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Age and outcomes of keratorefractive lenticule extraction: visual recovery, refractive accuracy, enhancement and the contribution of an age-banded nomogram

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Abstract

Background/Objectives: To test whether eyes of patients aged 40 years or older reach uncorrected distance visual acuity (UDVA) of 20/20 or better 3 months after keratorefractive lenticule extraction (KLEx) less often than younger eyes, and to separate age from nomogram.

Subjects/Methods: Single-surgeon registry (SmartSight, SCHWIND ATOS, 2022 to 2026) of 2817 eyes of 1455 patients (226 aged 40 or older); patient-clustered models adjusted for attempted correction, cylinder, profile, zone, era. From July 2024 the added myopic correction decreased with age; those refractions were recomputed under a common offset.

Results: UDVA of 20/20 or better at 3 months was reached by 1615/1727 eyes (93.5%) under 40 and 134/157 (85.4%) at 40 or older (adjusted odds ratio (OR) 0.43, 95% confidence interval (CI) 0.25 to 0.74, P = 0.002; per decade 0.59), equally in both eras. Manifest spherical equivalent at 12 months was − 0.11 ± 0.39 and − 0.54 ± 0.57 D (adjusted difference − 0.42 D): −0.32 D in the first era and − 0.52 D in the second, where a common offset would leave − 0.19 D (− 0.45 to + 0.07). Enhancement was needed in 1.6% and 3.4% (OR 3.28); 2 or more lines of corrected acuity were lost in 0/1243 and 1/119.

Conclusions: Attainment of 20/20 declined with age independently of the nomogram. In refracted eyes the residual after 40 combined an offset-related gradient with a step of about 0.3 to 0.4 D beyond it; a smaller reduction of the offset after 35 needs prospective study. Patients over 40 should be counselled accordingly.

Summary box

What was known before

- • Keratorefractive lenticule extraction nomograms were built on cohorts in their twenties and thirties, and most series exclude or pool patients over 40.
- • A multicentre series found lower efficacy, less predictable refraction and more re-treatments in patients aged 55 years or older than in a matched group aged 35 or younger.
- • Whether such differences reflect the ageing cornea, age-dependent treatment planning or the loss of accommodative compensation was not known.

What this study adds

- • In 2817 eyes treated by one surgeon, the odds of 20/20 uncorrected acuity at 3 months fell by about 41% per decade of age, without a threshold, equally before and after an age-banded nomogram was introduced.
- • Eyes of patients aged 40 or older settled about 0.4 D more myopic and were enhanced about twice as often; in refracted eyes, recomputing the second-era refractions under a common offset reversed

the continuous refractive gradient, which is therefore related to the smaller added correction given to older eyes, whereas a step of about 0.3 to 0.4 D at 40 was present in the first era and, pooled across eras, within one offset band.

- • Corrected acuity at 12 months, day-1 scatter and adjusted aberration change were unaffected by age; counselling should reflect the slower attainment of 20/20; whether a smaller reduction of the offset after 35 improves the endpoint is a question for prospective study.

Introduction

Keratorefractive lenticule extraction (KLEx), including small incision lenticule extraction (SMILE), is a standard correction for myopia [1–3]. Its nomograms were built on cohorts with a mean age in the late twenties, and most series exclude patients over 40 or pool them with younger patients [4–6]; whether older eyes recover as fast and reach the same endpoint is not known.

Age is a plausible modifier: the stroma stiffens, accommodative compensation of a residual error is lost in the fifth decade, and older age predicts regression [7, 8]. In laser in situ keratomileusis (LASIK), efficacy and predictability at 40 to 69 years were lower than in younger series [9], and a multicentre KLEx series reported inferior efficacy, more re-treatments and less predictable refraction at 55 or older than in a matched group aged 35 or younger [10]. Where the change begins, and whether it reflects the cornea, the nomogram or the loss of accommodative compensation, has not been described across a continuous age range.

We analysed a single-surgeon KLEx registry of 2880 eyes to test the hypothesis that eyes of patients aged 40 years or older reach uncorrected distance visual acuity (UDVA) of 20/20 or better at 3 months less often than younger eyes, to describe visual recovery, manifest refraction, corrected acuity and enhancement across age, and, because the nomogram changed to an age-banded offset in July 2024, to separate the effect of age from the effect of the offset.

Subjects and methods

Study design and subjects

This retrospective cohort study used a prospectively maintained registry of all KLEx procedures performed by one surgeon (IG) with the SCHWIND ATOS femtosecond laser (SCHWIND eye-tech-solutions, Kleinostheim, Germany) at Eye Clinic Svjetlost, Zagreb, Croatia. Surgery took place from 19 May 2022 to 19 June 2026; extraction was on 30 July 2026. The registry and this analysis were approved by the Ethics Committee of Eye Clinic Svjetlost, Zagreb, Croatia (KS-KLEx-Reg001). The study adhered to the Declaration of Helsinki; patients gave written consent for research use of anonymised data. Some eyes appear in earlier registry reports [11, 12].

All registry eyes treated for myopia or myopic astigmatism were eligible. Eyes were excluded for pseudophakia or amblyopia (12 eyes of 9 patients). Enhanced eyes (51 eyes of 41 patients) contributed to the enhancement analysis and were removed from the other analyses; sensitivity analyses counted them as failures. Age was analysed continuously, in bands (18 to 24, 25 to 29, 30 to 34, 35 to 39, 40 to 44, 45 or older; completed years) and as a prespecified dichotomy at 40.

