



Professional Use Information

AMO **STAR S4 IR** Excimer Laser System and **iDesign Advanced WaveScan Studio** System

Advanced CustomVue Treatments for Myopia

For the reduction or elimination of myopia up to -11.00 D SE, with cylinder up to -5.00 D

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the **STAR S4 IR** Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the **STAR S4 IR** Excimer Laser System Operator's Manual.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.



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Section Affected	Part Number	Rev.	Description
All	0030-7702	XA	Initial Release of <i>Advanced CustomVue</i> Myopia Treatment Professional Use

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General Warnings

STAR S4 IR EXCIMER LASER SYSTEM

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

Performance of procedures, use of controls, or any other adjustments other than those specified herein may result in a hazardous condition.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

GAS HANDLING: High-pressure gas cylinders are contained in a protected compartment within the **STAR S4 IR** Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with “Gas Safety” (Section 4.5) and “Gas Maintenance” (Section 14.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

The premix (argon/fluorine) gas mixture used in this laser system is highly toxic. Abbott Medical Optics Inc. (**AMO**) recommends that anyone working with the gas cylinders: 1) be trained in the proper handling of toxic and compressed gases, 2) know the location of the emergency exhaust fan/room purifier switch, 3) have easy access to all required protective equipment, and 4) be familiar with safety procedures and Materials Safety Data Sheets (MSDS) provided by the site’s safety officer. Gas discharge into the atmosphere may be evidenced by a sharp, penetrating odor and by eye, nose, and throat irritation.

SKIN AND EYE EXPOSURE: The **STAR S4 IR** System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. The fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms, including surgical instruments, is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance from the primary beam.

PRECAUTIONS: Carefully read all instructions prior to use. The laser beam is invisible. The user cannot tell if the laser is emitting radiation by looking for the beam. Observe all contraindications, warnings, and precautions noted in this manual. Failure to do so may result in patient and/or user complications.

ELECTROMAGNETIC FIELD (EMF): The thyatron emits an electromagnetic pulse which is shielded by the metal coverings of the **STAR S4 IR** Excimer Laser System. This metal covering reduces the EMF below the limits set by applicable standards for electromagnetic compliance.

WARNING: The effects of electromagnetic emissions from the excimer laser system on other devices, such as cardiac pacemakers or implanted defibrillators, are unknown. Operation of the laser in proximity to such devices is not recommended.

AIRBORNE CONTAMINANTS: Airborne contaminants which are produced by the ablation process are captured in proximity to the cornea near the point of production and fed into an aspirator with a filter. This aspirator is designed to prevent any of the products of ablation from contaminating the surgical suite.

iDESIGN ADVANCED WAVESCAN STUDIO SYSTEM

PRECAUTIONS:

Any service requiring access to the interior of the system should be performed only by **AMO** service personnel or by qualified service technicians who have received specific system training. Never try to defeat safety interlocks after removing covers. The safety interlocks are there for user protection. All power cords must be connected to the medical grade isolation transformer in the system.

Carefully read all instructions prior to use. Retain all safety and operating instructions for future use. Observe all contraindications, warnings, and precautions noted in the ***iDesign Advanced WaveScan Studio System Operator's Manual*** and the ***Star S4 IR Excimer Laser Operator's Manual***.

1 Device Description

1.1 STAR S4 IR Excimer Laser System

The **STAR S4 IR** System is designed to create a superficial lamellar keratectomy on exposed corneal tissue. Corneal tissue is removed by a process known as Ablative Photodecomposition. Ablative Photodecomposition occurs when far-ultraviolet radiation reacts with organic molecules, resulting in the photochemical breakdown of the molecular bonds without a significant local thermal effect. The source of the far-ultraviolet photons is a high-efficiency, gas-discharge excimer laser that electronically excites a combination of argon and fluorine, producing an ultraviolet wavelength of 193 nm. The **STAR S4 IR** Excimer Laser System combines the submicron precision and non-thermal tissue removal qualities of an excimer laser with a sophisticated computer controlled delivery system.

Features and components of the **STAR S4 IR** System include:

Excimer Laser

An argon-fluoride excimer laser module, with an output wavelength of 193 nm

Gas Management System

A gas cabinet containing a working gas cylinder for laser operation; a gas cleaning system; a gas leak audio alarm with a sensor to detect fluorine (one part-per-million); a gas discharge system, using an activated charcoal filter to absorb fluorine; an emergency safety system using a positive-action solenoid safety valve, which automatically seals the premix cylinder in the event of a power failure; and a second charcoal scrubber to neutralize fluorine in case of a leak. The **STAR S4 IR** laser software also contains a refinement to the method of STAR laser beam energy control by inclusion of an ozone compensation system.

Laser Beam Delivery System

The **STAR S4 IR** laser system delivers spatially scanning ultraviolet pulses of variable diameters and slits on to the cornea. The range of diameters and slits available during treatments are 0.65 mm to 6.5 mm. Beam shaping and homogenizing optics designed to produce a uniform, coaxial beam profile; a spatial integrator and beam rotator for temporal integration; and an iris diaphragm and rotating slit blades used to shape the beam. Conventional STAR treatments utilize sphere, cylinder and axis components which are entered manually into the laser by the operator to generate the ablation treatment. **Advanced CustomVue** treatment information is generated on the **WaveScan** System and transferred to the **STAR S4 IR** Excimer Laser System. The transferred information includes patient information, eye and refraction information, image of the eye, eye alignment information, and ablation instructions to the laser for beam diameters and the exact locations of the beam on the cornea. The variable spot scanning (**VSS**) feature of the laser, used for **Advanced CustomVue** treatments, delivers variable diameter ultraviolet pulses to

precise locations by the scanning delivery system. The **VSS** algorithm optimizes the ablation pattern by choosing the best combination of beam diameters and locations to achieve a target shape. **VSS** expands the laser capability to achieve a broader spectrum of ablation shapes than conventional treatments because the conventional algorithm optimizes only the diameter for myopic treatments and slits for hyperopic treatments.

Patient Management System

The **ActiveTrak** System, which enables the laser beam to track the patient's eye movements during the treatment, an operating microscope with reticle, used to observe a patient procedure and to facilitate accurate focus and laser beam alignment; a debris-removal system designed to evacuate the debris plume that occurs during ablation; a patient operating chair used to align the patient for treatment; a video camera and monitor used to monitor patient treatment; an illumination device used to illuminate the patient's eye for observation and treatment, and a fixation LED used by the patient to maintain proper alignment during treatment. Wavefront-guided treatments using the **STAR S4 IR** and **iDesign Advanced WaveScan Studio (AWS)** systems utilize an automated iris registration system. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the comparing features of the iris in the eye image taken during the wavefront measurement to the same features located in the image of the iris taken using the **STAR S4 IR** camera. The treatment is rotated to align precisely with the rotation of the patient's eye under the laser.

Computer Control

A PC-compatible computer, video monitor, keyboard with touchpad for user interface (Windows¹ standard), printer, a USB drive slot to store patient information on a USB flash drive, a USB port, an **AMO** treatment card driver, and system software.

AMO Treatment Card

The **AMO** Treatment Card system comprises a card drive and treatment cards. The AMO treatment card defines the number and the types of treatments available.

- A **Advanced CustomVue PreVue Card** is required to ablate an **Advanced CustomVue PreVue** lens plastic.
- An **Advanced CustomVue Card** is required to perform **Advanced CustomVue** treatments that were calculated on the **iDesign Advanced WaveScan Studio** System.

The final two digits of the card part number (90) is displayed on the **PATIENT MANAGER** screen. When preprogramming a treatment, an **AMO** Treatment Card with a part number (0040-XXXX-90) matching the Card PN displayed on the screen is required to perform the programmed treatment.

¹ Windows is a registered trademark of Microsoft Corporation.

1.2 *iDesign Advanced WaveScan Studio* System

The *iDesign Advanced WaveScan Studio* System is a diagnostic instrument indicated for the automated measurement of wavefront aberrations (including coma, spherical aberration, trefoil, and other higher order aberrations), corneal topography and pupillometry; and the calculation of wavefront-guided laser assisted in situ keratomileusis (LASIK) (***Advanced CustomVue***) treatments for myopia.

The *iDesign Advanced WaveScan Studio* System measures the wavefront of the eye within a defined range using the Hartmann-Shack wavefront sensor. The sensor evaluates the deflection of rays emanating from a small beam of light projected onto the retina. The measurements determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that cause reduced visual function.

The *iDesign Advanced WaveScan Studio* System software uses these data to compute the eye's refractive errors and wavefront aberrations using a polynomial expansion. The system displays the refractive errors and wavefront aberrations as the optical path difference (OPD) between the measured outgoing wavefront and the ideal plane wave. The *iDesign Advanced WaveScan Studio* System software subtracts the refractive errors from the wavefront errors map and displays the higher order aberrations as OPD errors. Regions of the pupil with positive OPD are in front of the ideal plane wave and areas with negative OPD are behind the ideal plane wave.

Features and components of the *iDesign Advanced WaveScan Studio* System, include:

Computer Control

The *iDesign Advanced WaveScan Studio* System includes software to calculate the desired laser vision correction treatment (***Advanced CustomVue*** treatment) from the wavefront measurement. The *iDesign Advanced WaveScan Studio* software generates the laser instructions for the patient and can optionally also create instructions for a ***PreVue*** plastic lens. The instructions are components of the treatment file that is loaded on to the ***STAR S4 IR*** System and are used to define the patient treatment.

Computer Central Processing Unit (CPU) and Monitor

The monitor is a flat-panel LCD display. The keyboard and glide-pad are Windows compatible.

Isolation Transformer

The medical-grade isolation transformer complies with IEC 601-1-:2005/01/01 and IEC 60601-1-2:2007/03/01 regulations. All power cords connect to the isolation transformer.

