• Clinical Research •

Comparison of clinical outcome of small-incision lenticule intrastromal keratoplasty and FS-LASIK for correction of moderate and high hyperopia

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Abstract

● **AIM:** To compare the clinical outcome of small-incision lenticule intrastromal keratoplasty (sLIKE) and femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) for correction of moderate and high hyperopia.

● **METHODS:** A case-controlled clinical study was performed. Twenty right eyes of 20 moderate and high hyperopia patients underwent sLIKE (sLIKE group) and 22 right eyes of 22 moderate and high hyperopia patients underwent FS-LASIK (FS-LASIK group) were enrolled in this study from October 2015 to October 2017. Visual acuity, refractive error, corneal thickness, and keratometry were compared between the groups before and 1y postoperatively.

● **RESULTS:** The postoperative uncorrected near visual acuity (UNVA) and uncorrected distance visual acuity (UDVA) were improved in the two groups. The UNVA reached J1 in 15 eyes (75.0%) in the sLIKE group and 5 eyes (22.7%) in the FS-LASIK group 1y after surgery (χ^2=11.476, *P*=0.001). The UDVA was equal or better than the preoperative CDVA in 16 eyes (80.0%) in the sLIKE group and 8 eyes (36.4%) in the FS-LASIK group, respectively (χ^2=8.145, *P*=0.004). No eyes lost any line of best-corrected visual acuity (BCVA) in either group. The amount of postoperative residual hyperopia in the sLIKE group was significantly less than in the FS-LASIK group (*Z*=-2.841, *P*=0.004). The postoperative keratometry and corneal thickness were significantly higher in the sLIKE group than in the FS-LASIK group (*t*=4.411, 10.279, *P*<0.001). The SRI and SAI of the sLIKE group were significantly higher than that in the FS-LASIK group. There was no statistically significant difference in mean decentration between the two groups.

● **CONCLUSION:** sLIKE has better visual and refractive outcome than FS-LASIK for correction of moderate and high hyperopia.

● **KEYWORDS:** hyperopia; small-incision lenticule intrastromal keratoplasty; laser *in situ* keratomileusis; femtosecond laser

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INTRODUCTION

The prevalence of hyperopia in the adult population was reported to be 25.2%-31.8% in Europe[1-2]. In general, distant vision is normal and near vision can be compensated by accommodation in low hyperopia patients. Low hyperopia usually needs no intervention. Clinical manifestations of moderate and high hyperopia patients include distant vision and near vision blurry, and asthenopia. Many adult patients with moderate and high hyperopia suffer from vision troubles for years. Therefore, they are eager to receive better treatment to reduce spectacle dependence. Femtosecond laser assisted laser *in situ* keratomileusis (FS-LASIK) has become the most popular surgical approach for the correction of refractive error worldwide, which is widely used in myopia treatment. However, FS-LASIK for correction of hyperopia has been limited. Researches show that a high incidence of refractive regression happened in moderate and high hyperopia patients who underwent FS-LASIK[3-4]. Small-incision lenticule intrastromal keratoplasty (sLIKE) is a new surgical approach to correct hyperopia by implanting an allogeneic (or autologous) lenticule. Previous studies have confirmed the

safety, effectiveness, and predictability of sLIKE[5-9]. However, no study has compared the clinical results between sLIKE and FS-LASIK. In this study, we compared the results of the two surgical procedures for correcting hyperopia after one year, and assessed the differences between the two surgical procedures and provided a guidance for the selection of clinical surgical methods.

SUBJECTS AND METHODS

Ethical Approval The study was approved by the Ethics Committee of Beijing Tongren Hospital (No.TRECKY 2014-026) and conducted following the principles of the Declaration of Helsinki. The informed consent was signed by the patients.

Patients Forty-two right eyes of 42 hyperopia patients (22 males, 20 females), who aged 20 to 47 years old, were performed refractive surgery at the Refractive Center of Beijing Tongren Hospital from October 2015 to October 2017. The patients were divided into two groups according to different procedures received: 20 eyes of 20 patients in the sLIKE group and 22 eyes of 22 patients in the FS-LASIK group. To avoid the effects of similarity between the eyes of the same patients, only the right eye of each patient was selected for analysis. Inclusion criteria: corrected distance visual acuity (CDVA) is more than 0.9; corrected near visual acuity (CNVA) is more than J2; central corneal thickness is more than 480 μm; preoperative spherical equivalent (SE) is from +3.00 to +7.00 diopter (D), astigmatism is less than 2.00 D; all patients had been tested for evidence of viral and microbial diseases before surgery; all donors' blood tests related to infectious disease were normal. Exclusion criteria: patients with systemic disease, previous intraocular surgery, history of ocular trauma, active ocular inflammation, any sign of ectasia, and those who were pregnant were excluded.

