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Original Research Article

Effect of different laser energy settings on the formation of opaque bubble layer and visual performance in SMILE surgery: a single-center clinical study

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Abstract

Purpose: *To investigate the effect of different laser energy settings, including varying combinations of energy and spot distance setting, on the formation of opaque bubble layers in the first stage of preoperative and postoperative visual quality in patients with myopia and astigmatism.*
Methods: *A total of 72 patients were enrolled in this study. They all had myopia and/or astigmatism and had undergone small incision lenticule extraction (SMILE) in both eyes between April 2021 and February 2022 at Huizhou Municipal Central Hospital, Huizhou, China. They were randomly assigned to four groups of 18 patients each. The energy parameters were set in the four groups, with a pulse energy of 120 or 130 nJ and spot distance of 3.0 μm or 4.5 μm. The indices assessed included formation of opaque bubble layer in the first stage after surgery, uncorrected distance visual acuity (UCVA), higher-order aberrations (HOAs), and visual sensitivity under different light levels at 3 months postoperatively.*
Results: *Total HOAs at 3 months were smaller, and contrast sensitivity at various luminance levels under specific spatial frequencies was better when the laser energy was set to 120 nJ and the spot distance was set to 4.5 μm when compared with the laser energy set at 130 nJ and spot distance set at 3.0 μm, respectively ($p < 0.05$).*
Conclusion: *Lower energy and larger spot spacing laser settings produce better visual outcomes for patients, and also affect the formation of a first-stage opaque bubble layer, which is a useful laser for clinical ophthalmologists during SMILE surgery. The energy setting provides a reliable basis to achieve better visual outcomes for patients after surgery.*

Keywords: *Comparative study, Contrast sensitivity, Different energy parameters of a femtosecond laser, Higher-order aberrations small-incision lenticule extraction, Visual outcomes*

INTRODUCTION

Corneal refractive surgery has been applied in clinical practice for more than 30 years, with continuous advances in surgical techniques, improved postoperative outcomes, and higher market acceptance [1]. Instead of creating the corneal laser-assisted *in situ* keratomileusis (LASIK) flap, femtosecond laser small incision lenticule extraction (SMILE) utilized a femtosecond laser to scan the corneal stroma at a specific depth within the corneal stroma, cut the lens and create a corneal cap, followed by aspiration for lens removal [2]. Previous studies have confirmed the safety and efficacy of this surgical approach in the correction of myopia, near-sightedness, and astigmatism [3]. The smaller incision in SMILE reduces the duration of wound healing when compared to the traditional "flap" procedure [4]. The biomechanical strength of the cornea after SMILE is reported to be greater than that in femtosecond LASIK. Moreover, SMILE causes less damage to corneal nerve fibers, and the risk of dry eye after the procedure is significantly lower than that in femtosecond lenticule extraction [5].

Compared to other refractive procedures such as LASIK and photorefractive keratectomy (PRK), SMILE surgery is more complex. Many factors have an impact on postoperative visual outcomes after SMILE such as age, refractive level, and corneal curvature [6]. Femtosecond laser operation is the most vital factor affecting postoperative outcomes, such as the repetition frequency, spot distance, and energy level settings of the laser system [7]. The femtosecond laser in SMILE surgery is a near-infrared laser which precisely and effectively localizes the corneal stroma with varying depths, improving the safety and stability of SMILE surgery and minimizing postoperative inflammatory responses [8]. In October 2018, FDA approved new indications for SMILE surgery (up to 10D for myopia and 3D for astigmatism) and new parameters for laser settings. A smaller incision of 60 degrees is used, and more importantly, the spot distance may be increased from 3.0 to 4.5 um. The low energy level can significantly reduce damage to the cornea and it has been shown to shorten visual recovery time. The opaque bubble layer (OBL) is due to the accumulation of water and carbon dioxide in the corneal tissue that is associated with the tissue-destructive effect of lasers during surgery [9].

In recent years, the influencing factors of FS-LASIK surgery on the formation of the opaque bubble layer have been investigated. The results show that factors such as thicker cornea, higher corneal astigmatism, and greater corneal curvature are all risk factors for formation of postoperative OBL [10]. For the emerging technology SMILE, there have been no objective and quantitative studies on the evaluation of the factors related to OBL formation and its impact on postoperative visual acuity.

