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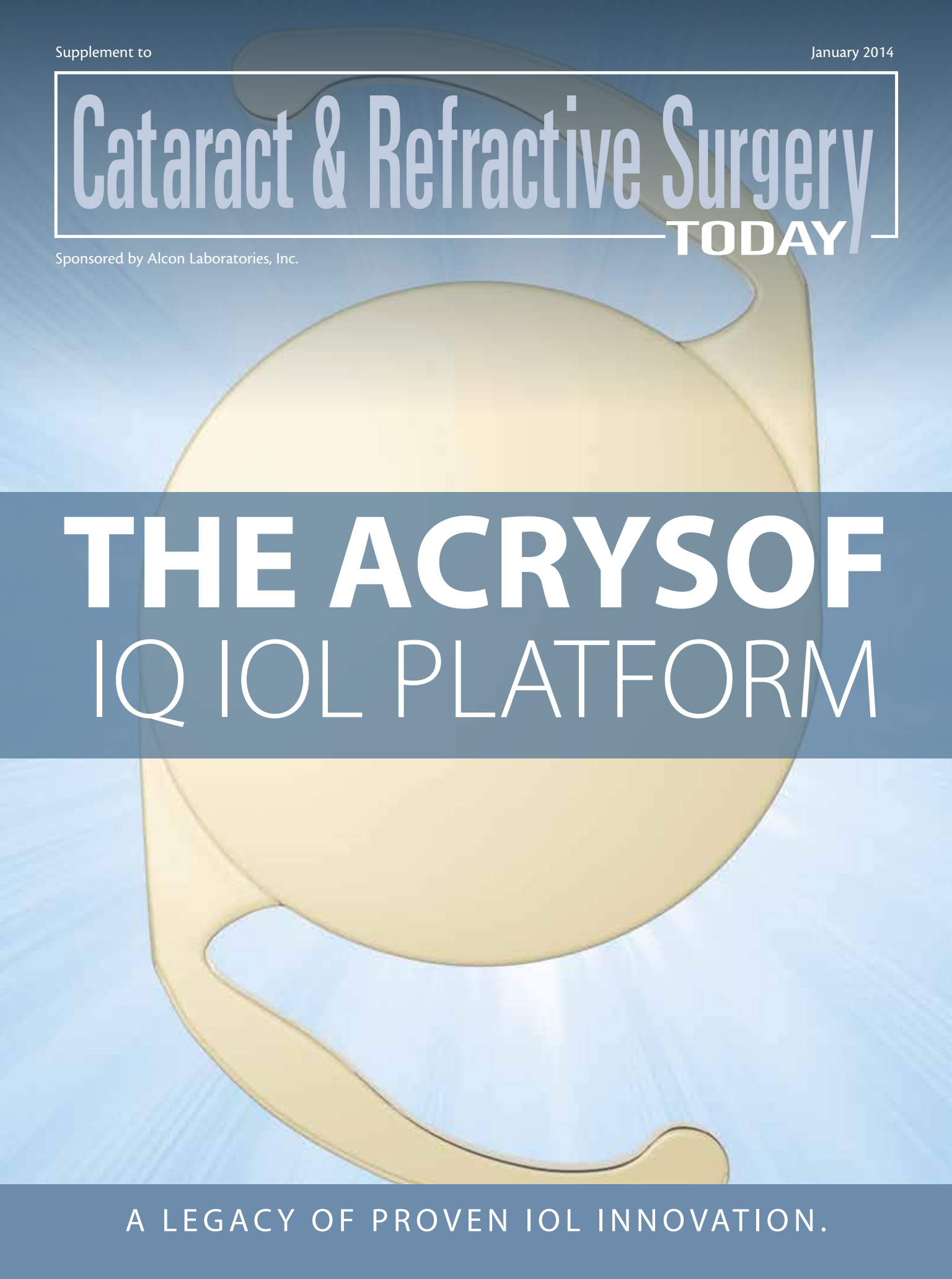

THE ACRYSOF IQ IOL PLATFORM

A LEGACY OF PROVEN IOL INNOVATION.

A Full Spectrum of AcrySof IOLs Provides Excellent Outcomes

Trendsetting platform covers the gamut from monofocal to toric to multifocal optics.

