



Doyle Stulting, MD, PhD

Topography-guided LASIK: A paradigm shift in refractive laser treatment

by Doyle Stulting, MD, PhD

Refractive surgery has advanced significantly in the past 2 decades. When it was first introduced, we were able to reduce or eliminate patients' dependence on glasses or contact lenses. In exchange for spectacle independence, however, patients sometimes had to accept less than 20/20 uncorrected visual acuity (UCVA) and induced visual aberrations. Today, topography-guided treatment LASIK with the WaveLight Allegretto Wave Eye-Q Laser (Alcon, Fort Worth, Texas) can provide not only freedom from glasses and contact lenses, but also improved quality of vision.¹

There are several differences between topography-guided customized LASIK and wavefront-guided customized LASIK. Wavefront-guided customized LASIK has traditionally been based on wavefront measurements obtained by projecting multiple light beams into the eye and measuring the location of the corresponding light reflected from the retina. With topographers, we can measure many more points of curvature on the cornea over a wider area than is possible with wavefront measurement devices. For example, the Topolyzer (Alcon), used in conjunction with the WaveLight Laser, measures corneal curvature at approximately 22,000 locations on the cornea, while the WaveLight wavefront analyzer (Alcon) measures only 168 sites, and the WaveScan (Abbott Medical Optics, Santa Ana, Calif.) measures only 240 points per WaveScan technology specifications.

Another benefit of topography is that measurements are not limited by the pupil. Wavefront measurements require light to reach the retina through the pupil, so the size and location of the pupil limits the area that can be measured. In contrast, corneal topographic measurements can be applied to the entire cornea.

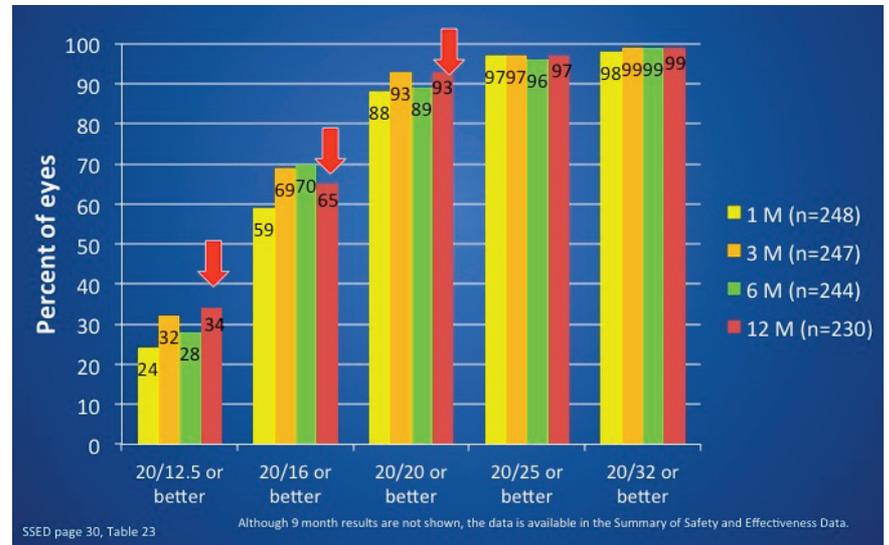


Figure 1: Cumulative postop UCVA (ETDRS)

Additionally, highly aberrated eyes and those with corneal opacities can produce inaccurate aberrometer measurements because aberrometers cannot always identify the source of light leaving the eye and because light may be scattered by the corneal opacities. In contrast, topography-guided treatment can be used successfully to evaluate highly aberrated eyes.

Aberrometer measurements are also affected by the state of accommodation (which can induce high-order aberrations in addition to spherical refractive changes), early cataract, and vitreous opacities. Surgical correction of lenticular high-order aberrations can be problematic because they tend to change with time. Additionally, wavefront-guided treatments do not necessarily compensate for off-axis rays of light passing through lenticular opacities from different locations on the cornea.

Because corneal topography does not provide information about low-order optical abnormalities of the eye—spherical error and regular astigmatism—topography-guided refractive treatments cannot be based on corneal topography alone. For topography-guided treatment, refractive measurements of the eye's

optical system must be obtained independently of topographic measurements. Topography-guided treatment software combines both refractive and topographic information to generate the pattern of laser shots that will improve vision.

Study summary

The Topography-guided Treatment Study Group recently investigated the visual outcomes of topography-guided LASIK. This prospective, non-randomized study was performed at 9 clinical sites in the United States and included 249 eyes of 212 patients with myopia or myopic astigmatism treated with topography-guided treatment LASIK using the WaveLight Allegretto Wave Eye-Q Laser. Outcome measures included manifest refraction, UCVA, best spectacle-corrected visual acuity (BSCVA), visual complaints, adverse events, responses to questionnaires, and complete ophthalmologic examinations.

