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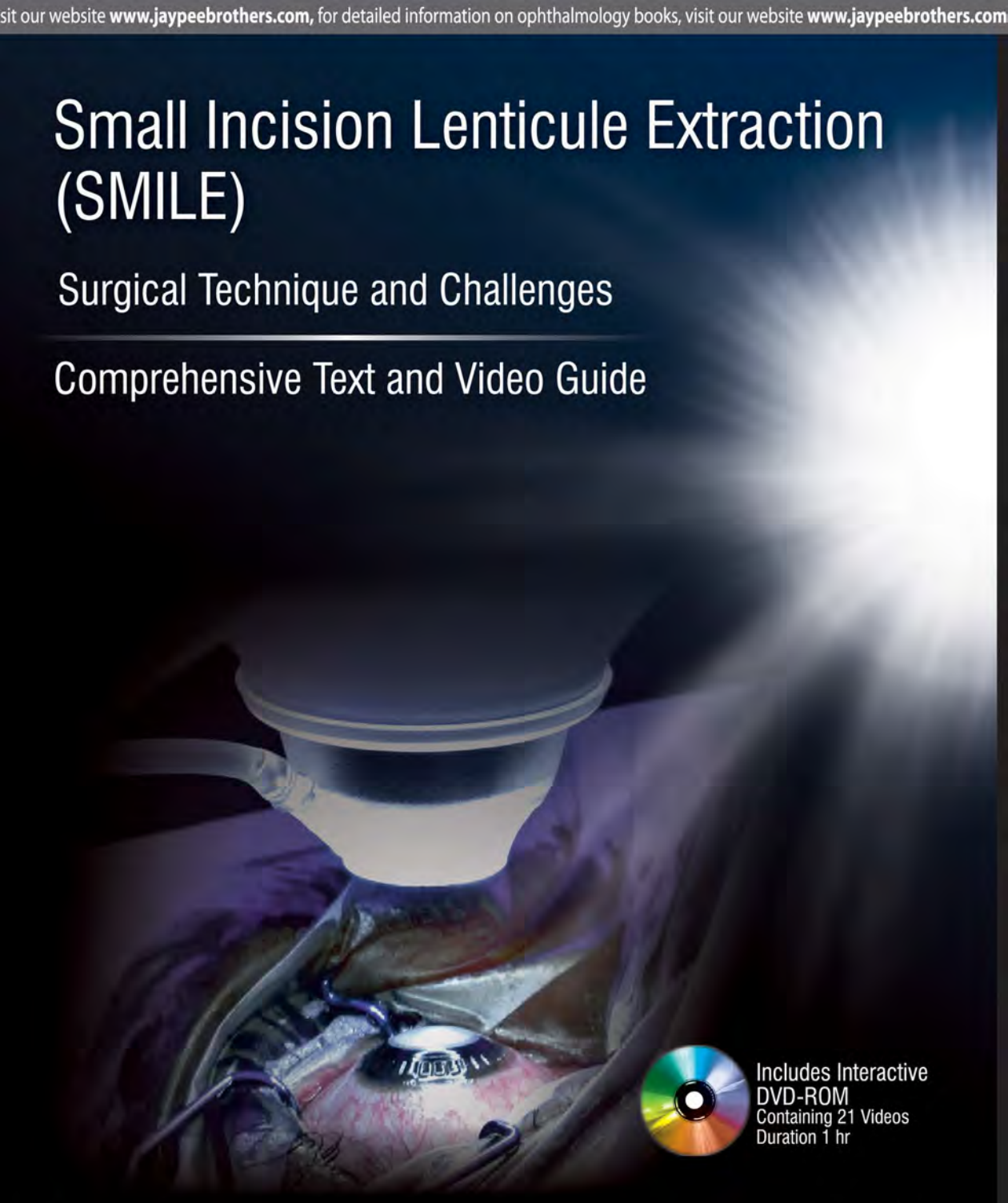
Small Incision Lenticule Extraction (SMILE)