BY ANDREW MAXWELL, MD, PHD

In this era of refractive cataract surgery, it is not uncommon for patients to have exceedingly high expectations. Fortunately, we have the technology and skills to meet or exceed those demands. With the AcrySof platform (Alcon Laboratories, Inc.), we have a family of IOLs that share the key components necessary to provide excellent IOL stability, IOL performance, and postoperative refractive outcomes. These components include highly bioadhesive hydrophobic acrylic material, a trendsetting single-piece lens design with STABLEFORCE haptics (Alcon Laboratories, Inc.), a yellow chromophore with blue-light–filtering properties, and a remarkably high index of refraction—while also having a low incidence of glistenings.[1]

In this supplement to *Cataract & Refractive Surgery Today*, noted practitioners who have extensive experience with AcrySof IOLs discuss their use of this platform and highlight topics such as the evolution of AcrySof from the monofocal through today's toric lens; the benefits of AcrySof IQ's natural chromophore and how it provides more natural transmission than its UV-only filtering counterparts; and the fibronectin-binding properties of the AcrySof optics and haptics, and how this bioadhesion is so important to the centration and stability of IOLs—and perhaps even more crucial to advanced-technology IOLs. Finally, Warren Hill, MD, addresses the topic of 0.25 D-increment IOLs, and informs us that cataract surgery outcomes are dependent upon a multipart process, and that there is no practical or refractive advantage today to implanting lenses in 0.25 D steps—a point with which I concur.

Alcon has dedicated itself to producing premium products that continually set the trends in vision restoration, and AcrySof is the most widely utilized lens platform in the world. I have been closely involved with the development and evolution of AcrySof from its early monofocal days through its most recent multifocal and toric incarnations. As the authors of the articles in this supplement explain it, the AcrySof platform gives us the full spectrum of products designed to help us provide premium outcomes to satisfy the demands of our increasingly savvy patients—for every visual goal. At the end of the day, giving our patients the absolute best vision possible is what it's all about. ■

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Innovation and Improvement Describe Evolution of AcrySof IOLs

AcrySof platform continually meets the needs of surgeons and patients alike.

BY DONALD N. SERAFANO, MD

For close to 20 years, I have relied on the Alcon AcrySof family of IOLs (Alcon Laboratories, Inc.). My patient outcomes have inspired my continued loyalty to this platform, and the evolution of these products throughout this time has shown me that the company has a remarkable commitment to patient outcomes and physician partnership through its product improvement and innovation.

In the 1980s, I began implanting silicone IOLs, because they were the first foldable lenses available in the United States. However, we know that these lenses had problems with their insertion and delivery, as well as with posterior capsular opacification (PCO) and capsular fibrosis, which led to distortion of the IOLs' haptics and subsequent subluxation and/or displacement.

SWITCH TO ACRYLIC

When the three-piece Alcon hydrophobic acrylic IOL came out in 1994, I was happy to change to implanting acrylic material. Insertion and delivery was more predictable, and their long-term centration was predictable and dependable.

The next developmental step for "in-the-bag" IOLs came when Alcon introduced the AcrySof single-piece acrylic implant in 2001. Insertion and delivery became even easier and more predictable, and the Nd:YAG rates dropped considerably.[1] In 2005, Alcon expanded the AcrySof platform to include aspheric optics with a thinner profile and decreased spherical aberrations.[2] The thinner profile enabled surgeons to implant the lenses through smaller incisions. Additionally, the lens' yellow chromophore, in combination with the existing UV blocker, now also blocked out the short wavelengths' high energy visible light, also referred to as *blue light*, which more closely mimics a youthful crystalline lens.[2]

PATIENT DEMANDS

The patient demand for presbyopia correction led to the release of the AcrySof ReSTOR IOL+4.0 D—also in 2005. Likewise, patient demand for improved monofocal uncorrected visual acuity led to the release of the AcrySof Toric IOL in 2006. In 2007, Alcon was able to combine characteristics of the AcrySof platform to release the aspheric AcrySof IQ ReSTOR IOL +4.0 D. This was followed up in 2008 with the aspheric AcrySof IQ ReSTOR IOL +3.0 D for an expanded intermediate range of vision. Truly, Alcon had found a winning platform to launch such remarkable evolutions in such a time frame, meeting wider and wider needs for our ever demanding patients.

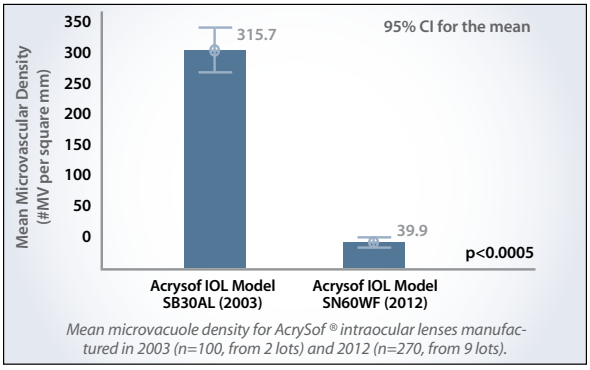

Figure 1. Alcon lenses produced in 2012 showed an 87% reduction in glistenings over those produced in 2003. Glistenings were experimentally created as aqueous-filled microvacuoles utilizing an accelerated laboratory method by immersing the lens in water at 45°C for 24 hours and then at 37°C for 2.5 hours.

