Comparison of Early Visual Quality in Patients using Different Optical Zones Based on Dark Pupil Diameters in Small Incision Lenticule Extraction (SMILE)

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Research Article

Keywords: small incision lenticule extraction (SMILE), optical zone diameter, dark pupil diameter, objective visual quality, subjective visual quality,

Posted Date: October 14th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-963499/v1

Abstract

AIM: The early visual qualities of patients were evaluated after small incision lenticule extraction (SMILE) using different optical zones based on dark pupil diameters.

METHODS: A case-control study was conducted to include 49 myopic patients (96 eyes) who underwent SMILE surgery. Patients were divided into three groups according to the difference between the diameter of the optical zone and the diameter of the dark pupil: Group A (<0 mm, N=30), Group B (0-1 mm, N=36), and Group C (>1 mm, N=30). In all groups, the dark pupil diameter was measured preoperatively. Subjective visual quality, uncorrected vision acuity (UCVA), spherical equivalent (SE), modulation transfer function cut-off frequency (MTF_{cutoff}), objective scattering index (OSI), simulated contrast visual acuity (VA100%, VA20%, VA9%), total corneal higher-order aberration (tot-HOA), corneal spherical aberration (totZ40) and corneal coma (tot-coma) were measured preoperatively and 3 months postoperatively. P< 0.05 was considered statistically significant.

RESULTS: There were no statistically significant differences in age, sex, UCVA, SE, corneal higher-order aberration, OQAS or subjective visual quality among the three groups before surgery (P>0.05). At 3 months postoperatively, there was no significant difference in UCVA, SE, MTF_{cutoff}, OSI, VA100%, VA20%, or VA9% among the three groups (P>0.05). However, the tot-HOA, totZ40 and tot-coma indexes and the changes in corneal higher-order aberrations (Dtot-HOA, DtotZ40, Dtot-coma) at 3 months postoperatively were as follows: Group A > Group B > Group C (P<0.05). At 3 months postoperatively, the difference in subjective visual quality between the three groups was statistically significant (P<0.05). The difference in the amount of change in subjective visual quality between Groups A and C was statistically significant (P<0.05).

CONCLUSION: Although the difference between the diameter of the optical zone and the diameter of the dark pupil does not affect the VA or the same diopter of patients after SMILE myopia correction, the optical zone diameter should be greater than the dark pupil diameter as far as possible in the design of SMILE surgery, in order to improve the objective visual quality and subjective satisfaction of patients after surgery.

Introduction

With the development of new technology and improvements in quality of life in modern society, an increasing number of myopic patients have developed a strong desire to stop using their glasses[1]. Since its clinical application, small incision lenticule extraction (SMILE) has been favoured by doctors and patients because of its advantages of being valveless, being minimally invasive, leading to eyes that are less dry after surgery and having good safety, effectiveness and predictability[2]. However, with the gradual development of SMILE surgery, reports of postoperative halo, glare and night visual impairment, as well as reports of other problems, have increased; because the visual quality of the human eyes is not only the embodiment of vision but also a comprehensive overview of interactions among multiple factors

such as aberrations, SMILE postoperative visual quality has become a hot spot of common concern for both doctors and patients[3]. At present, the evaluation indexes of the postoperative visual quality of SMILE can be divided into subjective indexes and objective indexes. The subjective evaluation indexes mainly include visual acuity (VA) and the subjective visual quality questionnaire[4]. Objective evaluation methods can be roughly divided into two types: wavefront aberrometers with different principles and a two-channel objective visual quality analysis system (OQAS2)[5–8]. The cutting area of SMILE is the optical area, and its effect on visual quality correlates with the size of the patient's dark pupil[9]. However, there are few studies on the impact of the difference between the diameter of the optical zone and the diameter of the dark pupil on the postoperative visual quality of SMILE. This study aims to design different optical zone diameters according to the size of the dark pupil diameter of patients and evaluate the impact of the difference on the subjective and objective visual quality of patients after surgery under two different parameter differences.

Subjects And Methods

Participants

A total of 49 myopic patients (96 eyes) were selected, including 41 eyes among 21 males and 55 eyes among 28 females, and their average age was 27.32±6.63 years. These patients underwent SMILE surgery in the ophthalmic optometry center of the First Affiliated Hospital of Hunan Normal University in October 2020. This study complied with the basic principles of the Helsinki Declaration and was approved by the Medical Ethics Review Committee of Hunan People's Hospital (First Affiliated Hospital of Hunan Normal University). After fully understanding the procedure and risks of the whole operation, each patient signed a written informed consent form. The inclusion criteria were as follows: 1. patients with myopia and myopic astigmatism between the ages of 18 and 40 years; 2. patients with spherical and cylindrical lenses of myopia ranging from -1.00 D to -9.00 D and from 0 D to -2.5 D; 3. a stable diopter over the past two years, with an annual increase in the spherical lens<0.5 D, and the best corrected visual acuity (BCVA) before surgery≥0.8; 4. central corneal thickness (CCT)>450 μm, and corneal stroma thickness after cutting≥280 μm; 5. no active ocular surface, ocular or ocular accessory lesions, history of trauma, or history of serious systemic or psychological diseases; and 6. preoperative discontinuation of soft contact lens use, rigid gas permeable contact lens use and orthokeratology lens use for at least 1 week, 1 month and 3 months, respectively. The exclusion criteria were as follows: 1. age < 18 years; 2. preoperative BCVA< 0.8, central corneal thickness≤450 μm, or corneal stroma thickness after cutting< 280 μm; 3. dark pupil diameter >7.5 mm; of 4. history of refractive or intraocular surgery or presence of corneal trauma, keratoconus, cataract, glaucoma or other eye diseases that cause vision loss.

