

Sensations of Chinese Ametropia Patients under Laser-Assisted Keratomileusis Surgical Techniques

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Abstract

Purpose: To investigate the sensations experienced by Chinese patients during refractive surgery including the laser in situ keratomileusis (LASIK), Epi-Lasik, and Sub-Bowman keratomileusis (SBK) techniques. A prospective, randomized, and self-matched clinical study was conducted.

Methods: The participants included 44 men and 58 women aged 16 to 47 years old (mean 24.3±0.6 years) who underwent bilateral refractive surgery. Data were collected by using a standardized questionnaire regarding intraoperative experiences including light perception, perception of the green fixation light, pain, fear, and so on.

Results: A higher proportion of patients experienced temporary loss of light perception in the LASIK group compared with the Epi-Lasik and SBK groups (97% vs. 92% vs. 73%; $\chi^2 = 0.0072$, $p < 0.05$). Moreover, 71 patients were frightened by their intraoperative experiences [20 Epi-Lasik patients (71%); 23 LASIK patients (68%); 28 SBK patients (70%)]. These patients were mostly younger, aged ≤ 20 years ($\chi^2 = 0.0182$, $p < 0.05$). Moreover, the younger age group was significantly associated with the higher level of fear ($\chi^2 = 0.0011$, $p < 0.05$). Patients included in the group who felt pain with a mean duration of surgery ranging from five to 10 minutes (8.471±1.566) were significantly less in number compared with those who did not feel pain (7.100±1.820) ($\chi^2 = 0.0154$, $p < 0.05$). Patients also saw colors and movement, but the differences were not significant among the techniques. Patients experienced various visual sensations.

Conclusion: Younger age and relatively longer surgical durations were found to be the risk factors for the visual sensations of fear and pain during surgery. Preoperative counseling is an important factor in preparing patients for such visual experiences.

Keywords: Laser in Situ Keratomileusis, Sub-Bowman Keratomileusis, Epipolis Laser in Situ Keratomileusis, Myopia, Refractive surgery, Human

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Introduction

Over the past two decades, refractive surgery has undergone significant progress and evolution with the introduction of the excimer laser as an instrument for the reshaping of corneal stroma. Laser in situ keratomileusis (LASIK) is a popular procedure for the correction of refractive errors, and its application in clinical practice has been increasing over the past decade.^{1,2} Millions of individuals worldwide have reduced their dependence on spectacles and contact lenses because of the success of LASIK and surface ablation.^{3,4} In LASIK, a flap is cut in the corneal stroma and then pulled back to expose the corneal bed, which is then shaped and ablated by using an excimer laser. The flap is replaced, and the cornea is allowed to recover. Epi-Lasik, also called laser epithelial keratomileusis (LASEK), uses a typical vibrating plastic blade called epikeratome to loosen the epithelial sheet and to achieve planar separation. Subsequently, the flap is folded back, and excimer laser remodeling is performed to keep the Bowman's membrane intact.⁵ Sub-Bowman keratomileusis (SBK) is the newest surface ablation treatment. SBK combines LASIK and LASEK. A femtolaser is used to cut a thinner and shorter flap (110 μm vs. 160 μm LASIK flaps) in the sub-Bowman membrane to preserve the structural integrity of the eye while molding the cornea into a preferred shape. SBK combines the faster visual recovery of flap-based LASIK with the biomechanical benefits of surface ablation.⁶ A sub-Bowman flap should have a sufficient amount of anterior stromal collagen to prevent tenting.

Recent studies on patients undergoing LASIK^{7,8} focused on patients' perception of light, movement, and fear arising from their intraoperative experience. However, studies rarely compare different refractive surgeries with respect to a range of variables. Therefore, we investigated whether Chinese patients experienced different perceptions while undergoing one of the three different refractive surgeries performed under local anesthesia. Patients were able to see the fixation light clearly and to perceive the variation in fixation light size while the corneal flap was being lifted. We also attempted to determine whether feelings of fear and pain could be related to patient age, surgical

duration, education, as well as intention for surgery. Risk factors that may be associated with these variables were also identified.

Methods

Object

A cohort of 102 patients suffering from myopia (-2.00 to -18.00 diopters) underwent bilateral refractive surgery. To prevent variability caused by intersurgeon variation, all operations were performed by the same individual (Y.F.H.). Regardless of the method used, the first procedure was always performed on the right eye. Patients must not have undergone any previous ocular surgery. Moreover, patients who had a serious preexisting ocular pathology were excluded from the study.

