Statistical Analysis Plan

Clinical Investigation of the Safety and Effectiveness of an Investigational Model of the TECNIS® Intraocular Lens

NCT Number: NCT03949335

Document date: 12 May 2020

STATISTICAL ANALYSIS PLAN

Clinical Investigation of the Safety and Effectiveness of an Investigational Model of the TECNIS® Intraocular Lens

PROTOCOL NUMBER: SUR-CAT-652-2001

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1 INTRODUCTION

This document summarizes the statistical methods to be implemented during the analysis of data for the investigational intraocular lens (IOL), Model ZFR00V (SUR-CAT-652-2001) study. This study will be a 6-month, prospective, multicenter, bilateral, three-way masked (sponsor, subject and evaluator), randomized clinical trial conducted at up to 15 sites. Subjects will be bilaterally implanted with either the Model ZFR00V IOL or the control Model ZCB00 IOL. Up to 300 subjects will be enrolled to achieve approximately 270 subjects randomized and bilaterally implanted, resulting in approximately 244 evaluable subjects (122 in the test arm and 122 in the control arm) at 6 months.

The key time point for reporting and submitting the PMA supplement will be at 6 months. The primary effectiveness endpoint for this study is mean (LogMAR) monocular distance corrected near visual acuity (DCNVA) under photopic conditions at a fixed distance (40 cm) at 6 months postoperative.

The secondary effectiveness endpoints are mean (LogMAR) monocular distance corrected intermediate visual acuity (DCIVA) at 66 cm, mean (LogMAR) monocular distance corrected near visual acuity (DCNVA) at 33 cm, mean (LogMAR) monocular best corrected distance visual acuity (BCDVA), monocular defocus curve and spectacle wear via PRSIQ. The key time frame for all secondary effectiveness endpoint will be at 6 months postoperative.

The primary safety endpoints are the rate of secondary surgical interventions (SSIs) related to optical properties of the lens, the rate of other SPE types of adverse events compared to ISO SPE rate (ISO 11979-7: 2018) and rate of other non-SPE types of adverse events. The co-primary safety endpoint will be proportion of BCDVA achieving 20/40 or better and secondary safety endpoint will be monocular and binocular contrast sensitivity.

Other key endpoints include binocular defocus curve, other visual acuity, refractive data, medical findings, lens findings, ocular/visual symptoms (non-directed), visual symptoms via PRO questionnaire, subject satisfaction and other questionnaire responses.

2 ANALYSIS POPULATIONS

2.1 ANALYSIS POPULATIONS/HANDLING OF MISSING DATA

For the primary effectiveness endpoint (DCNVA at 40 cm) and monocular secondary effectiveness endpoints (DCIVA, DCNVA (at 33 cm), and BCDVA),

For eyes that do not have data available at the 6-month postoperative visit, data will be imputed for the mITT analyses. For continuous variables (DCNVA, BCDVA and DCIVA), the planned method to use is the MCMC full-data imputation as described in Little & Rubin[2].

A Per-Protocol (PP) analysis will also be presented for primary effectiveness and secondary endpoints. The PP population for monocular data will include eyes with an investigational or control lens implanted, evaluated within the proper study interval and without clinically-relevant protocol deviations (deviations that could potentially impact the primary or secondary endpoints) as determined prior to database lock. The PP population for binocular data will include subjects that do not have any of the deviations stated above in either eye. PP tables will include available data at the time of analysis (i.e., no data imputation).

The safety population for monocular variables will consist of all eyes implanted with either a test or control IOL(s) and with data available at the time of analysis (i.e., no data imputation). The safety population for binocular variables will consist of all subjects implanted with the same test or same control IOLs in both eyes and with data available at the time of analysis (i.e., no data imputation). For secondary monocular defocus curve, safety population will be used for the primary analysis since there is no inferential statistics required for that endpoint. For all safety endpoints and other endpoints, the safety population will be used. For BCDVA percent 20/40 or better vs. ISO SPE rate, a best-case population will also be used, consisting of eyes in the safety population without any clinically-relevant preoperative ocular pathologies or macular degeneration detected at any time.

