·Clinical Research·

# Comparisons of morphologic characteristics between thin-flap LASIK and SBK

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## Abstract

• AIM: To compare the morphologic characteristics between thin-flap laser *in situ* keratomileusis (LASIK) and Sub-Bowman keratomileusis (SBK), and to evaluate the uniformity of flap and to explore the correlative factors of corneal flap thickness.

• METHODS: A prospective, randomized, comparative clinical study was performed in Department of Ophthalmology, West Hospital of China, Chengdu, Sichuan Province, China. Totally 59 patients 114 eyes underwent LASIK or SBK to correct myopia, 29 patients 57 eyes underwent SBK, 30 patients 57 eyes underwent LASIK. Anterior optical coherence tomography (OCT) was used to measure corneal flap thickness in all the patients 1 week after surgeries, 16 positions were set to be measured in each eye. Comparisons of flap thickness in each group and between 2 groups were evaluated. Correlative factors of flap thickness were evaluated.

• RESULTS: Coefficient of variation(CV, $s/\overline{x}\times\%$)in SBK group were lesser than that in LASIK group, *t* test showed there was significant statistical difference between 2 groups ($P$= 0.000). Comparisons of the difference of 2 paired positions (temporal-nasal; superior-inferior) showed there were no significant differences in each group, but between 2 groups , there were statistical significance of value of difference (D-value) of superior and inferior positions between SBK and LASIK group ($P$ =0.036). Linear regression analysis of correlative factors of flap thickness showed there were no statistic significances related to central corneal thickness(CCT) ($P$ =0.060, $t$=1.921)and corneal curvature($P$=0.083, $t$ =1.766).

• CONCLUSION: SBK is better than LASIK in creating much uniform corneal flap. There was no evidence showing correlations between flap thickness and CCT or corneal curvature.

• KEYWORDS: Sub-Bowman; keratomileusis; flap thickness

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## INTRODUCTION

The most common surgery to correct ametropia nowadays is laser *in situ* keratomileusis (LASIK), Sub-Bowman keratomileusis(SBK) as a modified surgery of LASIK can create thinner corneal flap, thicker residual stroma bed, its safety and efficacy are similar to those of LASIK [1]. Both the surgeries correct myopia by change the curvature of cornea through keratectomy. The most important procedure is creating good corneal flap with suitable thickness and uniformity for reducing postoperative complications and aberrations of cornea. Although femtosecond laser[2] is a new surgical technique for creating corneal flap with better postoperative uniformity , mechanical keratome still is a major choice in most developing countries. To find out which is the better choice between LASIK and SBK, we explored the morphologic characteristics of corneal flap in both surgeries through anterior optical coherence tomography(OCT). We observed flap thickness and uniformity in LASIK and SBK, analysis correlative factors of corneal thickness.

## MATERIALS AND METHODS

**Subjects** We performed a prospective nonrandomized, comparative clinical study in our institution during the time from Jan 2011 to May 2011. The initial cohort consisted of myopic patients who sought for our refractive surgery treatment. All patients underwent a detailed assessment for their surgeries, including a full ophthalmologic examination preoperatively: uncorrected visual acuity (UCVA); best-corrected visual acuity (BSCVA), normal and cycloplegic refractions; slit-lamp examination; funduscopy; optometry, tonometry (Topcon CT-80, Tokyo, Japan), keratometry and corneal topography (Obscan Ⅱ , Bausch&Lomb Inc., America; ALLegretto Topolyzer, Wavelight, Germany),

central corneal pachymetry (DGH 500 contact pachymeter, Exton, America). The exclusion criteria: minimum corneal thickness less than 470μm, residual bed thickness less than 280μm at a 6.0mm optical zone, relative contraindications such as suspicious keratoconus, keratitis, dry eye, other ocular diseases and systemic diseases. All the patients were told about characteristics and indications about LASIK and SBK particularly, they freely chose one from these two surgical procedures except for some patients whose corneal thicknesses were only available for SBK, all of them signed the consent forms. A total number of 59 patients 114 eyes were included finally. We divided them into two groups according to their different surgery types, 29 patients 57 eyes of SBK group, 30 patients 57 eyes of LASIK group.

