WaveLight®

WaveLight® EX500

ADDENDUM Procedure Manual
INNOVEYES™ Treatments
Information for professional use

Alcon

Manual Revision

Creation Date	Revision	Description
August 07, 2023	00	Release of WaveLight® EX500 1016-3 Addendum Procedure Manual INNOVEYES™, valid as from Database Portal Software Version 1.516

Please also refer to the content information of your Product Folder.

This Procedure Manual WaveLight® EX500 is valid as from **Database Portal Software Version 1.516** (please refer to the User Manual).

USING THE ADDENDUM PROCEDURE MANUAL INNOVEYES™ (Ray Tracing-Guided Vision Correction)

This manual provides information for the intended clinical use of the INNOVEYES™ option with the WaveLight® EX500 for INNOVEYES™ treatments.

“wavelight plus” is the alternative equivalent trade name for “INNOVEYES™” treatments.

This manual provides only information that is specific for INNOVEYES™ treatments. Refer to the User Manual of the laser console, to its addendums, its Procedure Manuals and to the User Manuals of the approved accessories for information regarding these components.

Carefully read and understand this manual and all related documents and instructions before using the WaveLight® EX500 laser system for performing INNOVEYES™ treatments.

Observe all warnings, precautions and contra-indications as described in these documents.

Do not perform adjustments and procedures other than those described in these documents. Failure to do so may result in harm to patient and / or user.

Consult the Table of Contents, Appendices or Indices for specific information. If you have questions that are not addressed in this manual, contact the hotline shown in the User Manual of the laser console.

Alcon WaveLight®

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Made in Germany

TYPOGRAPHICAL CONVENTIONS

The following conventions and symbols are used in this manual for Warnings, Precautions and Notes:

WARNING

A “Warning” alerts the user to potential serious outcomes to the patient or user in case of non-observance of this warning.

CAUTION

“Precautions” alert the reader to exercise special care necessary for the safe and effective use of the device.

NOTE

“Notes” provide helpful or supplementary information to the user.

NOTICE TO USERS

CAUTION

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 practitioner. U.S. Federal Law restricts 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.

CAUTION

Other Manuals

This addendum is only valid in conjunction with related

Read this Addendum Procedure Manual and all related manuals of the laser system and its approved accessories carefully before starting to use the WaveLight® EX500 laser system.

The system user alone is responsible for having sufficient medical knowledge for carrying out all surgical procedures.

There are no legitimate claims to system upgrades in the event of the introduction of product improvements based on new technological developments.

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1. DEVICE DESCRIPTION

1.1. Intended Use

The WaveLight® EX500 is used for correction of refractive error or anterior corneal disorders.

The WaveLight® EX500 is a scanning-spot Excimer Laser system indicated to be used in refractive surgery for the treatment of

- myopia, myopic astigmatism,
- hyperopia, hyperopic astigmatism,
- mixed astigmatism,

including customized refractive surgery based on data delivered by WaveLight® diagnostic devices.

The evaluation of benefits is consistent with the available data, there are no limitations, gaps, uncertainties, unanswered questions or assumptions. There is sufficient clinical evidence for the intended performance of the WaveLight® EX500.

The WaveLight® EX500 laser system is not intended to perform treatments other than those indicated in the indications for use statement.

The WaveLight® EX500 laser system is intended for use solely by the physicians trained in the use of this laser system and its accessories. During its operation, it does not come into contact with the eye, and treatment usually lasts 1.3 seconds per diopter. The WaveLight® EX500 laser can be applied to the cornea multiple times.

The distinctiveness of the system consists in a combination of technologically refined features, including a compact excimer laser with high pulse frequency, a galvanometer scanner for positioning the laser spot and a fast eyetracker for determining eye position and laser-beam direction. The Gaussian shaped beam profile of the individual pulses and an ablation diameter of approximately 0.95 mm (0.68 mm FWHM - Full Width at Half Maximum) assure the desired contour and minimize surface irregularities during ablation.

This attribute enables photorefractive WAVEFRONT OPTIMIZED™ (WFO) applications (myopia and hyperopia with and without astigmatism and mixed astigmatism) as well as a range of customized treatment options, such as Wavefront-Guided or Topography-Guided treatments, as well as INNOVEYES™ treatments.

A further advantage of the small spot diameter is that the WaveLight® EX500 requires the use of only minimal pulse energy. The result is a compact excimer laser beam source with minimal gas volume and minimal gas consumption. In addition, a Nitrogen purged beam path enhances energy stability by reducing the formation of ozone in the optical system. As the excimer laser is operated at a high repetition frequency, short treatment times are assured. The integrated eyetracker offers automatic centering of the ablation and tracking of eye movements.

During treatment, hundreds / thousands of laser pulses might be delivered to the cornea in a complex pattern. As the excimer laser is operated with a high repetition rate of 500 pulses per second, treatment times are short.

For treatments at least the following components of the system have to be operated:

Laser Console	-	containing operating elements, laser head, optical transmission system, energy and system controls, eyetracker, scanner motors, gas supply, plume evacuator, head-up display, video system, N_2 generator focusing and fixation lights, system software and ablation profiles with scanning spot patterns, microscope with illumination, LED slit illumination system and test systems.
Patient Bed	-	with moving motors and bed control
System PC	-	containing software for programming treatment parameters

A microkeratome or femtosecond laser unit of the physician’s choice is utilized to create the flap before the laser portion of the treatment can be conducted.

The WaveLight® EX500 works with manually entered data as well as with data transferred from the WaveLight® diagnostic devices. Data transfer can be done via a network interface or via USB stick.

2. INDICATIONS, CONTRAINDICATIONS, PRECAUTIONS, WARNINGS AND PATIENT SELECTION

2.1. Indications For Use

The WaveLight® EX500 laser system in conjunction with INNOVEYES™ Sightmap is indicated for use in INNOV EYES™ Laser Assisted In-Situ Keratomileusis **("wavelight plus"[1] LASIK)** treatments:

- for the reduction or elimination of myopia or myopia with astigmatism, in eyes with spherical equivalent (SE) more than -1.00 diopters (D) and up to - 9.00 D, with up to - 8.00 D of spherical component (in minus cylinder format) and up to - 3.00 D of astigmatic component at the spectacle plane, based on the INNOVEYES™ Sightmap Measured Refraction,
- in patients with magnitude of the spherical equivalent (SE) difference between the Manifest Refraction (MRSE) and the Sightmap Measured Refraction SE being less than 0.75 D,
- in patients who are 18 years of age or older, and
- for patients with documentation of a stable manifest refraction defined as ≤ 0.5 D preoperative spherical equivalent shift over one year prior to surgery.

2.2. Contraindications

INNOVEYES™ LASIK treatments using the WaveLight® EX500 lasers are contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list:

- patients with severe dry eyes,
- patients with a thin cornea and a calculated residual stromal bed thickness that is less than 250 microns,
- pregnant or nursing women,
- patients with a weakened immune system including diagnosed collagen vascular, autoimmune or immunodeficiency disease or connective tissue disease, which can cause corneal melting,
- patients with degenerations of structure of the cornea including diagnosed keratoconus or any clinical pictures suggestive of keratoconus,
- patients with a recurrent corneal erosion,
- patients with uncontrolled diabetes,
- patients with uncontrolled glaucoma. It is unknown whether LASIK is safe and effective for such patients,

[1] "wavelight plus" is the alternative equivalent trade name for "INNOVEYES™" treatments.

- patients with active eye infections or active inflammations (e.g. keratitis, iritis, or uveitis) and
- patients with recent herpes eye infections or problems resulting from past herpes eye infections.

2.3. Warnings

INNOVEYES™ LASIK with the WaveLight® EX500 is not recommended in patients who have:

- systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status,
- a history of Herpes simplex or Herpes zoster keratitis,
- significant dry eye that is unresponsive to treatment,
- severe allergies,
- glaucoma, elevated IOP, ocular hypertension, or being followed for possible glaucoma (glaucoma suspect),
- unreliable preoperative INNOVEYES™ Sightmap examination that precludes INNOVEYES™ LASIK,
- taking the medication isotretinoin (Accutane®[2])
- moderate or mild dry eyes,
- activities that could damage the LASIK flap,
- controlled diabetes,
- history of crossed eyes (strabismus),
- decreased vision in one eye,
- epithelial basement membrane dystrophy.

INNOVEYES™ LASIK procedures require accurate and reliable data from the INNOVEYES™ Sightmap device. Every step must be validated by the user. Inaccurate or unreliable data will lead to an inaccurate treatment.

[2] *Accutane® is a registered trademark of Hoffmann-La Roche Inc.*

2.4. Precautions

Safety and effectiveness of the WaveLight® EX500 for INNOVEYES™ treatments has not been established for patients:

- with progressive myopia, with unstable refraction having changed by more than 0.5 diopters in the prior 12 months,
- with ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone,
- with corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage,
- with residual corneal thickness after ablation of less than 250 microns increasing the risk for corneal ectasia,
- with history of glaucoma or ocular hypertension of > 23 mmHg,
- taking the medication sumatriptan succinate (Imitrex®[3]),
- taking the medication amiodarone hydrochloride (Cordarone®[4]),
- under 18 years of age,
- over the long term (more than 12 months after surgery),
- with corneal, lens and/or vitreous opacities including, but not limited to cataract,
- with iris problems including , but not limited to, coloboma and previous iris surgery compromising proper eye tracking,
- taking medications likely to affect wound healing including, but not limited to antimetabolites,
- with treatment targets different from emmetropia (plano) in which the defocus (spherical term) and the astigmatism (cylinder term) has been adjusted. You should discuss with your patient the potential risks and benefits associated with treatment targets different from emmetropia.
- with magnitude of the baseline spherical equivalent difference between the manifest refraction (MRSE) and the INNOVEYES™ Sightmap Measured Refraction being less than 0.75D,
- Safety and effectiveness of the WaveLight® EX500 for INNOVEYES™ treatments has not been established for patients with a baseline difference between manifest and INNOVEYES™ Sightmap measured cylinder ≥ 0.75D.
- any other medical condition that might be expected to make the patient an unsuitable candidate for treatment,

[3] Imitrex® is a registered trademark GlaxoSmithKline Inc.
[4] Cordarone® is a registered trademark of Wyeth Inc.