Optical Head

The optical head projects a light beam onto the retina. The light is reflected back through the eye's optical path and into the wavefront sensing device. A lenslet

array images the reflected beam onto the CMOS sensor (digital camera). Each lens of the array gathers light information (deflection information) from a different pupil region, forming an image of the light passed through that pupil region. An array of spots is imaged on the CMOS sensor. The system compares the locations of the array of spots gathered from the CMOS sensor to the theoretical ideal (the ideal plane wave).

Printer

A high resolution color printer is included with the system.

Motorized table

The motorized table supports the *iDesign Advanced WaveScan Studio* System. Electrical ratings: 120 V ~, 50/60 Hz, 6 A. Vertical position is controlled by a rocker control switch (vertical height can range from 630 mm to 1030 mm). Table top supports the *iDesign Advanced WaveScan Studio* System and USB keyboard. Shelves hold the printer and isolation transformer.

iDesign Model Eye

A model eye with a calibrated fixed diopter value is shipped with the system. This model eye is used to confirm the proper operation and calibration of the system.

2 Indications, Contraindications, Warnings, Precautions, and Adverse Events

2.1 Indications for Use

The **STAR S4 IR** Excimer Laser System and **iDesign Advanced WaveScan Studio** System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) in patients:

- with myopia as measured by **iDesign Advanced WaveScan Studio** System up to -11.00 D spherical equivalent, with up to -5.00 D cylinder;
- with agreement between manifest refraction (adjusted for optical infinity) and **iDesign Advanced WaveScan Studio** System refraction as follows:
 - Spherical Equivalent: Magnitude of the difference is less than 0.625 D.
 - Cylinder: Magnitude of the difference is less than or equal to 0.5 D.
- 18 years of age or older, and
- with refractive stability (a change of ≤ 1.0 D in sphere or cylinder for a minimum of 12 months prior to surgery).



Refer to the preceding General Warnings section of this Professional Use Information Manual, in addition to the warnings and precautions found in this section.

2.2 Contraindications

Laser refractive surgery is contraindicated:

- in patients with collagen vascular, autoimmune or immunodeficiency diseases.
- in pregnant or nursing women.
- in patients with corneal abnormalities including signs of keratoconus, abnormal corneal topography, epithelial basement membrane disease (EBMD) and degenerations of the structure of the cornea.
- in patients with symptoms of significant dry eyes. If the patients have severely dry eyes, LASIK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery. It may result in poor vision after LASIK.
- in patients whose corneal thickness would cause anticipated treatment would violate the posterior 250 microns (μm) of corneal stroma.
- in patients with advanced glaucoma.

- in patients with uncontrolled diabetes.

2.3 Warnings

LASIK is not recommended in patients who:

- have systemic diseases likely to affect wound healing, such as autoimmune connective tissue disease, diabetes or an immunocompromised status.
- have a history of Herpes simplex or Herpes zoster keratitis.
- have severe allergies or tendency rub their eyes often.
- have glaucoma, elevated IOP, ocular hypertension or being followed for possible glaucoma (glaucoma suspect).
- are taking the medication Isotretinoin (Accutane).
- are taking antimetabolites for any medical conditions.

2.4 Precautions

A. General

To reduce the risk of corneal ectasia, the posterior 250 microns (μm) of corneal stroma should not be violated.

The treatment of highly myopic eyes necessitates the removal of significant amounts of corneal tissue. The iDesign Advanced WaveScan Studio System calculates the estimated residual bed depth using the pachymetry and intended flap thickness entered by the user. Actual flap thicknesses may vary. If the estimated residual stromal bed is ≤ 320 microns, an in-the-bed pachymetric measurement should be performed.

The safety and effectiveness of this laser for LASIK correction have **NOT** been established in patients:

- with progressive myopia, ocular disease; corneal abnormality; previous corneal or intraocular surgery; or trauma in the ablation zone.
- with a residual corneal thickness less than 250 microns at the completion of ablation.
- who are taking the medication Sumatriptan (Imitrex²).
- who are taking the medication Amiodarone hydrochloride (Cordarone³).

Preoperative evaluation for dry eye should be performed. Preoperative

² Imitrex is a registered trademark of GlaxoSmithKline, Inc.

pachymetry measurement must be performed.

The safety and effectiveness of wavefront-guided LASIK surgery has **ONLY** been established with an optical zone of 6 mm and an ablation zone of 8 mm.

The wavefront sensor measures the higher order aberrations over the patient's pupil diameter up to 8.5 mm. No optical zone diameters other than 6 mm were studied in the U.S. wavefront-guided clinical trial for myopia.

No higher order aberrations can be measured or treated outside the wavefront measurement region. If the surgeon extends the optical zone beyond the measured wavefront diameter, the non-uniform wavefront transition zone will overlie the attempted spherocylindrical treatment. Many treatments (89/334) based on **iDesign Advanced WaveScan Studio** system measurement diameters of less than 6.0 mm were used to establish the safety and effectiveness of wavefront-guided myopia treatments with 6.0 mm optical zones. A comparison of results from these treatments and treatments based on measurements that were 6.0 mm or larger showed no differences in outcomes.

It is important to maintain a carefully controlled surgical environment. AMO recommends that all **Advanced CustomVue** treatments be performed in surgical environments where the humidity is between 40-45% and the temperature is between 68-72° F for best results.

The safety and effectiveness of the **STAR S4 IR iDesign Advanced WaveScan Studio** System have **NOT** been established for wavefront-guided LASIK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone.
- over the long term (more than 1 year after surgery).
- with prior intraocular or corneal surgery of any kind.
- For eyes with myopia or myopic astigmatism:
 - Whose difference between manifest refraction (adjusted for optical infinity) and **iDesign Advanced WaveScan Studio** refraction chosen for treatment exceeds:
 - Spherical Equivalent: Magnitude of the difference is less than 0.625 D.
 - Cylinder: Magnitude of the difference is less than or equal to 0.5 D.
 - Cylinder Axis: If either the manifest cylinder entered into the **iDesign AWS** System or the **iDesign AWS** cylinder selected for treatment is less than 0.5 D, there is no requirement for axis tolerance. When both cylinders have a magnitude of at least 0.5 D, the axis tolerance is linearly reduced from 15° (0.5 D) to 7.5° (7.0 D or greater) based on the average magnitude of both cylinders.
- whose BSCVA is worse than 20/20.

- whose wavefront measurement diameter is < 4mm.
- for treatments greater than -11.00 D diopters of Spherical Equivalent or greater than -5.00 D diopters of astigmatism as measured by **iDesign Advance WaveScan Studio** System.
- for retreatment with **Advanced CustomVue** LASIK.
- who were wearing contact lenses unless they had evidence of stability.
- for patients who engage in activities that could endanger or damage the LASIK flap.
- patients taking amiodarone hydrochloride (e.g., Cordarone®).
- for patients who have a family history of degenerative corneal disease.
- history of inflammation of the iris or other structures in the eye (iritis, uveitis or chronic inflammation of the eye).
- for patients who have naturally occurring pupils smaller than 4.0 mm, as they are not eligible for treatment with Advanced CustomVue LASIK. The maximum pupil size allowed for treatment is 9.5 mm and there are no safety or effectiveness data for eyes with pupils larger than 8.7 mm.
- for patients who have a history of crossed eyes (strabismus) or who have undergone strabismus surgery.
- the effects of Advanced CustomVue LASIK on future IOP calculations were not studied.
- the effects of Advance CustomVue LASIK on future cataract surgery were not studied. Who are not within the studied age groups: Patients who are younger than 18 years of age.
- the effects of medications and medical conditions that were excluded from the clinical trial on LASIK are unknown.
- prior LASIK or Refractive Surgery.
- with history of any eye diseases or abnormalities such as:
 - corneal scars
 - active disease
 - history of glaucoma or IOP greater than 21 mmHg.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for **Advanced CustomVue** treatment:

All patients must be given the opportunity to read and understand the Patient

Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK).

- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology and indirect ophthalmoscopy through a dilated pupil is essential.
- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 1 week for soft lenses and at least 3 weeks for Rigid Gas Permeable or hard lenses or toric lenses of any type.
- Prior to treatment and after appropriate contact lens abstinence, contact lens wearers must have manifest refraction and keratometric measurement stability confirmed. A second refraction and keratometry reading are to be repeated at least 7 days after baseline measurement. Refractive stability is defined as a change of not more than 0.50 D in both MRSE and keratometric meridian (either axis) as compared to the preoperative refraction and keratometric measurements.
- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary.
- Preoperative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- Baseline evaluation of patients requesting **Advanced CustomVue** treatments should be performed within 30 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the **iDesign Advanced WaveScan Studio** system refraction, BSCVA, and wavefront diameter as outlined in the previous section of these Precautions.
- The minimum size of the wavefront measurement diameter must be ≥ 4 mm to calculate an **Advanced CustomVue** treatment.
- If a **PreVue** lens is used in the baseline evaluation of patients requesting **Advanced CustomVue** treatments, the vision obtained by the patient through the **PreVue** lens is not meant to be predictive of the end result that a patient might achieve. In situations where there is a clinical question regarding the applicability of the computer-generated treatment, a **PreVue** lens can be ablated to assist both the practitioner and the patient in evaluating the appropriateness of this generated treatment.
- The patient should have the ability to tolerate local or topical anesthesia.

- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the laser refractive procedure.
- The patient must be able to understand and give an informed consent. Patients must be clearly informed of all alternatives for the correction of myopia. These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries.

C. Procedure

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam.

All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

D. Post-Procedure

The following postoperative examinations are recommended on day 1, and at 1, 3, and 6 months:

Table 2-1 Recommended Postoperative Examinations

Examination	Recommended Visit
<i>iDesign Advanced WaveScan Studio</i> System measurement	1, 3 and 6 months
Uncorrected Visual Acuity (UCVA or VA-sc)	1 day, 1, 3 and 6 months
Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc)	1, 3 and 6 months
Manifest refraction.	1, 3 and 6 months
Intraocular pressure (Goldmann applanation)	1, 3 and 6 months
Slit-lamp examination.	1 day, 1, 3 and 6 months
Keratometry and videokeratography	1, 3 and 6 months

2.5 Adverse Events

Safety analyses are based on the 334 treated eyes in the US IDE clinical investigation of the AMO STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System. A summary of adverse events are provided in Table 2-2. Complications are presented in Table 2-3.