I became comfortable implanting the single-piece AcrySof IOL, and one by one I adopted the advanced-technology AcrySof lenses as they became available. This single family of lenses shares important characteristics—such as highly biocompatible material and advanced design features—that offer predictability and refractive stability that in my experience consistently equate to excellent long-term outcomes. Given the number of years that I have been implanting AcrySof IOLs, it is not uncommon for me to see patients who were early recipients of these implants, and I consistently see long-term stability. In my experience, the track record for this family of lenses is remarkable; although not always the case, the patients in whom I have implanted AcrySof lenses have never required a secondary intervention because of an IOL defect.

EVOLUTIONARY STEP

The AcrySof platform has evolved over time by meeting my needs with the same material and new optic designs that foster smooth implantation and reliable outcomes. The AcrySof platform's most recent evolutionary step and improvement comes in the form of reduced glistenings. Glistenings, which are also referred to as *microvacuoles*, are reflections of light that occur from migrations of water within the matrix of hydrated IOL material.[3]

Reports of glistenings began to emerge in the literature in 1996, about 2 years after Alcon released hydrophobic acrylic IOLs. These early papers pointed to an association between glistenings and packaging.[4] Interestingly, while glistenings tend to occur at a high rate in hydrophobic acrylic IOLs, the literature shows that they have actually been observed in most modern IOL materials including polymethylmethacrylate (PMMA), silicone, and hydrophilic acrylic IOLs.[5-9] Glistenings are visible due to differences in refractive indices between the IOL material and water within the IOL material. The larger the difference between these two refractive indices, the more apparent the microvacuoles. Hydrophobic acrylic has a refractive index of 1.47 to 1.55, and water has a refractive index of 1.33, which is why glistenings may be more visible in these lenses (and AcrySof has the highest refractive index amongst any hydrophobic acrylic IOL currently on the market).

Since then peer-reviewed literature has demonstrated that glistenings do not adversely affect visual function, as measured using BCVA and low-contrast visual acuity.[7,10] Glistenings also appear to have no measurable effect on lens optics when measured in a laboratory setting.[11,12] Long-term studies, which included a significant percentage of eyes with severe glistenings, have shown no effect on best corrected visual acuity, low contrast visual acuity, or higher-order aberrations of the eye.[8,13]

The literature shows that glistenings are not clinically significant—and they certainly have not been in my practice. Alcon lenses produced in 2012 showed an 87% reduction in glistenings over those produced in 2003 (Figure 1).[14] The AcrySof lenses manufactured in 2012 had a glistenings density of less than 40/mm^2. This is the result of continuous updates to the manufacturing processes.

ACRYSOF CONFIDENCE

The reduction in glistenings reflects Alcon's commitment to the patient, and really to the physician as well. The way I see it, the company's effort to minimize glistenings suggests that despite the evidence that glistenings do not adversely affect visual function, Alcon recognizes and appreciates that we surgeons need to feel confident about the products and devices we use in order to engender that all-important sense of confidence in our patients.

A common glistenings grading system, known as the Miyata Scale, was developed by Dr. Miyata out of Japan to determine the number of microvacuoles per square millimeter. The system was derived from a study by Miyata et al in which IOLs were monitored for any changes that occurred with the passage of time as they were immersed first in 50°C saline solution for 2 hours, and then in another saline solution with a temperature of 35°C.[15] The Miyata scale shows that IOLs that have glistening particles of less than 50/mm^2 rank grade 0.[15]

More meaningful to me, however, is that in my career, I have implanted more than 5,000 Alcon AcrySof hydrophobic acrylic IOLs, and I have never had to explant a single one related to decreased vision due to glistenings.

CONTINUED DEDICATION

Based on my anecdotal experience with AcrySof IOLs, and Alcon's continued dedication to not only making the best possible lenses, but developing lenses that patients ask for, I am comfortable and confident when I use their products.

As a refractive cataract surgeon in the 21st century, the vast majority of advances that I have been able to offer my patients are in large part due to innovations made by Alcon. I believe Alcon is dedicated to providing the best possible lenses and equipment. I trust this company to continually improve and innovate. This helps me to do my best for my patients today, and based on the products that this company has available, I anticipate being able to meet evolving patient demand with ground-breaking Alcon products for many years to come. ■

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The AcrySof IQ Aspheric IOL: My Monofocal IOL of Choice

Decreasing the positive spherical aberration at the cornea with a negative spherical aberration of the IOL improves mesopic contrast sensitivity and clarity of vision.[1]

BY BONNIE AN HENDERSON, MD

I have found the AcrySof IOL platform (Alcon Laboratories, Inc.) to be reliable, and it is trusted by ophthalmic surgeons who have implanted tens of millions of these lenses worldwide. For more than a decade, we have known that these IOLs are extremely stable, well tolerated, and their performance is excellent.