Surgical Technique and Challenges

Comprehensive Text and Video Guide



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Contents

1. **Evolution of Femtosecond Laser Technology in Refractive Surgery** 1
   Sridevi Nair, Manpreet Kaur, Jeewan S Titiyal
2. **Patient Counseling and Preoperative Evaluation** 9
   Sridevi Nair, Manpreet Kaur, Jeewan S Titiyal
3. **Corneal Wound Healing, Morphological and Biomechanical Changes after Small Incision Lenticule Extraction** 21
   Pranita Sahay, Manpreet Kaur, Anand Singh Brar, Jeewan S Titiyal
4. **Understanding the Machine and Laser Settings** 32
   Anubha Rathi, Manpreet Kaur, Jeewan S Titiyal
5. **Surgical Technique of Small Incision Lenticule Extraction** 46
   Manpreet Kaur, Jeewan S Titiyal
6. **Stepwise Approach for Beginners: Navigating the Learning Curve** 65
   Anubha Rathi, Manpreet Kaur, Jeewan S Titiyal
7. **Refractive and Physiological Outcomes of Small Incision Lenticule Extraction** 77
   Pranita Sahay, Manpreet Kaur, Jeewan S Titiyal
8. **Intraoperative Complications in Small Incision Lenticule Extraction** 88
   Manpreet Kaur, Jeewan S Titiyal
9. **Postoperative Complications in Small Incision Lenticule Extraction** 113
   Ruchita Falera, Manpreet Kaur, Anand Singh Brar, Jeewan S Titiyal
10. **Post-SMILE Enhancement and Retreatment** 137
    Manpreet Kaur, Jeewan S Titiyal
11. **SMILE versus Femtosecond LASIK: Weighing the Pros and Cons** 148
    Anubha Rathi, Manpreet Kaur, Anand Singh Brar, Ramkishor Sah, Jeewan S Titiyal
12. **Future Technological Advances in Small Incision Lenticule Extraction** 161
    Harathy Selvan, Manpreet Kaur, Jeewan S Titiyal

Index *175*

Chapter

4

Understanding the Machine and Laser Settings

Anubha Rathi, Manpreet Kaur, Jeewan S Titiyal

INTRODUCTION

The concept of refractive lenticule extraction (ReLEx) heralded a landmark shift in the concept of refractive surgery from the conventional two-step flap-based corneal ablative procedures to a single-step femtosecond laser procedure.[1] The initial procedure involved lifting the flap to extract the refractive lenticule and was known as *femtosecond lenticule extraction (FLEx)*.[2,3] The technique evolved over the years to a novel flap-less procedure called *small incision lenticule extraction (SMILE)*, which rapidly gained popularity with favorable outcomes.[4] The VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) is the only laser platform approved for the creation of an intrastromal refractive lenticule.[5] A complete and thorough knowledge of the machine and its parameters is of paramount importance before undertaking any refractive surgery. This chapter is aimed at describing in detail the machine, its components and the pretreatment settings which are required for successful completion of the procedure.

BASIC PRINCIPLE OF THE MACHINE

Femtosecond lasers are near-infrared lasers with ultrashort duration of pulses to the order of 10^{-15} seconds which result in minimal collateral tissue damage. They work on the principle of *photodisruption*. Photodisruption involves the nonlinear absorption of laser energy in the target, which results in optical breakdown of the tissue. The highly focused femtosecond laser pulses form plasma of free electrons and ionized molecules at the laser focus and the phenomenon is called *laser-induced optical breakdown (LIOB)*. The rapid expansion of plasma results in the formation of cavitation bubbles, which enlarge and coalesce to allow separation of tissue with minimal damage to the surrounding tissue.

The VisuMax femtosecond laser system (Fig. 4.1) delivers focused pattern of femtosecond pulses on to the cornea and cuts at a precise pre-decided depth and position.

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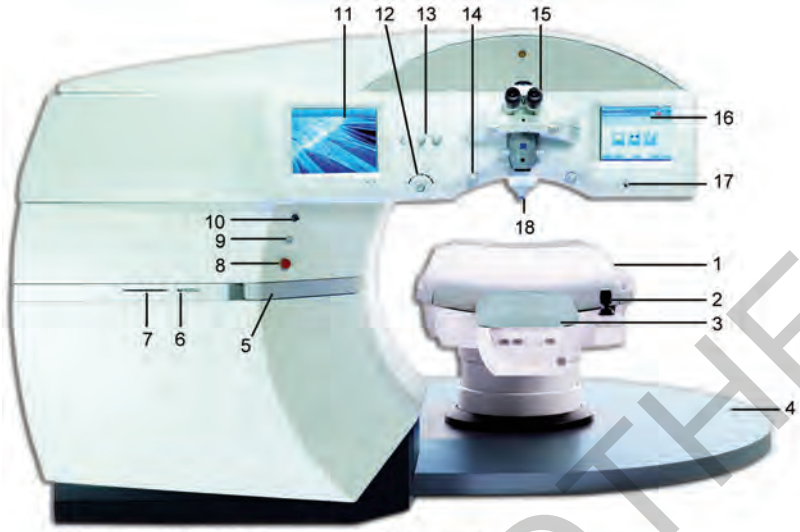

1 Patient supporting system
2 Joystick
3 Headrest
4 Rotating platform
5 Keyboard tray
6 USB 2.0 interface
7 DVD RAM drive
8 Emergency stop button
9 System start button
10 Key switch
11 Monitor (system control)
12 Vacuum suction control and display
13 Illumination control
14 Slit illumination system
15 Surgical microscope with integrated video camera
16 Touch screen (procedure control)
17 Treatment pack vacuum connection
18 Laser aperture

Fig. 4.1: VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany).

