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A Nomogram to Improve Predictability of Small-Incision Lenticule Extraction Surgery

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Background: This study aimed to determine and validate that use of a nomogram could enhance the predictability of small-incision lenticule extraction (SMILE) surgery.

Material/Methods: 195 eyes from 98 patients were enrolled in group 1, and 46 eyes from 26 patients in group 2. Uncorrected and corrected distance visual acuity (UDVA and CDVA), manifest refraction spherical equivalent (SE) preoperatively and 1 day, 1 week, 1 month, and 3 months postoperatively were measured. A nomogram based on the error in SE correction was generated by using multifactor regression method in group 1. After applying this nomogram to redesign the refraction target, the predictability, safety, and efficacy of the SMILE procedure were determined.

Results: A linear regression formula (SE error=0.259+0.113×$SE_{preoperative}$) was derived as a nomogram to adjust the SE target. In group 2, the predictability of error was 86.21% within 0.50 D and 97.83% within 1.00 D, compared with 70.25% and 95.90%, respectively, in group 1. The use of the nomogram significantly reduced the variance in postoperative SE. The efficacy and safety of SMILE did not differ significantly in the 2 groups 3 months postoperatively.

Conclusions: The nomogram can optimize the target refractive prediction of the SMILE procedure without compromising safety and efficiency.

MeSH Keywords: Myopia • Nomograms • Regression Analysis

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Background

In 1990s, femtosecond laser technology was first used by Dr. Kurtz at the University of Michigan, then it was rapid developed for use in surgical ophthalmology [1]. Because the femtosecond laser causes minimal collateral damage, this technology can perform bladeless incisions at various depths and patterns, with high precision [2,3]. Thus, use of the femtosecond laser has been introduced into corneal refractive surgery to create corneal flaps. Previous studies showed that the visual results after femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) are at least as good as after microkeratome LASIK, and it is safer, which led FS-LASIK to become even more popular [4,5]. Then, following the introduction of the VisuMax femtosecond laser (Cark Zeiss Meditec, Jena, Germany), the intrastromal lenticule method was readopted, and together it is called the Femtosecond Lenticule Extraction (FLEx) method. The results of FLEx in refractive correction were similar to those of LASIK, but the visual recovery time was longer [5]. Afterwards, small-incision lenticule extraction (SMILE), a no-flap procedure to extract the corneal lenticule through a small arcuate incision using femtosecond laser–based techniques, has become a less invasive alternative method compare to the previous LASIK in myopia correction [6,7]. In previous studies, the refractive outcome was stable and predictable after SMILE surgery, but the refraction could be overcorrected or undercorrected, which may put the patients and surgeons in an awkward position [8]. Compared to SMILE, a variety of additional treatments, including laser-assisted subepithelial keratectomy (LASEK) and subepithelial photorefractive keratectomy (PRK), have been introduced to reduce the postoperative compromised thickness of the corneas, ectasia, and the flap-related complications. There was no formally established method for enhancement after SMILE procedures [9–12]. However, it was also reported that corneal opacity problems emerged after PRK-derived enhancement treatment, and these supplementary enhancement treatments negate the principles of SMILE surgery; therefore, the accuracy of preoperative design is very important for SMILE surgery. Nomograms are considered as reliable and pragmatic prediction tools. Nomograms incorporate multiple significant prognostic factors to quantify individual risk and they achieve good performance in prediction [13–15]

We carried out this study to establish an appropriate preoperative design. Linear regression analysis was conducted to determine possible factors influencing postoperative spherical equivalent (SE) error. Patient satisfaction with the surgery also needs to be improved. Thus, we aimed to conduct this study to develop a nomogram that could refine the visual recovery assessment.

Material and Methods

We retrospectively analyzed 195 eyes from 98 patients (group 1) and 46 eyes from 26 patients (group 2). Patients were randomly allocated to the 2 groups. We used the nomogram for patients in group 2, but group 1 we did not use the nomogram. There was no significant difference in the ophthalmic parameters between the 2 groups. The eye operations were performed in Beijing Tongren Hospital of Capital Medical University. The study protocols were approved by the Institutional Review Board and complied with the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants.

Inclusion criteria for the study were as follows: spherical myopia up to –8.00 D, myopic astigmatism up to –3.00 D cylinder, corrected distance visual acuity (CDVA) of 20/40 or better (the Logarithm of the Minimum Angle of Resolution (logMAR) >0.3), and minimum calculated postoperative residual stromal bed of 250 μm.