Table 2-2 Summary of Adverse Events, All Eyes, N=334

Complications	<1 Month (n=334)		1 Month (n=334)		3 Months (n=334)		6 Months (n=334)		9 Months (n=320)		12 Months (n=292)		Cumulative (n=334)	
	n	%	N	%	n	%	n	%	n	%	n	%	n	%
Corneal infiltrate or ulcer	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any persistent corneal epithelial defect at 1 month or later	N/A	N/A	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema at 1 month or later (specify “flap”, “bed”, or both)	N/A	N/A	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface with loss of 2 lines (10 letters) or more of BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Miscreated flap (decentered, lost, incomplete, too thin, or other)	1 (a)	0.3 (a)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1 (a)	0.3 (a)
Melting of the flap	0	0.0	0	0.0	0	0.0	1 (b)	0.3	1 (b)	0.3	1 (b)	0.3	1 (b)	0.3
IOP with increase >10 mmHg above baseline on two consecutive examinations or an IOP >30 mmHg on two consecutive examinations	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Haze beyond 6 months with loss of 2 lines or greater (≥10 letters)	N/A	N/A	N/A	N/A	N/A	N/A	0	0.0	0	0.0	0	0.0	0	0.0
Ocular penetration	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Severe glare, dry eye, or halos at 3 months or later	N/A	N/A	N/A	N/A	2 (c)	0.6	0	0.0	0	0.0	0	0.0	2 (c)	0.6
Decrease in BSCVA of greater than or equal to 2 lines (≥10 letters) not due to irregular astigmatism, at 3 months or later	N/A	N/A	N/A	N/A	0	0.0	1 (d)	0.3	0	0.0	0	0.0	1 (d)	0.3
Any other vision-threatening event	0	0.0	2 (e)	0.6	0	0.0	2 (f)	0.6	2 (f)	0.6	2 (f)	0.6	4 (e,f)	1.2
Diffuse Lamellar Keratitis (DLK, grade 3 or above)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal vascular accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

(a) One eye was unable to be treated due to incomplete flap (unable to be lifted) and not included in treated study cohort; incidence 0.3%; 1/335.
 (b) One eye was reported with adverse event of melting of the flap beginning at 6 months; UCVA 20/16 at 12 months.
 (c) Two eyes (of same subject) reported with adverse events of severe dryness at 3 months; resolution prior to 6 months. In addition, 4 subjects (2.4%; 4/170) in the study reported being very bothered by glare with marked severity.
 (d) One eye reported with a transient 2-line loss in BSCVA vs. preoperative. BSCVA was 20/16 at 6 months vs. 20/10 preoperative; improved to 20/12.5 at 9 months.
 (e) Two eyes (of same subject) reported with serious (sight-threatening) Transient Light Sensitivity Syndrome (TLSS); resolution prior to 3 months.
 (f) Two eyes (of same subject) reported with serious (sight-threatening) primary open angle glaucoma.

Table 2-3 Summary of Complications Over Time, All Eyes, N=334

Complications	<1 Month (n=334)		1 Month (n=334)		3 Months (n=334)		6 Months (n=334)		9 Months (n=320)		12 Months (n=292)		Cumulative (n=334)	
	n	%	N	%	n	%	n	%	n	%	n	%	n	%
Corneal edema between 1 week and 1 month after procedure	26	8.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Peripheral corneal epithelial defect at 1 month or later	N/A	N/A	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface (epithelial ingrowth; trace/mild)	3	0.9	9	2.7	10	3.9	9	2.7	10	3.1	6	2.1	17	5.1
Diffuse Lamellar Keratitis (DLK, Grade 2 or less)	17 (a)	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	17 (a)	5.1
Foreign body sensation at 1 month or later	N/A	N/A	38 (b)	11.4	26 (b)	7.8	17 (b)	5.1	14 (b)	4.2	8 (b)	2.7	68 (b)	20.4
Pain at 1 month or later	N/A	N/A	13 (c)	3.9	9 (c)	2.7	14 (c)	4.2	0	0.0	6 (c)	2.1	40 (c)	12.0

Note: Shaded areas represent time frames outside complication definition.

- (a) All reports of DLK were Grade 1 or less.
- (b) Most reports were mild; no marked or severe reports.
- (c) Most reports were mild; one moderate report at 3 and 6 months, one marked report at 6 months and at an interim visit.

3 Clinical Results

A prospective, non-randomized, unmasked, multicenter clinical study was conducted for the treatment of myopia using the AMO **STAR S4 IR** Excimer Laser System and the **iDesign Advanced WaveScan Studio** System.

The refractive inclusion criteria allowed **iDesign Advanced WaveScan Studio (AWS)** system measured myopia (with or without astigmatism) of up to -12.00 D spherical equivalent, with cylinder up to 8.00 D.

To qualify for the study, agreement between the manifest and **iDesign AWS** refraction and a wavefront measurement size ≥ 4 mm was to be demonstrated. All study treatments were conducted using a 6 mm optical zone and an 8 mm ablation zone with intention of full correction to emmetropia.

A total of 334 eyes were treated and comprised the cohort used for both safety and effectiveness evaluations.

Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopy.

A. About the Study

Analyses of results were performed at 1, 3, 6, 9, and 12 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, and refractive stability.

Safety analyses included change in best spectacle-corrected visual acuity (BSCVA), induced manifest refractive astigmatism, and adverse events.

Other endpoints included contrast sensitivity, higher order aberrations, complications, directed visual symptoms assessment, NEI-RQL visual functioning and vision-related wellbeing questionnaire results, keratometric analyses, and vector and non-vector analyses of manifest refractive cylinder.

The key outcome variables were assessed postoperatively at the periodic exams. Refractive stability was achieved at 6 months; therefore, the key safety and effectiveness study endpoints were evaluated at 6 months as the primary study analysis.

B. Patient Accountability

Three hundred and thirty four (334) eyes of 170 subjects treated at twelve centers in the United States were evaluated for safety and effectiveness. The mean age of the 170 subjects participating in this trial was 32.3 ± 8.3 years (range 18 to 58).

There were 77 women and 93 men. Table 3-1 presents the demographic

characteristics of the patient population. Table 3-2 presents the percent accountability for all eyes treated in the study: 100% (334/334) completed visits through 6 months, 95.8% (320/334) completed the 9-month visit and 87.4% (292/334) completed 12-month study visit.

Table 3-1 Demographics: All Subjects, N=170

Category	Classification	All Myopic Subjects
Gender	Male	93 (54.7%)
	Female	77 (45.3%)
Race	Caucasian	113 (66.5%)
	Black/African Descent	5 (2.9%)
	Asian	10 (5.9%)
	Pacific Islander	3 (1.8%)
	Other (a)	39 (22.9%)
Age (Years)	Mean	32.3
	SD	8.31
	Min	18
	Max	58
Contact Lens History	None	49 (28.8%)
	Soft	71 (41.8%)
	Rigid/Toric	50 (29.4%)

(a) Includes Hispanic, Caucasian/Asian, Caucasian/Hispanic, Eurasian, Hispanic/Italian, Indian.

Table 3-2 Patient Accountability: All Eyes, N=334

Status	Periodic Study Exams									
	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Available for Analysis	334	100	334	100	334	100	320	95.8	292	87.4
--Out of Interval	8	2.4	6	1.8	12	3.6	2	0.6	2	0.6
Missing Subjects	0	0.0	0	0.0	0	0.0	14	4.2	42	12.6
--In interval or past interval	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
--Active (not yet in visit interval)	0	0.0	0	0.0	0	0.0	12	3.6	42	12.6
--Missed visit	0	0.0	0	0.0	0	0.0	2	0.6	0	0.0
--Lost-to-Follow-Up	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
--Discontinued	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

C. Data Analysis and Results

1) Preoperative Characteristics

All refractions were measured at four meters and converted to optical infinity for data analysis and presentation. Table 3-3 presents preoperative refractive error stratified by *iDesign Advanced WaveScan Studio* system sphere and cylinder, while Table 3-4 presents preoperative refractive error stratified by *iDesign Advanced WaveScan Studio* system spherical equivalent and cylinder, expressed in minus cylinder notation.

