ALLEGRETTO WAVE EYE-Q

Scanning Spot LASIK Laser System

ADDENDUM Procedure Manual T-CAT
Topography-Guided Treatments
Information for professional use

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USING THE ADDENDUM PROCEDURE MANUAL T-CAT (Topography-Guided Treatments)

This manual provides information for the intended clinical use of the ALLEGRETTO WAVE EYE-Q laser system for “Topo-guided” or “T-CAT” (Topography-guided Custom Ablation Treatment) treatments.

This manual provides only information that is specific for topo-guided LASIK.
Refer to the Operator’s Manual of the laser console, to its addendums, its Procedure Manual 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 ALLEGRETTO WAVE EYE-Q laser system for performing topo-guided LASIK 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 Operator’s Manual of the laser console.

This Addendum Procedure Manual **ALLEGRETTO WAVE EYE-Q Version 1010-3** is valid as from **Notebook Portal Software Version 2.020** (please refer to the Addendum Operator’s Manual Notebook Portal Software).

TYPOGRAPHICAL CONVENTIONS

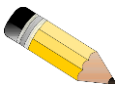
The following conventions are used in this manual for Warnings, Precautions and Notes:

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 manuals.

Read and understand this Addendum Procedure Manual, the Operator's Manual and all related manuals of the laser system and its approved accessories before starting to use the ALLEGRETTO WAVE EYE-Q laser system.

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

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

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1. SAFETY OF TOPOGRAPHY-GUIDED TREATMENTS

The topo-guided LASIK procedure requires accurate and reliable data from the topography examination. Every step of every topography measurement that may be used as the basis for a topo-guided LASIK procedure must be validated by the user.

Inaccurate or unreliable data from the topography examination will lead to an inaccurate treatment.

2. SYSTEM DESCRIPTION

2.1. Device Description (T-CAT Option)

The ALLEGRETTO WAVE EYE-Q laser system is able to perform customized LASIK treatment according to data provided by WaveLight GmbH's "ALLEGRO Topolyzer" if the "T-CAT" option is enabled. These procedures are called "Topo-guided" or "T-CAT" (Topography-guided Custom Ablation Treatment) treatments.

The ALLEGRO Topolyzer measures the height data of the patient's cornea and generates the required topography data for planning and carrying out topo-guided treatments. This data can be transferred to the notebook computer of the ALLEGRETTO WAVE EYE-Q laser system via media, such as an USB-stick, where it is used for planning and carrying out topo-guided treatments of the eye.

Note that the treatment planning function of the notebook portal software for topo-guided treatments (T-CAT option) requires specific licensing of this software.
This involves authorization for specific ALLEGRO Topolyzers and ALLEGRETTO WAVE EYE-Q laser devices. Devices that have not been authorized cannot be used for topo-guided treatments.

2.2. Treatment Description (T-CAT Option)

A topo-guided treatment uses a tissue ablation profile based upon the eye's individual topography errors. Errors are not limited to just spherical and astigmatic errors, they also include tilt. Therefore, a topo-guided treatment represents a higher level of customization than a Wavefront Optimized LASIK treatment, which is based on the eye's refraction, and K-readings. Such treatments are often called "Standard", "Classic" or "Traditional" LASIK.

3. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

3.1. Indications For Use

The WaveLight® ALLEGRETTO WAVE EYE-Q excimer laser system used in conjunction with the WaveLight® ALLEGRO Topolyzer (topographer) and T-CAT treatment planning software is indicated for performing topography-guided laser assisted in-situ keratomileusis (Topo-guided (T-CAT) LASIK):

- for the reduction or elimination of up to - 9.0 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to - 8.0 D of spherical component and up to 3.0 D of astigmatic component at the spectacle plane,
- in patients who are 18 years of age or older; and
- in patients with documentation of a stable manifest refraction defined as ≤ 0.5 D or less of preoperative spherical equivalent shift over one year prior to surgery.

3.2. Contraindications

Topo-guided LASIK treatments are contraindicated in:

- Pregnant or nursing women
- Patients with a weakened immune system, including diagnosed collagen vascular, autoimmune or immunodeficiency disease
- Patients with degenerations of structure of the cornea, including diagnosed keratoconus or any clinical pictures suggestive to keratoconus
- Patients with severe dry eyes
- Patients with eyes that have a calculated residual stromal bed thickness that is less than 250 microns
- Patients with a recurrent corneal erosion
- Patients with advanced glaucoma
- Patients with uncontrolled diabetes.

3.3. Warnings

Topo-guided LASIK treatment is not recommended for patients who have any of the following:

- 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 topography examination that precludes topo-guided treatment
- Taking the medication Isotretinoin (Accutane®)[1]

[1] Accutane® is a registered trademark of Hoffmann-LaRoche, Inc.

3.4. Precautions

3.4.1. General

Safety and effectiveness of the ALLEGRETTO WAVE EYE-Q laser system for topo-guided treatments has not been established for patients:

- With progressive myopia and/or astigmatism,
- With ocular disease,
- With 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 corneas that are too thin to cut the surgical flap
- Taking the medication sumatriptan succinate (Imitrex®[2])
- Taking the medication amiodarone hydrochloride (Cordarone®[3])
- Under 18 years of age
- Over the long term (more than 12 months after surgery)
- For treatment targets different from emmetropia (plano) in which the defocus (spherical term) and astigmatism (cylinder term) has been adjusted, additionally, physician adjustment of topography-calculated defocus may negate the potential benefits of the topo-guided procedure to reduce corneal abnormalities. You should discuss with your patient the potential risks and benefits associated with treatment targets different from emmetropia.
- With media problems, 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 eyetracking
- Taking medications likely to affect wound healing including, but not limited to, antimetabolites
- With large pupils
- With undiagnosed dry eyes
- For the treatment of myopia with or without astigmatism that is not within the FDA-approved treatment range of - 9.0 D MRSE, up to - 8.0 D sphere, or up to - 3.0 D cylinder.
- With any other medical condition that might be expected to make the patient an unsuitable candidate for LASIK treatment.
- With history of crossed eyes (strabismus)
- With decreased vision in one eye

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

- 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 with Topo-guided LASIK 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 eyes under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in such 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.

Preoperative evaluation for dry eyes must be performed. Patients should additionally be advised of the potential risk for dry eyes after any LASIK treatment (including after topo-guided treatments).

3.4.2. Patient Selection

In addition to previously described contraindications, warnings and general precautions, the following points must be considered to identify good candidates for topo-guided treatments and to get sufficient information for the treatment plan.

The following examinations must have been performed prior to the treatment:

- 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 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 emmetropic patients. 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.
- Topography measurements have to be performed with the ALLEGRO Topolyzer in order to provide necessary topography data for the topo-guided treatment plan.

For contact lens wearers, the following must additionally be considered:

- Contact lens wearers must discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 3 days **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 3 days **prior to surgery**.

The patients must meet certain general requirements for the treatment:

- 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 consent form.

The patient must be informed about and understand all alternatives to the topo-guided LASIK treatment for correcting myopia and/or astigmatism:
With glasses or contact lenses, or other surgical procedures such as classic LASIK, radial keratotomy, automated lamellar keratoplasty or clear lens exchange.

Additionally patients should be instructed not to wear makeup at the day of surgery, because this poses risk for contamination of the stromal interface. Patients must not use perfumes, aftershave, Eau de Cologne or other substances applied to the skin containing alcohol at that day.

3.4.3. Topography Examination

The topo-guided treatment is completely reliant on accurate and reliable topography examination data.
For this reason, all topography examinations have to be performed with great care. Only well-trained personnel shall perform, validate and export examinations, according to instructions given in the ALLEGRO Topolyzer manual and in this Procedure Manual.

Pay attention to the following during the topography examination with ALLEGRO Topolyzer:

- Enter and check all patient data carefully.
- Enter the patient's pachymetry correctly in the five zones, as they will be transferred to the laser and provided as default values. For the manifest refraction enter zero, as the topo-guided treatment is only correcting the corneal abnormalities in the first step.
- Make sure that the eye to be examined has not had applanation tonometry or contact pachymetry during 12 hours prior to the topography examination.
- A proper tear film is essential for good image contrast. Use only artificial tears that are recommended by WaveLight GmbH.
- Instruct the patient about what she/he has to do, what she/he and should avoid and what she/he will notice during examination.

Perform topography examination as well as image and data validation according to the ALLEGRO Topolyzer manual and the validation checklist provided in the appendix of this manual. Examination procedure steps and validation checkpoints shall include, but are not limited to the following:

- Confirm the proper head alignment (0°-Axis) with the "eye-to-eye test".
- Double-check the eye actually measured with the eye identifier shown on the device screens.
- Get a sharp image of the placido rings on the eye.
- Check the centering and focusing of the topographer on the pupil.
- Check the captured pupil image (shadow of nose and eyelid).
- Take up to eight measurements and check there consistency.
- Check for enough analyzed data in the optical zone of the planed treatment.

Multiple topography examinations of each eye are recommended to ensure reproducibility and to identify possible examination outliers.

CAUTION

Topography Examination Use

All topography examinations have to pass validation checks for topo-guided procedures. Use of inaccurate or unreliable examinations will lead to unreliable or inaccurate treatments.

All data entered at the examination device must be accurate. This data will be transferred and used at the notebook portal software for treatment plans and their validation.

3.4.4. Data Transfer

Use a formatted, virus-free USB-stick to transfer treatment data from the ALLEGRO Topolyzer to the ALLEGRETTO WAVE EYE-Q laser system. Follow the instructions in the appropriate manuals and their addendums.

3.4.5. Laser Preparation

- Transfer treatment data and entered patient and eye data from the ALLEGRO Topolyzer to the ALLEGRETTO WAVE EYE-Q laser system.
- Verify the transferred examination data is correct 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.

3.4.6. Patient Preparation

When preparing the patient for the treatment, pay attention to the following points:

- Ensure that the data on the laser matches the patient and eye to be treated. Patient and eye data will show on the laser LCD screen.
- Pupil size for treatment should be within 2 mm of the size during the topography examination. Medications likely to dilate the pupil should be administered with careful supervision prior to surgery, as the ALLEGRETTO WAVE EYE-Q's eyetracker will not be able to track pupils of more than 8.0 mm diameter.

3.4.7. Procedure

Ablation Depth and Ablation Zone:

The area of the deepest ablation as well as shape and size of the ablation zone may differ from the general pattern of ALLEGRETTO WAVE EYE-Q Wavefront Optimized myopic LASIK treatments.

The notebook portal software provides a graphical display to check value and location of the highest ablation depth as well as shape and size of the overall ablation.
“Hotter” colors show areas of deeper ablation.

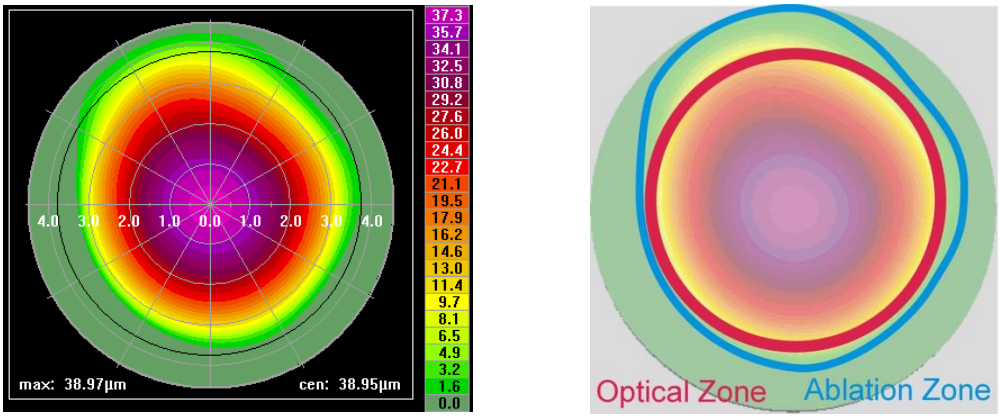

Figure 1: Examples Ablation Depth Display (Left) And Optical / Ablation Zone Borders (Right)

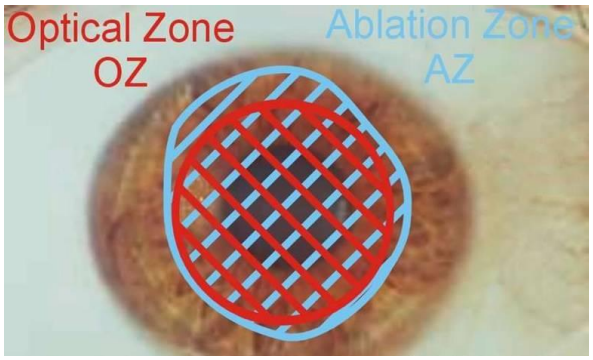

Figure 2: Example Optical And Ablation Zone Over Pupil

The ablation zone has no specific shape. It is specific for the individual treatment.

Optical Zone:

Optical zones are always circular. The ablation zone shape depends on the individual aberrations. Its diameter can be chosen by selection of the transition zone surrounding the optical zone. The laser LCD display of the laser console shows the optical zone diameter only.

Ablation Details:

During the course of the ablation, the zone already corrected will be enlarged to the programmed Optical Zone diameter. The currently achieved diameter is not indicated.

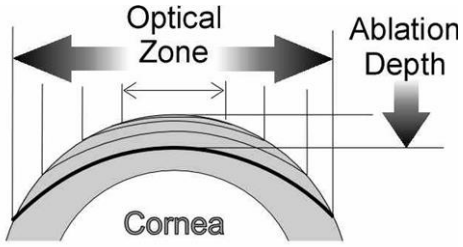

Figure 3: Evolution Of Mainly Myopic Ablation Treatment

Ablation depth profiles for topo-guided treatments are as individual as the aberrations of the specific eye. Mainly myopic spherical treatments flatten the cornea, mainly myopic astigmatism treatments flatten the axis of the positive cylinder.

The following figure shows an example of an ablation depth profile for a myopic topo-guided treatment (the higher the profile, the deeper the ablation).

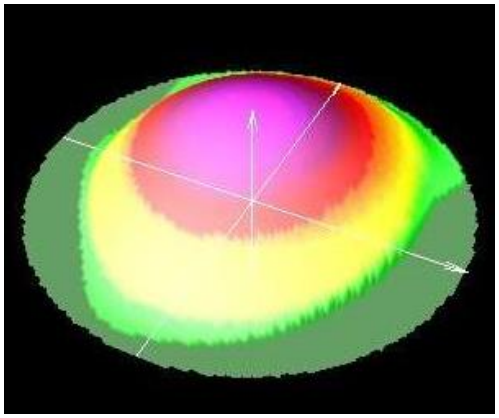

Figure 4: Example Topo-Guided Ablation Depth Profile

4. STUDY DATA

4.1. Study Design

The T-CAT-001 study was a prospective, non-randomized, multicenter study conducted at nine (9) clinical sites. A total of 249 eyes with myopia, with or without astigmatism, were treated with Topography-guided Custom Ablation Treatment (T-CAT) LASIK with the ALLEGRETTO WAVE EYE-Q Excimer Laser System.

Corneal topography, manifest refraction, measurements of uncorrected visual acuity (UCVA), and measurements of best spectacle-corrected visual acuity (BSCVA) were obtained at baseline and at appropriate times after the Topo-guided LASIK treatment to evaluate the efficacy of the Topo-guided (T-CAT) LASIK treatment. Safety monitoring throughout the study included observations at all scheduled and unscheduled visits for subjective complaints, complications, and adverse events, as well as, clinically significant findings from ophthalmic measurements, dilated fundus examination, slit lamp examination, and contrast sensitivity testing. Subject reported outcome questionnaires were used to evaluate subjective visual complaints, quality of vision, and quality of life preoperatively and postoperatively.