Preoperative Assessment Uncorrected distance visual acuity (UDVA) and CDVA at 5 m, uncorrected near visual acuity (UNVA), and CNVA at 40 cm. Distance and near visual acuity were tested using a standardized logarithmic visual acuity chart and a Jaeger visual acuity chart, respectively. Other examinations include manifest and cycloplegic refraction, slit-lamp examination, fundus evaluation, non-contact intraocular pressure (Canon, Tokyo, Japan), ultrasonic pachymetry (Tomey, Nagoya, Japan), corneal topography (Tomey, Nagoya, Japan).

Surgical Procedures The same experienced surgeon (Zhou YH) performed all surgeries. sLIKE was performed using a VisuMax femtosecond laser system (Carl Zeiss, Jena, Germany). Preparation of donor lenticule: Refraction matched myopia eye was selected to undergo small incision lenticule extraction (SMILE) procedure, then the donor lenticule was soaked in riboflavin solution; Hyperopia correction for recipient cornea: The SMILE program created an 8.0 mm diameter pocket with a depth of 120 μm cap and a 3 mm wide incision at 90° meridian. Surgical design refraction was set at -1.00 D spere combined expectant corrected astigmatism. The donor lenticule was then implanted into the intrastromal pocket. To confirm whether the lenticules were ideally located, optical coherence tomography (OCT) was performed immediately after surgeries.

During the FS-LASIK procedure, the VisuMax femtosecond laser system (Carl Zeiss, Jena, Germany) was used to make corneal flap, and a VISX S4 excimer laser system (VISX, Santa Clara, USA) was used for subsequent photoablation. The intended flap diameter and thickness were set at 8.5 mm and 110 μm, respectively. The optical zone diameter was set at 6.5 mm. Postoperatively, patients are instructed to instill fluorometholone 0.1% four times per day for 3d, tapered over 2wk, and levofloxacin and artificial tears four times per day for 2wk.

Observation Index Early clinical studies of sLIKE for hyperopia have been reported in our groups[5-6]. Therefore, this study only focuses on the results of 1y after surgery. The follow-up examinations include UDVA, CDVA, UNVA, CNVA, manifest and cycloplegic refraction, slit-lamp examination, central corneal thickness, and corneal topography.

Statistical Analysis All data were analyzed using SPSS version 23.0 (SPSS Inc., Chicago, IL, USA). Shapiro-Wilk test was used to check the normality of quantitative variables. Normally distributed data were analyzed with *t*-test. For samples that did not satisfy normal distribution, we used the Mann-Whitney *U* test. Postoperative residual refractive errors at different time points were assessed with repeated measures analysis of variance (ANOVA). Dunnett's test was used for posthoc multiple comparisons. Comparisons between proportions were made with the Chi-square test. *P* values less than 0.05 were considered statistically significant.

RESULTS

Forty-two right eyes of 42 patients (22 males, 20 females) were studied. sLIKE group comprised 20 eyes of 20 patients and FS-LASIK group, 22 eyes of 22 patients. The mean patient age was 28.05±7.33 (18 to 40)y in the sLIKE Group and 33.64±8.51 (18 to 42)y in the FS-LASIK group. All patients completed a one-year follow-up. Preoperative baseline data of both groups are shown in Table 1 and there were no statistically significant differences between the two groups.

Visual Acuity The UNVA reached J1 in 15 eyes (75%) in the sLIKE group and 5 eyes (22.7%) in the FS-LASIK group 1y after surgery. There is a significant difference between the two groups (χ^2=11.476, *P*=0.001). The UDVA was equal or better than the preoperative CDVA in 16 eyes (80%) in the sLIKE group and 8 eyes (35%) in the FS-LASIK group, respectively (χ^2=8.145, *P*=0.004). No eyes lost any line of BCVA in either group. Postoperative clinical outcomes, including visual acuity, are summarized in Table 2.

