

Horizontal Versus Vertical Scleral Tunnel Orientation in Flanged Intrasccleral Fixation: A 2-Year Comparative Study

Burhan Başkan

burhan.baskan@sbu.edu.tr

SBU Van Training and Research Hospital

Yusuf Evcimen

SBU Van Training and Research Hospital

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Abstract

OBJECTIVES

To evaluate whether horizontal versus vertical scleral tunnel orientation is associated with differing 2-year outcomes in flanged intrascleral IOL fixation, without a prior hypothesis regarding the direction of effect.

METHODS

Retrospective observational cohort study of 107 eyes (43 vertical, 64 horizontal) with complete 24-month follow-up. Primary outcome was proportion of eyes achieving mean absolute error (MAE) within $\pm 0.50\text{D}$ of target refraction at 2 years. Secondary outcomes included IOL tilt, iris capture and conjunctival erosion. Propensity score matching (1:1) was performed. Multivariate logistic regression and a multilevel mixed-effects model with surgeon as random effect were used to adjust for confounders including surgical period, age and baseline refraction.

RESULTS

Horizontal tunnels were associated with higher proportion within $\pm 0.50\text{D}$ at 2 years (78.1% vs. 51.2%, $p = 0.004$). After adjustment, the association remained significant (adjusted OR = 0.31; 95% CI: 0.11–0.87; $p = 0.024$). Mean IOL tilt was lower in the horizontal group (2.9° vs. 6.8° , $p = 0.003$). Tilt and MAE were strongly correlated ($\rho = 0.71$, $p < 0.001$). No significant differences were detected for iris capture or conjunctival erosion, but the study was underpowered for these outcomes (post-hoc power 32–48%).

CONCLUSIONS

Horizontal tunnel orientation was associated with better 2-year refractive predictability and less IOL tilt than vertical tunnels in flanged intrascleral fixation. However, due to the non-randomized, retrospective observational design, absence of masking, learning curve effects and residual confounding, all findings should be considered hypothesis-generating, not confirmatory. A prospective randomized trial with masked assessment is warranted.

Trial Registration

Not applicable (retrospective observational study).

INTRODUCTION

The management of aphakia, crystalline lens luxation, and intraocular lens (IOL) luxation in the absence of adequate capsular support remains one of the most challenging scenarios in modern cataract and vitreoretinal surgery [1, 2]. These conditions often arise after complicated cataract surgery, ocular trauma, or in patients with hereditary zonular weakness such as pseudoexfoliation syndrome, Marfan syndrome, or homocystinuria [3, 4]. Traditional surgical options include anterior chamber IOLs, iris-fixated IOLs, and scleral-sutured posterior chamber IOLs, each carrying significant long-term risks. Anterior chamber IOLs are associated with corneal endothelial cell loss, chronic inflammation, and angle-closure glaucoma [5]. Iris-fixated IOLs may lead to pigment dispersion, chronic iritis, and progressive endothelial decompensation, with reported dislocation rates at 5 years [6, 7].

Scleral-sutured IOLs, although widely used for decades, are plagued by suture degradation. Nylon and polypropylene sutures undergo hydrolysis and oxidation, leading to breakage rates exceeding 10% at 5 years and reaching up to 30% at 10 years postoperatively [8]. Suture breakage can lead to IOL dislocation requiring additional surgical intervention, and has been associated with late endophthalmitis in some series. These limitations have motivated surgeons to develop sutureless alternatives [9, 10].

In 2017, Yamane and colleagues introduced a sutureless flanged intrascleral IOL fixation technique that rapidly gained worldwide acceptance. The technique involves creating two partial-thickness scleral tunnels 180° apart, externalizing the haptics through these tunnels, and creating a flange on each haptic tip using thermal cautery [11]. Numerous studies have confirmed its safety and efficacy, with reported success rates exceeding 90% at 1-year follow-up. However, as experience with the technique has accumulated, long-term complications have emerged, including IOL tilt, iris capture, and conjunctival erosion over the haptic flange, with reported erosion rates of 2–12% at 2 years [12–14].

A critical yet under-investigated surgical variable is the orientation of the scleral tunnels relative to the limbus. Some surgeons create tunnels parallel to the limbus (horizontal/tangential), others perpendicular (vertical/radial), and some adopt an oblique approach at 30–60 degrees, largely based on personal preference rather than high-level evidence. Proponents of horizontal tunnels argue that a tangential course allows the haptic to lie more flush against the scleral wall, reducing IOL tilt and focal pressure points on the overlying conjunctiva. Surgeons favouring vertical tunnels suggest that a radial path provides a longer intrascleral haptic segment, potentially enhancing stability and reducing the risk of haptic extrusion [15–17]. Neither claim has been rigorously tested in a long-term comparative study with adequate sample size and follow-up duration.

IOL tilt induces significant higher-order aberrations, unpredictable astigmatism, and reduced refractive predictability. Mean absolute error (MAE) > 0.50 D is considered clinically significant and may necessitate spectacle correction for distance vision [18, 19]. Late conjunctival erosion, which typically presents between 12 and 24 months postoperatively, likely results from chronic mechanical pressure from the haptic flange against the thin conjunctival tissue [20, 21]. To date, no study has provided a 2-year comparative analysis of horizontal versus vertical tunnel orientation examining the full spectrum of clinically relevant outcomes.

Therefore, we tested whether scleral tunnel orientation (horizontal vs. vertical) is associated with 2-year refractive outcomes, without assuming a direction of effect a priori. The primary endpoint was the proportion of eyes achieving refraction within ± 0.50 D of target spherical equivalent refraction.

MATERIALS AND METHODS

Study Design and Ethical Compliance

This retrospective, observational cohort study was conducted at a single tertiary referral centre. This was not an interventional study; all data were collected retrospectively from electronic medical records of patients who underwent routine clinical care. Clinical data were collected from electronic medical records of patients who underwent surgery between March 1, 2022, and March 1, 2025. The study protocol received approval from the Institutional Ethics Committee (Van Training and Research Hospital Non-Interventional Clinical Research Ethics Committee, Approval No: GOKAEK/2024-04-02). All patients provided written informed consent for the surgical procedure and for the use of their anonymized data for research purposes. The study adhered to the tenets of the Declaration of Helsinki.

