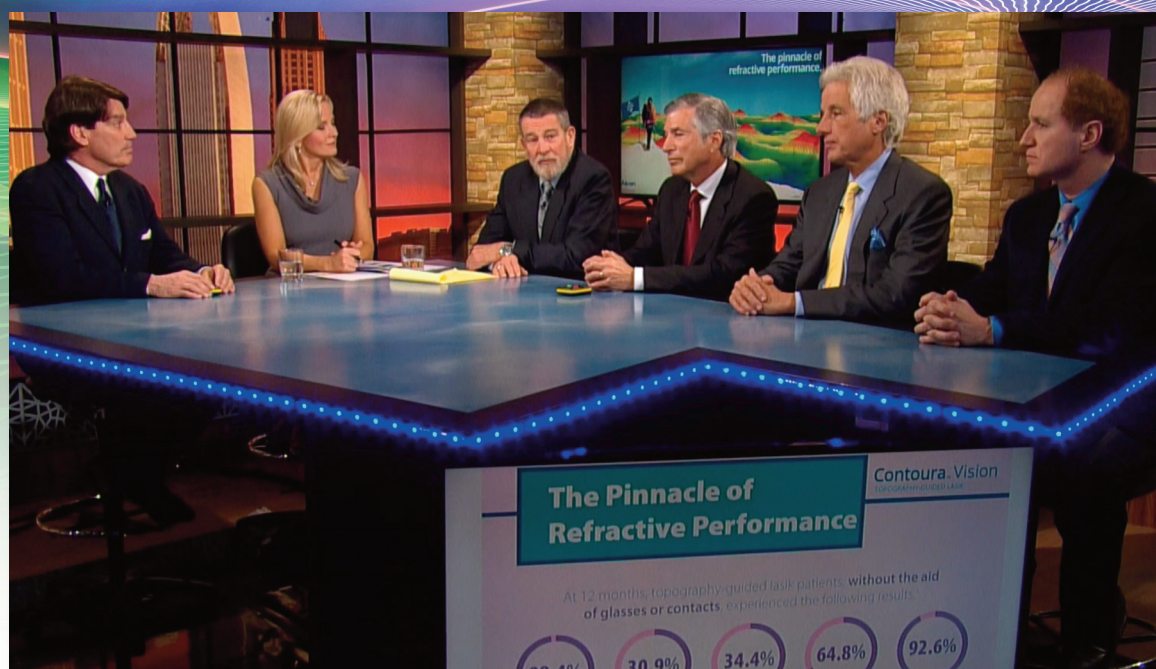


3-2-1 Action ... Live from Atlanta



From left: Karl Stonecipher, MD, Patricia Stark (host), Doyle Stulting, MD, PhD, Michael Gordon, MD, Stephen Slade, MD, and Ronald Krueger, MD

Alcon trains close to 500 ophthalmologists in more than 35 locations across the United States in one day.

On March 22, 2016, Alcon launched the latest technology in refractive surgery, **Contoura™ Vision**

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REFRACTIVE PORTFOLIO

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Why I believe in topography-guided ablations

by John Kanellopoulos, MD

“Contoura™ Vision offers such great results, it should be offered to every eligible patient.”

Topography-guided ablations have been an integral part of my practice for a dozen years. My primary practice is based in Athens, and topography-guided ablations are time-tested and common outside the U.S. Now, with the FDA's approval of topography-guided custom ablation treatment (T-CAT) for eyes with myopia and myopic astigmatism, topography-guided LASIK ablations are an option here in the U.S.¹

A new paradigm

The FDA study of topographic-guided refractions in virgin eyes establishes a new paradigm of even better outcomes. An intrinsic advantage of topography-guided ablations became evident as a result of the phase 3 clinical study that was the basis for T-CAT approval: A large percentage of eyes gained lines of vision.¹ This is probably associated with the subtle cornea irregularities that even normal eyes have. These irregularities are addressed by topography-guided ablations, which by definition normalize any cornea to maximum symmetry and apply the correction on the cornea apex (taking into account angle kappa). This appears to enhance visual function.

