· Clinical Research ·

# Effects of different side-cut angles on ocular surface recovery after FS-LASIK

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## Abstract

● **AIM:** To compare the effects of different side-cut angles on postoperative ocular surface recovery after femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK).

● **METHODS:** The prospective and randomized study enrolled 99 patients (198 eyes) with ametropia who underwent FS-LASIK in the Eye Institute at the Affiliated Hospital of Nantong University from September 2021 to December 2022. The patients were categorized into the 45°, 90°, and 135° side-cut angle groups. Preoperatively and at 10d, 1mo, and 6mo after surgery, patients in the three groups had their visual acuity, corneal flap edge scar, corneal region sensation, dry eye-related index changes, and nerve fiber repair at the corneal flap margin compared and analyzed.

● **RESULTS:** In the groups with 45°, 90°, and 135° side-cut angles, 56, 58, and 62 eyes, respectively, finished the 6-month follow-up. The incidence of flap edge healing scar was the lowest in the 90° side-cut angle group (74.1%). At 10d postoperatively, corneal sensation at all sites decreased significantly compared with preoperative corneal sensation in the three groups ($P<0.05$), while patients in the 90° side-cut angle group had the highest sensation among the three groups. After surgery, the Ocular Surface Disease Index (OSDI) scores of the three groups showed a substantial rise 10d later, a reduction 1mo later, and a continued increase beyond preoperative values 6mo later ($P<0.05$). The 90° side-cut angle group had the lowest OSDI score at each follow-up time. At each time point after surgery, the number of eyes repaired by corneal flap nerves in the scarless group was higher than that in the scarred group ($P<0.05$), and the corneal flap nerve growth was relatively fast in the scarless area.

● **CONCLUSION:** Different side-cut angles in FS-LASIK may have different effects on the postoperative ocular surface recovery. The 90° side-cut angle has a low incidence of corneal flap scar, the highest corneal sensation in the early postoperative period, and the lowest subjective dry eye symptom scores at each postoperative follow-up time. Therefore, the selection of a 90° side-cut angle for the FS-LASIK corneal flap may help patients to recover the ocular surface after surgery.

● **KEYWORDS:** femtosecond laser; laser *in situ* keratomileusis; side-cut angle; ocular surface recovery

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## INTRODUCTION

Femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) is a popular corneal refractive surgery used to correct myopia. Studies have shown that FS-LASIK has a high level of safety, effectiveness, and postoperative patient satisfaction[1-4]. Compared with previous LASIK with conventional mechanical microkeratome flap making, femtosecond laser provides more selectivity for corneal flap, and the surgeon can customize the flap thickness, flap diameter, flap shape, and side-cut angle through femtosecond program settings[5-7]. While conventional microkeratome flaps are made with a fixed acute angle of lateral incision, flaps made by the femtosecond laser can be customised with any side cut angle between 45° and 135°, and the cut surface is smoother, resulting in a more precise corneal flap.

Decreased corneal sensation and dry eye disease are common complications of refractive surgery[8-9]. There are fewer studies on the relationship between the angle of flap side cut angle and corneal sensation and postoperative dry eye. The effects of 70° versus 130° side-cut angle on postoperative corneal sensation and dry eye symptoms had been investigated, but the effect of different side-cut angles on the scar of the incision margin was not included[10]. Differences in corneal incision margin healing patterns between 90° side-cut angle and 120° side-cut angle had been investigated, but the influence of various side-cut angles on postoperative corneal sensation, dry eye, and other indicators linked to ocular surface recovery was not investigated in this study, nor was an acute side-cut angle group established[11]. The effect of various side-cut angles on postoperative corneal nerve repair has not yet been clearly established. In general, the choice of side-cut angle in FS-LASIK is mostly based on the manufacturer's recommendations and the surgeon's experience. Therefore, there is no unanimous conclusion as to which side-cut angle results in the least healing response at the corneal flap incision edge, produces the least amount of scarring, results in faster postoperative return of corneal sensation, and its effect on postoperative dry eye and corneal nerve repair.

In our study, three different lateral side cut angles were proposed including acute side-cut angle (45°), right side-cut angle (90°), and obtuse side-cut angle (135°). By observing the preoperative and postoperative changes in corneal sensation, dry eye index, and other related parameters, as well as using *in vivo* corneal confocal microscopy to observe the changes in corneal flap incision scar and nerve fibers before and after surgery, we explored how various side-cut angles affected FS-LASIK ocular surface repair, including postoperative visual acuity, recovery of corneal sensation, postoperative dry eye, and corneal nerve repair, *etc.*, so that we can provide a reference basis for the selection of side-cut angle in surgery.

## PARTICIPANTS AND METHODS

**Ethical Approval** The Institutional Review Committee of the Affiliated Hospital of Nantong University gave its approval for this study (2021-K118-02), which was carried out in accordance with the Declaration of Helsinki. Prior to surgery, written informed consent was given by each patient.

**Participants** Patients with myopia and myopic astigmatism treated with FS-LASIK at the Department of Ophthalmology, Affiliated Hospital of Nantong University, between September 2021 and December 2022, were included in this prospective comparative research.

The inclusion criteria were as follows: patients between the ages of 18 and 40y who met the indications for FS-LASIK with an annual refractive error increase of -0.50 diopter (D) or less for 2 consecutive years. Preoperative best corrected visual acuity (BCVA) ≥4.8, able to co-operate with ophthalmological examination, and completing 6-month postoperative follow-up. The exclusion criteria were as follows: previous ocular surgery or trauma, conical cornea, history of ocular diseases such as uveitis, scleritis, and other ocular inflammatory diseases, systemic connective tissue diseases and autoimmune diseases, keloids patients. Patients were randomly divided into 3 groups including 45° side-cut angle group (45° group), 90° side-cut angle group (90° group), and 135° side-cut angle group (135° group) depending on the setting of cornea flap side-cutting angle during FS-LASIK surgery (Figure 1).

**General Examination** All patients were examined pre- and post-operatively for visual acuity and intraocular pressure. Preoperative BCVA and refraction as well as postoperative uncorrected distance visual acuity (UDVA) was measured. Visual acuity data were converted to the logarithm of the minimal angle of resolution (logMAR) to calculate the mean value.

