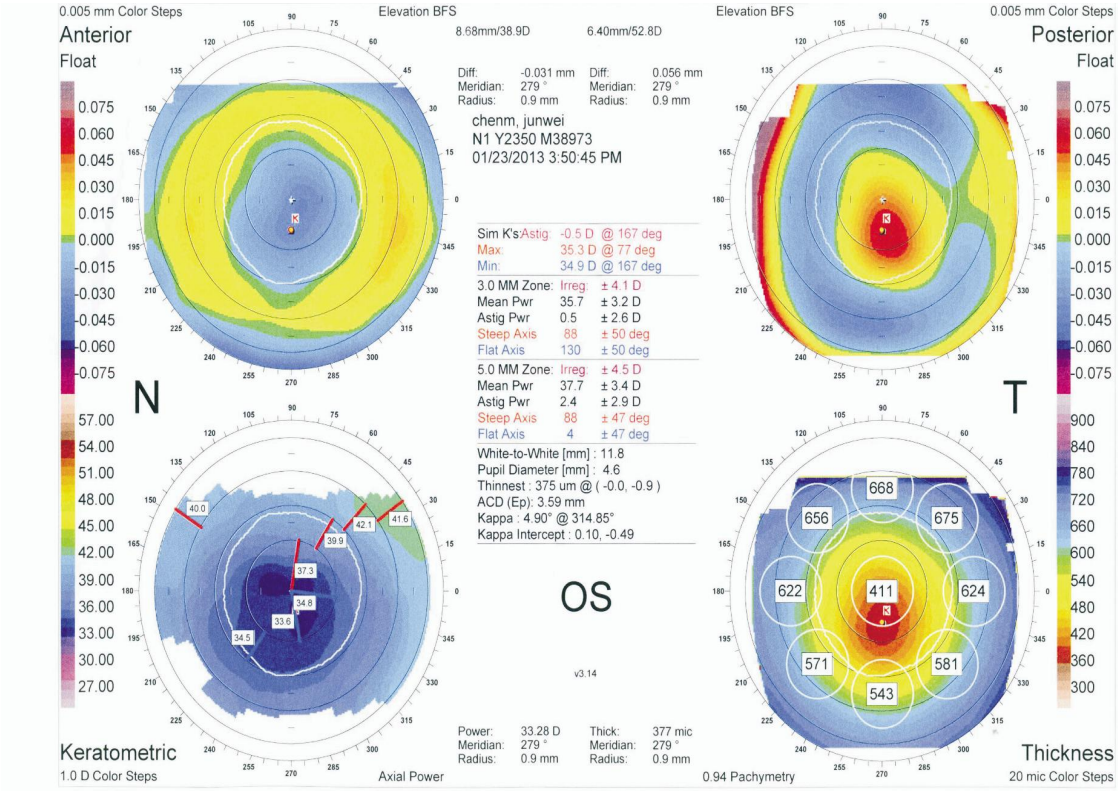


**Figure 2 In case 1, the corneal topography postoperatively showed an irregular surface and an decentration.**

immediately converted to femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) and accordingly the laser treatment parameters were adjusted, including the initial value of the diameter of corneal flap being reduced by 0.4 mm and the thickness of corneal flap being increased by 20 μm. The FS-LASIK surgery was completed successfully.

One day after the surgery, the right cornea was completely transparent; the UDVA in the right eye was 20/20 (20/20 with plano -0.25×175). Three months postoperatively, the patient's UDVA and CDVA was 20/20 or better; the SE was +0.25 D. The patient was satisfied with the surgical efficacy.

**CASE 4**

A 20-year-old man had SMILE for the correction of myopia and myopic astigmatism of -2.75-1.00×10 in the left eye. The CDVA was 20/20 preoperatively. The contact glass lost suction almost during the end of the laser therapy (*i.e.* the

cap side-cut was almost completely cut and only the epithelium had not yet been cut) (Figure 1D) due to the sudden eyeball movement, resulting in corneal incision incomplete opening. A diamond knife was immediately utilized to perform the keratotomy to open the incision to form a 2.0 mm incision, from which the lenticule was extracted successfully. A bandage contact lens was used to protect the incision afterward.

One day after the operation, the patient had relatively severe symptoms of irritation in the operative eye. A patchy epithelial defect was noted near the incision by means of the slit lamp, and mild edema was seen paracentrally in the cornea. The bandage contact lens continued to be used till the third day postoperatively; the epithelial detect was healed completely and the cornea recovered to be transparent. At this stage, the UDVA was 20/25; with +0.25-0.50×165 and the CDVA was 20/25. Two weeks after operation, the UDVA in the left eye was 20/20 (20/20 with +0.25 D). Three months after operation, both the UDVA and CDVA were 20/20, and the SE was -0.25 D.

