Contralateral Study of Clareon PanOptix Pro vs. Clareon PanOptix

STUDY ID

ILQ137-C002 Study A

STATISTICAL ANALYSIS PLAN v2

04-Oct-2024

NCT06400745

Alcon

-

Statistical Analysis Plan for ILQ137-C002

Title: Contralateral Study of Clareon PanOptix Pro vs. Clareon PanOptix

[redacted]

[redacted]

Executive Summary:

Key Objectives:

The primary objective of the studies under this protocol (Sub-Study A and Sub-Study B) is to demonstrate noninferiority of monocular photopic Best Corrected Distance Visual Acuity (BCDVA) of the 2 Clareon PanOptix Pro models (PXYWT0 and PAYWT0) compared to Clareon PanOptix at 2 months postoperative.

Decision Criteria for Study Success:

Each sub-study will be considered successful if the data indicate a noninferior visual acuity (VA) for the Clareon PanOptix Pro model compared to Clareon PanOptix. Study success will be concluded if the upper bound of the one-sided 95.1% confidence interval does not exceed the noninferiority margin of 0.1 logMAR for mean difference in monocular photopic BCDVA at 2 months postoperative for Clareon PanOptix Pro Intraocular Lenses (IOLs) vs the Clareon PanOptix IOLs. The primary analysis will be based on the All-Implanted Analysis Set (AAS).

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List of Tables

[redacted]

1 STUDY OBJECTIVES AND DESIGN

All study conduct, effectiveness, and safety data will be reported for each sub-study (A and B) separately.

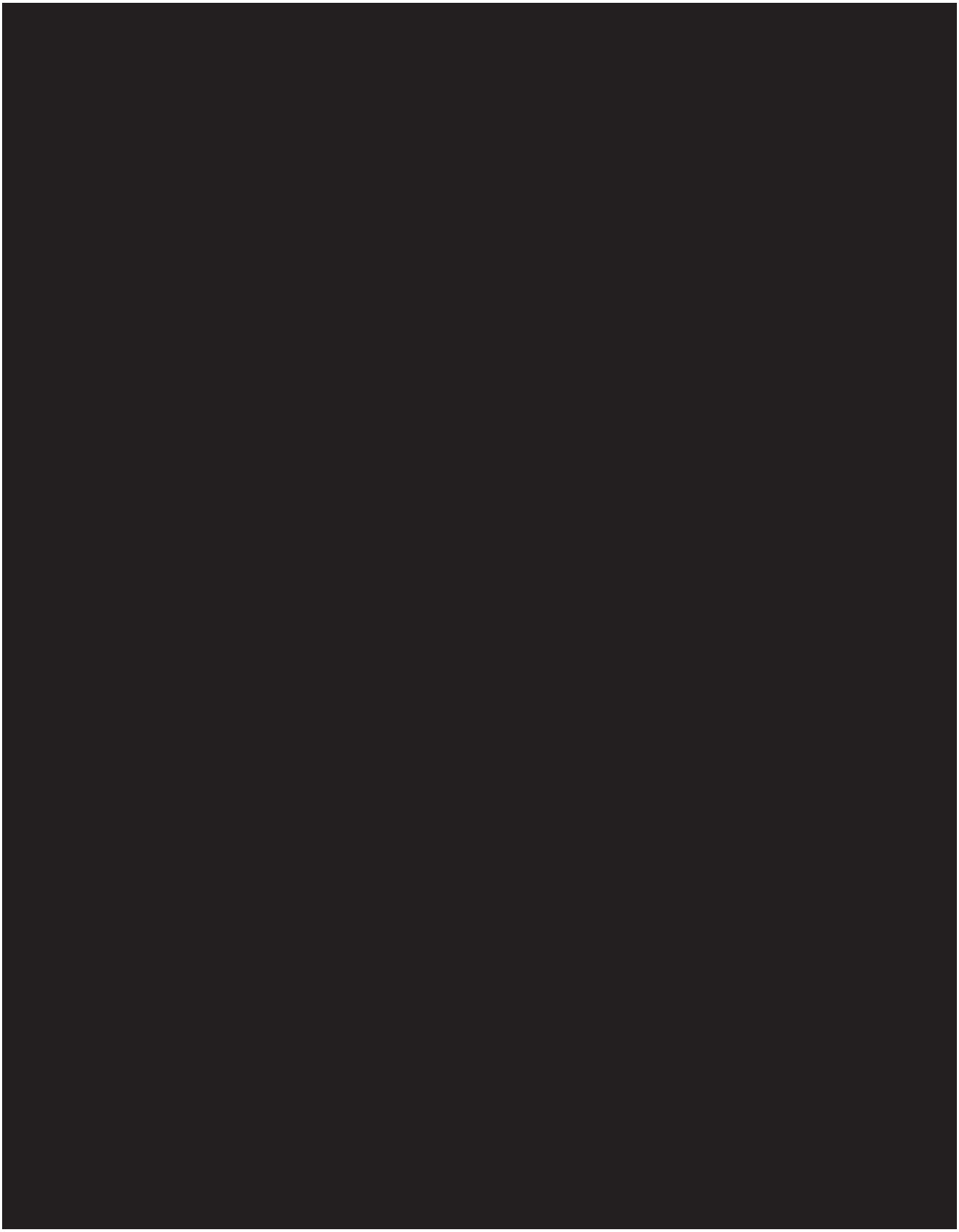
1.1 Study Objectives

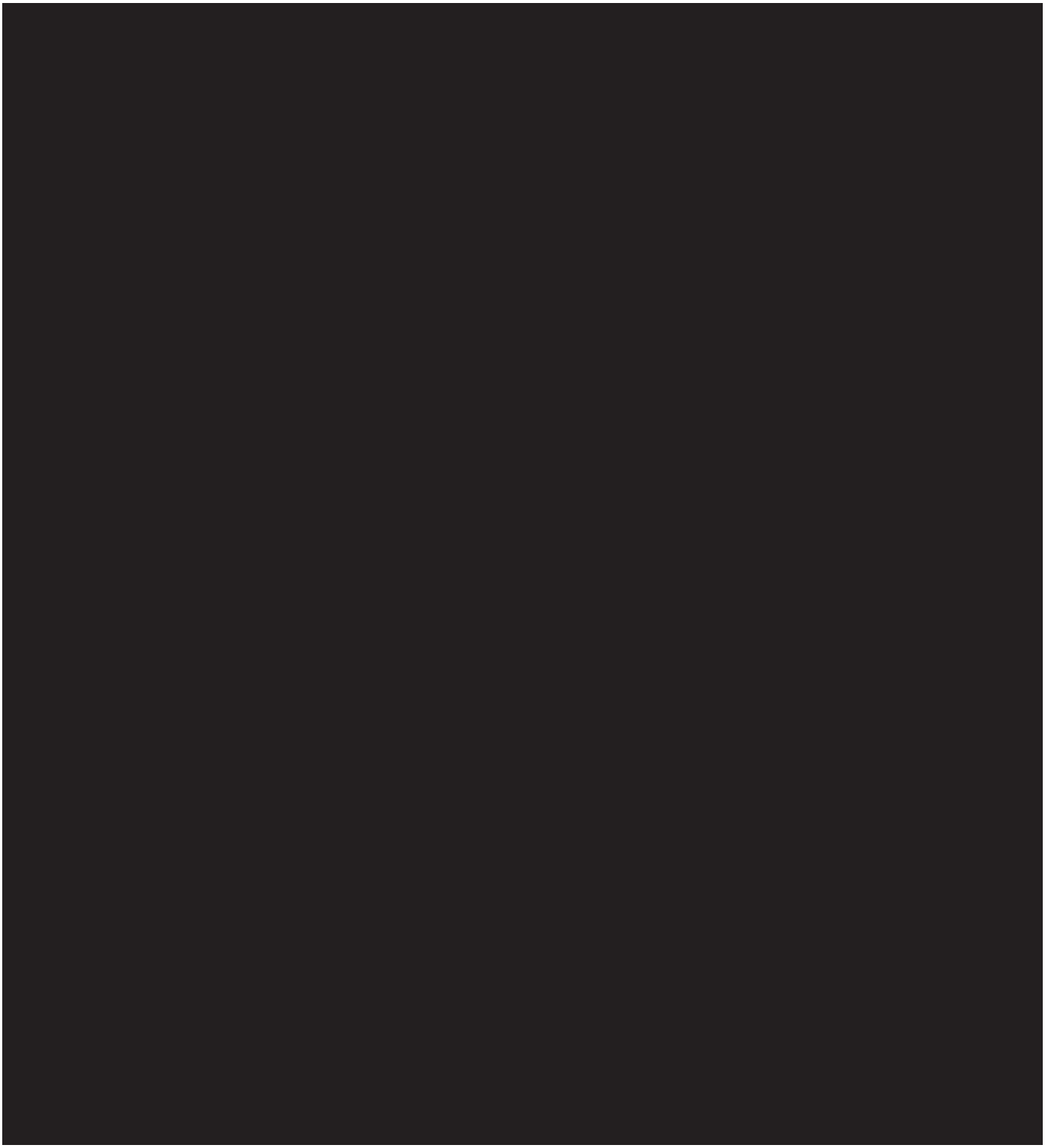
Primary Objective: Sub-Study A and Sub-Study B

To demonstrate noninferiority of monocular photopic BCDVA of the Clareon PanOptix Pro models (PXYWT0 and PAYWT0) compared to Clareon PanOptix at 2 months postoperative (Visit 3A).

