Evaluation and Clinical Outcomes After Routine Cataract Surgery with the Quatera® 700 and the Centurion® Vision System

Sponsor:

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Study Product:

Zeiss Quatera® 700
Alcon Centurion® Vision System

Protocol Number:

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Investigator Agreement:

I have read the clinical study described herein, recognize its confidentiality and agree to conduct the described trial in compliance with 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.

Name of the Investigator: _____

Name of the Institution: _____

Address: _____

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Investigator: _____

Signature Date

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INTRODUCTION

Accordingly with the last report from Word Health Organization (WHO) at least 2.2 billion people globally have a near or distance vision impairment and almost 94 million of those people present age–related cataract, considered the second cause of visual impairment[1] and the main cause for reversible blindness worldwide. Characterized by the darkening and solidification of a previously transparent crystalline lens; the condition is responsible for both vision impairment and also for a decreased quality of life, due to restriction to independent living; and increased risk of body injuries[2], anxiety and depression levels; in individuals with non–operated cataracts[3].

At the early stages the cataracts can be managed by changing the prescribed glasses, however their progression is unpredictable, and sometimes changes associated with the progression could lead to rapidly increasing refractive errors, significant anisometropia and to lower visual acuity, leading to the necessity of a surgical procedure to restore the visual capacity to patients with age-related cataract.

Phacoemulsification is the most common treatment for cataract surgery in the developed countries and over the years it gained importance due to several factors: small incision, surgery performed under topical anesthesia - which reduce injection-related complications – short recovery time, low post operatory induced astigmatism, and low incidence of surgical complications, when compared to the conventional surgeries.

Although phacoemulsification has fewer complications when compared to previous types of cataract surgeries, it still burdens undesirable side effects, in the form of intraoperative and/or post–operative complications.[4] Anterior segment changes occur after phacoemulsification surgery, and corneal endothelium seems to be the most adversely affected structure with significant loss of corneal endothelial cells density and corneal thickness during cataract surgery.[5] Corneal endothelial cell loss can be caused by the heat originated from the ultrasound, excessive irrigation, turbulence of fluid, bubble generation in the anterior chamber, and direct trauma, leading to a reduced corneal metabolism postoperatively. In severe cases, corneal decompensation may occur, following an ineffective endothelial pumping, resulting in persistent corneal edema, and decreased vision leading to subsequent corneal transplantation.[6] Some factors act as adjuvants to increase the risk of cell damage like intraoperative phacoemulsification time, shorter eyes, and a shallow anterior segment, and because of all that it is important to perform surgery as effectively and safely as possible to avoid disrupting the delicate balance of the eye.

Corneal thickness changes after phacoemulsification can be used to assess surgically induced corneal edema and it was already observed that the degree of permanent corneal endothelial damage is related to the degree of early postoperative corneal swelling.[7] Moderate damage of the corneal endothelium during surgery may lead to a transient increase in corneal thickness, although data about it are contradictory since some authors reported that all patients recovered preoperative values after 4 weeks[8,9], while others reported sustained increases up to 6 months or even 1 year postoperatively; however, those discrepancies may reflect inadequate measurement of central corneal thickness (ultrasonic pachymetry) and in the estimation of endothelial cell numerical density. Nowadays modern technology, such as optical low coherence reflectometry, allows more precise measurements of the central corneal thickness and published data show that a moderate decrease in the endothelial cell numerical density does not influence the central corneal thickness, if accurately determined, at various time intervals up to 1 year after surgery.[10]

The purpose of this study is to evaluate and compare the performance of 2 different phacoemulsification systems: the Zeiss Quatera® 700 and the Centurion® Vision System, when using the optimized settings for each device, in patients undergoing routine cataract surgery.

1. OBJECTIVE:

The purpose of this study is to evaluate the Zeiss Quatera® 700 and compare it to the Centurion® Vision System using the optimized settings for each device in patients undergoing uneventful routine cataract surgery. Main end points include central corneal thickness at day 1 postoperatively and lens removal time (from end of rhexis to complete nucleus removal) as measured digitally by the Zeiss Surgery Optimizer and manually with a stopwatch.

