Cover Page

Official Title: Expanding Visual Horizons: Comparative Outcomes of a Novel Extended Depth-of-Focus IOL Versus Enhanced and Standard Monofocal IOLs

NCT Number: NCT not assigned

Document Date: 2024-02-06

Document Type: Study Protocol with Statistical Analysis Plan (SAP)

Ethics Committee: Sakarya University Faculty of Medicine Non-Interventional Ethics Committee (Approval 2022/294)

Site: Sakarya Education and Research Hospital, Sakarya, Turkey

Study Protocol

Background and Rationale

Patients undergoing cataract surgery increasingly expect functional vision at distance, intermediate, and near without disturbing photic phenomena. Standard monofocal IOLs offer excellent distance acuity but limited intermediate and near vision. Enhanced monofocal and extended depth-of-focus (EDOF) lenses aim to broaden the range of clear vision while minimizing dysphotopsia. This study compares outcomes across these IOL categories.

Objectives

Primary Objective: To compare binocular uncorrected distance, intermediate, and near visual acuity and patient satisfaction at 6 months among monofocal, enhanced monofocal, and EDOF IOLs.

Secondary Objectives: To compare monocular and binocular corrected acuities, refraction, defocus curve performance, and halo/glare symptoms among the three IOL groups.

Study Design

Consecutive, comparative, retrospective case series of patients undergoing bilateral phacoemulsification with implantation of the same IOL model in both eyes.

Study Period

June 2019 to January 2024. Primary completion in 2024.

Study Population

Adults aged 45–75 years with age-related cataract undergoing bilateral cataract surgery.

Inclusion Criteria

- Age-related cataract in both eyes.
- Eligible for bilateral IOL implantation.
- Willingness to complete follow-up.

Exclusion Criteria

- Preoperative corneal astigmatism ¿ 1.0 D.
- Axial length ¡ 21 mm or ¿ 26 mm.
- Prior intraocular or corneal surgery.
- Ocular comorbidities affecting vision (severe dry eye, amblyopia, ocular surface disease, corneal pathology, retinal diseases, uveitis, glaucoma, pseudoexfoliation, pterygium).
- Intraoperative or postoperative complications, or failure to complete 6-month follow-up.

Interventions / Exposures

Patients received one of the following IOLs in both eyes:

- Monofocal: Tecnis ZCB00 (Johnson & Johnson Vision)
- Enhanced monofocal: Tecnis Eyhance ICB00 (Johnson & Johnson Vision)
- EDOF: Asqelio EDOF ETLIO130C (AST Products)

Surgical Technique and Postoperative Care

Standard phacoemulsification using manufacturer-recommended injector systems. IOL power selected to target approximately -0.25 D (first myopic-leaning power). Postoperative regimen: topical 0.5% moxifloxacin + 0.1% dexamethasone five times daily for one week, tapered over three weeks. Follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months.

Assessments and Outcome Measures

At 6 months, visual acuity measured at distance (6 m), intermediate (66 cm), and near (40 cm) under photopic conditions, converted to logMAR. Refraction (manifest and objective), binocular defocus curves (+1.00 D to -2.50 D in 0.50 D steps), and patient questionnaires on halos/glare and spectacle independence were recorded.

Primary Outcomes (6 months):

- Binocular UDVA, UIVA, UNVA (logMAR).
- Patient satisfaction scores for distance, intermediate, and near spectacle-free vision (0–10 scale).

Secondary Outcomes (6 months):

- Monocular UDVA, UIVA, UNVA (logMAR).
- Monocular and binocular CDVA, CIVA, CNVA.
- Manifest and objective spherical equivalent refraction.
- Binocular defocus curve performance.

- Halo and glare scores (NEI-RQL-42 items 17 and 38; 0–100 scale).

Sample Size

A post hoc power analysis (one-way ANOVA; Cohen's f = 0.25, alpha 0.05, three groups, n = 197) yielded power of 0.96.

Ethics

The study adhered to the Declaration of Helsinki and was approved by the Sakarya University Faculty of Medicine Non-Interventional Ethics Committee (Approval 2022/294). Written informed consent was obtained.

Data Sharing

Individual participant data will not be shared.

Statistical Analysis Plan (SAP)

Analysis Population

All eligible patients completing 6-month follow-up were included. Both eyes contributed to outcomes; inter-eye correlation was addressed using GEE for selected analyses.

Descriptive Statistics

Continuous variables summarized as mean ±SD. Categorical variables summarized as counts and percentages.

Normality Testing

Kolmogorov–Smirnov and Shapiro–Wilk tests assessed normality.

Comparative Analyses

- Kruskal–Wallis tests with Dunn–Bonferroni post hoc comparisons for non-normally distributed continuous outcomes.
- One-way ANOVA with Tukey HSD for key binocular outcomes when appropriate.
- Chi-square or Fisher's exact tests for categorical variables.
- GEE model with exchangeable correlation structure for binocular UIVA to account for within-subject correlation.

Significance Threshold

Two-tailed p ¡ 0.05 considered statistically significant.

Software

IBM SPSS Statistics version 24.0 (IBM Corp., Armonk, NY, USA).