Grouping

According to the optical zone diameter used in surgery combined with the dark pupil diameter of patients, the affected eyes were divided into 3 groups: Group A (difference between the optical zone diameter and dark pupil diameter <0 mm, N=30 eyes), Group B (difference between the optical zone diameter and dark

pupil diameter 0-1 mm, N=36 eyes), and Group C (difference between the optical zone diameter and dark pupil diameter >1 mm, N=30 eyes). The mean ages of the patients in Groups A (25.75±5.28 years), B (26.14 ±6.34 years), and C (25.00±5.48 years) were not significantly different (F=0.179, P=0.836).

Small incision lenticule extraction (SMILE)

All patients received routine levofloxacin eye drops 4 times a day for 3 consecutive days before surgery, and antibiotic eye drops were prophylactically administered 12 to 16 times before surgery. All SMILE surgeries were performed by the same experienced surgeon. The operation was performed using the VisuMax femtosecond laser treatment platform (Carl Zeiss, Germany). Preoperative anaesthesia was performed using propimecaine hydrochloride eye drops 3 times. After local anaesthesia, the eyelid was opened with an eyelid opener, and the centre of the flattening cone was aligned with the patient's cornea apex. The corneal stroma was then cut with a femtosecond laser in the following sequence[10]. The front and back surfaces of the stromal lens of the cornea were first cut, and the anterior surface diameter of the stromal lens was 0.5 mm larger than the posterior surface diameter. Its purpose was to form a corneal cap. Then, a small incision was made on the corneal cap. Next, blunt separation of the anterior and posterior surfaces of the stromal lens was performed, with tweezers with the clip out of the lens from the slit. Before the end of the operation, a careful check that the removed lens was intact was performed to avoid lens residue. Femtosecond laser scanning parameters: corneal cap thickness 110~120 μm, corneal cap diameter 7.0~7.8 mm, optical zone diameter 6.0~6.8 mm, limbal incision at 90°. All patients were treated with levofloxacin hydrochloride eye drops (4 times a day for 1 week). Flumilone eye drops (4 times a day for the first week, decreasing to once every 7 days for 4 weeks), Befudone eye drops (4 times a day for 1 week) and sodium hyaluronate eye drops (4 times a day for 1 month).

Observational index

The dark pupil diameter (mm) was measured for all patients before surgery in a dark room using an optical biometric instrument. The optical zone diameter (mm) used during the operation was recorded. Before and after surgery, the following data were collected. 1. Uncorrected vision acuity (UCVA), spherical equivalent (SE), and the UCVA was converted to LogMAR, with each index being measured 3 times and the average value being recorded. 2. High-order corneal aberration was determined via sirius corneal topographic examination on all patients in a darkroom by the same tester, and the absolute values of high-order corneal aberration within a 5-mm diameter, including total high-order corneal aberration (tot-HOA), corneal spherical aberration (totZ40), and corneal coma (tot-coma), were recorded. 3. For the OQAS2 measurement (Visiometrics, Spain), the OQAS2 system was used to directly collect retinal images of the point light source through dual-channel technology, analyse all the optical information on a surface with consideration of the influence of scattering and diffraction, and obtain the correct point spread function (PSF) image. Some studies have explained the significance of their measurement indicators[11, 12]. These indicators mainly included the following: modulation transfer function cut-off (MTF_{cutoff}), which represents the highest frequency (≥30 c/deg) at which the eye can image the retina with 1% contrast, which can reflect the effects of scattering and aberration on visual imaging quality; the object scatter index (OSI), which is a quantification of the opacity of refractive media of the eye and increases

with increasing opacity degree of refractive media; and the OSI value of normal eyes, which was approximately one. Simulated contrast VA (VA100% VA20% VA9%) refers to optical acuity corresponding to daytime, evening and night. Compared with subjective VA, this acuity is related only to the optical system of the human eye and is not affected by the retina or nervous system. VA values were all converted to LogMAR values. 4. The subjective visual quality evaluation scale was used in this study. Specifically, the visual behaviour and visual quality evaluation questionnaire[13, 14] in the optometrist handbook of the optometry clinic was used to conduct a questionnaire-based survey of the patients' preoperative and postoperative feelings about their eyes. The total number of points was 45; the higher the score was, the worse the visual quality would be.

Statistical analysis

All measurement data are presented as the mean ± standard deviation (mean ± SD). A paired T test was used for comparisons of all test indexes before and after the operation. Univariate ANOVA was used for comparisons of intergroup indexes conforming to a normal distribution and homogeneity of variance, and the Wilcoxon test and Kruskal-Wallis test were used for comparisons of intergroup indexes not conforming to a normal distribution. All data were processed and analysed by SPSS 23.0, and $P<0.05$ was considered statistically significant.

