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Innovative technologies designed to improve outcomes

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Bret Fisher, MD

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Blue light filtering IOLs: I'm a believer

by Bret Fisher, MD

Early in my experience as a cataract surgeon, I had the subjective impression that the yellow appearance of the lens implant that contained a chromophore was not as aesthetically appealing and might even be a functional limitation of the lens. I wondered why we would take out something yellow and then put something yellow back in. This was my completely unscientific, subjective bias or approach to forming an impression of the chromophore early on. In fact, when we first started using Alcon lenses, when there was a choice between the same lens with or without the chromophore, I would always specify without the chromophore, thinking that I was getting a better lens or doing something better for my patients, without any scientific justification.

Over the years, there have been a number of studies and a lot of discussion about the issue of blue light filtration. Like many surgeons, I followed that with interest, and over time, I began to see that the weight of scientific evidence seemed to be on the side of blue light filtration and enhancing the visual performance of a lens and the visual performance of my patients' eyes. The initial studies that caught my attention were the driving simulation studies first by Hammond and coworkers[1] and then by Gray and co-authors.[2] These studies were the first to demonstrate a real-world benefit for patients who had received intraocular lenses with blue light filtration.

Prior to these publications, most of the purported benefit of blue light filtration had been for long-term macular protection, an effect that had been difficult to demonstrate in the absence of large long-term studies. Other studies followed, including studies that looked at the question of the safety of blue light filtration, especially relating to sleep and circadian rhythm. The excellent review article by Henderson and colleagues[3] was a very comprehensive review of the literature until that point, with the conclusion that blue light filtration was not harmful. Other studies and review articles have followed, with the balance of scientific opinion continuing to show benefit from the addition of the chromophore and no harm. I was also aware that many of my colleagues who I respected were using implants with blue light filtration and were reporting good results. Based on all of this, I made the decision to switch to blue light filtration for my patients.

What drove home the importance of blue light filtration, though, was a recent study that I was fortunate enough to participate in.[4] The purpose of the study was to evaluate the within-eye visual benefit of blue light filtering among pseudophakic eyes previously implanted with IOLs largely transparent to visible wavelengths. The study included 154 pseudophakes with no blue light filtering IOL. All patients had bilateral pseudophakia 3 or more months after surgery, both eyes had a best corrected visual acuity of 20/40 or better, and no eyes had ocular pathology/degeneration. This was the first study that ever looked at within-eye comparisons as opposed to comparing 2 different eyes from the same patient or groups of eyes from different patients.

This study evaluated the same eye from the same patient and compared a clear lens and then a clear lens plus a blue light filter that would simulate the transmission through the chromophore present in the AcrySof platform (Alcon, Fort Worth, Texas). The results were significant and quite impressive. The addition of the blue light filter provided faster photostress recovery time compared to the placebo filter among pseudophakes with IOLs that are largely transparent to visible light. The difference in photostress recovery time between the blue light filter and the placebo filter was 1.37 seconds.

The addition of the blue light filter provided greater glare disability threshold compared to the placebo filter among pseudophakes with IOLs that are largely transparent to visible light. The difference in the glare disability threshold was 0.12 log unit.

Visual acuity and pupil size were similar with blue light filtering and placebo filters. The corrected visual acuity was 0.05±0.11 logMAR for blue light filtering and 0.05±0.10 for placebo. Pupil size was 3.54±0.80 for blue light filtering and 3.52±0.79 for placebo. No adverse events or medical defects were reported in the study.

This means that in situations where a person is driving under a bright mid-day sun or is looking into oncoming headlights, filtering the blue light could improve visual performance, although additional studies would be required to demonstrate the direct functional benefit of blue light filtering.

