PROTOCOL TITLE: Visual Outcomes and Patient Satisfaction with Vivity IOL in Post Refractive Patients

PROTOCOL # 69865263

STUDY TREATMENTS: Non-interventional (None).

Background:

The Vivity IOL provides excellent distance and intermediate vision, but some surgeons are hesitant to implant the IOL in post-refractive patients, the majority of which are post-operative myopic LASIK/PRK. Those surgeons may have the concern that the elevated spherical aberration or other high order aberrations may lead to decreased visual outcomes or increased visual disturbances.

Clinical Hypothesis:

The hypothesis is that post-myopic refractive patients that have high spherical aberration (SAs) will have excellent outcomes and satisfaction with a Vivity IOL

Scientific Rationale:

Patients typically have increased higher order aberrations (HOAs), in particular, higher spherical aberration after myopic refractive surgery (LASIK/PRK).

Study Objectives:

The objective of this study is to test the hypothesis that the Vivity non-diffractive Extended Vision IOL performs well in patients that had prior myopic refractive surgery and high residual SA after the refractive procedure.

OVERALL STUDY DESIGN

This is a non-interventional, prospective, single center, bilateral, observational study of the outcomes for 40 post myopic refractive surgery patients following successful, uncomplicated cataract surgery with bilateral implantation of the Vivity IOL (DAT***/CCWET*) performed by 4 surgeons using similar surgical techniques. 40 subjects will be enrolled.

Duration:

12 months or longer to meet required enrollment.

Administration:

Patients with healthy eyes and a history of myopic LASIK or PRK with a spherical aberration greater than 0.3 as measured by the Atlas topographer who meet the inclusion criteria and have had bilateral Vivity 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 (best corrected), intermediate (60 cm), and near (40 cm) visual acuity
3) Monocular and binocular distance corrected (best corrected) monocular distance visual acuity
4) Uncorrected monocular and binocular distance, intermediate (60 cm), and near (40 cm) visual acuity visual acuity
5) Binocular defocus curve (+1.00 D to -3.00 D, 0.5 D steps)
6) Binocular best corrected distance visual acuity in mesopic lighting
7) Patient survey regarding satisfaction and glare, halos, starbursts using IOLSAT and QUVID questionnaires, respectively
8) Self-reported visual disturbance questionnaire
9) Atlas topography; potentially additional topography/tomography with iTrace and/or pentacam

STUDY POPULATION CHARACTERISTICS:

Condition

Patients with healthy eyes, prior myopic LASIK or PRK with SA greater than 0.3, and uncomplicated bilateral implantation of the Vivity IOL (DAT***/CCWET*).

Number of Subjects:

This is a non-interventional, observational study with 40 patients (80 eyes).

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 with implantation of the Vivity IOL (DAT***/CCWET*)

2) Prior uncomplicated, distance-targeted, bilateral myopic LASIK or PRK surgery and corneal spherical aberration greater than ≥ 0.30 µ and ≤ 1.20 µ in at least one eye (6.00 mm) as measured at their cataract pre-op visit

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 ≤0.50 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 or myopic LASIK/PRK surgery, (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 that the Vivity IOL is well-tolerated with high patient satisfaction in patients who have had prior myopic refractive surgery with high spherical aberration.

Primary Clinical Endpoint:

Binocular Best Corrected Distance Visual Acuity

Secondary:

1) Monocular UCDVA, UCIVA (66 cm), UCNVA (40 cm)
2) Monocular BCDVA
3) Binocular Distance Corrected Intermediate (66cm) and near (40cm) Visual Acuity
4) Binocular UCDVA, UCIVA (66 cm), UCNVA (40 cm)
5) Unsolicited self-reported visual disturbances
6) QUVID questionnaire
7) Patient reported satisfaction by IOLSAT
8) Post-op refraction

Exploratory

1) Binocular BCDVA under mesopic room lighting conditions
2) Any SA changes pre cataract surgery and post cataract surgery
3) Binocular defocus curve
4) Spectacle independence (IOLSAT)