Intermediate Vision in Patients with Clareon IOLs Compared to Eyhance IOLs

NCT05226884

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PROTOCOL TITLE: Intermediate Vision in Patients with Clareon IOLs Compared to Eyhance IOLs

PROTOCOL **BEC001-69901155, NCT05226884**

STUDY TREATMENTS: **Non-interventional (None).**

Principal Investigator: **J. Morgan Micheletti, MD**

Location: **Berkeley Eye Center, Houston, Texas**

Background:

The recently launched Eyhance IOL is a monofocal designed to slightly extend the depth of focus.

Indications for use "TECNIS Eyhance IOL for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction."

In two prior Vivity registration studies, the AcrySof IQ monofocal lens was used as the control lens and showed functional intermediate vision (~20/32) via binocular IVA measurement.

Defocus curves also demonstrated a slightly extended depth of focus with the AcrySof IQ and mean visual acuities remained above 0.0 logMAR (20/20 Snellen) between +0.50D~-0.50D defocus.

Clinical data is needed to determine if the Clareon monofocal IOLs can provide similar range of vision as the Eyhance monofocal IOLs.

Clinical Hypothesis:

Patients with bilateral Eyhance IOLs may have improvements in intermediate vision, however, it has previously been reported that bilateral Clareon IOLs also provide improved intermediate vision (see Vivity - Directions For Use).

This study aims to determine the non-inferiority of bilateral Clareon IOLs compared to bilateral Eyhance IOLs at intermediate vision.

Scientific Rationale:

The Eyehance IOL was approved as a Level A Modification of the ZCB00 IOL, thus no clinical data was required for that approval. The inference is that the Eyhance provides an extended range of vision due to the slight modification to the optic design

Study Objectives:

Compare distance and intermediate visual acuities and a defocus curve in patients with bilateral Clareon Monofocal IOLs versus bilateral Eyhance IOLs.

OVERALL STUDY DESIGN

This is a non-interventional prospective, single center, bilateral, non-randomized, open-label, two-arm comparative study of the outcomes for patients following successful, uncomplicated cataract surgery. 155 subjects will be enrolled in each arm of the study, with 310 total subjects. All patients will have had bilateral implantation of an Eyhance IOL (DIB00/DIU***) or Clareon IOL (CNA0T0/CCA0T0) at the time of uncomplicated cataract surgery. These patients will then be assessed at least 3 months post-operatively.

Duration:

12 months or longer to meet required enrollment.

Administration:

Patients with healthy eyes and previously implanted Eyhance IOLs or Clareon IOLs will be offered the opportunity to participate in the study.

Visit Schedule:

All subjects will undergo 1 visit. At the study visit and after informed consent, the subjects' demographic information will be collected, and the subject will have the following testing:

1) Manifest refraction (both groups)
2) Binocular corrected distance visual acuity (BDVA) at 4m (both groups)
3) Distance corrected intermediate visual acuity (DCIVA) at 66 cm (both groups)
4) Distance targeted-corrected binocular distance and intermediate visual acuity with +0.25D offset (Clareon group)
5) Binocular distance corrected defocus curve from +1.0 D to -3.0 D at 0.5D steps, with 0.25 D steps between -0.50 D and +0.50 D

STUDY POPULATION CHARACTERISTICS:

Condition

Patients with healthy eyes and uncomplicated bilateral implantation of Eyhance IOLs or Clareon IOLs.

Number of Subjects:

Under the assumption that the difference between binocular targeted corrected intermediate visual acuity between the two arms is 0.05 logMAR, thus demonstrating non-inferiority, then 155 patients per arm would be required, for a total of 310 patients. The standard deviation for each measurement is 0.15 logMAR, a power of 80% and Type I error probability of 0.05.

Source: Kohn MA, Senyak J. Sample Size Calculators [website]. UCSF CTSI. 8 August 2021. Available at https://www.sample-size.net/ [Accessed 28 September 2021]

Inclusion/Exclusion Criteria (all study criteria apply to each study eye unless otherwise indicated):

Inclusions

1) Adults, at least 40 years of age having already undergone uncomplicated cataract removal by phacoemulsification with a clear corneal incision in both eyes.

2) Implantation of bilateral Clareon IOLs or Eyhance IOLs (DIB00/DIU***).

3) Able to comprehend and willing to sign informed consent and complete all required testing procedures

4) Best Corrected Distance Visual Acuity (BCDVA) projected to be 0.10 logMAR (Minimum Angle of Resolution) or better

5) Clear intraocular media

6) Minimum of two weeks post YAG capsulotomy to treat PCO

7) Residual refractive astigmatism ≤0.75 diopters

8) Post op refractive results for the Clareon subjects are from 0.00 to -0.50 SE

9) Post op refractive results for the Eyhance subjects are from +0.25 to -0.25 SE

Exclusions

Subjects will not be permitted to enroll in this study if they meet any of the following exclusion criteria:

1) Any corneal abnormality, other than regular corneal astigmatism (as determined by pre-operative testing) that in the opinion of the investigator would confound the outcome(s) of the study

2) Any complication during cataract surgery (capsular tear, vitrectomy, etc)

3) History of or current retinal conditions or predisposition to retinal conditions

4) Amblyopia or strabismus in either eye

5) History of or current anterior or posterior segment inflammation of any etiology

6) Any form of neovascularization on or within the eye

7) Glaucoma (uncontrolled or controlled with medication)

8) Optic nerve atrophy

9) Subjects with diagnosed degenerative eye disorders

10) Postoperative CDVA worse than 0.10 logMAR in either eye.

11) Subjects who have an acute or chronic disease or illness that would confound the results of this investigation (e.g. immunocompromised, connective tissue disease, clinically significant atopic disease, diabetes, etc)

Outcome Measures:

Primary Endpoints:

1. Non-inferiority of Target-corrected Binocular Intermediate (66 cm) Visual Acuity with Offset: Target-corrected binocular intermediate (66 cm) visual acuity of Clareon monofocal subjects at -0.25 sphere versus Eyhance subjects at plano sphere.

2. Non-inferiority of Distance Corrected Binocular Intermediate Visual Acuity: Distance corrected binocular intermediate visual acuity (measured at 66 cm) of Clareon subjects versus Eyhance subjects with both groups set at plano sphere.

3. Non-inferiority of Best Corrected Distance Visual Acuity: Comparison of Best Corrected Distance Visual Acuity (measured at 4m) of Clareon subjects versus Eyhance subjects.

4. Non-inferiority of Target-corrected Binocular Distance (4 m) Visual Acuity With Offset: Comparison of Best Corrected Distance Visual Acuity (measured at 4m) of Clareon subjects versus Eyhance subjects.

5. Binocular Distance Corrected Defocus Curve: Comparison of the binocular distance corrected defocus curve of Clareon subjects versus Eyhance subjects from +1.0D to -3.00D.

Secondary Endpoints:

1. Post-operative Spherical Equivalent

2. Post-operative Residual Astigmatism

Statistical Analysis

Welch Two Sample t-test for parametric data and Wilcoxon rank-sum test for non-parametric data. Non-inferiority will be defined as within 0.1 LogMAR.