Patients included in this study were between the ages of 18 and 65 years (mean: 34 years) and had up to -9.0 D of spherical equivalent myopia at the spectacle plane with up to 6.0 D of astigmatism, correctible to at least 20/25 in each eye.

continued on page 3

“With topography-guided treatment, we should tell our patients there is an excellent likelihood that they will have better vision without correction than they had preoperatively with correction and that the quality of their vision is likely to improve.”

This supplement was produced by EyeWorld and sponsored by Alcon. The doctors featured in this supplement received compensation from Alcon for their contributions to this supplement.

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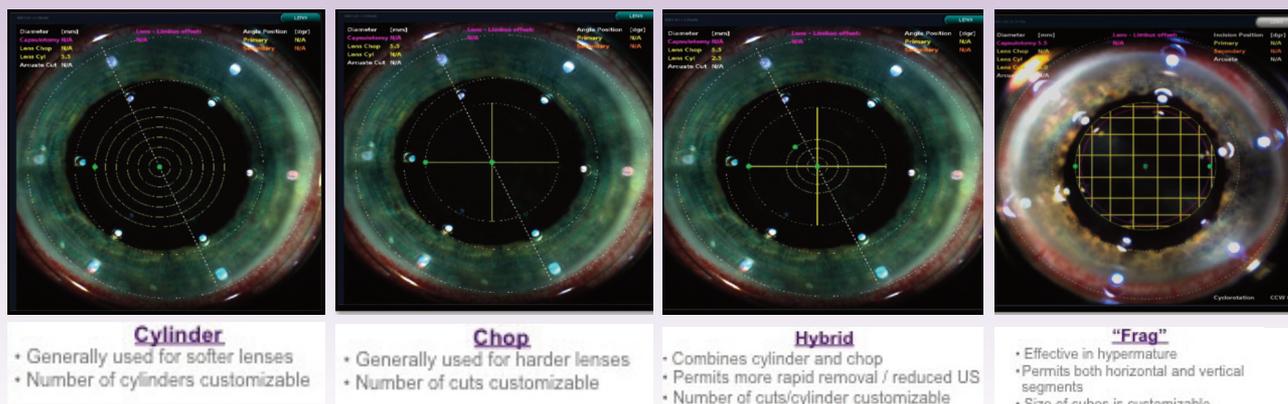


Michael Diesenhouse, MD

“The SoftFit Patient Interface, which has a hydrogel contact lens, has none of the disadvantages associated with other contact or liquid interfaces.”

Using the LenSx Laser in mature cataract cases

by Michael Diesenhouse, MD



The LenSx Laser offers several customizable fragmentation patterns that surgeons can select based on pathology or their preference.

Today, more and more surgeons who use the LenSx Laser (Alcon, Fort Worth, Texas) are exploring the potential benefits of this technology in challenging cases. This article details my successful use of the LenSx Laser in very dense cataracts cases.

Cataract surgery in patients with very dense cataracts represents a particular challenge. It is associated with a greater risk of complications. In my experience with these dense cataracts, the LenSx Laser has reduced phaco energy and balanced salt solution use, and the procedures have been done quickly. Beginning with the patient docking, the lack of a fixed bed allows us to get patients ready for the procedure quickly. This is especially helpful in elderly patients who may have difficulty moving from lasers with a fixed bed. Even in dense cases, the average time from suction on to suction off has been less than 2 minutes, and this includes imaging, all settings, lens fragmentation, capsulotomy, and all corneal incisions.

Phacoemulsification is more efficient when the lens is treated with the LenSx Laser. I am confident that these cases benefit from reduced corneal endothelial damage during laser cataract surgery. The LenSx Laser helped me in these specific cases by reducing the phaco manipulation required during surgery, which protected the incision architecture during emulsification and I/A.

Another concern with dense cataracts is there can be high pressure in the bag. Because the LenSx Laser completes the treatment rapidly, I am able to get a complete rhexis. I think the LenSx Laser helps the surgeon to perform the capsulotomy confidently. The SoftFit Patient Interface, which has a hydrogel contact lens, has none of the disadvantages associated with other contact or liquid interfaces. I am very confident that I will get a free-floating rhexis in nearly all of my cataract cases.