**Methods** In all the patients the laser were programmed to correct their full refractions. Two surgeons performed all the procedures. Artificial tears (Hyaluronate) and antibiotic drops (Levofloxacin) were applied to the eyes for 3-5 days before surgery. Surface anesthesia (Alcaine drop) after routine wash of conjuctival sac before surgery, and a sterile surgical drape and rigid eyelid speculum were positioned. According to everyone's preoperative curvature and diameter of cornea, different vacuum suction rings were chosen for them respectively. In the SBK group, Moria One-use plus microkeratome (Moria, Antony, France) was used to create the flap while the Moria2 90 rotary microkeratome (Moria, Antony, France) was used to create the flap in LASIK group, flap hinge located in inferior position in SBK group while it located in superior position in LASIK group. In both groups, after the creating of flap, the flap was raised by a spatula, the stromal bed was dried with a sponge, the ablation was performed with Allegretto Wave excimer laser (Lumenis, America)by using a conventional treatment algorithm. When the ablation finished, corneal flap was gently put back, balanced salt solutions were used to rinse the cornea, and there were no crease and displacement of the flaps, no residual corneal tissue under flaps. Antibiotic and steroid drops (Fluorometholone) and artificial tear drops were applied.

**Postoperative follow-up** All patients used artificial tears and topical antibiotic and steroid drops (Fluorometholone) for 1 month after surgeries, artificial tears in both groups were applied 4 times daily, antibiotic and steroid drops were applied 4 times daily during the first week and 3 times daily during the second week, followed by 2 times daily during the third week and 1 times daily during the last week. We recorded and compared clinical examination results including visual outcome and refractive results. For this study, we measured the flap thickness of each patient with anterior OCT(Vinsante OCT, Carl Zeiss Meditec, Germany) 1 week after surgeries, all the measurement went smoothly by 1 skilled clinical technician who were masked to the type of surgery.We excluded patients who could not follow the instruction of OCT examination、who had unstable fixation during the OCT examination、who suffered from unstable tear-films, and who had any other problem which affected the quality of OCT images. We used the caliper tool with manual override to analyze flap thickness. The flap thickness outcomes at each of the zones (from the corneal vertex, "+" is in the positive X-axis and "-" is in the negative X-axis direction of the image): ±2mm, ±3mm were calculated along the 4 axes (0 degrees →180 degrees, 45 degrees →225 degrees, 90 degrees →270 degrees, 135 degrees→315 degrees), the flap thicknesses were measured at each degree mentions above.

**Statistical Analysis** All the data were analysis using SPSS 13.0 software for windows. The data were expressed using mean ±SD, independent *T* test was used to evaluate the coefficient of variation (CV, s/ $\bar{x}$ ×%) of corneal thickness in both groups, paired *T* test was used to evaluate corneal thickness among different positions in each group, independent *T* test was used to evaluate the diversity difference of corneal thickness between 2 groups. The P value was considered significant at less than 0.05. Linear regression were used to analysis the related factors of corneal thickness.

## RESULTS

**Preoperative- and Postoperative Comparison of Visual Outcomes** Totally 114 eyes were included in our study(57 eyes each group). Preoperative data are shown in Table 1, except for spherical and central corneal thickness (CCT), there were no statistics significant differences between both groups preoperatively. The significant differences were mostly because most patients with thinner corneal thicknesses or/and high myopia preferred to choose SBK procedure. Postoperative data are shown in Table 2, it shows no significant differences between visual outcomes in both groups postoperatively. No complication was detected in all the patients.

**Comparisons of uniformity of corneal flap thicknesses in each group and between both groups** Flap thicknesses at 16 positions of both groups are shown in Table 3. Coefficient of variation (CV, s/ $\bar{x}$ ×%) were used to describe the degree of variation in each group, we evaluated the CV of flap thickness in each patient respectively, comparisons of CV index between 2 groups were evaluated

**Table 1 Comparisons of preoperative evaluation in both groups** mean±SD

| | SBK | LASIK | *P* |
|---|---|---|---|
| Age(a) | 26.14±7.81(18~47) | 23.17±5.90(17~40) | 0.660 |
| Spherical(D) | -5.88±2.05（-1.25~-11.5） | -4.03±1.59(-7.25~-1.5) | 0.00 |
| Cyclinder(D) | -0.74±0.79(0~-3.5) | -0.65±0.79(0~-3) | 0.532 |
| Keratometry (D) | 43.50±1.54(39.9~46.9) | 43.63±1.45（40.55~46.85） | 0.709 |
| CCT (μm) | 531.22±33.95(471~595) | 549.61±31.14(502~625) | 0.00 |

**Table 2 Comparisons of postoperative evaluation in both groups** mean±SD

| | SBK | LASIK | *P* |
|---|---|---|---|
| UCVA | 0.98±0.21(0.4~1.5) | 1.05±0.16(0.7~1.5) | 0.051 |
| Spherical(D) | 0.19±0.59（-1.5~1.25） | 0.24±0.31(-0.25~1) | 0.587 |
| Cyclinder(D) | -0.18±0.59(-1.75~0.75) | -0.09±0.54(-1.25~0.75) | 0.405 |