- with any other medical condition that might be expected to make the patient an unsuitable candidate for LASIK treatment,
- with large pupils,
- with undiagnosed dry eyes,
- with decreased vision in one eye
- family history of thinning of the cornea,
- allergies or eye rubbing. This is because the flap may become dislodged. Also, some allergy medicines can cause dry eye symptoms, which can increase risk for severe dry eyes.
- elevated eye pressure or being followed for possible glaucoma. This is because it is more difficult to measure IOP after LASIK, which can delay diagnosis or detection of elevated IOP. Also, while brief, there is a sharp rise in IOP during the LASIK procedure that places greater risk of damage to vision in the eyes with possible glaucoma.
- irregular astigmatism. Patients with irregular astigmatism may not be good candidates because of an increased risk for visual symptoms after LASIK.

If there is an infection or problem with healing after the surgery, it is more likely that both eyes will be affected if both eyes are treated at the same session. If only one eye is treated, the difference in vision between the treated eye and the one without treatment might make vision difficult. In such a case, the patient might not have functional vision unless the second eye is treated or by wearing glasses or contact lenses that compensate for the difference.

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see such in conditions as very dim light, rain, fog, snow and glare from bright lights. 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.

The refraction is determined in the spectacle plane, but treated in the corneal plane. In order to determine the right treatment program to achieve the right correction, assessment of the vertex distance during refraction test is recommended.

Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes post INNOVEYES™ LASIK.

2.5. Patient Selection

In addition to contraindications, precautions and warnings the following should be considered and discussed with your patient in order to find good candidates for INNOVEYES™ and to get sufficient information for the treatment plan:

- A complete baseline exam including, but not limited to, cycloplegic refraction within 60 days prior to surgery is necessary.
- A slit lamp exam has to be performed. The status of the lens has to be evaluated to ensure that neither nuclear sclerosis nor other lens opacities are present. These opacities may adversely affect final visual result.
- Dilated fundus exam by indirect ophthalmoscopy has to be performed, as retinal pathology is more likely in patients with myopia.
- Optical nerve and intraocular pressure have to be examined as glaucoma is more common in myopic than in emmetropic subjects. If elevated pressure or signs of glaucomatous damage are found, topical steroids should be used only under careful medical supervision or the patient should not be treated.
- Contact lens wearers must discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 1 week **prior to preoperative evaluation**.
- Contact lens wearers must also discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 1 week **prior to surgery**.
- The patient must be able to lie flat in a supine position.
- Topical or local anesthesia must be tolerated.
- The patient must be able to fixate steadily.
- The patient must be able to understand and give the informed consent and sign the informed consent form.
- All alternatives to the INNOVEYES™ procedure for correcting myopia with or without astigmatism by spectacles, contact lenses and other surgical procedures such as LASIK, radial keratotomy, automated lamellar keratoplasty or clear lens exchange should be clearly communicated and understood by the patient.
- Additionally patients should be instructed not to wear makeup at the day of surgery. Patients must not use perfumes, aftershave, Eau de Cologne or other substances applied to the skin containing alcohol at that day.
- Patients with heart pacemakers may not be treated.

3. PROCEDURE

3.1. Procedure Steps

The determined patient and eye data have to match with the patient presenting and with the eye prepared for surgery. Make sure that treatment parameters are precisely transferred from the files to the laser system. A double check with the patient and assisting personnel is recommended. It is the sole responsibility of the operating surgeon to ensure that all data is accurate.

Carefully clean and prepare the microkeratome according to the manuals supplied by manufacturer of the device. When using a mechanical microkeratome, make sure that the blade is free of burrs and nicks. Check if the chosen plate thickness/cutting head/cutting thickness with femtosecond lasers matches the intended flap thickness.

When using a laser microkeratome, make sure that the flap thickness and energy levels are set correctly.

Instruct patients not to wear makeup as this poses risk for contamination of the stromal interface. Patients must not use fragrances like perfumes, after shave, eau de cologne or other substances applied to the skin containing alcohol.

Aromatic substances and solvents including, but not limited to alcohol, fresh glue and paint should not be noticeable at the laser aperture. Vapors of all such substances absorb energy of the laser pulses and therefore may cause undercorrections.

Strong disturbances of the air between the laser aperture and the patient’s head during laser ablation must be avoided. Switch off any ventilation device causing a noticeable airflow during ablation, with exception of the plume evacuator of the laser system. Instruct personnel not to move around and keep doors and windows closed during ablation. Uncontrolled airflow may have an effect on the quality of the ablation.

Potentially noisy devices such as telephones that may cause a sudden sound during the procedure should be switched off. Sudden noise may distract surgeon and / or patient.

The use of mobile telephones is restricted in the treatment area.

Medications likely to dilate or constrict the pupil should be administered with careful supervision during the last 6 hours prior to surgery as the eyetracker will not be able to track pupils of less than 1.5 mm and more than 8.0 mm diameter. Furthermore, such medication might influence the physiological center of the pupil and compromise centration of the eye tracking system.

Check that the patient is able to see the green blinking fixation light and to distinguish it from other light sources around the laser aperture (see Procedure Manual, chapter “Patient’s Views”).

Perform an Energy Check according to the User Manual prior to treating a new patient. The cross-line projector can be used to align the patient’s head position, but must be switched off during the course of the ablation process.

Repeat the test if more than 30 minutes have elapsed before the treatment is begun.

Head alignment in order to apply cylinder treatment in the right axis is essential.

The ablation treatment is triggered by pressing the LASER foot pedal. It can be interrupted at any time by leaving the pedal. The laser will stop automatically when the treatment process is finished.

3.1.1. Patients Preparation And Surgery

Position the patient's head under the microscope.

Adjust the focus with the distance diodes.

Switch-on the cross line projector pressing the "Cross Line Projector Key" (if not activated by default)

Adjust the brightness of the cross-line to your personal needs using the "Cross Line Brightness Knob".

Check patient's head position using the cross line projector (see picture below) and deactivate the cross line projector thereafter.

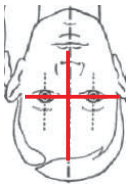

Figure 1: Crossline Overlay - Patient's Head

Move eye to be treated into a roughly focused and centered position.

Instruct patient about fixation light: It can be distinguished from all other light-sources of the WaveLight® EX500 by its blinking characteristic and green color.

Note that the patient can see the Fixation Light best from an almost centered position.

As long as the patient fixates well, the observer (at the microscope) will see a small green blinking light projection (Purkinje image) on the cornea (in the center of the op-field illumination). The fixation light can temporarily be reduced or switched off completely to assist the patient in recognizing the fixation light.

Drape operational field or eye and drape lids and lashes according to your needs.

Apply topical anesthetic before or after inserting the lid speculum to the surgeon's discretion.

Insert lid speculum.

3.2. Treatment Interruption

If laser ablation is interrupted, the parameters remain in the system and the system will proceed with the ablation pattern exactly at that point, at which the treatment was interrupted. The progress of the ablation procedure is indicated on the monitor screen of the laser console.

If for any reason a treatment has to be terminated before ablation was completed, the residual time of treatment accomplished has to be recorded and kept in the patient files.

The system will automatically store the progress of the surgery, if a treatment is terminated for any reason. The system allows loading the previously aborted treatment. The treatment will continue from the point of termination.

Please also refer to the User Manual.

Figure 1: Treatment Window - Progress Indicators

3.3. Ablation Details

Please note that the treatment progress indicated by the software is neither related to the amount of ablated diopters, nor to a certain ablation zone.

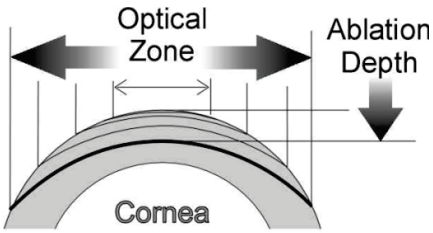

Figure 2: Relation Of Optical Zone To Ablation Depth; Myopic

Myopic astigmatism treatments flatten the axis of the (positive) cylinder.

Keep the stromal surface dry and clean during ablation. Prevent liquid from running towards the ablation zone. Liquid and debris will shield the stromal surface against ablation. Irregular ablations will most likely result, if liquid reaches the optical zone area. Irregular ablations may lead to deviation of the best possible clinical results.

Do not move instruments across or in the area of the intended optical zone during laser ablation. The instrument may shield the stroma partially against ablation. Resulting irregular ablations may lead to a deviation of the best possible clinical result. Optical zones have always a round circumferential shape. The ablation zone shape depends on treatment type. Optical and ablation zone diameters are indicated on the monitor screen.

Avoid shadowing of any of the three infra-red illumination spots during registration and ablation, as this might cause interference to the detection of the pupil and centration.

3.4. Typical Treatment Profiles

The following figures show typical ablation depth profiles for myopic spherical and cylindrical treatments (the higher the profile or the “hotter” the color, the deeper the ablation).

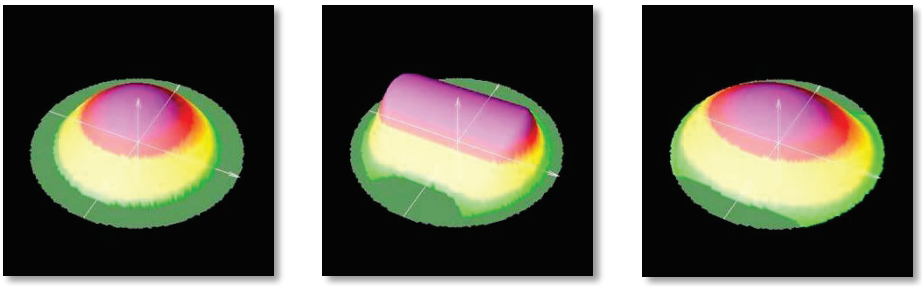

Figure 3: Myopic Ablation Depth Profiles For Sphere (Left), Cylinder (Middle) And Spherocylinder (Right)

3.5. Optical Zones

The optical zone is the area where the intended correction treatment is applied. Optical zones treatments have a round circumferential shape for all types of treatments. They are surrounded by a blend zone, called transition zone. Both add up to the ablation zone. The ablation zone determines the area hit by laser pulses. The shape of transition and ablation zone varies with treatment type.

Ablation zones of myopic spheres are circular. Ablation zones of myopic cylinders are elliptical.

