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Enhancement after keratorefractive lenticule extraction: incidence, timing, refractive patterns, and management in a 3,396-eye single-center registry

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Abstract

Background

The literature on enhancement after keratorefractive lenticule extraction (KLEx) remains limited, particularly when retreatment frequency is anchored to a large real-world denominator. The purpose of this study was to evaluate the incidence, timing, refractive patterns, and management of secondary enhancement after KLEx in a large single-center clinical registry and to examine whether a revised treatment nomogram introduced on July 1, 2024 was associated with lower subsequent enhancement frequency.

Methods

A retrospective registry study was performed at Eye Clinic Svjetlost, Zagreb, Croatia. The denominator registry comprised 3,396 KLEx eyes treated on the SCHWIND ATOS platform. Enhancement eyes were identified from dedicated cap-to-flap and transepithelial photorefractive keratectomy (TransPRK) workbooks. Main outcomes were enhancement rate, time to enhancement, pre-enhancement refractive characteristics, technique distribution, observed postoperative uncorrected distance visual acuity (UDVA), and paired ocular and corneal wavefront outcomes. Because postoperative corrected distance visual acuity (CDVA) was not systematically captured, an exploratory surrogate CDVA analysis was performed using pre-enhancement CDVA and observed postoperative UDVA; the safety index derived from this analysis represents an upper-bound estimate. Exact era denominators were 1,198 eyes before July 1, 2024 and 2,198 eyes on or after July 1, 2024.

Results

A total of 61 eyes of 48 patients underwent enhancement, corresponding to an overall enhancement rate of 1.80% (61/3,396; 95% confidence interval [CI], 1.38% to 2.30%). Median time to enhancement was 4.1 months (interquartile range [IQR], 2.7 to 5.5 months; range, 1.1 to 51.0 months), and 47 of 61 eyes (77.0%) were enhanced within 6 months. Mean pre-enhancement spherical equivalent (SEQ) was − 0.80 ± 0.72 D (range, − 2.25 to 1.00 D). Forty eyes underwent cap-to-flap conversion and 21 underwent TransPRK. Cap-to-flap conversion was technically successful in 39 of 40 eyes (97.5%). In harmonized analyses, mean observed UDVA improved from 0.18 ± 0.18 to − 0.03 ± 0.10 logMAR at 1 month (n = 41, P < .001) and from 0.15 ± 0.12 to − 0.05 ± 0.08 logMAR at 3 months (n = 20, P < .001). Ocular wavefront metrics remained stable. Corneal trefoil at 6 mm increased modestly from 0.18 ± 0.09 to 0.22 ± 0.13 μm (n = 58, P = .035) without correlation to latest observed UDVA. Era analysis showed 46 enhancements among 1,198 eyes treated before July 1, 2024 (3.84%) versus 15 among 2,198 eyes treated thereafter (0.68%), corresponding to an 82.2% relative reduction ($\chi^2 = 43.82$, P < .001; risk ratio for post- versus pre-nomogram enhancement frequency, 0.18, 95% CI 0.10 to 0.32).

Conclusions

Secondary enhancement after KLEx was uncommon in this 3,396-eye registry and usually occurred early after primary surgery. A revised age-adjusted nomogram introduced on July 1, 2024 was associated with a markedly lower enhancement frequency in the subsequent era. Cap-to-flap conversion and TransPRK were both viable enhancement strategies in routine practice, but the principal contribution of this study is denominator-anchored reporting of enhancement incidence, timing, and workflow rather than proof of optical superiority between enhancement techniques.

Introduction

Lenticule-based keratorefractive procedures — referred to throughout this manuscript as keratorefractive lenticule extraction (KLEx) — have become an established option for the correction of myopia and myopic astigmatism. Early prospective studies of small-incision lenticule extraction demonstrated that flap-free stromal tissue removal could achieve predictable refractive correction with good visual outcomes [1]. Subsequent clinical experience and more recent studies on the SCHWIND ATOS/SmartSight platform have extended this evidence base [2, 3].

As with all corneal refractive procedures, a small proportion of eyes require secondary treatment for residual refractive error. In LASIK, enhancement is relatively straightforward because the original flap can often be relifted. In lenticule extraction, enhancement is less standardized because the primary procedure does not create a broad anterior stromal flap. Published enhancement options include surface ablation, cap-to-flap conversion, thin-flap LASIK, and, in selected reports, repeat lenticule-based approaches [5–10].

Most enhancement studies after lenticule extraction focus on retreated eyes only. Denominator-anchored data are sparse; one exception is the report by Liu and colleagues [4], which provided incidence and risk-factor data for enhancement after SMILE in a defined surgical cohort. Without such denominators, the published literature does not provide the context that surgeons need when counseling patients or benchmarking performance in a high-volume refractive practice. A denominator-anchored registry can answer three clinically important questions: how often enhancement is required, when it tends to occur, and how it is managed in routine workflow.

The aim of the present study was therefore to describe the incidence, timing, refractive patterns, and management of enhancement after KLEx in a 3,396-eye single-center registry. A secondary aim was to evaluate whether a revised treatment nomogram introduced on July 1, 2024 was associated with a change in enhancement frequency. The goal of this study was not to prove that one enhancement technique is optically superior to another, but rather to document real-world enhancement incidence and clinical workflow after KLEx.

Methods

Study design and setting

This was a retrospective single-center registry study performed at Eye Clinic Svjetlost, Zagreb, Croatia.

Registry denominator

The denominator for the enhancement rate consisted of 3,396 KLEx eyes treated on the SCHWIND ATOS platform from October 20, 2020 through December 31, 2025. The denominator was assembled from three internal source-system strata in the clinic registry export: 2,221 eyes labeled “Lenticule,” 686 labeled “Nova,” and 489 labeled “SmartSight 2025 label.” The “SmartSight 2025 label” stratum reflects a platform software release designation applied retroactively in the 2025 registry export and does not indicate that the eyes within it were treated in 2025. These labels represented non-overlapping KLEx procedure records and were verified to contain no duplicate entries before aggregation. They were not modeled separately in the present analysis.

Enhancement cohort

Enhancement eyes were identified from two dedicated enhancement workbooks: cap-to-flap conversion (40 eyes) and TransPRK after KLEx (21 eyes), yielding a total cohort of 61 eyes in 48 patients.