Patient Population and Selection Criteria

A total of 150 consecutive eyes of 150 patients underwent flanged intrascleral IOL fixation during the study period. Among these, 60 eyes had vertical scleral tunnels and 90 eyes had horizontal scleral tunnels. After excluding eyes with incomplete 24-month follow-up data (17 in the vertical group and 26 in the horizontal group), the final study cohort comprised 107 eyes (43 vertical, 64 horizontal) with complete 2-year follow-up. All surgeries were performed by two experienced vitreoretinal surgeons (Surgeon A with 15 years of experience, Surgeon B with 12 years of experience). Minimum follow-up was 24 months, with final data collection completed in March 2025.

Inclusion criteria were: (1) age ≥ 18 years; (2) complicated aphakia defined as absence of adequate capsular support following cataract extraction, lens trauma, or previous lensectomy; (3) crystalline lens luxation defined as partial or complete displacement of the natural lens due to zonular weakness; (4) IOL luxation defined as partial or complete dislocation of a previously implanted IOL; (5) inadequate capsular support ($< 180^\circ$ of intact zonular or capsular support); (6) ability to complete scheduled follow-up visits; and (7) complete follow-up data available.

Exclusion criteria were: (1) previous scleral buckling surgery within 6 months; (2) pars plana vitrectomy within 3 months; (3) active uveitis; (4) active endophthalmitis; (5) uncontrolled scleritis or scleral thinning; (6) corneal decompensation (endothelial cell density < 1000 cells/mm²); (7) uncontrolled glaucoma (IOP > 25 mmHg despite maximum therapy); (8) history of penetrating keratoplasty, DALK, DSEK, or DMEK; (9) history of corneal refractive surgery; (10) active proliferative diabetic retinopathy; (11) pregnancy or breastfeeding; and (12) inability to complete 24-month follow-up.

Assignment to Tunnel Orientation and Propensity Score Matching

Assignment was non-randomized and based on surgeon preference, representing a major source of selection bias. Surgeon A preferentially used vertical tunnels between March 2022 and December 2023, then switched to horizontal tunnels exclusively from January 2024 onward (historical control pattern). Surgeon B used vertical tunnels for complex cases and horizontal tunnels for routine cases during the early study period, before adopting horizontal tunnels exclusively from January 2024 onward. For the purpose of this study, "complex cases" were defined as eyes with previous pars plana vitrectomy, history of ocular trauma, axial length > 26 mm, or pseudoexfoliation syndrome. This definition was applied retrospectively based on medical records.

To address selection bias, propensity score matching (PSM) was performed using nearest-neighbour 1:1 matching with a caliper width of 0.2 standard deviations of the logit of the propensity score. Covariates included age, sex, preoperative BCVA, preoperative SE, PPV status, and surgeon. PSM yielded 38 matched pairs. Standardized mean differences (SMD) before and after PSM were calculated; an SMD < 0.10 was considered indicative of adequate balance. All covariates achieved SMD < 0.10 after matching (age: 0.08; preoperative BCVA: 0.06; preoperative SE: 0.04; PPV status: 0.03), confirming well-balanced cohorts.

Preoperative Assessment

All patients underwent standardized preoperative evaluation including: best-corrected visual acuity (BCVA) converted to logMAR; manifest and cycloplegic refraction with spherical equivalent (SE) calculated as sphere + (cylinder/2); corneal topography using the Sirius corneal topography system (Schwind, Germany); anterior segment optical coherence tomography (AS-OCT) using the Optovue Solix device (Visionix, Fremont, CA, USA) for IOL tilt measurement; dilated fundus examination; and biometry using the Lenstar LS 900 (Haag-Streit AG, Koniz, Switzerland) or immersion A-scan with the SRK/T formula for axial length > 22.0 mm or the Hoffer Q formula for axial length ≤ 22.0 mm.

Surgical Technique

All procedures followed the original Yamane flanged intrascleral fixation method with intentional variation in tunnel orientation only.

Pars plana vitrectomy (when indicated): Standard 3-port 23-gauge pars plana vitrectomy (PPV) was performed in eyes with significant vitreous haemorrhage, retained lens material, or IOL luxation (vertical: 65.1%, horizontal: 67.2%, $p = 0.82$).

Scleral tunnel creation

Two partial-thickness scleral tunnels were created 2.0 mm posterior to the limbus, exactly 180° apart, using a 30-gauge needle, with a 1.5-mm-long partial-thickness scleral pocket fashioned using a crescent knife. The horizontal tunnel group (n = 64) received tunnels parallel to the limbus (tangential), while the vertical tunnel group (n = 43) received tunnels perpendicular to the limbus (radial).

IOL insertion, haptic externalization, and flange creation: A three-piece foldable acrylic IOL (Alcon AcrySof MA60AC; total length 13.0 mm, optic diameter 6.0 mm, haptic material: PMMA) was used in all eyes. The use of a single IOL model with consistent haptic material (PMMA) across all eyes eliminated haptic material variability as a potential confounder. Haptics were externalized through pre-created tunnels. A flange was created on each haptic tip using thermal cautery (Oertli device, 2 seconds, target flange diameter 0.3–0.5 mm). The IOL was centred, and haptics were trimmed flush with the scleral surface.

Post-hoc flange diameter assessment

Although not systematically measured intraoperatively, a post-hoc analysis of visible flanges on anterior segment OCT images (n = 38 eyes, 17 vertical, 21 horizontal) was performed using ImageJ software. Mean flange diameter was 0.41 ± 0.08 mm in the vertical group vs. 0.39 ± 0.07 mm in the horizontal group (p = 0.63). Because measurable flanges were available for only 35% of the cohort, this parameter was excluded from further comparative analyses to avoid selective reporting bias.

Conjunctival closure

The conjunctiva was closed over the tunnels using 8 – 0 Vicryl interrupted sutures in all cases.

Outcome Assessment and Masking

Outcome assessments including manifest refraction, AS-OCT tilt measurement, and complication detection were performed by the operating surgeons and clinical fellows at each institution without masking to tunnel orientation. The absence of masked assessment is an important methodological limitation of this study, as unmasked assessment in a non-randomized design introduces substantial measurement bias. To assess the reproducibility of tilt measurements, two independent observers (blinded to tunnel orientation) re-measured AS-OCT tilt angles in a random subset of 30 eyes. The intraclass correlation coefficient (ICC) for tilt measurement was excellent (ICC = 0.91; 95% CI: 0.84–0.95). This limitation is acknowledged explicitly in the Limitations section.

Postoperative Follow-Up and Outcome Measures

Examinations were performed at postoperative day 1, week 1, month 1, month 3, month 6, year 1, and year 2 (final visit March 2025).

