Original Article

Visual outcomes for the initial 500 eyes treated with keratorefractive lenticule extraction (KLEx) for myopia and myopic astigmatism at a single-site

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ABSTRACT

Background: Keratorefractive lenticule extraction (KLEx) has become a widely used corneal refractive surgery. Since its approval by the United States Food and Drug Administration (FDA), there are relatively few studies from large US cohorts that have evaluated visual outcomes beyond one year using KLEx for myopia and myopic astigmatism. Studies are often limited by their small sample size and short follow-up duration.

Methods: This was a retrospective study of 577 eyes from 314 patients who underwent KLEx between March 2017 and May 2024 at a single refractive surgery center. Inclusion criteria were myopia between - 9.25 and - 1.00 D, cylinder up to - 3.00 D, and preoperative corrected distance visual acuity (CDVA) of 20/20 or better. Uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, and complications were evaluated at 3 and 12 months postoperatively. Clinical outcomes were also compared to FDA premarket trials and large international cohorts.

Results: Of 577 treated eyes, data were available at 3 months for 511 eyes (88.6% follow-up) and 12 months for 440 eyes (76.3% follow-up). Mean spherical equivalent (SEQ) improved from - 5.35 ± 1.62 D (- 9.63 to - 1.38 D) to - 0.04 ± 0.44 D (- 1.88 to 1.88 D) ($P < 0.001$). Mean cylinder improved from - 0.66 ± 0.66 D (- 3.00 to 0.00 D) at baseline to - 0.40 ± 0.32 D (- 1.75 to 0.00 D) at 12 months ($P < 0.001$). Additionally, postoperative UDVA was 20/20 or better in 81% of eyes and 20/25 or better in 94% of eyes. Postoperative SEQ was within ± 0.50 D in 85% of eyes and within ± 1.00 D in 97% of eyes at 12 months. The SEQ remained stable across all postoperative visits, with a mean change of - 0.03 ± 0.38 D from 3 to 12 months. There was a gain of one line of CDVA in 16% of eyes at 12 months, with no eyes losing two or more CDVA lines. Target-induced and surgically induced astigmatism were strongly correlated at both 3 and 12 months, with a mean undercorrection of 20% by one year ($R^2 = 0.69$).

Conclusions: KLEx demonstrates predictable and safe correction of myopia and myopic astigmatism over 12 months in a US cohort. Visual outcomes meet or exceed FDA benchmarks and are consistent with published literature, although a potential need for improved cylindrical correction remains.

KEYWORDS

myopias, myopic astigmatism, nomogram, wavelight, refractive surgery, laser in situ keratomileusis, SMILE, ReLEx, KLEx, VisuMax

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INTRODUCTION

Keratorefractive lenticule extraction (KLEx) is a minimally invasive laser refractive surgery indicated for the treatment of myopia and myopic astigmatism. The small incision lenticule extraction (SMILE®) is a KLEx procedure that has become widely adopted since its approval by the U.S. Food and Drug Administration (FDA) in 2016 [1]. Compared to traditional laser-assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK), KLEx eliminates the creation of a flap or epithelial removal. Instead, KLEx uses the VisuMax 500 femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) to create an intrastromal lenticule, which is subsequently removed through a small incision [2]. The procedure has been associated with improved corneal structural stability, reduced disruption of corneal nerve fibers, and a lower incidence of dry eye compared to LASIK and PRK [3]. However, KLEx has notable drawbacks compared to traditional LASIK, including slower visual recovery and a steeper learning curve [4–6].

Despite its growing popularity, there remain relatively few studies from the United States that report visual outcomes following KLEx, often limited by their small sample size and short follow-up duration [7, 8]. The current literature primarily reflects large Asian and European cohorts with thousands of eyes and follow-ups extending beyond one year [6, 9, 10]. This gap highlights the need for large-scale US data to validate KLEx outcomes against FDA performance benchmarks and to provide meaningful comparisons with international cohorts. Therefore, the purpose of this study is to evaluate visual outcomes from 577 eyes that underwent KLEx at a single US site. We also compare our findings to those of large international cohorts and the FDA multicenter clinical trial [1, 8].

METHODS

This is a single-center retrospective study analyzing 577 eyes from 314 patients who underwent KLEx for myopia or myopic astigmatism in Draper, Utah, between March 2017 and May 2024. Full approval was granted by the Biomedical Research Alliance of New York Institutional Review Board (# A20-12-547-823). The study adhered to the tenets of the Declaration of Helsinki and HIPAA regulations were followed. All patients provided written informed consent prior to their inclusion in the study.

Inclusion criteria consisted of patients aged 18 years or older with myopia (- 9.25 to - 1.00 D) with or without astigmatism (- 3.00 to 0.00 D) in one or both eyes who underwent SMILE® using the VisuMax® 500, had a preoperative corrected distance visual acuity (CDVA) of 20/20 or better, and completed 3-month and 12-month postoperative evaluations. Patients were excluded if they had missing data at 3 and 12 months or clinically significant dry eyes, ocular disease, infectious or autoimmune disease, hyperopia, or hyperopic astigmatism.

Preoperative visits included a comprehensive ophthalmic examination, including uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, intraocular pressure measurement, slit-lamp biomicroscopy (Haag-Streit BQ 900; Haag-Streit AG, Koniz, Switzerland), dilated fundus examination, and keratometry. Corrected and uncorrected visual acuities were obtained by an optometrist using a Snellen chart (M&S Technologies Inc., Niles, IL, USA) displayed on a high-resolution screen at 4 meters. Corneal topography and pachymetry were assessed using the Pentacam HR (Oculus Optikgeräte GmbH, Wetzlar, Germany). Primary outcome measures included postoperative UDVA, CDVA, and manifest refraction assessed at 1-week, 1-month, 3-month, and 12-month follow-up examinations when data were available.

