


# VISULYZE-Generated Nomogram-Assisted KLEx for Myopia and Astigmatism Correction: 3-Month Follow-Up Results

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**Purpose:** To evaluate the efficacy, safety, and predictability of Keratorefractive Lenticule Extraction (KLEx) surgery guided by a VISULYZE-generated nomogram for myopia and astigmatism correction.

**Methods:** This prospective cohort study included 130 consecutive patients (260 eyes) undergoing KLEx surgery using a VISULYZE-generated nomogram. Patients were followed for 3 months postoperatively. The primary outcome measures were uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and spherical equivalent (SE). “Nine Standard Graphs” were generated using VISULYZE software and analyzed according to international standards for evaluating the quality of corneal refractive surgery. Subgroup analyses based on age ( $\leq 30$  years vs  $> 30$  years) and preoperative SE ( $\leq -6.00$  D vs  $> -6.00$  D) were performed.

**Results:** At 3 months postoperatively, 96% of eyes achieved UDVA of 20/20 or better, and 96.2% maintained or improved CDVA compared to preoperatively. No eyes lost 1 or more lines of CDVA. The correlation coefficient ( $R^2$ ) between attempted and achieved SE was 0.9732. 98.1% of eyes were within  $\pm 0.50$  D of the attempted SE. 99.2% of eyes achieved a postoperative cylinder  $\leq 0.50$  D. Subgroup analysis revealed that older patients ( $> 30$  years) had slightly lower UDVA compared to younger patients, while high myopes ( $\leq -6.00$  D) showed a trend towards slight under-correction and lower efficacy compared to moderate and low myopes. However, astigmatism correction was comparable between subgroups.

**Conclusion:** KLEx surgery guided by a VISULYZE-generated nomogram demonstrates excellent efficacy, safety, and predictability for myopia and astigmatism correction. While age and preoperative myopia degree may subtly influence efficacy, the nomogram provides a valuable tool for personalized surgical planning. Further research is warranted to refine nomogram development, particularly for older and highly myopic patients.

**Keywords:** KLEx, nomogram, refractive surgery, VISULYZE

## Introduction

Refractive surgery, a significant branch of modern ophthalmic medicine, is continuously advancing the field of myopia and astigmatism correction through technological innovation. Among the various surgical techniques, Keratorefractive Lenticule Extraction (KLEx) has emerged as a mainstream choice for refractive correction due to its unique technological advantages.<sup>1,2</sup> Compared to traditional laser vision correction surgeries, KLEx, with its innovative lenticule design and small incision technique, achieves true minimally invasive operation. Furthermore, its flapless nature significantly reduces the risk of postoperative corneal biomechanical changes and complications, providing patients with faster visual recovery and more stable long-term outcomes.<sup>3–5</sup>

However, clinical practice reveals that accurately predicting postoperative refractive status remains challenging, even with advanced surgical techniques. This is primarily because personalized settings of surgical parameters require comprehensive consideration of multiple factors, including but not limited to the patient's corneal characteristics, refractive error, and age-related accommodative ability.<sup>6</sup> Currently, Nomogram adjustment, a critical step in personalized surgical planning, relies heavily on the clinical experience of the surgeon for parameter setting and lacks a unified

quantitative standard.<sup>7–9</sup> This subjective dependence can lead to postoperative refractive deviations, affecting the optimization of visual quality.

Addressing this clinical challenge, ZEISS has developed the VISULYZE intelligent analysis software. This platform, based on big data analysis and machine learning algorithms, integrates multi-dimensional clinical parameters to generate personalized Nomogram suggestions through quantitative analysis. Its core value lies in: first, reducing human bias through standardized data processing; second, comprehensively considering device characteristics, surgical habits, and individual patient differences; and finally, providing evidence-based decision support to enhance the scientific validity and reproducibility of surgical plans.

This study employs a prospective, controlled design to systematically evaluate the clinical outcomes of KLEx surgery guided by a VISULYZE-Nomogram. Through rigorous study design and data analysis, we aim to provide new scientific evidence for personalized refractive surgery and validate the potential of VISULYZE software in improving postoperative refractive accuracy and patient satisfaction. We anticipate that this research will offer valuable insights for clinical practice, optimize surgical precision and safety, and serve as a reference for the future development of refractive surgical techniques.

