Statistical Analysis Plan

A Clinical Study Comparing Postoperative Outcomes Between the TECNIS Intraocular Lens

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STATISTICAL ANALYSIS PLAN

A Clinical Study Comparing Postoperative Outcomes Between the TECNIS [redacted] Intraocular Lens [redacted]

PROTOCOL NUMBER: JJSV201EYST

SPONSOR
Johnson & Johnson Surgical Vision, Inc. ("JJSV")
31 Technology Dr., Suite 200
Irvine, CA 92618

SAP CHANGE HISTORY

1 INTRODUCTION

This document summarizes the statistical methods for the safety and effectiveness analyses of the JJSV201EYST study, comparing the TECNIS Eyhance® Toric II IOL and the TECNIS Synergy® Toric II IOL to the TECNIS Toric 1-Piece IOL. [redacted] Prospective, multi-center, three-arm, randomized, controlled study conducted at up to 20 sites located in North America t[redacted] Subjects will be randomized to a treatment group (masked) in ratio 1:1:1 of the three treatments. [redacted]

The sponsor has decided to terminate the study early. [redacted] Due to a much smaller sample size than planned, only descriptive summaries of safety and selected effectiveness endpoints will be presented. All implanted subjects will be followed to at least 1-month postoperative.

1.1 STUDY OBJECTIVES

The purpose of this clinical study was to compare the performance outcomes of eyes implanted with the TECNIS Eyhance® Toric II IOL and the TECNIS Synergy® Toric II IOL to the TECNIS Toric 1-Piece IOL (control) [redacted]

1.2 SELECTED STUDY ENDPOINTS

- Rotational stability
- [redacted]
- [redacted]
- Adverse events

1.3 STUDY HYPOTHESES

[redacted]

1.4 RANDOMIZATION AND MASKING

A randomization list will be created [redacted] Subjects will be randomized to either the test #1, test #2, or control IOL on a 1:1:1 basis. Randomization will take place after the subject has signed the informed consent document, has met all inclusion and exclusion criteria, and the investigator has documented which eye will be the first implanted (if bilaterally enrolled).

The subjects and the study technicians performing the postoperative vision tests are to be masked through study completion. [redacted]

2 ANALYSIS POPULATIONS AND GENERAL STATISTICS

2.1 ANALYSIS POPULATIONS

- All Implanted Safety population: all subjects randomized and bilaterally or unilaterally implanted with test or control lens and analyzed per treatment received. All eyes will include both study eyes from bilaterally implanted subjects and one study eye from unilaterally implanted subjects.

2.2 MISSING DATA HANDLING RULE

There will be no imputation for missing data in safety population(s).

2.3 VISIT WINDOWS

Enrolled subjects will have a study lens implanted in one or both eyes. [redacted]The exact number of days allowed 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.

2.4 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 visual acuity data, data will be converted to LogMAR prior to analysis. [redacted]

3 ACCOUNTABILITY/ENROLLMENT

The number of enrolled subjects will be tabulated by site. 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.

4 DEMOGRAPHIC PARAMETERS

Subject demographic data including age, sex, race, and ethnicity will be presented. Age will be determined at the time of the preoperative visit [redacted] In addition, age will be summarized with descriptive statistics. The frequency distributions of sex, race, and ethnicity will also be tabulated.

5 DEFINITION AND ANALYSIS OF SELECTED EFFECTIVENESS AND SAFETY ENDPOINTS

ROTATIONAL STABILITY

The absolute axis rotation compared to operative visit will be reported at all postoperative visits collected. The frequency counts and proportion of eyes with [redacted]≤10°, [redacted] of axis change at all postoperative visits will be reported by lens group.

[redacted]

ADVERSE EVENTS

[redacted]

Listing of all serious adverse events (including IOL repositioning and/or IOL exchange due to IOL misalignment) and adverse device-related events will be presented.

6 SAMPLE SIZE CALCULATIONS

[redacted]

[redacted]

[redacted]

[redacted]