·Clinical Research·

Comparison of visual acuity of the patients on the first day after sub-Bowman keratomileusis or laser *in situ* keratomileusis

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Abstract

• AIM: To compare recovery of the visual acuity in patients one day after sub-Bowman keratomileusis (SBK) or laser *in situ* keratomileusis (LASIK).

• METHODS: Data from 5923 eyes in 2968 patients that received LASIK (2755 eyes) or SBK (3168 eyes) were retrospectively analyzed. The eyes were divided into 4 groups according to preoperative spherical equivalent: between -12.00 to -9.00 D, extremely high myopia (*n*=396, including 192 and 204 in SBK and LASIK groups, respectively); -9.00 to -6.00 D, high myopia (*n*=1822, including 991 and 831 in SBK and LASIK groups, respectively), -6.00 to -3.00 D, moderate myopia (*n*=3071, including 1658 and 1413 in SBK and LASIK groups, respectively), and -3.00 to 0.00 D, low myopia (*n*=634, including 327 and 307 in SBK and LASIK groups, respectively). Uncorrected logMAR visual acuity values of patients were assessed under standard natural light. Analysis of variance was used for comparisons among different groups.

• RESULTS: Uncorrected visual acuity values were 0.0115±0.1051 and 0.0466±0.1477 at day 1 after operation for patients receiving SBK and LASIK, respectively (P<0.01); visual acuity values of 0.1854±0.1842, 0.0615±0.1326, -0.0033±0.0978, and -0.0164±0.0972 were obtained for patients in the extremely high, high, moderate, and low myopia groups, respectively (P<0.01). In addition, significant differences in visual acuity at day 1 after operation were found between patients receiving SBK and LASIK in each myopia subgroup.

• CONCLUSION: Compared with LASIK, SBK is safer and more effective, with faster recovery. Therefore, SBK is more likely to be accepted by patients than LASIK for better uncorrected visual acuity the day following operation.

• KEYWORDS: sub-Bowman keratomileusis; laser *in situ* keratomileusis; visual acuity; myopia; recovery

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INTRODUCTION

Previous studies [1-2] have reported several advantages for laser *in situ* keratomileusis (LASIK), including fast vision recovery, less pain, and no corneal haze. Several surgical methods have been developed in recent years such as full-laser and full-femtosecond techniques. However, LASIK remains the most popular method for the correction of myopia, hyperopia, and astigmatism. Preparation of the corneal flap is critical in LASIK. Indeed, the thickness of the corneal flap is tightly associated with that of residual corneal stromal bed, which is a critical factor in the occurrence of posterior corneal ectasia following LASIK. In addition, thicker corneal flap could also restrict the range of refractive surgery. In conventional LASIK, the thickness of the corneal flap is about 130-180 μm and depends on the keratome used[3]. The progress in femtosecond laser and microkeratome allowed the reduction of corneal flap thickness to 90-110 μm; this includes the Bowman's membrane and small portion of inferior corneal stroma, and has thus been named sub-Bowman keratomileusis (SBK)[4]. Technically, SBK is therefore a variant of LASIK, and can be called super-thin corneal flap LASIK; it combines the advantages of conventional LASIK and EPI-LASIK, while avoiding their disadvantages. With no surprise, SBK is gradually replacing LASIK. SBK could be classified as femtosecond and mechanical, according to the processes by which corneal flap preparation is carried out. Both traditional LASIK and SBK display good effectiveness and predictability, and the visual acuity is rapidly recovered within a day after operation [5]. Most patients worry seriously about their visual acuity the day after operation for study or work, especially teenagers; in addition, other patients from distant provinces desire to go home as soon as possible. This underscores the need of investigating the difference between patient treatment with LASIK and SBK, which has not been reported to date. In the present study, visual acuity at day 1 after operation was retrospectively analyzed to evaluate the difference between SBK and LASIK treatments.

