Short Title:

Statistical Analysis Plan
ILI875-P001 / NCT04098367

Full Title:

Statistical Analysis Plan
ILI875-P001

Protocol Title:	A Prospective, Randomized, Controlled, Multi-Center Clinical Investigation of the AcrySof IQ Vivity Extended Vision IOL vs. TECNIS Symfony and AT LARA Extended Depth of Focus IOLs
[redacted]	[redacted]
Protocol TDOC Number:	TDOC-0056186
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]

Job Notes:

This is the first amendment (Version 2.0) of the Statistical Analysis Plan for this study. This version of the Statistical Analysis Plan is based on Version 2.0 of the study protocol, effective 18-Feb-2020.

The purpose of this statistical analysis plan (SAP) is to describe the related procedures and methodologies to be used for statistical analyses outlined in protocol ILI875-P001. This SAP should be read in conjunction with the latest version of the designated study protocol and its Case Report Forms (CRF) and Tables, Figures and Listing (TFL) shells.

Executive Summary:

Key Objectives

The primary study objective is to demonstrate superiority of ACRYSOF® IQ VIVITY over SYMFONY® or over AT LARA® for the proportion of subjects responding "not bothered at all" by halos on the QUVID questionnaire (Q2.3) at 3 months post bilateral implantation.

Decision Criteria for Study Success:

Primary effectiveness will be considered supported if VIVITY demonstrates a superior proportion of subjects responding "not bothered at all" by halos on the QUVID questionnaire at 3 months post implantation of at least one of the two independent hypothesis tests (VIVITY vs. SYMFONY and/or VIVITY vs. AT LARA).

Table of Contents

1 Study Objectives and Design

1.1 Study Objectives

Primary Study Objective

The primary study objective is to demonstrate superiority of VIVITY over SYMFONY or over AT LARA for the proportion of subjects responding "not bothered at all" by halos on the QUVID questionnaire (Q2.3) at 3 months post bilateral implantation.

Secondary Study Objectives

The secondary study objectives are:

- To demonstrate superiority of VIVITY over SYMFONY or over AT LARA for the proportion of subjects responding "not bothered at all" by glare on the QUVID questionnaire (Q3.3) at 3 months post bilateral implantation.
- To demonstrate superiority of VIVITY over SYMFONY or over AT LARA for the proportion of subjects responding "not bothered at all" by starbursts on the QUVID questionnaire (Q1.3) at 3 months post bilateral implantation.

[redacted]

[redacted]

Safety Objective

The safety objective is to assess safety parameters out to 6 months post bilateral implantation.

1.2 Study Description

This is a post-market, prospective, multi-center, randomized, parallel group, controlled, assessor and subject-masked, bilateral implant study. Eligible subjects will be randomly assigned in a 1:1:1 ratio to receive either VIVITY Extended Vision IOL Model DFT015 (test article) or TECNIS SYMFONY Extended Range of Vision IOL Model ZXR00 (control article), or AT LARA extended depth of focus IOL Model 829MP (control article) in both eyes. Subjects and site assessors will be masked to subject treatment assignment until the end of the study.

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

[redacted]

Approximately 218 bilaterally implanted subjects will be enrolled (consented) at up to 14 sites in Australia and New Zealand to achieve 180 subjects who complete the study, with a target of 9-24 subjects enrolled per site. Site-specific targets may vary based upon individual site capabilities. Estimated time needed to recruit subjects for the study is approximately 6 months.

