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Thin-flap (sub-Bowman keratomileusis) versus thick-flap laser in situ keratomileusis for moderate to high myopia: Case-control analysis

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Abstract

PURPOSE—To compare the refractive and visual outcomes of Sub-Bowman Keratomileusis (SBK) and thick-flap LASIK for moderate-to-high myopia, and evaluate the effect of corneal flap thickness on outcomes.

SETTING—Massachusetts Eye and Ear Infirmary, Boston, Massachusetts, USA.

METHODS—Two studies were performed. In the first study, we retrospectively analyzed the refractive and visual outcomes of 33 eyes that underwent SBK (flap thickness 82–120 μm) and 62 eyes that underwent thick-flap LASIK (flap thickness ≥ 160). Inclusion criteria were: spherical equivalent (SE) -4 to -10 diopters (D), astigmatism ≤ 3 D, and follow-up of ≥ 3 months. In the second study, we evaluated the influence of flap thickness. We performed a case-control matched study (n=21 pairs) in which we controlled for residual stromal bed (RSB) thickness.

RESULTS—The mean flap thickness in SBK was 110.2 ± 9.2 versus 179.2 ± 19.5 in thick-flap LASIK. There were no significant differences in the visual outcomes. In the second study with equivalent RSB thickness, case control matched comparisons between SBK (108.6 ± 8.0 μm) and thick flap LASIK (165.7 ± 12.6 μm) showed no differences in preoperative and postoperative refractive and visual outcomes. Comparison of the intended versus achieved correction revealed no significant differences between the two groups.

CONCLUSIONS—Our retrospective analyses showed that the safety, efficacy, and predictability of SBK are similar to conventional thick-flap LASIK for corneas with equivalent RSB thickness.

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Keywords

Sub-Bowman Keratomileusis; Laser in situ keratomileusis; LASIK; flap thickness; thin flap; thick flap; LASIK outcomes; myopia

INTRODUCTION

Sub-Bowman Keratomileusis (SBK) is a type of LASIK procedure in which the flap is thinner. A major advantage of creating a thin flap during SBK is leaving sufficient stromal tissue to allow for safer excimer laser ablation, especially in patients with moderate and high myopia.[1,2] Sufficient residual stromal bed (RSB) thickness (exceeding 250 μm) is important to reduce the likelihood of corneal ectasia, a complication that leads to dramatic visual loss after LASIK.[1–6] One of the factors that may affect the RSB thickness is the flap thickness.[7] Variability in flap thickness has been well documented.[8] Some reports have advocated that the ideal flap thickness in LASIK should exceed 130 μm because thin flaps may be associated with higher frequency of potential complications such as flap folds, striae, epithelial ingrowth, and irregular astigmatism.[9–13] A more recent report advocates performing SBK with flaps ranging between 90–110 μm in thickness.[14]

The incidence of thin flaps after LASIK has been reported to vary between 0.3% and 0.75%.[10] Recent retrospective studies evaluated the effect of intended thin flaps on the outcomes of LASIK at 1, 3, and 6 months after surgery, and proposed that *intended* thin flaps (≤ 100 μm) may be advantageous over thicker flaps for myopic LASIK.[15–17] Prandi et al. showed that thin flaps were associated with better UCVA at 1 month and better residual SE at 6 months.[15] Eleftheriadis et al. reported a faster visual recovery (UCVA at 1 week and 1 month) and lower postoperative myopic SE in thinner flaps.[16] Cobo-Soriano et al. showed that patients with thin flaps achieved better contrast sensitivity and lower retreatment rates.[17] These studies have paved the way to SBK, which may combine the advantages of LASIK and surface ablation.[14]

The purpose of this study was to compare the visual outcomes of patients with moderate-to-high myopia treated with SBK versus thick-flap LASIK. In addition, we investigated the influence of flap thickness on the final refractive and visual results after myopic SBK and LASIK (using a control-matched analysis after controlling for pre-and intra-operative characteristics as well as RSB thickness).

