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Evaluation of corneal flap thickness in relation to central corneal thickness after laser assisted in situ keratomileusis using two types of micro keratomes

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#### Abstract

**Background:** The most common refractive surgical surgery for the treatment of myopia, hyperopia, and astigmatism is laser assisted in situ keratomileusis (LASIK). A very important step in LASIK surgery is the formation of the flap. The corneal flap was made using a variety of microkeratomes. The purpose of this study was to compare the central corneal thickness following LASIK to the corneal thickness of the flap.

**Methods:** This retrospective comparative study was performed on 200 eyeballs divided into four groups each of 50 eyeballs according to the type of microkeratome used for surgery; group 1 (M2 90), group 2 (M2 130), group 3 (SBK 90), group 4 (SBK 130). Cases were operated during the last seven years by ALCON WAVELIGHT EX500 unit (year of production: 2012).

**Results:** Two hundred eyeballs of 100 patients were treated. Mean thickness of the flap of 103.3±9.54 mm, 126.05±17.07 mm, 120.9±14.4 mm, and 141.19±11.63 mm The SBK head created the thinnest flaps in the first cut utilising the SBK 90, SBK 130, M2 90, and M2 130 heads, respectively. The SBK 90 head produced the most exact and precise thickness of the flap, followed by the SBK 130 head, the M2 90 head, and the M2 130 head, as shown by the standard deviation and difference from the desired value.

**Conclusions:** Of the 4 types, the SBK generally produced the thinnest and most accurate flaps.

Keywords: LASIK, Corneal Flap thickness, microkeratomes

## Introduction

A transparent tissue called the cornea serves as a structural barrier and guards against infections in the eye. It offers the eye's proper anterior refractive surface along with the tear film [1].

The cornea is aspheric and convex. The posterior curvature is roughly 6.5 mm, while the anterior curvature is 7.8 mm. The cornea contributes between 40 to 44 D of refractive power, or around 70% of total refraction. The cornea has a refractive index of 1.376. The thickness of the cornea gradually increases from the centre to the edges <sup>[2]</sup>. Increased collagen content in the peripheral stroma is the cause of the change in tissue thickness. The centre corneal thickness of normal eyeballs ranges from 551 to 565 microns, and the peripheral corneal thickness is found to be between 612 and 640 microns using various diagnostic techniques. Age-related reductions in corneal thickness have been observed <sup>[3]</sup>.

Lamellar laser ablation is used in the laser assisted in situ keratomileusis (LASIK) technique. The most common refractive surgery method for treating myopia, hyperopia, and astigmatism is this one <sup>[4]</sup>. The operation is quick, with painless vision recovery and no subepithelial haze, which are mostly owing to the use of a microkeratome to create a corneal flap <sup>[5]</sup>.

The development of a flap during LASIK is a crucial step in this procedure <sup>[6]</sup>. First, they ensure the procedure's safety. Second, they play an important part in flap morphological reproduction. Second, they affect the appearance <sup>[7]</sup>.

With the microkeratome, a number of variables, including the quality of the blade's cutting edge, the speed of the microkeratome pass, the speed of blade oscillation, and the progress of the microkeratome along the track of the suction ring, determine the thickness of the corneal flap. Clinical research has demonstrated the inaccuracy of many microkeratomes. There have also been reports of differences between the first and second eyeballs using the same blade [8]. The corneal flap was made using a variety of microkeratomes.

The popular superior hinge microkeratome is an automated, plastic, single-use head microkeratome with a mechanical stop that is compact, safe, and convenient. In order to create flaps, nasal hinge microkeratomes are also used, and the results are more precise [9-10].

So this study aimed to evaluate corneal thickness of the flap in relation to central corneal thickness after laser assisted in situ keratomileusis using two types of microkeratomes.

# **Patients and Methods**

This retrospective comparative study was performed on 200 eyeballs divided into four groups each of 50 eyeballs according to the type of microkeratome used for surgery; group 1 (M2 90), group 2 (M2 130), group 3 (SBK 90), group 4 (SBK 130). Cases were operated during the last seven years by ALCON WAVELIGHT EX500 unit (year of production: 2012) and they were between 18 and 50 years old, with stable eyeglass prescription for at least 2 to 3 years, Diagnosed with myopia or hyperopia with or without low astigmatism and Pentacam showing k reading between 42 and 46 D.

Age restrictions of less than 18 years old, Female candidates who are pregnant or nursing, those with autoimmune diseases (such as Lupus, rheumatoid arthritis), immunodeficiency diseases (such as HIV), and uncontrolled diabetes who may prevent proper healing after refractive surgery, as well as those taking systemic medications likely to affect wound healing, such as retinoic acid and steroids, as well as those with Keratoconus or other active eye diseases were the criteria of exclusion.