Table 3-3 Preoperative Refractive Error Stratified by Sphere and Cylinder, N=334

iDesign AWS Sphere	iDesign AWS Cylinder									Total
	0 to ≤-0.5 D	>-0.5 to ≤-1 D	>-1 to ≤-2 D	>-2 to ≤-3 D	>-3 to ≤-4 D	>-4 to ≤-5 D	>-5 to ≤-6 D	>-6 to ≤-7 D	>-7 to ≤-8 D	
≥ 0 to ≤-1 D	0	1	5	4	6	2	2	2	0	22
>-1 to ≤-2 D	10	4	0	2	6	5	3	2	0	32
>-2 to ≤-3 D	8	2	8	4	1	3	3	1	0	30
>-3 to ≤-4 D	14	6	5	3	5	8	0	0	0	41
>-4 to ≤-5 D	14	5	11	7	6	4	1	0	1	49
>-5 to ≤-6 D	3	8	6	5	2	2	1	0	1	28
>-6 to ≤-7 D	8	12	6	5	1	0	0	0	0	32
>-7 to ≤-8 D	4	7	8	8	1	0	0	0	0	28
>-8 to ≤-9 D	6	8	2	3	3	0	0	0	0	22
>-9 to ≤-10 D	9	3	4	4	1	2	0	0	0	23
>-10 to ≤-11 D	6	6	5	2	2	0	0	0	0	21
>-11 to ≤-12 D	5	1	0	0	0	0	0	0	0	6
Total	87	63	60	47	34	26	10	5	2	334

Table 3-4 Preoperative Refractive Error Stratified by iDesign Advanced WaveScan Studio System Spherical Equivalent and Cylinder, N=334

iDesign AWS SE	iDesign AWS Cylinder									Total
	0 to ≤-0.5 D	>-0.5 to ≤-1 D	>-1 to ≤-2 D	>-2 to ≤-3 D	>-3 to ≤-4 D	>-4 to ≤-5 D	>-5 to ≤-6 D	>-6 to ≤-7 D	>-7 to ≤-8 D	
>-1 to ≤-2 D	9	2	5	4	2	0	0	0	0	22
>-2 to ≤-3 D	9	5	4	1	6	2	0	0	0	27
>-3 to ≤-4 D	12	5	6	5	4	5	2	1	0	40
>-4 to ≤-5 D	15	5	6	3	3	3	5	2	0	42
>-5 to ≤-6 D	4	6	11	6	5	8	1	2	0	43
>-6 to ≤-7 D	6	9	6	5	6	4	0	0	0	36
>-7 to ≤-8 D	6	10	4	6	1	2	2	0	0	31
>-8 to ≤-9 D	5	10	7	7	0	0	0	0	2	31
>-9 to ≤-10 D	9	4	4	3	3	0	0	0	0	23
>-10 to ≤-11 D	7	5	6	5	1	0	0	0	0	24
>-11 to ≤-12 D	5	2	1	2	3	2	0	0	0	15
Total	87	63	60	47	34	26	10	5	2	334

2) Uncorrected Visual Acuity (UCVA)

All eyes were targeted for emmetropia. At the 6-month visit, 82.6% (276/334) of all eyes achieved UCVA of 20/20 or better, and 61.7% achieved 20/16 or better. Table 3-5 presents UCVA over time for all eyes.

Table 3-5 UCVA Over Time: All Eyes, N=334

Acuity	Preoperative (n=334)	1 Month (n=334)	3 Months (n=334)	6 Months (n=334)	9 Months (n=320)	12 Months (n=292)
	n, %	n, %	n, %	n, %	n, %	n, %
20/10 or better	0, 0.0%	8, 2.4%	10, 3.0%	8, 2.4%	10, 3.1%	9, 3.1%
20/12.5 or better	0, 0.0%	70, 21.0%	81, 24.3%	70, 21.0%	68, 21.3%	62, 21.4%
20/16 or better	0, 0.0%	215, 64.4%	208, 62.3%	206, 61.7%	202, 63.1%	178, 61.4%
20/20 or better	0, 0.0%	294, 88.0%	283, 84.7%	276, 82.6%	268, 83.8%	231, 79.7%
20/25 or better	0, 0.0%	323, 96.7%	315, 94.3%	311, 93.1%	291, 90.9%	263, 90.7%
20/32 or better	0, 0.0%	331, 99.1%	330, 98.8%	325, 97.3%	304, 95.0%	277, 95.5%
20/40 or better	6, 1.8%	332, 99.4%	332, 99.4%	328, 98.2%	313, 97.8%	280, 96.6%
20/50 or better	14, 4.2%	334, 100%	332, 99.4%	330, 98.8%	315, 98.4%	288, 99.3%
20/63 or better	23, 6.9%	334, 100%	332, 99.4%	330, 98.8%	317, 99.1%	289, 99.7%
20/80 or better	28, 8.4%	334, 100%	332, 99.4%	331, 99.1%	317, 99.1%	290, 100%
20/100 or better	48, 14.4%	334, 100%	333, 99.7%	334, 100%	320, 100%	290, 100%
Worse than 20/100	286, 85.6%	0, 0.0%	1, 0.3%	0, 0.0%	0, 0.0%	0, 0.0%
Not Reported	0	0	0	0	0	2

Table 3-6 presents postoperative uncorrected visual acuity compared to preoperative best spectacle-corrected visual acuity. At 6 months, 67.1% of eyes were able to achieve a postoperative uncorrected vision that was either the same or better than their preoperative best spectacle-corrected vision.

Table 3-6 Postoperative Uncorrected Visual Acuity Compared to Preoperative Best Spectacle-Corrected Visual Acuity: All Eyes, N=334

Acuity	1 Month (n=334)	3 Months (n=334)	6 Months (n=334)	9 Months (n=320)	12 Months (n=292)
	n, %	n, %	n, %	n, %	n, %
>2 lines better	0, 0.0%	1, 0.3%	0, 0.0%	1, 0.3%	0, 0.0%
2 lines better	8, 2.4%	11, 3.3%	11, 3.3%	13, 4.1%	6, 2.1%
1 line better	86, 25.7%	94, 28.1%	88, 26.3%	76, 23.8%	82, 28.3%
Equal	154, 46.1%	128, 38.3%	125, 37.4%	133, 41.6%	102, 35.2%
1 line worse	59, 17.7%	65, 19.5%	71, 21.3%	57, 17.8%	53, 18.3%
2 lines worse	16, 4.8%	17, 5.1%	16, 4.8%	13, 4.1%	18, 6.2%
>2 lines worse	11, 3.3%	18, 5.4%	23, 6.9%	27, 8.4%	29, 10.0%
Not Reported	0	0	0	0	2

Note: Percentages calculated based on non-missing values.

3) Accuracy of MRSE Over Time

At 6 months, 68.9% (230/334) of eyes were within 0.50 D and 93.4% (312/334) were within 1.0 D of attempted correction. Table 3-7 presents the accuracy of MRSE over time for all eyes.

Table 3-7 Accuracy of Manifest Refraction Attempted vs. Achieved: All Eyes, N=334

	Preoperative (n=334)	1 Month (n=334)	3 Months (n=334)	6 Months (n=334)	9 Months (n=320)	12 Months (n=292)
MRSE	n, %	n, %	n, %	n, %	n, %	n, %
± 0.50 D	0 0.0%	261 78.1%	240 71.9%	230 68.9%	209 65.3%	191 65.9%
± 1.00 D	0 0.0%	326 97.6%	314 94.0%	312 93.4%	288 90.0%	265 91.4%
± 2.00 D	25 7.5%	334 100%	332 99.4%	332 99.4%	318 99.4%	289 99.7%
Not Reported	0	0	0	0	0	2
Under-corrected						
> 1.00 D	N/A	8 2.4%	20 6.0%	22 6.6%	32 10.0%	25 8.6%
> 2.00 D	N/A	0 0.0%	2 ^a 0.6%	2 ^a 0.6%	2 ^a 0.6%	1 ^b 0.3%
Over-corrected						
> 1.00 D	N/A	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
> 2.00 D	N/A	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%

Note: Percentages calculated based on non-missing values.

4) Stability of Outcome

Refractive stability was evaluated using both a consecutive cohort of eyes (eyes with data available for two consecutive visits) as well as a consistent cohort of eyes (eyes with data available at all visits). Results were similar between both cohorts; Table 3-8 presents the refractive stability results for the consecutive cohort. Refractive stability was achieved at 6 months and confirmed at the 9-month visit.

Table 3-9 presents mean refractive outcomes over time with mean MRSE of -0.46 D (SD 0.42 D) at 6 months for all myopic eyes.

Table 3-8 Stability of MRSE and Manifest Refractive Cylinder (MRC) for Eyes that Underwent Two Consecutive Visits: All Eyes N =334

Refractive Stability All Eyes - Consecutive Cohort				
Distributions	Between 1 and 3 Months (n=334) n, %	Between 3 and 6 Months (n=334) n, %	Between 6 and 9 Months (n=320) n, %	Between 9 and 12 Months (n=284) n, %
Change in MRSE by ≤ 1.0 D (a)	332, 99.4%	331, 99.1%	319, 99.7%	282, 99.3%
Change in MRC by ≤ 1.0 D (a)	332, 99.4%	332, 99.4%	319, 99.7%	284, 100%
Mean Outcomes	D \pm SD	D \pm SD	D \pm SD	D \pm SD
Mean Change in MRSE	-0.096 \pm 0.293	-0.030 \pm 0.321	-0.024 \pm 0.288	-0.033 \pm 0.297
Mean Change in MRSE per Month (b)	-0.048	-0.010	-0.008	-0.011
Mean Change in MRC	-0.019 \pm 0.269	-0.026 \pm 0.287	-0.007 \pm 0.284	0.006 \pm 0.245
Mean Change in MRC per Month (b)	-0.009	-0.009	-0.002	0.002
Note: Percentages calculated based on non-missing values.				
(a) Refractive stability criterion: 95% of eyes with change of ≤ 1.00 D between visits				
(b) Refractive stability criterion: mean change of ≤ 0.04 D/month between visits				

Table 3-9 Mean Refractive Outcomes Over Time: All Eyes, N= 334

	Preoperative	1 Month	3 Month	6 Month	9 Month	12 Month
Variable	n=334	n=334	n=334	n=334	n=320	n=290
MRSE (D) ±SD	-6.21 ± 2.78	-0.33 ± 0.35	-0.43 ± 0.39	-0.46 ± 0.42	-0.49 ± 0.45	-0.49 ± 0.40
MRS (D) ±SD	-5.32 ± 2.97	-0.19 ± 0.39	-0.28 ± 0.42	-0.29 ± 0.45	-0.33 ± 0.46	-0.33 ± 0.41
MRC (D) ±SD	-1.77 ± 1.65	-0.28 ± 0.34	-0.30 ± 0.35	-0.33 ± 0.36	-0.33 ± 0.36	-0.33 ± 0.32

MRSE = manifest refraction spherical equivalent,
MRS = manifest refractive sphere,
MRC = manifest refractive cylinder

5) Effectiveness of Correction of Astigmatism

The effectiveness of astigmatism correction was evaluated at the point of stability (6 months) for eyes with myopic astigmatism. Table 3-10 displays the mean percent reduction of cylinder for eyes with myopic astigmatism (preoperative manifest refractive cylinder > 0.0 D), stratified by preoperative cylinder. Table 3-11 presents the proportions of eyes with residual manifest cylinder magnitude at 6 months and the absolute shift in axis from preoperative.