PATIENTS AND METHODS

I. Patients

Data from patients (n = 177 eyes of 144 patients) who underwent LASIK for moderate to-high myopia (-4 to -10 D) with the same surgeon (DTA), had a follow-up visit of ≥ 3 months, and preoperative astigmatism ≤ 3 were retrospectively analyzed. Two groups of analyses were performed.

In the first analyses, eyes that underwent SBK (n=33 eyes of 30 patients), flap thickness between 82–120 μm, were compared with eyes that underwent thick-flap LASIK (n=62 eyes of 53 patients), flap thickness ≥ 160 μm.

In the second analyses, SBK eyes were matched with eyes that underwent thick-flap LASIK with a flap thickness ≥ 144 μm. Case-control matched analyses was performed for twenty one matched pairs.

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II. Surgical Procedure

A corneal flap was created either with IntraLase FS laser (IntraLase Corp., Irvine, CA) or Hansatome microkeratome (Bausch & Lomb Inc., Claremont, CA). The flap was lifted and excimer laser ablation of the stromal bed was performed with VISX (Star S2 or S4, Visx Inc.) or B&L Technolas 217z (Zyoptix or PlanoScan, Bausch & Lomb Inc.). The flap was repositioned on the stromal bed. Corneal thickness was measured intraoperatively before and after flap creation with a contact ultrasound pachymetry (RK-5000 Pachymeter, KMI Surgical Products, West Chester, PA). The average of 3 central measurements was recorded as corneal pachymetry. The flap thickness was estimated by the subtraction method (measurement before flap creation minus stromal bed thickness). In SBK patients (n=33 eyes of 30 patients), 10 flaps were created using the Intralase and 23 using the mechanical microkeratome. In thick-flap LASIK patients (n=62 eyes of 53 patients), 15 flaps were created using the Intralase and 47 using the mechanical microkeratome. Analysis of the visual outcomes of the SBK and thick-flap LASIK groups was performed and is described below.

III. Comparative Study of SBK vs. Thick-Flap LASIK

Data were abstracted from patient charts in a systematic fashion. Preoperative data included age, gender, pachymetry, flap thickness, preoperative BSCVA, manifest refraction, date of surgery, type of laser and microkeratome, and method of laser treatment (wavefront-guided vs. non-customized). Postoperative data included date of last follow-up visit, UCVA, BSCVA, manifest refraction and need for enhancement. Snellen visual acuity data were converted to logarithm of minimum angle of resolution (LogMAR) as described by Holladay.[18] For visual acuity records of patients who did not read all of the letters on a single line correctly, the conversion was made by interpolating between the values of the LogMAR acuity using the fraction of the number of letters correctly read on a visual acuity line.[18] Efficacy (percentages of eyes with postoperative UCVA better than or equal to 20/20, 20/25, 20/30 and 20/40), predictability (percentage of eyes with postoperative manifest refractive SE within ± 0.50 D, ±1.00 D), and safety (percentage of eyes losing one line of BSCVA) were calculated.

Visual and refractive data from the final visit were analyzed using SPSS 15.0 software. T-tests and chi-squares were applied for analyses. A p value of ≤ 0.05 was considered statistically significant. Calculation of RSB thickness was performed by subtracting flap thickness and ablation depth from the central pachymetry. The ablation depth was estimated using the Munnerlyn approximation formula.[19]

IV. Influence of Flap Thickness on Outcomes after Controlling for Residual Bed Thickness

We performed control-matched paired analyses to control for RSB thickness. The preoperative data were matched for eyes with SBK and thick-flap LASIK. Each SBK eye was matched with a single eye with a thick-flap LASIK after fulfilling all of the criteria mentioned below. Due to our matching parameters, the thick-flap LASIK group was expanded to include eyes with corneal thickness ≥ 144 µm. The postoperative data were masked from the researchers throughout the matching process. The criteria used for matching were: (i) flap thickness (minimum of 40 µm difference) (ii) calculated RSB in the SBK eye within ± 40 µm of the matched thick-flap eye, (iii) preoperative myopic SE (-4.00 to -6.00 or > -6.00D), (iv) flap creation method (laser or mechanical), (v) laser ablation type (wavefront guided or non-custom), (vi) laser type (Visx, or B&L), and (vii) follow-up duration. After satisfying all of the above 6 criteria, eyes were matched to minimize the difference between patient age of case and control eyes. Twenty-one matched pairs satisfied these criteria. Analysis was performed using paired t-tests and Fisher’s Exact Test.