Visual and refractive outcomes were analyzed at 3 and 12 months postoperatively. Only eyes with data available at each follow-up were included; eyes lost to follow-up were excluded. Data were visualized using the nine standard graphs for reporting refractive surgery outcomes [11, 12]. Eyes targeted for monovision were excluded from the safety and efficacy graphs (parts A and B) of the nine standard graphs but were included for all other outcome assessments. Safety (the ratio of postoperative CDVA to preoperative CDVA) and efficacy indices (the ratio of postoperative UDVA to preoperative CDVA) were calculated [13]. The data were compared to FDA standards and relevant literature on KLEx visual outcomes.

Selection of published literature of KLEx: To identify articles relevant to KLEx with a sufficiently large sample size, we conducted a literature search using PubMed and Embase databases on 17 June 2025, with the following keywords: (“keratorefractive lenticule extraction” OR “KLEx” OR “small incision lenticule extraction” OR “SMILE®”) AND (“myopia” OR “astigmatism”) AND “visual outcome” (Tables 3 and 4).

Selection criteria were based on the following parameters: a sample size ≥ 95 eyes and visual outcomes, including safety, efficacy, predictability, and accuracy, were reported, plus a postoperative follow-up of at least 3 or 12 months. Studies were excluded if they were duplicates, reviews, case reports, animal studies, non-English-language, comparative, procedures performed with platforms other than VisuMax 500, or irrelevant to the study objective.

Two relevant studies meeting the criteria were excluded. The study by Ramirez-Miranda et al. was eligible for inclusion in our analysis [14], but all procedures were performed by cornea fellows-in-training. We decided to exclude the study, given the well-documented learning curve of KLEx [15]. Another eligible study, by Dishler et al., was excluded because it reported overlapping data that the FDA had already provided in the VisuMax 500 premarket approval study [8].

Surgical Technique: All KLEx procedures were conducted at a single site by two surgeons (M.M. and P.C.H.) using the VisuMax 500 kHz femtosecond laser system, with pulse durations ranging from 220 to 580 fs. Before surgery, limbal reference marks were made at the 3 and 9 o'clock positions with the patient seated upright. Intraoperatively, corresponding marks were placed just inside the limbus at the same clock positions. Careful attention was paid to detect any cyclotorsional eye movement following vacuum application. Manual rotational adjustments were made as needed, either clockwise or counterclockwise, to ensure alignment. Laser parameters were 3.93 mm superior corneal incision, 7.5 mm cap diameter, 120 μm cap thickness, 6.0–6.5 mm lenticule diameter, superior incision position, 90° side cut angle, and 50° incision angle. Laser-bed energy was set to 145 nJ with spot separations of 3 μm (lenticule), 2.5 μm (side-cut), 3 μm (cap), and 2 μm (incision side-cut).

For SMILE® performed on the VisuMax 500 kHz platform, we used an established nomogram that was originally developed using Datagraph-med version 5.80 (Datagraph, Chapel Hill, NC, USA) for the treatment of myopia and myopic astigmatism of ≤ 0.50 D cylinder. This nomogram increased the sphere by 7.5%, with no adjustments to the cylinder.

Postoperative management consisted of one drop of 0.5% moxifloxacin (Lifestar Pharma LLC, Mahwah, NJ, USA) ophthalmic solution in both eyes following the procedure. Patients continued moxifloxacin eye drops four times per day for one week and 1% prednisolone acetate (Lupin Pharmaceuticals, Inc., Baltimore, MD, USA) ophthalmic suspension drops four times per day for one week, then twice a day for one week, and then once a day for two weeks postoperatively. Preservative-free artificial tears (Allergan Inc., Irvine, CA, USA) were recommended as needed.

Descriptive statistics were calculated using IBM SPSS Statistics for Windows, version 30.0 (IBM Corp., Armonk, NY, USA). Values are reported as mean (standard deviation [SD]) for continuous variables and proportions (percentage) for categorical variables. Given that randomly selecting one eye per patient would reduce the sample size, we chose to include both eyes from each patient for our analysis. To appropriately account for correlation between fellow eyes, the general estimating equation (GEE) was applied using Python (version 3.13; Python Software Foundation, Lafayette Boulevard, Fredericksburg, VA, USA). GEE models specified each refractive outcome (spherical equivalent [SEQ], sphere, cylinder, logMAR UDVA, logMAR CDVA) as the dependent variable and time (preoperative, 3 months, 12 months) as a categorical independent variable, with the preoperative visit designated as reference category. Pairwise post-hoc contrasts were additionally performed to compare outcomes across timepoints. All available data were included at each visit, and eyes missing at follow-up were not required to have paired data, providing population-level estimates. An identity link function with a Gaussian distribution and an exchangeable working correlation structure was used. Models were adjusted for the covariates age and gender. A P-value < 0.05 was considered statistically significant. Nine standard graphs of visual outcomes were created [11, 12].

