

# Peripheral refraction with Eyhance versus Eyhance Pro intraocular lenses

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|----------------------------------------|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>23/09/2026   | <b>Recruitment status</b><br>Recruiting   | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>13/10/2026 | <b>Overall study status</b><br>Ongoing    | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>13/10/2026       | <b>Condition category</b><br>Eye Diseases | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

When cataract surgery is performed, the cloudy natural lens is replaced with an artificial lens called an intraocular lens (IOL). The TECNIS Eyhance IOL is an enhanced monofocal lens that provides excellent distance vision and improved intermediate vision (such as for computer use and cooking) compared to standard lenses. Johnson & Johnson has recently introduced a newer version called the TECNIS Eyhance Pro IOL, which is designed to additionally improve peripheral (side) vision while maintaining the same central vision quality. Both lenses are approved for routine NHS use and have excellent safety profiles.

This study aims to compare how these two lenses perform, particularly regarding peripheral vision. The study will recruit patients who need cataract surgery in both eyes. Each patient will receive one type of lens in one eye and the other type in the other eye (randomly allocated). This contralateral design eliminates differences between patients and allows direct comparison.

At one month after surgery, their peripheral vision will be measured using a specialised instrument (Grand Seiko WAM-5500 autorefractor), along with distance and intermediate vision, and ask patients about their visual experiences using questionnaires. The research assessments are entirely non-invasive and painless. This study will provide the first objective evidence of whether the newer Eyhance Pro lens truly offers advantages in peripheral vision compared to the standard Eyhance lens. The findings will inform lens selection for future cataract patients and advance understanding of how lens design influences peripheral visual performance

### Who can participate?

Adults over 18 years old who require cataract surgery in both eyes.

### What does the study involve?

Both eyes will be operated on the same day by experienced cataract surgeons. The surgery will be performed using the standard phacoemulsification technique (which uses ultrasound waves to break up and remove the cataract) with local anaesthesia (topical or sub-Tenon's). A small incision will be made, the cataract removed, and the IOL implanted in the lens capsule. The surgical technique and safety profile are identical to those of standard NHS cataract surgery. Participants will have a follow-up at 1 month after their surgery where they will conduct some research tests including visual acuity testing (testing with one eye closed and the other open, for

each eye separately), refraction (determining if they need glasses), peripheral refraction measurements (primary research assessment), clinical examination and questionnaires.

What are the possible benefits and risks of participating

Benefits:

Participants will receive two high-quality enhanced monofocal IOLs (either Eyhance or Eyhance Pro in each eye), both of which provide excellent distance vision and improved intermediate vision compared to standard monofocal lenses

- They will have thorough eye examinations at the 1-month research visit
- They will have the opportunity to directly compare two advanced lens technologies
- They may contribute to advancing knowledge that will benefit future cataract patients

The information obtained from this study will help:

- Determine whether the Eyhance Pro IOL offers measurable advantages in peripheral vision to improve peripheral visibility, which can help activities like driving and help patients with reduced central vision due to conditions like macular degeneration.
- Inform IOL selection and patient counselling for future cataract patients
- Advance our understanding of how IOL optical design influences peripheral visual performance
- Provide evidence for systematic reviews (comprehensive analyses of all available research evidence to guide medical practice) and clinical guidelines

Risks:

The general risks associated with any cataract surgery apply to this study. including:

- Infection (endophthalmitis): very rare, approximately 1 in 1,000-3,000 cases
- Inflammation
- Bleeding
- Retinal complications (such as retinal detachment)
- Cystoid macular oedema (swelling at the back of the eye)
- Posterior capsule opacification (clouding of the lens capsule requiring laser treatment)
- Corneal complications
- Refractive surprise (final glasses prescription different from target)

There are no additional surgical risks related to participating in this study. Both the Eyhance and Eyhance Pro IOLs are approved for NHS use and have excellent safety profiles identical to standard monofocal lenses.

Research-Related Risks

The research assessments (peripheral refraction measurements, iTrace scans, questionnaires) are:

- Non-invasive and painless
- Carry no additional risks

Where is the study run from?

Sussex Eye Hospital, UK.

When is the study starting and how long is it expected to run for?

The study is open to recruitment as of October 2026. Planned study end date is December 2027.

Who is funding the study?

Johnson & Johnson

Who is the main contact?