Subjects who agreed to participate in the T-CAT-001 study provided informed consent and underwent the required screening procedures to determine study eligibility for Topo-guided (T-CAT) LASIK. Subjects in whom one or both eyes had a preoperative refractive error within the specified range for myopia (MRSE up to - 9.0 D; sphere 0 to - 9.0 D, cylinder 0 to 6.0 D) and met all study eligibility criteria were further evaluated as potential candidates for a Topo-guided (T-CAT) LASIK procedure. Measurements taken preoperatively to determine study eligibility, and postoperatively to evaluate safety and efficacy, included manifest refraction, cycloplegic refraction, distance BSCVA and UCVA, slit lamp examination, corneal topography, pachymetry, intraocular pressure, and fundus examination.

Corneal topographies used to plan the Topo-guided (T-CAT) LASIK treatment were obtained prior to the treatment using the ALLEGRO Topolyzer topography system. The T-CAT software used data from the ALLEGRO Topolyzer and clinical refraction to determine the Topo-guided (T-CAT) LASIK treatment plan; then, the Topo-guided (T-CAT) LASIK procedure was delivered to the study eye using the ALLEGRETTO WAVE EYE-Q Excimer Laser System.

4.2. Primary Objective

The primary objective of this study was to evaluate the safety and efficacy of Topo-guided (T-CAT) LASIK for performing Topo-guided (T-CAT) LASIK using the ALLEGRETTO WAVE EYE-Q Excimer Laser System for the treatment of manifest and cornea-based myopic refractive errors.

4.3. Data Analysis

The safety and efficacy summaries presented in this section were based on the entire PMA cohort. Due to missing visits or examinations and different subgroup analyses, the safety and efficacy cohorts may differ for specific data analyses.

4.4. Demographics and Baseline Parameters

Demographic characteristics of the subjects enrolled in the study are summarized in Table 1 below.

Parameter		Myopia Cohort N=212 subjects (249 eyes)	
		n/N[4]	%
Gender	Male	93	43.87%
	Female	119	56.13%
Race	Caucasian	157	74.06%
	Asian	8	3.77%
	Black	4	1.89%
	Hispanic	37	17.45%
	Other	6	2.83%
Surgical Eye	Right	128	51.41%
	Left	121	48.59%
Age (in years)	Mean (std)	34.0 (9.3)	
	Min - Max	18 - 65	

Table 1: Summary Of Demographic Information

Age of the subjects in the Topo-guided (T-CAT) LASIK ranged from 18 to 65 years, with a mean age of 34.0 years, at the time the Topo-guided (T-CAT) LASIK treatment was performed. The subject population consisted of an approximately equal number of male (44%) and female (56%) subjects. The study was performed at nine sites in the United States. Study subjects treated at investigative sites located in the Midwest or Southeast were predominantly Caucasian, while the subject populations at sites located in the Southwest or West were primarily Caucasian or Hispanic. The eyes treated in the T-CAT-001 myopic study cohort were approximately equally distributed, with 128 (51%) right eyes treated and 121 (49%) left eyes treated. The age, race, and gender of each site's study cohort were characteristic of the site's typical LASIK patient population.

[4] Gender, Race, and Age n/N's are based on the 212 subjects enrolled in the study that had eyes treated. Surgical Eye n/N is based on the total 249 eyes treated in the study.

The preoperative bin distribution, based on the preoperative manifest refraction at the spectacle plane that was used in calculating the Topo-guided (T-CAT) LASIK treatment plan, is summarized below, with stratification based on sphere and cylinder in Table 2 and on MRSE and cylinder in Table 3 (see page 25). All Topo-guided (T-CAT) treated eyes were targeted for emmetropia, with the measured pre-treatment clinical manifest refraction entered into the T-CAT software to calculate the treatment plan used as the attempted refraction for the refractive predictability calculations. All 249 treated eyes are included in the safety and efficacy cohorts.

	Attempted Cylinder Correction								
Attempted Sphere Correction	**0.00D**	**-0.01 to -0.50 D**	**-0.51 to -1.00 D**	**-1.01 to -2.00 D**	**-2.01 to -3.00 D**	**-3.01 to -4.00 D**	**-4.01 to -5.00 D**	**-5.01 to -6.00 D**	**Total**
0.00 to -1.00 D	4	7	6	11	4	2	4	1	39
-1.01 to -2.00 D	2	9	11	7	9	2	0	1	41
-2.01 to -3.00 D	3	12	3	2	2	2	3	0	27
-3.01 to -4.00 D	6	8	7	4	5	3	0	0	33
-4.01 to -5.00 D	2	6	6	6	0	1	0	0	21
-5.01 to -6.00 D	4	11	2	3	5	2	0	0	27
-6.01 to -7.00 D	6	5	2	5	3	0	0	0	21
-7.01 to -8.00 D	6	6	5	5	1	0	0	0	23
-8.01 to -9.00 D	5	9	3	0	0	0	0	0	17
Total N	38	73	45	43	29	12	7	2	249

Table 2: T-CAT-001 Bin Distribution Stratified By Attempted Sphere And Cylinder

	Attempted Cylinder Correction								
Attempted MRSE	**0.00D**	**-0.01 to -0.50 D**	**-0.51 to -1.00 D**	**-1.01 to -2.00 D**	**-2.01 to -3.00 D**	**-3.01 to -4.00 D**	**-4.01 to -5.00 D**	**-5.01 to -6.00 D**	**Total**
0.00 to -1.00 D	4	2	1	1	0	0	0	0	8
-1.01 to -2.00 D	2	11	9	11	4	0	0	0	37
-2.01 to -3.00 D	3	10	7	6	8	3	2	1	40
-3.01 to -4.00 D	6	12	6	2	3	2	2	0	33
-4.01 to -5.00 D	2	5	6	7	5	1	2	1	29
-5.01 to -6.00 D	4	9	4	5	0	3	1	0	26
-6.01 to -7.00 D	6	6	3	2	3	1	0	0	21
-7.01 to -8.00 D	6	7	5	5	4	2	0	0	29
-8.01 to -9.00 D	5	11	4	4	2	0	0	0	26
Total N	38	73	45	43	29	12	7	2	249

Table 3: T-CAT-001 Bin Distribution Stratified By Attempted MRSE And Cylinder

4.5. Accountability By Eye

Accountability by eye is summarized below in Table 4 for the Topo-guided (T-CAT) LASIK myopic cohort. Accountability for the entire study is excellent, with accountability at each visit ranging from 95.0% to 100.0%. The accountability at the 12-month final visit is 95.0%.

Status[5]	1 Day		1 Week		1 Month		3 Months		6 Months		9 Months		12 Months	
Enrolled (N)	249		249		249		249		249		249		249	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
Available for Analysis	248	99.6	249	100	248	99.6	247	99.2	244	98.0	237	95.2	230	92.4
Discontinued	0	0	0	0	1	0.4	1	0.4	1	0.4	2	0.8	7	2.8
Active (Not Eligible for Interval)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lost to Follow-up	0	0	0	0	0	0	0	0	2	0.8	8	3.2	12	4.8
Missed Visit (Accounted for)	1	0.4	0	0	0	0	1	0.4	2	0.8	2	0.8	0	0
% Accountability		99.6		100		100		99.6		98.4		96.0		95.0

Table 4: Accountability By Eye For All Eyes Treated For Myopia

[5] N = Enrolled (total number of eyes that underwent a primary Topo-guided (T-CAT) LASIK treatment).
Discontinued = Total number of eyes no longer under observation.
Active = Total number of eyes that underwent a primary Topo-guided (T-CAT) LASIK treatment but had not reached the postoperative interval being reported.
Lost to Follow-up = Total number of eyes that failed to complete the specified examination interval and all subsequent examination intervals; includes eyes of subjects who moved, those who refused to come back for additional exams, and subjects who were contacted by telephone but did not complete any subsequent exams.
Missed Visit = Total number of eyes that failed to undergo the specified examination interval but completed a subsequent visit.

$$\%\ Accountability = \frac{Available\ for\ Analysis}{Enrolled - Discontinued - Not\ Yet\ Eligible}$$

4.6. Stability Of Manifest Refraction

Refractive stability was calculated as the mean change (paired differences) in MRSE (± S.D. and 95% C.I.) between pairs of successive refractions. Refractive stability for eyes that completed one or more pairs of successive postoperative visits is presented below in Table 5, and in Table 6 on page 28 for a consistent cohort of eyes that completed every postoperative visit at 1, 3, 6, 9, and 12 months. As shown in Table 6 on page 28, the mean annual change in MRSE from 1 to 3 months and from 3 to 6 months was -0.050 D/year and - 0.176 D/year, respectively, for the consistent cohort of eyes. The mean change is well below the target value of 0.5 D/year change in MRSE. Additionally, 99.6% of the eyes in the consistent cohort had a change in MRSE from 1 to 3 months that was ≤ 1.0 D; and 100% of the eyes achieved this same degree of refractive stability for the 3 to 6 month postoperative interval. Based on these analyses, refractive stability is achieved at 3 months and confirmed at 6 months postoperatively for this cohort of eyes treated with Topo-guided (T-CAT) LASIK.

		Week 1 to Month 1	Month 1 to Month 3	Month 3 to Month 6	Month 6 to Month 9	Month 9 to Month 12
Change of MRSE < = 1.0 D	n/N	247/248	246/247	243/243	236/236	227/228
	(%)	(99.60%)	(99.60%)	(100.0%)	(100.0%)	(99.56%)
	(CI)	(98.8, 100.0)	(98.8, 100.0)	(100.0, 100.0)	(100.0, 100.0)	(98.7, 100.0)
Change of MRSE <= 0.5 D	n/N	231/248	237/247	235/243	225/236	219/228
	(%)	(93.15%)	(95.95%)	(96.71%)	(95.34%)	(96.05%)
	(CI)	(90.0, 96.3)	(93.5, 98.4)	(94.5, 99.0)	(92.6, 98.0)	(93.5, 98.6)
Change of MRSE in diopters	Mean	0.051	-0.005	-0.043	-0.010	0.016
	Std	0.10	0.07	0.06	0.06	0.06
	(CI)	(0.01, 0.09)	(-0.04, 0.03)	(-0.08,-0.01)	(-0.04, 0.02)	(-0.02, 0.05)
Mean Change of MRSE per Year	Mean	0.617	-0.030	-0.173	-0.040	0.065
	Std	13.96	2.58	1.03	0.90	1.01
	(CI)	(0.15, 1.08)	(-0.23, 0.17)	(-0.30,-0.05)	(-0.16, 0.08)	(-0.07, 0.20)

Table 5: Refractive Stability For Eyes That Have Paired Differences At Any Of The Specified Visit Intervals (Completed One Or More Visits) - All Eyes Treated

		Week 1 to Month 1	Month 1 to Month 3	Month 3 to Month 6	Month 6 to Month 9	Month 9 to Month 12
Change of MRSE < = 1.0 D	n/N	227/227	226/227	227/227	227/227	226/227
	(%)	(100.0%)	(99.56%)	(100.0%)	(100.0%)	(99.56%)
	(CI)	(98.4,100.0)	(97.6,100.0)	(98.4,100.0)	(98.4,100.0)	(97.6,100.0)
Change of MRSE < = 0.5 D	n/N	212/227	217/227	219/227	216/227	218/227
	(%)	(93.39%)	(95.59%)	(96.48%)	(95.15%)	(96.04%)
	(CI)	(89.3, 96.3)	(92.0, 97.9)	(93.2, 98.5)	(91.5, 97.6)	(92.6, 98.2)
Change of MRSE in diopters	Mean	0.058	-0.008	-0.044	-0.017	0.014
	Std	0.09	0.07	0.06	0.06	0.06
	(CI)	(0.02, 0.10)	(-0.04, 0.03)	(-0.08,-0.01)	(-0.05, 0.01)	(-0.02, 0.05)
Mean Change of MRSE per Year	Mean	0.694	-0.050	-0.176	-0.068	0.057
	Std	13.40	2.66	1.04	0.89	1.00
	(CI)	(0.22, 1.17)	(-0.26, 0.16)	(-0.31,-0.04)	(-0.19, 0.06)	(-0.07, 0.19)

Table 6: Refractive Stability For Eyes That Have Paired Differences At All Of The Specified Visit Intervals (Completed All Visits) - All Eyes Treated

4.7. Safety Outcomes

Change in BSCVA, Complications, Adverse Events, And Subjective Symptoms

A summary of key safety and efficacy variables at each of the postoperative visits is provided below in Table 7 for the myopia cohort.

		Month 1	Month 3	Month 6	Month 9	Month 12
SAFETY VARIABLES						
Loss of 2 or more lines BCVA[6]	n/N	1/248	0/247	1/244	0/237	1/230
	(%)	(0.40%)	(0.00%)	(0.41%)	(0.00%)	(0.43%)
	(CI)	(0.0, 2.2)	(0.0, 1.5)	(0.0, 2.3)	(0.0, 1.5)	(0.0, 2.4)
BCVA worse than 20/40	n/N	0/248	0/247	1/244	0/237	0/230
	(%)	(0.00%)	(0.00%)	(0.41%)	(0.00%)	(0.00%)
	(CI)	(0.0, 1.5)	(0.0, 1.5)	(0.0, 2.3)	(0.0, 1.5)	(0.0, 1.6)
Increase > 2D cylinder (spherical only)	n/N	0/ 37	0/ 37	0/ 36	0/ 36	0/ 36
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 9.5)	(0.0, 9.5)	(0.0, 9.7)	(0.0, 9.7)	(0.0, 9.7)
BCVA worse than 20/40 if 20/20 or better preop	n/N	0/242	0/241	1/238	0/232	0/225
	(%)	(0.00%)	(0.00%)	(0.42%)	(0.00%)	(0.00%)

Table 7: Summary Of Key Safety Parameters After Topo-guided (T-CAT) LASIK

Excellent clinical safety outcomes were reported in the myopic Topo-guided (T-CAT) LASIK treated eyes. Loss of BSCVA was minimal, with only 5 single reports of BSCVA loss of 2 lines or more at any of the 1 month or later, scheduled or unscheduled, postoperative visits in the study. All five of these instances of BSCVA loss were transient, unrelated to the Topo-guided (T-CAT) LASIK treatment and resolved by the next postoperative follow-up visit.

[6] Two additional eyes had single reports of transient loss of 2 or more lines of BSCVA at unscheduled visits. These eyes are reported as occurring at unscheduled visits in table 10 “Adverse Events For All Myopic Eyes Treated With Topo-guided (T-CAT) LASIK” on page 32.

The key safety parameters at 3 months after Topo-guided (T-CAT) LASIK, stratified by each preoperative MRSE dioptric bin and by each preoperative cylinder bin, are presented in the Tables 8 below and 9 on page 31, respectively. Refractive stability is attained at 3 months postoperatively and confirmed at 6 months; thus, the 3-month time point of refractive stability visit was selected for presentation of these safety results. Similar safety results are observed in the stratified bins as are seen in the entire cohort. Thus, the clinical safety outcomes support the refractive range for the approved indications for use.