Secondary Objective:

Not applicable.





Safety Objectives: Sub-Study A and Sub-Study B

To describe the incidence of ocular adverse events including secondary surgical interventions.

1.2 Study Description

This is a prospective, multicenter, randomized, assessor and subject masked, contralateral, active controlled study.

The study protocol contains two sub-studies: sub-study A and sub-study B

- Sub-study A (n = ~66 implanted subjects) – Subjects implanted contralaterally with Clareon PanOptix Pro, Model PXYWT0 in one eye and Clareon PanOptix, Model CNWTT0 in the fellow eye
- Sub-study B (n = ~66 implanted subjects) – Subjects implanted contralaterally with Clareon PanOptix Pro, Model PAYWT0 in one eye and Clareon PanOptix, Model CNWTT0 in the fellow eye
- Subjects will be randomized in a 1:1 manner to either sub-study A and sub-study B and further randomized to receive Clareon PanOptix Pro or Clareon PanOptix in the first surgical eye, and the second eye will receive the other lens. Subjects will be block randomized by investigation site.

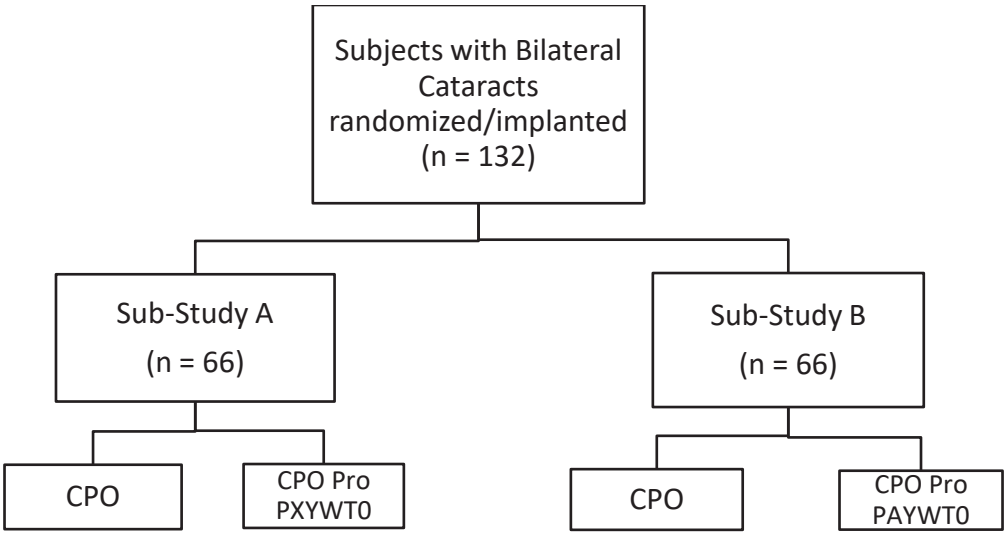
The protocol will be executed simultaneously and identically for both sub-studies by the sites. (All testing and assessments will be the same for both sub-studies.) Segregation by sub-study A and sub-study B will only be used for analysis and reporting.

Enrollment will commence at approximately 10 investigative sites. All of the study sites will be located in one country, the United States.

The total duration of a subject's participation in the study is approximately 7 months, attending 9 study visits (which includes the Screening Visit). Subjects will be followed for a total of approximately 6 months postoperatively with primary [redacted] being assessed at the 2-month (Visit 3A) follow-up visit.

The duration of the entire study is approximately one year.

Figure 1-1 Study Design Flowchart



The schedule of visits is included as Table 10-1 in the appendix.

The purpose of this study design is to establish the safety and effectiveness of two Clareon PanOptix Pro models (PXYWT0 and PAYWT0). [redacted]

Refer to the study protocol for further details on the rationale for study design.

1.3 Randomization

Only after signing the informed consent form (ICF), a subject will be assigned a subject number by the electronic data capture system (EDC). Lens model will be assigned by randomization via the EDC system on the day of or after the Screening visit if the subject meets all entry criteria.

Subjects will be randomized to one of two sub-studies and to contralateral lens model in a 1:1 ratio. Subjects will be block randomized by investigational site. Subjects at each site will be randomized to one of two sub-studies in a 1:1 ratio. Sub-study A will evaluate Model PXYWT0, and sub-study B will evaluate Model PAYWT0. Subjects randomized to sub-study A will be further randomized to receive Model PXYWT0 or Model CNWTT0 in the first surgical eye, and the second eye will receive the other lens. Similarly, subjects randomized to sub-study B will be further randomized to receive Model PAYWT0 or Model CNWTT0 in the first surgical eye and the second eye will receive the other lens. The 1st surgical eye will be the eye with the worse BCDVA at screening. When the BCDVA is equal between the two eyes, the right eye (OD) will be the 1st surgical eye.

1.4 Masking

This study is assessor-masked and subject-masked.

[redacted]. Alcon personnel (including biostatistics, masked data manager, and clinical project lead) will also be masked. All other members associated with the study (at the site and the study sponsor) are unmasked.

At the 1st interim lock, unmasking of Alcon personnel will be limited to the subset of subjects who complete the 2-Month postoperative visit for inclusion in the 1st interim analysis. For those subjects not included in the 1st interim analysis, Alcon personnel will remain masked to IOLs implanted in the eye until the 2nd interim study database lock. Masked assessors will be masked to the IOLs implanted until the final database lock.

Subjects will be provided with implant cards by unmasked personnel upon exiting the study and will become unmasked at that time.

Masked study personnel must avoid seeking information that may compromise masking. Unmasked study personnel must not disseminate information that is potentially unmasking to any masked personnel. The masked and unmasked site personnel must coordinate all study activities as necessary to protect masking and minimize bias during the study.

1.5 Interim Analysis

Two interim analyses are planned for this study.

The first interim analysis will be conducted when approximately 40 subjects (approximately 20 in each sub-study, minimum 30 subjects total) complete the 2-Month postoperative visit. This interim analysis is designed to review preliminary safety and effectiveness results for strategic business decision making purposes. There is no intention of stopping the study early. A second interim analysis will be conducted when all subjects complete the 2-Month postoperative visit, at this point treatment arms will be unmasked, and all inferential analysis will be conducted. To control the overall type I error rate (at one-sided alpha = 0.05) the Lan-DeMets method with an O'Brien-Fleming alpha spending function will be utilized to distribute the type I error rate between the first and second interim analyses. The first interim analysis will be conducted when approximately 1/3 of the information fraction (in this case 1/3 of the target sample size) is available, therefore for administrative purposes a one-sided alpha of approximately 0.001 will be spent at the first interim analysis and accordingly the

significance level at the second interim analysis (which is the primary inferential analysis point) will be one-sided 0.049 for all effectiveness endpoints. The power estimates provided below are based on a one-sided 0.049 significance level.

A final analysis will be performed once the 6-Month follow-up is complete, at which time the study database will be considered final and locked to report longer term effectiveness and safety results.

2 ANALYSIS SETS

All eligible subjects will be screened to determine if they meet all inclusion and no exclusion criteria. Subjects who provide informed consent will be considered enrolled in the study. Evaluability of all subjects will be determined before database lock.

2.1 Effectiveness Analysis Sets

There will be two effectiveness analysis datasets for each sub-study: the all-implanted analysis set and the best-case analysis set.

The all-implanted analysis set (AAS) will include all subjects with successful test and comparator article contralateral implantation, with at least one postoperative visit (same postoperative visit for both eyes).

The best-case analysis set (BAS) will include all subjects with successful contralateral implantation with the test and comparator article that had:

- At least one postoperative visit (same postoperative visit for both eyes),
- No preoperative ocular pathology or macular degeneration at any time in either eye, and
- No major protocol deviations

Subjects who become pregnant at any time during the study will also be excluded from the BAS.

The primary analysis set for effectiveness analyses will be the AAS, [redacted]

All effectiveness analyses will be conducted on an as-treated basis. Eyes will be categorized under the actual study IOL implanted.

2.2 Safety Analysis Set

The Safety Analysis Set (SAS) will include all eyes with attempted test or comparator article implantation (successful or aborted after contact with the eye). The SAS will be the primary set for all safety analyses.

All analyses for eye-level endpoints (such as ocular adverse events) will be presented separately by lens model. Analyses for subject-level endpoints (such as nonocular adverse events) will be based on the subjects.

Safety analyses will be conducted using the safety analysis set on a treatment-emergent basis. For treatment-emergent safety analyses, eyes will be categorized under the actual test or comparator article implanted (or attempted to implant).

3 SUBJECT CHARACTERISTICS AND STUDY CONDUCT SUMMARIES

Subject characteristics and study conduct summaries include tables and/or listings for subject disposition, demographics, and baseline characteristics, targeted medical history and concomitant medications, baseline eye biometry, baseline monocular visual acuity and manifest refraction spherical equivalent (MRSE), and surgical summary. All descriptive summary statistics will be displayed with number of subjects/eyes and percentage for categorical data, and with number of subjects/eyes, mean, standard deviation (SD), median, minimum, and maximum for continuous data. Tables will be presented by lens model (PXYWT0 (or PAYWT0) and CNWTT0) or total subjects as applicable.

Baseline will be defined as the last measurement prior to exposure to investigational product, except otherwise stated.