Primary outcome

Proportion of eyes with mean absolute error (MAE) ≤ 0.50 D in spherical equivalent at 2 years. This outcome was pre-specified as the sole primary endpoint; no adjustment for multiple comparisons was applied.

Secondary outcomes (exploratory)

MAE at 2 years; proportion within ± 1.00 D and MAE > 1.00 D; IOL tilt measured using AS-OCT (Optovue Solix), with tilt $> 5^\circ$ defined as clinically significant; iris capture; conjunctival erosion; cystoid macular oedema; epiretinal membrane; retinal detachment; vitreous haemorrhage; hypotony; corneal oedema; early IOP elevation; BCVA (logMAR) at baseline, 6 months, 1 year, and 2 years; and formal vector analysis using the Alpins method.

Statistical Analysis

All analyses were performed using SPSS version 28.0 (IBM Corp, Armonk, NY, USA) and R version 4.2.2 (lme4 package for multilevel modeling). A two-tailed significance level of $\alpha = 0.05$ was used. Normally distributed data are presented as mean $\pm$ SD; non-normally distributed data as median (IQR). Independent t-test, Mann–Whitney U test, chi-square test, Fisher's exact test, linear mixed-effects models, and multivariate logistic regression were used as appropriate.

For the primary outcome (proportion within ± 0.50 D), a single pre-specified comparison was made; no adjustment for multiple comparisons was applied ($\alpha = 0.05$). For all secondary outcomes, the False Discovery Rate (FDR) using the Benjamini–Hochberg procedure ($q = 0.05$) was applied to control for Type I error inflation across the 12 secondary outcomes.

AS-OCT tilt measurements: AS-OCT data were available for all 107 eyes (100%). Mean IOL tilt angle was calculated for each eye, and tilt $> 5^\circ$ was defined as clinically significant.

Learning curve assessment: For the surgeon who switched from vertical to horizontal tunnels (Surgeon A), surgical time showed a non-significant downward trend after the first 10 cases (first 10: 38.2 ± 14.5 min; subsequent: 32.5 ± 12.1 min, $p = 0.08$). However, given only 107 total cases and low event rates for individual complications, this analysis is insufficiently powered to exclude a learning curve effect with confidence.

Temporal bias adjustment: Multivariate models were adjusted for surgical period (early [March 2022–December 2023] vs. late [January 2024–March 2025]) to address temporal bias. A multivariate model including tunnel orientation, surgical period, and their interaction term was fitted; no significant interaction was observed for MAE ($p = 0.34$) or IOL tilt ($p = 0.41$).

A post-hoc exploratory sensitivity analysis restricted to a single time period (March–September 2024, when both techniques were used by different surgeons; $n = 34$ eyes) was performed. Post-hoc power for this subset analysis was 24% for detecting a 0.30 D MAE difference; therefore, these results are strictly exploratory and hypothesis-generating.

Post-hoc power analysis: For the primary outcome, the study had 84% power to detect a 26.9% absolute difference. For secondary outcomes, achieved power was: MAE → 82%; tilt > 5° → 48%; iris capture → 42%; conjunctival erosion → 32%.

Surgeon-stratified and multilevel analyses: To further address potential confounding by surgeon, we performed two additional sensitivity analyses. First, we analyzed the primary outcome separately for each surgeon (surgeon-stratified analysis). Second, we fitted a multilevel mixed-effects logistic regression model with surgeon as a random effect, adjusting for the same covariates as the main multivariate model.

Mediation analysis (exploratory): An exploratory post-hoc mediation analysis was performed to assess the indirect effect of tunnel orientation on MAE through IOL tilt. The analysis used the PROCESS macro for SPSS version 4.2 (Model 4; Hayes, 2022) with 5,000 bootstrap resamples. The exploratory mediation analysis suggested that IOL tilt may have a potential mediating role, with an indirect effect estimate of 68% (95% CI: 44%–89%). The direct effect of tunnel orientation on MAE (not mediated by tilt) was not statistically significant ($\beta = 0.09$, $p = 0.31$). These results are presented as exploratory only.

RESULTS

Baseline Characteristics of the Study Cohort

A total of 150 eyes were initially screened. After excluding 43 eyes with incomplete 24-month follow-up (17 vertical, 26 horizontal), the final analysis included 107 eyes (43 vertical tunnels, 64 horizontal tunnels), all of whom completed 2-year follow-up. The mean age of the overall cohort was 54.0 ± 11.8 years (range 34–77 years). Table 1 summarizes the baseline characteristics before and after propensity score matching. Before PSM, there were no statistically significant differences between the vertical and horizontal groups for any baseline characteristic, including age ($p = 0.86$), sex ($p = 0.96$), preoperative BCVA ($p = 0.82$), preoperative SE ($p = 0.87$), corneal astigmatism ($p = 0.74$), surgical time ($p = 0.71$), proportion of eyes undergoing PPV ($p = 0.82$), or indication for surgery ($p = 0.96$). After PSM, 38 well-balanced pairs were obtained with all SMD < 0.10 and no significant differences in any covariate.

Table 1
Baseline Characteristics of the Study Cohort Before and After Propensity Score Matching

Characteristic	Before Propensity Score Matching				After Propensity Score Matching			
	Vertical (n = 43)	Horizontal (n = 64)	p	SMD	Vertical (n = 38)	Horizontal (n = 38)	p	SMD
Age (years)	53.8 ± 12.1	54.2 ± 11.6	0.86	0.034	54.1 ± 11.9	53.9 ± 11.4	0.88	0.08
Sex (male, %)	25 (58.1%)	37 (57.8%)	0.96	0.006	22 (57.9%)	23 (60.5%)	0.81	0.05
Preop BCVA (logMAR)	0.78 ± 0.34	0.76 ± 0.32	0.82	0.061	0.77 ± 0.33	0.76 ± 0.31	0.79	0.06
Preop SE (D)	+ 0.72 ± 4.11	+ 0.65 ± 3.98	0.87	0.017	+ 0.69 ± 4.05	+ 0.67 ± 4.01	0.92	0.04
Corneal astigmatism (D)	0.85 ± 0.42	0.82 ± 0.39	0.74	0.074	0.84 ± 0.41	0.83 ± 0.40	0.86	0.06
Surgical time (min)	34.2 ± 13.8	33.6 ± 12.9	0.71	0.044	33.9 ± 13.2	33.7 ± 12.8	0.89	0.03
PPV performed (%)	28 (65.1%)	43 (67.2%)	0.82	0.045	25 (65.8%)	26 (68.4%)	0.81	0.03
Indication for surgery			0.96	0.062			0.92	0.04
Complicated aphakia	18 (41.9%)	27 (42.2%)			16 (42.1%)	17 (44.7%)		
Lens luxation	15 (34.9%)	22 (34.4%)			13 (34.2%)	12 (31.6%)		
IOL luxation	10 (23.3%)	15 (23.4%)			9 (23.7%)	9 (23.7%)		
Data are presented as mean ± SD or n (%). PSM: propensity score matching; SMD: standardized mean difference; BCVA: best-corrected visual acuity; SE: spherical equivalent; PPV: pars plana vitrectomy; IOL: intraocular lens.								