Refraction At the 1y follow-up, 9 eyes (45%) of sLIKE group and 3 eyes (13.6%) of FS-LASIK group had an SE within ±0.50 of intended correction (χ^2=5.050, *P*=0.025), 16 eyes (80%) of sLIKE group and 10 eyes (45.5%) of FS-LASIK group had SE within ±1.00 D of intended correction, respectively (χ^2=5.301, *P*=0.021). The mean amount of postoperative residual hyperopia in the sLIKE group was significantly lower than in the FS-LASIK group (*Z*=-2.841, *P*=0.004; Table 2).

In each pairwise comparison of postoperative SE among different time points, there was no statistically significant difference in sLIKE group (all *P*>0.05). There was a statistical difference in the overall comparison of SE after surgery (*F*=40.777, *P*=0.001). The SE of 6mo and 12mo were significantly higher than 1 and 3mo in the FS-LASIK group (all *P*<0.05). When residual astigmatism refractive errors were compared, there were no statistically significant differences among different time points in both groups (all *P*>0.05; Tables 3 and 4).

Cornea Keratometry and Central Corneal Thickness The mean keratometry was significantly higher in the sLIKE group than in the FS-LASIK group (*t*=4.411, *P*<0.001; Table 5 and Figure 1). The SRI and SAI of sLIKE group were significantly higher than that in FS-LASIK group. Decentration over 0.5 mm occurred in 5 eyes (25%) in the sLIKE group and 2 eyes (9%) in the FS-LASIK group, all the other eyes were between 0 and 0.5 mm. There was no statistically significant difference in mean decentration between the two groups. The mean postoperative corneal thickness was significantly thicker in the sLIKE group than that in the FS-LASIK group (*t*=10.279, *P*<0.001; Table 5 and Figure 2).

Table 1 Demographic and preoperative characteristics of patients

Parameters	sLIKE	FS-LASIK	*t*-test *t*	*P*
Age (y)	28.05±7.33	33.64±8.51	-2.268	0.468
SE (D)	4.96±0.93	5.13±0.70	-0.717	0.067
Astigmatism (D)	0.68±0.53	0.95±0.58	-1.637	0.869
Km (D)	42.44±0.91	42.21±0.98	0.782	0.364
CCT (μm)	548.75±28.65	548.77±36.68	0.002	0.204

SE: Spherical equivalent; Km: Mean keratometry; CCT: Central corneal thickness.

Table 2 Postoperative visual acuity and refractive results

Parameters	sLIKE	FS-LASIK	*t*-test *t/Z*	*P*
UDVA	0.95±0.26	0.73±0.26	2.74	0.009
UNVA	1.00 (0.26)	0.66 (0.25)	-3.430	0.001
CDVA	1.00 (0.10)	1.00 (0.10)	-0.029	0.977
CNVA	1.00 (0.00)	1.00 (0.08)	-0.629	0.529
SE (D)	0.66 (0.44)	1.13 (0.50)	-2.841	0.004
Astigmatism (D)	-0.56±0.57	-0.37±0.48	-1.182	0.244

UDVA: Uncorrected distance visual acuity; UNVA: Uncorrected near visual acuity; CDVA: Corrected distance visual acuity; CNVA: Distance-corrected near visual acuity; SE: Spherical equivalent.

Table 3 Comparison of SE and astigmatism among different periods after surgery in the sLIKE group D

Parameters	1mo	3mo	6mo	12mo
SE	-0.18±0.58	-0.02±0.71	0.41±0.51	0.63±0.28
Astigmatism	-0.15±0.55	0.23±0.48	-0.17±0.83	-0.66±0.48

SE: Spherical equivalent.

Table 4 Comparison of SE and astigmatism among different periods after surgery in the FS-LASIK group D

Parameters	1mo	3mo	6mo	12mo
SE	-0.16±0.76	0.23±0.67	0.92±0.68	1.01±0.57
Astigmatism	0.26±0.53	-0.02±0.74	0.24±0.40	-0.41±0.46

SE: Spherical equivalent.

Table 5 Postoperative topography indices and corneal thickness

Parameters	sLIKE	FS-LASIK	*t/Z*	*P*
Km (D)	47.86±1.17	46.06±1.45	4.411	<0.001
SRI	0.59 (0.29)	0.26 (0.32)	-3.930	<0.001
SAI	0.71 (0.47)	0.22 (0.51)	-3.755	<0.001
Decentration (mm)	0.40 (0.29)	0.33 (0.20)	-1.841	0.066
CCT (μm)	620.65±33.18	518.55±31.19	10.279	<0.001

Km: Mean keratometry; SRI: Surface regularly index; SAI: Surface asymmetry index; CCT: Central corneal thickness.