The machine weighs 870 kg and serves as a one-stop station for SMILE unlike femtosecond laser-assisted in situ keratomileusis (FS-LASIK) that requires two separate stations for excimer and femtosecond laser.

UNDERSTANDING THE MACHINE

The functional components of the VisuMax femtosecond laser system are highlighted and summarized in Table 4.1 (Figs. 4.1 and 4.2). The machine is switched on by pushing the system start button, followed by inserting the key in the key switch. The machine houses a computer unit, laser arm and vacuum system, microscope, patient supporting system and a foot switch. Different illumination systems are integrated in the machine, including diffuse, slit and infrared illumination (Fig. 4.3). The treatment pack is a single-use disposable contact lens with attached tubing that provides the interface between the patient and the machine (Fig. 4.4).

Computer Unit

An integrated computer with a graphic user-interface enables easy control of the laser keratome (Fig. 4.3). The graphic user interface allows the user

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Table 4.1: Components of VisuMax femtosecond laser system

Component	*Description*
Computer unit	▪ In-built graphic user interface ▪ Feeding treatment data ▪ Two output screens i. *Left screen*: Treatment planning and live monitoring ii. *Right screen*: Graphic user interface, displays progress of treatment.
Laser arm and vacuum system	▪ Directs the laser radiation from the laser unit to the exit aperture ▪ Vacuum system provides attachment for contact lens onto laser aperture, and fixes the eye on the contact lens
Microscope	▪ Surgical microscope ▪ Switches between observation and treatment mode ▪ Diffuse, infrared and slit illumination ▪ In-built video recording
Patient supporting system	▪ Operating table with headrest ▪ *Three positions*: (1) starting, (2) observation and (3) treatment positions ▪ Allows comfortable patient positioning ▪ Movements controlled automatically by laser keratome, manually by joystick
Foot switch	▪ Controls laser delivery • *Press*: Opens laser shutter and activates laser delivery • *Release*: Closes laser shutter and stops laser
Treatment pack	▪ Single-use disposable contact lens with attached tubing ▪ Provides interface between the patient and the machine ▪ Three sizes: (1) small, (2) medium and (3) large (*S*, *M* and *L*), based on white-to-white diameter of the patient.

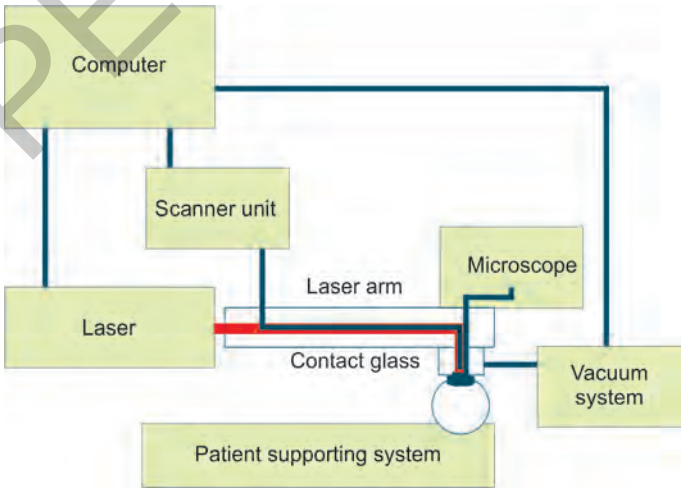

Fig. 4.2: Functional components of the VisuMax femtosecond laser system.

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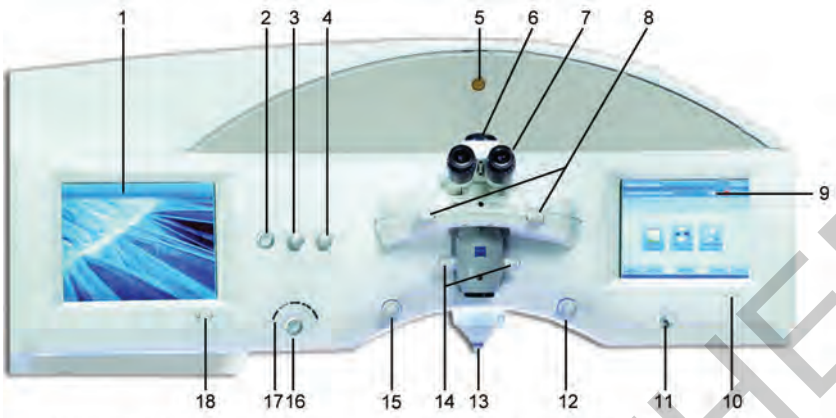

1 Monitor (system control)
2 Infrared illumination
3 Illumination control (observation)
4 Illumination control (treatment)
5 Laser radiation emission indicator
6 Interpupillary distance adjustment
7 Eyepiece
8 Fine focus adjustment
9 Touch screen (procedure control)
10, 18 Brightness control
11 Vacuum suction connection for treatment pack
12, 15 Slit illumination system
13 Laser treatment aperture
14 Magnification control (Objective)
16 Vacuum suction control element (on/off)
17 Vacuum suction display

Fig. 4.3: Control elements and display on the laser keratome.