Phacoemulsification of the very dense cataract presents the surgeon with a series of specific and difficult challenges. Many of my LenSx Laser patients have very dense/4-grade nuclear cataracts. The LenSx Laser successfully divides these nuclei into pie-shaped fragments, permitting either pre-chop or other chopping techniques. The total power required for emulsification was decreased by about a third in my hard cataract cases. While I am able to get “zero phaco” now in routine phaco cases, I do not believe this should be the objective. I try to focus on the outcome and use the right amount of energy required for each case, especially in very dense cataract cases.

The LenSx Laser allows for customizable lens fragmentation based on patients’ pathology and surgeon preference. In these dense cases, I typically use a hybrid pattern that combines cylinder and chop patterns and permits more rapid removal with reduced ultrasound.

The number of cuts/cylinder is customizable. Radial incisions aid in removing epi-nuclear plates. This pattern allows me to make the deep cracks through the entire thickness of the nucleus. Once the segments of the dense nucleus are fragmented by the laser, I am able to phaco because the phaco energy is delivered more posteriorly, and the endothelium is usually well-protected.

The recently released “Frag” pattern is designed to be effective in all cataract cases. This pattern will permit both horizontal and vertical segments, and because it is customizable, it will allow surgeons to adjust the size of cubes.

The LenSx Laser’s user interface is simple to understand and easy to adjust. I make the primary incision 0.1 to 0.2 mm larger than my manual incision to ensure there is no thermal injury from the phaco handpiece. Additionally, with the LenSx Laser, the lens cortex is cut cleanly, with no strands of cortex floating in the bag. During I/A, I go further into the fornix of the capsular bag to grab the cortex. I recommend that surgeons approach the subincisional cortex first to aid in cortical removal.

I’ve had good success with the LenSx Laser, even in challenging cases.

Dr. Diesenhouse is medical director of Eye Associates of Tucson and Catalina Surgery Center in Tucson, Ariz. He can be contacted at mcd4@mindspring.com.

continued from page 1

Forty-four percent were men, and 56% were women. Eyes with prior refractive surgery, significant lenticular astigmatism, abnormal topographies, a calculated residual stromal bed thickness less than 250 μm, or other ocular pathology that might affect the results of LASIK were excluded.

Postoperative examinations were performed at day 1, week 1, and months 1, 3, 6, 9, and 12. Visual acuities and refractive errors were measured with the Early Treatment Diabetic Retinopathy (ETDRS) charts and protocol.

The study found that topography-guided treatment resulted in a significant reduction in manifest refraction spherical equivalent (MRSE) and cylinder, reaching stability at 3 months after treatment. Mean MRSE was 0.06±0.33 D at 3 months and 0.00±0.27 D at 1 year. Mean cylinder was 0.19±0.32 D at 3 months and 0.19±0.30 D at 1 year. Three months postoperatively, 91.9% of eyes were within 0.50 D of plano, and at 1 year, 94.8% of eyes were within 0.50 D of plano.

At 3 months postoperatively, 7.7% of eyes saw 20/10 or better without correction; 31.6% of eyes saw 20/12.5 or better; 68.8% of eyes saw 20/16 or better; 92.7% of eyes saw 20/20 or better; and 97.2% of eyes saw 20/25 or better. At 1 year, 15.7% of eyes saw 20/10 or better without correction; 34.4% of eyes saw 20/12.5 or better; 64.8% of eyes saw 20/16 or better; 92.6% of eyes saw 20/20 or better; and 96.5% of eyes saw 20/25 or better. Eyes treated with topography-guided treatment achieved an improvement in UCVA compared to preoperative BSCVA, with 29.6% of eyes gaining 1 or more lines of UCVA, and 89.9% of eyes seeing at least as well without correction postoperatively as they did with best spectacle correction preoperatively (Figure 1).

The safety of topography-guided treatment was excellent, with only 5 single reports of loss of BSCVA of two or more lines at 1 month or later. One patient suffered bilateral retinal detachments 6 months after topography-guided treatment. Complications were transient and did not result in significant loss of vision. In fact, there was a tendency toward an improvement in BSCVA after topography-guided treatment, compared to preoperatively, with a trend toward further improvement with time (Figure 2.)

Most visual symptoms improved at 3 months after topography-guided treatment compared to preoperative levels with habitual correction, reaching statistical significance for light sensitivity, difficulty driving at night, reading difficulty, and glare. Only double vision and foreign body sensation were reported as worse after 3 months, with minimal increases of 0.8% and 0.4%, respectively. The incidence and severity of visual symptoms continued to decline during the 12 months of the study (Figure 3).

The Refractive Status and Vision Profile (RSVP) showed an improvement in all subscales and in the total composite score that is computed for each visit, 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 months postoperatively, compared to their vision while wearing glasses or contact lenses preoperatively. The only exception was glare at the 1-month visit, which showed a worsening that changed to improvement at 3 months and all subsequent visits.