For the primary DCNVA (at 40 cm), secondary DCIVA, DCNVA (at 33 cm), BCDVA, and spectacle wear endpoints, the mITT, sensitivity, PP and safety populations will be used for data reporting. For defocus curve secondary endpoint, only safety and PP populations will be used for data reporting. For safety endpoints and other endpoints, the safety population will be used. The primary analysis will be based on first-eye data, unless stated otherwise. Some visual acuity variables will also be reported separately for second eyes as supportive data only. Safety (adverse events in both ISO SPE and non-SPE, medical findings, lens findings and non-directed ocular visual findings), monocular effectiveness endpoints (DCNVA, BCDVA, DCIVA) and monocular mesopic DCNVA will also be reported using all eyes (i.e., pooling first and second eyes by adding them together) as supporting data. Descriptive statistics will be presented for all eyes analysis. Appendix I lists the analysis tables including the endpoints and the populations used to report the results.

2.2 VISIT WINDOWS

Subject visits will occur at Preoperative for both eyes, Operative, 1 day and 1 week for each eye, and 1 month 6 months for both eyes together. The exact number of days for each interval is described in the protocol. The number of eyes with missing visits or data outside of the visit interval will be reported.

2.3 DATA CONVENTIONS

Descriptive statistics will typically include sample size (N), mean, standard deviation (SD), median, minimum (Min.), and maximum (Max.) as appropriate for continuous variables. For categorical data, the frequency and proportion will be computed.

For continuous variables, statistical tests assuming normality will generally be used. However the data will be reviewed to evaluate whether the normality assumption is appropriate. If it is found not to be appropriate, either an appropriate transformation of the data (i.e., logarithmic) may be used or the corresponding non-parametric tests may be used. Deviations from the proposed statistical guidelines will be substantiated by sound statistical rationale. For categorical data, Fisher's exact test will be used for comparison between IOL groups. Comparisons for ordinal data will be done using the Wilcoxon rank-sum test.

Unless otherwise indicated, alpha will be set to 0.05 for two-sided statistical testing with alpha set to 0.025 for one-sided testing. See Section 2.4 Multiplicity Adjustment below for the secondary endpoints related to product claims.

For visual acuity data, letter scores will be converted to LogMAR prior to analysis[6]. Formulas used for visual acuity analysis are included in Appendix II. For refractive data, all values will be converted to plus cylinder with sphere adjusted for infinity[7]. Formulas used for refractive data are also included in Appendix II. For contrast sensitivity, percent contrast will be converted to log scores prior to analysis. Formulas used for contrast sensitivity analysis are included in Appendix II.

2.4 RANDOMIZATION

If a surgeon implants the wrong study lens, i.e., other than the one on the randomization schedule, the subject's study data will be analyzed according to the randomization schedule in the mITT population and will be analyzed according to the lens received in the safety population. The subject will be excluded from the Per-Protocol population analysis. If a surgeon implants a non-study IOL (e.g., due to capsule rupture prior to IOL implantation) or if the surgery is canceled in the few days between randomization and surgery (e.g., due to death, illness), the subject will not be part of the mITT, safety or Per-Protocol populations but will be placed in the intended IOL group (IOL group based

on randomization schedule) and included in the sensitivity analyses.

2.5 MULTIPLICITY ADJUSTMENT

2.6 SITE POOLABILITY ANALYSIS

For the primary and secondary effectiveness endpoints, data will be reported by site. A mixed effects analysis will be used for primary DCNVA (at 40 cm) and secondary DCIVA, DCNVA (at 33 cm), BCDVA and spectacle wear endpoints.

3 ACCOUNTABILITY/DEMOGRAPHICS

3.1 ACCOUNTABILITY

The number of enrolled subjects will be tabulated by site for first and second eyes. Subject accountability will be summarized as a frequency distribution by scheduled visits. A frequency table by IOL will be generated, showing the number of available eyes (those in interval and outside of the interval) and the number of missing and active subjects.