The primary benefits of the AcrySof IQ IOL are that it is on the original AcrySof IOL platform and that it shares the characteristics associated with this family of lenses: highly biocompatible material as well as easy insertion and delivery. The AcrySof IQ series has the same chemical composition as the original AcrySof but on an aspheric platform, and it also has a proprietary covalently bound yellow polymerizable chromophore. This feature enables the lens to transmit light that more mimics a youthful, natural crystalline lens.[1] For these reasons, the AcrySof IQ Aspheric IOL (Figure 1) is my primary monofocal IOL of choice.

In 2010, I completed a comprehensive literature review of IOLs that filter both ultraviolet and blue wavelength light (<500 nm). This article summarizes the findings, which are still valid today. Since 2010, several other articles have been published showing that the natural chromophore is a good choice for patients undergoing cataract surgery.[2-4]

Figure 1. The AcrySof IOL model SN60WF.

CHROMOPHORE BENEFITS

As the natural crystalline lens ages, it turns yellow and starts to filter out harmful short-wavelength light. When the natural lens is removed during cataract surgery and replaced with an artificial lens that also filters out similar short-wavelength light, it more closely mimics the natural lens' abilities.[1] This is the case with the Alcon AcrySof IQ IOL, which provides a lens that essentially transmits[1] a similar level of light as that of a youthful crystalline lens (Figure 2).

The proprietary AcrySof IOL chromophore filters both UV and high-energy blue light and more closely approximates the light transmission of a healthy human lens.[1] The chromophore is a more natural light transmission over UV-only light.[1] The AcrySof IQ, with the combination of asphericity and the yellow chromophore, has been shown to reduce glare and cyanopsia and improve contrast sensitivity.[5]

IMPORTANCE AND EFFECTS OF LIGHT FILTRATION

As long as there have been IOLs, there have been debates about the importance and effects of light filtration of various lenses. I had heard the criticisms regarding light filtration, so I performed an independent investigation by reviewing the published peer-reviewed literature to gain insight into the topic. I found that blue-light–filtering (BLF) IOLs do not decrease visual acuity, nor do they impair color perception in photopic, scotopic, or mesopic conditions. I took a comprehensive, objective look at all available literature on the issue published from 1962 to 2009 on subjects related to BLF lenses, including sleep disturbance, visual outcomes, cataract surgery, lens transmittance, and sunlight exposure. Of the 56 reports, I found that the vast majority of literature supports that these lenses are beneficial and do not appear to be harmful.[3]

BLF IOLs

My prior assessment of the literature clearly supports that BLF IOLs do not negatively affect visual performance.[6] Eleven reports specifically compared visual outcomes between BLF IOLs and non-BLF IOLs. Of those 11 reports, 10 concluded that an IOL that filters blue light has no significant detrimental effect on various measures of visual performance, including visual acuity; contrast sensitivity; color perception; and photopic, mesopic, and scotopic sensitivities.[6] A larger randomized, prospective study compared the visual performance of subjects receiving either the Alcon AcrySof Natural IOL with a yellow chromophore or the clear AcrySof single-piece IOL. There were no significant differences between the two IOL groups postoperatively in tests of color perception, visual acuity, or contrast sensitivity.[6]

YELLOW-TINTED IOLs

Years before natural chromophore IOLs were available, yellow-tinted sunglasses were shown to improve clarity of vision and reduce glare in patients with both photopic and mesopic conditions, and in 2004, Yuan et al showed that those same visual advantages are seen when IOLs are tinted yellow.[5] In a randomized controlled clinical trial, Yaun et al found the yellow-tinted IOLs significantly improved contrast sensitivity in lower to middle frequencies without affecting color vision. They also noted that yellow-tinted IOLs lowered the incidence of photophobia and cyanopsia, which are both associated with postoperative recovery.

CONCERNS ABOUT FILTERING BLUE LIGHT

There has been concern that filtering blue light might have an impact on the entrainment of the circadian rhythm and lead to sleep disturbances. In my literature review, however, I investigated this concern and found very little evidence that a blue-light–filtering IOL leads to clinically significant sleep disturbance.[6] For instance, Landers et al demonstrated that there was no statistically significant difference in sleeping habits between subjects with non-chromophore and chromophore-enhanced IOLs.[7] Patel and Dacey found that photoentrainment in eyes with BLF IOLs was actually better, and therefore BLF IOLs do not affect melatonin suppression in average illuminations.[8] My review of the relevant literature suggests that IOLs with a yellow chromophore do not have a clinical effect on sleep.