Published literature has indicated that a difference of 6 points or more on the composite score is a clinically significant change,² so 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 3 times the minimum threshold for clinically significant improvement at each postoperative visit, ranging from a change of -15.97 points at 3 months to a change of -16.39 points at 12 months. Most of these patients (98.4%) were satisfied with their outcomes and said they would have topography-guided treatment LASIK treatment again.

The results of this study exceeded our expectations. We thought that we would see good outcomes but did not think that topography-guided treatment on “normal” eyes without significant topographic abnormalities would exceed the outcomes we are accustomed to seeing with currently available treatments. To our surprise, we found excellent UCVA, significant improvements in BSCVA, and a reduction in visual symptoms. In fact, a majority of eyes had better

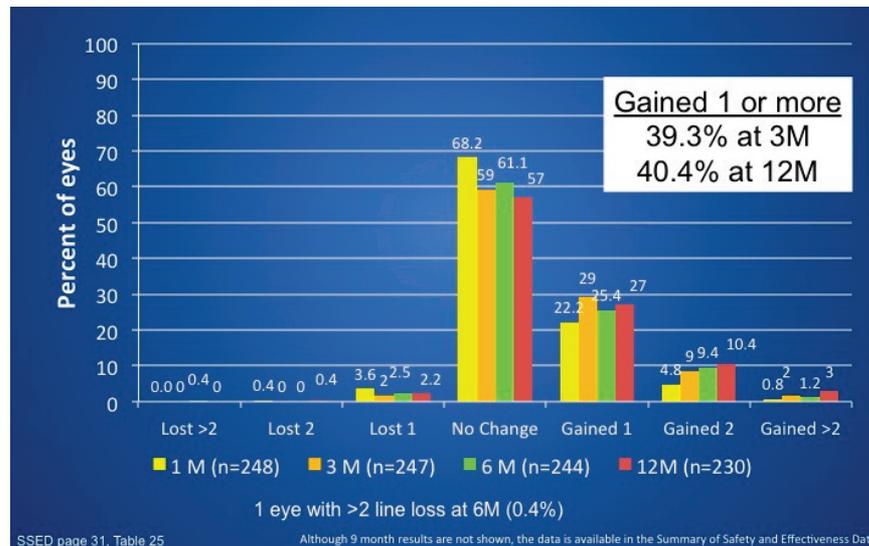


Figure 2: Postop BSCVA compared to prep BSCVA (change in lines)

Question	None - Moderate		Marked - Severe		Difference in Marked - Severe	p-value
	Baseline	3 M	Baseline	3 M		
Light sensitivity	94.8%	98.4%	5.2%	1.6%	-3.6%	0.0269
Difficulty driving at night	91.6%	96.0%	8.4%	4.1%	-4.4%	0.0431
Reading difficulty	90.0%	96.4%	10.1%	3.6%	-6.4%	0.0045
Double vision	98.8%	98.0%	1.2%	2.0%	0.8%	0.4697
Fluctuation in vision	98.4%	99.6%	1.6%	0.4%	-1.2%	0.1871
Glare	95.2%	99.2%	4.8%	0.8%	-4.0%	0.0066
Halos	96.8%	99.2%	3.2%	0.8%	-2.4%	0.0562
Starbursts	96.8%	98.8%	3.2%	1.2%	-2.0%	0.1303
Dryness	95.2%	96.8%	4.8%	3.2%	-1.6%	0.3714
Pain	99.6%	100.0%	0.4%	0.0%	-0.4%	0.3183
FBS	99.6%	99.2%	0.4%	0.8%	0.4%	0.5587

Figure 3: Visual symptoms: prep to 3 M, n=247

postoperative UCVA than preoperative BSCVA. I feel that topography-guided treatment should be considered as a first-line treatment for the reduction of myopia and astigmatism within the approved FDA ranges.

We have come a long way with corneal refractive surgery in the past 2 decades. The days when we had to warn patients that loss of BSCVA and visual aberrations might be the price they would have to pay for spectacle independence have passed. With topography-guided treatment, we should tell our patients there is an excellent likelihood that they will have better vision without correction than they had preoperatively with correction and that the quality of their vision is likely to improve. We can now be confident that

topography-guided treatment is likely to have a positive impact on quality of life of our patients.

Reference

1. Summary of Safety and Effectiveness Data PMA P020050/S12
2. Schein, OD, et al. Patient outcomes of refractive surgery. The refractive status and vision profile. *J Cataract Refract Surg.* 2001; 27(5):665-73.