Basic ophthalmic evaluation of the patients including anterior segment and posterior segment examination by slit lamp biomicroscopy. Slit lamp model is SHIN-NIPPON and biomicroscopy done using OCULAR Maxfield STD 90 D lens. The intraocular pressure measurement by TOPCON CT80 non-contact air puff tonometer. Auto refraction measured using TOPCON RM 800 autorefractometer. Measurement of uncorrected visual acuity (UCVA), and best spectacle- corrected visual acuity (BSCVA) using Logarithmic Landolt "C" eye chart. Utilizing the OCULUS Pentacam TYP 70700, the preoperative central corneal thickness was assessed. Pachymetry was used to measure the corneal thickness intraoperatively before and after the formation of the flap (EX500 optical pachymetry). Corneal

pachymetry is the average of three central measurements. Before beginning excimer laser ablation, the flap thickness was achieved using the subtraction approach (corneal pachymetry before creating the flap minus stromal bed thickness after lifting the flap). The corneal flaps created using nasal hinge SBK microkeratomes (90-130 $\mu$ ) or superior hinge M2 microkeratomes (90-130 $\mu$ ) and suction ring with size varies according to k readings. The identical blade was used for the same topic by the first and second eyeballs. Maintain a steady suction pressure by keeping the temperature between 20 °C and 22 °C, the humidity between 45% and 55%, and the barometric pressure between 65mmHg and 70mmHg.

Preoperative, cases used antibiotic eye drops; moxifloxacin 0.5% (Vigamox 0.5% by Novartis, Novartis scientific office, Egypt) four times per day for one week before operation. During operation; benoxinate 0.4% eye drops (Benox 0.4% by Eipico, Egypt) used as topical anesthesia. Postoperative; cases used antibiotic eye drops; moxifloxacin 0.5% (Vigamox 0.5% by Novartis, Egypt) five times per day for one week after operation, anti-inflammatory eye drops used; prednisolone acetate 1% (Orchapred 1% by Orchidia pharmaceutical industries, Egypt) five times per day then gradual withdrawal over 4 weeks, Preservative free tear substitute eye drops in form of polyethylene glycol 400 0.4% + propylene glycol 0.3% (Systane original by Alcon, Egypt) for six months after operation and vitamin C oral capsules 500 mg (C-retard by Hikma pharma, Egypt) dosage daily for three months after operation.

# Statistical analysis

The SPSS v25 statistical analysis programme was used (IBM Inc., Chicago, IL, USA). The mean and standard deviation (SD) of quantitative variables were reported, and they were compared for the same group using a paired Student's t-test. Significant results were defined as two tailed P values 0.05.

## Results

Two hundred eyeballs of 100 patients were treated. The mean age of the 37 men and 63 women was 25.2 years; five of them were hyperopic while other ninety-five were myopic.

Table 1: Flap thickness produced by SBK90, SBK130, M2 90 and M2 130 Microkeratome in first and second cut of LASIK

	Microkeratome		<500u	500 -550u	>550	<i>p</i> <value< th=""></value<>
Flap thickness created by first cut	SBK 90	Mean±SD	99.29±9.27	95.21±7.46	115.5±11.9	0.002*
		Range	88-115	80-106	99-126	
	M2 90	Mean±SD	114±19.8	120.14±12.03	128.63±11.51	0.508
		Range	100-128	101-142	110-141	
		P value	0.151	<0.001*	0.229	-
	SBK 130	Mean±SD	-	122.11±6.16	130±10.91	0.031*
		Range		108-131	109-142	
	M2 130	Mean±SD	-	132.75±10.47	149.63±12.8	0.006*
		Range		117-146	120-170	
		P value	-	<0.002*	<0.003*	-
Flap thickness created by Second cut	SBK 90	Mean±SD	90.86±6.07	92±8.20	92.33±15.05	0.951
		Range	84-99	75-107	81-110	
	M2 90	Mean±SD	98±6.24	105.77±8.55	108.13±11.9	0.317
		Range	91-103	91-127	93-128	
		P value	0.129	<0.001*	0.101	
	SBK 130	Mean±SD		114.8±8.83	113.1±11.37	0.683
		Range		103-129	97-134	
	M2 130	Mean±SD		119.5±12.39	129.4±17.28	0.168