## Methods

### Study Design

This study was a prospective cohort study that enrolled 130 consecutive cases (260 eyes) undergoing KLEx surgery assisted by a VISULYZE-generated Nomogram at the Refractive Surgery Center of West China Hospital, Sichuan University, from August 2024 to April 2025, with a 3-month follow-up. The study protocol was approved by the Ethics Committee of West China Hospital, Sichuan University. All subjects signed written informed consent forms, and the study adhered to the principles of the Declaration of Helsinki. Inclusion criteria were: 1) age 18–45 years; 2) myopic spherical equivalent (SE)  $-1.00$  to  $-10.00$  D, astigmatism  $\leq -2.00$  D; 2) central corneal thickness  $\geq 480$   $\mu\text{m}$ , estimated postoperative residual stromal bed thickness  $\geq 280$   $\mu\text{m}$ ; 3) preoperative best-corrected visual acuity (BCVA, LogMAR)  $\leq 0$ . Exclusion criteria were: 1) keratoconus or abnormal corneal topography; 2) active ocular diseases (eg, dry eye syndrome, keratitis); 3) systemic diseases affecting wound healing (eg, autoimmune diseases, diabetes); and 4) pregnancy or lactation.

### VISULYZE-Generated Nomogram

ZEISS VISULYZE software (version 1.1) was used to construct the Nomogram prediction model. The training dataset consisted of clinical data from 169 patients (339 eyes) who underwent KLEx surgery at our center from December 2022 to May 2023 and completed a 3-month follow-up, including preoperative refractive error, postoperative actual correction effect, etc. Through linear regression analysis, a functional relationship between the refractive adjustment value and preoperative parameters was established (model fit  $Y = 0.9436 * X$ ;  $R^2 = 0.996$ ), generating a personalized Nomogram chart to guide the setting of laser parameters for new cases.

### Surgical Procedures

All surgeries were performed by the same surgical team. The surgical technique strictly followed the classic KLEx scanning steps and lenticule extraction specifications required by the VisuMax femtosecond laser system (Carl Zeiss, Germany). The brief operating process was as follows: corneal apex positioning with fixation light  $\rightarrow$  initiation of negative pressure suction  $\rightarrow$  creation of posterior surface  $\rightarrow$  sidecut creation  $\rightarrow$  creation of anterior surface  $\rightarrow$  incision creation  $\rightarrow$  release of negative pressure  $\rightarrow$  dissection and extraction of corneal lenticule. The laser scanning system (VisuMax, Carl Zeiss, Germany) was set to a 500 kHz repetition rate and a pulse energy of 130–160 nJ. The corneal cap diameter was 8 mm, and the thickness was 110–130  $\mu\text{m}$ ; the lenticule diameter was 6.0–6.8  $\mu\text{m}$ . Specific parameters were adjusted according to pupil diameter, corneal thickness, and spherical equivalent. Routine perioperative medication regimen included: preoperative use of antibiotic eye drops (0.5% levofloxacin, Santen Pharmaceutical, Japan) and preservative-free artificial tears (0.1% sodium hyaluronate, Ursapharm, Germany) four times daily for 3 days.

Immediately after surgery, antibiotic (0.3% tobramycin, Alcon, Belgium) and steroid eye drops (0.1% tobramycin dexamethasone, Alcon, Belgium) were used. 0.1% sodium hyaluronate artificial tears were used four times daily for 3 months postoperatively; steroid eye drops were initially used four times daily and tapered once weekly until discontinued at 1 month; antibiotics were continued for 1 week.

## Statistical Analysis

VISULYZE software (V1.1) and R software (version 4.2.2) were used for data processing. “Nine Standard Graphs” were generated with reference to the international standards for evaluating the quality of corneal refractive surgery, including: Accuracy: the percentage of eyes with postoperative SE within  $\pm 0.50$  D and  $\pm 1.00$  D; Efficacy: the percentage of eyes with uncorrected distance visual acuity (UDVA)  $\geq$  preoperative corrected distance visual acuity (CDVA); Safety: change in postoperative CDVA compared to preoperative level (loss/gain  $\geq 1$  line); Predictability: linear regression analysis ( $R^2$ ) of actual SE vs target SE. Normally distributed continuous data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ). Paired t-tests were used for intergroup comparisons. For categorical variables, statistical descriptions of count data were performed with the composition ratio, and comparisons were performed using the chi-square test or Fisher’s exact test. A P-value  $< 0.05$  was considered statistically significant for all analyses.

