Patient Reported Satisfaction with Contoura LASIK utilizing the Phorcides Analytic Software

An investigator-initiated clinical trial

1. TITLE PAGE

Protocol Number:	PB-23-01
Amendment Number	Version 1.0
IRB / ERC	Salus IRB 2111 West Braker Lane, Suite 400 Austin, Texas 78758
Sponsor Name & Address:	Phillip Brunson, OD Mann Eye Institute 5115 Fannin St Suite 1000, Houston, TX 77004 ***(funding only, this is an investigator-initiated study IIT # 76882857)*** Alcon 6201 South Freeway, Fort Worth, TX 76134-2099, USA
Test Articles:	WaveLight® EX500 Contoura laser
Investigator:	Phillip Brunson, OD
Sub-Investigator:	Paul Mann, MD

2 . INVESTIGATOR AGREEMENT

I confirm that I have read and that I understand this protocol entitled "Patient Reported Satisfaction with Contoura LASIK utilizing the Phorcides Analytic Software", and understand the use of the study products. I agree to conduct this study in accordance with the requirements of this protocol and also protect the rights, safety, privacy, and well-being of study subjects in accordance with the following:

- The ethical principles that have their origin in the Declaration of Helsinki.
- All applicable laws and regulations, including, without limitation, data privacy laws and regulations.
- Regulatory requirements for reporting serious adverse events defined in Section 13 of this protocol.

Signature of Investigator (Date)

Investigator Name (print or type)

Investigator's Title

Name of Facility

Location of Facility (City)

3. GENERAL INFORMATION

Objective	To determine the percentage of subjects satisfied (Completely Satisfied or Very Satisfied) with vision after Phorcides Planned Contoura LASIK. The hypothesis is that a high percentage of subjects receiving the Phorcides Planned Contoura LASIK will be satisfied with their vision.
Test Article(s)	WaveLight® EX500 Contoura laser
Control Article(s)	None.
Sample size	104 eyes of 52 subjects
Study Population	Subjects 21 to 39 years of who are appropriate candidates for laser refractive surgery.
Number of sites	One
Study Design	Single site, single-arm, prospective, observational study
Masking	None
Variables	Primary: Percentage of subjects satisfied (Completely Satisfied or Very Satisfied) with vision after Phorcides Planned Contoura LASIK based on PROWL Questionnaire preoperative vs postoperative (question #1 only). Secondary: • Percentage of eyes with post-op spherical equivalent within +/- 0.50 D. Exploratory: • Preoperative and postoperative higher order aberrations (spherical aberration and coma). • Preoperative and postoperative responses on the PROWL questionnaire (Q2-Q33). • Preoperative and postoperative OSDI scores. • Correlation of postoperative OSDI score and responses on the postoperative PROWL questionnaire (Q1).
Duration / Follow-up	Preoperative to 3 months postoperative

The study will be registered with clinicaltrials.gov.

The study will be conducted in compliance with the protocol, GCP and applicable regulatory requirements

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5. INTRODUCTION

Phorcides reproducibly and accurately applies geographic imaging software to topographic corneal measurements, utilizes optical physics of lens theory, and the refractive effect of treating corneal irregularities.[1,2] It allows for a vector analysis that accounts for anterior corneal astigmatism, posterior corneal astigmatism, manifest refraction measured astigmatism, and internal astigmatism into a suggested topography-guided treatment. Combining all these vectors and compensating for the postoperative spherical effect that can be directly impacted by the ablation profile of the corneal higher order aberrations yields a mathematical based surgical plan for the suggested treatment of the patient's refractive spherical magnitude, the astigmatic magnitude, and the astigmatic axis. Consequently, it is anticipated that Phorcides will prove to be a powerful surgical planning tool directly resulting in improved postoperative patient satisfaction with visual acuity and visual symptoms.

The decision to choose between a Phorcides derived Contoura LASIK ablation versus other various refractive procedures often times can be a difficult decision because of a lack of previous research analyzing patient satisfaction with their postoperative uncorrected visual acuity and visual symptoms. The purpose of this study is to determine the percentage of subjects satisfied with vision after Phorcides Planned Contoura LASIK.

6. OBJECTIVE(S)

To determine the percentage of subjects satisfied (Completely Satisfied or Very Satisfied) with vision after Phorcides Planned Contoura LASIK**.**

7. SUBJECTS

7.1. Subject Population

Eligible test subjects will be 21 to 39 years of age or older and who are interested in and appropriate candidates for LASIK.