Subject characteristics and study conduct summaries will be presented on the AAS and SAS. Subject characteristics and study conduct summaries will be presented on the BAS if the number of eyes excluded from the BAS exceeds 10% of the AAS.

3.1 Subject Disposition and Study Conduct

A subject disposition table will be presented that displays the number of subjects enrolled in the study, in addition to the number of screen failures, the number randomized, the number with attempted implantation, successful implantation, completed study, and discontinued

study. This table will also contain counts for each reason for premature study discontinuation. Corresponding listings of reasons for early study discontinuation will also be provided separately for discontinuations prior to attempted implantation (including screen failures) and for discontinuations after attempted implantation.

Accountability at each postoperative visit will be presented for AAS and SAS (BAS if applicable) for each lens model. Accounting at each postoperative visit will also be presented for the primary effectiveness endpoint (i.e., monocular photopic BCDVA) for AAS and BAS by lens model.

Summaries of subject eye evaluability for each analysis set will be provided by lens model and by subject.

In addition, summary tables or listings will be provided including:

- Number of subjects treated by investigator
- Lens model assignment (including demographics (see below) and study exit status)
- Eyes receiving lens model different than planned
- Subject eyes excluded from analysis and/or from study
- Protocol deviations

3.2 Demographics

Demographics will be summarized by the number and percentage of subjects for the categorical variables, and descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum) for the continuous variables based on AAS and SAS (BAS if applicable).

Demographics (subject-level)

Categorical variables:

- Sex (Female, Male, Unknown, Undifferentiated)
- Race (per Case Report Form (CRF))
- Ethnicity (per CRF)

Continuous variable:

- Age (years)

3.3 Medical History and Concomitant Medications

Targeted medical history and concomitant medications will be listed for all subjects based on the SAS.

Medical history includes the subject's full ocular history and targeted systemic history at screening visit; and concomitant medications include all ocular and nonocular medications taken within 30 days prior to the informed consent date.

3.4 Baseline Eye Biometry

Assessments of eye biometry will be summarized preoperatively by descriptive statistics (number of eyes, mean, SD, median, minimum, and maximum) for continuous variables by lens model. Assessments will be presented based on AAS and SAS (BAS if applicable).
Continuous variables:

- Axial length (mm)
- Anterior chamber depth (mm)
- Corneal astigmatism (D) = abs (K1-K2)

3.5 Baseline Visual Acuity and MRSE

Baseline visual acuity and MRSE will be summarized preoperatively using descriptive statistics (number of eyes, mean, SD, median, minimum, and maximum) for continuous variables by lens model. Results will be presented based on AAS and SAS (BAS if applicable).

Continuous variables:

- Monocular photopic BCDVA (logMAR)
- Monocular MRSE (D) = sphere + ½ cylinder

3.6 Surgical Summary

Surgical factors will be summarized by descriptive statistics (number of eyes, mean, SD, median, minimum, and maximum) for continuous variables by lens model. Results will be presented based on AAS.

Continuous variables:

- Target residual refractive error (TRRE) (D)
- Predicted residual astigmatism (D)
- Lens power (D) (Median, Min, Max only)

4 EFFECTIVENESS ANALYSIS STRATEGY

The protocol defines 1 primary [redacted] effectiveness endpoint for each sub-study. Within each sub-study, a success on the primary effectiveness endpoint would be indicated by achieving noninferiority of the Clareon PanOptix Pro model IOLs to the Clareon PanOptix IOLs in mean monocular photopic BCDVA at 2 months postoperative. [redacted]

All effectiveness endpoints will be summarized descriptively according to the type of parameter (i.e., whether data are categorical or continuous) being analyzed. For categorical variables, the descriptive statistics will include number of observations, count in the category, and percent in the category. For continuous variables, the descriptive statistics will include number of observations, mean, median, standard deviation, standard error, minimum, and maximum. Confidence intervals will be provided as applicable. Summaries of continuous endpoints will also include mean differences between lens models and associated descriptive statistics.

Unless otherwise specified, effectiveness endpoints will be summarized by lens model at the postoperative scheduled visits.

All data obtained in evaluable subjects/eyes will be included in the analysis. Missing data will not be imputed.

4.1 Effectiveness Endpoints – Sub-Study A

Primary Effectiveness Endpoint

Mean monocular photopic BCDVA (logMAR) at 4 m at 2 months postoperative (Visit 3A)

[redacted]

[redacted]

4.1.1 Effectiveness Hypotheses

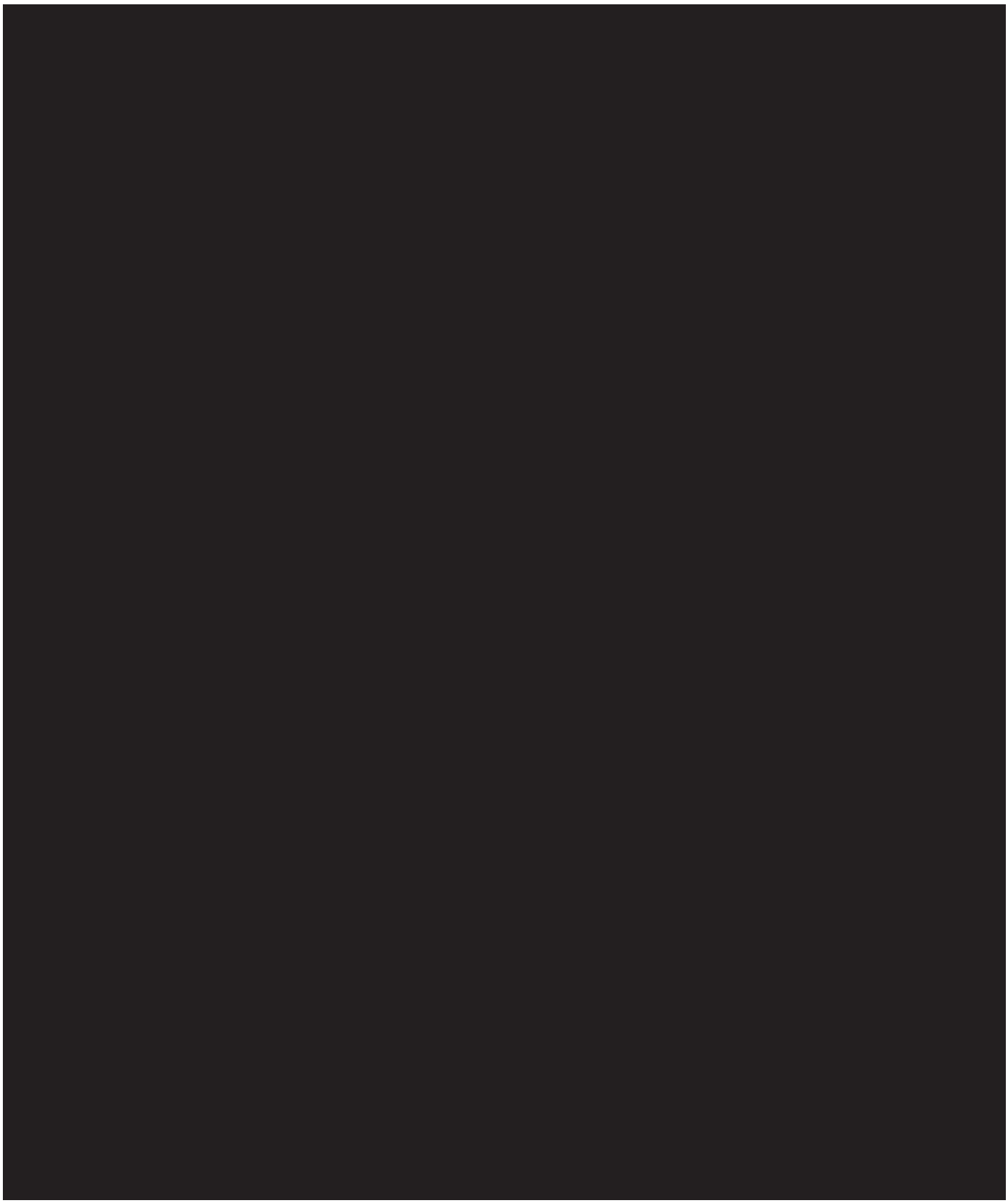
Primary Effectiveness

The null and alternative hypotheses to be evaluated in support of the primary noninferiority objective are as stated below:

$$H_0: \mu_D \geq \Delta$$
$$H_a: \mu_D < \Delta$$

where, Δ refers to the noninferiority margin, set at 0.1 logMAR, and μ_D refers to the mean of the difference between paired observations of each subject's eyes (test minus comparator) for monocular photopic BCDVA at 2 months post implantation.