Surgical technique

All procedures used the SmartSight lenticule profile, in the original or the NOVA workflow (automated compensation of docking decentration, from April 2025), pooled. Treatment was vertex-centred with automated cyclotorsion compensation, the cap 100 to 150 µm thick with a 3.0-mm incision at 135°, the optical zone 5.5 to 8.0 mm, enlarged whenever tissue permitted. The treated refraction was the cycloplegic refraction. Until 30 June 2024 the programmed correction equalled the treated refraction; from 1 July 2024 the nomogram added myopic correction at the corneal plane (0 mm vertex distance) that decreased with age (1.00 D under 25 years, 0.75 D from 25, 0.60 D from 30, 0.50 D from 35, none from 45). Every eye was targeted at emmetropia. Postoperative treatment was a topical antibiotic for 3 days and a steroid for 3 weeks. Enhancement was a secondary procedure on the operated eye, transepithelial photorefractive keratectomy (SCHWIND AMARIS) until early 2024 and cap-to-flap conversion on the ATOS from December 2023, indicated clinically without a fixed threshold; the registry extract holds neither date nor indication.

Examinations

Uncorrected (UDVA) and corrected (CDVA) distance visual acuity were measured at 4 m on a computerised chart (CC-100, Topcon, Tokyo, Japan) in Early Treatment Diabetic Retinopathy Study logMAR mode; preoperative CDVA was recorded as 20/20 when that line was read, better only when the patient continued. Manifest refraction was performed unmasked by the surgeon or a resident at 3, 6 and 12 months when the patient reported blur or UDVA was below 20/20, and otherwise at the examiner's discretion, in quarter-dioptre steps. At day 1, 1 week and 1 month the refraction was the objective refraction of a pyramidal wavefront aberrometer (Osiris, CSO, Florence, Italy) in a mesopic room with the natural pupil, computed over a 4-mm analysis diameter, which also provided the micro-aberration scatter index (MASI, reported ×1000) [12]; total corneal wavefront at 6 mm came from a Scheimpflug-Placido tomographer (MS-39, CSO, Florence, Italy). Visits were assigned to windows (day 1, 1 to 3 days; 1 week, 4 to 20; 1 month, 21 to 60; 3 months, 61 to 135; 6 months, 136 to 270; 12 months, 271 to 460 days), taking the examination closest to nominal. Acuity entries exported without a date were assigned to a window by matching to dated tomography and surgery records, and the analyses were repeated on dated records alone.

Outcomes and statistical analysis

The primary outcome was UDVA of 20/20 or better at 3 months (logMAR 0.00 or better, all five letters of the line), compared between eyes aged 40 or older and younger eyes. Secondary outcomes were UDVA at each visit, UDVA worse than 20/25 (logMAR above 0.10) as the worst-case measure, change in CDVA in whole lines (each full 0.1 logMAR counted as one line), CDVA worse than 20/40 in eyes with preoperative CDVA of 20/20 or better, spherical equivalent (SEQ) at each visit with the proportions within ± 0.50 D and undercorrected by more than 0.50 D, attempted versus achieved correction, refractive change from 3 to 12 months, enhancement, day-1 MASI and change in 6-mm wavefront aberrations.

Fellow eyes were retained; every 95% confidence interval (CI) is a patient-cluster bootstrap (2000 resamples) or, where no eye met a criterion, exact binomial. Age effects were estimated in patient-cluster-robust logistic and linear models adjusted for attempted SEQ and cylinder magnitude, profile version (NOVA versus original), planned optical zone and nomogram era (before or from 1 July 2024); outcomes with fewer than 30 events are given as unadjusted risk ratios (RR) with cluster-bootstrap CIs. Odds ratios (OR) are given per decade and for the dichotomy at 40; age was also modelled in bands, as a restricted cubic spline (four knots, cluster-robust Wald test of nonlinearity) and within each nomogram era. Because the second-era offset is a function of age, the two cannot be separated within that era; every second-era postoperative SEQ was therefore recomputed as if the eye had received the 0.60 D offset of the 30 to 34 band (observed SEQ plus 0.60 D minus the eye's offset), assuming one-to-one transfer, and the models refitted; the 35 to 44 band, which shares one offset, was compared within itself; and SEQ was regressed on the programmed correction, age and their product to test whether the response per programmed dioptre changes with age. The primary comparison was tested at two-sided alpha 0.05; all others are exploratory, with CIs and unadjusted P values. Sensitivity analyses added sex, used dated records only and counted enhanced eyes as failures; attendance was described among eyes whose window had closed before the extract. Analyses used Python 3.11 (SciPy 1.17, statsmodels 0.15); a large language model (Claude, Anthropic) was used under author supervision to write and check code and draft text, for which the authors take full responsibility.

Results

Subjects

Of 2880 registry eyes (1484 patients), 2868 eyes of 1479 patients remained after exclusion, and 2817 eyes of 1455 patients (1362 bilateral) formed the outcome set (Supplementary Figure S1). Age was 30.2 ± 6.6 years (range 18 to 69); 226 eyes of 121 patients were aged 40 or older, 36 of them 45 or older. Baseline characteristics were balanced (standardised differences 0.17 or less; Table 1) except a smaller optical zone at 40 or older (− 0.58), and 92% of the 45-and-older band was operated in the second nomogram era against 69% overall.