SUBJECTS AND METHODS

Subjects A total of 5923 eyes from 2968 patients (1367 males and 1601 females) received SBK or LASIK treatment in the refractive surgery center of Xijing hospital between January 2008 and January 2013. A total of 3168 eyes were treated with SBK between 2011 and 2013, while 2755 eyes underwent LASIK treatment (between 2008 and 2010). The eyes were divided into 4 groups according to preoperative spherical equivalent: between -12.00 to -9.00 D, extremely high myopia (n=396, including 192 and 204 in SBK and LASIK groups, respectively); -9.00 to -6.00 D, high myopia (n =1822, including 991 and 831 in SBK and LASIK groups, respectively), -6.00 to -3.00 D, moderate myopia (n= 3071, including 1658 and 1413 in SBK and LASIK groups, respectively), and -3.00 to 0.00 D, low myopia (n=634, including 327 and 307 in SBK and LASIK groups, respectively). The inclusion criteria were: 1) more than 18 years old; 2) spherical power lower than -12.00 D and astigmatism less than -3.00 D; 3) stable spherical power over the last two years; 4) corneal thickness more than 480 μm; 5) best corrected visual acuity ≥0.8; 6) no other eye diseases pre-operation. The exclusion criteria were: 1) intraoperative corneal flap complications; 2) edema of corneal epithelium, epithelial implantation, hemorrhage sub-flap or epithelial dot defects affecting the uncorrected visual acuity (UCVA) the first day post-operation; 3) severe irritation preventing patients from cooperating with the vision test the first day post-operation. As a result, 32/3200 (1%) and 44/2799 (1.57%) eyes in the SBK and LASIK groups were excluded due to complications. This study have been appoved by the Ethics Committee of Xijing Hospital.

Operation Methods ALLEGRETTO WAVE Eye-Q (Germany) was used for the operation, with automatically rotary microkeratomes (Moria M2, France) or automatic microkeratomes (Moria OUP-SBK, France). All operations were performed by the same experienced surgeon. Immediately after operation, a drop each of 0.5% levofloxacin (Santen, Japan) and 0.1% fluorometholone (Santen, Japan) were administered to each eye. This was followed by administration of levofloxacin (one drop every 2h) until the patient fell asleep.

Table 1 All patients' pre-operation data

Parameters	SBK n=1585, 3168 eyes	LASIK n=1383, 2755 eyes	P
Age (a)			0.654
$\bar{x} \pm s$	24.54±5.84	24.39±5.45	
Range	17-45	17-48	
Gender, n (%)			0.782
M	732 (46.18)	635 (45.91)	
F	853 (53.82)	748 (54.09)	
BSCVA			0.498
Mean logMAR±SD	0.004±0.05	0.008±0.06	
Range logMAR	-0.30 to 0.22	-0.18 to 0.22	
Spherical equivalent (D)			0.719
$\bar{x} \pm s$	-5.46±2.07	-5.48±2.20	
Range	-0.25 to -13.25	-0.75 to -14.00	
CCT (μm)			0.523
$\bar{x} \pm s$	543.59±33.77	541.02±27.36	
Range	469 to 660	478 to 637	
Mean residual bed thickness (μm)			<0.001
$\bar{x} \pm s$	330.49±33.77	308.86±32.65	
Range	259 to 490	250 to 451	

BSCVA: Best spectacle corrected visual acuity; CCT: Central cornea thickness.

Postoperative examinations An eye mask was put on each eye immediately after operation and removed at 8:00 a.m. the next day; then, slit lamp examination was performed to rule out abnormalities in the corneal flap, edema of the corneal epithelial layer, corneal epithelial punctate defects, bleeding under flap, and epithelial ingrowth. Afterward, an experienced vision examiner examined and recorded the UCVA of the patients under standard natural light, using the international standard logarithmic visual acuity chart and decimal visual acuity values were recorded.

Statistical Analysis The SPSS 16.0 software was used for statistical analyses. Data were expressed as mean±standard deviation. UCVA (using logMAR visual acuity which calculated by decimal visual acuity) values for patients were compared among different operation methods, spherical power degrees, and operation methods in each spherical power degrees, with the Mann-Whitney U test, independent sample t-test, or analysis of variance (ANOVA). P<0.05 was considered statistically significant.

RESULTS

Preoperative Data As shown in Table 1, no statistically significant differences were found between the SBK and LASIK groups in age (P=0.654), gender (P=0.782), best spectacle corrected visual acuity (BSCVA, P=0.498), spherical equivalent refraction (P=0.719), and CCT (P=0.523), but a statistically significant difference was found in mean residual bed thickness (P<0.001). Similar data were obtained when various subgroups were analyzed, including extremely high, high, moderate, and low myopia patients (data not shown).

Comparison Between Uncorrected Visual Acuity Values Obtained After Laser *in situ* Keratomileusis and Sub-Bowman Keratomileusis UCVA values were 0.0115±0.1051

Table 2 Visual acuity of the patients in the SBK and LASIK groups the day after operation *n* (%)

Groups	Decimal visual acuity				Total
	≥1.0	0.8	0.6	<0.6	
SBK	2399 (75.7)	512 (16.2)	157 (5.0)	100 (3.1)	3168 (100.0)
LASIK	1771 (64.2)	490 (17.8)	211 (7.7)	283 (10.3)	2755 (100.0)

The Mann-Whitney *U* test showed *P*<0.05, suggesting that visual acuity was significantly different between the 2 groups. More patients were found with visual acuity ≥1.0 in the SBK group in comparison with the LASIK group (75.7% *vs* 64.2%); less patients were with visual acuity <0.6 in the SBK group compared with the LASIK group (3.1% *vs* 10.3%).