Fig. 4.4: Single-use treatment pack with contact glass interface.

to enter the patient details and preoperative data, as well as saves the treatment data. The laser settings and treatment parameters may be modified by the surgeon as per requirements. Other computers control and monitor the internal sequences.

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The VisuMax femtosecond laser system for ReLEx SMILE is user friendly with two computer output screens. Instructions for the surgeon and the real-time status of treatment are displayed on the touch screens. The left screen is for treatment planning and live monitoring of the surgery, while the screen on the right side of the surgeon is the graphic user interface and shows the progress of the treatment. The progress of treatment planning can also be analyzed on this screen graphically.

Laser Arm and Vacuum System

Laser arm directs the laser radiation from the laser unit to the exit aperture of the treatment lens. A contact glass is coupled to the patient's eye connecting it to the laser exit aperture.

The vacuum system provides the attachment for the contact lens onto the laser aperture, and fixes the eye on the contact lens. It stabilizes patient's eye and ensures that the eye is aligned with the contact glass and the laser exit aperture.

Suction is initiated by pressing the top button on the joystick. The vacuum level is monitored by in-built pressure sensors and displayed by the blue LED scale on the vacuum suction pressure display. The presence of four or more blue bars on the LED display denotes an adequate quality of the generated vacuum. Laser application is possible only after generation of adequate vacuum.

Patient Supporting System

The patient supporting system consists of an operating table along with the headrest. It is mobile and the position is controlled automatically by the laser keratome and manually by the joystick. Three positions of the patient supporting system are: (1) the starting position, (2) the observation position and (3) the treatment position. It allows comfortable positioning of the patient and ensures accurate and precise movement during the surgery.

Surgical Microscope

The surgical microscope with a binocular eyepiece aids in ocular examination, preparation for surgery as well as observation and completion of the surgical process. The inter-pupillary distance, magnification (objective: 0.4–2.5×, eyepiece: 10×) and fine-focus can be adjusted with the help of in-built knobs. Integrated video camera in the microscope aids in recording the surgical videos. The provision of an integrated slit-illumination system allows an on-table assessment of the interface at the end of surgery. The surgical microscope can shift between the treatment position (for docking and laser delivery) and observation position (for lenticule dissection and extraction), in concordance with the movement of the patient supporting system.

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Foot Switch

The foot switch is connected to the machine and is used to control the laser delivery. Pressing the foot switch opens the laser shutter and activates the laser treatment. Releasing the foot switch closes the laser shutter and stops the laser treatment.

Illumination Systems (Fig. 4.3)

- *Observation position*: The patient's eye is illuminated by the microscope lamp in observation position beneath the surgical microscope. Two knurled knobs are present that allow the adjustment of brightness levels by turning the knobs.
- *Treatment position*: The patient's eye is illuminated by the illumination at the contact glass mount in the treatment position beneath the therapy lens. The brightness can be adjusted by turning the knurled knob, and illumination can be turned on or off by pushing the knob.
- *Slit illumination*: Slit illumination is available on the left or right-hand side of the surgical microscope with a fixed slit dimension (0.5 mm × 12 mm). It is activated by pushing on the knurled knob on either side, which switches off the diffuse white illumination and activates the slit illumination. The slit position and angle can be adjusted by rotating the knurled knob. It is switched off by pushing the knob again.
- *Infrared illumination*: The infrared button can be used to switch between white light and infrared illumination. It aids in centering the contact lens during docking. The infrared image is displayed on the left-hand side monitor.

Treatment Pack

The *treatment pack* (Fig. 4.4) refers to the single use curved treatment interface or contact lens which is docked to the patient's eye and aligns it to the laser exit beam aperture. It consists of a patient interface with a contact glass, connecting tubing, filter and a vacuum connection which is subsequently attached to the control panel.