RESULTS

I. Comparative Study of SBK vs. Thick-Flap LASIK Groups

The preoperative data are shown in table 1.

The postoperative UCVA (-LogMAR, mean ± SD) was 0.16 (20/29) ± 0.22 for SBK, and 0.14 (20/28) ± 0.15 for thick-flap LASIK at a mean follow up of 10.2 and 11.1 months, respectively (Table 2). The postoperative BSCVA was 0.002 (20/20) ± 0.06 for SBK and 0.003 (20/20) ± 0.04 for thick-flap LASIK. The change in BSCVA was 0.002 ± 0.07 for SBK and −0.006 ± 0.05 for thick-flap LASIK (Table 2). No significant differences in the postoperative UCVA, BSCVA and change in BSCVA were found between groups. Although retreatment rates were higher in SBK (24.2%) compared to thick-flap LASIK (19.4%), the differences were not significant ($P = 0.58$).

The postoperative sphere (Diopters, mean ± SD) was −0.33 ± 0.67 in SBK, and −0.22 ± 0.62 in thick-flap LASIK at a mean follow up of 10.2 and 11.1 months, respectively (Table 2). The postoperative SE (spherical equivalent) was −0.55 ± 0.70 in SBK and −0.51 ± 0.64 in thick-flap LASIK. No significant differences in the postoperative sphere and SE were found between the two groups. No flap complications were reported.

The postoperative cylinder in SBK was 0.43 ± 0.33 D as compared to 0.58 ± 0.41 D in thick-flap LASIK. No differences in predictability and efficacy parameters were found between SBK and thick-flap LASIK (Table 3). In both groups, no eyes lost 2 or more lines. However, 27.3% eyes that underwent SBK lost one line of BSCVA compared to 8.1% of eyes in thick-flap LASIK ($P = 0.01$).

II. Influence of Flap Thickness Control-matched Analyses

Paired analyses were performed for 42 eyes (21 matches) with SBK or thick-flap LASIK that satisfied all of the matching criteria. The flap was created using the Intralase in 5 matches and the manual microkeratome in 16 matches. Although matching considerably reduced our sample size and statistical power of our data, we consider control matched analysis to be useful in determining whether corneal flap thickness independently affects postoperative outcomes. The preoperative controlled matched data did not show any difference in vision or refractive data between SBK and thick-flap LASIK groups (Table 4). There were no significant differences in postoperative refractive and visual outcomes (Table 5). Safety, efficacy, and predictability parameters were better in eyes that underwent thick-flap LASIK as compared to SBK. However, no statistical significant differences were evident (Table 6).

Comparison of the intended versus achieved correction was performed in these control matched eyes to ascertain whether corneal flap thickness affects the refractive outcome. There was no significant difference between the intended-achieved refractive error in SBK (−0.33 ± 0.78) versus intended-achieved in thick flaps [(−0.47 ± 0.47) (P=0.44)].

DISCUSSION

In this study, we evaluated the safety, efficacy and predictability of SBK, by retrospectively analyzing the pooled data of SBK (82–120 microns) and thick-flap LASIK (≥160 microns). Our study showed that the visual and refractive outcomes for SBK and thick-flap LASIK are similar; this is true in corneas with equivalent residual stromal bed (RSB) thickness.

The importance of a thick RSB after LASIK is widely accepted.[1–6] The RSB thickness depends on the preoperative corneal thickness, the thickness of the corneal flap, and the amount of tissue ablation by the excimer laser. Thus, a thin flap (as in SBK) may be desirable; it can help maximize the RSB thickness, and preserve the biomechanical stability of the cornea.[14] With SBK, it is possible to safely perform LASIK in patients with thin corneas as the RSB thickness is greater than that achieved by conventional LASIK. To our knowledge, this is the first study to evaluate the effect of flap thickness in matched SBK and thick-flap LASIK patients having similar RSB values.

