Research Square

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Preoperative Scotopic Pupil Diameter and Postoperative Vault Dynamics After Implantable Collamer Lens Implantation

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Abstract

Purpose

To assess associations of preoperative scotopic pupil diameter with early postoperative vault reduction and 3-month vault after implantable collamer lens (ICL) implantation.

Methods

The study included 30 patients (60 eyes) undergoing EVO ICL implantation. Pupillary diameter and light responses were assessed preoperatively and at 1 week and 1 month. Central vault was measured by anterior segment optical coherence tomography at 1 day, 1 week, 1 month, and 3 months. Early vault reduction was defined as day-1 minus week-1 vault. Associations were examined using Pearson correlations and multivariable linear regression adjusted for anterior chamber depth and Oversizing, with HC3 robust inference.

Results

Mean vault decreased from 915.9 μm at day 1 to 695.8 μm at month 3. Preoperative scotopic pupil diameter was positively correlated with 3-month vault (r = 0.346; P=.007) and inversely correlated with first-week vault reduction (r = − 0.371; P=.003). After adjustment, each 1-mm larger scotopic pupil was associated with a 100.7-μm higher 3-month vault (HC3 95% CI, 25.4 to 175.9; P=.010). Model adjusted R^2 was 0.183. Mesopic pupil diameter decreased by 0.451 mm at week 1 (P<.001).

Conclusions

Preoperative scotopic pupil diameter was associated with higher 3-month vault and less early vault reduction. Pupillometry may complement anatomical assessment during ICL planning, although its value for clinical sizing requires further validation.

INTRODUCTION

Posterior chamber phakic ICL implantation provides effective correction of moderate to high myopia, with long-term studies and reviews reporting stable refractive outcomes and an acceptable safety profile[1–4]. The postoperative distance between the ICL and crystalline lens remains central to safety assessment because insufficient vault can permit lens contact and is associated with anterior subcapsular cataract, whereas excessive vault is associated with anterior-segment crowding and pressure-related concerns[1,2,5,6]. Contemporary planning therefore considers ACD, white-to-white

distance, sulcus-to-sulcus dimensions, crystalline-lens position, ICL size, and implantation orientation, but postoperative vault remains imperfectly predictable[7–12].

Static anatomical measurements may not fully describe the physiological environment surrounding the ICL. The iris lies anterior to the lens and changes configuration with illumination and accommodation. Dynamic AS-OCT and UBM studies show that light-induced pupil changes, accommodation, and pharmacologic dilation or constriction can be accompanied by measurable changes in central or peripheral vault and, in some studies, haptic position[13–18]. Preoperative pupillometry may therefore provide a physiological dimension complementary to conventional anatomical assessment, although pupil diameter is not a direct measure of iris stiffness, contact area, or mechanical force.

The present study had four objectives: to describe changes in static pupil diameter and direct and consensual PLR after ICL implantation; to assess correlations of preoperative anatomical and pupillary variables with vault across four postoperative visits; to examine the association between preoperative scotopic pupil diameter and positive first-week vault reduction; and to evaluate the adjusted association between scotopic pupil diameter and 3-month vault after accounting for ACD and Oversizing. We further considered whether preoperative pupillometry might serve as a supplementary reference during ICL planning without treating it as a validated sizing determinant.

METHODS

Study Design and Participants

This prospective observational study included 30 patients (60 eyes) undergoing EVO ICL V4c implantation at the Eye and ENT Hospital of Fudan University from October to December 2024. The institutional ethics committee approved the protocol (No. 2016038), and all participants provided written informed consent.

Preoperative Anatomical and Pupillary Assessments

Preoperative anatomical assessment included anterior chamber depth (ACD), white-to-white corneal diameter (WTW), and sulcus-to-sulcus diameter (STS). Corneal and anterior-segment measurements were obtained using the Pentacam HR (Oculus Optikgeräte GmbH, Wetzlar, Germany). Ultrasound biomicroscopy (Compact Touch STS UBM; Quantel Medical) was performed to measure STS along four meridians: horizontal (0°), oblique (45° and 135°), and vertical (90°). Oversizing was defined as the difference between the implanted ICL size and the corresponding implantation-meridian STS diameter.

Static pupil diameter and pupillary light responses (PLRs) were assessed using a dynamic pupillometer (ATONGMU-PM01, Damacare, Guangzhou, China). Static pupil diameter was recorded under scotopic (0.04 lux), mesopic (4 lux), and photopic (40 lux) conditions. Pupillary constriction amplitude was also

calculated. Dynamic pupillary assessments included direct and consensual PLR amplitude, latency, constriction velocity, redilation time, and redilation velocity.

Pupillometry and PLR examinations were performed preoperatively and repeated at postoperative week 1 and month 1 using the same examination protocol.

Surgical Technique

One experienced surgeon implanted the EVO ICL V4c (STAAR Surgical) through a 3.0-mm temporal corneal incision after viscoelastic injection. All viscoelastic material was removed at the end of surgery.

ICL size selection in this cohort was not a passive function of a single biometric input. Two surgeon-driven adjustments were routinely applied: (i) because the ciliary sulcus is typically wider vertically than horizontally (vSTS > hSTS), the implantation axis was rotated in selected eyes to align the ICL long axis with the wider sulcus meridian, thereby optimizing the effective sulcus fit[19,20]; and (ii) ACD was used to inform the target vault, with a slightly higher vault deliberately accepted in eyes with a deeper anterior segment, given the greater anterior segment volume and lower theoretical risk of angle compromise[20]. These surgical planning considerations were taken into account when interpreting the associations between anatomical parameters and postoperative vault, as the observed relationships may reflect both anatomical characteristics and surgeon-guided ICL selection.