This study was designed to investigate the effect of different laser energy settings, including combinations of energy levels and spot distance, on the formation of first-stage OBL and the visual quality of patients. Uncorrected distance vision, higher-order aberrations, and visual acuity under different lighting conditions.

METHODS

Patients and ethical matters

All patients and procedures were performed in accordance with the principles of the Declaration of Helsinki [13], and were approved by the ethics committee of Huizhou Municipal Central Hospital (approval no. XJTU2021-108). All patients read and signed informed consent forms before undergoing the SMILE procedure. This prospective randomized clinical trial included patients with myopia or myopic astigmatism in both eyes who underwent SMILE correction between April 2021 and February 2022 at Huizhou Municipal Central Hospital, Huizhou, China.

Patients who met the following criteria were included in the study: 1. 18 – 36 years of age with myopia (spherical refraction -3.00 D to -7.50 D), with or without astigmatism (columnar refraction <-3.00 d); 2. patients with stable refractive error for at least 2 years; 3. patients with corneal thickness ranging from 500 microns to 600 microns; 4. patients with best corrected distance visual acuity (BCVA) of 20/20 or higher.

Patients who met the following criteria were excluded from this study: 1. patients with abnormal corneal topography; 2. patients with ocular diseases such as keratoconus, glaucoma and cataract; 3. patients with systemic diseases such as dry syndrome, diabetes mellitus and thyroid disease; 4. patients who underwent previous retinal surgery; 5. patients with ocular surface disease.

A total of 72 patients with 144 eyes were enrolled in this study. All patients stopped using soft contact lenses 2 weeks prior to surgery, hard contact lenses 4 weeks prior to surgery, and keratoplasty lenses 3 months prior to surgery.

Randomization

A total of 72 patients were randomly assigned to four groups using the random number table, with 18 patients (36 eyes) in each group. Different energy parameters were set in the four groups, with a pulse energy of 120 or 130 nJ and spot distance of 3.0 μm or 4.5 μm. Group A: 120 nJ, 4.5 μm; Group B: 130 nJ, 4.5 μm; Group C: 120 nJ, 3.0 μm; Group D: 130 nJ, 3.0 μm.

Examinations

All patients underwent a series of ophthalmologic examinations, including strabismus examination (SL-D701; Topcon), corneal topography (Pentacam HR; Oculus Optikgeräte GmbH), uncorrected distance visual acuity (UCVA) and BCVA (Comprehensive Optometry System, TOPCON CV-5000, Topcon, Japan), objective and subjective refraction (Topcon DK-800), contrast sensitivity at different spatial frequencies under different lighting levels (DOBOSO, Topeye, China), and higher-order aberrations (HOAs) (VISX Wave Scan-HD, Vishay, the USA). The examinations were performed preoperatively and 3 months postoperatively. All tests are performed according to standard procedures by experienced optometrists who are specially trained.

Surgical procedures

All procedures were performed by the same senior surgeon using the VisualMax laser (SMILE software version 3.0; Carl Zeiss Meditec AG) at a repetition rate in excess of 500 kHz. The parameters of the femtosecond laser were: The spot distance was 4.5 or 3.0 μm between the corneal lens and the corneal cap. A 110-μm thickness of corneal cap was set since it improves the quality of vision after SMILE surgery. The diameter of the corneal lens ranged from 6.3 to 7.2 mm, depending on the pupil size measured in the darkroom.

In order to remove the corneal lens, a 3 mm lateral incision was made. During the procedure, the corneal lens was completely separated using lens forceps and then removed through the 2.0 mm incision. Gatifloxacin eye drops (Otsuka Pharmaceutical Co., Ltd, China) were administered 4 times daily for 2 weeks, and 0.1 % fluorolmetholone eye drops (Santen Pharmaceutical Co., Ltd.) were administered 4 times daily for 4 weeks. Hypromellose 2910, Dextran 70 and Glycerol eye drops (Alcon Research LLC) were administered four times a day for 1 month.