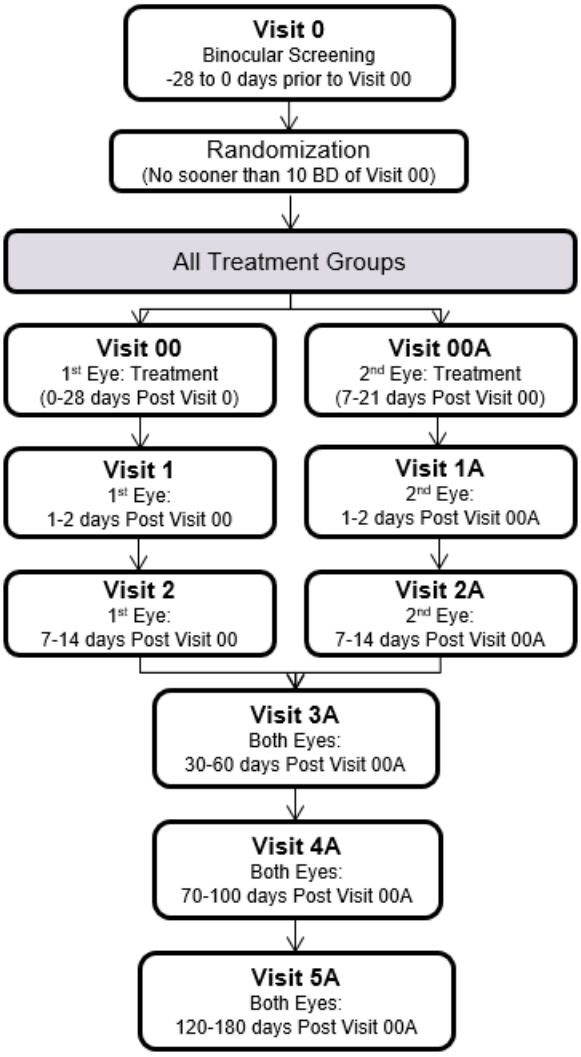
The planned number of evaluable completed subjects per each treatment group is:

- 60 Bilateral VIVITY
- 60 Bilateral SYMFONY
- 60 Bilateral AT LARA

[redacted]

The study design is illustrated in Figure 1-1 of the study protocol as follows:

Figure 1–1 Study Design Diagram



1.3 Randomization

Subjects will be randomized in a 1:1:1 ratio to receive treatment with the VIVITY or the SYMFONY or the AT LARA IOLs, respectively. Randomization will be stratified by site.

Only after signing the ICF, will a subject be assigned a subject number by the electronic data capture (EDC) system. If all eligibility criteria are met and the subject desires to continue in the study, randomization will proceed.

No sooner than 10 business days of Visit 00, each eligible subject will be randomized to one of the treatment arms. Subjects will be assigned treatment according to the randomization list

contained within the EDC system and the corresponding treatment assignment will be communicated to the unmasked site user.

1.4 Masking

This study is effectiveness assessor and subject masked. Subjects will be randomized for bilateral implantation with one of the three studied IOLs. The effectiveness assessor and subject masking will be maintained throughout the conduct of the study until all study data is validated and final database lock occurs.

2 Analysis Sets

2.1 Efficacy Analysis Sets

The primary analysis set for effectiveness analyses will be the All-Implanted Analysis Set (AAS). AAS includes all randomized eyes with successful study IOL implantation.

All effectiveness analyses will be conducted according to actual IOL implanted.

[redacted]

2.3 Safety Analysis Set

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

All analyses at the eye-level endpoints (such as ocular adverse events) will be presented separately for first implanted eyes and second implanted eyes. While analyses at the subject-level endpoints (such as non-ocular 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 IOL implanted (or attempted to implant).

3 Subject Characteristics and Study Conduct Summaries

Subject characteristics and study conduct summaries include tables and listings such as a subject disposition table, demographics and baseline characteristics tables (including age, gender, race), listing of treatment assignments by site, summary of screen failures by reason, and listing of subjects/eyes excluded from the analysis sets including reasons.

All summary statistics will be based on the type of variable. For categorical variables (eg, sex, race), summary statistics will include sample size, number in category, and % in each category. For continuous variables (eg, age, axial length), number of subjects/eyes, mean, median, standard deviation, minimum and maximum will be reported. Tables will be presented by treatment and overall.

[redacted]

3.1 Subject Disposition

A subject disposition table will be presented that displays the number of subjects enrolled in addition to the number of screen failures, as well as the number subjects treated, completed, and discontinued. This table will also contain counts for each reason for premature study discontinuation. A corresponding listing of reasons for early study discontinuation will also be provided.

3.2 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized by the number and percentage of subjects/eyes for the categorical variables and descriptive statistics for the continuous variables.

4 Efficacy Analysis Strategy

A success on the primary effectiveness endpoint would be indicated by successful outcome on at least one of the two independent hypothesis tests (VIVITY vs. SYMFONY and/or

VIVITY vs. AT LARA). There are two independent hypotheses for each effectiveness endpoint for comparisons between 1) VIVITY vs. SYMFONY, and 2) VIVITY vs. AT LARA. There will be no comparison between the two non-Alcon comparators. The family-wise alpha of 0.05, two-sided, will be expensed equally between the two hypothesis tests, 0.025, two-sided, for each comparator.

