Statistical Analysis Plan

A PROSPECTIVE, MULTI-CENTER EVALUATION OF CORNEAL FLAP CREATION USING CHEETAH FEMTOSECOND LASER SYSTEM AND CHEETAH PATIENT INTERFACE

PROTOCOL NUMBER: CHTA-103-FLAP

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STATISTICAL ANALYSIS PLAN

Clinical Investigation of the

A PROSPECTIVE, MULTI-CENTER EVALUATION OF CORNEAL FLAP CREATION USING CHEETAH FEMTOSECOND LASER SYSTEM AND CHEETAH PATIENT INTERFACE

PROTOCOL NUMBER: CHTA-103-FLAP

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1 INTRODUCTION

This document summarizes the statistical methods to be implemented during the analysis of data for the evaluation of corneal flap creation using Cheetah femtosecond laser system and Cheetah patient interface. [redacted]

[redacted]

[redacted] The investigators will use the Cheetah femtosecond laser, with the following possible procedures performed: 1) A comparison between the one piece PI (study eye) and two piece PI (control) with the Cheetah system in both eyes and/or 2) A comparison of commercial iFS femtosecond laser (IntraLase iFS) and PI (control) in one eye and the Cheetah femtosecond laser (with the one or two piece PI; study) on the other eye, both to create a LASIK flap on subjects' corneas. [redacted] The eye to receive Cheetah flap will be randomized (ratio of 1:1 for right eye and left eye) and will be considered the study eye. Subjects [redacted] will undergo refractive correction via corneal ablation on both eyes using a commercial excimer laser for vision correction (same excimer laser system will be used on both eyes).

[redacted]

The primary endpoint is the proportion of subjects with a score ≥3 in [redacted] stromal bed surface quality, [redacted]

Other endpoints include [redacted] anterior segment optical coherence tomography (OCT), [redacted] adverse events, [redacted]

2 ANALYSIS POPULATIONS

2.1 ANALYSIS POPULATIONS

[redacted]

The analysis population [redacted] will be both eyes [redacted] treated subjects and will be used for all endpoints [redacted]

[redacted]

[redacted]

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 counts and proportions will be computed.

[redacted]

2.4 RANDOMIZATION

A randomization list stratified by site will be created [redacted] Subjects' eyes [redacted] will be randomized on a 1:1 basis between the study eye and the control eye.

3 ACCOUNTABILITY/DEMOGRAPHICS

Demographics/enrollment/accountability data and binocular data will be reported for all subjects.

3.1 ACCOUNTABILITY

The number of enrolled subjects will be tabulated by site. Subject accountability will be summarized as a frequency distribution by scheduled visits. The frequency counts and proportions of available subjects, including those outside of the interval, and the frequency and proportion of missing subjects (forms not yet completed, active, missed visit, lost to follow-up or discontinued) will be reported.

3.2 DEMOGRAPHICS

Subject demographic data including age, sex, race and ethnicity will be presented. Age will be summarized with descriptive statistics with mean, standard deviation, minimum and maximum. The frequency distributions of sex, race and ethnicity will be tabulated.

3.3 PREOPERATIVE PARAMETERS

[redacted]

[redacted]

[redacted]

5 STUDY ENDPOINTS

5.1 PRIMARY STUDY ENDPOINTS [redacted]

[redacted] stromal bed surface quality, [redacted] of the study eye will be evaluated relative to the control eye on a scale of 1 to 5, with higher scores indicating a better performance of the study eye over the control eye. The scoring is as follows:

1 – Control eye is much better than study eye

2 – Control eye is better than study eye

3 – Study eye is similar to control eye

4 – Study eye is better than control eye

5 – Study eye is much better than control eye

The frequency counts and proportions of the final score will be reported [redacted] stromal bed surface quality [redacted].

The primary endpoint is the proportion of subjects with a score ≥3 in [redacted] surface quality [redacted].

Analysis of The Primary Endpoint

The counts and proportions of subjects with a score ≥3 in [redacted] surface quality [redacted] will be tabulated. The 95% two-sided CI [redacted] be calculated using the normal approximation method.

At least 90% of subjects are expected to have a score equal to or greater than 3 [redacted]

5.2 OTHER ENDPOINTS

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] The type and rates of adverse events will be summarized.

[redacted] [redacted]

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