References

1. Hammond B, et al. Contralateral comparison of blue-filtering and non-blue-filtering intraocular lenses: glare disability, heterochromatic contract, and photostress recovery. *Clin Ophthalmol*. 2010;4:1465–1473.
2. Gray R, et al. Reduced effect of glare disability on driving performance in patients with blue light filtering intraocular lenses. *J Cataract Refract Surg*. 2011;37:38–44.
3. Henderson B, et al. Blue-blocking IOLs: a complete review of the literature. *Surv Ophthalmol*. 2010;55(3):284–289.
4. Hammond B. Attenuating photostress and glare disability in pseudophakic patients through the addition of a short-wave absorbing filter. *Journal of Ophthalmology*. 2015; vol. 2015, article ID 607635.

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Correcting astigmatism at the time of cataract surgery

by Elizabeth Yeu, MD

Elizabeth Yeu, MD

The visual impact of astigmatism

"Successful toric IOL surgery comes down to three steps: accuracy of preoperative measurements of the corneal astigmatism, proper steep meridian identification during cataract surgery, and technique to ensure stability of the IOL's position"

Most Americans have some refractive astigmatism, and upward of 40% have more than 1.0 D of corneal astigmatism. Toric lenses are continuing to gain popularity and are an ideal choice for patients with higher levels of astigmatism who desire reduced spectacle dependence after cataract surgery. I perform astigmatism correction in half of my cataract surgeries. Of my overall cases, 10–25% of my total volume is toric IOLs. I typically correct astigmatism using arcuate incisions or toric IOLs, and arcuate incisions can more accurately correct upward of 1.25 D of total corneal astigmatism.

For those with visually significant astigmatism (more than 1.0 D), spectacle independence is the main reason to correct astigmatism with a toric IOL as opposed to LRIs, and spectacle independence is a hugely attractive benefit to these patients because most have never been able to see clearly without glasses or contacts.

Patients with higher levels of astigmatism are often drawn to toric IOLs, and the adoption of this technology happens with little hesitation because patients recognize my enthusiasm for and endorsement of it. Once a relationship is established, they often trust me to help guide their decision process. I know that patients will have a higher-definition type of vision postoperatively. Patients with higher levels of astigmatism should consider toric IOLs because if left uncorrected at the time of cataract surgery, they will require prescription spectacles postoperatively for the rest of their lives, which can be an expensive proposition.

Toric IOL surgery has brought to light how little we once knew and understood about astigmatism management prior to the availability of accurate toric technology. Pre-toric IOL utilization, inaccuracies and the unpredictable outcomes were attributed to the actual unpredictability of arcuate incisions in and of themselves. Once toric technology platforms came about and we were able to nail the corneal astigmatism, that's when a lot of other things came into play, including the importance of effective lens position as well as total corneal astigmatism and the contribution of the posterior cornea to it.

Successful toric IOL surgery comes down to 3 steps: accuracy of preoperative measurements of the corneal astigmatism, proper steep meridian identification during cataract surgery, and technique to ensure stability of the IOL's position. It is important to be as accurate as possible because for every degree that the lens is off, the patient loses 3.3% of astigmatism correction. As an example, if the toric IOL is off by just 10 degrees, it causes a 33% loss in desired astigmatic effect and a potentially unhappy postoperative patient.

There are several ways to measure the axis of astigmatism. I identify the total corneal astigmatism with the Cassini (i-Optics, The Hague, the Netherlands), which is able to more accurately determine the astigmatic contribution of the posterior cornea. The LENSTAR biometry (Haag-Streit, Koniz, Switzerland) provides beautiful anterior K values, and I verify that with another topography device. We have the Atlas (Carl Zeiss Meditec, Jena, Germany) and the Nidek OPD (Fremont, Calif.), but I generally will use the OPD because it also offers angle kappa information.

Additionally, there are several methods for marking the axis of astigmatism, and they vary in accuracy. The standard of care for marking the axis has been ink, but ink pens are not ideal because of the precision required for both measuring and marking the target axis. Marking at the slit lamp and/or incorporating various astigmatic tools to identify the reference axes and align the steep meridian can increase accuracy.

Other methods include imaging or fingerprinting, limbal registration, and wavefront intraoperative aberrometry.