Table 1

Baseline and treatment characteristics of the outcome set by age band (2817 eyes of 1455 patients)

Characteristic	18–24 y	25–29 y	30–34 y	35–39 y	40–44 y	45 + y	All	SMD, 40 y and older vs under 40 y
Eyes / patients	667 / 343	799 / 411	658 / 339	467 / 241	190 / 101	36 / 20	2817 / 1455	
Age, y, mean ± SD	22.2 ± 1.8	27.4 ± 1.5	32.4 ± 1.5	37.1 ± 1.4	42.2 ± 1.5	48.6 ± 3.9	30.2 ± 6.6	
Female, % of eyes with sex recorded	40%	46%	48%	59%	56%	42%	48%	+ 0.12
Attempted SEQ, D, mean ± SD	−4.16 ± 1.82	−3.81 ± 1.85	−3.60 ± 1.86	−3.73 ± 2.08	−4.10 ± 2.10	−4.28 ± 2.04	−3.86 ± 1.91	−0.15
Attempted SEQ 6.00 D or more, %	17%	14%	12%	14%	21%	19%	15%	+ 0.17
Attempted cylinder, D, mean ± SD	1.10 ± 1.10	1.06 ± 0.97	1.03 ± 0.97	1.05 ± 0.91	1.18 ± 1.12	1.12 ± 1.09	1.07 ± 1.01	+ 0.10
Attempted cylinder above 1.00 D, %	34%	36%	33%	36%	38%	33%	35%	+ 0.06
Optical zone, mm, mean ± SD	7.09 ± 0.35	7.08 ± 0.30	7.08 ± 0.30	6.99 ± 0.34	6.88 ± 0.34	6.85 ± 0.33	7.05 ± 0.33	−0.58
Optical zone above 7.0 mm, %	45%	42%	40%	30%	21%	11%	38%	−0.47
Cap thickness, µm, mean ± SD	126 ± 14	126 ± 13	127 ± 13	127 ± 14	126 ± 15	130 ± 11	126 ± 14	+ 0.00
Central lenticule thickness, µm, mean ± SD	103 ± 27	99 ± 28	93 ± 25	91 ± 27	95 ± 29	91 ± 26	97 ± 27	−0.08
NOVA workflow, %	31%	29%	29%	33%	27%	33%	30%	−0.05
Operated from July 2024 (age-	68%	70%	69%	69%	72%	92%	69%	+ 0.14

CDVA = corrected distance visual acuity; D = dioptre; SD = standard deviation; SEQ = spherical equivalent refraction; SMD = standardised mean difference (mean of eyes aged 40 y or older minus mean of eyes under 40 y, divided by the pooled SD; for percentages, of the indicator variable); y = years. Age bands are completed years. Sex was recorded for 2331 eyes, optical zone for 2805, lenticule thickness for 2204 and preoperative CDVA for 2457. Enhanced eyes are excluded.

Characteristic	18–24 y	25–29 y	30–34 y	35–39 y	40–44 y	45 + y	All	SMD, 40 y and older vs under 40 y
banded nomogram), %								
Preoperative CDVA, logMAR, mean ± SD	0.00 ± 0.03	0.00 ± 0.03	0.00 ± 0.04	0.00 ± 0.04	0.00 ± 0.03	0.01 ± 0.05	0.00 ± 0.03	+ 0.03
Preoperative CDVA better than 20/20, %	5%	6%	7%	7%	5%	3%	6%	−0.06

CDVA = corrected distance visual acuity; D = dioptre; SD = standard deviation; SEQ = spherical equivalent refraction; SMD = standardised mean difference (mean of eyes aged 40 y or older minus mean of eyes under 40 y, divided by the pooled SD; for percentages, of the indicator variable); y = years. Age bands are completed years. Sex was recorded for 2331 eyes, optical zone for 2805, lenticule thickness for 2204 and preoperative CDVA for 2457. Enhanced eyes are excluded.

A 3-month acuity was recorded in 71% of time-eligible eyes and a 12-month acuity in 60%, similar across age (Supplementary Table S1); dated 12-month examinations were at a median of 357 and 364.5 days. A manifest refraction was recorded in 32% and 34% of attending eyes at 3 months and 27% and 37% at 12 months; refracted eyes saw less well in both groups (Table 2).

Table 2

Visual, refractive and enhancement outcomes in eyes under 40 years and 40 years or older

Outcome	Under 40 y	40 y and older	Effect of age 40 y or older (95% CI); P; eyes in model
UDVA 20/20 or better, Day 1, n/N (%; 95% CI)	1522/2507 (60.7%; 58.3 to 63.0)	116/218 (53.2%; 45.6 to 60.2)	OR 0.80 (0.57 to 1.11); 0.181; 2713
UDVA 20/20 or better, 1 week, n/N (%; 95% CI)	1634/2154 (75.9%; 73.8 to 77.9)	117/180 (65.0%; 56.7 to 72.8)	OR 0.61 (0.41 to 0.91); 0.015; 2328
UDVA 20/20 or better, 1 month, n/N (%; 95% CI)	1829/2139 (85.5%; 83.8 to 87.2)	135/182 (74.2%; 66.7 to 81.2)	OR 0.51 (0.32 to 0.81); 0.004; 2309
UDVA 20/20 or better, 3 months, n/N (%; 95% CI)	1615/1727 (93.5%; 92.2 to 94.8)	134/157 (85.4%; 79.4 to 91.1)	OR 0.43 (0.25 to 0.74); 0.002; 1874
UDVA 20/20 or better, 6 months, n/N (%; 95% CI)	1406/1483 (94.8%; 93.5 to 96.1)	123/137 (89.8%; 84.6 to 94.7)	OR 0.53 (0.28 to 0.99); 0.048; 1613
UDVA 20/20 or better, 12 months, n/N (%; 95% CI)	1252/1301 (96.2%; 95.0 to 97.3)	110/119 (92.4%; 86.5 to 97.2)	OR 0.55 (0.25 to 1.22); 0.143; 1414
UDVA 20/20 or better, 3 months, dated records only, n/N (%; 95% CI)	540/622 (86.8%; 83.8 to 89.7)	41/57 (71.9%; 60.0 to 83.3)	OR 0.47 (0.23 to 0.93); 0.030; 677
UDVA 20/20 or better, 12 months, dated records only, n/N (%; 95% CI)	316/353 (89.5%; 85.9 to 92.6)	31/38 (81.6%; 66.7 to 93.1)	OR 0.75 (0.29 to 1.92); 0.548; 391
UDVA worse than 20/25, 3 months, n/N (%)	20/1727 (1.2%)	4/157 (2.5%)	RR 2.20 (0.43 to 5.65); 24 events*
UDVA worse than 20/25, 6 months, n/N (%)	16/1483 (1.1%)	6/137 (4.4%)	RR 4.06 (1.14 to 9.46); 22 events*
UDVA worse than 20/25, 12 months, n/N (%)	10/1301 (0.8%)	4/119 (3.4%)	RR 4.37 (0.72 to 13.57); 14 events*
CDVA loss of 1 or more lines, 3 months, n/N (%)	12/1571 (0.8%)	1/144 (0.7%)	RR 0.91 (0.00 to 3.80); 13 events*

