Professional Use Information

STAR S4 IR® Excimer Laser System and *iDESIGN®* Refractive Studio

iDESIGN® System-driven Photorefractive Keratectomy (PRK) Treatments for Patients with Myopia and Myopic Astigmatism

For the correction of myopia up to -8.00 D spherical equivalent as measured by ***iDESIGN®*** Refractive Studio, with cylinder between 0.00 and -3.00 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.

AMO Manufacturing USA, LLC
510 Cottonwood Drive

Milpitas, CA 95035 USA
1-877-266-4543

Product of USA

Revision Date: 12/05/2018

Section Affected	Part Number	Rev.	Description
All	0030-5601	A	Initial Release of ***iDESIGN®*** System PRK Professional Use Info

TABLE OF CONTENTS

TABLE OF CONTENTS iv

1 Device Description 1

1.1 *STAR S4 IR®* Excimer Laser System 1

1.2 iDESIGN® Refractive Studio 2

2 Indications, Contraindications, Warnings, Precautions, and Adverse Events 4

2.1 Indications for Use 4

2.2 Contraindications 4

2.3 Warnings 4

2.4 Precautions 5

2.5 Risks of PRK 9

3 Clinical Results 11

3.1 About the Study 11

3.2 Patient Accountability 12

3.3 Data Analysis and Results 14

Summary of Key Safety and Effectiveness Endpoints 31

3.4 STAR-125-ARID Study Summary 32

4 Surgical Planning and Procedures 33

4.1 Introduction 33

4.2 Pre-Operative (Examination of the Patient) 33

4.3 Peri-Operative (Anesthesia and Analgesia) 33

4.4 Post-Operative 33

5 STAR S4 IR® Laser Surgical Procedure 33

5.1 Step-by-Step Procedure 34

5.2 Using the Iris Registration System 37

5.3 Using the ActiveTrak System 39

List of Tables

Table 3-1 Demographic Characteristics All Subjects (N=167) 12
Table 3-2 Subject Accountability 13
Table 3-3 Preoperative Manifest and iDesign Refractive Error All Treated Eyes (N=334) 14
Table 3-4 Preoperative Refractive Error Stratified by iDesign Sphere and Cylinder All Treated Eyes (N=334) 14
Table 3-5 Preoperative Refractive Error Stratified by iDesign Spherical Equivalent (SE) and Cylinder All Treated Eyes (N=334) 15
Table 3-6 Monocular UCVA Over Time All Eyes (N=334) 16
Table 3-7 Binocular UCVA Over Time Safety Population 16
Table 3-8 Postoperative Monocular UCVA Compared to Preoperative Monocular BSCVA All Eyes (N=332) 17
Table 3-9 Accuracy of MRSE: Intended vs. Achieved Outcome (N=332) 18
Table 3-10 Stability of Manifest Refraction Spherical Equivalent (MRSE) 19
Consecutive Cohort[a] 19
Table 3-11 Stability of Manifest Refraction Spherical Equivalent (MRSE) 19
Table 3-12 Stability of Manifest Cylinder Consecutive Cohort[a] 20
Table 3-13 Stability of Manifest Cylinder Consistent Cohort[a] 20
Table 3-14 Residual Manifest Refractive Astigmatic Axis Error at 6 Months 21
Table 3-15 Vector Analysis Summary at 6-Months[a] (N = 186) 21
Table 3-16 Higher Order Aberration RMS (HOA) (µm) Over Time 22
Table 3-17 Schirmer Score Distribution Over Time 22
Table 3-18 Corneal Clarity Over Time 23
Table 3-19 Change in BSCVA Over Time vs. Preoperative All Eyes 24
Table 3-20 Summary of Adverse Events Over Time 25
Table 3-21 Summary of Complications 26
Table 3-22 Contrast Sensitivity Change (Log Units) from Preoperative to 6 Months Using Non-Parametric Analysis (N=72 Eyes) 27
Table 3-23 Summary of Visual Symptoms All Subjects at 6 Months[a]: Key Results (N=161) 28
Table 3-24 Mean Scores of NEI-RQL-42 Questionnaire Measures 6 Month vs Preoperative (N= 161 Subjects) 28
Table 3-25 OSDI Dry Eye Severity Categories Over Time 29
Table 3-26 OSDI Within-Subject Category Status Change from Preoperative to 6 months (n=161) 29
Table 3-27 Summary of Satisfaction with Vision Quality Over Time All Subjects 30
Table 3-28 Summary of Safety and Effectiveness Endpoints Over Time (N=332) 31
Table 3-29 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Spherical Equivalent (IDSE) 33
Table 3-30 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Sphere (IDS) 34
Table 3-31 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Cylinder (IDC) 35
Table 3-32 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Age Groups 36
Table 3-33 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Gender 37

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 16.1) 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. Johnson & Johnson Vision, 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 thyratron 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, is 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.

PRECAUTIONS: Any service requiring access to the interior of the system should be performed only by manufacturers 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®* Refractive Studio 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 light of an ultraviolet wavelength of 193 nm.

The *STAR S4 IR®* Excimer Laser System combines submicron precision of tissue removal by 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 S4 IR®*** Laser treatments utilize sphere, cylinder and axis components which are entered manually into the laser by the operator to generate the ablation treatment. The ***iDESIGN®*** System-driven PRK treatment information is generated on the ***iDESIGN®*** Refractive Studio 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 ***iDESIGN®*** System-driven PRK 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®*** Laser and ***iDESIGN®*** Refractive Studio 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®*** Laser 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 inter- face (Windows standard), printer, a Universal Serial Bus (USB) drive slot to store patient information on a USB flash drive, a USB port, a treatment card driver, and system software.

Treatment Card

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

- An ***iDESIGN*** Procedure ***PreVue*** Lens card is required to ablate an ***iDESIGN*** Procedure ***PreVue*** lens plastic.
- An ***iDESIGN*** Procedure Card is required to perform ***iDESIGN*** Treatments that were calculated on the ***iDESIGN®*** Refractive Studio.
- The final two digits of the card part number (94) are displayed on the **PATIENT MANAGER** screen. When preprogramming a treatment, a Treatment Card with a part number (0030-XXXX-94) matching the Card PN displayed on the screen is required to perform the programmed treatment.

1.2 iDESIGN® Refractive Studio

The ***iDESIGN®*** Refractive Studio is a diagnostic instrument indicated for the automated measurement of wavefront aberrations (including coma, spherical aberration, trefoil, and other higher order aberrations), corneal topography, keratometry and pupillometry; and the calculation of wavefront-guided photorefractive keratectomy (PRK) (***iDESIGN*** Treatments) treatments for myopia and myopic astigmatism and laser assisted in situ keratomileusis (LASIK) (***iDESIGN*** Treatments) treatments for myopia, hyperopia and mixed astigmatism as well as monovision in myopic patients with presbyopia.

The ***iDESIGN®*** Refractive Studio hardware components include optomechanical systems, a built-in computer and monitor, and a motorized table. For information about the hardware components that make up the ***iDESIGN®*** Refractive Studio, refer to "***iDESIGN®*** Refractive Studio component descriptions" Section 19 of the ***iDESIGN®*** Refractive Studio -Operator's Manual.

The ***iDESIGN®*** Refractive Studio measures the wavefront of the eye within a defined range using a Hartmann-Shack 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 acuity. The ***iDESIGN®*** Refractive Studio also measures and displays corneal topography, pupil size, and keratometry. Wavefront-guided photorefractive keratectomy (PRK) and wavefront-guided laser assisted in situ keratomileusis (LASIK) treatments can be calculated using measurements obtained from the ***iDESIGN®*** Refractive Studio. Treatment calculations for wavefront-guided PRK and wavefront-guided LASIK include full gradient

topography for propagating the wavefront and compensating for the cosine effect (peripheral loss of laser energy due to corneal curvature).

***iDESIGN®* System** software version 2.1 is required for wavefront guided PRK treatments. In addition to user interface changes enabling PRK treatments, version 2.1 software introduces an optional setting to slow down the rate of fogging during the measurement capture sequence.

iDESIGN® System Model Eye

A model eye with a fixed and known dioptric 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 the ***iDESIGN***® Refractive Studio is indicated for wavefront-guided photorefractive keratectomy (PRK) in patients:

- With myopia, with or without astigmatism, as measured by ***iDESIGN***® Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D.
- With agreement between manifest refraction (adjusted for optical infinity) and ***iDESIGN***® Refractive 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.
- in patients 18 years of age or older
- with refractive stability (a change of ≤ 1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery), and
- with wavefront capture diameter of at least 4 mm.

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

iDESIGN® System driven PRK surgery is contraindicated:

- in patients with any type of active connective tissue disease or autoimmune disease
- in patients with signs of keratoconus, abnormal corneal topography, and degenerations of the structure of the cornea
- in patients with significant dry eyes. If the patients have severely dry eyes, PRK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing or interfere with the surface of the eye after surgery. It may result in poor vision after PRK.
- in patients whose corneal thickness would cause anticipated treatment would violate the posterior 250 microns (μm) of corneal stroma
- in patients with uncontrolled diabetes
- in patients with active eye infection or active inflammation
- in patients with recent herpes eye infection or problems resulting from past infection

2.3 Warnings

iDESIGN® System driven PRK is not recommended in patients who:

- have systemic diseases that may affect wound healing, such as controlled autoimmune or connective tissue disease, or controlled diabetes
- have an immunocompromised status or take medications that may result in a weakened immune system such as antimetabolites for any medical conditions or affect wound healing such as Isotretinoin (Accutane)
- have a history of Herpes simplex or Herpes zoster keratitis
- have glaucoma
- In patients with a cardiac pacemaker, implanted defibrillator or other implanted electronic device
- have mild to moderate dry eye
- have decreased vision in one eye (e.g., amblyopia)

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.

2.4 Precautions

A. General

Precautions should be taken for patients:

- that have severe allergies or tendency rub their eyes often
- that have or have a history of elevated intraocular pressure (IOP) greater than 21 mmHg (ocular hypertension), or are being followed for possible glaucoma (glaucoma suspect)
- that are pregnant or nursing

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

- With progressive refractive errors, ocular disease; corneal abnormality; previous corneal or intraocular surgery; or trauma in the ablation zone.
- Who are taking the medication Sumatriptan (Imitrex)
- Who are taking the medication Amiodarone hydrochloride (Cordarone).

Pupil size should be evaluated under mesopic illumination conditions. Patients with large mesopic pupil size should be advised of the potential for negative effects on vision after surgery, such as increased frequency of glare and halos, and decreased satisfaction at night under conditions with glare, such as night driving. This has been shown to occur more frequently in the presence of residual refractive error and perhaps in patients with pupil sizes larger than the optical zone size.

Pre-operative evaluation for dry eye should be performed. Patients should be advised of the potential for dry eye post-PRK surgery.

Preoperative pachymetry measurement must be performed.

The safety and effectiveness of wavefront-guided PRK surgery has ONLY been established with an optical zone of 6 mm and an ablation zone of 8 mm[1].

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.

It is important to maintain a carefully controlled surgical environment. Johnson & Johnson Vision recommends that all ***iDESIGN®*** System-driven PRK treatments be performed in surgical environments where the humidity is between 40-45% and the temperature is between 68-72º F for best results.

Patients with more than 6 diopters of nearsightedness may be at increased risk for less accurate results and the development of visual symptoms.