Postoperative Follow-up and Vault Measurement

Postoperative evaluations were performed at day 1, week 1, month 1, and month 3. Central ICL vault was measured using swept-source anterior-segment optical coherence tomography (CASIA2; Tomey Corporation, Nagoya, Japan). Vault was the central distance between the posterior ICL surface and anterior crystalline lens surface, measured in micrometers under standardized room illumination (approximately 50 lux).

Outcome Measures

The primary outcome was central ICL vault at postoperative month 3.

An important secondary outcome was early postoperative vault reduction, defined as:

Vault reduction = Vault at postoperative day 1 − Vault at postoperative week 1.

A larger positive value indicated a greater decrease in vault during the first postoperative week.

Additional secondary outcomes included associations between preoperative anatomical and pupillary parameters and vault at each postoperative visit, as well as changes in static pupil diameter and PLR

parameters from preoperative measurements to postoperative week 1 and month 1.

Statistical Analysis

Statistical analyses were performed using R software (version 4.5.1; R Foundation for Statistical Computing, Vienna, Austria).

Continuous variables were summarized using means, standard deviations, medians, interquartile ranges, and ranges as appropriate.

Preoperative measurements were compared with week-1 and month-1 static pupil and PLR measurements using two-sided paired t tests. Unadjusted P values were reported for these exploratory analyses.

Pearson correlations assessed associations of preoperative anatomical and pupillary measurements with postoperative vault; Spearman correlations were used in sensitivity analyses of principal pupil-related associations.

Pearson and Spearman correlations also assessed scotopic pupil diameter versus first-week vault reduction.

A multivariable ordinary least-squares linear regression model was constructed to examine the association between preoperative scotopic pupil diameter and 3-month vault after adjustment for ACD and Oversizing. These three variables were selected on the basis of their clinical relevance: ACD represented anterior-segment anatomical space, Oversizing represented ICL–sulcus dimensional matching, and scotopic pupil diameter represented an additional physiological characteristic of the iris.

Coefficients were estimated by ordinary least squares; HC3 robust standard errors, 95% confidence intervals, and P values informed inference. Standardized coefficients facilitated comparison across predictors.

Performance measures included adjusted R^2, RMSE, MAE, AIC, and BIC. An anatomical model containing ACD and Oversizing evaluated incremental information from scotopic pupil diameter.

Diagnostics included residual and Q–Q plots, Breusch–Pagan tests, variance inflation factors, leverage, studentized residuals, and Cook's distance. Internal validation used 1,000 bootstrap resamples.

All tests were two-sided, with $P<.05$ considered statistically significant.

RESULTS

Baseline Characteristics

The cohort comprised 30 patients (60 eyes). Mean ACD was 3.26 ± 0.24 mm; implantation-meridian STS, 12.17 ± 0.57 mm; and ICL size, 13.05 ± 0.44 mm. Mean Oversizing was 0.88 ± 0.19 mm, and preoperative scotopic pupil diameter was 7.22 ± 0.61 mm (Table 1).

Table 1

parameter	unit	mean	SD	minimum	maximum
Manifest sphere	D	-6.159	2.230	-10.50	-2.00
Manifest cylinder	D	-1.078	1.067	-4.00	0.000
Spherical equivalent	D	-6.698	2.515	-11.50	-2.250
Anterior chamber depth	mm	3.258	0.236	2.88	3.840
White-to-white	mm	12.074	0.432	11.50	13.200
Horizontal sulcus-to-sulcus	mm	11.975	0.507	11.10	13.430
Vertical sulcus-to-sulcus	mm	12.545	0.492	11.45	13.61
Implantation-meridian sulcus-to-sulcus diameter	mm	12.169	0.566	11.18	13.43
Implanted ICL size	mm	13.048	0.436	12.60	13.700
Oversizing	mm	0.884	0.187	0.27	1.418
Preoperative scotopic pupil diameter	mm	7.217	0.607	5.72	9.06
Preoperative mesopic pupil diameter	mm	3.968	0.787	2.59	5.84
Preoperative photopic pupil diameter	mm	3.178	0.457	2.45	4.63
Preoperative constriction amplitude	mm	4.007	0.543	2.84	5.52
Vault at 1 day	um	915.85	218.90	261	1268
Vault at 1 week	um	775.30	225.87	183	1214
Vault at 1 month	um	732.50	202.76	183	1148
Vault at 3 months	um	695.78	192.79	170	1123

Postoperative Vault Trajectory

Mean central vault progressively decreased from 915.9 μm at postoperative day 1 to 775.3 μm at week 1, 732.5 μm at month 1, and 695.8 μm at month 3 (Fig. 1). The greatest mean reduction occurred during the first postoperative week (140.6 μm), followed by smaller reductions during subsequent follow-up intervals. This pattern indicated that the most pronounced change in ICL vault occurred during the early postoperative period.

Associations of Preoperative Anatomical and Pupillary Parameters With Vault

Among the preoperative anatomical parameters, ACD showed a positive correlation with 3-month vault (r = 0.370, P=.004). Implantation-meridian STS and implanted ICL size were also positively correlated with 3-month vault (r = 0.280, P=.033; and r = 0.317, P=.014, respectively), whereas Oversizing showed no significant linear correlation (r = − 0.060, P=.633; Fig. 3).

Preoperative scotopic pupil diameter demonstrated a distinct pattern of association with postoperative vault. The correlation was relatively weak at postoperative day 1 (r = 0.224, P=.086) but became statistically significant at week 1 (r = 0.324, P=.012). This positive association persisted at month 1 (r = 0.306, P=.017) and month 3 (r = 0.346, P=.007; Fig. 4).