The differences between wavefront-guided methods and topography-guided methods are quite simple; wavefront-guided removes a lot of tissue to make a cornea more spherical based on the flattest part of the cornea. Topography-guided methods “shave” off the peaks of cornea curvature and aim to steepen flatter areas by ablating around them and indirectly steepening those flatter areas. This bimodal approach of simultaneous hyperopic and myopic treatment provides an advantage, in my opinion, because it removes much less tissue. In some instances, one-third less tissue is removed with topographic-guided ablations than with wavefront-guided ablations.

I find topography-guided methodology much easier to understand than wavefront-guided

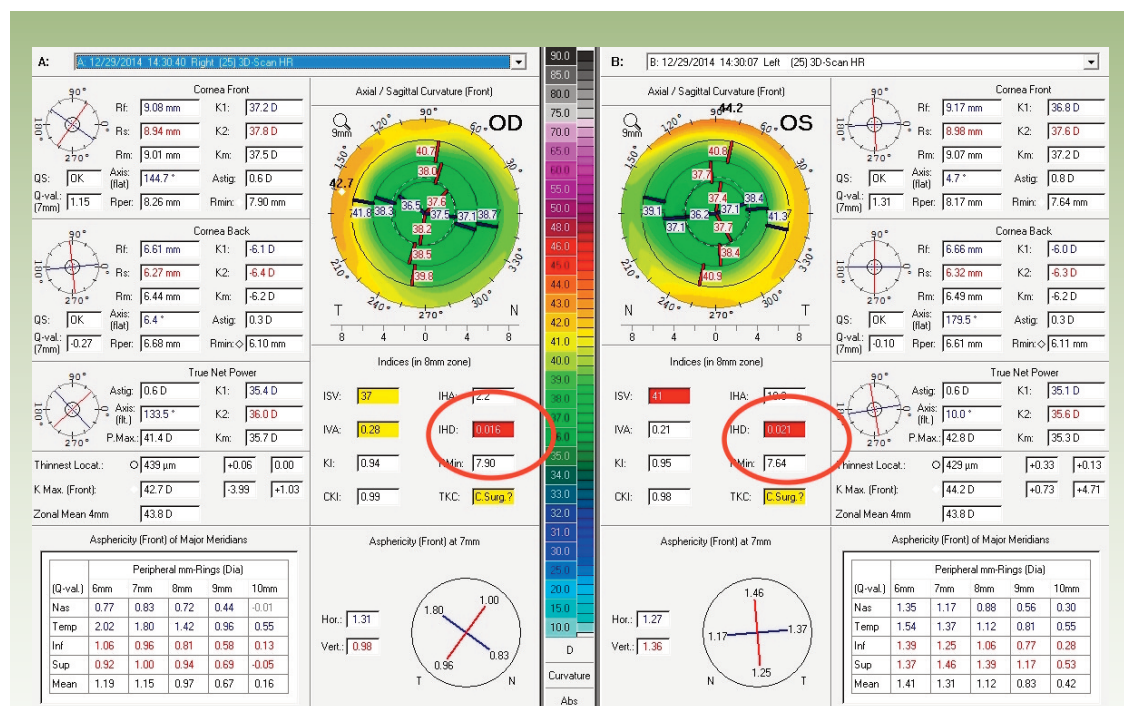


Figure 1: These scans illustrate a -6 D female who underwent routine femtosecond laser LASIK with the Alcon Refractive Suite. The right eye was treated with T-CAT, and the left eye with wavefront-optimized. The IHD values improved in the right and deteriorated slightly in the left, perhaps explaining the improvement in UCVA in the right from CF (CDVA 20/20) to 20/10 and in the left from CF (CDVA 20/20) to 20/20. Two lines were gained in the OD and no lines gained in the OS; these corneas would be classified as normal, but the slightly steeper superior half benefited from the T-CAT normalization, and this improved the visual outcome.

methodology. Wavefront is an approach dependent on theory that I cannot necessarily grasp by looking at objective topography data.

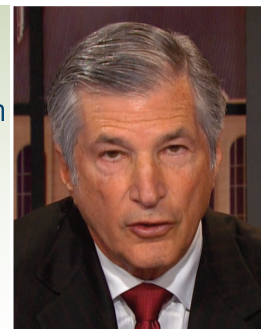
Beneficial for routine cases

Even as a seasoned topography-guided surgeon, I have learned a great deal from the FDA study data that further supports my reliance on topography-guided methodology. The findings show that T-CAT is beneficial for virgin eyes, and this has led me to use it in my routine LASIK cases. I see a significant advantage in the fact that in “normal” corneas T-CAT can further normalize the cornea and offer better visual acuity and more lines of gained vision (Figure 1). For this as well as the reasons stated earlier, I consider topography-guided treatment to have advantages over wavefront-guided treatment.

