REFRACTIVE OUTCOMES EVALUATION OF THE VERIONTM IMAGE GUIDED SYSTEM + ORA SYSTEM WITH VERIFEYE

Sponsor:	**Carolina Eyecare Physicians, LLC** **1101 Clarity Rd., Suite 100** **Mt. Pleasant, SC 29466** **(843) 881 3937** **Kerry D. Solomon, MD, Principal Investigator** **Helga P. Sandoval,MD, MSCR, Research Manager**
Study Device(s):	**VERION™ Image Guided System: Digital Surgical Planning and Positioning Tools** **ORA System with VerifEye or VerifEye +**
Protocol Number:	**CEP-14-003** **Initial version date: 09.APR.2015**
Investigator(s):	**Kerry D. Solomon, MD**
Investigator Agreement:	**I have read the clinical study described herein, recognize its confidentiality and agree to conduct the described trial in compliance ith Good Clinical Practices (GCP), the Declaration of Helsinki, this protocol and all applicable regulatory requirements. Additionally, I will comply with all procedures for obtaining informed consent, data recording and reporting, will permit monitoring, auditing, and inspection of my research center, and will retain all records until notified by the sponsor.**

Principal Investigator: _____

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Refractive Outcomes Evaluation of the VERION™ Image Guided System + ORA System with VerifEye

Nowadays cataract patient's expectations are closer to those of refractive surgery patients. Patients want to be spectacle independent. However, fifteen to twenty percent of cataract surgery patients have from 1.00 to 3.00 diopters (D) of corneal astigmatism[1] which makes achieving spectacle independence unlikely in this patients unless the astigmatism is treated at the time of cataract surgery.

Currently available treatments include corneal or limbal incisions,[2] the use of toric intraocular lenses (IOLs) or LASIK. Limbal relaxing incisions (LRIs) are the most commonly used manual method2[,4,5,7-12] Traditionally, LRIs have been made manually (with a surgical knife). With the introduction of femtosecond laser to assist during cataract surgery, a new alternative is available for creating corneal incisions.[13] The stability of the LRIs and visual outcomes using toric IOLs have been shown.[14, 15]

Regardless of the treatment of choice to correct the astigmatism at time of cataract extraction, a treatment plan has to be calculated preoperatively. This planning include: keratometry measurements and the use of a calculator to estimate the treatment and orientation of IOL and placement of the LRIs.

Keratometry can be measured using a variety of devices including manual keratometers (i.e. Javal-Shiotz), automated keratometers, corneal topography, and optical biometry (IOL master and Lenstar).

Once keratometry to be used has been selected, if the treatment of choice are LRIs, a calculator is used to determine the location and size of the LRI. Many nomograms have been developed; the choice of nomogram is the surgeon's prefer one, usually based on prior experience, and their preferred knife.[4] LRIs calculators are available on line. One frequently used is available at: http://www.lricalculator.com/. Accessed August 28, 2014. (Abbott Laboratories Inc. Abbott Park, Illinois, USA).[A] This calculator offers The Nichamin Age and Pachymetry Adjusted nomogram (NAPA), and the Donnenfeld Nomogram (DONO) that have been used to correct 0.75 to 3.75 D and 0.50 to 3.00 D of preoperative astigmatism respectively.[2,4,5,6,A] Both nomograms specify the location, length, size, and number of incisions based on the patient's age, the type of astigmatism, and the amount of astigmatism correction needed.[2,4,6,A]

If a toric IOL has been chosen then planning the appropriate orientation of the toric IOL is accomplished using an online software such as the Alcon Laboratories, Inc., AcrySof Toric IOL Calculation Online. Available at: http://www.acrysoftoriccalculator.com/. Accessed August 28, 2014).[B] The software selects the optimal AcrySof Toric IOL power and location based on the keratometry and the surgically induced astigmatism (SIA) values entered by the surgeon.[15]

Intraoperatively, marking the eye and placing the incisions or aligning the toric IOL in the right axis are key steps for the success of astigmatism correction. Marking of the eye can be done using a variety of instruments using ink and it is routinely done with the patient in the upright position to avoid cyclorotation. Once patient is on the table in supine position, axis should be checked once again. Additional suggested methods to mark the eye include taking pictures preoperatively to identify anatomical landmarks similar to iris registration in refractive surgery. The use of iris registration during LASIK was introduced in 2008. Several publications have shown that patients undergoing wavefront-

guided LASIK with iris recognition achieved better visual and refractive outcomes compared to conventional LASIK.[16-19]