In comparison, preoperative mesopic pupil diameter showed no significant correlation with vault at any postoperative visit. Photopic pupil diameter was positively correlated with 3-month vault (r = 0.280, P=.030), whereas preoperative constriction amplitude showed no significant association with 3-month vault.

Primary Multivariable Linear Regression for 3-Month Vault

The primary multivariable model assessed scotopic pupil diameter and 3-month vault adjusted for ACD and Oversizing.

After adjustment, each 1-mm larger preoperative scotopic pupil diameter was associated with a 100.7-μm higher 3-month vault (HC3 95% CI, 25.4 to 175.9; P=.010; standardized β = 0.36). The adjusted coefficients for ACD and Oversizing were 155.6 μm/mm (HC3 95% CI, − 92.1 to 403.2; P=.213) and 127.3 μm/mm (HC3 95% CI, − 266.5 to 521.2; P=.520), respectively (Fig. 5B).

The model had an adjusted R^2 of 0.183, with an RMSE of 149.5 μm and an MAE of 122.4 μm. Compared with the anatomical model containing ACD and Oversizing alone, adding preoperative scotopic pupil diameter increased adjusted R^2 by 0.074, with a partial R^2 of 0.100. RMSE and MAE decreased by 8.1 and 5.5 μm, respectively, while AIC and BIC decreased by 4.1 and 2.0.

Association Between Preoperative Scotopic Pupil Diameter and Early Vault Reduction

First-week vault reduction was defined as day-1 minus week-1 vault; positive values indicated decreases.

Preoperative scotopic pupil diameter was inversely correlated with first-week vault reduction (Pearson r = − 0.371, P=.003; Spearman ρ=−0.323, P=.012; Fig. 5A). Accordingly, eyes with smaller preoperative scotopic pupils tended to exhibit greater vault reduction during the first postoperative week, whereas eyes with larger pupils tended to show less reduction.

This unadjusted association complemented the positive relation between scotopic pupil diameter and later vault.

Postoperative Changes in Static Pupil Diameter

Static pupil diameter showed several changes during early postoperative follow-up (Fig. 2A).

At postoperative week 1, mesopic pupil diameter decreased by 0.451 mm compared with preoperative measurements (95% CI, − 0.611 to − 0.290; P<.001). Scotopic pupil diameter also decreased by 0.174 mm (P=.023). The photopic pupil diameter showed a smaller reduction that did not reach statistical significance (P=.065).

At postoperative month 1, the differences in static pupil diameter were generally smaller. However, pupillary constriction amplitude increased by 0.110 mm compared with preoperative values (P=.028).

Postoperative Changes in Pupillary Light Responses

Several direct and consensual pupillary light response (PLR) parameters changed after ICL implantation (Fig. 2B).

At postoperative week 1, direct and consensual constriction velocities decreased compared with preoperative values (mean changes, − 0.125 and − 0.153, respectively; P=.015 and P=.003). Consensual PLR latency increased by 0.039 seconds (P<.001).

At postoperative month 1, consensual PLR latency remained longer than its preoperative value (mean increase, 0.043 seconds; P=.007), while most other PLR parameters showed no statistically significant differences.

These postoperative pupil and PLR comparisons were exploratory and are reported using unadjusted paired t-test P values.

Bootstrap Internal Validation

In 1,000 bootstrap resamples of the primary 3-month model, the percentile 95% interval for the preoperative scotopic pupil diameter coefficient was 18.4 to 171.5 μm/mm. After correction for optimism, adjusted R^2 was 0.060, RMSE was 162.9 μm, and MAE was 131.8 μm, compared with apparent values of 0.183, 149.5 μm, and 122.4 μm, respectively. The reduction in corrected model performance indicated that the apparent predictive accuracy was optimistic.

DISCUSSION

Preoperative scotopic pupil diameter was positively associated with 3-month vault after adjustment for ACD and Oversizing and inversely correlated with first-week vault reduction. Together, these findings suggest that pupillary measurements may add physiological information to conventional anatomical assessment of postoperative ICL vault.

An important observation was the evolving association between scotopic pupil diameter and postoperative vault over time. Although the correlation was relatively weak on postoperative day 1, it became evident at week 1 and persisted through months 1 and 3. Reinstein et al. included scotopic pupil diameter among candidate biometric variables and reported it as a significant predictor in a model of 1-month vault[11]. In a different population, a study of eyes with thick crystalline lenses found pronounced vault differences between concave and convex iris configurations, providing indirect support for the relevance of iris shape but not directly testing preoperative pupil diameter[21]. The present study adds serial observations from day 1 to month 3 and an analysis of first-week vault reduction. The adjusted estimate of approximately 101 μm per 1-mm larger scotopic pupil should be interpreted as an association rather than a validated sizing rule.

The anatomical relationship between the iris and ICL offers a plausible explanation for these observations. The iris lies immediately anterior to the implanted lens, and its configuration changes with pupil dilation and constriction. Variations in iris curvature, iris-ICL contact, and the distribution of forces acting on the ICL may contribute to differences in postoperative vault. Dynamic imaging and pharmacological studies have demonstrated that illumination, accommodation, and induced miosis or mydriasis can be accompanied by changes in vault and haptic position[13–18]. These studies concern immediate dynamic changes and do not by themselves establish the mechanism of longer-term vault stabilization. Our findings suggest that preoperative scotopic pupil diameter may be associated with postoperative vault behavior, but pupil diameter remains an indirect indicator of iris configuration rather than a direct measurement of iris biomechanics or mechanical force.