## Results

### Baseline Data

A total of 260 eyes of myopic patients who underwent KLEx surgery assisted by the VISULYZE-generated Nomogram were included in this study. The average age of the patients was  $27.32 \pm 4.51$  years (range: 18–35 years). In terms of gender distribution, females accounted for 66.9% (87 cases) and males accounted for 33.1% (43 cases). Right eyes (OD) accounted for 50.4% (131 eyes), and left eyes (OS) accounted for 49.6% (129 eyes). Preoperative sphere (SPH) was  $-4.78 \pm 1.44$  D (range:  $-8.2$  D to  $-0.5$  D), cylinder (CYL) was  $-0.62 \pm 0.43$  D (range:  $-1.8$  D to 0 D), and axis (AX) was  $112.59 \pm 70.97$  degrees (range: 0 degrees to 180 degrees). Preoperative uncorrected distance visual acuity (UDVA) was  $1.21 \pm 0.23$  (range: 0.4 to 2), and best-corrected distance visual acuity (CDVA) was  $0.00 \pm 0.01$  (range:  $-0.1$  to 0.1). The surgical optical zone diameter was  $6.38 \pm 0.19$  mm (range: 6.0 to 6.5 mm). Postoperative 3-month uncorrected distance visual acuity (Post\_UDVA) was  $-0.05 \pm 0.06$  (range:  $-0.2$  to 0.1), and best-corrected distance visual acuity (Post\_CDVA) was  $-0.06 \pm 0.05$  (range:  $-0.2$  to 0.1) (Table 1).

**Table 1** Preoperative Patient Demographics

	Level	Overall	Range
N (eye)		260	
Age (years) (mean (SD))		27.32 (4.51)	(18, 35)
Gender (%)	f	87 (66.9)	
	m	43(33.1)	
Eye (%)	OD	131 (50.4)	
	OS	129 (49.6)	
SPH(D) (mean (SD))		$-4.78$ (1.44)	( $-8.2$ , $-0.5$ )
CYL (D)(mean (SD))		$-0.62$ (0.43)	( $-1.8$ , 0)
AX (mean (SD))		112.59 (70.97)	(0, 180)
UDVA (logMar)(mean (SD))		1.21 (0.23)	(0.4, 2)
CDVA (logMar) (mean (SD))		0.00 (0.01)	( $-0.1$ , 0.1)
Optical Zone(mm) (mean (SD))		6.38 (0.19)	(6, 6.5)
Post_UDVA (logMar) (mean (SD))		$-0.05$ (0.06)	( $-0.2$ , 0.1)
Post_CDVA(logMar) (mean (SD))		$-0.06$ (0.05)	( $-0.2$ , 0.1)

**Abbreviations:** SPH, spherical lens; CYL, cylinder; AX, axis; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity.

## Postoperative 3-Month Follow-Up Results

The VISULYZE software visualized the refractive results in Nine Standard Graphs (Figure 1), showing that 96% of eyes achieved a UDVA of 20/20 or better at three months postoperatively (Figure 1A), and 96.2% of eyes maintained or improved compared to preoperative CDVA (Figure 1B). Safety analysis showed that no eyes lost 1 line or more of CDVA compared to preoperative levels (Figure 1C). Predictability analysis showed that the correlation coefficient  $R^2$  between the actual corrected SE and the attempted corrected eyes SE at three months postoperatively was 0.9732 (Figure 1D). 98.1% of eyes had a postoperative SE within  $\pm 0.50D$  (Figure 1E). The average SE observed at the 3-month follow-up was 0.03D (Figure 1F). In addition, three months postoperatively, 99.2% of eyes had CYL  $\leq 0.50D$  (Figure 1G). The correlation coefficient  $R^2$  between the actual corrected CYL (D) and the attempted corrected CYL (D) was 0.8552 (Figure 1H), and 80.3% of eyes had an astigmatism axis deviation within  $-5$  to  $5$  degrees (Figure 1I).

## Age-Based Subgroup Analysis

Patients were divided into two groups based on age:  $\leq 30$  years group (n=202 eyes) and  $>30$  years group (n=58 eyes). The average age in the  $\leq 30$  years group was  $25.65 \pm 3.63$  years, and the average age in the  $>30$  years group was  $33.07 \pm 1.37$  years.



