Supplement to

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Cataract & Refractive Surgery TODAY

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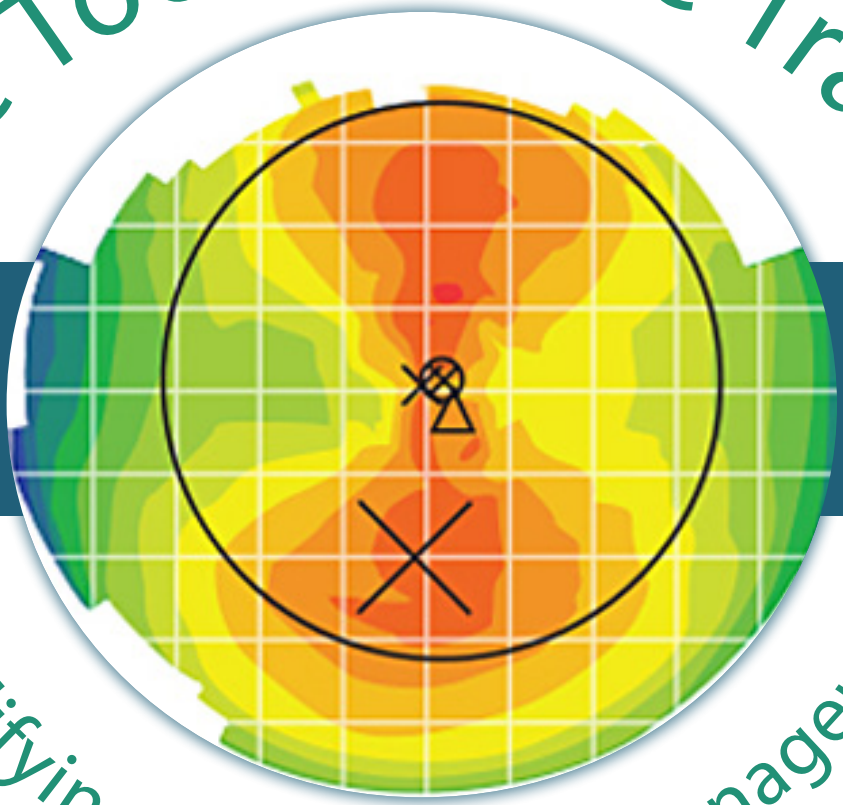
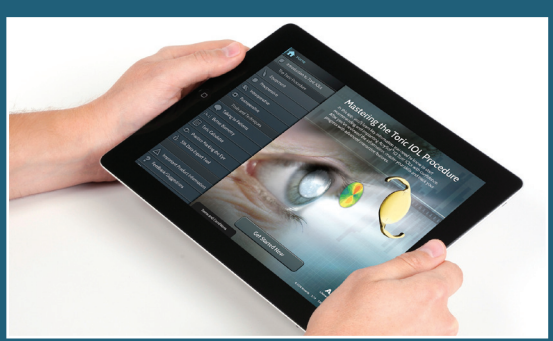
The Tools Of The Trade



Simplifying Astigmatism Management

Toric-aspheric technology, best implantation practices, and new surgical planning tools combine to raise the standard of astigmatism correction.



Corneal astigmatism presents an easy win for ophthalmic surgeons, because correcting it has a direct, positive impact on patients' quality of vision. Astigmatism-correcting technologies such as the AcrySof IQ Toric IOL (Alcon Laboratories, Inc.) allow for the easy integration of atigmatism management into surgical plans. Here, respected practitioners describe the fundamental steps of using toric IOL correction, as well as the myriad clinical benefits of the AcrySof IQ Toric IOL: its proven adherence to the capsule that ensures rotational stability; its aspheric optics for excellent visual quality; and the widest range of treatment powers of any toric lens, which can treat even low amounts of cylinder. Furthermore, we present clinical experience of implanting the AcrySof IQ Toric IOL with the new VERION Image Guided System, Alcon's integrated system for surgical planning, guidance, and execution.

CONTRIBUTORS

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The Importance of Rotational Stability of a Toric IOL

Bioadhesion plays a role.

BY BONNIE AN HENDERSON, MD

The AcrySof IQ platform (Alcon Laboratories, Inc.) is a family of IOLs that provides dependable, robust performance in modern refractive cataract surgery for a wide range of patients' needs. Whether surgeons choose the standard monofocal IQ Aspheric IOL, the AcrySof IQ ReSTOR Multifocal, or the AcrySof IQ Toric IOL to meet a particular patient's needs, the platform provides reliability and excellent visual outcomes.

PROVEN STABILITY

The AcrySof IQ Toric IOL, in particular, has long demonstrated the ability to remain on the correct axis of cylinder after implantation, thereby providing accurate and durable correction of astigmatism.[1] The advent of reliable toric IOLs, such as the AcrySof IQ Toric, has transformed the practice of managing astigmatism at the time of cataract surgery. Nowadays, if a patient has visually significant corneal astigmatism (of 0.75 D of cylinder or greater) along with a cataract, correcting the astigmatism with a toric IOL is becoming more routine and likely will become the standard of care.

UNIQUE BINDING CHARACTERISTIC

In the era of refractive cataract surgery, when patients expect excellent unaided postoperative vision, it is essential for the surgeon to have confidence that he or she can achieve a predicted refractive outcome. This is especially true with advanced technology IOLs, such as multifocal or toric models, for which the patient pays additional money out of pocket.

With toric IOLs in particular, the lens must be positioned along the steep axis of astigmatism when initially implanted and must stay in its proper position postoperatively. A lens that is able to adhere to the surrounding capsule and maintain its position without moving is crucial in the correction of astigmatism. Postoperative rotational stability of the lens helps to ensure that the axis of astigmatism correction will not change over time, altering the toric refractive outcome.

Research has demonstrated that the ability of the proprietary AcrySof hydrophobic acrylic material to bind to fibronectin is excellent.[2] Fibronectin is a major extracellular protein that binds to other receptor-containing surfaces. In the eye, it can bind to the anterior or posterior capsules, as well as to IOLs. Of the materials used in the composition of IOLs, fibronectin has been reported to be most strongly adherent to soft hydrophobic acrylate, such as the material used in the AcrySof IOL platform.[2]

> "The reliability of the AcrySof IQ Toric IOL is why I choose this toric lens for my astigmatic cataract patients."

Because fibronectin can bind strongly to the AcrySof material, this characteristic may be responsible for the excellent stability of the IOL within the capsular bag. This may help to explain why the IOL's astigmatism correction, as documented in clinical trials,[1] remains consistent over time. This bioadhesive quality decreases the likelihood of rotation of the lens.