For each VIVITY comparison between the two non-Alcon IOLs, hypothesis tests to evaluate statistical significance of the secondary effectiveness endpoints will be conducted only after a successful outcome on the primary endpoint for that IOL comparison is demonstrated. The Type I error for comparison against each comparator lens will be maintained at the 0.025, two-sided, level using a step down approach described in Section 4.4.

4.1 Efficacy Endpoints

Primary Endpoint:

- Percentage of subjects not bothered at all by halos (on the QUVID questionnaire Q2.3) at 3 months post-implantation.

Secondary Endpoints:

- Percentage of subjects not bothered at all by glare (on the QUVID questionnaire Q3.3) at 3 months post-implantation.

- Percentage of subjects not bothered at all by starbursts (on the QUVID questionnaire Q1.3) at 3 months post-implantation.

[redacted]

[redacted]

[redacted]

4.2 Efficacy Hypotheses

4.2.1 Primary Effectiveness Hypotheses

The primary effectiveness objective is to demonstrate the superiority of VIVITY to SYMFONY or AT LARA in % of subjects not bothered at all by halos at 3 months post bilateral implantation.

The null and alternative hypotheses in support of the primary effectiveness objective are:

H_0: $p_{Vivity} \leq p_{Comparator}$
H_A: $p_{Vivity} > p_{Comparator}$

Where p_{Vivity} and $p_{Comparator}$ refer to the percent of subjects not bothered at all by halos in the VIVITY group and the comparator groups respectively. The two comparator groups are SYMFONY and AT LARA.

4.2.2 Secondary Effectiveness Hypotheses

The secondary effectiveness objectives are to demonstrate the superiority of VIVITY to SYMFONY or AT LARA in:

1) % of subjects not bothered at all by glare at 3 months post bilateral implantation
2) % of subjects not bothered at all by starbursts at 3 months post bilateral implantation

If the primary null hypothesis is rejected for either or both comparisons to VIVITY, the following null and alternative hypotheses in support of the secondary effectiveness objectives will be tested independently for each comparator (if applicable) in the order of glare, then starburst, if glare is successful:

H_0: $p_{Vivity} \leq p_{Comparator}$
H_A: $p_{Vivity} > p_{Comparator}$

Where p_{Vivity} and $p_{Comparator}$ refer to the percent of subjects not bothered at all by glare (then starbursts in a step down manner) in the VIVITY group and the comparator groups respectively. The two comparator groups are SYMFONY and AT LARA.

[redacted]

4.3 Statistical Methods for Efficacy Analyses

To account for multiplicity, two sets of three hypotheses will be tested independently (eg, VIVITY vs. SYMFONY; and VIVITY vs. AT LARA) in sequence: primary hypothesis, followed by the first secondary hypothesis, followed by the second secondary hypothesis. The primary effectiveness objective is considered met if at least one pairwise comparison of the primary hypothesis is met. The type I error for each superiority test is 2.5% (2-sided). Each of the secondary hypotheses will be tested at 2.5% (2- sided).

4.3.1 Primary Effectiveness Analyses

The superiority hypothesis for each comparator will be evaluated using the Miettinen-Nurminen method (1985). The superiority hypothesis will be deemed supported if the lower limit of the two-sided 97.5% confidence interval exceeds zero. Primary analysis will be based on AAS. [redacted]

Success on the primary effectiveness hypothesis test will be concluded independently between VIVITY and SYMFONY, and between VIVITY and AT LARA.

[redacted]

4.3.2 Secondary Effectiveness Analyses

For each comparator, if the primary effectiveness hypothesis is not successful, no hypothesis test for secondary effectiveness endpoints will be further conducted for that comparator. If the primary effectiveness hypothesis is successful, hypotheses for glare will first be tested. If the hypothesis for glare is successful, the hypothesis for starbursts will be tested.

The superiority hypothesis for each comparator will be evaluated using the Miettinen-Nurminen method (1985). The superiority hypothesis will be deemed supported if the lower limit of the two-sided 97.5% confidence interval exceeds zero. Main analysis will be based on AAS. [redacted]

Success on the secondary hypothesis tests, sequentially for glare then starbursts, will be concluded independently for between VIVITY and SYMFONY, and between VIVITY and AT LARA.