A total of 104 eyes of 52 subjects at one site will be enrolled. Both eyes of a subject must be enrolled. Subjects must meet the inclusion criteria. Prior to enrollment, subjects will be provided information on the study and asked to sign a patient information and consent form to participate. The patient information and consent form will be approved by an appropriate ethics committee.

7.2. Inclusion Criteria

Subjects are eligible for the study if they meet the following criteria:

Note: Ocular criteria must be met in both eyes.

- Appropriate candidate for uncomplicated bilateral LASIK surgery
- Gender: Males and Females.
- Age: 21 to 39 years of age.

- Refractive error range - SE refractive errors up to 0.00 to -9.00 D with maximum cylinder up to 3.00 D and sphere ≤ -8.00 D.
- If currently wearing contact lenses:
  - Soft CTL wearers discontinue for minimum 3 days
  - RGP CTL wearers discontinue for 1 month per decade of wear
  - Stable refraction (2 consecutive manifest refractions within 0.25 SE)
  - Stable K readings (2 consecutive K readings in 2 consecutive visits)
- Residual bed thickness 250μm or greater
- Willing and able to comply with scheduled visits and other study procedures.
- Pre-surgery BCDVA of 20/20 (0.00 logMAR) or better in each eye.

7.3. Exclusion Criteria

If any of the following exclusion criteria are applicable to the subject or either eye, the subject should not be enrolled in the study.

- Subjects with history of previous ocular surgery.
- Subjects with topographic evidence of keratoconus, or ectasia.
- Subjects with autoimmune diseases.
- Subjects who are pregnant or nursing.
- Systemic disease likely to affect wound healing, such as diabetes and severe atopy.
- Any ocular disease (including un-controlled dry eye) which in the investigator's opinion would affect the outcome of refractive surgery.

The principal investigator reserves the right to declare a patient ineligible or non-evaluable based on medical evidence that indicates they are unsuitable for the trial.

Pregnancy has a known effect on the stability of refractions and visual acuity. As such, subjects who become pregnant during the study will not be discontinued but their data may be excluded from analyses of effectiveness.

8. STUDY DESIGN

8.1. Study Design

This study is a single site, single-arm, prospective, observational study of subject satisfaction, after successful bilateral LASIK surgery. Subjects will be assessed pre-operatively, operatively and at 1 week, 1 month, and 3 months post-operatively. Clinical evaluations will include measurement of visual acuity, manifest refraction, and topography, aberrometry, and administration of the OSDI and PROWL questionnaires.

The primary outcome measure will be the percentage of subjects satisfied (Completely Satisfied or Very Satisfied) with vision after Phorcides Planned Contoura LASIK based on PROWL Questionnaire preoperative vs postoperative (question #1 only).

Secondary outcome measures are as follows:

- Percentage of eyes with post-op spherical equivalent within +/- 0.50 D.

Exploratory outcome measures are as follows:

- Preoperative and postoperative higher order aberrations (spherical aberration and coma).
- Preoperative and postoperative responses on the PROWL questionnaire (Q2-Q33).
- Preoperative and postoperative OSDI scores.
- Correlation of postoperative OSDI score and responses on the postoperative PROWL questionnaire (Q1).

8.2. Methods Used to Minimize Bias

As a single-arm study there is no expected bias. Patient selection will be based on the patient's interest and the surgeon's opinion as to whether they are a suitable candidate for LASIK.

The measurement of visual acuity will be conducted in a systematic fashion to minimize bias. Individuals conducting visual acuity measures will be instructed to perform the same testing in the same fashion for all subjects, with the same level of encouragement to subjects. Questionnaire instructions will be provided to all patients in a similar manner.

All data collection will be completed through provided Case Report Forms (CRFs) or computer files generated by automated test equipment. All site personnel involved in the study will be trained in regard to conducting study-specific procedures.

9. STUDY PROCEDURE

9.1. Informed Consent / Subject enrollment

No subject will be enrolled into the study who does not meet the inclusion/exclusion criteria and does not sign the current approved informed consent document. Informed consent will be obtained prior to collecting any data for the study. The original signed documents will be maintained by the investigator as a permanent part of the subject's medical records. A signed copy will be provided to the subject.

9.2. Visits and Examinations

Subjects will participate in 3 study visits, including one visit for bilateral surgery. Visits will include an uptake visit, and one operative visit (Visit numbers 1-2 below). The visit schedule, complete with window and associated CRF forms, are displayed in Table 9.2-1. Details of each study visit, including testing to be conducted, are provided below.

