Biometry Compare Trial

Protocol # 64989743

Principal Investigator: SAM MULTACK, D.O., FAOCO

Sub investigator: N/A

Site: Private Practice and Research Center

Surgery Center: Tinley Woods Surgery Center

Measurements: Multack Eye Care @ Laser and Cataract Institute, 22200 Wolf Road, Frankfort, IL 60423

Post Operative visits: Multack Eye Care @ Laser and Cataract Institute, 22200 Wolf Road, Frankfort, IL 60423 and Olympia Fields, IL 60461

Background: Cataract surgery is projected to be the most commonly performed surgical procedure over the next 10-15 years. Patient expectations of good visual outcomes have risen with the increase in the advancing technology being offered. Cataract surgeons are in need of a clear and consistent process in order to deliver the best possible outcomes with the least amount of error.

Rationale: Biometry data and accurate intraocular lens (IOL) calculations are arguably the most important steps in achieving the desired refractive outcomes. There is limited evidence comparing the two biometers, Zeiss IOL Master 700 to Alcons Argos.

Randomized Observational Prospective Trial:

Hypothesis: The Alcon Argos Biometer's measurements, when used in conjunction with the Barrett Universal II formula, will provide statistically non-inferior outcomes (Mean Absolute Prediction Error of Predicted Spherical Equivalents), when compared to the IOL Master 700 utilizing the (PCA) with the Barrett Universal II (TK) Formula for IOL power calculations.

Primary Objective: To assess if the Alcon Argos Biometer utilizing the Barrett Universal II formula for IOL calculations can give a non-inferior outcome when compared to the Zeiss IOL master 700 utilizing the (PCA) with the Barrett Universal II (TK) formula, when comparing the (mean absolute prediction error of the predicted target spherical equivalencies).

Primary End Point: Mean Absolute Prediction Error (MAPE) of predicted spherical equivalents per biometer. (The absolute value of the difference between the Predicted Post-OP MRSE to the Actual Achieved Post-OP MRSE for the IOL implanted). 2 biometers (Argos and IOL Master 700). Primary End Point (MAPE) will be based on the manifest refraction SE obtained at the postoperative visit day 30 (-2/+14 days).

Secondary End Points:

a) Percentage of eyes with an Absolute Prediction Error of Predicted SE < or = to (0.5D) with Argos vs IOL Master 700

b) Median Absolute Prediction Error of Predicted Spherical Equivalents per biometer

(The absolute value of the difference between the Predicted Post Op MRSE to the actual achieved Post Op MRSE for the IOL implanted) Secondary end points will be based on manifest refraction SE obtained at the postoperative visit day 30 (-2/+14 days)

Exploratory End Points:

a) Percentage of eyes with an Absolute Prediction Error of Predicted SE < or = to (0.25D) with Argos vs IOL Master 700

Safety: All subjects enrolled in the study will be evaluated for safety.

Proposed Method: To enroll approximately 80 patients, 80 right eyes in a randomized observational prospective study over the course of approximately 4 months (8.5 month estimated total study time), randomizing the patients into one of two arms.

Two Arms: All scanned by the same technician (Over 2000 scans a year experience)

A. ARGOS, IOL Master 700, 40 patients, 40 right eyes

B. IOL Master 700, ARGOS, 40 patients, 40 right eyes

Randomization of the actual order for biometry measurements will occur utilizing a randomization program, with blocking on every 2 or 4 subjects.

Rationale: Two arms ensure we eliminate dry eye or fatigue bias for each biometer reading by randomizing the order of the preoperative biometry measurements. In between measurements patient will take a timed 2 min break. No drops will be given prior to measurements, no physical contact with the eye will occur prior to any measurements. This will allow for the most accurate keratometry readings.

Barrett Universal Formula II “K” and (TK) are now considered the gold standard in biometry formulas.

The Barrett Universal II Formula “K” Is available on both biometers, while the Barrett Universal II (TK) is only available on the Zeiss IOL Master 700 biometer.

Surgeon will have access to all biometry readings prior to surgery and at the time of surgery. Surgeon will make the lens selection by choosing the IOL (Intraocular lens) power closest to plano for all biometers involved. If the two IOL diopter powers are not in consensus, the surgeon will utilize the Argos Biometer for the selection.

We will utilize the Barrett Universal II “K” formula for the Argos, and the Barrett Universal II (TK) for the IOL Master 700 to compare the mean absolute prediction error for the predicted spherical equivalents by back calculating.

Utilizing the Barrett Universal II (TK) (Anterior and Posterior corneal measurements) available only on the IOL Master 700 and comparing it to the Barrett Universal II “K” on the Alcon Argos biometer will allow us to assess if K measurements give non inferior outcomes to the TK Formula.

The Barrett Universal 2 formula uses a theoretical model eye in which anterior chamber depth (ACD) is related to axial length (AL) and keratometry. A relationship between the A-constant and a "lens factor" is also used to determine ACD.[1] The important difference between

the Barrett formula and other formulas is that the location of the principle plane of refraction of the IOL is retained as a relevant variable in the formula. (1)

1. An improved universal theoretical formula for intraocular lens power prediction. Barrett GD. J Cataract Refract Surg. 1993 Nov;19(6):713-20.

Surgery: Surgery will be performed by 1 surgeon, who routinely performs over 20-25 cases weekly. Optimized lens settings will be used for each biometer.