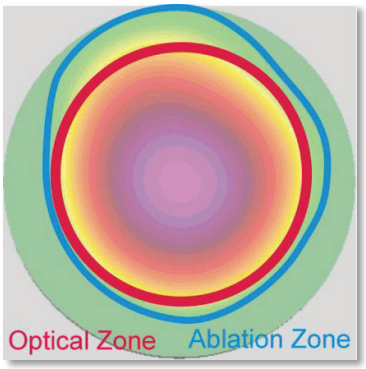

Figure 4: Optical And Ablation Zone Borders

3.6. Post Procedure

After ablation, the operative eye should be irrigated with a balanced salt solution (BSS). A bandage contact lens can be used on the treated eye until re-epithelialization has occurred. Antibiotics and steroid anti-inflammatory drops may be used after treatment as needed. Ocular or oral pain medications may be prescribed for early postoperative pain management. Postoperative follow-up should occur, at minimum, the first day after surgery and very day until the re-epithelialization is complete.

4. INNOVEYES™ STUDY DATA

4.1. Study Design

The study was a prospective, single-arm, multi-center, interventional study conducted at 9 investigational sites in the US. Patients were treated between 05 October 2020 and 09 December 2021. A total of 168 patients (336 eyes) with myopia, with or without astigmatism had bilateral INNOVEYES™ LASIK. The postoperative state of each treated eye was compared to the preoperative state of the same eye.

Patients who agreed to participate in the clinical study provided informed consent and underwent the required screening procedures to determine study eligibility, including preoperative refractive errors within the specified range (myopia up to - 11.00 D with or without astigmatism up to - 4.50 D, with spherical equivalent no more than - 12.00 D as shown from INNOVEYES™ Sightmap Measured Refraction). INNOVEYES™ LASIK was planned with the preoperative data from the INNOVEYES™ Sightmap. All eyes were targeted for emmetropia; nomograms were not used.

The safety analysis set (SAF) included all eyes that underwent surgery or attempted surgery (defined as eye drops given for flap treatment). The full analysis set (FAS) included all eyes that successfully underwent refractive surgery. The consistent cohort (CC) included all eyes in the FAS that had manifest refraction data at all post-operative visits from one month up to and including the visit where refractive stability was established.

Descriptive statistics and frequency distributions were used to summarize clinical outcomes. For analysis of refractive outcomes, the sphere component of the manifest refraction (as tested at 4.0 m) was adjusted for optical infinity by adding -0.25 D to the sphere magnitude. Similarly, MRSE was calculated using the adjusted manifest sphere value. Analyses of Snellen lines were based on the conversion from logMAR line ± 2 letters (e.g., 20/20 Snellen = -0.04 to 0.04 logMAR).

4.1.1. Clinical Inclusion And Exclusion Criteria

Enrollment in the INNOVEYES™ study was limited to patients who met the following inclusion criteria:

- At least of 18 years of age
- Myopia up to -11.00 D with or without astigmatism up to -4.50 D, with spherical equivalent no more than -12.00 D as shown from INNOVEYES™ Sightmap Measured Refraction
- Best corrected photopic distance visual acuity of 20/20 or better ≤ 0.04 logMAR
- Uncorrected photopic distance visual acuity of 20/40 or worse ≥ 0.34 logMAR
- Less than 0.75 D MRSE difference between cycloplegic and subjective manifest refractions
- Less than 0.75 D (SE) difference between INNOVEYES™ Sightmap Measured Refraction and manifest refraction
- Stable refraction (within ± 0.50 D) as determined by MRSE for a minimum of 12 months prior to surgery
- Stable refraction for contact lens wearers within ± 0.5 D MRSE on two consecutive exam dates 7 days apart after lenses are not worn for at least 3 weeks (rigid or toric contact lenses) or 1 week (soft contact lenses)

Patients were not permitted to enroll in the INNOVEYES™ study if they met any of the following exclusion criteria:

- Women who were pregnant or breastfeeding
- Acute or chronic disease or illness that would increase the operative risk
- Systemic medications that may confound the outcome of the study or increase the risk to the subject, including, but not limited to steroids, antimetabolites, isotretinoin, or amiodarone hydrochloride
- Ocular condition that may predispose the subject to future complications (e.g., history or evidence of active or inactive corneal disease, evidence of retinal vascular disease, keratoconus or keratoconus suspect, glaucoma)
- Previous intraocular or corneal surgery
- Predicted residual stromal bed thickness < 250 µm
- Intended to have monovision treatment

4.1.2. Follow-up Schedule

All patients were evaluated at the visits listed below:

Exam		Visit Window
Preoperative Evaluation		1 to 30 days prior to Surgery
Visit 0		Operative Visit
Visit 1	1 Day	Day 1 postoperative
Visit 2	1 Week	Day 5 to 9 postoperative
Visit 3	1 Month	Day 21 to 35 postoperative
Visit 4	3 Months	Day 70 to 98 postoperative
Visit 5	6 Months	Day 147 to 182 postoperative
Visit 6	9 Months	Day 245 to 301 postoperative
Visit 7	12 Months	Day 330 to 420 postoperative

Preoperatively and postoperatively, the objective parameters measured during the study included: manifest refraction, uncorrected distance visual acuity, best corrected distance visual acuity, contrast sensitivity, cycloplegic refraction (6 months), keratometry, intraocular pressure, corneal pachymetry, corneal tomography, slit-lamp evaluation of the anterior segment, Patient Reported Outcomes with LASIK (PROWL) questionnaire, and determination of adverse events and complications. Treatment plans were based on preoperative INNOVEYES™ Sightmap measurements. Adverse events and complications were recorded at all visits.

4.1.3. Clinical Endpoints

With regards to safety, the key endpoints evaluated at the time of refractive stability, were:

- Percentage of eyes with Best Corrected Distance Visual Acuity (BCDVA) worse than 20/40 (for eyes with BCDVA of 20/20 or better pre-op (Target ≤ 1%
- Percentage of eyes that lose 2 lines or more of BCDVA Target ≤5%
- Percentage of eyes that have an increase of manifest refractive astigmatism of greater than 2.00 D of absolute cylinder as compared to the preoperative refraction (Target ≤ 5%
- Percentage of eyes with a serious, non-flap related, ocular adverse event at the postoperative visits Target ≤ 1%)

With regards to effectiveness, the key endpoints evaluated at refractive stability were:

- Percentage of eyes with Uncorrected Distance Visual Acuity (UCDVA) of 20/40 or better (in eyes with preoperative BCDVA of 20/20 or better) at refractive stability Target ≥ 85%)
- Percentage of eyes with MRSE within 0.50 D at refractive stability Target ≥ 50%
- Percentage of eyes with MRSE within 1.00 D at refractive stability Target ≥ 75%
- Percentage of eyes that achieve refractive stability (Target ≥ 95%

With regard to success/failure criteria, the effectiveness criteria were considered met if the percentage of eyes met or exceeded the target rate at the time of refractive stability. Additionally, the safety criteria were considered to have been met if the percentage of eyes was less than or equal to the target rate at the time of refractive stability for all the primary safety endpoints.

4.2. Study Conduct

4.2.1. Accountability

At the completion of the study, 163 of the 168 treated subjects (326/336 treated eyes, 97%) had reached the 12 month postoperative visit (**Table 1**). The SAF consisted of 336 eyes. The FAS consisted of 334 eyes. The CC included 326 eyes.

Table 1
Accountability by Postoperative Visit by Eye (Safety Analysis Set)

Eye Status (n/N (%))		1 Day	1 Week	1 Month	3 Months	6 Months	9 Months	12 Months
Enrolled and Treated (N)	336							
Available for Analysis		336/336 (100.0)	332/336 (98.8)	336/336 (100.0)	330/336 (98.2)	334/336 (99.4)	324/336 (96.4)	326/336 (97.0)
Active		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)
Missed Visit:								
Discontinued		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	4/336 (1.2)	4/336 (1.2)
Retreatment		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)
Adverse Event		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)
Withdrawal by Subject		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	4/336 (1.2)	4/336 (1.2)
Other causes		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)
Lost to Follow-up		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	4/336 (1.2)	6/336 (1.8)
Missed visit, but seen at a later visit		0/336 (0.0)	4/336 (1.2)	0/336 (0.0)	6/336 (1.8)	2/336 (0.6)	4/336 (1.2)	0/336 (0.0)
Not Seen, But Status Obtained		0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)	0/336 (0.0)
% Accountability		100.0	98.8	100.0	98.2	99.4	97.6	98.2

4.2.2. Study Population

The mean age of the study population was 33.3 years (Standard Deviation (SD) 6.98; range 21 to 56) at the time of screening, **Table 2**. The patient population consisted of 37.1% male and 62.9% female patients and was predominantly white (76.6%) of non-Hispanic or Latino ethnicity 85.6% .

Table 2
Demographic Statistics (Full Analysis Set)

Parameter	INNOVEYES™
Age (Years)	
n	167
Mean (SD)	33.3 (6.98)
Median	32.0
(Min, Max)	(21, 56)
Age Group, n/N (%)	
≤21	3/167 (1.8)
>21	164/167 (98.2)
Sex, n/N (%)	
Female	105/167 (62.9)
Male	62/167 (37.1)
Unknown	0/167 (0.0)
Undifferentiated	0/167 (0.0)
Ethnicity, n/N (%)	
Hispanic or Latino	23/167 (13.8)
Not Hispanic or Latino	143/167 (85.6)
Not Reported	1/167 (0.6)
Unknown	0/167 (0.0)
Race, n/N (%)	
White	128/167 (76.6)
Black or African American	10/167 (6.0)
American Indian or Alaska Native	1/167 (0.6)
Asian	16/167 (9.6)
Native Hawaiian or Other Pacific Islander	1/167 (0.6)
Multi-Racial	2/167 (1.2)
Other	9/167 (5.4)

N = Number of subjects
n = Number of subjects with non-missing response
SD = Standard deviation

Tables 3 and **4** present the preoperative refractive error bin distributions for the study population based on preoperative INNOVEYES™ Sightmap Measured Refraction. The approved refractive treatment ranges for the approved Indications for Use are represented by unshaded areas of **Tables 3** and **4** (those with outcomes available for more than 20 eyes per dioptric bin), and the shaded areas of these tables are locked out by the INNOVEYES™ software.