CDVA = corrected distance visual acuity; CI = confidence interval (patient-cluster bootstrap; exact binomial where no eye met the criterion); D = dioptre; OR = odds ratio; RR = risk ratio; SD = standard deviation; SEQ = spherical equivalent refraction; UDVA = uncorrected distance visual acuity; y = years. Adjusted effects are from patient-clustered logistic (OR) or linear (D) models with attempted SEQ, attempted cylinder, profile version, optical zone and nomogram era as covariates; eyes without a recorded optical zone are absent from the models, hence the smaller N. *Outcomes with fewer than 30 events are given as unadjusted RR with patient-cluster bootstrap CI; with a single event in one group the lower bound is not estimable and is shown as 0.00. †Enhancement model adjusted for attempted SEQ, cylinder and era; 15 of the 51 enhanced eyes lack a recorded attempted refraction and are absent from the model. – = not modelled (too few events) or not applicable. Dated records = examinations with a recorded date inside the visit window; the remaining records were date-matched from the electronic medical record export. Day-1 SEQ is the objective aberrometer refraction of all eyes measured; manifest SEQ is that of eyes refracted at the visit. Enhancement is reported in the registry set including enhanced eyes; all other rows exclude enhanced eyes.

Outcome	Under 40 y	40 y and older	Effect of age 40 y or older (95% CI); P; eyes in model
CDVA loss of 2 or more lines, 3 months, n/N (%)	0/1571 (0.0%)	0/144 (0.0%)	–
CDVA loss of 1 or more lines, 12 months, n/N (%)	10/1243 (0.8%)	1/119 (0.8%)	RR 1.04 (0.00 to 5.01); 11 events*
CDVA loss of 2 or more lines, 12 months, n/N (%)	0/1243 (0.0%)	1/119 (0.8%)	–
Objective SEQ, day 1, D, mean ± SD (N)	−0.15 ± 0.78 (1962)	−0.38 ± 0.70 (172)	–
Manifest SEQ, 3 months, D, mean ± SD (N)	−0.20 ± 0.55 (605)	−0.42 ± 0.57 (61)	−0.18 D (− 0.34 to − 0.03); 0.023; 665
SEQ within ± 0.50 D, 3 months, n/N (%)	433/605 (71.6%)	43/61 (70.5%)	OR 1.01 (0.50 to 2.03); 0.978; 665
SEQ undercorrected by more than 0.50 D, 3 months, n/N (%)	131/605 (21.7%)	18/61 (29.5%)	OR 1.45 (0.71 to 2.93); 0.308; 665
Manifest SEQ, 6 months, D, mean ± SD (N)	−0.21 ± 0.49 (466)	−0.41 ± 0.53 (53)	−0.17 D (− 0.32 to − 0.02); 0.028; 518
SEQ within ± 0.50 D, 6 months, n/N (%)	344/466 (73.8%)	32/53 (60.4%)	OR 0.54 (0.28 to 1.07); 0.077; 518
SEQ undercorrected by more than 0.50 D, 6 months, n/N (%)	96/466 (20.6%)	20/53 (37.7%)	OR 2.24 (1.15 to 4.36); 0.018; 518
Manifest SEQ, 12 months, D, mean ± SD (N)	−0.11 ± 0.39 (378)	−0.54 ± 0.57 (46)	−0.42 D (− 0.61 to − 0.23); < 0.001; 424
SEQ within ± 0.50 D, 12 months, n/N (%)	317/378 (83.9%)	27/46 (58.7%)	OR 0.24 (0.11 to 0.54); < 0.001; 424
SEQ undercorrected by more than 0.50 D, 12 months, n/N (%)	48/378 (12.7%)	18/46 (39.1%)	OR 4.78 (2.08 to 11.02); < 0.001; 424

CDVA = corrected distance visual acuity; CI = confidence interval (patient-cluster bootstrap; exact binomial where no eye met the criterion); D = dioptre; OR = odds ratio; RR = risk ratio; SD = standard deviation; SEQ = spherical equivalent refraction; UDVA = uncorrected distance visual acuity; y = years. Adjusted effects are from patient-clustered logistic (OR) or linear (D) models with attempted SEQ, attempted cylinder, profile version, optical zone and nomogram era as covariates; eyes without a recorded optical zone are absent from the models, hence the smaller N. *Outcomes with fewer than 30 events are given as unadjusted RR with patient-cluster bootstrap CI; with a single event in one group the lower bound is not estimable and is shown as 0.00. †Enhancement model adjusted for attempted SEQ, cylinder and era; 15 of the 51 enhanced eyes lack a recorded attempted refraction and are absent from the model. – = not modelled (too few events) or not applicable. Dated records = examinations with a recorded date inside the visit window; the remaining records were date-matched from the electronic medical record export. Day-1 SEQ is the objective aberrometer refraction of all eyes measured; manifest SEQ is that of eyes refracted at the visit. Enhancement is reported in the registry set including enhanced eyes; all other rows exclude enhanced eyes.