Nomogram revision

Before July 2024, all KLEx eyes were treated with a target SEQ of plano. On July 1, 2024, a revised age-adjusted nomogram was introduced in which a positive SEQ offset was programmed into the laser platform target based on patient age at the time of surgery, with the intent of achieving a mild myopic residual and reducing the risk of over-correction and subsequent enhancement.

The age-stratified offsets applied were + 1.00 D for age 19–25 years, + 0.75 D for age 25–30 years, + 0.60 D for age 30–35 years, and + 0.50 D for age 35–45 years. In addition, the cylinder correction factor was revised and energy and spot-track parameters were updated concurrently. The revised protocol was applied consistently from July 1, 2024 onward.

Enhancement techniques

TransPRK enhancement was performed using the transepithelial PRK module of the SCHWIND AMARIS excimer laser. No attempt was made to reopen or modify the prior lenticule interface; excimer ablation was applied directly to the corneal surface using the TransPRK workflow. Following ablation, mitomycin C (MMC) 0.02% was applied to the ablation zone for 20 seconds in all cases.

Cap-to-flap enhancement was introduced in December 2023. The original KLEx treatment log was reviewed to identify the centration used during the primary procedure. A femtosecond side cut was then planned to intercept the prior cap edge while reducing the programmed diameter by 0.5 mm relative to

the original cap diameter. This strategy was used to improve the likelihood of reliably entering the cap interface. For the 15 cap-to-flap eyes in which the original cap diameter was not recorded in the workbook, the 0.5 mm reduction was applied relative to an assumed standard cap diameter of 9.0 mm. After flap lifting, excimer laser ablation was performed.

Among the 25 of 40 cap-to-flap eyes with original cap diameter available in the workbook, the mean recorded original cap diameter was 8.98 ± 0.10 mm (range, 8.5 to 9.0 mm). One additional failure case had an original 7.7-mm cap according to the operative record.

Follow-up structure

The two enhancement workbooks had different postoperative schedules. Cap-to-flap eyes were followed at postoperative day 1, week 1, month 1, and month 3. TransPRK eyes were followed at month 1, month 3, month 6, and year 1. Because of this asymmetry, the main paired postoperative visual analyses were harmonized at 1 month and 3 months.

Visual acuity and refractive definitions

Visual acuity values recorded in decimal notation were converted to logMAR using the standard formula logMAR = − log10(decimal acuity).

For descriptive categorization, enhancement eyes were grouped as residual myopia, residual astigmatism, residual myopia with astigmatism, or low residual error/fine-tuning. Eyes were classified as low residual error/fine-tuning when pre-enhancement SEQ was within ± 0.25 D of plano and enhancement was indicated primarily on the basis of higher-order aberration burden or suspected treatment zone decentration rather than residual sphere or cylinder, as assessed by corneal topography and wavefront analysis.

Exploratory surrogate CDVA analysis

Because postoperative CDVA was not systematically recorded in the enhancement workbooks, an exploratory surrogate CDVA analysis was performed. In this analysis, postoperative CDVA was estimated as equal to pre-enhancement CDVA unless observed postoperative UDVA was better than pre-enhancement CDVA, in which case postoperative CDVA was estimated as equal to postoperative UDVA. Because this method sets postoperative CDVA equal to postoperative UDVA when UDVA exceeds pre-enhancement CDVA, the resulting safety index represents an upper-bound estimate; true postoperative CDVA cannot exceed UDVA under standard clinical conditions. This analysis was used only as an exploratory surrogate approach and was not treated as a substitute for directly observed postoperative CDVA.

Wavefront analysis

The source workbooks exported ocular wavefront metrics at 4 mm and corneal wavefront metrics at 6 mm. These measurements were therefore analyzed as separate optical domains defined by the underlying clinical export. Because HOA magnitude is proportional to pupil area, the absolute values of ocular (4 mm) and corneal (6 mm) metrics are not directly comparable; the directional difference in magnitude between domains is an expected optical consequence of the aperture difference and should not be interpreted as a measurement inconsistency. Evaluated parameters included total higher-order aberrations (HOA), coma, trefoil, and spherical aberration.

Statistical analysis

Continuous variables are reported as mean ± standard deviation or median with interquartile range, together with ranges. Categorical variables are reported as count and percentage. The overall enhancement rate is reported with an exact Clopper-Pearson 95% confidence interval.

Paired pre/post visual analyses used the Wilcoxon signed-rank test on available pairs. Correlation between corneal trefoil change and latest observed UDVA used Spearman analysis. For the era analysis, exact denominator counts were 1,198 KLEx eyes before July 1, 2024 and 2,198 eyes on or after July 1, 2024. All 61 enhancement eyes were assigned to an era based on the date of the primary KLEx procedure or source verification. Enhancement frequencies were compared using a chi-square test, and the relative risk for post- versus pre-nomogram enhancement frequency was calculated with a 95% confidence interval.

Results

Among 3,396 registry KLEx eyes, 61 eyes of 48 patients underwent enhancement, corresponding to an overall enhancement rate of 1.80% (61/3,396; 95% CI, 1.38% to 2.30%).

Forty-one of 61 enhancement eyes (67.2%) were from female patients. Mean age at primary KLEx was 31.12 ± 7.06 years (range, 19.1 to 44.8 years; n = 60 with complete date-of-birth and surgery-date data). There were 35 right eyes and 26 left eyes.

Before primary KLEx, the enhancement cohort had a mean sphere of − 4.26 ± 2.10 D (range, − 7.50 to 0.25 D), a mean cylinder of − 1.28 ± 1.16 D (range, − 5.00 to − 0.25 D), and a mean SEQ of − 4.69 ± 1.99 D (range, − 7.75 to 0.00 D).

Time-to-enhancement data were available for all 61 eyes after source verification of the previously missing interval. Median time to enhancement was 4.1 months (IQR, 2.7 to 5.5 months; range, 1.1 to 51.0 months). Forty-seven of 61 eyes (77.0%) were enhanced within 6 months of the primary KLEx procedure.

The timing distribution was 19 eyes (31.1%) at 3 months or earlier, 28 eyes (45.9%) at more than 3 to 6 months, 7 eyes (11.5%) at more than 6 to 12 months, 4 eyes (6.6%) at more than 12 to 24 months, and 3 eyes (4.9%) beyond 24 months.

