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Corneal allogenic intrastromal ring segment implantation in post crosslinked keratoconus: one-year outcomes from a UK tertiary centre

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Abstract

Objectives

To report visual, refractive, topographic, and wavefront outcomes of corneal allogenic intrastromal ring segment (CAIRS) implantation in keratoconus stabilised by prior collagen cross-linking (CXL) in a UK National Health Service setting.

Methods

A case series of 17 consecutive eyes of 17 patients undergoing primary CAIRS implantation with KeraNatural segments (Lions VisionGift) at Queen Victoria Hospital, East Grinstead. All eyes had prior epithelium-off CXL. Outcomes were assessed pre-operatively and at 1, 3, 6, and 12 months including visual, refractive and topographic data.

Results

UCVA improved from 0.93 ± 0.38 to 0.74 ± 0.41 logMAR at 12 months (N = 8, p = 0.003). Autorefractor sphere improved from − 5.3 ± 3.5 to − 0.7 ± 4.5 D (p < 0.001) and spherical equivalent from − 7.5 ± 3.5 to − 3.2 ± 4.3 D (p = 0.002). K_1, K_2, and mean keratometry were significantly lower at all timepoints (all p ≤ 0.005 at 12 months); maximum keratometry although lower did not reach significance. Anterior best-fit sphere radius increased at all timepoints (p < 0.001), consistent with anterior corneal flattening. Coma decreased (1.12 ± 0.81 to 0.70 ± 0.53 μm, p = 0.028), while cylinder and topographic astigmatism did not change significantly. No intra-operative or post-operative complications were recorded.

Conclusions

CAIRS implantation with KeraNatural segments was associated with improved vision, reduced myopic spherical equivalent, anterior corneal flattening, and reduced coma through 1 year in post-CXL keratoconic eyes. These are the first reported UK outcomes of CAIRS implantation in an NHS setting.

Summary

What was known before

- CAIRS implantation improves visual, refractive and topographic outcomes in keratoconus across heterogeneous nomograms and follow-up durations, but published series include few previously cross-linked eyes.
- Prior CXL stiffens the cornea and may attenuate the biomechanical response to subsequent intracorneal segment implantation, with limited UK NHS data available.

What this study adds

- This is the first reported UK NHS series of CAIRS outcomes in keratoconus.
- The largest published cohort of post-CXL keratoconic eyes treated with commercially pre-cut KeraNatural CAIRS segments.
- An overall pattern of corneal surface regularisation with topographic and visual improvement and reduction in visually disabling aberrations through 12 months.

Introduction

Keratoconus is a bilateral corneal ectasia characterised by progressive stromal thinning and conical protrusion, producing irregular astigmatism and myopic refractive shift (1) (link).). Contemporary management separates disease stabilisation from visual rehabilitation: corneal collagen cross-linking (CXL) is used to arrest progression in progressive keratoconus, whereas spectacles, contact lenses, intracorneal ring segments, refractive procedures and keratoplasty address residual optical dysfunction. Although CXL reduces progression and has reduced the need for keratoplasty, it does not reliably reverse established irregular astigmatism or restore tolerance of rigid or scleral contact lenses in all patients (2). (link).

Synthetic intracorneal ring segments (ICRS), including Intacs (Addition Technology), Ferrara rings and KeraRing (Mediphacos) are intrastromal polymethyl methacrylate (PMMA) implants that reshape the cornea through an arc-shortening and tissue-addition effect. However, they are associated with material specific complications including segment extrusion, migration, sterile keratitis, stromal melting, and dysphotopsias (3, 4). Corneal allogenic intrastromal ring segments (CAIRS) replaced the synthetic material with donor corneal tissue implanted into femtosecond laser-created intrastromal tunnels. In Jacob's pilot series of 24 eyes in 2018, CAIRS improved visual acuity, keratometry, and spherical equivalent with no segment-related complications, establishing this approach as a viable alternative to the material-specific risks inherent to synthetic ICRS (5).

The evidence base for CAIRS has expanded rapidly. A 2025 systematic review and meta-analysis by Friedrich et al. pooling 14 studies and 442 eyes reported a mean improvement in corrected distance visual acuity of 0.37 logMAR, a reduction in maximum keratometry of 4.49 D with a low complication rate (6). More recent series have examined customised or femtosecond-cut segments, post CXL eyes and advanced keratoconus with heterogenous outcomes depending on nomogram and segment design, prior CXL status and follow-up duration. Published series now span multiple countries and nomogram systems (7).

We report the visual, refractive, topographic, and wavefront aberrometry outcomes and safety profile of primary CAIRS implantation through the first post-operative year in a cohort of patients with keratoconus stabilised by prior CXL at a UK tertiary referral centre.

Methods

Study design and setting

This was a non-comparative chart review of a series of patients undergoing CAIRS procedures performed at the Corneoplastic Unit, Queen Victoria Hospital NHS Foundation Trust, East Grinstead, UK. The study adhered to the tenets of the Declaration of Helsinki and was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies. This study was approved by the local institutional review board (project ID 2073) and adhered to the tenets of the Declaration of Helsinki. All patients provided informed consent for surgery and for use of anonymised data.

Participants

Seventeen eyes of 17 patients were reviewed. All cases had a diagnosis of keratoconus confirmed clinically and using topographic data from Pentacam Scheimpflug topography (Oculus Optikgeräte, Wetzlar, Germany), and disease was considered stable after undergoing epithelium-off collagen cross-linking (CXL) at least 1 year prior to CAIRS. All cases had visually significant reduced uncorrected acuity with reported contact lens intolerance, and no other ophthalmic surgery other than previous CXL.