**Figure 1** VISULYZE-generated Nomogram for assisting refractive outcomes 3 months after Keratorefractive Lenticule Extraction (KLEx) surgery: (A) Efficacy, proportion of postoperative uncorrected distance visual acuity (UDVA); (B) Comparison of postoperative UDVA and corrected distance visual acuity (CDVA); (C) Safety, comparison of preoperative and postoperative CDVA; (D) Predictability, correlation between target correction and actual correction in spherical equivalent (SE); (E) Accuracy, proportion of eyes with postoperative SE within  $\pm 0.50 D$  and  $\pm 1.00 D$ ; (F) Stability, showing changes in SE over time postoperatively; (G) Astigmatism, reflecting residual astigmatism in postoperative refractive examination; (H) Predictability, correlation between target astigmatism correction and actual astigmatism correction; (I) Error in astigmatism axis angle.

There were no statistically significant differences between the two groups in gender, eye, preoperative sphere, preoperative axis, preoperative uncorrected visual acuity, preoperative best-corrected visual acuity, or surgical optical zone ( $p>0.05$ ). However, there was a statistically significant difference in preoperative cylinder between the two groups ( $p=0.022$ ), with the  $\leq 30$  years group averaging  $-0.65 \pm 0.44$  D and the  $>30$  years group averaging  $-0.52 \pm 0.38$  D. There was a statistically significant difference in postoperative 3-month uncorrected visual acuity between the two groups ( $p<0.001$ ), with the  $\leq 30$  years group at  $-0.06 \pm 0.06$  and the  $>30$  years group at  $-0.02 \pm 0.06$ . However, there was no statistically significant difference in postoperative 3-month best-corrected visual acuity between the two groups ( $p>0.05$ ) (Table 2).

The proportion of eyes achieving UDVA  $\geq 20/20$  in the two groups was 97% in the  $\leq 30$  years group and 91% in the  $>30$  years group ( $P=0.09$ ) (Figures 2A and 3A). The proportion of eyes with UDVA maintained or improved relative to preoperative CDVA was 97.5% in the  $\leq 30$  years group and 91.4% in the  $>30$  years group ( $P=0.16$ ) (Figures 2B and 3B). The proportion of eyes losing two lines of postoperative CDVA was 0% in both groups (Figures 2C and 3C). The correlation  $R^2$  between actual and target SE (D) was 0.9809 in the  $\leq 30$  years group and 0.9368 in the  $>30$  years group (Figures 2D and 3D). The proportion of eyes with postoperative SE within  $\pm 0.50$ D was 99% in the  $\leq 30$  years group and 94.8% in the  $>30$  years group ( $P=0.10$ ) (Figures 2E and 3E); The average SE value observed during the 3-month follow-up was 0.05D in the  $\leq 30$  years group and  $-0.03$  D in the  $>30$  years group (Figures 2F and 3F). Postoperative astigmatism correction analysis showed that 99% of eyes in the  $\leq 30$  years group had CYL  $\leq 0.50$ D, while 100% of eyes in the  $>30$  years group had CYL  $\leq 0.50$ D (Figures 2G and 3G). The  $R^2$  for actual versus target CYL was 0.8491 for the  $\leq 30$  age group and 0.8769 for the  $>30$  age group (Figures 2H and 3H). The proportion of eyes with astigmatism axis deviation within  $-5$  to  $5$  degrees was 81.9% in the  $\leq 30$  years group and 74.5% in the  $>30$  years group ( $P=0.13$ ) (Figures 2I and 3I).

## Spherical Equivalent (SE)-Based Subgroup Analysis

Patients were divided into two groups based on preoperative SE:  $\leq -6.00$  D group ( $n=109$  eyes) and  $>-6.00$  D group ( $n=151$  eyes). The average SE in the  $\leq -6.00$  D group was  $-6.66 \pm 0.63$  D, and the average SE in the  $>-6.00$  D group was  $-4.22 \pm 1.09$  D. There were no statistically significant differences between the two groups in age, gender, eye, preoperative cylinder, preoperative axis, postoperative 3-month uncorrected visual acuity, and postoperative 3-month best-corrected visual acuity ( $p>0.05$ ). However, there was a statistically significant difference in preoperative uncorrected visual acuity between the two groups ( $p<0.001$ ), with the  $\leq -6.00$  D group averaging  $1.47 \pm 0.26$  and the  $>-6.00$  D group averaging  $1.13 \pm 0.14$ . In addition, there was also a statistical difference between the two groups in surgical optical zone ( $p<0.001$ ), with the  $\leq -6.00$  D group averaging  $6.28 \pm 0.20$  mm and the  $>-6.00$  D group averaging  $6.41 \pm 0.17$  mm (Table 3).