[redacted]

[redacted]

4.3.3.6 % of Subjects Responding by Category to QUVID Questionnaire Items (3 and 6 months)

For AAS, the number and percentages of subjects in each category of responses to each question on the QUVID questionnaire will be reported by treatment group at each visit this questionnaire is administered.

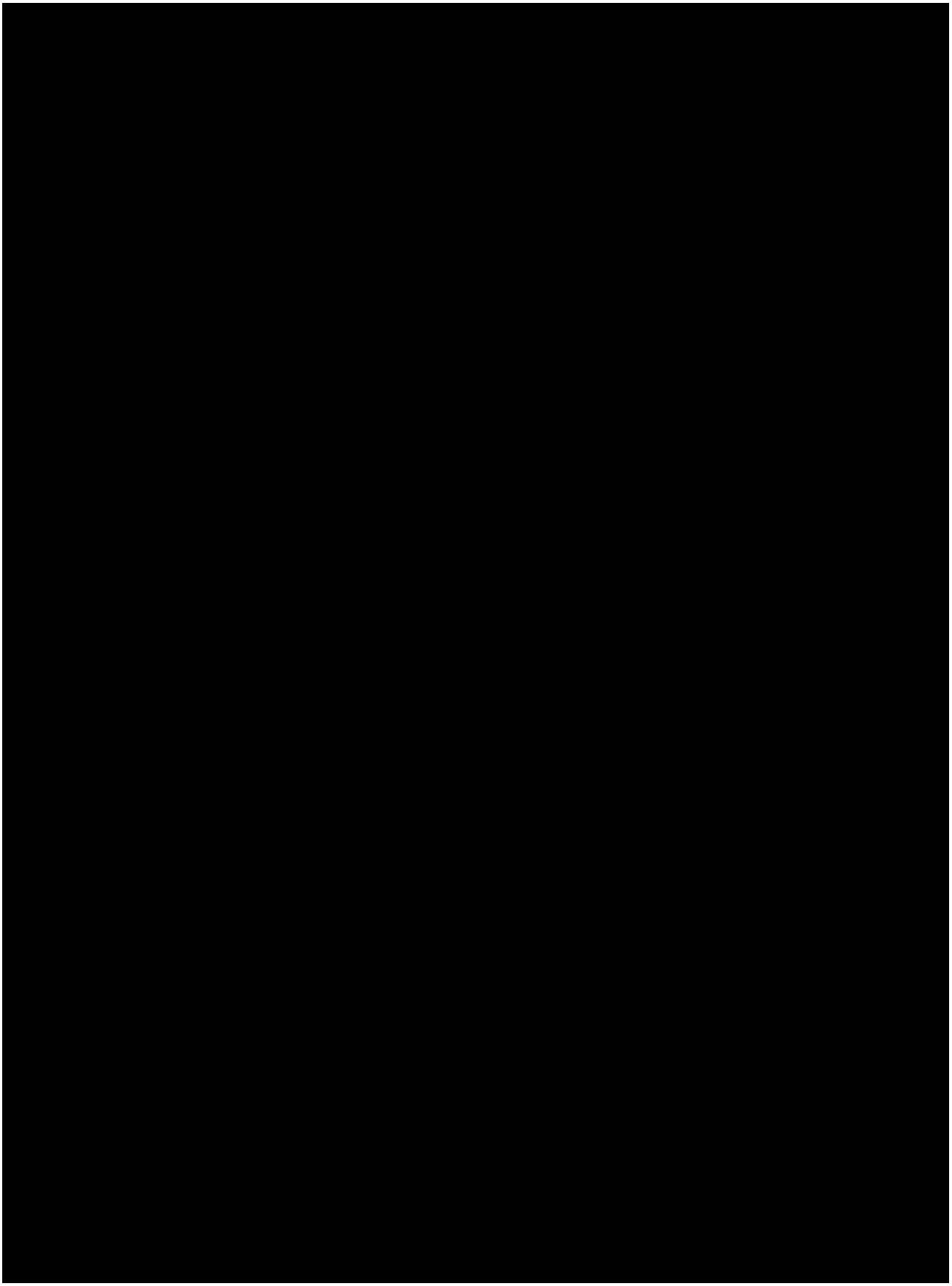
[redacted]