Surgical Technique

All procedures were performed by consultant corneal surgeons. CAIRS planning was dependent on the tomography data derived from MS-39 (Costruzione Strumenti Oftalmici, Florence, Italy) and utilised a standardised protocol (Table 1), which was modified from the Istanbul nomogram as described by Haciagaoglu et al (8), Intrastromal tunnels were created using a Ziemer Z8/Z6 femtosecond laser (Ziemer Ophthalmic Systems, Port, Switzerland) at a depth of 300 μm. The KeraNatural segment was inserted into the tunnel without prior dehydration and positioned by in-theatre topography maps. Pre-cut CAIRS segments (KeraNatural; Lions VisionGift, Portland, OR, USA) were used in all cases. Full-thickness segments were used in all 17 eyes; Sixteen received a 6 mm segment and one received an 8 mm segment. Sixteen patients received one segment and one patient received two segments based on preoperative tomographic assessment of the cone morphology.

Table 1
Surgical marking and laser parameters.

Parameter	Specification
Pre-operative marking (slit-lamp, gentian violet, Fig. 1)	
Centre of cornea	1 dot
Horizontal temporal	1 dot
Steep meridian (anterior K-steep, Pentacam axial map)	3 dots
Opposite meridian (180° from K-steep)	1 dot
Tunnel planning	
Topography for tunnel mapping	MS-39 tangential and Gaussian curvature maps
Incision axis	Anterior K_{steep} meridian
Target tunnel depth	300 µm
Minimum residual stromal roof	250 µm above the tunnel
Minimum residual stroma below tunnel	120 µm below the thinnest point on the trajectory
Tunnel arc length	180°, single arc, commencing at K_{steep}
Offset / overlap rule	30° offset applied to centre the tunnel on the steep meridian
Ziemer Z6 femtosecond laser parameters	**AFR6 software profile**
Tunnel position	Aligned to anterior K_{tteep}
Tunnel depth	300 µm (per case plan)
Cutting velocity	5 mm/s
Vertical velocity	15 mm/s
Stromal power	120%
Tunnel arc length	40
Tunnel width	0.45 mm
Insertion area, width	1.3 mm
Insertion area, length	10 mm
End incisions	Enabled

Outcome measures

Pre-operative and post-operative assessments were at 1, 3, 6 and 12 months (POM1, POM3, POM6 and POM12). Data were not available for all patients at all follow-up timepoints; sample sizes at each visit are reported with the results.

Visual acuity was measured uncorrected (UCVA), corrected (CDVA) and pinhole (PHVA) and converted into the logarithm of the minimum angle of resolution (logMAR) using standard conversion tables.

Autorefraction data were recorded as sphere, cylinder, and calculated spherical equivalent. Insufficient subjective refraction data were available for analysis and were excluded.

Corneal topography was measured with the Pentacam HR rotating Scheimpflug camera. Parameters recorded were: flat keratometry (K_1), steep keratometry (K_2), mean keratometry (K_{mean}), maximum keratometry (K_{max}), topographic astigmatism, thinnest corneal thickness, and anterior and posterior best-fit sphere (BFS) radius.

Epithelial thickness was measured using the CSO MS-39 anterior segment optical coherence tomographer (Costruzione Strumenti Oftalmici, Florence, Italy). Wavefront measurements were extrapolated using the in-built wavefront function in Phoenix software (Costruzione Strumenti Oftalmici, Florence, Italy) using tomographic data acquired from the MS-39 device over a 4 mm pupil diameter. Parameters recorded were: total optical path difference (OPD), higher-order aberrations (HOA) root mean square (RMS), astigmatism RMS, absolute cylinder magnitude, coma, and spherical aberration. All wavefront values are reported in micrometres.

Statistical Analysis

Paired two-tailed t-tests were used for all comparisons between pre-operative and post-operative timepoints across visual, refractive, topographic, epithelial, and wavefront outcome domains. One eye per patient was included, precluding inter-eye correlation. Shapiro-Wilk testing on paired differences confirmed normality in 71 of 83 comparisons (86%). Wilcoxon signed-rank tests were performed as a sensitivity analysis of the non wavefront comparisons; results were concordant in 56 of 59 main comparisons, with the three discordances occurring where sample size precluded the non-parametric test from reaching significance.

Descriptive statistics are presented as mean ± standard deviation. Ninety-five per cent confidence intervals were calculated as mean ± $t(0.025, n - 1) \times$ standard error of the mean. Sample sizes are reported for each comparison as not all patients had reached all follow-up timepoints at the time of data collection. Uncorrected two-sided p-values are reported throughout, with significance set at $p < 0.05$. Bonferroni correction was not applied: all outcomes were pre-specified clinical endpoints, the comparisons are correlated (corneal flattening improves keratometry, vision, and aberrations together) and therefore not independent, and the sample size already limits power such that correction would

eliminate the ability to detect clinically meaningful changes. Multiple testing is acknowledged as a limitation. Data were collected and analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) with statistical verification performed using Python 3.12 (scipy 1.13).

Results

Seventeen eyes of 17 patients were included. Mean age at surgery was 32.9 ± 10.3 years. Baseline UCVA was 0.93 ± 0.38 logMAR, PHVA was 0.33 ± 0.28 logMAR, mean K_{max} was 58.2 ± 7.0 D, autorefractor sphere was − 5.3 ± 3.5 D and autorefractor cylinder was − 4.3 ± 2.6 D cylinder. The baseline characteristics are displayed in Table 2. Data availability varied by outcome and visit as not all patients had reached each follo-up timepoint at the time of data extraction. No intra-operative or post-operative complications were recorded and no eye required further surgery or segment removal in the follow up period.

Table 2
Baseline characteristics. UCVA = uncorrected visual acuity; CDVA = corrected distance visual acuity; PHVA = pinhole visual acuity; D = dioptres; BFS = best-fit sphere; SD = standard deviation.