Dr. Stulting is affiliated with the Stulting Research Center at Woolfson Eye Institute, Atlanta. He can be contacted at dstulting@woolfsoneye.com.

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James Davison, MD, FACS

“In this particular case, I had more than 1,000 of my peers observing the case via live satellite feed at the 2013 American Academy of Ophthalmology meeting, so the pressure was really on.”

Just another day at the office: How the Cataract Refractive Suite helped

by James Davison, MD, FACS

The Cataract Refractive Suite (Alcon, Fort Worth, Texas) features the VERION Image Guided System,* LuxOR Microscope, LenSx Laser, and the CENTURION Vision System. Each component of the Cataract Refractive Suite is designed to help ensure accuracy at every step of the procedure, so that surgeons can consistently deliver excellent refractive outcomes, even in unusual or difficult cases. Cases can be difficult because of the anatomy of the patient or eye, and sometimes they can be difficult because of disinhibition from the relaxing medication used during surgery. I recently had a case in which the patient had an extraordinarily deep anterior chamber and hard cataract, and then turned out to be unable to cooperate very well in the OR. Each of the components provided by the Cataract Refractive Suite was recruited to help me achieve the outcome I had hoped to achieve under normal circumstances.

The patient was a 40-year-old woman with a hard cataract. She had 3+ nuclear sclerosis with an LOCS III grading of NO 4.2 NC 3.9. I had planned femtosecond laser-assisted cataract surgery to implant a 21.5 D AcrySof IQ ReSTOR multifocal IOL (Alcon).

In her preop examination, we used the VERION Reference Unit to create a digital image of her conjunctival vessels and iris features, including the position of the undilated pupil. During surgery, this would confirm incision locations by projecting them through the microscope oculars and assist in making sure that the IOL was well centered at the conclusion of the case.

Before moving into the OR, we used the LenSx Laser to accomplish the critical steps of incision creation and capsulotomy as well as to create a chop pattern for lens dissection. Once in the OR, the patient was prepped and draped and received some relaxing medication through the IV. Everything was fine as we placed the speculum, but as we were opening the incisions with a blunt spatula, the patient started to move excessively and tried to reach her hands to her face. This happened repeatedly throughout the case. To accomplish surgery, my OR technician stabilized her forehead, and the anesthetist held her arms while I repeatedly reminded her of where

she was and what we were doing and appealed for cooperation.

Fortunately, the most critical parts of the surgery had already been accomplished before she started moving. It could have been disastrous to have the patient move suddenly while using a keratome blade because the incision would then be too large and would allow too much fluid outflow, which would rapidly produce iris trauma and miosis and shallow the anterior chamber. If the patient had moved

during the capsulorhexis, the capsular opening would be at least imperfect and could even extend through an anterior radial tear, which could become a posterior tear and could lead to a sunken nucleus and vitreous loss with no IOL implanted. The relief of having those steps accomplished before things got difficult cannot be overstated.

Fortunately, I was using the LuxOR Ophthalmic Microscope, another component of the Cataract Refractive Suite. One of the features

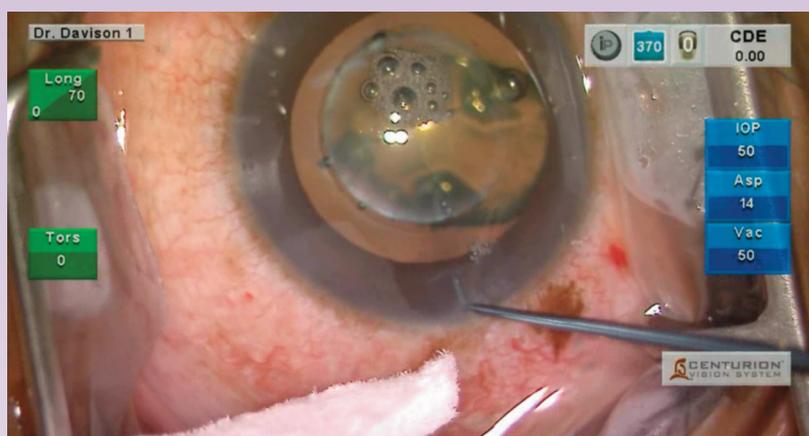


Figure 1. The LenSx femtosecond laser-created 2.5-mm incision was easily opened with a blunt dissection instrument.