Results

All patients successfully completed SMILE surgery, and no surgical complications (such as infection, dry eye or light sensitivity syndrome) occurred. Table 1 shows the demographic composition and preoperative baseline of the three groups. There were statistically significant differences in optical zone diameter and dark pupil diameter among the three groups ($P<0.01$), but there were no significant differences in age, sex, UCVA, SE, corneal higher-order aberrations, OQAS measurements, subjective visual quality or other general data ($P>0.05$).

Table 1
Demographic and preoperative baselines data of the three groups (mean±SD).

	A	B	C	P
No. of eyes	30	36	30	-
Sex(M/F)	7/10	13/10	10/7	0.740
Age(years)	25.75±5.28	26.14±6.35	25.00±5.48	0.836
Spherical equivalent (SE)	-5.60±1.18	-4.76±1.96	-5.23±1.41	0.196
UCVA (LogMAR)	1.19±0.28	1.00±0.43	1.18±0.28	0.083
Tot-coma(μm)	0.12±0.05	0.14±0.08	0.14±0.08	0.750
totZ40(μm)	0.14±0.04	0.14±0.05	0.12±0.04	0.285
Tot-HOA(μm)	0.25±0.06	0.26±0.07	0.26±0.08	0.930
MTF_{cutoff}	40.09±8.58	39.54±9.78	35.89±8.54	0.249
OSI	0.61±0.32	0.75±0.55	0.71±0.29	0.577
VA100%	-0.13±0.08	-0.10±0.14	-0.06±0.10	0.176
VA20%	0.05±0.15	0.04±0.16	0.07±0.11	0.459
VA9%	0.26±0.15	0.25±0.16	0.30±0.13	0.529
Subjective visual quality	10.83±2.82	9.75±4.05	11.00±6.35	0.610
Optical zone diameter(mm)	6.34±0.17	6.53±0.20	6.51±0.12	0.001^{**}
Dark pupil diameter(mm)	6.99±0.31	5.95±0.33	4.96±0.51	0.000^{***}

UCVA = uncorrected visual acuity, MTF_{cutoff} = modulation transfer function cut-off frequency, OSI = objective scattering index, VA = simulated contrast vision. *: P<0.05,**:P<0.01***:P<0.001

UCVA and SE

At 3 months after the operation, there was no significant difference in UCVA or SE between the three groups (P>0.05), indicating that the intraoperative difference between the diameter of the optical zone and the diameter of the dark pupil had little influence on postoperative VA or diopter

Corneal higher-order aberrations

At 3 months after surgery, the tot-HOA, totZ40 and tot-coma indexes were as follows: Group A > Group B > Group C (P<0.05). Pairwise comparison showed that the difference in corneal higher-order aberrations between Groups A and B and Groups A and C was statistically significant (P<0.05), while there was no significant difference in corneal higher-order aberrations between Groups B and C (P>0.05) (Fig. 2),

indicating that when the diameter difference between the optical zone and the dark pupil was less than 0 mm, the postoperative corneal higher-order aberration was larger.

Measured index of OQAS

There was no significant difference in MTF_{cutoff}, OSI, VA100%, VA20% or VA9% between the three groups at 3 months after the operation (P>0.05) (Fig. 3), indicating that the difference between the diameter of the optical zone and the diameter of the dark pupil had little influence on postoperative objective visual quality. It also showed that the difference between the diameter of the optical zone and the diameter of the dark pupil had no influence on postoperative visual quality, the scattering index or daytime, evening or night vision.

Variation in the corneal higher-order aberration

At 3 months after surgery, the tot-HOA, totZ40 and tot-coma values of the three groups were all higher than those before surgery, with statistically significant differences (P < 0.05) (Table 2), indicating that postoperative corneal higher-order aberrations in the three groups increased compared with those before surgery.

At 3 months postsurgery, the changes in corneal high-order aberrations (Dtot-HOA, DtotZ40, Dtot-coma) between the three groups were statistically significant (P<0.05). Pairwise comparisons showed that there were statistically significant differences in the changes in corneal higher-order aberrations between Groups A and B and between Groups A and C (P<0.05) and that there was no significant difference in the changes in corneal higher-order aberrations between Groups B and C (P>0.05) (Fig. 4), which also indicates that when the difference between the diameter of the optical zone and the diameter of the dark pupil was less than 0 mm, the postoperative corneal higher-order aberration was larger.

Change in OQAS index

Regarding MTF_{cutoff}, VA100%, VA20% and VA9%, there was no statistically significant difference between 3 months postoperatively and preoperatively in the three groups (P>0.05). In Group A, the OSI at 3 months after the operation was higher than that before the operation, and the difference was statistically significant (P=0.007); however, there was no statistically significant difference between 3 months after the operation and before the operation in Group B or C (P>0.05) (Table 2), indicating that the patient's visual quality and contrast VA had been restored to the preoperative level at 3 months after surgery. When the difference between the diameter of the optical zone and the diameter of the dark pupil was less than 0 mm, the scattering index after surgery was increased compared with that before surgery. The variations in OQAS values between the three groups ($DMTF_{cutoff,}$ ΔOSI, DVA100%, DVA20% and ΔVA9%) were not statistically significant (P>0.05)