2. STUDY DESIGN AND METHODS:

A. **Test article:** Zeiss Quatera® 700 and Alcon Centurion® Vision System

B. **Study Design:** Prospective, randomized, double-masked contra lateral eye study.

C. **Subjects:** A total of 40 subjects who met the Inclusion/Exclusion criteria will be enrolled.

1. Inclusion Criteria:

Subjects MUST fulfill the following conditions to qualify for enrollment into the trial

1. Subject is undergoing bilateral lens extraction with implantation of a posterior chamber intraocular lens.
2. Gender: Males and Females.
3. Age: 40 years or 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.
6. Scheduled to undergo standard cataract surgery with topical anesthesia in both eyes within 1 to 15 days between surgeries
7. Subjects requiring an IOL power in the range of +10.0 D to +30.0 D only.
8. Potential postoperative visual acuity of 0.2 logMAR (20/32 Snellen) or better in both eyes.

2. Exclusion Criteria:

Subjects with ANY of the following conditions on the eligibility exam (Visit 0) 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. Clinically significant corneal dystrophy.
7. Corneal irregularities potentially affecting visual acuity: keratoconus, corneal dystrophy, corneal opacities.
8. Endothelial cell count less than 1500 cells/mm2
9. History of chronic intraocular inflammation.
10. History of retinal detachment.
11. Femtosecond arcuates at time of surgery.
12. Femtosecond laser assisted cataract surgery in one eye only.
13. Pseudoexfoliation syndrome or any other condition that has the potential to weaken the zonules.
14. Previous intraocular surgery.
15. Previous radial keratotomy (RK).
16. Previous keratoplasty
17. Pupil abnormalities
18. Subject who may reasonably be expected to require a secondary surgical intervention at any time during the study (other than YAG capsulotomy, i.e. LASIK)
19. Anesthesia other than topical anesthesia (i.e. retrobulbar, general, etc).
20. Other ocular procedures at the time of the cataract extraction (i.e., iStent)

21. Any clinically significant, serious or severe medical or psychiatric condition that may increase the risk associated with study participation or may interfere with the interpretation of study results.
22. Participation in (or current participation) any ophthalmic investigational drug or ophthalmic device trial within the previous 30 days prior to the start date of this trial.

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.

3. 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. Different surgical technique in each eye (traditional/femtosecond laser)
2. Other planned ocular surgery procedures, i.e iStent.
3. Significant vitreous loss.
4. Significant anterior chamber hyphema.
5. Uncontrollable intraocular pressure.
6. Zonular or capsular rupture.
7. Bag-sulcus, sulcus-sulcus or unknown placement of the haptics.
8.
9. Intraocular lens tilt or decentration
10. Significant sedation or retrobulbar block during surgery.
11. Other procedure, such as pupil stretch, expanders, iris hooks, capsular tension ring, etc. 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

3. Study Procedures

A. Informed Consent / Subject enrollment

Potential subjects will be identified from the patients presenting at the clinic. Additionally, an ad will be placed in social media and in the practice website, if deemed necessary. Once identified as a study candidate, the patient will be asked if he/she would like to participate. The sub-investigator, 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 research records.

B. Surgery Procedures:

The first eye undergoing surgery will be randomized to either the Quatera® 700 or the Centurion® Vision System. The fellow eye will receive the alternate treatment. The first operative eye will be the eye with the worse cataract. If the cataract is the same in both eyes, the clinic's standard of care will be followed. The randomization list will be provided by a third-party consultant. Research staff not attending or participating in surgery will be masked to the extent possible.

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

1. Visit Schedule: Subjects will be examined at the following intervals:

1. Visit 0: Screening and enrollment: Preoperative evaluation completed not more than eight weeks before surgery
2. Visit 1: Day of Surgery each eye
3. Visit 2: Day 1: (12 to 48 hours) after surgery each eye
4. Visit 3: Week 1: 7 ±2 days after surgery each eye
4. Visit 3: Month 1: 30 ±7 days postoperative after second eye surgery
4. Visit 4: Month 3: 90 ±15 days postoperative after second eye surgery

D. Measurements and evaluations

1. Visit 0: Informed consent process will be conducted at this visit. Assessments include best-corrected distance visual acuity (BCDVA, Snellen chart), manifest refraction, intraocular pressure (IOP, Goldman), corneal tomography (Pentacam), ultrasound pachymetry, specular microscopy, macular OCT, slit lamp examination including dilated fundus exam, cataract density and type (LOCS III). 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 CRF. The surgeon's standard pre cataract surgery treatment will be used in all his patients

   First eye undergoing surgery will be randomized to Group A (Quatera 700) or B (Centurion).