[redacted]

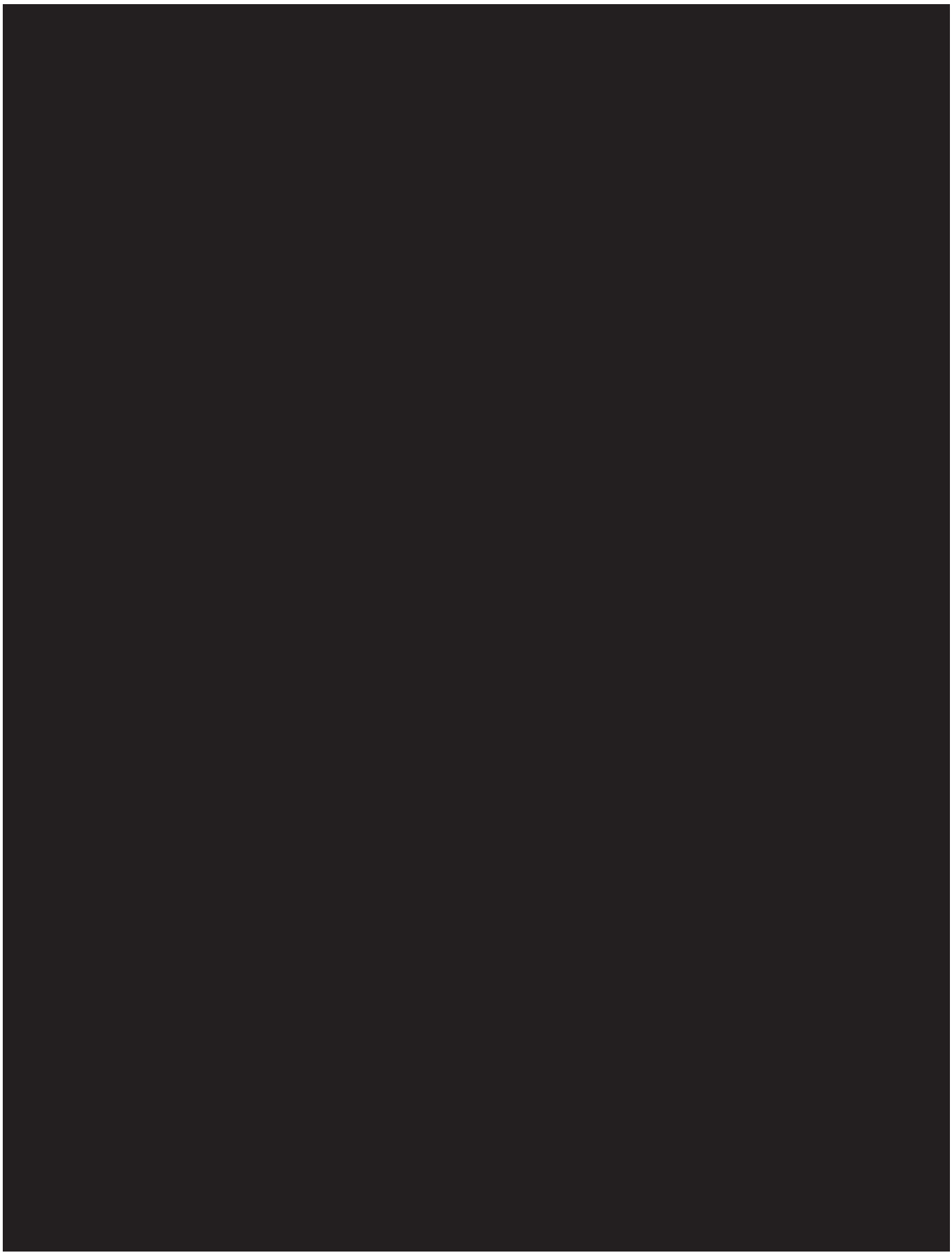


4.1.2 Statistical Methods for Effectiveness Analyses

Table 4-1 summarizes the primary [redacted] Supportive analyses using the BAS will be conducted only if the number of eyes excluded from the BAS exceeds 10% of the AAS.

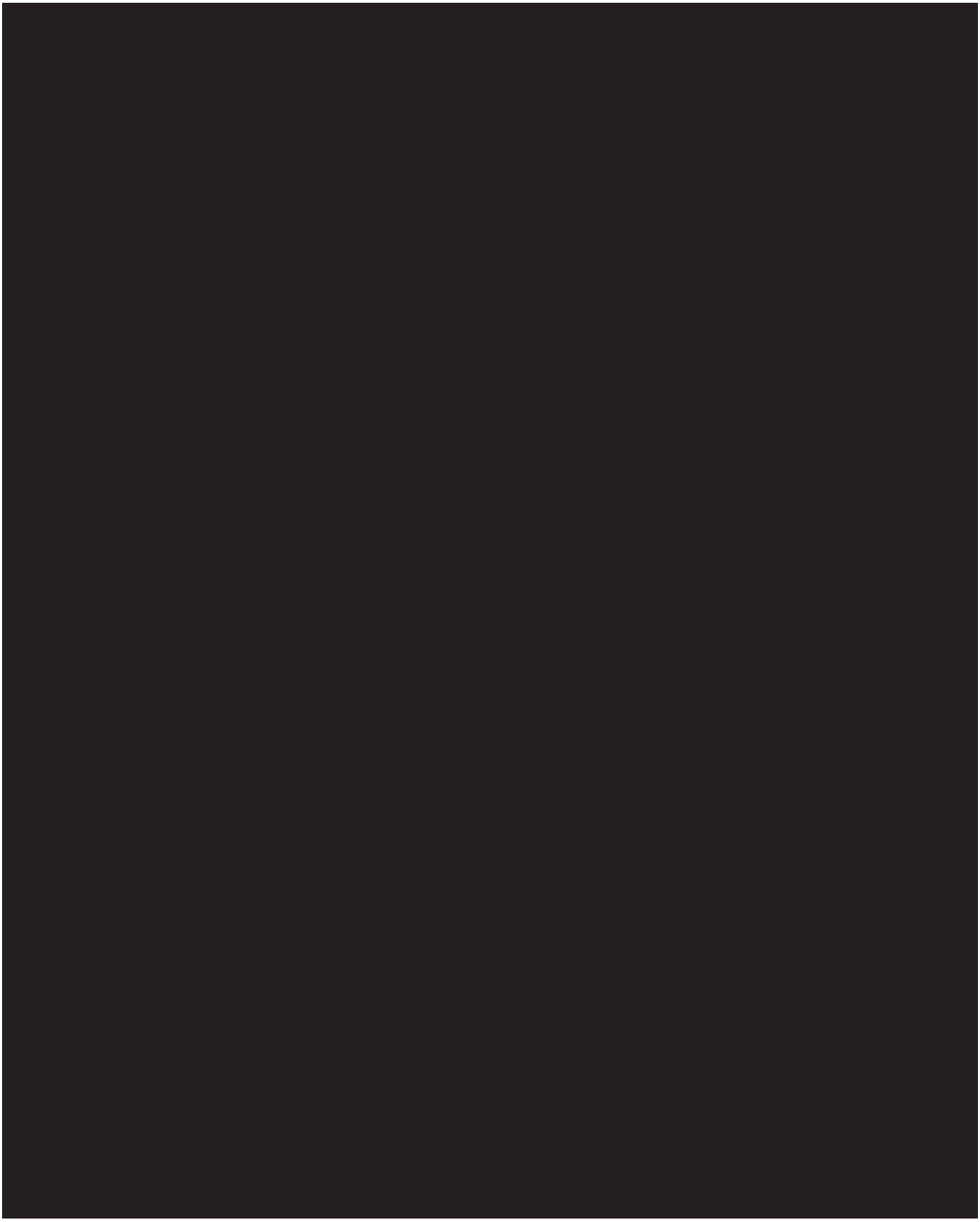
Table 4-1 Sub-Study A – Summary of Analysis Strategy for Primary [redacted]

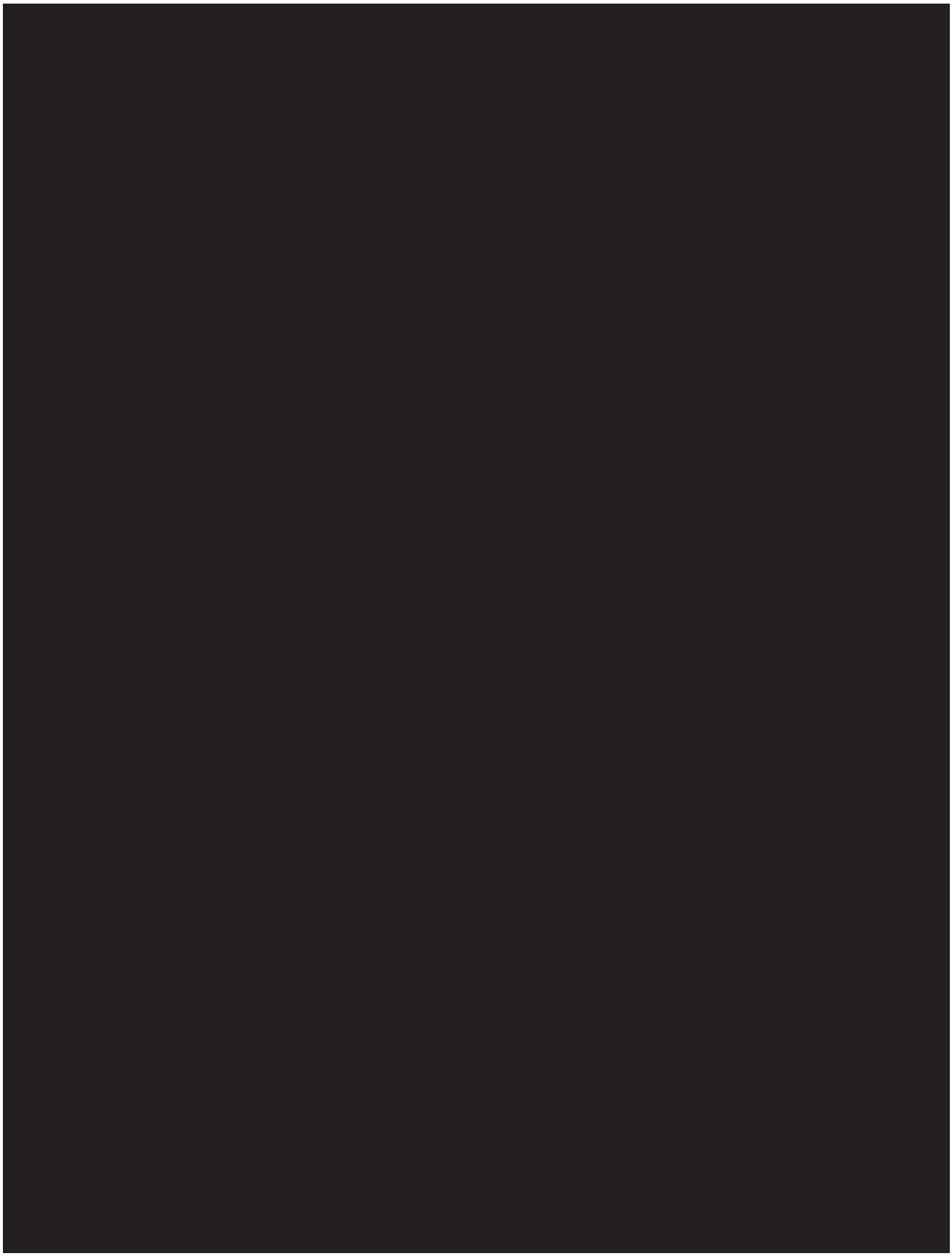
Endpoint	Main vs. Supportive Approach[a]	Comparison/ Statistical Method	Analysis Set	Missing Data Approach
Primary				
Mean monocular photopic BCDVA (logMAR) at 4 m at 2 months postoperative (Visit 3A)	M S	One-sample t-test for noninferiority	AAS BAS	Observed data only
[redacted]				