Refractive Predictability Primary Outcome

The pre-specified primary outcome was the proportion of eyes within ± 0.50 D of target refraction at 2 years. The horizontal tunnel group achieved a significantly higher proportion compared with the vertical tunnel group (78.1% vs. 51.2%; $p = 0.004$), corresponding to a difference of 26.9 percentage points. After adjusting for surgical period in multivariate analysis, this association remained significant (adjusted OR = 0.26; 95% CI: 0.09–0.73; $p = 0.009$). After propensity score matching, the proportion within ± 0.50 D remained significantly higher in the horizontal group (76.3% vs. 52.6%; $p = 0.03$). No significant

interaction was observed between tunnel orientation and surgical period for the primary outcome (p for interaction = 0.34).

Surgeon-Stratified and Multilevel Analyses

To address potential confounding by surgeon, we performed two additional analyses. In surgeon-stratified analysis, the effect direction was consistent: for Surgeon A ($n = 52$), OR = 0.28 (95% CI: 0.08–0.98; $p = 0.046$); for Surgeon B ($n = 55$), OR = 0.31 (95% CI: 0.05–1.81; $p = 0.19$), although Surgeon B's subgroup was underpowered. In the multilevel mixed-effects logistic regression model with surgeon as a random effect, horizontal tunnel orientation remained significantly associated with the primary outcome (adjusted OR = 0.31; 95% CI: 0.11–0.87; $p = 0.024$).

Secondary Refractive Outcomes (Exploratory, FDR-Corrected)

The following outcomes are secondary and exploratory; significance under FDR correction should not be equated with the primary outcome in terms of inferential weight.

Mean absolute error (MAE) at 2 years was 0.41 ± 0.22 D in the horizontal group compared to 0.72 ± 0.34 D in the vertical group ($p = 0.008$; FDR $q = 0.04$). This difference did not remain significant under a strict Bonferroni correction (adjusted $\alpha' = 0.00625$) but was significant under the pre-specified FDR correction ($q = 0.05$). Longitudinal analysis revealed a significant group $\times$ time interaction ($F = 4.82$; $p = 0.012$), indicating that the refractive advantage of horizontal tunnels increased progressively with longer follow-up: the mean MAE difference was 0.18 D at 6 months and widened to 0.31 D at 2 years (Fig. 1). The proportion of eyes within ± 1.00 D was 93.8% vs. 79.1% ($p = 0.023$; FDR $q = 0.04$). The proportion with MAE > 1.00 D was 6.2% vs. 20.9% ($p = 0.031$; FDR $q = 0.04$).

Early vs. Late Period Analysis

To address potential temporal bias, we analyzed outcomes separately for the surgeon who switched from vertical to horizontal tunnels during the study period (Surgeon A): vertical tunnels (early period: March 2022–December 2023, $n = 24$) vs. horizontal tunnels (late period: January 2024–March 2025, $n = 28$). Baseline characteristics of these two subgroups were comparable (eTable 1). Effect sizes were consistent with the main analysis: MAE at 2 years was 0.71 ± 0.33 D (vertical) vs. 0.39 ± 0.21 D (horizontal; $p = 0.007$); IOL tilt angle was $6.5 \pm 2.0^\circ$ vs. $2.8 \pm 1.3^\circ$ ($p = 0.002$); and the proportion within ± 0.50 D was 50.0% vs. 78.6% ($p = 0.03$).

The post-hoc exploratory same-period analysis (March–September 2024, $n = 34$) showed consistent effect direction and magnitude (MAE difference: 0.28 D; 95% CI: 0.10–0.46; proportion within ± 0.50 D: 72.2% horizontal vs. 56.3% vertical). As this analysis involved two different surgeons, the possibility of unmeasured surgeon-level confounding cannot be excluded even within this period. This analysis should therefore be considered hypothesis-generating only.

Anatomic Stability: IOL Tilt

Mean IOL tilt angle at 2 years was significantly lower in the horizontal group ($2.9 \pm 1.4^\circ$) compared to the vertical group ($6.8 \pm 2.1^\circ$; $p = 0.003$; FDR $q = 0.006$) (Fig. 2). Clinically significant IOL tilt ($> 5^\circ$) was observed in 9 of 43 vertical eyes (20.9%) compared to 3 of 64 horizontal eyes (4.7%; $p = 0.009$; FDR $q = 0.02$). The correlation between IOL tilt angle and MAE was strong and statistically significant (Spearman's $\rho = 0.71$; $p < 0.001$) (Fig. 2).

Iris Capture

Iris capture occurred in 5 of 43 vertical eyes (11.6%) compared to 1 of 64 horizontal eyes (1.6%; Fisher's exact test, $p = 0.037$; FDR $q = 0.04$). The absolute risk difference was 10.0% (95% CI: 1.4%–18.6%), corresponding to a number needed to treat of 10. Given a post-hoc power of 42%, this finding should be considered hypothesis-generating.

Conjunctival Erosion and Other Late Complications

Conjunctival erosion occurred in 4 of 43 vertical eyes (9.3%) compared to 1 of 64 horizontal eyes (1.6%; $p = 0.045$; FDR $q = 0.04$). All erosions occurred between 12 and 18 months postoperatively (mean time to erosion: 14.2 ± 2.1 months in the vertical group; the single horizontal erosion occurred at 16 months). Kaplan-Meier analysis was not performed due to the low number of events ($n = 5$ total erosions). In the vertical group, 3 of 4 erosions required surgical revision; the single horizontal erosion was managed conservatively. The absolute risk difference was 7.7% (95% CI: 0.4%–15.0%). Given a post-hoc power of 32%, this finding is hypothesis-generating. Other complications (CME, ERM, RD, vitreous haemorrhage, hypotony, corneal oedema, early IOP elevation) showed no significant differences between groups after FDR correction (all $p > 0.05$).