Recently, Alcon introduced VERION™ Image Guided System: Digital Surgical Planning and Positioning Tools. This system encompasses a reference unit that takes a picture of the eye with the patient in the sitting position creating a high-resolution digital image of the patient's eye, capturing scleral vessels, limbus and iris features. It measures keratometry as well as the corneal diameter (limbus) and pupil size. The information captured is then transferred automatically to the planner where additional information including target refraction, manifest refraction, axial length, anterior chamber depth, and lens thickness is entered for IOL power calculation and astigmatism correction planning. Astigmatism correction options include corneal incisions, toric IOL and a combination of both. Intraoperatively, The VERION™ Digital Marker displays patient information and images from the VERION™ Reference Unit. Additionally it positions all incision locations and assists with lens alignment in real time while accounting for the variable impact of cyclorotation and patient eye movement. In the OR, it displays a reticle that helps to align the IOL to the axis according the surgical plan.[C] It also helps to position manual LRIs.

Additionally, intraoperative wavefront aberrometry has been used in the last couple of years with increase success. The Optiwave Refractive Analysis (ORA) system can refract the eye in phakic, aphakic, and pseudophakic states at any time during cataract surgery and assists in IOL power selection and recommendations for toric IOL positioning before and after implantation as well as LRIs confirming the surgery plan calculated preoperatively. Furthermore, VerifEye, an ORA hardware upgrade, provides continuous assessment of the patient's eye allowing for more precise measurements; therefore, more accurate results and improved refractive outcomes and VerifEye +, the latest upgrade that provides streaming information on the refractive status and correct IOL positioning through the right ocular of the surgical microscope. This enables the surgeon to visualize all the information without having to look up at the monitor screen during the surgical procedure.

This new technology is an alternative to plan and treat astigmatism at the time of cataract surgery. It could make this treatment easier for less experience surgeons by facilitating the calculations and making the identification of the correct axis easier by reducing the need for manual marks.
Our hypothesis is that if VERION™ Image Guided System: Digital Surgical Planning and Positioning Tools + ORA System with VerifEye or VerifEye + is used for measuring, planning and executing the astigmatism correction treatment at time of cataract surgery then refractive outcomes will be better.

OBJECTIVES:

The main objective of this study is to evaluate spherical and astigmatism outcomes post routine cataract surgery when the complete VERION™ Image Guided System packet + ORA System with VerifEye or VerifEye + are used in the treatment of pre-existing astigmatism using toric intraocular lens (IOL) or corneal incisions compared to the surgeon's standard of care.

Exploratory objective is to evaluate the LRI enhancement feature of the ORA System with VerifEye or VerifEye + in subjects undergoing standard IOL implantation and corneal incisions.

STUDY DESIGN AND METHODS:

1. **Test article:** The VERION™ Image Guided System: Digital Surgical Planning and Positioning Tools + ORA System with VerifEye or VerifEye +.
2. **Study Design:** Prospective, randomized, contralateral eye study.
3. **Subjects:**
   a. **Inclusion Criteria:**

   Subjects **MUST** fulfill the following conditions to qualify for enrollment into the trial
   1. Subject is undergoing bilateral cataract extraction or refractive lens exchange with intraocular lens implantation and astigmatism correction.
   2. Gender: Males and Females.
   3. Age: 50 years and older.
   4. Willing and able to provide written informed consent for participation in the study
   5. Willing and able to comply with scheduled visits and other study procedures.

   b. **Exclusion Criteria:**

   Subjects with **ANY** of the following conditions on the eligibility exam may **NOT** be enrolled into the trial.
   1. Severe preoperative ocular pathology: amblyopia, rubella cataract, proliferative diabetic retinopathy, shallow anterior chamber, macular edema, retinal detachment, aniridia or iris atrophy, uveitis, history of iritis, iris neovascularization, medically uncontrolled glaucoma, microphthalmos or macrophthalmos, optic nerve atrophy, macular degeneration (with anticipated best postoperative visual acuity less than 20/30), advanced glaucomatous damage, etc.
   2. Uncontrolled diabetes.
   3. Use of any systemic or topical drug known to interfere with visual performance.
   4. Contact lens use during the active treatment portion of the trial.
   5. Any concurrent infectious/non infectious conjunctivitis, keratitis or uveitis.
   6. Pseudoexfoliation syndrome or any other condition that has the potential to weaken the zonules
   7. Previous refractive surgery.
   8. Any clinically significant, serious or severe medical or psychiatric condition that may increase the risk associated with study participation or study device implantation or may interfere with the interpretation of study results.
   9. Participation in (or current participation) any investigational drug or device trial within the previous 30 days prior to the start date of this trial.
   10. Intraocular conventional surgery within the past three months or intraocular laser surgery within one month in the operated eye.