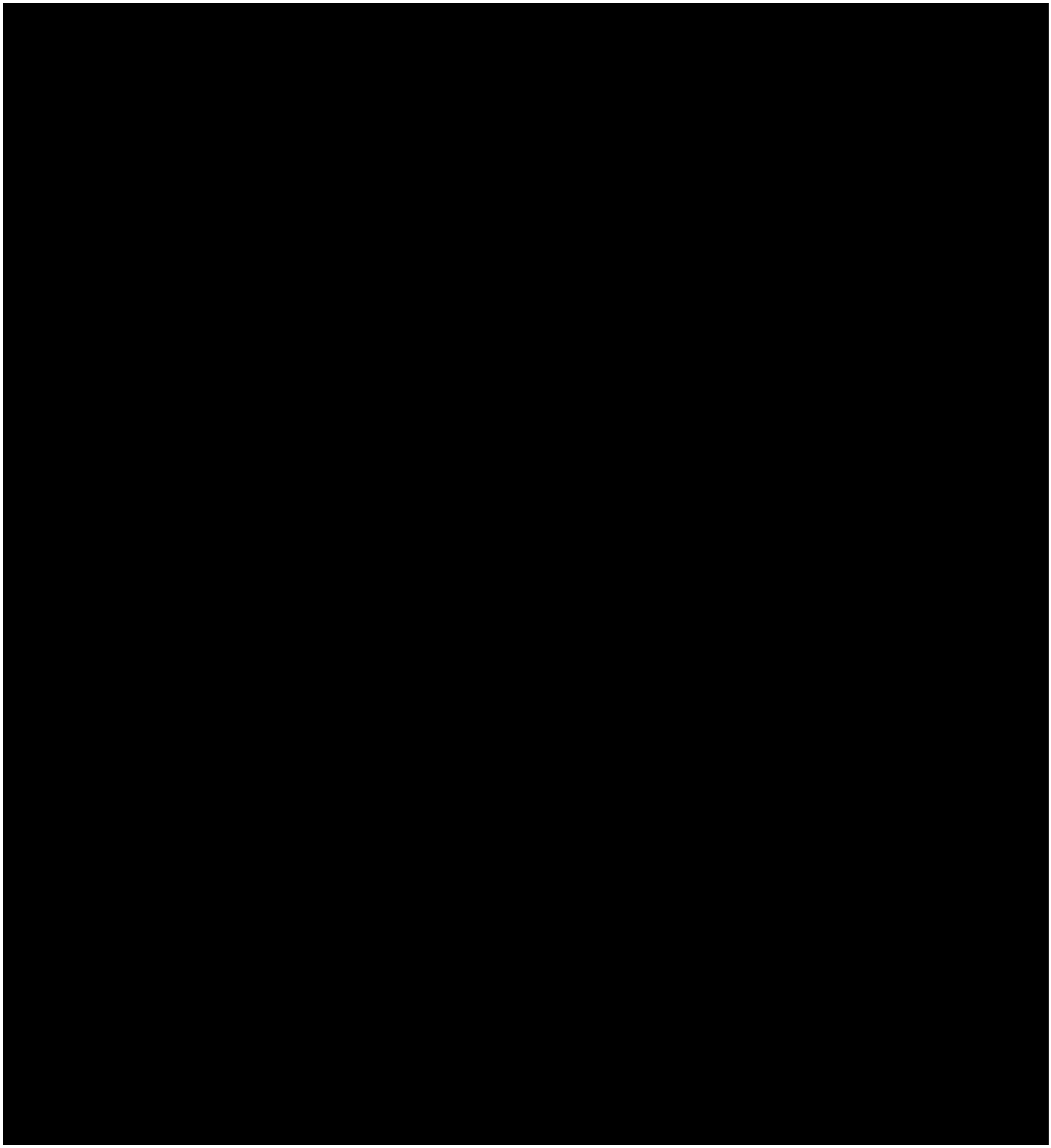
[redacted]

Table 4-1 summarizes the key effectiveness analyses.

Table 4–1 Summary of Analysis Strategy for Key Effectiveness Endpoints

Endpoint	Main vs. Sensitivity Approach[a]	Statistical Method[b]	Analysis Set	Missing Data Approach
Primary				
Percentage of subjects not bothered at all by halo (on the QUVID questionnaire Q2.3) at 3 months	M	Miettinen-Nurminen method	AAS	Observed data only
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Secondary				
Percentage of subjects not bothered at all by glare (on the QUVID questionnaire Q3.3) at 3 months	M	Miettinen-Nurminen method	AAS	Observed data only
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Percentage of subjects not bothered at all by starbursts (on the QUVID questionnaire Q1.3) at 3 months	M	Miettinen-Nurminen method	AAS	Observed data only
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				





4.6 Handling of Missing Data

There be no imputation for missing data. The influence of missing data is expected to be minimal.