		-0.01 TO -1.00D	-1.01 TO -2.00D	-2.01 TO -3.00D	-3.01 TO -4.00D	-4.01 TO -5.00D	-5.01 TO -6.00D	-6.01 TO -7.00D	-7.01 TO -8.00D	-8.01 TO -9.00D	CUM TOTAL
SAFETY VARIABLES											
Loss of 2 or more lines BCVA	n/N	0/8	0/37	0/40	0/33	0/28	0/26	0/20	0/29	0/26	0/247
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 36.9)	(0.0, 9.5)	(0.0, 8.8)	(0.0, 10.6)	(0.0, 12.3)	(0.0, 13.2)	(0.0, 16.8)	(0.0, 11.9)	(0.0, 13.2)	(0.0, 1.5)
BCVA worse than 20/40	n/N	0/8	0/37	0/40	0/33	0/28	0/26	0/20	0/29	0/26	0/247
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 36.9)	(0.0, 9.5)	(0.0, 8.8)	(0.0, 10.6)	(0.0, 12.3)	(0.0, 13.2)	(0.0, 16.8)	(0.0, 11.9)	(0.0, 13.2)	(0.0, 1.5)
Increase > 2D cylinder	n/N	0/4	0/2	0/3	0/6	0/2	0/4	0/5	0/6	0/5	0/37
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 60.2)	(0.0, 84.2)	(0.0, 70.8)	(0.0, 45.9)	(0.0, 84.2)	(0.0, 60.2)	(0.0, 52.2)	(0.0, 45.9)	(0.0, 52.2)	(0.0, 9.5)
BCVA worse than 20/40 if 20/20 or better preop	n/N	0/8	0/37	0/40	0/32	0/28	0/25	0/19	0/26	0/26	0/241
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 36.9)	(0.0, 9.5)	(0.0, 8.8)	(0.0, 10.9)	(0.0, 12.3)	(0.0, 13.7)	(0.0, 17.6)	(0.0, 13.2)	(0.0, 13.2)	(0.0, 1.5)

Table 8: Summary Of Key Safety Parameters Stratified By Pre-Treatment MRSE - Results At 3 Months After Topo-guided (T-CAT) LASIK

		0.00D	0.01 TO 0.50D	0.51 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	3.01 TO 4.00D	4.01 TO 5.00D	5.01 to 6.00D	CUM TOTAL
SAFETY VARIABLES										
Loss of 2 or more lines BCVA	n/N	0/37	0/72	0/45	0/43	0/29	0/12	0/7	0/2	0/247
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 9.5)	(0.0, 5.0)	(0.0, 7.9)	(0.0, 8.2)	(0.0, 11.9)	(0.0, 26.5)	(0.0, 41.0)	(0.0, 84.2)	(0.0, 1.5)
BCVA worse than 20/40	n/N	0/37	0/72	0/45	0/43	0/29	0/12	0/7	0/2	0/247
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 9.5)	(0.0, 5.0)	(0.0, 7.9)	(0.0, 8.2)	(0.0, 11.9)	(0.0, 26.5)	(0.0, 41.0)	(0.0, 84.2)	(0.0, 1.5)
Increase > 2D cylinder (spherical only)	n/N	0/37	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/37
	(%)	(0.00%)								(0.00%)
	(CI)	(0.0, 9.5)								(0.0, 9.5)
BCVA worse than 20/40 if 20/20 or better preop	n/N	0/37	0/70	0/45	0/42	0/28	0/10	0/7	0/2	0/241
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 9.5)	(0.0, 5.1)	(0.0, 7.9)	(0.0, 8.4)	(0.0, 12.3)	(0.0, 30.8)	(0.0, 41.0)	(0.0, 84.2)	(0.0, 1.5)

Table 9: Summary Of Key Safety Parameters Stratified By Pre-Treatment Cylinder - Results At 3 Months After Topo-guided (T-CAT) LASIK

Adverse events and complications that occurred during the study at all scheduled and unscheduled visits are presented in Tables 10 below and 11 on page 33, respectively. All other ocular or vision-related postoperative observations recorded during the study are summarized in Table 12 (see page 35). As shown in Table 10 below, the cumulative rate of safety events classified as adverse events was 1.6% for BSCVA loss of 2 or more lines, all of which were transient and unrelated to the Topo-guided (T-CAT) LASIK procedure, and 0.8% for retinal detachments, occurring bilaterally in the same subject. At the final 12-month postoperative study visit, the safety observations of any type included reports of dry eye requiring no treatment or ocular lubricants as needed (8.7%), blurred vision at distance or near (2.6%), mild superficial punctuate keratitis (1.7%), ocular irritation (1.4%), dry eyes requiring punctal plugs or prescribed use of ocular lubricants (1.3%), fluctuation in vision (1.3%), starbursts (1.3%), itching (0.9%), esophoria (0.4%), vitreous floaters (0.4%), headache (0.4%), difficulty night driving (0.4%), and superficial punctate keratitis ungraded (0.4%)

ADVERSE EVENTS	Intraop (N=249)	Day 1 (N=248)	Week 1 (N=249)	Month 1 (N=248)	Month 3 (N=247)	Month 6 (N=244)	Month 9 (N=237)	Month 12 (N=230)	Un-scheduled[7] (n)
Diffuse lamellar keratitis with progressive melt		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Corneal infiltrate or ulcer		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Any corneal epithelial defect involving keratectomy site at 1 month or later				0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Corneal edema at 1 month or later				0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Epithelium in interface with loss of 2 or more lines of BSCVA		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Miscreated flap (lost, incomplete, too thin)		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Melting of the flap		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
IOP on 2 consecutive exams that is > 10 mm Hg above baseline or > 30 mm Hg		0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Haze beyond 6 mos. with loss of ≥2 lines (≥ 10 letters) BSCVA							0 (0.00%)	0 (0.00%)	0
Decrease of BSCVA of ≥ 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 3 months or later					0 (0.00%)	1 (0.41%)	0 (0.00%)	1 (0.43%)	2
Retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2(0.82%)	0 (0.00%)	0 (0.00%)	0
Retinal vascular accidents	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Any other vision threatening event	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Ocular penetration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	

Table 10: Adverse Events For All Myopic Eyes Treated With Topo-guided (T-CAT) LASIK

[7] BSCVA loss, new reports n = 2

COMPLICATIONS	Intraop (N=249)	Day 1 (N=248)	Week 1 (N=249)	Month 1 (N=248)	Month 3 (N=247)	Month 6 (N=244)	Month 9 (N=237)	Month 12 (N=230)	Un-scheduled[8] (n)
Corneal edema between 1 week and 1 month after procedure			1 (0.40%)	0 (0.00%)					0
Peripheral corneal epithelial defect at 1 month or later				0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Epithelium in interface, >2mm				0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Foreign body sensation at 1 month or later				7 (2.82%)	5 (2.02%)	3 (1.23%)	0 (0.00%)	0 (0.00%)	0
Pain at 1 month or later				2 (0.81%)	0 (0.00%)	0 (0.00%)	2 (0.84%)	0 (0.00%)	0
Double images in the operative eye		0 (0.00%)	0 (0.00%)	2 (0.81%)	1 (0.40%)	1 (0.41%)	2 (0.84%)	0 (0.00%)	1
Ghost images in the operative eye		0 (0.00%)	1 (0.40%)	2 (0.81%)	2(0.81%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2
Flap is not of the size and shape as initially intended or microkeratome stopped mid-cut or resultant flap is misaligned	0 (0.00%)	2 (0.80%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Diffuse lamellar keratitis		5 (2.01%)	2 (0.80%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4
Dry eyes requiring punctal plugs or prescribed use of ocular lubricants at 3 months or later					10 (4.05%)	8 (3.28%)	6 (2.53%)	3 (1.30%)	6

Table 11: Complications For All Myopic Eyes Treated With Topo-guided (T-CAT) LASIK

[8] Double images, new report n=1; Ghost images, new report n = 2; Diffuse lamellar keratitis, new report n = 1, ongoing reports n = 3; Dry eyes with treatment, new reports n = 4, ongoing reports n = 2.

Observation	Day 1 (N=249)	Week 1 (N=249)	Month 1 (N=248)	Month 3 (N=247)	Month 6 (N=244)	Month 9 (N=237)	Month 12 (N=230)	Un-scheduled (n)
Abrasion, corneal	1 (0.40%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2
BSCVA Loss 10 or more Letters, before 3 months	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2
Blepharitis	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	0 (0.00%)	0
Blurred vision	0 (0.00%)	11 (4.42%)	10 (4.03%)	5 (2.02%)	7 (2.87%)	3 (1.27%)	6 (2.61%)	14
Chalazion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	0 (0.00%)	0
Conjunctivitis	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	2 (0.84%)	0 (0.00%)	2
Discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.41%)	1 (0.42%)	0 (0.00%)	0
Discomfort	3 (1.20%)	4 (1.61%)	0 (0.00%)	2 (0.81%)	2 (0.82%)	2 (0.84%)	0 (0.00%)	1
Dry eye	0 (0.00%)	25 (10.04%)	32 (12.90%)	25 (10.12%)	25 (10.25%)	23 (9.70%)	20 (8.70%)	9
Dry eye, with treatment	0 (0.00%)	5 (2.01%)	13 (5.24%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5
Edema, corneal	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Epithelial defect, peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Epithelium in interface, 2 mm or less	0 (0.00%)	1 (0.40%)	2 (0.81%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Esophoria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.43%)	1
Eye fatigue	1 (0.40%)	3 (1.20%)	2 (0.81%)	2 (0.81%)	2 (0.82%)	0 (0.00%)	0 (0.00%)	1
Eyelid swelling	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Foreign body sensation	0 (0.00%)	4 (1.61%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Flare	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	0 (0.00%)	0
Floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.64%)	1 (0.42%)	1 (0.43%)	2
Fluctuation	0 (0.00%)	7 (2.81%)	6 (2.42%)	0 (0.00%)	7 (2.87%)	3 (1.27%)	3 (1.30%)	0
Folliculitis	0 (0.00%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Foreign Body	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2
Glare	1 (0.40%)	0 (0.00%)	5 (2.02%)	2 (0.81%)	5 (2.05%)	3 (1.27%)	0 (0.00%)	1
Halo	2 (0.80%)	13 (5.22%)	7 (2.82%)	3 (1.21%)	6 (2.46%)	2 (0.84%)	0 (0.00%)	0
Headache	0 (0.00%)	2 (0.80%)	3 (1.21%)	0 (0.00%)	4 (1.64%)	2 (0.84%)	1 (0.43%)	1
Hordeolum	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	1 (0.42%)	0 (0.00%)	0
Infiltrate, subepithelial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	0 (0.00%)	1
Injury, trauma	0 (0.00%)	2 (0.80%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.42%)	0 (0.00%)	2
Interface inflammation	1 (0.40%)	1 (0.40%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7
Intraocular Pressure Elevation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3

Observation	Day 1 (N=249)	Week 1 (N=249)	Month 1 (N=248)	Month 3 (N=247)	Month 6 (N=244)	Month 9 (N=237)	Month 12 (N=230)	Un-scheduled (n)
Irritation	0 (0.00%)	12 (4.82%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.84%)	4 (1.74%)	2
Itching	3 (1.20%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.87%)	1
Keratitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.42%)	0 (0.00%)	0
Light Flashes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Meibomian Gland Dysfunction	0 (0.00%)	1 (0.40%)	3 (1.21%)	2 (0.81%)	5 (2.05%)	2 (0.84%)	0 (0.00%)	3
Night driving difficulty	0 (0.00%)	2 (0.80%)	2 (0.81%)	3 (1.21%)	3 (1.23%)	5 (2.11%)	1 (0.43%)	0
Pain	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Papilloma	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	0 (0.00%)	0
Photophobia	1 (0.40%)	7 (2.81%)	8 (3.23%)	5 (2.02%)	3 (1.23%)	2 (0.84%)	0 (0.00%)	4
Reading difficulty	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.40%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0
Redness	2 (0.80%)	1 (0.40%)	2 (0.81%)	3 (1.21%)	0 (0.00%)	2 (0.84%)	0 (0.00%)	1
Superficial punctate keratitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.41%)	0 (0.00%)	1 (0.43%)	2
Superficial punctate keratitis, mild	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.81%)	5 (2.05%)	4 (1.69%)	4 (1.74%)	4
Superficial punctate keratitis, moderate	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.40%)	1 (0.41%)	1 (0.42%)	0 (0.00%)	0
Secondary Surgical Intervention	2 (0.80%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.82%)	0 (0.00%)	0 (0.00%)	1
Starburst	0 (0.00%)	4 (1.61%)	3 (1.21%)	1 (0.40%)	2 (0.82%)	0 (0.00%)	3 (1.30%)	0
Striae	2 (0.80%)	4 (1.61%)	2 (0.81%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1
Tearing	1 (0.40%)	0 (0.00%)	2 (0.81%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1

Table 12: Observations Occurring In All Myopia Eyes Treated With Topo-guided (T-CAT) LASIK

Contrast sensitivity was evaluated preoperatively and at 3 and 6 months after the topography-guided LASIK procedure, with and without glare, under mesopic (3 cd/m^2) and photopic (85 cd/m^2) chart luminance conditions. For the T-CAT-001 study, each treated eye was tested at each of the five spatial frequencies with and without glare under the following test conditions:

- Photopic (85 cd/m^2) without glare
- Photopic (85 cd/m^2) with glare (10 lux)
- Mesopic (3 cd/m^2) without glare
- Mesopic (3 cd/m^2) with glare (1 lux)

All testing was performed at screening with the subject's best correction for viewing. Postoperatively, testing was performed with the subject's best correction for viewing or could be performed uncorrected if the subject's measured UCVA was equal to, or better than, the subject's measured BSCVA at the visit.

The changes in Log_{10} mesopic (3 cd/m^2) and photopic (85 cd/m^2) contrast sensitivity (Log_{10} [Threshold $Contrast^{-1}$]) without and with glare at 3 months after LASIK are presented in Tables 13 and 14 below, respectively. Testing without glare and with glare demonstrated statistically significant improvement in Log_{10} mesopic (3 cd/m^2) and photopic (85 cd/m^2) contrast sensitivity (Log_{10} [Threshold $Contrast^{-1}$]) at 3 months and 6 months after LASIK for nearly all tested spatial frequencies.

Visit	Type	Cycles per Degree	Total N	Preop n	PreOp N_0	Preop Mean	Preop SD	Postop n	Visit N_0	Postop Mean	Postop SD	Paired Difference n	Difference N_0	Paired Difference Mean	Paired Difference SD
Postop Month 3	Mesopic	(1.5)	247	245	1	1.6019	0.2323	245	0	1.6609	0.2521	243	1	0.0613	0.1806
		(3)	247	245	1	1.6116	0.3450	245	0	1.6546	0.3778	243	1	0.0372	0.4946
		(6)	247	240	6	1.7107	0.2718	245	0	1.7850	0.2539	239	6	0.0828	0.2512
		(12)	247	213	33	1.3893	0.2947	228	17	1.4017	0.3005	204	41	0.0430	0.3096
		(18)	247	166	79	1.0022	0.2972	178	67	1.0205	0.2830	135	109	0.0371	0.3310
	Photopic	(1.5)	247	237	0	1.5969	0.2408	245	0	1.6379	0.2271	235	0	0.0435	0.1937
		(3)	247	236	1	1.6223	0.3755	245	0	1.6835	0.4092	234	1	0.0681	0.4870
		(6)	247	235	2	1.7995	0.2453	245	0	1.9140	0.2223	233	2	0.1132	0.2120
		(12)	247	230	7	1.4752	0.2840	242	3	1.6134	0.2581	226	10	0.1371	0.2876
		(18)	247	202	34	1.0924	0.2939	229	16	1.2167	0.3054	192	44	0.1424	0.3670
Postop Month 6	Mesopic	(1.5)	244	241	1	1.6016	0.2375	244	0	1.6725	0.2581	241	1	0.0712	0.1974
		(3)	244	241	1	1.6048	0.3484	244	0	1.6826	0.3950	241	1	0.0738	0.4925
		(6)	244	235	7	1.7003	0.2615	243	1	1.7962	0.2660	234	8	0.0990	0.2798
		(12)	244	206	36	1.3875	0.2911	226	18	1.4441	0.3051	198	44	0.0757	0.3306
		(18)	244	161	80	0.9893	0.2825	186	58	1.0592	0.3212	140	101	0.0871	0.3872
	Photopic	(1.5)	244	235	0	1.5921	0.2372	244	0	1.6602	0.2488	235	0	0.0703	0.2178
		(3)	244	234	1	1.6257	0.3708	244	0	1.7204	0.4115	234	1	0.1016	0.5311
		(6)	244	234	1	1.8015	0.2542	244	0	1.9227	0.2385	234	1	0.1217	0.2510
		(12)	244	230	5	1.4720	0.2903	240	4	1.6186	0.2659	228	7	0.1440	0.2849
		(18)	244	201	33	1.0992	0.3064	234	10	1.2298	0.2924	198	36	0.1516	0.3395

Table 13: Changes In Log_{10} Mesopic And Photopic Contrast Sensitivity (Log_{10} [Threshold Contrast^{-1}]) Without Glare At 3 Months And 6 Months After T-CAT LASIK[9]

[9] ** N_o patients are not included in the mean because they could not see any contrast level. Mean results with N_o>0 are, therefore, biased upward; and, the corresponding standard deviations are biased downward.*
Preop Mean: Calculated as the average of the log values of each individual preoperative contrast sensitivity measurement.
Postop Mean: Calculated as the average of the log values of each individual postoperative contrast sensitivity measurement.
Percent Change Mean: Calculated as the average of the individual paired differences (postop-preop) of the log values for each eye.