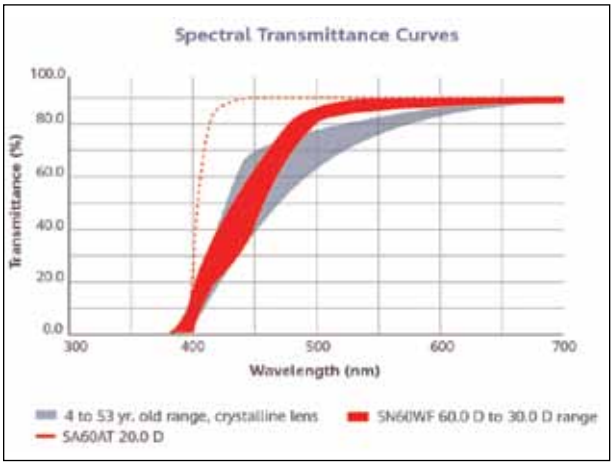

Figure 2. A spectral Transmittance Curve shows that the AcrySof chromophore more closely approximates the light transmission of a healthy human lens.[1]

> "The Alcon AcrySof IQ IOL essentially transmits a similar level of light as that of a youthful crystalline lens."

CONCLUSION

With respect to the AcrySof IQ Aspheric performance, it is well known that decreasing the positive spherical aberration at the cornea with a negative spherical aberration of the IOL improves the contrast sensitivity and the clarity of vision.[1] Therefore, in addition to having the features of the original AcrySof platform—the tried-and-true moldable, flexible acrylic design and material—the IQ component also benefits from the yellow chromophore and the aspheric optic. The bottom line is that a yellow-tinted IOL such as the AcrySof IQ does not decrease quantity or quality of vision compared to clear IOLs, while offering the benefits of the aspheric platform and blue-light filtration that provide a natural light transmission for your patients.[1] I continue to implant the AcrySof IQ IOL with the confidence that it is a safe and effective choice for my patients. ■

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Bioadhesion Boosts the AcrySof IOL's Stability and Centration

Fibronectin adhesion and STABLEFORCE haptics support effective lens positioning.

BY TERRY KIM, MD

When you discover a product or solution that consistently provides excellent results, there is rarely a reason to consider an alternative. This has been my experience with AcrySof IOLs (Alcon Laboratories, Inc.). I was first introduced to AcrySof monofocal IOLs during my training in the mid-1990s, and for almost 20 years now, I have seen my patients benefit from the technology and I have remained loyal to the platform.

DESIGN AND MATERIAL

The AcrySof IOL was the first to transition to a single-piece design, and it set the trend; ever since then, most foldable lenses have relied on the single-piece model. I have become accustomed to the AcrySof's design and the many benefits it affords in terms of loading, implantation, controlled unfolding, and fixation, as well as its ability to center so well. Another feature that is integral to my continued use of the AcrySof platform is its proprietary hydrophobic acrylic material, which provides excellent optics and refractive outcomes in terms of stability and predictability.[1]

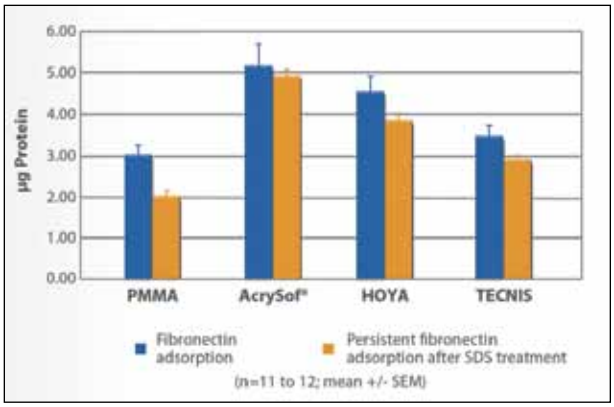

Figure 1. AcrySof IOL material has the highest fibronectin bioadhesion compared with other hydrophobic acrylic materials. Sodium dodecyl sulfate (SDS) was used to characterize fibronectin protein binding affinity to various IOL materials from a mechanistic perspective in an attempt to elucidate the type of bonds formed between the material surface and protein.

> "AcrySof hydrophobic acrylic lenses, both monofocal and advanced technologies, are very user friendly—they fold and unfold in a controlled predictable manner."

CONSISTENT PERFORMANCE

The primary factor behind my continued use of these lenses is the outstanding results that I am able to achieve. This is especially important in today's age of cataract refractive surgery, because patients expect exceptional visual outcomes—even more so than when I started practicing. There are other attractive factors, such as their consistent intraoperative predictability and performance. For instance, AcrySof hydrophobic acrylic lenses are very user friendly—they fold and unfold in a controlled predictable manner, unlike some other acrylic lenses that are stiff and unfold very slowly, or silicone IOLs, which quickly spring open and can potentially lead to unanticipated and unwanted surprises.