5 Safety Analysis Strategy

5.1 Safety Endpoints

Safety endpoints are:

- Adverse events including SSIs
- Device deficiencies
- IOP (clinically significant change)
- Slit lamp exam findings
- Dilated fundus exam findings
- IOL observations including IOL tilt/decentration
- Subjective PCO assessment
- Posterior capsulotomy
- Intraoperative surgical problems
- Other procedures at surgery (combined and/or additional).

5.2 Safety Hypotheses

There are no formal safety hypotheses for this study.

5.3 Statistical Methods for Safety Analyses

The focus of the safety analysis will be a comprehensive descriptive assessment of safety endpoints listed in Section 5.1. Except otherwise stated, the analysis set for all safety analyses is the safety analysis set as defined in Section 2.3. Baseline will be defined as the last measurement prior to exposure to investigational product, except otherwise stated.

5.3.1 Adverse Events

The number and percentage of all ocular adverse events will be tabulated by preferred term with a breakdown by treatment, separately for first, second and all eyes. An eye with multiple ocular AEs of the same preferred term is only counted once toward the total of this preferred term.

Adverse events will be summarized in the following tables, by treatment group:

1. All Adverse Events (Serious and Non-Serious Combined)
    a. Ocular
    b. Nonocular

2. All Adverse Device Effects
    a. Ocular
    b. Nonocular

3. All Serious Adverse Events (including Serious Adverse Device Effects)
    a. Ocular
    b. Nonocular

3. Subject Listings
    a. Non-serious Ocular
    b. Non-serious Nonocular
    c. Serious Ocular
    b. Serious Nonocular

All ocular tables will be presented separately for first and second implanted eyes.

In addition, listings of adverse events will be provided. The listings will include the following variables: treatment, site, subject, eye, days from surgery, duration, adverse event description, causality, severity, seriousness, outcome and preferred term.

5.3.2 Secondary Surgical Interventions

Descriptive summaries (counts, percentages, and two-sided 95% exact confidence intervals) of secondary surgical interventions (SSIs) will for presented for each treatment group and the difference between the groups, separately for first and second implanted eyes in each of the following categories:

1. Related to IOL – due to optical properties
2. Related to IOL – not due to optical properties
3. Unrelated to IOL
4. Overall

A listing of all SSIs will be also be presented.

[redacted]

[redacted]

5.3.3 Device Deficiencies

The applicable definition of a device deficiency is in the study protocol. The number and percentage of all device deficiencies will be tabulated with a breakdown by treatment group and implanted eye. A listing of all device deficiencies will also be provided.

5.3.4 Intraocular Pressure

Intraocular pressure (IOP) measurements will be recorded in mmHg and rounded to the nearest whole mmHg. All analyses will be presented by treatment group, separately for first and second operative eyes.

Descriptive summaries (n, mean, median, standard deviation, minimum, maximum and 95% (two-sided) confidence interval) of observed values and change from baseline values will be presented at each study visit by treatment group, separately for first and second implanted eyes.

A listing will be provided which presents all eyes with an increase or decrease in IOP of more than 10 mmHg at any visit compared to the same eye at baseline. The listing will include the following variables: treatment, site, subject, age, sex, eye, visit, days from surgery, baseline value, value at the visit, and a change from baseline value.

5.3.5 Slit Lamp Examination Findings

For each slit-lamp parameter, number and percentages of eyes that experience abnormality at any post-operative visit will be presented by treatment group, separately for first and second implanted eyes.

A listing will be provided which presents all eyes with an abnormality in any slit-lamp parameter at any post bilateral implantation visit. The listing will include all slit-lamp data from all visits with the following variables: treatment, site, subject, age, sex, eye, parameter, visit, baseline value, and value at the visit.

5.3.6 Dilated Fundus Exam Findings

For each dilated fundus parameter, number and percentages of eyes that experience abnormality at any post-operative scheduled and unscheduled visit will be presented by treatment group, separately for first and second implanted eyes.