	Range	98-139	100-158	
	P value	0.302	0.016*	

Figure 1 and 2 shows Flap thickness created by first cut; there was statistically significant correlation between thickness of the flap created by SBK 90, SBK 130 and M2 130 head and preoperative CCT in the first cut in thickness with p value 0.002, 0.031 and 0.006, respectively. While there was no statistically significant correlation between thickness of the flapes created by M2 90 head with preoperative CCT in the first cut in thickness. When compare Thickness of the flap produced by SBK-90 and M2 90 microkeratomes thickness of the flap which produced by SBK-90 head was thinner than the M2-90 microkeratome head, with statistically significant between 500 - 550u with p value <0.001. When compare Thickness of the flap produced by SBK-130 and M2 130 microkeratomes thickness of the flap which produced by SBK-130 head was thinner than the M2-130 microkeratome head, with statistically significant between 500 – 550u and > 550 with p value 0.002 and 0.003, respectively Flap thickness created by second cut; there was no statistically significant correlation between thickness of the flap created by SBK 90, SBK 130, M2 90 and M2 130 head and preoperative CCT in the second cut in thickness. When compare Thickness of the flap produced by SBK-90 and M2 90 microkeratomes thickness which produced by SBK-90 head was thinner than the M2-90 microkeratome head, with statistically significant between 500 – 550u with p value <0.001. When compare Thickness of flap produced by SBK-130 and M2 130 microkeratomes thickness which produced by SBK-130 head was thinner than the M2-130 microkeratome head, with statistically significant > 550 with p value 0.016.

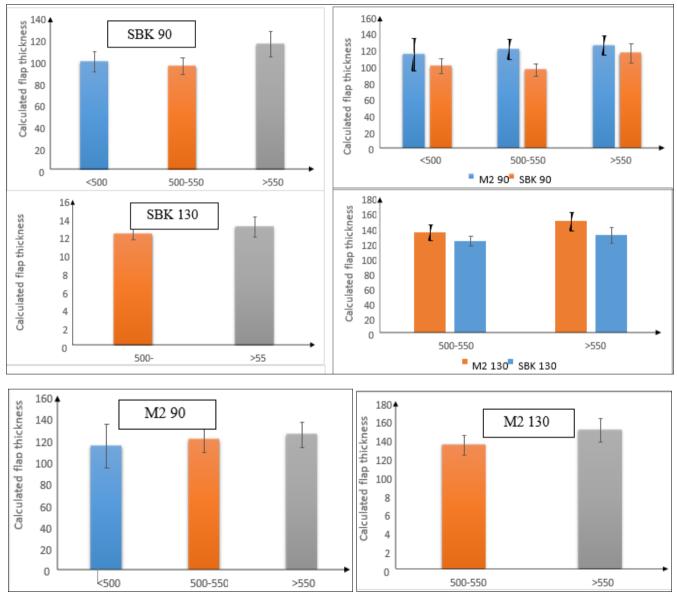


Fig 1: Flap thickness produced by SBK 90, SBK130, M290 M2 130 head in first cut and Flap variation between M2 90 & SBK 90 and M2 130 & SBK 130

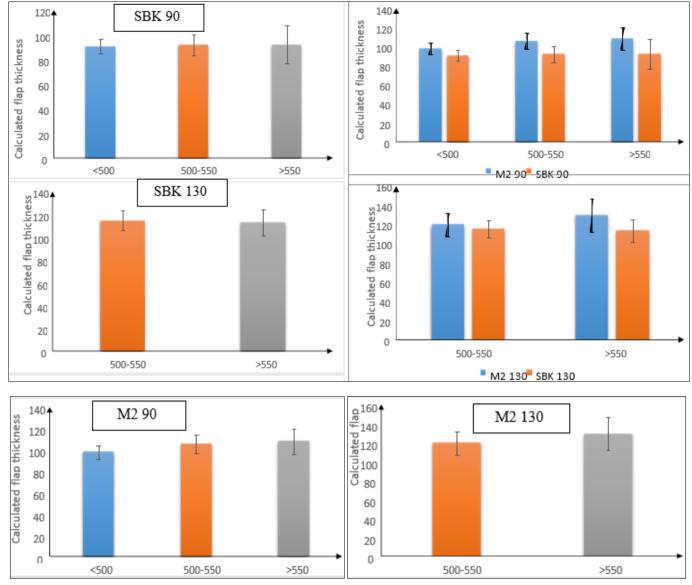


Fig 2: Flap thickness produced by SBK 90, SBK130, M290 M2 130 head in seconf cut and Flap variation between M2 90 & SBK 90 and M2 130 & SBK 130

# Discussion

The most popular method for correcting refractive defects during the past ten years is laser in situ keratomileusis (LASIK). Planning and achieving successful LASIK results both depend on the consistency and predictability of corneal flap thickness. Flap slippage, striae, irregularity, astigmatism, buttonholes, free caps, and corneal haze are complications connected to thin flaps. Reduced stromal-bed thickness brought on by thicker flaps raises the possibility of biomechanical corneal alterations and iatrogenic corneal ectasia [11-14].

