Clinical and refractive outcomes after Contoura® refractive surgery planned using Phorcides surgery planning software

1. TITLE PAGE

Protocol Number:	ML-2020-01
Amendment Number	Version 1.0
IRB / ERC	Salus IRB 2111 West Braker Lane, Suite 400 Austin, Texas 78758
Sponsor Name & Address:	Mark Lobanoff, MD American Corneal Consultants North Oaks, Minnesota 15 Island Rd. North Oaks, MN 55127 mlobanoff@gmail.com ***(Alcon Inc., Fort Worth, TX, USA is providing funding only - this is an investigator-initiated study, IIT# 57571751)***
Test Article:	Phorcides Analytical Engine with Wavelight laser
Control Article:	None
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2 . INVESTIGATOR AGREEMENT

I confirm that I have read and that I understand this protocol entitled "Clinical and refractive outcomes after Contoura® refractive surgery planned using Phorcides surgery planning 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	The objective of the current study is to prospectively evaluate 3-month clinical outcomes from LASIK performed using the Phorcides surgical planning software with Contoura topography-guided ablation in both eyes of subjects with myopia and myopic astigmatism seeking refractive surgery for distance correction. Data will be compared to published results for wavefront optimized LASIK and LASIK performed with Contoura using other refractive algorithms. The hypothesis is that use of the Phorcides planning software will result in a higher percentage of eyes with residual refractive cylinder ≤ 0.25D than will be achieved with wavefront-optimized (WFO) LASIK. It is also expected that unaided postoperative visual acuity and visual symptoms will be improved.
Test Article(s)	Phorcides Analytical Engine refractive surgery planning software
Control Article(s)	None
Sample size	140 eyes of 70 subjects
Study Population	Subjects ≥20 years of age with myopia and myopic astigmatism, who are suitable candidates for LASIK, meet the approved range of treatment for Contoura topography-guided LASIK and desire optimal uncorrected distance visual acuity in both eyes.
Number of sites	Four
Study Design	Prospective, single arm, open-label study.
Masking	None
Variables	Primary: ● Residual refractive cylinder Secondary: ● Monocular uncorrected distance visual acuity

- Monocular corrected distance visual acuity
- Residual refractive sphere
- Corneal aberrations
- Ocular aberrations (at sites equipped for such measurement)
- Subjective questionnaire evaluating visual symptoms such as light sensitivity glare, halos, and starbursts

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

The Contoura software for the Alcon WaveLight excimer laser was approved several years ago, but some surgeons are unsure about how to plan treatments when the manifest cylinder determined by refraction differs significantly from the Contoura-derived cylinder. This has caused some surgeons to abandon the Contoura procedure. The Phorcides Analytical Engine (Phorcides) refractive surgical planning software has demonstrated efficacy in addressing this issue.[1,2] Use of the Phorcides software is expected to simplify surgical planning and improve overall outcomes with topography-guided ablations; as a result, it may increase use of Contoura in clinical practice.

It is expected that clinical refractive outcomes with Phorcides will be superior to those obtained with wavefront-optimized refractive surgery using the same laser that have been reported in the literature. It is also expected that results with Phorcides will be superior to, and more consistent than, Contoura results reported in the literature that were based on alternative algorithms.

6. OBJECTIVE

The objective of the study is to prospectively compare 3-month clinical outcomes of LASIK performed using the Phorcides surgical planning software with Contoura topography-guided ablation to wavefront-optimized (WFO) LASIK results and Contoura results based on other algorithms reported in the literature.

7. SUBJECTS

7.1. Subject Population

Eligible test subjects will be patients presenting for LASIK who meet the approved refractive range and clinical indications for topography-guided ablation. Both eyes must be eligible for treatment.

A total of 140 eyes of 70 subjects will be enrolled across four clinical sites. A minimum of 10 and a maximum of 25 subjects will be enrolled at any one site, based on speed of enrollment. 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.

- Candidate for Contoura excimer laser vision correction
- Gender: males and females.

- Age: 20 or older
- Willing and able to provide written informed consent for participation in the study.
- Willing and able to comply with scheduled visits and other study procedures.
- Good ocular health, with no pathology that compromises visual acuity (other than refractive error)
- Corrected preoperative visual acuity of 20/20 (0.0 logMAR) or better in the eye being treated
- Meet Contoura eligibility requirements (approved range): up to -8.00 D sphere, up to -3.00 D cylinder, and a spherical equivalent no greater than -9.00 D
- Desire good vision at distance in both eyes

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.