DISCUSSION

Innovation in femtosecond and excimer technology in the last two decades has dramatically advanced the progress in corneal refractive surgery. The accuracy of the myopia correction continues to improve, but there is no further improvement in the accuracy of hyperopia correction. Previous studies found a high incidence of regression rate in patients undergoing hyperopia correction surgeries[3-4,10-14]. The mechanism of optical regression is epithelium cellular proliferation in the peripheral cornea after hyperopia ablation[15-16].

With the development of SMILE technology, it has been found that the extracted corneal lenticule during surgical can be used as donor refractive material to implant into hyperopia cornea. Fortunately, several studies have reported promising results after the lenticule implantation surgical in hyperopia patients[5,17].

In sLIKE, the femtosecond laser creates an intrastromal pocket, and the donor lenticule is then implanted into the pocket. Hyperopia was corrected during this process. sLIKE for hyperopia have advantages over FS-LASIK: 1) Subtraction *vs* addition operation design: FS-LASIK procedure was performed by laser ablation to correct hyperopia, whereas sLIKE was performed by implanting a lenticule. 2) During the FS-LASIK procedure, peripheral corneal stromal tissue was ablated and may cause epithelium cellular proliferation.

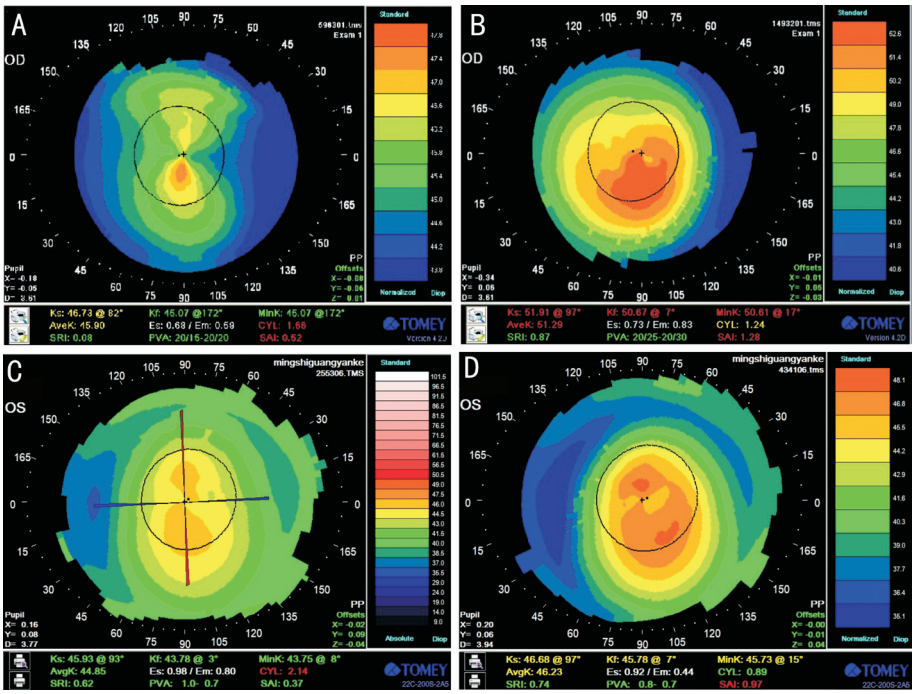

Figure 1 Cornea topography of the 2 groups A: sLIKE preop.; B: sLIKE postop.; C: FS-LASIK preop.; D: FS-LASIK postop.

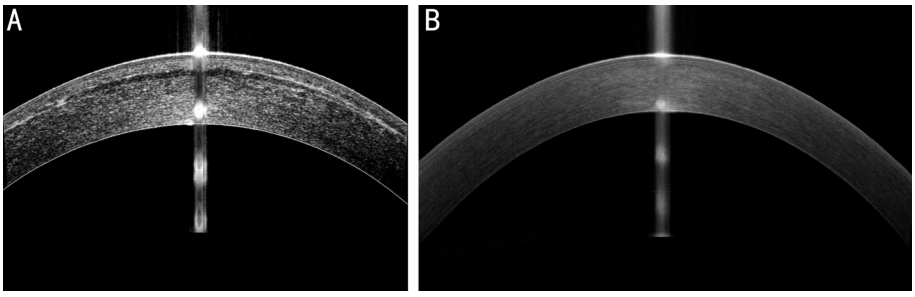

Figure 2 Postoperative OCT of the 2 groups A: sLIKE postop.; B: FS-LASIK postop.