Outcome	Under 40 y	40 y and older	Effect of age 40 y or older (95% CI); P; eyes in model
Enhancement, n/N (%; 95% CI)	43/2634 (1.6%; 1.1 to 2.2)	8/234 (3.4%; 0.8 to 6.7)	OR 3.28 (1.15 to 9.30); 0.026; 2841†

CDVA = corrected distance visual acuity; CI = confidence interval (patient-cluster bootstrap; exact binomial where no eye met the criterion); D = dioptre; OR = odds ratio; RR = risk ratio; SD = standard deviation; SEQ = spherical equivalent refraction; UDVA = uncorrected distance visual acuity; y = years. Adjusted effects are from patient-clustered logistic (OR) or linear (D) models with attempted SEQ, attempted cylinder, profile version, optical zone and nomogram era as covariates; eyes without a recorded optical zone are absent from the models, hence the smaller N. *Outcomes with fewer than 30 events are given as unadjusted RR with patient-cluster bootstrap CI; with a single event in one group the lower bound is not estimable and is shown as 0.00. †Enhancement model adjusted for attempted SEQ, cylinder and era; 15 of the 51 enhanced eyes lack a recorded attempted refraction and are absent from the model. – = not modelled (too few events) or not applicable. Dated records = examinations with a recorded date inside the visit window; the remaining records were date-matched from the electronic medical record export. Day-1 SEQ is the objective aberrometer refraction of all eyes measured; manifest SEQ is that of eyes refracted at the visit. Enhancement is reported in the registry set including enhanced eyes; all other rows exclude enhanced eyes.

Uncorrected visual acuity

UDVA of 20/20 or better at 3 months was reached by 1615/1727 eyes under 40 (93.5%; 95% CI 92.2 to 94.8) and 134/157 aged 40 or older (85.4%; 79.4 to 91.1). After adjustment, eyes aged 40 or older had lower odds of 20/20 (OR 0.43, 95% CI 0.25 to 0.74, P = 0.002), and the odds fell by 41% per decade (OR 0.59, 95% CI 0.43 to 0.80, P < 0.001) (Supplementary Table S2). The age effect was the same in both nomogram eras (OR 0.45 before and 0.42 from July 2024, per decade 0.62 and 0.55; interaction P = 0.876), with sex added and in dated records only (Supplementary Table S2). Relative to the youngest band, the adjusted odds were 0.73, 0.73, 0.55, 0.38, 0.15 for the five older bands, a gradient without a step (Supplementary Figure S2; nonlinearity P = 0.524). With enhanced eyes as failures, 20/20 was reached by 91.2% and 81.2%.

The gradient was present at every visit (Fig. 1A, Table 2): 20/20 on day 1 in 60.7% and 53.2%, at 1 week 75.9% and 65.0%, at 1 month 85.5% and 74.2% (OR 0.51, 95% CI 0.32 to 0.81, P = 0.004), and at 12 months 1252/1301 (96.2%) and 110/119 (92.4%; OR 0.55, 95% CI 0.25 to 1.22, P = 0.143). UDVA worse than 20/25 at 12 months occurred in 10/1301 younger (0.8%) and 4/119 older eyes (3.4%; RR 4.37, 95% CI 0.72 to 13.57; Fig. 1B, Table 2). In dated 12-month records (353 of 1301 and 38 of 119), 20/20 or better was reached by 89.5% and 81.6% (Table 2).

The day-1 objective SEQ was more myopic in older eyes (− 0.15 ± 0.78 D in 1962 younger and − 0.38 ± 0.70 D in 172 older eyes). The day-1 difference belonged to the second era: adjusted, − 0.01 D (− 0.30 to + 0.27) before July 2024 and − 0.28 D (− 0.42 to − 0.15) from July 2024, which a common offset turned into + 0.02 D (− 0.12 to + 0.16) (Supplementary Table S3). With the same-day objective SEQ in the day-1 model the age term moved from OR 0.80 to 0.93; the day-1 20/20 gradient per decade was similar in

both eras (OR 0.86 and 0.81), as at 1 month (0.61 and 0.73). Day-1 CDVA loss of 2 or more lines was the same in both groups (5.8% and 6.3%).

Corrected visual acuity

At 12 months, CDVA fell by 2 or more lines in 0/1243 younger eyes and 1/119 older eye (0.8%; 95% CI 0.0 to 2.6), and by 1 or more lines in 10/1243 (0.8%) and 1/119 (0.8%; RR 1.04, 95% CI 0.00 to 5.01). At 3 months no eye lost 2 lines (Table 2). No eye with preoperative CDVA of 20/20 or better was worse than 20/40 (0/1120 and 0/99 at 12 months; exact upper bounds 0.3% and 3.7%).