The curved nature of the interface ensures that the corneal apex does not shift during applanation. It is illuminated at the time of surgery and serves as an illuminated fixation target for patient eye alignment. It is available in three sizes: (1) small, (2) medium and (3) large (*S*, *M* and *L*). The choice of size of treatment pack for surgery depends on the white-to-white diameter of the patient. The diameter of the suction ring should be less than the effective white-to-white diameter of the patient. Moreover, the effective maximum cap diameter possible with the selected treatment pack should be more than or at least equal to the proposed cap diameter. The smallest possible treatment pack should ideally be selected. If the ring is too large, it may cause suction on

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Table 4.2: Manufacturer recommended treatment pack size and the minimum white-to-white diameters for small incision lenticule extraction

Size of treatment pack	*Small**	*Medium*	*Large*
Minimum WTW diameter	11.2	11.7	12.4

Note: *Universally preferred size for WTW < 11.2 mm.
(WTW: White-to-white diameter).

adjacent conjunctiva and lead to subconjunctival hemorrhage, conjunctival bogging or premature abortion of the treatment due to loss of suction.

The recommended treatment pack size as per the white-to-white measurement is given in Table 4.2.

Safety Systems

The laser keratome has an outer protective housing to prevent inadvertent laser exposure to the medical personnel. A beam attenuator is installed on the laser keratome as well as the viewing optics to limit the radiation exposure. An internal power supply provides a failsafe mechanism in the event of intraoperative power failures, and can provide an uninterrupted power supply for up to 3 minutes.

An emergency stop button provides the option to immediately abort the procedure if required. A key switch switches on the laser keratome and boots up the computer on inserting the key. It requires the insertion of a key during the surgical procedure, and laser cannot be triggered after removing the key. The laser radiation warning indicator is illuminated when the laser is being fired.

UNDERSTANDING THE LASER PARAMETERS

The VisuMax laser system has in-built surgical applications for FLEx, flap, circle, keratoplasty and intracorneal ring segment incisions along with that of ReLEx SMILE. Hence, the first step in planning is to choose the right procedure. This chapter deals with planning of the ReLEx SMILE procedure.

Treatment planning involves accurate entry of the treatment data which includes the lenticule and the cap parameters (Figs. 4.5 and 4.6). Lenticule dimensions mainly depend on the manifest refraction, optical zone (OZ) diameter, transition zone (TZ) and minimum lenticule thickness predefined. All these parameters need to be entered while planning the treatment. The lenticule and cap treatment parameters are summarized in Table 4.3.

Lenticule Parameters (Table 4.3 and Fig. 4.5)

- *Optical zone* diameter ranges from 5 mm to 8 mm. The OZ is selected on the basis of pupil size, and may be increased in patients with a large

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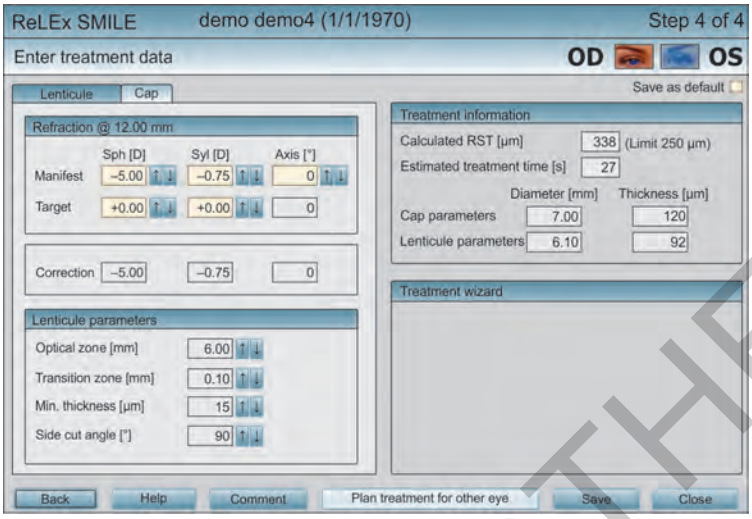

Fig. 4.5: Lenticule parameters for small incision lenticule extraction.

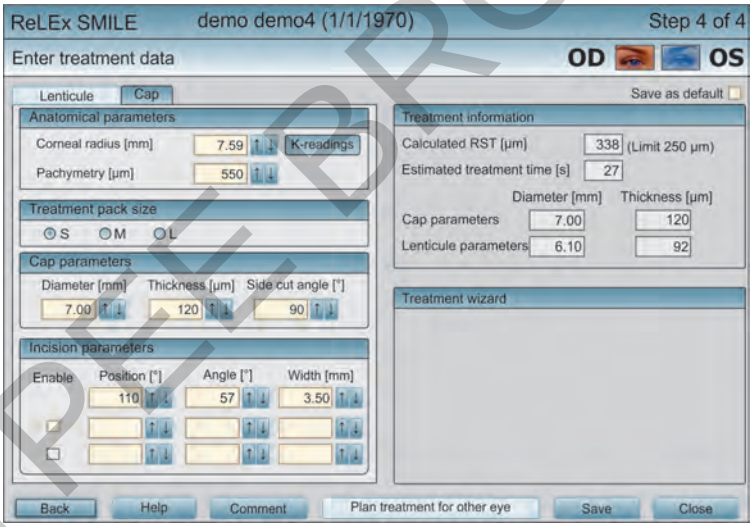

Fig. 4.6: Cap parameters for small incision lenticule extraction.

mesopic pupil. It is usually set at 6–6.5 mm for average corneal diameters of 10–12 mm.