Table 9.2-1. Visit Schedule

Visit Number	Visit Name	Visit Window	CRF Number
1	Preoperative	-90 to 0 days from surgery	1
2	Operative	0 from surgery	2
3	1 Week Postoperative	7 (±3) days postoperative	3
4	1 Months Postoperative	30 (±7) days postoperative	4
5	3 Months Postoperative	90 (±20) days postoperative	5

9.2.1. Preoperative

Pre-operative qualification should take place no more than 90 days prior to the LASIK treatment, unless otherwise specified, except for Informed Consent (which must be obtained prior to any protocol-specific non-standard of care assessments). After subjects are consented, they will be qualified for the study (compared with inclusion/exclusion criteria) and assigned a study ID/subject number. Subject numbers will be assigned sequentially at each site in the order of enrollment.

A medical history will be taken and exams will include the tests described below:

- manifest refraction,
- visual acuity,
- slit lamp exam,
- dilated fundus exam,
- topography,
- aberrometry,
- OSDI questionnaire,
- PROWL questionnaire

In addition, all site-specific, routine, usual standard of care preoperative measures should be undertaken.

Measurements should be made as described in section 9.3 below.

9.2.2. Operative (Surgery)

All subjects will undergo bilateral LASIK surgery. The surgeon's usual standard of care with regard to treatment and medication will be used for all study subjects. Surgery planning will be performed using the surgeon's preferred method.

Any adverse events/serious adverse events (AEs/ SAEs) occurring during surgery will be noted at this visit. Any other problems during surgery and comments regarding surgery will be documented.

Any subject whose surgery is not completed successfully will be documented in the appropriate case report form. These subjects will be monitored for safety but clinical performance data may be excluded from the analysis.

9.2.3. Postoperative 1 Week
All routine, usual standard of care postoperative measures should be undertaken. In addition, the subject will undergo VA, manifest refraction, slit lamp examination (Section 9.3). Any device deficiencies or adverse events will be monitored.

9.2.4. Postoperative 1 Month
All routine, usual standard of care postoperative measures should be undertaken. In addition, the subject will undergo VA, manifest refraction, slit lamp examination (Section 9.3). Any device deficiencies or adverse events will be monitored.

9.2.4. Postoperative 3 Month
All routine, usual standard of care postoperative measures should be undertaken. In addition, the subject will undergo VA, manifest refraction, slit lamp examination, dilated fundus exam, topography, aberrometry, and complete the OSDI and PROWL questionnaires (Section 9.3). Any device deficiencies or adverse events will be monitored.

9.2.3. Exit Procedures
In the event of premature exit from the study, all study related examinations should be completed where possible. The Exit CRF should be completed, noting that the subject did not complete the study and the reason for premature study exit. If no premature exit from the study occurs, the Exit CRF should be completed at the end of Visit 5.

9.3. Study Methods and Measurements

All routine testing and basic eye examinations should be carried out at each study visit. Abnormalities should be recorded in the CRF "Comment" section. Specific study examination procedures are outlined below.

9.3.1. Manifest Refraction
Perform a manifest refraction with a high contrast early treatment diabetic retinopathy study (ETDRS) chart under photopic lighting conditions. Document refraction results with sphere, cylinder and axis readings. If uncorrected visual

acuity is not improved by manifest refraction, use zero for sphere and cylinder and draw a line through the blank for the axis.

Note: Each subject should be manually refracted to his/her best correction by an ophthalmologist, optometrist, or a skilled technician using a phoropter or trial lenses.

9.3.2. Visual Acuity (VA)
Distance VA
Measure distance visual acuity using a high contrast ETDRS chart under photopic lighting at a distance of 20 ft.

Conduct testing uncorrected and with the manifest distance refraction in place at all non-surgical visits.

9.4. Unscheduled Visits

Unscheduled exams may be conducted at the discretion of the Investigator with all relevant information from the exam recorded in the source documents and on the Unscheduled Visit pages within the CRF booklet.

9.5. Discontinued Subjects

Discontinued subjects are those who do not have an exit visit or who come into the office to be exited prior to the scheduled final study visit. Subjects may be discontinued from the study at any time if, in the opinion of the investigator, their continued participation in the study poses a risk to their health. The reasons for discontinuation include:

a. Adverse event;
b. Lost to follow-up;
c. Subject decision unrelated to an adverse event;
d. Protocol violation;
e. Treatment failure;
f. Other.