RESULTS

Patient Demographics: A total of 577 eyes from 314 patients underwent KLEx (Table 1); 347 eyes (60.1%) were from female patients and 230 eyes (39.9%) from male patients. Mean (SD) age was 33.95 (7.45) years (range: 18 to 57). Of the 577 eyes, 32 were targeted for monovision and had a mean (SD) SEQ of - 6.14 (1.48) D (range: - 9.13 to - 3.38 D). A total of 127 eyes were treated for simple myopia with a mean (SD) SEQ of - 5.03 (1.74) D (range: - 8.75 to - 1.50 D), while 450 were treated for astigmatic myopia with a mean (SD) SEQ of - 5.47 (1.58) D (range: - 9.63 to - 1.38 D). The mean (SD) preoperative cylinder for all eyes was - 0.66 (0.65) D (range: -3.00 to 0.00 D) and - 0.85 (0.62) D (range: -3.00 to -0.25 D) for eyes with astigmatic myopia.

Of the 577 eyes, 3-month data were available for 511 eyes (88.6% follow-up) and 12-month data were available for 440 eyes (76.3% follow-up). After excluding eyes lost to follow-up and those targeted for monovision, 545 eyes (94.5%) were available at the preoperative visit, 484 eyes (83.9%) at 3 months, and 422 eyes (73.1%) at 12 months (Table 2).

Efficacy: Mean (SD) UDVA (logMAR) improved from 1.40 (0.25) preoperatively to 0.01 (0.10) by 12 months (P < 0.001) (Table 2). UDVA of 20/20 or better was achieved in 79% of eyes at 3 months, while 99% achieved a UDVA of

20/40 or better (Figure 1A). At 12 months, 81% of eyes achieved a UDVA of 20/20 or better and 94% achieved 20/25 or better (Figure 2A). All eyes (100%) had a UDVA of 20/40 or better. Additionally, 70% of eyes had a UDVA that was the same or better than preoperative CDVA at both 3 and 12 months (Figures 1B and 2B). The efficacy index at 3 months was 0.94 ± 0.17 (n = 484 eyes), which improved slightly to 0.95 ± 0.17 by 12 months (n = 422 eyes).

Safety: The safety index was 1.01 ± 0.12 and 1.02 ± 0.13 at 3 and 12 months, respectively (Table 2). Two eyes (0.4%) lost ≥ 2 lines of CDVA at 3 months, while no eyes lost ≥ 2 CDVA lines at 12 months (Figures 1C and 2C). At 3 months, over 12% of eyes gained at least one line of CDVA, which increased to 16% by 12 months (Figures 1C and 2C).

Predictability and Stability: Mean (SD) SEQ decreased in magnitude from - 5.35 (1.62) D at baseline to - 0.04 (0.44) D at 12 months ($P < 0.001$) (Table 2). Of the 511 eyes at 3 months, 87% were within ±0.50 D of the intended SEQ target, while 97% were within ±1.00 D (Figure 1E). At 12 months, 85% of 440 eyes were within ±0.50 D of the intended SEQ target and 97% of eyes were within ±1.00 D (Figure 2E). Postoperative SEQ remained stable across all visits, with a mean (SD) change of -0.03 (0.38) D from 3 to 12 months (Figure 2F). Additionally, 16% of eyes experienced a change greater than 0.50 D from 1 week to 12 months.

Refractive Astigmatism: At 3 months postoperatively, 85% of eyes had a refractive cylinder of ≤ 0.50 D, whereas 80% of eyes had this outcome at 12 months (Figures 1G and 2G). Mean (SD) postoperative cylinder improved from - 0.66 (0.66) D at baseline to - 0.36 (0.32) D at 3 months ($P < 0.001$) (Table 2). Between 3 and 12 months, cylinder improved slightly to -0.40 (0.32) D ($P = 0.042$). The mean (SD) target-induced astigmatism (TIA) vector at 12 months was 0.84 (0.62) D, the surgically induced astigmatism (SIA) vector was 0.81 (0.59) D (Figure 2H). Correlation between TIA and SIA showed a coefficient of determination (R^2) of 0.69, indicating an undercorrection of 20% per diopter of attempted correction. This is further supported by the correction index (CI = SIA/TIA), which was found to be 0.96, although close to the ideal value of 1.00. At 3 months, the angle of error for 45% of eyes (n = 176) was within -5° to 5° (Figure 1I), whereas 38% of eyes (n = 129) fell within this range at 12 months (Figure 2I).

Table 1. Patients demographics

Parameters	All Eyes (n = 577)	Simple Myopia (n = 127)	Astigmatic Myopia (n = 450)	Monovision Target (n = 32)
Sex (Male / Female), n (%)	230 (39.9) / 347 (60.1)	57 (44.9) / 70 (55.1)	173 (38.4) / 277 (61.6)	10 (31.3) / 22 (68.7)
Laterality (OD / OS), n (%)	291 (50.4) / 286 (49.6)	64 (50.4) / 63 (49.6)	223 (49.6) / 22 7 (50.4)	8 (25.0) / 24 (75.0)
Age (y), Mean ± SD (Range)	33.95 ± 7.45 (18 to 57)	33.13 ± 6.83 (18 to 54)	34.18 ± 7.61 (18 to 57)	46.06 ± 4.47 (39 to 54)
Sphere (D), Mean ± SD (Range)	-5.06 ± 1.59 (-9.25 to -1.00)	-5.03 ± 1.74 (-8.75 to -1.50)	-5.04 ± 1.54 (-9.25 to -1.00)	-5.80 ± 1.43 (-8.50 to -3.00)
Cylinder (D), Mean ± SD (Range)	-0.66 ± 0.65 (-3.00 to 0.00)	-	-0.85 ± 0.62 (-3.00 to -0.25)	-0.70 ± 0.51 (-2.00 to 0.00)
SEQ (D), Mean ± SD (Range)	-5.39 ± 1.63 (-9.63 to -1.38)	-5.03 ± 1.74 (-8.75 to -1.50)	-5.47 ± 1.58 (-9.63 to -1.38)	-6.14 ± 1.48 (-9.13 to -3.38)

Abbreviations: n, number; %, percentage; OD, right eye; OS, left eye; y, years; SD, standard deviation; D, diopters; SEQ, spherical equivalent.