2. Visit 1: The surgeon may use his preferred small incision cataract extraction technique (manual phacoemulsification or laser assisted). The same technique must be used in both eyes. The intraocular lens will be implanted in the bag. The following information will be captured the day of surgery: phaco metrics, lens removal time, duration of surgery, incision size (prior to lens implantation), estimated fluid used, lens implanted and power, target refraction for IOL power implanted, additional surgical procedures, intraoperative complications, and any device deficiencies. Additionally, the surgery will be recorded, and the videos will be analyzed digitally using the Surgery Optimizer and manually using a stopwatch. The surgeon's standard post cataract surgery treatment will be used in all patients.

3. Visit 2: monocular pinhole uncorrected visual acuity (UCVA), slit lamp examination, IOP, ultrasound pachymetry and Pentacam.

4. Visit 3: Manifest refraction, best distance corrected visual acuity (BCVA), IOP, slit lamp examination, ultrasound pachymetry, Pentacam and macular OCT.

5. Visit 4: Manifest refraction, best distance corrected visual acuity (BCVA), IOP, slit lamp examination, ultrasound pachymetry, Pentacam, macular OCT, and dilated fundus exam if deemed necessary by the investigator.

6. Visit 5: Manifest refraction, best distance corrected visual acuity (BCVA), IOP, slit lamp examination, ultrasound pachymetry, Pentacam macular OCT will be performed. Dilated fundus exam to be performed if deemed necessary by the investigator.

All adverse events and complaints will be monitored and recorded at all study visits.

Table 1. Visits and Study Assessments

	Visit 0 Screening	Visit 1/1A DOS	Visit 2/2A 1-day	Visit 3/3A 1-week 7 ±2 days	Visit 4/4A 1-Month 30 ±5 days	Visit 5/5A 3-Month 90 ±15 days
Informed Consent	X					
Inclusion/Exclusion	X	X				
Demographics	X					
Past medical & ocular history	X					
Concomitant medications	X					
BCVA Snellen	X					
Pinhole uncorrected distance VA (ETDRS)			X			
Manifest refraction	X			X	X	X
Best corrected distance VA (ETDRS)				X	X	X
Intraocular Pressure (Goldman)	X		X	X	X	
Specular microscopy	X					X
Ultrasound Pachymetry	X		X	X	X	X
Pentacam	X		X	X	X	X
SLE	X		X	X	X	X

Signs of inflammation (cells and flare)	X		X	X	X	X†
Dilated fundus exam	X				X††	X††
Macular OCT	X			X	X	X
Cataract density / type (LOCS III)	X					
Phaco metrics		X				
Lens removal time		X				
Duration of surgery		X				
Incision size		X				
Surgical optimizer		X				
Estimated fluid use		X				
Adverse events	X	X	X	X	X	X

X To be performed as scheduled
† To be performed if cells and flare still present at the 1-month visit
†† To be performed as deem necessary by the investigator.

BCVA, best corrected visual acuity
ETDRS, Early Treatment Diabetic Retinopathy Study
SLE, Slit lamp exam
OCT, Optical Coherence Tomography
LOCS, The Lens Opacities Classification System

4. Study endpoint 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: 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.

5. STATISTICAL CONSIDERATIONS

A. Sample size

A total of 40 subjects will be enrolled. In order to calculate the sample size, we need to know an accurate estimate of the standard deviation of the outcome measure which we do not know; therefore, we consider this study a pilot trial. When estimating the sample size for a pilot study, the simplest method is to apply a sample size rule of thumb. Browne suggests a general flat rule to 'use at least 30 subjects or greater to estimate a parameter'. However, since analysis comparing manual phaco vs. femtosecond laser assisted cataract surgery will be conducted, at least 20 subjects will be enrolled in each surgical technique (femtosecond laser/manual phaco)

B. Statistical Analysis

All data will be collected by the site and entered into a database. 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. Comparisons between the groups will be made. Data analysis will be conducted by a third-party consultant.

C. Study Endpoints:

1. Primary Endpoints:

a. Central corneal thickness at day 1 postoperatively
b. Lens removal time (from end of rhexis to complete nucleus removal)

2. Secondary Endpoints:

a. Duration of surgery (from incision to wound hydration)
b. Incision size (prior to intraocular lens implantation)
c. Estimated fluid use
d. Subjective signs of inflammation (cells and flare) at day 1, 7 and 30.
e. Endothelial cell density at 3 months
f. Central corneal thickness at day 7, 30 and 90
g. Best corrected distance visual acuity at day 7, 30 and 90
h. Intraocular pressure at day 1, 7, and 30
i. Macular thickness day 7, 30 and 90
j. Intraoperative complication rate

3. Exploratory Endpoint:
   a. Accuracy of the Surgical Optimizer

D. 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 Fisher's Exact Test.

6. DATA HANDLING AND RECORD KEEPING

A. Confidentiality

To ensure confidentiality in this study, records of the participants will be examined only by the principal investigator, sub-investigators and research staff involved in the study. Study records will be kept on file. Any statistical analysis and publication will not include any subject identifiers. Medical records will be made available only for review by the investigators, or Research Institution, the IRB, and other State or Federal Regulatory Agencies, if necessary. All information in these records will be kept confidential.