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

   c. **Exclusion Criteria during surgery**

If any of the following exclusion criteria are applicable to the study eye, the subject should not continue in the study.

1. Digital Marker L failure
2. Digital Marker M failure
3. Failure to capture ORA System with VerifEye or VerifEye + images
4. Significant vitreous loss.
5. Significant anterior chamber hyphema.
6. Uncontrollable intraocular pressure.
7. Zonular or capsular rupture.
8. Bag-sulcus, sulcus-sulcus or unknown placement of the haptics.
9. Suturing of incision required at time of surgery.
10. Intraoperative vitreous loss or intraocular lens tilt or decentration
11. Significant sedation or retrobulbar block during surgery.
12. Unable to maintain adequate fixation for image capture.
13. Other procedure, such as pupil stretch, expanders, iris hooks during surgery.

Note: Any subject in which 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 up as per the clinic standard of care, monitored for safety, and their data will be excluded from the study efficacy analysis (obtained from FDA Database Research Results Feb, 05, 2009). All adverse events will be appropriately documented and reported.

Additionally, participants who are considered to be a vulnerable subject population are not to be enrolled into the study without prior written authorization from both the Sponsor and the IRB to ensure that a description of additional safeguards are in place during the consenting and enrollment processes. Vulnerable populations include, but are not limited to, the following:

1. Prisoners
2. Nursing home residents /institutionalized individuals
3. Mentally disabled /cognitively impaired individuals
4. Sponsor employees and their family members
5. Site employees and their family members that are directly and indirectly involved with the study
6. Students of the university or the principal investigator participating in the study
7. Economically and/or educationally disadvantaged individuals
8. Comatose individuals / traumatized individuals
9. Adults who do not read and/or write
10. Hearing impaired individuals
11. Terminally ill individuals / individuals with life-threatening conditions

4. Study Enrollment Procedures

Potential subjects will be identified from the patients presenting at the clinic. Additionally, an ad will be placed in the local newspaper and in the practice website. Once identified as a study candidate, the

patient will be asked if he/she would like to participate. The subinvestigator, study coordinator or an appropriately trained staff member will answer any and all questions and will obtain informed consent. A copy of the signed informed consent document will be given to the subject. The principal investigator will be available if the subject wants to discuss further details with him. Any testing that is part of the investigative site's standard preoperative cataract evaluation may be performed prior to the informed consent being signed, provided these tests are conducted within 90 days of surgery. The patient will understand that participation in the study, or declining to participate, will not affect his/her quality of care.

No subject will be enrolled into the study that 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.

5. Study Surgery Procedures

Eyes of the study participants will be randomly assigned to one of two groups:

a. Group A, surgeon standard of care prior to getting VERION™ Image Guided System. Spherical power will be selected using the surgeon's preferred formula (Haigis, Holladay 2, Holladay, or other) and biometry method (IOL Master, Lenstar). Astigmatism correction will be planned using the surgeon's preferred keratometry method and calculator/nomogram to determine toric power and corneal incisions (i.e. Alcon toric calculator, Holladay toric calculator, AMO LRI calculator, etc). At time of surgery, axis of placement will be marked using blue ink marks. Corneal incisions will be made manually.

b. Group B, VERION™ Image Guided System: Digital Surgical Planning and Positioning Tools + ORA System with VerifEye or VerifEye +. Spherical power of the IOL will be selected using the Verion™ Planner with the surgeon's preferred formula with an optimized A-constant (Haigis, Holladay 2, Holladay, or other). Both toric lenses and corneal incisions will be calculated with the Verion™ Planner using the Verion™ Reference Unit keratometry and white to white measurements, and Lenstar biometry. The VERION™ Digital Markers L and M will be used for axis of placement and confirmed using ORA System with VerifEye or VerifEye +.