Studies evaluating the effect of corneal flap thickness on LASIK outcomes have shown conflicting results. Yi and Joo[20] in a prospective study on 69 eyes found slightly better visual outcomes in a thick flap group (> 165 µm) compared to a thin one (< 135 µm). Yeo and Song[21] observed a higher incidence of central corneal opacity after LASIK with thin flaps (mean thickness of 88.89 ± 8.07 µm). A possible explanation would be the injury of Bowman's layer by the blade or a hidden / masked buttonhole, camouflaged by intact epithelium, which may have caused central corneal scarring. Other studies found increased keratocyte activation on confocal microscopy associated with thin flaps after LASIK.[22, 23] In a study by Vesaluoma et al.[23], patients with increased interface reflectivity due to abnormal extracellular matrix or activated keratocytes had significantly thinner flaps than patients with normal interface reflectivity. Pisella et al.[22] found a higher postoperative cellular activation in the posterior stroma in patients with thin flaps. The reason for a better outcome with thick-flap LASIK in these studies seems to be that the thin flap was an unintended complication; hence, it may have been irregular.

Other studies have shown that as compared to thick flaps, thin flaps were associated with better early visual and refractive results.[15–17] These include some of the more recent studies where a thin flap was intentionally created as part of SBK.[14] Prandi et al. reported that patients with flaps ≤ 100 µm had better functional results at 1 month than those with thicker flaps.[15] Eleftheriadis et al. observed better early UCVA with thinner flaps compared to thicker flaps at 1 week and 1 month but not at 1 day and 3 months after myopic LASIK.[16] At one month post-LASIK sphere and cylinder were not related to flap thickness, but SE was negatively correlated. In both reports flap thickness was unrelated to BSCVA.[15,16] Cobo-Soriano et al.[17] reported better contrast sensitivity and lower retreatment rates with thin flaps. Although not statistically significant, there was a trend towards a lower retreatment rate in the thin flap group compared to the thick flap group (13.7% vs. 19.7%; $P = 0.32$).

Kymionis et al, reported the long-term refractive results of PRK and LASIK in patients with thin corneas (< 500 µm). Intraoperative flap thickness ranged between 69 to 110 µm. After flap lifting and stromal ablation, the mean RSB thickness was 341.93 in LASIK and 368.99 in PRK (after epithelial removal and stromal ablation). The authors reported that both procedures resulted in safe and predictable results, with no post-refractive corneal ectasia.[24] A recent report on 3009 eyes that underwent SBK using the femtosecond laser shows a low complication rate. Intraoperative complications included flap tear, free cap, bubble escape, and flap folds. Postoperative complications included DLK and epithelial in-growth. Flap-related complications such as an uneven-bed, buttonhole, short flap, flap striae or wrinkles did not occur. [25] No complications were noted in our study.

Data from our series have certain limitations. The retrospective nature of our study, and the fact that our data were obtained only at the last follow-up are obvious limitations. Problem-free patients with a good outcome tend not to return for longer follow-up visits. This may have biased the results towards some overestimation of the visual loss, which may have a similar effect on all groups. One rationale for performing case-control matched analyses in this study is to overcome limitations in data analyses due to difference in sample size and the presence of laser ablation variables.

Mechanical microkeratomes create flaps with a thickness directly dependent on corneal pachymetry.[8,20,22,26,27] Flap thickness varies widely, especially with mechanical microkeratomes, according to microkeratome type, turbine and translational blade velocities, reuse of blades and nominal labeled head.[20,21,23,26,27] The achieved flap thickness frequently differs from the expected.[5,8,20,26,27] The actual flap may be much thicker than planned, making the RSB less than expected, which may increase the risk of corneal ectasia.[1–6] In our study, we estimated the actual flap thickness by performing intraoperative pachymetry before and after flap creation. This practice is especially useful when treating moderate-to-high myopic eyes and relatively thin corneas, or when performing LASIK retreatments. Future prospective controlled matched studies may be needed to ascertain whether SBK is advantageous over thick-flap LASIK in patients with moderate-to-high myopia.