Mean pre-enhancement SEQ was − 0.80 ± 0.72 D (range, − 2.25 to 1.00 D). Mean pre-enhancement UDVA was 0.17 ± 0.17 logMAR (range, 0.00 to 1.00; n = 59), whereas mean pre-enhancement CDVA was 0.00 ± 0.07 logMAR (range, − 0.15 to 0.35; n = 57). Residual myopia was the most common retreatment pattern, followed by isolated residual astigmatism, mixed residual myopia with astigmatism, and a small fine-tuning subgroup of 4 eyes whose near-plano SEQ placed them outside the refractive retreatment categories; coma-dominant HOA patterns and topographic evidence of treatment zone decentration were the primary drivers of enhancement in this subgroup.

Cap-to-flap enhancement accounted for 40 eyes (65.6%) and TransPRK for 21 eyes (34.4%). Cap-to-flap conversion was technically successful in 39 of 40 eyes (97.5%). One cap-interception failure occurred in an eye with an original 7.7-mm cap diameter.

For cap-to-flap eyes, the latest available observed UDVA came from postoperative day 1 in 1 eye, postoperative week 1 in 11 eyes, postoperative month 1 in 14 eyes, and postoperative month 3 in 13 eyes; 1 cap-to-flap eye had no postoperative UDVA recorded. For TransPRK eyes, the latest available observed UDVA came from month 1 in 6 eyes, month 3 in 2 eyes, month 6 in 8 eyes, and year 1 in 5 eyes.

In the harmonized 1-month analysis, paired observed UDVA was available in 41 eyes and improved from 0.18 ± 0.18 to − 0.03 ± 0.10 logMAR ($P < .001$). Technique-specific 1-month results were 0.14 ± 0.11 to − 0.06 ± 0.08 logMAR for cap-to-flap ($n = 21$, $P < .001$) and 0.22 ± 0.23 to 0.00 ± 0.12 logMAR for TransPRK ($n = 20$, $P < .001$). At 1 month, 30 of 41 eyes (73.2%) had observed UDVA of 20/20 or better and 37 of 41 eyes (90.2%) had observed UDVA of 20/25 or better.

In the harmonized 3-month analysis, paired observed UDVA was available in 20 eyes and improved from 0.15 ± 0.12 to − 0.05 ± 0.08 logMAR ($P < .001$). Technique-specific 3-month results were 0.15 ± 0.10 to − 0.03 ± 0.08 logMAR for cap-to-flap ($n = 12$, $P < .001$) and 0.15 ± 0.16 to − 0.07 ± 0.08 logMAR for TransPRK ($n = 8$, $P = .008$). Among the 21 eyes with any available 3-month postoperative UDVA (20 paired plus 1 eye with postoperative 3-month UDVA but no pre-enhancement UDVA recorded), 16 of 21 eyes (76.2%) achieved 20/20 or better and 20 of 21 eyes (95.2%) achieved 20/25 or better.

Using the latest available observed postoperative visit, paired UDVA was available in 59 eyes and improved from 0.17 ± 0.17 to − 0.06 ± 0.10 logMAR ($P < .001$). At the latest available observed postoperative visit, 47 of 60 eyes (78.3%) achieved 20/20 or better and 57 of 60 eyes (95.0%) achieved 20/25 or better.

An exploratory surrogate CDVA analysis was performed in 57 of 61 eyes because 4 cap-to-flap eyes lacked pre-enhancement CDVA. At the latest available follow-up, estimated postoperative CDVA changed from 0.00 ± 0.07 logMAR (range, − 0.15 to 0.35) pre-enhancement to − 0.07 ± 0.09 logMAR (range, − 0.26 to 0.35), with an estimated safety index of 1.17. As noted in the Methods, this index represents an upper-bound estimate. Under this surrogate analysis, 13 of 57 eyes (22.8%) were estimated to gain at least 1 line, 4 of 57 eyes (7.0%) were estimated to gain at least 2 lines, and 0 of 57 eyes were estimated to lose at least 1 line.

Ocular wavefront metrics remained stable: ocular total HOA at 4 mm changed from 0.21 ± 0.08 to 0.20 ± 0.07 μm (n = 47, P = .770), ocular coma from 0.12 ± 0.07 to 0.10 ± 0.05 μm (n = 47, P = .136), ocular trefoil from 0.09 ± 0.05 to 0.09 ± 0.07 μm (n = 47, P = .633), and ocular spherical aberration from − 0.001 ± 0.053 to 0.003 ± 0.048 μm (n = 47, P = .574).

Corneal wavefront metrics were also largely stable: total HOA at 6 mm changed from 0.53 ± 0.16 to 0.56 ± 0.23 μm (n = 58, P = .272), corneal coma from 0.34 ± 0.17 to 0.32 ± 0.19 μm (n = 58, P = .260), and corneal spherical aberration from − 0.14 ± 0.23 to − 0.17 ± 0.26 μm (n = 58, P = .075). The only statistically significant wavefront change was a modest increase in corneal trefoil at 6 mm, from 0.18 ± 0.09 to 0.22 ± 0.13 μm (n = 58, P = .035); the majority of individual eyes showed postoperative values above the line of identity (Fig. 6). Change in corneal trefoil did not correlate with latest observed UDVA (Spearman rho = 0.024, P = .857).

All 61 enhancement eyes were assigned to an era based on the date of the primary KLEx procedure or source verification. Forty-six primary surgeries occurred before July 1, 2024 and 15 occurred on or after July 1, 2024. Using exact era denominators of 1,198 KLEx eyes before and 2,198 after the nomogram change, the enhancement rate declined from 3.84% (46/1,198) before July 1, 2024 to 0.68% (15/2,198) thereafter, corresponding to an 82.2% relative reduction ($\chi^2 = 43.82$, P < .001; risk ratio for post- versus pre-nomogram enhancement frequency, 0.18; 95% CI, 0.10 to 0.32).

Safety

No structured adverse-event field for haze, epithelial ingrowth, ectasia, or sight-threatening events was present in either workbook extract. The single documented technical complication was one cap-interception failure in a cap-to-flap eye with an original 7.7-mm cap diameter. Formal complication rates beyond this event cannot be derived from the available data.

Discussion

This registry study evaluated enhancement after KLEx in the context of a clearly defined denominator of 3,396 treated eyes. The principal finding is that secondary enhancement was uncommon, occurring in 1.80% of eyes. That denominator-anchored frequency is clinically useful because most enhancement reports in the lenticule-extraction literature describe retreatment eyes only, without showing how often retreatment is actually required in routine practice.