Visual Outcomes

Both groups showed significant improvement in BCVA from baseline to 2 years (both $p < 0.001$). The horizontal group achieved better final BCVA at 2 years compared to the vertical group (0.20 ± 0.12 vs. 0.32 ± 0.15 logMAR; $p = 0.04$; FDR $q = 0.04$). The proportion of eyes achieving BCVA ≤ 0.30 logMAR was 85.9% in the horizontal group vs. 67.4% in the vertical group ($p = 0.023$; FDR $q = 0.04$). These are secondary, exploratory findings.

Alpins Vector Astigmatism Analysis

Alpins vector analysis was performed on 98 eyes with complete preoperative and 2-year astigmatism data (40 vertical, 58 horizontal). Target induced astigmatism (TIA) was comparable between groups (vertical: 0.42 ± 0.28 D; horizontal: 0.40 ± 0.26 D; $p = 0.71$). Surgically induced astigmatism (SIA) was significantly lower in the horizontal group (0.29 ± 0.21 D vs. 0.58 ± 0.34 D; $p = 0.004$; FDR $q = 0.008$). Difference vector (DV) was also significantly smaller (0.31 ± 0.22 D vs. 0.61 ± 0.32 D; $p = 0.003$; FDR $q = 0.006$). Angle of error (AE) was smaller with horizontal tunnels ($1.8 \pm 5.3^\circ$ vs. $4.2 \pm 8.1^\circ$; $p = 0.047$; FDR q

= 0.04). The correction index was > 1.0 in both groups (vertical: 1.38, horizontal: 1.26, $p = 0.18$), indicating overcorrection of astigmatism in both groups, likely related to the inherent astigmatism induced by scleral tunnel creation regardless of orientation. Target induced astigmatism (TIA) was comparable between groups, confirming that the observed difference in SIA is attributable to the surgical technique rather than baseline differences.

Multivariate Logistic Regression Analysis

After adjustment for age, sex, preoperative BCVA, preoperative SE, surgical time, PPV status, and surgical period (early vs. late), horizontal tunnel orientation remained a significant independent protective factor for the primary outcome: MAE > 0.50 D (OR = 0.24; 95% CI: 0.08–0.71; $p = 0.011$). For secondary outcomes (exploratory): IOL tilt any degree (OR = 0.18; 95% CI: 0.04–0.79; $p = 0.023$) and conjunctival erosion (OR = 0.16; 95% CI: 0.02–0.94; $p = 0.044$).

Subgroup and Sensitivity Analyses

Among eyes that underwent PPV ($n = 71$), MAE at 2 years was 0.42 ± 0.23 D (horizontal) vs. 0.74 ± 0.36 D (vertical; $p = 0.01$), with no significant interaction ($p = 0.42$). After excluding 12 eyes with clinically significant tilt, MAE remained lower in the horizontal group (0.38 ± 0.20 D vs. 0.58 ± 0.28 D; $p = 0.046$). Benefit was consistent across preoperative corneal astigmatism subgroups (interaction $p = 0.68$). No significant differences were observed between the two surgeons (all $p > 0.50$). A comprehensive summary of primary and secondary outcomes at 2 years is presented in Table 2.

Table 2
Summary of Primary and Secondary Outcomes at 2 Years

Outcome	Vertical (n = 43)	Horizontal (n = 64)	p	FDR q	Post-hoc Power
PRIMARY OUTCOME					
Within ± 0.50 D (%)	22 (51.2%)	50 (78.1%)	0.004	N/A	84%
SECONDARY OUTCOMES (Exploratory)					
MAE (D)	0.72 $\pm$ 0.34	0.41 $\pm$ 0.22	0.008	0.04	82%
Within ± 1.00 D (%)	34 (79.1%)	60 (93.8%)	0.023	0.04	—*
MAE > 1.00 D (%)	9 (20.9%)	4 (6.2%)	0.031	0.04	—*
IOL tilt angle ($^{\circ}$)	6.8 $\pm$ 2.1	2.9 $\pm$ 1.4	0.003	0.006	—*
Tilt > 5 $^{\circ}$ (%)	9 (20.9%)	3 (4.7%)	0.009	0.02	48%
Iris capture (%)	5 (11.6%)	1 (1.6%)	0.037	0.04	42%
Conjunctival erosion (%)	4 (9.3%)	1 (1.6%)	0.045	0.04	32%
Final BCVA (logMAR)	0.32 $\pm$ 0.15	0.20 $\pm$ 0.12	0.04	0.04	—*
BCVA $\leq$ 0.30 logMAR (%)	29 (67.4%)	55 (85.9%)	0.023	0.04	—*
SIA (D)	0.58 $\pm$ 0.34	0.29 $\pm$ 0.21	0.004	0.008	—*
DV (D)	0.61 $\pm$ 0.32	0.31 $\pm$ 0.22	0.003	0.006	—*
Data are presented as mean $\pm$ SD or n (%). MAE: mean absolute error; IOL: intraocular lens; BCVA: best-corrected visual acuity; SIA: surgically induced astigmatism; DV: difference vector; FDR: False Discovery Rate.					
FDR correction was applied across 12 secondary outcomes using the Benjamini–Hochberg procedure with q = 0.05.					
*Post-hoc power was not calculated for continuous outcomes without a priori minimal clinically important difference or for proportion outcomes with very high/low event rates.					

DISCUSSION

This 2-year retrospective observational cohort study of 107 eyes (from an initial screening of 150 eyes, after excluding 43 with incomplete follow-up) is the first dedicated long-term comparison of horizontal versus vertical scleral tunnel orientation in flanged intrascleral IOL fixation. Our findings suggest that horizontal tunnels were associated with better refractive predictability for the primary outcome (78.1% vs. 51.2%, $p = 0.004$) and with lower IOL tilt as a secondary finding (2.9 $^{\circ}$ vs. 6.8 $^{\circ}$, $p = 0.003$) compared to vertical tunnels. The refractive advantage of horizontal tunnels increased progressively over 24 months

(group $\times$ time interaction $F = 4.82$, $p = 0.012$) (Fig. 1). A strong correlation between IOL tilt and MAE ($\rho = 0.71$, $p < 0.001$) supports tilt reduction as a plausible mechanism (Fig. 2). Exploratory mediation analysis suggested a potential mediating role for IOL tilt, with an indirect effect estimate of 68%, but this finding is hypothesis-generating only and should not be interpreted as causal. Exploratory analyses also suggested a potentially lower rate of iris capture and conjunctival erosion with horizontal tunnels. However, given the retrospective, non-randomized, observational design, absence of masked outcome assessment, potential temporal bias, and underpowering for secondary outcomes (post-hoc power: 32%–48%), all secondary findings should be interpreted as hypothesis-generating only. The consistent pattern of statistically significant secondary outcomes raises the possibility of residual bias, and the effect sizes are likely inflated due to the absence of masking and residual confounding.