- Corneal pathology (e.g. opacities, epithelial basement membrane dystrophy, Fuchs' dystrophy, etc.)
- Previous corneal surgery (e.g., radial keratotomy, corneal refractive surgery or corneal transplant, DSAEK, DMEK, lamellar keratoplasty)
- Previous anterior or posterior chamber surgery (e.g., vitrectomy, laser iridotomy)
- Desire for good uncorrected near vision in one or both eyes
- Participation in (or current participation) any investigational drug or device trial within the previous 30 days prior to the start date of this trial
- Unsuitability for the trial, in the opinion of the investigator, for any reason
- Pregnancy or desire to become pregnant during the trial

7.4. Exclusion Criteria during surgery

The following exclusion criteria are applicable to the study eye during the study

- Intraoperative complications.

Any subject whose surgery has been aborted for either eye should immediately be discontinued from the study and an exit form completed for that subject. These subjects will be followed according to the clinic standard of care and monitored for safety, but their data will be excluded from the study efficacy analysis. All adverse events will be appropriately documented and reported.

Participants who are considered to be in a vulnerable population will not be enrolled into the study. Vulnerable populations include, but are not limited to, the following:

- Prisoners
- Nursing home residents
- Institutionalized individuals
- Mentally disabled and cognitively impaired individuals
- Sponsor employees and their family members
- Site employees and their family members that are directly or indirectly involved in the study
- Economically disadvantaged individuals
- Educationally disadvantaged individuals
- Adults who do are illiterate
- Subjects who are deaf or have a severe hearing disability
- Terminally ill individuals
- Individuals with life-threatening conditions

8. STUDY DESIGN

The study is a prospective, single-arm open clinical trial to evaluate residual refractive error and distance visual acuity after excimer laser treatment for the correction of refractive error to produce good uncorrected distance vision. All eyes enrolled will have surgery planned with Phorcides and treated using the Contoura topography-guided surgery algorithm.

Subjects will be assessed pre-operatively and at 1 day, 1 month and 3 months post-operatively.

Clinical evaluations at 1 month and 3 months will include measurement of uncorrected distance visual acuity (UCDVA), manifest refraction, and corrected distance visual acuity (CDVA). At 3 months, corneal aberrations will be measured, and subjects will complete a questionnaire evaluating satisfaction with their visual outcome, quality of vision, and visual symptoms (light sensitivity, difficulty driving at night, reading difficulty, fluctuation in vision, glare, halos, and starbursts).

The primary outcome measure will be the residual refractive cylinder.

Secondary outcome measures will be the following:

- Uncorrected distance visual acuity
- Residual sphere
- Corneal aberrations
- Ocular aberrations, at sites with the appropriate equipment to measure such.
- Satisfaction with the visual outcome, quality of vision, and visual symptoms (light sensitivity, difficulty driving at night, reading difficulty, fluctuation in vision, glare, halos, and starbursts).

Safety measures will be

- Change in corrected distance visual acuity
- Satisfaction with the visual outcome, quality of vision, and visual symptoms (light sensitivity, difficulty driving at night, reading difficulty, fluctuation in vision, glare, halos, and starbursts).

8.2. Methods Used to Minimize Bias

This is a single-arm study with both eyes of any subject enrolled. Patients will not be pre-selected for study inclusion. Any eligible patient presenting for, and eligible for, binocular Contoura treatment may be invited to participate.

The measurement of the postoperative refraction and visual acuity will be conducted in a systematic fashion to minimize bias. Individuals conducting visual acuity measures will be refracted with the methodology used in the Early Treatment Diabetic Retinopathy Study, with the same level of encouragement to subjects. Subjective questions will be asked in a similar manner to all patients. Alternatively, at the discretion of the investigator, patients may be asked to complete the questionnaire themselves.

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.

Subjects will each receive a rebate of their refractive surgery payment when they complete the 3-month visit. This rebate will amount to $250 per eye, so subjects will receive a $500 rebate in total.