However, the peripheral corneal stroma is undisturbed during sLIKE. 3) The shape of the cornea is more natural after sLIKE. 4) sLIKE is a reversible procedure, whereas FS-LASIK is an unreversible procedure. 5) FS-LASIK may induce more negative spherical aberration than sLIKE[18-20]. 6) As a result of poor adhesion of flap edge, higher chances of epithelial ingrowth happen after FS-LASIK[21-22]. sLIKE is a flap-less procedure, thereby causing fewer postoperative dry eye symptoms, lower chances for epithelial ingrowth. 7) sLIKE procedure can correct higher hyperopia refractive error than FS-LASIK.

The first autologous lenticule intrastromal keratoplasty surgery was performed successfully by our study group in 2012[5]. Therefore, we started exploring allogeneic lenticule intrastromal keratoplasty surgeries in 2013. We obtain satisfactory clinical results, either[6-7].

Previous studies mainly focused on the safety, effectiveness, and predictability of sLIKE. However, there is currently no comparative studies between sLIKE and FS-LASIK procedures. This study retrospectively analyzed the postoperative clinical results between the two surgical approaches after one-year and assessed which one is better for correction of moderate and high hyperopia.

In this study, we found that no eyes lost any line of CDVA, indicating good safety in both groups. Regarding postoperative uncorrected visual acuity, UNVA and UCVA of the sLIKE group were statistically better than that in the FS-LASIK group. The UNVA reached J1 in 15 eyes (75%) in the sLIKE group and only 5 eyes (22.7%) in the FS-LASIK group. The UDVA was equal or better than the preoperative CDVA in 16 eyes (80%) in the sLIKE group and only 8 eyes (35%) in the FS-LASIK group. Wu *et al*[23] reported that none of the ten hyperopia eyes underwent lenticule intrastromal keratoplasty (LIKE) lost any line of CDVA, six eyes obtained UDVA that equal or better than the preoperative CDVA. The study results of Ganesh *et al*[18] show that UDVA was equal or better than the preoperative CDVA in all the eight eyes after sLIKE. Our results were consistent with the previous studies.

The results from this study show that regression occurred after 6mo in the FS-LASIK group. One year postoperatively, 45%

eyes of the sLIKE group and 13.6% eyes of the FS-LASIK group had SE within ±0.50 D, 80% eyes of the sLIKE group, and 45.5% eyes of FS-LASIK group had SE within ±1.00 D, respectively. The mean amount of postoperative residual hyperopia refraction in the sLIKE group was significantly lower than in the FS-LASIK group. Ganesh *et al*[18] found that all the eight hyperopia eyes after sLIKE achieved ±1.00 D. However, the study was included a relatively small sample size.

Our results revealed that both the visual acuity and refractive errors were better after sLIKE than FS-LASIK. One possible reason is that FS-LASIK for hyperopia was limited by preoperative corneal keratometry, whereas sLIKE is relatively unlimited. The other reason is that a higher incidence of regression happens in patients undergoing FS-LASIK than sLIKE.

Our results revealed that the postoperative regular and asymmetry indexes of the FS-LASIK group were superior to that of the sLIKE group. Decentration greater than 0.5 mm is thought to be clinically significant. In our study, decentration over 0.5 mm occurred in 5 eyes (25%) in the sLIKE group and only 2 eyes (9%) in the FS-LASIK group. However, there was no statistically significant difference in mean decentration between the two groups. We think that the reason for poor regularity and asymmetry after the sLIKE procedure may be related to the lenticule implantation process.

Because sLIKE is an "addition operation" design, the mean postoperative central corneal thickness in the sLIKE group was statistically thicker than in the FS-LASIK group. The mean keratometry was significantly higher in the sLIKE group than that in the FS-LASIK group.

One limitation of this study is that the data were analyzed retrospectively. Another limitation is that the research lack aberration assessment pre and postoperatively. Further research requires a larger sample size and a more extensive visual quality evaluation to confirm the results.

In summary, this study demonstrated that sLIKE has better visual and refractive results than that in FS-LASIK for moderate and high hyperopia correction.

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