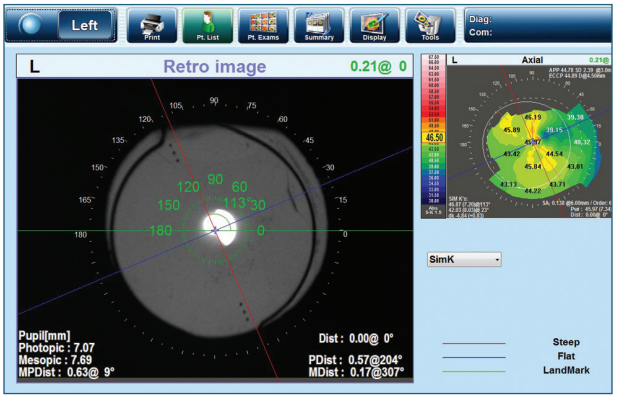

Figure 1. A retroilluminated image of an AcrySof IQ Toric IOL showing the lens'correct placement with respect to the steep axis.

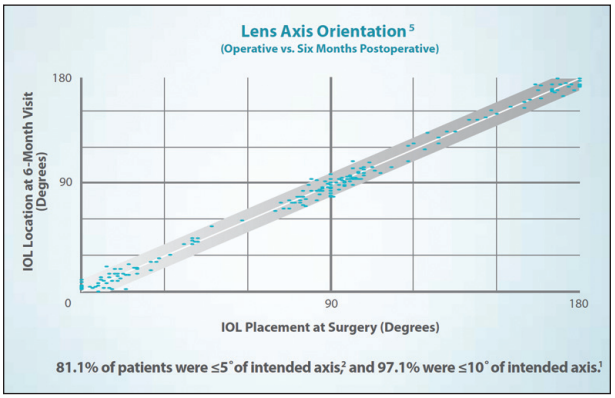

Figure 2. In the clinical trial, 97.1% of patients achieved less than or equal to 10° of their intended axis, and 81.1% achieved less than or equal to 5° of their intended axis.[5]

Studies have evaluated the fibronectin-binding abilities of several IOL materials. In the 1990s, Linnola et al[3] evaluated the adhesion of soluble, radiolabeled fibronectin to IOLs of several materials including silicone, acrylate, and hydrogel. Fibronectin bound best to the acrylate IOL. The differences between acrylate and the other foldable lens materials were statistically significant (P<.01 to .001).

The study authors reasoned that, if an IOL has more fibronectin bound to it, the lens can attach to the capsule better because the capsule is composed mostly of collagen. They hypothesized that the stronger binding of fibronectin to the capsule could explain the stronger adhesion of acrylic IOLs to the anterior and posterior capsules, theoretically reducing or minimizing the opportunity for the lens to rotate.

More recently, Ong and colleagues compared the bioadhesive properties of several hydrophobic acrylic materials and PMMA.[4] The investigators performed an in vitro fibronectin protein adhesion assay to compare the amounts of fibronectin adsorbed to AcrySof (SN60WF), Hoya (AF-1 iMicS 1 NY-60), and Abbott Medical Optics (Tecnis ZCB00) hydrophilic acrylic IOLs and to a PMMA IOL.

Significantly more fibronectin was adsorbed to the AcrySof and Hoya lenses, compared with the Tecnis and PMMA lenses (P<.001). After treatment with a nonionic detergent (sodium dodecyl sulfate), persistent fibronectin adsorption was highest with the AcrySof, followed by the Hoya, Tecnis, and PMMA lenses (P<.001).

The investigators concluded that the higher fibronectin retention observed with the AcrySof material suggests the presence of stronger bonds and interaction between the hydrophobic acrylic material surface and the fibronectin protein structure.

It may also be that the stronger bioadhesion of the AcrySof hydrophobic acrylic material to the capsule helps the AcrySof IQ Toric to retain its original postoperative positioning better than other IOL materials.

CLINICAL EXPERIENCE

My clinical experience with the AcrySof IQ Toric IOL has been excellent. The AcrySof material is very different from those used in other toric lenses, and the clinical performance of the AcrySof IQ Toric is outstanding.

The hydrophobic acrylic material of the AcrySof is sticky—*tackiness* was the word often used to describe this characteristic. In my opinion, the AcrySof IQ Toric IOL feels as though it will stay on the axis on which I place it.

In my clinical practice, my staff and I use an imaging system to take retroillumination photos after placement of a toric lens (Figure 1). Sequential images can help to determine whether the lens has shifted over time since the original surgery. These images demonstrate that, consistently, AcrySof IQ Toric lenses have very little to no movement from their intended axis (Figure 2). My impression is that this has to do with the fibronectin-binding capabilities of the material.

ACHIEVING DESIRED OUTCOMES

The reliability of the AcrySof IQ Toric IOL is why I choose this toric lens for my astigmatic cataract patients. With the AcrySof IQ platform, the surgeon can feel confident about the rotational stability of the lens because of its unique biochemistry. This should give surgeons a sense of assurance that choosing the AcrySof IQ Toric IOL will translate into the desired visual outcome. ■

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3. Linnola RJ, Sund M, Ylönen R, Pihlajaniemi T. Adhesion of soluble fibronectin, laminin, and collagen type IV to intraocular lens materials. *J Cataract Refract Surg.* 1999;25(11):1486-1491.
4. Ong M, Wang L, Karakelle M. Fibronectin adhesive properties of various intraocular lens materials. Poster presented at: The Association for Research in Vision and Ophthalmology (ARVO) annual meeting. May 5, 2013; Seattle, Washington.
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See page 15 for important product information.

Treating Visually Significant Astigmatism

The importance of correcting low amounts of cylinder in cataract patients.

BY LAWRENCE WOODARD, MD

In order to provide all my patients with the best UCVA after cataract surgery, astigmatism correction has long been a routine component of my surgical planning. I have been using the AcrySof Toric IOL (Alcon Laboratories, Inc,) for years, and now I implant several hundred AcrySof IQ Toric IOLs annually.

MANY PATIENTS HAVE LOW CYLINDER

According to the high-quality data from Warren E. Hill, MD, from his database of 6,000 cataract surgical patients, approximately 34.6% of cataract patients have 0.75 to 1.50 D of preoperative corneal astigmatism,[1,2] which is a visually significant amount of error[3] (Figure 1). Patients with as little as 0.75 D of cylinder can have blurred or distorted vision. If there is a chance that a patient will need spectacles after cataract surgery, then surgeons should inform them of the toric option. The only aspheric toric IOL currently on the market that can treat as low as 0.75 D of astigmatism is the AcrySof IQ Toric IOL.

PATIENT SELECTION

The version of the AcrySof IQ Toric IOL with the lowest cylinder power, Model SN6AT3, provides between 0.75 and 1.50 D of cylinder correction. The AcrySof IQ Toric IOL Online Calculator (http://www.acrysoftoriccalculator.com/) uses vector analysis to identify the axis of placement and proper location of the primary cataract incision to help the surgeon achieve the desired astigmatic effect. By factoring in the surgeon's surgically induced astigmatism, the online calculator can show that patients who have between 0.75 and 1.03 D of preoperative corneal astigmatism can still benefit from the SN6AT3.

I approach the discussion with patients about their toric lens options by informing them that we have several ways to address their corneal astigmatism while they are undergoing cataract surgery. In my opinion, toric lenses correct corneal astigmatism more predictably than limbal relaxing incisions made with a microkeratome blade. So, for many patients who have slightly less than 1.00 D of corneal astigmatism, the SN6AT3 is an excellent option.