Additional considerations that could affect eye health:

- It is possible, following PRK treatment that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.
- patients with a family history of degenerative corneal diseases (such as keratoconus, pellucid marginal degeneration, Fuchs' Corneal Dystrophy, Granular Corneal Dystrophy (Types 1 and 2), Lattice Corneal Dystrophy) may not be good candidates for PRK treatment

The safety and effectiveness of the ***STAR S4 IR®*** Excimer Laser and the ***iDESIGN®*** Refractive Studio have NOT been established for wavefront- guided PRK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone
- under 18 years of age
- over the long term (more than 6 months 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®*** Refractive 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®*** Refractive Studio or the ***iDESIGN®*** Refractive Studio 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 BSCVA is less than 2 lines (10 letters) better than distance uncorrected visual acuity (UCVA).
- who had greater than 0.75 D difference between cycloplegic and manifest refraction sphere.
- whose wavefront measurement diameter is < 4mm.
- for treatments, greater than -8.0 D of Spherical Equivalent or greater than -3.0 D of astigmatism as measured by ***iDESIGN®*** Refractive Studio.
- for retreatment with ***iDESIGN®*** System-driven PRK treatments
- who were wearing contact lenses unless they had evidence of stability[1].patients taking amiodarone hydrochloride (e.g., Cordarone).
- 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 ***iDESIGN®*** System-driven PRK treatments. 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[2].
- for patients who have a history of crossed eyes (strabismus) or who have undergone strabismus surgery.
- the effects of ***iDESIGN®*** System-driven PRK treatments on future IOP calculations were not studied.
- the effects of ***iDESIGN®*** System-driven PRK treatments on future cataract surgery were not studied.
- who are not within the studied age groups: Patients who are younger than 18 years of age or older than 47 years of age
- the effects of medications and medical conditions that were excluded from the clinical trial on PRK are unknown (e.g. the use of inhaled or systemic corticosteroids).
- prior LASIK or Refractive Surgery.

With history of any eye diseases or abnormalities such as:

- corneal scars
- 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 ***iDESIGN®*** System-driven PRK treatments:

- 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 Photorefractive Keratectomy (PRK).

---

[1] Rigid contact lenses (toric or spherical) must be removed for at least 4 weeks and soft contact lenses (toric or spherical) for at least 2 weeks prior to the first refraction used to establish stability. Refractive stability is defined as a change of not more than 0.50 D in manifest refraction sphere, cylinder or keratometry between measurements taken at least 7 days apart.

2 Effectiveness data for eyes that were treated with myopia as measured by iDesign System up to -10.00 D spherical equivalent, with up to -4.00 D cylinder;

- 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 2 weeks 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 at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard lenses must have 3 central keratometry readings and manifest refractions taken at 1-week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.
- 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. If there are any concerns regarding the appearance of the optic nerve, a thorough threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo laser refractive surgery.
- Pre-operative 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 ***iDESIGN®*** System-driven PRK treatments should be performed within 120 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the ***iDESIGN®*** Refractive Studio refraction, best spectacle-corrected visual acuity (BSCVA), and wavefront diameter, as outlined in the previous section of these Precautions.
- The minimum size of the wavefront measurement must be ≥4 mm to calculate ***iDESIGN®*** System-driven PRK treatments.
- If an ***iDESIGN*** Procedure ***PreVue*** Lens is used in the baseline evaluation of patients requesting ***iDESIGN®*** System-driven PRK Treatments, the vision obtained by the patient through the ***iDESIGN*** Procedure ***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, an ***iDESIGN*** Procedure ***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 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 with myopic astigmatism. These alternative corrections include:
    - Glasses or contact lenses
    - Implantable lens surgery (phakic intraocular lens)
    - Wavefront-guided or corneal topography-assisted LASIK
    - LASIK, refractive lenticule extraction or PRK using manifest refraction

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 post-operative examinations are recommended on day 1, and at 1, 3, 6 and 12 months:

- ***iDESIGN®*** Refractive Studio measurement of aberrometry, keratometry and corneal topography at 1, 3, and 6 and 12 months.
- Uncorrected Visual Acuity (UCVA or VA-sc) at 1 day, 1, 3, and 6 months.
- Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc) at 1, 3, and 6 months.
- Manifest refraction at 1, 3, and 6 months.
- Intraocular pressure (Goldmann applanation) at 1, 3, and 6 months.
- Slit-lamp examination at 1 day, 1, 3, and 6 months.

2.5 Risks of PRK

The potential risks associated with PRK include: decrease in best corrected visual acuity (vision that is corrected with glasses or contact lenses), over-correction or under-correction that may require eyeglasses or contact lens wear, increase in astigmatism, a reduction in the refractive correction over time (regression), unintentional imbalance between the two eyes (anisometropia) that may cause headaches, eye strain, double vision and/or difficulty judging distance or depth perception, patients around 40 years of age or older may need glasses for close work such as reading due to presbyopia, foreign body sensations, pain (including chronic eye pain that is resistant to therapy referred to as neuropathic pain), dry eyes, halos, glare, starbursts, hazy vision, blurred vision, distortion, double or multiple images (ghost images,

images that appear to have a shadow), fluctuating vision, difficulty focusing, difficulty with night driving, eye pain or soreness, feeling of something in the eye, grittiness, light sensitivity, decreased ability to see in low-light conditions (e.g., reading a street sign at dusk), corneal damage (scarring, swelling, cloudiness, haziness, irregular shape, bulging of the cornea (ectasia)), corneal epithelial defect, corneal erosion, corneal ulceration or perforation, corneal decompensation, persistent corneal edema, corneal infection and corneal inflammation, drooping eyelid (ptosis) that may require surgical intervention, increased intraocular pressure, cataract, and retinal detachment.

Please refer to **Section 3.3 G Adverse Events and Complications** of the Clinical Study of wavefront-guided PRK correction of myopic refractive errors with the ***iDESIGN®*** System and ***STAR S4 IR®*** Excimer Laser for additional information of risks that this procedure may pose.

Also, for future assessments of your patient, please provide your patient with their pre- and post-operative surgery information such as suggested by the American Academy of Ophthalmology. This information can be found on the last page of the **Patient Information Brochure** (Patient Assistance Information).

There may be difficulty with future assessment of IOP changes due to change in corneal biomechanics from PRK.

3 Clinical Results

A prospective, multi-center, bilateral, open-label, non-randomized clinical study was conducted with the ***iDESIGN®*** **Advanced WaveScan Studio** System, using v 1.3 software, and **Star S4 IR™** Excimer Laser System, using v 5.32 software, to create wavefront- guided PRK treatments. The ***iDESIGN®*** Advanced WaveScan Studio System and ***iDESIGN®*** Refractive Studio treatment plans are equivalent.

The refractive inclusion criteria specified that the patient have myopia with up to -10.00 D spherical equivalent and cylinder up to -4.0 D, as measured using the iDesign aberrometer.

To qualify for the study, patients also had to demonstrate agreement between the manifest and iDesign AWS System refraction with a magnitude of the difference for spherical equivalent less than 0.625 D; and a magnitude of the difference of less than or equal to 0.5 D for cylinder. Cylinder Axis Tolerance: If either the manifest cylinder entered into the iDesign AWS System or the iDesign cylinder selected for treatment was less than 0.5 D, there was no requirement for axis tolerance. When both cylinders had a magnitude of at least 0.5 D, the axis tolerance as determined by the iDesign AWS System was linearly reduced from 15° (0.5 D) to 7.5° (7.0 D) based on the average magnitude of both cylinders.

All study treatments were conducted using a 6-mm minimum optical zone and an 8-mm ablation zone with intention of full correction to emmetropia. Mitomycin-C 0.01% was applied for 15 seconds to the exposed corneal stroma immediately after excimer ablation and then thoroughly irrigated with 15 cc of balanced sterile saline solution. Mitomycin-C is not approved for use during PRK procedures.

Three hundred and thirty-four (334) eyes of one hundred sixty-seven (167) subjects 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.

3.1 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, binocular UCVA, higher order aberrations, complications, directed visual symptoms assessment, National Eye Institute Refractive Error Quality of Life (NEI-RQL) questionnaire, Ocular Surface Disease Index (OSDI) questionnaire, Schirmer I Tear Test, anterior segment evaluation, keratometric analyses, and vector and non-vector analyses of manifest refractive cylinder.

The key outcome endpoints were assessed postoperatively at the periodic exams. Refractive stability was achieved at 6 months and confirmed at 9 months, the key safety and effectiveness study endpoints were evaluated at 6 months as the primary study analysis. The point of refractive stability in the study was determined when the following criteria were met:

- At least 95% of the treated eyes have a change ≤1.00 D of MRSE and manifest cylinder (MRC) between refractions performed at 1 month and 3 months after surgery or any two refractions performed at least 3 months apart.
- The mean rate of change in MRSE and MRC, as determined by a paired analysis, is ≤0.5 D per year (0.04 D/month) over the same time period.
- The mean rate of change in MRSE and MRC decreases monotonically over time, with a projected asymptote of zero or a rate of change attributable to normal aging.
- The 95% confidence interval for the mean rate of change includes zero or a rate of change attributable to normal aging.
- Stability is confirmed at least 3 months after the stability time point by a statistically adequate subgroup.

3.2 Patient Accountability

Three hundred and thirty-four (334) eyes of 167 subjects treated at seven centers in the United States were evaluated for safety and effectiveness. The mean age of the subjects participating in this trial was 26.6 ± 5.4 years (range 19 to 47). There were 53 women and 114 men, and 65.9% were white. **Table 3-1** presents the demographic characteristics of the patient population.

Table 3-1 Demographic Characteristics All Subjects (N=167)

	Classification	All Subjects (n=167)
Gender	Male	114 (68.3%)
	Female	53 (31.7%)
Race	American Indian/Alaska Native	3 (1.8%)
	Asian (Includes Indian)	12 (7.2%)
	Black or African American	22 (13.2%)
	White	110 (65.9%)
	Other[a]	20 (12.0%)
Age (Years)	Mean	26.6[b]
	SD	5.4
	Min	19
	Max	47
Preoperative CL Wear[c]	No	162 (97.0%)
	Soft	5 (3.0%)
	Rigid/Toric	0 (0.0%)
	Soft/Toric	0 (0.0%)

[a] Other includes Hispanic and Mixed.

[b] There were 54 eyes from subjects < 22 years old.

[c] Within the 4 weeks (28 days) prior to the screening visit.

Note: The participants in this trial tended to be younger and composed of more males than has been the case for the refractive surgery population in general. Summaries of key trial results stratified by age and gender are provided on **Table 3-27** and **Table 3-28**.

Table 3-2 presents the accountability for all eyes treated in the study. At the time of database closure, most visits through 6 months were completed, and the 9- and 12-month study visits were ongoing. The 6-month data are available for 322 eyes (96.4%; 322/334), 9-month visit data available for 228 eyes (68.3%; 228/334), and 12-month visit data available for 184 eyes (55.1%; 184/334). 97% accountability was achieved at 6 months, determined to be the stability time point and thus the endpoint target for analysis.

Table 3-2 Subject Accountability

	1 Day		1 Week		1 Month		3 Month		6 Month		9 Month		12 Month	
Subject status	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Available for Analysis	334	100.0	334	100.0	332	99.4	328	98.2	322	96.4	228	68.3	184	55.1
- In Interval (included in analysis)	334	100.0	332	99.4	330	98.8	310	92.8	300	89.8	222	66.5	180	53.9
- Out of Interval (included in analysis)	0	0.0	2	0.6	2	0.6	18	5.4	22	6.6	6	1.8	4	1.2
Missing Eyes	0	0.0	0	0.0	2	0.6	6	1.8	10	3.0	20	6.0	22	6.6
- Discontinued	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
- Missed visit	0	0.0	0	0.0	0	0.0	4	1.2	2	0.6	2	0.6	0	0.0
- Not seen but accounted for	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
- Lost-to-follow-up	0	0.0	0	0.0	2	0.6	2	0.6	8	2.4	18	5.4	22	6.6
Active	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	86	25.7	128	38.3
- Active (not yet in visit interval)	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	58	17.4	104	31.1
- In interval or Past interval (form not yet received)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	28	8.4	24	7.2
Percent Accountability* (ANSI Z80.11-2012)		100.0		100.0		99.4		98.2		97.0		91.9		89.3

*Percent Accountability = (Available for Analyses * 100)/(Enrolled [treated] - Discontinued - Active)

3.3 Data Analysis and Results

A. Pre-Operative Characteristics

All refractions were tested at four meters and converted to optical infinity for data analysis and presentation.