3.2 DEMOGRAPHICS

Subject demographic data including age, sex, race, and iris color will be presented by IOL group. Age will be determined at the time of the preoperative visit and will be categorized by less than 60, 60 to 69, 70 to 79, and equal to or older than 80 years old.

In addition, age will be summarized with descriptive statistics. The frequency distributions of sex, race, and iris color will also be tabulated.

Comparisons between IOL groups will be performed using Fisher's exact test for demographic categorical data. The null hypothesis is that there is no difference in the proportion with specific responses between IOL groups, whereas the alternative hypothesis is that there is a difference in at least one proportion between IOL groups. For comparisons between IOL groups for mean age, the two-sample t-test will be used. The null hypothesis is that there is no difference in mean values between IOL groups, whereas the alternative hypothesis is that there is a difference in mean values between IOL groups. Two-sided testing with an alpha level of 0.05 will be used for all demographic variables.

4 PREOPERATIVE/OPERATIVE PARAMETERS

Preoperative and operative parameters for first and second eyes will be reported for each IOL model. The frequency and proportion of eyes with selected responses will be tabulated for categorical data with descriptive statistics used for continuous data. Statistical comparisons between IOL groups will be performed as described above for demographic data. Two-sided testing with an alpha level of 0.05 will be used for all preoperative and operative parameters.

5 POSTOPERATIVE ANALYSES – PRIMARY AND SECONDARY EFFECTIVENESS ENDPOINTS

5.1 PRIMARY EFFECTIVENESS ENDPOINT

MONOCULAR DISTANCE-CORRECTED NEAR VISUAL ACUITY (DCNVA)

The primary effectiveness endpoint is mean (LogMAR) first-eye, monocular, distance-corrected near visual acuity (40 cm) under photopic conditions at 6 months postoperative. The mean, SD, median, minimum, maximum and two-sided 95% C.I. will be presented by IOL group.

5.2 SECONDARY EFFECTIVENESS ENDPOINTS

5.2.1 MONOCULAR DISTANCE CORRECTED INTERMEDIATE VISUAL ACUITY (DCIVA)

The first secondary endpoint is mean (LogMAR) first-eye, monocular, distance-corrected intermediate visual acuity (66 cm) under photopic conditions at 6 months postoperative. The mean, SD, median, minimum, maximum and two-sided 95% C.I. will be presented by IOL group.

5.2.2 MONOCULAR DISTANCE CORRECTED NEAR VISUAL ACUITY (DCNVA) AT 33 CM

The second secondary endpoint is mean (LogMAR) first-eye, monocular, distance-corrected near visual acuity (33 cm) under photopic conditions at 6 months postoperative. The mean, SD, median, minimum, maximum and two-sided 95% C.I. will be presented by IOL group.

where

5.2.3 MONOCULAR BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)

The third secondary effectiveness endpoint is mean (LogMAR) first-eye, monocular, best- corrected distance visual acuity (4 m) under photopic conditions at 6 months postoperative. Results will be compared between lens groups for first eyes using a non-inferiority approach. The mean, SD, median, minimum, maximum and two-sided 95% C.I. will be presented by IOL group.

5.2.4 MONOCULAR DISTANCE-CORRECTED DEFOCUS CURVE

The fourth secondary effectiveness endpoint is monocular distance-corrected defocus curve at 6 months postoperative. The mean of each diopter will be plotted for the range of testing conducted (including positive and negative diopters).

5.2.5 SPECTACLE WEAR

The fifth secondary effectiveness endpoint is decreased spectacle wear determined via the PRO instrument PRSIQ and is defined as wearing glasses or contacts “none of the time” in all 4 conditions (distance vision, intermediate vision, near vision and overall vision) at 6 months postoperative.

