

# **EVALUATION OF THE ACCURACY OF SBK MICROKERATOME IN FLAP CREATION DURING LASIK SURGERY**

**Thesis**

*Submitted For Partial Fulfillment Of The Master  
Degree (M.Sc) In Ophthalmology*

**By**

**Mona Medhat Ahmed Abd El Rahman El  
Gammal**

**M.B.B.Ch**

**Under Supervision Of**

**Prof. Dr. Yehia Mahmoud Salah EL Din**

*Professor Of Ophthalmology  
Faculty Of Medicine, Cairo University*

**Prof. Dr. Rania Ahmed Abdel Salam**

*Professor Of Ophthalmology  
Faculty Of Medicine Cairo University,*

**Dr. Lamia Samy Aly**

*Lecturer Of Ophthalmology  
Faculty Of Medicine, Cairo University*


**Faculty Of Medicine  
Cairo University**

**2015**



بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ  
قَالُوا سُبْحَانَكَ لَا عِلْمَ لَنَا  
إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ الْعَلِيمُ  
الْحَكِيمُ

صدق الله العظيم  
سورة البقرة الآية (32)



## Acknowledgement

*First and foremost, I would like to express my deepest gratitude to ALLAH the most Merciful who is praised for all His favors and blessings.*

*I would like to express my sincere gratitude to **Professor .Dr. Yehia Mahmoud Salah EL Din**, Professor of Ophthalmology, Cairo University, not only for his valuable supervision and great help throughout the study but also for his constant support, encouragement and patience to produce this work in its present form. It is a great honor to work under his supervision.*

*I would like to express my deepest gratitude to **Professor Dr. Rania Ahmed Abdel Salam**, Professor of Ophthalmology, Cairo University, for her generous guidance, supervision, kindness, and support throughout the process of producing this work.*

*I would like to express my special appreciation and thanks to **Dr. Lamia Samy Aly**, Assistant Lecturer of Ophthalmology, Cairo University, you have been a tremendous advisor for me. I would like to thank you for encouraging me and for guiding me through this work.*

*A special thanks to **Dr. Hanan El Ghoneimy**, Professor of Ophthalmology, Memorial Institute of Ophthalmology. Words cannot express my gratefulness towards her support and help.*

*A special thanks to **my Family**. Words cannot express how grateful I am for all of their efforts, their continuous support and patience. Your prayer for me was what supported me and sustained me this far.*

*I'd like to thank all staff members of Eye Care Center Maadi for their hospitality and support. Special thanks and sincere appreciation to **Dr Fady Refaat**, Specialist of Ophthalmology at Eye Care Center for his encouragement and help.*

# *Abstract*

**Purpose:** To evaluate the accuracy of SBK microkeratome in flap creation during myopic LASIK surgery using Anterior Segment Optical Coherence Tomography (AS OCT)

**Design:** A Prospective non-randomized non comparative interventional clinical study.

**Methods:** Flaps were created using the One Use-Plus SBK microkeratome (intended flap 90 $\mu$ m) in 100 eyes of 50 patients. Flap thickness was measured using AS OCT one week after surgery.

**Results:** The mean achieved central corneal flap thickness in both eyes was  $88.67 \pm 7.19$ , 1.33 $\mu$ m thinner than the intended 90  $\mu$ m thickness (difference from intended thickness  $-1.33 \pm 7.19$ ) with a p value of 0.067 which is statistically insignificant ( $p > 0.05$ ). The mean achieved central corneal thickness in the right eye was  $88.56 \pm 7.95$   $\mu$ m, (ranging from 70  $\mu$ m to 112 $\mu$ m), 1.44  $\mu$ m thinner than the intended 90  $\mu$ m (difference from intended thickness  $-1.44 \pm 7.95$ ) thickness with a p value of 0.206 which is statistically insignificant ( $p > 0.05$ ). The mean achieved central corneal flap thickness in the left eye was  $88.78 \pm 6.41$   $\mu$ m, (ranging from 77 $\mu$ m to 105 $\mu$ m) showing a difference from intended thickness of  $-1.22 \pm 6.41$   $\mu$ m deviation from the intended thickness that is statistically insignificant (p value of 0.185,  $p > 0.05$ ).