**Slit-Lamp Examinations** All patients underwent preoperative and postoperative slit lamp examination. Before surgery, patients were checked for keratitis, keratoconus, corneal trauma, scarring or lesions, *etc*. After surgery, patients were examined for corneal transparency and corneal flap side cut healing. Whether or not the patients showed scarring after surgery was determined by the same follow-up physician who photographed and observed them through a slit lamp microscope (Switzerland), and the grade of scarring was recorded. The grading criteria for side-cut scarring were as follows[12]: Grade 0: clear flap margins with no scarring; Grade 1: scarring of the flap margins with slight opacity; Grade 2: marked opacity of the flap margins with scarring (Figure 2).

**Corneal Sensation Examinations** Patients' corneal sensation was measured superiorly, inferiorly, temporally, nasally and centrally using a Cochet-Bonnet corneal perceptometer (France) under a slit lamp microscope. Measurement was started by adjusting the length of the nylon wire to 60 mm and touching the patient's cornea vertically until a slight curvature was detected, then the patient was asked if he/she had any sensation. The measurements were repeated three times, and if there was sensation in at least two of the three measurements, the length of the nylon wire at that moment was recorded as the corneal sensation in that area. If there was no sensation on at least two occasions, the wire was shortened by 5 mm until there was sensation on at least two occasions. This examination was done by the same operator.

**OCULUS Keratograph 5M** Preoperative and postoperative noninvasive tear meniscus height (NITMH) and noninvasive tear film break-up time (NITBUT) measurements, meibomian gland analysis, and ocular redness analysis were performed using the OCULUS Keratograph 5M (Germany). At the same time, each patient completed an Ocular Surface Disease Index (OSDI) Dry Eye Questionnaire. A score out of 100 was assigned, with higher scores indicating more severe dry eye symptoms in the patient.

**Anterior Segment Optical Coherence Tomography** Images of five-layer of the cornea were acquired using anterior

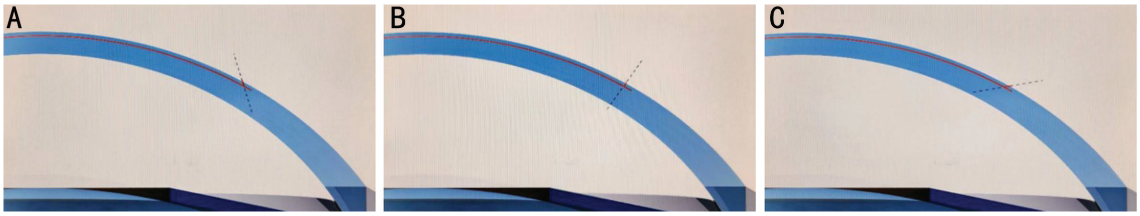


**Figure 1 Pictures of the three side-cut angles (from the VisuMax femtosecond laser device corneal flap parameter setting interface)** A: 45° side-cut angle; B: 90° side-cut angle; C: 135° side-cut angle.

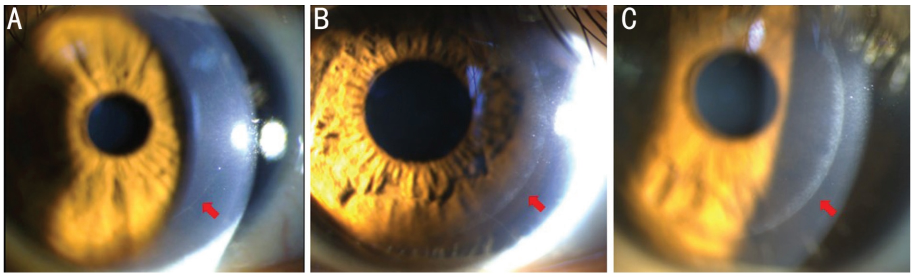


**Figure 2 Grade criteria of the scar** A: The corneal flap margin heals clear with no scarring; B: The corneal flap margin shows scarring and is slightly opaque; C: The corneal flap margin scarring is markedly opaque (red arrows).

segment optical coherence tomography (AS-OCT; Germany) in horizontal scanning mode to observe the healing of the corneal flap edge.

***In vivo* Confocal Microscopy** Images of the central cornea, the subepithelial and anterior stromal layers at the cut edge of the corneal flap on the superior, temporal, inferior and nasal sides were examined and recorded using *in vivo* confocal microscopy (IVCM; Germany) in vertical scanning mode. Emphasis was placed on scarring and nerve fibre repair in the area of the flap margins. Then, the area of the pixels marked highlighted on the image was calculated as the area of the scar using ImageJ software.

**Statistical Analysis** Data was statistically analyzed using SPSS 26.0 (USA) statistical software. Mean±standard deviation was used to represent data that fit the normal distribution, whereas constitutive ratios were used to express count data. Preoperative comparisons of three groups of normally distributed data were performed using one-way analysis of variance (ANOVA). Comparisons of the component ratios were performed using the Chi-square test. The test indications in the three groups were compared before and after surgery using an ANOVA with repeated-measures design data. When the interaction effect was statistically significant, further simple effect analysis was conducted for two-by-two comparisons. The difference was statistically significant if $P<0.05$.

## RESULTS

This study involved 198 eyes from 99 individuals with refractive errors, including 66 eyes in each group. Six months after surgery, 88 individuals (176 eyes) eventually finished the follow-up. Of these, 56 eyes were in the 45° side-cut angle group, 58 eyes in the 90° side-cut angle group, and 62 eyes in the 135° side-cut angle group. All the patients' surgeries were successfully completed without any adverse corneal flap, such as: free flap, incomplete flap, and other complications. In the postoperative follow-up, it was not possible to obtain 3-month data because of the coronavirus disease 2019 (COVID-19) in China. The corneal flap was intact at 10d, 1mo, and 6mo postoperatively by slit lamp examination, and there were no abnormalities such as flap wrinkles. All patients were relatively satisfied with the surgical results, and all completed all postoperative periods of review.

Prior to surgery, there was no significant difference among the three groups in terms of age, IOP, sphere, cylinder, mean keratometry (Km), central corneal thickness (CCT), flap thickness, and cutting depth (Table 1).

In all three groups, UDVA reached preoperative BCVA at 10d postoperatively ($P>0.05$), and there was no statistically significant difference in the UDVA of patients in each side-cut angle group at different time points (Table 2).

During postoperative follow-up, it was found that opaque white clouding at the corneal flap incision margins was observed in some patients, which was manifested as diffuse hyperdense shadows in the subepithelial and anterior stromal layers of the cornea on AS-OCT (Figure 3). The incidence of this white opaque scar did not change significantly throughout the follow-up period.

There was no significant change in the occurrence of scarring throughout the follow-up period. At 6mo postoperatively, the incidence of scarring was shown in Table 3, with the lowest incidence of scarring in the 90° side cut angle group, and the difference between the three groups was not statistically significant ($\chi^2=1.284$, $P=0.526$).