Exclusion criteria were previous ocular pathology, ocular surgery history, and operative complications that influence the visual results such as unintended abandonment of residual intrastromal lenticule fragments.

All patients underwent the SMILE procedure by the same surgeon (G.L.) under topical anesthesia using the VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) between February 2014 and September 2014. A thorough preoperative evaluation was performed, including uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), cycloplegic refraction, corneal pachymetry, intraocular pressure measurement, slit lamp biomicroscopy examination, dilated fundus examination, dry eye assessment, and topography.

The patients were positioned under the curved contact lenses in the VisuMax femtosecond laser system and asked to stare at the target light for centration. The vacuum suction was activated afterwards. After laser treatment, the lenticule was separated using standard surgical techniques and removed through the incision.

The pulse frequency of the VisuMax femtosecond laser system was set to 500 kHz. The spot distance and track distance were 4.5 μm and the energy was set to 140 nJ. The cap thickness was 120 μm, the lenticule diameter was from 6.0 to 6.8 mm, the minimum lenticule thickness was from 10 to 15 μm, the side cut angle was set as 110°, and the incision was set at 120° at a circumferential width of 2.0 mm. During the investigation, patients had complications as follows: 4 eyes had lenticule broken and the patients were excluded from the study, 5 eyes had errhysis at incision edge, 5 eyes had suction loss, 12 eyes had a minor tear at the incision edge, 12 eyes had black

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Table 1. The preoperative baseline characteristics of included patients.

Parameter	Group 1 (N=195)		Group 2 (N=46)		*P* value
	Mean ±SD	Range	Mean ±SD	Range	
Age (years)	24.45±5.59	17–45	25.00±3.97	20–37	0.44
Sphere (D)	–4.23±0.91	–6.75 – –2.25	–4.12±1.19	–7.00 – –2.25	0.45
Cylinder (D)	–0.59±0.46	–2.25–0	–0.43±0.49	–2.25–0	0.06
Spherical Equivalent Refraction (D)	–4.53±0.90	–7.00 – –2.25	–4.33±1.13	–7.38 – –2.25	0.2
Corneal Power (D)	43.25±1.41	39.25–46.75	43.17±1.37	40.30–46.70	0.71
Central Corneal Thickness (D)	540.78±28.29	487–606	540.96±23.75	491–586	0.96
Spherical Treatment Attempt (D)	–4.62±0.88	–7.25 – –2.75	–4.68±1.19	–7.50 – –2.75	0.66
Cylinder Treatment Attempt (D)	–0.44±0.40	–2.00–0.00	–0.38±0.43	–2.00–0.00	0.36
Spherical Equivalent Treatment Attempt (D)	–4.84±0.87	–7.50 – –2.75	–4.88±1.15	–7.88 – –2.75	0.81

P<0.05 means statistically significant.

spots, and 35 eyes had an opaque bubble layer. Of the 5 eyes with suction loss, 2 of them immediately restarted the procedure and completed surgery uneventfully, 1 received surgery 2 weeks later, and the other 2 were excluded from the study.

Patients were examined at 1 day, 1 week, 1 month, and 3 months postoperatively. Recordings of UDVA, CDVA, topography, and slit lamp examination for corneal state and any adverse effects were done on all postoperative visits.

At each postoperative follow-up, intraoperative parameter, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), and refraction correction of the 2 groups were recorded. The main refractive outcome measures included predictability, safety, and efficacy. Safety was evaluated by CDVA before and after surgery, while the safety index was the mean postoperative CDVA divided by the mean preoperative CDVA (expressed in decimal notation). Efficacy was evaluated by the change of CDVA before surgery and the UDVA 3 months postoperatively, and the efficacy index was the UDVA 3 months postoperatively divided by the CDVA preoperatively (expressed in decimal notation). Predictability was evaluated by calculating the error in SE correction: the attempted change in SE refraction subtracted by the achieved change, including the arithmetic and absolute refractive error of the SE correction (expressed as the percent of SE correction error within 0.5 D and 1.0 D).