**Table 2** Comparison of Baseline Information Between the Younger Group ( $\leq 30$  Years) and the Older Group ( $>30$  Years)

Variables	Level	Age $\leq 30$	Age $>30$	p
N (eye)		202	58	
Age(years)		25.65 $\pm$ 3.63	33.07 $\pm$ 1.37	<0.001
Gender	f	65 (64.3)	22 (75.9)	0.121
	m	36 (35.9)	7 (24.1)	
Eye	OD	102 (50.5)	29 (50.0)	1.000
	OS	100 (49.5)	29 (50.0)	
SPH(D)		$-4.81 \pm 1.48$	$-4.66 \pm 1.30$	0.442
CYL(D)		$-0.65 \pm 0.44$	$-0.52 \pm 0.38$	0.022
AX		116.15 $\pm$ 71.12	100.56 $\pm$ 69.77	0.154
UDVA(logMar)		1.22 $\pm$ 0.24	1.18 $\pm$ 0.16	0.148
CDVA(logMar)		0.00 $\pm$ 0.02	0.00 $\pm$ 0.00	NaN
Optical.Zone(mm).		6.37 $\pm$ 0.19	6.41 $\pm$ 0.17	0.142
Post_UDVA(logMar).		$-0.06 \pm 0.06$	$-0.02 \pm 0.06$	<0.001
Post_CDVA(logMar).		$-0.07 \pm 0.05$	$-0.06 \pm 0.05$	0.189

**Abbreviations:** SPH, spherical lens; CYL, cylinder; AX, axis; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; N/A, not applicable.



**Figure 2** Refractive outcomes 3 months after Keratorefractive Lenticule Extraction (KLEx) surgery in patients aged  $\leq 30$  years: (A) Efficacy, proportion of postoperative uncorrected distance visual acuity (UDVA); (B) Comparison of postoperative UDVA and corrected distance visual acuity (CDVA); (C) Safety, comparison of preoperative and postoperative CDVA; (D) Predictability, correlation between target correction and actual correction in spherical equivalent (SE); (E) Accuracy, proportion of eyes with postoperative SE within  $\pm 0.50 D$  and  $\pm 1.00 D$ ; (F) Stability, showing changes in SE over time postoperatively; (G) Astigmatism, reflecting residual astigmatism in postoperative refractive examination; (H) Predictability, correlation between target astigmatism correction and actual astigmatism correction; (I) Error in astigmatism axis angle.

The proportion of eyes achieving UDVA  $\geq 20/20$  in the two groups was 93% in the  $\leq -6.00 D$  group and 98% in the  $> -6.00 D$  group ( $P=0.024$ ) (Figures 4A and 5A). The proportion of eyes with UDVA maintained or improved relative to preoperative CDVA was 92.7% in the  $\leq -6.00 D$  group and 98.7% in the  $> -6.00 D$  group ( $P=0.004$ ) (Figures 4B and 5B). The proportion of eyes losing two lines of postoperative CDVA was 0% in both groups (Figures 4C and 5C). The correlation  $R^2$  between actual and target SE (D) was 0.9051 in the  $\leq -6.00 D$  group and 0.9438 in the  $> -6.00 D$  group (Figures 4D and 5D). 97.2% of eyes in the  $\leq -6.00 D$  group had postoperative SE within  $\pm 0.50D$ ; while 98.7% of eyes in the  $> -6.00 D$  group had postoperative SE within  $\pm 0.50D$  ( $P=0.39$ ) (Figures 4E and 5E). The average SE value observed during the 3-month follow-up was  $-0.04D$  in the  $\leq -6.00 D$  group and  $0.08 D$  in the  $> -6.00 D$  group (Figures 4F and 5F). Postoperative astigmatism correction analysis showed that 100% of eyes in the  $\leq -6.00 D$  group had CYL  $\leq 0.50D$ , while 98.7% of eyes in the  $> -6.00 D$  group had CYL  $\leq 0.50D$  (Figures 4G and 5G). The  $R^2$  for actual versus target CYL was 0.8537 for the  $\leq -6.00 D$  group and 0.8559 for the  $> -6.00 D$  group (Figures 4H and 5H). The proportion of eyes with