Table 3 LogMAR visual acuity the day after operation in patients of the SBK and LASIK groups

Groups	Overall	Diopter			
		Low myopia group	Moderate myopia group	High myopia group	Extremely high myopia group
SBK	0.0115±0.1051	-0.0097±0.0963	-0.0138±0.0807	0.0358±0.1067	0.1416±0.1589
LASIK	0.0466±0.1477	-0.0234±0.0978	0.0091±0.1135	0.0922±0.1525	0.2266±0.1968
t	-10.638	-2.071	-6.518	-9.252	-4.711
P	<0.001	0.301	<0.001	<0.001	<0.001

and 0.0466 ±0.1477 the day after operation for patients treated by SBK and LASIK, respectively (*P* <0.01). Among the 3168 eyes of the SBK group, visual acuity of 2399 (75.7%) eyes were ≥1.0 (Decimal visual acuity), 512 (16.2%) eyes were 0.8, 157 (5.0%) were 0.6, and 100 (3.1%) were <0.6, respectively. For the 2755 eyes of the LASIK group, visual acuity of 1771 (64.2%) eyes were ≥1.0, 490 (17.8%) eyes were 0.8, 211 (7.7%) were 0.6, and 283 (10.3%) were <0.6, respectively. Interestingly, the Mann-Whitney *U* test showed that the distribution of visual acuity was significantly different between the two groups (*P*<0.05). Indeed, more patients in the SBK group (75.7%) were found with UCVA ≥1.0 compared with LASIK treated patients (64.2%); in addition, less patients in the SBK group (3.1%) showed UCVA <0.6 compared with the LASIK group (10.3%) (Table 2).

Comparison of Uncorrected Visual Acuity Among Patients with Different Diopters The visual acuity values were 0.1854±0.1842, 0.0615±0.1326, -0.0033±0.0978, and -0.0164±0.0972 for extremely high, high, moderate, and low myopia patients, respectively, indicating a statistically significant difference among these groups (*P* <0.01).

Comparison of Uncorrected Visual Acuity Between Sub-Bowman Keratomileusis and Laser *in situ* Keratomileusis Subgroups Within Patients with Different Diopters No statistically significant difference was obtained in UCVA between the SBK and LASIK treatment groups in low myopia patients (*P*>0.05). However, the difference in UCVA was statistically significant between the patients administered SBK and LASIK in the extremely high, high, and moderate myopia groups (*P* <0.001) (Table 3).

DISCUSSION

Several new techniques including femtosecond laser, full-laser, and full-femtosecond methods developed in recent years could greatly improve the preparation of corneal flap. However, conventional LASIK, which only prepares corneal flaps with a thickness of about 130-180 μm, is still often used for the treatment of myopia, hyperopia, and astigmatism due to its relatively low cost, good postoperative effects, and fast recovery [6-7]. Another new method, namely SBK, is increasingly rated as first choice among patients since it preserves more residual corneal stromal bed, while displaying comparable effectiveness with LASIK and a better safety profile [8-9]. Postoperative recovery is very fast for both LASIK and SBK; this is of great importance for patients, among which some seriously worry as to when their visual acuity would return to normal. Indeed, visual acuity the day after operation is a great concern for the patients. Surprisingly, no study has investigated the differences in visual acuity between patients receiving SBK and LASIK the day after operation. In the present study, the UCVA values recorded the day after operation for patients treated with LASIK and SBK in the past 5y was compared. We found that visual acuity the day after operation was significantly better in patients treated with SBK than those of the LASIK group (0.0115 ±0.1051 *vs* 0.0466 ±0.1477, *P*<0.01). The distribution of visual acuity was also significantly different between the LASIK and SBK groups (*P* <0.05). More patients displayed visual acuity ≥1.0 in the SBK group compared with LASIK treated individuals (75.7% *vs* 64.2%), while less patients with visual acuity <0.6 were found in the SBK group (3.1% *vs* 10.3%). In addition, significantly differences were obtained between SBK and LASIK in patients with different myopia degrees(*P*<0.01 for extremely high, high, and moderate myopia groups). These findings are in agreement with previous reports[3]. Furthermore, the visual acuity was significantly different among extremely high, high, moderate, and low myopia patients (0.1854 ±0.1842 0.0615 ±0.1326, -0.0033 ±0.0978 and -0.0164 ±0.0972, respectively, *P* <0.01) the day after operation, suggesting that visual acuity at day 1 after operation is affected by the degree of myopia. Importantly, the visual quality and subjective feeling of the patients were also better in the SBK group compared with the LASIK group. Fewer dry eyes were observed and less drug was needed in the SBK group at 1-month after the operation, while dry eyes were found in several patients of the LASIK group, requiring treatment with artificial tears. However, follow-up was not regular in many patients, making it difficult to obtain data from all these patients for accurate statistical analysis.