Statistical analyses were performed using the SPSS software (ver. 18; SPSS Inc., Chicago, IL, USA). The continuous data were reported as the mean ± standard deviation, and the range and median values were also given. The independent-samples *t* test was used to compare data in normal distribution between any 2 groups, as assessed by the Kolmogorov-Smirnov test. When the data did not fit normal distribution, the Mann-Whitney test was used for comparison. Linear regression analysis was performed to evaluate the relationships between error in SE correction and intraoperative parameters, including age, preoperative spherical equivalent, corneal power (CP), and central corneal thickness (CCT). The chi-square test was used to compare the proportions between the different groups. *P* values less than 0.05 were considered statistically significant.

Results

Baseline characteristics

The preoperative baseline characteristics of included patients are presented in Table 1. There was no significant difference in the ophthalmic parameters between the 2 groups. A total of 195 eyes from 98 patients (47 male, 51 female) were enrolled in group 1, while 46 eyes from 26 patients (25 male, 21 female) were enrolled in group 2. The mean age was 24.45±5.59 years (range: 17 to 45 years) for group 1 and 25.00±3.97 years (range: 20 to 37 years) for group 2.

Linear regression analysis in group 1

The linear regression analysis of groups 1 was done to analyze the relationship between the attempted correction and the achieved correction. Figure 1 shows the scatterplot and linear regression analyses of the attempted correction of SE against the achieved correction of SE at month 3 postoperatively. Although the relationship between the attempted correction and achieved correction was strong (correlation coefficient=0.868, *P*<0.01), there is a slight overcorrection in the achieved SE refraction (Figure 1).

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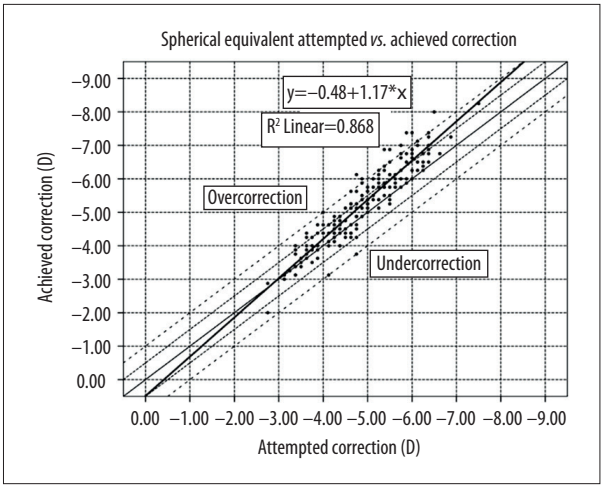

Figure 1. Linear regression analysis of the SE attempted correction against the SE achieved correction 3 months postoperatively in group 1. The relationship between the attempted correction and achieved correction is high (correlation coefficient=0.868, *P*<0.01), and there is a slight overcorrection in the achieved SE refraction.

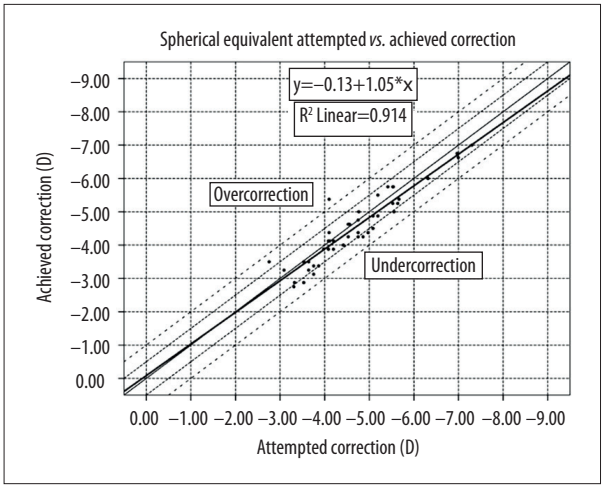

Figure 2. Linear regression analysis of the SE attempted correction against the SE achieved correction 3 months postoperatively in group 2. 82.61% (38/46) of eyes were within ±0.5 D of the intended refractive target and 97.83% (45/46) were within ±1.0 D 3 months after surgery.

Table 2. The regression analysis results of the relationship between the age, pre-SE, CP, CCT and the error in SE correction.