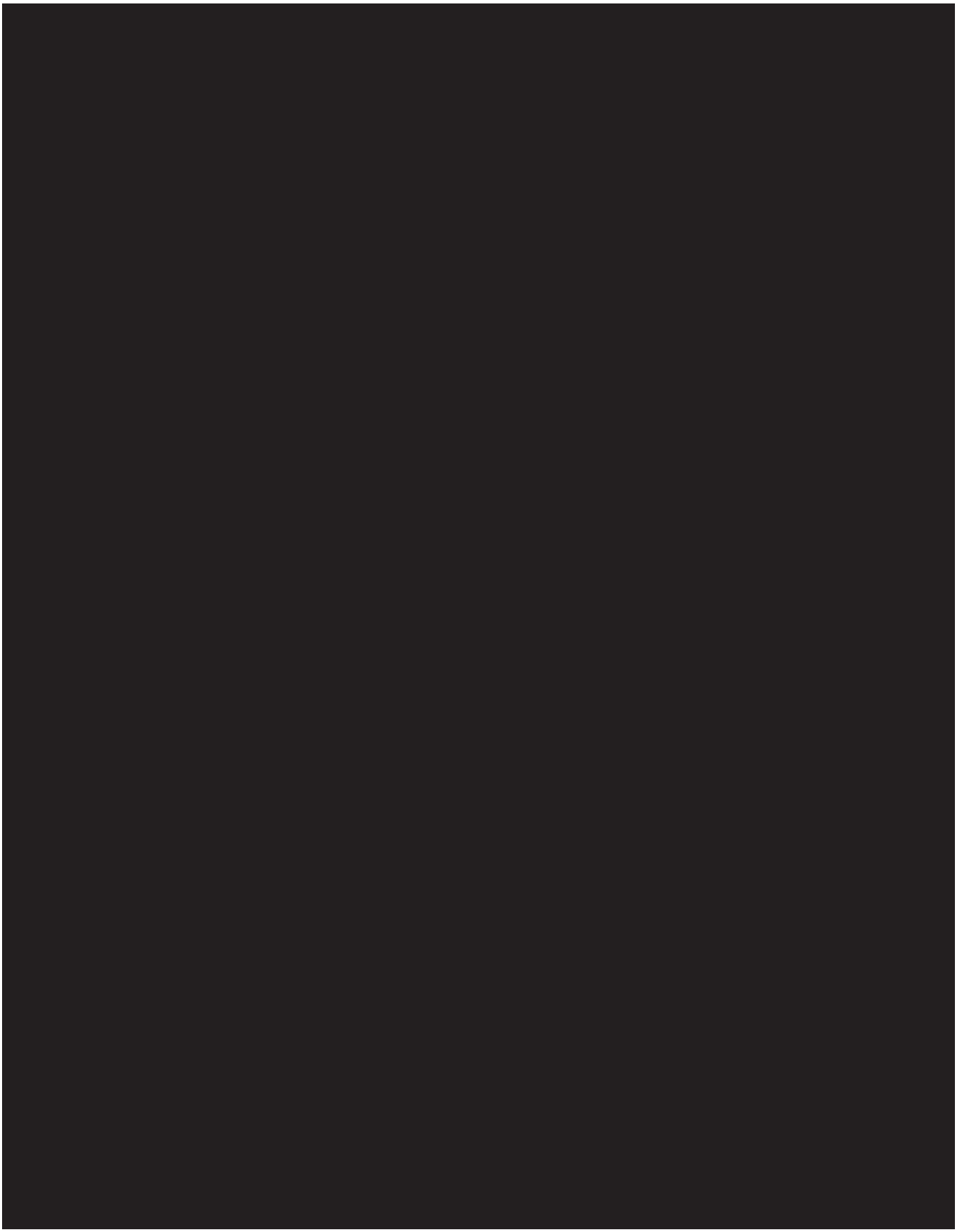


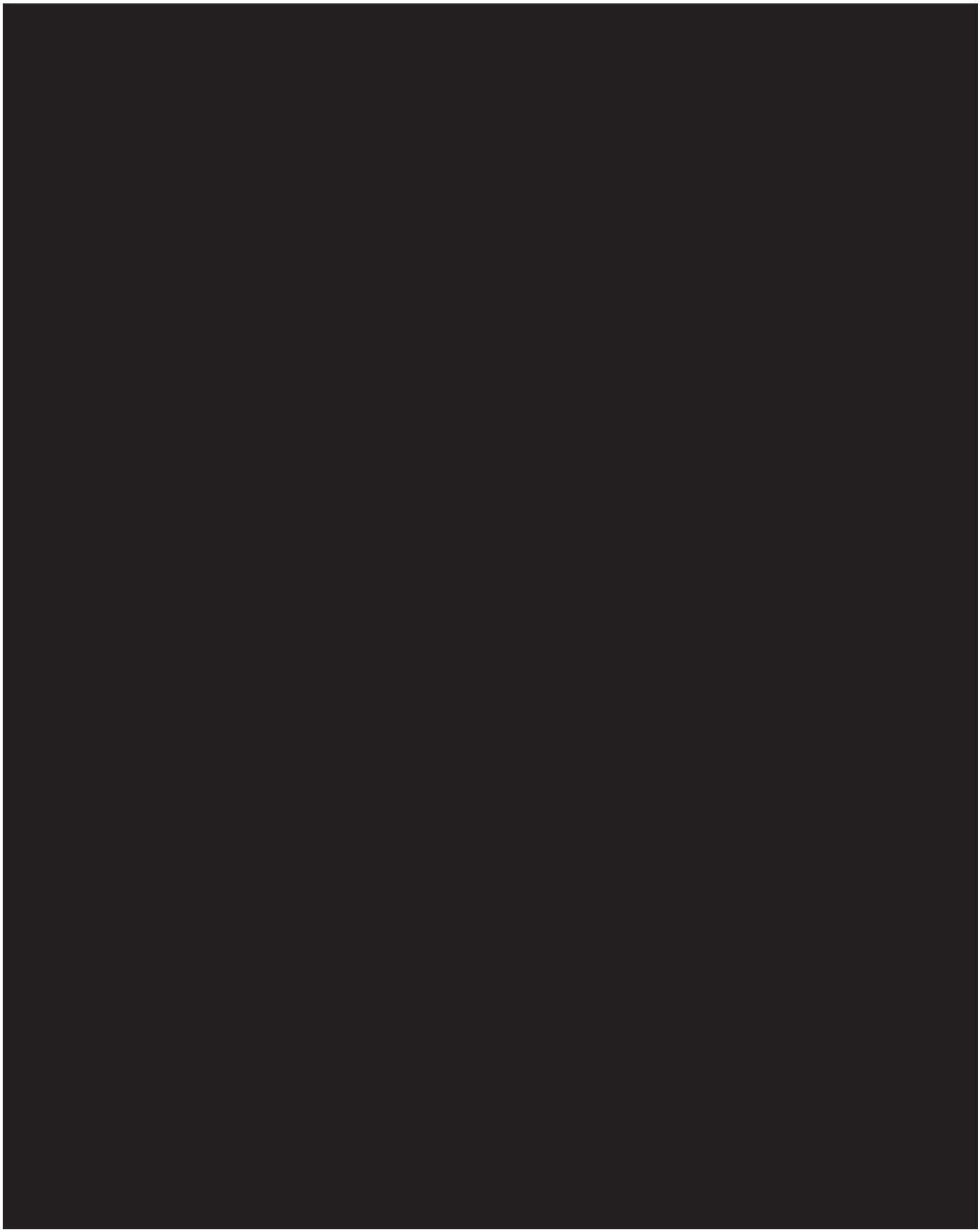
Primary Effectiveness Analyses

The primary effectiveness endpoint, associated with the above hypotheses, will be tested by generating a one-sided 95.1% upper confidence limit based on the mean paired difference (Clareon PanOptix Pro – Clareon PanOptix) using a one-sample t-test. The upper bound of the one-sided 95.1% confidence limit will be compared to the margin, 0.10 logMAR. If the upper bound is less than the margin, the null hypothesis will be rejected, and it will be concluded that Clareon PanOptix Pro is non-inferior to Clareon PanOptix for monocular photopic BCVDA at 4 m. The difference in means (Clareon PanOptix Pro minus Clareon PanOptix), standard error, and the associated one-sided 95.1% upper confidence limit will be presented.