- *Transition zone* is preset and depends on the manifest refraction. In case of purely spherical errors, the machine automatically sets the value at 0 while in case of any cylinder, the value changes to 0.10 mm.
- *Lenticule diameter* is the sum of OZ diameter and the TZ.

Lenticule diameter = OZ + TZ.

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Table 4.3: Treatment parameters for small incision lenticule extraction using VisuMax femtosecond laser system

Parameter	*Range*
Cap parameters	
▪ Cap thickness	100–160 µm
▪ Cap diameter	6–9.6 mm
▪ Incision position	0–359°
▪ Incision width	2–5 mm
▪ Cap side-cut angle	45–135°
Lenticule parameters	
▪ Lenticule diameter	5–8 mm
▪ Transition zone	0.10 mm for CYL 0 for SPH
▪ Minimum lenticule thickness	10–30 µm
▪ Lenticule side cut angle	90–179°

- *Minimum thickness of the lenticule (LT_{min})* in myopic SMILE refers to the peripheral edge of the lenticule. While the central thickness varies with the refractive error, the peripheral minimum thickness can be prefixed. It can be altered by the user as per surgeon's ease in handling thinner lenticule and in cases of lower refractive errors. In most cases, the minimum thickness of lenticule is fixed at 15 µm, though it can be increased to 25–30 µm in case of lower refractive errors where a thinner lenticule is expected. The height of lenticule side cut is equal to the lenticule minimum thickness.
- *Total lenticule thickness (LT_{total})* is the sum of minimum thickness of lenticule (LT_{min}) and the amount of tissue (n) that will be removed as per the amount of refractive error. This is usually extrapolated from Munnerlyn formula and is considered to be around 13 µm for every diopter correction at 6 mm OZ.

$$LT_{total} = LT_{min} + n.$$

Cap Parameters

Cap parameters that need to be entered in the graphic-user interface during treatment planning include the keratometry and the thinnest corneal thickness measured (Table 4.3 and Fig. 4.6).

- *Cap diameter* is 0.5–1 mm oversized from the OZ diameter. The effective maximum cap diameter ranges from 6 mm to 9.6 mm, and depends on the size of treatment pack, cap thickness, radius of the corneal curvature and the side cut angle.

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- *Cap thickness* is 120 microns in standard cases, though it may be varied from 100 microns to 160 microns depending upon the refractive error and corneal thickness.
- *Cap side-cut* is usually placed between 90° and 180° depending on surgeon's dexterity and ease of functioning. The incision width may vary from 2 mm to 5 mm, with wider incision for initial cases. One or two cap side-cut incisions may be selected, depending upon the surgeon preference.
- *Residual stromal bed thickness (RSBT)* is calculated by the machine using in-built nomograms for lenticule thickness according to refractive error. The acceptable limit for RSBT is 250–280 microns.
- *Keratometry* is entered as per the corneal topography of the patient. Both the radius of curvature and the dioptric power may be entered.

Selection of Laser Settings

Laser settings are preset in the machine and depend on the mode selected (Table 4.4). Three modes of treatment are available, that is (1) *Standard*, (2) *Fast* and (3) *Expert modes*. The *standard mode* refers to the default laser parameters set by the manufacturers. The *fast mode* may be altered only by the application specialists, and consists of pre-set laser parameters customized according to the region. The *expert mode* has modifiable laser settings which may be optimized by the surgeon, according to the surgeon preference and patient response. The expert mode allows the surgeon to make modifications in the laser parameters of the fast mode (which have been set by the application specialist for that region), within a certain range. It is advisable to consult the application specialist regarding the optimal laser and energy settings.

- *Spot spacing*
  Spot spacing refers to the distance between two adjacent laser spots (Fig. 4.7) and ranges from 2.0 µm to 4.5 µm. In the expert mode, the surgeon may modify spot spacing in steps of ±0.1 microns each, by a maximum of ±0.5 microns.
- *Track spacing*
  Track spacing refers to the distance between two laser spots in adjacent tracks (Fig. 4.7) and ranges from 2.0 µm to 4.5 µm. In the expert mode, the surgeon may modify track spacing in steps of ±0.1 microns each, by a maximum of ±0.5 microns.
- *Pulse energy*
  Pulse energy defines the size of the cavitation bubbles which are produced during femtosecond laser cuts. It lies in the range of 100–260 nJ (recommended 100–160 nJ). Energy offset is set for each cut separately in expert mode.

