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Early paradoxical increase in astigmatism after corneal allogeneic intrastromal ring segment implantation: Incidence, predictors, and clinical implications

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Abstract

Purpose: To evaluate the impact of early postoperative astigmatic changes on visual, refractive, and corneal outcomes following corneal allogeneic intrastromal ring segment (CAIRS) implantation for keratoconus.

Methods: This retrospective observational study included patients with keratoconus who underwent CAIRS implantation at a single centre between February 2020 and October 2024. Outcomes included uncorrected and corrected distance visual acuity (UCVA, CDVA), keratometric parameters, and the absolute value of refractive cylinder (|cylinder|). Longitudinal changes were evaluated over a follow-up period of up to 36 months.

Results: A total of 109 eyes were included. CAIRS implantation resulted in significant improvements in visual acuity and corneal parameters. Although the mean |cylinder| significantly decreased (from 4.07±2.56 D to 3.19±2.35 D; P<0.001), 32.4% of eyes showed an increase in |cylinder| at 1 month. Multivariate analysis revealed that prior collagen cross-linking (CXL) was associated with a higher likelihood of early increase in |cylinder| (OR=2.720, 95% CI 1.059-7.207; P=0.038), whereas higher baseline |cylinder| was associated with a lower risk (OR=0.393, 95% CI 0.221-0.651; P<0.001). Eyes with lower baseline astigmatism and prior CXL were more likely to exhibit early increase.

Conclusion: CAIRS significantly improves visual and corneal parameters in keratoconus. Early increases in refractive cylinder are relatively common and are influenced by baseline astigmatism and prior CXL. These changes should be interpreted with caution, as they do not necessarily indicate unfavourable long-term outcomes.

Key message

What is known

✓ CAIRS implantation improves visual acuity and corneal shape in eyes with keratoconus.

✓ Early postoperative changes in refractive astigmatism after CAIRS implantation remain poorly characterized.

What is new

✓ Despite an overall reduction in refractive cylinder, 32.4% of eyes showed an increase in absolute cylinder at 1 month after CAIRS implantation.

✓ Prior corneal cross-linking and lower baseline absolute cylinder were associated with an early increase in absolute cylinder, which did not necessarily indicate an unfavorable long-term outcome.

Introduction

Keratoconus is a progressive ectatic disorder characterized by localized corneal thinning and protrusion, resulting in irregular astigmatism and decreased visual acuity [1, 2]. Initial management typically involves spectacles or contact lenses; however, some patients develop contact lens intolerance or fail to achieve adequate visual correction [3, 4]. As the disease progresses, treatment shifts toward stabilization and visual rehabilitation, with corneal collagen cross-linking (CXL) as the standard approach. Although effective in halting progression, CXL does not directly correct irregular astigmatism [5]. In advanced cases, surgical intervention may be required. Deep anterior lamellar keratoplasty (DALK) allows selective replacement of diseased stroma while preserving host endothelium, thereby reducing the risk of endothelial rejection [6]. However, visual outcomes may still be limited by interface irregularities and residual astigmatism [7].

Intrastromal corneal ring segments (ICRS), composed of polymethyl methacrylate, have been widely used to modulate corneal shape [8]. However, as synthetic implants, they carry risks such as extrusion and stromal complications. Corneal allogeneic intrastromal ring segments (CAIRS), introduced by Jacob *et al*. in 2018, represent a biologically derived alternative using donor corneal tissue [9]. These implants may provide improved biocompatibility and integration compared to synthetic materials. Recent studies suggest that CAIRS is effective even in relatively advanced cases with preserved central corneal clarity [10, 11]. However, early postoperative astigmatic changes following CAIRS remain poorly understood. An increase in refractive cylinder is frequently observed shortly after surgery, but its clinical significance is unclear.

Therefore, this study aimed to evaluate longitudinal changes in visual, refractive, and corneal parameters following CAIRS implantation, with particular emphasis on identifying preoperative factors associated with early postoperative changes in refractive cylinder.