Mean preoperative manifest and iDesign refractive error for the 334 treated eyes are presented in **Table 3-3**. Mean preoperative refractive measurements were consistent between iDesign and manifest refractions with almost no difference in means (all within 0.05 D of each other).

Table 3-3 Preoperative Manifest and iDesign Refractive Error All Treated Eyes (N=334)

	Variable	Mean	SD	Median	Minimum	Maximum
Manifest Refraction	**MRS**	-3.58	1.96	-3.25	-8.25	-0.25
	MRC	-1.00	0.84	-0.75	-4.00	0.00
	MRSE	-4.08	1.97	-3.75	-8.75	-0.63
iDesign Refraction	**IDS**	-3.56	1.96	-3.23	-7.99	-0.07
	IDC	-1.05	0.83	-0.80	-3.98	-0.03
	IDSE	-4.09	1.97	-3.69	-8.99	-0.64

MRS = manifest refractive sphere
MRC = manifest refractive cylinder
MRSE = manifest refractive spherical equivalent
IDS = iDesign sphere
IDC = iDesign cylinder
IDSE = iDesign spherical equivalent

Table 3-4 presents preoperative refractive error stratified by ***iDESIGN®*** System sphere and cylinder, while **Table 3-5** presents preoperative refractive error stratified by ***iDESIGN®*** System spherical equivalent and cylinder, expressed in minus cylinder notation.

Table 3-4 Preoperative Refractive Error Stratified by iDesign Sphere and Cylinder All Treated Eyes (N=334)

	iDesign Cylinder					
	0 to ≥-0.5 D	**<-0.5 to ≥-1 D**	**<-1 to ≥-2 D**	**<-2 to ≥-3 D**	**<-3 to ≥-4 D**	**Total**
iDesign Sphere	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**
≤0 to ≥-1 D	8 2.4%	5 1.5%	2 0.6%	4 1.2%	4 1.2%	**23 6.9%**
<-1 to ≥-2 D	19 5.7%	22 6.6%	16 4.8%	8 2.4%	2 0.6%	**67 20.1%**
<-2 to ≥-3 D	12 3.6%	17 5.1%	22 6.6%	7 2.1%	2 0.6%	**60 18.0%**
<-3 to ≥-4 D	19 5.7%	17 5.1%	17 5.1%	1 0.3%	2 0.6%	**56 16.8%**
<-4 to ≥-5 D	13 3.9%	17 5.1%	9 2.7%	4 1.2%	0 0.0%	**43 12.9%**
<-5 to ≥-6 D	15 4.5%	9 2.7%	8 2.4%	2 0.6%	3 0.9%	**37 11.1%**
<-6 to ≥-7 D	9 2.7%	7 2.1%	8 2.4%	3 0.9%	1 0.3%	**28 8.4%**
<-7 to ≥-8 D	6 1.8%	4 1.2%	8 2.4%	2 0.6%	0 0.0%	**20 6.0%**
Total	**101 30.2%**	**98 29.3%**	**90 26.9%**	**31 9.3%**	**14 4.2%**	**334 100%**

Table 3-5 Preoperative Refractive Error Stratified by iDesign Spherical Equivalent (SE) and Cylinder All Treated Eyes (N=334)

	iDesign Cylinder					
	0 to ≥-0.5 D	<-0.5 to ≥-1 D	<-1 to ≥-2 D	<-2 to ≥-3 D	<-3 to ≥-4 D	Total
iDesign SE	n %	n %	n %	n %	n %	n %
≤0 to ≥-1 D	3 0.9%	2 0.6%	0 0.0%	0 0.0%	0 0.0%	**5 1.5%**
<-1 to ≥-2 D	21 6.3%	18 5.4%	6 1.8%	3 0.9%	0 0.0%	**48 14.4%**
<-2 to ≥-3 D	12 3.6%	13 3.9%	20 6.0%	7 2.1%	5 1.5%	**57 17.1%**
<-3 to ≥-4 D	20 6.0%	25 7.5%	21 6.3%	7 2.1%	2 0.6%	**75 22.5%**
<-4 to ≥-5 D	11 3.3%	14 4.2%	11 3.3%	3 0.9%	1 0.3%	**40 12.0%**
<-5 to ≥-6 D	13 3.9%	15 4.5%	10 3.0%	4 1.2%	2 0.6%	**44 13.2%**
<-6 to ≥-7 D	14 4.2%	6 1.8%	10 3.0%	2 0.6%	1 0.3%	**33 9.9%**
<-7 to ≥-8 D	4 1.2%	5 1.5%	7 2.1%	2 0.6%	3 0.9%	**21 6.3%**
<-8 to ≥-9 D	3 0.9%	0 0.0%	5 1.5%	3 0.9%	0 0.0%	**11 3.3%**
Total	**101 30.2%**	**98 29.3%**	**90 26.9%**	**31 9.3%**	**14 4.2%**	**334 100%**

B. Uncorrected Visual Acuity (UCVA)

All eyes were targeted for emmetropia. Uncorrected visual acuity (UCVA) was measured monocularly and binocularly under photopic lighting conditions at 4 meters, without any lens correction, using an Early Treatment Diabetic Retinopathy Study (ETDRS) chart.

At 6 months, UCVA of 20/40 or better was achieved in 100% (322/322) of eyes monocularly, exceeding the study effectiveness endpoint target of 85% of eyes with 20/40 or better UCVA, and UCVA of 20/20 or better was achieved in 99.4% (320/322) of eyes (**Table 3-6**).

At 6 months, binocular UCVA of 20/40 or better was achieved in 100% (161/161) of subjects and binocular UCVA of 20/20 or better was also achieved in 100% (161/161) of subjects. Overall, all subjects (100%) achieved a binocular UCVA of 20/40 or better across all postoperative visits at 1 month or later (**Table 3-7**).

Table 3-6 Monocular UCVA Over Time All Eyes (N=334)

LogMAR Value	Acuity	Preoperative (n=334) n % (95% CI)	1 Month (n=332) n % (95% CI)	3 Months (n=328) n % (95% CI)	6 Months (n=322) n % (95% CI)	9 Months (n=228) n % (95% CI)	12 Months (n=184) n % (95% CI)
≤ -0.06	20/16 or better	0 0.0% (- , -)	171 51.5% (46.0, 57.0)	290 88.4% (84.4, 91.7)	296 91.9% (88.4, 94.7)	208 91.2% (86.8, 94.6)	175 95.1% (90.9, 97.7)
≤ 0.04	20/20 or better	2 0.6% (0.1, 2.1)	265 79.8% (75.1, 84.0)	325 99.1% (97.4, 99.8)	320 99.4% (97.8, 99.9)	226 99.1% (96.9, 99.9)	184 100% (98.4, 100)
≤ 0.14	20/25 or better	3 0.9% (0.2, 2.6)	314 94.6% (91.6, 96.8)	328 100% (99.1, 100)	320 99.4% (97.8, 99.9)	227 99.6% (97.6, 100)	184 100% (98.4, 100)
≤ 0.34	20/40 or better	19 5.7% (3.5, 8.7)	328 98.8% (96.9, 99.7)	328 100% (99.1, 100)	322 100% (99.1, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
≤ 0.74	20/100 or better	96 28.7% (23.9, 33.9)	332 100% (99.1, 100)	328 100% (99.1, 100)	322 100% (99.1, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
> 0.74	Worse than 20/100	238 71.3% (66.1, 76.1)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Not Reported	Not reported	0	0	0	0	0	0

Percentage is calculated based on non-missing values.

Table 3-7 Binocular UCVA Over Time Safety Population

LogMAR Value	Acuity	Pre-Op (n=167) n % (95% CI)	1 Month (n=166) n % (95% CI)	3 Months (n=164) n % (95% CI)	6 Months (n=161) n % (95% CI)	9 Months (n=114) n % (95% CI)	12 Months (n=92) n % (95% CI)
<=-0.06	20/16 or better	1 0.6% (0.0, 3.3)	128 77.1% (70.0, 83.3)	161 98.2% (94.7, 99.6)	160 99.4% (96.6, 100)	112 98.2% (93.8, 99.8)	92 100% (96.8, 100)
<= 0.04	20/20 or better	3 1.8% (0.4, 5.2)	155 93.4% (88.5, 96.6)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.14	20/25 or better	8 4.8% (2.1, 9.2)	165 99.4% (96.7, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.34	20/40 or better	27 16.2% (10.9, 22.6)	166 100% (98.2, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
<= 0.74	20/100 or better	72 43.1% (35.5, 51.0)	166 100% (98.2, 100)	164 100% (98.2, 100)	161 100% (98.2, 100)	114 100% (97.4, 100)	92 100% (96.8, 100)
> 0.74	Worse than 20/100	95 56.9% (49.0, 64.5)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Not Reported	Not Reported	0	0	0	0	0	0

[a] Confidence Interval is calculated based on Clopper-Pearson Exact method.
[b] Percentage is calculated based on non-missing values.

At 6-months postoperative, 81.4% (262/322) of eyes achieved the same or better uncorrected vision as they achieved preoperatively with best spectacle correction (**Table 3-8**).

Table 3-8 Postoperative Monocular UCVA Compared to Preoperative Monocular BSCVA All Eyes (N=332)

		1 Month (n=332)	3 Months (n=328)	6 Months (n=322)	9 Months (n=228)	12 Months (n=184)
LogMAR Change	**Acuity Line Change**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**
<-0.24	**>2 lines better**	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
≥-0.24 to <-0.14	**2 lines better**	0 0.0% (- , -)	1 0.3% (0.0, 1.7)	5 1.6% (0.5, 3.6)	3 1.3% (0.3, 3.8)	6 3.3% (1.2, 7.0)
≥-0.14 to <-0.04	**1 line better**	16 4.8% (2.8, 7.7)	62 18.9% (14.8, 23.6)	88 27.3% (22.5, 32.5)	76 33.3% (27.2, 39.9)	70 38.0% (31.0, 45.5)
≥-0.04 to ≤0.04	**Equal**	91 27.4% (22.7, 32.5)	197 60.1% (54.5, 65.4)	169 52.5% (46.9, 58.0)	117 51.3% (44.6, 58.0)	91 49.5% (42.0, 56.9)
>0.04 to ≤0.14	**1 line worse**	131 39.5% (34.2, 44.9)	61 18.6% (14.5, 23.2)	55 17.1% (13.1, 21.6)	27 11.8% (8.0, 16.8)	14 7.6% (4.2, 12.4)
>0.14 to ≤0.24	**2 lines worse**	56 16.9% (13.0, 21.3)	7 2.1% (0.9, 4.3)	3 0.9% (0.2, 2.7)	3 1.3% (0.3, 3.8)	3 1.6% (0.3, 4.7)
>0.24	**>2 lines worse**	38 11.4% (8.2, 15.4)	0 0.0% (- , -)	2 0.6% (0.1, 2.2)	2 0.9% (0.1, 3.1)	0 0.0% (- , -)
Not Reported		0	0	0	0	0

Percentage calculated based on non-missing values.

