A Prospective, Randomized, Fellow Eye Comparison of Fellow Eyes Undergoing LASIK With the Intralase IFS150 Versus the Visumax

NCT03063164

March 6, 2018

Edward E. Manche, Principal Investigator
Stanford University
Stanford, California 94305

1. PURPOSE OF THE STUDY

a. Brief Summary

The purpose of the study is to compare the results of LASIK surgery when using two brands of femtosecond lasers in patients with nearsightedness with and without astigmatism.

b. Objectives

I hope to determine if one manufacturers femtosecond laser is superior to another when performing wavefront-guided LASIK surgery. We will be performing tests of visual performance to see if there are any advantages of one femtosecond laser over the other.

c. Rationale for Research in Humans

We want to evaluate which of these commonly used femtosecond laser devices produces superior results in humans.

2. STUDY PROCEDURES

a. Procedures

The patients will have a comprehensive eye examination once they express an interest in the study. This includes a slit lamp examination of the front of the eye and a dilated fundoscopic examination of the back of the eye. If there is any pathology noted that would exclude the patient from the study, then we will inform the patient and make an appropriate referral. if the patient is deemed appropriate for the study after a comprehensive examination included computerized videokeratography, then they can be enrolled. The patient will undergo bilateral simultaneous eye surgery. Which eye is

treated with the Intralase IFS 1500 and which eye is treated with VisuMax will be randomized so there is a 50% chance for either eye to receive one treatment. The patients will be seen on the day of surgery, post op day one, one month, three months, six months and one year. The patient will receive topical antiobiotics in each eye for one week following the procedure. The patient will receive pred forte 1% ophthalmic drops for one week after treatment. The patient will also receive vigamox ophthalmic drops for four days after treatment. All of this is within the usual and customary standard of care for the treatment of patients undergoing LASIK surgery.

b. Procedure Risks

We are studying two brands of femtosecond lasers. Both lasers are FDA approved and commonly used in clinical practice. The research procedures are the least risky that can be performed consistent with sound research design.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

No audio or video recordings are planned for the study.

e. Alternative Procedures or Courses of Treatment

Alternative procedures include no surgery and continuing to wear glasses and contact lenses.

Alternatives also include performing LASIK or PRK surgery on both eyes outside of the study.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

The surgery is performed in both eyes at the same time. Once a patient has had a LASIK flap created there is no need to create an additional LASIK flap. Patients in both groups will receive the same postoperative care.

g. Study Endpoint(s)

We plan to follow the patients for one year. Patients can experience improvement in their vision 6-12 months following surgery so we will need to gather the full data to determine final outcomes. We will terminate the study prior to enrolling the projected participant population if we determine that one procedure is superior to the other. The study will end after a minimum of 50 subjects are enrolled and up to 100 subjects.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Most reports in the literature report comparable outcomes between different manufacturers of femtoecond lasers for similar levels of nearsightedness with and without astigmatism.

b. Findings from Past Animal Experiments

None.

4. DEVICES USED IN THE STUDY

a. IDE-Exempt Devices

IND-Exempt Device 1	
Name:	Intralase IFS; Abbott Medical Optics, Inc.
IND-Exempt Device 2	
Name:	AMO Visx CustomVue; Abbott Medical Optics, Inc.
IND-Exempt Device 3	
Name:	VisuMax; Zeiss

5. PARTICIPANT POPULATION

a. Planned Enrollment

Up to 100 healthy subjects with myopia with and without astigmatism. These are the patients who typically seek out LASIK surgery to lessen or reduce their dependence on glasses and contact lenses.

b. Age, Gender, and Ethnic Background

Subjects age 21 and older with myopia will be eligible to participate. All genders and ethnic backgrounds are eligible to participate in the study.

c. Vulnerable Populations

Not applicable.

d. Rationale for Exclusion of Certain Populations

Minors are not included because the lasers are not indicated for use in minors. Additionally, vision is not stable in minors.

e. Stanford Populations

Employees and students are eligible to participate in the study if they qualify. They will get the same written informed consent.

f. Healthy Volunteers

All subjects are healthy with myopia. We are studying outcomes of LASIK surgery in healthy nearsighted eyes.

g. Recruitment Details

We plan to run advertisements in the local paper regarding the study. The patients will be informed of the details of the study on the telephone.

h. Eligibility Criteria

i. Inclusion Criteria

Subjects age 21 and older with healthy eyes. Nearsightedness between -0.25 diopters and -7.00 diopters with or without astigmatism of up to 3.00 diopters.

ii. Exclusion Criteria

Subjects under the age of 21.
Patients with excessively thin corneas.
Patients with topographic evidence of keratoconus.
Patients with ectactic eye disorders.
Patients with autoimmune diseases.
Patients who are pregnant or nursing.
Patients must have similar levels of nearsightedness and farsightedness in each eye. They cannot be more than 1.5 diopter of difference between eyes.
Patients must have similar levels of astigmatism in each eye. They cannot have more than 1.5 diopter of difference between eyes.