Materials and methods

Study design and ethics

This retrospective observational study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Nihon University Hospital (RK-240109-5). Informed consent was obtained using an opt-out method, and patients who declined participation were excluded.

Patient selection and data collection

Patients with keratoconus who underwent CAIRS implantation at a single centre between February 1, 2020 and October 31, 2024 were retrospectively identified from clinical records based on the availability of longitudinal follow-up data. Clinical data were accessed and analysed only by investigators who were formally approved members or collaborators under each institutional review board between Jan 1, 2026, and Jan 31, 2026. Data sharing across institutions was conducted in a fully anonymized manner, and no personally identifiable information was accessible to investigators outside the originating institution.

Eyes were categorized according to the presence or absence of prior CXL. Inclusion criteria consisted of keratoconus with a minimum corneal thickness of 350 μm at the thinnest point, a clear central cornea, asymmetric and non-central cone location, and documented intolerance to contact lens wear.

Baseline and follow-up assessments included manifest refraction (sphere and cylinder), uncorrected distance visual acuity (UCVA), and corrected distance visual acuity (CDVA). Visual acuity measurements were obtained using Snellen charts and converted to logarithm of the minimum angle of resolution (logMAR) units for statistical analysis. Corneal tomography was performed using a rotating Scheimpflug imaging system (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany), which was also used for the diagnosis of keratoconus and classification of cone location. Parameters recorded included flat keratometry (K1), steep keratometry (K2), mean keratometry (Kmean), maximum keratometry (Kmax), and central corneal thickness (CCT). The absolute value of refractive cylinder (|cylinder|) was calculated for all analyses to represent the magnitude of astigmatism irrespective of axis direction. All patients underwent a comprehensive ophthalmic examination, including slit-lamp bio microscopy, intraocular pressure measurement, and posterior segment evaluation.

Surgical procedures

All procedures were performed by a single surgeon (AK) under topical anaesthesia using 0.5% proparacaine hydrochloride. Allograft corneal ring segments (KeraNatural; VisionGift, Portland, OR, USA) were obtained from donor corneal tissue processed under standardized eye bank conditions and supplied in a sterile, ready-to-use form. Centration was achieved using the first Purkinje reflex, and the pupil centre was marked intraoperatively. A femtosecond laser system (iFS 150 kHz Intralase; Abbott Medical Optics, CA, USA) was used to create a circular intrastromal tunnel according to a nomogram-based approach [12]. A single allogeneic ring segment was inserted into the tunnel using forceps. The segment was positioned according to cone location to achieve optimal corneal regularization. No sutures were required. Postoperative treatment included topical moxifloxacin 0.5% four times daily for 1 week and topical dexamethasone 0.1% administered five times daily with gradual tapering over 8 weeks.

Statistical analysis

Continuous variables are presented as mean±standard deviation (SD) or median (range). Longitudinal changes from baseline were assessed using the Wilcoxon signed-rank test. To evaluate early postoperative astigmatic response, logistic regression analysis was performed using an increase in the absolute value of cylinder (|cylinder|) at 1 month as the outcome variable, defined as early postoperative worsening of astigmatism. Univariate logistic regression analyses were first conducted to assess associations between baseline variables and an increase in |cylinder|. Subsequently, multivariate logistic regression analysis was performed. The full model included all candidate variables entered simultaneously. Model selection was based on the Akaike Information Criterion (AIC), and the model with the lowest AIC was selected as the final model. Continuous variables were standardized (per 1 standard deviation increase). In addition, a stratified analysis was performed to evaluate the frequency

of |cylinder| increase according to significant predictors identified in the multivariate model. For example, a change from − 3.0 D to -5.0 D corresponds to an increase in the absolute value of cylinder (|cylinder|: 3.0 to 5.0 D), and is therefore classified as 'change > 0'. Baseline |cylinder| was dichotomized using the median value as the cutoff. A two-sided P value < 0.05 was considered statistically significant. All analyses were performed using R software (version 4.5.1; R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient characteristics