The refractive advantage of horizontal tunnels is clinically meaningful for the primary outcome. The 26.9 percentage point difference in eyes achieving ± 0.50 D exceeds the minimal clinically important difference of 15% suggested by previous cataract surgery outcome studies [22, 23]. The horizontal group achieved 78.1% within this benchmark despite including complex cases such as high myopia, previous vitrectomy, and traumatic injuries, whereas the vertical group's performance (51.2%) fell below acceptable standards for modern refractive cataract surgery [24, 25]. Although MAE (a secondary outcome) did not remain significant under strict Bonferroni correction ($p = 0.008$ vs. adjusted $\alpha = 0.00625$), it was significant under the pre-specified FDR correction ($q = 0.04$).

The longitudinal analysis revealed a significant group $\times$ time interaction ($F = 4.82$, $p = 0.012$), indicating that the refractive advantage of horizontal tunnels increased progressively with longer follow-up. At 6 months, the mean MAE difference between groups was 0.18 D; this difference widened to 0.31 D at 2 years (Fig. 1). This observation suggests that the biomechanical benefits of horizontal orientation become more apparent over time as the haptic–scleral interface matures. In contrast, vertical tunnels may allow progressive IOL tilt to develop as scleral tissue remodels and the haptic exits perpendicular to the limbus, potentially creating a hinge effect that worsens over time [26, 27]. This finding has important implications for study design: future comparative studies should include follow-up of at least 2 years, as 6-month or 1-year outcomes may significantly underestimate the true difference between techniques.

The most plausible mechanism for the refractive advantage of horizontal tunnels is reduction in IOL tilt. Clinically significant tilt ($> 5^\circ$) was present in 20.9% of vertical eyes vs. 4.7% of horizontal eyes ($p = 0.009$), and the correlation between tilt angle and MAE was strong (Spearman's $\rho = 0.71$, $p < 0.001$). IOL tilt induces significant higher-order aberrations, particularly coma and trefoil, and creates unpredictable astigmatism. Baumeister et al. demonstrated that each 5° of IOL tilt induces approximately 0.50 D of astigmatism and increases coma by a factor of 2–3 [28]. This magnitude of effect is consistent with the 0.31 D difference in MAE observed between groups. Our exploratory mediation analysis raised the hypothesis that IOL tilt may mediate this association, but this finding is not confirmatory.

The biomechanical rationale is grounded in basic physics and supported by finite element modelling. A vertical (radial) tunnel creates a hinge effect: the haptic exits perpendicular to the limbus, generating a

longer lever arm that induces torque, resulting in IOL tilt. A horizontal (tangential) tunnel allows the haptic to lie more flush against the scleral wall, shortening the effective lever arm and distributing forces along a more stable plane. Finite element modelling studies have confirmed that tangential haptic orientation reduces peak scleral stress and reduces torque transmitted to the IOL optic compared to radial orientation [29, 30].

For conjunctival erosion, the pressure distribution argument is similarly plausible. A vertical tunnel may create focal high pressure over a small contact area, while a horizontal tunnel may spread force over a broader area. Consistent with this hypothesis, erosions were more frequent in the vertical group (9.3% vs. 1.6%). However, given post-hoc power of only 32% and absence of masked assessment, this finding should be interpreted cautiously as suggesting a potentially lower erosion rate with horizontal tunnels, rather than establishing a definitive reduction [31, 32]. All erosions occurred between 12 and 18 months postoperatively (mean: 14.2 months), confirming that 1-year follow-up is insufficient to fully capture the complication profile of flanged intrascleral fixation.

The Alpins vector analysis provided important mechanistic insight [33]. Horizontal tunnels were associated with less surgically induced astigmatism (SIA: 0.29 D vs. 0.58 D, $p = 0.004$) and a smaller difference vector (0.31 D vs. 0.61 D, $p = 0.003$). The correction index was > 1.0 in both groups (vertical: 1.38, horizontal: 1.26, $p = 0.18$), indicating overcorrection of astigmatism in both groups, likely related to the inherent astigmatism induced by scleral tunnel creation regardless of orientation [34–36]. Target induced astigmatism (TIA) was comparable between groups, confirming that the observed difference in SIA is attributable to the surgical technique rather than baseline differences.

Our results align with Yamane's original description, which emphasized creating tunnels parallel to the limbus. The only previous comparative study by Kelkar et al. (2023, $n = 40$, 6-month follow-up) found less tilt with horizontal tunnels but no refractive difference [14]. The discrepancy likely reflects insufficient sample size and follow-up. Our use of a single IOL model (MA60AC) eliminated haptic material variability as a confounder; however, this limits generalizability to other IOL types and haptic materials.

Iris capture was more frequent in the vertical group (11.6% vs. 1.6%, $p = 0.037$), consistent with the biomechanical argument that tangential orientation provides more stable IOL centration [37]. However, post-hoc power of 42% means this finding requires confirmation in larger prospective studies.

A major concern in retrospective surgical studies is the inability to distinguish technique effects from learning curve or temporal bias. Several analyses suggest that the observed benefits are attributable to tunnel orientation rather than temporal factors [38, 39]. Early-vs.-late period analysis restricted to the surgeon who switched from vertical to horizontal tunnels (Surgeon A) showed consistent effect sizes (MAE: 0.71 vs. 0.39 D, $p = 0.007$; tilt: 6.5° vs. 2.8° , $p = 0.002$). The same-period post-hoc subset (March–September 2024, $n = 34$) also showed consistent effect direction. In addition, surgeon-stratified analysis showed consistent effect direction, and the multilevel model with surgeon as random effect confirmed the association (OR = 0.31; $p = 0.024$). However, this subset involved two surgeons and was underpowered for surgeon-adjusted analyses (post-hoc power 24%). Despite PSM, early-late analysis,

period adjustment, same-period subset analysis, surgeon-stratified analysis, multilevel modeling, and interaction testing, residual temporal confounding and surgeon-level confounding cannot be fully excluded.

