Date: 13Feb2022

PROTOCOL TITLE: Visual Outcomes and Patient Satisfaction with Bilateral PanOptix Versus Bilateral Synergy

PROTOCOL # 69881171

STUDY TREATMENTS: Non-interventional (None).

Background:

The Tecnis Synergy IOL has a claim to allow patients to experience continuous high-contrast vision from far through near even in low-light conditions.

A J&J-sponsored post marketing study done outside of the US claim superiority of range of vision for the Tecnis Synergy IOL over the PanOptix IOL

Clinical Hypothesis:

Patients with bilateral Panoptix IOLs have non-inferior distance, intermediate, and near visual acuity compared to patients with Synergy IOLs in both photopic and mesopic conditions with less glare, haloes, and/or starbursts.

Scientific Rationale:

The Synergy IOL is a combination of two previous technologies, the ZLB00 and the ZXR00, into a single IOL. Each had relatively significant rates of glare and halos, and the inference is that the Synergy IOL has a similar glare profile. There is a need to look at patient visual outcomes and the visual disturbance profile comparing trifocal technology with combined EDOF/Bifocal technology in the United States

Study Objectives:

The objective of this study is to test the hypothesis that bilateral Panoptix patients targeted corrected at plano sphere OU will have non-inferior distance, intermediate, and near vision compared to patients with bilateral Synegy IOL with fewer complaints of glare, halos, or starbursts as quantified by a survey.

The objective will be completed by measuring binocular corrected visual outcomes at distance, intermediate, and near when at plano sphere.

In addition, the patients will also fill out a questionnaire to determine their level of satisfaction.

OVERALL STUDY DESIGN

This is a non-interventional prospective, single center, bilateral, examiner blinded, two-arm comparative study of the outcomes for patients following successful, uncomplicated cataract surgery performed by 4 surgeons using similar surgical techniques. 155 subjects will be enrolled in each arm of the study, with 310 total subjects. All patients will have had bilateral implantation of a Synergy IOL (DFR00/DFW***) or Panoptix IOL (TFAT*0) at the time of uncomplicated cataract surgery.

Duration:

3 months or longer to meet required enrollment.

Administration:

Patients with healthy eyes who meet the inclusion criteria and have had bilateral Synergy IOLs or Panoptix IOLs implanted at the time of cataract surgery 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) Distance corrected binocular distance, intermediate (60 cm), and near (40 cm and 33 cm) visual acuity
3) Uncorrected binocular distance, intermediate (60 cm), and near (40 cm) visual acuity visual acuity
4) Patient survey regarding satisfaction and glare, halos, starbursts using IOLSAT and QUVID questionnaires, respectively
5) Binocular defocus curve (+1.00 D to -4.00 D, 0.5 D steps)
6) Halo and Glare testing using VS Halo & Glare
7) Self-reported visual disturbance questionnaire

STUDY POPULATION CHARACTERISTICS:

Condition

Patients with healthy eyes and uncomplicated bilateral implantation of Panoptix IOLs or Synergy IOLs.

Number of Subjects:

Under the assumption that the difference between binocular targeted corrected distance, intermediate, and near visual acuity between the two arms greater than 0.05 logMAR, thus demonstrating superiority, 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 October 2021]

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

Inclusions

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

2) Implantation of bilateral Synergy IOLs (DFR00/DFW***) or bilateral Panoptix IOLs (TFAT*0), toric or non-toric

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-operative refractive spherical equivalent from +0.50 to -0.50 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 in the opinion of the principal investigator (e.g. immunocompromised, connective tissue disease, clinically significant atopic disease, etc)

EVALUATION CRITERIA:

The main objective of this study is to demonstrate superiority of distance, intermediate, and near vision with bilateral Panoptix IOLs compared to bilateral Synergy IOLs in both photopic and mesopic conditions with less glare, haloes, and/or starbursts.

Primary Clinical Endpoints:

Binocular DCNVA of Trifocal (Alcon PanOptix) versus EDOF/Bifocal (Johnson and Johnson Tecnis Synergy) at 40 cm.

Secondary Exploratory Clinical Endpoints

Patient self-reported visual disturbances

QUVID questionnaire (Percentage of subjects not bothered by halos)

Binocular BCDVA and DCIVA (60 cm)

Binocular UCDVA, UCIVA (60 cm), UCNVA (40 cm)

Patient reported satisfaction by IOLSAT

Binocular defocus curve

Post-op refraction

Exploratory:

Spectacle independence (IOLSAT)

Halo and Glare reported using VS Halo & Glare (visu-med.com)

Binocular DCNVA (33 cm)