Table 3-10 Reduction of Absolute (Non-vector) Manifest Refractive Cylinder (MRC) at 6 Months, Eyes with Preoperative Myopic Astigmatism N = 247

Preoperative Manifest Refractive Cylinder	Percent Reduction of Absolute Manifest Refractive Cylinder			
	N	Mean	Min	Max
All	247	76.3%	-450.0%	100.0%
< 0.0 to ≥ -0.5 D	28	33.9%	-450.0%	100.0%
< -0.5 to ≥ -1.0 D	52	65.4%	0.0%	100.0%
< -1.0 to ≥ -2.0 D	54	85.5%	40.0%	100.0%
< -2.0 to ≥ -3.0 D	44	86.7%	51.0%	100.0%
< -3.0 to ≥ -4.0 D	30	87.5%	66.7%	100.0%
< -4.0 to ≥ -5.0 D	22	86.9%	70.0%	100.0%
< -5.0 to ≥ -6.0 D	10	86.3%	57.1%	100.0%
< -6.0 to ≥ -7.0 D	4	94.0%	80.0%	100.0%
< -7.0 to ≥ -8.0 D	3	96.6%	96.6%	96.7%

Note: Eyes with zero cylinder preoperatively were not included.

Note: Percent of Reduction defined as (Preop CYL- Postop CYL)/Preop CYL.

**Table 3-11 Residual Astigmatic Axis Error (Non-Vector) at 6 Months
Eyes with Preoperative Myopic Astigmatism (N=247)**

Residual Manifest	Absolute Shift in Axis						Total (n=247)
	0° (n=84)	≤5° (n=36)	>5° to ≤10° (n=19)	>10° to ≤15° (n=21)	>15° to ≤30° (n=41)	>30° (n=46)	
Cylinder Magnitude	n %	n %	n %	n %	n %	n %	n %
0.0 D	78 92.9%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	78 31.6%
>0 to ≤0.5D	6 7.1%	24 66.7%	14 73.7%	15 71.4%	31 75.6%	0 0.0%	134 54.3%
>0.5 to ≤1.0D	0 0.0%	7 19.4%	4 21.1%	4 19.0%	6 14.6%	2 4.3%	23 9.3%
>1.0 to ≤2.0D	0 0.0%	5 13.9%	1 5.3%	2 9.5%	2 4.9%	0 0.0%	10 4.0%
>2.0 to ≤3.0D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	2 4.9%	0 0.0%	2 0.8%
Total	84 100%	36 100%	19 100%	21 100%	41 100%	46 100%	247 100%
Note: Percentages calculated based on non-missing values.							

Table 3-12 presents a summary of the vector analysis which includes mean Intended Refractive Change (IRC), Surgically Induced Refractive Cylinder (SIRC), Correction Ratio (CR), and Error Ratio (ER), at the point of stability (6 months).

Table 3-12 Vector Analysis at Stability (6 Months): Eyes with Myopic Astigmatism, N=221, Vector Analysis Summary at 6 Months

Preoperative Cylinder magnitude	N	IRC (Mean ± SD)	SIRC (Mean ± SD)	EV (Mean ± SD)	CR (Mean ± SD)	ER (Mean ± SD)
All	221	2.51 ± 1.58	2.32 ± 1.49	0.36 ± 0.36	0.94 ± 0.18	0.19 ± 0.20
>0.5 D to ≤1.0 D	54	0.86 ± 0.13	0.81 ± 0.25	0.30 ± 0.23	0.95 ± 0.29	0.36 ± 0.28
>1.0 D to ≤2.0 D	54	1.61 ± 0.31	1.57 ± 0.39	0.23 ± 0.22	0.98 ± 0.17	0.14 ± 0.15
>2.0 D to ≤3.0 D	44	2.54 ± 0.26	2.31 ± 0.38	0.34 ± 0.30	0.91 ± 0.11	0.13 ± 0.12
>3.0 D to ≤4.0 D	30	3.57 ± 0.29	3.29 ± 0.49	0.44 ± 0.38	0.92 ± 0.13	0.12 ± 0.11
>4.0 D to ≤5.0 D	22	4.47 ± 0.26	3.96 ± 0.45	0.59 ± 0.45	0.89 ± 0.10	0.13 ± 0.10
>5.0 D to ≤6.0 D	10	5.55 ± 0.31	5.06 ± 0.75	0.75 ± 0.75	0.91 ± 0.11	0.14 ± 0.14
>6.0 D to ≤7.0 D	4	6.63 ± 0.32	6.30 ± 0.85	0.38 ± 0.60	0.95 ± 0.09	0.06 ± 0.10
>7.0 D to ≤8.0 D	3	7.33 ± 0.14	7.18 ± 0.11	0.25 ± 0.00	0.98 ± 0.02	0.03 ± 0.00
<p>Eyes with preoperative manifest refractive cylinder (MRC) magnitude >0.50 D IRC = Intended refractive change SIRC = Surgically induced refractive change EV = Error vector (IRC-SIRC) CR = Correction ratio (SIRC/IRC) ER = Error ratio (EV/IRC)</p>						

6) Higher Order Aberrations

Table 3-13 presents Higher Order Aberrations (HOA) RMS (μm) with 4 mm and 5 mm standardized wavefront diameters at preoperative and 6 Months.

Table 3-13 Higher Order Aberrations (HOA) RMS with 4 mm and 5 mm Standardized Wavefront Diameters at Preoperative and 6 Months

	4 mm Standardized Wavefront Diameters		5 mm Standardized Wavefront Diameters	
	Preoperative (n=334)	6 Months (n=310)	Preoperative (n=316)	6 Months (n=290)
	Mean+/-SD	Mean+/-SD	Mean+/-SD	Mean+/-SD
HOA RMS (μm)	0.09 +/- 0.04	0.13 +/- 0.07	0.17 +/- 0.07	0.24 +/- 0.11
Coma	0.06 +/- 0.04	0.09 +/- 0.06	0.10 +/- 0.07	0.16 +/- 0.11
Spherical Aberration	0.02 +/- 0.02	0.03 +/- 0.03	0.06 +/- 0.04	0.07 +/- 0.05
Trefoil	0.05 +/- 0.03	0.06 +/- 0.04	0.09 +/- 0.05	0.09 +/- 0.06
Secondary Coma	0.00 +/- 0.00	0.01 +/- 0.01	0.01 +/- 0.01	0.03 +/- 0.02
Secondary Astigmatism	0.02 +/- 0.01	0.03 +/- 0.02	0.04 +/- 0.02	0.06 +/- 0.05
Secondary Spherical Aberration	0.00 +/- 0.00	0.01 +/- 0.00	0.01 +/- 0.01	0.02 +/- 0.02
Fifth Order	0.01 +/- 0.01	0.01 +/- 0.01	0.02 +/- 0.01	0.04 +/- 0.02
Sixth Order	0.00 +/- 0.00	0.01 +/- 0.01	0.01 +/- 0.01	0.03 +/- 0.02
Spherical Aberration Signed	0.02 +/- 0.03	0.00 +/- 0.04	0.04 +/- 0.06	0.04 +/- 0.08

7) Wavefront Diameter

A minimum wavefront diameter of 4 mm is required for treatment with **Advanced CustomVue** LASIK. The **iDesign Advanced WaveScan Studio** System is capable of capturing a maximum wavefront diameter of up to 8.5 mm in diameter. To capture the largest wavefront diameter, the recommended ambient light level setting is 0.01 to 3.0 candelas per square meter.

Table 3-14 presents the key safety and effectiveness results at 6 months for all myopic eyes stratified by wavefront capture diameter (>4 to ≤5 mm, >5 to < 6 mm, and ≥6 mm).

Table 3-14 Effect of Preoperative iDesign AWS Wavefront Diameter at 6 Months: All Eyes, N =334

Variables	Preoperative Wavefront Diameter			Total
	>4 and ≤5mm	>5 and <6mm	≥ 6mm	
	n, %	n, %	n, %	
MRSE ± 0.50 D	16, 80.0%	49, 71.0%	165, 67.3%	230, 68.9%
MRSE ± 1.00 D	20, 100%	64, 92.8%	228, 93.1%	312, 93.4%
MRSE ± 2.00 D	20, 100%	67, 97.1%	245, 100%	332, 99.4%
UCVA 20/40 or Better	20, 100%	67, 97.1%	241, 98.4%	328, 98.2%
BSCVA Worse than 20/40	0, 0.0%	0, 0.0%	0, 0.0%	0, 0.0%
Loss of > 2 Lines BSCVA	0, 0.0%	0, 0.0%	0, 0.0%	0, 0.0%
	n=20	n=69	n=245	n=334

8) Best Spectacle-Corrected Visual Acuity (BSCVA)

At 6 months, no eyes lost >2 lines of BSCVA, and 55.7% of eyes had at least a line improvement in BSCVA compared to preoperative.

Table 3-15 presents the change in lines of BSCVA over time.

Table 3-15 Change in BSCVA Over Time: All Eyes, N=334

Acuity Change	1 Week		1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%	n	%
>2 line increase	0	0.0%	1	0.3%	1	0.3%	0	0.0%	2	0.6%	0	0.0%
2 line increase	12	3.6%	16	4.8%	22	6.6%	25	7.5%	32	10.0%	18	6.2%
1 line increase	104	31.1%	143	42.8%	169	50.6%	161	48.2%	139	43.4%	143	49.3%
No change	172	51.5%	155	46.4%	129	38.6%	143	42.8%	136	42.5%	121	41.7%
1 line decrease	38	11.4%	18	5.4%	13	3.9%	4	1.2%	11	3.4%	8	2.8%
2 line decrease	7	2.1%	1	0.3%	0	0.0%	1 ^a	0.3%	0	0.0%	0	0.0%
>2 line decrease	1	0.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
All	334	100.0%	334	100.0%	334	100.0%	334	100.0%	320	100.0%	290	100.0%

^a One eye had a transient decrease in BSCVA of 2 lines from preoperative BSCVA of 20/10 to 20/16 at 6 months; BSCVA improved to 20/12.5 at 9 months.