The relationship between scotopic pupil diameter and early vault reduction provides an additional perspective. Published longitudinal studies confirm that vault is not static, although the reported early pattern varies with measurement timing, ICL model, and study design. Zhu et al. observed a decrease from 2 hours to day 1 followed by an increase through week 1 and month 1, whereas longer follow-up studies generally reported progressive decline and later stabilization[22–25]. In the present cohort, the greatest mean vault decrease occurred between postoperative day 1 and week 1. During this interval, smaller preoperative scotopic pupils were associated with greater vault reduction, whereas larger pupils tended to show less reduction. This inverse relationship is consistent with the positive association between scotopic pupil diameter and subsequent vault level. However, the early reduction analysis was univariable and may reflect initial vault or other anatomical differences; it does not establish a direct mechanical or causal pathway.

The interpretation of conventional anatomical predictors also requires consideration of surgical planning. ACD and sulcus-related measurements have appeared repeatedly in ICL sizing and vault-prediction studies, although the variables retained and prediction errors differ among models[7–12]. In this cohort, ACD represented not only available anterior-segment space but also a factor used by the surgeon when judging an acceptable target vault. In eyes with a deeper anterior chamber, a relatively higher target vault was considered acceptable because of the greater available anterior-segment space and lower

theoretical concern about angle crowding. The observed relationship between ACD and postoperative vault may therefore partly reflect surgeon-guided target selection in addition to anatomy. The nonsignificant adjusted ACD coefficient in this sample does not negate its established role in planning.

Similarly, the limited association between Oversizing and vault should be interpreted in the context of individualized ICL selection. STS-based sizing studies support the importance of ICL-sulcus dimensional matching, but no single anatomical method completely determines the achieved vault[7,8,12]. In this cohort, surgical planning aimed to maintain a relatively consistent degree of Oversizing, resulting in a restricted distribution. The discrete range of available ICL sizes and individualized implantation-meridian selection may also limit the observable linear association. A weak statistical association in this dataset therefore should not be interpreted as evidence that mechanical fit is unimportant.

Postoperative pupillary measurements provided additional information regarding early iris behavior. Prior findings have not been uniform: Li et al. reported smaller photopic and scotopic pupils at 1 and 3 months, whereas Kamiya et al. found a transient decrease at day 1 that had largely recovered by week 1 and no significant association between pupil diameter and vault at 1 year[26,27]. A recent prospective dynamic-light study also reported that photopic vault reduction was associated with pupil-diameter change, while scotopic vault changed little relative to room light[28]. In the present study, mesopic and scotopic pupil diameters decreased during the first postoperative week, and selected direct and consensual PLR parameters changed. These comparisons were exploratory and do not show that postoperative pupillary changes mediate the association between preoperative pupil diameter and vault.

From a clinical perspective, the present findings support greater attention to preoperative pupillary assessment during ICL planning. Conventional strategies emphasize static anatomical parameters, but comparative work shows that vault-prediction formulae have materially different errors and performance across ICL sizes[29]. Preoperative scotopic pupil diameter is straightforward to measure and may provide supplementary information when anatomy alone does not fully explain postoperative vault. It should not yet be used as a stand-alone sizing determinant or assumed to improve outcomes without prospective external validation.

Adding scotopic pupil diameter modestly improved explained variance and reduced prediction error, but bootstrap correction revealed limited individual predictive accuracy. Influential-observation sensitivity analysis also suggested imprecision in the pupil coefficient. Thus, the association should not be interpreted as a validated sizing algorithm. Larger cohorts with direct iris imaging and external validation are needed to evaluate its role in ICL planning.

Limitations include the single-center design, small cohort, 3-month follow-up, unavailable sulcus-to-sulcus lens rise and crystalline lens rise, and lack of external validation. Some observations were influential. Pupil diameter indirectly reflects iris configuration, vault was measured under one lighting condition, and postoperative pupil and PLR analyses were exploratory.

In conclusion, preoperative scotopic pupil diameter was associated with both the postoperative vault level and its early changes following ICL implantation. Larger scotopic pupils were associated with higher 3-month vault, whereas smaller pupils tended to exhibit greater vault reduction during the first postoperative week. These findings highlight the potential clinical relevance of preoperative pupillary assessment and support its consideration as a supplementary parameter alongside conventional anatomical measurements during ICL planning. Further studies are warranted to determine whether pupillary measurements can improve individualized ICL sizing strategies.

Declarations

Ethics approval

This study was approved by the Institutional Ethics Committee of the Eye and ENT Hospital of Fudan University (Approval No. 2016038).

Consent to participate

Written informed consent was obtained from all participants prior to their inclusion in the study.

Consent for publication

Not applicable. The manuscript contains no identifiable individual patient information or images.

Author Contribution

Z.L. and W.R. contributed equally to data collection, statistical analysis, and preparation of the original manuscript. Y.Q. assisted with data collection and data organization. X.W. and X.Z. contributed to study design, clinical supervision, and critical revision of the manuscript. P.Y. contributed to study conception, methodology, supervision, and manuscript revision. All authors reviewed and approved the final manuscript.