Table 2. Visual acuity and refractive outcomes from preoperative to 12 months

Parameters	Preop (n = 545[a])	3 Months Postop (n = 484[a])	12 Months Postop (n = 422[a])	[1] *P*-value	[2] *P*-value
CDVA (logMAR), Mean ± SD (Range)	- 0.02 ± 0.05 (- 0.30 to 0.40)	- 0.02 ± 0.06 (- 0.30 to 0.20)	- 0.03 ± 0.06 (- 0.30 to 0.10)	0.674	0.306
UDVA (logMAR), Mean ± SD (Range)	1.40 ± 0.25 (0.40 to 1.70)	0.02 ± 0.10 (- 0.30 to 0.40)	0.01 ± 0.10 (- 0.30 to 0.80)	**< 0.001**	**0.001**
Sphere (D), Mean ± SD (Range)	- 5.02 ± 1.58 (- 9.25 to - 1.00)	0.18 ± 0.39 (- 2.00 to 1.75)	0.16 ± 0.43 (- 1.75 to 2.25)	**< 0.001**	0.797
Cylinder (D), Mean ± SD (Range)	- 0.66 ± 0.66 (- 3.00 to 0.00)	- 0.36 ± 0.32 (- 2.00 to 0.00)	- 0.40 ± 0.32 (- 1.75 to 0.00)	**< 0.001**	**0.042**
SEQ (D), Mean ± SD (Range)	- 5.35 ± 1.62 (- 9.63 to - 1.38)	- 0.01 ± 0.38 (- 2.13 to 1.38)	- 0.04 ± 0.44 (- 1.88 to 1.88)	**< 0.001**	0.637
Efficacy Index[b]	-	0.94 ± 0.17	0.95 ± 0.17	-	-
Safety Index[c]	-	1.01 ± 0.12	1.02 ± 0.13	-	-

Abbreviations: CDVA, corrected distance visual acuity; logMAR, logarithm of minimum angle of resolution; UDVA, uncorrected distance visual acuity; SD, standard deviation; D, diopters; SEQ, spherical equivalent; Preop, preoperative; Postop, postoperative. Note: *P*-values < 0.05 are shown in bold; *P*-values were derived using generalized estimating equation Wald tests; [1] *P*-value compares preoperative values with 3 months postoperative values; [2] *P*-value compares 3 months postoperative values with 12 months postoperative values; SEQ, spherical equivalent was calculated by adding the spherical component of the refraction to half of the cylindrical component; [a] Monovision targeted eyes were excluded from these measurements; [b] Efficacy index, postoperative UDVA / preoperative CDVA; [c] Safety Index, postoperative CDVA / preoperative CDVA.