> "Patients do not realize the amount of distortion in their glasses until they experience the view through the implant."

PATIENT SATISFACTION

My patients have been pleased with the refractive outcomes with the AcrySof IQ Toric IOL. They are able to achieve crisp, clear distance vision with reduced dependency on glasses, usually for the first time in their lives (Figure 2). Many patients express how much better they see with the astigmatic correction incorporated into the IOL instead of in their spectacle prescription.

Toric IOL patients often report postoperatively that they are seeing the best they have ever seen. This is especially true for those who have previously worn glasses for astigmatic correction. Spectacle lenses with a cylindrical component

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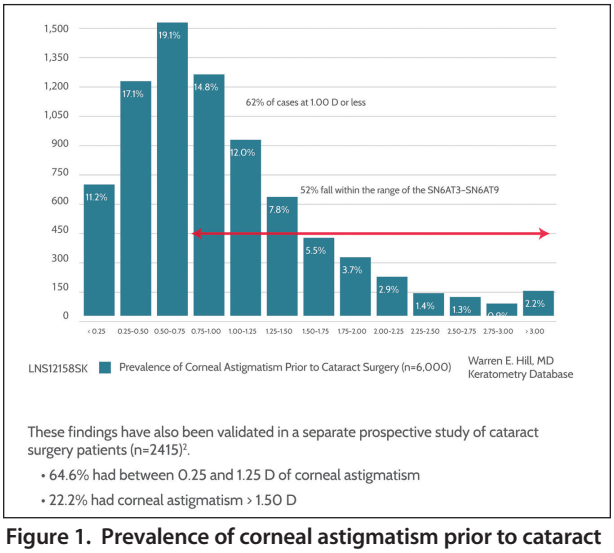

Figure 1. Prevalence of corneal astigmatism prior to cataract surgery (n=6,000).[1]

Astigmatism Management Has Entered a New Paradigm

Simple techniques are important for success with toric IOLs.

BY STEVEN D. VOLD, MD

In cataract surgery, the treatment of astigmatism is evolving to include ever-broader ranges of correction, aspheric optics that reduce patients' dependence on spectacle correction at near distances, and new technologies to assist with IOL calculations and surgical planning. With options such as the AcrySof IQ Toric IOL (Alcon Laboratories, Inc.), aspheric toric implants are swiftly becoming the standard of care for those with astigmatism and cataracts.

This is encouraging news, because there seems to be a gap in the number of astigmatic cataract patients who receive toric implants. Most of us have seen the data compiled by Warren E. Hill, MD, of Mesa, Arizona, regarding the prevalence of astigmatism in cataract patients. Out of 6,000 individuals, Dr. Hill reported that approximately 52% of cataract patients have more than 0.75 D of pre-existing corneal astigmatism.[1] By contrast, in the fourth quarter of 2013, only about 9% of IOLs implanted were toric (Figure 1).[2] The gap between those numbers represents a tremendous opportunity for us to improve how we care for cataract patients with astigmatism.

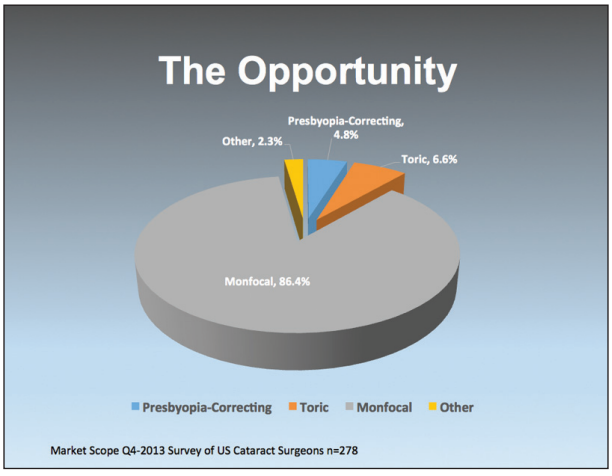

Figure 1. Market Scope data show that as of Q4 of 2013, toric IOLs represented only about 9% of all implanted IOLs.

> "When I see astigmatism, I feel strongly that most patients will benefit tremendously from and deserve toric IOL technology when undergoing cataract surgery."

Currently, four models of toric IOLs have regulatory approval for use in the US market. The plate-haptic STAAR Toric IOL was the first to become available, followed by the AcrySof Toric IOL, and more recently the Tecnis Toric (Abbott Medical Optics, Inc.) and the Trulign Toric (Bausch + Lomb) lenses.

While it is always good for physicians and patients to have a range of choices available, my toric lens of choice is the AcrySof IQ Toric IOL, because of its long track record of proven performance and stability, as well as its capacity to treat the widest range of astigmatism. The AcrySof family of IOLs fits my style of surgery and practice and yields outstanding results for my patients. I treat a large number of astigmatic patients, many of whom have glaucoma, and I make sure to evaluate each one for the suitability of a toric IOL. This article outlines some of the reasons for my preference for the AcrySof IQ Toric IOL and includes some technique tips that have helped me achieve successful refractive results with this lens in my cataract patients with astigmatism.

DESIGN FEATURES

One element of the AcrySof IQ Toric IOL that makes it attractive to me is the superb design of the AcrySof family of IOLs. Because I have implanted other AcrySof IOLs in cataract patients for years, I am comfortable with the platform. The centering ability and rotational stability of the AcrySof IQ Toric IOL, in particular, are outstanding.[3,4] Rotational stability is one of the key criteria on which to base one's choice of toric IOL, because postoperative rotation naturally equals a less-than-optimal outcome.

See page 15 for important product information.

DR. VOLD'S STRATEGIES FOR SUCCESSFUL TORIC IMPLANTATION

I believe that with attention to some of the details of cataract surgical technique, we can achieve excellent refractive outcomes. I have found the following to be important factors in consistently hitting my refractive targets with astigmatic patients.

1. The capsulorhexis should be as circular as possible to help achieve good centration of the lens and well-centered over the pupil (which is positioned slightly nasally in most eyes). It should slightly overlap the edge of the optic, so as to hold the lens in place. I like to make the capsulorhexis approximately 5.0 to 5.5 mm in diameter so that it overlaps the 6.0-mm optic for 360°.

2. Cortical cleanup must be meticulous. I like to remove the lens epithelial cells from both the posterior capsule and the posterior surface of the anterior capsule. This reduces the fibrotic response and resulting phimosis, so that the lens is less likely to change position.

3. To achieve the best postoperative lens positioning, I initially under-rotate the lens by about 10° to 20° when dialing it into place. I use the polymer tip on the I/A handpiece (Alcon Laboratories, Inc.), which has a blunt tip that does not tear the capsule or damage the IOL to precisely move the IOL into its final position.

4. It is vital to remove all the viscoelastic from behind the IOL; I do this while the IOL is still under-rotated by 10° to 20°.