Presurgical preparations

This study is part of a larger prospective and randomized clinical practice survey about the safety and predictability of refractive surgeries. This study was conducted at the Ametropia Therapy Center of the People's Liberation Army General Hospital, Beijing, China. The Declaration of Helsinki tenets were adhered to, and written consent was obtained from all patients prior to inclusion in the study. All patients underwent a detailed assessment including anterior segment slit-lamp microscopy, corneal topographic analysis by Orbscan IIz (Bausch & Lomb, Rochester, New York, USA), wave front assessment by Zywave aberrometry (Bausch & Lomb), biometry, as well as dilated retinal indirect ophthalmoscopy.

Operative methods of design and implementation

A total of 34 patients (68 eyes) underwent LASIK treatment with the corneal flap fashioned by using a Moria 2 microkeratome with a 110 single-use head (Moria). A total of 40 (80 eyes) underwent SBK treatment with the corneal flap fashioned by using a One-Use Plus microkeratome (Moria). Finally, 28 patients (56 eyes) had Epi-Lasik with the corneal flap fashioned by using a mechanical microkeratome (Table 1). When the flap was lifted, stromal ablation was accomplished by using an excimer laser (Wavelight-Allegretto; Lumenis Ltd. USA). After excimer laser

ablation, the stromal bed was irrigated with a balanced salt solution to remove any debris, after which the flap was repositioned. All patients were advised beforehand that they would be asked some questions either during or after the procedure. These questions may include any feeling of pain, degree of fear, and visual experiences. Patients were interviewed for 30 min after each refractive surgery by the same consulting nurse who used a standardized questionnaire.

Design and implementation of questionnaire

Patients were informed that the questions were related to visual experiences through the operated eye. The patients were asked the following questions: (1) whether they experienced a loss of light perception and whether the loss was transient; (2) whether the green fixation light moved, remained stationary, or had change in size during the application of the excimer laser; and (3) whether they perceived colors, instruments, the surgeon's fingers, or flashes during the surgery. The patients were also asked to rate the degree of pain or fear associated with these experiences by using a scale of 0 to 3, (0 representing a lack of response and 3 representing the maximum level). Patient surgery times were grouped based on duration as 0 min to 5 min, 5 min to 10 min, or longer than 10 min (the time was calculated from the instance that the eyelids were held open during the procedure). In addition, to prevent the effect of postoperative recall bias, some patients were asked whether the green fixation light changed in size after the flap was lifted during surgery.

Statistical analysis

All statistical analyses were conducted by using SPSS version 11.5 (SPSS Inc, Chicago, Illinois, USA), with p -values ≤ 0.05 (two-tailed) considered as statistically significant. χ^2 tests were used to compare the results of various groups, and unpaired t tests were used to compare means.

Results

Of the 102 patients who participated in this study, 44 (43%) were men, and 58 (57%) were women. The mean age of the patients was 24.3 ± 0.6 years (range, 16 to 47 years).

The presented data refer to both eyes, and the patient report covers experiences through both eyes. No marked difference was observed in the spherical equivalent or error among the three groups (Table 1).

Receive loss of light

Almost all patients who underwent LASIK treatment (33; 97.1%) experienced a loss of light perception for several seconds during the operation (Table 2), which was similar to the experience of patients who underwent Epi-Lasik treatment (24; 92.3%). Patients who underwent SBK treatment were less likely to experience a loss of vision (27; 73.0%). The findings significantly differed from the expected distribution of the three patient groups ($\chi^2 = 0.007$, $p < 0.05$; Table 2).

Sensation of fixation light

All patients reported seeing the instrument movement and the green fixation light, but not all patients were able to perceive other parameters such as the surgeon's fingers, various colors, or the lifting of the corneal flap. However, no consistent and significant differences were observed among the techniques. Patients also reported a range of experiences with respect to the size of the green fixation light, with some reporting an increase in size, while others reported that it remained the same or decreased in size. Patients were then regrouped into two. The first group included patients with a spherical equivalent ranging from -2.00 to -5.00 diopters (SD ± 1.8 diopters), and the second group included patients with a spherical equivalent from -5.00 diopters to -18.00 (SD ± 1.6 diopters; t test, $p = 0.657$). Majority of the patients (34; 69.4%) in the -2.00 to -5.00 diopter group perceived an increase in the size of the green fixation light compared with only 15 patients (30.6%) in the greater than -5.00 to -18.00 diopter group. A decrease in size was perceived by one patient (16.7%) in the -2.00 to -5.00 diopter group compared with five patients (83.3%) in the -5.00 to -18.00 diopter, thus presenting a significant difference ($\chi^2 = 0.042$, $p < 0.05$). In comparison, 13 patients (72.2%) in the -2.00 to -5.00 diopter group perceived an increase compared with five patients (27.8%) in -5.00 to -18.00 diopter group. However, the green