Table 4 showed that there was no statistically significant difference in the grading of the corneal flap margin scar

**Table 1 Comparison of preoperative data of the three groups of patients** mean±SD

| Parameters | 45° group (56 eyes) | 90° group (58 eyes) | 135° group (62 eyes) | $P^a$ |
|---|---|---|---|---|
| Age (y) | 28.04±4.54 | 27.90±4.46 | 27.52±4.16 | 0.799 |
| IOP (mm Hg) | 16.37±2.21 | 15.79±2.29 | 16.72±2.06 | 0.064 |
| Sphere (D) | -6.10±1.89 | -5.54±1.70 | -5.81±1.84 | 0.260 |
| Cylinder (D) | -1.12±0.88 | -1.00±0.76 | -1.04±0.79 | 0.741 |
| Km (D) | 43.22±0.91 | 43.43±1.26 | 44.49±6.81 | 0.202 |
| CCT (μm) | 525.36±26.72 | 529.40±34.29 | 521.60±24.01 | 0.330 |
| Flap thickness (μm) | 87.50±5.56 | 90.00±5.54 | 88.71±6.07 | 0.070 |
| Cutting depth (μm) | 97.82±19.30 | 93.45±20.02 | 92.48±19.50 | 0.299 |

[a]One-way analysis of variance (ANOVA). IOP: Intraocular pressure; CCT: Central corneal thickness; Km: Mean keratometry; SD: Standard deviation.

**Table 2 Preoperative BCVA (logMAR) and postoperative UDVA (logMAR) in the three groups of patients** mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 0.00±0.02 | 0.00±0.03 | -0.01±0.04 | -0.01±0.02 |
| 90° group | 0.00±0.03 | -0.01±0.05 | -0.01±0.05 | -0.02±0.05 |
| 135° group | 0.00±0.04 | -0.01±0.05 | -0.02±0.04 | -0.02±0.03 |
| $P^a$ | 0.524 | 0.473 | 0.085 | 0.308 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation; BCVA: Best corrected visual acuity; UDVA: Uncorrected distance visual acuity; logMAR: Longarithm of the minimal angle of resolution.

**Table 3 Incidence of scarring in three groups at 6mo postoperatively**

| Groups | Number of scarred eyes | Total eyes | Incidence |
|---|---|---|---|
| 45° group | 45 | 56 | 80.4% |
| 90° group | 43 | 58 | 74.1% |
| 135° group | 51 | 62 | 82.3% |

**Table 4 Comparison of the distribution of scar grading in patients who developed scarring in three groups** *n* (%)

| Groups | Total eyes | Number of different graded eyes | | | $P^b$ |
|---|---|---|---|---|---|
| | | Grade 0 | Grade 1 | Grade 2 | |
| 10d postop. | | | | | 0.266 |
| 45° group | 56 | 11 (19.6) | 17 (30.4) | 28 (50.0) | |
| 90° group | 58 | 15 (25.9) | 24 (41.4) | 19 (32.8) | |
| 135° group | 62 | 11 (17.7) | 19 (30.6) | 32 (51.6) | |
| 1mo postop. | | | | | 0.197 |
| 45° group | 56 | 11 (19.6) | 20 (35.7) | 25 (44.6) | |
| 90° group | 58 | 15 (25.9) | 27 (46.6) | 16 (27.6) | |
| 135° group | 62 | 11 (17.7) | 21 (33.9) | 30 (48.4) | |
| 6mo postop. | | | | | 0.094 |
| 45° group | 56 | 11 (19.6) | 30 (53.6) | 15 (26.8) | |
| 90° group | 58 | 15 (25.9) | 37 (63.8) | 6 (10.3) | |
| 135° group | 62 | 11 (17.7) | 32 (51.6) | 19 (30.6) | |

[b]Chi-square test.

between the three side-cut angle groups at 10d, 1mo, and 6mo after surgery.

The differences in the area of the scar between the three side-cut angle groups were statistically significant at 10d, 1mo, and 6mo postoperatively (Table 5). The area of the scar in the 135° side-cut angle group was more than that in the 45° and 90° side-cut angle groups at any of the postoperative

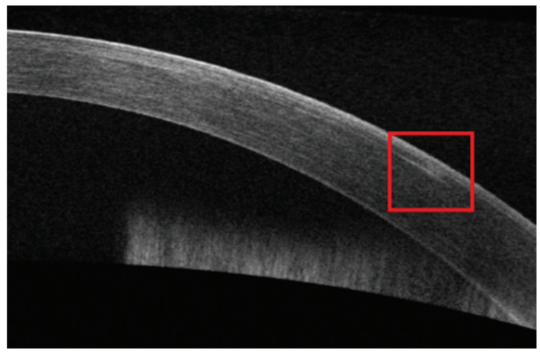

**Figure 3 Postoperative AS-OCT of the anterior segment of the eye** Diffuse white highlighting (red box) at the cut edge of the corneal flap, involving the subepithelial and anterior stromal layers of the cornea; AS-OCT: Anterior segment optical coherence tomography.

**Table 5 Area of scarring in patients (126 eyes) who developed scarring in three side-cut angle groups** $\mu m^2$, mean±SD

| Groups | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|
| 45° group | 21166.31±5352.38 | 19452.77±6131.99 | 17472.24±5235.58 |
| 90° group | 16551.26±6184.91 | 14267.28±6410.42 | 13234.49±5441.64 |
| 135° group | 26504.14±11624.39 | 24514.21±13372.68 | 21211.83±10200.13 |
| $P^a$ | <0.001 | <0.001 | <0.001 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation.

follow-up times ($P<0.05$), and the area of the scar in the 45° side-cut angle group was more than that in the 90° group at any of the follow-up times, and the differences were statistically significant ($P=0.033$; $P=0.035$; $P=0.027$). There was no statistically difference in the area of the scar at the three follow-up time points in each group ($P>0.05$). In three groups, the area of the scar decreased with the progression of time, but the difference in the area of the scar between 1mo postoperatively and 10d postoperatively was not statistically significant ($P=0.449$, $P=0.225$, $P=0.266$). The difference was statistically significant in the area of the scar in 6mo postoperatively compared with that in 1mo postoperatively ($P=0.004$, $P=0.014$, $P<0.001$).

The cornea was observed before and after surgery using IVCM. Preoperatively, the corneal layers were structurally clear and free of scarring. Ten days after surgery, ring-shaped scar tissue was visible at the edge of the corneal flap (Figure 4).