5. After I extract the viscoelastic, I fine-tune the rotational placement of the lens. The new VERION Image Guided System (Alcon Laboratories, Inc.) can be helpful to verify that the IOL is aligned along the correct axis. Even before the availability of this system, however, when participating in the clinical trials of the AcrySof IQ Toric IOL, my co-investigators and I found that we could reliably align the IOL within 1° to 2° of target just by using limbal landmarks such as blood vessels. Now, with tools such as the VERION Image Guided System, we are more easily able to consistently achieve outstanding results.

Toric IOLs especially must be able to resist the contractional forces of the capsule in the early postoperative period. As the accompanying article by Bonnie An Henderson, MD, suggests, the rotational stability of this IOL platform may be due to the bioadhesive properties of the hydrophobic acrylic material used in all AcrySof IOLs (*see page 3*). In my hands, the AcrySof IQ Toric IOL has demonstrated tremendous refractive results and stability over time. The single-piece AcrySof IOL platform centers extremely well in all eyes and has superb aspheric optics. Amazingly, many of my patients actually report increased contrast sensitivity with the AcrySof Toric IOL (Figure 2).

Another criterion I look for in a toric implant is its treatment range. The AcrySof IQ Toric IOL currently offers the widest available range of spherical and cylindrical powers. Its cylinder powers range from 0.75 D up to more than 4.11 D, and its spherical powers range from 6.00 D to 34.00 D,[5] making this lens an appropriate choice for cataract patients with astigmatism. Other toric IOL products on the market currently do not offer this wide range of powers, which creates potential challenges for surgical planning and inefficiencies in the OR. With other toric IOL options, surgeons may need to perform additional corneal incisions in addition to simply placing a toric IOL to completely manage patient astigmatism.

PATIENTS WITH GLAUCOMA

My practice includes a large number of patients who present with cataracts and astigmatism and often glaucoma as well. Cataract and glaucoma are frequent comorbidities, and I consider the AcrySof IQ Toric IOL an excellent lens choice for many of these individu-

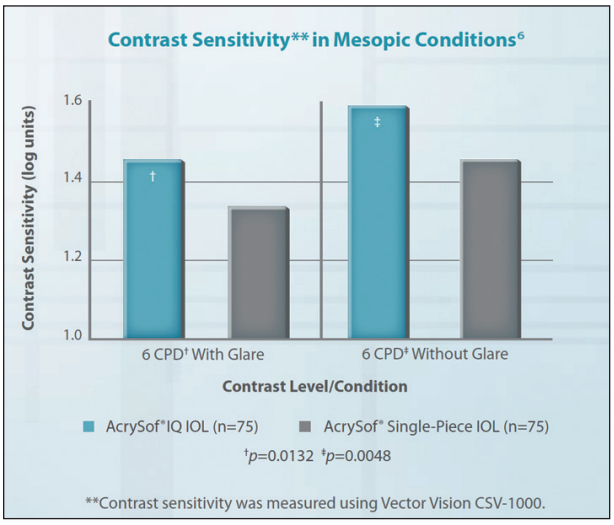

Figure 2. The AcrySof IQ IOL showed statistically significant improvement in mesopic contrast sensitivity over the control lens in situations with and without glare at 6 cycles per degree (cpd).[6]

als. By treating astigmatism at the time of cataract surgery with a toric IOL, we may be able to optimize the vision of these patients. To give our astigmatic cataract patients with glaucoma the best care, these options should be considered.

CONCLUSIONS

With all the technologies now available to help achieve precision placement of toric lenses, I think surgeons who practice modern refractive cataract surgery should be able to routinely exceed the published data on how often these lenses are used to treat a cataract patient's astigmatism. For example, as of 2009, surgeons were achieving a UCVA of 20/20 in approximately 63% of their AcrySof IQ Toric IOL patients at 6 months postoperatively.[8] However, in my practice, with the addition of modern technologies like the LenSx Laser and the VERION Image Guided System (both by Alcon Laboratories, Inc.), I find that we are currently approaching 85% to 90% of patients achieving 20/20 UCVA at 3 months postoperatively with the AcrySof IQ Toric lens.

The target I am shooting for is at least 90% of patients with 20/20 UCVA. That is an ambitious goal, but with the LenSx Laser (Alcon Laboratories, Inc.) to create perfectly round capsulotomies and the VERION Image Guided System (Alcon Laboratories, Inc.) to help me verify proper astigmatic placement—plus, of course, good surgical technique and the reliability of the AcrySof IQ platform—I believe it is achievable. ■

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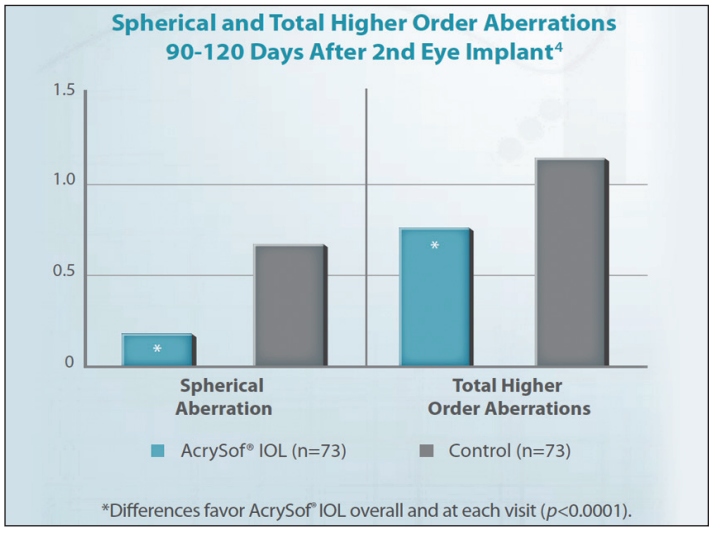

Figure 2. In clinical trials, patients implanted with the AcrySof IQ Toric IOL showed a statistically significant reduction in both spherical and total higher-order aberrations.[4]

can present distortion, particularly in the peripheral field of view. Patients do not realize the amount of distortion in their glasses until they experience the view through the implant. Suddenly, more of their visual field is undistorted. In fact, this may be one of the greatest benefits for patients receiving the AcrySof IQ Toric IOL.

Another feature that contributes to the high satisfaction rate with the AcrySof IQ Toric IOL is its remarkable rotational stability. If it is on axis on the first postoperative day, it will be at or very near the same orientation at 1 week, 1 month, and thereafter. As the surgeon, I know that this lens will always enter the eye and unfold in a predictable manner, and once placed on axis, will remain in its final position.

CONCLUSION

This article has concentrated on the visual benefits of treating small amounts of cylinder, but it is worth noting that higher ranges of cylinder correction are also available with the AcrySof IQ Toric IOL, up to +6.00 D. Although more people have lower degrees of astigmatism, certainly we want the ability to treat higher degrees of cylinder as well, and again, I appreciate the range of correction that the AcrySof IQ IOL offers. It remains the only brand approved to treat from 0.75 D to more than 4.11 D of astigmatism, which is a very large population of patients.