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Biography

Table 1

Preoperative data of patients having SBK or thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Parameter	**SBK (82–120 μm) (33 Eyes, 30 Patients)**	**Thick-Flap LASIK (=160 μm) (62 Eyes, 53 Patients)**	***P* Value**
Sex, n (%)			.757[‡]
Female	16 (53.33)	29 (54.72)	
Male	14 (46.67)	24 (45.28)	
Age (y)			.752[§]
Mean ± SD	38.67 ± 9.44	39.32 ± 9.03	
Range	24 to 55	23 to 58	
BSCVA			.623[§]
Mean logMAR ± SD	0.003 ± 0.06	0.009 ± 0.03	
Range logMAR	−0.12 to 0.18	−0.12 to 0.10	
Mean Snellen[*]	20/20	20/20	
Sphere (D)			.462[§]
Mean ± SD	−6.18 ± 1.67	−5.91 ± 1.75	
Range	−3.50 to −9.50	−3.50 to −10.00	
Cylinder (D)			.906[§]
Mean ± SD	−0.80 ± 0.61	−0.82 ± 0.60	
Range	0.00 to −2.75	0.00 to −2.75	
SE (D)			.482[§]
Mean ± SD	−6.58 ± 1.69	−6.32 ± 1.79	
Range	−4.00 to −9.75	−4.25 to −10.00	
Pachymetry (μm)			<.001[§]
Mean ± SD	533.15 ± 34.32	567.19 ± 31.67	
Range	472 to 598	497 to 634	
Flap thickness (μm)[†]			<.001[§]
Mean ± SD	110.18 ± 9.19	179.15 ± 19.51	
Range	82 to 120	160 to 261	
Mean residual bed (μm) ± SD	355.01 ± 34.26	322.14 ± 36.26	<.001[§]

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK = sub-Bowman keratomileusis; SE = spherical equivalent

[*] Converted from -logMAR

[†] Calculated by subtracting ultrasonic pachymetry before and after flap creation

[‡] Pearson chi square

[§] Independent-samples *t* test

Table 2

Outcomes of SBK and thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Parameter	**SBK (82–120 μm) (n = 33)**	**Thick-Flap LASIK (=160 μm) (n = 62)**	***P* Value**
Postoperative UCVA*			.503‡
Mean logMAR ± SD	0.16 ± 0.22	0.14 ± 0.15	
Range logMAR	−0.12 to 0.70	−0.12 to 0.54	
Mean Snellen Acuity†	20/29	20/28	
Postoperative BSCVA			.947‡
Mean logMAR ± SD	0.002 ± 0.06	0.003 ± 0.04	
Range logMAR	−0.12 to 0.14	−0.12 to 0.10	
Mean Snellen†	20/20	20/20	
Change in BSCVA			.708‡
Mean ± SD	0.002 ± 0.07	−0.006 ± 0.05	
Range	−0.12 to 0.14	−0.13 to 0.12	
Postoperative sphere (D)			.412‡
Mean ± SD	−0.33 ± 0.67	−0.22 ± 0.62	
Range	−1.75 to 1.00	−1.50 to 1.00	
Postoperative cylinder (D)			.054‡
Mean ± SD	−0.43 ± 0.33	−0.58 ± 0.41	
Range	−1.25 to 0.00	−1.50 to 0.00	
Postoperative SE (D)			.791‡
Mean ± SD	−0.55 ± 0.70	−0.51± 0.64	
Range	−2.00 to 1.00	−1.88 to 0.88	
Follow-up, m			.511‡
Mean ± SD	10.24 ± 5.76	11.13 ± 7.02	
Range	3 to 24	3 to 48	
Retreatment rate (%)	24.2	19.4	.58§