Table 3

Preoperative Refractive Error Stratified by INNOVEYES™ Sightmap Measured Refraction Sphere and Cylinder (Full Analysis Set)

	INNOVEYES™ Sightmap Measured Cylinder						
INNOVEYES™ Sightmap Measured Sphere	**0 to ≤ -0.50 D n/N (%)**	**> -0.50 to ≤ -1.00 D n/N (%)**	**>-1.00 to ≤ -2.00 D n/N (%)**	**>-2.00 to ≤ -3.00 D n/N (%)**	**>-3.00 to ≤ -4.00 D n/N (%)**	**>-4.00 to ≤ -4.50 D n/N (%)**	**Total n/N (%)**
0 to ≤ -1.0 D	2/334 (0.6)	2/334 (0.6)	8/334 (2.4)	12/334 (3.6)	5/334 (1.5)	0/334 (0.0)	29/334 (8.7)
> -1.0 to ≤ -2.0 D	12/334 (3.6)	16/334 (4.8)	11/334 (3.3)	4/334 (1.2)	3/334 (0.9)	1/334 (0.3)	47/334 (14.1)
> -2.0 to ≤ -3.0 D	20/334 (6.0)	6/334 (1.8)	9/334 (2.7)	7/334 (2.1)	2/334 (0.6)	0/334 (0.0)	44/334 (13.2)
> -3.0 to ≤ -4.0 D	11/334 (3.3)	8/334 (2.4)	11/334 (3.3)	3/334 (0.9)	2/334 (0.6)	0/334 (0.0)	35/334 (10.5)
> -4.0 to ≤ -5.0 D	16/334 (4.8)	9/334 (2.7)	3/334 (0.9)	4/334 (1.2)	4/334 (1.2)	0/334 (0.0)	36/334 (10.8)
> -5.0 to ≤ -6.0 D	16/334 (4.8)	14/334 (4.2)	5/334 (1.5)	5/334 (1.5)	1/334 (0.3)	0/334 (0.0)	41/334 (12.3)
> -6.0 to ≤ -7.0 D	12/334 (3.6)	25/334 (7.5)	7/334 (2.1)	3/334 (0.9)	1/334 (0.3)	0/334 (0.0)	48/334 (14.4)
> -7.0 to ≤ -8.0 D	15/334 (4.5)	7/334 (2.1)	10/334 (3.0)	2/334 (0.6)	0/334 (0.0)	0/334 (0.0)	34/334 (10.2)
> -8.0 to ≤ -9.0 D	7/334 (2.1)	6/334 (1.8)	1/334 (0.3)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	14/334 (4.2)
> -9.0 to ≤ -10.0 D	3/334 (0.9)	3/334 (0.9)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	6/334 (1.8)
> -10.0 to ≤ -11.0 D	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)
Total	114/334 (34.1)	96/334 (28.7)	65/334 (19.5)	40/334 (12.0)	18/334 (5.4)	1/334 (0.3)	334/334 (100.0)

% Percentage is calculated by dividing the total number of eyes in the bin (n)/ by the total number of eyes N 334) x 100
Treatment of diopter ranges indicated by shaded rows and columns is locked out by INNOVEYES™ software.

Table 4
Preoperative Refractive Error Stratified by INNOVEYES™ Sightmap Measured Refraction Spherical Equivalent and Cylinder (Full Analysis Set)

	INNOVEYES™ Sightmap Measured Cylinder						
INNOVEYES™ Sightmap Measured Refraction Spherical Equivalent	**0 to ≤ -0.50 D n/N (%)**	**> -0.50 to ≤ -1.00 D n/N (%)**	**>-1.00 to ≤ -2.00 D n/N (%)**	**>-2.00 to ≤ -3.00 D n/N (%)**	**>-3.00 to ≤ -4.00 D n/N (%)**	**>-4.00 to ≤ -4.50 D n/N (%)**	**Total n/N (%)**
0 to ≤ -1.0 D	0/334 (0.0)	0/334 (0.0)	1/334 (0.3)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	1/334 (0.3)
> -1.0 to ≤ -2.0 D	13/334 (3.9)	14/334 (4.2)	11/334 (3.3)	9/334 (2.7)	2/334 (0.6)	0/334 (0.0)	49/334 (14.7)
> -2.0 to ≤ -3.0 D	15/334 (4.5)	8/334 (2.4)	11/334 (3.3)	6/334 (1.8)	4/334 (1.2)	0/334 (0.0)	44/334 (13.2)
> -3.0 to ≤ -4.0 D	13/334 (3.9)	6/334 (1.8)	7/334 (2.1)	7/334 (2.1)	2/334 (0.6)	1/334 (0.3)	36/334 (10.8)
> -4.0 to ≤ -5.0 D	17/334 (5.1)	6/334 (1.8)	10/334 (3.0)	4/334 (1.2)	2/334 (0.6)	0/334 (0.0)	39/334 (11.7)
> -5.0 to ≤ -6.0 D	18/334 (5.4)	15/334 (4.5)	2/334 (0.6)	3/334 (0.9)	4/334 (1.2)	0/334 (0.0)	42/334 (12.6)
> -6.0 to ≤ -7.0 D	12/334 (3.6)	22/334 (6.6)	9/334 (2.7)	6/334 (1.8)	3/334 (0.9)	0/334 (0.0)	52/334 (15.6)
> -7.0 to ≤ -8.0 D	13/334 (3.9)	16/334 (4.8)	5/334 (1.5)	1/334 (0.3)	1/334 (0.3)	0/334 (0.0)	36/334 (10.8)
> -8.0 to ≤ -9.0 D	9/334 (2.7)	4/334 (1.2)	9/334 (2.7)	3/334 (0.9)	0/334 (0.0)	0/334 (0.0)	25/334 (7.5)
> -9.0 to ≤ -10.0 D	4/334 (1.2)	4/334 (1.2)	0/334 (0.0)	1/334 (0.3)	0/334 (0.0)	0/334 (0.0)	9/334 (2.7)
> -10.0 to ≤ -11.0 D	0/334 (0.0)	1/334 (0.3)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	0/334 (0.0)	1/334 (0.3)
Total	114/334 (34.1)	96/334 (28.7)	65/334 (19.5)	40/334 (12.0)	18/334 (5.4)	1/334 (0.3)	334/334 (100.0)

% Percentage is calculated by dividing the total number of eyes in the bin n / by the total number of eyes N (334 x 100
Treatment of diopter ranges indicated by shaded rows and columns is locked out by INNOVEYES™ software.

4.3. Results

4.3.1. Refractive Stability

Refractive stability was evaluated using the CC analysis set. Refractive stability was achieved at 3 months and confirmed at 6 months (**Table 5**). Therefore, the key safety and effectiveness study endpoints were evaluated at 3 months.

Table 5
Criteria for Refractive Stability (Consistent Cohort Analysis Set)

		1 Month to 3 Months (N = 326)	3 Months to 6 Months (N = 326)	6 Months to 9 Months (N = 316)	9 Months to 12 Months (N = 314)
Change in MRSE by ≤ 1.0 D [a]	n/N %	324/326 (99.4)	321/326 (98.5)	315/316 (99.7)	312/314 (99.4)
Change in MRSE by ≤ 0.5 D	n/N %	304/326 (93.3)	306/326 (93.9)	300/316 (94.9)	305/314 (97.1)
Change in MRSE in Diopters	Mean	-0.011	0.010	-0.018	0.000
	SD	0.3063	0.3232	0.2946	0.2674
Change in MRSE per Month [b]	Mean	-0.005	0.003	-0.006	0.000
	SD	0.1532	0.1077	0.0982	0.0891
Change in Cylinder by ≤ 1.0 D	n/N %	326/326 (100.0)	326/326 (100.0)	316/316 (100.0)	314/314 (100.0)
Change in Cylinder by ≤ 0.5 D	n/N %	316/326 (96.9)	321/326 (98.5)	308/316 (97.5)	309/314 (98.4)
Change in Cylinder in Diopters	Mean	0.026	0.004	-0.017	0.021
	SD	0.2698	0.2492	0.2367	0.2105
Change in Cylinder per Month	Mean	0.013	0.001	-0.006	0.007
	SD	0.1349	0.0831	0.0789	0.0702

N = Number of eyes with data at all visits
n = Number of eyes in specified category
SD = Standard deviation
[a]Refractive stability criterion: at least 95% of eyes with change ≤1.00 D of MRSE between the 2 refractions
[b]Refractive stability criterion: mean change of ≤0.04 D per month (≤0.5 D per year) as determined by paired analysis

4.3.2. Safety Results

Primary Safety Outcomes

The safety analysis set consisted of the 330 eyes available at the 3 month visit. The key safety outcomes for this study are presented in **Table 6**. No eyes had a co-primary safety endpoint observation at this timepoint.

Table 6

Co-Primary Safety Endpoints at Refractive Stability (Safety Analysis Set)

Outcome	INNOVEYES™ n/N (%)	Target Rate (%)
BCDVA loss of 2 lines (10 letters) or more from pre-op	0/330 (0.0)	≤ 5%
BCDVA worse than 20/40 (with BCDVA 20/20 or better pre-op)	0/329 (0.0)	≤ 1%
Increase of manifest refractive astigmatism >2.00 D of absolute cylinder compared to pre-op	0/330 (0.0)	≤ 5%
Non-Flap related, ocular serious adverse events*	0/330 (0.0)	≤ 1%

N = Number of eyes in Safety Analysis Set

n = Number of eyes in specified category

Refractive stability achieved at 3 months

*Cumulative number of events reported at refractive stability or earlier

Line difference categories determined using logMAR values; a 0.1 difference in logMAR equals a 1 line difference.

Snellen lines were based on the conversion from logMAR line +/- 2 letters (e.g., 20/20 Snellen = -0.04 to 0.04 logMAR).

Adverse Events

A summary of ocular adverse events (AEs) that occurred during the study are presented in **Table 7**. Ocular AEs were reported in 37 of 336 11.0% of eyes. Common ocular AEs included, corneal flap complication (3.3% and blepharitis (1.2%). These events were nonserious and mild. Other ocular AEs occurred at an incidence of ≤ 0.9%. The incidence of dry eye was 0.6%. Non-ocular AEs were infrequent; the most common non-ocular adverse event was coronavirus infection which resolved in all cases. No subjects discontinued the study due to a treatment emergent AE.

