SMALL INCISION LENTICULE EXTRACTION (SMILE) PROCEDURE FOR THE CORRECTION OF MYOPIA AND MYOPIC ASTIGMATISM

Essay

Submitted for partial fulfillment of Master Degree in Ophthalmology

By

Mohamed Yousry Mohamed
M.B.B.Ch.
Ain Shams University

Under Supervision of

Prof. Dr. Fekry Mohamed Zaher
Professor of Ophthalmology
Faculty of Medicine _ Ain Shams University

Prof. Dr. Tamer Mohamed EL-Raggal
Professor of Ophthalmology
Faculty of Medicine _ Ain Shams University

Faculty of Medicine
Ain Shams University
Cairo _ 2016

بسم الله الرحمن الرحيم

قَالُوا سُبحَانَكَ لا عِلمَ لَنَا
إلا مَا عَلَّمتَنَا إنَّكَ أَنتَ
العَلِيمُ الحَكِيمُ

صدق الله العظيم

(البقرة ٣٢)

Acknowledgment

Thanks to Allah, for giving me the will, patience and perseverance to carry on and finish this work to the almost of my ability.

I would like to express my deep thanks and sincere gratitude to **Prof. Dr. Fekry Mohamed Zaher,** ***Prof. of Ophthalmology, Faculty of Medicine, Ain Shams University*** for planning the present work helping in writing and for his keen supervision, generous cooperation and valuable guidance.

Very special thanks for **Prof. Dr. Tamer Mohamed EL-Raggal,** ***Prof. of Ophthalmology, Faculty of Medicine, Ain Shams University.***I am truly indebted and thankful for the valuable time he devoted in suggesting, planning, writing and supervising this work. It is a great honor to work under his guidance, valuable advice and supervision.

Lastly, I owe a great deal of gratitude and thanks to my family, specially my parent for their kind support, help and encouragement.

Mohamed yousry Mohamed

CONTENTS

Subject	page
List of abbreviations	i
List of figures	ii
Introduction and aim of the work ……………………….	1
• Introduction………………………………………………………	1
• Aim of the work …………………………………………………	4
Chapter 1: Refractive errors……………………………………	5
• Optical view……………………………………………………..	7
• Diagnosis and examination …………………………………………	10
• Management of refractive errors………………………………………	12
• Eye glasses ………………………………………………… …………..	12
• Contact lens……………………………………………………...	12
• Refractive surgery for Myopia, Astigmatism, and Hyperopia…………	14
• Surface Ablation Techniques Photorefractive Keratectomy……………	15
• Incisional Astigmatic Keratotomy………………………………..	18
• Laser Assisted In Situ Keratomileusis [LASIK]…………………….	19
• Femtosecond laser in refractive surgery…………………………….	20
• Intra-ocular refractive surgery…………………………………….	22
Chapter 2: LASIK &FemtoLASIK……………………………….	25
• Pre-operative examination…………………………………………	25
• Surgical procedure…………………………………………………	26
• Complications after LASIK procedures …………………………..	28

- Femtosecond laser in refractive surgery……………………………….… 32
- Surgical procedure……………………………………………………. 33
- Advantages of Femtosecond laser in comparison with LASIK ……… 35
- Complications of Femtosecond laser in refractive surgery…………… 39

Chapter 3:Small incision lenticule extraction (SMILE)………… 43

- Surgical Procedure…………………………………………………… 43
- Safety of SMILE Procedures ………………………… 48
- Complications of SMILE Procedures……………………………. 50
- Diffuse lamellar keratitis (DLK)……………………………. .
- Dry eye………………………………………………………………… 52
- Effect of SMILE procedure on the cornea……………………… 53
- Corneal wound healing……………………………………….... 53
- Corneal biomechanical effects…………………………………… 55
- The Relative Tensile Strength of the Cornea…………………...... 57
- Corneal sensitivity………………………………………………. 59
- Corneal regeneration …………………………………………… 60
- Cryo-preservation of Extracted Corneal Lenticules after SMILE 63