[redacted]

4.2.1 Effectiveness Hypotheses

Primary Effectiveness

The null and alternative hypotheses to be evaluated in support of the primary noninferiority objective are as stated below:

$$H_0: \mu_D \geq \Delta$$
$$H_a: \mu_D < \Delta$$

where, Δ refers to the noninferiority margin, set at 0.1 logMAR, and μ_D refers to the mean of the difference between paired observations of each subject's eyes (test minus comparator) for monocular photopic BCDVA at 2 months post implantation.

[redacted]

[redacted]

4.2.2 Statistical Methods for Effectiveness Analyses

Table 4-2 summarizes the primary [redacted]. Supportive analyses using the BAS will be conducted only if the number of eyes excluded from the BAS exceeds 10% of the AAS.

Table 4-2 Sub-Study B - Summary of Analysis Strategy for Primary [redacted]

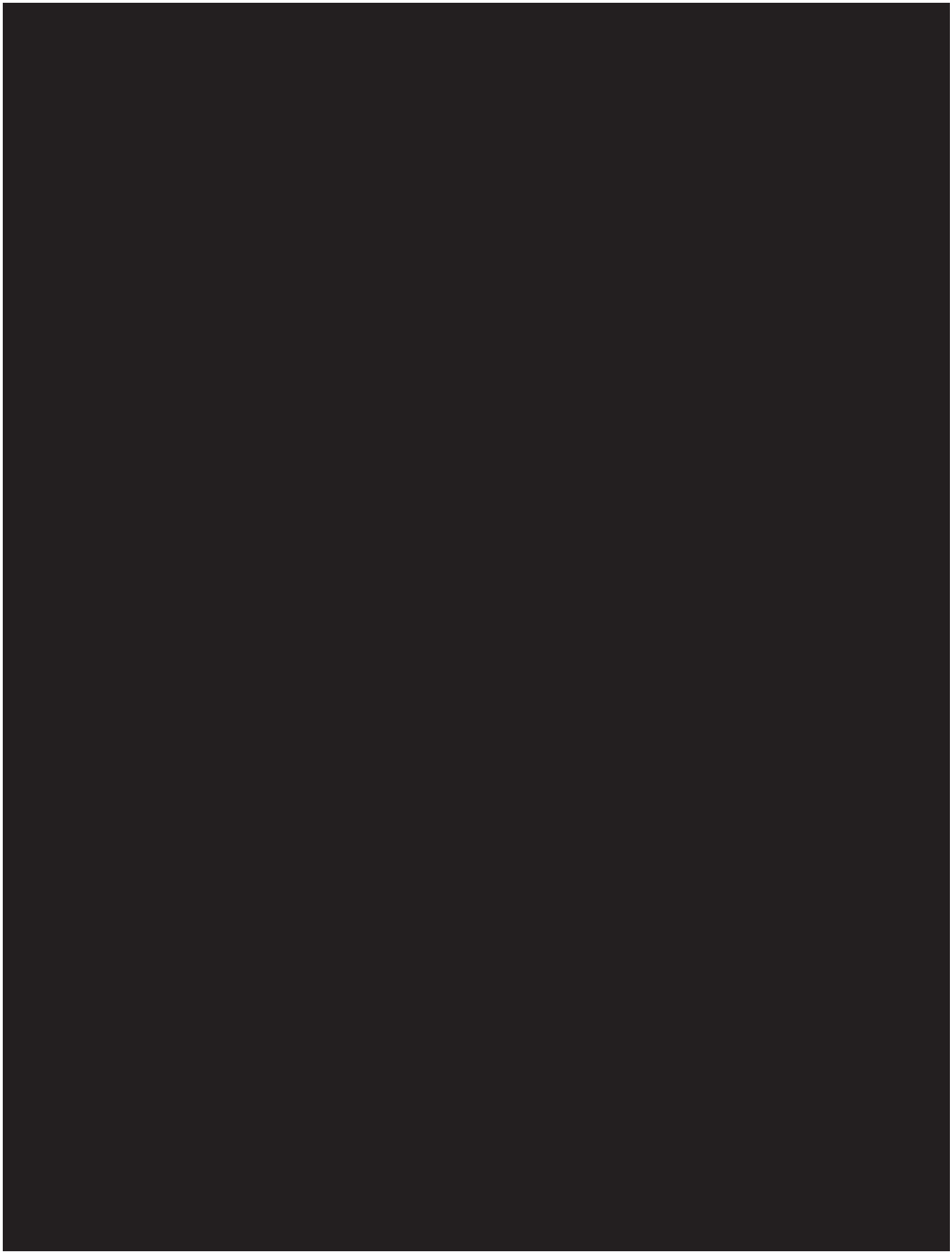
Endpoint	Main vs. Supportive Approach[a]	Comparison/ Statistical Method	Analysis Set	Missing Data Approach
Primary				
Mean monocular photopic BCDVA (logMAR) at 4 m at 2 months postoperative (Visit 3A)	M S	One-sample t-test for noninferiority	AAS BAS	Observed data only

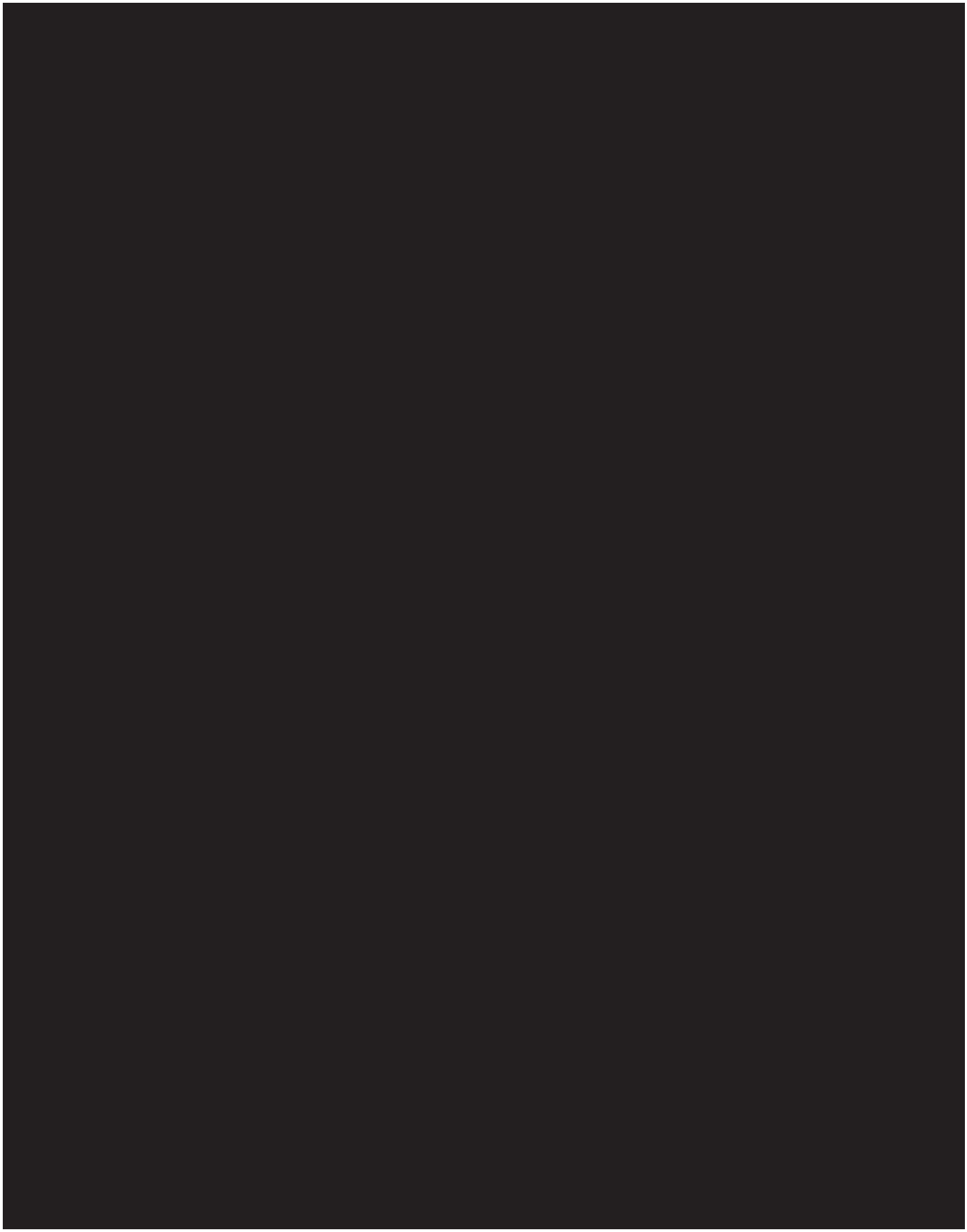
[redacted]