Subjective visual quality

The subjective visual quality scores of the three groups after operation were lower than those before operation; however, there was no significant difference in Group A (P>0.05), but the differences in Groups B and C were statistically significant (t=-3.345, -3.263, P=0.002, 0.003) (Table 2). At 3 months postoperatively, the difference in subjective visual quality between the three groups was statistically significant (P<0.05), and pairings showed statistically significant differences between Groups A and B and between Groups A and C (P=0.009, 0.020) but no statistically significant differences between Groups B and C (P>0.05) (Fig. 6A). The difference in the amount of change in subjective visual quality (Dsubjective visual quality) between Groups A and C was statistically significant (P=0.023) (Fig. 6B). All the above results indicate that when the difference between the diameter of the optical zone and the diameter of the dark pupil is less than 0 mm, the subjective visual quality score is higher, that is, the subjective visual quality is worse.

Discussion

The visual quality of corneal refractive surgery, as a concept, is at a higher level than VA, which encompasses VA, clarity, comfort, stability and other indicators. At present, more accurate and stable visual quality is the common pursuit of both doctors and patients. In the intraoperative, we hope to have a large enough optical area to maintain postoperative visual quality, but a large optical area can make the peripheral cornea too thin and increase the risk of surgery[15]. The setting of the surgical optical area is related mainly to the size of the patient's dark pupil. It is generally believed that the diameter of the optical area should not be less than that of the dark pupil when possible, but the appropriate range in which the difference between the two indicators should be set for optimal postoperative visual quality is still unclear. Therefore, we reviewed the patients who underwent SMILE surgery in our hospital's optometry centre in October 2020 and analysed the changes in visual quality based on the difference between the diameter of the optical zone and the diameter of the dark pupil.

In this study, the UCVA and SE results in the three groups at 3 months after surgery were similar (Fig. 1), indicating that the difference between the diameter of the optical zone and the diameter of the dark pupil does not affect the correction of myopia. In this study, the tot-HOA, totZ40 and tot-coma values at 3 months after surgery all increased compared with those before surgery (Table 2). This finding is similar to that of Chen Songlin[16] in his research on the changes in visual quality in the early postoperative stage, in which spherical aberration and high-order aberration increased after SMILE compared with before surgery. Therefore, it can be concluded that regardless of the size of the difference between the diameter of the optical zone and the diameter of the dark pupil, SMILE surgery can increase early postoperative corneal higher-order aberrations. Ağca[17] and Wu Yan[15] believed that spherical aberration, coma and trefoil were decreased after SMILE surgery. This study also found that when the difference between the diameter of the optical zone and the diameter of the dark pupil was less than 0 mm, the postoperative tot-HOA, totZ40 and tot-coma increased (Fig. 2), and the subjective visual quality was poor (Fig. 6), indicating that the difference between the diameter of the optical zone and the diameter of the dark pupil

should be no less than 0 mm in the surgical design to achieve good postoperative visual quality, which may be related to the “edge effect” hypothesis of Mok[18]. The “edge effect” hypothesis means that the closer the light is to the centre of the lens, the less deflection there is, which shows that the aberration decreases with the increase in the diameter of the optical zone. This is because the larger the optical zone is, the more easily the pupil will be covered by the edge of the optical zone; additionally, the less light passes through the edge region, the less aberration is introduced. However, Oshika T et al.[19] believed that keeping the diameter difference between the optical area and dark pupil greater than 1 mm can reduce night visual symptoms and improve postoperative visual quality. The differences between the two conclusions may be related to the following factors affecting visual quality: (1) preoperative diopter and eye adjustment affect the distribution of postoperative wavefront aberration, thus affecting postoperative visual quality[20, 21]; (2) intraoperative deviation of the cutting centre can cause a significant decrease in VA and contrast sensitivity (CS), accompanied by glare, halo, monocular diplopia, irregular astigmatism, and significantly increased postoperative coma and spherical aberration[22].

This study also found that the difference between the optical region and the diameter of the dark pupil at 3 months after surgery had no effect on the scattering index and VA during the day, evening or night after surgery (Fig. 3, Fig. 5). This is consistent with Yan Wu's conclusion[15] that appropriate reduction in the optical area during SMILE surgery resulted in only a mild decline in night vision but had no significant impact on other visual quality indicators. At the same time, this study compared the MTF_{cutoff}, OSI and VA (100%, 20%, 9%) before and after the operation in each group. It was found that visual quality and contrast VA recovered to the preoperative level at 3 months after surgery, and the scattering index at 3 months after surgery increased when the difference between the diameter of the optical zone and the diameter of the dark pupil was less than 0 mm, suggesting that the difference between the diameter of the optical zone and the diameter of the dark pupil should not be less than 0 mm in the surgical design, to improve patient satisfaction with the postoperative visual quality.