fixation light perception after the lifting of the corneal flap was not significantly different.

Subjective sensations

Whole undergoing one of the three types of refractive surgery, patients were asked to rate their perceived pain or level of fear as well as their anxiety in a subjective scale from 0 to 3 (Figure 1). When the subjective levels of pain induced by the procedure were compared, a higher number of patients who underwent the SBK procedure reported a lack of pain compared with the Epi-Lasik and LASIK patient groups (29, 73%; 16, 57%; 16, 47%, respectively; Figure 1). Overall, no statistical difference was observed among the groups ($\chi^2 = 0.0656$, $p > 0.05$). The level of fear or anxiety reported by the patients was unrelated to the particular surgical technique ($\chi^2 = 0.7611$, $p > 0.05$). The patients' age and the degree to which they feel frightened about

the procedure exhibited a linear relation ($\chi^2 = 0.0011$, $p < 0.05$, Figure 2). Patients younger than 20 years were more likely to be frightened (37, 36%) compared with those aged 20 to 29 (25, 25%) or older (9, 9%; χ^2 test, $N=102$; $\chi^2 = 0.0182$, $p < 0.05$) (Figure 1). However, the level of fear for younger patients was not excessive (level 0, 16%; level 1, 32%; level 2, 11%; and level 3, 9%; $n=42$). When the duration of the surgery was compared, the surgery techniques were equal. Patients in the 5 min to 10 min group had significantly different perceptions of pain ($\chi^2 = 0.0154$, $p < 0.05$). The comparison between the other two groups, namely, the 0 min to 5 min ($\chi^2 = 0.9047$, $p > 0.05$) and >10 min groups ($\chi^2 = 0.1778$, $p > 0.05$), showed no significant differences. The degree of fear or anxiety felt by the patients was found to be unrelated to educational level ($p > 0.5$, $\chi^2 = 0.7526$).

Table 1. Summary data for refractive surgeries

Surgical technique	Epi-LASIK [†] (n=28) [¶]	LASIK [‡] (n=34)	SBK [§] (n=40)	p
Male	12	15	17	0.9896
Female	16	19	23	
Age	22.40±4.26	26.15±5.89	24.73±4.82	1.000
Spherical (D)	-6.72±1.89	-4.47±1.74	-5.95±1.78	0.7376
Cylinder	-0.84±0.78	-0.44±0.62	-0.61±1.78	
Corneal curvature				
K1	43.12±1.48	42.88±1.41	43.49±1.23	1.000
K2	44.39±1.63	43.71±1.46	43.95±1.60	
Flap dimensions				
Flap diameter (mm)	8.0 ~ 10.0	8.5 ~ 9.0	8.5 ~ 8.7	0.2680
Flap thickness (µm)	50 ~ 70	120 ~ 130	80 ~ 100	0.5623
Flap creation (sec)	20 ~ 25	20 ~ 25	20 ~ 25	1.000
Ablation time (sec)	44±11	38±16	43±10	0.8497

[†]: Epi-LASIK: Epipolis laser in situ keratomileusis

[‡]: LASIK: Laser-assisted in situ keratomileusis

[§]: SBK: Sub-bowman keratomileusis

n: The number of patients, * $p \leq 0.05$, χ^2 test

Table 2. Visual Perception during surgery

Surgical technique	Epi-LASIK [†] (n=28) [¶]	LASIK [‡] (n=34)	SBK [§] (n=40)	p
Light perception	26 (92%)	34 (100)	37 (93)	0.2680
Interrupted light perception	24 (92%)	33 (97%)	27 (73%)	0.0072*
Perceived corneal flap lifting				
Yes	10 (36%)	8 (24%)	14 (35%)	0.4817
No	18 (64%)	26 (77%)	26 (65%)	