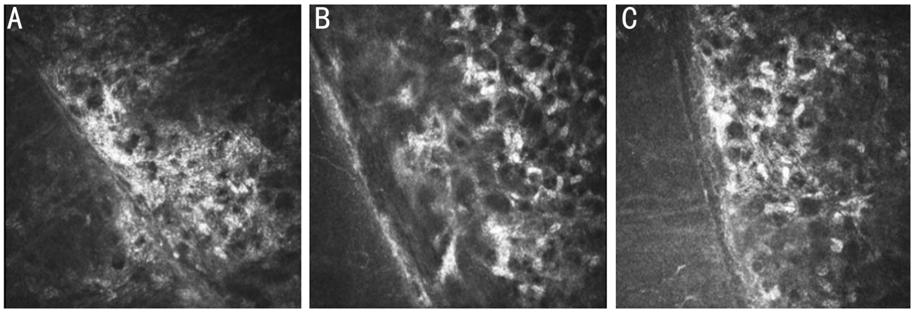


**Figure 4 Corneal flap scarring in three groups at 10d postoperatively** A: 45° side-cut corneal flap edge; B: 90° side-cut corneal flap edge; C: 135° side-cut corneal flap edge showed good apposition, and irregular, highly reflective white scar tissue in the corneal subepithelial and superficial stromal layers was observed.

**Table 6 Comparison of five parts of corneal sensation before and after surgery in three side-cut angle groups** mm, mean±SD

| Parts | Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|---|
| Superior | 45° group | 58.57±2.82 | 48.21±10.64 | 51.43±9.99 | 56.96±4.54 |
| | 90° group | 59.31±1.74 | 55.52±6.33 | 54.31±6.59 | 57.41±5.72 |
| | 135° group | 58.79±2.67 | 52.10±8.47 | 54.27±6.20 | 58.23±3.85 |
| | *P*[a] | 0.256 | <0.001 | 0.075 | 0.343 |
| Temporal | 45° group | 58.93±2.28 | 50.71±8.86 | 53.13±8.72 | 57.59±4.95 |
| | 90° group | 58.88±2.10 | 55.34±5.45 | 54.57±5.72 | 57.24±5.48 |
| | 135° group | 58.87±2.78 | 52.18±7.05 | 53.55±6.30 | 57.27±4.15 |
| | *P*[a] | 0.990 | 0.003 | 0.525 | 0.915 |
| Inferior | 45° group | 59.11±2.15 | 42.14±11.36 | 46.34±11.02 | 54.64±6.60 |
| | 90° group | 57.76±4.51 | 51.81±7.30 | 50.09±8.19 | 54.22±8.62 |
| | 135° group | 58.31±4.70 | 46.94±9.38 | 49.68±8.19 | 54.60±7.54 |
| | *P*[a] | 0.197 | <0.001 | 0.060 | 0.949 |
| Nasal | 45° group | 59.02±2.22 | 45.89±10.05 | 47.86±11.11 | 55.09±5.84 |
| | 90° group | 58.36±3.30 | 52.59±6.96 | 51.21±8.39 | 55.52±8.97 |
| | 135° group | 58.47±4.30 | 48.06±10.06 | 51.29±7.46 | 55.08±6.24 |
| | *P*[a] | 0.547 | 0.001 | 0.072 | 0.931 |
| Central | 45° group | 58.57±2.47 | 25.89±8.69 | 30.27±7.71 | 44.91±6.07 |
| | 90° group | 58.53±2.30 | 31.29±8.35 | 34.57±7.57 | 46.55±4.51 |
| | 135° group | 58.47±3.69 | 27.34±8.08 | 32.66±7.34 | 46.61±6.26 |
| | *P*[a] | 0.981 | 0.002 | 0.011 | 0.193 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation.

Some patients showed high reflections under the cutting interface within the corneal flap, which were under the corneal epithelium and at the superficial stromal layer. The stromal cytoplasmic protrusions there were interconnected, the cells were activated, and irregular patches of white scar-like changes of varying sizes were seen. At 1mo postoperatively, irregular hyperreflective deposits were still present at the scar within the cut edge of the corneal flap. At 6mo postoperatively, the scar tissue was less reflective, suggesting a gradual decrease in activated stromal cells. The healing pattern of the corneal flap margins was similar for the different side-cut angle.

Preoperatively, 1mo and 6mo postoperatively, the difference in superior corneal sensation among the three side-cut angle groups was not statistically significant (Table 6). At 10d postoperatively, the difference in superior corneal sensation among the three groups was statistically significant ($P$<0.001), with the 90° group and the 135° group having higher sensation than the 45°group ($P$<0.001; $P$=0.046), and there was no statistically significant difference in superior sensation between the 90° group and the 135° group ($P$=0.091). Superior corneal sensation declined in the 45° group at 10d and 1mo after surgery ($P$<0.001; $P$<0.001) and regained its preoperative levels at 6mo ($P$=0.084). In the 90° group, superior corneal sensation decreased compared with preoperative levels at 10d, 1mo, and 6mo after surgery, with statistically significant differences ($P$=0.008; $P$<0.001; $P$=0.020). In the 135° group, superior corneal sensation decreased at 10d and 1mo postoperatively compared with preoperatively ($P$<0.001; $P$<0.001) and regained its preoperative levels at 6mo ($P$=0.933).

At 10d postoperatively, the difference in temporal corneal sensation among the three groups was statistically significant (*P*=0.003; Table 6). The temporal corneal sensation was higher in the 90° group than in the 45° group (*P*=0.002), whereas there was no statistically significant difference between the 90° and 135° groups (*P*=0.052) or between the 45° and 135° groups (*P*=0.617). The difference between the three groups at its three times was not statistically significant. In the 90° group, corneal sensation was decreased from preoperative levels at 10d and 1mo postoperatively (*P*=0.002; *P*<0.001), and the difference was not statistically significant at 6mo postoperatively compared with preoperative levels (*P*=0.075). In both 45° and 135° group, temporal corneal sensation was statistically significant at 10d and 1mo after surgery compared with preoperative levels (all *P*<0.001), which returned to preoperative levels at 6mo after surgery (*P*=0.241; *P*=0.071).