C. Accuracy of Manifest Refraction Spherical Equivalent (MRSE)

At 6 months post-operative, 85.4% (275/322) of eyes were within 0.50 D, and 96.3% (310/322) within 1.0 D of attempted correction (emmetropia). **Table 3-9** presents the accuracy of MRSE over time for all treated eyes. At 6 months, 1 eye (0.3%; 1/322) was undercorrected >1.00 D and 11 eyes (3.4%; 11/322) were overcorrected >1.00 D, of which 1 eye (0.3%; 1/322) was overcorrected >2.00 D.

Table 3-9 Accuracy of MRSE: Intended vs. Achieved Outcome (N=332)

	Preoperative (n=334)	1 Month (n=332)	3 Months (n=328)	6 Months (n=322)	9 Months (n=228)	12 Months (n=184)
MRSE	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**
+/- 0.50 D	0 0.0% (- , -)	223 67.2% (61.8, ,72.2)	274 83.5% (79.1, ,87.4)	275 85.4% (81.1, ,89.1)	185 81.1% (75.4, ,86.0)	157 85.3% (79.4, ,90.1)
+/- 1.00 D	6 1.8% (0.7, 3.9)	310 93.4% (90.1,, 95.8)	316 96.3% (93.7,, 98.1)	310 96.3% (93.6, ,98.1)	221 96.9% (93.8, ,98.8)	182 98.9% (96.1, ,99.9)
+/- 2.00 D	62 18.6% (14.5, 23.2)	331 99.7% (98.3, 100)	328 100% (99.1, 100)	321 99.7% (98.3, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
Not Reported	0	0	0	0	0	0
Undercorrected						
> 1.00 D		16 4.8% (2.8, 7.7)	2 0.6% (0.1, 2.2)	1 0.3% (0.0, 1.7)	1 0.4% (0.0, 2.4)	1 0.5% (0.0, 3.0)
> 2.00 D		0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)	0 0.0% (- , -)
Overcorrected						
> 1.00 D		6 1.8% (0.7, 3.9)	10 3.0% (1.5, 5.5)	11 3.4% (1.7, 6.0)	6 2.6% (1.0, 5.6)	1 0.5% (0.0, 3.0)
> 2.00 D		1 0.3% (0.0, 1.7)	0 0.0% (- , -)	1 0.3% (0.0, 1.7)	0 0.0% (- , -)	0 0.0% (- , -)

Percentage is calculated based on non-missing values.

D. Stability of Outcome

Stability of Refractive Spherical Equivalent (MRSE)

MRSE stability over time for all treated eyes was evaluated using both a consecutive cohort (eyes with data for at least two consecutive study visits) and a consistent cohort (eyes with data at all periodic visits through the point of stability and the confirmatory time point; in this case, 1, 3, 6, and 9 months).

Table 3-10 presents the stability of MRSE across visits for all eyes with at least two consecutive study visits. **Table 3-11** presents the stability of MRSE across visits for all eyes with data at 1, 3, 6, and 9 months. The defined criteria for refractive stability were met at the 6-month visit and confirmed at the 9-month visit. At least 95.0% of eyes had ≤1.00 D change in MRSE between 3 and 6 months and between 6 and 9 months, meeting the criterion of at least 95% of the treated eyes having a change of ≤1.00 D in MRSE at any two refractions performed at least 3 months apart.

Stability of Manifest Refractive Cylinder (MRC)

Non-vector analysis of the stability of refractive cylinder over time was performed using both a consecutive cohort (eyes with data for at least two consecutive study visits) and a consistent cohort (eyes with data at 1, 3, 6, and 9 months). **Table 12** presents the stability of absolute (non-vector) cylinder across visits for all eyes with at least two consecutive study visits. **Table 13** presents the stability of absolute (non-vector) cylinder across visits for all eyes with data at 1, 3, 6, and 9 months. At least 95.0% of eyes had ≤1.00 D change in manifest refractive cylinder (MRC) between 3 and 6 months and between 6 and 9 months, meeting the criterion of at least 95% of the treated eyes having a change of ≤1.00 D in MRC at any two refractions performed at least 3 months apart.

Table 3-10 Stability of Manifest Refraction Spherical Equivalent (MRSE)

Consecutive Cohort[a]

Distributions	Between 1 and 3 Months (n=328) n %	Between 3 and 6 Months (n=318) n %	Between 6 and 9 Months (n=226) n %	Between 9 and 12 Months (n=182) n %
Change in MRSE by ≤1.00 D 95% CI	312 95.1% (92.2, 97.2)	311 97.8% (95.5, 99.1)	216 95.6% (92.0, 97.9)	181 99.5% (97.0, 100)
Change in MRSE by ≤0.50 D 95% CI	256 78.0% (73.2, 82.4)	281 88.4% (84.3, 91.7)	180 79.6% (73.8, 84.7)	163 89.6% (84.2, 93.6)
Mean Outcomes	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**
Mean Change in MRSE	0.16 +/- 0.51 (0.10, 0.21)	0.07 +/- 0.39 (0.02, 0.11)	0.00 +/- 0.50 (-0.07, 0.06)	-0.01 +/- 0.35 (-0.06, 0.04)
Mean Change Per Month	0.08	0.02	0.00	0.00

Change defined as current visit value minus previous visit value.

[a] Includes only eyes with data at two consecutive visits.

Table 3-11 Stability of Manifest Refraction Spherical Equivalent (MRSE)

Consistent Cohort[a]

Distributions	Between 1 and 3 Months (n=224) n %	Between 3 and 6 Months (n=224) n %	Between 6 and 9 Months (n=224) n %
Change in MRSE by ≤1.00 D	212 94.6% (90.8, 97.2)	217 96.9% (93.7, 98.7)	214 95.5% (91.9, 97.8)
Change in MRSE by ≤0.50 D	172 76.8% (70.7, 82.1)	195 87.1% (81.9, 91.2)	178 79.5% (73.6, 84.6)
Mean Outcomes	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**	**D +/-SD (95% CI)**
Mean Change in MRSE	0.17 +/- 0.54 (0.10, 0.24)	0.09 +/- 0.42 (0.03, 0.14)	0.00 +/- 0.50 (-0.07, 0.06)
Mean Change Per Month	0.08	0.03	0.00

Change defined as current visit value minus previous visit value.

Confidence Intervals calculated based on Clopper-Pearson Exact method.

[a]Includes only eyes with data at 1, 3, 6, and 9 Months visits.

Table 3-12 Stability of Manifest Cylinder Consecutive Cohort[a]

Magnitude of Change in Non-vector Cylinder Distributions	Between 1 and 3 Months (n=328) n %	Between 3 and 6 Months (n=318) n %	Between 6 and 9 Months (n=226) n %	Between 9 and 12 Months (n=182) n %
Eyes with ≤1.00 D Change	310 94.5%	318 100%	226 100%	182 100%
95% CI	(91.5, 96.7)	(99.1, 100)	(98.7, 100)	(98.4, 100)
Eyes with ≤0.50 D Change	269 82.0%	313 98.4%	220 97.3%	180 98.9%
95% CI	(77.4, 86.0)	(96.4, 99.5)	(94.3, 99.0)	(96.1, 99.9)
Mean Outcomes (D)				
Mean Change between Visits	0.28	0.03	-0.02	0.02
SD	0.47	0.23	0.24	0.20
95% CI	(0.23, 0.33)	(0.01, 0.06)	(-0.05, 0.01)	(-0.01, 0.05)
Mean Change Per Year	1.70	0.13	-0.08	0.09
Mean Change Per Month[b]	0.14	0.01	-0.01	0.01

Change defined as current visit value minus previous visit value.

[a]Includes only eyes with data at two consecutive visits.

[b]Refractive stability criterion: mean change of ≤0.04 D/month between visits

Table 3-13 Stability of Manifest Cylinder Consistent Cohort[a]

Magnitude of Change in Non-vector Cylinder Distributions	Between 1 and 3 Months (n=224) n % (95% CI)	Between 3 and 6 Months (n=224) n % (95% CI)	Between 6 and 9 Months (n=224) n % (95% CI)
Eyes with ≤1.00 D Change	209, 93.3% (89.2, 96.2)	224, 100% (98.7, 100)	224, 100% (98.7, 100)
Eyes with ≤0.50 D Change	182, 81.3% (75.5, 86.1)	219, 97.8% (94.9, 99.3)	218, 97.3% (94.3, 99.0)
Mean Outcomes (D)			
Mean Change between Visits	0.29	0.03	-0.02
SD	0.49	0.25	0.24
95% CI	0.23, 0.36	0.00, 0.06	-0.05, 0.01
Mean Change Per Year	1.75	0.13	-0.07
Mean Change Per Month	0.15	0.01	-0.01

Change defined as current visit value minus previous visit value.

Confidence Intervals calculated based on Clopper-Pearson Exact method.

[a]Includes only eyes with data at 1, 3, 6, and 9 Months visits.

Efficacy of correction of astigmatism was evaluated at the point of stability (6 months) for eyes with myopic astigmatism.

Table 3-14 presents the proportions of eyes with residual manifest cylinder magnitude at 6 months and the absolute shift in axis from preoperative. At 6 months, an axis shift of > 30° from preoperative was noted for 18.9% (61/322) of eyes; of which 2 eyes (3.3%; 2/61) had a residual cylinder magnitude > 0.50 D, all the rest were less than 0.5 D of cylinder. **Table 3-15** presents a summary of the vector analysis which includes mean Intended Refractive Change (IRC), Surgically Induced Refractive Cylinder (SIRC), Correction Ratio (CR), Error Vector (EV) and Error Ratio (ER), at the point of stability (6 months). The mean correction ratio (CR; ratio of surgically induced refractive change compared to the intended refractive change) of 0.96 demonstrates a slight under correction of cylinder.

Table 3-14 Residual Manifest Refractive Astigmatic Axis Error at 6 Months

	Absolute Shift in Axis						
Residual Cylinder Magnitude	**0 (n=117)**	**>0 to ≤5 (n=31)**	**>5 to ≤10 (n=34)**	**>10 to ≤15 (n=26)**	**>15 to ≤30 (n=53)**	**>30 (n=61)**	**Total (n=322)**
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**
0.0 D	90 76.9%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	90 28.0%
>0 to ≤0.5 D	24 20.5%	27 87.1%	26 76.5%	20 76.9%	51 96.2%	59 96.7%	207 64.3%
>0.5 to ≤1.0 D	2 1.7%	4 12.9%	7 20.6%	6 23.1%	2 3.8%	2 3.3%	23 7.1%
>1.0 to ≤2.0 D	1 0.9%	0 0.0%	1 2.9%	0 0.0%	0 0.0%	0 0.0%	2 0.6%
>2.0 to ≤3.0 D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Total	**117 100**	**31 100**	**34 100**	**26 100**	**53 100**	**61 100**	**322 100**

Table 3-15 Vector Analysis Summary at 6-Months[a] (N = 186)

Preoperative Cylinder	**N (%, n/N)**	**|IRC| (Mean +/- SD)**	**|SIRC| (Mean +/- SD)**	**|EV| (Mean +/- SD)**	**CR (Mean +/- SD)**	**ER (Mean +/- SD)**
All Eyes (N)	324 (100%)	1.01 +/- 0.84	0.93 +/- 0.75	0.29 +/- 0.26	0.96 +/- 0.38	0.41 +/- 0.58
0.0 D	21 (6.5%)	0.00 +/- 0.00	0.29 +/- 0.28	0.29 +/- 0.28		
>0.0 D to ≤0.5 D	115 (35.5%)	0.39 +/- 0.12	0.42 +/- 0.20	0.23 +/- 0.23	1.10 +/- 0.54	0.69 +/- 0.83
>0.5 D to ≤1.0 D	90 (27.8%)	0.88 +/- 0.13	0.77 +/- 0.23	0.24 +/- 0.22	0.88 +/- 0.23	0.27 +/- 0.25
>1.0 D to ≤2.0 D	60 (18.5%)	1.56 +/- 0.29	1.36 +/- 0.43	0.38 +/- 0.31	0.87 +/- 0.23	0.26 +/- 0.24
>2.0 D to ≤3.0 D	27 (8.3%)	2.56 +/- 0.29	2.29 +/- 0.41	0.37 +/- 0.24	0.89 +/- 0.11	0.14 +/- 0.09
>3.0 D to ≤4.0 D	11 (3.4%)	3.50 +/- 0.30	3.12 +/- 0.41	0.48 +/- 0.21	0.89 +/- 0.09	0.14 +/- 0.06

IRC = intended refractive change
SIRC = surgically induced refractive change
EV = error vector (IRC-SIRC)
CR = correction ratio (SIRC/IRC)
ER = error ratio (EV/IRC)

[a] The analysis was based on 324 evaluable patients at the 6-month time-point at final database lock on August 24, 2018. This analysis was submitted in P930016/S057/A001.