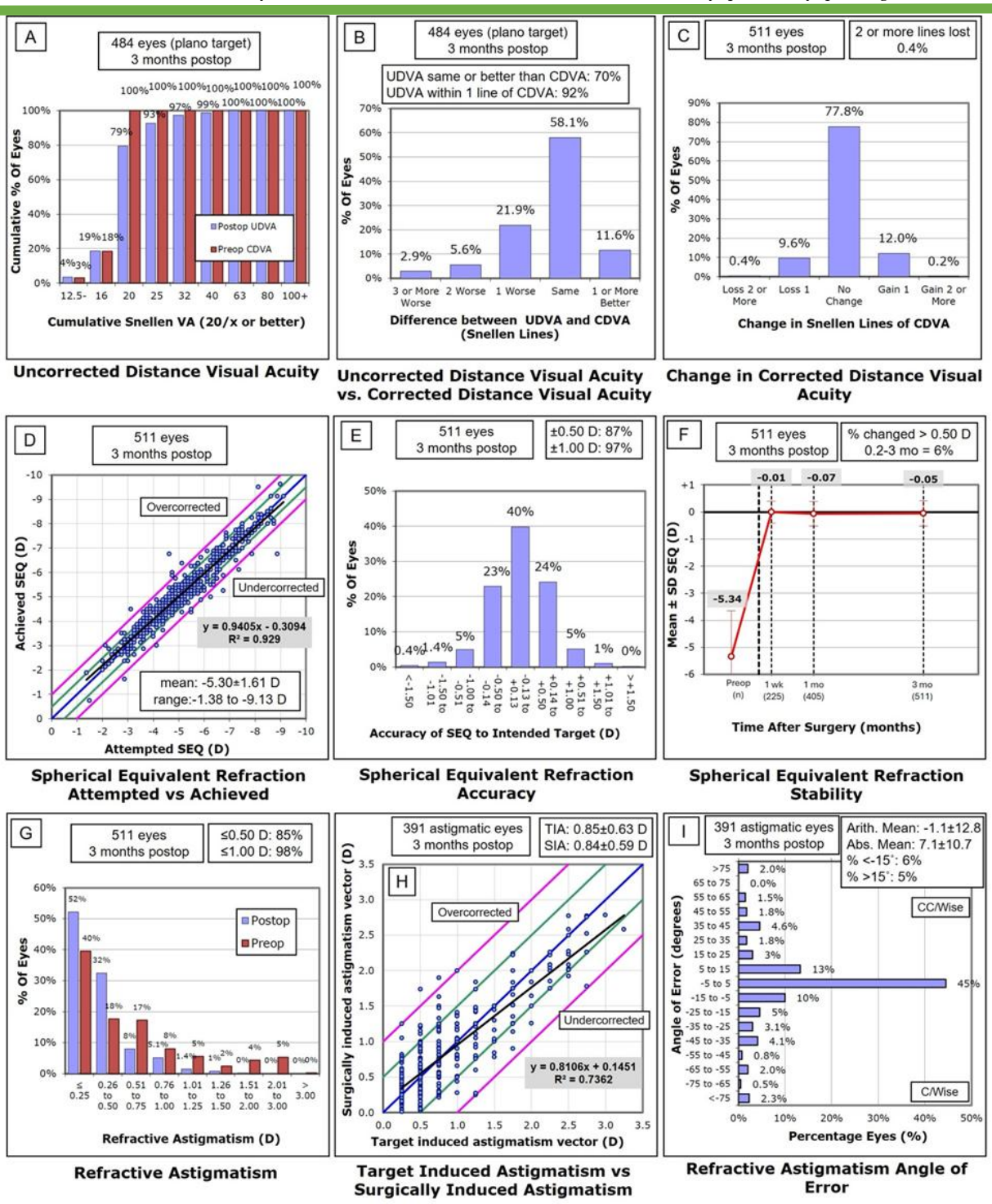

Figure 1. Standard nine graphs after keratorefractive lenticule extraction at 3 months. Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; D, diopters; SIA, surgically induced astigmatism; TIA, target-induced astigmatism.

Complications and enhancements: Out of 577 eyes, one eye (0.17%) was converted to LASIK because of suction loss. Intraoperatively, one eye (0.17%) experienced a small corneal cap tear. Postoperatively, epithelial ingrowths occurred in 9 eyes (1.56%), epithelial defects in 14 eyes (2.42%), diffuse lamellar keratitis in 2 eyes (0.34%), staphylococcal marginal keratitis in 1 eye (0.17%), and corneal erosions in 2 eyes (0.34%). Additionally, 4 eyes (0.69%) developed postoperative microstriae, though not visually significant.

Seventeen eyes (2.9%) required subsequent PRK enhancement. Before enhancement, 15 of these 17 eyes (88.2%) had a UDVA of 20/40 or better, and no eyes had an UDVA of 20/20 or better. Following enhancement, all eyes had a UDVA of 20/40 or better and 15 eyes (88.2%) had a UDVA of 20/20 or better. Additionally, no eyes experienced a change in UDVA from baseline CDVA, and no eyes had lost any lines of CDVA.