Characteristic	Value (mean ± SD)
N (eyes)	17
Age at surgery, years	32.9 ± 10.3
Laterality, right : left	5 : 12
Pre-operative visual acuity (logMAR)	
UCVA	0.9 ± 0.4
CDVA	0.6 ± 0.4
PHVA	0.3 ± 0.3
Autorefraction (D)	
Sphere	-5.3 ± 3.5
Cylinder	-4.3 ± 2.6
Spherical equivalent	-7.5 ± 3.5
Corneal Topography (Pentacam)	
K_1 (D)	47.3 ± 3.8
K_2 (D)	51.6 ± 3.9
K_{mean} (D)	49.3 ± 3.5
K_{max} (D)	58.2 ± 7.0
Topographic astigmatism (D)	4.3 ± 3.3
Thinnest corneal thickness (μm)	449.6 ± 24.6
BFS elevation, anterior surface (D)	7.4 ± 0.4
BFS elevation, posterior surface (D)	6.1 ± 0.3
Epithelial thickness, thinnest point (μm)	42.4 ± 5.4

Visual and refractive outcomes

UCVA was significantly better at all timepoints than the paired preoperative visit (0.93 ± 0.38 pre-operatively to 0.68 ± 0.31 logMAR at POM1, p = 0.002, and 0.74 ± 0.41 logMAR at POM12, N = 8, p =

0.003; Fig. 2A, Table 3), though the magnitude of improvement varied across visits as different patient subsets reached each timepoint. CDVA reached statistical significance at POM6 (0.41 ± 0.39 logMAR, N = 7, p = 0.019) and POM12 (0.32 ± 0.29 logMAR, N = 5, p = 0.044; Fig. 2A, Table 3). PHVA improved at POM1 (0.22 ± 0.20 logMAR, N = 13, p = 0.002) and POM12 (0.22 ± 0.26 logMAR, N = 6, p = 0.004) but did not reach significance at POM3 or POM6 (Fig. 2A, Table 3). Autorefractor sphere and spherical equivalent was significantly less myopic at all postoperative visits (sphere − 5.3 ± 3.5 to − 0.7 ± 4.5 D at POM12, N = 8, p < 0.001; spherical equivalent − 7.5 ± 3.5 to − 3.2 ± 4.3 D at POM12, N = 8, p = 0.002; Fig. 2B, Table 3). Cylinder did not improve at any timepoint (− 4.3 ± 2.6 D to − 5.1 ± 2.6 D at POM12, p = 0.459; Fig. 2B, Table 3).

Table 3

Visual acuity and refractive outcomes through 12 months after primary CAIRS implantation. Outcomes shown graphically in Fig. 2 (panel a: visual acuity; panel b: autorefraction). Values are mean ± SD; n indicates paired observations available at each timepoint. Bold values indicate statistical significance compared with preoperative, *p < 0.05; **p < 0.01; ***p < 0.001. UCVA = uncorrected visual acuity; CDVA = corrected distance visual acuity; PHVA = pinhole visual acuity; D = dioptres.

Parameter	Pre-op	POM1	POM3	POM6	POM12
Visual acuity					
UCVA (logMAR)	0.93 ± 0.38 (n = 17)	**0.68 ± 0.31 (n = 16) p = 0.002****	**0.53 ± 0.32 (n = 10) p < 0.001*****	**0.84 ± 0.45 (n = 10) p = 0.004****	**0.74 ± 0.41 (n = 8) p = 0.003****
CDVA (logMAR)	0.56 ± 0.40 (n = 11)	0.57 ± 0.35 (n = 7) p = 0.486	0.22 ± 0.19 (n = 4) p = 0.288	**0.41 ± 0.39 (n = 7) p = 0.019***	**0.32 ± 0.29 (n = 6) p = 0.044***
PHVA (logMAR)	0.33 ± 0.28 (n = 15)	**0.22 ± 0.20 (n = 15) p = 0.002****	0.15 ± 0.15 (n = 8) p = 0.457	0.27 ± 0.26 (n = 7) p = 0.226	**0.22 ± 0.26 (n = 6) p = 0.004****
Autorefraction					
Sphere (D)	−5.3 ± 3.5 (n = 16)	**−2.2 ± 2.9 (n = 14) p = 0.002****	**−1.6 ± 3.2 (n = 8) p = 0.003****	**−1.6 ± 4.1 (n = 6) p = 0.005****	**−0.7 ± 4.5 (n = 8) p < 0.001*****
Cylinder (D)	−4.3 ± 2.6 (n = 16)	−3.8 ± 2.1 (n = 14) p = 0.254	−4.0 ± 1.5 (n = 8) p = 0.530	−4.0 ± 1.9 (n = 6) p = 0.739	−5.1 ± 2.6 (n = 8) p = 0.459
Spherical equivalent (D)	−7.5 ± 3.5 (n = 16)	**−4.2 ± 3.1 (n = 14) p < 0.001*****	**−3.7 ± 3.6 (n = 8) p < 0.001*****	**−3.6 ± 3.8 (n = 6) p = 0.010***	**−3.2 ± 4.3 (n = 8) p = 0.002****

Topographic changes

K_1, K_2, and K_{mean} was significantly lower than paired preoperative baseline to all post-operative timepoints (K_1 47.3 ± 3.8 to 43.0 ± 4.7 D at POM12, N = 8, p = 0.003; K_2 51.6 ± 3.9 to 46.7 ± 3.9 D at POM12, N = 8, p = 0.001; K_{mean} 49.3 ± 3.5 to 44.8 ± 4.3 D at POM12, N = 8, p = 0.001; Fig. 3A, Table 4). K_{max} was numerically lower at all postoperative visits but did not reach statistical significance (58.2 ± 7.0

D pre-operatively to 54.5 ± 5.7 D at POM12, all $p > 0.05$; Fig. 3A, Table 4). Topographic astigmatism was also non-significant throughout (4.3 ± 3.3 pre-operatively to 3.7 ± 1.5 D at POM12, $p = 0.334$; Table 4). Anterior BFS radius increased at all timepoints, consistent with anterior corneal flattening (7.42 ± 0.38 mm pre-operatively to 7.81 ± 0.31 mm at POM12, $p < 0.001$; Fig. 3B, Table 4). Posterior BFS radius showed a borderline change at POM3 only (6.08 ± 0.34 mm, $N = 8$, $p = 0.042$) but was non-significant at all other timepoints (Fig. 3B, Table 4). Thinnest corneal thickness increased at POM6 and POM12 (449.6 ± 24.6 µm pre-operatively to 460.9 ± 30.8 µm at POM12, $N = 8$, $p = 0.006$; Fig. 3C, Table 4). Thinnest epithelial thickness did not change throughout (42.4 ± 5.4 µm pre-operatively to 40.2 ± 3.0 µm at POM12, $p = 0.338$; Table 4).