E. High Order Aberrations

Table 3-16 presents higher order aberration (HOA) over time for all treated eyes. This analysis is limited to those eyes with a wavefront measurement with a 5-mm minimum diameter, as aberration analysis is standardized at and calculated over a 5-mm diameter. The HOA root mean square (RMS) minimally increased postoperatively, and HOAs were stable over time.

Table 3-16 Higher Order Aberration RMS (HOA) (µm) Over Time

	Preoperative (n=326) Mean +/- SD	1 Month (n=315) Mean +/- SD	3 Months (n=312) Mean +/- SD	6 Months (n=302) Mean +/- SD	9 Months (n=210) Mean +/- SD	12 Months (n=172) Mean +/- SD
Total HOA RMS	0.16 ± 0.05	0.24 ± 0.10	0.18 ± 0.07	0.19 ± 0.08	0.19 ± 0.07	0.19 ± 0.08
Coma	0.10 ± 0.05	0.14 ± 0.09	0.11 ± 0.07	0.12 ± 0.08	0.12 ± 0.07	0.12 ± 0.08
Trefoil	0.08 ± 0.05	0.11 ± 0.07	0.07 ± 0.04	0.07 ± 0.04	0.07 ± 0.04	0.07 ± 0.04
Spherical Aberration	0.05 ± 0.03	0.07 ± 0.06	0.07 ± 0.05	0.07 ± 0.06	0.07 ±- 0.05	0.07 ± 0.05

F. Schirmer I Tear Test

The distribution of Schirmer scores over time is presented in **Table 3-17.** At 6 months, the mean Schirmer score was 20.79 mm (SD 9.31), and the mean change in Schirmer score from preop was 0.11 mm (SD 7.73). At 6 months, 89.7% (288/322) had Schirmer scores of ≥10 mm (normal) and 3.4% (11/322) eyes had Schirmer scores of ≤5 mm (severe dryness; **Table 3-25**); however, there were no AEs of dry eyes (predefined as a Schirmer score of ≤ 5 mm at 3 months or later and an OSDI score of ≥33).

Table 3-17 Schirmer Score Distribution Over Time

	Preoperative (n=334)		1 Month (n=332)		3 Month (n=328)		6 Month (n=322)		9 Month (n=228)		12 Month (n=184)	
	n	%	n	%	n	%	n	%	n	%	n	%
≤5 mm (severe dry)	8	2.4	22	6.6	13	4.0	11[a-k]	3.4	10	4.4	6	3.3
>5 mm to <10 mm	33	9.9	31	9.3	27	8.2	23	6.9	19	8.3	24	13.0
≥10 mm (normal)	293	87.7	279	84.0	288	87.8	288	89.7	199	87.3	154	83.7

[a] Eye #20442 - Preoperative Schirmer 12; 6 mo visit Schirmer 5, OSDI 10.4, UCVA 20/10, BSCVA 20/10

[b] Eye #30231 - Preoperative Schirmer 5; 6 mo visit Schirmer 5, OSDI 2.5, UCVA 20/12.5, BSCVA 20/12.5

[c] Eye #30232 - Preoperative Schirmer 5; 6 mo visit Schirmer 3, OSDI 2.5, UCVA 20/12.5, BSCVA 20/12.5

[d] Eye #30381 - Preoperative Schirmer 22; 6 mo visit Schirmer 5, OSDI 2.1, UCVA 20/16, BSCVA 20/12.5

[e] Eye #30382 - Preoperative Schirmer 18; 6 mo visit Schirmer 3, OSDI 2.1, UCVA 20/16, BSCVA 20/12.5

[f] Eye #30412 - Preoperative Schirmer 13; 6 mo visit Schirmer 4, OSDI 0, UCVA 20/12.5, BSCVA 20/12.5

[g] Eye #30451 - Preoperative Schirmer 12; 6 mo visit Schirmer 5, OSDI 4.2, UCVA 20/20, BSCVA 20/16

[h] Eye #30452 - Preoperative Schirmer 8; 6 mo visit Schirmer 3, OSDI 4.2, UCVA 20/16, BSCVA 20/12.5

[i] Eye #50052 - Preoperative Schirmer 8; 6 mo visit Schirmer 5, OSDI 2.1, UCVA 20/16, BSCVA 20/16

[j] Eye #60042 - Preoperative Schirmer 9; 6 mo visit Schirmer 3, OSDI 0, UCVA 20/12.5, BSCVA 20/12.5

[k] Eye #60221 - Preoperative Schirmer 3; 6 mo visit Schirmer 2, OSD 2.1, UCVA 20/16, BSCVA 20/12.5

G. Additional Anterior Segment Evaluation Findings

The anterior segment was evaluated for corneal clarity (**Table 3-18**) and changes in IOP. At 6 months, most eyes were noted with clear corneal clarity (score of 0) (90.1%; 290/322), 7.8% of eyes (25/322) were noted with faint/trace haze (score of 0.5), 1.9% (6/322) of eyes had mild haze (score of 1), and 1 eye (0.3%) had moderate haze (score of 2). At 6 months, the mean IOP was 12.33 mmHg (SD 2.05), and most eyes (90.1%; 290/322) had no change or decrease in IOP compared to preoperative. No eyes had an IOP >30 mmHg at any visit.

Table 3-18 Corneal Clarity Over Time

Corneal Clarity	Preop (n=334)		1 Day (n=334)		1 Week (n=334)		1 Month (n=332)		3 Month (n=328)		6 Month (n=322)		9 Month (n=228)		12 Month (n=184)		Cumulative (n=334)	
(Grade)	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Clear (0)	332	99.4	321	96.1	311	93.1	295	88.9	275	83.8	290	90.1	212	93.0	176	95.7	334	100.0
Faint/Trace Haze (0.5)	2	0.6	13	3.9	21	6.3	35	10.5	51	15.5	25	7.8	12	5.3	8	4.3	90	26.9
Mild Haze (1)	0	0.0	0	0.0	2	0.6	2	0.6	2	0.6	6	1.9	4	1.8	0	0.0	11	3.3
Moderate Haze (2)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1[a]	0.3	0	0.0	0	0.0	1	0.3
Dense Haze; Opacity prevents refraction; AC visible (3)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dense Haze: Anterior chamber not visible (4)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
--Haze present, but rating not recorded	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Cumulative including unscheduled visit.

[a] Eye #30352 had moderate haze (score of 2) and a loss of >2 lines of BSCVA that was reported as a serious, device-related adverse event. Preoperative BSCVA for this eye was 20/16 (LogMAR -0.14); at 6 months, BSCVA was 20/25 (LogMAR 0.14). At the 9-month visit, corneal haze was noted as mild and BSCVA had returned to 20/16 (LogMAR -0.14)

H. Best Spectacle-Corrected Visual Acuity

Table 3-19 presents the change in lines of BSCVA over time. At 6 months, 97.2% (313/322) of eyes had either no change or an improvement in BSCVA compared to preoperative. One eye (0.3%; 1/322) had a decrease in BSCVA of >2 lines at 6 months vs. preoperative, meeting the safety criterion of <5% of eyes with a loss of >2 lines of BSCVA.

Table 3-17 Change in BSCVA Over Time vs. Preoperative All Eyes

		1 Month (n=332)	3 Months (n=328)	6 Months (n=322)	9 Months (n=228)	12 Months (n=184)
Change in LogMAR	**Change in Acuity**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**	**n % (95% CI)**
<-0.24	**Increase >2 lines**	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
≥-0.24 to <-0.14	**Increase =2 lines**	1 0.3% (0.0, 1.7)	6 1.8% (0.7, 3.9)	10 3.1% (1.5, 5.6)	10 4.4% (2.1, 7.9)	18 9.8% (5.9, 15.0)
≥-0.14 to <-0.04	**Increase =1 line**	40 12.0% (8.7, 16.0)	134 40.9% (35.5, 46.4)	151 46.9% (41.3, 52.5)	124 54.4% (47.7, 61.0)	108 58.7% (51.2, 65.9)
≥-0.04 to ≤0.04	**No Change**	196 59.0% (53.5, 64.4)	174 53.0% (47.5, 58.6)	152 47.2% (41.6, 52.8)	90 39.5% (33.1, 46.1)	56 30.4% (23.9, 37.6)
>0.04 to ≤0.14	**Decrease =1 line**	77 23.2% (18.8, 28.1)	13 4.0% (2.1, 6.7)	8 2.5% (1.1, 4.8)	4 1.8% (0.5, 4.4)	2 1.1% (0.1, 3.9)
>0.14 to ≤0.24	**Decrease =2 lines**	15 4.5% (2.6, 7.3)	1 0.3% (0.0, 1.7)	0 0.0% -	0 0.0% -	0 0.0% -
>0.24	**Decrease >2 lines**	3 0.9% (0.2, 2.6)	0 0.0% -	1[a] 0.3% (0.0, 1.7)	0 0.0% -	0 0.0% -
Not Reported		0	0	0	0	0
Total		332	328	322	228	184

[a] One eye had a decrease in BSCVA of 2 lines from preoperative BSCVA of 20/16 to 20/25 at 6 months: BSCVA improved to 20/12.5 at 9 months.

I. Adverse Events (AE) and Complications

A summary of adverse events is provided in **Table 3-20** . The results of this study support the safety and effectiveness of ***iDESIGN®*** wavefront-guided PRK Treatment. Three hundred and thirty-four (334) treated eyes were used for safety analyses in the US IDE clinical investigation of the ***STAR S4 IR®*** Excimer Laser System and the ***iDESIGN®*** . There were twenty-seven (27) serious and/or device-related ocular adverse events in nineteen (19) subjects. Of these, 11 serious AEs occurred in 10 subjects (four serious, non-device related and seven serious, device-related AEs). The four serious, non-device related AEs occurred in 4 eyes of 4 subjects: retinal detachment (n = 1), anterior uveitis (n = 1), and corneal abrasion (n = 2). The seven serious, device-related AEs occurred in 7 eyes of 6 subjects: corneal infiltrate (n = 2 eyes), corneal haze (n = 3 eyes), and corneal erosion (n = 2 eyes). The rate of each type of serious, device-related adverse event was <1% (corneal infiltrate: 0.6%, 2/334; corneal erosion: 0.6%. 2/334; corneal haze: 0.9%, 3/334), meeting the safety endpoint for serious, device-related AEs. None were considered un-anticipated and most events resolved during the study (90.9%). In addition, 16 AEs were non-serious, device-related and occurred in 9 subjects. All device-related events resolved without sequelae except for chronic dry eye, which remained ongoing at study exit (12 months). Complications are presented in **Table 3-21**.