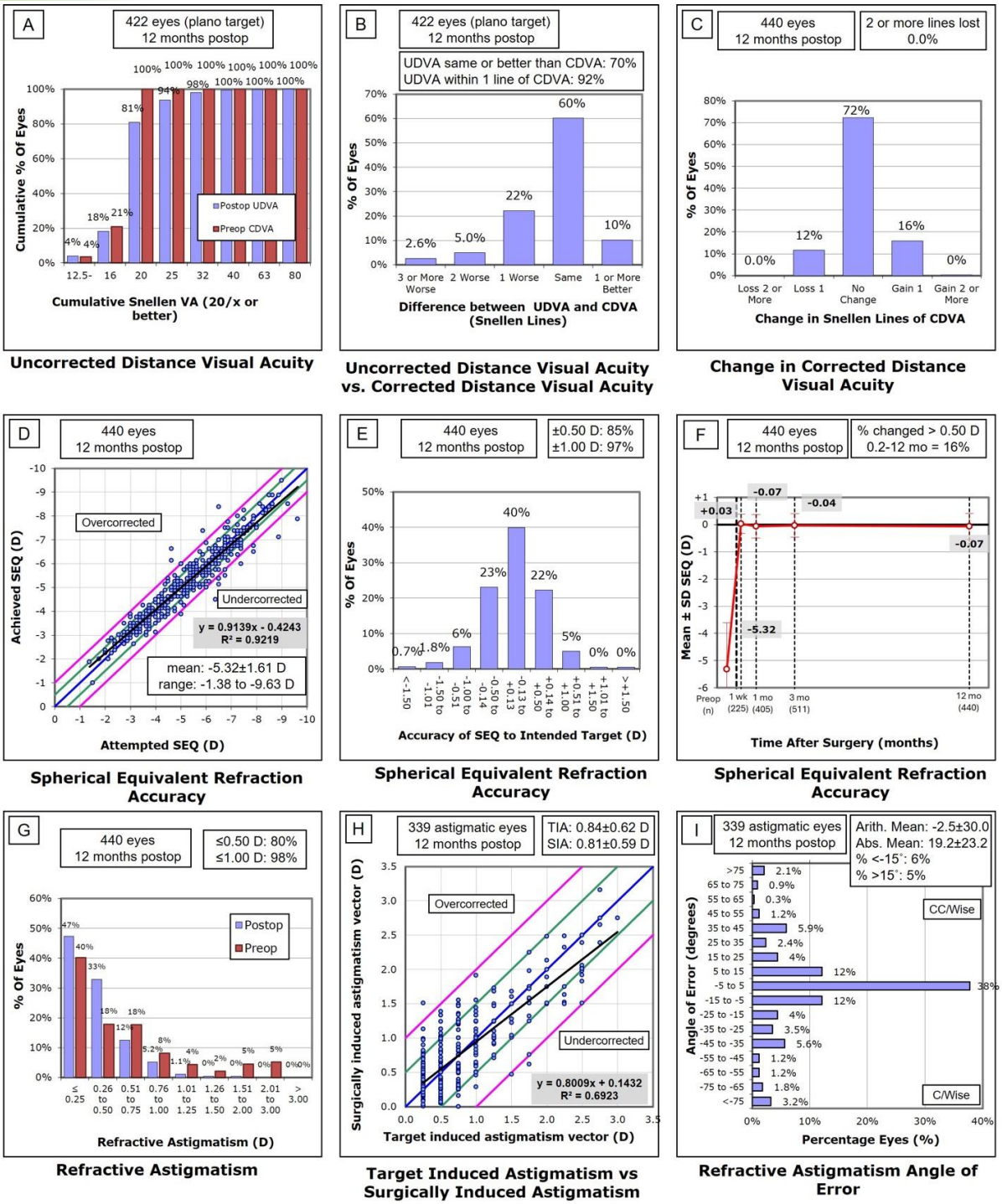

Figure 2. Graphs of refractive and visual outcomes after keratorefractive lenticule extraction at 12 months. Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; D, diopters; SIA, surgically induced astigmatism; TIA, target-induced astigmatism.

DISCUSSION

Since the introduction of KLEx over 15 years ago, this flap-free technique has gained global prominence with several international studies supporting its safety and efficacy profile [9, 10, 16–20]. This single-center US study is among the largest in a North American population to report 1-year clinical outcomes following KLEx for the correction of myopia and myopic astigmatism.

Of the 308 relevant studies screened, 13 studies met the inclusion criteria and evaluated visual and refractive outcomes of KLEx [1, 6, 7, 9, 10, 17–24]. Among these studies, an average 57–96% of eyes achieved a postoperative UDVA of 20/20 or better at 12 months [9, 10, 17–19]. Although Pedersen et al. [17] reported acceptable UDVA 20/40 or better outcomes, the proportion of eyes achieving 20/20 was 24% lower than that observed in our study. In contrast, most other studies reported

greater efficacy outcomes compared to our findings—including those by Reinstein et al. [10] and Chuckpaiwong et al. [9], which showed 14% and 11% more eyes achieving UDVA 20/20 or better, respectively. Nevertheless, the efficacy index in our study was 0.95 ± 0.17, which is well-above the accepted threshold of 0.80 [25]. Additionally, the FDA target criteria require at least 85% of eyes with a preoperative CDVA of 20/20 or better to achieve a UDVA of 20/40 or better at 12 months postoperatively [1], with our results exceeding these targets at both 3 and 12 months.

Regarding safety outcomes at one year, no eyes lost more than two lines of CDVA, and the safety index was 1.02 ± 0.13. The safety profile of KLEx may be attributed to its minimally invasive nature, which results in less corneal biomechanical disruption [26]. These findings surpass the accepted safety index benchmark of 0.85 [25] and meet the FDA requirement that no more than 5% of eyes can experience a loss of more than two lines of CDVA [1]. Our findings were relatively similar to those of Chuckpaiwong et al. [9], who reported a safety index of 1.07 ± 0.15. In contrast, other large cohort studies reported greater safety indices, like Wu et al. [20], who observed a safety index of 1.13 ± 0.13 (≥ -6.0 D of SEQ) and 1.17 ± 0.14 (< -6.0 D of SEQ). Direct comparisons across analyzed studies were limited, as not all studies reported safety or efficacy indices. A recent meta-analysis by Liu et al. [27], however, found that KLEx achieved safety outcomes comparable to other corneal refractive surgeries for the treatment of myopia, supporting its use as a safe treatment option.

KLEx is approved for the correction of myopia up to -10.00 D and astigmatism up to - 3.00 D (up to - 5.00 D in countries requiring CE marking) [1]. Previous studies showed a tendency toward undercorrection of astigmatism following KLEx [18, 28–31]. This is evidenced by the correlational analysis between SIA and TIA at 12 months (R^2 = 0.69) and a CI of 0.96 in our study, indicating 20% undercorrection. In contrast to KLEx, excimer lasers like the WaveLight Allegretto have shown a CI of 1.18 in the FDA approval studies, indicating overcorrection predominantly in low astigmatic eyes [32]. Slight undercorrection may be preferred clinically, as overcorrection with axis shift tends to be less tolerated by patients [31].

The astigmatic outcomes in our study are likely attributed to the limitations in rotational alignment inherent to the VisuMax 500 platform, which lacks automated cyclotorsion control [29]. Compared to wavefront-guided LASIK, which incorporates automated iris registration and eye tracking, KLEx demonstrated a higher angle of error, a larger difference vector, and a lower CI [30]. Several methods have been proposed to improve the astigmatic outcomes in KLEx, including intraoperative manual cyclotorsion to reduce axis misalignment [31], preoperative limbal marking in the upright position with subsequent rotational alignment once supine [17], and nomogram-based adjustments [33]. No standardized astigmatic nomogram for KLEx has been widely implemented to date, though a 10% adjustment in the magnitude of astigmatism correction has been suggested [17]. This should be considered with caution though, as one study of 180 eyes with myopic astigmatism (2.50–4.50 D) and predominantly with-the-rule astigmatism found that applying such an adjustment led to postoperative against-the-rule astigmatism and subsequent visual complaints [33]. Although limbal markings, intraoperative manual cyclotorsion, and nomogram adjustments were used at our refractive surgery center, residual misalignment remains a plausible contributor to undercorrected cylinder, particularly in patients with high astigmatism. Perhaps the integration of automated eye tracking and cyclotorsion, as seen in newer KLEx platforms like the VisuMax 800, along with further refinement of the cylindrical nomogram, could help mitigate the astigmatic undercorrection observed with KLEx [34].