  1 Energy offset = 5 nJ pulse energy.

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Table 4.4: Laser parameters used for small incision lenticule extraction

Parameter	*Range*	*Expert mode*[1]	*Standard mode*[2]	*Fast mode*[3]
Pulse energy	100–260 nJ (recommended 100–160 nJ)	140–200 nJ	130 nJ	170 nJ
Energy offset (1 offset = 5 nJ)	20–52	28–40	26	34
Track distance	2.0–4.5 µm	▪ Lenticule and cap cuts: 4.5 ± 0.5 µm ▪ Lenticule and cap side-cuts: 2 ± 0.5 µm	▪ 3 µm for lenticule and cap cuts ▪ 2 µm for lenticule and cap side-cuts	▪ 4.5 µm for lenticule and cap cuts ▪ 2 µm for lenticule and cap side-cuts
Spot distance	2.0–4.5 µm	▪ Lenticule and cap cuts: 4.5 ± 0.5 µm ▪ Lenticule and cap side-cuts: 2 ± 0.5 µm	▪ 3 µm for lenticule and cap cuts ▪ 2 µm for lenticule and cap side-cuts	▪ 4.5 µm for lenticule and cap cuts ▪ 2 µm for lenticule and cap side-cuts
Scan direction	Spiral in for lenticule cut; spiral out for cap cut	Fixed	Fixed	Fixed
Scan mode	Single	Fixed	Fixed	Fixed
Wavelength	1,043 nm	Fixed	Fixed	Fixed
Pulse duration	220–580 fs	Fixed	Fixed	Fixed
Laser repetition rate	500 kHz	Fixed	Fixed	Fixed

[1] The expert mode allows the surgeon to vary the “fast” mode settings within a certain range.
[2] The standard settings are preset by the manufacturer.
[3] The fast settings are set by the application specialist, and may vary from surgeon to surgeon.

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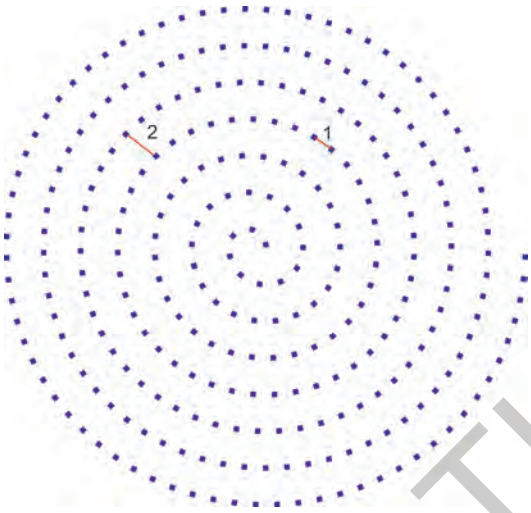

Fig. 4.7: Concentric arrangement of laser spots depicting spot distance (1) and track distance (2).

The energy offset may lie in the range of 20–52 (recommended 20–32), and may be titrated by the surgeon as per the observed clinical effects, in terms of smooth dissection and minimal opaque bubble layer (OBL) formation. The expert mode allows the surgeon to modify energy offset by ±6 steps (total energy ± 30 nJ).

- *Scan direction and mode*

  Scan direction refers to the direction of the spiral that the laser follows while making the cuts. Conventionally, it is spiral in for posterior plane and spiral out for anterior plane. In SMILE, for the lenticule formation, these spirals must be elliptical and not circular.

  Scan mode is preset as "single", and refers to the creation of the entire lenticule in one go. Scan mode can be changed only by the application specialist, and may be single or double; however, only single scan mode is preferred.

These settings affect the amount of energy being delivered to the cornea and the quality of cut as well as duration of surgery (Table 4.5). Decreased laser *spot distance or track distance* will deliver the laser spots close to each other and hence, cumulatively more energy is delivered to cornea. This may produce smoother cuts with more complete dissection and possibly less adhesions. On the other hand, widely spaced spots or tracks may lead to more intraoperative difficulty owing to increased possibility of adhesions. Higher *pulse energy* for cuts has been seen to be associated with suboptimal visual recovery and increased higher order aberrations. OBL is seen to occur with both excessively high energy and low energy. In case of higher pulse energy,

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Table 4.5: Effect of spot distance, track distance and pulse energy on small incision lenticule extraction