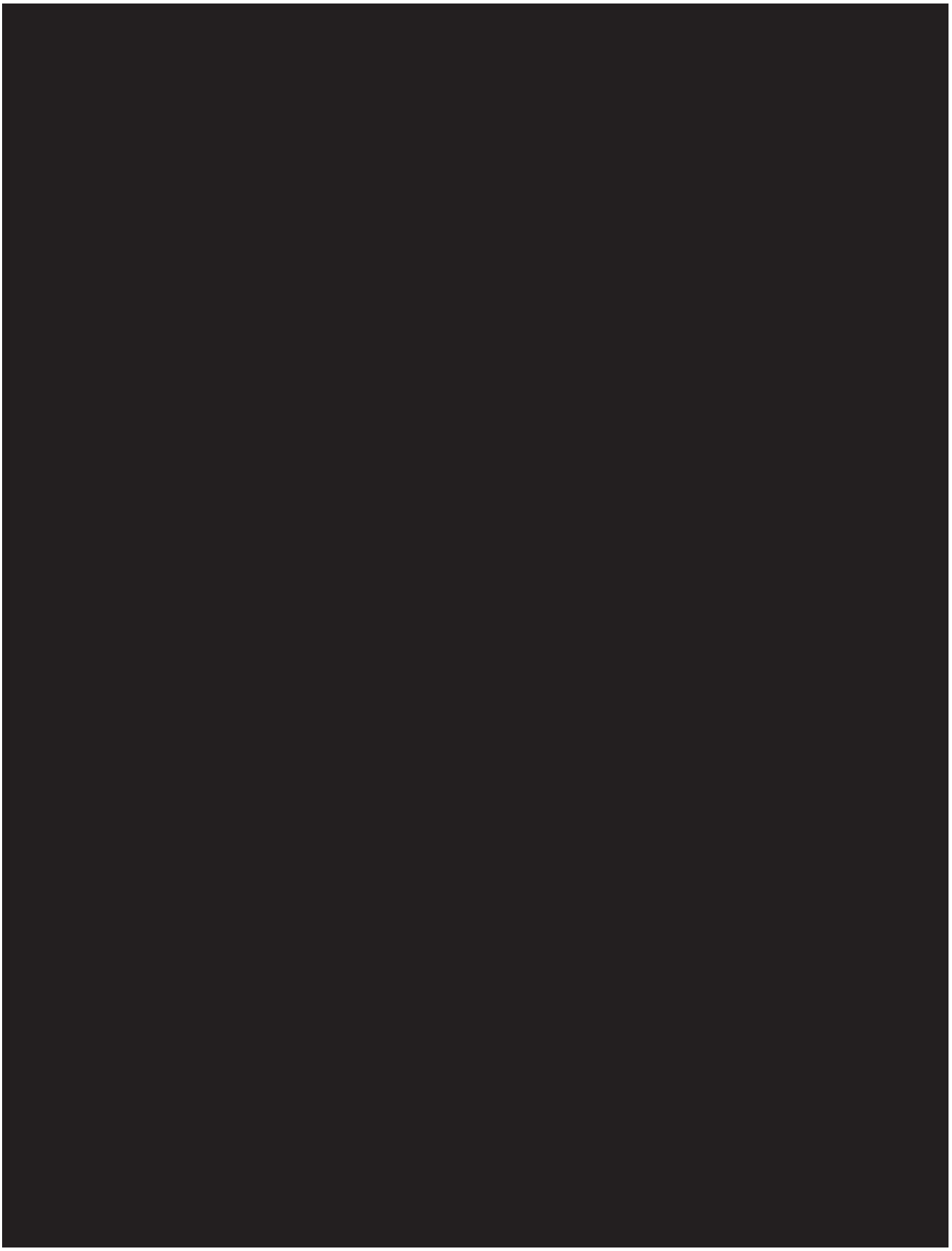
Primary Effectiveness Analyses

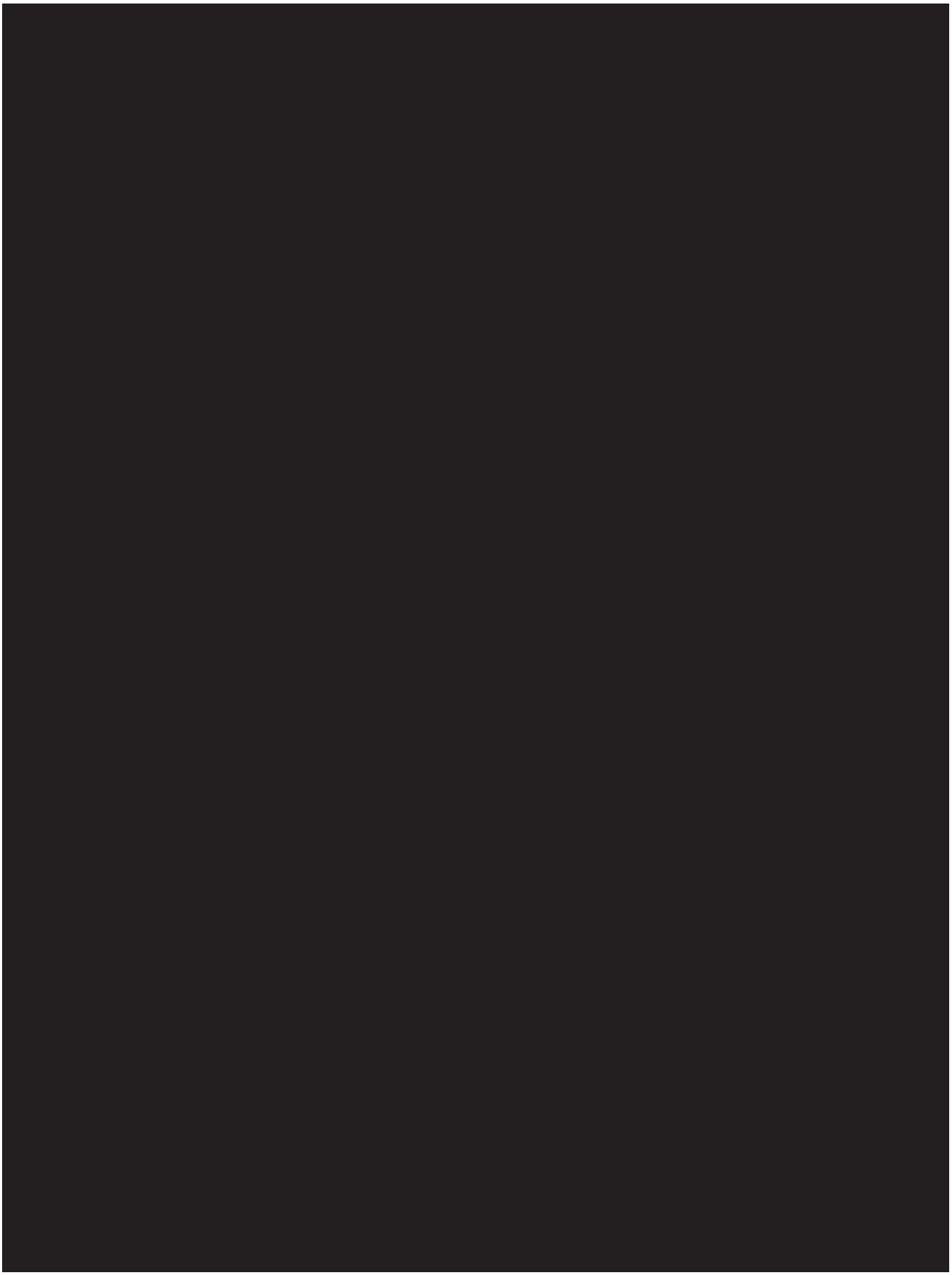
The primary effectiveness endpoint, associated with the above hypotheses, will be tested by generating a one-sided 95.1% upper confidence limit based on the mean paired difference (Clareon PanOptix Pro - Clareon PanOptix) using a one-sample t-test. The upper bound of the one-sided 95.1% confidence limit will be compared to the margin, 0.10 logMAR. If the upper bound is less than the margin, the null hypothesis will be rejected, and it will be concluded that Clareon PanOptix Pro is non-inferior to Clareon PanOptix for monocular photopic BCVDA at 4 m. The difference in means (Clareon PanOptix Pro minus Clareon PanOptix), standard error, and the associated one-sided 95.1% upper confidence limit will be presented.

[redacted]









4.5 Interim Analysis for Effectiveness

See Section 1.5 above.

5 SAFETY ANALYSIS STRATEGY – Sub-Study A and Sub-Study B

The safety objective for this study is to describe the incidence of ocular adverse events including secondary surgical interventions.

There are no safety hypotheses planned in this study. All safety endpoints will be summarized descriptively according to the type of parameter (i.e., whether the data were categorical or continuous) being analyzed. For categorical variables, the descriptive statistics will include number of observations, count in the category, and percent in the category. For continuous variables, the descriptive statistics will include number of observations, mean, median, standard deviation, minimum, and maximum. Confidence intervals will be provided as

applicable.

Unless otherwise specified, safety endpoints will be presented by lens model.