Professor Mayank Nanavaty, [mayank.nanavaty@nhs.net](mailto:mayank.nanavaty@nhs.net)

## Contact information

**Type(s)**

Principal investigator, Scientific, Public

**Contact name**

Prof Mayank Nanavaty

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**Additional identifiers****Integrated Research Application System (IRAS)**

370734

**Central Portfolio Management System (CPMS)**

74165

**Study information****Scientific Title**

Prospective, randomised, contralateral comparative study of peripheral refraction after implantation of an enhanced monofocal and an enhanced monofocal with improved peripheral vision intraocular lenses

**Study objectives**

Primary:

To compare peripheral astigmatism profiles at 20° horizontal nasal eccentricities between eyes implanted with TECNIS Eyhance IOL and TECNIS Eyhance Pro IOL using Grand Seiko WAM-5500 autorefractometry at 1 month postoperatively

Secondary:

1. Compare peripheral blur and astigmatism at 30° nasal, 20° and 30° temporal
2. Compare monocular UCDVA at 4m
3. Compare monocular BCDVA at 4m
4. Compare monocular UCIVA at 66cm
5. Compare monocular DCIVA at 66cm
6. Assess patient-reported visual function and symptoms
7. Determine patient preference
8. Assess central wavefront aberrations (iTrace, 5mm pupil)
9. Document adverse events

**Ethics approval required**

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### **Ethics approval(s)**

Approved 21/09/2026, London - Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; surrey.rec@hra.nhs.uk), ref: 26/PR/0818

### **Primary study design**

Interventional

### **Allocation**

Randomized controlled trial

### **Masking**

Open (masking not used)

### **Control**

Active

### **Assignment**

Parallel

### **Purpose**

Treatment

### **Study type(s)**

### **Health condition(s) or problem(s) studied**

Disorders of lens

### **Interventions**

This is a prospective, randomised study comparing two intraocular lenses (TECNIS Eyhance and TECNIS Eyhance Pro) in patients having cataract surgery on both eyes.

Before Surgery: Patients will undergo standard NHS cataract assessments (no additional research procedures).

Eligible patients will be given information about the study and asked to provide consent.

On Surgery Day: A computer will randomly assign which lens goes in which eye. Both eyes will be operated on the same day by experienced cataract surgeons using the standard surgical technique (phacoemulsification). The surgery is identical to routine NHS cataract surgery.

One Month After Surgery (Research Visit, approximately 60-75 minutes):

- Vision testing for each eye separately (distance at 4 metres and intermediate at 66 cm)
- Glasses prescription check
- Peripheral vision measurements using the Grand Seiko autorefractor at various angles (central, 20° and 30° nasal and temporal). This involves sitting with the head stabilised while the instrument takes automatic readings. This is completely painless and non-invasive, taking approximately 15-20 minutes.
- iTrace scan to measure optical quality (a few seconds per eye, non-invasive)
- Standard clinical eye examination
- Questionnaire about visual function, symptoms, satisfaction, and preference (10-15 minutes)

Patients are masked (they do not know which lens is in which eye). The person measuring vision is also masked.

After the 1-month visit, participation in the study is complete.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Intraocular lenses

**Primary outcome(s)**

1. Difference in relative peripheral astigmatism (dioptres) at 20 degrees nasal eccentricity measured using Grand Seiko WAM-5500 autorefractometry at 1 month

**Key secondary outcome(s)**

1. Relative peripheral astigmatism and blur at additional eccentricities measured using Grand Seiko WAM-5500 autorefractometry at 1 month
2. Monocular UCDVA (logMAR) at 4m measured using ETDRS charts at 1 month
3. Monocular BCDVA (logMAR) at 4m measured using ETDRS charts at 1 month
4. Monocular DCIVA (logMAR) at 66cm measured using ETDRS charts at 1 month
5. Monocular UCIVA (logMAR) at 66cm measured using ETDRS charts at 1 month
6. Visual Function and Satisfaction measured using Visual Function and Satisfaction Questionnaire at 1 month
7. Patient preference (which eye/IOL preferred) measured using patient preference questionnaire at 1 month
8. Wavefront aberration measurements (iTrace) measured using iTrace aberrometer at 1 month
9. Adverse event rates and severity measured using patient notes at day 0 and 1 month

**Completion date**

01/12/2027

**Eligibility****Key inclusion criteria**

1. Adults aged 18 years and over
2. Bilateral cataracts scheduled for routine cataract surgery on both eyes
3. Potential for good postoperative visual acuity (no significant ocular comorbidity)
4. Able to provide written informed consent
5. Able to attend the research follow-up visit at 1 month postoperatively.

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

120 Years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Amblyopia (lazy eye)
2. Eyes with any ocular comorbidity with cornea, uvea, retina or optic nerve, which may be detrimental to visual outcomes
3. Previous ocular refractive surgery

**Date of first enrolment**

07/10/2026

**Date of final enrolment**

01/12/2027

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

University Hospitals Sussex NHS Trust

51 Chesswood Road

Worthing

England

BN11 2AA

**Sponsor information****Organisation**

University Hospitals Sussex NHS Foundation Trust

**ROR**

<https://ror.org/03wvsyq85>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Johnson and Johnson

**Alternative Name(s)**

Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson&Johnson, Johnson & Johnson Private Limited, , , J&J, JNJ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Data sharing statement to be made available at a later date