Statistical analysis

All data were analyzed using Statistical Package for the Social Sciences (SPSS) (version 21.0, IBM Corp, Armonk, NY, USA). Visual acuity value is expressed in logMAR units. A normal distribution test was conducted. One-way ANOVA was applied in comparing the intergroup difference, and further paired t-test was used. Continuous variables are expressed as mean ± standard deviation (SD), and discrete variables are expressed as frequency and ratio. $P < 0.05$ were considered statistically different.

RESULTS

Patients' baseline data

A total of 72 patients (144 eyes) were included in this prospective study and randomly assigned to four groups with different energy levels. There were no statistically significant differences in gender and age among the four groups. Patients were examined preoperatively to ensure that the best corrected visual acuity was 20/20, and that the spherical and cylindrical lenses met the inclusion criteria. The ocular surface of patient could tolerance SMILE surgery. There were no statistical differences in UCVA, spherical and cylindrical lenses, and spherical equivalent among the four groups ($P > 0.05$) (Table 1).

Formation of Stage I OBL

In SMILE surgery, OBL may occur in two planes. The first-stage OBL refers to the posterior surface of the lens, while the second-stage OBL is the anterior surface. All spectacles in this study were manually examined for the formation of primary OBL by two different ophthalmologists. There were no significant differences in the proportion of OBL formation among the four groups (4.3, 5.1, 4.6, and 4.9 %).

Preoperative HOAs in patients

Preoperatively, HOAs over a 6-mm pupil diameter of four groups were compared. The HOAs comprised total higher-order aberration (tHOA), Trefoil Z (33), horizontal coma Z (31), and spherical aberration Z (40) (Table 2).

Table 1: Patients demographic and refractive data (mean ± SD, N = 36)

Parameter	Group A	Group B	Group C	Group D	P-value
BCVA	-0.07±0.08	-0.08±0.03	-0.07±0.04	-0.08±0.01	0.762
Sphere (D)	-5.50±1.20	-5.50±0.50	-5.00±1.98	-5.25±0.85	0.693
Cylinder (D)	-1.07±0.59	-1.02±0.73	-0.97±0.24	-1.00±0.98	0.439
SE (D)	-6.03±2.25	-5.95±2.09	-5.93±1.25	-6.12±1.79	0.536

SE = equivalent spherical mirror luminosity = BCVA, best corrected visual acuity = D, diopter

There are no statistical differences in HOAs among the four groups (P > 0.05) (Figure 1).

In addition, higher order aberrations were measured to ensure that they were at the same level, including Astigmatism 4th order 0° (Z42), Foil 4th order 0° (Z44), Coma 5th order 0° (Z51), Trefoil 5th order 0° (Z53), Spherical aberration 6th order 0°(Z60), and Astigmatism 6th order 0° (Z62); as shown in Table 3.

Postoperative visual acuity

After surgery, all four groups of patients regained normal visual acuity without abnormalities such as corneal bulging or corneal stromal edema, or serious complications such as ocular surface and intraocular infection. At 3 months postoperatively, visual acuity examination and optometry were performed in all four groups, and UCVA (LogMAR) reached at least 0, and visual acuity improved, showing no statistical difference among four groups (p > 0.05). There were improvements in both spherical and cylindrical lens prescriptions (Table 5).

Contrast sensitivity

Contrast sensitivity was measured under different light levels (dark and light environment). Under bright light, all four groups of patients showed the best contrast sensitivity at 6 c/d spatial frequency. In dark light, the contrast sensitivity showed the best performance at 10.5 c/d.