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK = sub-Bowman keratomileusis; SE = spherical equivalent; UCVA = uncorrected visual acuity

*Without monovision

†Converted from -logMAR

‡Independent-samples *t* test

§Pearson chi square

Table 3

Safety, efficacy, and predictability of SBK and thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Parameter	SBK (82–120 μm) (n = 33)	Percentage Thick-Flap LASIK (≥160 μm) (n = 62)	*P* Value*
Safety (BSCVA)			
Loss of 1 line	27.27	8.06	.012
No loss	48.48	72.58	.020
Gain of 1 line	24.24	19.35	.578
Efficacy			
≥20/20	45.46	40.32	.630
≥20/25	66.67	66.13	.958
≥20/40	81.82	88.71	.352
Predictability			
±0.50 D	51.52	58.06	.541
±1.00 D	78.79	82.26	.681

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK = sub-Bowman keratomileusis

*Pearson chi square

Table 4

Preoperative visual and refractive results in 21 matched eyes having SBK or thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Preoperative Data	Mean ± SD SBK (89–119 µm)	Thick-Flap LASIK (144–199 µm)	*P* Value[†]
Age (y)	39.81 ± 9.68	36.38 ± 7.83	.045
Sphere (D)	−6.19 ± 1.88	−6.12 ± 1.79	.782
Cylinder (D)	−0.69 ± 0.52	−0.63 ± 0.61	.710
SE (D)	−6.53 ± 1.87	−6.43 ± 1.89	.703
BSCVA			.832
LogMAR	0.001± 0.07	0.005 ± 0.03	
Snellen[*]	20/20	20/20	
Flap thickness (µm)	108.57 ± 8.02	165.67 ± 12.58	<.001
Residual bed (µm)	343.58 ± 27.03	337.23 ± 27.06	.139
Follow-up (mo)	10.19 ± 6.09	12.29 ± 9.20	.300

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK = sub-Bowman keratomileusis; SE = spherical equivalent

[*] Converted from -logMAR

[†] Paired-samples *t* test

Table 5

Postoperative visual and refractive results in 21 matched eyes having SBK or thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Postoperative Data	Mean ± SD SBK (89–119 μm)	Thick-Flap LASIK (144–199 μm)	*P* Value
Sphere (D)	−0.39 ± 0.78	−0.20 ± 0.5	.313†
Cylinder (D)	−0.54 ± 0.32	−0.58 ± 0.43	.742†
SE (D)	−0.66 ± 0.80	−0.49 ± 0.56	.354†
BSCVA			.253†
LogMAR	0.001 ± 0.07	−0.01 ±0.05	
Snellen*	20/20	20/21	
UCVA			.266†
gMAR	0.17 ± 0.22	0.11 ± 0.07	
Snellen*	20/30	20/26	
BSCVA change	0.01 ± 0.07	0.009 ± 0.05	.387†
Retreatment rate (%)	23.81	19.05	.707‡

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK =sub-Bowman keratomileusis; SE = spherical equivalent; UCVA = uncorrected visual acuity

*Converted from LogMAR

†Paired-samples *t* test

‡Pearson chi- square

Table 6

Safety, efficacy, and predictability in 21 matched eyes having SBK or thick-flap LASIK for moderate to high myopia (−4.0 to −10.0 D).

Parameter	Percentage SBK (89–119 μm)	Percentage Thick-Flap LASIK (144–199 μm)	*P* Value*
Safety (BSCVA)			
Loss of 1 line	33.33	14.29	.277
No loss	47.62	66.67	.350
Gain of 1 line	19.05	19.05	1.000
Efficacy			
≥20/20	38.10	42.86	1.000
≥20/25	64.90	71.43	.744
≥20/40	80.95	95.24	.343
Predictability			
±0.50 D	42.86	66.67	0.215
±1.00 D	71.43	90.48	.238*

BSCVA = best spectacle-corrected visual acuity; LASIK = laser in situ keratomileusis; SBK = sub-Bowman keratomileusis

*Fisher exact test