Summary…………………………………………………………….. 69

References.. 74

Arabic Summary…………………………………………………….. ١

List of abbreviations

AK	Astigmatic Keratotomy
ALK	Automated Lamellar Keratoplasty
DLK	Diffuse Lamellar Keratitis
DMSO	Dimethyl Sulfoxide
FILI	Femtosecond Laser Intra-stromal Lenticular Implantation
FLEx	Femtosecond Lenticule Extraction
FLK	Femtosecond Laser Keratomileusis
FSL	Femtosecond Laser
GPC	Giant Papillary Conjunctivities
HRT ш	Heidelberg Retinal Tomo-graphy ш
IL(1)	Interleukin 1
IOL	Intra-Ocular Lens
IVCM	In Vivo Confocal Microscopy
LASIK	Laser Assisted In Situ Keratomileusis
OBL	Opaque Bubble Layer
PRK	Photo Refractive Keratectomy
ReLEX	Refractive Lenticule Extraction

RSB	Residual Stromal Bed
SMILE	Small Incision Lenticule Extraction
TLSS	Transient Light Sensitivity Syndrome
TNF	Tumour Necrosis Marker

List of Figures

Items	Figure	page
Fig. 1	Myopia	7
Fig. 2	Hypermetropia	8
Fig. 3	Astigmatism	8
Fig. 4	Astigmatism; classification, image position relative to retina	9
Fig. 5	*Severe GPC after continuous wear of hydrogel lenses for several years*	13
Fig. 6	Corneal neovascularization	13
Fig. 7	Multiple corneal infiltrates in the mid-peripheral and central cornea	13
Fig. 8	Fine reticular corneal haze 2 months after PRK	16
Fig. 9	*Incisional Astigmatic Keratotomy*	18
Fig. 10	Surgical steps in Femtosecond lenticule extraction (FLEx)	21
Fig. 11	*Iris-claw aphakic intraocular Len*s.	23
Fig.12	LASIK Steps.	27
Fig. 13	Epithelial cells growing under the flap along the flap margin.	29
Fig. 14	Femtosecond laser systems available in the refractive surgery market.	33
Fig. 15	*Cone docked in* Suction ring.	33
Fig. 16	The flap elevation with a blunt dissection using a spatula.	34

Fig.17	Anterior segment OCT showing: Horizontal cross section of the cornea.	36
Fig. 18	OBL during flap creation.	40
Fig. 19	Slit lamp photograph of an eye with grade 3 DLK on the first post-operative day.	42
Fig. 20	SMILE procedure steps.	45
Fig. 21	*A*: SMILE procedure *B*:After docking, the Visumax femtosecond laser creates the back and the front of the intra-stromal lenticule.	47
Fig. 22	Slit lamp photograph of an eye with grade 1 DLK on the first post-operative day.	51
Fig. 23	Mathematical model The relevant stromal depths after PRK, LASIK, and SMILE.	58
Fig. 24	In Vivo Confocal Microscopy (IVCM) images of observed sub basal nerves before and after SMILE in the central 3 μm area of the cornea.	61
Fig.25	Heidelberg Retinal Tomo-graphy ш images (HRTш) showing surgical interface after 1 week and 6 months after SMILE.	62
Fig. 26	Tissue processing & Cryo-preservation of lenticule.	64

Introduction

In the original keratomileusis procedure for myopia, an approximately 300 mm thick disc was dissected from the anterior cornea in a freehand fashion and reshaped using a cryolathe. In the late 1980 developed an automated microkeratome that controlled speed as it passed across the cornea, leading to more consistent results. This procedure has become known as automated lamellar keratoplasty (ALK) [1].

In the 1990s the combination of a microkeratome and an excimer laser (for the refractive cut) was developed, further improving the predictability of the refractive procedure. This procedure, known as laser assisted in situ keratomileusis (LASIK) has gained wide acceptance worldwide.[1]

However, LASIK is not without post-operative complications, which includes dry eye syndrome [2], transient light sensitivity [3] and keratectasia [4].

One of the most interesting technical developments in laser refractive surgery during the last few years has been the emergence of the new ultra short pulse lasers (picosecond and femtosecond) [5, 6].

Current clinical applications of femtosecond lasers have been developed to create flaps for LASIK. The femtosecond laser is a focusable infrared (1053 nm) laser that uses ultrafast pulses in the 100 femtosecond (100 x 10^{-15} second) duration range. The laser delivers closely spaced spots that can be focused at a preset depth to photodisrupt tissue within the corneal stroma with minimal inflammation and collateral tissue damage [7, 8].