Many factors, including abnormal corneal flap, edema of the corneal epithelial layer, corneal epithelial punctate defects, accommodation of the patients, cloudy or bleeding under flap, and lacrimal secretion affect the recovery of visual acuity [10-11]. After exclusion of these factors, we found improved visual acuity in the SBK group compared with LASIK patients. The thinner corneal flap used in the SBK method could be one of the reasons. Indeed, the thickness of the corneal flap used in SBK patients was about 20-70 μm less than that used in the LASIK group; the central corneal thickness was about 110 μm, which made it an ideal corneal flap that could maximize the preservation of the thickness of corneal stromal bed and stability of corneal biomechanics[12]. Previous studies have shown that the uniformity and repeatability of the thickness of corneal flaps prepared by OUP microkeratome are comparable with those obtained by the femtosecond technique [8-9,13]. In contrast, the thickness of corneal flaps for conventional LASIK is highly dependent on the times of microkeratome use[14]; thus, either the uniformity of the corneal flap or the thickness of corneal stromal bed cannot be ensured. The thickness of the corneal stromal bed should be higher than 250 μm after LASIK to avoid keratectasia and iatrogenic keratoconus; while in most cases, clinicians believe that the thickness of the corneal stromal bed should be at least 280 μm to ensure good postoperative biomechanics [15]. Herein, we have demonstrated that the difference in visual acuity the day after operation between the SBK and LASIK subgroups was more pronounced in extremely high myopia patients, while this difference was relatively reduced within the low myopia group, suggesting that SBK better preserved the thickness of the corneal stromal bed in addition to using less corneal tissues in patients with high myopia degree, and thus provided better biomechanical features and visual quality[16].

In addition, other advantages could be obtained with thin corneal flaps but not with thick ones. First, thin corneal flaps allow the extension of ablation diameter, which reduces the risk of postoperative glare, thus further improving the postoperative visual quality. Second, thin corneal flaps allow the preservation of corneal stromal bed thickness, which could increase the laser ablation extent and correction range of myopia. This could be used for patients with high myopia, making it possible to perform secondary correction for refractive regression[9]. Interestingly, we found that the visual acuity values were comparable in patients receiving SBK and LASIK at 1-month post-operation (data not shown), in accordance with previous studies[3,17].

As shown above, visual acuity was significantly different among various myopia groups the day after operation. Indeed, the visual acuity was poorer in the high and extremely high myopia groups the day after operation, but better in the moderate and low myopia groups. These findings demonstrated that for patients with extremely high or high myopia, overcorrection could generally be found at the early stage after operation, leading to relatively poor visual acuity; however, the overcorrection could become an excellent correction within 10d to 1mo, when the visual acuity increases. Therefore, visual acuity was not statistically different among extremely high, high, and moderate myopia groups at 1-month post-operation (data not published).

SBK not only results in better postoperative visual acuity, but also makes patients more comfortable. In the conventional LASIK, the corneal flaps show relatively poor uniformity, which could more or less damage the corneal nerve plexus and result in decreased postoperative corneal perception and prolonged recovery time [18-19]. In SBK, the corneal flap is prepared with higher precision with more superficial ablation layer, which makes the postoperative recovery faster and less depending on the artificial tears[11,20].

One of the limitations of this study is that it was carried out in a single center and analyses were done retrospectively. Second, the vision acuity was affected by a lot of factors such as precision of preoperative examination, the compliance of patient when visual acuity examination and stability of excimer laser machine every operation days. In addition, the Early Treatment Diabetic Retinopathy Study (ETDRS) visual chart, which may be more suitable for high myopia and fundus diseases patients, was not used in the present work.

Nevertheless, our data showed that SBK is a safer method with better efficacy and faster recovery compared with LASIK. In addition, visual acuity the day after operation was better with SBK, which should have higher patient compliance. Furthermore, SBK preserved the corneal stromal bed thickness and extended the correction range of patients, providing an additional opportunity for patients with high myopia, thin cornea, or in need of secondary correction[3,12]. Overall, SBK is the better choice for corneal flap preparation with either femtosecond or OUT-SPK microkeratomes, and should be considered a good choice for patients.

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