Table 7
Incidence of Ocular Adverse Events by Preferred Term (Safety Analysis Set)

	INNOVEYES™ n/N %	E
Any Event	37/336 (11.0)	58
Corneal flap complication	11/336 (3.3)	12
Blepharitis	4/336 (1.2)	4
Conjunctivitis	3/336 (0.9)	3
Conjunctivitis allergic	3/336 (0.9)	3
Corneal operation	3/336 (0.9)	3
Diffuse lamellar keratitis	3/336 (0.9)	3
Dry eye	3/336 (0.9)	3
Punctate keratitis	3/336 (0.9)	4
Visual acuity reduced	3/336 (0.9)	3
Corneal opacity	2/336 (0.6)	2
Eye allergy	2/336 (0.6)	2
Punctal plug insertion	2/336 (0.6)	2
Retinal laser coagulation	2/336 (0.6)	2
Retinal tear	2/336 (0.6)	2
Vision blurred	2/336 (0.6)	2
Abscess drainage	1/336 (0.3)	1
Abscess of eyelid	1/336 (0.3)	1
Chalazion	1/336 (0.3)	1
Chorioretinal atrophy	1/336 (0.3)	1
Corneal abrasion	1/336 (0.3)	1
Corneal disorder	1/336 (0.3)	1
Hordeolum	1/336 (0.3)	1
Vitreous disorder	1/336 (0.3)	1

N = Total number of eyes; n = Number of eyes with the events; E = Number of events.
If an eye has multiple occurrences of an AE, the eye is presented only once in the respective eye count column (n) for the corresponding AE.
Events are counted each time in the event (E) column.
Adverse events coded using MedDRA version 22.0

Ocular serious adverse events (SAEs) were reported in 4 eyes (1.2% in 3 subjects (**Table 8**). One subject was reported to have a retinal tear OD and OS, both on Day 167, 1 subject had visual acuity reduced OS on Day 250 and corneal opacity on Day 213, and 1 subject had visual acuity reduced OS on Day 336. All events were not related to the device and recovered. No non-ocular SAEs were reported in the study.

Table 8
Incidence of Ocular Serious Adverse Events by Preferred Term (Safety Analysis Set)

	INNOVEYES™ n/N %	E
Any Event	4/336 (1.2)	5
Retinal tear	2/336 (0.6)	2
Visual acuity reduced	2/336 (0.6)	2
Corneal opacity	1/336 (0.3)	1

N = Total number of eyes; n = Number of eyes with the events; E = Number of events.
If an eye has multiple occurrences of an AE, the eye is presented only once in the respective eye count column (n) for the corresponding AE.

Preservation of BCDVA

The change in lines of BCDVA postoperatively compared to preoperatively for all myopic eyes is presented in **Table 9**. At 3 months, 97.9% 319/326) of eyes had no change or an improvement in BCDVA compared to preoperative. No eyes were reported with a loss of >2 lines of BCDVA.

Table 9
BCDVA Line Differences from Preoperative
(Full Analysis Set)

Difference from Preoperative	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
> 2 lines better	0/330 (0.0)	0/334 (0.0)	0/326 (0.0)	0/330 (0.0)	0/320 (0.0)	0/322 (0.0)
2 lines better	1/330 (0.3)	4/334 (1.2)	5/326 (1.5)	3/330 (0.9)	7/320 (2.2)	6/322 (1.9)
1 line better	35/330 (10.6)	62/334 (18.6)	61/326 (18.7)	72/330 (21.8)	72/320 (22.5)	80/322 (24.8)
0 lines	253/330 (76.7)	247/334 (74.0)	253/326 (77.6)	244/330 (73.9)	232/320 (72.5)	229/322 (71.1)
1 line worse	40/330 (12.1)	20/334 (6.0)	7/326 (2.1)	11/330 (3.3)	8/320 (2.5)	6/322 (1.9)
2 lines worse	1/330 (0.3)	1/334 (0.3)	0/326 (0.0)	0/330 (0.0)	1/320 (0.3)	1/322 (0.3)
> 2 lines worse	0/330 (0.0)	0/334 (0.0)	0/326 (0.0)	0/330 (0.0)	0/320 (0.0)	0/322 (0.0)

N = Number of eyes with data at visit
n = Number of eyes in category
Line difference categories determined using logMAR values; a 0.1 difference in logMAR equals a 1 line difference.

Patient Reported Outcomes

The Patient Reported Outcomes with LASIK (PROWL) questionnaire was administered preoperatively and at all postoperative visits at refractive stability and later. Visual symptoms were reported at a lower prevalence both at 3 months and 12 months compared to preoperative (**Table 10**).

Table 10

Categorical Statistics for PROWL Questionnaire: Reported Visual Symptoms at Refractive Stability Visit and Later (Safety Analysis Set)

Outcomes[a]	Symptom	Preoperative n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
Symptom Prevalence[b,c]	Any type of symptom	130/167 (77.8)	88/165 (53.3)	66/167 (39.5)	64/162 (39.5)	57/163 (35.0)
	Double Images	76/167 (45.5)	10/165 (6.1)	12/167 (7.2)	10/162 (6.2)	4/163 (2.5)
	Glare	76/167 (45.5)	47/165 (28.5)	37/167 (22.2)	29/162 (17.9)	22/163 (13.5)
	Halos	92/167 (55.1)	68/165 (41.2)	53/167 (31.7)	49/162 (30.2)	39/163 (23.9)
	Starbursts	110/167 (65.9)	63/165 (38.2)	51/167 (30.5)	44/162 (27.2)	49/163 (30.1)
Symptom Development[b,d]	No symptoms of any type to at least 1 symptom		12/37 (32.4)	6/37 (16.2)	4/35 (11.4)	3/35 (8.6)
	Double Images		5/91 (5.5)	5/91 (5.5)	3/87 (3.4)	1/88 (1.1)
	Glare		14/89 (15.7)	10/90 (11.1)	10/85 (11.8)	3/86 (3.5)
	Halos		24/75 (32.0)	15/75 (20.0)	14/71 (19.7)	7/72 (9.7)
	Starbursts		11/57 (19.3)	7/57 (12.3)	7/55 (12.7)	8/55 (14.5)
Symptom Resolution[b,e]	Any type of symptom to none at all		51/127 (40.2)	70/129 (54.3)	67/126 (53.2)	73/127 (57.5)
	Double Images		68/73 (93.2)	68/75 (90.7)	68/74 (91.9)	71/74 (95.9)
	Glare		42/75 (56.0)	49/76 (64.5)	57/76 (75.0)	57/76 (75.0)
	Halos		45/89 (50.6)	54/91 (59.3)	56/90 (62.2)	58/90 (64.4)
	Starbursts		55/107 (51.4)	65/109 (59.6)	69/106 (65.1)	66/107 (61.7)
Difficulty Performing Activities Due to Symptoms[f,g]	Any type of symptom	4/167 (2.4)	4/165 (2.4)	2/167 (1.2)	1/162 (0.6)	1/163 (0.6)
	Double Images	0/167 (0.0)	1/165 (0.6)	0/167 (0.0)	0/162 (0.0)	0/163 (0.0)
	Glare	1/167 (0.6)	1/165 (0.6)	0/167 (0.0)	0/162 (0.0)	0/163 (0.0)
	Halos	0/167 (0.0)	2/165 (1.2)	1/167 (0.6)	0/162 (0.0)	1/163 (0.6)
	Starbursts	3/167 (1.8)	1/165 (0.6)	1/167 (0.6)	1/162 (0.6)	0/163 (0.0)
No Difficulty Performing Activities Due to Symptoms[f]	No difficulty due to any symptom	97/167 (58.1)	117/165 (70.9)	132/167 (79.0)	125/162 (77.2)	135/163 (82.8)
	Double Images	154/167 (92.2)	163/165 (98.8)	161/167 (96.4)	156/162 (96.3)	162/163 (99.4)
	Glare	128/167 (76.6)	140/165 (84.8)	152/167 (91.0)	146/162 (90.1)	151/163 (92.6)
	Halos	122/167 (73.1)	138/165 (83.6)	147/167 (88.0)	135/162 (83.3)	141/163 (86.5)
	Starbursts	110/167 (65.9)	134/165 (81.2)	143/167 (85.6)	135/162 (83.3)	140/163 (85.9)
Very or Extremely Bothersome Symptoms[f]	Any type of symptom	22/167 (13.2)	4/165 (2.4)	4/167 (2.4)	2/162 (1.2)	1/163 (0.6)
	Double Images	2/167 (1.2)	1/165 (0.6)	1/167 (0.6)	0/162 (0.0)	0/163 (0.0)
	Glare	10/167 (6.0)	1/165 (0.6)	2/167 (1.2)	0/162 (0.0)	0/163 (0.0)
	Halos	7/167 (4.2)	3/165 (1.8)	2/167 (1.2)	2/162 (1.2)	0/163 (0.0)
	Starbursts	15/167 (9.0)	1/165 (0.6)	4/167 (2.4)	1/162 (0.6)	1/163 (0.6)

N = Number of subjects in specified category

a The percentages may add up to more than 100% because the categories are not mutually exclusive and subjects may have more than 1 symptom

b The symptom was considered present if it was experienced either with or without optical correction

c The number of subjects with a symptom divided by the number of subjects with both eyes treated who completed the questionnaire at the scheduled visits

d Analysis includes only subjects with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit

e Analysis includes only subjects with a symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit

f Responses are based on wearing an optical correction preoperatively and wearing no optical correction postoperatively

g Rates based on either of the following responses: 'A lot of difficulty' or 'So much difficulty that I can no longer do some of my usual activities

Dry eye symptoms were assessed using the Ocular Surface Disease Index (OSDI) scores. The percentage of subjects with moderate or severe OSDI scores both at 3 months (approximately 5%) and 12 months (5.5%) was lower than at preoperative (approximately 25% of subjects . Development of dry eye symptoms was reported in 11.5% of subjects at 3 months and 11.7% of subjects at 12 months. Most subjects reporting dry eye (mild, moderate, or severe) preoperatively experienced a resolution in dry eye symptoms both at 3 months 70.6% and 12 months 72.1%), however, this is likely a result of dry eye treatment(s) administered rather than due to the LASIK procedure (**Table 11**).