A listing will be provided which presents all eyes with abnormality in any fundus parameter at any post-operative visit. The listing will include the following variables: treatment, site, subject, age, sex, visit, days from surgery, eye, baseline value and value at the visit.

5.3.7 IOL Observations

IOL observations will be summarized by treatment group using descriptive statistics, including frequency and percent of eyes, by treatment group, separately for first and second implanted eyes, at each scheduled and unscheduled visit where the data were collected.

5.3.8 IOL Position Change (Tilt/Decentration)

Descriptive statistics (number and percentages) on eyes with a change from last visit in IOL position category (Tilted, Decentered) will be presented by treatment group, separately for first and second implanted eyes.

In addition, a listing of eyes with IOL position change will be provided. The listing will include the following variables: treatment, site, subject, age, sex, visit, days from surgery, eye and amount of tilting or decentration.

5.3.9 Subjective Posterior Capsule Opacification (PCO) Assessment

Subjective posterior capsule opacification will be summarized using descriptive statistics, including number and percent of eyes, at each scheduled and unscheduled visit where the data were collected, by treatment group, separately for first and second implanted eyes.

A listing of eyes with clinically significant posterior capsule opacification, clinically significant posterior capsule opacification requiring YAG or posterior capsulotomy will be presented which includes the posterior capsule opacification or capsulotomy values at all visits. The listing will include the following variables: treatment, site, subject, age, sex, visit, days from surgery, eye and posterior capsule opacification or capsulotomy value at the visit.

5.3.10 Posterior Capsulotomy

An incidence table of eyes with posterior capsulotomy will be tabulated with a breakdown by treatment group, separately for first and second implanted eyes.

5.3.11 Intraoperative Surgical Problems

Descriptive statistics (numbers and percentages) on eyes with surgical problems will be presented, separately for first and second implanted eyes.

In addition, a listing of subjects with surgical problems will be provided. The listing will include the following variables: treatment, site, subject, age, sex, eye, and description of surgical problem.

5.3.12 Other Procedures at Surgery (Combined and/or Additional)

A listing of all other surgical procedures will be provided. The listing will include the following variables: treatment, site, subject, age, sex, eye, and type of other surgical procedure.

7 Sample Size and Power Calculations

Approximately 218 subjects will be enrolled to achieve 180 subjects who complete the study.

10 Appendix

Table 10–1 Schedule of Study Procedures and Assessments

Visit	Visit 0	Visit 00	Visit 1	Visit 2	Visit 00A	Visit 1A	Visit 2A	Visit 3A	Visit 4A[1]	Visit 5A	Unscheduled visit
Eye	Both Eyes	1st Eye	1st Eye	1st Eye	2nd Eye	2nd Eye	2nd Eye	Both Eyes	Both Eyes	Both Eyes	N/A
Day Number	Day -28 to 0	Day 0	Day 1-2 Post Visit 00	Day 7-14 Post Visit 00	Day 7-21 Post Visit 00	Day 1-2 Post Visit 00A	Day 7-14 Post Visit 00A	Day 30-60 Post Visit 00A	Day 70-100 Post Visit 00A	Day 120-180 Post Visit 00A	N/A
General Assessments and Procedures											
Informed Consent	X										
Demographics	X										
Medical History	X										
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X
Inclusion/Exclusion	X										
Urine Pregnancy Test[2]	X										
Ophthalmic Assessments											
Questionnaires											
• QUVID (for visual disturbance)	X							X	X	X	
[redacted]	[redacted]							[redacted]	[redacted]		
[redacted]								[redacted]	[redacted]		

Visit	**Visit 0**	**Visit 00**	**Visit 1**	**Visit 2**	**Visit 00A**	**Visit 1A**	**Visit 2A**	**Visit 3A**	**Visit 4A[1]**	**Visit 5A**	**Unscheduled visit**
Eye	**Both Eyes**	**1st Eye**	**1st Eye**	**1st Eye**	**2nd Eye**	**2nd Eye**	**2nd Eye**	**Both Eyes**	**Both Eyes**	**Both Eyes**	**N/A**
Day Number	**Day -28 to 0**	**Day 0**	**Day 1-2** Post Visit 00	**Day 7-14** Post Visit 00	**Day 7-21** Post Visit 00	**Day 1-2** Post Visit 00A	**Day 7-14** Post Visit 00A	**Day 30-60** Post Visit 00A	**Day 70-100** Post Visit 00A	**Day 120-180** Post Visit 00A	**N/A**
[redacted]	[redacted]							[redacted]	[redacted]		
Biometry (collect all available measurements including ACD, AL, keratometry, corneal thickness, crystalline lens thickness, white-to-white)	X								X		
Manifest Refraction	X			X			X	X	X	X	(✓)
[redacted]											
[redacted]									[redacted]		
[redacted]	[redacted]			[redacted]			[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]									[redacted]		
[redacted]											
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]											