We also employ the Verion System (Alcon). While it takes time to initially get comfortable incorporating the Verion System into the practice, once it is incorporated, I believe this technology will continue to improve and make toric surgery faster because the reference landmarks have already been identified. Intraoperatively, you no longer have to ink mark the steep meridian on the cornea beyond image registration of the eye, as the Verion System projects this onto the cornea. Preoperatively, the Verion System requires an extra image capture for the surgical planning. Intraoperatively, this does help to increase efficiency and accuracy with toric IOL surgery.

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Please refer to pages 7 and 8 for important product information about the Alcon products described in this supplement.

Correcting astigmatism with the AcrySof IQ Toric IOL

by Brad Black, MD

While discussing current "state of the art" cataract surgery with patients, one is constantly reminded of how highly sophisticated and advanced the procedure has become. The evolution of cataract surgery over the last 2 decades has been quite dramatic, and nowhere is it more evident than with the development and use of the toric intraocular lens to correct astigmatism at the time of cataract surgery.

It is up to us as surgeons to explain all that is available to patients, educate them as to their "opportunities," and allow them to make an informed decision as to what direction they would like to take. The technology explosion that has occurred has allowed us to greatly improve our outcomes and offer so much more to our patients. There is no question that we have truly raised the bar with our ability to offer femtosecond laser-assisted cataract surgery, new measuring instrumentation and technology, more sophisticated IOL calculation formulas, recently developed surgical planning software, improved intraoperative aberrometry, etc.

As an original investigator of the AcrySof IQ Toric IOL (Alcon, Fort Worth, Texas), I became particularly enamored with the technology very early on. I was very familiar with acrylic material, and the AcrySof platform was the perfect starting point for a toric intraocular lens. As all surgeons know, the material is particularly bioinert and very "friendly" to the capsule. There is a tackiness that stabilizes the implant within the bag, minimizing any rotation postoperatively. There is very little fibrosis and contraction of the capsule and nearly perfect centration. As compared to the previous toric IOL, the AcrySof IQ Toric is a quantum leap improvement.

In a landmark study of 6,000 patients,[1] **Warren Hill, MD**, evaluated preoperative keratometry readings and demonstrated that nearly one third to one half of all cataract patients would benefit from a toric lens. Initially, we were limited to fully correcting astigmatism of up to 2 diopters only while utilizing 3 different powers of toricity. Recently, however, an expanded range of toric powers has enabled us to treat virtually 99% of all patients with astigmatism, based on Dr. Hill's study. We can now correct up to 4 D of cylinder in half diopter increments, making this an extremely valuable resource for surgeons and their patients.

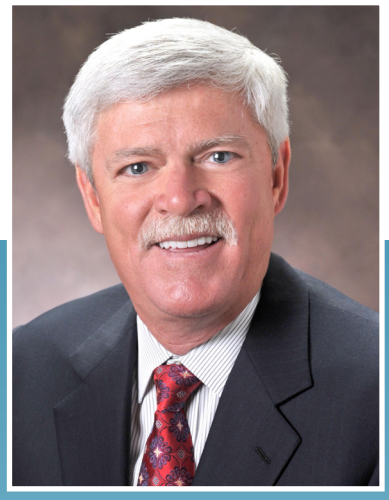
Surgically, implantation of the AcrySof IQ Toric lens requires very little modification to one's technique. Traditionally, the limbus is marked preoperatively at the 3, 6, and 9 o'clock positions with the patient sitting upright using various instruments that have been designed specifically for this. This can be done either by the surgeon or a nurse in the preoperative area. These marks are then used intraoperatively to orient the toric IOL onto the intended axis when the patient is in the supine position accounting for any cyclorotation that may have occurred.

The recently developed Verion System (Alcon) has helped improve this entire process and made it much more accurate, in my opinion. By utilizing an overlay visible in the microscope ocular that highlights the intended axis, the surgeon simply rotates the toric IOL, removes any remaining viscoelastic material, and makes any final adjustments for an extremely accurate alignment. The system does not require any preoperative marking because it utilizes a high definition image taken preoperatively that identifies limbal vessels and iris structures that are then used intraoperatively to identify the exact orientation for the toric implant. Axis power and orientation can be confirmed with intraoperative aberrometry as well, further refining our outcomes. This system has been extremely useful and beneficial in our surgical facility. The Verion System has helped improve our efficiency in the OR while offering a very high degree of accuracy and eliminating the need to mark the limbus both pre- and intraoperatively.