**Conclusion:** In the current study it was found that the use of the One Use-Plus SBK microkeratome for creating an SBK flap is safe and effective. The results of the current study were comparable to the results in previous studies using a femtosecond laser. In conclusion, our results indicate that the One Use-Plus SBK microkeratome created flaps with good central accuracy, predictability and reproducibility, with variable increase in flap thickness towards the periphery.

**Recommendations for future research:** Studying the effect of variations in flap thickness on post-operative visual outcomes. The effect of flap thickness on corneal biomechanical stability. Increasing sample size. Assessing of flap thickness accuracy using a more objective tool such as real-time online optical coherence pachymetry.

**Key words:**

**LASIK, SBK Microkeratome, Femtosecond laser, Ectasia, Myopia**

## *List of Contents*

	Page
List of Abbreviations	I
List of Tables	III
List of Figures	IV
Introduction	1
Aim of the Work	2
Review of Literature	
Chapter (1): ○ Anatomy Of The Cornea	3
Chapter (2): ○ Corneal Biomechanics And Wound Healing	11
Chapter (3): ○ Sub Bowman's Keratomileusis	20
Patients and Methods	48
Results	57
Discussion	63
Conclusion and Recommendations	70
Summary	71
References	72
Arabic Summary	94

## *List of Abbreviations*

<b>µm</b>	<b>Micrometer</b>
<b>AS OCT</b>	<b>Anterior Segment Optical Coherence Tomography</b>
<b>BCVA</b>	<b>Distant Best Corrected Visual Acuity</b>
<b>BUT</b>	<b>Break up time</b>
<b>CCT</b>	<b>Central corneal thickness</b>
<b>CD</b>	<b>Corneal diameter</b>
<b>CSNFs</b>	<b>Corneal sub-basal nerve fibers</b>
<b>DLK</b>	<b>Diffuse lamellar keratitis</b>
<b>ECM</b>	<b>Extracellular matrix</b>
<b>FS</b>	<b>Femtosecond laser</b>
<b>FS-LASIK</b>	<b>Femtosecond assisted LASIK</b>
<b>HOAs</b>	<b>Higher order aberrations</b>
<b>IFS</b>	<b>Intralase femtolaser</b>
<b>IOP</b>	<b>Intraocular pressure</b>
<b>K</b>	<b>Keratometry</b>
<b>kHz</b>	<b>Kilo Hertz</b>
<b>LASIK</b>	<b>Laser assisted in situ keratomileusis</b>
<b>MMPs</b>	<b>Matrix metalloproteases</b>
<b>MRSE</b>	<b>Mean refractive spherical equivalent</b>
<b>OBL</b>	<b>Opaque bubble layer</b>
<b>OUP-SBK</b>	<b>One Use-Plus SBK microkeratome</b>
<b>PRK</b>	<b>Photorefractive keratectomy</b>
<b>RSB</b>	<b>Residual stromal bed</b>
<b>SBK</b>	<b>Sub-Bowman's keratomileusis</b>
<b>SD</b>	<b>Standard deviation</b>
<b>SKMB</b>	<b>Summit-Krumeich-Barraquer microkeratome</b>

<b>TLSS</b>	<b>Transient light sensitivity syndrome</b>
<b>UCVA</b>	<b>Uncorrected visual acuity</b>



## *List of Tables*

<b>Tables. No.</b>	<b>Description</b>	<b>Page</b>
<b>1</b>	Demonstrating descriptive baseline demographic patients' data and optical preoperative data of both eyes before LASIK surgery with Moria SBK microkeratome (Mean, SD, Minimum, Maximum)	<b>65</b>
<b>2</b>	Correlation between mean preoperative K readings, mean preoperative refractive spherical equivalent and mean preoperative central corneal thickness of patients who underwent LASIK (with Moria SBK Microkeratome) with the achieved flap thickness in both eyes. (P value)	<b>66</b>
<b>3</b>	showing descriptive data of achieved and intended central corneal flap thickness in both eyes and the correlation between them (P value)	<b>67</b>
<b>4</b>	Showing descriptive data of flap reproducibility (difference between mean achieved central flap thickness in both eyes).	<b>68</b>
<b>5</b>	Showing mean $\pm$ SD of mean flap thickness measurements at each of the 12 locations measured in both eyes. (Variation in flap thickness from the center to the periphery).	<b>70</b>
<b>6</b>	Showing mean deviation from mean achieved central flap thickness in both eyes, at each of the 12 measured points from the flap center.	<b>70</b>

