Effect of Preoperative Keratometric Power on Intraoperative Complications in LASIK in 34,099 Eyes

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ABSTRACT

PURPOSE: To evaluate the effect of preoperative keratometric power on the intraoperative complications in LASIK for myopia, hyperopia, and astigmatism.

METHODS: In this retrospective study, the records of 34,099 eyes of 17,388 patients who underwent LASIK for myopia, hyperopia, and astigmatism using the Moria LSK One manual microkeratome and the Bausch & Lomb Technolas 217 Z excimer laser were reviewed.

RESULTS: One thousand three hundred thirty-eight (3.92%) intraoperative microkeratome complications were identified in the total number of eyes: 571 (1.67%) free caps, 320 (0.93%) epithelial abrasions, 282 (0.82%) thin/irregular flaps, 126 (0.36%) incomplete flaps, and 39 (0.11%) flap buttonholes. When eyes were stratified according to preoperative keratometric power, eyes with flatter corneas usually had more free caps and incomplete flaps than eyes with steeper corneas ($P<.05$), whereas eyes with steeper corneas usually had more epithelial abrasions and thin/irregular flaps than eyes with flatter corneas ($P<.05$). The risk of free caps, incomplete flaps, and epithelial abrasions was greater when bigger keratome rings (H) were used than when smaller rings (−1) were used ($P<.05$). The incidence of buttonholes was independent of the preoperative keratometric power, keratome plate (100 or 130 μm), and keratome ring (−1, −2, or H).

CONCLUSIONS: No statistically significant relationship was found between preoperative keratometric power and incidence of flap buttonholes in this series. Eyes with flatter corneas tended to have more free caps and incomplete flaps, whereas eyes with steeper corneas tended to have more epithelial abrasions and thin/irregular flaps. [*J Refract Surg*. 2007;23:592-597.]

Laser in situ keratomileusis (LASIK) has been shown to be safe and effective for the treatment of myopia, hyperopia, and astigmatism.[1-3] The creation of the flap can, however, be associated with complications that can cause significant loss of vision.[4-6] Flap complication rates have been reported from 0.3% to 14%, depending on the microkeratome and surgeons involved.[7-11] Few studies were found regarding the relationship between flap complication rates and preoperative keratometric power.[2,5]

Results of patients having undergone LASIK at our centers with a manual, mechanical microkeratome (Moria LSK One; Moria, Antony, France) were analyzed to assess the relationship between preoperative keratometric power and intraoperative complications.

PATIENTS AND METHODS

Computerized case records of 34,099 consecutive eyes of patients who underwent LASIK for myopia, hyperopia, and/or astigmatism between June 2002 and September 2003 were retrospectively analyzed. Policies were implemented at all centers to ensure standardized reporting of flap complications. Inclusion criteria for the surgery were stable refraction for ≥1 year—evidenced by prior spectacle prescriptions—and patient age ≥18 years. Exclusion criteria were abnormal ocular examination, topographic evidence of keratoconus or warpage from contact lenses, and pregnancy.

A corneal flap was created in all patients, and only intraoperative complications related to the creation of the corneal flap were included. Forty-eight surgeons operating in 15 centers performed the surgeries. All eyes were operated

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TABLE 1

Preoperative Refraction of Eyes Undergoing LASIK

Refractive Status	No. of Eyes (%)	Mean Spherical Equivalent Refraction (Range) (D)
Myopia	3471 (10.18)	−3.72 (−0.50 to −12.50)
Hyperopia	450 (1.32)	+2.84 (+1.00 to +6.00)
Simple myopic astigmatism	632 (1.85)	−1.36 (−0.50 to −7.75)
Compound myopic astigmatism	24,464 (71.74)	−4.61 (−0.50 to −13.00)
Simple hyperopic astigmatism	231 (0.68)	+1.53 (+0.50 to +3.75)
Compound hyperopic astigmatism	3178 (9.32)	+2.84 (0.00 to +6.75)
Mixed astigmatism	1663 (4.88)	−0.24 (sphere: +0.25 to +7.00; cylinder: −1.25 to −8.00)