9.2. Surgery Procedures

Following a complete ophthalmic examination (history, visual acuity, refraction, slit-lamp exam, fundus exam, topography), patients who meet inclusion criteria and choose to participate in the study after informed consent will be brought to the operating room where bilateral LASIK will be performed using the techniques routinely used by each investigator.

9.3. Visits and Examinations

Subjects will participate in five study visits. Visits will include a preoperative/enrollment visit (Visit 1), one operative visit (Visit 2), and 3 postoperative visits (Visit numbers 3, 4, and 5). The preoperative visit and operative visit may occur on the same day if a fundus exam has been performed within the previous 6 months and the findings are available at the time of the preoperative/operative visit. The visit schedule, visit windows, and associated Case Report Forms (CRFs), are displayed in Table 9.3-1. Details of each study visit, including testing to be conducted, are provided in Table 9.3-4 and below.

Table 9.3-1. Visit Schedule

Visit Number	Visit Name	Visit Window	CRF Number
1	Preoperative	-30 to 0 days before surgery	1
2	Operative	0 from surgery	2
3	1 Day Postoperative	1-7 days after surgery	3
4	1 Month Postoperative	1 month (1 month – 2 ½ months)	4
5	3 Months Postoperative	3 months (2 ½ - 5 months) after surgery	5

Table 9.3-2. Testing Schedule

	Visit				
Test	1	2	3	4	5
UCVA	X		X	X	X
MR	X			X	X
CDVA	X			X	X
Slit lamp exam	X	X	X	X	X
Fundus exam	X*				X
IOP	X			X	X
Topography	X			X	X
Ocular HOA (site specific)	X				X
Questionnaire	X				X

*****Not required if fundus exam has been performed by any physician within 6 months and results are available for review by the investigator.

All data will be recorded on the provided CRFs. All site personnel involved in the study will be trained to follow the study protocol, conduct study-specific procedures, and record data properly. CRFs will be identified by the subject number assigned at each site. No protected health information (PHI) will be included on any CRF, but a separate record of patient names and study identifying numbers will be maintained at each investigational site.

9.3.1. Preoperative

Subjects who meet inclusion criteria and provide informed consent will undergo the following procedures.

- Medical history
- Testing as shown in Table 9.3-2 as described in Section 9.4 below
- Site-specific, routine preoperative procedures and measurements

9.3.2. Operative (Surgery)

Preoperative examination and testing procedures (with the exception of the fundus examination) may be performed or repeated on the operative day at the discretion if the investigator. A brief slit lamp examination will be performed. The patient will then be brought into the operating room, where bilateral LASIK surgery (planned using the Phorcides analytical engine) will be performed with routine procedures specific for each site.

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

Any complications preventing successful completion of surgery will be documented, and any subject whose surgery is not completed successfully will be excluded from further participation in the study and followed according to procedures that are standard for each individual study site.

Postoperatively, patients will be managed according to standard procedures for each individual study site.

9.3.3. Postoperative Day 1, Month 1, and Month 3

All routine postoperative procedures and measurements will be performed according to the standard operating procedures for each study site. Testing will be performed as specified in Table 9.3-2 above and Section 9.4 below. Adverse events will be monitored and documented. Additional tests specific for this study will be administered at Visit 5.

9.3.4. Exit Procedures

In the event of premature exit from the study, all study-related examinations should be completed whenever 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 (3 Months Postoperative).

9.4. Study Methods and Measurements

All routine testing and basic eye examinations (the usual standard of care for the practice) should be carried out at each study visit. Abnormalities should be recorded in the CRF "Comment" section. Specific study examination procedures are outlined below.

9.4.1. Manifest refraction
Perform a manifest refraction with a high contrast logMAR ETDRS chart under photopic lighting conditions (>85 cd/m^2). Document refraction results with sphere, cylinder and axis readings using the ETDRS protocol. 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. All visual acuities should be recorded as letters read on the ETDRS chart.

9.4.2. Visual acuity (VA)
Measure uncorrected and corrected distance visual acuity using the MR according to the ETDRS protocol using 100% contrast letters. Record visual acuities as number of letters read on the ETDRS chart.