Manifest refraction

Manifest SEQ at 12 months was − 0.11 ± 0.39 D in 378 younger eyes and − 0.54 ± 0.57 D in 46 older eyes; the adjusted difference was − 0.42 D (− 0.61 to − 0.23), P < 0.001, or − 0.12 D (− 0.20 to − 0.04) per decade. It was − 0.32 D (− 0.60 to − 0.04) in the first era (229 eyes) and − 0.52 D (− 0.77 to − 0.27) in the second (195; interaction P = 0.390); per decade − 0.05 D (P = 0.432) and − 0.18 D (P < 0.001). Recomputed under a common 0.60 D offset, the second-era difference fell to − 0.19 D (− 0.45 to + 0.07) and the gradient became + 0.07 D per decade (− 0.02 to + 0.16) (Supplementary Table S3). Within the 35 to 44 band, which shares one offset, eyes aged 40 to 44 were − 0.37 D (− 0.62 to − 0.12) more myopic than eyes aged 35 to 39 at 12 months, pooled across eras (41 and 66 eyes; −0.33 D (− 0.67 to + 0.01) in the first era and − 0.46 D (− 0.84 to − 0.08) in the second), against + 0.00 D (− 0.22 to + 0.22) on day 1 and + 0.02 D (− 0.21 to + 0.24) at 3 months. By band, the adjusted difference from the youngest band was + 0.01, + 0.09, − 0.00, − 0.37, − 0.57 D, flat to the mid-thirties (spline nonlinearity P = 0.024; Supplementary Figure S2, Supplementary Table S2). SEQ was undercorrected by more than 0.50 D in 48/378 (12.7%) and 18/46 (39.1%; OR 4.78, 95% CI 2.08 to 11.02, P < 0.001; Figs. 1C and 2, Supplementary Figures S3 and S4). With enhanced eyes as undercorrected, the proportions were 21.6% and 48.1%. The age difference did not vary with attempted correction (Fig. 2; P = 0.264). The response per programmed dioptre did not change measurably with age (product term − 0.02 D per dioptre per decade, − 0.05 to + 0.01, at 12 months; −0.03 and − 0.04 on day 1 and at 3 months, CIs including zero; Supplementary Table S3, Supplementary Figure S5).

At 3 months, SEQ was − 0.20 ± 0.55 D (605 eyes) and − 0.42 ± 0.57 D (61 eyes; adjusted difference − 0.18 D, 95% CI − 0.34 to − 0.03, P = 0.023), undercorrected beyond 0.50 D in 21.7% and 29.5% (OR 1.45, 95% CI 0.71 to 2.93, P = 0.308). In eyes refracted at both visits, SEQ did not change between 3 and 12 months (− 0.12 to − 0.10 D, 270 younger; −0.34 to − 0.34 D, 33 older eyes).

Enhancement

Enhancement was performed in 43/2634 eyes of 36 patients under 40 (1.6%; 95% CI 1.1 to 2.2) and 8/234 eyes of 5 patients aged 40 or older (3.4%; 0.8 to 6.7) (none aged 45 or older); before July 2024 the rates were 3.6% (30/834) and 8.2% (5/61) and from July 2024 0.7% (13/1800) and 1.7% (3/173). The unadjusted risk ratio was RR 2.09, 95% CI 0.51 to 4.49. Adjusted for attempted SEQ, cylinder and era, age

40 or older was associated with enhancement (OR 3.28, 95% CI 1.15 to 9.30, P = 0.026; 36 events; 15 enhanced eyes lacked an attempted refraction) whereas age per decade was not (OR 1.54, 95% CI 0.79 to 2.98, P = 0.204). No NOVA eye (850) was enhanced, so profile version could not be included.

Optical quality

Day-1 MASI rose by 21.3 (95% CI 20.5 to 22.2) in younger and 21.5 (18.1 to 25.2) in older eyes; age did not predict the rise (P = 0.543). The day-1 rise in 6-mm corneal higher-order aberration was larger in older eyes before adjustment (+ 0.16 vs + 0.28 μm) but not after it (+ 0.05 μm, 95% CI − 0.03 to + 0.12), and the change in corneal spherical aberration was unrelated to age (Supplementary Table S4).

Discussion

In 2817 eyes, the odds of 20/20 uncorrected acuity at 3 months fell about 41% per decade of age, without a threshold, and to the same extent before and after the July 2024 nomogram. Eyes of patients aged 40 or older ended 0.42 D more myopic after adjustment and were enhanced about twice as often. In refracted eyes that residual appears to have two parts. The second-era offset gave a patient under 25 one dioptre more added correction than a patient of 45, twice the observed age difference, and recomputing the second-era refractions under a common offset reduced the 40-and-older difference from − 0.52 to − 0.19 D and reversed the per-decade gradient on day 1 and at 3 months (+ 0.14 and + 0.11 D) and flattened it at 12 months (+ 0.07 D), so part, and possibly all, of the continuous gradient reflects the nomogram. A step at 40 is not explained by it: it was present in the first era, without any offset (− 0.32 D on 21 refracted eyes, all aged 40 to 44, with no per-decade slope), and within the 35 to 44 band, where the offset is identical, refracted eyes aged 40 to 44 ended 0.37 D more myopic than eyes aged 35 to 39, with the same sign in each era. Corrected acuity was preserved.