AcrySof lenses are not the only hydrophobic acrylic IOL on the market, but they do not all perform the same. Although many IOLs are made of hydrophobic acrylic material, their overall chemical compositions may differ considerably.

COMPOSITION

Even when compared to similar materials, the unique hydrophobic acrylic composition of AcrySof IQ IOLs demonstrates improved adhesion to the lens capsule.[2] Clinical evidence shows that improved capsule adhesion correlates to excellent IOL stability[3] and a lower percentage of patients requiring Nd:YAG laser therapy to address posterior capsular opacification.[4]

AcrySof IOLs are made of a copolymer of phenylethyl acrylate and phenylethyl methacrylate, cross-linked with butanediol diacrylate. The AcrySof IOL material has been shown to have the highest fibronectin bioadhesion compared with other hydrophobic acrylic materials, such as that of the

Tecnis and Hoya lenses, as well as PMMA IOL materials (Figure 1). Recently, Alcon R&D employees performed an in vitro fibronectin protein adhesion assay to compare the fibronectin adsorbed to four different PMMA and hydrophobic acrylic lenses. They incubated 12 IOLs of each type with soluble fibronectin in Tris-buffered BSS at 37ºC for 24 hours. They also incubated another group of IOLs (n = 12 per group) with soluble fibronectin in Tris-buffered BSS at 37ºC for 24 hours and followed that with treatment with 2% sodium dodecyl sulfate at 37ºC for 30 minutes. The AcrySof lenses had the lowest fibronectin loss after sodium dodecyl sulfate treatment.[5] The higher fibronectin retention observed for AcrySof IOL material suggests the presence of stronger bonds between this hydrophobic acrylic surface and the fibronectin protein structure.[5]

This higher fibronectin retention may be responsible for AcrySof lenses' exceptional IOL stability.[2] A study comparing the adhesion of soluble fibronectin laminate and collagen type 4 to various IOL materials found that if an IOL has more fibronectin bound to it, the IOL has better capsular adhesion, as the capsule consists mainly of collagen.[2] If the surface of the IOL achieves a stronger bond with the fibronectin protein structure that exists on the capsular bag, then the lens stays in place.

THE POTENTIAL BENEFITS OF BIOADHESION

AcrySof's fibronectin binding characteristics contribute to the stability and the centration of this lens from three aspects: (1) from the anterior-posterior position, (2) from the centration standpoint, and (3) from a rotational aspect.[2,6] First, you want the lens to be in that anterior-posterior position where you align it, because if it shifts anteriorly or posteriorly, there will be a myopic or hyperopic shift. Second, you do not want the IOL moving in the x–y axis. This is important if you are implanting an aspheric lens, such as the AcrySof IQ, and it is even more crucial if you are implanting a multifocal lens, such as the AcrySof ReSTOR IOL (Alcon Laboratories, Inc.), because if you decenter that lens, you can end up with a suboptimal result. Third, rotational stability is extremely important for toric lenses, because you want the lens to remain in the correct orientation regarding the steep axis of astigmatism. You invest time and effort into marking the eye pre- and intraoperatively, performing the surgery, and positioning the lens where you want it to be. You want that lens to stay where you put it, whether it is a monofocal, toric, or multifocal lens. That is the benefit of exceptional fibronectin adhesion—the AcrySof lens stays where you put it at the end of the case.

SURGICAL TECHNIQUE

Ophthalmologists pay particular attention to surgical technique to help ensure a satisfactory anatomic and visual outcome, and IOL stability is a crucial component of the procedure. Rotational stability is especially important with respect to toric lenses. Malrotation of these toric lenses can have a significant and adverse impact on astigmatism correction. Generally, for every 1º of IOL rotation off axis, 3.3% of lens cylinder power is lost.[7] AcrySof IQ Toric IOLs have demonstrated minimal rotation in clinical trials, with less than or equal to 5º of average rotation 6 months after implantation.[6] In my view, the high level of rotational stability is due to the bioadhesion and fibronectin properties of the AcrySof material.

KEY POINTS

Two important surgical pearls I recommend may be helpful in maximizing IOL stability in the capsular bag: (1) After IOL implantation, I aspirate viscoelastic from behind the single-piece acrylic lens to remove all of the viscoelastic material that can prevent the bioadhesion between the lens and the posterior capsule. If any residual viscoelastic remains trapped behind the lens, the lens' posterior surface will not contact the capsular bag. (2) During the final steps of lens centering and positioning at the end of the case, I gently push the lens posteriorly with a BSS irrigating solution (Alcon Laboratories, Inc.) cannula tip through the paracentesis incision to help ensure that the posterior surface of that hydrophobic acrylic AcrySof lens is in contact with the capsular bag because that is where the majority of the bioadhesion takes place.