Table 4

Topographic outcomes through 12 months after primary CAIRS implantation. Values are mean ± SD; n indicates paired observations available at each timepoint. Bold values indicate statistical significance compared with preoperative, *p < 0.05; **p < 0.01; ***p < 0.001. K_1 = flat meridian keratometry; K_2 = steep meridian keratometry, K_{mean} = mean keratometry; K_{max} = maximum keratometry; BFS = best-fit sphere; D = dioptres.

Parameter	Pre-op	POM1	POM3	POM6	POM12
Keratometry					
K_1 (D)	47.3 ± 3.8 (n = 17)	**44.6 ± 3.3 (n = 12) p = 0.004****	**43.4 ± 3.9 (n = 8) p = 0.016***	**44.1 ± 4.1 (n = 8) p = 0.003****	**43.0 ± 4.7 (n = 8) p = 0.003****
K_2 (D)	51.6 ± 3.9 (n = 17)	**49.1 ± 4.6 (n = 12) p < 0.001*****	**48.1 ± 3.8 (n = 8) p = 0.002****	**47.4 ± 4.6 (n = 8) p < 0.001*****	**46.7 ± 3.9 (n = 8) p = 0.001****
K_{mean} (D)	49.3 ± 3.5 (n = 17)	**46.7 ± 3.5 (n = 12) p = 0.002****	**45.6 ± 3.6 (n = 8) p = 0.005****	**45.6 ± 4.2 (n = 8) p < 0.001*****	**44.8 ± 4.3 (n = 8) p = 0.001****
K_{max} (D)	58.2 ± 7.0 (n = 17)	56.8 ± 5.2 (n = 12) p = 0.146	55.7 ± 4.3 (n = 8) p = 0.204	54.6 ± 6.0 (n = 8) p = 0.086	54.5 ± 5.7 (n = 8) p = 0.563
Topographic astigmatism (D)	4.3 ± 3.3 (n = 17)	4.5 ± 3.5 (n = 12) p = 0.560	4.7 ± 2.7 (n = 8) p = 0.160	3.3 ± 2.1 (n = 8) p = 0.425	3.7 ± 1.5 (n = 8) p = 0.334
Best-fit sphere radius					
Anterior surface (mm)	7.42 ± 0.38 (n = 17)	**7.67 ± 0.41 (n = 12) p < 0.001*****	**7.75 ± 0.35 (n = 8) p = 0.008****	**7.77 ± 0.37 (n = 8) p < 0.001*****	**7.81 ± 0.31 (n = 8) p < 0.001*****

Parameter	Pre-op	POM1	POM3	POM6	POM12
Keratometry					
Posterior surface (mm)	6.13 ± 0.29 (n = 17)	6.11 ± 0.39 (n = 12) p = 0.719	**6.08 ± 0.34** **(n = 8)** **p = 0.042***	6.22 ± 0.34 (n = 8) p = 0.535	6.28 ± 0.26 (n = 8) p = 0.573
Pachymetry					
Thinnest corneal thickness (µm)	449.6 ± 24.6 (n = 17)	451.0 ± 40.0 (n = 12) p = 0.671	442.0 ± 27.1 (n = 8) p = 0.512	**463.4 ± 36.7** **(n = 8)** **p = 0.027***	**460.9 ± 30.8** **(n = 8)** **p = 0.006****
Thinnest epithelial thickness (µm)	42.4 ± 5.4 (n = 17)	42.5 ± 6.5 (n = 14) p = 0.910	41.0 ± 6.8 (n = 9) p = 0.655	43.1 ± 7.1 (n = 9) p = 0.528	40.2 ± 3.0 (n = 8) p = 0.338

Corneal Wavefront changes

Among wavefront parameters, coma showed the clearest improvement. Coma decreased throughout follow-up (1.12 ± 0.81 µm pre-operatively to 0.70 ± 0.53 µm at POM12, N = 8, p = 0.028; Fig. 4A, Table 5). Spherical aberration increased by POM12 (0.170 ± 0.169 µm pre-operatively to 0.217 ± 0.159 µm, N = 8, p = 0.046; Fig. 4B, Table 5). Other wavefront parameters including OPD, overall HOA, astigmatism RMS, and absolute cylinder did not change significantly at any timepoint (Table 5).

Table 5

Corneal wavefront aberrometry outcomes through 12 months after primary CAIRS implantation. Values are mean ± SD; n indicates paired observations available at each timepoint. Bold values indicate statistical significance compared with preoperative, *p < 0.05; **p < 0.01; ***p < 0.001. RMS = root mean square; D = dioptres.

Parameter	Pre-op	POM1	POM3	POM6	POM12
Coma					
Coma (μm)	1.12 ± 0.81 (n = 17)	**0.88 ± 0.63 (n = 16) p = 0.034***	0.67 ± 0.53 (n = 9) p = 0.087	**0.81 ± 0.71 (n = 10) p = 0.005****	**0.70 ± 0.53 (n = 8) p = 0.028***
Spherical aberration					
Spherical aberration (μm)	0.170 ± 0.169 (n = 17)	0.289 ± 0.178 (n = 16) p = 0.087	0.231 ± 0.151 (n = 9) p = 0.279	**0.247 ± 0.154 (n = 10) p = 0.022***	**0.217 ± 0.159 (n = 8) p = 0.046***
Complete wavefront outcomes					
Optical path difference (μm)	2.71 ± 1.29 (n = 17)	2.15 ± 1.18 (n = 16) p = 0.331	2.40 ± 1.29 (n = 9) p = 0.207	2.48 ± 1.43 (n = 10) p = 0.259	2.14 ± 0.48 (n = 8) p = 0.819
Higher-order aberrations RMS (μm)	1.52 ± 0.86 (n = 17)	1.32 ± 0.71 (n = 16) p = 0.183	1.05 ± 0.66 (n = 9) p = 0.136	1.30 ± 0.73 (n = 10) p = 0.130	1.13 ± 0.55 (n = 8) p = 0.521
Astigmatism RMS (μm)	2.16 ± 1.15 (n = 17)	1.59 ± 1.13 (n = 16) p = 0.342	2.06 ± 1.31 (n = 9) p = 0.268	2.00 ± 1.42 (n = 10) p = 0.378	1.71 ± 0.59 (n = 8) p = 0.814
Absolute cylinder, wavefront-derived (D)	5.30 ± 2.81 (n = 17)	3.90 ± 2.77 (n = 16) p = 0.340	5.05 ± 3.22 (n = 9) p = 0.269	4.99 ± 3.43 (n = 10) p = 0.470	4.20 ± 1.45 (n = 8) p = 0.816