Reference

1. Topography-guided Custom Ablation Treatment or T-CAT Summary of Safety and Effectiveness Data (SSED), available at: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm372964.htm.

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Pearls for selecting patients and setting expectations

by David W. Friess, OD, FAAO

Carefully selecting patients for treatment with topography-guided LASIK can help surgeons achieve the best possible outcomes, and carefully setting expectations can help patients achieve the best possible satisfaction levels. The key to both is for ophthalmic surgeons to familiarize themselves with the FDA trial outcomes upon which approval of topography-guided custom ablation treatments (T-CAT) were based.

The FDA approved T-CAT LASIK for the treatment of eyes with myopia and myopic astigmatism. Specifics of the approval state that the WaveLight Allegretto Wave Eye-Q excimer laser system (Alcon, Fort Worth, Texas) used in conjunction with the WaveLight ALLEGRO Topolyzer (topographer) and T-CAT treatment planning software is indicated for performing T-CAT LASIK for the reduction or elimination of up to -9 D of spherical equivalent myopia or myopia with astigmatism, with up to -8 D of spherical component and up to -3 D of astigmatic component at the spectacle plane. This indication is for patients who are 18 years of age or older and in patients with documentation of a stable manifest refraction defined as 0.50 D or less of preoperative spherical equivalent shift over 1 year prior to surgery.¹

Safe and effective

The data derived from the FDA clinical trial demonstrated that T-CAT LASIK is a safe and effective treatment for myopia and myopic astigmatism. Notable visual acuity and quality of vision results were achieved for analyses of uncorrected visual acuity (UCVA) postop compared to best spectacle-corrected visual acuity (BSCVA) preoperatively, postoperative BSCVA compared to preoperative baseline, and improvements in visual symptoms.

Efficacy of T-CAT LASIK was excellent. At 3 months postoperatively, 31.6% of eyes achieved a UCVA of 20/12.5 or better; 68.9% of the eyes had a UCVA of 20/16 or better; and 92.7% of eyes had a UCVA of 20/20 or better. Over time, there was a slight improvement in UCVA through the 12-month examination after T-CAT LASIK. At 12 months, 34.4% of eyes saw 20/12.5 or better; 64.8% of eyes saw 20/16 or better; and 92.6% of eyes saw 20/20 or better. At 3 months, 91.9% of eyes had an MRSE within 0.5 diopters (D) of the intended treatment, and 98.8% had an MRSE within 1.00 D of the intended treatment. At 12 months, 94.8% of eyes

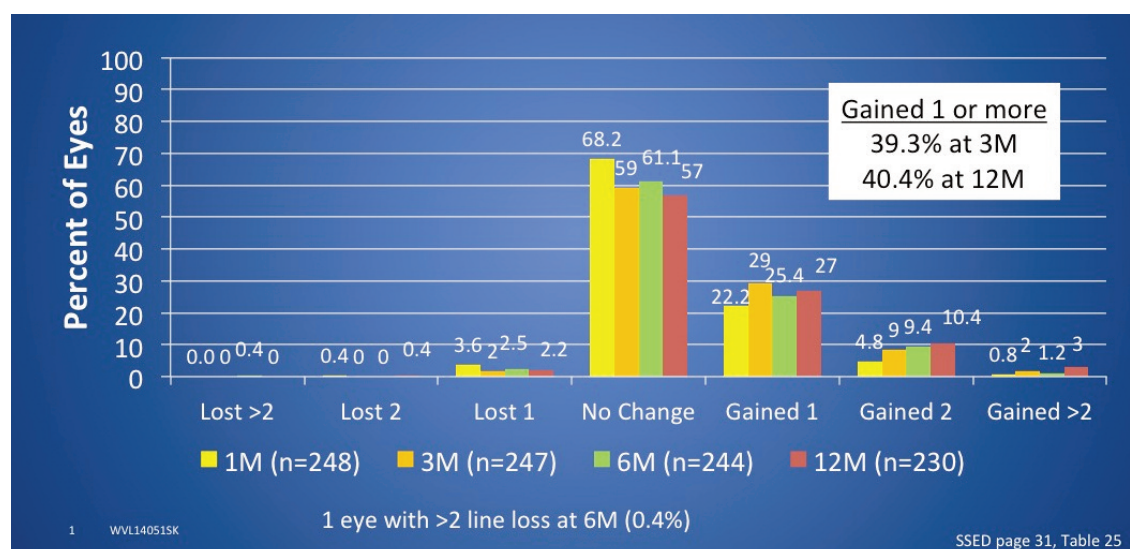


Figure 1. Postoperative BSCVA compared to preoperative BSCVA (change in lines)