Visit	Type	Cycles per Degree	Total N	Preop n	PreOp N_0	Preop Mean	Preop SD	Postop n	Visit N_0	Postop Mean	Postop SD	Paired Difference n	Difference N_0	Paired Difference Mean	Paired Difference SD
Postop Month 3	Mesopic	(1.5)	247	242	4	1.5055	0.2758	244	1	1.5650	0.2703	239	5	0.0646	0.2269
		(3)	247	241	5	1.6835	0.2735	243	2	1.7323	0.2636	239	5	0.0502	0.2316
		(6)	247	229	16	1.6355	0.2964	241	4	1.7072	0.2577	226	18	0.0897	0.3025
		(12)	247	191	54	1.3714	0.3061	210	35	1.3590	0.2899	176	68	0.0178	0.3166
		(18)	247	146	99	1.0063	0.3021	168	77	0.9726	0.3013	119	125	0.0100	0.3791
	Photopic	(1.5)	247	237	0	1.5689	0.2493	245	0	1.6574	0.2405	235	0	0.0935	0.2087
		(3)	247	235	2	1.7827	0.2229	245	0	1.8845	0.2151	233	2	0.1051	0.2022
		(6)	247	229	2	1.7926	0.2617	241	0	1.8936	0.2288	224	2	0.0999	0.2377
		(12)	247	223	14	1.4741	0.2853	242	3	1.5966	0.2663	220	16	0.1312	0.2911
		(18)	247	203	33	1.0776	0.2928	234	11	1.2248	0.2866	196	40	0.1619	0.3551
Postop Month 6	Mesopic	(1.5)	244	238	4	1.5004	0.2770	244	0	1.5809	0.2711	238	4	0.0838	0.2548
		(3)	244	237	5	1.6710	0.2642	242	2	1.7480	0.2847	236	6	0.0785	0.2789
		(6)	244	225	16	1.6228	0.2966	237	7	1.7281	0.2603	222	19	0.1053	0.3086
		(12)	244	185	56	1.3632	0.3001	219	25	1.3918	0.2989	177	64	0.0669	0.3138
		(18)	244	140	101	0.9968	0.2806	167	76	1.0124	0.2797	112	130	0.0374	0.3536
	Photopic	(1.5)	244	235	0	1.5684	0.2502	244	0	1.6803	0.2562	235	0	0.1162	0.2405
		(3)	244	233	2	1.7905	0.2283	244	0	1.8821	0.2345	233	2	0.0918	0.2132
		(6)	244	227	2	1.7990	0.2572	243	1	1.9260	0.2428	226	3	0.1269	0.2646
		(12)	244	223	12	1.4746	0.2942	240	4	1.6296	0.2749	222	13	0.1610	0.3185
		(18)	244	203	31	1.0827	0.3105	231	13	1.2439	0.3152	195	39	0.1726	0.3688

Table 14: Changes In Log_{10} Mesopic And Photopic Contrast Sensitivity (Log_{10} [Threshold Contrast^{-1}]) With Glare At 3 Months And 6 Months After T-CAT LASIK[10]

[10] ** N_o patients are not included in the mean because they could not see any contrast level. Mean results with N_o>0 are, therefore, biased upward; and, the corresponding standard deviations are biased downward.*
Preop Mean: Calculated as the average of the log values of each individual preoperative contrast sensitivity measurement.
Postop Mean: Calculated as the average of the log values of each individual postoperative contrast sensitivity measurement.
Percent Change Mean: Calculated as the average of the individual paired differences (postop-preop) of the log values for each eye.

Clinically significant changes in contrast sensitivity, at 3 and 6 months after Topo-guided (T-CAT) LASIK, are summarized in Table 15 below. A clinically significant increase or decrease in contrast sensitivity is defined as an increase or decrease of at least 0.3 log units at two or more spatial frequencies. In addition, any transition from seeing to not seeing, or, from not seeing to seeing a grating at the highest available contrast is considered equivalent to a ≥ 0.3 log unit change for the purpose of assessing clinical significance. As shown in Table 15, the percentage of Topo-guided (T-CAT) LASIK treated eyes with a clinically significant increase in contrast sensitivity was two to three folds higher than those eyes with clinically significant decreases, both with and without glare under mesopic and photopic testing conditions at 3 and 6 months postoperatively.

Visit	Luminance	Glare	Clinically Significant Decrease n/N (%)	Clinically Significant Increase n/N (%)
Postop Month 3	Mesopic	Glare	25/210 (11.90)	50/210 (23.81)
		No Glare	15/210 (7.14)	43/210 (20.48)
	Photopic	Glare	18/210 (8.57)	58/210 (27.62)
		No Glare	19/210 (9.05)	55/210 (26.19)
Postop Month 6	Mesopic	Glare	31/207 (14.98)	68/207 (32.85)
		No Glare	16/207 (7.73)	52/207 (25.12)
	Photopic	Glare	20/207 (9.66)	65/207 (31.40)
		No Glare	17/207 (8.21)	66/207 (31.88)

Table 15: Clinically Significant Changes In Log_{10} Mesopic And Photopic Contrast Sensitivity (Log_{10} [Threshold Contrast-^{1}]) With And Without Glare At 3 Months And 6 Months After Topo-guided (T-CAT) LASIK

4.8. Efficacy Outcomes

Changes In Manifest Refraction, Refractive Stability, Vector Analyses, Changes In UCVA, Patient-Reported Outcomes

A summary of key efficacy variables at each of the postoperative visits is provided below in Table 16 for the myopia cohort treated with Topo-guided (T-CAT) LASIK.

		Month 1	Month 3	Month 6	Month 9	Month 12
EFFICACY VARIABLES						
MRSE ± 0.50 D	n/N	220/248	227/247	227/244	221/237	218/230
	(%)	(88.71%)	(91.90%)	(93.03%)	(93.25%)	(94.78%)
	(CI)	(84.1, 92.4)	(87.8, 95.0)	89.1, 95.9)	(89.3, 96.1)	(91.1, 97.3)
MRSE ± 1.00 D	n/N	244/248	244/247	241/244	235/237	229/230
	(%)	(98.39%)	(98.79%)	(98.77%)	(99.16%)	(99.57%)
	(CI)	(95.9, 99.6)	(96.5, 99.7)	(96.4, 99.7)	(97.0, 99.9)	(97.6,100.0)
MRSE ± 2.00 D	n/N	248/248	247/247	243/244	237/237	230/230
	(%)	(100.0%)	(100.0%)	(99.59%)	(100.0%)	(100.0%)
	(CI)	(98.5,100.0)	(98.5,100.0)	(97.7,100.0)	(98.5,100.0)	(98.4,100.0)
UCVA 20/20 or better	n/N	217/248	229/247	217/244	212/237	213/230
	(%)	(87.50%)	(92.71%)	(88.93%)	(89.45%)	(92.61%)
	(CI)	(82.7, 91.3)	(88.7, 95.6)	(84.3, 92.6)	(84.8, 93.1)	(88.4, 95.6)
UCVA 20/40 or better if BCVA 20/20 or better preop	n/N	239/242	239/241	235/238	231/232	224/225
	(%)	(98.76%)	(99.17%)	(98.74%)	(99.57%)	(99.56%)
	(CI)	(96.4, 99.7)	(97.0, 99.9)	(96.4, 99.7)	(97.6,100.0)	(97.5,100.0)

Table 16: Summary Of Key Efficacy Parameters After Topo-guided (T-CAT) LASIK

Excellent clinical efficacy outcomes were reported in the myopic Topo-guided (T-CAT) LASIK treated eyes. At all postoperative visits from 3 to 12 months, 89% or more of the eyes saw 20/20 or better without correction; and 92% or more of the eyes were within ± 0.5 D of attempted MRSE.

The key efficacy parameters at 3 months after Topo-guided (T-CAT) LASIK, stratified by preoperative MRSE and by each preoperative cylinder, are presented in Tables 17 below and 18 on page 42, respectively. Refractive stability is attained at 3 months postoperatively and confirmed at 6 months; thus, the 3-month time point of refractive stability visit was selected for presentation of these results. Similar clinical results are observed in the stratified bins at 3 months postoperatively as are seen in the entire cohort. Thus, the clinical efficacy outcomes support the refractive range for the proposed indication for use:

		-0.01 TO -1.00D	-1.01 TO -2.00D	-2.01 TO -3.00D	-3.01 TO -4.00D	-4.01 TO -5.00D	-5.01 TO -6.00D	-6.01 TO -7.00D	-7.01 TO -8.00D	-8.01 TO -9.00D	CUM TOTAL
EFFICACY VARIABLES											
MRSE ± 0.50 D	n/N	8/8	36/37	37/40	32/33	24/28	25/26	18/20	26/29	21/26	227/247
	(%)	(100.0%)	(97.30%)	(92.50%)	(96.97%)	(85.71%)	(96.15%)	(90.00%)	(89.66%)	(80.77%)	(91.90%)
	(CI)	(63.1, 100.0)	(85.8, 99.9)	(79.6, 98.4)	(84.2, 99.9)	(67.3, 96.0)	(80.4, 99.9)	(68.3, 98.8)	(72.6, 97.8)	(60.6, 93.4)	(87.8, 95.0)
MRSE ± 1.00 D	n/N	8/8	37/37	40/40	33/33	27/28	26/26	19/20	29/29	25/26	244/247
	(%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(96.43%)	(100.0%)	(95.00%)	(100.0%)	(96.15%)	(98.79%)
	(CI)	(63.1, 100.0)	(90.5, 100.0)	(91.2, 100.0)	(89.4, 100.0)	(81.7, 99.9)	(86.8, 100.0)	(75.1, 99.9)	(88.1, 100.0)	(80.4, 99.9)	(96.5, 99.7)
MRSE ± 2.00 D	n/N	8/8	37/37	40/40	33/33	28/28	26/26	20/20	29/29	26/26	247/247
	(%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(63.1, 100.0)	(90.5, 100.0)	(91.2, 100.0)	(89.4, 100.0)	(87.7, 100.0)	(86.8, 100.0)	(83.2, 100.0)	(88.1, 100.0)	(86.8, 100.0)	(98.5, 100.0)
UCVA 20/20 or better	n/N	8/8	36/37	36/40	32/33	26/28	24/26	16/20	27/29	24/26	229/247
	(%)	(100.0%)	(97.30%)	(90.00%)	(96.97%)	(92.86%)	(92.31%)	(80.00%)	(93.10%)	(92.31%)	(92.71%)
	(CI)	(63.1, 100.0)	(85.8, 99.9)	(76.3, 97.2)	(84.2, 99.9)	(76.5, 99.1)	(74.9, 99.1)	(56.3, 94.3)	(77.2, 99.2)	(74.9, 99.1)	(88.7, 95.6)
UCVA 20/40 or better if BCVA 20/20 or better preop	n/N	8/8	37/37	40/40	32/32	27/28	24/25	19/19	26/26	26/26	239/241
	(%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(96.43%)	(96.00%)	(100.0%)	(100.0%)	(100.0%)	(99.17%)
	(CI)	(63.1, 100.0)	(90.5, 100.0)	(91.2, 100.0)	(89.1, 100.0)	(81.7, 99.9)	(79.6, 99.9)	(82.4, 100.0)	(86.8, 100.0)	(86.8, 100.0)	(97.0, 99.9)

Table 17: Summary Of Key Efficacy Parameters Stratified By Pre-Treatment MRSE -- Results At 3 Months After Topo-guided (T-CAT) LASIK

		0.00D	0.01 TO 0.50D	0.51 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	3.01 TO 4.00D	4.01 TO 5.00D	5.01 to 6.00D	CUM TOTAL
EFFICACY VARIABLES										
MRSE ± 0.50 D	n/N	33/37	66/72	43/45	40/43	27/29	11/12	5/7	2/2	227/247
	(%)	(89.19%)	(91.67%)	(95.56%)	(93.02%)	(93.10%)	(91.67%)	(71.43%)	(100.0%)	(91.90%)
	(CI)	(74.6, 97.0)	(82.7, 96.9)	(84.9, 99.5)	(80.9, 98.5)	(77.2, 99.2)	(61.5, 99.8)	(29.0, 96.3)	(15.8, 100.0)	(87.8, 95.0)
MRSE ± 1.00 D	n/N	36/37	71/72	44/45	43/43	29/29	12/12	7/7	2/2	244/247
	(%)	(97.30%)	(98.61%)	(97.78%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(98.79%)
	(CI)	(85.8, 99.9)	(92.5, 100.0)	(88.2, 99.9)	(91.8, 100.0)	(88.1, 100.0)	(73.5, 100.0)	(59.0, 100.0)	(15.8, 100.0)	(96.5, 99.7)
MRSE ± 2.00 D	n/N	37/37	72/72	45/45	43/43	29/29	12/12	7/7	2/2	247/247
	(%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(90.5, 100.0)	(95.0, 100.0)	(92.1, 100.0)	(91.8, 100.0)	(88.1, 100.0)	(73.5, 100.0)	(59.0, 100.0)	(15.8, 100.0)	(98.5, 100.0)
UCVA 20/20 or better	n/N	36/37	67/72	44/45	42/43	25/29	9/12	4/7	2/2	229/247
	(%)	(97.30%)	(93.06%)	(97.78%)	(97.67%)	(86.21%)	(75.00%)	(57.14%)	(100.0%)	(92.71%)
	(CI)	(85.8, 99.9)	(84.5, 97.7)	(88.2, 99.9)	(87.7, 99.9)	(68.3, 96.1)	(42.8, 94.5)	(18.4, 90.1)	(15.8, 100.0)	(88.7, 95.6)
UCVA 20/40 or better if BCVA 20/20 or better preop	n/N	37/37	69/70	45/45	42/42	28/28	10/10	6/7	2/2	239/241
	(%)	(100.0%)	(98.57%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(85.71%)	(100.0%)	(99.17%)
	(CI)	(90.5, 100.0)	(92.3, 100.0)	(92.1, 100.0)	(91.6, 100.0)	(87.7, 100.0)	(69.2, 100.0)	(42.1, 99.6)	(15.8, 100.0)	(97.0, 99.9)

Table 18: Summary Of Key Efficacy Parameters Stratified By Pre-Treatment Cylinder -- Results At 3 Months After Topo-guided (T-CAT) LASIK

In the stratified MRSE and stratified cylinder analyses, at least 90.0% of the eyes in each dioptric group (except the highest MRSE - 8.01 to - 9.00 D, MRSE - 4.001 to - 5.00, and 4.01 to 5.00 D cylinder groups) achieved a postoperative refraction that was within ± 0.5 D of the attempted refraction. This closely approximates the results for the entire cohort, in which 91.9% of all Topo-guided (T-CAT) LASIK treated eyes were within ± 0.5 D of the attempted achieved manifest refraction.