Three mechanisms can produce an age-associated myopic endpoint: a smaller corneal response in the stiffer older stroma [8]; an age-dependent nomogram; and age-dependent expression of the same residual, because accommodative reserve masks a small myopic error before 40 and not after. The day-1 objective refraction showed no age difference in the first era (− 0.01 D, − 0.30 to + 0.27, 36 older eyes) and the full gradient in the second, where the recomputation removed the 40-and-older difference (+ 0.02 D), which points to the nomogram rather than the cornea for the day-1 gap. Treatment used the cycloplegic refraction and the aberrometer is closed-field, so accommodation could only make young eyes appear more myopic. The 20/20 gradient, present in both eras from 1 month, when the first-era refractive difference was small (− 0.16 D at 3 months), may be expression: the older eye tolerates the same small residual less well. The 12-month step at 40 within one offset band, absent earlier, is compatible with a late myopic shift, expression or the stroma [8]; the response per programmed dioptre did not change measurably with age, so the age effect behaves as an offset, not as a change in efficiency. That refractive age effects depend on procedure and nomogram is also the lesson of aspheric high-myopic LASIK, where older age went with a more hyperopic endpoint [13].

These findings extend the multicentre report of Neuhann et al. (20/20 in 79% versus 93%, re-treatment 9% versus 1%, at 55 or older versus 35 or younger) [10]: the same pattern is present at 40 to 44, part of it related to how such eyes were treated. The early effect agrees with the SMILE series of Zhou et al. [14], and the myopic residual with older age as a regression risk factor [7] and with LASIK in the presbyopic age group [9].

The 2024 rule, introduced before the first-era age pattern had been characterised, reduced the added correction with age deliberately: an overcorrected myope after 40 loses near vision and, in our view, is worse off than one left slightly myopic. These data describe the cost of that trade, up to about 0.3 D of the second-era residual in refracted eyes, not that another rule was better. They do not support a flat offset, under which the youngest band would end near − 0.49 D at 12 months; they raise the question whether the reduction after 35 could be smaller, since refracted eyes aged 40 to 44 given the same offset as eyes aged 35 to 39 still ended 0.37 D more myopic. That needs a prospective study with cycloplegic refraction of every eye, a fixed enhancement criterion and near-vision outcomes, so that overshoot can be weighed against residual. Until then, patients over 40 should be told that at 1 month about one in four eyes is not yet 20/20, against one in seven in younger patients, that at 3 months 15% are not, that the eye tends to settle slightly myopic and that enhancement is needed in 3 to 5%; 92% nevertheless saw 20/20 at 12 months.

The limitations are those of a retrospective single-surgeon registry. The recomputation assumes that the offset was applied exactly by band, since it is not stored per eye, and one-to-one transfer of programmed correction into refraction. The transfer is not identifiable: the second-era slopes would be fully explained by the nomogram at 0.50 to 0.64 D per dioptre of offset, whereas the youngest band moved from − 0.36 to − 0.05 D on day 1 between eras, about 0.3 per dioptre, and the eras differ in other respects. Within the second era age and offset are collinear; all refractive results are those of refracted eyes. Attendance was 60% at 12 months. About 72% of the 12-month acuity records were date-matched rather than dated; dated records alone gave lower rates and the same direction of effect. Manifest refraction was unmasked and more often performed in eyes that were not 20/20 or reported blur, so the residual SEQ overstates the population mean. Enhanced eyes were removed from all visits because their enhancement date is unknown, which biases differences towards the null. Only 36 eyes were aged 45 or older; the enhancement finding rests on 5 patients and a surgeon decision offered perhaps more readily after 40. Preoperative CDVA was recorded as exactly 20/20 in most eyes, so the safety conclusion rests on absolute postoperative thresholds. Corneal biomechanics were not measured.

In conclusion, after KLEx the attainment of 20/20 uncorrected acuity declined continuously with age in both nomogram eras. In refracted eyes the myopic residual after 40 appeared to have two sources: a continuous gradient related to an age-banded nomogram that gave older eyes less added correction, and a step of about 0.3 to 0.4 D at 40 not explained by the offset. Corrected acuity was preserved. Age-specific counselling follows now; whether a smaller reduction of the offset after 35 improves the endpoint without costing near vision is a question for prospective study.

Declarations

Supplementary information is available at Eye's website.

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None.

Author contributions

IG designed the study, performed all procedures, maintained the registry, verified the refractions, analysed the data and wrote the manuscript. SAM contributed to the interpretation of the refractive and optical results and revised the manuscript critically. ISM, FG and MJ collected the data and reviewed the charts. NG supervised the study and revised the manuscript critically. All authors approved the final version.

Conflict of interest

IG is a consultant for SCHWIND eye-tech-solutions, Johnson & Johnson Vision, SIFI and CSO. SAM is an employee of SCHWIND eye-tech-solutions. The other authors declare no competing interests.

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Data availability

The analysis code and de-identified aggregate data are available from the corresponding author on reasonable request. Patient-level data are not publicly available.