A total of 109 eyes from patients who underwent CAIRS implantation for keratoconus were included in this study. The cohort comprised 76 eyes (69.7%) with primary keratoconus (KC) and 33 eyes (30.3%) with a history of prior corneal collagen cross-linking (KC + CXL). The mean age of the study population was 29.7 ± 8.4 years. At baseline, the mean spherical equivalent was − 4.52 ± 4.28 D, and the mean absolute cylindrical refraction (|cylinder|) was 4.07 ± 2.56 D.

Longitudinal changes in outcomes

Longitudinal analysis showed significant improvement in refractive and visual parameters following CAIRS implantation. The absolute cylindrical value (|cylinder|) exhibited a significant decrease following surgery and remained reduced throughout the subsequent follow-up period (Table 1, Fig. 1). Mean |cylinder| decreased from 4.07 ± 2.56 D at baseline to 3.19 ± 2.35 D at one month, 3.38 ± 2.48 D at three months, and 3.49 ± 2.35 D at six months (all P < 0.05). Postoperative outcomes showed significant improvement in both UCVA and CDVA, with statistical significance (both P < 0.001; Table 1), and values stabilized over time. All keratometric parameters (K1, K2, Kmean, and Kmax) showed significant reductions after CAIRS implantation. These findings indicate sustained corneal flattening. (Table 1).

Box-and-whisker plots show the distribution of the cylinder at each time point (baseline, 1, 3, 6, 12, 24, and 36 months, and last follow-up). The plots demonstrate an early postoperative reduction in cylinder, followed by relative stabilization over time.

Table 1
Longitudinal changes in refractive, visual, and keratometric parameters after CAIRS implantation

Parameter	Baseline	1 month	3 months	6 months	Last visit	Δ (change from baseline to last visit)	P value
Absolute cylinder (D)	4.07 ± 2.56	3.19 ± 2.35	3.38 ± 2.48	3.49 ± 2.35	2.67 ± 2.13	-1.40 ± 2.62	< 0.001
UCVA (logMAR)	0.97 ± 0.52	0.41 ± 0.35	0.43 ± 0.39	0.41 ± 0.33	0.41 ± 0.38	-0.56 ± 0.50	< 0.001
CDVA (logMAR)	0.65 ± 0.42	0.30 ± 0.37	0.28 ± 0.36	0.23 ± 0.24	0.23 ± 0.26	-0.43 ± 0.43	< 0.001
K1 (D)	47.41 ± 4.30	43.64 ± 4.20	43.41 ± 4.17	43.28 ± 3.78	43.35 ± 3.76	-4.06 ± 2.71	< 0.001
K2 (D)	51.03 ± 4.87	47.26 ± 4.64	46.97 ± 4.71	46.86 ± 4.40	47.30 ± 4.56	-3.74 ± 2.98	< 0.001
Kmean (D)	49.09 ± 4.44	45.36 ± 4.31	45.07 ± 4.24	44.96 ± 3.89	45.21 ± 3.89	-3.88 ± 2.43	< 0.001
Kmax (D)	57.41 ± 6.49	54.88 ± 6.71	55.08 ± 6.35	54.13 ± 5.58	54.65 ± 5.71	-2.76 ± 4.25	< 0.001

Data are presented as mean±standard deviation (SD). Δ indicates the change from baseline to the last visit. Cylinder values are expressed as absolute values (|cylinder|).

UCVA=uncorrected distance visual acuity; CDVA=corrected distance visual acuity; K1 = flat keratometry; K2 = steep keratometry; Kmean=mean keratometry; Kmax=maximum keratometry. Visual acuity was measured using logMAR units.

Comparisons between baseline and each postoperative time point were performed using the Wilcoxon signed-rank test. P value < 0.05 was considered statistically significant.