Discussion

CAIRS implantation in this post-CXL cohort regularised the corneal surface without flattening the cone apex. UCVA, K_1, K_2, K_{mean}, anterior best-fit sphere radius, and coma all improved through 12 months; K_{max}, autorefractor cylinder, and topographic astigmatism did not. The pattern fits a stiffened cornea responding to segment placement: the apex resists arc-shortening, but the surface still regularises, and that regularisation drives the visual gain. CXL is the established first-line stabilisation procedure across the NHS and most public health systems. Outcomes in post-CXL or simultaneous CAIRS-CXL populations are therefore the most clinically translatable. We observed no intra-operative or post-operative complications across the cohort and no eye required further surgery or segment removal.

The visual and refractive findings are consistent with the broader CAIRS literature. Friedrich et al pooled 14 studies and 442 eyes and found improvements in UDVA, CDVA, spherical equivalent, K_{max}, and higher-order aberrations across heterogenous techniques and follow up duration (6). Our 12-month spherical equivalent and Kmean changes are broadly aligned with that literature, but our UCVA improvement appears more modest than the pooled UDVA estimate and our CDVA analysis is limited by incomplete corrected-acuity data. These differences are perhaps due to our cohort consisting entirely of previously cross-linked eyes treated in routine NHS practice, with incomplete follow-up maturity and reliance on autorefraction rather than manifest refraction.

Coma was the wavefront parameter most clearly improved after CAIRS. Coma is the dominant disabling aberration in keratoconus, accounting for over half of HOA variance in moderate disease(9). Reductions in coma from ICRS placement correlates with improved corrected visual acuity even after the keratometric and refractive gains regress with time (10). In our cohort, total higher order aberration HOA did not reduce significantly at any timepoint, suggesting that CAIRS preferentially reduces the asymmetric component of the aberration profile over the aggregate aberration burden.

K_{max} was numerically lower at all postoperative visits, but did not reach statistical significance despite significant reductions in K_1, K_2, K_{mean}, and anterior BFS radius. The meta-analysis found a pooled improvement of 4.49 D (95% CI 2.92 to 6.05; 13 studies, 439 eyes) (6). Several explanations are possible. Firstly it is likely that CXL induces stiffening changes in the cornea that would alter the biomechanical response to CAIRS: cross-linked collagen fibres resist mechanical deformation, so CAIRS meets greater biomechanical resistance in a stiffened cornea. Yucekul et al. found that CAIRS flattened both CXL and non-CXL corneas but prior CXL resulted in less improvement in CDVA, K_1, and K_{mean} compared with groups that had not had prior CXL (11) and our data is consistent with this concept. Secondly, K_{max} is a focal parameter and may be more vulnerable than Kmean to measurement variability, tear-film quality, local epithelial/stromal remodelling, and shifts in the location of the steepest point after segment implantation. This leads to a high baseline K_{max} variability (SD 7.0 D) which was not compensated by the limited 8 paired observations at POM12 to generate a statistically significant result.

Spherical aberration increased modestly at later visits. This is similar to a CAIRS-post CXL study of 23 eyes by Kirgiz (12) and an Intacs/CXL study of 158 eyes by Greenstein (13). A plausible explanation is that central flattening with relative peripheral curvature redistribution can increase spherical aberration.

However, Mechleb found a significant reduction in spherical aberration after CAIRS when they used Pentacam values at a 5.0mm pupil diameter on patients who were CXL-naïve (14). Overall, our findings of an increase in SA is dwarfed by the improvement in coma, which is known to be a more disabling aberration in keratoconus (9, 15).

The visual improvement in our cohort appears to be driven by corneal surface regularisation more than opposed to cone flattening. Anterior BFS radius increased at all timepoints, consistent with prior CAIRS studies (5, 16). Though posterior BFS radius showed a borderline transient change at POM3 ($p = 0.042$), a finding also reported by Jacob et al. in their original series, the biomechanical effect appears toward the anterior surface.

Astigmatism as measured by autorefractor and Pentacam topography did not show any improvement, consistent with the findings of other groups (11, 14, 17). This pattern suggests that single-segment CAIRS may regularise cone geometry without reliably reducing overall astigmatic magnitude. Patients should be counselled that CAIRS is shape-regularising as opposed to a predictable astigmatic correction procedure. Future customised segment planning may change this but at present, any residual astigmatism may require spectacles, contact lenses, phakic or toric correction or cautious laser vision correction.

The thinnest corneal thickness increased at POM6 and POM12, a finding also seen by Mechleb between 0–3 months in their case series (14). The thinnest point in keratoconus is not a fixed coordinate and postoperative tomographic reshaping may shift the location of the minimum pachymetric point. This increase may reflect stromal redistribution, measurement-location shift, epithelial/stromal remodelling, and segmentation variability.

No intraoperative or postoperative complications were observed in this cohort, and no eye required segment explantation or repeat surgery during the available follow-up. Larger published CAIRS datasets and meta-analyses report low complication rates overall, but rare clinically important adverse events, including rejection requiring explantation, have been reported.

The principal limitation of this study is the per-visit paired sample varied after reaching different follow-up timepoints. The small sample size limits statistical power, particularly for CDVA and PHVA and variable follow-up limited data extraction at later timepoints. Values at each post-operative visit derive from different patient subsets, which limits the interpretation of temporal trends across visits. Refractive data were taken from the autorefractor only as manifest refraction is impractical in many keratoconus patients in the NHS surgical follow up clinic, but this limits comparison with literature that reports manifest refraction. Two surgeons performed the procedures, which may introduce inter-surgeon variability, though the consistency of results across the cohort argues against this being a major confounder. No patient-reported outcome measures were collected and data on contact lens tolerability were not available.