The AcrySof IQ Toric IOL is a highly effective tool that provides excellent postoperative UCVA for cataract patients with astigmatism. In general, my astigmatic patients implanted with this lens are among my happiest patients. ■

1. Hill Distribution data provided courtesy of Dr. Warren Hill. Accessed at http://www.doctor-hill.com/iol-main/astigmatism_chart.htm on October 16, 2013.
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4. Results of a controlled, randomized, double-masked, multicenter, contralateral implant clinical study of the AcrySof® IQ IOL versus an AcrySof® Single-Piece IOL (SA60AT). See Directions for Use.

See page 15 for important product information.

Four-Step Process for Success With Toric IOLs

Toric implantation is not so different from surgery with monofocal implants.

BY RICHARD TIPPERMAN, MD

Ophthalmology is entering a new era of astigmatism correction in which technologies are changing the standard of care. AcrySof IQ Toric IOLs (Alcon Laboratories, Inc.) have redefined how cataract patients with astigmatism should be treated. The widest range of astigmatic correction available coupled with the same excellent unaided aspheric vision that patients without astigmatism routinely achieve with monofocal IOLs is making aspheric toric implants such as the AcrySof IQ Toric IOL a great visual opportunity for most patients with astigmatism.

Yet, there are still some surgeons who have not yet adopted aspheric astigmatism-correcting IOLs in their practices or who are implanting very few of these lenses. They may be reluctant to do so because of seemingly unfamiliar aspects of the toric IOL implantation procedure. Having accumulated extensive experience with the AcrySof IQ Toric IOL since it became available on the market, it is my opinion that implanting these lenses is not such a foreign experience as some may think. With attention to certain details, experienced cataract surgeons should be able to achieve excellent refractive outcomes with the AcrySof IQ Toric IOL in their cataract patients with astigmatism.

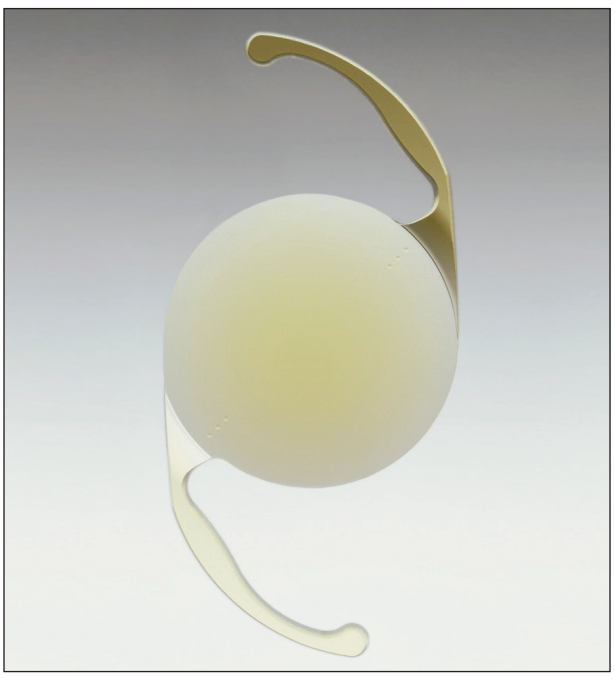

Figure 1. The AcrySof IQ Toric IOL (Alcon Laboratories, Inc.).

FOUR STEPS FOR SUCCESS WITH TORIC IOLs

In my opinion, there are four fundamental steps for success with toric IOLs: (1) patient identification, (2) surgical planning, (3) the implantation procedure itself, and (4) the postoperative assessment. Once the ophthalmologist understands these four steps, the process of toric IOL selection and implantation will seem simpler.

STEP 1: PATIENT IDENTIFICATION

Identifying a target postoperative refraction is already part of the surgeon's workup for every patient who undergoes cataract surgery. Most of the time, the target is emmetropia, but occasionally, the patient may desire a small amount of myopia or some other alternative target. Once he or she determines the refractive target that will provide good distance UCVA for a given patient, generally the surgeon will choose the closest spherical or aspheric IOL power to achieve that goal.

Now, consider a world in which a toric IOL costs the same as a standard spherical or aspheric IOL. If that were the case, the next step after determining the best spherical power for the patient would be to consider his or her keratometric readings. In this reality, if the patient had 1.00 D of cylinder, the surgeon would then choose a low-power toric lens, such as the AcrySof IQ Toric SN6AT3, with a spherical power appropriate for that patient. After all, if the goal is strong UCVA at distance, there would be no reason not to choose a toric lens to correct this patient's 1.00 D of astigmatic refractive error.

When most surgeons adopt toric IOL implantation, however, they begin at the high end of the refractive spectrum. That is, they start by identifying high astigmats

as potential candidates for toric lenses, become comfortable with correcting high degrees of astigmatism, and then work their way down to lower levels of cylinder.

In my opinion, candidates for toric IOL implantation should include any patient with regular astigmatism of 0.75 D or more. The key to identifying patients who are toric lens candidates is to consider both biometry and keratometry measurements as part of the initial evaluation for cataract surgery. This is something that ophthalmologists should be doing anyway, as part of good quality eye care, whether they are implanting toric lenses or not.

Toric lens implantation is not much different from what most cataract surgeons are already doing with spherical or aspheric IOLs; it just involves looking at things differently. If a patient has a cylindrical component to his or her refraction, an ophthalmologist would never prescribe sphere-only spectacles for that patient. An optometrist would never fit that patient for contact lenses without discussing the options for correcting the cylinder. Why perform a permanent surgical procedure and fail to take that patient's astigmatic error into account?

In presenting the choice of a toric IOL to patients, some surgeons will say, "You have the option of selecting a toric implant." As Bradley C. Black, MD, has said, it is really an opportunity to select a toric implant. Why not say to the patient, "You are going to have cataract surgery only once in your life. If you want the best vision you can possibly get, you have the opportunity to be implanted with a toric lens"? This presentation would then be followed by a discussion of fees.

This first step, patient identification, depends on the surgeon considering both sphere and cylinder as a part of the routine evaluation of patients for cataract surgery. Once he or she determines that the patient has 0.75 D or more of corneal astigmatism and would receive improved uncorrected distance vision with a toric IOL, the surgeon can discuss this opportunity with the patient. I generally tell these patients, "You can have cataract surgery with a basic lens that does not correct your astigmatism and will maximize your dependency on spectacles, or you have the opportunity to receive an astigmatism-correcting lens and achieve the least dependency on glasses for near vision. Since you are only going to have cataract surgery once in your life, it may make sense to try to get the best vision you possibly can." Making a recommendation to the patient is an important part of the conversation.

> "Toric lens implantation is not much different from what most cataract surgeons are already doing with spherical or aspheric IOLs."

STEP 2: SURGICAL PLANNING

Alcon has designed the AcrySof Toric IOL Web-Based Calculators (http://www.acrysoftoriccalculator.com/) that any surgeon can access online. The calculation process is straightforward, requiring the input of a few parameters, which can be performed by either doctors or staff to determine the strength of toric lens needed for a given patient. The online AcrySof IQ Toric Calculator will display data to allow the surgeon to determine the correct toric power for the IOL as well as the axis where the IOL should be positioned. The results can then be printed and taken to the OR to use as a reference during surgery.