achieved MRSE within 0.50 D of the intended treatment, and 99.6% of eyes achieved an MRSE within 1.00 D of the intended treatment.

Based on the clinical study outcomes, the potential for gains in vision performance are significant. Eyes treated with T-CAT demonstrated a shift toward an improvement in UCVA compared to preoperative BSCVA, with 29.6% of eyes gaining 1 or more lines of UCVA at 3 months compared with preoperative BSCVA. At 12 months, 30.9% of eyes gained 1 or more lines of UCVA compared to preoperative BSCVA.¹ In total, 89.9% of eyes were seeing at least as well without correction postoperatively as they did with best spectacle correction preoperatively. In comparing preoperative BSCVA to postoperative BSCVA, 39.3% of eyes gained 1 or more lines at 3 months and 40.4% of eyes gained 1 or more lines at 12 months (Figure 1).

Now that T-CAT is approved in the U.S., it is important for eye surgeons who want to effectively position it in their practice to choose patients who would be expected to respond similarly to the subjects who were treated in the FDA study. The ophthalmic community in the U.S. has been eagerly awaiting T-CAT with good reason. In addition to providing technology that has been shown to result in high rates of improved vision performance, it offers clinicians something new and exciting to discuss with and attract patients.

In order to achieve outcomes similar to those produced by the FDA clinical trial, surgeons who employ this technology must commit to being involved in topography acquisition, interpretation and selection. In addition, it is important for the

practice staff to understand and appreciate the difference between topography-guided ablations and other forms of refractive correction, such as wavefront-optimized and wavefront-guided LASIK. Topography use in driving ablation patterns offers a new opportunity to discuss personalized vision correction with patients and (the perhaps more easily understood) concepts of corneal topographic mapping in eyecare.

T-CAT procedures do require additional planning beyond that of wavefront-optimized procedures, primarily with close attention to diagnostic topography scans for treatment export. However, as the FDA trial outcomes show, the additional attention to detail and planning time are well spent. With T-CAT LASIK, there is an opportunity to raise the bar even further on visual performance, and that is ultimately what is most exciting about it.

Reference

1. FDA device approvals website, **Topography-guided Custom Ablation Treatment, or T-CAT Summary of Safety and Effectiveness Data (SSED)**, available at: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm372964.htm.

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Interpreting topographic information with T-CAT diagnostics

by Arthur B. Cummings, MB ChB, FCS(SA), MMed(Ophth), FRCS(Edin)

“Contoura™ Vision brings a new approach to help drive accurate outcomes for patients and enhanced visual outcomes.”

The ultimate goal of topography-guided custom ablation treatment (T-CAT) diagnostics is to capture a reproducible topographical image of the corneal irregularity that can then be used to drive a topography-guided procedure. When I am considering the use of T-CAT, I find that it is helpful to identify the patient's primary complaint. This information combined with a sketch that I ask the patient to draw to illustrate his or her visual symptoms (while best corrected) helps to inform my decision about whether T-CAT is the appropriate treatment.

In the FDA clinical trial of T-CAT technology, investigators used a minimum of 4 topography images of each eye captured with the ALLEGRETTO Topolyzer (Alcon, Fort Worth, Texas) to create a treatment plan. Some important clinical pearls to keep in mind in an effort to get a good scan include selecting patients with good correlation between topographic (corneal) astigmatism and refractive astigmatism; using the same target Q value as the preoperative value; using the “tilt-off” tissue-sparing default setting; making sure that the patient is properly aligned under the laser; and comparing ablation profiles of T-CAT vs. wavefront (when available).