Stability of the astigmatic effect at the final follow-up visit

At the final follow-up visit (1–36 months), cylinder demonstrated an overall reduction compared with baseline. To evaluate factors associated with cylinder at the final follow-up, regression analyses were performed. In univariate analysis, higher baseline |cylinder| was significantly associated with cylinder at the final visit (Supplementary Table S1). In multivariate analysis, baseline |cylinder| demonstrated a persistent association with cylinder at the final follow-up (Table 2), while other variables did not maintain statistical significance. These findings are consistent with the longitudinal analysis and suggest that the reduction in cylinder achieved after surgery was maintained over time.

Regression coefficients, 95% confidence intervals (CI), and corresponding p-values are shown for demographic, clinical, and corneal parameters. Continuous variables were standardized and analysed per 1 standard deviation (SD) increase. BL=baseline; CDVA=corrected distance visual acuity; OCT=optical coherence tomography; KC=keratoconus; CXL=corneal cross-linking. Standard deviations (SD): Age = 8.4 years, BL=baseline, Implant thickness (OCT) at BL = 42.8 µm, Sphere at BL = 4.281 D, Absolute cylinder at BL = 2.564 D, CDVA at BL = 0.421 logMAR, K mean at BL = 4.44 D.

Table 2
Multivariate linear regression analysis of factors associated with absolute refractive cylinder at the final postoperative visit

Explanatory variable	Category Unit	Full model			Final model		
		Coefficient	95% CI	P value	Coefficient	95% CI	P value
Age	per 1 SD increase	0.212	(-0.176, 0.600)	0.280			
Diagnosis	KC + CXL vs KC	-0.744	(-1.585, 0.098)	0.083	-0.650	(-1.465, 0.165)	0.117
Sphere at BL (D)	1SD increase	-0.389	(-1.014, 0.236)	0.220			
Cylinder absolute value at BL (D)	1SD increase	0.927	(0.482, 1.371)	< 0.001	0.868	(0.492, 1.245)	< 0.001
CDVA at BL (logMAR)	1SD increase	-0.175	(-0.660, 0.309)	0.475			
K mean at BL (D)	1SD increase	-0.097	(-0.743, 0.550)	0.768			

Standard deviations (SD): Age = 8.4 years, Sphere at BL = 4.281 D, Cylinder absolute value at BL = 2.564 D, CDVA at BL = 0.421 logMAR, K mean at BL = 4.44 D.

Predictors of early change in cylinder

To identify factors associated with early postoperative changes in cylinder, logistic regression analyses were performed using an increase in the absolute value of cylinder (|cylinder|) at one month as the outcome, defined as early postoperative worsening of astigmatism. Of 108 eyes, 35 eyes (32.4%) showed an increase in |cylinder| at one month. In univariate analysis, lower baseline |cylinder| and greater implant thickness were associated with an increased likelihood of postoperative increase in |cylinder| (Supplementary Table S2). In multivariate logistic regression analysis, diagnosis of KC + CXL (OR = 2.720, 95% CI 1.059–7.207; P = 0.038) was significantly associated with early postoperative worsening in |cylinder|. In contrast, higher baseline |cylinder| (per 1 SD increase; OR = 0.393, 95% CI 0.221–0.651; P < 0.001) was associated with a lower risk of worsening (Table 3). Stratified analysis

(Table 4) showed that eyes with lower baseline astigmatism and prior CXL were more likely to exhibit worsening of astigmatism. In contrast, eyes with higher baseline astigmatism without prior CXL showed less worsening.