9) Contrast Sensitivity Analysis

Contrast sensitivity was tested at four spatial frequencies (3, 6, 12, and 18 cycles per degree (cpd)) with best spectacle correction in place under 3 different lighting conditions: photopic with glare, mesopic with glare and mesopic without glare. Table 3-16 presents the change in contrast sensitivity at 6 months vs. preoperative including mean change, standard error, and multiplicity-adjusted p-values. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease.

Table 3-16 Mean Change in Contrast Sensitivity at 6 Months from Preoperative: N=334

Lighting Condition	Mean Change			
	3 cpd	6 cpd	12 cpd	18 cpd
Photopic without Glare				
Mean (Log units)	-0.01	0.02	0.08	0.06
Standard error	0.011	0.015	0.019	0.018
Adjusted P-value	0.618	0.618	<0.0001	0.0008
Mesopic with Glare				
Mean (Log units)	0.04	0.16	0.23	0.22
Standard error	0.015	0.019	0.024	0.024
Adjusted P-Value	0.045	<0.0001	<0.0001	<0.0001
Mesopic with Glare				
Mean (Log units)	0.07	0.17	0.22	0.24
Standard error	0.015	0.022	0.026	0.024
Adjusted P-Value	<0.0001	<0.0001	<0.0001	<0.0001
Note: Positive values for "change from preoperative" represent increase in contrast sensitivity scores. Note: Data for eyes that were unable to see the reference pattern were imputed; therefore, means are < values and standard errors are > values. Note: P-values abased on one-sample t-test and adjusted for multiplicity using the Bonferroni step-down method.				

Table 3-17 presents proportions of eyes that experienced clinically significant changes in contrast sensitivity from baseline of ≥ 0.30 log units at 2 or more spatial frequencies, at 6 months for all eyes.

Table 3-17 Clinically Significant Changes^a in Contrast Sensitivity at 6 Months from Preoperative, All Eyes, N = 334

Lighting Condition	Decrease n %	No change n %	Increase n %
Photopic without Glare	36 10.8%	234 70.1%	64 19.2%
Mesopic without Glare	32 9.6%	164 49.1%	138 41.3%
Mesopic with Glare	36 10.8%	142 42.5%	156 46.7%

Note: Percentages calculated based on non-missing values.
^a A difference of ≥ 0.30 log units from preoperative at 2 or more spatial frequencies is considered a clinically significant change in contrast sensitivity.

10) Retreatments

At the time of database closure, no eyes (0%; 0/334) had undergone retreatment in the study.

11) *iDesign Advanced WaveScan Studio* System software

This investigation used *iDesign Advanced WaveScan Software Studio* system software version 1.1 with a manual software adjustment to compensate for coupling of preoperative cylinder and postoperative sphere outcome observed in a prior clinical trial. *iDesign Advanced WaveScan Software Studio* system software v1.3 was developed to automate the coupling adjustment used in the clinical study and to further compensate for the observed under-corrections in the study.

12) Patient Symptoms

The National Eye Institute-Refractive Error Quality of Life instrument (NEI-RQL-42) was administered to subjects at the periodic study exams. Table 3-18 presents subjective results for each scale of the NEI-RQL-42 at baseline and 6 months. Table 3-19 presents subjective results from the individual items of the far vision scale of the NEI-RQL-42 at baseline and 6 months.

Table 3-20 presents the rates of postoperative symptoms reported by subjects as none or mild, compared to those reported as moderate, marked or severe at baseline and 6 months.

Table 3-18 Mean Scores of NEI-RQL Questionnaire Domains at 6 Months vs. Preoperative

All Subjects (n=170)				
Domains	Preop	6 Months	Change	% Change (Change/Preop)
Clarity of Vision	80.29	91.52	+11.23	14%
Expectations	6.91	76.03	+69.12	1000%
Near Vision	80.59	93.55	+12.97	16%
Far Vision	80.09	92.63	+12.54	16%
Diurnal Fluctuations	79.07	92.30	+13.24	17%
Activity Limitations	63.35	97.87	+34.52	54%
Glare	78.16	84.56	+6.40	8%
Symptoms	83.68	92.25	+8.57	10%
Dependence on Correction	38.14	93.61	+55.35	145%
Worry	42.43	81.18	+38.75	91%
Suboptimal Correction	88.82	98.97	+10.15	11%
Appearance	36.74	91.07	+54.34	148%
Satisfaction with Correction	58.00	92.00	+34.00	59%

Note: Change calculated as 6 months minus preoperative. Positive change value indicates improvement.

Typical optical visual symptoms reported by LASIK subjects such as glare, halos and difficulty with night driving were assessed by the NEI-RQL: improvements in the glare measure, were found at 6 months vs. preoperative.

Table 3-19 Mean Scores of NEI-RQL Questionnaire Far Vision Scale Items at 6 Months vs. Preoperative

All Subjects (n=170)				
Far Vision Items	Preop	6 Months	Change	% Change (Change/Preop)
Difficulty judging distances	85.29	97.65	12.35	14%
Difficulty seeing things off to the side	83.73	97.84	14.12	17%
Difficulty getting used to the dark	76.67	89.02	12.35	16%
Difficulty driving at night	81.03	90.88	9.85	12%
Difficulty driving at night in difficult conditions	73.96	87.72	13.76	19%

The mean scores for “difficulty judging distances”, difficulty seeing things off to the side”, difficulty getting used to the dark”, “difficulty driving at night”, and “difficulty driving at night in difficult conditions” all improved at 6 months as compared to preoperative scores with correction.

Table 3-20 Changes in Symptoms from Directed Symptoms Assessment: Preoperative vs. 6 Months. All Eyes N = 334

Subjective Symptoms	Preoperative				6 Months			
	None or Mild		Moderate, Marked or Severe		None or Mild		Moderate, Marked or Severe	
	n	%	n	%	n	%	n	%
Pain	332	99.4%	2	0.6%	332	99.4%	2	0.6%
Tearing	332	99.4%	2	0.6%	334	100.0%	0	0.0%
Photophobia	323	96.7%	11	3.3%	325	97.3%	9	2.7%
Foreign Body Sensation	334	100.0%	0	0.0%	334	100.0%	0	0.0%
Dryness	295	88.3%	39	11.7%	306	91.6%	28	8.4%
Vision Fluctuation	332	99.4%	2	0.6%	328	98.2%	6	1.8%
Day Glare	327	97.9%	7	2.1%	327	97.9%	7	2.1%
Night Glare	296	88.6%	38	11.4%	314	94.0%	20	6.0%
Binocular Diplopia	334	100.0%	0	0.0%	334	100.0%	0	0.0%
Monocular Diplopia	334	100.0%	0	0.0%	334	100.0%	0	0.0%
Ghosting	334	100.0%	0	0.0%	330	98.8%	4	1.2%
Halos	295	88.3%	39	11.7%	305	91.3%	29	8.7%
Driving at night	282	84.4%	52	15.6%	311	93.1%	23	6.9%

13) Summary of Key Safety and Effectiveness Variables

The key safety variables for all eyes over time are presented in Table 3-21. No eyes had BSCVA worse than 20/25 at 6 months. All (100%; 334/334) myopic eyes had BSCVA of 20/20 or better at 6 months. Additionally, no eyes (0%; 0/334) had BSCVA worse than 20/40 postoperatively at any time during the study.

Table 3-21 Summary of Key Safety Variables: All Eyes, N=334

	1 Week (n=334)	1 Month (n=334)	3 Months (n=334)	6 Months (n=334)	9 Months (n=320)	12 Months (n=292)
Safety Variable	n %	n %	n %	n %	n %	n %
Loss of >2 lines BSCVA (a)	1 0.3%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Loss of ≥2 lines BSCVA	8 2.4%	1 0.3%	0 0.0%	1 0.3%	0 0.0%	0 0.0%
BSCVA 20/16 or better	249 74.6%	286 85.6%	298 89.2%	303 90.7%	289 90.3%	267 92.1%
BSCVA 20/20 or better	323 96.7%	331 99.1%	333 99.7%	334 100%	319 99.7%	290 100%
BSCVA 20/25 or better	332 99.4%	334 100%	334 100%	334 100%	320 100%	290 100%
BSCVA worse than 20/40 (b)	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Induced Manifest Cylinder >2.0 D (c)	0 0.0%	0 0.0%	1 0.3%	1 0.3%	0 0.0%	0 0.0%

Note: Percentages calculated based on non-missing values.

- (a) **Safety endpoint target:** <5% of eyes with loss of >2 lines BSCVA vs. preoperative
- (b) **Safety endpoint target:** <1% of eyes with BSCVA of 20/20 or better preoperative have BSCVA of worse than 20/40 postoperative. All eyes had preoperative BSCVA of 20/20 or better.
- (c) **Safety endpoint target:** <5% of eyes with induced manifest refractive astigmatism >2.00 D

The key effectiveness variables over time are presented in Table 3-22.