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Figures

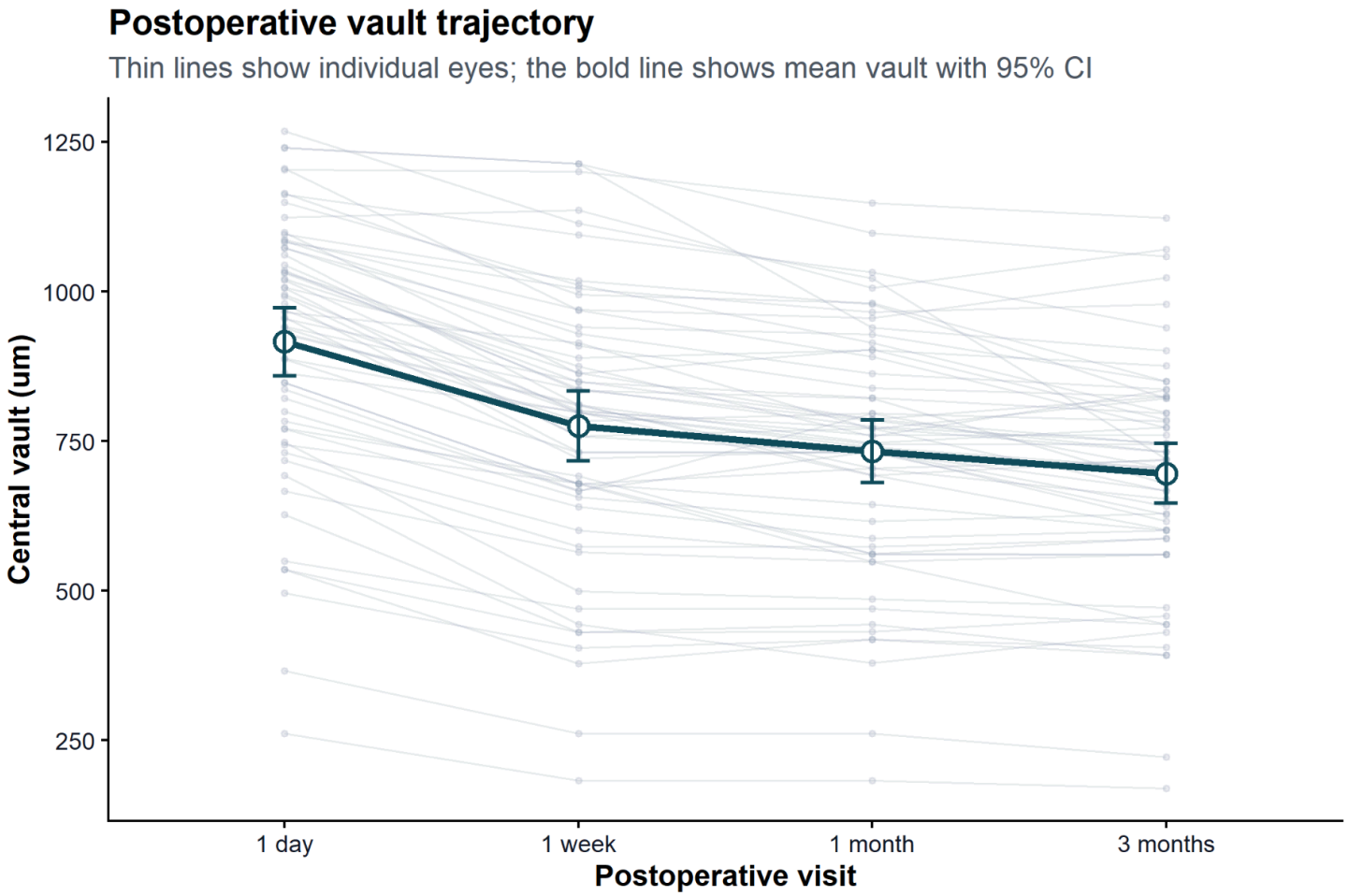


Figure 1

Postoperative vault trajectory after implantable collamer lens implantation.

Thin gray lines indicate individual eyes. The bold line and open circles indicate the mean central vault at each postoperative visit, and error bars indicate 95% confidence intervals. Central vault was measured at postoperative day 1, week 1, month 1, and month 3.