I feel it is very important when discussing surgery with patients to explain that the toric IOL offers much more than just "going without glasses." I feel it is optically superior and makes so much more sense to correct astigmatism internally rather than at the spectacle plane. For those who "want to wear glasses" postoperatively, their spectacles are clear except for the bifocal, less expensive, thinner, and lighter weight. Further, there certainly is less dependency on the spectacles and the capability of wearing non-prescription sunglasses. We often use a modified or partial monovision to minimize the need for readers in these patients as well.

Toric IOLs are quite useful in patients who have known ocular pathology. The goal with cataract surgery is to maximize the image at the fovea so that even patients with some ocular pathologies can benefit from this lens. Importantly, the surgeon must manage expectations in these situations preoperatively as well as postoperatively.

We have found the AcrySof IQ Toric to be extremely beneficial for our patients. Some of our happiest patients are those who come in for their day 1 postoperative visit and realize that in a matter of 15 minutes we have corrected a problem that they have had since they were born. This can be very dramatic for patients as well as their family and is often a "life changing" experience.



Brad Black, MD

> ***"The evolution of cataract surgery over the last 2 decades has been quite dramatic, and nowhere is it more evident than with the development and use of the toric intraocular lens to correct astigmatism at the time of cataract surgery"***

Reference

1. Provided courtesy of Warren Hill, MD. www.doctor-hill.com/iol-main/astigmatism_chart.htm. Accessed March 18, 2015.

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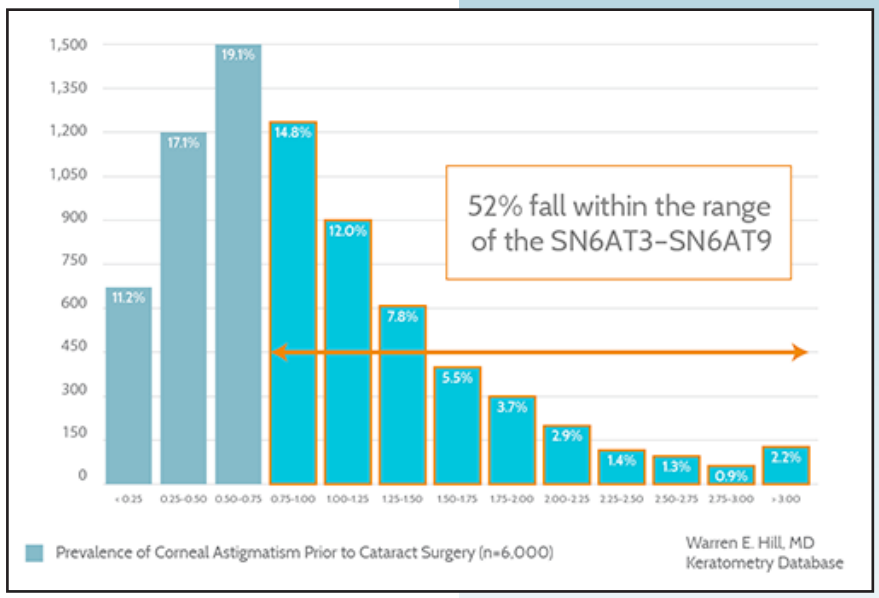
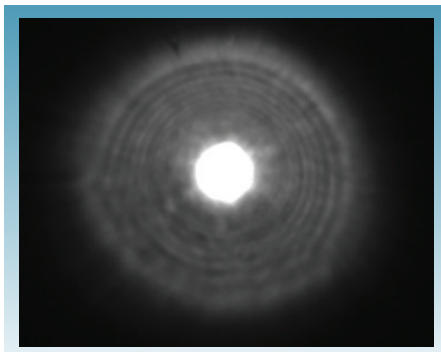