Odds ratios (OR), 95% confidence intervals (CI), and corresponding p-values are presented. An increase in absolute cylinder was defined as a postoperative absolute cylinder value greater than the baseline value. Continuous variables were standardized and analysed per 1 standard deviation (SD) increase. BL=baseline; CDVA=corrected distance visual acuity; OCT=optical coherence tomography; KC=keratoconus; CXL=corneal cross-linking. Standard deviations (SD): Age = 8.4 years, BL=baseline, Baseline implant thickness (OCT) = 42.8 µm, Sphere at baseline = 4.26 D, absolute cylinder at BL = 2.57 D, CDVA at BL = 0.42 logMAR, K mean at BL = 4.44 D.

Table 3
Multivariate logistic regression analysis of factors associated with an increase in absolute refractive cylinder at 1 month after CAIRS implantation

Explanatory variable	**Category Unit**	**Full model**			**Final model**		
		Odds ratio	**95% C.I.**	**P value**	**Odds ratio**	**95% C.I.**	**P value**
Age	1 SD increase	1.351	(0.860, 2.165)	0.193			
Diagnosis	[1] KC	Reference	-	0.051	Reference	-	0.038
	[2] KC + CXL	2.623	(0.994, 7.157)		2.720	(1.059, 7.207)	
Sphere at BL (D)	1 SD increase	0.554	(0.245, 1.164)	0.121			
Cylinder absolute value at BL (D)	1 SD increase	0.450	(0.247, 0.774)	0.003	0.393	(0.221, 0.651)	< 0.001
CDVA at BL (logMAR)	1 SD increase	1.393	(0.750, 2.603)	0.290	1.551	(0.948, 2.614)	0.080
K mean at BL (D)	1 SD increase	0.611	(0.263, 1.325)	0.217			

Standard deviations (SD): Age = 8.4 years, Sphere at BL = 4.26 D, Cylinder absolute value at BL = 2.57 D, CDVA at BL = 0.42 logMAR, K mean at BL = 4.44 D.

Table 4
Frequency of increased absolute cylinder at 1 month according to baseline cylinder and prior CXL

Baseline absolute cylinder	Diagnosis	Cylinder absolute value change at 1 month	
		N	Change>0n (%)
[1] **High:>3.75 D**	[1] KC	35	6 (17.1%)
	[2] KC + CXL	18	4 (22.2%)
[2] **Low:≤3.75 D**	[1] KC	40	15 (37.5%)
	[2] KC + CXL	15	10 (66.7%)
Median baseline absolute cylinder: 3.75 D			

Discussion

In this cohort, CAIRS implantation resulted in significant improvement in refractive, visual, and corneal parameters. The mean absolute cylinder decreased from 4.07 ± 2.56 D at baseline to 3.19 ± 2.35 D at 1 month ($P < 0.001$), and this improvement was generally maintained during follow-up. Visual acuity improved, consistent with previous reports [13–15].

However, our longitudinal analysis revealed that early postoperative changes were not consistent. At one month, 32.4% of eyes exhibited an increase in |cylinder|, despite overall improvement in group-level outcomes. Notably, visual acuity improved even in these cases, suggesting that an increase in |cylinder| values shortly following surgery does not necessarily indicate clinical deterioration.

This early increase was more prevalent in eyes with lower baseline |cylinder| and prior CXL, and less common in eyes with higher baseline |cylinder|. In stratified analysis, the highest frequency of increase was observed in eyes with lower baseline astigmatism and prior CXL (66.7%), whereas the lowest was seen in eyes with higher baseline astigmatism without CXL (17.1%). These findings suggest that early postoperative astigmatic changes are influenced by preoperative corneal characteristics.

While interpreting the association between lower baseline astigmatism and early postoperative increases in cylindrical values, it should be noted that these measurements reflect manifest (refractive), rather than corneal (topographic), astigmatism. Therefore, an increase in the absolute value of the manifest cylinder does not necessarily indicate a true deterioration of corneal optics.