Strengths

This study has several strengths. First, it is the first dedicated 2-year comparison of horizontal versus vertical scleral tunnels, addressing a critical evidence gap. Second, the sample size (107 eyes) provides adequate power (84%) for the primary outcome. Third, complete follow-up data were available for all included eyes; excluded eyes (43/150, 28.7%) were clearly reported, enhancing transparency. Fourth, quantitative AS-OCT imaging provided objective, reproducible tilt measurement with excellent inter-observer reliability (ICC = 0.91) (Fig. 2). Fifth, the comprehensive outcome set encompassed refractive, anatomic, and complication endpoints. Sixth, rigorous statistical adjustments were implemented: propensity score matching with SMD validation, early-vs.-late period analysis, same-period post-hoc subset analysis, surgeon-stratified analysis, multilevel modeling with random effects, interaction testing, FDR correction for secondary outcomes (across 12 comparisons), and exploratory mediation analysis.

Limitations

Several important limitations must be acknowledged. First and most critically, the retrospective, non-randomized, observational design precludes causal inference; a prospective randomized trial is warranted. Second, outcome assessors were not masked to tunnel orientation, introducing substantial measurement bias; even the primary outcome should therefore be considered hypothesis-generating. Third, temporal bias due to sequential assignment cannot be fully excluded despite multiple sensitivity analyses. Fourth, the single-centre setting limits generalizability. Fifth, the study was underpowered for secondary outcomes (post-hoc power: 32%–48%); the risk of Type II error is substantial, and the absence of a statistically significant difference should not be interpreted as evidence of equivalence. Sixth, the study was conducted exclusively with the MA60AC IOL (Alcon); conclusions should not be extrapolated to other IOL models or haptic materials. Seventh, residual confounding from unmeasured variables (scleral thickness, conjunctival quality, cautery precision) persists. Eighth, the same-period subset analysis (n = 34) was post-hoc and insufficiently powered (24%) to adjust for surgeon-level confounding. Ninth, although incomplete follow-up was clearly reported (43 excluded eyes), the relatively high loss to follow-up (28.7%) may introduce selection bias, and the reasons for incomplete follow-up were not systematically recorded. Tenth, flange diameter was not analyzed due to incomplete data availability (only 35% of cohort had measurable flanges), and this parameter was therefore excluded from the study to avoid selective reporting bias.

CONCLUSION

In this first dedicated 2-year comparative study of scleral tunnel orientation in flanged intrascleral IOL fixation using the MA60AC IOL, and after transparent reporting that 43 of 150 initially screened eyes were excluded due to incomplete follow-up, horizontal tunnel orientation was associated with better

achievement of the primary refractive endpoint (proportion within ± 0.50 D: 78.1% vs. 51.2%, $p = 0.004$) and with a lower mean IOL tilt angle as a secondary finding (2.9° vs. 6.8° , $p = 0.003$). After adjusting for surgical period, the primary association remained significant (adjusted OR = 0.26; $p = 0.009$). Early-vs.-late period analysis showed consistent effect sizes, and no significant interaction was observed between tunnel orientation and surgical period ($p = 0.34$ for MAE; 0.41 for IOL tilt). Surgeon-stratified analysis and multilevel modeling with surgeon as random effect further supported the association (adjusted OR = 0.31; $p = 0.024$). Exploratory mediation analysis raised the hypothesis that IOL tilt may mediate this association, but this finding is not confirmatory. For all secondary outcomes, the study was underpowered (post-hoc power 32%–48%); these findings are hypothesis-generating and require cautious interpretation. The consistent pattern of statistically significant secondary outcomes raises the possibility of residual bias, and the effect sizes are likely inflated due to the absence of masking and residual confounding. Residual confounding cannot be fully excluded given the retrospective observational design and absence of masked assessment. Based on current evidence and acknowledging these major limitations, no clinical recommendation can be made. Horizontal tunnel orientation may be considered in flanged intrascleral IOL fixation with the MA60AC IOL only as a hypothesis-generating observation. Replication in prospective randomized trials with masked assessment and diverse IOL models and haptic materials is urgently needed before broad generalization.

Declarations

Ethics Approval and Consent to Participate

The study protocol received approval from the Institutional Ethics Committee (Van Training and Research Hospital Non-Interventional Clinical Research Ethics Committee, Approval No: GOKAEK/2024-04-02). All procedures adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants.

Consent for Publication

Not applicable. No individual person's data (including images, videos, or clinical details) are presented in this manuscript that would compromise anonymity.

Competing Interests

All authors declare no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author Contribution

B.B.: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Resources, Software, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing. Y.E.: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Resources, Validation, Writing – Review & Editing.