with identical equipment, including the Moria LSK One manual microkeratome and the Bausch & Lomb Technolas 217 Z excimer laser (Bausch & Lomb, Rochester, NY). Surgeons selected the microkeratome plate, ring, and stop ring according to each case: bigger rings (H) and stop rings (9.5 mm) for hyperopic ablations and flatter keratometries; smaller rings (−2 and −1) and stop rings (8.5 and 9 mm) for myopic ablations and steeper keratometries; and thinner plates (100 µm) for thinner corneas and myopic ablations, when compared to thicker corneas and hyperopic ablations (130-µm plates). All corneas were lubricated prior to keratome transit (after suction). Three circles were marked on the cornea with gentian violet solution (by means of a circular marker dyed for this purpose) to favor posterior flap repositioning. Intraoperative applanation tonometry was not performed because it could increase the risk of infection, but mydriasis and/or blurred vision was looked for prior to keratome transit. In simultaneous bilateral LASIK (96.1% of primary cases), the left eye was always done first. The same microkeratome blade was used in both eyes in bilateral simultaneous procedures.

Preoperative keratometric power readings were obtained from corneal topographic maps (Orbscan II), and patients were grouped according to the results (<41.00 diopters [D]; 41.00 to 46.00 D; >46.00 D). Data obtained from case records included preoperative refraction, keratometric power, and details of intraoperative complications.

Statistical analysis was performed using the SPSS program (SPSS Inc, Chicago, Ill). Means were compared using the unpaired *t* test (2-tailed), whereas nonparametric data were analyzed using the chi-square test. Trends in data were tested using an analysis of variance.

TABLE 2

Mean±Standard Deviation of Preoperative Keratometric Power

Keratometric Power (D)	Mean±Standard Deviation (D)
<41.00	40.53±0.54
41.00 to 46.00	42.71±1.05
>46.00	46.54±0.56

RESULTS

From June 2002 to September 2003, 34,099 eyes of 17,388 patients who had primary LASIK for myopia, hyperopia, and astigmatism were identified (Table 1). These comprised 18,049 (52.93%) female eyes and 16,050 (47.07%) male eyes. Mean patient age was 34.1±8.9 years (range: 19 to 79 years).

The mean preoperative spherical equivalent refraction was −4.30±2.09 D (range: 0.37 to −13.00 D) in the 28,577 myopic eyes and 2.19±1.94 D (range: −1.75 to 6.75 D) in the 5522 hyperopic and mixed astigmatism eyes. Preoperative astigmatism was −1.14±1.13 D (range: 0 to −8.00 D). The most common preoperative refraction was compound myopic astigmatism (Table 1).

The mean preoperative keratometric power was 43.70±1.48 D (range: 38.25 to 49.50 D). One thousand three hundred seventy-four (4.03%) eyes had preoperative keratometric power <41.00 D, 30,248 (88.70%) eyes were between 41.00 and 46.00 D, and 2477 (7.26%) eyes were >46.00 D (Table 2).

One thousand three hundred thirty-eight (3.92%) intraoperative microkeratome complications were identified in the 34,099 eyes. The most common intraoperative flap complication was the creation of a free

TABLE 3

Overview of Intraoperative Complications That Occurred During LASIK With the LSK One and Technolas 217 Z Excimer Lasers