Table 11

Categorical Statistics for PROWL Questionnaire: Ocular Surface Disease Index (OSDI) Scores at Refractive Stability Visit and Later (Safety Analysis Set)

Measure	Response	Preoperative n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
Distribution of OSDI Scores[a]	Normal	98/167 (58.7)	134/165 (81.2)	132/167 (79.0)	128/162 (79.0)	133/163 (81.6)
	Mild	28/167 (16.8)	23/165 (13.9)	24/167 (14.4)	24/162 (14.8)	21/163 (12.9)
	Moderate	22/167 (13.2)	6/165 (3.6)	8/167 (4.8)	9/162 (5.6)	7/163 (4.3)
	Severe	19/167 (11.4)	2/165 (1.2)	3/167 (1.8)	1/162 (0.6)	2/163 (1.2)
Development of Dry Eye Symptoms[b]	Total		11/96 (11.5)	13/97 (13.4)	12/94 (12.8)	11/94 (11.7)
	Mild		8/96 (8.3)	9/97 (9.3)	8/94 (8.5)	7/94 (7.4)
	Moderate		1/96 (1.0)	2/97 (2.1)	3/94 (3.2)	3/94 (3.2)
	Severe		2/96 (2.1)	2/97 (2.1)	1/94 (1.1)	1/94 (1.1)
Resolution of Dry Eye Symptoms[c]			48/68 (70.6)	47/69 (68.1)	45/67 (67.2)	49/68 (72.1)

n = Number of subjects in specified category

Preoperative = Screening visit

OSDI based on composite score from 0 to 100; scores were categorized as normal (0-12), mild (13-22), moderate (23-32), and severe (33-100) dry eye disease

[a] N = Number of subjects with both eyes treated who completed the questionnaire at the scheduled visits

[b] N = Number of subjects with a normal OSDI score at preoperative visit who submitted a questionnaire at the postoperative visits (normal OSDI score at preoperative visit to worse-than-normal score at postoperative visit)

[c] N = Number of subjects with a worse-than-normal OSDI score at preoperative visit who submitted a questionnaire at the postoperative visits (worse-than-normal OSDI score at preoperative visit to normal score at postoperative visit

Both at 3 months and 12 months post-operative, most subjects were either very satisfied (30.3% at 3 months; 18.4% at 12 months) or completely satisfied (65.5% at 3 months; 79.1% at 12 months) with their vision **Table 12**).

Table 12
Categorical Statistics for PROWL Questionnaire: Satisfaction with Current Vision at Refractive Stability Visit and Later (Safety Analysis Set)

Question	Preoperative n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	12 Months n/N (%)
In general, how satisfied or dissatisfied are you with your present vision?					
Completely satisfied	26/167 (15.6)	108/165 (65.5)	125/167 (74.9)	112/162 (69.1)	129/163 (79.1)
Very satisfied	65/167 (38.9)	50/165 (30.3)	37/167 (22.2)	46/162 (28.4)	30/163 (18.4)
Somewhat satisfied	47/167 (28.1)	6/165 (3.6)	4/167 (2.4)	3/162 (1.9)	4/163 (2.5)
Somewhat dissatisfied	11/167 (6.6)	0/165 (0.0)	1/167 (0.6)	0/162 (0.0)	0/163 (0.0)
Very dissatisfied	12/167 (7.2)	1/165 (0.6)	0/167 (0.0)	1/162 (0.6)	0/163 (0.0)
Completely dissatisfied	6/167 (3.6)	0/165 (0.0)	0/167 (0.0)	0/162 (0.0)	0/163 (0.0)

N = Number of subjects with both eyes treated with data at visit
n = Number of subjects in specified category

Preoperatively, 2/167 (1.2%) of subjects reported not using glasses or contact lenses for vision in a typical day. Following INNOVEYES™ LASIK, 149/163 91.4%) of subjects reported not using glasses or contacts at 12 months with 9.2% of 163 subjects (12 who wore glasses and 3 who wore contact lenses) needing correction when reading. At 12 months, 158/161 (98.1% of subjects who drove reported no difficulty driving during the daytime in familiar places; 3/161 (1.9%) reported a little difficulty. Throughout the postoperative period, no subjects reported giving up driving due to vision.

Contrast Sensitivity

Contrast sensitivity was evaluated preoperatively and postoperatively under mesopic (3 cd/m^2) conditions with and without glare at 4 spatial frequencies (1.5, 3, 6, and 12 cycles per degree, cpd). Eight eyes which were unable to see the reference pattern at a particular spatial frequency were excluded from the analysis. **Table 13** shows that contrast sensitivity improved from baseline, across most spatial frequencies, at refractive stability (3 months).

Table 13

Descriptive Statistics for Change from Baseline for Best Corrected Distance Mesopic Contrast Sensitivity (log unit) at Refractive Stability Visit (Safety Analysis Set)

Visit	Spatial Frequency	n	Mean +/- SD	Median	Percentiles 25%, 75%	Min, Max
Without Glare	1.5 CPD	330	0.018 +/- 0.2982	0.000	-0.100, 0.200	-1.20, 1.30
	3 CPD	330	0.050 +/- 0.2611	0.000	-0.100, 0.200	-1.10, 1.00
	6 CPD	330	0.118 +/- 0.3726	0.100	-0.100, 0.340	-1.10, 1.10
	12 CPD	330	0.074 +/- 0.4172	0.075	-0.200, 0.300	-1.20, 1.60
With Glare	1.5 CPD	330	0.096 +/- 0.4594	0.060	-0.200, 0.340	-2.00, 1.80
	3 CPD	330	0.115 +/- 0.4129	0.100	-0.100, 0.360	-1.40, 1.30
	6 CPD	328	0.168 +/- 0.4514	0.145	-0.135, 0.440	-1.40, 1.70
	12 CPD	326	0.174 +/- 0.4758	0.200	-0.150, 0.500	-1.30, 1.60

SD = Standard deviation, CPD = Cycles per degree

n = Number of eyes with contrast sensitivity test

A clinically significant change in contrast sensitivity was defined as a difference of ≥ 0.30 log unit decrease (loss)/increase (gain) at 2 or more spatial frequencies from preoperative. As shown in **Table 14**, most eyes had either no change in clinically significant contrast sensitivity or an increase in clinically significant contrast sensitivity both at 3 and 12 months compared to preoperative under mesopic conditions with or without glare.

Table 14
Incidence of Clinically Significant Changes in Best Corrected Distance Contrast Sensitivity at Refractive Stability Visit and Later (Safety Analysis Set)

Condition	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	12 Months n/N (%)
Mesopic With Glare				
Decrease	52/330 (15.8)	52/334 (15.6)	40/324 (12.3)	46/326 (14.1)
No Change	147/330 (44.5)	142/334 (42.5)	137/324 (42.3)	134/326 (41.1)
Increase	132/330 (40.0)	142/334 (42.5)	152/324 (46.9)	147/326 (45.1)
Mesopic Without Glare				
Decrease	33/330 (10.0)	34/334 (10.2)	31/324 (9.6)	26/326 (8.0)
No Change	216/330 (65.5)	209/334 (62.6)	213/324 (65.7)	208/326 (63.8)
Increase	83/330 (25.2)	93/334 (27.8)	81/324 (25.0)	93/326 (28.5)

N = Number of eyes with data at visit
n = Number of eyes in specified category
Decrease/Increase categories are not mutually exclusive.
Data for eyes that were unable to see the reference patterns were excluded.

Aberrations

Aberrations were calculated from the Zernike coefficient values collected from the INNOVEYES™ Sightmap. All coefficient values were resized to represent a wavefront diameter of either 4 mm or 5.5 mm (**Table 15**). Overall, there was small increase in mean total HOA at 3 months following surgery, evident with the 5.5 mm standardized wavefront diameter, due to a slight increase in coma. Trefoil was unchanged and there was a decrease in mean spherical aberration.

Table 15
Descriptive Statistics for Aberrometry Results
(Safety Analysis Set)

	4 mm OZ		5.5 mm OZ	
	Preoperative (n=336)	3 Months (n=328)	Preoperative (n=336)	3 Months (n=326)
Parameter	**Mean +/- SD**	**Mean +/- SD**	**Mean +/- SD**	**Mean +/- SD**
Astigmatism (µm)	0.398 +/- 0.3450	0.164 +/- 0.1209	0.760 +/- 0.6526	0.260 +/- 0.1926
Sphere (µm)	2.641 +/- 1.2135	-0.090 +/- 0.2720	5.202 +/- 2.3237	-0.096 +/- 0.4986
Trefoil (µm)	0.052 +/- 0.0289	0.054 +/- 0.0357	0.109 +/- 0.0586	0.107 +/- 0.0694
Coma (µm)	0.056 +/- 0.0300	0.085 +/- 0.0515	0.125 +/- 0.0646	0.208 +/- 0.1256
Spherical Aberration (µm)	0.034 +/- 0.0293	-0.005 +/- 0.0385	0.109 +/- 0.0854	0.052 +/- 0.1112
Total Higher Order Aberrations (RMSh) (µm)	0.116 +/- 0.0322	0.134 +/- 0.0553	0.254 +/- 0.0713	0.314 +/- 0.1266

OZ = optical zone
n = Number of eyes with data at visit
SD = Standard deviation
RMSh = root mean square, higher order aberrations

4.3.3. Effectiveness Results

Primary Effectiveness Outcomes

The analysis of effectiveness was based on the 326 evaluable eyes at the 3-month time point. Key effectiveness outcomes are presented in **Table 16**. At refractive stability (3 months) all primary effectiveness targets were exceeded.

Table 16
Primary Effectiveness Endpoints at Refractive Stability (Full Analysis Set)

	INNOVEYES™		Target Rate
Co-Primary Endpoints	n/N	(%)	(%)
UCDVA of 20/40 or better (with pre-op BCDVA of 20/20 or better)	325/325	(100.0)	≥85%
MRSE within ±0.50 D	300/326	(92.0)	≥50%
MRSE within ±1.00 D	321/326	(98.5)	≥75%

N = Number of eyes with data

n = Number of eyes in specified category

Refractive stability achieved at 3 months

Snellen lines were based on the conversion from logMAR line +/- 2 letters (e.g., 20/20 Snellen = -0.04 to 0.04 logMAR).