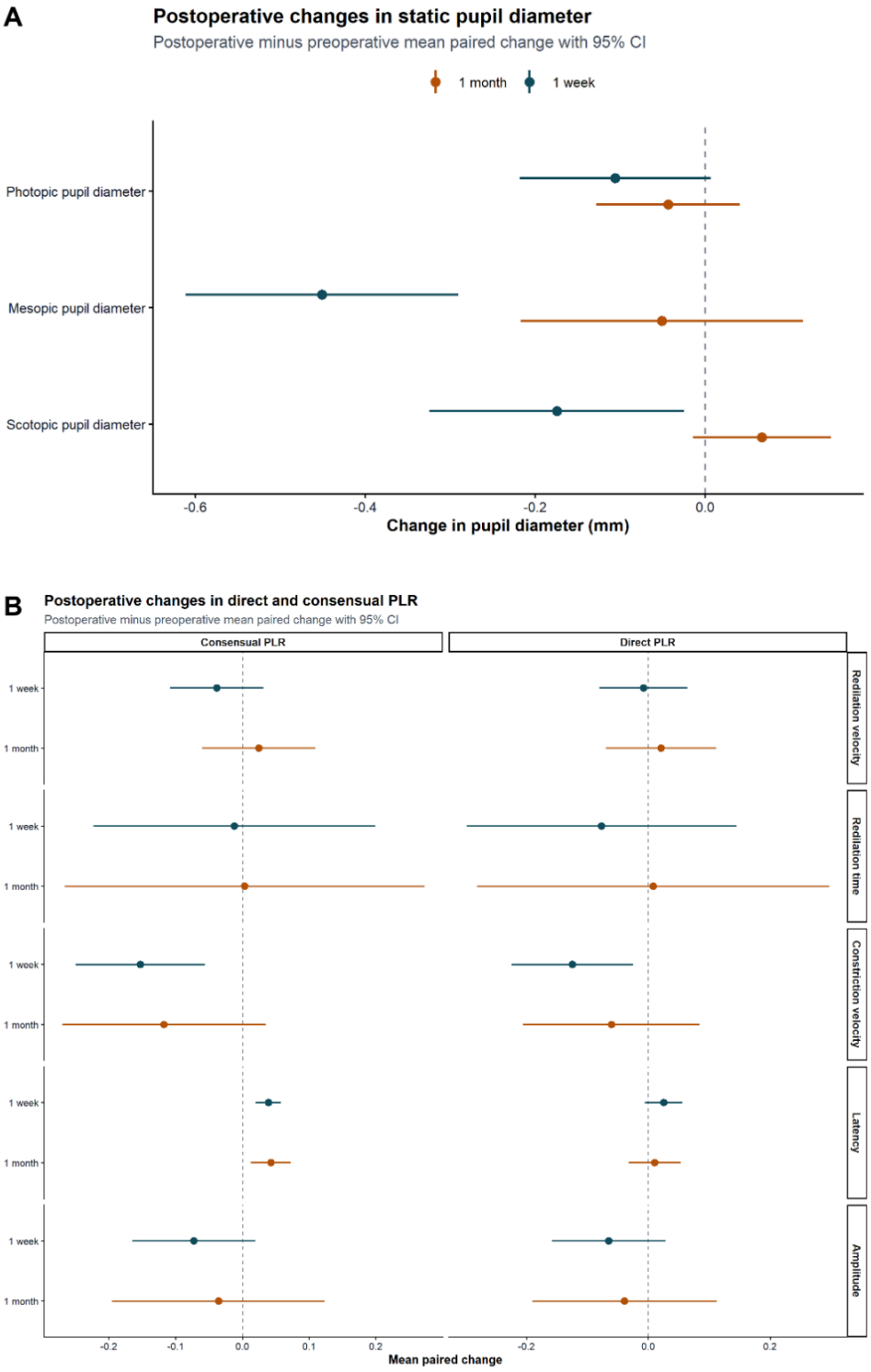


Figure 2

Postoperative pupillary changes after implantable collamer lens implantation

(A) Mean paired postoperative minus preoperative changes in static pupil diameter under photopic, mesopic, and scotopic conditions at postoperative week 1 and month 1. Points indicate mean paired

changes and horizontal bars indicate 95% confidence intervals. Negative values indicate smaller postoperative pupil diameters than preoperative values.

(B) Mean paired postoperative minus preoperative changes in direct and consensual pupillary light reflex (PLR) parameters at postoperative week 1 and month 1. Points indicate mean paired changes and horizontal bars indicate 95% confidence intervals. PLR parameters include redilation velocity, redilation time, constriction velocity, latency, and amplitude.