The differences in lower corneal sensation among the three groups were not statistically significant preoperatively, at 1mo postoperatively, and at 6mo postoperatively (Table 6). At 10d postoperatively, the difference in corneal sensation among the three groups was statistically significant (*P*<0.001). Sensation was higher in the 90° group than in the 45° group versus the 135° group (*P*<0.001, *P*=0.016), and in the 135° group than in the 45° group (*P*=0.020). In the 45° group, corneal sensation was decreased at 10d, 1mo, and 6mo after surgery compared with preoperatively (*P*<0.001; *P*<0.001; *P*<0.001). In the 90° group, corneal sensation was decreased from preoperative at 10d, 1mo, and 6mo after surgery (*P*<0.001; *P*<0.001; *P*=0.003). In the 135° group, corneal sensation was lower than preoperatively at 10d, 1mo, and 6mo after surgery (*P*<0.001; *P*<0.001; *P*=0.001).

At 10d postoperatively, the difference between the nasal corneal sensations of the three groups was statistically significant (*P*=0.001; Table 6). The 90° group had higher sensations than the 45° group and the 135° group (*P*<0.001, *P*=0.022), and the difference in corneal sensations between the 45° side-cut angle group and the 135° group was not statistically significant (*P*=0.487). The difference between the three side-cut angle groups at the remaining time points was not statistically significant. In the 45° group, corneal sensation decreased at 10d, 1mo, and 6mo after surgery compared with preoperatively (*P*<0.001; *P*<0.001; *P*=0.001). In the 90° group, corneal sensation was decreased from preoperative at 10d, 1mo, and 6mo after surgery (*P*<0.001; *P*<0.001; *P*=0.021). In the 135° group, corneal sensation was lower than preoperatively at 10d, 1mo, and 6mo after surgery (*P*<0.001; *P*<0.001; *P*=0.002).

The difference in central corneal sensation among the three groups of patients with side-cut angles was statistically significant at 10d postoperatively (*P*=0.002; Table 6), and central corneal sensation was higher in the 90° group than in the 45° group versus the 135° group (*P*=0.002 and *P*=0.031, respectively), and there was no statistically significant difference in corneal sensation between the 45° and 135° groups (*P*=0.725). At 1mo postoperatively, central corneal sensation was higher in the 90° group than in the 45° group and the difference was statistically significant (*P*=0.008). At 6mo postoperatively, there was no statistically significant difference in corneal central corneal sensation among the three groups of side-cut angle patients. At 10d postoperatively, central corneal sensation was the lowest in the three groups of patients with side-cut angles, and the difference was statistically significant compared with the preoperative level (*P*<0.001), and it still did not return to the preoperative level at 6mo postoperatively (*P*<0.001).

There was no statistically significant preoperative difference in NITMH among the three groups of patients (*P*=0.067; Table 7). NITMH fluctuated over time in all three groups, with the lowest level of NITMH at 10d postoperatively, followed by a recovery toward preoperative levels. At 10d postoperatively, participants in the 135° group had substantially greater NITMH than those in the 45° and 90° groups (*P*<0.001, *P*<0.001). At 1mo postoperatively, NITMH was significantly higher in patients in the 135° group than in the 45° group (*P*=0.036). At 6mo postoperatively, the difference in NITMH among patients in the three groups was not statistically significant (*P*=0.212). In the 45° and 90°group, NITMH was significantly lower at 10d postoperatively than preoperatively (*P*<0.001, *P*=0.003) and went back to preoperative levels at 1mo postoperatively (*P*=0.061, *P*=0.812). For patients in the 135° side-cut angle group, none of the differences between time points were statistically significant (*P*>0.05).

The first non-invasive tear break-up time ($NITBUT_f$) of the three groups of patients changed in trend over time (*P*<0.001), they were significantly lower at 10d after surgery compared with the preoperative period (all *P*<0.001), and at 1mo postoperatively, the difference in the $NITBUT_f$ of the three groups was not statistically significant compared with the preoperative period (*P*=0.284, *P*=0.542, *P*=0.399). At 10d postoperatively, $NITBUT_f$ was longest in the 135° side-cut angle group and the difference was statistically significant compared to the 90° side-cut angle group (*P*=0.026), while none of the other changes were statistically significant (Table 8).

Changes in average non-invasive tear break-up time ($NITBUT_{av}$) at different follow-up times before and after surgery in the three groups are shown in Table 9. Trend changes in $NITBUT_{av}$ over time (*P*<0.001). $NITBUT_{av}$ in patients in three groups were all significantly lower at 10d after surgery (*P*<0.001) and returned to preoperative levels at 1mo after surgery (*P*=0.089, *P*=0.887, *P*=0.999). At 1mo

**Table 7 Comparison of NITMH at different follow-up times before and after surgery in three side-cut angle groups** mm, mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 0.24±0.07 | 0.20±0.05 | 0.21±0.07 | 0.24±0.06 |
| 90° group | 0.23±0.03 | 0.19±0.06 | 0.24±0.07 | 0.24±0.06 |
| 135° group | 0.25±0.06 | 0.24±0.07 | 0.25±0.08 | 0.28±0.24 |
| $P^a$ | 0.067 | <0.001 | 0.036 | 0.212 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation; NITMH: Noninvasive tear meniscus height.

**Table 8 Comparison of $NITBUT_f$ at different follow-up times before and after surgery in three side-cut angle groups** s, mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 11.87±6.16 | 7.07±3.05 | 9.83±5.53 | 10.62±5.16 |
| 90° group | 10.02±5.82 | 6.55±4.05 | 11.63±6.22 | 10.25±6.39 |
| 135° group | 12.37±5.67 | 8.42±4.30 | 10.62±5.94 | 10.78±5.86 |
| $P^a$ | 0.075 | 0.025 | 0.268 | 0.880 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation; $NITBUT_f$: First non-invasive tear break-up time.

**Table 9 Comparison of $NITBUT_{av}$ at different follow-up times before and after surgery in three side-cut angle groups** s, mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 16.65±3.71 | 11.55±3.95 | 14.84±4.78 | 15.90±4.42 |
| 90° group | 15.75±3.60 | 13.00±4.34 | 15.00±5.27 | 14.46±5.98 |
| 135° group | 15.79±4.22 | 12.52±4.19 | 15.98±4.10 | 14.98±4.61 |
| $P^a$ | 0.373 | 0.171 | 0.360 | 0.304 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation; $NITBUT_{av}$: Average non-invasive tear break-up time.

postoperatively, $NITBUT_{av}$ was longer in patients in the 135° side-cut angle group than in the 45° group and the 90° group, but there was no statistical difference between them (*P*=0.472, *P*=0.590).

Meibomian gland analysis scores at different follow-up times before and after surgery in the three groups are shown in Table 10. The difference in meibomian gland analysis scores between the three groups at each time point before and after surgery was not statistically significant (*P*>0.05), nor was the difference in meibomian gland analysis scores among the different follow-up times in the group of every side-cut angle (*P*>0.05).