A second key finding is that enhancement occurred early. Median time to enhancement was 4.1 months, and 77.0% of enhancements were performed within 6 months. This distribution suggests that most retreatments reflected early residual refractive miss rather than long-term regression. Nevertheless, the presence of three late enhancers beyond 24 months, all from the pre-nomogram era, indicates that a small subgroup may represent a different clinical phenotype, such as late regression or delayed presentation of dissatisfaction.

The most clinically actionable result of the present study is the era analysis surrounding the July 1, 2024 nomogram revision. Using exact denominator counts, enhancement frequency decreased from 3.84% (46/1,198) before the revision to 0.68% (15/2,198) thereafter, corresponding to an 82.2% relative reduction and a substantially lower post-nomogram enhancement risk (risk ratio, 0.18; 95% CI, 0.10 to 0.32). The pre-nomogram era spanned October 2020 to June 2024 (approximately 44 months), whereas the post-nomogram era spanned July 2024 to December 2025 (approximately 18 months). This asymmetry means that late-presenting enhancers — such as the three eyes beyond 24 months, all of which originated in the pre-nomogram era — could not yet have emerged in the post-nomogram cohort. The post-nomogram enhancement rate may therefore rise modestly as follow-up matures, though the magnitude of the observed difference makes a meaningful reversal unlikely.

The revised protocol incorporated an age-adjusted positive SEQ offset, a revised cylinder correction factor, and concurrent energy and spot-track changes. Because these changes were introduced together, this observational comparison is consistent with an overall improvement in treatment calibration but does not isolate the effect of any individual component; the relative contribution of the age-adjusted offset, the revised cylinder correction factor, and the updated energy and spot-track parameters cannot be determined from this dataset.

The present study was not designed to determine whether cap-to-flap or TransPRK is optically superior. Instead, it documents how enhancement was managed in routine practice. In that context, both pathways were effective. Cap-to-flap conversion had a technical success rate of 97.5%, and the described side-cut strategy offers a practical surgical pearl: targeting the original centration and reducing the programmed diameter by 0.5 mm relative to the original cap appears to be a feasible standardized approach for intercepting the prior interface. This detail may be useful for surgeons planning KLEx retreatments. The single cap-interception failure occurred in an eye with an unusually small 7.7-mm original cap, which may mark a lower technical margin for this method.

The observed postoperative UDVA results support satisfactory short-term visual recovery after enhancement, but they should be interpreted within the limits of the available follow-up schedules. Cap-to-flap and TransPRK workbooks had structurally different postoperative epochs, so harmonized 1-month and 3-month analyses are more appropriate than direct latest-visit comparison. The exploratory surrogate CDVA analysis provides some additional context, but the derived safety index of 1.17 should be interpreted as an upper-bound estimate: the surrogate method sets postoperative CDVA equal to postoperative UDVA when UDVA exceeds pre-enhancement CDVA, a ceiling that cannot be exceeded under standard clinical conditions. This analysis does not replace directly observed postoperative CDVA safety data, which is a central limitation of the dataset.

Wavefront analysis suggests that optical quality remained broadly stable after enhancement. Ocular wavefront metrics did not change significantly, and most corneal wavefront parameters were similarly stable. Corneal trefoil showed a modest but statistically significant increase in pooled analysis, with the

majority of individual eyes showing postoperative values above the line of identity (Fig. 6), but this change did not correlate with latest observed UDVA, suggesting limited immediate clinical relevance.

The strengths of this study are its denominator-anchored design, large single-center clinical volume, and transparent reporting of what the extract can and cannot support. The limitations are equally important. This was a retrospective single-center registry study. Follow-up was heterogeneous and structurally different between enhancement techniques. Postoperative CDVA and postoperative manifest refraction were not systematically captured in the exported enhancement workbooks. The workbook extract also lacked structured complication fields beyond the documented cap-interception failure. Finally, the nomogram-era comparison was observational rather than randomized, the post-nomogram era had shorter maximum follow-up time at risk than the pre-nomogram era (approximately 18 versus 44 months), and several protocol changes were introduced concurrently.

Conclusions

In this 3,396-eye single-center KLEx registry, secondary enhancement was required in 1.80% of eyes and occurred predominantly within 6 months of primary surgery. A revised age-adjusted nomogram introduced on July 1, 2024 was associated with a markedly lower subsequent enhancement frequency (3.84% before vs 0.68% after). The principal value of this study is its denominator-anchored description of enhancement incidence, timing, refractive patterns, and management in routine practice; both cap-to-flap conversion and TransPRK functioned as feasible enhancement strategies, but the study was not designed to establish optical superiority between them.

Abbreviations

CDVA	Corrected distance visual acuity
CI	Confidence interval
HOA	Higher-order aberrations
IQR	Interquartile range
KLEx	Keratorefractive lenticule extraction
logMAR	Logarithm of the minimum angle of resolution
MMC	Mitomycin C
SEQ	Spherical equivalent
SMILE	Small incision lenticule extraction
TransPRK	Transepithelial photorefractive keratectomy
UDVA	Uncorrected distance visual acuity

Declarations

Ethics approval and consent to participate: This study was conducted in accordance with the tenets of the Declaration of Helsinki. Ethics approval was obtained from the Eye Clinic Svjetlost Institutional Review Board (approval reference: KS-REG-KLEx-rev001). All patients provided written informed consent for the use of their clinical data for research purposes.

Consent for publication: Not applicable (no individually identifiable patient data are included in this manuscript).

Availability of data and materials: The datasets used and analyzed during the current study are not publicly available owing to patient privacy considerations and institutional data governance policy, but are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: IG: Conceptualization, study design, data collection and curation, surgical procedures, statistical analysis, writing — original draft. MJ: Data collection and curation, surgical procedures, writing — review and editing. KB: Data collection and curation, statistical analysis. MB: Surgical procedures, supervision. All authors read and approved the final manuscript.