STEP 3: TORIC IOL IMPLANTATION

Preoperatively, the surgeon makes a reference mark on the limbus. This can be as simple as a dot with a marking pen at 6 o'clock on the limbus, or he or she could use a hand-held marker with or without a bubble level to mark the 3-, 6-, and 9-o'clock positions of the limbus. Alternatively, a variety of markers are available to identify the axis of toric alignment. These markings allow the sur-

LENTICULAR ASTIGMATISM

In a very small number of patients implanted with a toric IOL, a disparity between the targeted and achieved refraction may be due to presumed lenticular astigmatism. In the great majority of patients, astigmatism is present in the cornea. If a patient has astigmatism in his or her lens, then a toric IOL calculation based on that patient's keratometry will not address the whole-eye astigmatism.

In the preoperative assessment, if a significant mismatch is noted between the cylindrical component of the patient's refraction and the keratometric astigmatism, this may be a red flag for lenticular astigmatism. A toric IOL may still be the best choice for this patient, but the informed consent process should address the possibility of an unusual result.

See page 15 for important product information.

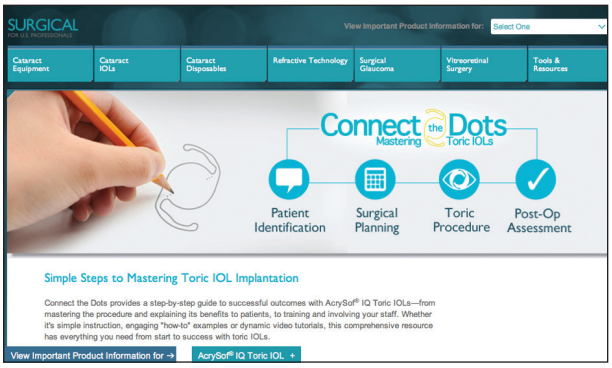

Figure 2. Alcon's new website Connect the Dots (www.toriciols.com) offers a step-by-step guide to implanting AcrySof IQ Toric IOLs using Dr. Tipperman's four steps as described herein.

geon to take into account any cyclorotation that occurs when the patient moves from the seated to the supine position.

The surgery for implantation of a toric IOL is the same as standard cataract surgery. When surgeons begin implanting toric lenses, the part that they generally find stressful is having to align the lens in the specific axis dictated by the toric calculator. The way to overcome this is to realize that rotation of the IOL is already part of routine cataract surgery. Generally, the ophthalmologist does not think twice about this process, because it is part of the normal implantation process. When the IOL has to be placed in a specific orientation, however, it suddenly becomes viewed as difficult.

My advice, therefore, is to practice by orienting nontoric IOLs in a specific axis. I tell novice toric IOL surgeons that they should pick an arbitrary axis of alignment for every patient on the OR schedule on an ordinary surgery day. The surgeon can say, "For my first three patients, I will leave the lens oriented at 90°, and for the next two, I'll leave it at 180°, and the next two at 45°," and so on. There is no pressure, because these IOLs have no toric component, but the surgeon gets to practice targeting a specific axis of implantation. I call this a training-wheel step surgeons can use to become comfortable with rotating the implant to the desired axis.

At the end of surgery, it is important to remove all the viscoelastic completely, including from behind the implant. Viscoelastic left in the capsular bag can prevent the IOL from binding with the capsule, and the lens position can shift in the early postoperative period.

The lens is relatively easy to rotate with viscoelastic in the eye, but, once it is taken out and replaced with balanced saline solution, rotation becomes more difficult. I suggest positioning the IOL 10° to 20° shy of the desired position, removing the viscoelastic, then rotating the IOL to its final spot. I like to use the I/A tip, with infusion on, to nudge the IOL into its definitive position.

Finally, when the eye is inflated with balanced saline solution at the end of surgery, overinflation may lead to early lens rotation, so it is best to leave the eye physiologically firm but not over-firm.

POSTOPERATIVE ASSESSMENT

Generally, the postoperative assessment for the AcrySof IQ Toric IOL amounts to a simple question: How big is the patient's smile? These patients, after needing external correction for astigmatism all their lives, are some of the happiest patients ophthalmologists will see. Most patients will have excellent distance UCVA, so postoperative management is generally uncomplicated.

The most common errors when implanting toric IOLs are placing the lens on the flat rather than the steep axis, marking the flat axis instead of the steep, and making an error when inputting the K readings into the online calculator. If there is residual astigmatism, the patient can be dilated to make sure that the IOL has not shifted or rotated from its intended axis. The dots on the IOL's haptics can be seen when the patient is well dilated, and this will indicate the current axis of the lens.

Some surgeons will dilate the patient to see the toric marks even when the postoperative refraction is good. But if the patient's distance UCVA is 20/20 or 20/25, one can be assured, without dilating, that the lens must be on or close to the desired position. Uncorrected astigmatism of 1.00 D or more would not yield distance UCVA that good.

CONNECT THE DOTS

Alcon also has a new online resource called Connect the Dots (www.toricIOLs.com; Figure 2), which is a step-by-step guide to integrating and implanting AcrySof IQ Toric IOLs using these four simple steps I have described. The site includes simple, straightforward instructions, useful "how-to" examples, and video tutorials to help surgeons master the toric implantation procedure and explain the benefits of these lenses to their patients.

In addition to this online tool, surgeons now are able to purchase the VERION Image Guided System (Alcon Laboratories, Inc.), which is an in-office system that provides diagnostic imaging, surgical planning, and surgical guidance for all forms of intraoperative surgery. For implanting toric IOLs, the VERION Image Guided System is an exciting new tool designed to help the surgeon minimize the human input component of IOL calculations and axis alignment. For those who wish to streamline their surgical planning and implantation, I suggest reading more about the VERION Image Guided System in the article on page 12 by Michael Jones, MD. ■

Astigmatism Management: Streamlining the Process

How the new VERION Image Guided System helps to enhance surgery with the AcrySof IQ Toric IOL.

BY MICHAEL P. JONES, MD

In late January of this year, my practice, Quantum Vision in St. Louis, adopted the VERION Image Guided System (Alcon Laboratories, Inc.; Figure 1A and B), the newest component of Alcon's new Cataract Refractive Suite, which also includes the LenSx Laser, the CENTURION Vision System, and the LuxOR operating microscope. Prior to the advent of the VERION Image Guided System, several steps of the surgical planning were still performed manually; specifically, the values for corneal measurements, biometric and topographic interpretations, IOL calculations, and corneal marking were all entered by hand, and thus susceptible to the potential for error. By automating many of the preoperative measurements and calculations and eliminating manual data entry into operating microscopes and cataract femtosecond lasers, the VERION Image Guided System helps to reduce the potential for human error and thereby creates the opportunity for more precise, accurate surgery.

As of this writing, my colleagues and I have collected 1 month of follow-up data on patients treated with the VERION Image Guided System, and so far it has truly delivered on its commitment to simplifying the steps of cataract surgery and lens implantation. This article focuses on the system's utility when implanting toric IOLs. For a longer discussion on all the ways this system is improving my surgical practice, please see the VERION Image Guided System monograph also accompanying this issue of *Cataract & Refractive Surgery Today*.