To ensure the safety of all subjects who discontinue prior to Visit 5, investigators should assess each subject and, if necessary, advise them of any therapies and/or medical procedures that might be needed to maintain their health. Any changes in medical health and/or use of concomitant medications should also be captured.

10. ANALYSIS PLAN

10.1. Analysis Data Sets

All subjects who are enrolled in the study will be evaluated for safety. Efficacy analyses will be performed based on data from those eyes with uncomplicated LASIK surgery.

10.2. Statistical Methodology

A summary of the data will be prepared for all measurement time points.

For variables measured on a continuous scale, these summaries will include the sample size, as well as the mean, standard deviation, median, minimum, and maximum. For variables measured on a categorical scale, summaries will provide the number and percentage of subjects in each category. These summaries will be provided for all eyes completing the study.

10.2.1. Within-treatment Changes

For variables measured on a continuous scale, the statistical significance of each parameter will be investigated using a paired t-test.

10.3. General Statistical Considerations

The statistical analyses will be performed using R, version 4.1.2 or higher. Any statistical tests of hypotheses will employ a level of significance of alpha=0.05.

11. SAMPLE SIZE JUSTIFICATION

We estimate that the study would require a sample size of 46 subjects (number of pairs) to achieve a power of 90% and a level of significance of 5%, for detecting a mean of difference of 25 points in satisfaction (using the PROWL questionnaire) between pairs, and assuming the standard deviation of the differences to be 50 points.[3] To account for dropout, 52 subjects will be enrolled.

12. CONFIDENTIALITY/PUBLICATION OF THE STUDY

The existence of this Study is confidential and should not be discussed with persons outside of the Study. Results will be submitted for publication and presentation at national and/or international meetings. A manuscript will be submitted to peer-review journals for publication but there is no guarantee of acceptance.

All study data will be collected on appropriate Case Report Forms (CRFs). No protected health information will be included on the forms. CRFs will be retained in the patient's file for a minimum period of 3 years. Collected information will only be used for purposes of this study and no information will be sold to third parties. The following people will have access to your study records:

- Study Doctor and staff involved with the study
- Study Monitor or Auditor
- Sponsor Company or Research Institution
- Review boards or accrediting agencies
- Other State or Federal Regulatory Agencies

The de-identified data may be shared with other researchers for future analysis.

13. QUALITY COMPLAINTS AND ADVERSE EVENTS

All subjects will be monitored for adverse events over the course of the study. A place to record any adverse event is included on each case report form.

13.1. General Information

An Adverse Event (AE) is any untoward medical occurrence in a subject who is administered. a study treatment regardless of whether or not the event has a causal relationship with the treatment. An AE, therefore, can be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the study treatment, whether or not related to the treatment. In clinical studies, an AE can include an untoward medical occurrence occurring at any time, including run-in or washout periods, even if no study treatment has been administered.

13.2. Monitoring for Adverse Events

At each visit, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking if the patient has any problems.

13.3. Procedures for Recording and Reporting AEs and SAEs

Subsequent to signing an informed consent form, all untoward medical occurrences that occur during the course of the study must be documented on an Adverse Event Form (AEF). A separate AEF must be filled out for each event. When possible, signs and symptoms indicating a common underlying pathology should be documented as one comprehensive event. For each recorded event, the AE documentation must include the onset date, outcome, resolution date (if event is resolved), intensity (i.e., severity), any action with study treatment taken as a result of the event, and an assessment of the adverse event’s relationship to the study treatment.

Nonserious Adverse Events

A nonserious AE is defined as any untoward change in a subject's medical health that does not meet serious criteria noted below (e.g., is not life-threatening, does not require hospitalization, does not prolong a current hospitalization, is not disabling, etc.). All adverse events must be reported regardless of whether or not they are related to the study treatment.

For nonserious adverse events, an AEF containing all available information will be collected on a routine basis and submitted to the Medical Monitor at the close of the study.

Serious Adverse Events

A serious adverse event (SAE) is defined as any adverse experience that meets any of the following criteria:

- Results in death.