Table 11 displays the ocular redness scores for every subject at every stage of the procedure. The difference in ocular redness scores between the three groups was not statistically significant (*P*=0.890), and the difference between the different follow-up times was statistically significant (*P*<0.001). Patients in each group scored higher on ocular redness at 10d after surgery than they did before (*P*=0.010, *P*=0.002, *P*=0.035), while the differences at the remaining time points were not statistically significant (*P*>0.05).

To assess the corneal epithelium's spotting rate, sodium fluorescein staining was applied to all three groups at all follow-up intervals (Table 12), and there was no statistically significant difference between the groups at the different time points.

**Table 10 Comparison of meibomian gland analysis scores (points) at different follow-up times before and after surgery in three side-cut angle groups** mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 1.96±0.69 | 1.96±0.63 | 1.84±0.65 | 1.84±0.68 |
| 90° group | 1.97±0.67 | 2.05±0.69 | 2.02±0.66 | 2.00±0.70 |
| 135° group | 1.98±0.56 | 1.95±0.53 | 1.85±0.60 | 1.95±0.49 |
| $P^a$ | 0.982 | 0.632 | 0.252 | 0.378 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation.

**Table 11 Comparison of ocular redness scores (points) at different follow-up times before and after surgery in three side-cut angle groups** mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 0.62±0.25 | 0.75±0.31 | 0.69±0.26 | 0.66±0.26 |
| 90° group | 0.60±0.29 | 0.75±0.31 | 0.67±0.30 | 0.69±0.34 |
| 135° group | 0.63±0.30 | 0.74±0.28 | 0.66±0.28 | 0.64±0.28 |
| $P^a$ | 0.881 | 0.963 | 0.833 | 0.633 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation.

**Table 12 Corneal spotting rate after surgery at different follow-up times before and after surgery in three side-cut angle groups** *n* (%)

| Groups | Number of eyes at different times | | | |
|---|---|---|---|---|
| | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
| 45° group | 0 | 14 (25.0) | 10 (17.9) | 5 (8.9) |
| 90° group | 0 | 20 (34.5) | 14 (24.1) | 7 (12.1) |
| 135° group | 0 | 19 (30.6) | 12 (19.4) | 8 (12.9) |
| $P^b$ | – | 0.541 | 0.683 | 0.777 |

[b]Chi-square test.

**Table 13 Comparison of OSDI scores (points) at different follow-up times before and after surgery in three side-cut angle groups** mean±SD

| Groups | Preoperative | 10d postop. | 1mo postop. | 6mo postop. |
|---|---|---|---|---|
| 45° group | 3.05±2.78 | 20.46±8.43 | 13.17±7.58 | 9.67±6.56 |
| 90° group | 2.95±2.95 | 15.37±9.69 | 9.84±7.28 | 7.76±6.98 |
| 135° group | 2.35±2.76 | 19.02±5.76 | 10.35±6.28 | 9.14±7.69 |
| $P^a$ | 0.348 | 0.003 | 0.027 | 0.332 |

[a]One-way analysis of variance (ANOVA). SD: Standard deviation; OSDI: Ocular Surface Disease Index.

The difference in OSDI scores among the three groups preoperatively was not statistically significant (*P*=0.348; Table 13). The scores increased significantly in all three groups at 10d postoperatively, decreased at 1mo postoperatively, and remained higher than the preoperative level at 6mo postoperatively (*P*<0.001). At 10d postoperatively, OSDI scores were higher in patients in the 45° group and 135° group than in the 90° group (*P*=0.003 and *P*=0.043, respectively). OSDI scores were higher in patients in the 45° group than in the 135° group, but the difference was not statistically significant (*P*=0.705). At 1mo postoperatively, the OSDI scores of patients in the 90° group were statistically significantly lower than those of patients in the 45° group (*P*=0.037). At

**Table 14 Comparison of the distribution of the number of eyes with corneal flap nerve repair in the scarless group versus the scarred group**

*n* (%)

| Groups | Total eyes | Number of eyes with nerve repair at different time points | | |
|---|---|---|---|---|
| | | 10d postop. | 1mo postop. | 6mo postop. |
| Scarless group | 37 | 10 (27.0) | 17 (45.9) | 30 (81.1) |
| Scarred group | 139 | 13 (9.4) | 21 (15.1) | 34 (24.5) |
| $P^b$ | – | 0.005 | <0.001 | <0.001 |

[b]Chi-square test.

6mo postoperatively, there was no statistically significant difference in OSDI scores between the three groups of patients ($P$>0.05).

All eyes were divided into a scarless group and a scarred group according to the presence or absence of corneal flap margin scarring, and the number of eyes with corneal flap nerve repair in the scarless group was greater than that in the scarred group at all postoperative time points, and the difference was statistically significant (Table 14).

The observation of nerve in the subbasal and anterior stromal layers of the corneal epithelium using IVCM at different times was shown in Figure 5. Normally, the peripheral corneal nerves were distributed centripetally and radially, thick nerve trunks and their branches were visible in the subbasal and anterior stromal layers of the corneal epithelium, showing thread-like, clearly dense and thick white nerve fibres in the picture. The nerve branches at the centre of the cornea were numerous and intricately intertwined, forming an irregular meshwork. We used IVCM to observe the corneal wound margins and found that regardless of the angle of side cut, corneal apposition was better in the scarless group, and subbasal nerve regeneration could be detected. At 10d postoperative, the corneal flap incision was aligned neatly. Sparse nerve fibres, short and discontinuous, were seen outside the flap margin. No nerve fibres were seen within the flap margin. After 1mo, there were nerves crawling inside and outside the corneal flap without scar, nerve fibres were seen outside the corneal flap, and nerve growth was slow in the scar inside the flap margin, with few or no nerve fibres seen. At 6mo postoperative, bright, continuous, well-defined nerve fibres were seen in the scarless area, and the severed nerve fibres inside and outside the corneal flap were reconnected, thickened and lengthened, and grew tightly against the flap rim. However, in the scarred group, nerve regeneration would not be found where there was evident hypercellular fibrotic stromal scarring.

In FS-LASIK, the number of nerve fibres above the corneal flap is greater than at other sites because the corneal flap hinge positioned above is preserved and elongated nerves can be seen. As time progresses and the corneal flap margin continued to heal, the area showed progressively enhanced hyper-reflectivity.