5.1 Safety Endpoints

The safety endpoints are:

- Adverse Events (AEs)
- Secondary surgical interventions (SSIs)
- Device deficiencies
- IOP
- Slit lamp examination findings including:
    - Proportion of eyes with subjective posterior capsular opacification (PCO)
    - Proportion of eyes with posterior capsulotomy
    - IOL observations
- Dilated fundus observation findings
- Intraoperative surgical problems
- Other procedures at surgery (combined and/or additional)

5.2 Safety Hypotheses

There are no formal safety hypotheses in this study. The focus of the safety analysis will be a comprehensive descriptive assessment of safety endpoints listed in Section 5.1.

5.3 Statistical Methods for Safety Analyses

Except otherwise stated, the analysis set for all safety analyses is the safety analysis set as defined in Section 2.2. Baseline will be defined as the last measurement prior to exposure to investigational product, except otherwise stated.

5.3.1 Adverse Events

The applicable definition of an AE is in the study protocol. All AEs occurring from when a subject signs informed consent to when a subject exits the study will be accounted for in the reporting.

Descriptive summaries (counts and percentages) for AEs will be presented by Preferred Term.

Adverse events will be summarized in the following tables:

1. Overall Summary of Treatment-Emergent Adverse Events
2. All Adverse Events (Serious and Nonserious Combined)
    a. Ocular
    b. Nonocular
3. All Serious Adverse Events (including Serious Adverse Device Effects)
    a. Ocular
    b. Nonocular
4. Subject Listings
    a. All Ocular
    b. All Nonocular

In addition, listings of AEs that occur after signing informed consent but prior to exposure to investigational product will be provided separately for ocular and nonocular AEs.

Secondary surgical interventions (SSIs) will be summarized descriptively (counts and percentages) and will be presented separately by lens model in each of the following categories:

- Any
- Related to IOL – due to optical properties
- Related to IOL – not due to optical properties
- Unrelated to IOL

Additionally, descriptive summaries (counts and percentages) for SSIs will be presented by Preferred Term. Confidence intervals/limits will be presented as applicable.

A listing of all SSIs will also be provided.

5.3.2 Device Deficiencies

The applicable definition of a device deficiency is in the study protocol. A frequency table showing counts for each Device Deficiency category, as well as eyes having any device deficiency, will be presented by lens model. In addition, a listing of all device deficiencies, as recorded on the Device Deficiency Form will be provided.

5.3.3 Intraocular Pressure

Intraocular pressure (IOP) measurements will be recorded in mmHg and rounded to the nearest whole mmHg. All analyses will be presented by lens model.

Descriptive summaries (number of observations, mean, median, standard deviation, minimum and maximum) of observed values will be presented at each visit (preoperative and all applicable postoperative scheduled visits).

In addition, a listing of all eyes with an increase or decrease in IOP of more than 10 mmHg at any visit (scheduled or unscheduled) compared to the same eye at baseline will be provided.

5.3.4 Slit Lamp Examination

For each slit lamp parameter as per the CRF, numbers and percentages of eyes that experience an abnormality at each scheduled visit will be presented by lens model.

A listing will be provided which presents all eyes with an abnormality in any slit lamp parameter at any postoperative visit. The listing will include all slit lamp examination data from all visits.

5.3.5 Subjective Posterior Capsule Opacification (PCO) Assessment

The number and percentage of eyes representing the maximum rating for an eye during the study will be tabulated by the response categories presented on the CRF (i.e., none, clinically nonsignificant, clinically significant, clinically significant requiring a YAG) and summarized by lens model. Similarly, eyes with a ‘worst case’ rating of clinically significant PCO or posterior capsulotomy (YAG) will be summarized by the response categories on the CRF.

A listing of eyes with clinically significant PCO, clinically significant PCO requiring YAG, or posterior capsulotomy will be presented which includes the PCO or capsulotomy results at all visits.

5.3.6 Posterior Capsulotomy

The number and percentage of eyes with posterior capsulotomy (overall and by reason) will be tabulated by lens model.

5.3.7 IOL Observations

The number and percentage of IOL observations reported at each scheduled visit will be tabulated by lens model. A listing of all IOL observations will also be provided.

5.3.8 Dilated Fundus Examination

For each dilated fundus parameter as per the CRF, numbers and percentages of eyes that experience abnormality at each scheduled visit will be presented by lens model.

A listing will be provided which presents all eyes with an abnormality in any fundus parameter at any postoperative visit. The listing will include all fundus examination data from all visits.

5.3.9 Surgical Problems

Descriptive statistics (numbers and percentages) on eyes with surgical problems as per the CRF (eg, anterior capsular tear) will be presented by lens model. In addition, a listing of subjects with surgical problems will be provided.

5.3.10 Other Procedures at Surgery

Descriptive statistics (numbers and percentages) on eyes with other surgical procedures as per the CRF (eg, anterior vitrectomy) will be presented by lens model. In addition, a listing of all other surgical procedures will be provided.

7 SAMPLE SIZE AND POWER CALCULATIONS

A total of 132 subjects will be randomized (approximately 66 per sub-study). Assuming a drop-out rate of 10%, approximately 60 subjects will be evaluable at 2 months post-operative period (visit 3A) for each sub-study. The power estimates for each of the planned analyses are presented below:

[redacted]

8 REFERENCES

9 REVISION HISTORY

This is the first revision (Version 2.0) of the Statistical Analysis Plan for this study.

[redacted]

10 APPENDIX

Table 10-1 Schedule of Study Procedures and Assessments

	Visit 0	Visit 00[b]	Visit 1	Visit 2	Visit 00A[c]	Visit 1A	Visit 2A	Visit 3A[d]	Visit 4A	USV[e]
Procedure/Assessment	Screening **Preoperative**	Day 0 **1st Eye Surgery**	Day 1-2 Post Visit 00	Day 7-14 Post Visit 00	Day 0 for **2nd Eye Surgery**	Day 1-2 Post Visit 00A	Day 7–14 Post visit 00A	Day 45-70 (2 Months) Post Visit 00A	Day 180-210 (6 Months) Post Visit 00A	Unscheduled Visit
Informed Consent	X									
Demographics	X									
Medical History	X									
Concomitant Medications	X	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test[a*]	X									
Inclusion/Exclusion criteria	X	X			X					
Slit lamp Exam	X[h]		X	X		X	X	X	X	(X)
Dilated fundus examination	X[h]								X	(X)
Keratometry	X[h]									
Axial length	X[h]									
Anterior Chamber Depth	X[h]									
Target Residual Refractive Error	X[h]									
Predicted Residual Astigmatism	X[h]									
Intraocular pressure	X		X	X		X	X	X	X	(X)

[redacted]

	Visit 0	Visit 00[b]	Visit 1	Visit 2	Visit 00A[c]	Visit 1A	Visit 2A	Visit 3A[d]	Visit 4A	USV[e]
Procedure/Assessment	Screening **Preoperative**	Day 0 **1st Eye Surgery**	Day 1-2 Post Visit 00	Day 7-14 Post Visit 00	Day 0 for **2nd Eye Surgery**	Day 1-2 Post Visit 00A	Day 7–14 Post visit 00A	Day 45-70 (2 Months) Post Visit 00A	Day 180-210 (6 Months) Post Visit 00A	Unscheduled Visit
[redacted]										

	Visit 0	Visit 00[b]	Visit 1	Visit 2	Visit 00A[c]	Visit 1A	Visit 2A	Visit 3A[d]	Visit 4A	USV[e]
Procedure/Assessment	Screening **Preoperative**	Day 0 **1st Eye Surgery**	Day 1-2 Post Visit 00	Day 7-14 Post Visit 00	Day 0 for **2nd Eye Surgery**	Day 1-2 Post Visit 00A	Day 7–14 Post visit 00A	Day 45-70 (2 Months) Post Visit 00A	Day 180-210 (6 Months) Post Visit 00A	Unscheduled Visit
Subjective Posterior Capsule Opacification			X	X		X	X	X	X	(X)
Nd:YAG capsulotomy[i]			(X)	(X)		(X)	(X)	(X)	(X)	(X)
IOL observations			X	X		X	X	X	X	(X)
Secondary Surgical Interventions		X	X	X	X	X	X	X	X	(X)
Randomization	X[j]									
Device Deficiencies		X	X	X	X	X	X	X	X	X
Adverse Events (including SSI), both volunteered and elicited	X	X	X	X	X	X	X	X	X	X

a. In women of child-bearing potential only
b. It is recommended that Visit 00 (1st eye surgery) occur within 14 days of the Screening Visit (Visit 0).
c. It is recommended that Visit 00A (2nd eye surgery) occur a minimum of 7 days and a maximum of 14 days after Visit 00 (1st eye surgery).
d. If necessary, Visit 3A may be completed over 2 days within a two week period. Visit 3A must be completed within the specified window.
e. Unscheduled Visit: Assessments marked as (X) are optional as per the investigator's discretion.
f. In the surgical eye that is applicable to the visit
g. Unscheduled Visit: [redacted] monocular photopic BCDVA done using the standard of care method (e.g., Snellen, LogMAR).
h. Historical data collected prior to informed consent and within 60 days of Screening (Visit 0), may be used if collected per study requirements.
i. (X): Procedure performed as necessary.
j. Randomization must occur after confirmation of eligibility and prior to 1st eye surgery.
*Documented in source document only. No entry into database