Methodical map analysis

When analyzing the topographic map quality, it is important to review the entire treatment zone. The surgeon should examine the rings for continuity using the measurement function in the overview screen, and make sure the mires are as crisp and clear as possible. Then, the surgeon should look for discontinuity and dry spots (Figure 1); compare and analyze higher order aberrations; ensure that there is a good correlation between refractive astigmatism and topographic astigmatism; ensure that the detection of the concentric rings and the detection of the pupil are accurate; and ensure that the image is centered.

Once I am satisfied that the patient's topographical maps are of high quality, I upload that

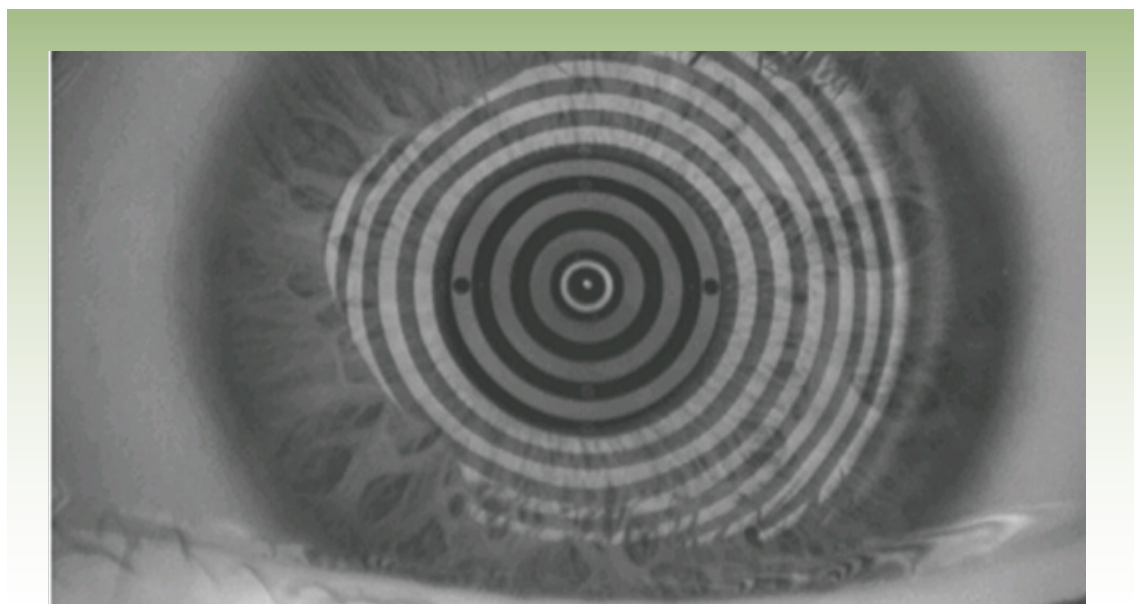


Figure 1. Ring pattern: Look for discontinuity, dry spots, etc. within the ring pattern.

information to the excimer laser to generate the ablation profile. The next step is to choose a target Q value for the treatment. The Q value is the rate of change of corneal curvature; a perfect circle has a Q value of zero. All the spots, left, right, central or peripheral to this particular spot, will fall away at the same rate. A normal prolate cornea is steeper in the center and flatter toward the corneal periphery, and this is the ideal shape in order to have no spherical aberration within the system as a whole. For example, the normal cornea of someone who has not undergone previous surgery may be 43.00 D or 44.00 D in the center, while farther out in the periphery, it may flatten down to 42.00 D or 41.00 D. Applying a laser treatment just to the central cornea will flatten the center relative to the periphery, creating an oblate cornea. This will induce aberrations on a wavefront map and visual symptoms for the patient. Choosing a target Q that is prolate helps the laser to achieve the final desirable corneal shape. For primary eyes, I try to preserve whatever Q value the patient presents with, i.e., the delta-Q is zero. Most primary eyes are quite prolate and the goal is to preserve that prolate shape. So, for those patients, the Q value does not change. It is important to remember that the patient's primary concern is his or her final visual acuity, and this depends largely on the refractive outcome, so our primary duty is to try to address the refractive component at the time of surgery.

Rating the map

With practice, it becomes easier to identify topographic maps as high or low quality. One nice feature is that the Topolyzer provides an automated rating of the map by placing a green tick next to a map you may want to use, a yellow tick next to a map you need more time to think about, and a red tick next to a map that is of poor quality. Then, it only takes a minute to load all the maps into the ALLEGRETTO WAVE excimer laser. It may take an extra few minutes to decide which maps to use and to amend or tweak the refraction if necessary, but those few extra minutes are time well spent to give patients the vision they deserve.