6. Study Visit Schedule and Assessments (Table 1).

a. **Visit Schedule:** Patients will be examined at the following intervals:

1. Visit 1: Screening and enrollment: Preoperative evaluation completed not more than eight weeks before surgery

2. Visit 2: Day of Surgery
3. Visit 3: Day 1 (12 to 48 hrs) after surgery
3. Visit 4: Month 1: 30 ±10 days postoperative after second eye surgery
4. Visit 5: Month 3: 90 ±15 days postoperative after second eye surgery

b. Measurements and evaluations

1. Visit 1: Informed consent process will be conducted at this visit. Assessments include uncorrected and best-corrected ETDRS visual acuity (UCVA / BCVA), manifest refraction, intraocular pressure (IOP), and slit lamp examination including dilated fundus exam, auto refractor keratometry, Lenstar, VERION™ Reference Unit, and corneal topography (Atlas). Both IOL power and astigmatism correction will be calculated using the surgeon's current standard of care as well as using the VERION™ Image Guided System: Digital Surgical Planning. Any testing that is part of the site's standard of care preoperative cataract surgery evaluation may be performed prior to the informed consent being signed provided these tests are conducted within 90 days of the surgery and notation of the date performed is entered onto the source document.

   The first eye undergoing surgery will be randomized to either one of the two groups: Group A (surgeon standard of care) or B (VERION™ Image Guided System + ORA System with VerifEye or VerifEye +). The fellow eye will be assigned to the alternate group. Eyes will be randomized after all calculations have been completed. Prior to randomization, all measurements, IOL power and astigmatism correction calculations will be reviewed following the practice standard of care to determine subject's eligibility for astigmatism correction with toric lens or corneal incisions. If it is determined that the measurements are not consistent then subject will be excluded from the study.

   The surgeon's standard pre cataract surgery treatment will be used in all his patients.

2. Visit 2: The surgeon may use his preferred cataract extraction technique (manual or laser) for eyes randomized to Group A. Eyes randomized to Group B will undergo laser assisted phacoemulsification (primary incision, capsulorhexis and lens fragmentation) using the surgeon's preferred laser settings. The secondary incision will be made with the laser or manually, at the surgeon's discretion. The lens will be implanted in the bag. The surgeon's standard post cataract surgery treatment will be used in all his patients.

3. Visit 3: Assessment will include uncorrected ETDRS visual acuity, intraocular pressure, slit lamp examination, corneal incision location and/or toric IOL orientation.

4. Visit 4 and 5: Assessment will include uncorrected and best-corrected ETDRS visual acuity (UCVA / BCVA), manifest refraction, auto refractor keratometry, Lenstar, VERION™ Reference Unit, corneal topography, intraocular pressure, and slit lamp examination. The location of all corneal incisions as well as toric IOL orientation will be documented.

Adverse events and device deficiencies/quality complaints will be monitored and recorded at all study visits.

Table 1. Visits and Study Assessments

Study Assessments	Visit 1 Preoperative	Visit 2 Operative	Visit 3 Day 1	Visit 4 Day 20-40	Visit 5 Day 75-105
Inclusion/Exclusion Criteria	x				
Consent Subject	x				
Patient demographics (age, gender, race, ethnicity)	x				
Manifest Refraction	x			x	x
UCDVA	x		x	x	x
BCDVA	x			x	x
Tonometry (IOP)	x		x	x	x
Complete slit lamp exam	x		x	x	x
Dilated fundus exam	x			†	†
Auto refractor keratometry	x			x	x
Atlas corneal topography	x			x	x
Lenstar LS900 measurements	x			x	x
Verion™ Reference Unit measurements	x			x	x
Verion™ Planner	x				
Alcon Toric calculator	x				
LRI calculator	x				
Incision Size and Location		x			
Record Lens Model Implanted *(Attach label, or record manufacturer, model, power)*		x			

VerifEye or VerifEye + information		x			
Post-IOL implantation incision size		x			
LenSx parameters		x			
Corneal arcs/toric IOL orientation		x	x	x	x
Adverse events / device deficiency	x	x	x	x	x

x To be performed as scheduled
† To be performed as deem necessary by the investigator.

7. Study endpoint/completion criteria

a. 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.

b. Patient Discontinuation/Withdrawal: 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.

c. 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.

d. 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.