**Figure 3** Refractive outcomes 3 months after Keratorefractive Lenticule Extraction (KLEx) surgery in patients aged >30 years: **(A)** Efficacy, proportion of postoperative uncorrected distance visual acuity (UDVA); **(B)** Comparison of postoperative UDVA and corrected distance visual acuity (CDVA); **(C)** Safety, comparison of preoperative and postoperative CDVA; **(D)** Predictability, correlation between target correction and actual correction in spherical equivalent (SE); **(E)** Accuracy, proportion of eyes with postoperative SE within  $\pm 0.50$  D and  $\pm 1.00$  D; **(F)** Stability, showing changes in SE over time postoperatively; **(G)** Astigmatism, reflecting residual astigmatism in postoperative refractive examination; **(H)** Predictability, correlation between target astigmatism correction and actual astigmatism correction; **(I)** Error in astigmatism axis angle.

astigmatism axis deviation within  $-5$  to  $5$  degrees was 79.6% in the  $\leq -6.00$  D group and 80.8% in the  $> -6.00$  D group ( $P=0.45$ ) (Figures 4I and 5I).

## Discussion

Numerous international studies have demonstrated that KLEx surgery exhibits excellent safety, efficacy, and stability in short-term and long-term observations.<sup>10,11</sup> This procedure is favored for its minimally invasive nature and rapid recovery. However, to further improve the accuracy of KLEx surgery, preoperative parameter adjustment is crucial. Nomograms are considered an indicator to improve the accuracy of KLEx, but their quantitative standards have not been unified and are mainly based on the experience of the surgeon.<sup>8,12</sup> Literature reports show that the Nomogram values used by surgeons range from 5% to 10%,<sup>13</sup> and due to their uncertainty, refractive deviations occur after KLEx surgery.

This study is the first to introduce a ZEISS VISULYZE software-generated Nomogram in a standardized manner to guide KLEx surgery, aiming to improve refractive accuracy through scientific data analysis. Our primary outcome

**Table 3** Comparison of Baseline Information Between the High Myopia Patients ( $SE \leq -6.00$  D) Group and the Moderate and Low Myopia Patients ( $SE > -6.00$  D) Group

Variables	Level	SE $\leq$ -6D	SE $>$ -6D	p
N(eye)		109	151	
Age(years).		27.08 $\pm$ 4.32	27.38 $\pm$ 4.56	0.652
Gender	f	34 (61.8)	53(70.6)	0.289
	m	21 (48.2)	22 (29.4)	
Eye	OD	44 (40.3)	87 (57.6)	0.336
	OS	65 (59.7)	64 (42.4)	
SPH(D)		-6.66 $\pm$ 0.63	-4.22 $\pm$ 1.09	<0.001
CYL(D)		-0.65 $\pm$ 0.46	-0.61 $\pm$ 0.42	0.545
AX		125.27 $\pm$ 70.92	108.76 $\pm$ 70.73	0.134
UDVA(logMar).		1.47 $\pm$ 0.26	1.13 $\pm$ 0.14	<0.001
CDVA(logMar).		0.00 $\pm$ 0.02	0.00 $\pm$ 0.01	0.194
Optical.Zone(mm).		6.28 $\pm$ 0.20	6.41 $\pm$ 0.17	<0.001
Post_UDVA(logMar).		-0.05 $\pm$ 0.06	-0.05 $\pm$ 0.06	0.396
Post_CDVA(logMar).		-0.06 $\pm$ 0.05	-0.07 $\pm$ 0.05	0.164

**Abbreviations:** SPH, spherical lens; CYL, cylinder; AX, axis; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity.

measures indicate that VISULYZE-Nomogram-assisted KLEx surgery demonstrated good postoperative results. In the overall data, 96% of eyes achieved a UDVA of 20/20 or better at three months postoperatively, and 96.2% of eyes maintained or improved compared to preoperative CDVA. Safety analysis showed that no eyes lost 1 line or more of CDVA compared to preoperative levels. Predictability analysis showed that the correlation coefficient  $R^2$  between the actual corrected SE and the attempted corrected SE at three months postoperatively was 0.9732, 98.1% of eyes had a postoperative SE within  $\pm 0.50$ D, and the average SE observed at the 3-month follow-up was 0.03D. In addition, three months postoperatively, 99.2% of eyes had CYL  $\leq 0.50$ D, the correlation coefficient  $R^2$  between the actual corrected CYL (D) and the attempted corrected CYL (D) was 0.8552, and 80.3% of eyes had an astigmatism axis deviation within  $-5$  to  $5$  degrees.