Table 3-22 Summary of Key Effectiveness Variables: All Eyes, N=334

	1 Month (n=334)	3 Months (n=334)	6 Months (n=334)	9 Months (n=320)	12 Months (n=292)
Effectiveness Variable	n, % (95% CI)	n, % (95% CI)	n, % (95% CI)	n, % (95% CI)	n, % (95% CI)
UCVA 20/16 or better	215 64.4% (59.0, 69.5)	208 62.3% (56.8, 67.5)	206 61.7% (56.2, 66.9)	202 63.1% (57.6, 68.4)	178 61.4% (55.5, 67.0)
UCVA 20/20 or better	294 88% (84.1, 91.3)	283 84.7% (80.4, 88.4)	276 82.6% (78.1, 86.5)	268 83.8% (79.2, 87.6)	231 79.7% (74.6, 84.1)
UCVA 20/40 or better	332 99.4% (97.9, 99.9)	332 99.4% (97.9, 99.9)	328 98.2% (96.1, 99.3)	313 97.8% (95.5, 99.1)	280 96.6% (93.8, 98.3)
MRSE ± 0.50 D	261 78.1% (73.3, 82.5)	240 71.9% (66.7, 76.6)	230 68.9% (63.6, 73.8)	209 65.3% (59.8, 70.5)	191 65.9% (60.1, 71.3)
MRSE ± 1.00 D	326 97.6% (95.3, 99.0)	314 94% (90.9, 96.3)	312 93.4% (90.2, 95.8)	288 90% (86.2, 93.1)	265 91.4% (87.5, 94.3)
MRSE ± 2.00 D	334 100% (99.1, 100)	332 99.4% (97.9, 99.9)	332 99.4% (97.9, 99.9)	318 99.4% (97.8, 99.9)	289 99.7% (98.1, 100)
Note: Confidence Intervals calculated based on Clopper-Pearson Exact method. Note: Percentages calculated based on non-missing values.					

4 Surgical Planning and Procedures



After reading this section, please refer to the procedures provided in Section 5.1, Step-By-Step Procedure, before proceeding with surgery.

4.1 Introduction

Laser refractive surgery uses the energy of the excimer laser to create a superficial lamellar keratectomy of a shape designed to correct or ameliorate a specific refractive error. It is essential that the information upon which these surgical procedures are based is accurate and is correctly transmitted to the laser. It is the sole responsibility of the operating doctor to ensure that the information for each individual patient is accurate.

4.2 Preoperative (Examination of the Patient)

A complete examination, including but not limited to cycloplegic evaluation, must be performed. The patient's eye should be evaluated for dry eye syndromes. Pachymetry measurement is required. Preoperative assessment of pupil size is also required. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary.

To treat a patient using the wavefront data, the appropriate exams should be captured and reviewed by the surgeon in accord with the **iDesign Advanced WaveScan Studio System Operator's Manual** (Chapters 8 and 9).

The treatment is then generated at the **iDesign Advanced WaveScan Studio System**, refer to the **iDesign Advanced WaveScan Studio System Operator's Manual** (Chapter 10).. The USB drive containing the treatment should be placed into the laser and the surgeon must verify that the patient loaded to be treated by the laser is the same as the patient lying under the laser.

Preoperative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients desiring refractive surgery should be performed within 30 days of laser refractive surgery. Patients who wear soft contact lenses must discontinue their use for at least 2 weeks, and those who wear gas permeable or hard lenses must discontinue their use for at least 3 weeks. Failure to do so will adversely affect the end surgical result.

4.3 Perioperative (Anesthesia and Analgesia)

Extensive clinical experience has shown that laser refractive surgery is well tolerated and rarely causes significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Topical anesthesia applied just before insertion of the lid speculum will provide adequate control of pain during the surgery. For those patients with a high degree of anxiety, appropriate medication may be given preoperatively.

4.4 Postoperative

Medications

Following completion of the excimer laser surgery, appropriate medications should be applied to the eye in a sterile manner. It is critical that the flap not be disturbed. Instruct patients not to touch their eyes. Patients will need to instill lubricating drops and wear eye shields to bed for at least a week.

Follow-up Care

A typical follow-up regimen consists of next-day check, followed by refractive examinations at 1 week, 1 month, and at 3 and 6 months.

5 STAR S4 IR System Surgical Procedure



Before proceeding, please refer to the laser preparation and shut-down procedures presented in the STAR S4 IR System Operator's Manual, Section 6.2, Turning System On and Off.

The STAR S4 IR System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. However, the fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms (including surgical instruments) is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if there is a possibility that healthcare personnel will approach closer than this distance from the primary beam.

The Professional Use Information Manual is to be used in conjunction with the STAR S4 IR System Operator's Manual.

5.1 Step-by-Step Procedure

1. Power ON the system.
2. Complete all daily calibrations, as described in the **STAR S4 IR** System Operator's Manual, Chapter 8, Calibrating the System.



Ablate a spherical lens after every third ocular treatment to verify the calibration of the STAR S4 IR System. Refer to the Operator's Manual, Chapter 8, Calibrating the System, for additional information on the calibration procedure.

3. Ensure that all persons in the operating room obey all safety regulations. Caution all attendees in the operating room against touching the laser, patient, or patient chair during the procedure. Movement of personnel in the operating room should be minimized during the procedure. It is recommended that all attendees, including the doctor, wear surgical masks and protective eyewear.
4. Ensure that the device to create the LASIK flap is functioning correctly.
5. Transfer the saved **Advanced CustomVue** treatment file from the **iDesign AWS** System to the **STAR S4 IR** Excimer Laser using the AMO-supplied USB drive. The instructions for transferring the file appear in Chapter 13, **iDesign Advanced CustomVue** Treatments, in the **STAR S4 IR Excimer Laser Operator's Manual**.
6. Follow the system software prompts. An **Advanced CustomVue** Treatment Card is required to perform the treatment.
7. Check the surgical parameters entered into the computer against the surgical plan and confirm that all interlocks are cleared. The accuracy of the entered data is the responsibility of the doctor. Center the mechanical position of the chair using the guide marks found on the chair base.
8. The patient may be given a systemic medication (e.g., analgesic or sedative) at the physician's discretion before the procedure.
9. Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.
10. Position the patient so the lateral canthus aligns to the mark on the headrest.
11. Instruct the patient to remove earrings prior to using the vacuum pillow.
12. Place the vacuum pillow under the patient's head with the bottom portion of the "U" supporting the patient's neck. Assure that there is no head tilt or rotation present. This is accomplished by assuring that a line from the vertex of the chin through the nasion is parallel to the operating table. Holding the pillow support against the occiput, power ON the suction pump switch, which is on the patient's left side of the headrest. After several seconds, the pillow will harden and conform to the patient's head. This creates a comfortable, stable platform for the patient. Disconnect the tubing after the pillow has hardened.
13. If desired, apply topical ophthalmic antibiotic agent to the operative eye.

14. Instill topical ophthalmic anesthetic to the operative eye.
15. Disinfect/clean around the eye with cleaning solution.
16. Cover the untreated eye with an opaque shield that protects the eye and occludes vision.
17. Instruct the patient to keep both eyes opened during the surgical procedure.
18. Allow the patient the opportunity to become familiar with the sounds of the laser during the calibration procedure. At this time, prep and drape may be performed if using a microkerotome.
19. Create the LASIK flap using either a microkeratome or a femtosecond laser.
20. Monitor patient clearance while rotating the patient chair to the treatment position, then lock the patient chair in place by pressing the foot pedal in the locked position. The chair must be fully rotated and the foot pedal locked for the laser to operate. Correct positioning is confirmed by the green status bar on the computer screen, which allows the procedure to continue.



If the patient chair is not in the treatment position and securely locked, the laser will not fire. Check the interlock message on the status screen.

21. Place small sticky drapes on the eyelids to cover the eyelashes then insert a lid speculum into position. It is important to assess exposure and the degree of laxity when spreading the lids apart.
22. Lift the flap with a blunt instrument. Gently wipe the exposed corneal surface with an ophthalmic surgical sponge to ensure that the surgical area is free of epithelium and other debris. Remove fluid from the fornices with an ophthalmic surgical sponge. Remind the patient that vision may become blurred temporarily.
23. Continually encourage the patient to maintain fixation on the fixation light throughout the procedure.
24. The microscope oculars must be properly focused to accommodate the doctor's refraction. This will assure that the microscope focal plane and the laser focal plane are coincident,
25. Position the patient with the microscope set at low zoom magnification. When the cornea is visible in the microscope, focus the image of the corneal stroma and increase the magnification. Refer to the Operator's Manual, Section 6.9, Focusing Instructions for the **STAR S4 IR** System Microscope. Instruct the patient to begin fixating on the fixation light.

26. Move the patient so the microscope reticle is centered over the patient's pupil. Chair movement is controlled by the doctor's keypad. Refer to the Operator's Manual, Section 6.4, Preparing Chair for Patient, for information regarding chair movement.
27. Verify that all color status bars are green in the procedure screen of the system software. If a yellow status bar is displayed, you may continue with the procedure; however, a condition exists that warrants attention as soon as possible after completion of treatment. A red status bar will prevent system operation. Therefore, any interlock must be cleared prior to a treatment.
28. After verification of green system status bars, warn all attendees to stand clear of the laser, patient, and patient chair. Movement in the operating room must be kept to a minimum during patient treatment.
29. Verify alignment of the operative eye so that the reticle is centered on the entrance pupil while the patient views the fixation light. Again, verify that the patient's globe is in primary position and not in an upward or downward gaze. If the patient is unable to maintain fixation to the surgeon's satisfaction a fixation handpiece may be used to hold the eye.
30. Adjust and maintain the focus on the anterior corneal surface.



WARNING! Do not use a Chayet LASIK drain or similar device that obscures the limbus during the surgery.

31. Activate **ActiveTrak** system (see section 0) and the Iris Registration system (see section 5.2).
32. After ensuring that the reticle is centered over the patient's pupil and the patient is viewing the fixation light, fully depress the foot pedal to perform the laser treatment. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration.



Keep the patient relaxed by explaining the process as you go along. Use the oblique halogen illumination at its lowest intensity during laser ablation.



WARNING! Make sure all laser pulses have been fired.



The doctor may interrupt the procedure for any reason, at any time, by releasing the laser footswitch. This may be done if the patient should move and the treatment area becomes decentered. The doctor then realigns the eye and continues the procedure by depressing the laser footswitch again. The procedure will automatically start from the point of interruption.