Ronald Krueger, MD
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Applying T-CAT FDA study outcomes to clinical practices

by Doyle Stulting, MD, PhD

“Proper patient selection, pay attention to detail, and educate everyone in your practice.”

Topography-guided custom ablation treatment (T-CAT) corrects first- and second-order refractive abnormalities based on clinical refractions and higher order aberrations (HOA) based on corneal topography.

In 2013, the FDA approved T-CAT LASIK for the treatment of eyes with myopia and myopic astigmatism.¹ Clinical trial of T-CAT was conducted on subjects who had not undergone previous corneal refractive surgery or demonstrated pathology other than refractive error, and outcomes in normal subjects were outstanding, objectively and subjectively. Treatment was indicated for the reduction or elimination of up to -9.00 D of spherical equivalent myopia or myopia with astigmatism, with up to -8.00 D of spherical component and up to -3.00 D of astigmatic component at the spectacle plane.

Throughout the clinical trial, the 3 devices used to plan and perform the topography-guided LASIK treatments were the ALLEGRETTO WAVE EYE-Q 400 Hz laser system (Alcon, Fort Worth, Texas), ALLEGRO Topolyzer topography system (Alcon), and T-CAT software for treatment planning. The meticulous attention to the accurate acquisition and selection of at least 4 corneal topographic images was critical to the outstanding clinical outcomes that were obtained during the clinical trial.

Outcomes

Subjects in the clinical trial reported an improvement in parameters measured by the Refractive Status and Vision Profile (RSVP), including physical/social functioning, driving, visual symptoms, optical problems and problems with corrective lenses that were evident at 3 months and continued to improve through 12 months¹; 98.4% of subjects stated that they were satisfied with their outcomes and would have T-CAT LASIK treatment again.¹

Data derived from the FDA clinical trial demonstrated that T-CAT LASIK is a safe and effective treatment for myopia and myopic astigmatism, with an increase in UCVA postoperatively compared to BSCVA preoperatively, an increase in BSCVA compared to preoperatively, and an improvement in visual

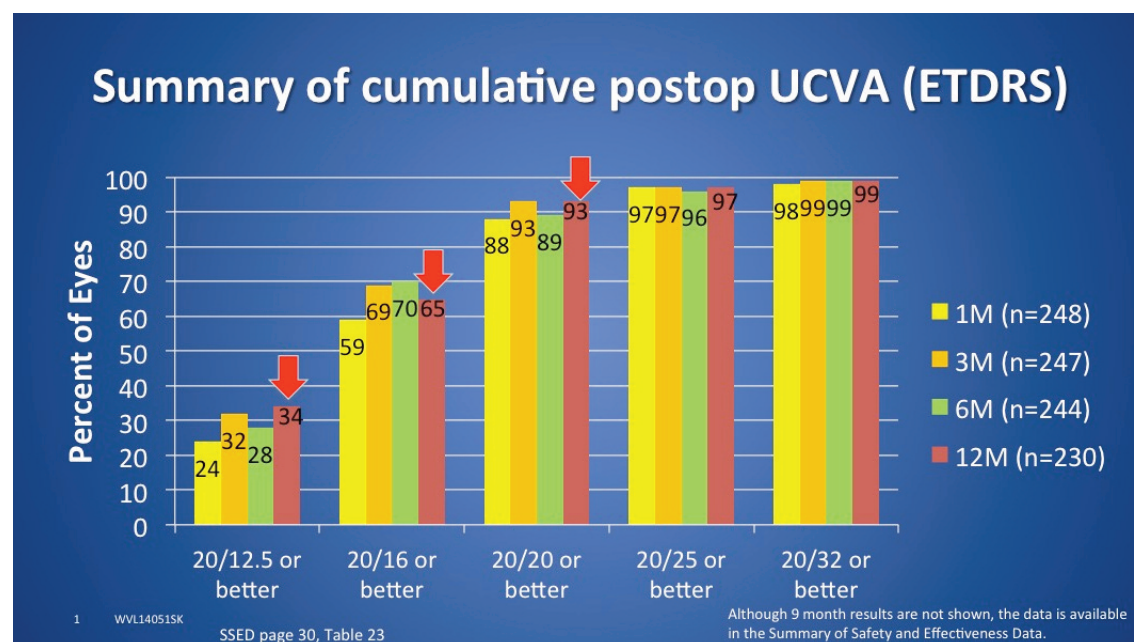


Figure 1. Cumulative postoperative UCVA (ETDRS)