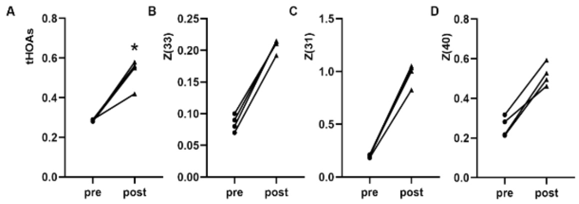

Figure 1: Comparisons of preoperative and postoperative total higher order aberrations (tHOAs) (A), Trefoil (Z33) (B), horizontal coma (Z31) (C), and spherical aberration (Z40) (D). *P < 0.05

Table 2: Preoperative measured results of total higher order aberrations (tHOAs), Trefoil (Z33), horizontal coma (Z31), and spherical aberration (Z40); (mean ± SD, N = 36)

Parameter	Group A	Group B	Group C	Group D	P-value
tHOAs	0.29±0.20	0.28±0.22	0.29±0.16	0.28±0.67	0.683
Z(33)	0.07±0.159	0.10±0.352	0.08±0.732	0.09±0.109	0.372
Z(31)	0.182±0.019	0.209±0.624	0.196±0.272	0.212±0.235	0.428
Z(40)	0.213±0.318	0.317±0.426	0.282±0.912	0.217±0.572	0.402

Table 3: Preoperative measurements of Astigmatism 4th order 0° (Z42), Foil 4th order 0° (Z44), Coma 5th order 0° (Z51), Trefoil 5th order 0° (Z53), Spherical aberration 6th order 0° (Z60), Astigmatism 6th order 0° (Z62); (mean ± SD, N = 36)

Parameter	Group A	Group B	Group C	Group D	P-value
Z(42)	0.071±1.542	0.080±1.835	0.072±1.264	0.081±1.174	0.625
Z(44)	0.224±0.174	0.297±0.213	0.227±0.732	0.252±0.835	0.407
Z(51)	0.032±0.189	0.029±0.166	0.025±0.274	0.028±0.214	0.352
Z(53)	0.027±0.218	0.019±0.463	0.025±0.135	0.024±0.221	0.433
Z(60)	0.013±0.263	0.009±0.183	0.012±0.093	0.027±0.282	0.342
Z(62)	0.032±0.172	0.030±0.216	0.033±0.103	0.035±0.168	0.572

Table 4: Preoperative measurements of the contrast sensitivity under dark and light environment (mean ± SD, N = 36)

Condition	Dose (c/d)	Group A	Group B	Group C	Group D	P-value
Dark environment	0.5 c/d	79.23±8.23	78.62±9.15	77.64±10.13	78.63±12.32	0.672
	10.5 c/d	121.67±13.28	119.68±12.23	123.69±11.26	120.68±10.31	0.762
	20.5 c/d	60.52±10.37	61.53±9.24	57.60±8.21	60.56±11.17	0.452
	30.5 c/d	40.87±9.29	39.89±8.24	41.90±11.41	42.88±9.36	0.671
	40 c/d	20.24±4.13	22.33±3.36	20.29±5.31	21.26±5.28	0.711
Light environment	1.5 c/d	101.64±18.17	100.63±21.20	93.64±17.09	98.64±16.12	0.772
	3 c/d	163.78±21.36	156.75±15.24	165.79±22.70	154.76±20.15	0.683
	6 c/d	165.83±19.13	167.33±15.93	165.83±16.75	162.83±18.16	0.816
	12 c/d	121.52±18.23	114.50±12.18	117.51±16.19	124.52±22.31	0.632
	18 c/d	23.23±16.15	21.20±20.36	25.24±15.29	28.22±18.91	0.712

There was no statistically significant difference in contrast sensitivity among four groups ($p > 0.05$; Table 4).

Postoperative high order aberration

At 3 months post-operation, the tHOA in Group A was lower than that in group D (Table 6). There were no statistical differences in Z (33), Z (31) and Z (40) among the four groups ($p > 0.05$). There were no statistical differences in Astigmatism 4th order 0° (Z42), Foil 4th order 0° (Z44), Coma 5th order 0° (Z51), Trefoil 5th order 0° (Z53), Spherical aberration 6th order 0° (Z60), and Astigmatism 6th order 0° (Z62) among the four groups ($p > 0.05$) (Table 7).

Postoperative contrast sensitivity

The postoperative contrast sensitivity in the light environment was improved in all four groups, and it was higher in group A than in group D at 6 c/d spatial frequency under bright luminance and higher in Group A than that of Group D at 10.5 c/d spatial frequency under dark luminance (Table 8). Therefore, the contrast sensitivity of patients was generally improved, and the improvement was pronounced in low energy level group at the optimal spatial frequency.