33. Instill antibiotics on the corneal bed and the flap, and replace the flap into position. Irrigate underneath the flap and on top with BSS to remove debris. Using a wet ophthalmic surgical sponge, gently stroke the flap into its original position. Check alignment of the flap
If necessary, use a dry ophthalmic surgical sponge to remove any excess moisture from the incision.
34. Apply topical ophthalmic medications to the cornea.
35. Print the laser treatment information.
36. Record the flap thickness, flap diameter, hinge diameter, hinge location, and environmental conditions (temperature and humidity).
37. If planned, and the first eye is without surgical complication, repeat this procedure on the fellow eye. Make sure the first eye is well occluded to avoid cross-fixation.
38. When the LASIK surgery is complete, remove the speculum and allow the patient to close the eye which has just undergone the laser surgery. Power OFF the microscope light and relieve the vacuum in the patient pillow.
39. Rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.
40. Place appropriate postoperative medications in the treated eye.
41. Assist the patient out of the chair and to a waiting area.
42. Examine the patient at the slit-lamp microscope for any abnormalities in or under the flap that can be adjusted at that time.

43. Ensure that the patient is given postoperative instructions. An analgesic may be given to the patient prior to leaving the facility.
44. Review postoperative instructions, confirm the first follow-up appointment, and discharge the patient when stable.
45. Clean the debris removal nozzle with isopropyl alcohol wipes and prepare the system for the next patient.



WARNING! *Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol, except for wiping down the debris removal nozzle with isopropyl alcohol.*

Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.

5.2 Using the Iris Registration System

The iris registration system is used to align the laser treatment as measured and calculated by the aberrometer (**iDesign Advanced WaveScan Studio** System) to the axis of the patient's eye under the laser. It is used in conjunction with the **ActiveTrak** eye tracking system. The **ActiveTrak** System must be on and tracking to perform the iris registration. In addition, the iris registration system verifies that the aberrometer image selected for treatment is correct.

The image of the patient's eye taken on the aberrometer during the measurement process is transferred to the **STAR S4 IR** System along with the **Advanced CustomVue** treatment file via a USB flash drive. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the **iDesign Advanced WaveScan Studio** image to the same features located on the image of the iris taken by the **STAR S4 IR** camera. The treatment is rotated by algorithms in the **STAR S4 IR** System to align precisely with the current rotation of the patient's eye under the laser.



The iris registration system is only available for CustomVue (using the WaveScan WaveFront System) and Advanced CustomVue (using the iDesign Advanced WaveScan Studio) treatments.



LASIK flap hinge location must be entered on the Operating Parameters screen for each Advanced CustomVue treatment when using the iris registration system.

To activate the iris registration system:

1. Transfer the ***iDesign Advanced WaveScan Studio*** treatment file using a USB flash drive. All files are saved automatically to the USB flash drive when saving a STAR treatment on the ***iDesign Advanced WaveScan Studio*** System.
2. Prepare the patient for the surgery. Center the patient's eye under the laser and focus on the corneal surface.
3. If the ***ActiveTrak*** System and the iris registration system are not already on, turn them on by pressing the **Track** button and then the **Rotation (Rot)** button on the Doctor's Keypad. The ***ActiveTrak*** System must be on to perform iris registration. If the iris registration is turned on first, iris registration will automatically start once the ***ActiveTrak*** System is turned on and the pupil is found. The iris registration system can be left on allowing the user to enable or disable both systems using the **Track** button alone. Iris registration can be re-initiated at any time during the treatment by turning iris registration off and back on using the **Rotation (Rot)** button.
4. A dialog box will appear on the computer screen with the messages
"Iris Registration started, please wait . . .
Capturing STAR S4 IR Image . . .
Verifying STAR S4 IR Image . . .
Performing Iris Registration Calculations . . ."
5. The captured eye image will appear with markers showing the degree of cyclotorsion between the aberrometer measurement and the ***STAR S4 IR*** measurement. The dialog box message changes to "**Eye Image: VERIFIED.**" The degree of rotation, the pupil diameter measurement, and the adjustment to the position of the treatment center will be shown.
6. These measurements are used to rotate the angle of the ***Advanced CustomVue*** treatment to precisely align the treatment to the current position of the eye.
7. The dialog box will add the message "**Treatment Registered to aberrometer eye image. Press footswitch to start treatment.**" Fully depress the laser footswitch to begin the treatment. This will automatically restore the live microscope camera image.



WARNING! It may not be possible to capture ALL irides for iris registration. Should iris registration fail to capture at first attempt, users are encouraged to alter the ambient illumination (ring, oblique, and/or room) to allow more iris features to be available for capture. Should all attempts fail at registration, users are encouraged to align the cornea using limbal landmarks noted at the slit lamp prior to the surgical procedure.

5.3 Using the *ActiveTrak* System

The **ActiveTrak** System allows the laser beam to follow the patient's eye movements during the surgery and enables the surgeon to select the treatment center of the ablation. The **ActiveTrak** System tracks the movement of the eye during the ablation. In addition, it has the capability of stopping the laser much faster than the surgeon can. The **ActiveTrak** System uses two infrared cameras to follow x and y motion. The **ActiveTrak** System also checks the vertical height (z axis) of the cornea relative to the initial treatment position from which the **ActiveTrak** System begins tracking.

The surgeon-selected treatment center must be within 0.5 mm of the center of the patient's natural pupil as determined by the tracking system. Do not use the **ActiveTrak** System if you intend to center the laser treatment more than 0.5 mm from the center of the pupil.

It is important to remember that the use of an eye tracking system does not replace a conscientious surgeon. The **ActiveTrak** System does not in any way automate the surgery, but rather is a useful accessory to the surgical procedure. Surgeons are reminded that an informed patient who is well instructed in the importance of good fixation on the Patient Fixation LED provides excellent treatment centration without an eye tracking system.

Surgeons are reminded that they should instruct the patient to fixate on the Patient Fixation LED during surgery with or without the use of the **ActiveTrak** System.



WARNING! Do not use pharmacological dilating or constricting agents immediately before surgery with the *ActiveTrak* System. It is not necessary to pharmacologically dilate or constrict the pupil. The tracking system's working range is from a minimum pupil diameter of 1.5 mm to a maximum pupil diameter of 6.0 mm.

Treatment will stop or pause when the **ActiveTrak** System detects the following conditions:

- The patient's eye moves more than 1.5 mm from the surgeon-selected treatment center (the initial position from which the **ActiveTrak** System begins tracking).

- The vertical position (z axis) of the corneal surface moves more than 2.0 mm from the initial treatment position.
- The pupil diameter is not circular to within 32% or becomes smaller than 1.5 mm or larger than 6.0 mm during treatment.
- Eye motion exceeds 0.2 mm between video frames.
- Dark objects or reflective objects are in the **ActiveTrak** System's field of view.
- Surgical instruments or the surgeon's hands cross the **ActiveTrak** System's field of view.

If the treatment stops or pauses for more than a few seconds, turn off the **ActiveTrak** System and treat as you normally would without the **ActiveTrak** System, or re-engage the **ActiveTrak** System.

The surgeon can choose to set the treatment center manually or use the automatic centering mode in which the treatment center is set by the **ActiveTrak** System. Auto centering is the default mode. The surgeon may choose manual centering on the Ablation Status screen before each treatment.

To use the **ActiveTrak** System:

1. Using the joystick, position the patient so that the patient's head is properly aligned under the laser and the corneal surface is properly focused (see Section 6.9 in the **STAR S4 IR** System Operator's Manual).
2. Ensure that the patient's pupil is centered in the reticle as the patient is fixating on the Patient Fixation LED. Instruct the patient to fixate on the Patient Fixation LED during the surgery.



If you see shadows on the iris or pupil, reposition the patient's head to eliminate these shadows. Make sure the patient's globe is in primary position and not in an upward or downward gaze. Ensure that the patient's head is centered and is not tilted to either side. If shadows are still present, tilt the patient's chin down towards his or her chest or gently depress the lid speculum.

3. Turn on the **ActiveTrak** System by pressing the **Track** button on the Doctor's Keypad. When the **ActiveTrak** System is turned on, the outside ring and the center cross of the reticle will flash.
- If you are using automatic centering, re-center the pupil and refocus so that

the corneal surface and the reticle are in sharp focus. The **ActiveTrak** System will then locate the pupil and set the treatment center. Once the pupil is located, the outside ring on the reticle will stop flashing and the treatment center will automatically be set to the center of the pupil.

- If you are setting the treatment center manually, re-center the pupil and refocus so that the corneal surface and the reticle are in sharp focus before pressing the laser footswitch to the first position to set the treatment center.
4. Once the treatment center is set, the center cross of the reticle flashes more slowly. (The **ActiveTrak** System will maintain this position throughout the treatment.)



WARNING! *The reticle must be centered to within 0.5 mm of the center of the pupil.*

Do not place any dark objects or reflective objects that potentially could appear dark in the camera's field of view when turning on the ActiveTrak System. The introduction of any object will make the location of the pupil center unavailable.

5. Fully depress the laser footswitch to begin the treatment.
6. The center cross of the reticle will flash slowly during the treatment when the **ActiveTrak** System is on and tracking the pupil.
7. If the **ActiveTrak** System loses track of the pupil or detects an artifact, the center cross of the reticle will flash quickly and the laser status bar displays **Pupil Tracking Lost**. Treatment will stop.



Treatment will stop if objects such as surgical instruments or the surgeon's hands cross the camera's field of view.

8. To continue the treatment, re-center the pupil and refocus so that the corneal surface and the reticle are in sharp focus before fully depressing the laser footswitch.



When the ActiveTrak System is activated, you may use the joystick to correct for head (translational) motion during the treatment. Do NOT use the joystick to correct for eye rotation when the ActiveTrak System is activated.