4.8.1. Mean Manifest Refraction Spherical Equivalent

Mean manifest refraction spherical equivalent (MRSE) outcomes at screening and through 12 months after Topo-guided (T-CAT) LASIK are presented in Table 19 below. As shown in the table, the mean MRSE was 0.06 D at 3 months after Topo-guided (T-CAT) LASIK, with very little change over time as the mean MRSE at 12 months decreased slightly to 0.00 D.

Visit	n	Mean MRSE	Standard Deviation	Lower Confidence Limit	Upper Confidence Limit
Screening	249	- 4.61	2.43	- 4.91	- 4.30
Postop Month 1	248	0.06	0.36	0.02	0.11
Postop Month 3	247	0.06	0.33	0.01	0.10
Postop Month 6	244	0.01	0.35	- 0.03	0.06
Postop Month 9	237	- 0.01	0.30	- 0.04	0.03
Postop Month 12	230	- 0.00	0.27	- 0.04	0.04

Table 19: Descriptive Statistics for Manifest Refraction Spherical Equivalent (MRSE)

4.8.2. Stability Of Manifest Refraction Cylinder Magnitude

Topo-guided (T-CAT) LASIK incorporates a cylinder treatment into the calculated treatment plan if any cylinder magnitude value is entered into the treatment refraction in the T-CAT software. A total of 210 eyes (210/249 eyes; 84.3%) treated in the T-CAT-001 study had an attempted cylinder correction.

Cylinder stability was calculated as the mean change (paired differences) in absolute manifest refraction cylinder magnitude (± S.D. and 95% C.I.) between pairs of successive refractions. Refractive stability for a consistent cohort of 191 eyes that had a cylinder component treated with Topo-guided (T-CAT) LASIK, and completed every postoperative visit at 1, 3, 6, 9, and 12 months, is summarized in Table 20 below. As shown in Table 20, the mean annual change in absolute cylinder magnitude from 1 to 3 months and from 3 to 6 months was 0.220 D/year and 0.047 D/year, respectively, for the consistent cohort of eyes. The mean change is well below the target value of 0.5 D/year change in absolute cylinder magnitude. Additionally, 100% of the eyes in the consistent cohort achieved a change of MRSE that was ≤ 1.0 D during the 1 to 3 months and 3 to 6 months intervals. Consistent with the evaluation of MRSE stability, cylinder stability is achieved at 3 months and confirmed at 6 months postoperatively for this cohort of eyes that had cylinder treatments performed with Topo-guided (T-CAT) LASIK.

		Week 1 to Month 1	Month 1 to Month 3	Month 3 to Month 6	Month 6 to Month 9	Month 9 to Month 12
Change of Absolute Cylinder < = 1.0 D	n/N	189/191	191/191	191/191	189/191	191/191
	(%)	(98.95%)	(100.0%)	(100.0%)	(98.95%)	(100.0%)
Change of Absolute Cylinder < = 0.5 D	n/N	182/191	179/191	187/191	187/191	189/191
	(%)	(95.29%)	(93.72%)	(97.91%)	(97.91%)	(98.95%)
Change of Absolute Cylinder in diopters	Mean	0.020	0.037	0.012	-0.013	-0.005
	Std	0.11	0.08	0.06	0.06	0.04
Mean Change of Absolute Cylinder per Year	Mean	0.236	0.220	0.047	-0.052	-0.021
	Std	15.53	3.05	0.91	0.94	0.72

Table 20: Stability Of Absolute (Non-Vector) Cylinder In A Consistent Cohort Of Eyes That Completed All Visits

The residual cylinder magnitudes and absolute axis shifts at 3 months after T-CAT LASIK surgery, the time point of refractive stability, are presented in Table 21 below. Further stratification by preoperative cylinder shows that the majority of eyes with absolute axis shifts >30 degrees had low cylinder treatments (> 0.0 to -1.0 D cylinder) with residual cylinder of ≤0.5 D.

Residual Cylinder Magnitude		Absolute Shift in Axis						
		0 deg	≤5 deg	>5 to ≤10 deg	>10 to ≤ 15 deg	>15 to ≤30 deg	>30 deg	Total
0D	n (%)	77 (36.67)	0	0	0	0	0	77
	(CI)	(30.14, 43.57)						
>0D to <0.5D	n (%)	0	9 (4.29)	6 (2.86)	4 (1.90)	8 (3.81)	65 (30.95)	92
	(CI)	(1.98, 7.98)	(1.06, 6.11)	(0.52, 4.80)	(1.66, 7.37)	(24.77, 37.68)	(CI)	
≥0.5D to <1.0D	n (%)	0	2 (0.95)	4 (1.90)	2 (0.95)	4 (1.90)	20 (9.52)	32
	(CI)	(0.12, 3.40)	(0.52, 4.80)	(0.12, 3.40)	(0.52, 4.80)	(5.91, 14.33)	(CI)	
≥1.0D to <2.0D	n (%)	0	1 (0.48)	0	2 (0.95)	3 (1.43)	3 (1.43)	9
	(CI)	(0.01, 2.62)	(0.12, 3.40)	(0.30, 4.12)	(0.30, 4.12)	(CI)	(0.01, 2.62)	
Total	Total	77	12	10	8	15	88	210

Table 21: Absolute Axis Shifts Stratified by Residual Cylinder

4.8.3 Zernike Analysis of Corneal Topography Measurements

T-CAT LASIK is based in part on corneal topography measurements in an attempt to reduce, or at least minimize, corneal irregularities that cannot be corrected by spherical or cylindrical ablations. To assess the effectiveness of these treatments, a Zernike analysis was performed to compare preoperative and 3-month postoperative corneal irregularities directly. All topography images were obtained using the ALLEGRO Topolyzer topographer. Corneal Zernike coefficient data were extracted from the raw data file for each selected topography image. Specifically, the median values from the preoperative images used in the T-CAT treatment plan were compared to a single image obtained 3 months after treatment.

Data for the paired preoperative and postoperative Topolyzer raw data files were extracted at a diameter that was 0.5 mm smaller than the optical zone (OZ) diameter used for treatment. OZ diameters of 6.0, 6.5, and 7.0 mm were included in the study, but the majority of eyes were in the 6.5 mm group. Although the analysis was conducted for all terms through the 8th order, terms above the 5th order did not contribute appreciably to the total RMS value. Also, the 2nd order terms were not used in planning the T-CAT treatments. Therefore, the 3rd – 5th order terms are sufficient for evaluation of the T-Cat treatment effects on corneal irregularities. All terms in this range show small increases but the changes are all less than a nanometer, too small to have an appreciable refractive effect. Overall RMS results for these terms are summarized in Table 22 below:

Aberration	Statistic	Preop (micron)	Visit (micron)	Difference (micron)	Mean of Percent Differences (%)
> 2nd Order RMS	mean	0.000537	0.000579	0.000043	8.8
	Std.	0.000088	0.000150	0.000135	26.3
	median	0.000534	0.000560	0.000012	2.5
	(Q1,Q3)	(0.000480 , 0.000596)	(0.000469 , 0.000674)	(-0.000051 , 0.000118)	(-9.5 , 23.7)

Table 22: 6.5 mm OZ Group; Preoperative and Postoperative Overall RMS magnitudes and changes for Zernike orders 3-5, n = 204 Eyes.

4.8.4. Cylinder Correction / Vector Analysis

All 210 eyes treated for cylinder are included in the vector analysis that is presented below. All vector analyses were performed using the methods described by Eydelman et al.[11]

A summary of the intended refractive correction (IRC), surgically induced refractive correction (SIRC), correction ratio (CR), and error ratio (ER) at 3 months postoperatively (time point of stability) is provided in Table 23 below.

Visit	Cylinder Group	N	IRC[12] MEAN(SD)	SIRC[13] MEAN(SD)	CR[14] MEAN(SD)	ER[15] MEAN(SD)
Postop Month 3	ALL	210	1.27 (1.09)	1.23 (1.06)	1.03 (0.40)	0.26 (0.54)
	> 0.0 D - 0.5 D	72	0.35 (0.12)	0.40 (0.21)	1.17 (0.61)	0.45 (0.79)
	> 0.5 D - 1.0 D	45	0.73 (0.10)	0.74 (0.18)	1.02 (0.25)	0.21 (0.42)
	> 1.0 D - 2.0 D	43	1.45 (0.30)	1.35 (0.38)	0.93 (0.18)	0.14 (0.20)
	> 2.0 D - 3.0 D	29	2.30 (0.27)	2.15 (0.43)	0.93 (0.15)	0.17 (0.21)
	> 3.0 D - 4.0 D	12	3.27 (0.25)	3.13 (0.58)	0.96 (0.15)	0.10 (0.14)
	> 4.0 D - 5.0 D	7	4.21 (0.26)	4.10 (0.44)	0.97 (0.09)	0.12 (0.14)
	> 5.0 D - 6.0 D	2	4.94 (0.02)	4.94 (0.02)	1.00 (0.00)	0.00 (0.00)

Table 2213: Refractive Correction Parameters Stratified By Preoperative Cylinder

At 3 months postoperatively, the SIRC of 1.23 D for the myopic astigmatism cohort closely approximates the intended refractive correction of 1.27 D for all eyes treated for myopic astigmatism. This is confirmed by the correction ratio (CR) of 1.03 for all treated eyes in the myopic astigmatism cohort. Similar trends in the data are observed for each of the individual cylinder groups, with a CR of 0.93 implying a slight undercorrection in the 1.0 to 3.0 D groups that approaches an ideal CR of 1.00 in the >3.0 D and higher corrections. As would be expected, the greatest variability in the correction ratio is observed in the smallest cylinder magnitude group, where eyes with a preoperative cylinder between 0.0 and 0.5 D had a slightly higher correction ratio of 1.17.

[11] Eydelman MB, Drum B, Holladay J, Hilmantel G, Kezirian G, Durrie D, Stulting RD, Sanders D, Wong B. Standardized analyses of correction of astigmatism by laser systems that reshape the cornea. J Refract Surg. 2006 Jan-Feb;22(1):81-95.
[12] IRC = Intended Refractive Correction (difference between intended and preoperative vectors)
[13] SIRC = Surgically Induced Refractive Correction (difference between postoperative and preoperative vectors)
[14] CR = Correction Ratio = SIRC/IRC (ratio of achieved vector magnitude to intended correction); 1 is ideal, <1 implies undercorrection, >1 implies overcorrection
[15] ER = Error Ratio = (IRC-SIRC)/IRC = Error Vector/Intended Vector Magnitude (proportion of intended correction not successfully treated)

4.8.5. Uncorrected Visual Acuity

Table 24 below shows that nearly one-third of the eyes treated for myopia with Topo-guided (T-CAT) LASIK (78/247, 31.6%) achieved a distance UCVA of 20/12.5 or better, and over two-thirds of the eyes (170/247; 68.8%) were seeing 20/16 or better without correction at 3 months postoperatively. Furthermore, a total of 92.7% of the Topo-guided (T-CAT) LASIK eyes had a UCVA of 20/20 or better at 3 and 12 months postoperatively, with slight shifts toward continuing improvement in the proportion of these eyes that attained UCVA of 20/16, 20/12.5, and 20/10 through 12 months after Topo-guided (T-CAT) LASIK.

		Preop	Month 1	Month 3	Month 6	Month 9	Month 12
20/10 or better	n/N	0/249	11/248	19/247	25/244	30/237	36/230
	(%)	(0.00%)	(4.44%)	(7.69%)	(10.25%)	(12.66%)	(15.65%)
20/12.5 or better	n/N	0/249	59/248	78/247	69/244	72/237	79/230
	(%)	(0.00%)	(23.79%)	(31.58%)	(28.28%)	(30.38%)	(34.35%)
20/16 or better	n/N	0/249	146/248	170/247	172/244	152/237	149/230
	(%)	(0.00%)	(58.87%)	(68.83%)	(70.49%)	(64.14%)	(64.78%)
20/20 or better	n/N	0/249	217/248	229/247	217/244	212/237	213/230
	(%)	(0.00%)	(87.50%)	(92.71%)	(88.93%)	(89.45%)	(92.61%)
20/25 or better	n/N	4/249	240/248	240/247	235/244	231/237	222/230
	(%)	(1.61%)	(96.77%)	(97.17%)	(96.31%)	(97.47%)	(96.52%)
20/32 or better	n/N	7/249	244/248	244/247	241/244	234/237	227/230
	(%)	(2.81%)	(98.39%)	(98.79%)	(98.77%)	(98.73%)	(98.70%)
20/40 or better	n/N	11/249	245/248	245/247	241/244	236/237	229/230
	(%)	(4.42%)	(98.79%)	(99.19%)	(98.77%)	(99.58%)	(99.57%)
20/50 or better	n/N	19/249	246/248	247/247	242/244	236/237	229/230
	(%)	(7.63%)	(99.19%)	(100.0%)	(99.18%)	(99.58%)	(99.57%)

		Preop	Month 1	Month 3	Month 6	Month 9	Month 12
20/63 or better	n/N	34/249	247/248	247/247	243/244	236/237	230/230
	(%)	(13.65%)	(99.60%)	(100.0%)	(99.59%)	(99.58%)	(100.0%)
20/80 or better	n/N	42/249	247/248	247/247	244/244	237/237	230/230
	(%)	(16.87%)	(99.60%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
20/100 or better	n/N	54/249	247/248	247/247	244/244	237/237	230/230
	(%)	(21.69%)	(99.60%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
20/125 or better	n/N	64/249	247/248	247/247	244/244	237/237	230/230
	(%)	(25.70%)	(99.60%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
20/160 or better	n/N	79/249	248/248	247/247	244/244	237/237	230/230
	(%)	(31.73%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
20/200 or better	n/N	104/249	248/248	247/247	244/244	237/237	230/230
	(%)	(41.77%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
20/400 or better	n/N	249/249	248/248	247/247	244/244	237/237	230/230
	(%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)

Table 24: Summary Of Changes In Uncorrected Visual Acuity

Table 25 below compares the postoperative visual acuity without correction to the preoperative visual acuity with correction in the eyes that were treated with Topo-guided (T-CAT) LASIK for myopia with or without astigmatism. Eyes treated with Topo-guided (T-CAT) LASIK achieved improvement in postoperative UCVA compared to preoperative BSCVA, with nearly one-third of the eyes (73/247; 29.6%) gaining 1, 2, or more than 2 lines of vision without correction at 3 months after Topo-guided (T-CAT) LASIK compared to their BSCVA before treatment. Additionally, 60.3% (149/247) of the eyes reporting a UCVA after Topo-guided (T-CAT) LASIK that was equal to their BSCVA before the refractive correction. In total, 89.9% of the eyes (222/247) treated with Topo-guided (T-CAT) LASIK saw as well without glasses as with glasses before surgery.