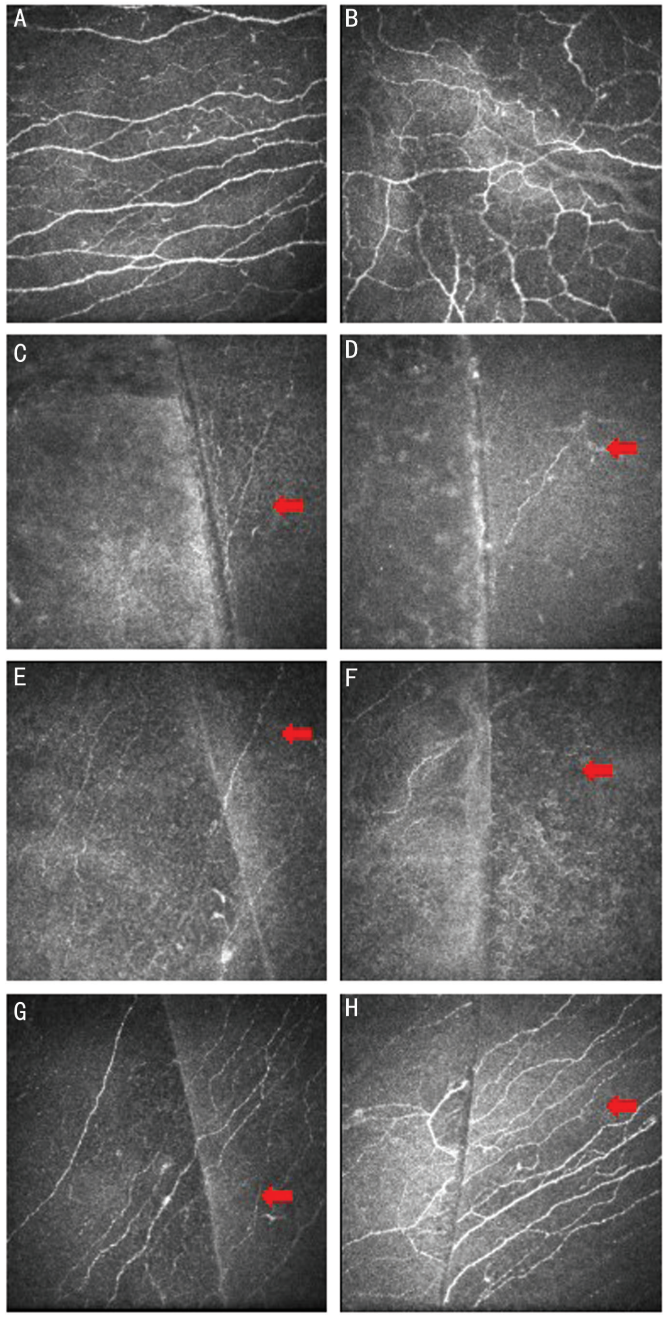


**Figure 5 Repair of corneal nerves at the cut edge of the corneal flap at different times** A–B: Preoperatively, thick white nerve trunks and their branches were seen in the subbasal and anterior stromal layers of the corneal epithelium in the peripheral and central portions, respectively; C–D: 10d postoperatively, sparse nerve fibres were seen outside the corneal flap margin, and no nerve fibres were seen inside the flap; E–F: 1mo postoperatively, nerve fibres crawled inside and outside the flap in small numbers; G–H: 6mo postoperatively, nerve fibres inside and outside the flap were reconnected, and they were thicker and longer than they had been at 1mo. Red arrows represented outside the corneal flap.

## DISCUSSION

In contrast to LASIK with conventional microkeratome flaps, FS-LASIK allows the parameters of the flap to be individually set. The side-cut angle of corneal flaps can be set to any integer number of degrees between 45° and 135°. In this study, three side-cut angle groups were established: acute side-cut angle (45°) group, right side-cut angle (90°) group and obtuse side-cut angle (135°) group, to observe how the three distinct side-cut angles affected the corneal recovery after surgery, including postoperative visual acuity, scarring of the flap incision margins, corneal sensation, dry-eye related parameters and corneal nerves at the flap incision margins.

In our study, we found that the postoperative UDVA of patients in all three side-cut angle groups could reach the preoperative BCVA, with no statistical difference between the groups, which is consistent with the results of previous studies[11,13]. It indicates that different side-cut angles do not affect postoperative visual recovery.

Femtosecond laser induces significant keratocyte activation, and subepithelial clouding of the cornea is observed under slit lamp microscopy[14]. By using IVCM, stromal cell loss and reflective material of varying brightness accompanied by stromal scarring were demonstrated at the cutting surface of the corneal cutting edge[15]. As the femtosecond and excimer lasers caused damage to the corneal stromal cells, they caused the release of cytokines and chemokines, which induced the activation of the corneal stromal cells and presented the activated state of the corneal stromal cells, which facilitated the healing reaction of the flap[16-17]. Studies have shown that compared with microkeratome flap making, the femtosecond laser produces tiny vacuoles that can ablate and separate corneal tissues during the flap making process, and a certain gap will be left between the flap edge and the cornea after flap reset, which induces keratocyte transformation and stromal inflammation, and the interactions between epithelial cells and keratocytes as well as stromal infiltration of inflammatory mediators of the tears are also involved in the corneal incision healing process, which produces a strong fibrotic scarring reaction[18], which may also contribute to the more pronounced scarring at the corneal flap edge with FS-LASIK than with microkeratome. Whereas, different side-cut angles may affect flap adhesion and possible epithelial ingrowth as they induce different healing processes at the corneal flap edge. Growth factors and cytokines that promote the wound healing process may increase the adhesion strength of the corneal flap by creating a more inflammatory response, and the corneal flap heals more firmly, with visible scarring at the edge of the flap observed by slit lamp microscopy[19].