[†]: Epi-LASIK: Epipolis laser in situ keratomileusis

[‡]: LASIK: Laser-assisted in situ keratomileusis

[§]: SBK: Sub-bowman keratomileusis

n: The number of patients, * $p \leq 0.05$, χ^2 test

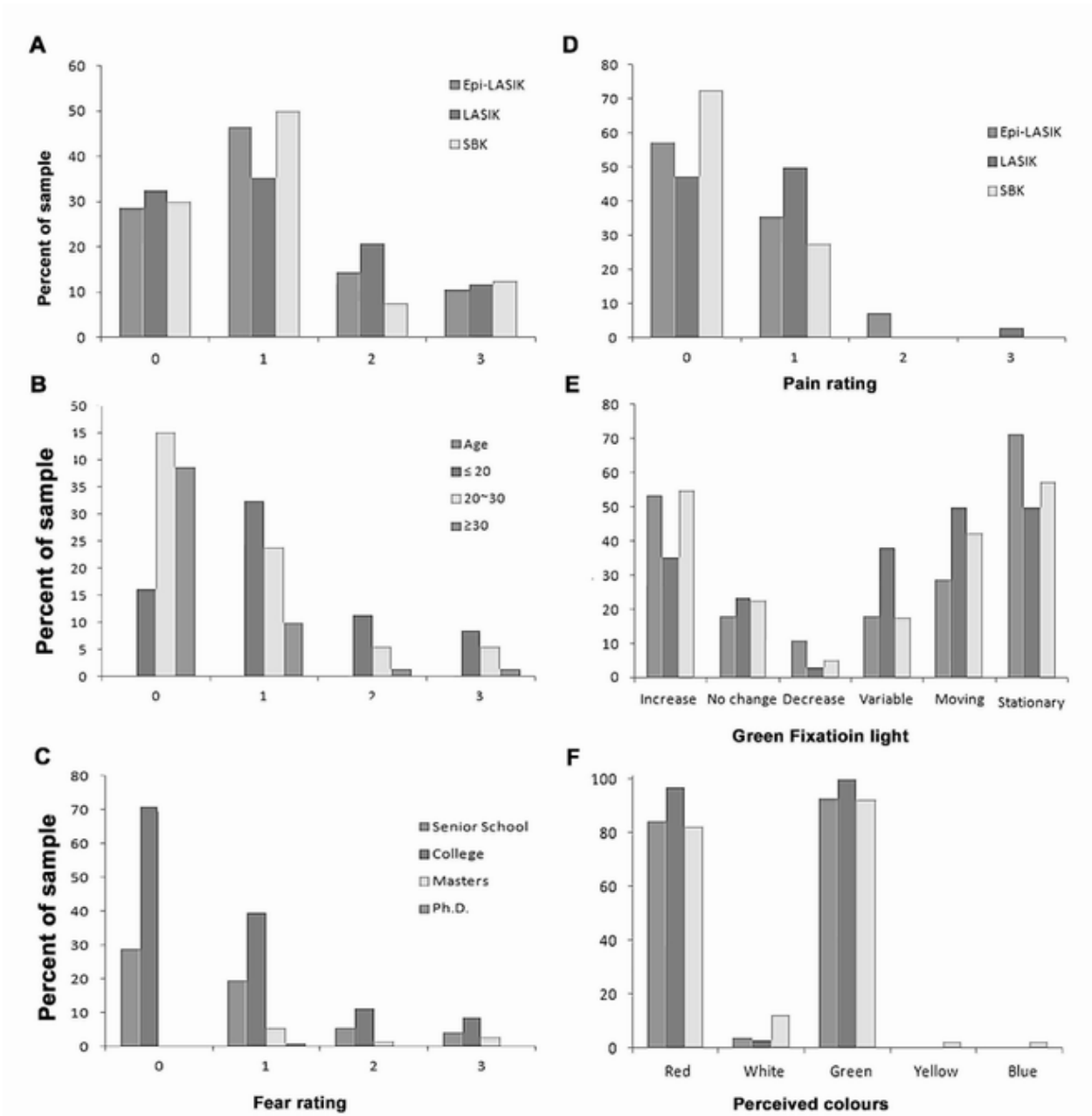


Figure 1. Bar graphs demonstrating the relationships between fear, pain level and various surgeries (A) Patients who experienced fear rate on a scale of 0-3 in the three refractive surgeries (χ^2 test, N=102; $\chi^2=0.7611$, $p>0.05$). (B) Patients who experienced fear rate on a scale of 0-3 in the three age durations (χ^2 test, N=102; $\chi^2=0.0182$, $p<0.05$). (C) Patients who experienced fear rate on a scale of 0-3 in the four education degrees (χ^2 test, N=102; $\chi^2=0.7526$, $p>0.05$). (D) Patients who perceived pain rate on a scale of 0-3 in the three refractive surgeries (χ^2 test, N=102; $\chi^2=0.0656$, $p>0.05$). (E) Patients' perception of the green fixation light in the three refractive surgeries (χ^2 test, N=102; $\chi^2=0.1890$, $\chi^2=0.8497$, $\chi^2=0.4131$, $\chi^2=0.0745$, $\chi^2=0.2278$, $p>0.05$). (F) Patients who perceived various colors in the three refractive surgeries (χ^2 test, N=102; $\chi^2=0.0734$, $\chi^2=0.1939$, $\chi^2=0.2680$, $\chi^2=0.4572$, $p>0.05$). LASIK: Laser in situ keratomileusis, Epi-LASIK=Epipolis laser in situ keratomileusis, SBK: Sub-Bowman keratomileusis

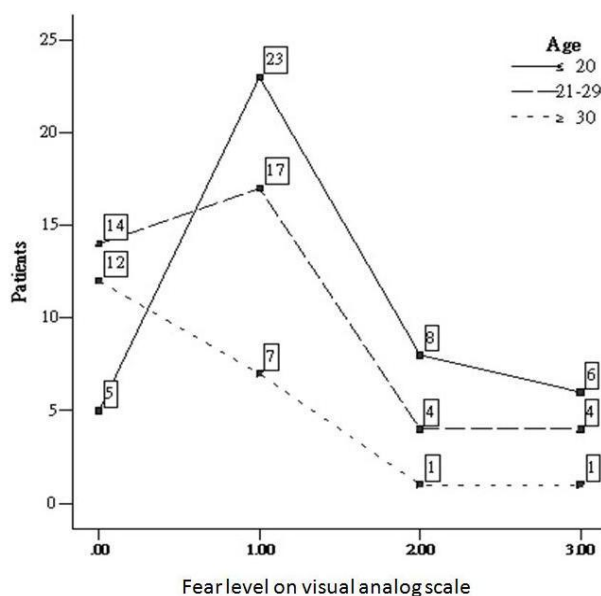


Figure 2. Graphs demonstrating the relationships between age and fear visual sensations

Rate on a scale of 0-3, the degree of fear associated with these experiences (0 representing a lack of response and 3 representing the maximum level). The patients' age groups to which they found the process fear formed a linear relation (χ^2 test, $N=102$; $\chi^2=0.0011$, $p<0.05$)

Discussion