		Month 1	Month 3	Month 6	Month 9	Month 12
UCVA > 2 Lines Better than Baseline BSCVA	n/N	1/248	1/247	2/244	3/237	7/230
	(%)	(0.40%)	(0.40%)	(0.82%)	(1.27%)	(3.04%)
UCVA 2 Lines Better than Baseline BSCVA	n/N	10/248	18/247	13/244	18/237	19/230
	(%)	(4.03%)	(7.29%)	(5.33%)	(7.59%)	(8.26%)
UCVA 1 Line Better than Baseline BSCVA	n/N	41/248	54/247	48/244	45/237	45/230
	(%)	(16.53%)	(21.86%)	(19.67%)	(18.99%)	(19.57%)
UCVA equal to Baseline BSCVA	n/N	160/248	149/247	153/244	138/237	134/230
	(%)	(64.52%)	(60.32%)	(62.70%)	(58.23%)	(58.26%)
UCVA 1 Line Worse than Baseline BSCVA	n/N	27/248	20/247	18/244	26/237	18/230
	(%)	(10.89%)	(8.10%)	(7.38%)	(10.97%)	(7.83%)
UCVA 2 Lines Worse than Baseline BSCVA	n/N	5/248	2/247	6/244	4/237	3/230
	(%)	(2.02%)	(0.81%)	(2.46%)	(1.69%)	(1.30%)
UCVA > 2 Lines Worse than Baseline BSCVA	n/N	4/248	3/247	4/244	3/237	4/230
	(%)	(1.61%)	(1.21%)	(1.64%)	(1.27%)	(1.74%)

Table 25: UCVA After Topo-guided (T-CAT) LASIK Compared To BSCVA Before Topo-guided (T-CAT) LASIK

4.8.6. Patient-Reported Outcomes

Subjective visual complaints were obtained from each study subject using a self-administered 12 item questionnaire to record symptoms. Study subjects were asked to rate the presence or absence of each visual complaint in their Topo-guided LASIK treated eye at baseline before the Topo-guided (T-CAT) LASIK treatment and at each postoperative visit, beginning with the 1 month visit. Study subjects were instructed to rate the absence of a visual complaint as "*none*" and the presence of a visual complaint as "*mild*", "*moderate*", "*marked*" or "*severe*".

Responses to the subjective visual complaints questionnaire at baseline and at each postoperative examination are summarized by symptom in Table 26 below. Visual symptoms after Topo-guided (T-CAT) LASIK were generally mild in severity. Eye dryness was the most commonly reported visual complaint that occurred in the early 1 or 3 month postoperative period. Only dryness (7% marked) and light sensitivity (7% marked) had an incidence of at least 5% at 1 month after Topo-guided (T-CAT) LASIK. Visual symptoms continued to improve with time; and none of the visual symptoms were rated as being "*marked*" or "*severe*" with an incidence of at least 5% at 3 months or later after Topo-guided (T-CAT) LASIK.

Symptoms that are traditionally associated with LASIK (glare, halos, difficulty driving at night, light sensitivity, and eye dryness)[16] actually improved after Topo-guided (T-CAT) LASIK treatment with the ALLEGRETTO WAVE EYE-Q Excimer Laser. Questionnaires administered 6 to 12 months after surgery not only confirmed that visual symptoms improved after Topo-guided (T-CAT) LASIK, they showed continued improvement with time. These data demonstrate that Topo-guided (T-CAT) LASIK with the ALLEGRETTO WAVE EYE-Q Excimer Laser produces a long-term improvement in visual symptoms.

[16] FDA website: LASIK, What are the Risks
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061354.htm

Changes in the degree of severity of visual symptoms reported via the self-administered questionnaire at 3 months (time point of refractive stability) compared to baseline are summarized in Table 27 on page 55. All categories of complaints showed a reduction in severity of complaints after the Topo-guided (T-CAT) LASIK procedure compared to baseline, except double vision (0.82%) and foreign body sensation (0.41%), both of which had an increase in severity postoperatively. Symptoms that are traditionally associated with LASIK (glare, halos, difficulty driving at night, light sensitivity, and eye dryness)[17] improved after Topo-guided (T-CAT) LASIK with the ALLEGRETTO WAVE EYE-Q Excimer Laser. The decreases in severity for light sensitivity (-3.6%), complaints of difficulty driving at night (-4.4%), reading difficulty (-6.4%), and glare (-2.4%) were all statistically significant improvements in the severity of these visual symptoms in the Topo-guided (T-CAT) treated eyes.

Question	Visit	None	Mild	Moderate	Marked	Severe
Light Sensitivity	Screening	136/249 (55%)	71/249 (29%)	29/249 (12%)	13/249 (5%)	
	Postop Month 1	77/247 (31%)	110/247 (45%)	40/247 (16%)	17/247 (7%)	3/247 (1%)
	Postop Month 3	125/247 (51%)	83/247 (34%)	35/247 (14%)	1/247 (0%)	3/247 (1%)
	Postop Month 6	141/244 (58%)	85/244 (35%)	17/244 (7%)	1/244 (0%)	
	Postop Month 9	144/237 (61%)	81/237 (34%)	12/237 (5%)		
	Postop Month 12	160/230 (70%)	56/230 (24%)	14/230 (6%)		
Difficulty Driving at Night	Screening	112/249 (45%)	81/249 (33%)	35/249 (14%)	18/249 (7%)	3/249 (1%)
	Postop Month 1	130/246 (53%)	76/246 (31%)	25/246 (10%)	11/246 (4%)	4/246 (2%)
	Postop Month 3	148/247 (60%)	73/247 (30%)	16/247 (6%)	9/247 (4%)	1/247 (0%)
	Postop Month 6	179/244 (73%)	43/244 (18%)	17/244 (7%)	5/244 (2%)	
	Postop Month 9	166/236 (70%)	56/236 (24%)	12/236 (5%)	2/236 (1%)	
	Postop Month 12	164/230 (71%)	51/230 (22%)	14/230 (6%)	1/230 (0%)	
Reading Difficulty	Screening	172/249 (69%)	38/249 (15%)	14/249 (6%)	11/249 (4%)	14/249 (6%)
	Postop Month 1	190/247 (77%)	24/247 (10%)	19/247 (8%)	10/247 (4%)	4/247 (2%)
	Postop Month 3	208/247 (84%)	23/247 (9%)	7/247 (3%)	8/247 (3%)	1/247 (0%)
	Postop Month 6	205/244 (84%)	26/244 (11%)	7/244 (3%)	5/244 (2%)	1/244 (0%)
	Postop Month 9	201/237 (85%)	26/237 (11%)	3/237 (1%)	3/237 (1%)	4/237 (2%)
	Postop Month 12	194/230 (84%)	29/230 (13%)	4/230 (2%)	2/230 (1%)	1/230 (0%)

[17] FDA website: LASIK, What are the Risks
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061354.htm

Question	Visit	None	Mild	Moderate	Marked	Severe
Double Vision	Screening	226/249 (91%)	14/249 (6%)	6/249 (2%)	3/249 (1%)	
	Postop Month 1	226/247 (91%)	14/247 (6%)	4/247 (2%)	3/247 (1%)	
	Postop Month 3	228/247 (92%)	13/247 (5%)	1/247 (0%)	5/247 (2%)	
	Postop Month 6	224/244 (92%)	15/244 (6%)	1/244 (0%)	4/244 (2%)	
	Postop Month 9	224/237 (95%)	8/237 (3%)	2/237 (1%)	3/237 (1%)	
	Postop Month 12	217/230 (94%)	12/230 (5%)	1/230 (0%)		
Fluctuation in Vision	Screening	197/249 (79%)	39/249 (16%)	9/249 (4%)	3/249 (1%)	1/249 (0%)
	Postop Month 1	130/247 (53%)	89/247 (36%)	21/247 (9%)	6/247 (2%)	1/247 (0%)
	Postop Month 3	168/246 (68%)	69/246 (28%)	8/246 (3%)	1/246 (0%)	
	Postop Month 6	172/244 (70%)	59/244 (24%)	12/244 (5%)	1/244 (0%)	
	Postop Month 9	167/237 (70%)	61/237 (26%)	8/237 (3%)	1/237 (0%)	
	Postop Month 12	169/230 (73%)	54/230 (23%)	7/230 (3%)		
Glare	Screening	156/249 (63%)	51/249 (20%)	30/249 (12%)	10/249 (4%)	2/249 (1%)
	Postop Month 1	107/247 (43%)	113/247 (46%)	21/247 (9%)	6/247 (2%)	
	Postop Month 3	142/247 (57%)	90/247 (36%)	13/247 (5%)	2/247 (1%)	
	Postop Month 6	148/244 (61%)	85/244 (35%)	11/244 (5%)		
	Postop Month 9	166/237 (70%)	65/237 (27%)	6/237 (3%)		
	Postop Month 12	153/230 (67%)	75/230 (33%)	2/230 (1%)		
Halos	Screening	184/249 (74%)	40/249 (16%)	17/249 (7%)	6/249 (2%)	2/249 (1%)
	Postop Month 1	100/247 (40%)	101/247 (41%)	32/247 (13%)	11/247 (4%)	3/247 (1%)
	Postop Month 3	147/247 (60%)	81/247 (33%)	17/247 (7%)	2/247 (1%)	
	Postop Month 6	158/244 (65%)	79/244 (32%)	7/244 (3%)		
	Postop Month 9	175/237 (74%)	55/237 (23%)	7/237 (3%)		
	Postop Month 12	173/230 (75%)	54/230 (23%)	3/230 (1%)		
Starbursts	Screening	189/249 (76%)	34/249 (14%)	18/249 (7%)	6/249 (2%)	2/249 (1%)
	Postop Month 1	144/245 (59%)	69/245 (28%)	27/245 (11%)	3/245 (1%)	2/245 (1%)
	Postop Month 3	179/247 (72%)	54/247 (22%)	11/247 (4%)	3/247 (1%)	
	Postop Month 6	183/244 (75%)	57/244 (23%)	3/244 (1%)	1/244 (0%)	
	Postop Month 9	193/237 (81%)	37/237 (16%)	6/237 (3%)	1/237 (0%)	
	Postop Month 12	186/229 (81%)	36/229 (16%)	6/229 (3%)	1/229 (0%)	

Question	Visit	None	Mild	Moderate	Marked	Severe
Dryness	Screening	120/249 (48%)	85/249 (34%)	32/249 (13%)	11/249 (4%)	1/249 (0%)
	Postop Month 1	41/247 (17%)	135/247 (55%)	49/247 (20%)	18/247 (7%)	4/247 (2%)
	Postop Month 3	57/247 (23%)	145/247 (59%)	37/247 (15%)	6/247 (2%)	2/247 (1%)
	Postop Month 6	90/244 (37%)	113/244 (46%)	35/244 (14%)	5/244 (2%)	1/244 (0%)
	Postop Month 9	91/237 (38%)	113/237 (48%)	27/237 (11%)	3/237 (1%)	3/237 (1%)
	Postop Month 12	114/230 (50%)	92/230 (40%)	18/230 (8%)	6/230 (3%)	
Pain	Screening	236/249 (95%)	9/249 (4%)	3/249 (1%)	1/249 (0%)	
	Postop Month 1	214/247 (87%)	26/247 (11%)	7/247 (3%)		
	Postop Month 3	229/247 (93%)	18/247 (7%)			
	Postop Month 6	232/243 (95%)	10/243 (4%)	1/243 (0%)		
	Postop Month 9	221/237 (93%)	15/237 (6%)	1/237 (0%)		
	Postop Month 12	218/230 (95%)	10/230 (4%)	1/230 (0%)	1/230 (0%)	
Foreign Body Sensation	Screening	211/249 (85%)	28/249 (11%)	9/249 (4%)	1/249 (0%)	
	Postop Month 1	174/246 (71%)	61/246 (25%)	7/246 (3%)	1/246 (0%)	3/246 (1%)
	Postop Month 3	195/247 (79%)	42/247 (17%)	8/247 (3%)	2/247 (1%)	
	Postop Month 6	205/244 (84%)	35/244 (14%)	4/244 (2%)		
	Postop Month 9	208/237 (88%)	27/237 (11%)	1/237 (0%)	1/237 (0%)	
	Postop Month 12	208/229 (91%)	16/229 (7%)	5/229 (2%)		
Other	Screening	5/10 (50%)	2/10 (20%)	1/10 (10%)		2/10 (20%)
	Postop Month 1		2/2 (100%)			
	Postop Month 3	2/3 (67%)	1/3 (33%)			
	Postop Month 6	7/10 (70%)	2/10 (20%)	1/10 (10%)		
	Postop Month 9	9/11 (82%)		2/11 (18%)		
	Postop Month 12	12/14 (86%)	2/14 (14%)			

Table 26: Visual Symptoms Recorded via Self-Administered Symptom Questionnaire[18]

[18] Any variation in the N for an observation at a specific time point is due to one or more subjects omitting the rating for that symptom at that time point. A blank cell means there were no reports of that symptom at that time point.

Question	Percent Baseline None - Moderate	Percent Baseline Marked - Severe	Percent 3 Month None - Moderate	Percent 3 Month Marked - Severe	Difference in Marked - Severe
Light Sensitivity	94.78	5.22	98.38	1.62	-3.60
Difficulty Driving at Night	91.57	8.43	95.95	4.05	-4.39
Reading Difficulty	89.96	10.04	96.36	3.64	-6.40
Double Vision	98.80	1.20	97.98	2.02	0.82
Fluctuation in Vision	98.39	1.61	99.59	0.41	-1.20
Glare	95.18	4.82	99.19	0.81	-4.01
Halos	96.79	3.21	99.19	0.81	-2.40
Starbursts	96.79	3.21	98.79	1.21	-2.00
Dryness	95.18	4.82	96.76	3.24	-1.58
Pain	99.60	0.40	100.0	0.00	-0.40
Foreign Body Sensation	99.60	0.40	99.19	0.81	0.41
Other	80.00	20.00	100.0	0.00	-20.0

Table 27: Changes in Degree of Severity of Visual Symptoms in All Eyes Treated with Topo-guided (T-CAT) LASIK

The Refractive Status and Vision Profile (RSVP) questionnaire is a validated instrument that measures self-reported vision-related health status (symptoms, functioning, expectations, concern) in persons with refractive error. Scores on the overall RSVP scale and on eight RSVP subscales (functioning, driving, concern, expectations, symptoms, glare, optical problems, and problems with corrective lenses) are scored so that higher scores indicate greater dissatisfaction or a greater negative outcome, except expectations, where a lower score represents an improvement. Thus a negative difference in a subscale score is desirable (i.e., lower score postoperatively compared to baseline; positive difference for expectations is desirable). The clinical outcomes measured by the RSVP are a range of visual, functional, and psychological impacts of refractive error that are likely to be important to patients.

In this study, the RSVP questionnaire was administered at baseline and at each postoperative visit, beginning with month 1, to evaluate study subject satisfaction, use of corrective lenses (spectacles or contact lenses, if appropriate), and the study subject's quality of vision and quality of life. The changes in the scores for each subscale that is evaluated in the questionnaire are summarized in Table 28 below.