POSITIONING AND STABILITY

Another AcrySof IOL feature that is designed to support the stable positioning and long-term refractive stability of this lens is the STABLEFORCE haptics (Alcon Laboratories, Inc.). These modified L-shaped haptics are designed to help ensure stable placement in the capsular bag.[8] This gives the IOL a biomechanical advantage and enables it to maintain its position, whether in a normal capsular bag or a compromised capsular bag supported by a capsular tension ring or other supporting device(s).[9]

HIGH REFRACTIVE INDEX

Yet another feature crucial to the AcrySof's performance is its high refractive index. At 1.55, the AcrySof has the highest refractive index of any IOL, which results in a very thin profile that enables me to deliver this lens safely and effectively through small incisions. I appreciate this feature, because I have been using small incisions for my cataract surgery procedure, with the INFINITI Vision System (Alcon Laboratories, Inc.), and also more recently with the CENTURION Vision System (Alcon Laboratories, Inc.). I like the refractive predictability and relative astigmatic neutrality of my small corneal wound, and I enjoy being able to consistently deliver this lens with my D cartridge and now with the AutoSert injector (Alcon Laboratories, Inc.).[10]

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Cataract Surgery Outcomes Depend on a Multipart Process

New technology helps optimize every component to hit the refractive target.

BY WARREN E. HILL, MD

Surgical advances are invariably fueled by a lively debate of divergent ideas. Sometimes a theory or suggestion sounds plausible, gains some attention, and finds a place in the zeitgeist. Sometimes the development is one that can change lives for the better—extracapsular cataract surgery giving way to phacoemulsification comes to mind. Other times, the concept or potential development is one that is without merit, and if it were implemented, it would not represent a genuine advantage.

A case in point of an idea that seems promising to the uninformed is 0.25 D-step IOLs, using current technology for IOL power calculations. A handful of ophthalmic surgeons have championed the development of IOLs made in 0.25 D steps, suggesting that this would significantly improve the predictability of refractive outcomes. As intuitive as that may seem, regrettably, it is simply not the case.

Refractive outcomes for cataract surgery are based upon a multipart process that involves the accurate measurement of axial length, the central corneal power, the configuration of the capsulorhexis (which helps to control the effective lens position), an estimation of the effective lens position by the formula being used, and the tolerance of the IOL's manufacturing. The resolution of each of these components determines the ultimate resolution of the final outcome.

> "The current weak link in the process of IOL power calculations is very often the use of an older, third-generation, 2-variable IOL power calculation formula in which the effective lens position estimate does not correspond to the actual postoperative position of the IOL."

IOL POWER CALCULATION PARADOX

The paradox of IOL power calculations is that in a multipart process, significantly improving one component in the midst of everything else will not necessarily improve the overall result for a series of patients. However, one component with poor resolution will guarantee a poor outcome. In other words, it is the component part with the worst resolution that typically drives outcomes.

For a process, such as IOL power calculations with multiple parts, each component has what is known as a mean absolute error. Absolute errors are those for which the plus (+) sign

Figure 1. The VERION Reference Unit (Alcon Laboratories, Inc.).

Figure 2. The VERION Digital Marker (shown on the LuxOR Ophthalmic Microscope [Alcon Laboratories, Inc.]).

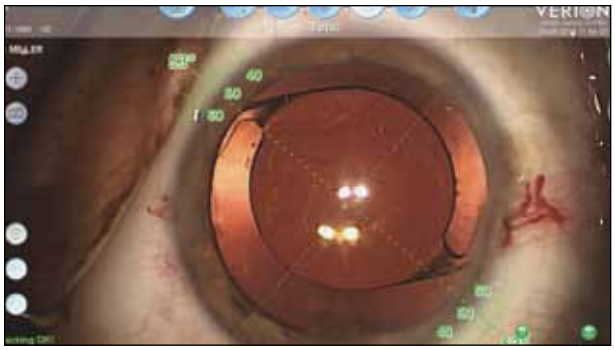

Figure 3. The VERION Digital Marker (during the Toric IOL orientation stage of the Image Guided System).

or the minus (-) sign has been removed. The mean error of +4.00 D and -4.00 D is plano, or perfection, but the mean absolute error would be 4.00 D. Each of these two outcomes had a 4.00 D error, just on opposite sides of plano.

We calculate the mean absolute error by taking a measurement, subtracting that from what we know the measurement should be, removing the plus (+) or minus (-) sign, and then taking the average of the number of observations.

The way that we determine the absolute error of a multipart process is to square the mean absolute error for each component part, add these values together, and then take the square root of the sum. This simple exercise, known as the square root of the sum of the squares, reveals the true contribution of each component to the overall accuracy (absolute error) of the process.

If you have five parts in a process and one part is improved from good to outstanding, the other four parts still drive the outcome. The worse the resolution may be of these other four parts, the less of an improvement the single part will realize due to the mathematical noise involved.