symptoms. At 3 months postoperatively, 31.6% of eyes achieved a UCVA of 20/12.5 or better; 68.9% of the eyes had a UCVA of 20/16 or better; and 92.7% of eyes had a UCVA of 20/20 or better. At 12 months, 34.4% of eyes saw 20/12.5 or better; 64.8% of eyes saw 20/16 or better; and 92.7% of eyes saw 20/20 or better¹ (Figure 1). Eyes treated with T-CAT demonstrated a shift toward an improvement in UCVA with time. In total, 89.9% of eyes were seeing at least as well without correction postoperatively as they did with best spectacle correction preoperatively.¹

Wavefront customized LASIK treatment is informally considered the standard of care in the U.S. by many. So if wavefront-guided treatment is the standard of care, why should we consider T-CAT? Topographic measurements are advantageous because they are static, reproducible, independent of pupil size, provide better peripheral data, provide more measurement points, and are based on the cornea where most visual aberrations are created. Topography gives a better measurement of highly aberrated corneas, which may create artifacts with wavefront sensors because of severely misdirected light rays.

Applying the lesson

The FDA study and its outcomes have taught us that in order to gain the most from T-CAT, the surgeon has to be familiar with the procedure, detail-oriented, and an active participant in topographic image

acquisition to achieve these results. The payoff is a unique new technology on a platform that offers tremendous potential for an improvement in uncorrected visual acuity, an improvement in best spectacle corrected acuity, and an improvement in certain visual symptoms.

Reference

Topography-guided Custom Ablation Treatment or T-CAT Summary of Safety and Effectiveness Data (SSED), available at: www.fda.gov/MedicalDevices/Product-sandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm372964.htm.

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WaveLight Excimer Laser Systems

Important product information

This information pertains to all WaveLight Excimer Laser Systems, including the WaveLight ALLEGRETTO WAVE, the ALLEGRETTO WAVE Eye-Q, and the WaveLight EX500.

Caution: Federal (U.S.) law restricts the WaveLight Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight Excimer Laser System.

Indications: FDA has approved the WaveLight Excimer Laser systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for:

- the reduction or elimination of myopia of up to -12.00 D and up to 6.00 D of astigmatism at the spectacle plane;
- the reduction or elimination of hyperopia up to +6.00 D with and without astigmatic refractive errors up to 5.00 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of +6.00 D;
- the reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 D at the spectacle plane; and
- the wavefront-guided reduction or elimination of myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane.

In addition, FDA has approved the WaveLight ALLEGRETTO WAVE Eye-Q Excimer Laser System, when used with the WaveLight ALLEGRO Topolyzer and topography-guided treatment planning software for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 D of myopia, or for the reduction or elimination of myopia with astigmatism, with up to -8.00 D of myopia and up to 3.00 D of astigmatism.

The WaveLight Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism) with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.

Contraindications: The WaveLight Excimer Laser Systems are contraindicated for use with patients who:

- are pregnant or nursing;
- have a diagnosed collagen vascular, autoimmune or immunodeficiency disease;
- have been diagnosed with keratoconus or if there are any clinical pictures suggestive of keratoconus;
- are taking isotretinoin (Accutane*) and/or amiodarone hydrochloride (Cordarone*);
- have severe dry eye;
- have corneas too thin for LASIK;

- have recurrent corneal erosion;
- have advanced glaucoma; or
- have uncontrolled diabetes.

Warnings: The WaveLight Excimer Laser Systems are not recommended for use with patients who have:

- systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status;
- a history of Herpes simplex or Herpes zoster keratitis;
- significant dry eye that is unresponsive to treatment;
- severe allergies;
- a history of glaucoma;
- an unreliable preoperative wavefront examination that precludes wavefront-guided treatment; or
- a poor quality preoperative topography map that precludes topography-guided LASIK treatment.

The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

Topography-guided LASIK requires preoperative topography maps of sufficient quality to use for planning a topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the topography-guided LASIK treatment and may result in poor vision after topography-guided LASIK.