Visit	Subscale	N Diff	Mean Base	Mean Score	Mean Diff	Effect Size
Postop Month 1	Concern	211	45.69	18.50	-27.19	-1.3178
	Expectations	208	59.44	63.10	3.67	0.1450
	Physical/social functioning	177	17.55	5.11	-12.44	-0.6409
	Driving	177	23.26	13.82	-9.44	-0.4100
	Symptoms	176	14.40	12.42	-1.98	-0.1288
	Optical problems	174	7.54	5.63	-1.90	-0.1596
	Glare	176	14.80	16.67	1.87	0.1203
	Problem with corrective lenses	25	24.12	22.94	-1.18	-0.0685
	Total Score	211	19.98	4.03	-15.96	-1.3233
Postop Month 3	Concern	210	45.65	13.87	-31.78	-1.5374
	Expectations	205	59.33	65.24	5.91	0.2347
	Physical/social functioning	198	16.46	3.44	-13.02	-0.7505
	Driving	196	22.62	11.08	-11.54	-0.5140
	Symptoms	195	14.08	8.63	-5.45	-0.3780
	Optical problems	196	7.49	4.15	-3.34	-0.2761
	Glare	195	14.79	12.54	-2.24	-0.1425
	Problem with corrective lenses	26	26.67	12.02	-14.65	-0.9796
	Total Score	210	19.97	3.99	-15.97	-1.3218
Postop Month 6	Concern	207	45.57	12.26	-33.31	-1.6213
	Expectations	205	59.39	63.54	4.15	0.1638
	Physical/social functioning	200	16.18	3.18	-13.00	-0.7606
	Driving	200	22.38	10.38	-12.00	-0.5418
	Symptoms	199	13.97	7.34	-6.62	-0.4457
	Optical problems	198	7.66	3.61	-4.05	-0.3140
	Glare	198	14.73	10.04	-4.69	-0.2891
	Problem with corrective lenses	32	26.84	1.17	-25.67	-1.5522
	Total Score	207	19.93	3.87	-16.06	-1.3354

Visit	Subscale	N Diff	Mean Base	Mean Score	Mean Diff	Effect Size
Postop Month 9	Concern	201	45.46	12.73	-32.73	-1.5937
	Expectations	197	59.64	64.21	4.57	0.1795
	Physical/social functioning	191	16.31	3.16	-13.15	-0.7585
	Driving	188	22.03	9.69	-12.34	-0.5628
	Symptoms	190	14.02	6.99	-7.03	-0.4675
	Optical problems	190	7.95	3.00	-4.95	-0.3742
	Glare	191	15.01	8.40	-6.61	-0.4034
	Problem with corrective lenses	38	28.60	2.96	-25.64	-1.3174
	Total Score	201	19.89	3.64	-16.25	-1.3439
Postop Month 12	Concern	195	44.89	11.18	-33.71	-1.6601
	Expectations	193	59.26	65.35	6.09	0.2403
	Physical/social functioning	189	16.41	2.27	-14.14	-0.7807
	Driving	188	22.03	8.29	-13.74	-0.6184
	Symptoms	188	13.64	5.87	-7.77	-0.5237
	Optical problems	188	7.22	2.65	-4.57	-0.3592
	Glare	190	14.71	7.26	-7.46	-0.4563
	Problem with corrective lenses	37	27.86	3.04	-24.82	-1.1559
	Total Score	195	19.54	3.15	-16.39	-1.3822

Table 28: Change in Refractive Status Vision Profile (RSVP) Score[19]

[19]The number of respondents (N) for each subscale varies based on whether the subscale question applies to that subject.

The RSVP shows an improvement in all subscales evaluated at each of the postoperative visits and in the total composite score that is computed for each visit. The only exception is glare at the 1 month visit, which shows a worsening that changes to improvement at 3 months and all subsequent visits. Published literature indicates that a difference of 6 points or more on the composite score is a clinically significant change.[20] The difference in composite score from baseline to each postoperative visit showed a clinically significant improvement in the RSVP profile, with a mean improvement that is nearly three times the minimum threshold for clinically significant improvement at each postoperative visit, ranging from a change of -15.97 points at 1 month to a change of -16.39 points at 12 months. On the basis of these data, the Topo-guided (T-CAT) LASIK treatment leads to a clinically and statistically significant improvement in symptoms measured by the RSVP. Specifically, subjects who underwent Topo-guided (T-CAT) LASIK with the ALLEGRETTO WAVE EYE-Q Excimer Laser in the clinical trial experienced an improvement in physical/social functioning, driving, visual symptoms, optical problems, and problems with corrective lenses that was evident at three months and continued to improve through 12 months postoperatively, compared to their habitual refractive correction method (glasses or contact lenses) preoperatively.

Questions to evaluate the study subject's self-reported satisfaction with the Topo-guided (T-CAT) LASIK procedure were added during the course of the study. Of the 124 subjects who were polled, nearly all of the subjects (122/124 subjects; 98.4%) were satisfied with their outcomes and would have the Topo-guided (T-CAT) LASIK treatment again, as shown in Table **Error! Reference source not found.**9 below.

Question	Yes	No
Would you have the Topo-guided (T-CAT) treatment again?	122/124 (98%)	2/124 (2%)

Table 29: Summary of Satisfaction with the Topo-guided (T-CAT) LASIK Treatment

[20] Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery: The refractive status and vision profile. J Cataract Refract Surg. 2001 May;27(5):665-73.

4.9. Retreatments

No retreatments were performed in the study. Therefore, no safety or efficacy data are available for the use of Topo-guided (T-CAT) LASIK in performing a retreatment procedure or for Topo-guided (T-CAT) LASIK treated eyes that have a retreatment performed using another technology.

4.10. Factors Associated With Outcomes

Gender, age, race, postoperative medications, and keratectomy device used to create the LASIK flap were evaluated to determine the homogeneity of the study data across the clinical sites.
Statistical analysis indicated that there were no differences in the proportion of males and females across the nine clinical sites (p=0.4643), nor were there any differences in the age distribution across sites (p=0.4408). There was a significant difference in the distribution of minority races across the nine sites (p=<0.0001), primarily due to the number of Hispanics and other minority races enrolled at the four sites in the southwest and west coast areas. Hispanic subjects were the second most commonly enrolled race after Caucasians. Although there are statistically significant differences in ethnic distribution amongst the nine sites, the safety and efficacy outcomes are similar across the nine investigative sites. Furthermore, the ethnic diversity is desirable as it provides results from a cross-section of ethnic groups and mirrors the U.S. population.

Topo-guided (T-CAT) LASIK eyes at eight of the nine investigative sites were treated with topical Vigamox® (moxifloxacin) and prednisolone acetate after Topo-guided (T-CAT) LASIK to prevent infection and inflammation in the treated eye. One site prescribed Zymar® (gatifloxacin) and Flarex® (fluorometholone acetate) postoperatively instead of Vigamox® and prednisolone acetate. Zymar® and Vigamox® are both fourth generation fluoroquinolone antibiotics that are therapeutically interchangeable with nearly identical spectrums of antimicrobial activity. Flarex® and prednisolone acetate are both corticosteroid ophthalmic suspensions that are frequently prescribed after laser refractive surgery. The homogeneity of the key safety and efficacy parameters were evaluated; and there was no significant difference between the outcomes reported for the site that used Zymar® and Flarex® and the sites that used Vigamox® and prednisolone acetate. Thus, the use of a therapeutically equivalent antibiotic (Zymar®) and anti-inflammatory (Flarex®) did not affect the outcomes in the study cohort.

A femtosecond laser was used to create the LASIK keratectomy flap in the majority of eyes treated. The femtosecond laser was used exclusively at six of the nine investigative sites. A mechanical microkeratome was used on a proportion of the Topo-guided (T-CAT) LASIK eyes at two sites, and exclusively at one of the participating investigative sites. The effect of keratectomy device on the homogeneity of the key safety and efficacy parameters and the MRSE accuracy was evaluated. Statistical analysis demonstrated that the choice of keratectomy device used in the LASIK procedure has no significant effect (p<0.05) on any of the key safety and efficacy parameters or the MRSE accuracy.

5. TOPOGRAPHY EXAMINATION

5.1. General

Select only patients suitable for topo-guided treatments. Patients must meet inclusion and exclusion criteria provided in this manual. See section 3.4 “Precautions” on page 13 for details.

All topography examinations have to be performed with great care. Only well-trained personnel shall perform and validate topography examinations.

All steps have to be performed according to instructions given in the manual of the ALLEGRO Topolyzer. Additional notes related to measurements intended to be used for topo-guided treatments are provided in the following sections.

5.2. Data Entry

Enter and check all patient data carefully. All data entered at the topography ALLEGRO Topolyzer will be transferred to the treatment planning software and then to the laser console for treatment.

CAUTION

Name and Birthday entered at the ALLEGRO Topolyzer will be default values for treatment if a “Wavefront Optimized” LASIK shall be performed after the T-CAT (topo-guided) procedure planning was started at the laser notebook.

For this reason, make sure that entered values are correct - even if they will not be required for the T-CAT (topo-guided) treatment.

5.3. Patient Preparation And Examination

In order to provide raw topography data for the entire planned treatment area (optical zone), the patient's cornea should be measured in a large area (AA > 65%). Please refer to the ALLEGRO Topolyzer manual for details.

A proper tear film is essential for good topography image of the examination. Apply artificial tears approved by the manufacturer in patients with short tear-film break-up time. Please refer to the ALLEGRO Topolyzer manual for details.

Measured eyes must not have had any kind of applanation or indentation during the 12 hours before topography examination, e.g. applanation tonometry or contact pachymetry and contact biometry. All such procedures must be performed long before or after the topography examination.

5.4. Image Validation

Validate all steps of the topography examination according to the checkpoints, procedures and tolerances given in the ALLEGRO Topolyzer manual and in the checklist provided in the appendix of this manual.

CAUTION

Valid examinations

A valid measurement must pass all checkpoints / validation steps. If one single step is not fulfilled, the examination must not be used for treatment.

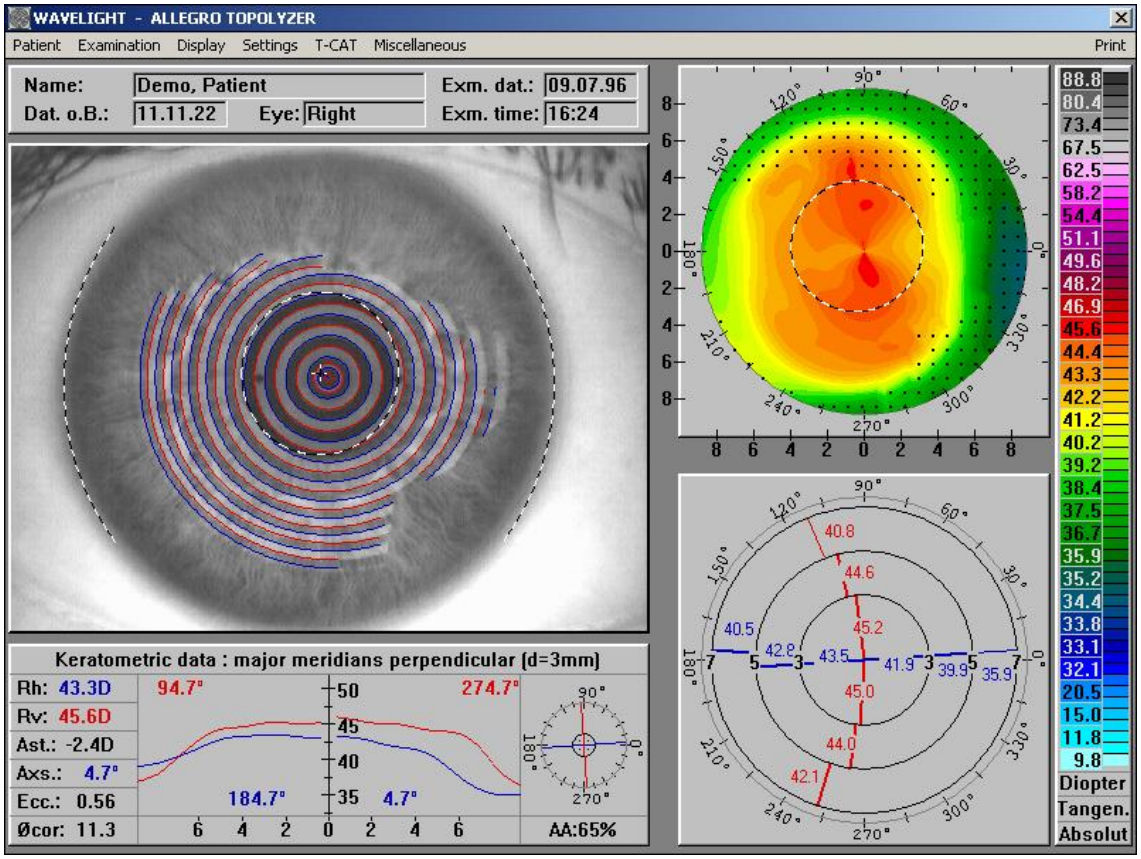

Figure 5: Example Topolyzer Image Of Measured Cornea

5.5. Single vs. Multiple Examination Use

The ALLEGRETTO WAVE EYE-Q laser system has two options for use of topography examinations:

- Treatment plan based on one single measurement.
- Treatment plan based on averaged multiple examinations. Up to 8 different examinations may be used for simultaneous “Multi” export.

Select the best examination(s) from all examinations that passed validation checks. Multi export will allow comparison of examination and identification of possible outlier measurements. Compare the following:

- Pattern of total topography maps

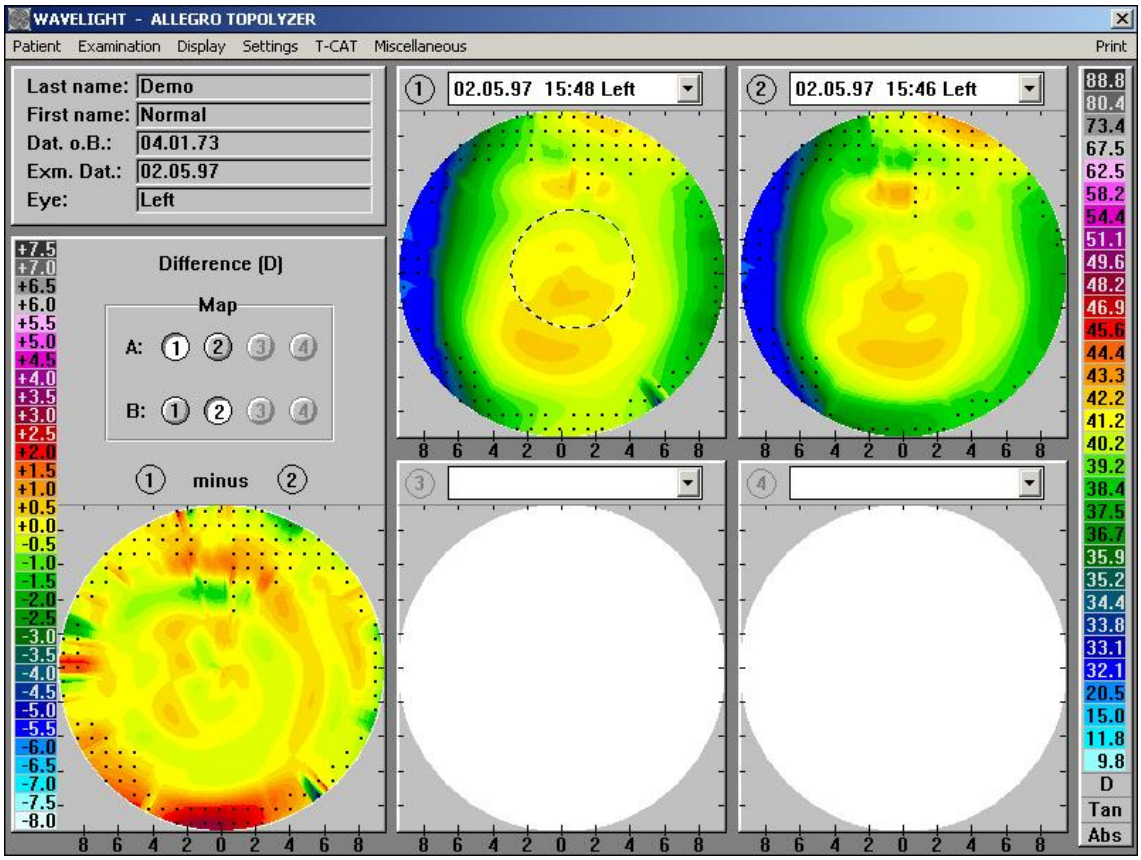

Figure 6: Examples Comparison Of Topography Maps

5.6. Topography Data Transfer

Use a formatted, virus-free USB-stick for data export at the ALLEGRO Topolyzer. Take the USB-stick to the laser notebook computer and import the data with the notebook portal software.