There haven't been many research that have looked for a relationship between preoperative factors and corneal-flap thickness when using a mechanical microkeratome. When employing the mechanical microkeratome, Yildirim *et al.* [15] discovered a weak connection with preoperative corneal thickness and no correlation with preoperative keratometry. Giledi *et al.* [6] used a mechanical microkeratome and found a counterintuitive association between preoperative spherical-equivalent refraction and thickness of the flap as well as thinner flaps in patients with larger corneas.

The SBK head in this study produced the thinnest flaps. Furthermore, the first cuts typically resulted in thicker flaps compared to the second cuts. The second flap is likely cut

thinner depending on the blade's cutting edge. The sharpness of the blade is probably affected by the first cut, and even slight variations in sharpness could lead to differences between the first and second cuts. This problem might be clarified by additional research, including scanning electron imaging of the blades both before and after the cuts are done. The most exact and precise thickness of the flap was produced by the SBK 90 head, followed by the SBK 130 head, the M2 90 head, and the M2 130 head. Plate thickness, incision site, suction time, head advance speed, oscillation rate, corneal diameter, and corneal elasticity are some of the variables that contribute to these erratic results. addition to the obvious connection between microkeratome heads and thickness of the flap, stepwise regression analysis also found links between preoperative CCT, horizontal corneal diameter, and patient age. Preoperative CCT was the most reliable systematic predictor of thickness of the flap among these variables in each group. The role of corneal compressibility may be important, and more research is required to investigate this. According to the results, thicker flaps and corneas are related, and vice versa [20].

To further focus on this relation between corneal and thickness of the flap, (the SBK-90 microkeratome head)

group was compared with (the M2-90 microkeratome head) group while (the SBK-130 microkeratome head) group with (the M2-130 microkeratome head) group. The SBK-90 microkeratome head produced thinner flaps than the M2-90 microkeratome head. In addition, the variance in M2-90 head was greater than in SBK-90 head. Also, The SBK-130 microkeratome head produced thinner flaps with lesser variance than the M2-130 microkeratome head. These findings corroborate those of Du et al. [21] and Zhai et al. [22] who claimed that the M2 head was inferior to the SBK head in terms of accuracy and precision. The right eyeballs (first cut) also had a thicker corneal flap than the left eyeballs, as in earlier studies [21-23-24] (second cut). Contrary to Du et alfindings.'s [21] who did not discover a statistically significant difference between the left and right eyeballs in each group, the findings of this investigation show a leftright eye-right-eye difference. We hypothesise that this discrepancy may result from the various numbers of eyeballs used in the research. It may also be brought on by additional factors that were not considered in this study but may have had an impact on thickness of the flap, such as IOP, [25] suction duration, suction pressure (26 corneal diameter).

A significant association between preoperative corneal thickness and thickness of the flap has been demonstrated in earlier research <sup>[21, 23, 24, 27]</sup>. With the exception of the M2 90 group, the precutting CCT in this study exhibits a substantial association with thickness of the flap. This is primarily due to the study's small sample size of eyeballs. As anticipated, increasing the accuracy of our results required including the implicated eye (first vs. second cut) in the study.

The flaps were typically thicker than anticipated, as seen by the mean thickness of the flap, while occasionally they were the same thickness or thinner than anticipated. In order to prevent residual stromal beds that are thinner than anticipated, especially in patients with high myopia and/or thin corneas, intraoperative pachymetry may be a useful supplementary measure [28].

In LASIK, there has been a recent tendency toward creating thinner flaps. The corneal stroma from ultrathin flaps positioned at 90 to 100 mm [29] might be adequate for excimer laser ablation. The SBK head can also produce extremely thin flaps, as seen by the mean thickness of the flap (103.3 9.54 mm) in our sample. Nowadays, many surgeons use mechanical microkeratomes or femtosecond lasers to cut flaps that are 100 mm thick or smaller. Mechanical microkeratomes are linked to less uniform thickness of the flap, less smooth stromal beds, and greater rates of flap problems as compared to flaps created by a femtosecond laser [30, 31]. However, femtosecond laser surgery is far more expensive than LASIK using a mechanical microkeratome and necessitates prolonged suction, which may harm the vitreous or the retina as a result of prolonged increases in intraocular pressure [32, 33].

# **Conclusions**

Of the 4 microkeratome used in this study, The SBK often generated the most precise and thin flaps. With the exception of the M2 90 group, a link between thickness of the flap and preoperative CCT was seen. These findings support the use of the M2 90 head for thin flap cuts and the SBK head for ultrathin flap cuts.

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# **Conflict of Interest: Nil**

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