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

ADVERSE EVENTS AND DEVIATION REPORTING

All efforts will be made to look for possible adverse events or untoward findings. If an adverse event occurs, the safety and welfare of the subject will be the priority. Appropriate medical intervention will be made. Ocular adverse events observed by the investigator or reported by the subject, and in the investigator's opinion to be directly related to any of the devices being evaluated, will be recorded on an Adverse Event Case Report Form. Resolution of the adverse event will be recorded on the Adverse Event Follow-Up Form.

This is an Investigator Initiated Trial; however, notification of a serious ocular adverse event directly related to the evaluated devices will be made to the device manufacturer within 24 hours. Carolina Eyecare Physicians will support the manufacturer in the following-up of all events so that complete information is available to maintain patient safety and for them to comply with the appropriate regulatory reporting requirements.

Adverse events and deviations will be reported to the IRB following the IRB's Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information.

SAMPLE SIZE

Sample size calculations are based on a presumed t-test of refractive cylinder and corneal astigmatism between the two study groups. An alpha of 0.05 and a power of 0.8 were used. The standard deviations of the variables above have been previously estimated at about 0.35D. A difference of 0.25D would be clinically relevant. Using the information above, to reliably detect a difference between groups would require 34 eyes in each group. Spherical equivalent refraction, corneal astigmatism and refractive cylinder are likely to be highly correlated. Allowing for multiplicity of results, approximately 10% more eyes are required per additional correlated endpoint. In this case, 20% more eyes would be required, for a total of 40 eyes (20 subjects) per group.

STATISTICAL CONSIDERATIONS

All data will be collected by the research team. Data will be entered into a database. The database will be password protected and access will be restricted to study personnel. Data analysis will be performed without patient identification. Statistical analysis will be done using standard descriptive statistics and other tests as deemed appropriate based on the characteristics of the data to be analyzed. Secondary endpoints will be analyzed only if the primary endpoint demonstrates a statistically significant difference between groups. Corneal and refractive astigmatism are likely to be correlated. A Bonferroni correction will be applied where indicated for evaluating significance. Mean spherical equivalent refraction is not expected to be highly correlated to the measured astigmatism, nor is mean keratometry, so multiplicity considerations will not be required for these variables. All statistical tests will be two-sided and interpreted at a 5% significance level. Comparisons between the two groups will be made. Data analysis will be conducted by a third party consultant.

Study Endpoints:

The study endpoints are related to the expected difference between the two groups with regard to the residual refraction after successful cataract surgery.

Primary Endpoint:

- Residual refractive cylinder at 3 months

Secondary Endpoints:

- Residual mean spherical equivalent refraction at 3 months
- Residual corneal astigmatism at 1 month and 3 months
- Residual refractive sphere at 1 month and 3 months
- Interim refractive cylinder at 1 month
- Percentage of eyes with postoperative MRSE accuracy to target ≤ 0.5D at 1 and 3months
- Uncorrected and best-corrected visual acuity at 1 month and 3 months
- Axis of placement (actual vs. intended)
- Lenstar K's vs. Verion K's
- Corneal incisions stability (manual vs. laser arcs) at 3 months after surgery - based on manifest cylinder and keratometry measurements from 1 and 3 months, noted above.

Safety Analyses

The type, severity, duration and frequency of reported ocular adverse events will be tabulated for each group. Adverse events will also be summarized for events that were considered treatment-related. Comparison of treatment groups with respect to the proportion of study patients reporting adverse events will be made using a chi-square test.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

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 instructions and requirements, the patient will be instructed to immediately contact the principal investigator and/or study staff. Treatment will be provided as needed for those injuries caused directly by this research study. In the event of injury or illness caused by or occurring during the participation in this study, all charges for medical care provided will be billed to the patient's insurance company. The medical care costs for injuries or illnesses that are not caused directly by the research study will not be covered.

CONFIDENTIALITY/PUBLICATION OF THE STUDY

The existence of this Study is confidential and should not be discussed with persons outside of the Study. Data to be collected is listed in Table 1. The source/CRF documents will have a subject study ID number and the subject's initials. 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. Further statistical analysis might be conducted if deemed necessary based on the results of the study. All data will be collected by the research team. Data will be

entered into a database. The database will be password protected and access will be restricted to study personnel. Data analysis will be performed without patient identification. Records will be kept for 2 years after completion of the study. Patient information and data collected will not be sold to third parties.

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