Model	b	SE b	B	Adjusted R^2	*P* value
First step					
Constant	–0.960	1.201		0.789	0.425
Age	–0.003	0.005	–0.044		0.527
Pre-SE	0.135	0.033	0.287		0.000
CP	0.015	0.022	0.050		0.486
CCT	0.001	0.001	0.079		0.267
Final step					
Constant	0.259	0.050		0.780	0.087
Pre-SE	0.133	0.033	0.283		0.000

P<0.05 means statistically significant; Pre-SE – preoperative SE; CP – corneal power; CCT – central corneal thickness.

In group 1, 70.25% (137/195) of eyes were within ±0.5 D of the intended refractive target and 95.90% (187/195) were within ±1.0 D at 3 months after surgery. The mean arithmetic error in SE correction was –0.34±0.43 D (median –0.25 D; range: –1.50 to 1.00 D), while the median absolute error of SE correction was 0.38 D (range: 0.00 to 1.50 D).

Multifactor regression analysis

The multifactor regression analyses results of the effects of operative parameter on predictability are summarized in Table 2. The results indicated that only preoperative SE (pre-SE) predicted changes in SE refractive error. Pre-SE increased by 1 diopter, and the refractive error was overcorrected by 0.113 D. The specific adjustments were derived in the new nomogram from the equation: SE error=0.259+0.113×$SE_{preoperative}$, or Adjusted Target SE correction=Target SE correction–(0.259+0.113×$SE_{preoperative}$).

Linear regression analysis in group 2

After applying the nomogram to adjust target SE correction in group 2, 82.61% (38/46) of eyes were within ±0.5 D of the intended refractive target and 97.83% (45/46) were within ±1.0 D at 3 months after surgery (Figure 2). The mean arithmetic error in SE refraction was –0.15±0.38 D (median: –0.50 D; range: –0.65 to 1.28 D), while the median absolute error was 0.30 D (range: 0.00 to 1.28 D).

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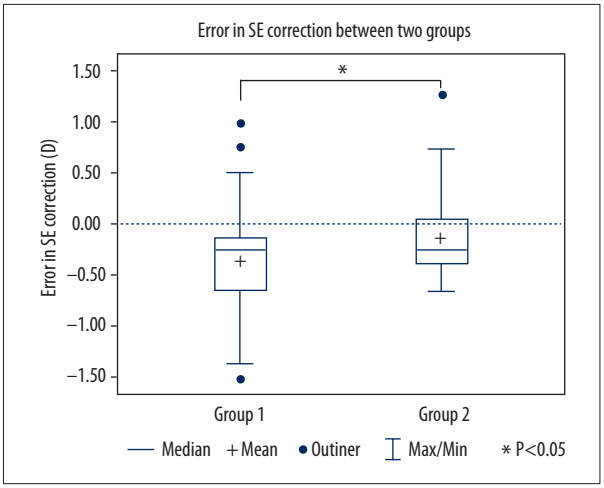

Figure 3. Boxplot showing the prediction of SE errors in 2 groups. A significant difference of the error in the SE correction between the 2 groups was seen.

In addition, there were significant differences of the error of SE correction between group 1 and group 2 (*P*=0.026, Mann-Whitney Test) (Figure 3), which indicated that the target SE correction can be better predicated by applying the nomogram.

Safety in group 1 and group 2

The visual recovery safety was compared between the 2 groups. Preoperative and postoperative (month 3) LogMAR CDVAs were –0.072±0.023, –0.076±0.016 in group 1, and -0.070±0.053, –0.079±0.055 in group 2, respectively. We found no significant difference between preoperative and postoperative (3 months after the surgery) CDVAs in either group (*P*=0.55, *P*=0.26, respectively). In addition, the safety index was 1.00±0.14 in group 1 and 1.02±0.15 in group 2, respectively. There was no significant difference in the safety index between the 2 groups (*P*=0.56) (Table 3).

Efficacy in group 1 and group 2

The visual recovery efficacy was compared between the 2 groups. At 3 months postoperatively, LogMAR UDVA was –0.064 ±0.065 in group 1 and –0.077±0.060 in group 2. The change of UDVA before surgery and 3 months after surgery was 0.008±0.069 in group 1 and –0.001±0.0065 in group 2. There was a significant difference in the UDVA change between the 2 groups (*P*<0.05) (Table 4).

The efficacy index was 1.00±0.16 in group 1 and 1.01±0.16 in group 2. There was no significant difference in efficacy index between the 2 groups (Table 4).