This study demonstrated that patients who underwent different refractive surgeries experienced a variety of visual sensations. These sensations were found to be unrelated to the marked differences in the spherical equivalent or spherical error among the three groups of patients. Majority of patients who underwent LASIK and Epi-Lasik surgery temporarily lost light perception. This finding is consistent with that of a previous report³ and is most likely attributable to an increase in intraocular pressure (IOP) caused by the vacuum suction. The difference between LASIK and the SBK treatment⁹ may be attributed to smaller IOP changes with suction during SBK (Table 2). Findings also show that IOP rapidly increases to more than 80 mmHg after suction ring application.¹⁰ Although the loss of light perception may also be affected by the patients' corneal diameter, axial length, and scleral rigidity, no statistical difference was found among the three techniques.

LASIK is a lamellar laser refractive surgery in which excimer laser ablation is performed under a partial-thickness of the lamellar corneal flap. Patients are asked to fixate on a

centering light, and an eye-tracker is employed for any eye movement adjustments during the preprogrammed excimer ablation. Epi-Lasik uses excimer laser refractive surgery to ablate the most anterior portion of the corneal stroma. These procedures do not require a partial thickness cut into the stroma, thus leaving a larger residual bed to retain the cornea's biomechanical strength. SBK is a LASIK procedure where the flap is thinner. A major advantage of creating a thin flap during SBK is that sufficient stromal tissue is left to allow for safer excimer laser ablation. A study on 3,009 eyes following SBK using a femtosecond laser exhibited a low complication rate.¹¹ Compared with surface ablation, LASIK results in an earlier and faster improvement in uncorrected visual acuity and has less (or almost no) postoperative discomfort as well as improved stability and predictability.¹²