5.3 SAFETY ENDPOINTS

PRIMARY SAFETY ENDPOINTS: RATE OF ADVERSE EVENTS

i. The rate of secondary surgical interventions (SSIs) related to optical properties of the lens in first-eyes of subjects in the investigational lens group

ii. All SPE types of adverse events reported among first eyes of subjects in the test group will be compared to ISO SPE rates (ISO 11979-7: 2018)

Where
i = indicator for the i^{th} AE
p_i = proportion of Model ZFR00V eyes with the i^{th} AE
θ_i = ISO SPE rates for the i^{th} AE (constant)

Reject the null hypothesis if one-sided p-value ≤ 0.025.

Success criterion is that the AE rate for the test lens is not statistically significantly higher than the ISO SPE rate (p> 0.025).

iii. All other types (non-SPE) of adverse events

CO-PRIMARY SAFETY ENDPOINTS: MONOCULAR BCDVA 20/40 OR BETTER

i. For the co-primary safety endpoint of ZFR00V eyes achieving monocular BCDVA of 20/40 or better, the proportion for ZFR00V eyes will be compared to the ISO SPE rate for posterior chamber IOLs (all first eyes)

SECONDARY SAFETY ENDPOINTS: CONTRAST SENSITIVITY

i. Binocular and monocular first eye contrast sensitivity will be reported by IOL group using descriptive statistics and a two-sided 90% confidence interval for all levels of contrast and lighting conditions. In addition, monocular results will be stratified by pupil size.

For primary and co-primary safety endpoints, additional secondary analyses consisting of second eyes and all eyes (pooling first and second eyes) will also be included.

6 POSTOPERATIVE ANALYSIS: OTHER ENDPOINTS

6.1 OTHER INTERMEDIATE AND NEAR VISUAL ACUITY ENDPOINTS

Other intermediate and near endpoints include binocular UCIVA, binocular UCNVA at 40 cm, binocular DCNVA at 40 cm and monocular and binocular mesopic DCNVA at 40 cm. These endpoints will be evaluated at 6 months using the safety population.

In addition, the frequency and proportion of first eyes and binocular subjects achieving each line of visual acuity will be reported at 6 months.

6.2 OTHER DEFOCUS CURVE ENDPOINTS

Binocular defocus data for the test group will be analyzed with the same method as that used for the monocular defocus curve described in the secondary effectiveness endpoint. In addition, monocular results will also be stratified by pupil group (≤ 2.5 mm, > 2.5 mm to < 4.0 mm and ≥ 4.0 mm) using pupil size under photopic no glare condition.

6.3 OTHER DISTANCE VISUAL ACUITY

In addition to the mean BCDVA analysis in 5.2.3, the proportion of first eyes achieving each acuity line equivalent for monocular BCDVA will also be reported over time. Descriptive statistics with two-sided 95% CI for mean LogMAR and frequency achieving acuity by line will also be reported for binocular BCDVA, monocular UCDVA and binocular UCDVA. To evaluate the effect of residual refractive error on monocular UCDVA, a scatterplot of residual refractive error vs. UCDVA will be presented by IOL group.

6.4 MEDICAL/LENS FINDINGS

Rates of postoperative medical and lens findings will be tabulated with the frequency and proportion of eyes with these events reported over time by IOL group. As mentioned above in Section 5.3.1 Safety Endpoints: Rates of Adverse Events, medical complication rates listed in ISO-11979 will be compared to the ISO SPE rates for ZFR00V first eyes

Reporting of cumulative complications and cumulative adverse events (occurring at any time postoperative either at standard visits or interim visits) will include data from all study eyes implanted.

6.5 OTHER MONOCULAR CONTRAST SENSITIVITY

In addition to the mean contrast sensitivity analysis in Section 5.3, monocular contrast sensitivity will also be stratified by pupil group. The pupil size corresponding to the contrast testing lighting condition will be used (i.e., mesopic no glare CS will be stratified using mesopic no glare pupil size group). The pupil group for mesopic lighting condition is as follows: ≤4.0 mm, >4.0 to ≤5.0 mm and >5.0 mm; the pupil group for photopic condition is as follows: ≤2.5 mm, >2.5 to <4.0 mm and ≥4.0 mm.