In this study, there was no significant difference in the grade of the scar between 45°, 90°, and 135° side-cut angle group, which indicated that different side-cut angles had no effect on the healing pattern of the corneal flap margins, which agreed with the conclusions of Wei *et al*[11]. Knorz and Vossmerbaeumer[19] who discovered that the 140° side-cut angle had significantly stronger flap adhesion than the 70° side-cut angle, and that side-cut angle would affect the cohesive tensile strength of the corneal flap. Li *et al*[20] showed that a 130° side-cut angle resulted in a more biomechanically stable cornea and more flap incision margin scar compared to a 90° side-cut angle. In our study, the area of scar was quantified, and the results showed that the area of scarring was higher in patients in the 135° group than in the 45° and 90° side-cut angle groups at either postoperative follow-up time, suggesting that patients in the 135° side-cut angle group had more pronounced scar of the corneal flap side-cut margins and a heavier healing response postoperatively. The area of scarring in the 90° side-cut angle group was lower than that in the 45° side-cut angle group, and the difference was statistically significant. The reason for this may be at a 135° side-cut angle, the laser propagates upward and inward from the stromal incision to the corneal surface, the postoperative adhesion between the flap and the cornea is stronger, and the flap has a large area of contact with the cornea after repositioning, resulting in more healing reactions. The healing reaction of the flap incision margins at a side-cut angle of 45° is similar to that at a side-cut angle of 135°, in that the laser will propagate upward and outward to the corneal surface. With a 90° side-cut angle, the femtosecond laser acts perpendicularly to the corneal surface, thus reducing the amount of scarring that occurs. Previous studies have shown that the healing response of the corneal flap incision margin can still be observed at 3mo postoperatively[11]. In this study, at 10d postoperatively, there was an irregularly shaped and variably highly reflective healing response at the anterior corneal stromal scar, which persisted at 6mo postoperatively. It has been shown that postoperative bandage contact lens application reduces the wound healing response at the edge of the corneal flap[18].

Our study showed that at 10d postoperatively, the 90° side-cut angle group had better sensation in all five orientations of the cornea than the 45° and the 135° group. This may be due to the fact that the 90° side-cut angle had the lowest incidence and area of scar in this study, and the postoperative healing response at the flap margin was less severe, which favoured the postoperative flap nerve growth. Kung *et al*[10] found that corneal sensation recovered faster in the 130° side-cut angle when compared to the 70° side-cut angle. However, the study did not use the same laser machine, so it is unclear whether there is a clear biomechanical difference between different laser platforms, thus affecting nerve healing. In our study, the same laser platform was used in all three side-cut angle groups during the surgery. In terms of long-term perceptual recovery, there was no difference in corneal sensation recovery among the three groups in this study. This is similar to the results of previous studies[20].

Dry eye parameters such as NITMH, $NITBUT_f$, and $NITBUT_{av}$ decreased in all three groups in the early postoperative period. This is consistent with the results of previous studies[21]. The reason for this may be related to postoperative corneal nerve damage. The cornea is rich in a network of nerve fibres, where nerves innervate tear secretion[22-23]. Femtosecond and excimer lasers disrupt the corneal-nerve-lacrimal reflex arc when making corneal flaps and ablating the corneal stroma, and corneal sensation decreases, leading to a decrease in the secretion of lacrimal components, such as tear proteins, electrolytes and water[17,24-25]. In the OSDI scores of the patients, it was found that the three groups with different side-cut angles had a significant increase at 10d postoperatively and remained higher than the preoperative level at 6mo postoperatively. The OSDI scores responded to the subjective dry eye symptoms of the patients. However, the symptoms of dry eye can be present for a long term and not parallel to the relevant dry eye parameter indicators such as the NITMH and the NITBUT. Kung *et al*[10] found that there was no significant difference in subjective scores of dry eye at 70° side-cut angle compared to 130° side-cut angle. Zhao *et al*[21] in their study found that significant dry eye symptoms can be seen in the early postoperative period after FS-LASK. At 6mo postoperatively, OSDI scores were still higher than preoperative levels, suggesting that dry eye symptoms can persist and take longer to recover in the postoperative period[26-27]. The results of the above studies are consistent with the present study.

The meibomian gland analysis scores of the three patient groups before and after surgery did not differ significantly, suggesting that the different side-cut angles of FS-LASIK do not affect the meibomian gland. The increase in the redness index in patients on in the 10d after surgery may be related to the irritation of the conjunctiva caused by the surgery. For another reason, the redness index is often used to reflect the inflammation of the ocular surface, and it is also a clinical sign for the dry eye diagnosis. After surgery, the patient's ability to produce tears declines, and aqueous-deficient dry eye, characterized by conjunctival congestion in both eyes and an increased redness index, decreased tear film stability, and reduced tear secretion, is frequently developed[28]. Conjunctival inflammation due to dry eye is a non-infectious inflammation related to immunity, and prolonged failure to heal exacerbates changes in tear film osmolality, damages the conjunctival epithelium, and aggravates dry eye, all of which interact with each other in a vicious circle, resulting in conjunctival vascular congestion and bright red colour[29]. The ocular redness index returns to preoperative levels by 1mo postoperatively.

In observations of nerve repair of corneal flap incision margins, it was found that the degree of nerve and scarring in the cornea correlated with the area. Grade 0 scarring had good alignment of the corneal flap incision margins and rapid nerve regeneration, while Grade 2 scarring had a distinctly highlighted fibrotic stromal scar within the corneal flap. If there is an epithelial plug between the corneal flap rim and the cornea, nerve regeneration is difficult at that site. Scar at the cutting edge of the corneal flap affects nerve regeneration from the flap. However, the healing patterns of different lateral cut corneal flap edges were similar, with fast nerve growth in the corneal flap without scar and slow or no nerve regeneration if scar was present within the flap margin. This is consistent with previous findings[11]. In our study, we found that longer nerve fibres were seen at the cutting plane in an increasing number of operated eyes with longer follow-up time, which was evident at 6mo postoperatively, indicating gradual corneal nerve regeneration over time. This is consistent with previous findings[30-31]. The peripheral corneal nerves were damaged by the femtosecond laser to create the flap, and the central nerves were damaged by the use of the excimer laser, and the recovery of the corneal nerves took a longer period of time postoperatively.

A limitation of this study is that this research was conducted during the COVID-19 pandemic, during which enrollment and follow-up were unavoidably affected. As a result, the final sample size was limited, and some participants who did not complete all follow-up visits were excluded from the analysis.

In conclusion, different side-cut angles in FS-LASIK may have different effects on the postoperative ocular surface recovery. The area of scar was greatest at the 135° side-cut angle. In the early postoperative period, corneal sensation was highest in the 90° side-cut angle group. Postoperative subjective dry eye symptoms were worse than preoperative in patients of all three side-cut groups, but patients in the 90° side-cut angle group had the lowest subjective dry eye symptom scores at each postoperative follow-up time. Therefore, choosing a 90° side-cut angle for FS-LASIK flaps may help patients with postoperative ocular surface recovery.

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**Data Availability Statement:** Due to privacy concerns, the data are not publicly accessible. However, they can be obtained from the corresponding author upon reasonable request.

**Conflicts of Interest: Wang ZC,** None; **Luo YX,** None; **Gao NN,** None; **Cheng XL,** None; **Yu Y,** None; **Ji HX,** None.

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