Conclusion

In conclusion, SMILE surgery can increase the corneal high-order aberration of myopia patients at 3 months after surgery, but the corneal high-order aberration increase is more obvious in the group with a difference between the diameter of the optical zone and the diameter of the dark pupil less than 0 mm, indicating that a difference between the diameter of the optical zone and the diameter of the dark pupil less than 0 mm will lead to greater high-order aberration of the cornea. At the same time, when the difference between the diameter of the optical zone and the diameter of the dark pupil was less than 0 mm, the subjective visual quality score at 3 months after surgery increased significantly, and subjective satisfaction decreased. Therefore, we can conclude that although the difference between the diameter of the optical zone and the diameter of the dark pupil does not affect the VA or the same diopter of patients after SMILE myopia correction, the optical zone diameter should be greater than the dark pupil diameter as far as possible in the design of SMILE surgery, in order to improve the objective visual quality and subjective satisfaction of patients after surgery. This study involves only a small sample and is a short-

term clinical study. A larger sample size with a long-term follow-up study of myopia patients undergoing SMILE surgery is required to understand the impact of the difference more comprehensively between the diameter of the optical zone and the diameter of the dark pupil after SMILE surgery on postoperative visual quality to further improve the postsurgical satisfaction of patients.

Abbreviations

SMILE, small incision lenticule extraction; UCVA, uncorrected vision acuity; SE, spherical equivalent; MTF_{cutoff}, modulation transfer function cut-off frequency; OSI, objective scattering index; VA100%, VA20%, VA9%, simulated contrast visual acuity; tot-HOA, total corneal higher-order aberration; totZ40, corneal spherical aberration; tot-coma, corneal coma; VA, visual acuity; OQAS2, objective visual quality analysis system; BCVA, best corrected visual acuity; CCT, central corneal thickness; PSF, point spread function;

Declarations

Ethics approval and consent to participate

After fully understanding the procedure and risks of the whole operation, each patient signed a written informed consent form. This study complied with the basic principles of the Helsinki Declaration and was approved by the Medical Ethics Review Committee of Hunan People's Hospital (First Affiliated Hospital of Hunan Normal University). (2020) Scientific Research Ethics Review NO: (49).

Consent for publication

Not Applicable.

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests.

Funding

This work was sponsored by the Program Project grant from the Key R&D project of Science and Technology Department of Hunan Province, China (Grant 2020SK2118 to Hua Wang).

Authors' contributions

JP, D-JZ, and HW designed the experiment, analyzed the data and prepared the manuscript; JP and D-JZ realized the experiments, collected, and analyzed the data. JP and D-JZ made equal contributions to the final manuscript. All of the authors discussed the results and approved the final manuscript.

Acknowledgments

The authors thank Dr. Xin-Xin Li (Central South University, Changsha, China) for editing and proof-reading of the manuscript.

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Tables

Due to technical limitations, table 2 is only available as a download in the Supplemental Files section.

Figures

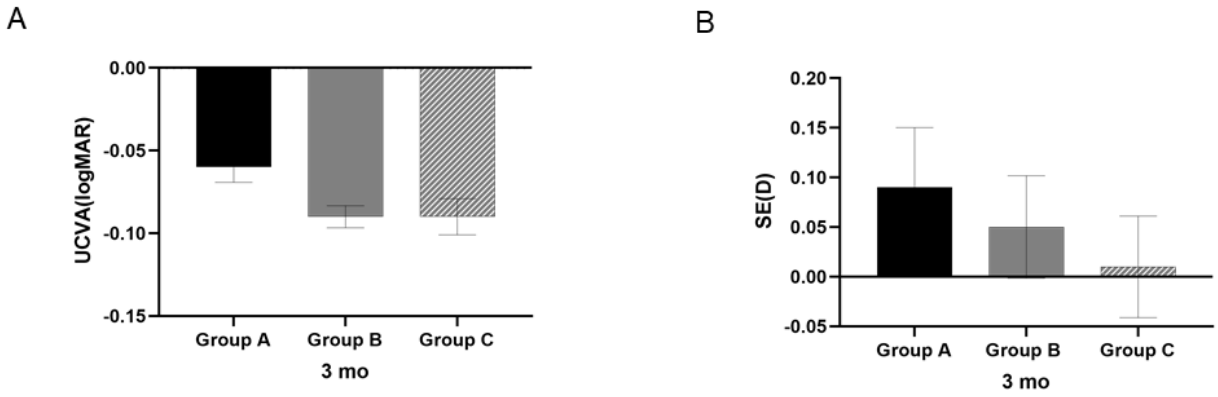

Figure 1

Three groups of UCVA(A) and SE(B) at 3 months postoperatively.