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Tables

Table 1. Enhancement cohort and registry context

Variable	Value
Total KLEx registry eyes	3,396
Enhancement eyes / patients	61 eyes / 48 patients
Overall enhancement rate	1.80% (61/3,396)
95% CI for enhancement rate (Clopper-Pearson)	1.38% to 2.30%
Technique distribution	40 cap-to-flap; 21 TransPRK
Female sex	41/61 eyes (67.2%)
Age at primary KLEx	31.12 ± 7.06 years (range, 19.1 to 44.8; n = 60)
Right / left eye	35 / 26
Baseline sphere before primary KLEx	−4.26 ± 2.10 D (range, −7.50 to 0.25)
Baseline cylinder before primary KLEx	−1.28 ± 1.16 D (range, −5.00 to −0.25)
Baseline SEQ before primary KLEx	−4.69 ± 1.99 D (range, −7.75 to 0.00)
Time to enhancement	Median 4.1 months (IQR, 2.7 to 5.5; range, 1.1 to 51.0; n = 61)
Pre-enhancement SEQ	−0.80 ± 0.72 D (range, −2.25 to 1.00)

CI = confidence interval; IQR = interquartile range; KLEx = keratorefractive lenticule extraction; SEQ = spherical equivalent; TransPRK = transepithelial photorefractive keratectomy.

Table 2. Timing and refractive-pattern category before enhancement

Category	n	%
≤3 months	19	31.1
>3 to 6 months	28	45.9
>6 to 12 months	7	11.5
>12 to 24 months	4	6.6
>24 months	3	4.9
Residual myopia	34	55.7
Residual astigmatism	13	21.3
Residual myopia + astigmatism	10	16.4
Low residual error / fine-tuning*	4	6.6

*Defined as SEQ within ±0.25 D of plano with enhancement indicated primarily by coma-dominant higher-order aberration burden and/or topographic evidence of treatment zone decentration rather than residual sphere or cylinder.

Table 3. Observed UDVA after enhancement at harmonized timepoints

Analysis	Pre-enhancement logMAR	Post-enhancement logMAR	n	P
Overall, 1 month	0.18 ± 0.18	−0.03 ± 0.10	41	< .001
Cap-to-flap, 1 month	0.14 ± 0.11	−0.06 ± 0.08	21	< .001
TransPRK, 1 month	0.22 ± 0.23	0.00 ± 0.12	20	< .001
Overall, 3 months	0.15 ± 0.12	−0.05 ± 0.08	20	< .001
Cap-to-flap, 3 months	0.15 ± 0.10	−0.03 ± 0.08	12	< .001
TransPRK, 3 months	0.15 ± 0.16	−0.07 ± 0.08	8	= .008

All P values by Wilcoxon signed-rank test. UDVA = uncorrected distance visual acuity.

Table 4. Exploratory surrogate CDVA analysis

Analysis	Pre-enhancement CDVA (logMAR)	Estimated postoperative CDVA (logMAR)	n	Estimated safety index†
Latest available, overall	0.00 ± 0.07	−0.07 ± 0.09	57	1.17
Latest available, cap-to-flap	0.00 ± 0.06	−0.07 ± 0.08	36	1.17
Latest available, TransPRK	0.00 ± 0.09	−0.06 ± 0.12	21	1.18
Harmonized 1 month, overall	0.00 ± 0.08	−0.05 ± 0.09	40	1.11
Harmonized 3 months, overall	0.01 ± 0.05	−0.05 ± 0.08	19	1.15

Additional latest-available line-change results: gain ≥1 line, 13/57 (22.8%); gain ≥2 lines, 4/57 (7.0%); loss ≥1 line, 0/57 (0.0%). †The safety index derived from this surrogate method represents an upper-bound estimate; see Methods for assumptions and limitations.

Table 5. Paired wavefront analysis from pre-enhancement to latest available postoperative visit

Parameter	n	Pre	Post	P (Wilcoxon)
Ocular total HOA (4 mm), µm	47	0.21 ± 0.08	0.20 ± 0.07	= .770
Ocular coma (4 mm), µm	47	0.12 ± 0.07	0.10 ± 0.05	= .136
Ocular trefoil (4 mm), µm	47	0.09 ± 0.05	0.09 ± 0.07	= .633
Ocular spherical aberration (4 mm), µm	47	−0.001 ± 0.053	0.003 ± 0.048	= .574
Corneal total HOA (6 mm), µm	58	0.53 ± 0.16	0.56 ± 0.23	= .272
Corneal coma (6 mm), µm	58	0.34 ± 0.17	0.32 ± 0.19	= .260
Corneal trefoil (6 mm), µm	58	0.18 ± 0.09	0.22 ± 0.13	= .035
Corneal spherical aberration (6 mm), µm	58	−0.14 ± 0.23	−0.17 ± 0.26	= .075

Ocular wavefront measured at 4-mm pupil diameter; corneal wavefront measured at 6-mm pupil diameter. Values are not directly comparable across domains because of pupil-area dependence of HOA magnitude; the higher absolute values for corneal metrics reflect the larger analysis aperture and are an expected optical consequence of the aperture difference.