Visit	**Visit 0**	**Visit 00**	**Visit 1**	**Visit 2**	**Visit 00A**	**Visit 1A**	**Visit 2A**	**Visit 3A**	**Visit 4A[1]**	**Visit 5A**	**Unscheduled visit**
Eye	**Both Eyes**	**1st Eye**	**1st Eye**	**1st Eye**	**2nd Eye**	**2nd Eye**	**2nd Eye**	**Both Eyes**	**Both Eyes**	**Both Eyes**	**N/A**
Day Number	**Day -28 to 0**	**Day 0**	**Day 1-2** Post Visit 00	**Day 7-14** Post Visit 00	**Day 7-21** Post Visit 00	**Day 1-2** Post Visit 00A	**Day 7-14** Post Visit 00A	**Day 30-60** Post Visit 00A	**Day 70-100** Post Visit 00A	**Day 120-180** Post Visit 00A	**N/A**
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]									[redacted]		
[redacted]										[redacted]	
Slit-lamp Examination											
• Observations	X		U	U		U	U	U	U	U	U(✓)
• IOL Position change (tilt/decentration)			U	U		U	U	U	U	U	U(✓)
IOP	X		X	X		X	X	X	X	X	(✓)
Dilated Fundus Examination	X										U(✓)

Visit	**Visit 0**	**Visit 00**	**Visit 1**	**Visit 2**	**Visit 00A**	**Visit 1A**	**Visit 2A**	**Visit 3A**	**Visit 4A[1]**	**Visit 5A**	**Unscheduled visit**
Eye	**Both Eyes**	**1st Eye**	**1st Eye**	**1st Eye**	**2nd Eye**	**2nd Eye**	**2nd Eye**	**Both Eyes**	**Both Eyes**	**Both Eyes**	**N/A**
Day Number	**Day -28 to 0**	**Day 0**	**Day 1-2** Post Visit 00	**Day 7-14** Post Visit 00	**Day 7-21** Post Visit 00	**Day 1-2** Post Visit 00A	**Day 7-14** Post Visit 00A	**Day 30-60** Post Visit 00A	**Day 70-100** Post Visit 00A	**Day 120-180** Post Visit 00A	**N/A**
	Surgical Procedures & Assessments										
Determination of 1st Operative Eye	X										
IOL Power Calculations (all 3 IOLs)	X										
[redacted]	[redacted]										
Randomization[4]		U									
Treatment		U			U						
IOL Information (Power, Model, SN)		U			U						
Problems During Surgery		U			U						
Other Surgical Procedures		U			U						
PCO and Posterior Capsulotomy			U	U		U	U	U	U	U	U(✓)
	Adverse Events & Device Deficiencies										

Visit	**Visit 0**	**Visit 00**	**Visit 1**	**Visit 2**	**Visit 00A**	**Visit 1A**	**Visit 2A**	**Visit 3A**	**Visit 4A[1]**	**Visit 5A**	**Unscheduled visit**
Eye	**Both Eyes**	**1st Eye**	**1st Eye**	**1st Eye**	**2nd Eye**	**2nd Eye**	**2nd Eye**	**Both Eyes**	**Both Eyes**	**Both Eyes**	**N/A**
Day Number	**Day -28 to 0**	**Day 0**	**Day 1-2** Post Visit 00	**Day 7-14** Post Visit 00	**Day 7-21** Post Visit 00	**Day 1-2** Post Visit 00A	**Day 7-14** Post Visit 00A	**Day 30-60** Post Visit 00A	**Day 70-100** Post Visit 00A	**Day 120-180** Post Visit 00A	**N/A**
AEs[4]	X	X	X	X	X	X	X	X	X	X	X
Device Deficiencies		X	X	X	X	X	X	X	X	X	X
Other											
Exit Form	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	X	(✓)

[redacted]

(✓) assessment performed as necessary

[redacted]

4. Collected from time of consent onward.

Signature Page for V-CLN-0006740 v3.0

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