In the age-based subgroup analysis, we observed that although patients over 30 years of age had good accuracy and safety in postoperative refractive outcomes, their efficacy was slightly inferior to that of younger patients under 30 years of age. Specifically, the proportion of eyes achieving UDVA  $\geq 20/20$  was 97% in the younger group ( $\leq 30$  years) and 91% in the older group ( $> 30$  years) ( $P=0.09$ ). This difference suggests that age may have a certain impact on the efficacy of VISULYZE-Nomogram-assisted KLEx surgery. This observation is consistent with the previous research results of Laura Primavera et al, which suggested that the increase in corneal stromal stiffness in the elderly group changes the remodeling ability of the corneal stroma after KLEx, thereby affecting the refractive and visual response of KLEx.<sup>14</sup> In this study, although there were no significant differences in postoperative SE and CDVA between the two groups of patients, the difference in UDVA suggested that age-related changes in corneal biomechanical properties may have affected the final visual quality to a certain extent. This may be due to differences in the corneal remodeling process after surgery due to increased corneal hardness, which ultimately affects the recovery of uncorrected visual acuity.

Furthermore, in the sphere-based subgroup analysis, we found that there were no statistically significant differences in age, gender, postoperative 3-month uncorrected visual acuity, and postoperative 3-month best-corrected visual acuity ( $p>0.05$ ) between the high myopia patients ( $SE \leq -6.00$  D) group and the moderate and low myopia patients ( $SE > -6.00$  D) group. After KLEx surgery assisted by VISULYZE-Nomogram, the two groups of patients had comparable accuracy and safety. However, in terms of effectiveness, the effectiveness of the high myopia group seemed to be slightly inferior to that of the moderate and low myopia group (UDVA  $\geq 20/20$ : 93% vs 98%,  $P=0.024$ ). Further analysis of the scatter plot of the correlation between actual and target SE (D) showed that moderate and low myopia patients had a slight



**Figure 4** Refractive outcomes 3 months after Keratorefractive Lenticule Extraction (KLEx) surgery in high myopia patients (SPH $\leq$ -6.00 D): **(A)** Efficacy, proportion of postoperative uncorrected distance visual acuity (UDVA); **(B)** Comparison of postoperative UDVA and corrected distance visual acuity (CDVA); **(C)** Safety, comparison of preoperative and postoperative CDVA; **(D)** Predictability, correlation between target correction and actual correction in spherical equivalent (SE); **(E)** Accuracy, proportion of eyes with postoperative SE within  $\pm 0.50 D$  and  $\pm 1.00 D$ ; **(F)** Stability, showing changes in SE over time postoperatively; **(G)** Astigmatism, reflecting residual astigmatism in postoperative refractive examination; **(H)** Predictability, correlation between target astigmatism correction and actual astigmatism correction; **(I)** Error in astigmatism axis angle.

overcorrection trend 3 months postoperatively, while high myopia patients showed a slight undercorrection trend. This phenomenon suggests that high myopia may have a certain impact on the efficacy of VISULYZE-Nomogram-assisted KLEx surgery. Although VISULYZE-Nomogram aims to optimize the amount of correction, in patients with high myopia, its prediction and correction effects may be affected by factors such as corneal ablation depth and corneal biomechanical response, resulting in slight undercorrection in the final refractive outcome.<sup>15,16</sup>

It is worth noting that although subgroup analyses of age and sphere show potential differences in overall efficacy, astigmatism correction did not show significant differences in either subgroup. This may be related to the algorithmic advantages of VISULYZE-Nomogram in astigmatism correction, enabling it to predict and correct astigmatism in patients of different ages and refractive errors relatively stably. In addition, the patients included in this study had lower degrees of astigmatism (0–1.8D), which may have led to insignificant differences in the effect of astigmatism correction. Future studies should consider increasing the sample size of patients with higher degrees of astigmatism and conduct a more detailed analysis of astigmatism types and axes to more comprehensively evaluate the effect of VISULYZE-Nomogram in astigmatism correction.



## Ethics Approval

The extended study was approved by the Ethics Committee of West China Hospital and performed in accordance with the Declaration of Helsinki.

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## Disclosure

The authors report no competing interests for this work.

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