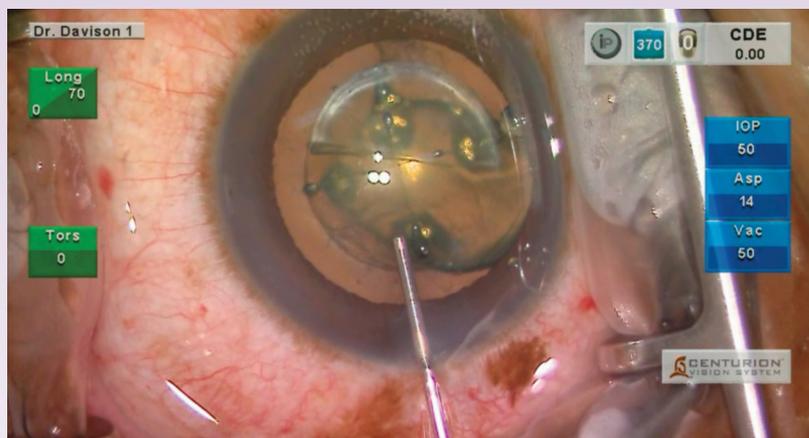


Figure 2. The injection of VISCOAT folded over the free-floating anterior capsule.

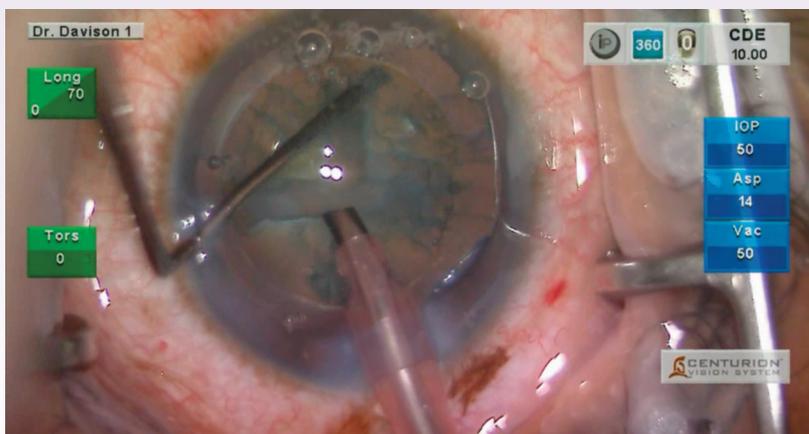


Figure 3. Even with this moving patient, the CENTURION and Balanced Tip helped to provide precision and control in the deep grooving process of the firm cataract.

make a difficult case successful

of the LuxOR Microscope is its broadly available red reflex. It has a six-times larger red reflex zone, greater red reflex stability, and greater depth of focus than traditional focused light microscopes. Because of these LuxOR features, I didn't need to make as many X-Y and focusing adjustments, and I could see what I was doing at all times.

Another asset of the Cataract Refractive Suite is the CENTURION Vision System. This phacoemulsification machine is an intelligent phaco platform designed to dynamically optimize every moment of cataract removal. It is designed to provide a new standard in anterior chamber stability and emulsification efficiency. In this difficult case, the CENTURION Vision System allowed me to emulsify the firm nucleus within the capsular bag and iris plane. Because of its advanced fluidics and its INTREPID Balanced Tip, the CENTURION is particularly good at emulsifying hard fragments, and we needed that efficiency in this case. Fortunately, we had used the

chop pattern during LenSx Laser nucleus dissection. This made it much easier to create four equally sized fragments without having to sculpt as deeply as usual. The chop was created so that it stopped 500 μ m from the posterior capsule.

The AutoSert feature of the CENTURION was also beneficial in this case because it allowed me to use both hands to control the eye and insert the IOL in a controlled fashion. Prior to insertion, I injected ProVisc but had to open another vial to add even more in order to deepen the anterior chamber enough to make sure that the posterior capsule was concave and taut. The IOL haptics could catch a flaccid flat or convex posterior capsule and create a posterior tear and potentially a sunken IOL. It would have been a shame to struggle all the way to that point and then have a problem, so it was worth it to take the time to put in extra viscoelastic. Before we introduced the I/A handpiece and silicone tip for viscoelastic removal, we adjusted the target IOP from 55 to 26 mmHg so that the eye didn't

overinflate, pushing the IOL/capsular bag complex posterior and causing pain that could have caused additional patient movement.

After the viscoelastic was removed, we used the final component of the Cataract Refractive Suite, the VERION Image Guided System, which had received preop patient data and images digitally from the Reference Unit. The VERION system is designed to add greater accuracy and efficiency for the incision, toric IOL orientation, as well as capsulorhexis and IOL optic centration. The system helped me to ensure that the multifocal lens was perfectly centered on the preoperative undilated pupil.