Table 5: Postoperative refractive data of; (mean ± SD, N = 36)

Parameter	Group A	Group B	Group C	Group D	*P*-value
UCVA	-0.15±0.03	-0.15±0.05	-0.14±0.04	-0.14±0.08	0.692
Sphere (D)	0.50±0.23	0.53±0.14	0.47±0.28	0.51±0.42	0.463
Cylinder (D)	-0.41±0.27	-0.42±0.43	-0.50±0.33	-0.48±0.28	0.378
SE (D)	-0.32±0.25	-0.34±0.32	-0.25±0.26	-0.28±0.29	0.516

SE = equivalent spherical mirror luminosity; UCVA = uncorrected visual acuity; D = diopter

Table 6: Postoperative measurements of total higher order aberrations (tHOAs), Trefoil (Z33), horizontal coma (Z31), and spherical aberration (Z40); (mean ± SD, N = 36)

Parameter	Group A	Group B	Group C	Group D	P-value
tHOAs	0.42±0.72	0.55±0.42	0.56±0.36	0.58±0.34	0.032*
Z(33)	0.192±0.173	0.210±0.625	0.215±0.628	0.214±0.452	0.179
Z(31)	0.825±0.624	1.003±0.615	1.036±0.342	1.052±0.624	0.212
Z(40)	0.495±0.356	0.593±0.471	0.462±0.528	0.528±0.342	0.342

* Compared between Groups A and D, $p < 0.05$

Table 7: Postoperative measurements of Astigmatism 4th order 0° (Z42), Foil 4th order 0° (Z44), Coma 5th order 0°(Z51), Trefoil 5th order 0°(Z53), Spherical aberration 6th order 0°(Z60), Astigmatism 6th order 0°(Z62). n = 36.

Parameter	Group A	Group B	Group C	Group D	*P*-value
Z(42)	0.218±0.252	0.143±0.463	0.183±0.362	0.198±0.352	0.266
Z(44)	0.344±0.741	0.356±0.882	0.231±0.702	0.308±0.663	0.323
Z(51)	0.031±0.362	0.021±0.242	0.026±0.239	0.028±0.534	0.634
Z(53)	0.069±0.813	0.089±0.441	0.074±0.625	0.067±0.264	0.421
Z(60)	0.023±0.211	0.019±0.632	0.023±0.523	0.018±0.523	0.153
Z(62)	0.029±0.305	0.038±0.342	0.035±0.273	0.028±0.241	0.241

Table 8: Postoperative measurements of the contrast sensitivity under dark and light environment; (mean ± SD, N = 36)

Condition	Dose (c/d)	Group A	Group B	Group C	Group D	*P*-value
Dark environment	0.5	81.73±10.31	83.70±7.15	79.71±8.48	80.70±9.34	0.473
	10.5	133.81±14.23	128.71±11.53	130.72±8.24	122.70±8.39	0.006*
	20.5	59.68±9.41	61.67±10.42	56.68±8.45	55.67±9.54	0.463
	30.5	44.94±6.31	40.94±5.43	42.94±8.35	39.93±7.45	0.527
	40	18.49±3.24	16.51±4.64	17.49±3.53	16.48±4.16	0.621
Light environment	1.5	119.78±16.34	122.75±21.25	117.76±14.28	120.73±17.39	0.427
	3	182.83±20.53	180.81±18.56	176.80±19.52	178.79±22.62	0.262
	6	176.86±16.68	172.76±18.43	173.77±23.73	163.75±19.32	0.032*
	12	131.62±26.55	133.61±19.47	128.62±25.36	132.60±22.62	0.836
	18	32.34±10.17	27.32±15.24	31.33±13.21	26.34±15.33	0.742