Prevalence of corneal astigmatism in patients undergoing cataract surgery

Jonathan Frantz, MD, FACS

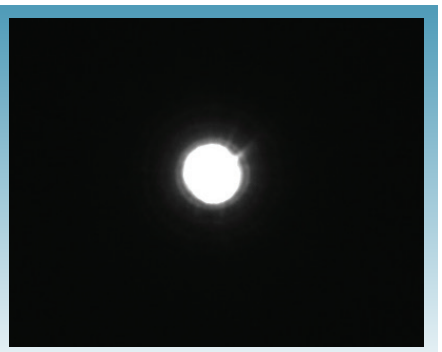
Apodization and light distribution of the ReSTOR Lens

by Jonathan Frantz, MD, FACS



Tecnis Multifocal ZMB00

AcrySof® IQ ReSTOR® SN6AD1



AcrySof® IQ SN60WF

Pinhole photographs (shot through a modified ISO model eye) are used to simulate halos that occur at nighttime while driving. Parameters of measurement included a 5-mm pupil, distance focus at 360.

"The apodized diffractive optic of the AcrySof IQ ReSTOR IOL improves image quality while minimizing visual disturbances. The result is an increased range of quality vision that delivers a high level of spectacle freedom."

The AcrySof IQ ReSTOR +3.0 D IOL (Alcon, Fort Worth, Texas) uses a combination of 3 complementary technologies (apodization, diffraction, and refraction) to allow patients to achieve a full range of high-quality vision generally without the need for reading glasses or bifocals.

Apodization is the gradual reduction or blending of diffractive step heights. This unique technology optimally distributes the appropriate amount of light to near and distant focal points, regardless of lighting. The apodized diffractive optic of the AcrySof IQ ReSTOR IOL improves image quality while minimizing visual disturbances.[1] The result is an increased range of quality vision that delivers a high level of spectacle freedom.[1]

This lens is the first and only apodized diffractive IOL in the U.S., and the apodized diffractive optics are found within the central 3.6-mm inner diffractive optic zone of the lens. This area comprises 9 concentric steps of gradually decreasing (1.3 to 0.2 µm) step heights that allocate energy based on lighting conditions and activity, providing high-quality vision at all distances.

The refractive region surrounds the apodized diffractive zone of the optic. This area directs light to a distance focal point for larger pupil diameter and is dedicated to distance vision.

We all know that when patients are reading, their pupils get small and when they are driving at night, their pupils get large. Because of this, we needed a mechanism to optimize near vision when the pupil is small and to minimize any rings or halos around lights at night when the pupil is large. Some ophthalmologists are using other lenses so that patients can read better in dim illumination, but the vast majority of people who are getting these lenses are reading in relatively good light. They are more concerned with retaining their night driving ability. In my experience with the ReSTOR, while patients may experience rings and halos around lights, for the most part, they find it very tolerable. In many instances, it goes away.

With an apodized lens, there are basically 2 focal points: a distance focal point and a near focal point. With a nonapodized lens, both images are on the retina at the same time, which results in more glare and halos. When people are driving at night, they still have the same light distribution for near as they would have if they were trying to read, and that can lead to some adaptation issues. Any patient with a multifocal lens will experience some adaptation problems, but they are minimized with the ReSTOR lens.

Because of the constantly evolving technology that we have right now—femtosecond lasers, laser relaxing incisions, the ORA with VerifEye (Alcon), and these new technology lenses—we are constantly updating and optimizing our outcomes assessment. I have found that the vast majority of patients who are implanted with the ReSTOR lens do extraordinarily well. Approximately 90% of them don't need glasses after surgery; that exceeds what was achieved in the FDA clinical trial, which was 78%.[1] Now, we can correct astigmatism with precise incisions during the surgical procedure and by choosing the correct lens implant power. All of those things combined provide outstanding results.

