Maximizing Visual Outcomes with Eyhance IOLs
NCT05611073
25 Jan 2022

PROTOCOL TITLE: Maximizing Visual Outcomes with Eyhance IOLs

STUDY TREATMENTS: None

Study Objectives:

The objective of this study is to demonstrate which pre-operative biometric findings or measurements could indicate increased intermediate or near vision in a patient receiving an Eyhance IOL.

The objective will be completed by measuring visual outcomes at distance, intermediate, and near when corrected to plano sphere as well as obtaining or reviewing biometric measurements in a controlled setting. In addition, the patients will also fill out a questionnaire to determine their level of spectacle independence and satisfaction.

Clinical Hypothesis:

Eyhance IOLs provide intermediate vision based on benchmark defocus curves. Some Eyhance patients also appear to have vastly improved intermediate and even near vision compared to other patients who have received an Eyhance IOL. This study aims to determine which biometric properties (such as spherical aberration, q value, pupil size, etc) can be targeted for these outcomes. Patients will be assessed for corrected monocular and binocular distance, intermediate, and near vision at plano. Lastly patient satisfaction score between the two groups will also be determined.

OVERALL STUDY DESIGN

This is a non-interventional prospective, single center, bilateral, non-randomized, open-label, observational clinical study. All patients will have had bilateral implantation of an Eyhance IOL at the time of cataract surgery. These patients will then be assessed in the 1–6-month post-operative period. Patients will be grouped into two arms: “distance with minimal intermediate” and “distance with enhanced intermediate/near” based on mean photopic binocular BCDVA and DCIVA (at 66 cm) of patients with bilateral Eyhance IOLs corrected to plano sphere. The “distance with minimal intermediate” group is defined by BCDVA of 0.1 logMAR or better but a DCIVA of 0.4 logMAR or worse. The “distance with enhanced intermediate/near” is defined by BCDVA of 0.1 logMAR or better and a DCIVA of 0.3 logMAR or better. In addition to binocular BCDVA and DCIVA, monocular measurements will be obtained as well. The two groups will be compared to assess which patient biometric properties (such as spherical aberration, q value, pupil size, etc) lead to an overall increase in near or intermediate vision as well as overall patient satisfaction. Biometric data will be obtained from the Zeiss IOL Master 700, Atlas 9000, and the iDesign.

Duration:

3 months or longer to meet required enrollment.

Administration:

Patients with previously implanted bilateral Eyhance 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
2) Best corrected distance visual acuity
3) Distance corrected intermediate visual acuity
4) Distance corrected near visually acuity
5) Binocular best corrected distance visual acuity
6) Binocular distance corrected intermediate visual acuity
7) Binocular distance corrected near visually acuity
8) Pupil measurements (photopic and/or mesopic – automated and manual)
9) Review or remeasurement of biometry (IOL Master 700 or Atlas 9000 topography)
10) iDesign measurement

STUDY POPULATION CHARACTERISTICS:

Condition

Patients with healthy eyes and bilateral implantation of Eyhance IOLs.

Number of Subjects:

Per Green, for multiple variables in a regression analysis, N = 50 + 8(m) per arm should be sufficient for appropriate power, assuming a beta of 0.2 and an alpha of 0.05 for a power of 80%. Assuming 6 variables (pupil size, q value, spherical aberration, AC depth, axial length, average K power), approximately 110 patients (220 eyes) will be required.

Source: Green, Samuel B. "How Many Subjects Does It Take To Do A Regression Analysis." *Multivariate behavioral research* 26 3 (1991): 499-510 .

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

Inclusions

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

2) Implantation of bilateral 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

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 (20/25 snellen).

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

EVALUATION CRITERIA:

The main objective of this study is to demonstrate which biometric characteristics can lead to enhanced intermediate or near vision in patients with prior bilateral Eyhance implantation.

Primary Clinical Endpoints:

1) To compare two groups categorized by “distance with minimal intermediate” and “distance with enhanced intermediate/near” based on mean photopic binocular BCDVA and DCIVA (66 cm) of patients with bilateral Eyhance IOLs targeted corrected at plano sphere.
2) To determine if any statistically significant differences in biometric data exists between the two groups including pupil size, spherical aberration, q value, etc. that may allow for pre-operative recognition of those patients who could have enhanced benefits of the Eyhance IOL. This will require multiple regression analysis given the large number of variables.
3) Comparison of a patient satisfaction survey between the two groups to assess for subjective differences in everyday life to determine if the enhanced vision plays a statistically significant difference in patients’ perceived quality of vision or quality of life.