Primary KeraNatural CAIRS implantation in previously cross-linked keratoconus eyes was associated with improved uncorrected visual acuity, less myopic spherical equivalent, anterior corneal flattening, and reduced coma through available follow-up to 12 months, without significant change in Kmax or astigmatism. The dominant effect in this post-CXL cohort was corneal optical regularisation rather than cone-apex flattening. To our knowledge this is the first reported UK series of CAIRS outcomes and the largest published cohort of post-CXL keratoconus eyes treated with commercially pre-prepared KeraNatural segments. Larger prospective studies with complete paired follow-up, manifest refraction, contact-lens outcomes, and patient-reported visual quality are required to define durability and optimal patient selection in post-CXL eyes.

Declarations

Competing Interests:

The authors declare no conflicts of interest.

Conflict of Interest

The authors declare no conflicts of interest.

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Author Contributions

CW: data collection, analysis, and manuscript drafting. AM: study conception and manuscript review. HN: study conception, surgical procedures, and manuscript review. ME: study conception, supervision, and manuscript review. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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None.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Figures

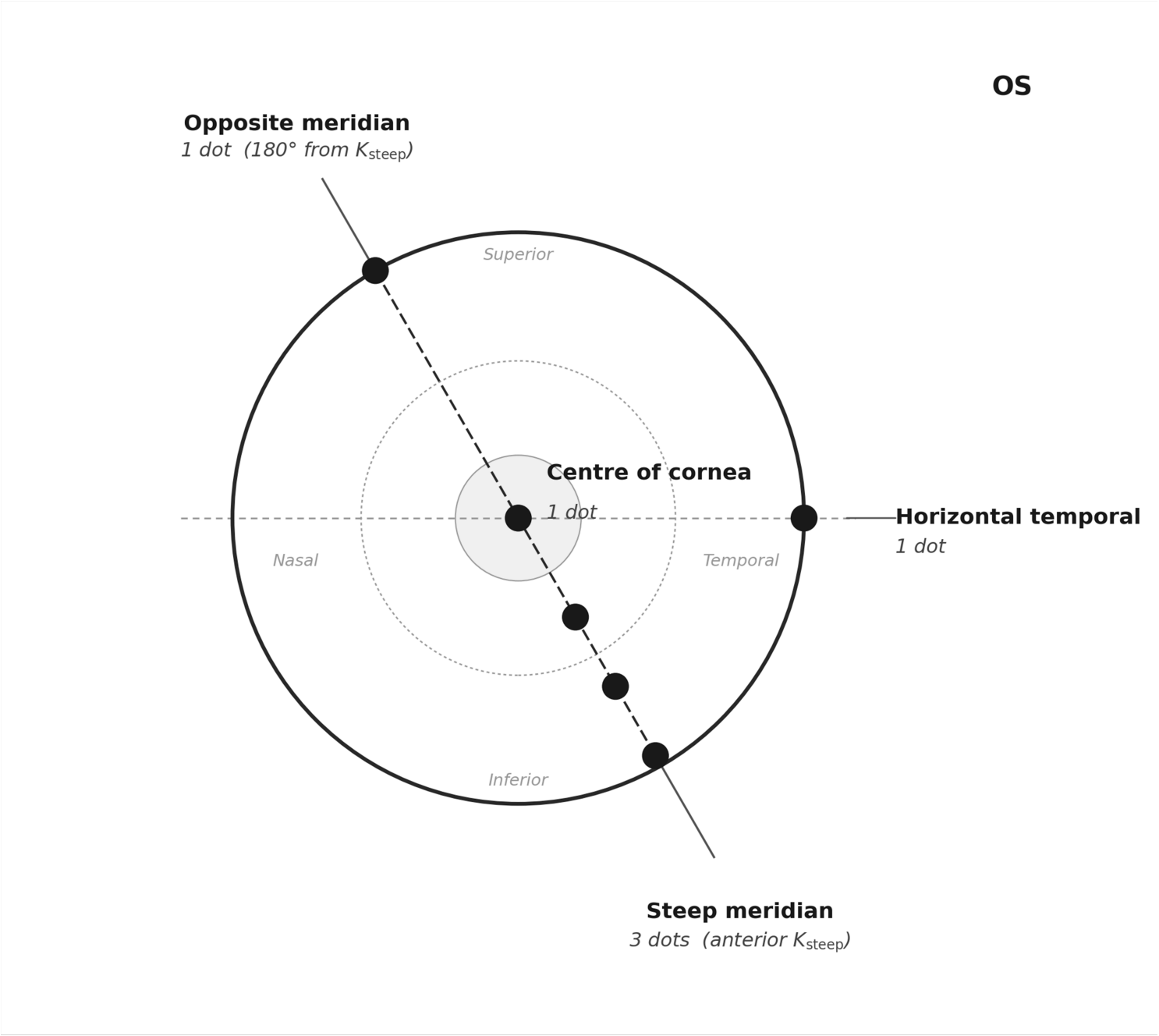


Figure 1

Pre-operative slit lamp markings as described in Table 1.