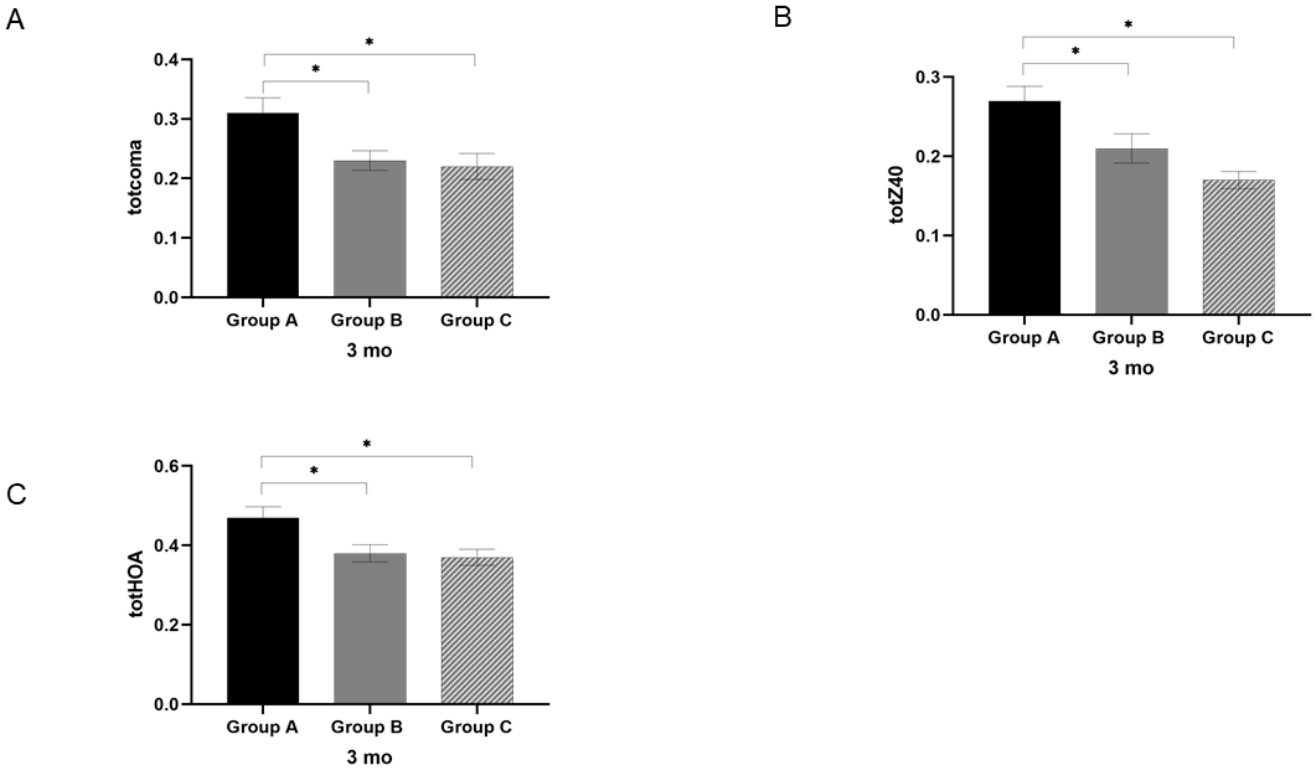

Figure 2

Three groups of tot-coma(A), totZ40(B) and tot-HOA(C) at 3 months postoperatively. * indicates P□0.05□** indicates P□0.01.