B. Records Retention

The PI is accountable for the integrity, retention and security of all study related data. The investigator must maintain accurate, complete and current records relating to the clinical

study. The investigator must maintain the required records during the investigation and for a period of 3 years after the date on which the investigation is terminated, completed or published.

7. STUDY MONITORING, AUDITING, AND INSPECTING

The nature and location of all source documents will be identified to ensure that original data required to complete the case report forms (CRFs) exist and are accessible for verification by the monitor. If electronic source records are maintained, these records must be 21 CFR Part 11 compliant and will be printed and certified for verification by the monitor as needed.

The required examination must be recorded on the CRFs. Provided CRFs can be used as source document. All data reported must have corresponding entries in the source documents. The principal investigator or sub-investigator must review the reported data and certify that the CRFs are accurate and complete. No subject identifiers should be recorded on the CRFs beyond subject number, subject initials and study specific identifiers.

Data from CRFs will be entered into a database created specifically for this study. Project manager or designee will monitor the data entered throughout the study.

Upon completion of the CRFs, the data will be reviewed by study manager and statistician for accuracy and completeness. If corrections and/or any additions to the data are deemed necessary, queries will be generated and forwarded to the site staff for resolution. Designated research staff is expected to respond to data queries in a timely manner and ensure that the corrections and changes made to the data in the database are reflected in the subjects' source documentation. Any changes will need to be initialed and dated by the authorized personnel making such changes.

Data will not be sold to third parties but may be used for future research.

Electronic data will be stored and accessed on a secured server.

8. INVESTIGATIONAL PRODUCT

A. Description

Zeiss Quatera® 700 (Zeiss – Germany) is a phacoemulsification unit for use in cataract procedures with a synchronized fluid exchange system that directly measures and simultaneously controls both infusion and aspiration volumes in real-time, actively compensating for incision leakage volume and, according to the manufacturer, providing chamber stability independent of IOP and flow.[11]

Centurion® Vision System (Alcon – Fort Worth -TX) is a phacoemulsification unit for use in cataract and vitrectomy procedures and, according to the manufacturer, this unit automatically adapts to the eye's changing conditions, while also provides smoother fluidics, anterior chamber stability, and surgical precision.[11]

B. Treatment/Dosing Regimen

The phacoemulsification devices are used at the time of surgery to remove the cataractous lens. The first eye undergoing surgery will be randomized to either the Quatera® 700 or the Centurion® Vision System. The fellow eye will receive the alternate treatment. The first operative eye will be the eye with the worse cataract. If the cataract is the same in both eyes, the clinic's standard of care will be followed. The randomization list will be provided by a third-party consultant. Research staff not attending or participating in surgery will be masked to the extent possible.

C. Method for Assigning Subjects to Treatment/Dosing Groups

Randomization envelopes will be provided to staff attending surgery. The envelopes will be sequentially numbered.

D. Subject Compliance Monitoring

Since the devices are used at the time of surgery to remove the cataract, subject compliance will not be an issue in this particular study.

E. Packaging, Receiving, Storage, Dispensing and Return

N/A

9. ETHICAL CONSIDERATION

This clinical trial will be conducted in accordance with the principles of the Declaration of Helsinki, and Good clinical practice. The Investigator and all clinical trial staff will conduct the clinical trial in compliance with this protocol. The Investigator will ensure that all personnel

involved in the conduct of the clinical trial are qualified to perform their assigned duties through relevant education, training, and experience. Deviations from the clinical protocol must be documented in each subject's study records including the dates and reasons for each deviation. The PI must ensure that all aspects of the trial are in compliance with the applicable regulatory laws and conditions of approval imposed by the IRB.

10. RISKS AND BENEFITS

The risk of being in the study is not greater than the risk of undergoing routine cataract surgery with implantation of an intraocular lenses. However, there is always the risk that uncommon or previously unknown side effects may occur. The study includes additional postoperative examinations at no cost.

11. 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.

12. CONFIDENTIALITY/PUBLICATION OF THE STUDY

The existence of this Study is confidential and should not be discussed with people 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.

13. REFERENCES

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