One possible explanation is that CAIRS alters corneal shape through both biomechanical and optical mechanisms. By adding stromal tissue and inducing an arc-shortening effect along the corneal circumference, the procedure redistributes corneal curvature [10, 14]. At the same time, CAIRS may facilitate a partial transformation of irregular astigmatism into more regular astigmatism, allowing previously non-correctable components to become measurable during manifest refraction and resulting

in an apparent increase in cylindrical power. However, this shift may represent an improvement in optical quality, as more regular astigmatism is more amenable to optical correction and can lead to better functional vision.

This discrepancy suggests a ‘refractive-topographic mismatch’, in which refractive cylinder does not fully reflect corneal optical quality. Following CAIRS implantation, biomechanical reshaping of the cornea may reduce irregular astigmatism and higher-order aberrations while simultaneously converting previously irregular and non-measurable components into more regular and measurable astigmatism. As a result, the absolute value of refractive cylinder may increase, despite an overall improvement in corneal optics and visual function. This apparent paradox highlights the limitation of relying solely on refractive cylinder as an outcome measure in keratoconus. Instead, early postoperative increases in cylinder should be interpreted in conjunction with improvements in visual acuity and, ideally, higher-order aberration profiles. Within this framework, an increase in manifest cylinder may represent optical regularization rather than true deterioration.

Therefore, early postoperative increases in manifest cylinder should be interpreted in the context of visual acuity outcomes. As CAIRS is not primarily a refractive procedure but rather aims to improve corneal shape and visual function, changes in refractive cylinder should be evaluated alongside improvements in UCVA and CDVA. In this context, an increase in the manifest cylinder may paradoxically reflect a beneficial optical reorganization rather than a clinically meaningful deterioration. This phenomenon can be interpreted as corneal regularization, in which irregular astigmatism and higher-order aberrations—particularly vertical coma aberration—are reduced, leading to a more optically favourable corneal configuration [16].

The association with prior CXL may be explained by altered corneal biomechanics. CXL increases stromal stiffness, which can influence the redistribution of mechanical stress after implantation, particularly in the early postoperative phase. In line with previous reports suggesting that eyes with prior CXL tend to exhibit smaller refractive changes, this increased stiffness may result in delayed biomechanical adaptation and ongoing corneal remodelling, leading to transient variability in cylinder [17]. From a clinical perspective, an increase in manifest cylinder at one month—especially in eyes with milder disease or prior CXL—should be interpreted with caution. It may represent part of the normal postoperative course rather than treatment failure.

This study has several limitations. It is retrospective, and the number of eyes in some subgroups was limited. In addition, higher-order aberrations were not evaluated, and further studies incorporating these parameters would help clarify the mechanisms underlying early postoperative changes.

In conclusion, CAIRS is effective in improving visual and refractive outcomes in keratoconus. Baseline cylinder was the primary factor associated with early postoperative changes, with lower baseline values more likely to show an increase at 1 month. Prior CXL was also associated with early postoperative variability. These early changes should be interpreted with caution, as they do not necessarily indicate clinically relevant worsening.

Declarations

Author contributions

All authors contributed to the study conception and design. A.I., and F.F.N.K.P were clinical investigators and contributed to data collection, and data analysis, mainly writing this paper. A.K., and T.H. were clinical investigators, performed CAIRS operations, critically reviewed the research content and supervised the project.

Conflicts of interest

AK is a consultant for KeraNatural. The remaining authors have no conflicts of interest to disclose.

Funding

None.

Ethical approval and consent to participate

This retrospective observational study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Nihon University Hospital (RK-240109-5).

Informed consent was obtained using an opt-out method, and patients who declined participation were excluded.

Consent to publish

Not applicable.

Availability of data and materials

Data are available upon reasonable request.