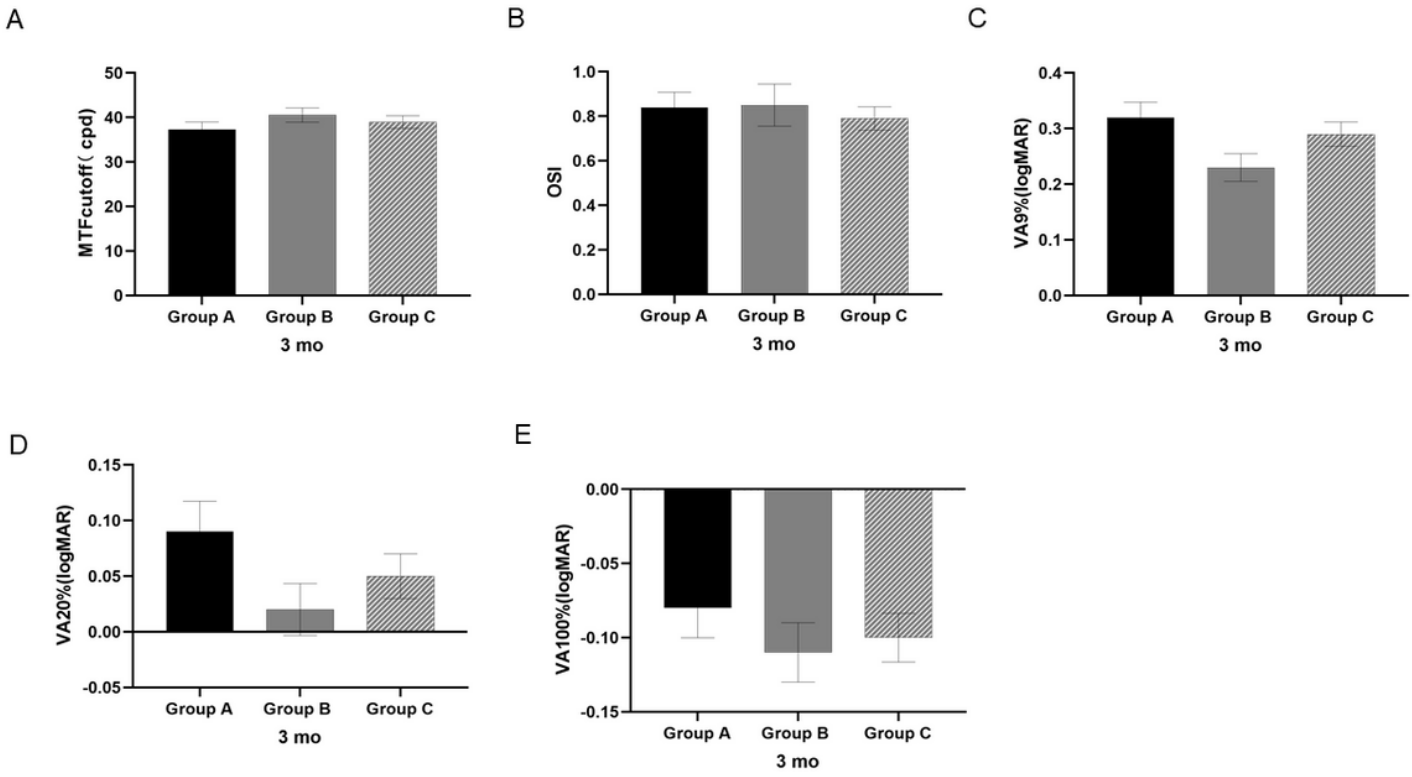

Figure 3

Three groups of MTFcutoff(A), OSI(B) and VA(9%、20%、100%) (C、D、E) at 3 months postoperatively. * indicates P＜0.05；** indicates P＜0.01.

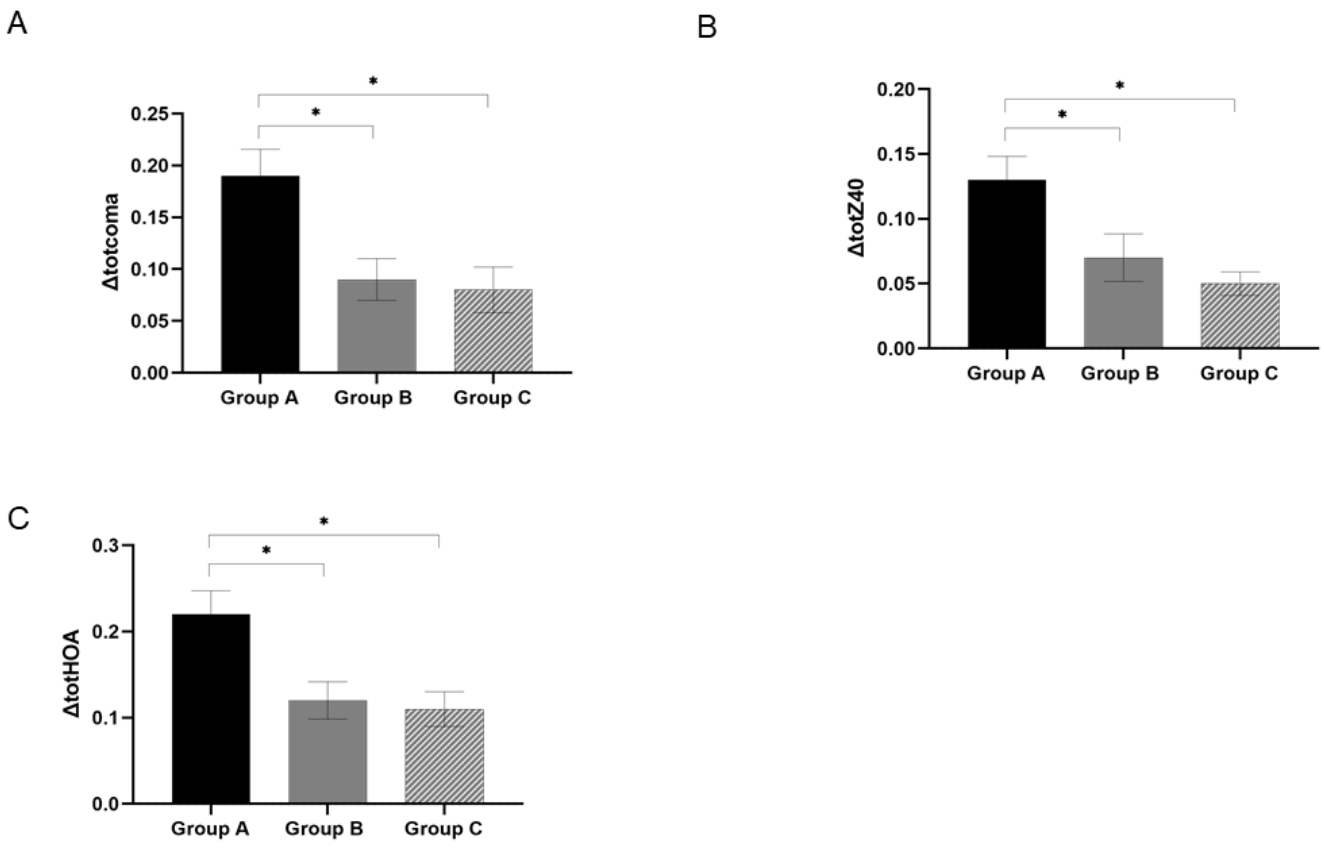

Figure 4

Three groups of Δtot-coma(A), ΔtotZ40(B) and Δtot-HOA(C) at 3 months postoperatively. * indicates P 0.05 ** indicates P 0.01 Δ indicates the changes in corneal higher-order aberrations.