## *List of Figures*

Fig. No.	Description	Page
1	Light micrograph of the anatomical layers of the cornea: (1)Epithelium, (2) Bowman membrane, (3)Stroma, (4) Descemet's membrane, (5) Endothelium.	3
2	Bowman scarring seen after herpes simplex keratitis showing the abrupt termination of Bowman membrane.	4
3	Transmission electron microscopy of the human corneal stroma. A: Keratocyte localized between stromal lamellae .B: Higher magnification view showing a keratocyte in relation to collagen fibers coursing in various directions.	6
4	Micrograph illustrating Descemet's membrane (DM) located between the posterior aspect of the corneal stroma (S) and the underlying endothelium (EN). The anterior "banded" region (A). Posterior "amorphous region" (P).	7
5	Specular photomicrograph of normal endothelium. Note the dark well-defined cell borders, the regular hexagonal array, and the uniform cell size.	8
6	Scanning electron micrographs. A, The anterior surface (star) of the Dua's layer (DL) showing parallel and regularly arranged collagen bundles. The posterior surface of the DL (triangle) shows a smooth pattern.	9
7	Major biomechanical loading forces in the cornea and a model of biomechanical central flattening associated with disruption of central lamellar segments	18
8	A flap with parallel sides is lifted using the microkeratome. The excimer laser is used to remove a lenticule of predetermined power from the exposed corneal stroma. The flap, with its intact epithelium, is then folded back, and as it drapes over the modified stromal surface, the refractive power	27

	of the anterior corneal surface is modified. The dotted area in the bottom panel corresponds to the lenticule that was removed. Usually, no sutures are required.	
9	Microcavitational bubbles coalesce and the cleavage plane is created	28
10	Zyoptix XP microkeratome. (a) Fully assembled microkeratome, (b) console unit, (c) blade, (d) suction ring, and (e) microkeratome blade holder.	30
11	A suction ring adherent to the globe and a pneumotonometer that measures IOP intraoperative.	31
12	Fully assembled AMO Amadues microkeratome.	32
13	Fully assembled Nidek Microkeratome [156].	33
14	Moria M2 microkeratome with a reusable head.[156]	34
15	Moria M2 microkeratome with a disposable head.[156]	34
16	Details of the single-use head with a pre-inserted blade[161]	39
17	The Moria One Use- <i>Plus</i> SBK with a single-use plastic ring[161]	39
18	The Moria One Use- <i>Plus</i> SBK with a reusable metal ring.[161]	40
19	Good visualization through the single-use plastic head for centration then confirmation of suction.[161]	40
20	Scanning Electron Microscopy comparing Moria One Use-Plus SBK vs. IntraLase 60 kHz FS (20x) [132, 176]	45
21	Scanning Electron Microscopy comparing Moria One Use-Plus SBK vs. IntraLase 60 kHz FS (80x) [132, 176]	44
22	Intraoperative picture of quality of a 100-micron flap created with OUP-SBK microkeratome: extreme smoothness of the backside of the flap & extreme smoothness of the residual stromal bed [177]	45
23	Flap thickness profile with One Use-Plus SBK (planar flap profile with one use plus SBK microkeratome) [181].	46

24	Post-operative pain score in One Use- <i>Plus</i> SBK and FS [108, 132].	47
25	Figure 25: illustrates a corneal topography showing some of the patient's preoperative data.: HVID= horizontal visible iris diameter (corresponds to corneal diameter), Thk= thinnest location, K readings (K1, K2)	60
26	Sirius Imaging System	61
27	Topcon 3D OCT-2000 series	63
28	Shows points measured in the horizontal meridian (180° meridian)	64
29	Shows points measured in the vertical meridian (90° meridian)	64
30	shows points measured in the horizontal meridian (180° meridian)	64
31	shows points measured in the vertical meridian (90° meridian)	65
32	shows points measured in the horizontal meridian (180° meridian)	65
33	shows points measured in the vertical meridian (90° meridian)	65
34	The bar graph showing the mean achieved central corneal flap thickness in right and left eyes compared with the intended flap thickness.	67
35-A	Shows a bar graph that demonstrates flap thickness variations in the superior and inferior portions from the flap vertex.	69
35-B	Shows a bar graph that demonstrates flap thickness variations at the nasal and temporal portions from the flap vertex.	69