NOTE

The send data function of the ALLEGRO Topolyzer will export all data for the selected examination date. It should not be selected more than 8 images of one eye. The notebook portal software will show all during import max.
8 images of each eye.

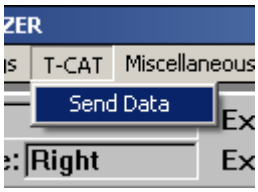

Figure 7: How To Send Topo-guided Data With The ALLEGRO Topolyzer

6. TREATMENT PLANNING

Observe all inclusion and exclusion criteria, adverse event, complication and precaution information given in this manual for patient selection.

6.1. Importing To The Notebook

Examinations have to be exported from WaveLight GmbH's ALLEGRO Topolyzer device and imported with the notebook portal software to the examinations database on the notebook. It is then possible to review the examinations for treatment planning on the notebook.

Topography examinations imported into the laser notebook contain all the patient's administrative data entered for the specific topography measurement. Additionally, K-readings, eccentricity values, topography maps, Zernike tables and topography refractions are imported.

When importing data from the USB-stick, all examinations or patients contained on the USB-stick will be imported at once.

NOTE

File integrity

In case the asphericity (Q-Value) is not in the limits of 0 to - 1.0, they have to be changed to values of within this range.

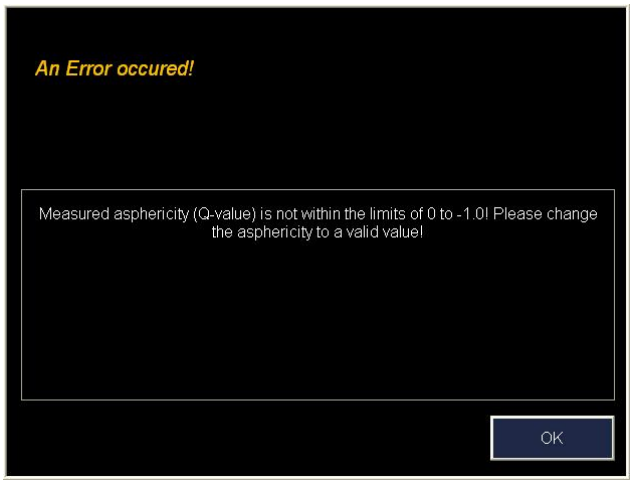

Figure 8: Positive Measured Asphericity

6.2. Treatment Plan And Data Entry

6.2.1. Proven Parameter Range

CAUTION

Approved Range

The Topo-guided procedure is in principle a two-step procedure. The first step is to reshape the corneal irregularity, to give the cornea a regular shape.

The second step would be a enhanced treatment, in order to correct refractive errors.

There are no safety and effectiveness data above - 9.0 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to - 9.0 D of spherical component and up to 4.0 D of astigmatic component at the spectacle plane.

6.2.2. Loading Measurements And Averaging Multiple Measurements

To start a topo-guided treatment, you must first import the measurement file of the specific eye from the ALLEGRO Topolyzer.

Multiple examinations exported together will be imported as one file with numbers of all examinations in a queue.

Select and load the measurement(s) you want to use.

All selected “Multi” measurements will be averaged for use for the treatment plan.

6.2.3. Completing Patient And Examination Data Entry

Advance to the next step: The input screen for patient data. All mandatory data is provided with the loaded measurement(s). Use this screen to verify that the data for the correct patient and correct eye is loaded.

Advance to the examination data entry screen. Some examination data will already be provided. Other data has to be entered. The data already displayed was imported and loaded with the topography data from the ALLEGRO Topolyzer. Check all entries and make corrections if the displayed data does not match the data on file.

CAUTION

Refraction Entry / Classic LASIK Treatment

Check refractions carefully. Refractions shown or modified in the “Examination Data Window” of the notebook software will be used to define the “Wavefront Optimized” LASIK treatment, if you and the patient decide after this point for a Wavefront Optimized LASIK treatment instead of a topo-guided (T-CAT) treatment.

6.2.4. Treatment Parameter Check

The “Treatment Plan Window” provides final planning capabilities for treatment type, corrections and zone sizes. Default values of all relevant treatment parameters are provided. A colored graphical display shows the ablation depth profile with regard to the pupil center. Depths are given in micron [µm].

CAUTION

Treatment Type Setting

Turn always the “TILT OFF”

Treatment Type:

The default setting for the treatment type selector box is “T-CAT” for topo-guided treatments. “Wavefront Optimized” can be selected instead to proceed with a non custom standard LASIK treatment plan at this point.
The selection can also be used to compare the ablation profiles of the intended topography treatment with the corresponding Wavefront Optimized treatment with regard to their tissue ablation requirements.

CAUTION

Treatment Type Setting

A classic LASIK procedure will be performed instead of a T-CAT (Topo-guided) treatment if the setting is not set back from “Wavefront Optimized” to “T-CAT” (Topo-guided). Set treatment type back to “T-CAT” (Topo-guided) to proceed with a topo-guided treatment. If for any reason a Wavefront Optimized LASIK treatment shall be performed, check all parameters that determine the Wavefront Optimized LASIK treatment. They are provided in the examination and treatment data screens of the notebook software.

Parameters determining a Wavefront Optimized treatment are “Clinical Refraction”, “Vertex Distance (VD)”, “K-Readings (Keratometry)”, “Optical Zone” and “Target (refraction)”.

Clinical, Topography and Modified Refractions:

"Clinical" refraction values are displayed only for final comparison purposes. The "Modified" refraction is the amount corrected. It is by default the value of the "Topography" refraction at the displayed optical zone.
The "Modified" refraction can be altered. This allows for individual adjustments of sphere and cylinder.

CAUTION

Nomogram Use

If a nomogram shall be applied to the T-CAT (Topo-guided) treatment plan, changes according to the nomogram must be made in the field "Modified" refractions. Changes made in the examination screen's clinical refraction will not affect the T-CAT (Topo-guided) treatment.

Records about changes according to nomogram should be made manually in the patient's files or in the notes section of the notebook portal software.

NOTE

Monovision

For intended undercorrection or monovision, calculate the required correction yourself and enter it in the section "Modified" refraction.
Do not change cylinder or axis for monovision purposes.

6.2.5. Tilt Treatment

Tilt is a lower-order aberration that describes a prism error of an eye. Pure prism errors would require a prism-like ablation profile with maximum ablation on one point of the optical zone and zero ablation at the opposite edge of the optical zone.
Because this would require removing large amounts of tissue, treating a prism error will always increase central ablation depth without affecting the refractive result.

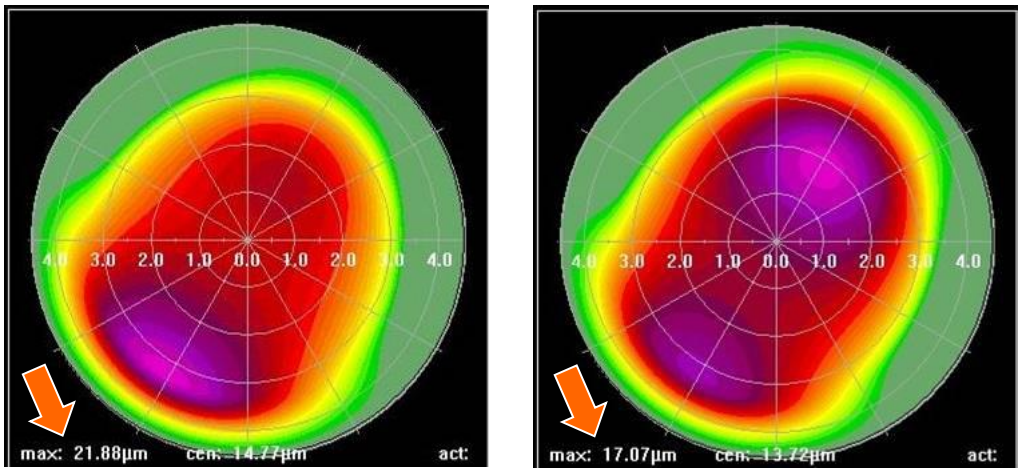

Figure 9: Example Ablation Tilt Treatment ON (Left) And OFF (Right)

Your may decide not to treat the tilt portion of the topography errors to reduce maximum ablation depth (and thus to save tissue). In such a case, select “Tilt off” in the “Treatment Plan Window”.

6.2.6. Optical Zone

The optical zone diameter is depending on the amount of measured area inside the OZ. If the area is less than 90% the image will not be used for the treatment plan. Between 90% and 98% it is possible and for more than 98% it is optimal to treat. The mean OZ is as large as there are minimum 90% of data available.

If an optical zone larger than the diameter of the detected topography is chosen, a warning will be displayed as no raw data are available for the treatment outside the diameter of the previously measured topography. Data will be extrapolated by software.

CAUTION

Extrapolated Optical Zones

DO NOT use optical zones larger than the determined topography area. Lack of raw topography data in areas outside the detected topography will make the correction treatment unreliable.

6.2.7. Transition Zone And Ablation Zone

The notebook portal software requires selection of a transition zone (TZ). This zone is surrounding the optical zone. It will provide a smooth transition from the ablation profile to the untreated cornea outside the transition zone. The shape of the transition zone depends on the type and magnitude of the optical aberrations. The displayed value is a maximum value and may not apply for full 360°.
Transition zone and optical zone (OZ) determine the ablation zone (AZ):
The ablation zone of a topo-guided treatment has no common shape. It is specific for the individual treatment. Please refer to the Procedure Manual regarding “hinge protection”.

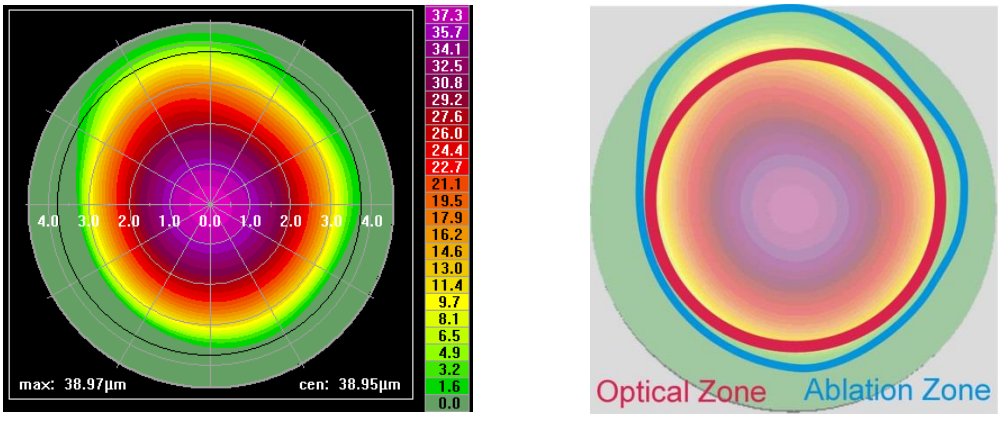

Figure 10: Examples Ablation Depth Display (Left) And Optical / Ablation Zone Borders (Right)

6.3. Feasibility Checks

Check if all mandatory entries for patient, 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 in the patient's file.

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

Ablation Depth And Remaining Stromal Thickness

Check resulting remaining stromal thickness indicated as "Remaining" or "Stroma". The resulting value for the residual stroma is displayed in microns (µm).

CAUTION

Corneal Thickness

Corneal thickness should be measured in five areas of the cornea for treatments. However, T-CAT (Topo-guided) treatments may not have the area of deepest ablation exactly in the center of the cornea. Check the location of the deepest ablation after the treatment plan was completed and consider additional pachymetry at this spot on the cornea.

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

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

The transition zone has no effect on ablation depth.

Tilt off/on and modification of sphere treatment amount may be used to modify ablation depth to maintain a certain residual stroma thickness.

A record of the finally chosen tilt treatment mode and targeted refractive outcome parameters should be made in the patient's files or in one of the notes sections of the notebook portal software.

6.4. Confirm And Save Data

The notebook portal software provides a “Summary Window”. This window will display treatment plan information, warnings and messages for final check and confirmation.

Double-check all data, messages and warnings. Accept data and possible warnings or consider a different plan for the patient.

If a treatment outside the proven parameter range is selected, a warning message will show. Use of such parameter outside the approved range can be confirmed in the summary window. For details, see the Addendum Operator’s Manual T-CAT.

6.5. Calculate And Send Ablation Data

The notebook portal software will calculate the treatment or “shot list” (numbers and position of single laser pulse ablations). Once the shot list has been calculated, it has to be transferred to the laser console for surgery.
Both processes require a certain amount of time, depending on the amount of correction and optical zone size.

Make sure that the laser console is calibrated and that treatments are left on the inserted WAVE CARD before starting the transfer to the laser. The laser LCD screen must display one of the Standby LCD screens.

Laser Console Programmed Mode

Notebook screen and LCD screen on the laser console will change to treatment screens and show the treatment data after the data transfer was completed.

Treatment type “T-CAT” (Topo-guided), patient’s name, planned refractive correction and the chosen optical zone will be displayed on the caser console for topo-guided treatments.

Displayed refraction values on the LCD screen will be “Modified” refractions of notebook treatment plan. The vertex distance is always 0 mm for topo-guided treatments.

NOTE

Decentration Values Display

Additionally decentration values are transferred and shown at the LCD screen. They shall compensate for the small amount of pupil decentration of the topography measurement(s).

Vertex distance and decentration values will disappear during treatment. Additional data will be displayed on the notebook computer screen throughout the treatment.

At this step, the laser console could be switched to the READY Mode. However, this is not recommended, as READY Mode switches back to STANDBY if the ablation is not started within 5 minutes. The right point of time to switch to READY Mode is indicated in section “Laser Ready” below.

7. PATIENT PREPARATION AND SURGERY

Almost all related procedures do not differ to the procedures required for Wavefront Optimized treatments.

Differences to Wavefront Optimized treatment preparation and surgery are:

- Different recommendation for pupil size during treatment.
- Different rule for intended decentration.
- Different LCD screen during surgery.

CAUTION

Pupil Size

Pupil size during T-CAT (Topo-guided) treatments should be within 2 mm of the pupil diameter of the topography examination.

CAUTION

Intended Decentration

Do NOT change centration for T-CAT (Topo-guided) treatments. The correct centration will be set automatically.

NOTE

Treatment LCD Screen

During a T-CAT (Topo-guided) treatment, the treatment screen will show the treatment type “T-CAT (Topo-guided)” as well as the patient’s name and date of birth.

Please see chapter 6.2.7 “Transition Zone And Ablation Zone” on page 71.

All other procedures have to be performed according to the ALLEGRETTO WAVE EYE-Q Operator’s Manual and Procedure Manual for Wavefront Optimized treatments.

8. APPENDIX

Checklist for Topography Examinations

The following checklist may be used for systematic validation of topography examinations intended to be used for a topo-guided treatment.

Screen	Check	Target
Measurement Screen (before capture)	CORRECT EYE	Patient's name and eye identifier indicated in screen (OD or OS) match eye in front of measurement aperture
Measurement Screen (after capture)	TOPOGRAPHY IMAGE	Rings should be clearly visible, no "data gaps", QS-field: OK
	IMAGE CENTRATION	"Centered" displayed AND Dotted line visible along pupil margin
	LID AND NOSE POSITION	Lid and Nose less as possible from the cornea
	PUPIL SIZE	Indicated Pupil not important
Validation	RINGS	The rings should be closed and clear visible in the treatment area, QS-field: OK
	PUPIL	The pupil should be well detected and show the center and the apex
	IMAGE	No "pizza cuts" should be visible in the topography image
Compare - and Indices Screen	Compare Images	The measurements should look similar to each other
	Indices	Check for keratoconus

Table 30: Topography Examinations

- End -