6.6 MANIFEST REFRACTION

Descriptive analysis and two-sided 95% confidence interval of refractive sphere, cylinder, spherical equivalent (SEQ) and postoperatively measured SEQ minus intended SEQ will be reported by IOL groups for both eyes. Since refraction was performed at 4M, 0.25D will be subtracted from the sphere value. Refractive data will then be converted to plus cylinder notation (see Appendix II).

MRSE is then calculated by the following formula: MRSE = sphere + ½ cylinder.

In addition, the frequency and proportion of each eye within certain diopter categories (≤0.50, 0.51-1.00, 1.01-1.50, 1.51-2.00,>2.00) will be tabulated for refractive cylinder and postoperatively measured SEQ minus intended SEQ by IOL groups for both eyes.

6.7 IOL POWER CONSTANT ANALYSIS

Descriptive statistics will be provided for IOL power constant analyses with refractive data at 6 months used for the evaluation.

6.8 FUNDUS VISUALIZATION

The fundus exam findings (within normal limits vs. abnormal) and ability to adequately visualize the fundus (adequate vs. not adequate) will be reported by IOL groups. The frequency and proportion with each outcome will be tabulated by IOL groups.

6.9 NON-DIRECTED OCULAR/VISUAL SYMPTOMS

Rates of postoperative non-directed ocular/visual symptoms will be tabulated with the frequency and proportion of eyes with these events reported over time by IOL group.

6.10 VISUAL SYMPTOMS VIA PRO INSTRUMENT

Visual symptom data obtained from the PRVSQ instrument at 6-month will be reported for subjects who have received the same test lenses or same control lenses in both eyes. The frequency and proportion of subjects with a given response will be reported by IOL group.

6.11 SATISFACTION AND OTHER QUESTIONNAIRE DATA

Satisfaction and other results from the 6-month questionnaire data will be reported for subjects who have received the same test lenses or same control lenses in both eyes. The frequency and proportion with each response will be tabulated by IOL groups.

6.12 SUBGROUP ANALYSIS

For the primary and secondary effectiveness endpoints, data will be reported by demographic variables including gender, race and age group (≤59, 60-69, 70-79, >80). Descriptive statistics will be presented by subgroup for DCNVA (at 40 cm), DCNVA (at

33 cm), BCDVA, and DCIVA endpoints. Number and percentage will be reported by subgroup for spectacle wear endpoint. Defocus curve will be plotted by subgroup for defocus curve endpoint.

7 SAMPLE SIZE CALCULATIONS

Study sample sizes are based on the requirements for a Level B modification of a parent lens as well as the requirement for contrast sensitivity testing. The minimum requirements are 100 evaluable test subjects per lens group for Level B and 122 evaluable test subjects per lens group for contrast sensitivity. The screen failure rate is assumed to be 10%, and the dropout rate is assumed to be 10%. To achieve the minimum of 122 evaluable subjects in each IOL group at 6 months postoperative and allowing for screen failures and drop out, up to 150 subjects will be enrolled in each lens group to achieve approximately 135 bilaterally implanted subjects in each lens group.

7.1 MONOCULAR, DISTANCE CORRECTED NEAR VISUAL ACUITY (DCNVA) AT 40 CM

For monocular (first-eye), distance corrected near visual acuity (DCNVA) at 40 cm, there is over 90% power to detect a 0.7-line or greater difference in mean visual acuity between the test and control lens groups (assumes one-sided testing with an alpha of 0.025 and standard deviation of 1.6 lines) with 122 subjects in each lens group.

7.2 MONOCULAR, BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)

For monocular (first-eye), best corrected distance visual acuity (BCDVA), there is over 90% power to detect a 1-line or greater difference in mean visual acuity between the test and control lens groups (assumes one-sided testing with an alpha of 0.025 and standard deviation of 1.2 lines) with 122 subjects in each lens group.

7.3 SPECTACLE WEAR

For spectacle wear, there is more than 90% power to detect a 20% difference between test and control subjects (assumes 80% for test and 60% for control, using a one-sided Fisher's Exact test with an alpha of 0.025) with 122 subjects in each lens group.