Table 3-20 Summary of Adverse Events Over Time

Adverse Event	<1 Month (n=334)		1 Month (n=332)		3 Months (n=328)		6 Months (n=322)		9 Months (n=228)		12 Months (n=184)		Cumulative[a] (n=334)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Corneal infiltrate or ulcer	2	0.6	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	3	0.9
Any persistent corneal epithelial defect at 1 month or later[b]	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[c]	n/a	n/a	10	3.0	0	0.0	0	0.0	0	0.0	0	0.0	10	3.0
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	1[d]	0.3	0	0.0	0	0.0	1[d]	0.3
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
Retinal detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.5	1	0.3
Retinal vascular accidents	0	0.0	0	0.0	0	0.0	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	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal melt	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Glaucoma or ocular hypertension	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Severe allergic reaction to study medication	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any other vision-threatening event (Serious)														
Corneal haze potentially affecting vision	0	0.0	0	0.0	0	0.0	2[e]	0.6	0	0.0	0	0.0	2[e]	0.6
Corneal abrasion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6
Corneal erosion	0	0.0	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	2	0.6
Anterior uveitis	0	0.0	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	1	0.3
Other adverse events (Non-serious)														
Corneal erosion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3
Chronic dry eye[f]	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6
Headaches	0	0.0	0	0.0	2	0.6	0	0.0	0	0.0	0	0.0	2	0.6

[a] Cumulative includes unscheduled visits.

[b] Defined as corneal epithelial defect as a result of surgery that persisted at 1 month or later.

[c] Includes only cases involving primary cases of corneal edema (i.e., does not include cases of edema secondary to corneal infiltrate, corneal erosion, and corneal abrasion)

[d] Same eye

[e] Both eyes from same subject

[f] Chronic Dry Eye diagnosis was not based the on protocol-defined dry eye definition (subject score of ≥ 33 on the OSDI in combination with a Schirmer score of ≤ 5 mm).

Table 3-21 Summary of Complications

Complication	1 Week to <1 Month (n=334)		1 Month (n=332)		3 Months (n=328)		6 Months (n=322)		9 Months (n=228)		12 Months (n=184)		Cumulative[a] (n=334)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Corneal edema between 1 week and 1 month after the procedure	116[b]	34.7	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	3	0.9
Corneal erosion at 1 month or later	n/a	n/a	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	3[c]	0.9
Foreign body sensation at 1 month or later	n/a	n/a	0	0.0	5	1.5	2	0.6	1	0.4	0	0.0	10	3.0
Pain at 1 month or later	n/a	n/a	5	1.5	9	2.7	11	3.4	1	0.4	0	0.0	28	8.4
Ghost/diplopia (PRSVQ PRO)[d]	74	44.3	47	28.3	15	9.1	7	4.3	4	3.5	2	2.2	96	57.5
Transient light sensitivity syndrome	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

[a] Cumulative includes unscheduled visits.

[b] Between 1 week and 1 month, there were 96 Grade 1 reports, 14 Grade 2 reports, two Grade 3 reports, and 4 reports of edema being present, but the rating was not recorded.

[c] Reported as a serious and/or device-related adverse events; Two cases documented as SADEs, one of which occurred and was treated by a primary care doctor between the 1- and 3-month study visits (no associated medical finding available at the time of occurrence); the other case was noted as corneal erosion at the time of occurrence (6 months). A third case was documented as an ADE with the medical finding of epithelial defect at an unscheduled visit between 3 and 6 months.

[d] Complications based on subject-based patient reported visual symptoms questionnaire (PRVSQ) Question 5a "Over the last 7 days, how often did you experience multiple or double vision?"

J. Contrast Sensitivity Analysis

Contrast sensitivity testing was conducted monocularly at 8 feet under photopic, mesopic, and mesopic with glare test conditions from preoperative to 6 months using the VectorVision CSV-1000E chart.

Subject responses to the five spatial frequencies (1.5, 3, 6, 12 and 18 cycles per degree (CPD)) were measured with the subject's best corrected vision at the testing distance and converted from linear to logarithmic values. The data are sorted to allow for a two-tailed paired-t for the means analyses. A positive mean change reflects an improvement in contrast sensitivity while a negative mean change reflects a decrease.

Table 3-22 presents the mean change in contrast sensitivity at 6 months vs preoperative using a non-parametric approach. Based on the information in the table, contrast sensitivity was not negatively affected on average.

Table 3-22 Contrast Sensitivity Change (Log Units) from Preoperative to 6 Months Using Non-Parametric Analysis (N=72 Eyes)

Lighting Condition	Spatial Frequency	Mean ± SD	Median 25th Percentile	Median 50th Percentile	Median 75th Percentile	95% C.I. of median
Mesopic without glare	1.5 cpd	0.10 ± 0.19	0.00	0.07	0.22	(0.00, 0.15)
	3.0 cpd	0.10 ± 0.23	0.00	0.14	0.23	(0.07, 0.21)
	6.0 cpd	0.14 ± 0.19	0.00	0.08	0.25	(0.07, 0.17)
	12.0 cpd	0.11 ± 0.33	-0.08	0.08	0.26	(0.00, 0.16)
Mesopic with glare	1.5 cpd	0.04 ± 0.20	-0.07	0.04	0.19	(0.00, 0.08)
	3.0 cpd	0.08 ± 0.22	-0.07	0.07	0.15	(0.00, 0.14)
	6.0 cpd	0.13 ± 0.24	0.00	0.08	0.29	(0.07, 0.15)
	12.0 cpd	0.17 ± 0.35	-0.07	0.16	0.35	(0.07, 0.26)
Photopic without glare	3.0 cpd	0.08 ± 0.20	-0.07	0.07	0.22	(0.00, 0.15)
	6.0 cpd	0.12 ± 0.20	0.00	0.14	0.23	(0.07, 0.17)
	12.0 cpd	0.18 ± 0.32	-0.00	0.15	0.40	(0.08, 0.26)
	18.0 cpd	0.15 ± 0.37	-0.09	0.15	0.35	(0.07, 0.25)

K. Retreatments

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

L. Patient Symptoms and Satisfaction

Patient questionnaires reflected the following patient responses at 6 months post-operatively. **Table 3-23** presents a summary of patient symptoms at 6 months. The questionnaire asked patients to rank the frequency (never, rarely, sometimes, often, always) and level of bother ('not bothered', 'slightly', 'moderately', 'very', 'extremely') of their visual symptoms over the last 7 days. At 6 months, of the patients who did experience a visual symptom, a low percentage of subjects (≤ 8.7%) often or always experienced the visual symptom. Most subjects (90% - 99.4%) were either not bothered or slightly bothered by symptoms or

did not experience the visual symptoms. Few subjects (≤3.7%) reported difficulty or limitation due to symptoms at 6 months.

Mean Scores from the National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL-42) questionnaire is presented in **Table 3-24**.

Table 3-23 Summary of Visual Symptoms All Subjects at 6 Months[a]: Key Results (N=161)

Symptom	Percentage of subjects reported experiencing[b]	Percentage of subjects often/always experiencing	Percentage of subjects did not experience[c] or not/slightly bothered	Highest bother rating and percentage of subjects	Percentage of subjects with limitation / difficulty
Halos	26.7% (43/161)	3.1% (5/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.6% (1/161)
Glare	33.5% (54/161)	2.5% (4/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.6% (1/161)
Starbursts[d]	35.4% (57/161)	4.9% (8/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.0% (0/161)
Sensitivity to Light	55.9% (90/161)	8.7% (14/161)	90.0% (145/161)	Very 1.9% (3/161)	3.7% (6/161)
Multiple/ Double Vision	4.3% (7/161)	0% (0/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.0% (0/161)
Fluctuating Vision	18.0% (29/161)	1.2% (2/161)	98.1% (158/161)	Moderate 1.9% (3/161)	2.5% (4/161)

[a] The questionnaire asked patients to rank the frequency and level of bother of their visual symptoms over the last 7 days both before and at 6 months after treatment

[b] Total subjects indicating rarely, sometimes, often and always experiencing the given symptom.

[c] Includes subjects that did not experience the symptom or not reported.

[d] One subject not reported

Table 3-18 Mean Scores of NEI-RQL-42 Questionnaire Measures 6 Month vs Preoperative (N= 161 Subjects)

Measure	Preoperative	6 Month
Clarity of vision	87.86	94.00
Expectations	4.35	91.15
Near vision	74.26	91.91
Far vision	83.60	96.94
Diurnal fluctuations	88.72	95.73
Activity limitations	54.90	98.95
Glare	77.80	86.02
Symptoms	87.79	89.06
Dependence on correction	39.93	97.88
Worry	44.57	85.71
Suboptimal correction	95.50	99.92
Appearance	38.96	96.65
Satisfaction with correction	62.36	95.78

NEI-RQL scores range from 0 to 100, higher scores represent better health. The changes in scores may not necessarily represent a clinically meaningful improvement or worsening in the NEI-RQ scores

Table 3-25 presents the distribution of dry eye severity categories (normal, mild, moderate and severe) over time.

Table 3-19 OSDI Dry Eye Severity Categories Over Time

OSDI Severity Category (scores)	Preoperative (n=167) N (%)	1 Month (n=166) N (%)	3 Months (n=164) N (%)	6 Months (n=161) N (%)	9 Months (n=114) N (%)	12 Months (n=92) N (%)
Normal (0-12)	138 (82.6%)	95 (57.2%)	132 (80.5%)	140 (87.0%)	107 (93.9%)	86 (93.5%)
Mild (13-22)	13 (7.8%)	32 (19.3%)	22 (13.4%)	13 (8.1%)	6 (5.3%)	5 (5.4%)
Moderate (23-32)	6 (3.6%)	19 (11.4%)	8 (4.9%)	5 (3.1%)	0 (0.0%)	0 (0.0%)
Severe (33-100)	10 (6.0%)	20 (12.0%)	2 (1.2%)	3 (1.9%)	1 (0.9%)	1 (1.1%)

% Percentage is calculated by dividing the number of subjects in the cell / by the total number of subjects per time period.

Table 3-26 presents the within-subject change in OSDI score from preoperative to 6 months stratified by baseline severity score category. The majority of subjects that were Normal at preoperative remained Normal at 6 months.

Table 3-20 OSDI Within-Subject Category Status Change from Preoperative to 6 months (n=161)

Preoperative OSDI Status	6M OSDI Status									
	Normal		Mild		Moderate		Severe		Total	
	n	%	n	%	n	%	n	%	n	%
Normal	123	90	9	7	3	2	1	1	136	100
Mild	8	67	4	33	0	0	0	0	12	100
Moderate	4	80	0	0	0	0	1	20	5	100
Severe	6	67	0	0	2	22	1	11	9	100

% Percentage is calculated by dividing the number of subjects in the cell / by the total number of subjects per category.

Twenty subjects showed OSDI status change towards less severity. Since the OSDI questionnaire includes questions related to vision, ocular comfort and visual symptoms, potential reasons for postoperative improvement in OSDI scores may include treatment of refractive error, general improvement in vision, reduced contact lens wear postoperatively and generally high levels of well-being (score of 85 or more) per the NEI-RQL questionnaire.

Table 3-27 presents satisfaction with vision over time. Patients rated their satisfaction with their present vision when not wearing glasses or contacts, when wearing glasses or contacts (if applicable), and overall satisfaction with present vision. At 6 months, 98.8% (159/161) of subjects indicated being 'completely' or 'very' satisfied when asked to rate their overall satisfaction with vision.