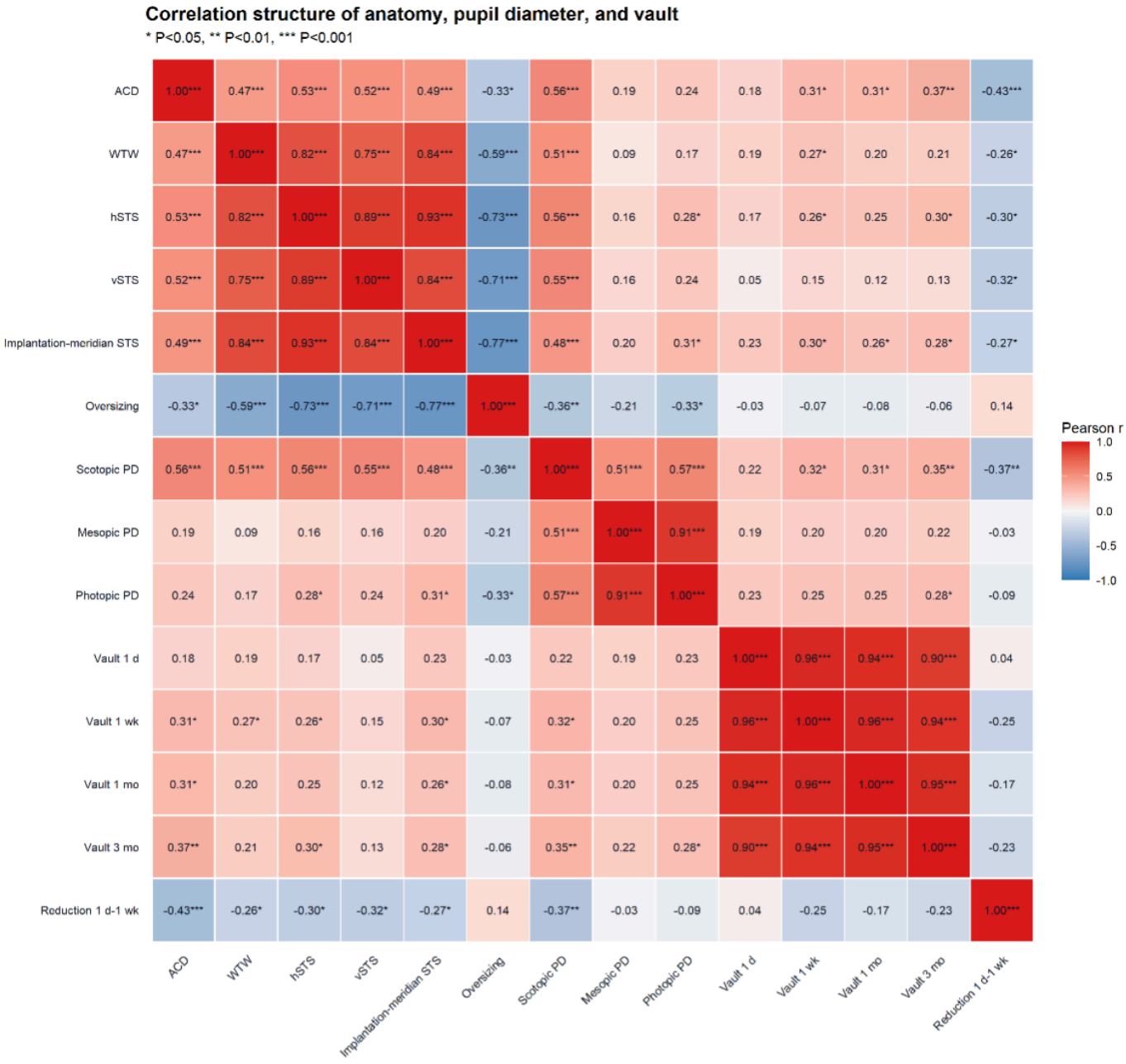


Figure 3

Correlation structure of anatomy, pupil diameter, and vault.

Heatmap showing Pearson correlation coefficients among anterior chamber depth (ACD), white-to-white distance (WTW), horizontal sulcus-to-sulcus diameter (hSTS), vertical sulcus-to-sulcus diameter (vSTS), implantation-meridian sulcus-to-sulcus diameter, oversizing, preoperative pupil diameters, postoperative vault measurements, and early vault reduction from postoperative day 1 to week 1. Positive correlations are shown in red and negative correlations in blue. Asterisks indicate nominal significance levels (*P*<0.05, **P*<0.01, ***P*<0.001).

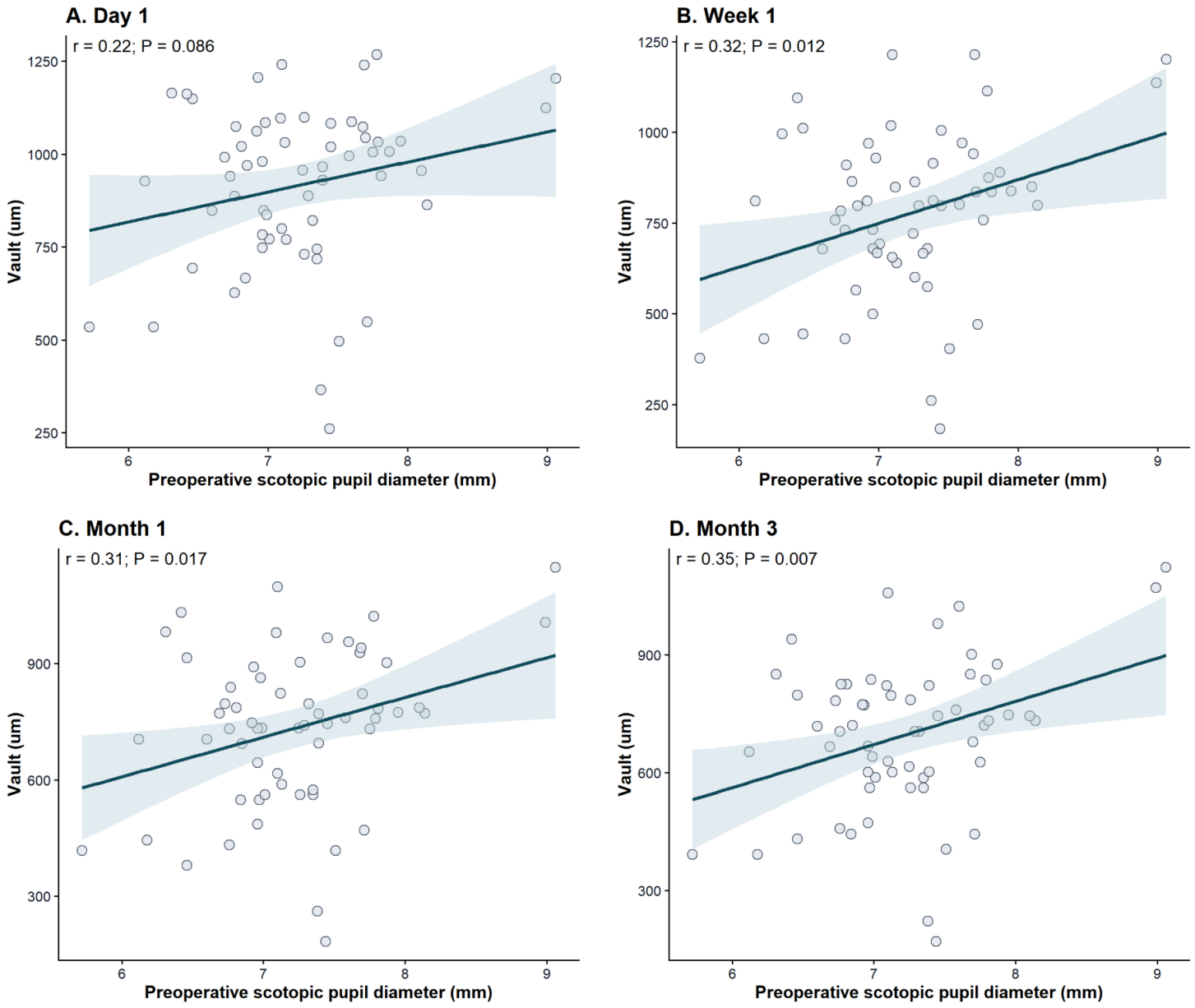


Figure 4

Associations between preoperative scotopic pupil diameter and postoperative vault at sequential postoperative visits.