7.4 MONOCULAR DEFOCUS CURVE

There is no statistical comparison for this endpoint; therefore, no sample size calculation is performed for this endpoint.

7.5 MONOCULAR, DISTANCE CORRECTED INTERMEDIATE VISUAL ACUITY (DCIVA)

For monocular (first-eye), distance corrected intermediate visual acuity (DCIVA), there is over 90% power to detect a 0.7-line or greater difference in mean visual acuity between the test and control lens groups (assumes one-sided testing with an alpha of 0.025 and standard deviation of 1.6 lines) with 122 subjects in each lens group.

7.6 MONOCULAR, DISTANCE CORRECTED NEAR VISUAL ACUITY (DCNVA) AT 33 CM

For monocular (first-eye), distance corrected near visual acuity (DCNVA) at 33 cm, there is over 90% power to detect a 0.7-line or greater difference in mean visual acuity between the test and control lens groups (assumes one-sided testing with an alpha of 0.025 and standard deviation of 1.6 lines) with 122 subjects in each lens group.

7.7 MONOCULAR AND BINOCULAR CONTRAST SENSITIVITY

For contrast sensitivity, the ISO 11979-7:2018 sample size criteria for contrast sensitivity analysis are met with 122 subjects in each lens group.

8.0 REFERENCES

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APPENDIX II: FORMULAS USED FOR VISUAL ACUITY, REFRACTIVE DATA AND CONTRAST SENSITIVITY

Postoperative distance, intermediate and near visual acuity testing will be performed using the M&S Technologies CTS-1000 Smart System© computerized vision testing system (M&S system).

Key : " * " = multiplication, " - " = subtraction, " / " = division, " ** " = exponent, log10 = log in base 10, CRF = Case Report Form

Formulas for Converting Distance, Intermediate and Near VA to LogMAR Values (M&S System):

LogMAR value = (85-letter score)/50

Example: A subject has distance letter score of 78
Converting to LogMAR: (85-78)/50 = 0.14 LogMAR

If the standard distance is not used for M&S system, no calculation adjustment will be needed since the M&S system already takes that into account.

Converting from LogMAR to Snellen and Decimal Equivalent:

Snellen denominator=20*(10**(LogMAR value))
Decimal VA= 20/(Snellen Denominator)

Example: A subject has a LogMAR score of 0.20
The Snellen denominator is: 20*(10**(0.20) = 20*(1.585) = 31.7=20/32
Decimal VA = 20/32=0.625

Formulas for Refractive Data

Converting to Plus Cylinder Notation:

If the original cylinder value is positive then the following formulas are used:

1. New sphere value=original sphere value
2. Final cylinder value=absolute value of the original cylinder value
3. Final axis value=original axis value

If the original cylinder value is negative then the following formulas are used:

1. New sphere value=original sphere value + original cylinder value
2. Final cylinder value=absolute value of the original cylinder value
3. Final axis value: if original axis is >0 and ≤90 then final axis=original axis +90; if the original axis >90 and ≤180 then final axis=original axis – 90

Adjusting for Infinity: Final sphere=new sphere (in plus cylinder notation) – 0.25

Spherical Equivalent

1. Spherical equivalent=final sphere + (0.5*final cylinder)
2. Spherical equivalent minus intended SEQ=spherical equivalent at postop – intended spherical equivalent (from op if available or preop if not)

Examples:

Refraction: sphere: -0.25 cylinder: -0.50 axis: 80 with intended SEQ=-0.13

In plus cylinder notation: sphere=-0.75, cylinder=0.50 axis=170
Adjusting for infinity: sphere=-1.00, cylinder=0.50 axis=170
Spherical equivalent=-1.00 + 0.5*(0.50) = -0.75
Spherical equivalent minus intended= -0.75 – (-0.13) = -0.62

Formulas for Converting Contrast Threshold to Contrast Sensitivity (M&S System):

The average of the two tests will be used for data analysis.