Precautions: The safety and effectiveness of the WaveLight Excimer Laser Systems have not been established for patients with:

- progressive myopia, hyperopia, astigmatism and/or mixed astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone;
- corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage;
- residual corneal thickness after ablation of less than 250 microns due to the increased risk for corneal ectasia;
- pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning;
- history of glaucoma or ocular hypertension of >23 mm Hg;
- taking the medications sumatriptan succinate (Imitrex*);
- corneal, lens and/or vitreous opacities including but not limited to cataract;

- iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eye tracking; or
- taking medications likely to affect wound healing including (but not limited to) antimetabolites.

In addition, safety and effectiveness of the WaveLight Excimer Laser Systems have not been established for:

- treatments with an optical zone <6.0 mm or >6.5 mm in diameter, or an ablation zone >9.0 mm in diameter; or
- wavefront-guided treatment targets different from emmetropia (plano) in which the wavefront calculated defocus (spherical term) has been adjusted.

In the WaveLight Excimer Laser System clinical studies, there were few subjects with cylinder amounts >4 D and ≤ 6 D. Not all complications, adverse events, and levels of effectiveness may have been determined for this population.

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery.

Adverse Events and Complications

Myopia: In the myopia clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect.

Hyperopia: In the hyperopia clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

Mixed Astigmatism: In the mixed astigmatism clinical study, two adverse events were reported. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. UCVA was decreased due to this event. The second event involved the treatment of an incorrect axis of astigmatism. The axis was treated at 60 degrees instead of 160 degrees.

The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye.

Wavefront-Guided Myopia: The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront-Optimized LASIK (Control Cohort). No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. In the Control Cohort, one subject undergoing traditional LASIK had the axis of astigmatism programmed as 115 degrees instead of the actual 155 degree axis. This led to cylinder in the left eye.

The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort.

Topography-Guided Myopia: There were six adverse events reported in the topography-guided myopia study. Four of the eyes experienced transient or temporary decreases in vision prior to the final 12 month follow-up visit, all of which were resolved by the final follow-up visit. One subject suffered from decreased vision in the treated eye, following blunt force trauma 4 days after surgery. One subject experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

Clinical Data

Myopia: The myopia clinical study included 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. Of the 782 eyes that were eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/40 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

Long-term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

Hyperopia: The hyperopia clinical study included 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. Of the 212 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 69.4% were corrected to 20/20 or better. Subjects who responded to a

patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "much worse" at 6 months post-treatment: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

Long-term risks of LASIK for hyperopia with and without astigmatism have not been studied beyond 12 months.

Mixed Astigmatism: The mixed astigmatism clinical study included 162 eyes treated, of which 111 were eligible to be followed for 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. Of the 142 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 97.3% achieved acuity of 20/40 or better, and 69.4% achieved acuity of 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline).

Long-term risks of LASIK for mixed astigmatism have not been studied beyond 6 months.

Wavefront-Guided Myopia: The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront-Optimized LASIK (Control Cohort). 166 of the Study Cohort and 166 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.

Of the 166 eyes in the Study Cohort that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 166 eyes in the Control Cohort eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20.

In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher at

3 months post-treatment than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

Long-term risks of wavefront-guided LASIK for myopia with and without astigmatism have not been studied beyond 6 months.

Topography-Guided Myopia: The topography-guided myopia clinical study included 249 eyes treated, of which 230 eyes were followed for 12 months. Accountability at 3 months was 99.2%, at 6 months was 98.0%, and at 12 months was 92.4%. Of the 247 eyes that were eligible for the UCVA analysis at the 3-month stability time point, 99.2% were corrected to 20/40 or better, and 92.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "marked" or "severe" at an incidence greater than 5% at 1 month after surgery: dryness (7% vs. 4% at baseline) and light sensitivity (7% vs. 5% at baseline). 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 surgery.

Long-term risks of topography-guided LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

Information for Patients: Prior to undergoing LASIK surgery with a WaveLight Excimer Laser System, prospective patients must receive a copy of the relevant Patient Information Booklet, and must be informed of the alternatives for correcting their vision, including (but not limited to) eyeglasses, contact lenses, photorefractive keratectomy, and other refractive surgeries.

Attention: Please refer to a current WaveLight Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects.

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