- Is life-threatening.
  NOTE: Life-threatening means that the subject was at immediate risk of death from the reaction as it occurred; i.e., it does not include a reaction which hypothetically might have caused death had it occurred in a more severe form.
- Requires inpatient hospitalization or prolongation of existing hospitalization.
  NOTE: In general, hospitalization signifies that the individual remained at the hospital or emergency ward for observation and/or treatment (usually involving an overnight stay) that would not have been appropriate in the physician's office or an out-patient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether “hospitalization” occurred, the event should be considered serious.
- Results in persistent or significant disability/incapacity. Disability is defined as a substantial disruption of a person’s ability to conduct normal life functions.
  NOTE: The term disability means a substantial disruption of a person’s ability to conduct normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza, or accidental trauma (e.g., sprained ankle) which may interfere or prevent everyday life functions but do not constitute a substantial disruption.
- Is an important medical event. An important medical event is an event that may not result in death, be life-threatening, or require hospitalization but may be considered an SAE when, based upon appropriate medical judgment, it may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in the definitions for SAEs. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in subject hospitalization, or the development of drug dependency or drug abuse.
  All available information on a serious adverse event(s) and any other associated AE, if applicable, must be forwarded to the study coordinator for forwarding to the Medical Monitor immediately (i.e., within one working day of the Investigator’s or site’s knowledge of the event) as follows:
  - In studies utilizing EDC (electronic data capture), all available information for the SAE and any associated AE(s) must be entered immediately into the EDC system.
  - Additional information for any applicable event is to be reported as soon as it becomes available.

In addition to the reporting of serious adverse events to the study Medical Monitor, the SAE must be reported to the IRB / IEC according to their requirements.

The investigator must document all adverse device events (serious and nonserious but related) and all serious adverse events (related and unrelated) on the Adverse Device Effect and Serious Adverse Event Form. Any device quality complaints will also be documented.

- **Both the Quality Complaint Form and the Adverse Device Effect and Serious Adverse Event Form must be e-mailed immediately to the study coordinator (Melissa Hamann Wright).**
- **Additional relevant information is to be reported as soon as it becomes available.**

Study coordinator contact information is provided below.

Table 13.3.-1:
Contact Information for FS200 Study

Study Staff	Business Phone	e-mail	24-hour Office Phone
Melissa Hamann Wright	713-580-2500 ext. 2389	Melissa.Wright@manneye.com	832-368-0117

Further, depending upon the nature of the adverse event (serious or nonserious) or quality complaint being reported, the study sponsor may request copies of applicable portions of the subject's medical records. The investigator must also report all adverse events and quality complaints according to the relevant IRB requirements.

12.3.1 Intensity and Causality Assessments

For every adverse event and quality complaint, the investigator must assess the causality as Related or Not Related to the medical device under investigation. An assessment of causality will also be performed by the Medical Monitor utilizing the same definitions, as shown below:

Causality

Related — An adverse event or quality complaint classified as related may be either definitely related or possibly related where a direct cause and effect relationship with the medical device has not been demonstrated, but there is a reasonable possibility that the adverse event or quality complaint was caused by the medical device.

Not Related — An adverse event or quality complaint classified as not related may either be definitely unrelated or simply unlikely to be related (i.e., there are other more likely causes for the adverse event or quality complaint).

Where appropriate, the investigator must assess the intensity (severity) of the adverse event as mild, moderate, or severe based on medical judgment with consideration of any subjective symptom(s), as defined below:

Intensity (Severity)

Mild	An adverse event is mild if the subject is aware of but can easily tolerate the sign or symptom.
Moderate	An adverse event is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities.
Severe	An adverse event is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

The investigator must document any action taken (i.e., medication, intervention, or treatment plan) and outcome of the adverse event or quality complaint when applicable.

13.4. Follow-Up of Adverse Events and Quality Complaints

The investigator is responsible for adequate and safe medical care of subjects during the study and for ensuring that appropriate medical care and relevant follow-up procedures are maintained after the study. Any additional data from these follow-up procedures must be documented and available to the study coordinator who, with the Medical Monitor, will determine when the data need to be documented on the CRFs.

13.5. Safety Analyses

The type, severity, duration and frequency of reported ocular adverse events will be tabulated. Adverse events will also be summarized for events that were considered treatment-related.

14. GCP, ICH and ETHICAL CONSIDERATIONS

This study will be conducted in compliance with Good Clinical Practices (GCPs), including International Harmonization (ICH) Guidelines, and in general, consistent with the 1996 version of the Declaration of Helsinki. In addition, all applicable local, state and federal requirements will be adhered to.