i. Screening Procedures

We will attempt to screen patients on the telephone to determine if they are eligible. If they appear to be eligible on the telephone, then we will have them come in for a screening examination.

j. Participation in Multiple Protocols

We will request that the subjects do not participate in more than one study and this will be stated on the consent form.

k. Payments to Participants

There is no payment for participating in the study. The patients will receive a reduced fee of $[redacted] per eye to participate in the study. The usual and customary fee is $[redacted] per eye.

l. Costs to Participants

The patient is responsible for a fee of $[redacted] per eye w/out discount and $[redacted] per eye with the discount.

m. Planned Duration of the Study

The study is for one year. We estimate that the study will take approximately three years to complete. Total time per participant during the screening process is approximately 45 minutes. Total time per participant for active participation in the study will be

approximately 10 to 12 hours. Total time per participant for analysis of the participant data is approximately 30 minutes.

6. RISKS

a. Potential Risks

i. Investigational devices

No investigational devices are to be used. The excimer laser(AMO Visx Star S4 CustomVue)is FDA approved for use in LASIK surgery. Both femtosecond lasers (VisuMax and Intralase IFS) are FDA approved for use in LASIK surgery. LASIK surgery is commonly performed in the excimer department.

ii. Investigational drugs

No investigational drugs are being used.

iii. Commercially available drugs, biologics, reagents or chemicals

Vigamox - ocular irritation, stinging, allergy.
Pred Forte - ocular irritation, increased intraocular pressure, cataract formation
Systane - ocular irritation, burning, transient blurring of vision
Voltaren - ocular irritation, burning, allergy
Proparacaine - ocular stinging, transient anesthesia of cornea
Diazepam - nausea, drowsiness
Vicodan - nausea, drowsiness

iv. Procedures

Corneal topography, slit lamp biomicroscopy, Snellen visual acuity testing, low contrast visual acuity testing, and anterior segment ocular coherence tomography testing are all routine non-contact examinations performed in the ophthalmology clinic with essentially little or no risk.
Applanation tonometry and pachymetry involve touching a probe to the eye to measure intraocular pressure and corneal thickness respectfully. There is a low risk of a corneal abrasion while performing these tests (less than 1%). These tests are routinely performed in all the patients seen in the excimer clinic.
Corneal sensation measurement using Cochet-Bonnet aesthesiometry utilizes a nylon filament to stimulate the corneal nerves to measure corneal sensation. This device is commonly used in the clinic with essentially little or no risk.
Fundus examination involves a dilated examination of the posterior pole of the eye. Bright light is projected into the eye. Patients can experience some discomfort secondary to the bright light. This test is also performed as a routine part of every comprehensive eye exam in the excimer clinic.

The following are non-investigational procedures:
LASIK
Corneal topography
Slit lamp biomicroscopy
Fundus examination

Pachymetry
Applanation Tonometry
Snellen visual acuity testing
Low contrast visual acuity testing
Anterior segment ocular coherence tomography
Ultrasonic pachymetry
Corneal sensation measurement using Cochet-Bonnet Aesthesiometry

v. Radioisotopes/radiation-producing machines

Not applicable.

vi. Physical well-being

Low risk.

vii. Psychological well-being

Low risk.

viii. Economic well-being

Low risk.

ix. Social well-being

Low risk.

x. Overall evaluation of risk

Low risk.

b. International Research Risk Procedures

Not applicable.

c. Procedures to Minimize Risk

We will perform regular examinations of subjects at frequent intervals. If any adverse effects are noted, the subject will receive the appropriate care as needed. Both eyes are being treated at the same time so we will be following patients after the treatment.

d. Study Conclusion

We expect the study to terminate after all subjects have been enrolled. We will terminate the study sooner if a clear advantage is seen with one laser system compared to the other. We may terminate the study earlier depending on our rate of enrollement.
Individual subjects may be terminated for a variety or reasons including but not limited to:
-failure to come to follow up visits
-failure to follow the appropriate medication regimen
-pregnancy
-the subject needs to receive treatment not allowed in the study
-the study is cancelled

-unanticipated circumstances
-other administrative reasons

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

All measures of visual performance including uncorrected visual acuity, best spectacle corrected visual acuity, low contrast visual acuity, higher order aberration analysis, anterior segment OCT imaging.

ii. Person(s) responsible for Data and Safety Monitoring

The principal investigator will be monitoring the data. All adverse events will be reported to the IRB within one week of discovery.

iii. Frequency of DSMB meetings

NA

f. Risks to Special Populations

NA

7. BENEFITS

Subjects should experience a reduction or elimination of their nearsightedness with and without astigmatism with a resultant improvement in their uncorrected visual acuity. We may discover that either the VisuMax or the Intralase IFS yields better results with LASIK surgery so future subjects can choose the better technology.

8. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.