Figures

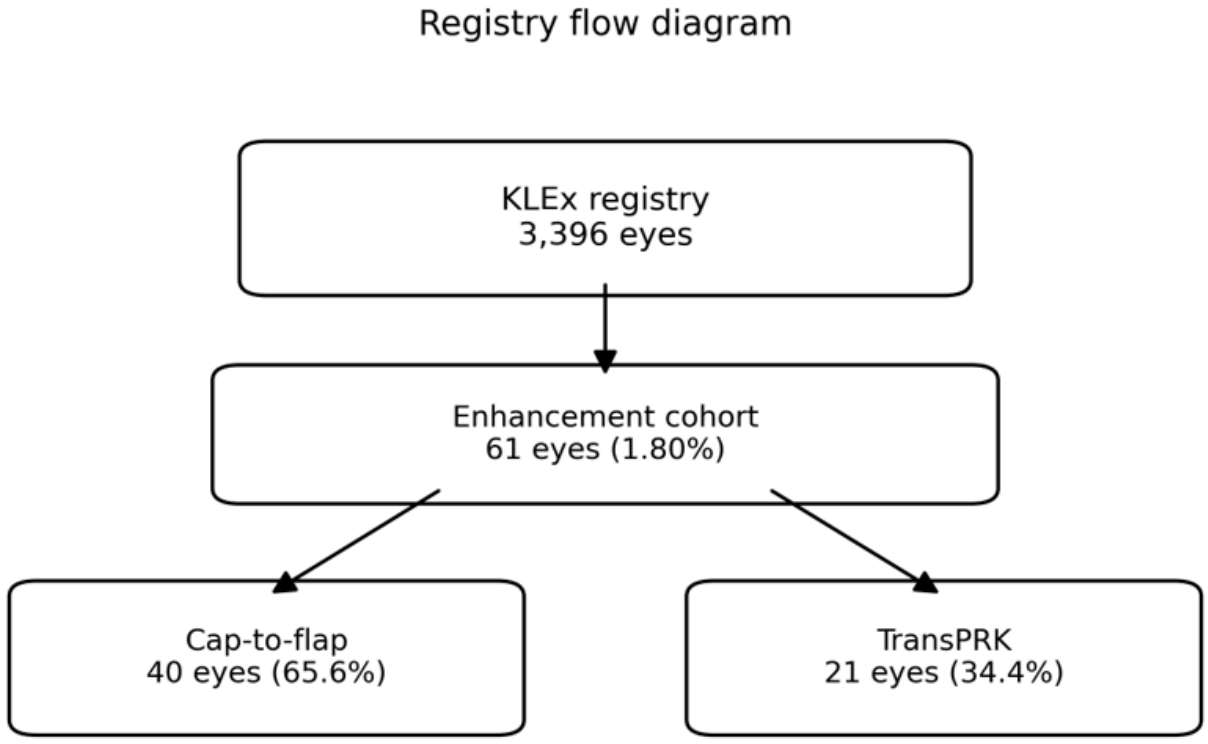


Figure 1

Registry flow diagram

Flow diagram of the registry and enhancement cohort. From 3,396 KLEx eyes, 61 eyes underwent enhancement: 40 cap-to-flap and 21 TransPRK.

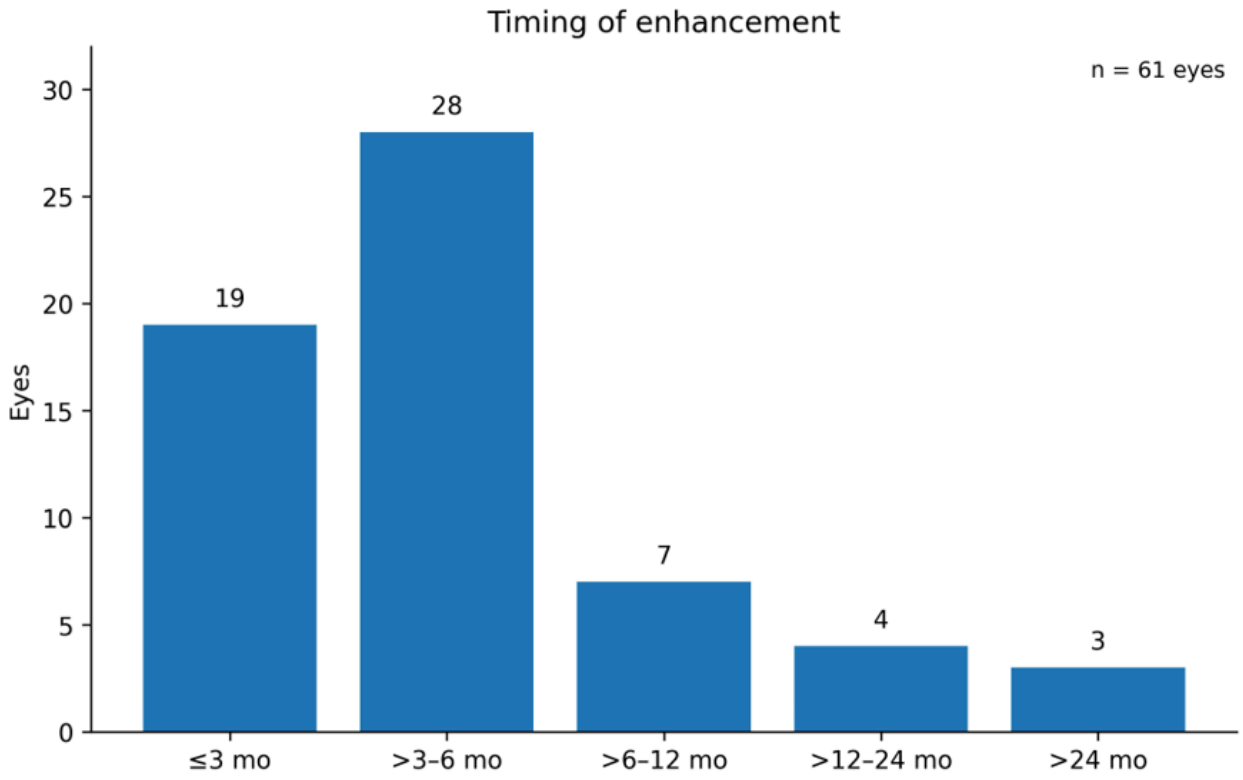


Figure 2

Timing of enhancement

Distribution of time from primary KLEx to enhancement (n = 61 eyes). Most enhancements occurred within 6 months of the primary procedure.