	No. of Occurrences According to Plate and Ring Size (%)					
	100 μm			130 μm		
Complication	−1 (N=16,965)	−2 (N=644)	H (N=12,519)	−1 (N=2507)	−2 (N=41)	H (N=1423)
Free cap	241 (1.42)	4 (0.62)	275 (2.20)	25 (1.00)	0 (0.00)	26 (1.83)
Epithelial abrasion	108 (0.64)	4 (0.62)	185 (1.48)	12 (0.48)	0 (0.00)	11 (0.77)
Thin/irregular flap	155 (0.91)	0 (0.00)	100 (0.80)	16 (0.64)	0 (0.00)	11 (0.77)
Incomplete flap	34 (0.20)	0 (0.00)	66 (0.53)	15 (0.60)	0 (0.00)	11 (0.77)
Flap buttonhole	16 (0.09)	0 (0.00)	8 (0.06)	6 (0.24)	0 (0.00)	7 (0.49)

cap (571 [1.67%] eyes), followed by epithelial abrasion (320 [0.93%] eyes), thin/irregular flap (282 [0.82%] eyes), incomplete flap (126 [0.36%] eyes), and flap buttonhole (39 eyes [0.11%]).

Of the complications, 701 occurred in the right eye and 637 in the left. No statistically significant difference ($P>.05$) was noted in the overall incidence of intraoperative flap complications between eyes, even though the same microkeratome blade was used in both eyes in bilateral simultaneous procedures, and the left eye was always done first.

When eyes were stratified by preoperative keratometric power, eyes with flatter corneas (<41.00 D) tended to have more free caps and incomplete flaps than eyes with steeper corneas (>46.00 D) ($P<.05$). Eyes with steeper corneas (>46.00 D) tended to have more epithelial abrasions than eyes with flatter corneas (<41.00 D) ($P<.05$). Eyes with steeper corneas (>46.00 D) also tended to have more thin/irregular flaps than eyes with medium keratometric powers (41.00 to 46.00 D) ($P<.05$). The risk of free caps, incomplete flaps, and epithelial abrasions also increased when bigger keratome rings (H) were used, when compared to smaller rings (−1) ($P<.05$) (Tables 3-5). Eyes tended to have more epithelial abrasions when thinner (100 μm) plates were used ($P<.05$) and tended to have more incomplete flaps when thicker (130 μm) plates were used ($P<.05$). The incidence of buttonholes was independent of the preoperative keratometric power, the plate (100 or 130 μm), and the ring (−1, −2, or H) used ($P>.05$) (Tables 3-5).

DISCUSSION

Previous studies of LASIK report flap complication rates from 0.3% to 14%, depending on the microkeratome and surgeons involved. The Hansatome and the Chiron Automated Corneal Shaper microkeratomes were the primary instruments in these studies,[2,5,6,10] and different microkeratomes can have different complication profiles. The Hansatome microkeratome appears less prone to creating free flaps[2,5] than the Moria LSK One manual microkeratome.

Most of the studies did not consider epithelial abrasions as an intraoperative complication.[2,6,12] If the criteria for serious intraoperative complications had not included epithelial abrasions, the adjusted complication rate in this series would have been 2.99% (1018 intraoperative complications in 34,099 primary LASIK procedures). The surgeons involved in this study agree that a "noncomplicated" free cap (when the gentian violet marks remain to favor posterior flap repositioning) is a minor complication, and continue with the laser ablation in the same session. If the criteria for serious intraoperative complications had not included epithelial abrasions and free caps, the adjusted complication rate in this series would have been 1.29% (447 intraoperative complications in 34,099 primary LASIK procedures).

Ito et al[13] reported that no patient profile (including preoperative keratometric power) increased the risk for intraoperative flap complications when one of the following microkeratomes was used to make the corneal flap: MK-2000 (NIDEK, Greensboro, NC), LSK One (Moria), Flapmaker (Refractive Technologies Inc, Cleveland, Ohio), Hansatome (Bausch & Lomb), or the K-3000 (BD Ophthalmic Systems, Waltham, Mass).