At one year, 85% of eyes achieved a SEQ within ±0.50 D of target and 97% within ±1.00 D of target. Our findings exceed the FDA criteria at both 3 and 12 months, which state that at least 50% of eyes must achieve a SEQ within ±0.50 D of the target and 75% of eyes within ±1.00 D of the target outcome [1]. In terms of SEQ within ±0.50 D of the target, our findings fall modestly below the accuracy reported in other large cohort studies, which range from 88% to 96% [9, 10, 20]. This discrepancy may be attributed to the higher preoperative SEQ in our study. Pedersen et al. [17] reported the highest mean preoperative SEQ (-6.47 ± 1.90 D) among the included studies, but also the lowest SEQ accuracy, with 74% within ±0.50 D and 93% within ±1.00 D of the SEQ target. A prior study [35] reported that higher baseline SEQ is associated with an increased likelihood of myopic regression, along with older age, female sex, and steeper corneas; the authors found that KLEx resulted in a myopic shift > 0.50 D in 10% of patients after one year, compared to 3.4% with LASIK and 4.5% with PRK [35]. There are multiple explanatory factors, including greater keratocyte activation or significant epithelial hyperplasia in high myopes after KLEx [20]. In contrast, refractive outcomes in our study remained stable between 3 and 12 months, indicating that most changes occur early on in the acute healing phase. However, there is still a possibility of myopic shifts after one year, particularly in patients with higher baseline myopia [35] (Tables 3 and 4).

Table 3. Summary of 3-month visual outcomes following keratorefractive lenticule extraction reported in published studies

Study	Year	Country	Eyes	%UDVA ≥20/20	%UDVA ≥20/40	%CDVA Loss of ≥2 Lines	%CDVA Loss of 1 Line	%CDVA No Change	%CDVA Gain of 1 Line	%CDVA Gain of ≥2 Lines	%Cyl ≤0.5D	%SEQ within ±0.5 D	%SEQ within ±1.0 D	Efficacy Index	Safety Index
Current Study	2025	USA	511	79.0	99.0	0.4	9.6	77.8	12.0	0.2	85.0	87.0	97.0	0.94 ± 0.17[a]	1.01 ± 0.12[b]
Taneri et al. [21]	2019	Germany	206	76.0	99.0	2.4	11.7	73.8	10.2	1.5	88	87.0	99.0	0.87	1.00
Liu et al. [7]	2021	USA	462	93.0	100.0	0.0	2.0	76.0	21.0	0.0	98.0	98.0	100.0	-	-
Kamiya et al. [22]	2019	Japan	252	100.0	100.0	0.8	11.0	65.0	23.0	0.0	92.0	88.0	99.0	-	-
Hjordtal et al. [23]	2012	Denmark	670	-	92.8	2.4	-	-	-	3.7	-	80.0	94.0	0.90 ± 0.25	1.07 ± 0.22
Ivarsen et al. [6]	2014	Denmark	1574	-	-	1.5	-	-	-	3.4	-	-	-	-	1.05 ± 0.32
Hansen et al. [24]	2016	Denmark	722	-	83.0[c]	1.6	-	-	-	-	83.0	88.0	98.0	-	-

Abbreviations: SEQ, spherical equivalent; Cyl, cylinder; D, diopters; FDA PMA, Food and Drug Administration Premarket Approval; USA, United States. Note: [a] Calculated using postoperative UDVA/preoperative CDVA; [b] Calculated using postoperative CDVA/preoperative CDVA; [c] Reported ≥20/25.

Table 4. Summary of 12-month visual outcomes following keratorefractive lenticule extraction reported in published studies

Study	Year	Country	Eyes	%UDVA ≥20/20	%UDVA ≥20/40	%CDVA Loss of ≥2 Lines	%CDVA Loss of 1 Line	%CDVA No Change	%CDVA Gain of 1 Line	%CDVA Gain of ≥2 Lines	%Cyl ≤0.5D	%SEQ within ±0.5 D	%SEQ within ±1.0 D	Efficacy Index	Safety Index
Current Study	2025	USA	440	81.0	100.0	0.0	12.0	72.0	16.0	0.0	80.0	85.0	97.0	0.95 ± 0.17[a]	1.02 ± 0.13[b]
VisuMax 500 FDA PMA [1]	2018	USA	311	88.1	99.7	0.0	2.6	72.0	22.8	2.6	-	93.9	98.7	-	-
Chuckpaiwong et al. [9]	2023	Thailand	5953	92.4	99.4	0.1	6.9	63.6	28.6	0.8	88.1	88.4	98.6	0.99 ± 0.19	1.07 ± 0.15
Pedersen et al. [17]	2017	Denmark	87	57.0	95.0	0.0	9.0	55.0	26.0	9.0	70.0	74.0	93.0	-	-
Zhang et al. [18]	2015	China	98	79.6	-	0.0	1.0	36.7	57.1	5.1	95.9	-	-	-	-
Reinstein et al. [19]	2014	UK	110	96.0	100.0	-	9.0	-	-	-	-	84.0	-	-	-
Reinstein et al. [10]	2022	UK	3722	95.5	100.0	0.1	3.0	45.5	46.3	3.1	91.0	88.1	99.6	-	-
Wu et al. [20] SEQ < -6.0 D	2016	China	91/156[c]	-	-	-	-	-	-	-	-	96.7	100.0	-	1.17 ± 0.14
Wu et al. [20] SEQ ≥ -6.0 D	2016	China	65/156[c]	-	-	-	-	-	-	-	-	95.4	100.0		1.13 ± 0.13