**Table 3 Corneal flap thickness in different positions in both groups** （mean±SD，μm）

| | SBK | | LASIK | |
|---|---|---|---|---|
| | 2mm | 3mm | 2mm | 3mm |
| 0° | 91.84±7.32 | 89.21±7.96 | 121.30±10.42 | 119.16±10.89 |
| 45° | 91.32±7.70 | 90.28±6.95 | 117.70±11.05 | 117.30±11.53 |
| 90° | 91.49±7.36 | 90.44±7.69 | 119.67±10.72 | 118.09±11.30 |
| 135° | 90.56±7.66 | 89.61±8.12 | 119.95±12.81 | 116.72±18.63 |
| 180° | 91.23±7.96 | 89.30±7.64 | 119.33±11.38 | 119.32±9.48 |
| 225° | 90.51±7.93 | 88.25±8.44 | 120.63±11.63 | 121.19±11.17 |
| 270° | 91.21±8.96 | 89.91±8.38 | 122.35±11.75 | 120.49±10.52 |
| 315° | 90.54±7.90 | 89.63±7.84 | 122.23±10.82 | 121.56±10.28 |
| Average | 91.09±7.85 | 89.58±7.88 | 120.40±11.32 | 119.23±11.73 |

0° :Nasal; 45° :Superior to nasal; 90° :Superior; 135° :Superior to temporal; 180° :Temporal; 225° :Inferior to temporal; 270° : Inferior; 315° :Inferior to nasal.

**Table 4 Comparison of CV index of flap thicknesses between 2 groups** mean±SD

| | SBK | LASIK | *T* | *P* |
|---|---|---|---|---|
| CV(%) | 4.69±1.18(2.33~7.94) | 6.50±2.81(3.6~24.4) | -4.492 | 0.000 |

**Table 5 Comparisons of flap thicknesses of each pair in both groups** mean±SD

| | | Temporal | Nasal | Superior | Inferior |
|---|---|---|---|---|---|
| SBK | Flap thickness(μm) | 89.30±7.64 | 89.2±7.96 | 89.91±8.38 | 90.44±7.69 |
| | *T* | 0.174 | | -0.821 | |
| | *P* | 0.862 | | 0.415 | |
| LASIK | Flap thickness(μm) | 119.3±9.48 | 119.16±10.89 | 118.09±11.3 | 120.49±10.52 |
| | *T* | 0.117 | | 1.966 | |
| | *P* | 0.907 | | 0.054 | |

**Table 6 Comparisons of D-value of both pairs between SBK and LASIK groups** (mean±SD, μm)

| | SBK | LASIK | *T* | *P* |
|---|---|---|---|---|
| D(temporal-nasal) | 0.09±3.80 | -0.53±4.84 | -0.049 | 0.961 |
| D(inferior-superior） | 0.16±10.19 | 2.40±9.23 | -2.123 | 0.036 |

by Independent T test, results are shown in Table 4. The CV index in SBK group was lesser than it in LASIK group, T test proved there were significant statistical difference of CV between 2 groups($P$=0.000<0.05).To explore deeply, 4 typical positions at ±3mm zone from the vertex of cornea were measured along 2 axes (0 degrees →180 degrees, 90 degrees →270 degrees), we put them into 2 pairs: temporal-nasal(0° -180° ); superior-inferior(90° -270° ), paired-t test were used to evaluate the differences of each pair in each group and between 2 groups. The results are shown in Table 5 and Table 6, all the $P$ values are more than 0.05, there were no significant differences of each pair (between temporal and nasal; superior and inferior) in each group. The evaluation of D-value of both pairs between SBK and LASIK groups are shown in Table 6, $P$ value of the pair (inferior-superior) between 2 groups is 0.036<0.05,