Parameter	*Effect*
Decreased spot distance, track distance	▪ More energy delivered to cornea ▪ Smoother cuts ▪ More complete dissection, less adhesions
Increased spot distance, track distance	▪ Less energy delivered to cornea ▪ Less smooth cuts ▪ May have more adhesions
Decreased pulse energy	▪ Less energy delivered to cornea ▪ Less smooth cuts ▪ May have more adhesions ▪ May have faster visual recovery ▪ Better quality of postoperative vision
Increased pulse energy	▪ More energy delivered to cornea ▪ Smoother cuts ▪ More complete dissection, less adhesions ▪ Increased risk of dense opaque bubble layer ▪ May have prolonged visual recovery ▪ May affect postoperative quality of vision

large cavitation bubbles and shock waves spread the corneal collagen lamellae apart with force and lead to OBL formation which shoots ahead of the laser beam. OBL may also occur when the pulse energy is much below the accepted limit though such OBLs are less dense and patchy and appear late during laser delivery.

MAINTENANCE OF THE MACHINE AND SET-UP CONDITIONS

Refractive surgery modules such as VisuMax femtosecond laser system require accurate temperature and humidity conditions for smooth functioning (Table 4.6). Maintenance and regular servicing are of utmost importance. The well being of the machine in several ways decides the surgical outcomes as well. Hence, only trained personnel should perform the calibration, maintenance and service of the machine.

VisuMax femtosecond laser system is a 870 kg refractive surgery module that should ideally be placed in a room with adequate floor area. The permitted range of ambient temperature lies between 18°C and 25°C and humidity in the range of 30–70%. A 100–240 V electrical connection is required for the functioning of the machine. It should be placed away from inflammable products. Cell phones should be kept away from the laser operation theatre (OT) as their signals may interfere with laser delivery. Sterilization and disinfection of OT is important and standard OT practices must be followed for the same.

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Table 4.6: Technical specifications of VisuMax femtosecond laser system for performing small incision lenticule extraction

Specifications	*Value*
Weight	870 kg
Electrical connection	100–240 V
Room temperature	18–25°C
Ambient humidity	30–70%
Other accessories	▪ Single use treatment packs ▪ Keratoplasty adapter (for wet lab training and performing femtosecond keratoplasty)

An internal calibration is automatically performed by the system (system test) prior to the surgical procedure, in order to ensure the highest accuracy of the cut surface geometry.

CONCLUSION

Understanding the machine and its settings lays out the first step toward mastering any surgery. SMILE is a novel entry in the world of refractive surgery; hence, not many surgeons are yet acquainted with the machine. Complete knowledge of the principle and various components of the machine as well as the laser and surgical parameters can simplify the procedure for the surgeons, especially the beginners.

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Surgical Technique and Challenges

Comprehensive Text and Video Guide

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- One of the first comprehensive books on SMILE with an enviable video collection, providing an overview of the surgical procedure, its refractive and physiological outcomes, complications, their management and future applications.
- Concise tables, self-explanatory diagrams, clinical pictures and ASOCT images interspersed with the text to re-capitulate the important points and enhance understanding.
- In-depth description of the machine and laser settings, emphasizing the customization of treatment parameters in the 'Expert Mode' by the surgeon to achieve optimal outcomes.
- Highlight of this book is the step-by-step video assisted guidance to master the surgical technique, with integrated animations to facilitate clarity of concepts.
- Detailed description of the difficulties faced during the initial learning curve, the pre-disposing factors, preventive measures as well as their management.
- A reference guide for refractive surgeons providing an in-depth understanding of the procedure, with surgical tips and tricks.



Jeewan S Titiyal MD began his academic sojourn as an undergraduate at the All India Institute of Medical Sciences (AIIMS), New Delhi, and subsequently went on to become the faculty of AIIMS in 1991. He is currently the Professor and heads the department of Cornea, Cataract and Refractive Surgery Services at Dr Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS. He has dedicated his academic career to the pursuit of excellence in the field of ophthalmology, and this book is a culmination of his endeavors to transmit knowledge and skills to the generation of ophthalmologists. He has been honored with invitation from various organizations to deliver keynote addresses, orations and guest lectures, and chair scientific sessions. Dr Titiyal has been the 'teacher of teachers', and has been invited to perform numerous live surgeries in his field of expertise at various international and national forums. He is the first Indian to perform live surgery in ASCRS, USA. He has to his credit numerous publications in peer-reviewed journals and various book chapters as well. He has been awarded the 'Achievement Award' in 2009, as well as the 'Senior Achievement Award' in 2016 by the American Academy of Ophthalmology for his dedication towards scientific research and teaching. He has also been awarded the 'Achievement Award' by the Asia Pacific Academy of Ophthalmology in 2015, and the 'APACRS Educator Award' in 2015. He was conferred the 'Padma Shri', one of the highest civilian awards in 2014, in recognition of his exemplary contributions in the field of medicine by the Government of India.



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