Abbreviations: SEQ, spherical equivalent; Cyl, cylinder; D, diopters; FDA PMA, Food and Drug Administration Premarket Approval; USA, United States; UK, United Kingdom. Note: [a] Calculated using postoperative UDVA/preoperative CDVA; [b] Calculated using postoperative CDVA/preoperative CDVA; [c] (n/N) Total number of eyes: 156.

Long-term studies further support the safety, efficacy, and stability of KLEx for myopia and myopic astigmatism [36, 37]. Blum et al. [36] reported that 16 of 56 eyes (29%) gained one or two lines of CDVA after 10 years, with no eyes losing two or more lines. They also found a mild regression of -0.30 D over 10 years, with most of the change occurring by 5 years (-0.48 D), attributing this to either an increase in axial length because of eye globe growth or early nuclear sclerosis and associated myopization rather than true regression at the corneal level. Although another 10-year study [37] observed a -0.32 D regression (-0.03 ± 0.06 D/year change), it reported stable refraction even after accounting for axial length, in contrast to the interpretation proposed by Blum et al. [36, 37].

The learning curve of KLEx is significantly steeper than that of other corneal refractive surgeries [15], with complications often related to lenticule creation, dissection, and extraction [5]. The overall intraoperative and postoperative complication rates in our study were 5.9%, which is relatively lower compared to those of other studies. For example, Ivarsen et al. [6] reported a higher overall incidence of 8.6% in a cohort of 1800 eyes. Vision-threatening complications were infrequent in our cohort, including diffuse lamellar keratitis (0.34%), corneal erosions (0.34%), and staphylococcal marginal keratitis (0.17%), as were minor complications like microstriae (0.96%). These rates were within the FDA-recommended threshold of < 1% incidence for each complication [1]. However, the most common etiology for complications in the large international studies was interface haze (trace to grade II), with an average incidence rate of 9.9% [19, 21, 22]. Our rate of suction loss (0.2%) was also lower compared to the 0.8% rate found by Reinstein et al. [19] and Ivarsen et al. [6]. In our study, 17 eyes (2.9%) required PRK enhancement within one year following KLEx, a rate that closely aligns with the findings of Liu et al. [38], who reported an overall enhancement rate of 2.7% among 524 eyes. Epithelial defects (2.42%) occurred at a

higher rate than other complications in our cohort, but still less frequently than the average incidence rate of 3.3% of eyes treated with KLEx [39]. Taneri et al. [21] experienced an epithelial defect rate of 26.2%, yet these resolved by the following day. In comparison, the rate of epithelial defects in LASIK ranges from 0.6% to 14.0% [39]. Given the increased risk of subsequent ingrowth or recurrent corneal erosions depending on the defect location, a low threshold for bandage contact lens placement is advised [40].

Limitations of our study include its retrospective, single-center design. There were 71 eyes (16%) lost to follow-up between 3 and 12 months, which potentially introduced attrition bias [41]. This may partly be due to patient satisfaction with early postoperative outcomes. Our study cohort was within the broader investigational ranges used in the pivotal PMA clinical trials (- 1.00 D to - 10.00 D sphere, up to - 0.50 D cylinder, SEQ ≤ - 10.25 D) [1]. However, these parameters extend beyond the narrower ranges specified in the current FDA-approved labeling (- 1.00 D to - 8.00 D sphere, up to -0.50 D cylinder, SEQ ≤ - 8.25 D). As such, a portion of our population falls outside the approved treatment indications, which may limit the generalizability of results. Another limitation is the inclusion of both eyes in the analysis, rather than single-eye randomization, which some may argue could bias findings. Not all eyes contributed data at every timepoint due to loss to follow-up, resulting in unbalanced longitudinal data. To address this, we used GEE, which provides population-level estimates under the assumption that the data are missing at random [42]. This statistical approach allowed us to use all available data rather than limit the sample to complete cases only, which increased our statistical power. In addition, the procedures were performed by two surgeons whose surgical techniques may vary slightly.

Given that KLEx is a relatively new platform with limited large-scale studies evaluating its visual outcomes, we compared our results to the FDA criteria, the PMA clinical trials, and other large-cohort studies. Despite most published literature originating from Asia and Europe [43], our US study established the safety, efficacy, and refractive predictability of KLEx at both the 3- and 12-month postoperative visits.

CONCLUSIONS

The visual and refractive outcomes observed in this large, single-site US cohort met or exceeded the FDA criteria and are consistent with other large international studies, though there is a potential need for refined cylindrical correction. This study supports KLEx as a safe, effective, and stable procedure in a North American population, where long-term data remain relatively limited.

ETHICAL DECLARATIONS

Ethical approval: Full approval was granted by the Biomedical Research Alliance of New York Institutional Review Board (# A20-12-547-823). The study adhered to the tenets of the Declaration of Helsinki, and HIPAA regulations were followed. All patients provided written informed consent prior to their inclusion in the study.

Conflict of interest: None.

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