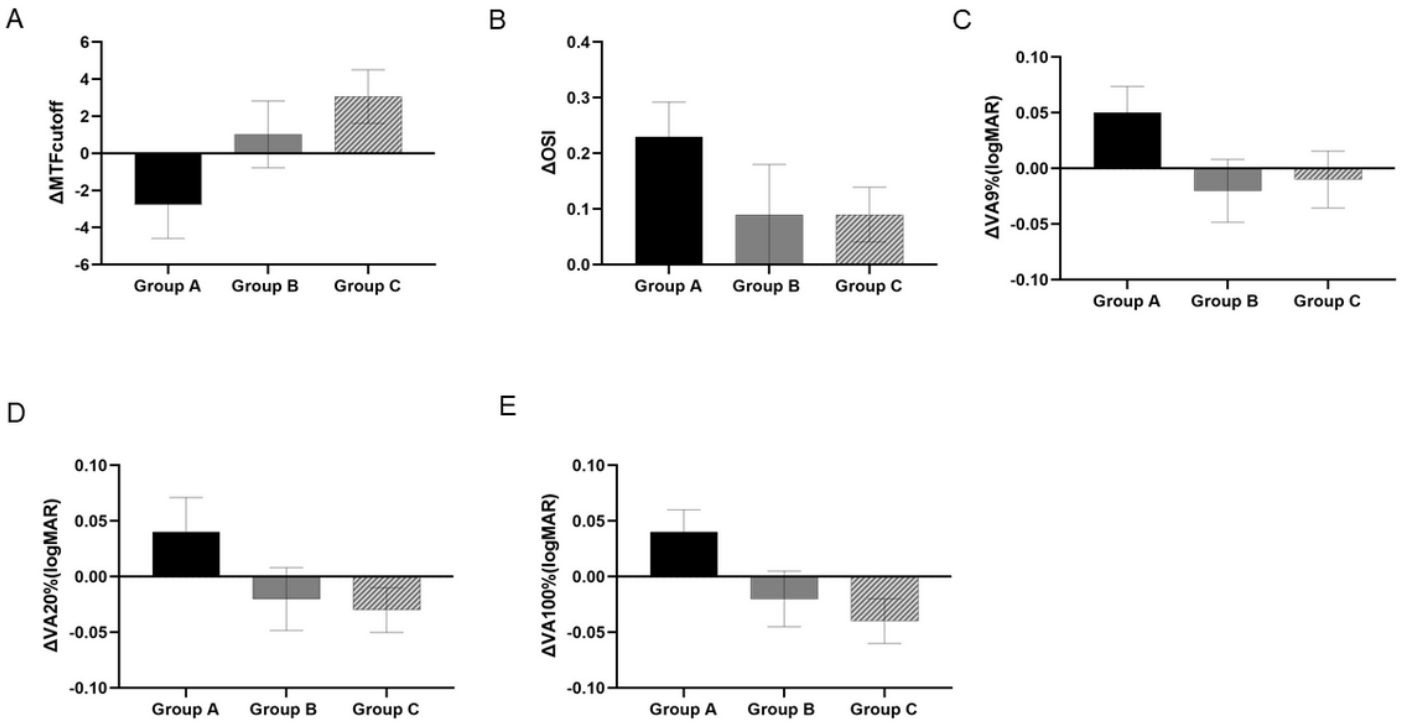

Figure 5

Three groups of ΔMTFcutoff(A), ΔOSI(B) and ΔVA(C、D、E) at 3 months postoperatively. Δ indicates the changes in Measured index of OQAS.

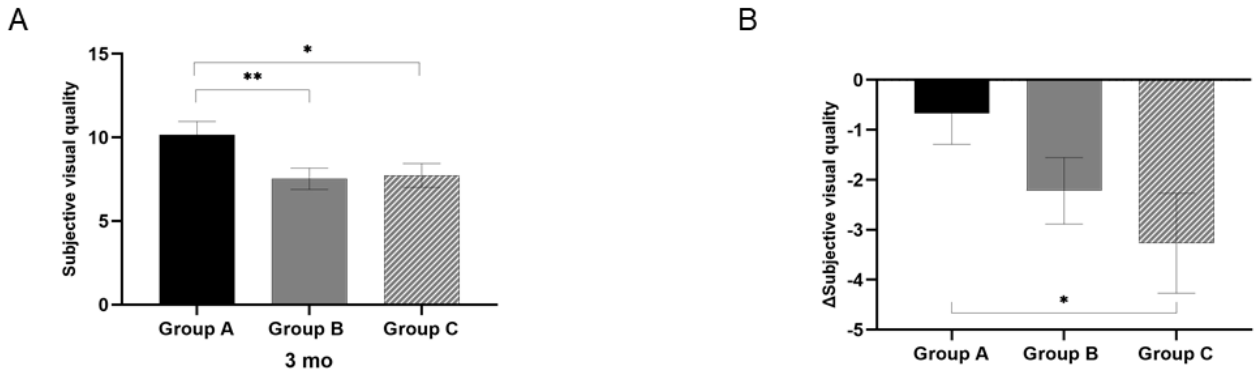

Figure 6

Three groups of subjective visual quality(A) and Δ subjective visual quality (B) at 3 months postoperatively. * indicates P＜0.05；** indicates P＜0.01；Δ indicates the changes in subjective visual quality.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table2.docx