> "After using the VERION for only 1 month, I cannot imagine having to position a toric IOL without it."

DATA CAPTURE AND ANALYSIS

The VERION Image Guided System has fundamentally changed my approach to surgical planning for astigmatic patients. Prior to having this technology, I would measure the patient's Ks using multiple devices and then enter the information manually into a web-based

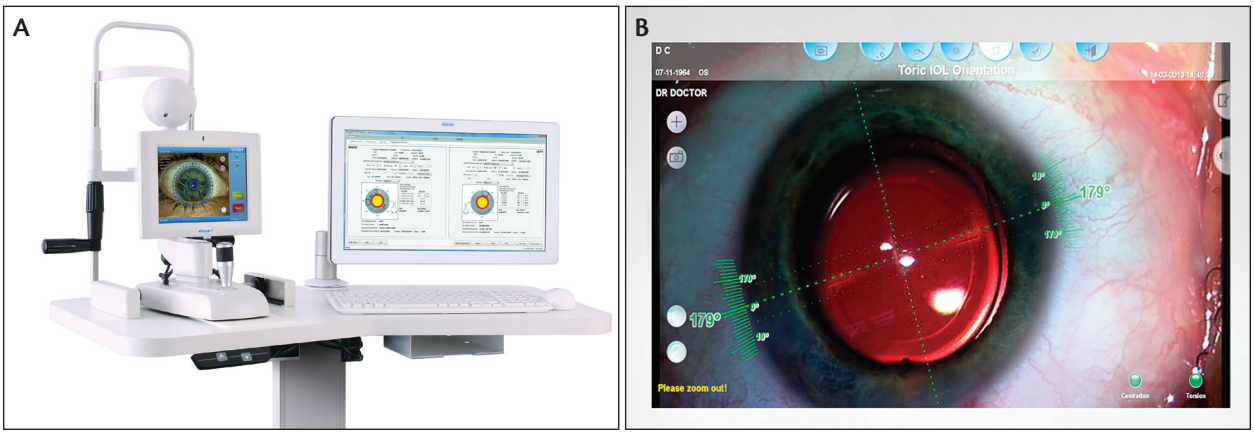

Figure 1. The new VERION Image Guided System comprises the VERION Reference Unit (A), which is used in the practice, and the VERION Digital Marker (B), which is compatible with the LenSx Laser as well as most surgical microscopes. Figure 2B shows the toric alignment overlay of the VERION Digital Marker.

See page 15 for important product information.

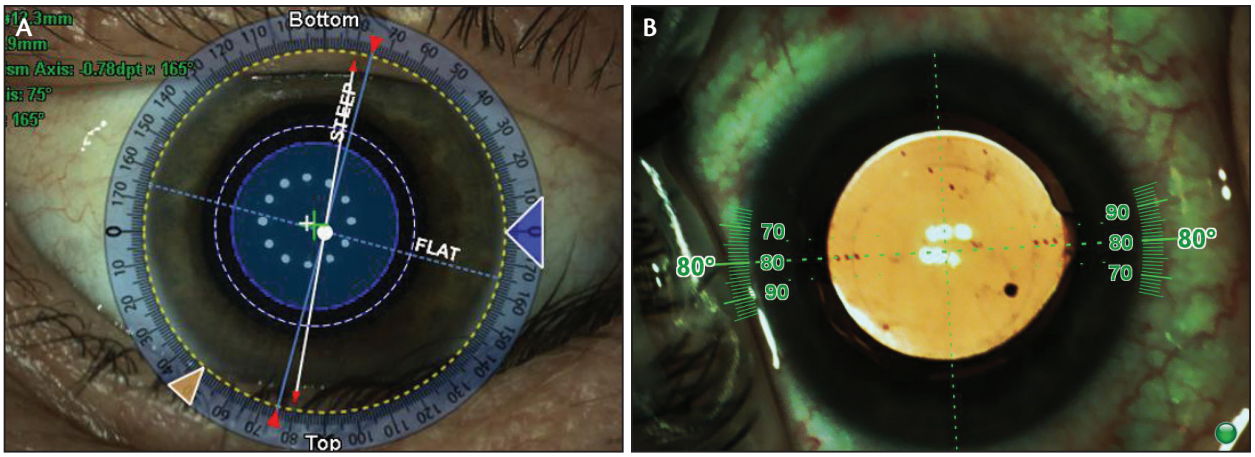

Figure 2. The preoperative planning overview screen of the VERION Digital Marker (A), where the surgeon can review the entire case plan he or she has previously created in the clinic. Note the 80° implantation axis. Figure 2B shows the same case during alignment mode, the final stage of image guidance with the VERION Image Guided System. An Acrysof IQ Toric IOL is clearly aligned on the 80° axis.

toric IOL planning calculator (thus introducing the potential for human error). With the VERION Image Guided System, all of this information is automatically populated into a high-tech astigmatism planner, thereby helping to reduce the human variable.

The VERION Reference Unit (Alcon Laboratories, Inc.) is the diagnostic component of the VERION system that captures a digital image of the patient's eyes in the office. It uses the resulting reference image to measure the scleral vessels, the limbus, and the undilated pupil; then it uses a proprietary astigmatism planning system to apply the appropriate biometry, pupillometry, and keratometry calculations, thereby combining multiple (and previously disconnected) calculations into a comprehensive surgical plan (Figure 2A and B). I then save this plan onto a USB stick that is compatible with any digital operating microscope or my LenSx Laser for cataract surgery.

A particularly useful feature of the VERION Image Guided System is the astigmatism slide bar, which enables the surgeon to calculate the optimal balance between corneal surface and intraocular astigmatism management. I have the option of correcting all of an eye's astigmatism with the IOL or via arcuate cuts. There is even an option for gradient blending. This level of customization afforded by the VERION Image Guided System allows the surgeon to create a customized plan for treating all prescriptions, such as low versus high cylinder.

FROM THE CLINIC TO THE OR

I have a LenSx Laser in my OR, into which I insert the VERION USB drive to automatically transfer the patient's preoperative data. Once the patient is under the laser, its

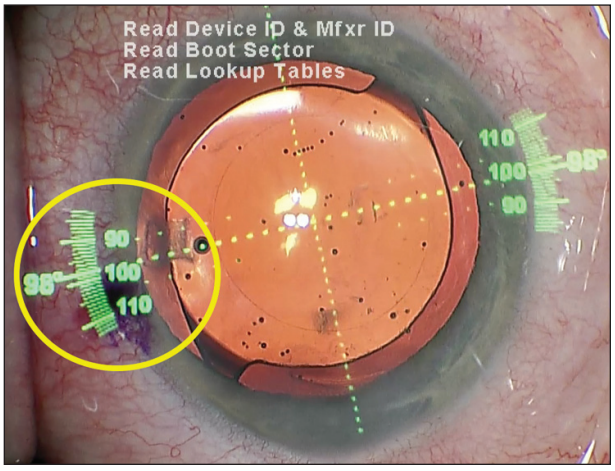

Figure 3. For reference, the author compared toric alignment with the VERION to a preoperative ink mark. Note the single degree mark with VERION versus the 10° to 15° mark with ink.

software matches the preoperative reference image from the clinic with the real-time image in the laser's microscope, and it overlays prepositioned outlines for making the corneal incisions. Not having to plan the corneal incisions or place them manually makes the surgery easier and less stressful, saves considerable procedural time, and reduces variability.