In group 1, all eyes had CDVA of 20/20 or better preoperatively; 78.97% (154/195) of the eyes had UDVA of 20/20 or better at 1 day after the operation, 96.92% (189/195) at 1 week after the operation, 97.95% (191/195) at 1 month after the operation, and 93.84% (183/195) at 3 months after the operation. In group 2, 86.96% (40/46) of the eyes had CDVA of 20/20 or better at 1 day after the operation, and 97.83% (45/46) of eyes at 1 week, 1 month, and 3 months after the operation.

Table 3. The safety analysis.

	LogMAR CDVA	P value	Safety index	*P* value
Group 1 pre	–0.072±0.023	0.550	1.00±0.14	
Group1 post	–0.076±0.016			0.560
Group 2 pre	–0.070±0.053	0.260	1.02±0.15	
Group 2 post	–0.079±0.055			

Pre – preoperative; post :– postoperative; LogMAR CDVA – the Logarithm of the Minimum Angle of Resolution corrected distance visual acuity.

Table 4. The efficacy analysis.

	LogMAR UDVA	Efficacy index	*P* value
Group 1 post	–0.064±0.065	1.00±0.16	
Group 1 post-pre	0.008±0.069		P>0.05
Group 2 post	–0.077±0.060	1.01±0.16	
Group 2 post-pre	–0.001±0.0065*		

Post – postoperative; post-pre – postoperative *vs.* preoperative; logMAR UDVA – the Logarithm of the Minimum Angle of Resolution uncorrected distance visual acuity. * *P*<0.05 *vs.* Group 1 post-pre.

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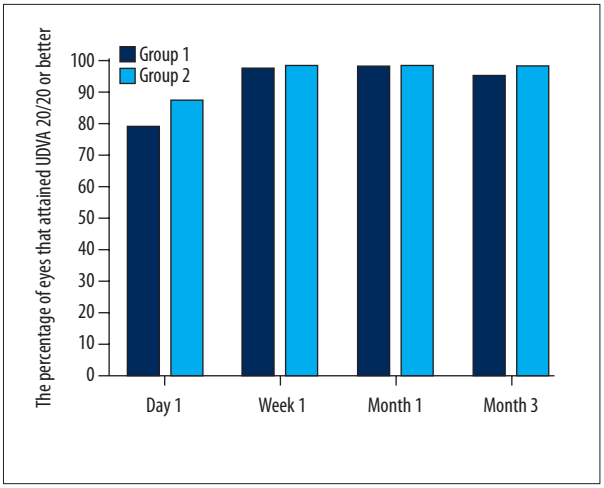

Figure 4. A histogram illustrating the percentage of eyes that reached UDVA of 20/20 or better after SMILE surgery in the 2 groups. There is no significant difference of the cumulative percentages of 20/20 or better CDVA postoperatively between the 2 groups at any indicating time points.

More eyes in group 1 had 20/20 or better UDVA than in group 2 at 1 day after the operation; however, no significant difference was found between them (P=0.187, Pearson's chi-square test). In addition, there is no significant difference of the cumulative percentages of 20/20 or better CDVA postoperatively between the 2 groups (Figure 4).

Disscussion

We conducted the current study to investigate the correlations between the operative parameters and the predictability of SMILE surgery. The findings indicate that the nomogram used in this study resulted in good eye refraction outcomes within 3 months after the operation. This study found the nomogram could be used in SMILE surgery.

