Cover Page

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

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Site: Sakarya Education and Research Hospital, Sakarya, Turkey

Informed Consent Form

Study Title

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

Principal Investigator

[Name, title, department, institution]

Sponsor / Funding

No external sponsor.

1. Invitation to Participate

You are invited to participate in a research study because you are undergoing cataract surgery and meet study eligibility criteria. Before you decide, please read this form carefully and ask any questions you may have.

2. Purpose of the Study

The purpose of this study is to compare visual outcomes and patient satisfaction after implantation of one of three intraocular lens (IOL) types used in routine clinical practice:

- Standard monofocal IOL
- Enhanced monofocal IOL
- Extended depth-of-focus (EDOF) IOL

3. Why You Are Eligible

You are being asked to participate because you have age-related cataract and are planned for bilateral cataract surgery, and you do not have exclusion criteria that would interfere with visual outcome assessment.

4. What Will Happen If You Participate

If you agree to participate:

- You will undergo standard-of-care cataract surgery in both eyes.
- The same IOL type will be implanted in both eyes.
- You will attend follow-up visits at approximately day 1, week 1, month 1, month 3, and month 6.

- At follow-up, the following may be performed: distance/intermediate/near visual acuity tests, refraction, binocular defocus curve testing, and questionnaires on glare/halos and satisfaction.

No experimental surgery is performed solely for research purposes.

5. Duration

Your participation will last approximately 6 months after surgery.

6. Risks and Discomforts

The risks are primarily those of routine cataract surgery and postoperative care, including but not limited to infection, inflammation, increased intraocular pressure, retinal complications, cystoid macular edema, and need for additional treatment. Some patients may notice glare, halos, or need for spectacles for some activities.

7. Potential Benefits

You may or may not receive direct benefit from participation. Cataract surgery usually improves vision as part of routine care. The study may help improve understanding of IOL performance for future patients.

8. Alternatives to Participation

You may choose not to participate and still receive standard medical care and cataract treatment.

9. Confidentiality and Data Protection

Your identity will be protected. Study records will be coded and stored securely. Your name and direct identifiers will not appear in publications or public study documents. Authorized regulatory and ethics authorities may review records for oversight.

10. Costs and Compensation

There is no additional payment for participation. No extra study-specific cost is expected beyond routine clinical care.

11. Voluntary Participation and Right to Withdraw

Participation is voluntary. You may refuse participation or withdraw consent at any time without affecting your current or future medical care.

12. Injury / Medical Care

If you experience a medical problem related to routine treatment, you will receive appropriate medical evaluation and care according to institutional practice.

13. Contacts

For questions about this study or research-related concerns:
Study team: [Phone] [Email]

For questions about participant rights:
Ethics Committee: Sakarya University Faculty of Medicine Non-Interventional Ethics Committee, [Phone], [Email]

14. Consent Statement

I confirm that:

- I have read and understood this information form.
- I had the opportunity to ask questions and received satisfactory answers.
- I voluntarily agree to participate in this study.

Participant Full Name: _____

Signature: _____ Date: _____

Person Obtaining Consent (Name): _____

Signature: _____ Date: _____

Witness (if required) Name: _____

Signature: _____ Date: _____