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Figures

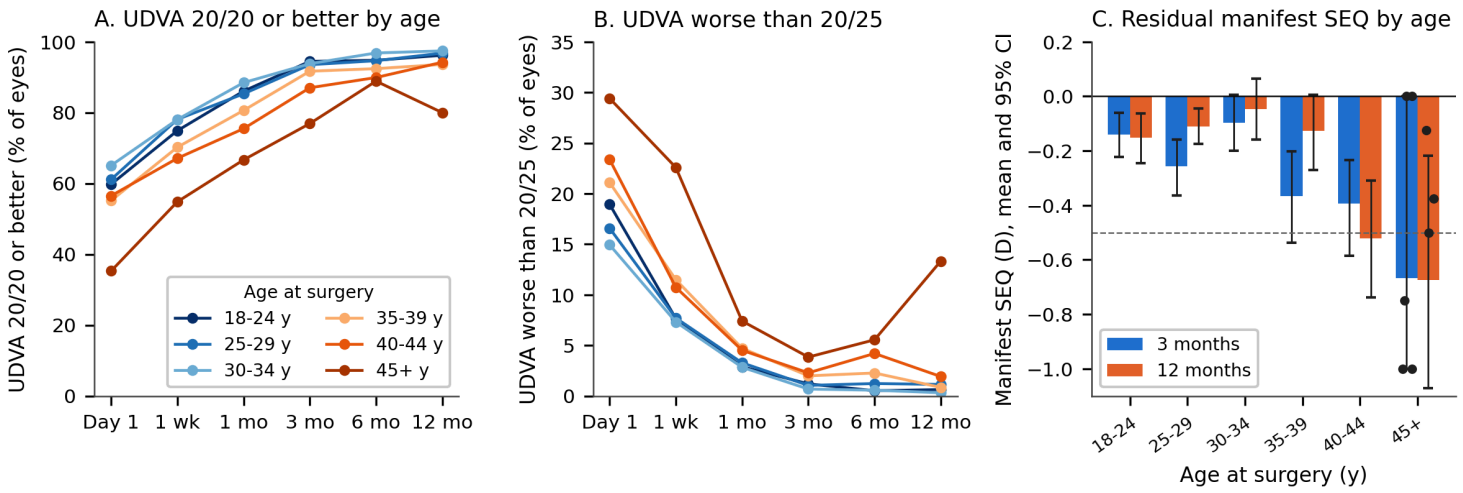


Figure 1

Uncorrected distance visual acuity (UDVA) and manifest refraction by age at surgery (bands in completed years: 18-24, 25-29, 30-34, 35-39, 40-44 and 45+). (A) Proportion of eyes with UDVA of 20/20 or better at each visit by age band. (B) Proportion with UDVA worse than 20/25. N per band from youngest to oldest: day 1 644, 772, 636, 455, 184, 34; 1 week 562, 662, 547, 383, 149, 31; 1 month 553, 640, 564, 382, 155, 27; 3 months 417, 572, 437, 301, 131, 26; 6 months 383, 487, 349, 264, 119, 18; 12 months 316, 438, 312, 235, 104, 15. (C) Mean manifest spherical equivalent (SEQ) at 3 months (N = 160, 210, 144, 91, 55, 6) and 12 months (N = 100, 123, 89, 66, 41, 5) by band; error bars are 95% patient-cluster bootstrap confidence intervals; individual eyes are plotted where N < 10; the dashed line marks −0.50 D. Enhanced eyes are excluded.

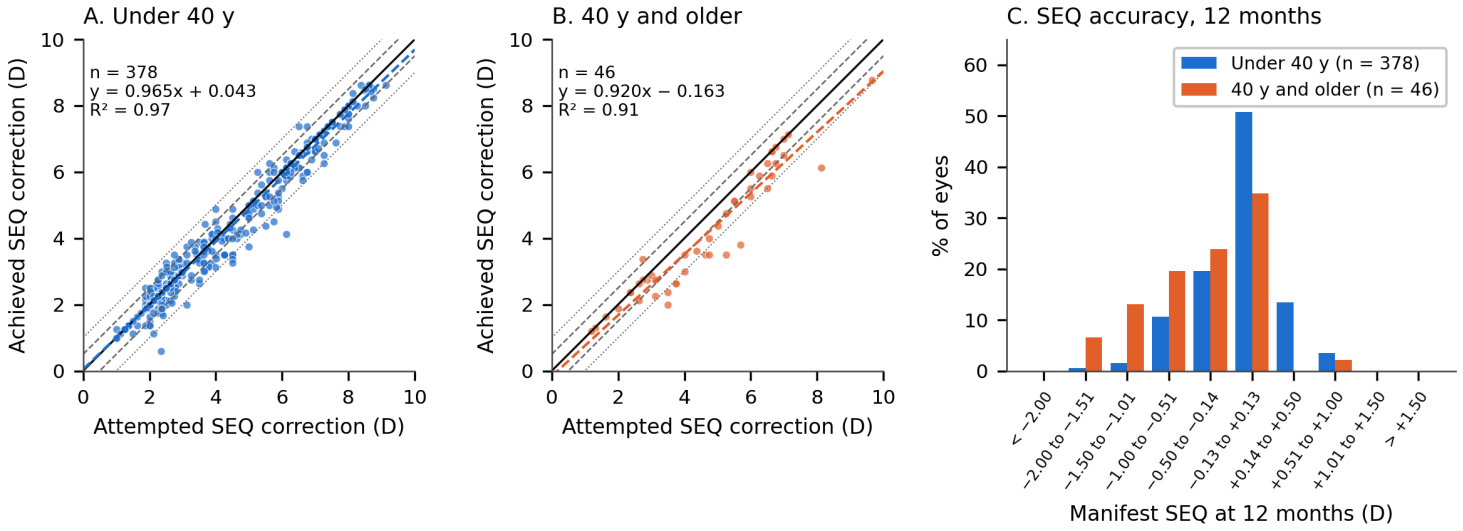


Figure 2

Manifest refractive outcome at 12 months in eyes under 40 years (N = 378) and 40 years or older (N = 46). (A, B) Attempted versus achieved spherical equivalent (SEQ) correction (myopic magnitude): the

solid black line is identity, the coloured dashed line the least-squares regression (equation and R^2 in the panel), grey dashed lines ±0.50 D and dotted lines ±1.00 D from identity. (C) Distribution of the postoperative manifest SEQ relative to the emmetropic target. Enhanced eyes are excluded.

Supplementary Files

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