There is mounting evidence demonstrating that the promising clinical outcomes of SMILE are comparable to those of femtosecond LASIK [7,16–18]. During the learning phase, mini-adjustments based on manufacturer's suggestions or experts' experiences are often implemented to get more accurate refraction results. Liyanage et al. [19] reported that factors such as Wavefront SE and central pachymetry could affect visual outcomes after femtosecond LASIK using multifactor regression analysis and established the model for analyzing the nomogram to achieve target SE. Allan et al. [20] also described a new multiple regression–derived nomogram to guide adjustments to the treatment cylinder alongside nomograms designed to optimize postoperative SE results in myopic LASIK procedure. Previous studies used the nomograms to achieve more precise target SE from the refractive surgery. The preoperative design for SMILE is similar to LASIK, thus the operative parameters of age, CP, CCT, and preoperative manifest refraction should be considered as the factors influencing the SE correction errors or the risk of enhancement surgery. Hjortdal et al. [21] reported that age, CP, sex (female), and eye (left) were predictors that could influence SE correction errors in the SMILE procedure. According to Kim et al. [22], however, none of these factors were the predictors that influenced SE correction errors. In the present study, the calculation suggested that preoperative SE was the only factor to influence the SE correction errors. Until now, there has been no nomogram available for the SMILE procedure to improve the predictability of SE correction in the Chinese population. This study evaluated a new multiple-regression analysis-based nomogram for myopic SMILE procedure that incorporated a simple method of refining target refraction results by calculation of preoperative parameter. The R2 values of linear regression between the achieved and attempted SE correction were 0.868 in group 1 and 0.914 in group 2, respectively, and the errors in SE correction were also significantly different in the 2 groups. Previous studies found the predictability of SMILE procedure ranged widely from 77% to 100% of eyes within 0.50 D and 94.2% to 100% of eyes within 1.00 D of the attempted refraction [6,17,21,23–26]. This study determined the predictability to be 70.25% of eyes within 0.50 D and 95.90% within 1.00 D, which was slightly lower than in previous studies. The discrepancy could be explained by the surgeons' techniques. Overcorrection was found in our study, especially with increasing attempt treatment, and it was also caused by the inexperienced surgeons who prefer the overcorrection to the under-corrected design. After utilizing the nomogram, the predictability improved to 82.61% and 97.83% of eyes being within 0.50 D and 1.00 D of the attempted SE correction, respectively.

As to the stability and efficacy, Vestergaard et al. [17] reported that the logMAR CDVA was –0.03±0.07 and 95% of eyes had UDVA of 20/40 or more 3 months postoperatively. Kamilya et al. [26] reported that the LogMAR UDVA and CDVA were –0.16±0.11 and –0.22±0.07, respectively, 1 year postoperatively. Correspondingly, the findings of this study showed that a LogMAR UDVA of –0.064±0.065 in group 1 at 3 months postoperatively. In group 2, the UDVA of –0.077±0.060 showed similar results with group 1. Hjortdal *et al.* also stated that the safety and efficacy indices were 1.07±0.22 and 0.90±0.25 at month 3 postoperatively, while Sekundo et al. reported safety and efficacy indices of 1.08 and 0.99, respectively. This study's safety and efficacy indices in this research were 1.00±0.14, 1.02±0.15 in group 1 and 1.00±0.16, 1.01±0.16 in group 2. These results indicated that the nomogram adjustment did not impact the safety and efficacy of the surgery.

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However, there are several limitations in our study. One is that both eyes of every patient were included in this study. Because of the compounding (correlation) of data between bilateral eyes, it is better to include only 1 eye of each patient in the study [27]. Analyses were performed on either eye and showed similar outcomes, but only half of the data were included in previous one-eye studies. Hjortdal et al. [21] had indicated that the correction was associated with a small worsening in CDVA in left eyes compared with right eyes. The small sample size is another limitation. A larger sample size could help identify more accurate predictors and regression formulas to the personalized SMILE procedure. In addition, the long-term stability of SMILE surgery was not evaluated in this study. Pedersen found that 82% and 93% of the eyes were within 0.50 D and 1.00 D, respectively, at 3 months postoperatively, while 78% and 90% were within 1.00 D of the attempted refraction at 3 years postoperatively [28], indicating that the long-term stability of SMILE can decrease. Therefore, a long-term follow-up study is necessary to confirm whether refractive regression occurs months or years after the surgery. Advanced investigation of the relationship between the refractive regression and surgical parameters is needed to determine the final accuracy of the refraction. There are many factors affecting the refraction, such as lenticule diameter, anterior chamber depth, axial length, white-to-white distance, and other corneal biomechanics or ocular surface parameters, and we only addressed the pre-SE in this work. The lenticule diameter varies among different surgeons, even in the same case, so it is not a preferred predicator. The anterior chamber and axial length are more relevant to refractive stability and may be included in future advanced long-term investigations. Discussion of femtosecond laser system error and other inherent errors needs to be considered in further studies.

Conclusions

In conclusion, SMILE surgery using the novel nomogram can be beneficial for the correction of myopia and shows significant improvement of predictability throughout the 3-month follow-up period. It is worth noting that the nomogram used in this study is not available to other surgeons. In addition, patient diversity [21] may influence eye biometric parameters, which would demand special design. We suggest that surgeons use this approach to enhance the results of their SMILE procedures.

Conflicts of interest

None.

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