*Compared between Groups A and D, $P < 0.05$

DISCUSSION

In SMILE surgery, femtosecond laser pulse energy results in corneal tissue separation, which is a desirable outcome as a high-precision scalpel, as well as gas production, which is clearly an effect that adversely affects the surgery. The generated gas causes small local tissue deformations which can lead to laser pulses acting on non-conceived areas, ultimately affecting the outcome of the procedure. Secondly, higher energy lasers or closer spots produce overlapping layers of gas bubbles that reduce the subsequent laser energy [12]. It was found that different energy levels cause different gas bubbles [13]. High energy lasers or small spot distance produce significant irregular bubbles, while lower energy levels and large spot distance greatly reduce gas bubbles. The subsequent laser pulses became less efficient, making separation of corneal tissue more difficult. A low-energy level laser with fewer gas bubbles make subsequent laser cuts smoother, despite the larger spot distance and discontinuous corneal tissue separation [14]. The gas bubbles may also be related to corneal and lens thickness, astigmatism level, and the density and size of the cornea [15]. Thus, laser energy levels and spot distance are not the only determinants. Nevertheless, it must be taken into account when setting up the surgical laser that lower laser energy and larger spot distance make corneal tissue separation more difficult, and may lead to tissue tearing and irregularities at the interface. Therefore, it is the pursuit and dream of every ophthalmologist to explore the appropriate femtosecond laser settings to achieve optimal separation while achieving less surface irregularities, faster visual recovery and lower higher-order aberrations.

The FDA has set strict energy setting guidelines for SMILE in the treatment of spherical myopia, and surgeons participating in the trial are restricted to using a spot distance of 3.0 mm and a minimum laser energy of 125 nJ. Nevertheless, there are a number of clinical studies that have further analyzed the effect of laser energy on postoperative uncorrected visual acuity. One study set the spot distance at 4.5 mm and compared the postoperative visual acuity at different time points under high energy of 180 nJ and low energy of 100 nJ [16]. As expected, the low-energy group had better uncorrected visual acuity at multiple time points from the first postoperative day until three months postoperatively and a higher percentage of patients achieved 20/20 visual acuity. Another study also set the spot distance at 4.5 mm and set the laser energy levels between 125 and 160 nJ, and it showed a significant correlation between the lower energy level and better UCVA at 3 months postoperatively. In addition, one study reported better postoperative visual acuity in the low laser energy group (100 - 110 nJ) than in the conventional energy (115 - 150 nJ) group [17]. Furthermore, a study has observed the surface roughness of corneal lenses removed at different energy levels (150, 180, and 195 nJ) and found that corneal lenses at 150 nJ has the most regular surface, demonstrating the superiority of low-energy lasers at the microanatomical level [18].

The clinical effectiveness of SMILE for myopia treatment has been confirmed [19]. However, these studies focused only on recovery of postoperative visual acuity and did not provide the specific metrics of higher-order aberrations. The present study is the first to compare postoperative outcomes amongst different combinations of laser energy and spot distance.

The opaque bubble layer is one of the main complications of femtosecond laser refractive surgery, which is understood as the destruction of corneal tissue by surgical laser, resulting in bubbles that cannot escape in time. These bubbles usually do not last very long, but may spread to the stroma of the cornea, the subconjunctival space. At present, the risk factors of stage 1 OBL formation in SMILE are not completely clear [15]. A study indicated that the formation of OBL during SMILE is mainly related to the refractive state of cornea itself, such as myopia diopter, astigmatism diopter and crystal thickness before surgery [15]. In this study, different laser energy settings had no significant effect on the formation of OBL.

Limitations of this study

The limitation of this study is that only changes at 3 months after surgery were monitored, and there is a lack of long-term follow-up. The energy settings and spot spacing grouping settings are limited. More long-term and multi-group studies are needed to explore the better laser setting in the future.

CONCLUSION

This study demonstrates that lower energy setting and larger spot spacing (120 nJ, 4.5 μm) perform better in the tHOAs and contrast sensitivity at 3 months post-operation, and achieves better visual outcomes in patients, which could provide a reliable basis for clinical ophthalmologists to set the laser energy during SMILE surgery.

DECLARATIONS

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Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Jing Li and Zilin Chen designed the study and performed the experiments Xiaoyi Wang and Ruidong Deng collected the data, Lei Shi and Yiting Zhang analyzed the data, Jing Li and Zilin Chen prepared the manuscript. All authors read and approved the final manuscript.

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