# **INTRODUCTION**

Over the past decades, laser in situ keratomileusis (LASIK) has become the most common refractive procedure for the correction of refractive errors[1]. The consistency and predictability of the corneal flap thickness is crucial in producing successful LASIK outcomes. The corneal flap thickness is directly related to LASIK predictability and safety; therefore, methods that improve the predictability and minimize the degree of variation in corneal flap thickness are worthy of attention.[2]

Today, a variety of microkeratomes, as well as femtosecond lasers, are in clinical use for flap creation.[3] Good microkeratomes are associated with accurate cuts, less flap variation, easy manipulation, and fewer complications. [4]

One of the most feared complications is post LASIK corneal ectasia. Among many other factors the residual corneal thickness after the ablation is crucial for decreasing the possibility of that complication. Also it has been shown that the thinner the flap the less risk for ectasia. Accuracy of the flap thickness produced using mechanical microkeratomes is crucial in this calculation.

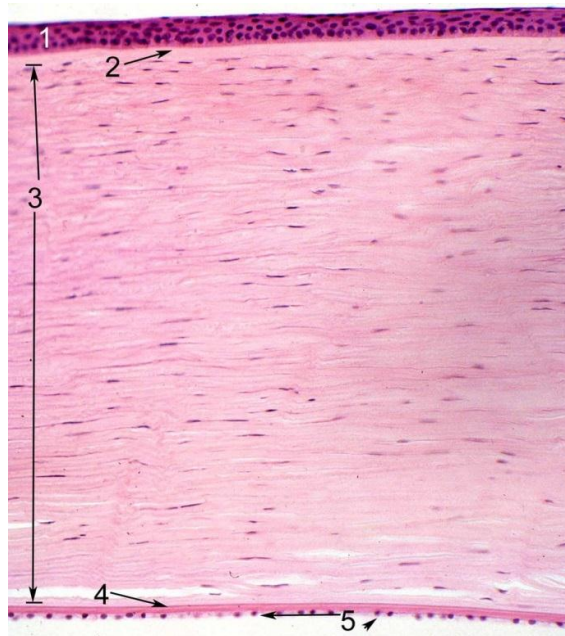
Earlier studies using microkeratomes showed that there was a high deviation from the marked thickness for a given blade. Hence the development of the Sub Bowman's keratomileusis microkeratome (SBK) with 90 microns thickness has shown high reproducible accuracy in different recent studies. This has made this type of mechanical microkeratome a competitor for Femtolaser flap creation that is gaining popularity in recent years with a main advantage of creating an accurate thin sub-Bowamn flaps. In this study we will measure the accuracy of flap thickness using the SBK microkeratome. [5-7]

## **AIM OF THE WORK**

- Major objective is studying the accuracy of the thickness of the LASIK flap created by the mechanical microkeratome SBK using anterior segment optical coherence tomography.
- Minor objective includes recording any associated complications.

## **ANATOMY OF THE CORNEA**

The cornea is a transparent avascular connective tissue that acts as a structural barrier of the eye. Together with the overlying tear film, it also provides a proper anterior refractive surface for the eye. Its clarity is the result of many factors including the structural anatomy and physiology of its cellular components[8]. In the average adult, the horizontal diameter of the cornea is 11.5 to 12.0 mm and about 1.0 mm larger than the vertical diameter. It is approximately 500µm thick at the center and gradually increases in thickness toward the periphery. The shape of the cornea is prolated (flatter in the periphery and steeper centrally). [9] The human cornea consists of 5 recognized layers, 3 cellular (epithelium, stroma, endothelium) and 2 interface (Bowman membrane, Descemet's membrane) as demonstrated in Figure 1.[8]



**Figure 1. Light micrograph of the anatomical layers of the cornea: (1)Epithelium, (2) Bowman membrane, (3)Stroma, (4)Descemet's membrane, (5) Endothelium.[8]**