9.4.3. Corneal aberrations
Measure the corneal topographic aberrations with the Pentacam analyzer.

9.4.4 Ocular high order aberrations
Measure ocular HOA at sites appropriately equipped to do so. The device used to measure HOA's should be indicated, and a 5 mm pupil size should be selected where feasible.

9.4.5. Subjective questionnaire
Have the subject complete the subjective questionnaire.

Note: Avoid interpreting survey questions for subjects. That is, avoid re-phrasing questions if subjects ask, "What does this mean?"

9.5. 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.

9.6. 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. Fear of exposure to infectious disease
g. 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 for which uncomplicated LASIK was completed.

10.2. Statistical Methodology

All data will be collected by the site and entered into a spreadsheet. Subjects will be assigned an ID number. Data analysis will be performed without patient identification. Statistical analysis will be performed using standard descriptive statistics and other tests as deemed appropriate based on the characteristics of the data to be analyzed. All statistical tests will be two-sided and interpreted at a 5% significance level.

10.3. General Statistical Considerations

The statistical analyses will be performed using Statistica, version 12 or higher. Any statistical tests of hypotheses will employ a level of significance of alpha=0.05.

11. SAMPLE SIZE JUSTIFICATION

The sample size has been chosen to be similar to that for comparable Contoura, WFO, WFG and ray tracing LASIK studies published in the peer-reviewed literature. Each of four sites will enroll up to 50 eyes, for a total potential study population of 140 eyes. With an expected 10% dropout rate before the 3M visit, 126 eyes would be available for analysis.

12. CONFIDENTIALITY/PUBLICATION OF THE STUDY

The existence of this study is confidential and should not be discussed with persons who are not involved with 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. Presentation or publication of data from individual sites or a subset of sites involved in the study is prohibited. The company funding this study may review manuscript(s) prior to publication, but it may not control their content or the interpretation of the results of the study.

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 be used for purposes of this study and possible future research, but no information will be sold to third parties. The following people will have access to study records:

- Investigators and staff involved with the study
- Study monitor or auditor
- Sponsoring company
- Research institution at which the study is being performed
- Review boards and accrediting agencies
- Other State or Federal regulatory agencies, as permitted by law

The de-identified data may be shared with other researchers for further 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 the event seems to have 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 it is related to the treatment. In clinical studies, an AE can include an untoward medical occurrence occurring at any time after the informed consent document is signed, 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 (ie., 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 they are related to the study treatment or not.

For nonserious adverse events, an AEF containing all available information will be collected on a routine basis and submitted to the Medical Monitor before 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 principal investigator at ophtrds@emory.edu.**

- **Additional relevant information is to be reported as soon as it becomes available.**

Principal investigator contact information is provided below.

Table 13.3.-1:
Contact Information for Phorcides Prospective Study

Study Staff	Business Phone	E-Mail	Home Phone
R. Doyle Stulting, MD, PhD	678-938-1011	ophtrds@emory.edu	678-938-1011

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.

13.3.1 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 providing adequate and safe medical care to 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 a manner 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.

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 Day	1 Month	3 Months
Informed consent	X				
Demographics	X				
General information: medical history	X				
Surgery		X			
Manifest refraction	X			X	X
Uncorrected distance VA (monocular)	X		X	X	X
Corrected distance VA (monocular)	X			X	X
Corneal aberrations	X				X
Ocular aberrations (site specific)	X				X
Subjective questionnaire	X				X
Monitor for adverse events		X	X	X	X
Complete Exit Form[1]					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 for study purposes; to ensure this, no PHI 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 be used for purposes of this study. No information will be sold to third parties, though the de-identified data collected may be used for additional research.

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 that 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. Neither the Study Doctor nor the Sponsor 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 he/she chooses. 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 for LASIK surgery in this study (topography-guided or wavefront-optimized) are not different from the standard risks. The excimer laser system used in the study has been approved for topography-guided and wavefront-optimized refractive surgery.
The most common side effects of laser refractive surgery are glare and halos, dry eye and residual refractive error.

19.2. Summary of benefits

Phorcides has been used to assist in surgical planning of topography-guided ablations with good results in the past. It is expected that eyes treated using the Phorcides planning software with the Contoura topography-guided LASIK algorithm will have results as good or better than can be achieved with wavefront-optimized LASIK, and Contoura results based on other algorithms.[1,2]

REFERENCES

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