This study is to be conducted in accordance with Institutional Review Board regulations. The investigator will obtain appropriate IRB/ethics committee approval prior to initiating the study.

The study will be registered with clinicaltrials.gov.

14.1 Confidentiality

The data collected will be data typical for the procedure(s) when performed on eyes outside the study. Any data collected will become part of the patient's clinical record. The data will be subject to the same privacy and confidentiality as other data in the clinical record.

Only the principal investigator, research consultant and clinic staff will have access to the data collected. All data shared outside the practice will be de-identified; patients' protected health information will not be available and will not be reported in any analyses or publications. No data will be sold to third parties. De-identified data may be used for future research.

15. STANDARD EVALUATION PROCEDURES

Table 15.1. Proposed Visits and Study Assessments

(visits are by patient, with both eyes tested)

Activity	Pre-operative	Operative	Postoperative		
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
			1 Week	1 Month	3 Months
Informed Consent	X				
Demographics	X				
General Information: Medical History	X				
Surgery		X			
Manifest refraction	X			X	X
Monocular uncorrected distance VA	X		X	X	X
Monocular corrected distance VA	X			X	X
Slit Lamp Exam	X		X	X	X
Dilated Fundus Exam	X				X
Topography (Vario and iTrace)	X				X
Aberrometry (Vario and iTrace)	X				X
PROWL Questionnaire	X				X
OSDI Questionnaire	X				X
Complete Exit Form[1]	X				X

[1] Complete Exit Form upon termination of subject participation, or at Visit 5, whichever occurs first.

16. CONFIDENTIALITY

No protected health information (PHI), including the patient's name and date of birth, will be collected; to ensure this, no PHI information is permitted to be entered on any of the Case Report Forms (CRFs). Subjects will only be identified by subject IDs and identities will be removed at the initial visit so that there is no further need to protect or destroy the information. Collected information will only be used for purposes of this study and no information will be sold to third parties. The non-PHI information collected may be used for future research, though there is currently no plan to do so.

17. FINANCIAL AND INSURANCE INFORMATION/STUDY RELATED INJURIES

Every effort to prevent study-related injury will be taken by the Study Doctor and staff. In the event a patient is injured as a direct result of the study while following the Study Doctor's instructions and the study requirements, the patient will be instructed to contact his or her doctor immediately. The Study Doctor is to treat the injured subject as needed for those injuries caused directly by this research study. In the event of injury or illness caused by or occurring during a subject's participation in this research study, all charges for medical care provided to the subject will be billed to his or her insurance company.

The Study Doctor or Sponsor does not offer to cover the medical care costs for injuries or illnesses that are not caused directly by the research study. The Sponsor does not offer to provide any other compensation, unless specifically agreed to elsewhere in this document. This information will be provided to each study subject before the start of the study in the consent form.

18. STUDY ENDPOINT CRITERIA

18.1. Patient Completion of Study

If a study patient has completed the final visit (Visit 5) of the study, he/she is considered to have completed the study.

18.2. Patient Discontinuation

Each study patient may voluntarily discontinue the study at any time they choose. Study patients who cannot complete the study for administrative reasons (e.g., non-compliance, failure to meet visit schedule, etc.) will be discontinued from the study. Study patients discontinued during the enrollment phase (prior to surgery) of the study will be replaced.

18.3. Patient Termination

A study patient will be terminated if the study patient develops any severe adverse event that may be related to the study. A study patient will receive appropriate treatment at the discretion of the investigator. Notification of termination will be clearly documented. These study patients are considered to have completed the study and will not be replaced.

18.4. Study Termination

The investigator with appropriate notification may terminate the study. If, after clinical observations, the investigator feels that it may be unwise to continue the study, he may stop the study.

18.5. Study Completion

The study will be complete when all enrolled patients have completed Visit 5 or have been terminated from the study.

19. SUMMARY OF RISKS AND BENEFITS

19.1. Summary of risks

The risks with this study are similar to those for any patient receiving bilateral LASIK.[4] There is no increased risk associated with the proposed study.

19.2. Summary of benefits

Previous studies have shown that the WaveLight® EX500 Contoura with Phorcides (Alcon, Fort Worth, Texas, USA) provides good visual outcomes for patients at distance.[1,2] Patients who participate in the study receive $400 reimbursement.

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3. Eydelman M, Hilmantel G, Tarver ME, et al. Symptoms and Satisfaction of Patients in the Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) Studies. *JAMA Ophthalmol.* 2017;135(1):13-22.
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