**CASE 5**

A 23-year-old woman had SMILE for the correction of myopia and myopic astigmatism. Her preoperative refraction was given as -5.75-1.00×60 in the right eye, with a CDVA of 20/20. During the scan pass at the anterior lenticule cut, suction loss occurred due to the patient's sudden eye contraction (Figure 1E) and the femtosecond laser scanning stopped automatically. According to the management protocol of suction loss (per manufacturer's recommendation), the SMILE procedure was re-started, and the surgery was completed successfully after reapplication of suction.

On the first postoperative day, the cornea was completely transparent. The UDVA was 20/20 in the right eye; with +0.50 D, and the CDVA was 20/16. It was found that the UDVA and CDVA were 20/20 or better, and the SE of the operative eye was -0.25 D and -0.50 D after one month and three months respectively.

In 2011, Sekundo *et al* [3] and Shah *et al* [4] reported the results of SMILE surgery for correcting refractive errors. Compared with FS-LASIK, the advantage of SMILE surgery is that there is no need for flap creation [6-9]. Therefore, the flap-related complications could be avoided. At present, SMILE surgery has been widely accepted in the field of corneal refractive surgery. Since SMILE surgery involves creating an intrastromal lenticule by femtosecond laser and extracting through the small corneal incisions, which have high technique challenges faced by a surgeon who is transforming to SMILE. Due to the latest achievements in the development of corneal refractive surgery, there are only a few reports addressing the occurrence and management of complications during SMILE surgery[3,6,8,10-11].

The reason why black spots occurs is generally the insufficient laser energy or an unclean interface (including the surfaces of the contact glasses or/and corneal surfaces). Like the development of black spots in case 1, it is due to the patient's uncooperativeness during the surgery. Repeated docking manipulation might have induced the adherence of lipids or other foreign bodies to the contact surfaces, inducing blockage of the laser energy conduction and resulting in the insufficient photodisruption of the influenced corneal tissues. Because the surgeon was at the initial learning curve of the SMILE technique, the situation was wrongly assessed at the critical juncture and the surgeon improperly considered that the lenticule should be separated successfully. However, it was found that the lenticular tissues and stromal bed were closely connected and the lenticular tissues were loosened after many attempts of separating. The separation manipulation might induce injuries in corneal stromal bed, subsequently resulting in an irregular astigmatism as well as the drop in CDVA postopertively. Furthermore, the decentered ablation might be another factor leading to the decreased CDVA [12]. In our present experience, the appropriate management should be as follows: when the black spots are found and it is pre-judged that the black spots could influence lenticule separation, measures should be promptly adopted to produce the active suction loss and the surgery should be discontinued immediately. After the contact glasses or the corneal surfaces are cleaned, the planned SMILE is suggested to be changed to FS-LASIK.

An opaque bubble layer (OBL) is a common complication during SMILE surgery. It is divided into the hard and diffuse types and their components are carbon dioxide and water vapor. According to literature reports [13-14], the occurrence of OBL is related to the intensity of laser energy, corneal thickness, size of the corneal flap diameter and degree of corneal flattened during the docking procedure. To minimize the possibility of OBLs, the optimal laser energy should be selected before the operation; the appropriate treatment parameters should be set and the surgeon should use a lighter applanation technique. In the case of very pronounced OBLs during surgery, the lenticule extraction operation can be postponed to allow the OBLs dissipate. In light of our clinical observation, the presence of an OBL does not affect the surgical operation and does not seem to adversely affect the results.

Suction loss is a significant complication in SMILE surgery and the incidence varies from 1% or less to 4.4% as reported in literature [6,10-11]. The reasons for suction loss are as follows: first, the patient is uncooperative and suddenly moves the eye or head during the docked state. Also, the excess liquid on the ocular surface enters the suction ports and the conjunctival tissues enter the regions between the cornea and

negative pressure ring. In addition, the longer duration of suction can predispose a patient to suction loss during SMILE surgery. How to proceed in the event of suction loss mainly depends on the different stages of laser cutting at which it occurs [11], as shown in cases 3 and 5, and the SMILE procedure is continued to be adopted or switched to FS-LASIK. The measures to prevent suction loss include: giving psychological comfort to patients to prevent anxiety arising during the laser therapy, reducing the duration of suction, eliminating excessive water on the surface of eyes or performing the centering correctly.