A significant relationship has been reported between preoperative keratometric power and incidence of flap buttonholes, concluding that eyes with higher preoperative keratometric power were at higher risk of flap buttonholes.[8] Gimbel et al[6] hypothesized that this complication occurred as a result of excess tissue being compressed beyond applanation by the keratome footplate, causing the apical cornea to buckle inward. Thus, although the microkeratome made a complete

TABLE 4

Intraoperative Complications Classified According to Preoperative Keratometric Power and Plate and Ring Size in Eyes That Underwent LASIK With the LSK One and Technolas 217 Z Excimer Lasers

Complication	No. of Total Occurrences (%)	No. of Occurences According to Plate and Ring Size (%)					
		100 μm			130 μm		
		−1 (N=16,988)	−2 (N=644)	H (N=12,572)	−1 (N=2454)	−2 (N=42)	H (N=1399)
Free cap							
K <41.00 D*	74 (5.39)	15/215 (6.98)	0/19 (0.00)	52/869 (5.98%)	5/58 (8.62%)	0/1 (0.00%)	2/212 (0.94)
K 41.00 to 46.00 D†	486 (1.61)	251/14.870 (1.69)	4/558 (0.72)	188/11,370 (1.65)	19/2240 (0.85)	1/35 (2.86)	23/1175 (1.96)
K >46.00 D‡	11 (0.44)	9/1903 (0.47)	0/67 (0.00)	2/333 (0.60)	0/156 (0.00)	0/6 (0.00)	0/12 (0.00)
Epithelial abrasion							
K <41.00 D*	11 (0.80)	2/215 (0.93)	0/19 (0.00)	8/869 (0.92)	0/58 (0.00)	0/1 (0.00)	1/212 (0.47)
K 41.00 to 46.00 D†	272 (0.90)	78/14,870 (0.52)	4/558 (0.72)	171/11,370 (1.50)	10/2240 (0.45)	0/35 (0.00)	9/1175 (0.77)
K >46.00 D‡	37 (1.49)	28/1903 (1.47)	0/67 (0.00)	6/333 (1.80)	2/156 (1.28)	0/6 (0.00)	1/12 (8.33)
Incomplete flap							
K <41.00 D*	15 (1.09)	1/215 (0.47)	0/19 (0.00)	8/869 (0.92)	4/58 (6.90)	0/1 (0.00)	2/212 (0.94)
K 41.00 to 46.00 D†	109 (0.36)	31/14,870 (0.21)	0/558 (0.00)	58/11,370 (0.51)	11/2240 (0.49)	0/35 (0.00)	9/1175 (0.77)
K >46.00 D‡	2 (0.08)	2/1903 (0.11)	0/67 (0.00)	0/333 (0.00)	0/156 (0.00)	0/6 (0.00)	0/12 (0.00)
Flap buttonhole							
K <41.00 D*	2 (0.15)	1/215 (0.47)	0/19 (0.00)	0/869 (0.00)	0/58 (0.00)	0/1 (0.00)	1/212 (0.47)
K 41.00 to 46.00 D†	31 (0.10)	11/14,870 (0.07)	0/558 (0.00)	10/11,370 (0.09)	4/2240 (0.18)	0/35 (0.00)	6/1175 (0.51)
K >46.00 D‡	6 (0.24)	4/1903 (0.21)	0/67 (0.00)	0/333 (0.00)	2/156 (1.28)	0/6 (0.00)	0/12 (0.00)
Thin/irregular flap							
K <41.00 D*	13 (0.95)	4/215 (1.86)	0/19 (0.00)	7/869 (0.81)	0/58 (0.00)	0/1 (0.00)	2/212 (0.84)
K 41.00 to 46.00 D†	228 (0.75)	111/14,870 (0.75)	0/558 (0.00)	93/11,370 (0.82)	15/2240 (0.67)	0/35 (0.00)	9/1175 (0.7)
K >46.00 D‡	41 (1.66)	40/1903 (2.10)	0/67 (0.00)	0/333 (0.00)	1/156 (0.64)	0/6 (0.00)	0/12 (0.00)

*n=1374.
†n=30,248.
‡n=2477.

pass and produced a normal size flap, the central area was thinned or buttonholed. Leung et al[12] hypothesized that the flap buttonhole occurred as a result of microkeratome malfunction. Stulting et al[5] hypothesized that flap buttonholes were related to defective microkeratome blades (ie, blade imperfections).