Table 3-21 Summary of Satisfaction with Vision Quality Over Time All Subjects

		Preop (n=167)[a]		1 Month (n=166)		3 Months (n=164)		6 Months (n=161)		9 Months (n=114)[b]		12 Months (n=92)	
Category	**Satisfaction**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Q1. Please rate your satisfaction with your present vision when not wearing glasses or contacts	Completely satisfied	0	0.0	59	35.5	117	71.3	127	78.9	91	79.8	80	87.0
	Very satisfied	0	0.0	77	46.4	42	25.6	32	19.9	22	19.3	9	9.8
	Somewhat satisfied	0	0.0	24	14.5	4	2.4	1	0.6	0	0.0	2	2.2
	Neither satisfied or dissatisfied	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
	Somewhat dissatisfied	14	8.4	4	2.4	0	0.0	0	0.0	0	0.0	0	0.0
	Very dissatisfied	57	34.1	1	0.6	0	0.0	0	0.0	1	0.9	1	1.1
	Completely dissatisfied	94	56.3	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0
Q2. Please rate your satisfaction with your present vision when wearing glasses or contacts	Completely satisfied	22	13.2	7	4.2	7	4.3	10	6.2	9	7.9	4	4.3
	Very satisfied	64	38.3	9	5.4	1	0.6	4	2.5	4	3.5	1	1.1
	Somewhat satisfied	61	36.5	6	3.6	5	3.0	0	0.0	1	0.9	1	1.1
	Neither satisfied or dissatisfied	10	6.0	1	0.6	2	1.2	1	0.6	0	0.0	0	0.0
	Somewhat dissatisfied	8	4.8	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0
	Very dissatisfied	3	1.8	4	2.4	1	0.6	2	1.2	1	0.9	2	2.2
	Completely dissatisfied	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	Not applicable, I never wear glasses or contacts	0	0.0	137	82.5	147	89.6	144	89.4	98	86.0	83	90.2
Q3. Please rate your OVERALL satisfaction with your present vision	Completely satisfied	6	3.6	59	35.5	116	70.7	128	79.5	94	82.5	79	85.9
	Very satisfied	21	12.6	79	47.6	44	26.8	31	19.3	19	16.7	11	12.0
	Somewhat satisfied	59	35.3	24	14.5	3	1.8	1	0.6	0	0.0	1	1.1
	Neither satisfied or dissatisfied	20	12.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
	Somewhat dissatisfied	32	19.2	3	1.8	0	0.0	0	0.0	0	0.0	0	0.0
	Very dissatisfied	15	9.0	0	0.0	0	0.0	1	0.6	1	0.9	1	1.1
	Completely dissatisfied	14	8.4	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0

% Percentage is calculated by dividing the number of subjects in the cell / by the total number of subjects per time period. Cumulative including unscheduled visit.

[a] At the preoperative visit, one subject marked two answers for Question 2: "Neither satisfied or dissatisfied" and "Somewhat dissatisfied"

[b] At the 9-month visit, one subject did not mark an answer for Question 2.

"n" represents total number of subjects.

Summary of Key Safety and Effectiveness Endpoints

The key safety and effectiveness endpoints over time are presented in **Table 3-28**. All key safety and effectiveness outcome targets were met. All serious, device-related adverse events of any one type had a rate of less than 1.0% and all resolved by the end of the clinical study.

Key safety and effectiveness outcomes at the 6-month timepoint of stability were stratified by subgroup based on the following characteristics: age, gender, race, site, preoperative contact lens wear, preoperative iDesign spherical equivalent (IDSE), preoperative iDesign sphere (IDS), preoperative iDesign cylinder, wavefront capture diameter, iris registration (IR) status, and clinically significant protocol deviations. Although some outcomes varied with respect to eyes achieving MRSE within 1.00 D and 0.5 D of target among age, gender, site, preoperative iDesign refractive parameters (IDSE and IDS), IR status, and clinically relevant protocol deviation subgroups, all subgroups met key effectiveness outcome targets. The number of safety events did not exceed 2 cases within any of the subgroups. No specific association between safety events and any subgroup was observed, given the low occurrence of those events in the study (less than 1% for the overall study population). In conclusion, there is reasonable assurance of safety for all subgroups.

The key safety and effectiveness endpoints at the point of stability, stratified by pre-operative IDSE, IDS, IDC, age, and gender are presented in **Table 3-29** through **Table 3-33**.

Table 3-22 Summary of Safety and Effectiveness Endpoints Over Time (N=332)

Effectiveness Endpoints	1 Month (n=332) n % (95% CI)	3 Months (n=328) n % (95% CI)	6 Months (n=322) n % (95% CI)	9 Months (n=228) n % (95% CI)	12 Months (n=184) n % (95% CI)
UCVA 20/20 or better	265 79.8% (75.1, 84.0)	325 99.1% (97.4, 99.8)	320 99.4% (97.8, 99.9)	226 99.1% (96.9, 99.9)	184 100% (98.4, 100)
UCVA 20/40 or better	328 98.8% (96.9, 99.7)	328 100% (99.1, 100)	322 100% (99.1, 100)	228 100% (98.7, 100)	184 100% (98.4, 100)
MRSE +/- 0.50 D	223 67.2% (61.8, 72.2)	274 83.5% (79.1, 87.4)	275 85.4% (81.1, 89.1)	185 81.1% (75.4, 86.0)	157 85.3% (79.4, 90.1)
MRSE +/- 1.00 D	310 93.4% (90.1, 95.8)	316 96.3% (93.7, 98.1)	310 96.3% (93.6, 98.1)	221 96.9% (93.8, 98.8)	182 98.9% (96.1, 99.9)
Safety Endpoints					
Loss of > 2 lines BSCVA from preoperative[a]	3 0.9% (0.2, 2.6)	0 0%	1 0.3% (0.0, 1.7)	0 0%	0 0%
Haze beyond 6 months with loss >2 lines of BSCVA[b]	N/A	N/A	1 0.3% (0.0, 1.7)	0 0%	0 0%
BSCVA of 20/20 preoperative and 20/40 postoperative[c]	0 0%	0 0%	0 0%	0 0%	0 0%
Induced manifest refractive astigmatism >2.00 D[d]	0 0%	0 0%	0 0%	0 0%	0 0%

Cumulative rate of eyes with Serious, Device-Related Adverse Events	7 eyes 2.1% The rate of each type of serious, device-related adverse events was <1% (corneal infiltrate 2/334, 0.6%; corneal erosion 2/334, 0.6%; corneal haze 3/334, 0.9%).

Percentage is calculated based on non-missing values.

[a] Safety endpoint target: <5% of eyes with a loss of >2 lines (*Defined as change in logMAR >0.24)of BSCVA from preoperative

[b] Safety endpoint target: <1 % of eyes with haze beyond 6 months with loss >2 lines (*Defined as change in logMAR >0.24) of BSCVA

[c] 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

[d] Safety endpoint target: <5% of eyes with induced manifest refractive astigmatism >2.00 D

Stability of MRSE	**Between 1 and 3 Months (n=328) n %**	**Between 3 and 6 Months (n=318) n %**	**Between 6 and 9 Months (n=226) n %**	**Between 9 and 12 Months (n=182) n %**
Change in MRSE by ≤1.00 D[a]	312 95.1% (92.2, 97.2)	311 97.8% (95.5, 99.1)	216 95.6% (92.0, 97.9)	181 99.5% (97.0, 100)
Change in MRSE by ≤0.50 D	256 78.0% (73.2, 82.4)	281 88.4% (84.3, 91.7)	180 79.6% (73.8, 84.7)	163 89.6% (84.2, 93.6)
Mean Change in MRSE	0.16 +/- 0.51 (0.10, 0.21)	0.07 +/- 0.39 (0.02, 0.11)	0.00 +/- 0.50 (-0.07, 0.06)	-0.01 +/- 0.35 (-0.06, 0.04)
Mean Change Per Month	0.08	0.02	0.00	0.00
Change in MRC by ≤1.00 D[a]	310 94.5% (91.5, 96.7)	318 100% (99.1, 100)	226 100% (98.7, 100)	182 100% (98.4, 100)
Mean Change in MRC	0.28 +/- 0.47 (0.23, 0.33)	0.03 +/- 0.23 (0.01, 0.06)	-0.02 +/- 0.24 (-0.05, 0.01)	0.02 +/- 0.2 (-0.01, 0.05)
Mean Change Per Month in MRC	0.14	0.01	-0.01	0.01

Change defined as current visit value minus previous visit value.

Confidence Intervals calculated based on Clopper-Pearson Exact method.

[a]Includes only eyes with data at two consecutive visits.

*Defined as change in logMAR >0.24.

Table 3-23 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Spherical Equivalent (IDSE)

	Preoperative IDSE										
Safety/Effectiveness Endpoints	**≥-1.0 D to ≤0.0 D (n=5)**	**≥-2.0 D to <-1.0 D (n=46)**	**≥-3.0 D to <-2.0 D (n=54)**	**≥-4.0 D to <-3.0 D (n=74)**	**≥-5.0 D to <-4.0 D (n=36)**	**≥-6.0 D to <-5.0 D (n=44)**	**≥-7.0 D to <-6.0 D (n=33)**	**≥-8.0 D to <-7.0 D (n=19)**	**≥-9.0 D to <-8.0 D (n=11)**	**Total (n=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	5 100%	46 100%	54 100%	74 100%	36 100%	44 100%	33 100%	19 100%	11 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	5 100%	42 91.3%	52 96.3%	66 89.2%	36 100%	34 77.3%	22 66.7%	12 63.2%	6 54.5%	275 85.4%	*≥50%*
MRSE +/- 1.00 D	5 100%	46 100%	54 100%	73 98.6%	36 100%	39 88.6%	32 97.0%	16 84.2%	9 81.8%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.8%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.3%	1 3.0%	0 0.0%	0 0.0%	2 0.6%	*<1%*
Serious Device related AE: Corneal Haze	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	2 18.2%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.

*Defined as change in logMAR >0.24.

Table 3-30 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Sphere (IDS)

	Preoperative IDS									
Safety/Effectiveness Endpoints	**≥-1.0 D to ≤0.0 D (n=22)**	**≥-2.0 D to <-1.0 D (n=64)**	**≥-3.0 D to <-2.0 D (n=59)**	**≥-4.0 D to <-3.0 D (n=54)**	**≥-5.0 D to <-4.0 D (n=40)**	**≥-6.0 D to <-5.0 D (n=37)**	**≥-7.0 D to <-6.0 D (n=27)**	**≥-8.0 D to <-7.0 D (n=19)**	**Total (n=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	22 100%	64 100%	59 100%	54 100%	40 100%	37 100%	27 100%	19 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	20 90.9%	61 95.3%	54 91.5%	48 88.9%	36 90.0%	26 70.3%	18 66.7%	12 63.2%	275 85.4%	*≥50%*
MRSE +/- 1.00 D	22 100%	64 100%	59 100%	51 94.4%	39 97.5%	35 94.6%	24 88.9%	16 84.2%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.5%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	2 5.4%	0 0.0%	0 0.0%	2 0.6%	*<1%*
Serious Device related AE: Corneal Haze	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.7%	0 0.0%	2 10.5%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.

*Defined as change in logMAR >0.24.

Table 3-31 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Preoperative iDesign Cylinder (IDC)

	Preoperative IDC						
Safety/Effectiveness Endpoints	**≥-0.5 D to ≤0.0 D (n=99)**	**≥-1.0 D to <-0.5 D (n=94)**	**≥-2.0 D to <-1.0 D (n=86)**	**≥-3.0 D to <-2.0 D (n=29)**	**≥-4.0 D to <-3.0 D (n=14)**	**Total (n=322)**	
	n %	**n %**	**n %**	**n %**	**n %**	**n %**	***Target***
UCVA 20/40 or better	99 100%	94 100%	86 100%	29 100%	14 100%	322 100%	*≥85%*
MRSE +/- 0.50 D	85 85.9%	85 90.4%	71 82.6%	24 82.8%	10 71.4%	275 85.4%	*≥50%*
MRSE +/- 1.00 D	97 98.0%	91 96.8%	82 95.3%	28 96.6%	12 85.7%	310 96.3%	*≥75%*
BSCVA Worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<1%*
Loss of >2 Lines BSCVA*	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<5%*
Haze with Loss of >2 Lines BSCVA*	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Induced Astigmatism >2D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	*<5%*
Serious Device related AE: Corneal Infiltration	0 0.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	1 0.3%	*<1%*
Serious Device related AE: Corneal Erosion	1 1.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	2 0.6%	*<1%*
Serious Device related AE: Corneal Haze	1 1.0%	0 0.0%	2 2.3%	0 0.0%	0 0.0%	3 0.9%	*<1%*

Percentages calculated based on non-missing values.