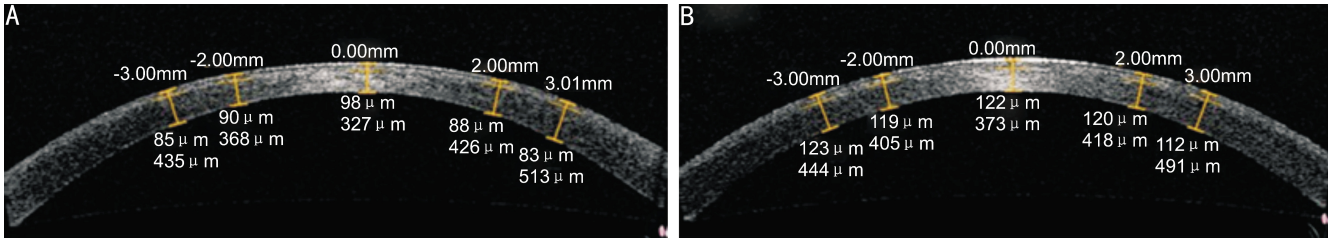


**Figure 1** A: Anterior OCT-based assessment of the flap thickness of a patient undergone SBK (315° : left; 135° : right); B: Anterior OCT-based assessment of the flap thickness of a patient undergone LASIK (180° left; 0° right). The measurement was carried out using caliper tool.

*P* value of the pair (temporal-nasal) between 2 groups is 0.960>0.05, there were statistical significance of D-value of superior and inferior positions between SBK and LASIK group, which means in LASIK group, the difference of flap thickness between superior and inferior positions were significantly more than that in SBK group(Figure 1).

**Correlative Factors of Flap Thickness** Our study used CCT and corneal curvature as independent variables, flap thickness (average thickness of 16 positions) as dependent variables, linear regression analysis were used to evaluate the correlations. LASIK group could not built valid linear regression model ($P$=0.958>0.05); Although SBK group could ($P$=0.02<0.05), after test of Coefficients, the results showed there were no statistical significances related to CCT($P$=0.060, $t$=1.921) and corneal curvature ($P$=0.083, $t$ = 1.766).

## DISCUSSION

LASIK is the most general surgical method to correct ametropia, it is a continuous concern about how to obtain better visual quality and reduce correlative complication. There were studies about biomechanics of cornea [3]showed that maintained residual stroma bed should be at least 280μm for preventing corneal ectasia postoperatively, flap thickness is an important factor related to residual stroma bed. The ideal flap is thin flap which can maintain thicker residual stroma bed and have better stability of corneal biomechanics. Mechanical microkeratome and Femtosecond laser are major techniques for creating corneal flap, each method has advantages and disadvantages, Femtosecond laser create uniform flap but costly, retina injury could be induced by air bubble tracing in anterior chamber and vacuum sucking too long [4,5]; Mechanical microkeratome cost less money but create heterogeneous flap. Studies showed that there were no statistical significance difference of clinical outcomes between these 2 methods[6], mechanical microkeratome still is the common choice for patients with less economic supports because it is much affordable. Studies already showed that SBK and LASIK can win a similar visual outcome [7], but rare report focused on the uniformity of corneal flap, which is an essential factor relating to the visual quality actually.

Prakash *et al* [6], Muscat *et al* [8], Murakami and Manche[9] have reported it is reliable to measure corneal thickness and flap thickness by using anterior OCT, we used Vinsante OCT to measure flap thickness postoperatively, there were no injury and contact through whole OCT process.

The postoperative comparisons of visual outcome had no significant differences, which made it feasible for our study, we used Moria 90 and One use-plus SBK microkeratome to create corneal flap, postoperatively flap thickness of each patient including±2mm and±3mm zone from corneal vertex were measured along four uniform axes in cornea by anterior OCT, all date were calculated automatically using caliper tool.

Our data of flap thickness were basically similar to some previous studies [10]. Since CV index represent dispersion, it was used to evaluate the uniformity of corneal flap. During preliminary description of CV index of the whole 16 positions in both groups, we found it was lesser in SBK group (2mm:SBK 8.62%<LASIK 9.4%; 3mm: SBK 8.80% <LASIK 9.84%), comparisons showed there were statistical significance between 2 group($P$=0.000<0.05), which means in SBK group, degree of dispersion was less than LASIK group, differences among 16 positions were less than LASIK group. According to our experience about surgeries, we speculated flap thickness may be different between superior and inferior position, temporal and nasal position, so these positions were chosen as representation for measurement, Paired $T$ test of these 2 pairs proved that there were no significant difference inside each pair neither for SBK nor LASIK group. However, difference of flap thickness between superior and inferior position in LASIK group was significantly more than in SBK group. Through all the analysis results, we concluded corneal flaps were much uniform in SBK group.

Linear regression results showed that in our study, there

were no significant linear correlations between CCT /corneal curvature and flap thickness, the results should be observed in future.

In conclusion, our study proved that safety and prognosis have no significant difference in SBK and LASIK, and there are no correlations between CCT /corneal curvature and flap thickness. Most importantly, we found SBK is better than LASIK in creating uniform corneal flap. But the reason is worth to study further and our results also need longer follow-up.

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