TABLE 5

Mean±Standard Deviation of Keratometric Power of Complications That Occurred During LASIK With the LSK One and Technolas 217 Z Excimer Lasers

Complication	Mean±Standard Deviation Keratometric Power (D)
Free cap	43.15±1.53
Epithelial abrasion	43.81±1.39
Thin/irregular flap	43.10±1.47
Incomplete flap	42.81±1.65
Flap buttonhole	42.70±2.07

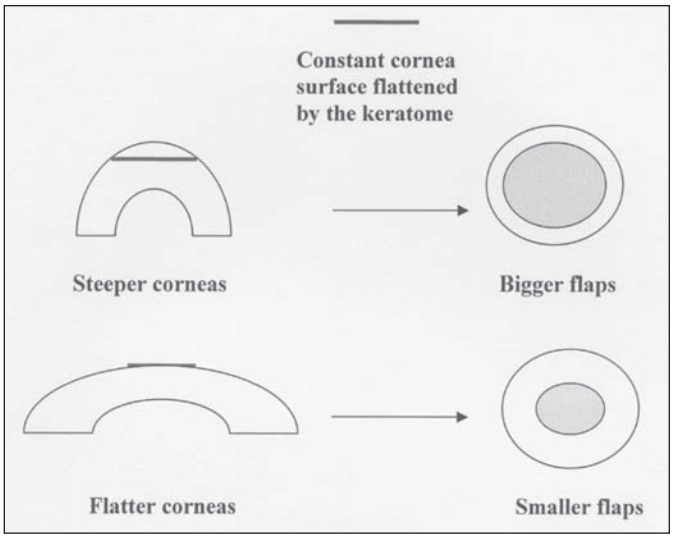

Figure. Mechanism by which flatter corneas could lead to a greater incidence of free caps.

In the present study, preoperative keratometric power did not affect flap buttonhole incidence in primary LASIK with the LSK One manual microkeratome. No significant trends were observed toward more buttonholed flaps in the second eye (the right eye in this series), as others authors have found.[2,10,14] The microkeratome and blade were inspected after any intraoperative complication, and no malfunction or blade imperfections were found.

The microkeratome flattens a constant surface of the cornea. More tissue enters into the suction head to be cut in steeper corneas than flatter corneas; thus, the steeper the cornea, the bigger the flap, and the flatter the cornea, the smaller the flap. This is the reason why flatter corneas and bigger rings can lead to a greater incidence of free caps (Fig).

In this large series, keratometric power and ring selection were found to influence the incidence of free caps, incomplete caps, thin/irregular flaps, and epithelial abrasions. The incidence of free caps and incomplete flaps was greater in flatter corneas, whereas the incidence of epithelial abrasions and thin/irregular flaps was greater in steeper corneas ($P<.05$). Larger ring sizes increased the incidence of free caps, incomplete flaps, and epithelial abrasions ($P<.05$).

Surgeons should be aware that free caps are more likely to occur when bigger rings are used and the cornea is flat; therefore, the microkeratome should be stopped earlier. Special care should be taken when performing the gentian violet marks to facilitate safe management of possible free caps. Also, when the cornea is steep, care should be taken when lubricating the cornea prior to keratome transit and also during keratome transit (forward and backward) to avoid epithelial abrasions.

No statistically significant relationship was found between preoperative keratometric power, keratome plate (100 or 130 µm) or keratome ring (−1, −2, or H), and incidence of flap buttonholes in this series, as other authors have reported.[10]

The overall complication rate was similar in both eyes. No trends were observed toward more buttonholed flaps in the second eye, as reported by other authors,[2,10,14] and the same microkeratome blade was used in both eyes in bilateral simultaneous procedures.

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