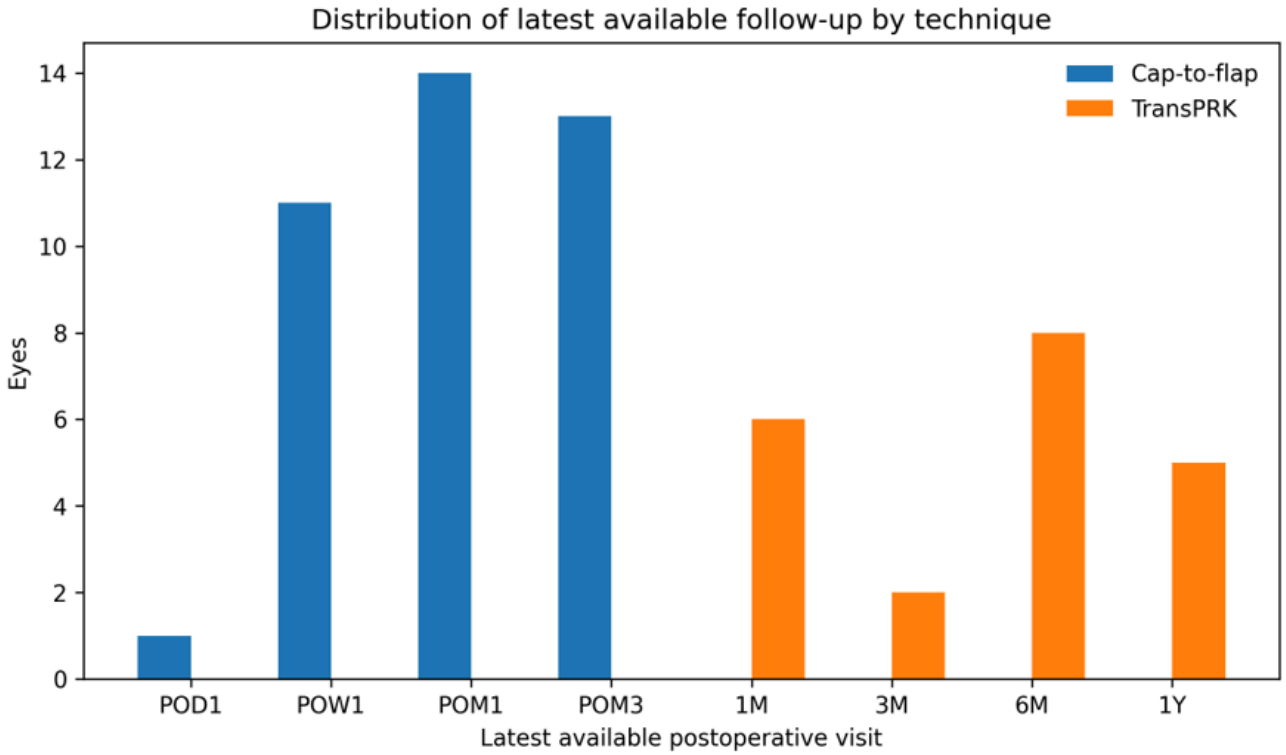


Figure 3

Distribution of latest available follow-up by technique

Latest available observed postoperative follow-up was structurally different between cap-to-flap and TransPRK workbooks, supporting emphasis on harmonized 1-month and 3-month analyses.

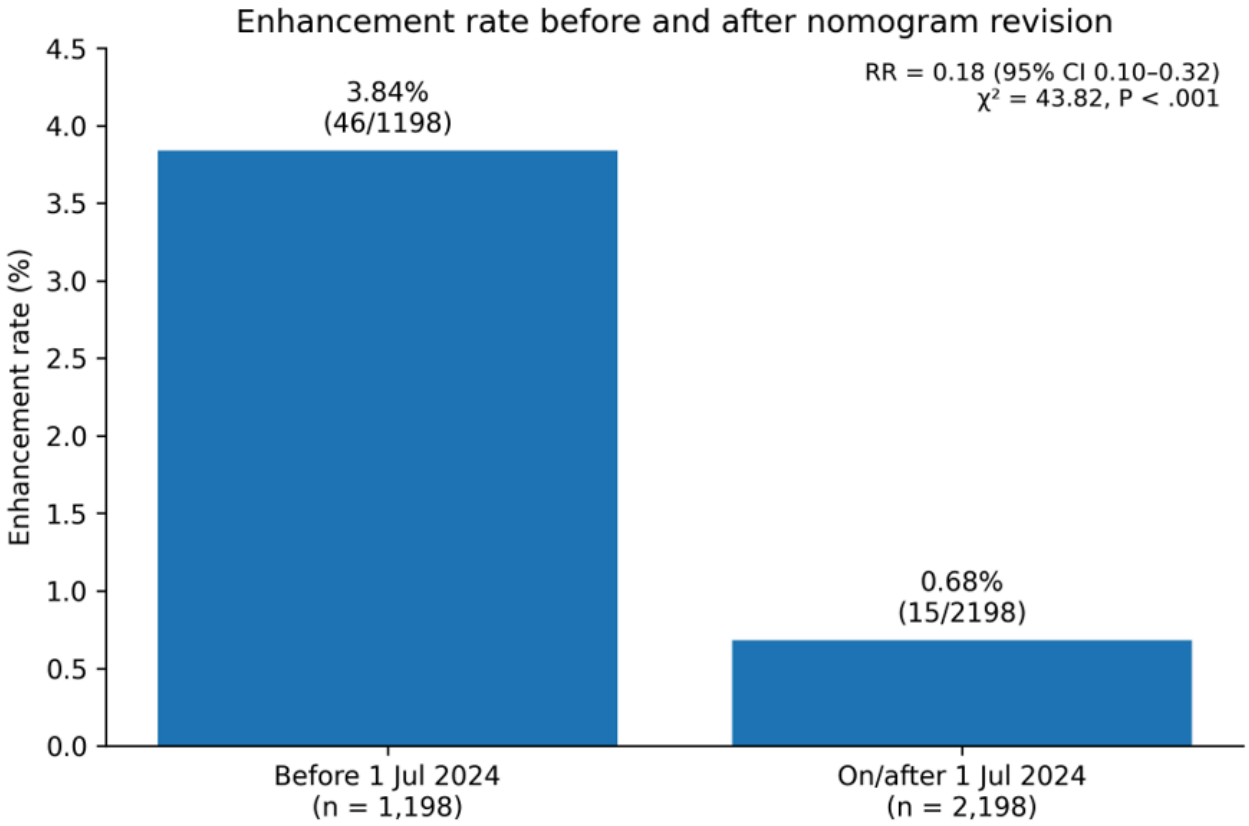


Figure 4

Enhancement rate before and after the July 1, 2024 nomogram revision

Using exact era denominators of 1,198 KLEx eyes before and 2,198 eyes after the nomogram change, enhancement frequency declined from 3.84% (46/1,198) to 0.68% (15/2,198), corresponding to an 82.2% relative reduction.