The primary effectiveness endpoints at 3 months stratified by preoperative INNOVEYES™ Sightmap Measured Refraction are presented in **Table 17**. All preoperative groups achieved the effectiveness study targets for UCDVA 20/40 or better (target 85% and MRSE within 0.50 D (target 50% and MRSE within 1.00 D (target 75%). The approved refractive treatment ranges for the approved Indications for Use are represented by unshaded areas of **Table 17** (those with outcomes available for more than 20 eyes per dioptric bin), and the shaded areas of these tables are locked out by the INNOVEYES™ software.

Table 17

Primary Effectiveness Endpoints at Refractive Stability by Preoperative INNOVEYES™ Sightmap Measured Refraction Spherical Equivalent (Full Analysis Set)

Preoperative INNOVEYES™ Sightmap Measured Refraction Spherical Equivalent	UCDVA 20/40 or better n/N %	MRSE within ±0.50 D n/N %	MRSE within ±1.00 D n/N %
All Eyes (N)	325/325 (100.0)	300/326 (92.0)	321/326 (98.5)
0 to ≤ -1 D (n=1)	1/1 (100.0)	1/1 (100.0)	1/1 (100.0)
> -1 to ≤ -2 D (n=49)	49/49 (100.0)	49/49 (100.0)	49/49 (100.0)
> -2 to ≤ -3 D (n=42)	42/42 (100.0)	42/42 (100.0)	42/42 (100.0)
> -3 to ≤ -4 D (n=34)	33/33 (100.0)	31/34 (91.2)	33/34 (97.1)
> -4 to ≤ -5 D (n=35)	35/35 (100.0)	34/35 (97.1)	35/35 (100.0)
> -5 to ≤ -6 D (n=42)	42/42 (100.0)	39/42 (92.9)	42/42 (100.0)
> -6 to ≤ -7 D (n=52)	52/52 (100.0)	43/52 (82.7)	51/52 (98.1)
> -7 to ≤ -8 D (n=36)	36/36 (100.0)	32/36 (88.9)	35/36 (97.2)
> -8 to ≤ -9 D (n=25)	25/25 (100.0)	19/25 (76.0)	23/25 (92.0)
> -9 to ≤ -10 D (n=9)	9/9 (100.0)	9/9 (100.0)	9/9 (100.0)
> -10 to ≤ -11 D (n=1)	1/1 (100.0)	1/1 (100.0)	1/1 (100.0)
> -11 to ≤ -12 D (n=0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)

UCDVA of 20/40 or better in eyes with preoperative BCDVA of 20/20 or better

n and N = Number of eyes with data

Numerators = Number of eyes in specified outcome category

Refractive stability achieved at 3 months

Snellen lines were based on the conversion from logMAR line +/- 2 letters (e.g., 20/20 Snellen = -0.04 to 0.04 logMAR).

Treatment of diopter ranges indicated by shaded rows and columns is locked out by INNOVEYES™ software.

Manifest Refraction

Predictability of refraction is shown in **Table 18**. The majority of eyes, 92% 300/326 , were within 0.5 D of target from the point of refractive stability. Most eyes, 91.1 % (260/326), were within 0.5 D of target sphere refraction at the point of refractive stability. At Month 3, 96.1% (174/181) of eyes treated for astigmatism (> -0.5 D) were within ± 1.0 D of cylinder target zero , and 88.4% 160/181) were within ± 0.5 D of cylinder target.

Table 18

Predictability of MRSE (Full Analysis Set)

Outcome	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
Predictability of MRSE within ±0.50 D	287/330 (87.0)	291/334 (87.1)	300/326 (92.0)	300/330 (90.9)	291/320 (90.9)	304/322 (94.4)
Predictability of MRSE within ±1.00 D	320/330 (97.0)	327/334 (97.9)	321/326 (98.5)	324/330 (98.2)	317/320 (99.1)	321/322 (99.7)
Predictability of MRSE within ±2.00 D	330/330 (100.0)	334/334 (100.0)	326/326 (100.0)	330/330 (100.0)	320/320 (100.0)	322/322 (100.0)

Manifest Refraction Sphere (Full Analysis Set)

Outcome	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
Manifest refraction sphere within ±0.5 D	295/330 (89.4)	285/334 (85.3)	297/326 (91.1)	294/330 (89.1)	284/320 (88.8)	297/322 (92.2)
Manifest refraction sphere within ±1.0 D	325/330 (98.5)	324/334 (97.0)	320/326 (98.2)	320/330 (97.0)	312/320 (97.5)	318/322 (98.8)

Manifest Refraction Cylinder (Full Analysis Set with Preoperative Astigmatic Myopia)

Outcome	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
Manifest refraction cylinder ≤ -0.5 D	146/179 (81.6)	145/183 (79.2)	160/181 (88.4)	158/181 (87.3)	145/176 (82.4)	148/177 (83.6)
Manifest refraction cylinder ≤ -1.0 D	176/179 (98.3)	177/183 (96.7)	174/181 (96.1)	179/181 (98.9)	169/176 (96.0)	172/177 (97.2)

Astigmatic myopia is defined as eyes with preoperative manifest refraction cylinder > -0.5 D

N = Number of eyes with data at visit

n = Number of eyes in category

Uncorrected Visual Acuity

Table 19 presents the distribution of UCDVA results over time for all myopic eyes. All eyes 100%) achieved UCDVA of 20/40 or better. The majority (≥64.1%) of eyes achieved 20/16 or better UCDVA across all postoperative study visits after the point of refractive stability.

Table 19
UCDVA (Full Analysis Set)

Outcome	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
UCDVA of 20/40 or better	329/330 (99.7)	334/334 (100)	326/326 (100)	330/330 (100)	320/320 (100)	322/322 (100)
UCDVA of 20/20 or better	260/330 (78.8)	288/334 (86.2)	301/326 (92.3)	302/330 (91.5)	288/320 (90.0)	304/322 (94.4)
UCDVA equal to or better than the pre-op BCDVA	129/330 (39.1)	174/334 (52.1)	177/326 (54.3)	180/330 (54.5)	174/320 (54.4)	209/322 (64.9)
UCDVA of 20/10 or better	4/330 (1.2)	5/334 (1.5)	4/326 (1.2)	8/330 (2.4)	7/320 (2.2)	8/322 (2.5)
UCDVA of 20/12.5 or better	41/330 (12.4)	69/334 (20.7)	67/326 (20.6)	63/330 (19.1)	74/320 (23.1)	85/322 (26.4)
UCDVA of 20/16 or better	162/330 (49.1)	204/334 (61.1)	218/326 (66.9)	212/330 (64.2)	205/320 (64.1)	226/322 (70.2)
UCDVA of 20/20 or better	260/330 (78.8)	288/334 (86.2)	301/326 (92.3)	302/330 (91.5)	288/320 (90.0)	304/322 (94.4)
UCDVA of 20/25 or better	307/330 (93.0)	320/334 (95.8)	320/326 (98.2)	324/330 (98.2)	314/320 (98.1)	318/322 (98.8)
UCDVA of 20/32 or better	324/330 (98.2)	330/334 (98.8)	325/326 (99.7)	330/330 (100)	319/320 (99.7)	322/322 (100)

N = Number of eyes with data at visit
n = Number of eyes in category
Snellen lines were based on the conversion from logMAR line +/- 2 letters (e.g., 20/20 Snellen = -0.04 to 0.04 logMAR).

Table 20 presents the line difference in postoperative UCDVA achieved compared to preoperative best corrected visual acuity (BCDVA) for all myopic eyes. At 3 months, 85.3% 278/326) of eyes achieved the same or better uncorrected visual acuity than their preoperative best corrected visual acuity.

Table 20
Line Differences for Postoperative UCDVA Compared to Preoperative BCDVA (Full Analysis Set)

Difference from Preoperative	1 Week n/N %	1 Month n/N %	3 Months n/N %	6 Months n/N %	9 Months n/N %	12 Months n/N %
> 2 lines better	0/330 (0.0)	0/334 (0.0)	0/326 (0.0)	0/330 (0.0)	1/320 (0.3)	0/322 (0.0)
2 lines better	0/330 (0.0)	3/334 (0.9)	1/326 (0.3)	1/330 (0.3)	1/320 (0.3)	5/322 (1.6)
1line better	25/330 (7.6)	31/334 (9.3)	41/326 (12.6)	42/330 (12.7)	52/320 (16.3)	40/322 (12.4)
0 lines	197/330 (59.7)	231/334 (69.2)	236/326 (72.4)	235/330 (71.2)	215/320 (67.2)	245/322 (76.1)
1 line worse	76/330 (23.0)	52/334 (15.6)	41/326 (12.6)	45/330 (13.6)	46/320 (14.4)	25/322 (7.8)
2 lines worse	25/330 (7.6)	12/334 (3.6)	4/326 (1.2)	5/330 (1.5)	3/320 (0.9)	6/322 (1.9)
> 2 lines worse	7/330 (2.1)	5/334 (1.5)	3/326 (0.9)	2/330 (0.6)	2/320 (0.6)	1/322 (0.3)

N = Number of eyes with data at visit
n = Number of eyes in category
Line difference categories determined using logMAR values; a 0.1 difference in logMAR equals a 1 line difference.

Cylinder Correction Analyses

Table 21 presents the percent reduction of cylinder for eyes with preoperative myopic astigmatism (manifest refraction cylinder > -0.5 D) at refractive stability stratified by preoperative cylinder. **Table 22** presents the proportions of eyes with residual manifest cylinder magnitude at 3 months and the absolute shift in axis from preoperative.