The femtosecond laser can increase the safety, efficiency, precision and versatility of the lamellar incision [9].

Recently, the femtosecond laser has also been used to create an intrastromal refractive lenticule, which is regarded as refractive lenticule extraction (ReLEx). ReLEx can be further divided into femtosecond lenticule extraction (FLEx) and small incision lenticule extraction (SMILE), based on how the lenticle is removed. The former allows creating and lifting corneal flaps followed by the lenticule extraction, while in SMILE, the lenticle is removed directly via a small incision [10].

The intra-stromal refractive lenticule is created by a 500 kHz femtosecond laser (VisuMax, Carl Zeiss Meditec, Jena, Germany) and the energy density is approximately 130 nJ. The femtosecond incisions are performed in the following sequence: the posterior surface of the lenticule, the lenticule border, the anterior surface of the lenticule and the side cut incision for the access to the lenticule. The lenticule diameter is set at 5.5-6.5 mm and the stromal cap is completed at 100-140 μm depth, 6.5 mm diameter centred at the pupil. The side cut is set at 2-4 mm width and located in the 12 o'clock position. After the femtosecond laser cutting procedure, a thin spatula is inserted via the side-cut incision to make the blunt dissection of intra-stromal lenticule. The refractive lenticule is then grasped with forceps and extracted from the cornea. The intra-stromal pocket is then flushed with a balanced salt solution [11].

This procedure may have a positive impact on health care as surgical time and costs could be reduced with this new, “all-in-one” laser procedure. SMILE procedures eliminates flap displacement, and there is no risk of the flap dislocating with trauma to the eye at a later point. Additional benefits may include post-operative reduction or elimination of dry eye problems and improvements in corneal biomechanical stability [12].

In the near future, SMILE may develop into a reversible surgical procedure. Unlike LASIK which uses an excimer laser to ablate corneal tissue, SMILE cuts and removes a piece of corneal lenticule, which may be stored and replaced into the cornea later on. This is important as we can potentially reverse the refractive procedure many years later when the patient’s myopia decreases. The ability to re-implant the corneal lenticule allows for treatment of corneal ectasia, reversal or monovision, or even the possibility of use as a presbyopic implant [12].

Aim of the Work

The aim of this work to review SMILE procedure for the correction of myopia and myopic astigmatism, with special emphasis on its advantages and disadvantages and the possible future advancement of this technique.

Chapter: 1

Refractive errors

Refractive error (ametropia) is present when parallel rays of light entering the non-accommodating eye do not focus on the retina. The visual effect is a blurry image [13].

Myopia is a common optical aberration in which the eye has too much optical power and parallel light rays from a distant image are focused on a point anterior to the retina [13].

Hyperopia is also a common aberration and is one in which the eye does not have enough optical power and distant light rays strike the retina before converging on the retina [13].

Astigmatism and other forms of optical aberrations occur when incident light rays do not converge at a single focal point. Total refractive astigmatism can be divided into corneal (or keratometric) astigmatism, lenticular astigmatism, and retinal astigmatism [13].

Most astigmatism is corneal in origin. Lenticular astigmatism is a result of uneven curvature, lens tilt, and differing refractive indices within the lens [13].

In regular astigmatism, the refractive power varies successively from one meridian to the next, and each meridian has a uniform curvature at every point across the entrance pupil. The meridians of greatest and least power, they called principal meridians, are located 90 degrees apart [13].

Low to moderate refractive errors are defined as less than 6.00 diopters (D) of myopia, less than 3.00 D of hyperopia, and less than 3.00 D of regular astigmatism. High refractive errors are defined as 6.00 D or more of myopia, 3.00 D or more of hyperopia, and 3.00 D or more of regular astigmatism [13].

Presbyopia is a condition that develops with aging and results in insufficient accommodation for near work in a patient whose distance refractive error is fully corrected. Although not truly a refractive error [13].

Individuals with high refractive errors are more likely to develop pathologic ocular changes over time [13].

Highly myopic patients have an increased incidence of progressive elongation of the eye with progressive retinal thinning, peripheral retinal degeneration, retinal detachment [14],cataract [15], and glaucoma [16, 17]. An increased risk of glaucoma and visual field defects with myopia has also been found [18, 19]. An increased risk of developing primary angle-closure glaucoma among individuals with hyperopia has been reported [20].