Incomplete laser incision opening happens for several reasons. First, the sudden movement of the patients' eyes during the last step of femtosecond scan (*i.e.* the cap opening incision) induces suction loss. Also, the excessive water accumulating in the surfaces of eyeballs blocks or reduces the energy conduction of the femtosecond laser. Prolapse of the superior conjunctival is the commonest reason for incomplete access incision. In this situation, a diamond knife or other suitable surgical instruments can be used to assist the opening of the corneal incisions [3]. More ideally, the circle software has to be used to perform another access incision to get entry and dissect the lenticule.

In summary, this is only a sample of complications that are possible with this surgery, and there may be more intraoperative complications that did not occur in this series. Intraoperative complications during SMILE surgery may cause potential loss of visual acuity. Adopting the appropriate management can effectively avoid or relieve the visual damage arising from the complications.

## ACKNOWLEDGEMENTS

**Author Contributions:** Conception and design (Qiu PJ, Yang YB); data collection (Qiu PJ, Yang YB); analysis and interpretation (Qiu PJ); writing the manuscript (Qiu PJ); critical revision of manuscript (Qiu PJ, Yang YB).

**Conflicts of Interest: Qiu PJ,** None; **Yang YB,** None.

## REFERENCES

1 Sekundo W, Kunert K, Russmann C, Gille A, Bissmann W, Stobrawa G, Sticker M, Bischoff M, Blum M. First efficacy and safety study of femtosecond lenticule extraction for the correction of myopia: six-month results. *J Cataract Refract Surg* 2008;34(9):1513-1520.

2 Blum M, Kunert K, Schröder M, Sekundo W. Femtosecond lenticule extraction for the correction of myopia: preliminary 6-month results. *Graefes Arch Clin Exp Ophthalmol* 2010;248(7):1019-1027.

3 Sekundo W, Kunert KS, Blum M. Small incision corneal refractive surgery using the small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism: results of a 6 month prospective study. *Br J Ophthalmol* 2011;95(3):335-339.

4 Shah R, Shah S, Sengupta S. Results of small incision lenticule extraction: all-in-one femtosecond laser refractive surgery. *J Cataract Refract Surg* 2011;37(1):127-137.

5 Reinstein DZ, Archer TJ, Gobbe M. Accuracy and reproducibility of cap thickness in small incision lenticule extraction. *J Refract Surg* 2013;29 (12):810-815.

6 Ramirez-Miranda A, Ramirez-Luquin T, Navas A, Graue-Hernandez EO. Refractive lenticule extraction complications. *Cornea* 2015;34 (10s): S65-67.

7 Qiu PJ, Yang YB. Early changes to dry eye and ocular surface after small-incision lenticule extraction for myopia. *Int J Ophthalmol* 2016;9(4): 575-579.

8 Zhao J, He L, Yao P, Shen Y, Zhou Z, Miao H, Wang X, Zhou X. Diffuse lamellar keratitis after small-incision lenticule extraction. *J Cataract Refract Surg* 2015;41(2):400-407.

9 Sekundo W, Gertnere J, Bertelmann T, Solomatin I. One-year refractive results, contrast sensitivity, high-order aberrations and complications after myopic small-incision lenticule extraction (ReLEx SMILE). *Graefes Arch Clin Exp Ophthalmol* 2014;252(2):837-843.

10 Ivarsen A, Asp S, Hjortdal J. Safety and complications of more than 1500 small-incision lenticule extraction procedures. *Ophthalmology* 2014; 121(4):822-826.

11 Wong CW, Chan C, Tan D, Mehta JS. Incidence and management of suction loss in refractive lenticule extraction. *J Cataract Refract Surg* 2014; 40(12):2002-2010.

12 Li M, Zhao J, Miao H, Shen Y, Sun L, Tian M, Wadium E, Zhou X. Mild decentration measured by a Scheimpflug camera and its impact on visual quality following SMILE in the early learning curve. *Invest Ophthalmol Vis Sci* 2014; 55(6):3886-3892.

13 Courtin R, Saad A, Guilbert E, Grise-Dulac A, Gatinel D. Opaque bubble layer risk factors in femtosecond laser-assisted LASIK. *J Refract Surg* 2015;31(9):608-612.

14 Kaiserman I, Maresky HS, Bahar I, Rootman DS. Incidence, possible risk factors, and potential effects of an opaque bubble layer created by a femtosecond laser. *J Cataract Refract Surg* 2008; 34(3):417-423.