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Figures

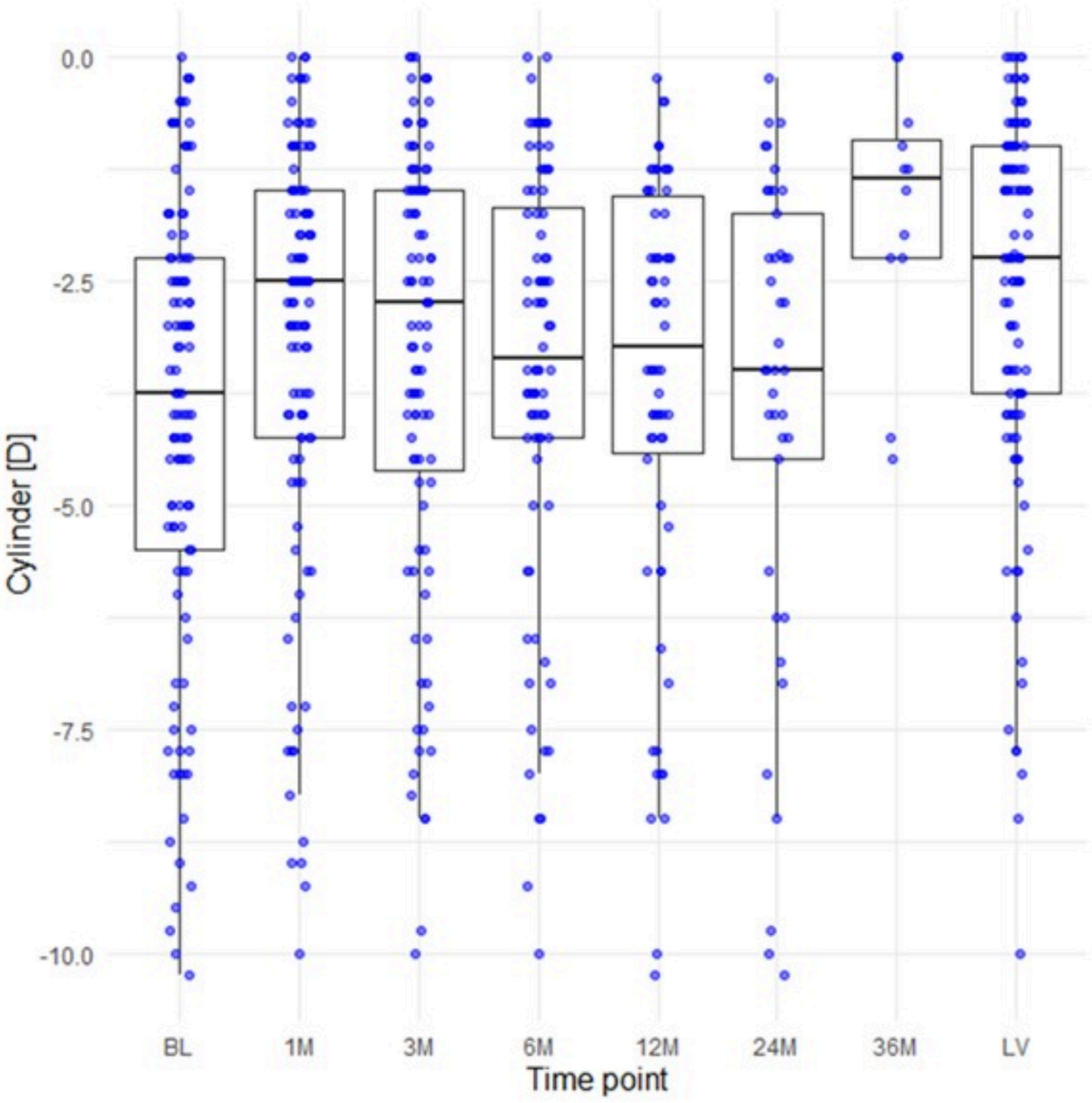


Figure 1

Longitudinal changes in the absolute value of refractive cylinder

Box-and-whisker plots show the distribution of the cylinder at each time point (baseline, 1, 3, 6, 12, 24, and 36 months, and last follow-up). The plots demonstrate an early postoperative reduction in cylinder, followed by relative stabilization over time.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryTables.pdf