Corneal Incision size: 2.4 mm Alcon Dual Bevel Blade (Temporal)

Capsulorhexis: Intended size of 4.8mm to 5.2 mm

Phaco: Alcon Centurion

Lens: Alcon IQ Acrysof SN60WF only

Complications: All subjects with any surgical complications will be excluded.

Exclusion Criteria:

Axial Length < 22.00 and > 26.00

Corneal Astigmatism > +1.00 Diopters

CCTS: < 490 and > 600

Prior Refractive Surgery: RK, PRK, LASIK, INTACTS

History of contact lens use: Soft lenses within 2 months of surgery, RGP within 60 months of surgery

Corneal Disease: Keratoconus, Corneal Dystrophies, Any prior corneal Surgery, Prior infections

Retinal Disease: Macular Pathology, CSCR, CME, Macular Degeneration, Drusen, Retinal Detachment, TPPV, SB, prior IVT, Prior PRP or Focal Laser, Diabetic Retinopathy

History of Uveitis

POAG: Undergoing any concomitant MIGS procedure- iStent, Omni, iTrack, Hydrus, etc

Enrollment in any prior clinical trial within 2 years

Systemic Disease that in the investigator's opinion may affect outcome

Currently Pregnant or Breastfeeding

Severe Dry Eye

Tear Osmolarity > 320mOsms/L (Moderate)

Any Surgical Complication(s)

IOL implanted outside of the capsular bag /capsular damage /weakness /CTR placement

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Inclusion Criteria:

Age: 50-85 years old

Clinically Significant Cataracts that interfere with daily activities

Patient is able to understand and able to consent to informed consent

Patient is able to come to all postoperative visits and agrees to follow up at 30 days -2/+14 days

Patient undergoing cataract surgery, with implantation of the Alcon SN60WF lens in the capsular bag.

Study Visit Time Line:

Visit 1: Screening and initial testing. Initiate dry eye protocol on all subjects

Dry Eye Protocol: Systane Hydration PF drops (or equivalent) 4 x daily and Warm Packs 10 mins nightly for 14 days (+ 5 days maximum).

Visit 2: Dry eye evaluation to occur at day 14 or greater (+ 5 days maximum), randomization for the order (Argos then 700 or 700 then Argos) of bilateral biometry measurements, consents, and study enrollment.

After dry eye protocol, subjects with (Tear Osmolarity > 320mOms/L) will be excluded from the study.

All enrolled subjects will continue to using Systane Hydration PF drop (or equivalent) 4 x a day for the entire duration of the study.

Subjects will discontinue nightly warm packs the night of surgery.

(To minimize the risk of pressure on the eye and potential risk of post operative infection).

Visit 3: Surgery right eye

Visit 4: Post Operative Day 1 right eye

Visit 5: Post Operative Day 6-14 right eye

Visit 6: Post Operative Day 30 (-2/+14) final manifest refraction right eye

The same Optometrist will perform all refractions on all subjects and will be masked to all biometry data.

Surgeon will be masked to all post-operative manifest refraction results until after study conclusion.

Initial Screening Testing Visit to include: Best Corrected Distance Visual Acuity, Auto Refraction, Manifest Refraction, confrontational fields, pupil reflexes, IOP, slit lamp exam anterior and posterior chamber, Tear Osmolarity, Pachymetry, screening for inclusion and exclusion criteria.

Post Op visits to include: Visual Acuity, IOP, Slit Lamp, final postoperative refraction at visit number 6

Study Estimated Time for Completion:

8.5 Months: After fully executed contract, encompassing first patient first visit to last patient last visit, plus full analysis, and final report / draft manuscript.

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Contract Review: 1 month

IRB: 1 month

Enrollment: 4 Months

8 weeks to measure, 2 weeks of dry eye treatment, 4-6 Week for surgery completion, 4 weeks postoperative final visit -2 +/14 days

Data Collection: 30 Days (-2/+14 days)

Data Analysis: 1 Month

Final Report/Draft Manuscript with safety information: 1 Month

Planned Presentations:

ASCRS Interim Data 2022 and/or AAO Full Data 2022

IAO/COS Illinois Academy of Ophthalmology, Chicago Ophthalmic Society (if not restricted) and/ or

AOCOO-HNS: American Osteopathic College of Ophthalmology- Annual meeting (if not restricted)

Planned Publication:

Peer Reviewed Journal: ASCRS- Journal of Cataract and Refractive Surgery or

AAO- Journal of Ophthalmology

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Sample size and statistical analysis:

For this test, a sample size of approximately 70 will provide acceptable power. Up to 10 more subjects will be enrolled to account for dropouts.

The endpoint is based on the absolute deviation from target MRSE measured by two biometers in the same subject. The difference is calculated for each subject where the Alcon biometer absolute error is subtracted from the XYZ biometer absolute error. A value of zero will reflect no difference, where a negative difference indicates that the Alcon biometer has greater error.

We expect the difference to be zero, however, for safety, knowing that the difference can fluctuate around zero, we set this at -1/20 D. In other words, we assume that the Alcon will, on average, have 0.05D more absolute error.

We set power at 90%. We use a one-tailed alpha of 0.025. The standard deviation if the difference in the two biometers is assumed to be 0.5 D and the NI Delta is set at 0.25 D. These settings and assumptions result in a required sample size of 68 subjects. SAS proc power output is provided:

Fixed Scenario Elements

Distribution	Normal
Method	Exact
Lower Equivalence Bound	-0.25
Upper Equivalence Bound	9999
Alpha	0.025
Mean	-0.05
Standard Deviation	0.5
Nominal Power	0.9

Computed N Total

Actual Power	N Total
0.902	68