I do tell people who need to read in conditions with dim illumination that this lens requires that light be able to reach it. With the ReSTOR +4, there was an issue where people felt like they had to get too close to the computer screen to read it. With the ReSTOR +3, we rarely hear that complaint.

Reference

1. AcrySof® IQ ReSTOR® +3.0 D IOL Directions for Use

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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 unwanted visual side effects. 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, Abbott Park, Ill.) 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.

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 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. 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.

continued on page 6

Doyle Stulting, MD, PhD

"Subjects who underwent topography-guided LASIK in the clinical trial experienced improvements in 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 habitual refractive correction method (glasses or contact lenses) preoperatively[1]"

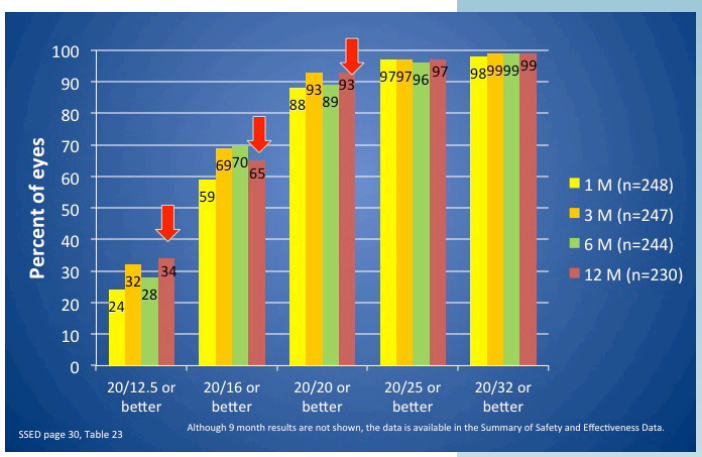

Figure 1: Cumulative postop UCVA (ETDRS)

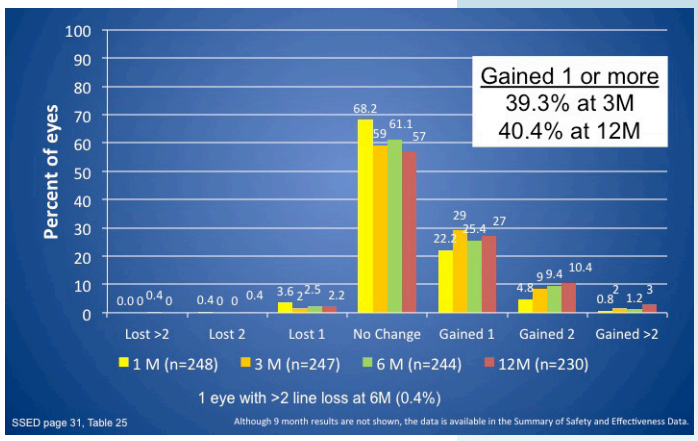

Figure 2: Postop BSCVA compared to preop BSCVA (change in lines)

continued from page 5

Charles Davis, DO

"Switching to the WaveLight refractive suite was an easy decision. A faster femtosecond laser means less chance of suction loss with apprehensive patients. Quick ablation times give patients a real sense of security. Every laser pulse is delivered exactly where it's supposed to be. Add to that a <1% enhancement rate in my hands, a wider range of treatable refractive errors, and fewer postop complaints from patients, it's easy to see why it is my choice for what is best for patients."

Charles Davis, DO

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: preop to 3 M, n=247

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 2 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 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 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.

References

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.

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Please refer to pages 7 and 8 for important product information about the Alcon products described in this supplement.

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 suggest 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.

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 mangement 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 mmHg;
- taking the medication 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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Verion® Image Guided System 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 addition, the Verion® Reference Unit provides preoperative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The Verion® Reference Unit also supports the export of the 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, details 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. The following conditions may affect the proper functioning of the Verion® Digital Marker: changes in a patient's eye between preoperative measurement and surgery, an irregular elliptic 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. Use only the provided medical power supplies and data communication cable. Power supplies for the Verion® Reference Unit and the Verion® Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. 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.

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