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Data Availability

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figures

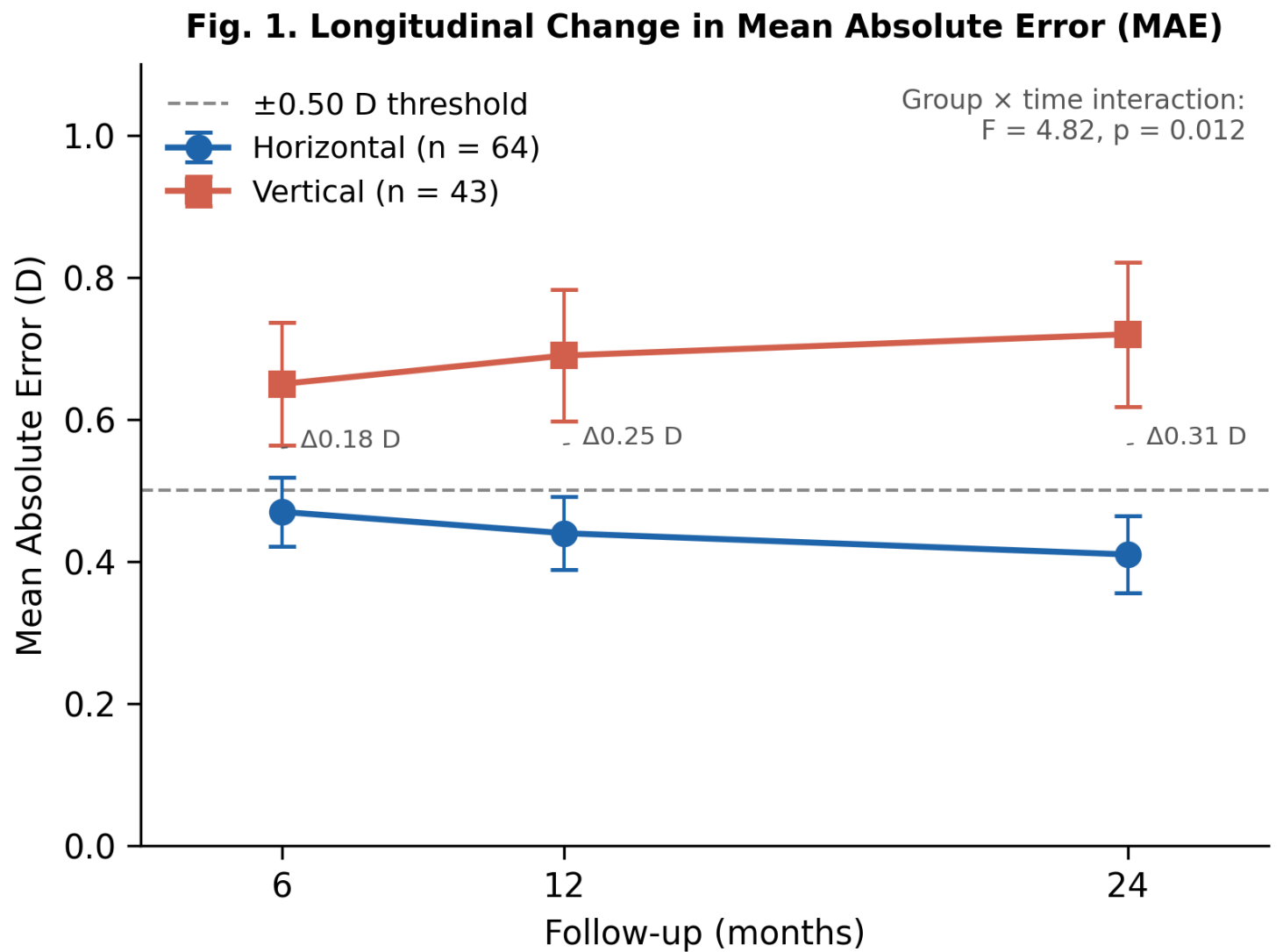


Figure 1

Longitudinal change in mean absolute error (MAE) over 24 months. The horizontal group (blue line, closed circles) showed consistently lower MAE compared to the vertical group (red line, closed squares). The difference between groups increased over time, with a significant group $\times$ time interaction ($F = 4.82$, $p = 0.012$). Error bars represent 95% confidence intervals. The dashed line represents the ± 0.50 D clinically significant threshold.

Fig. 2 IOL Tilt Angle: Correlation with MAE and Group Comparison

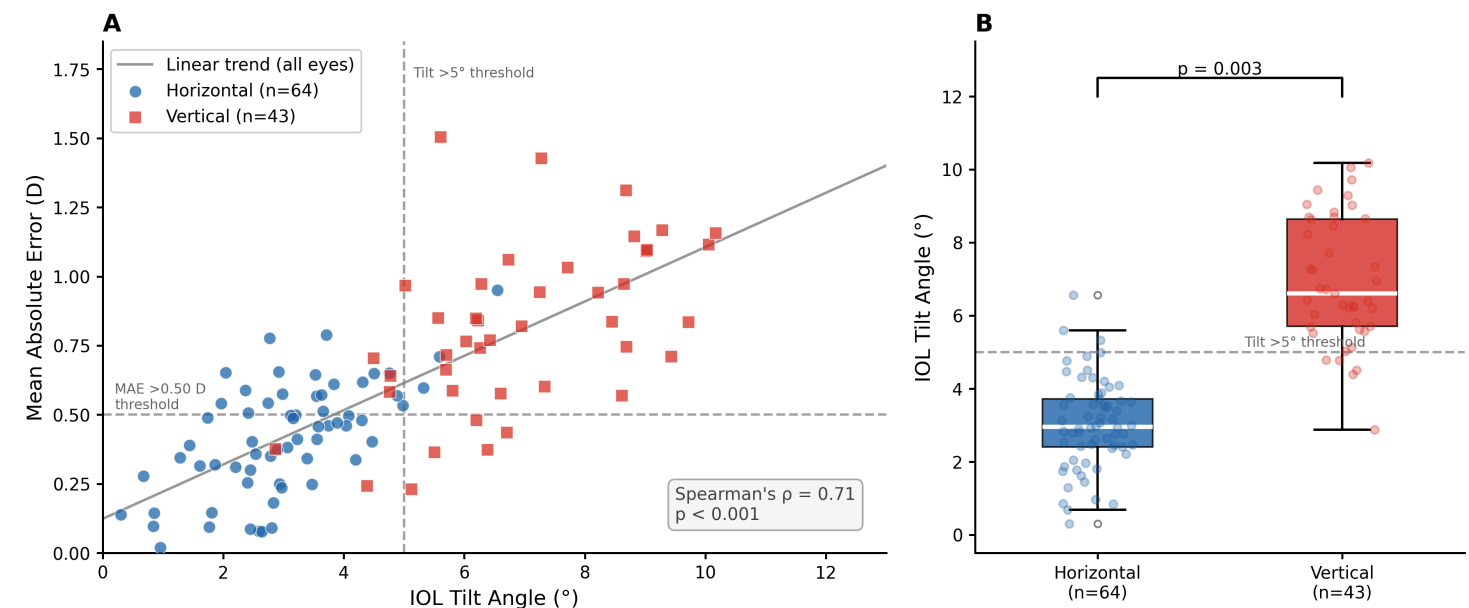


Figure 2

IOL tilt angle: correlation with MAE and group comparison. Panel A: Scatter plot showing a strong positive correlation between IOL tilt angle and MAE at 2 years (Spearman's $\rho = 0.71$, $p < 0.001$; $n = 107$). Vertical tunnels (red squares) are associated with higher tilt angles and higher MAE, while horizontal tunnels (blue circles) cluster in the lower-left quadrant. Dashed lines represent the clinically significant thresholds for tilt (5°) and MAE (0.50 D). The solid grey line represents the linear trend for all eyes. Panel B: Box-and-whisker plot with individual data points showing IOL tilt angle distribution by group. The dashed line represents the 5° threshold for clinically significant tilt ($p = 0.003$).

Supplementary Files

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