Heatmap of pairwise Pearson correlation coefficients among preoperative anatomical parameters, pupillary diameters, postoperative vault at day 1, week 1, month 1, and month 3, and first-week vault

reduction. Each cell shows Pearson's r, with red indicating positive correlations and blue indicating negative correlations. Asterisks indicate unadjusted two-sided P values (*P<.05; **P<.01; ***P<.001). First-week vault reduction was defined as day-1 vault minus week-1 vault, with larger positive values denoting a greater decrease. Implantation-meridian STS denotes the sulcus-to-sulcus diameter measured along the selected ICL implantation meridian; oversizing is the implanted ICL size minus implantation-meridian STS. ACD = anterior chamber depth; WTW = white-to-white distance; hSTS = horizontal STS; vSTS = vertical STS; PD = pupil diameter.

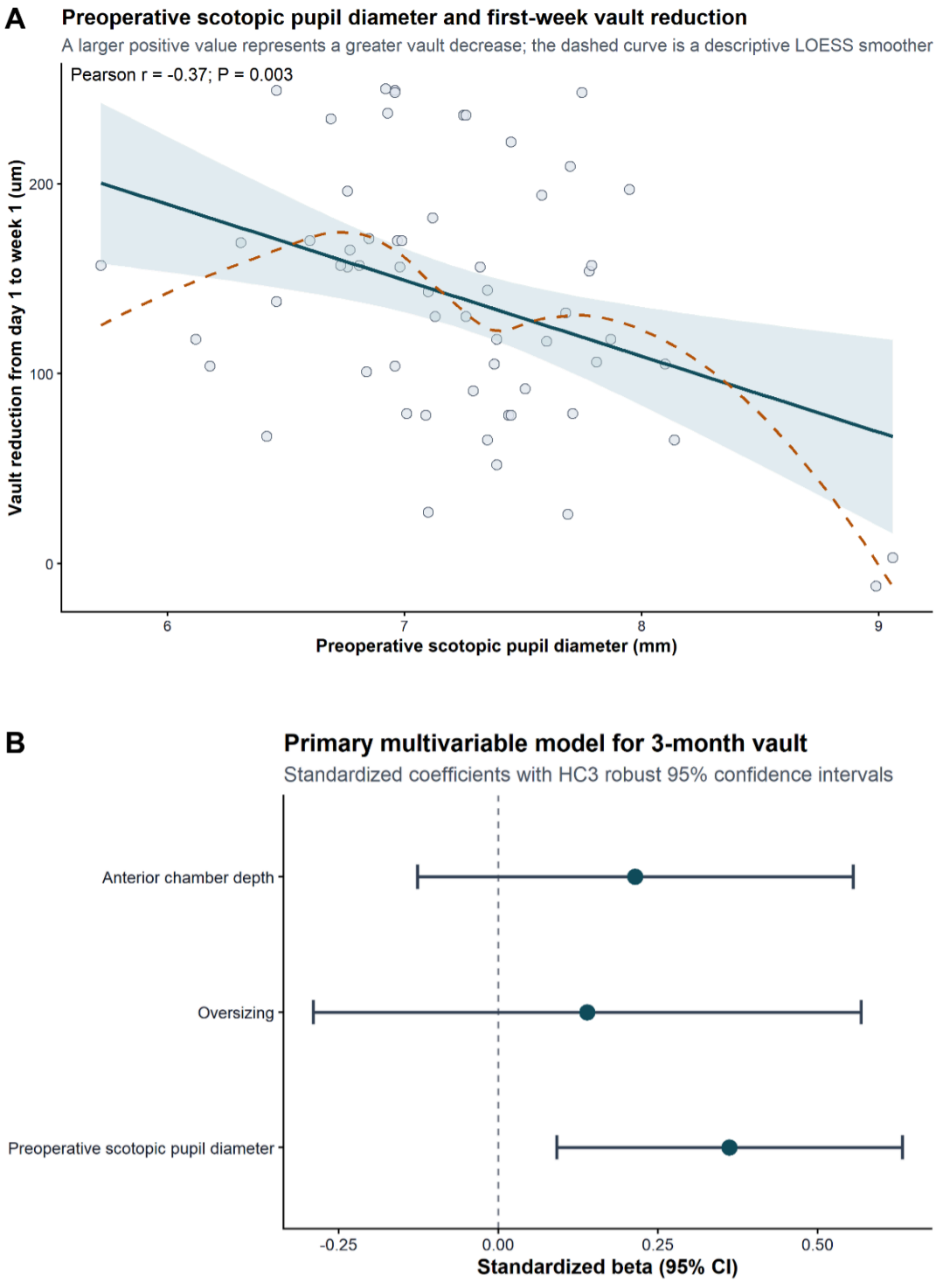


Figure 5

Preoperative scotopic pupil diameter, early vault reduction, and the primary multivariable model for 3-month vault.

(A) Scatterplot showing the association between preoperative scotopic pupil diameter and vault reduction from postoperative day 1 to week 1. A larger positive value indicates a greater vault decrease. The solid line indicates the linear regression fit with a shaded 95% confidence band, and the dashed curve indicates a descriptive LOESS smoother.

(B) Forest plot of the primary multivariable linear regression model for 3-month vault, showing standardized regression coefficients and HC3 robust 95% confidence intervals for anterior chamber depth, oversizing, and preoperative scotopic pupil diameter. The vertical dashed line indicates the null value.