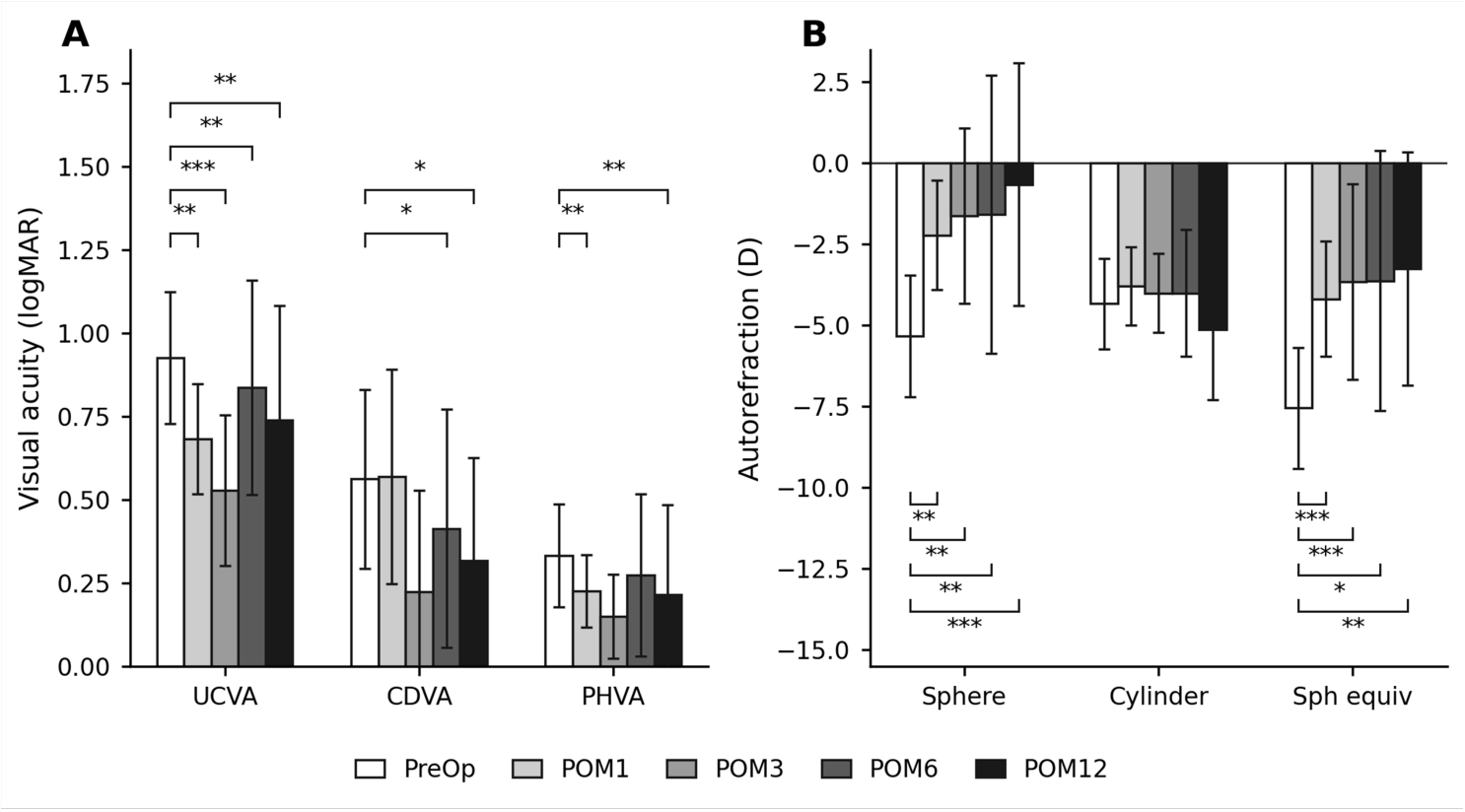


Figure 2

Visual acuity and refractive outcomes following primary CAIRS. (A) Uncorrected (UCVA), corrected distance (CDVA), and pinhole (PHVA) visual acuity. (B) Autorefractor sphere, cylinder, and spherical equivalent. Bars show the mean at pre-operative baseline and at postoperative months 1, 3, 6, and 12. Error bars are 95% confidence intervals. *p < 0.05; **p < 0.01; ***p < 0.001. POM = postoperative month.