*Defined as change in logMAR >0.24.

Table 3-32 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Age Groups

	Age Group (Years)				
Safety/Effectiveness Endpoints	**≥18 to ≤21 (n=54 eyes)**	**>21 to ≤25 (n=108 eyes)**	**>25 to ≤30 (n=110 eyes)**	**>30 to ≤47 (n=50 eyes)**	**Total (n=322 eyes)**
MRSE +/- 0.50 D 95% CI	48 88.9% (77.4, 95.8)	81 75.0% (65.7, 82.8)	103 93.6% (87.3, 97.4)	43 86.0% (73.3, 94.2)	275 85.4% (81.1, 89.1)
MRSE +/- 1.00 D 95% CI	52 96.3% (87.3, 99.5)	99 91.7% (84.8, 96.1)	109 99.1% (95.0, 100)	50 100% (94.2, 100)	310 96.3% (93.6, 98.1)
UCVA 20/40 or Better 95% CI	54 100% (94.6, 100)	108 100% (97.3, 100)	110 100% (97.3, 100)	50 100% (94.2, 100)	322 100% (99.1, 100)
BSCVA Worse than 20/40 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 0.9)
Loss of >2 Lines BSCVA* 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Haze with Loss of >2 Lines BSCVA* 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Induced Astigmatism>2.00D 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 2.7)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 0.9)
Serious Device-related AE: Corneal Infiltration 95% CI	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 2.7)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	1 0.3% (0.0, 1.7)
Serious Device-related AE: Corneal Erosion 95% CI	0 0.0% (0.0, 5.4)	1 0.9% (0.0, 5.1)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	2 0.6% (0.1, 2.2)
Serious Device-related AE: Corneal Haze 95% CI	0 0.0% (0.0, 5.4)	2 1.9% (0.2, 6.5)	1 0.9% (0.0, 5.0)	0 0.0% (0.0, 5.8)	3 0.9% (0.2, 2.7)

Percentages calculated based on non-missing values.
*Defined as change in logMAR >0.24.

Table 3-33 Key Safety and Effectiveness Endpoints at 6 Months Stratified by Gender

	Gender		
Safety/Effectiveness Endpoints	**Male (n=222 eyes)**	**Female (n=100 eyes)**	**Total (n=322 eyes)**
MRSE +/- 0.50 95% CI	188 84.7% (79.3, 89.2)	87 87.0% (78.8, 92.9)	275 85.4% (81.1, 89.1)
MRSE +/- 1.00 95% CI	210 94.6% (90.7, 97.2)	100 100% (97.0, 100)	310 96.3% (93.6, 98.1)
UCVA 20/40 or Better 95% CI	222 100% (98.7, 100)	100 100% (97.0, 100)	322 100% (99.1, 100)
BSCVA Worse Than 20/40 95% CI	0 0.0% (0.0, 1.3)	0 0.0% (0.0, 3.0)	0 0.0% (0.0, 0.9)
Loss of >2 Lines BSCVA* 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Haze with Loss of >2 Lines BSCVA* 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Induced Astigmatism>2.00D 95% CI	0 0.0% (0.0, 1.3)	0 0.0% (0.0, 3.0)	0 0.0% (0.0, 0.9)
Serious Device-related AE: Corneal Infiltration 95% CI	1 0.5% (0.0, 2.5)	0 0.0% (0.0, 3.0)	1 0.3% (0.0, 1.7)
Serious Device-related AE: Corneal Erosion 95% CI	1 0.5% (0.0, 2.5)	1 1.0% (0.0, 5.4)	2 0.6% (0.1, 2.2)
Serious Device-related AE: Corneal Haze 95% CI	1 0.5% (0.0, 2.5)	2 2.0% (0.2, 7.0)	3 0.9% (0.2, 2.7)

Percentages calculated based on non-missing values.
*Defined as change in logMAR >0.24.

3.4 STAR-125-ARID Study Summary

A prospective, single-center, monocular, measurement-only clinical study was conducted to evaluate if the modified ***iDESIGN***® settings proposed for ***iDESIGN*** Refractive Studio system software v2.1 (i.e., slower fogging prior to autorefraction) resulted in reducing instrument accommodation. For this study, the ***iDESIGN***® Advanced WaveScan Studio (version 1.3) with standard settings and modified settings to allow slower fogging speed were used. Inclusion criteria included: myopic refractive error with sphere and spherical equivalent (SE) up to -11.00 D, cylinder between 0.0 and -5.00 D, hyperopic refractive error with maximum SE of +6.00 D, and cylinder between 0.00 and 4.00 D, and mixed astigmatism where the magnitude of cylinder (up to 6.00 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs; subject age between 18 and 55 years; monocular distance best spectacle corrected visual acuity (BSCVA) of 20/25 or better in the study eye; no soft contact lens wear for at least 12 hours and no rigid gas permeable contact lens wear for 1 month prior to the day of study measurements in the study eye; no prior ocular surgery or injury, and no concomitant use of systemic or ocular medications that may affect vision; no concurrent participation in any other clinical study; and no pregnant or lactating women.

Manifest refraction and ***iDESIGN***® measurements were captured in one visit. Of the 70 subjects that were enrolled 53 eyes were included for analysis – 49 with myopia, 3 with hyperopia and 1 with mixed astigmatism. Out of the 17 excluded subjects, one subject was not eligible because of participation in another clinical trial and16 subjects were excluded due to procedural protocol deviations.

The results showed that ***iDESIGN***® baseline and proposed slow fog settings were not significantly different from each other in terms of the mean paired difference with manifest refraction spherical equivalent, -0.36 D and -0.33 D, respectively. When accommodation was stimulated by moving the fixation target vergence, the slow fogging resulted in a narrower range of paired differences (1.96 D) as compared to the range for baseline settings (3.67 D).

In conclusion, while the different ***iDESIGN***® settings showed no statistically significant differences based on mean outcomes, individual results indicated that some of the outliers may be eliminated by using a slower fog speed.

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 Pre-Operative (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. Ultrasonic pachymetry measurement is required. Pre-operative 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. If there are any concerns regarding the appearance of the optic nerve, a thorough threshold test of the visual field should be performed.

To treat a patient using the wavefront data, the appropriate exams should be captured and reviewed by the surgeon in accord with the ***iDESIGN®*** Refractive Studio Operator's Manual (Section 8).

Using the physician adjustment beyond the indicated range; with myopic astigmatism, greater than -8.00 D spherical equivalent as measured by iDESIGN® Refractive Studio, with cylinder greater than -3.00 D is not supported by clinical data.

The treatment is then generated at the ***iDESIGN®*** Refractive Studio and 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.

Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients desiring wavefront-guided PRK 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. Instruct patients not to wear makeup as this poses risk for contamination of the stromal interface. Patients must not use perfumes, after shave, eau de cologne or other substances applied to the skin containing alcohol.

4.3 Peri-Operative (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 pre-operatively , however it is critically important that the patient remain able to fixate during the laser treatment.

4.4 Post-Operative

A. Medications

Following completion of the excimer laser surgery, appropriate medications should be applied to the eye in a sterile manner. 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.

B. Follow-up Care

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

5 STAR S4 IR® Laser Surgical Procedure

Before proceeding, please refer to the laser preparation and shutdown 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) Transfer the saved ***iDESIGN®*** System-driven PRK treatment file from the ***iDESIGN®*** Refractive Studio to the ***STAR S4 IR®*** Excimer Laser using the Johnson & Johnson Vision supplied USB drive. The instructions for transferring the file appears in Chapter 13, ***iDESIGN*** Treatments, in the ***STAR S4 IR®*** **Excimer Laser Operator's Manual**.

5) Follow the system software prompts. An ***iDESIGN*** Procedure Card is required to perform ***iDESIGN*** Treatments that were calculated on the ***iDESIGN®*** Refractive Studio.

6) 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.

7) The patient may be given a systemic medication (e.g., analgesic or sedative) at the physician's discretion before the procedure, however it is critically important that the patient remain able to fixate throughout the excimer treatment.

8) Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.

9) Position the patient so the lateral canthus aligns to the mark on the headrest.

10) Instruct the patient to remove earrings prior to using the vacuum pillow.

11) 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.

12) If desired, apply topical ophthalmic antibiotic agent to the operative eye.

13) Instill topical ophthalmic anesthetic to the operative eye.

14) Disinfect/clean around the eye with cleaning solution

15) Cover the untreated eye with an opaque shield that protects the eye and occludes vision.

16) Instruct the patient to keep both eyes opened during the surgical procedure.

17) 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.

18) 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.

19) 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.

20) Allow the patient the opportunity to become familiar with the sounds of the laser during the calibration procedure. The corneal epithelium should be removed, with a total epithelium removal diameter of approximately 9.0 mm. Method of removal in the study included an Amoils Epithelial Scrubber with a 9.0 mm rotating brush. Instruct patients not to wear makeup as this poses risk for contamination of the stromal interface.

21) Continually encourage the patient to maintain fixation on the fixation light throughout the procedure.

22) 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,

23) 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.

24) 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.

25) 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.

26) After verification of green system status bars, warn all attendees to stand clear of the laser, patient, and patient chair. Accidental bumping of the laser, patient, or patient chair during the surgery can cause decentering of the treatment area. Movement in the operating room must be kept to a minimum during patient treatment.

27) 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.

28) Adjust and maintain the focus on the anterior corneal surface.

29) Remind patient to fixate on flashing LED. Activate ***ActiveTrak*** System (see section 5.2) and the Iris Registration system (see section 5.3).

30) 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.

31) Apply topical ophthalmic medications to the cornea

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. Check the Heads-Up Display to confirm treatment completion.

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.

32) Print the laser treatment information.

33) Record the environmental conditions (temperature and humidity).

34) 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.

35) When the PRK 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.

36) Rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.

37) Appropriate postoperative medications may be used after treatment as needed. A bandage contact lens can be used on the treated eye until re-epithelialization has occurred.

38) Assist the patient out of the chair and to a waiting area.

39) Examine the patient at the slit-lamp microscope.

40) Ensure that the patient is given postoperative instructions. An analgesic may be given to the patient prior to leaving the facility.

41) Review postoperative instructions, confirm the first follow-up appointment, and discharge the patient when stable.

42) 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®*** Refractive Studio) 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 ***iDESIGN®*** System-driven PRK 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®*** Refractive Studio image to the same features located on the image of the iris taken by the ***STAR S4 IR®*** Laser 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.

To activate the iris registration system:

1) Transfer the ***iDESIGN®*** Refractive Studio treatment file using a USB flash drive. The floppy drive cannot be used with the iris registration system. All files are saved automatically to the USB flash drive when saving an ***iDESIGN*** treatment on the ***iDESIGN®*** Refractive Studio

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 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 message "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 the markers showing the degree of cyclotorsion between the aberrometer measurement and the ***STAR S4 IR®*** Laser 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 ***iDESIGN*** 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 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.

WARNING! 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 light-emitting diode (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 6.14 in the ***STAR S4 IR®*** Laser 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 stops flashing. (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.

Johnson & Johnson VISION