At the conclusion of surgery, the incisions looked good and were watertight, and the procedure was complete. On postop day 1, no one would have ever known that the case had been challenging. The patient was happy, and everything looked fine, with uncorrected vision of 20/25.

We all have cases of suboptimal cooperation and anatomic challenge

like this from time to time, but thankfully all of the features of the Cataract Refractive Suite helped me achieve a high-quality successful outcome here. In this particular case, I had more than 1,000 of my peers observing the case via live satellite feed at the 2013 American Academy of Ophthalmology meeting, so the pressure was really on.

The Cataract Refractive Suite has great value because each component is designed to help you consistently achieve your targeted refractive goal. The Suite can afford critically needed additional value with difficult cases such as steep brows, pseudoexfoliation, small pupils, or a patient who is not perfectly cooperative, to name a few.

Dr. Davison is in private practice at Wolfe Eye Clinic in Marshalltown and West Des Moines, Iowa. He can be contacted at jdavison@wolfeclinic.com.

**The VERION Image Guided System is composed of the VERION Reference Unit and the VERION Digital Marker.*

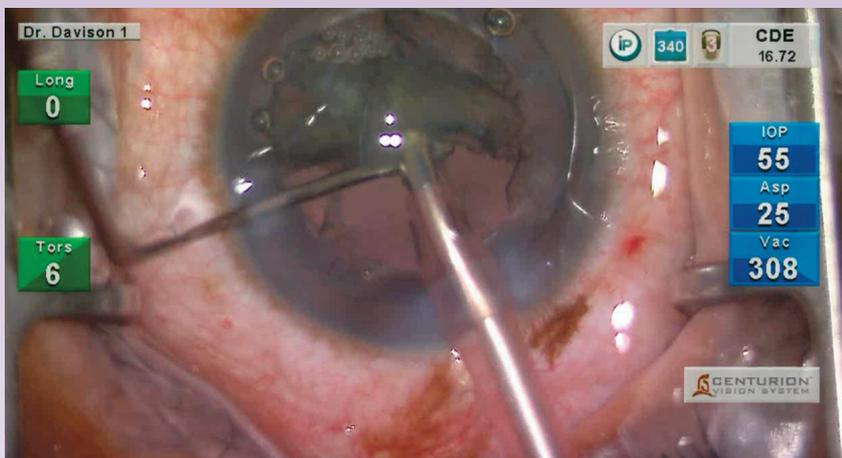


Figure 4. Two features were especially helpful while removing the quadrants in this moving patient: the broad-area red reflex provided by the LuxOR operating microscope and Active Fluidics from the CENTURION with its improved control and safety.

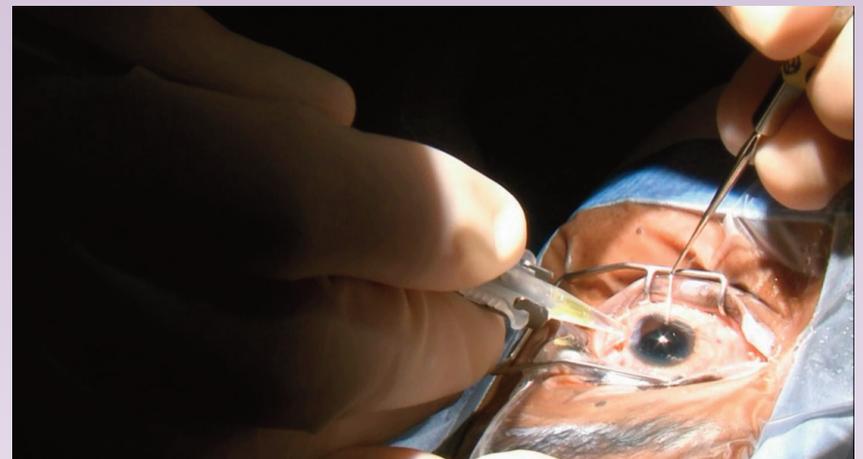


Figure 5. Bimanual control during IOL implantation was provided by the AutoSert injector cartridge and the cyclodialysis spatula.



Figure 6. The VERION System shows that the IOL is just slightly inferior to perfect position with respect to the preoperative pupil.



Figure 7. Dr. Davison performs live surgery at the 2013 American Academy of Ophthalmology meeting.

Important product information

AcrySof IQ Intraocular Lenses

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indications: The AcrySof IQ posterior chamber intraocular lens is intended for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. This lens is intended for placement in the capsular bag.