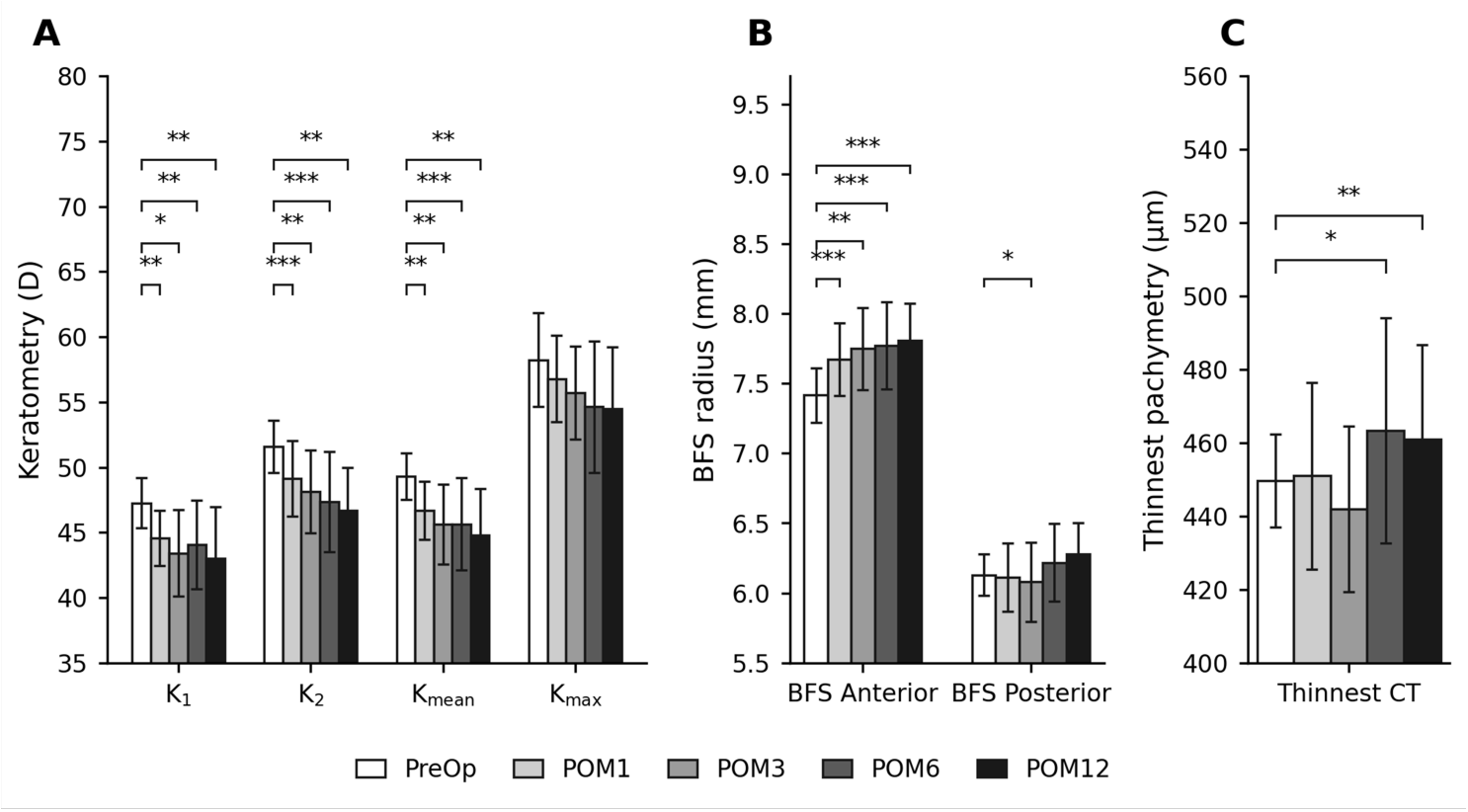


Figure 3

Corneal topographic outcomes following primary CAIRS. (A) Flat (K_1), steep (K_2), mean (K_{mean}), and maximum (K_{max}) keratometry in dioptres. (B) Best-fit sphere (BFS) radius of the anterior and posterior corneal surfaces in millimetres. (C) Thinnest corneal pachymetry. Bars show the mean at pre-operative baseline and at postoperative months 1, 3, 6, and 12. Error bars are 95% confidence intervals. *p < 0.05; **p < 0.01; ***p < 0.001. POM = postoperative month.

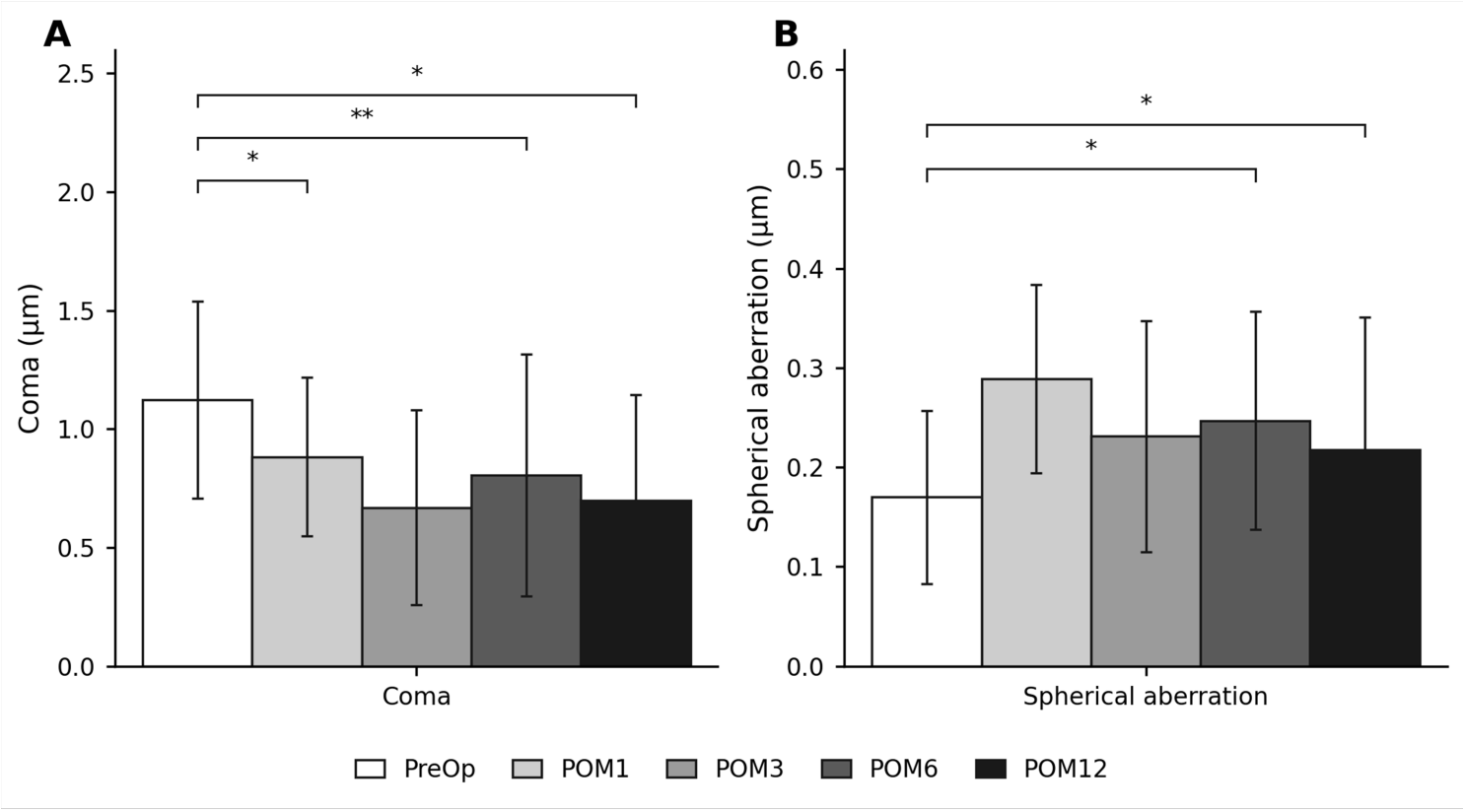


Figure 4

Corneal wavefront aberrations following primary CAIRS. (A) Coma. (B) Spherical aberration, reported as absolute magnitude. Bars show the mean at pre-operative baseline and at postoperative months 1, 3, 6, and 12. Error bars are 95% confidence intervals. *p < 0.05; **p < 0.01. POM = postoperative month.