Although the percentage of patients that reported a lack of pain was the highest in SBK group, no significant differences were generally observed. However, when the surgery was examined within terms of the

5 min to 10 min surgical duration group, significant pain was reported ($\chi^2 = 0.0154$, $p < 0.05$) compared with other surgical durations. The lack of perceived pain during the surgery may have been related to the ablation thickness and to the duration of surgery. The lack of perceived pain during longer surgical time periods may have been due to some adaptive mechanism.¹³

In this study, no pre or intraoperative sedation was given to eliminate the potential variable influences caused by such drugs to the patients' experiences. In the total cohort of patients, 71 (69.6%) experienced some level of fear or anxiety (66% of those reporting fear reported only a mild level, i.e., level 1). Fear was more likely to be experienced by younger patients regardless of the surgical procedure. This result is higher than the reported results for patients who underwent vitreous surgery (51.3%)¹⁴ or those who underwent various stages of laser surgery (19.5%).³ The number of patients who did not experience fear was the lowest in younger patients (5; 16%) compared with 20 to 30 year olds and those older than 30 years old (14, 45%, and 12, 39%, respectively). This result is statistically significant ($p = 0.0182$; Figure 1). This observation is clinically significant for the prevention of unwanted systemic side effects such as acute panic attacks, hypertension, and tachycardia.¹⁵ The degree of anxiety may decrease the patients' cooperation during the procedure and may affect their satisfaction with the surgery.¹⁶ Some studies of patients who underwent cataract surgery have reported similar findings.¹⁷ A previous report has demonstrated that patients who received detailed preoperative counseling from the surgeon concluded that the reassurance may reduce the fear caused by the surgical procedure.¹⁸ We found that the level of fear is not significantly affected by the patients' level of education. However, the younger patients were statistically more likely to be frightened.

Epidemiological data show that myopia has become an increasingly serious visual problem, specially in Asia.¹⁹ In China, juvenile myopia is very common, and many high school students may develop myopia early as a result of the heavy burden of academic courses. Given that military college admissions (a viable alternative school for many students who may not be able to afford

mainstream universities) require that the student have emmetropia, many juveniles seek refractive surgery. However, patients often do not understand the surgical process or understand the intent of the surgery. Thus, informed preoperative sessions can reduce fear, which is consistent with data obtained from patients undergoing their second cataract operation. Patients who are more aware of what to expect during the surgery are thus less likely to be frightened.²⁰

This study found no difference between the size perception of the green fixation light between the -2.00 to -5.00 and the -5.00 to -18.00 diopter groups. This finding appears to be in contrast to a previous report,³ which found that more patients in the higher diopter group reported an increase in the size of the fixation spot. We speculate that use of the same correction parameters for low diopter group resulted in a perception that is closer to normal vision. The refractive changes that arise once the corneal flap is lifted are greater in the lower myopia group compared with the higher myopia diopter group. This result is evidenced by the reported increase in size of the green fixation light. Another possible explanation is that the lower myopia cornea is relatively thicker in the lower myopia group than in the higher myopia group. Thus, after the flap is fashioned, the increased amount of light scattered from the stromal surface of the lower myopia may be more evident, which may account for the larger size of the light. Interestingly, the decrease in size between the two groups was significantly different ($\chi^2 = 0.042$, $p < 0.05$). Patients who were interviewed during surgery and after the flap was lifted (i.e., not relying on postoperation memory) reported either an increase or decrease, but no significant difference between the diopter groups was observed. We speculate that this finding may be attributed to that fact that the questions during the surgical procedure may have been implied to the patients, which certainly did not infer stress factors.

The advances in laser refractive surgery will be continuously driven by the available technology. Our study of clinical patients demonstrates that shorter surgery durations are desirable and that preoperative counseling is important. For patients who experienced fear and/or pain, longer duration and younger

age may possibly be risk factors. In addition, some patients exhibited different perceptions of the fixation light while focusing on the light during surgery.

Conclusion

Younger age and relatively longer surgical durations were risk factors for the visual sensations of fear and pain during surgery. Preoperative counseling would play an

important role in preparing patients for such visual experiences.

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