Warning/Precaution: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

Attention: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

AcrySof IQ ReSTOR Intraocular Lenses

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indications: The AcrySof IQ ReSTOR Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

Warning/Precaution: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof ReSTOR lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof IQ ReSTOR IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

Attention: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

AcrySof IQ Toric Intraocular Lenses

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

Indications: The AcrySof IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

Warning/Precaution: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggests that high astigmatic patients (i.e., >2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof IQ Toric Cylinder Power IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

Attention: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

CENTURION Vision System

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the AutoSert IOL Injector Handpiece does not perform as expected.

Indication: The CENTURION Vision system is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert IOL Injector Handpiece is intended to deliver qualified AcrySof intraocular lenses into the eye following cataract removal.

The AutoSert IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert IOL Injector Handpiece is indicated for use with the AcrySof lenses SN6OWE, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Warnings: Appropriate use of CENTURION Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/Complications: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

Attention: Refer to the Directions for Use and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

LenSx Laser

Caution: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eyecare practitioner.

Indication: The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Restrictions:

- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications:

- Corneal disease that precludes appplanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocoele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions that would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

Warnings: The LenSx Laser System should only be operated by a physician trained in its use.

The LenSx Laser delivery system employs one sterile disposable LenSx Laser Patient Interface consisting of an appplanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions:

- Do not use cell phones or pagers of any kind in the same room as the LenSx Laser.
- Discard used Patient Interfaces as medical waste.

AEs/Complications:

- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

Attention: Refer to the LenSx Laser Operator's Manual for a complete listing of indications, warnings and precautions.

ProVisc

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Indication: ProVisc OVD is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation. Ophthalmic viscoelastics serve to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. They help push back the vitreous face and prevent formation of a flat chamber during surgery.

Contraindications: At present there are no known contraindications of the use of ProVisc Ophthalmic Viscosurgical Device when used as recommended.

Warnings/Precautions:

- Postoperative increases in intraocular pressure have been reported with sodium hyaluronate products. The IOP should be carefully monitored and appropriate therapy instituted if significant increases should occur. It is recommended that ProVisc OVD be removed by irrigation and/or aspiration at the close of surgery. Do not overfill anterior chamber. Although sodium hyaluronate is a highly purified biological polymer the physician should be aware of the potential allergic risks inherent in the use of any biological material; care should be used in patients with hypersensitivity to any components in this material. Cannula assembly instructions should be followed to prevent patient injury.
- Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastics, as well as incidents of corneal edema, corneal decompensation, and a transient rise intraocular pressure.

Attention: Reference the directions for use for a complete listing of indications, warnings and precautions.

VERION Reference Unit and VERION Digital Marker

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Intended uses: The VERION Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION Reference Unit provides preoperative surgical planning functions that utilize the reference image and preoperative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION Digital Marker and other compatible devices through the use of a USB memory stick.

The VERION Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

Contraindications: The following conditions may affect the accuracy of surgical plans prepared with the VERION Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements.

Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION Reference Unit.

The following contraindications may affect the proper functioning of the VERION Digital Marker: changes in a patient's eye between preoperative measurement and surgery, an irregular elliptical limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings: Only properly trained personnel should operate the VERION Reference Unit and VERION Digital Marker.

Only use the provided medical power supplies and data communication cable. The power supplies for the VERION Reference Unit and the VERION Digital Marker must be uninterrupted. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.

Only use a VERION USB stick to transfer data. The VERION USB stick should only be connected to the VERION Reference Unit, the VERION Digital Marker, and other compatible

devices. Do not disconnect the VERION USB stick from the VERION Reference Unit during shutdown of the system.

The VERION Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

Precautions: To ensure the accuracy of VERION Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION Digital Marker in conjunction with compatible surgical microscopes.

Attention: Refer to the user manuals for the VERION Reference Unit and the VERION Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

VISCOAT

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Indication: VISCOAT OVD is indicated for use as a surgical aid in anterior segment procedures including cataract extraction and intraocular lens (IOL) implantation. VISCOAT OVD maintains a deep chamber during anterior segment surgeries, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissues. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery.

Contraindications: At present there are no known contraindications of the use of VISCOAT Ophthalmic Viscosurgical Device when used as recommended.

Warnings/Precautions:

- Failure to follow "Directions for Use" on attachment of the cannula or use of an alternate cannula may result in cannula detachment.
- Precautions are limited to those normally associated with the surgical procedure being performed. Although sodium hyaluronate and sodium chondroitin sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material.
- A transient rise in intraocular pressure in the early postoperative period may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. It is therefore recommended that VISCOAT OVD be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of the surgery to minimize postoperative IOP increases. Do not overfill anterior chamber.

Attention: Reference directions for use for a complete listing of indications, warnings and precautions.

WaveLight Excimer Laser Systems

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;

Important product information

- 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 mmHg;
- 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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