Additionally, my staff and I no longer have to mark patients' eyes preoperatively, which in my opinion is a significant improvement (Figure 3). The ink from a marking pen tends to bleed a little bit, or the patient's eye might have moved ever so slightly during the marking leading to variability and less precision. The VERION Image Guided System's digital, real-time overlay of the patient's eye shows me exactly where the axis is, and it tracks the eye

underneath the microscope to compensate for cyclorotation and movement.

The LenSx Laser lets me choose any diameter and position I want for the capsulorhexis—it is truly customizable, and I have enjoyed testing the various options. I can choose whether to center it on the visual axis, the limbus, or—my preference—on the preoperative pupil. In traditional cataract surgery, once the patient is dilated, there is no way to tell what the pupil looks like. The VERION Image Guided System allows me to center the capsulorhexis and the lens over the pupil—even in cases in which I choose to make the capsulorhexis manually (Figure 4). I have found this tool so helpful in surgery that I am planning to use it to train ophthalmology residents on making the capsulorhexis. The LenSx Laser provides an outline of the capsulotomy within which the cut is made.

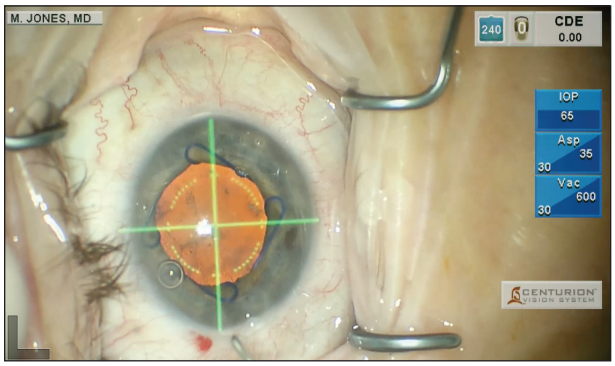

Figure 4. The VERION Image Guided System guides the creation of a manual capsulorhexis within a Malyugin ring in an eye with Floppy Iris Syndrome.

IOL IMPLANTATION AND POSITIONING

I consider the VERION Image Guided System an essential tool for implanting toric IOLs. Multifocal and toric lenses such as the AcrySof IQ Toric IOL need to be perfectly centered in order to perform optimally. After using the VERION for only 1 month, I cannot imagine having to position a toric IOL without it. Because the cornea is registered by the VERION Reference Unit preoperatively, I can place the AcrySof IQ Toric IOL right on the steep axis with no chance of error. I implant it 10° shy of the final position and then nudge the IOL into place. Centering an implant is infinitely easier compared with the manual technique, and the entire process is remarkably intuitive, fast, and easy to use.

So far, the biometric readings from the VERION Image Guided System have corresponded well with those from the Lenstar LS900 biometer (distributed in the US by Alcon Laboratories, Inc.), which is reassuring. I have found, however, that the VERION Image Guided System really shines with complex surgeries. One of the most challenging types of eyes on which I operate are those with a small pupil or Intraoperative Floppy Iris Syndrome. In these cases, preoperative markings get erased when a Malyugin ring or iris hooks are inserted to dilate the pupil. Because the VERION Image Guided System registers an image of the preoperative pupil, however, I am still able to position a capsulorhexis of the appropriate diameter over the location of the preoperative pupil even in these challenging cases, thus giving every kind of eye the same chance at an excellent refractive outcome.

TRACKING OUTCOMES

One of the greatest benefits of the VERION Image Guided System, in my opinion, is how it encourages and assists with tracking surgical results. My partners and I have always been compulsive about tracking our outcomes, and because of that, we consistently meet or exceed patients' expectations. Prior to installing the VERION Image Guided System, we had very few IOLs that were poorly positioned; in the month since, we have had none.

The process of manually inputting postoperative data can be time consuming. We have found it beneficial to perform a follow-up scan with the VERION Reference Unit at the 1-month check-up in order to capture these data. This enables us to measure myriad surgical parameters, such as the influence of customized A-constants and nomograms; the efficacy of particular powers of the AcrySof IQ Toric IOL in relation to degrees of corneal astigmatism; and the impact of various sizes of capsulotomies versus effective lens position—to name a few. I think the ability to take a snapshot of a patient's outcome 1 month postoperatively and have all of this information available to track and analyze will be fascinating and of great clinical value.

CONCLUSION

In summary, my partners, staff, and I have been very pleased with the LenSx Laser's effectiveness at automating certain steps of cataract surgery, and the VERION Image Guided System is the natural next step in helping to eliminate additional variables from the procedure. I am excited to see how the system will contribute to raising our standard of care for cataract surgery.

I think the VERION Image Guided System is especially helpful for surgeons who are just getting started with implanting toric IOLs (with or without a LenSx Laser). Astigmatism marking and lens placement are the two most difficult hurdles when implanting these lenses. The VERION Image Guided System removes the need for complicated and inaccurate marking systems before surgery, and its HUD alignment during surgery is easy to use. ■

See page 15 for important product information.

AcrySof® IQ ReSTOR® Intraocular Lenses – Important Safety Information

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° 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 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° 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.

Important Safety Information for the 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 pre-operative surgical planning functions that utilize the reference image and pre-operative 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 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.
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 uninterruptible. 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.

CENTURION® Vision System Important Safety Information

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 SN60WF, 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.

AcrySof® IQ Toric Intraocular Lenses – Important Safety Information

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° 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.

INFINITI® Vision System

CAUTION:
Federal 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 INFINITI® Vision System is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The INTREPID® AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.
The following system modalities additionally support the described indications:
- Ultrasound with UltraChopper® Tip achieves the functionality of cataract separation.
- AquaLase® Liquefracture Device achieves the functionality for removal of residual cortical material and lens epithelial cells.
- The INTREPID® AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The INTREPID® AutoSert® IOL Injector Handpiece is indicated for use with AcrySof® lenses SN60WF, 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 INFINITI® 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.
Adjusting aspiration rates or vacuum limits above the preset values, or lowering the IV pole below the preset values, may cause chamber shallowing or collapse which may result in patient injury.
When filling handpiece test chamber, if stream of fluid is weak or absent, good fluidics response will be jeopardized. 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:
Use of the NeoSoniX®, OZil® torsional, U/S, or AquaLase® handpieces in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential thermal injury to adjacent eye tissues.
ATTENTION: Refer to the directions for use for a complete listing of indications, warnings and precautions.

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LenSx® Laser Important Product Information

Caution
United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care 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 applanation of the cornea or transmission of laser light at 1030 nm wavelength
Descemetocele 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 which 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 applanation 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.

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Cataract & Refractive Surgery TODAY