Table 21
Reduction of Absolute Cylinder at Refractive Stability
(Full Analysis Set with Preoperative Astigmatic Myopia)

Preoperative Cylinder	n	Percent Reduction of Absolute Cylinder Mean [range]
All Eyes (N)	181	80.911 [-16.67,100.00]
> -0.50 to ≤ -1.00 D	76	76.645 [0.00,100.00]
> -1.00 to ≤ -2.00 D	57	83.496 [-16.67,100.00]
> -2.00 to ≤ -3.00 D	31	83.801 [44.44,100.00]
> -3.00 to ≤ -4.00 D	17	86.046 [46.15,100.00]
> -4.00 to ≤ -4.50 D	0	-

Astigmatic myopia is defined as eyes with preoperative manifest refraction cylinder > -0.5 D
n = Number of eyes with preoperative cylindrical component in category
Increases in cylinder are reported as negative numbers

Table 22
Residual Astigmatic Error at Refractive Stability
(Full Analysis Set with Preoperative Astigmatic Myopia)

	Absolute Shift in Axis*					
Residual Cylinder Magnitude	≤5º n/N (%)	>5º to ≤10º n/N (%)	>10º to ≤15º n/N (%)	>15º to ≤30º n/N (%)	>30º n/N (%)	Total
All Eyes (N)						181
0.0 D*	87/181 (48.1)					
> 0.0 D to ≤ -0.5 D	4/181 (2.2)	3/181 (1.7)	3/181 (1.7)	5/181 (2.8)	58/181 (32.0)	
>-0.5 D to ≤ -1.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	14/181 (7.7)	
>-1.0 D to ≤ -2.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	7/181 (3.9)	
>-2.0 D to ≤ -3.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	
>-3.0 D to ≤ -4.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	
>-4.0 D to ≤ -5.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	
>-5.0 D to ≤ -6.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	
> -6.0 D	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	

Astigmatic myopia is defined as eyes with preoperative manifest refraction cylinder > -0.5 D
*Shifts are defined to be zero for eyes with zero residual cylinder magnitude
n = Number of eyes in category

Vector analysis summary statistics at 3 months are presented in **Table 23** for eyes with preoperative manifest refractive astigmatism of > -0.50 D. The mean absolute error vector (EV) magnitude was less than 0.50 D for all astigmatic eyes (0.240 D ± 0.3198 D), the mean correction ratio (CR) was close to 1.0 (1.138 ± 0.2925) and the mean error ratio (ER) was close to zero (0.186 ± 0.2647).

Table 23
Vector Analysis Summary at Refractive Stability
(Full Analysis Set with Preoperative Astigmatic Myopia)

Preoperative Cylinder	n	|IRC| (Mean ±SD)	|SIRC| (Mean ±SD)	|EV| (Mean ±SD)	CR (Mean ±SD)	ER (Mean ±SD)
All Eyes (N)	181	1.473 ± 0.8126	1.662 ± 0.9448	0.240 ± 0.3198	1.138 ± 0.2925	0.186 ± 0.2647
> -0.50 to ≤ -1.00 D	76	0.764 ± 0.1211	0.883 ± 0.3042	0.170 ± 0.2294	1.151 ± 0.3520	0.227 ± 0.3080
> -1.00 to ≤ -2.00 D	57	1.445 ± 0.2762	1.623 ± 0.4451	0.226 ± 0.3455	1.131 ± 0.2887	0.163 ± 0.2716
> -2.00 to ≤ -3.00 D	31	2.344 ± 0.3175	2.634 ± 0.4544	0.357 ± 0.3516	1.132 ± 0.1883	0.160 ± 0.1650
> -3.00 to ≤ -4.00 D	17	3.150 ± 0.2447	3.500 ± 0.4698	0.386 ± 0.4256	1.114 ± 0.1494	0.125 ± 0.1402
> -4.00 to ≤ -4.50 D	0	-	-	-	-	-

Astigmatic myopia is defined as eyes with preoperative manifest refraction cylinder > -0.5 D
IRC = Intended refractive correction; SIRC = Surgically induced refractive correction; EV = Error vector;
CR = Correction ratio; ER = Error ratio
N = Number of eyes with data
n = Number of eyes in specified category

4.4. Conclusion

The primary effectiveness and safety objectives of the clinical investigation of INNOVEYES™ LASIK with the INNOVEYES™ Sightmap for correction of myopia with and without astigmatism clinical study were met. No unanticipated safety risks were revealed. The results of this study establish the effectiveness and safety of the WaveLight® EX500 excimer laser system for the INNOVEYES™ LASIK treatment in eyes with spherical equivalent (SE) more than -1.00 and up to - 9.00 diopters (D), with up to - 8.00 D of spherical component (in minus cylinder format) and up to - 3.00 D of astigmatic component at the spectacle plane, based on the INNOVEYES™ Sightmap Measured Refraction, in patients with magnitude of the spherical equivalent difference between the Manifest Refraction (MRSE) and the Sightmap Measured Refraction SE being less than 0.75 D.

5. PREPARATION OF DEVICES, INSTRUMENTS AND MATERIAL

Prepare all material, instruments and devices necessary for surgery. Arrange them conveniently for surgeon and his/her assistant(s) to provide a good workflow during surgery.

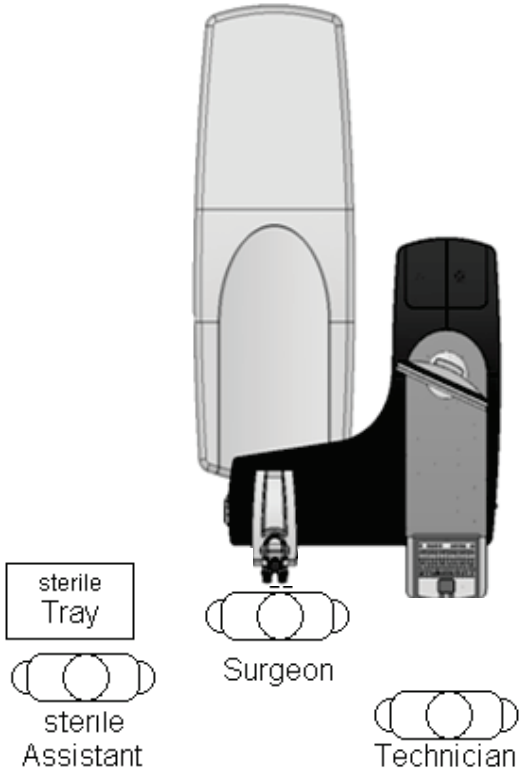

Figure 5: Suggestion For OR Arrangement

6. TREATMENT PLANNING AND DATA ENTRY

WARNING

Please also refer to the Procedure Manual, the User Manual and to its addendums of the WaveLight® EX500 laser system.

Observe all inclusion and exclusion criteria, adverse event, indication, contraindication, warning and precaution information given in this manual.

The treatment plan and data entry is made and controlled remotely at the laser system or the WAVENET™ Planning Software. For details regarding data entry and treatment programming please also refer to the User Manual.

6.1. Treatment Plan And Data Entry

If data transfer is not available, enter all mandatory entries in the “Refractive and Corneal Details” section or the rated area in “Diagnostic / Basic Diagnostics” and determine / check treatment parameter in Treatment Data section.

Manual entry does not include the registration option or centration on corneal vertex using ALLEGRO TOPOLYZER™ Vario or INNOVEYES™ Sightmap data.

Transfer treatment relevant diagnostic data and entered patient and eye data from the WaveLight® diagnostic device to the WaveLight® EX500 laser system and the planning station.

- Check the selected infrared image and the related centration data for repeatability in comparison to all other exams imported.
- Verify the transferred examination data and complete any additional entries.

Double-check with the patient and assisting personnel to ensure that there are no possible restrictions for the treatment. It is the sole responsibility of the operating surgeon to ensure that all data is accurate and that the treatment can be safely carried out.

Save treatment plan with all entries and for later use or retrieval.

6.2. Parameters Determining Ablation

The treatment is determined automatically by parameters entered in section “Refractive and Corneal Details” and “Treatment Design”.
Parameters determining treatment are “Subjective”, “Vertex Distance (VD)”, “K-Readings”, “Optical Zone” (OZ) and Refractive Aim (planned “Treatment 4mm” refraction).

Refraction:

Refraction parameters are automatically added and can be changed according to patient’s manifest refraction or to your preferred refraction for treatment. Modify refraction according to your nomogram, if available.
Change target refraction (aim) under “Treatment 4mm”, if not targeted for emmetropia.

NOTE

Refraction Entry And Vertex Distance

Input of refraction can be added in minus- or plus-cylinder notation. However, the planning uses minus-cylinder notation only.

Enter the Vertex Distance measured during refraction examination. This value will influence treatment, as the correction will be applied on the corneal plane instead of the spectacle plane.

Optical Zone:

The optical zone is displayed and entered in millimeters. Default optical zone depends on the Fitting Zone.
Check the optical zone size with the largest physiologic pupil size measured under mesopic conditions and resulting ablation depth (see Procedure Manual, chapter “Ablation Depth And Remaining Stromal Thickness”).

NOTE

To ensure plausibility and reproducibility of INNOVEYES™, it is recommended to take multiple data acquisitions for each examination sequence. In detail, at least 4 wavefront measurements, one biometric measurement, in which the majority of the six individual measurements were found to be good, and 2 tomography measurements must be carried out.

All individual measurements per method must in turn be comparable to one another. Otherwise, further measurements are necessary, and the outliers must be excluded for the export and treatment calculation.

6.3. Feasibility Checks

Check if all mandatory entries with patient's data, examination and treatment data are filled correctly. Check resulting correction and ablation depth and match them again with patient's eye and treatment plan data of the patient's file.

Optical zone and / or refractive parameters may have to be changed, if conflicts are determined in the feasibility checks.

6.3.1. Ablation Depth And Remaining Stromal Thickness

Check resulting remaining stromal thickness indicated as "Residual Stroma" or "Res. Stroma".

A warning will be displayed as soon as the set minimum value is be violated by actual treatment parameter. The manufacturer's setting for the alert level is 250 µm.

CAUTION

Remaining Thickness

Falling below the minimum thickness of 250 microns increases the risk for corneal ectasia following treatment.

6.4. Confirm And Save Data

The “Database Portal Software” of the laser system provides an “Overview”. This window will display the planed treatments and the related summary of the important treatment plan information, possible warnings and messages for final check and confirmation.

Double-check all data, messages and warnings before confirming treatment plan to accept data and possible warnings or consider a different plan for the patient.

Make sure a valid WaveCard is inserted.

Press on start to initiate a treatment sequence.

The “Database Portal Software” will change to treatment screen and show treatment data, the live images of the eye and eyetracker, the pachymetry and the laser status.

The refraction data (correction) and the optical zone will be displayed on the monitor screen. All refraction values are at spectacle plane. The vertex distance will be the one entered with the patient’s refraction.

Additional info and warnings will be displayed on the monitor screen only throughout the treatment.

7. INDEX

- End -