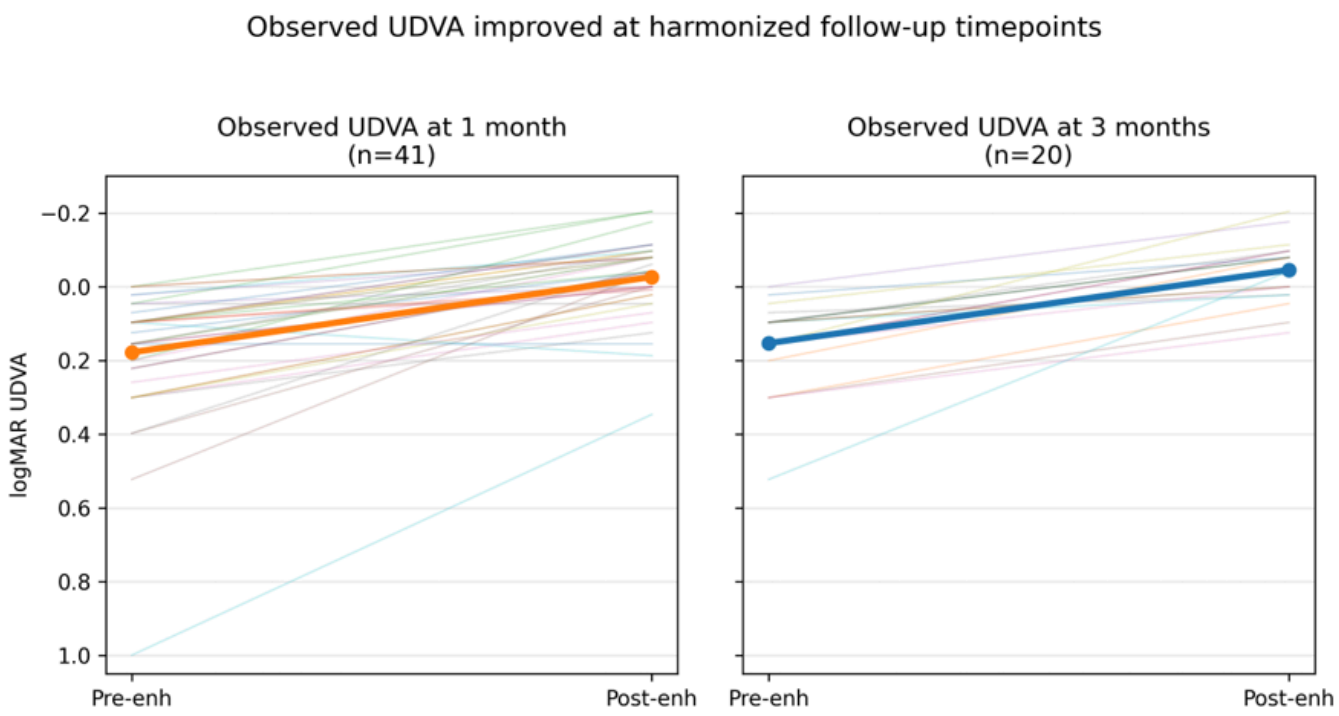


Figure 5

Observed UDVA before and after enhancement at harmonized timepoints

Observed UDVA improved at both 1 month and 3 months in the available paired analyses. The 3-month cumulative frequency panel includes 21 eyes (20 paired plus 1 eye with postoperative but no pre-enhancement UDVA).

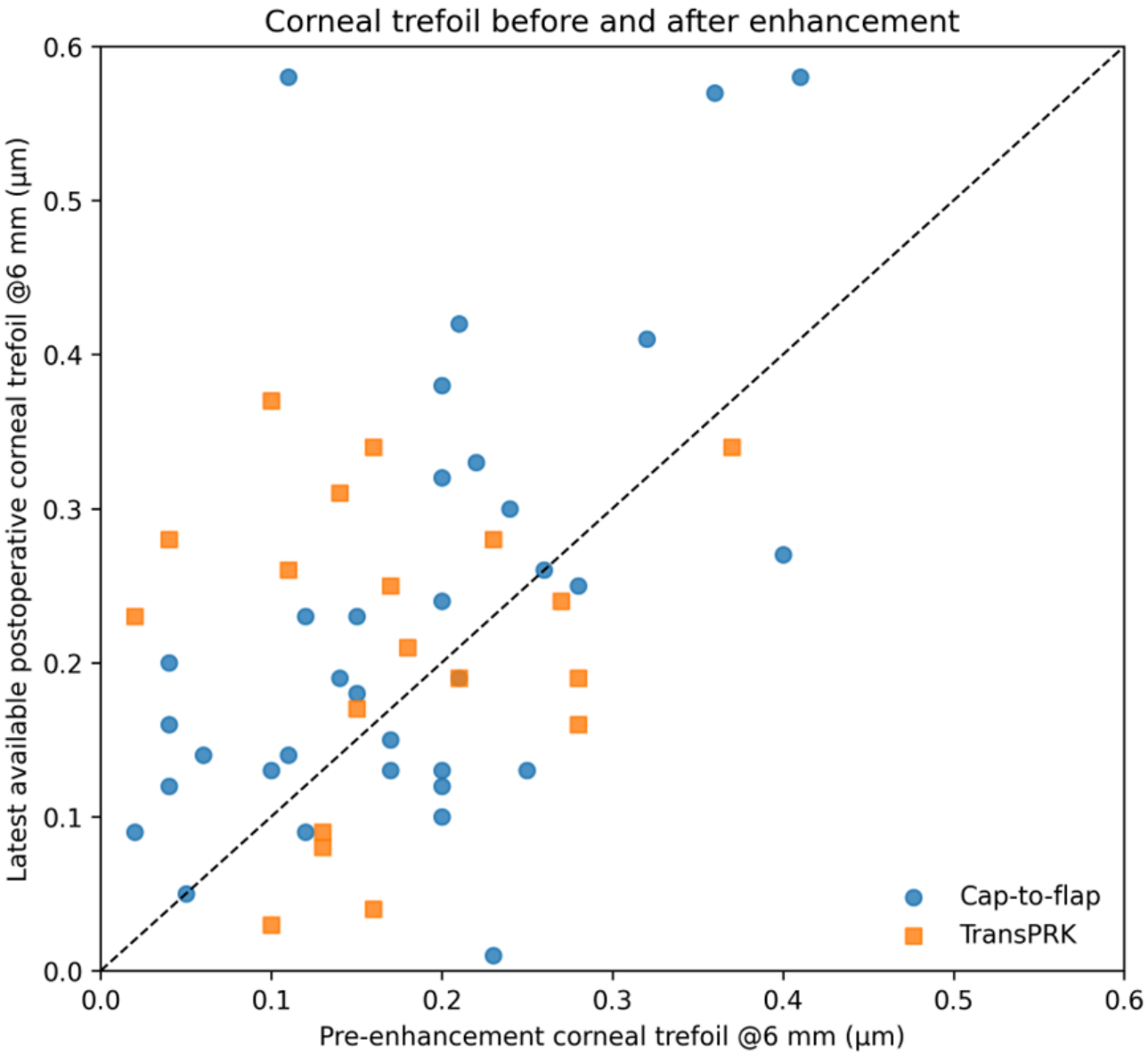


Figure 6

Corneal trefoil before and after enhancement

Paired latest-available corneal trefoil at 6 mm. The dashed line indicates identity; values above the line indicate higher postoperative trefoil. The majority of data points fall above the line of identity, consistent with the modest but statistically significant group-level increase (P = .035). Change in corneal trefoil did not correlate with latest observed UDVA (Spearman rho = 0.024, P = .857).