Current technology has certainly come a long way, and for most eyes, the measurements are no longer the problem. However, the current weak link in the process of IOL power calculations is very often the use of an older, third-generation, 2-variable IOL power calculation formula in which the effective lens position estimate does not correspond to the actual postoperative position of the IOL.

As we all know, the power of an IOL inside the eye is relative and not absolute, depending on its distance from the cornea. A +21.00 D IOL only adds +21.00 D to the human eye at a specific distance from the cornea. If the formula mis-estimates the IOL position by as little as 0.50 mm (try holding your fingers that distance apart), at physiologic IOL powers, this represents a +1.00 D error. A +21.00 D IOL placed more anterior by this very small amount effectively becomes a +22.00 D IOL.

So, with present technology, the limiting factor for IOL power calculation accuracy remains the formula being used.

> "There really is no practical advantage to implanting lenses in 0.25 D steps, as there is no detectable improvement in refractive outcomes for a series of patients."

IOLs can come in 0.25 D or even 0.10 D steps, but this type of elegant refinement only has meaning if the mathematical noise within the calculation process is low enough that such resolution can demonstrate an improvement.

ACTUAL OUTCOMES

Eight years ago, I conducted a study of 0.25 D-step IOLs that compared them to 0.50 D-step IOLs. I implanted 128 patients with 0.25 D-step SA60AT IOLs (Alcon Laboratories, Inc.). The mean absolute error for that series of patients was 0.183 D, which is exactly what we predicted. The bottom line is that with current technology, there really is no practical advantage to implanting lenses in 0.25 D steps, as the inaccuracy of the most commonly used formulas creates enough mathematical noise that it is not possible to see a detectable improvement in the refractive accuracy for a series of patients.

By carefully optimizing the individual components of IOL power calculations, combined with advanced surgical techniques, it is possible, in my opinion, to be within ±0.50 D for a majority of surgeries when physicians and staff optimize every aspect.

THE REFRACTIVE TARGET

In the year 2013, with our technology today, how does a surgeon consistently hit his or her preoperative refractive target? Again, you have to optimize every component part. You have to optimize the measurements, you have to use the best possible formula, and you have to optimize the capsulorhexis.

The VERION Image Guided System (Alcon Laboratories, Inc.) can help surgeons organize all of the crucial variables that work together to determine outcomes. The VERION Image Guided System is composed of two components—the VERION Reference Unit (Figure 1) (which would typically reside in the physician's practice) and the VERION Digital Marker (which would reside in the OR and can be placed on the majority of surgical microscopes on the market, as well as the LenSx Laser [Alcon Laboratories, Inc.], if present) (Figure 2).

This is a process that starts with dynamic keratometry to capture K readings and their corresponding meridians, as well as other measurements taken from the VERION Reference Unit. While taking these measurements, the

See page 12 for important safety information.

> "The VERION Image Guided System (Alcon) can help surgeons organize all of the crucial variables that work together to determine outcomes."

VERION Reference Unit simultaneously "fingerprints" the eye to capture all ocular surface landmarks it can find, such as iris and scleral vessel patterns. Once it has a detailed "fingerprint" of the eye and the associated ocular surface measurements in each meridian, the information is sent to the VERION Image Guided System's planning software, which uses a comprehensive calculator to provide the surgeon with a single tool designed to help plan the entire case. With this tool, a change to any one calculation variable is calibrated in the final outcome, so there is consistency in the process.

Having each critical step planned with image guidance and then seamlessly brought into the OR allows the surgeon to maintain orientation and intraoperative alignment at each step, visible through the oculars as well as the adjacent monitor—incisional placement, arcuates, capsulotomy sizing and placement, IOL centration, and TORIC alignment (Figure 3).

THE BOTTOM LINE

The bottom line is that determining refractive accuracy remains a multipart process, and the part with the worst resolution will always drive the refractive outcome for a series of patients. Changing one component—such as cutting in half the IOL power steps from 0.50 D to 0.25 D—will not dramatically improve overall refractive outcomes, and that is where proponents of 0.25 D-step IOLs have it wrong. ■

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(Continued from page 8)

EFFECTIVE LENS POSITIONING

The fact that the AcrySof IOL has the highest fibronectin bioadhesion as compared to the other lenses in the study review is a benefit not only to surgeons but also to patients who have increasingly high expectations from their cataract surgery. We can only meet or exceed those expectations if we can achieve the desired refractive outcome with higher accuracy and predictability. One crucial element of this outcome is effective lens positioning, which demands that the lens stay where it is placed at the end of the case. The excellent biomechanics and biocompatibility of the AcrySof lens help contribute to this optimum positioning.

CONCLUSION

The reliable performance of the AcrySof IOL is the reason why I have been committed to this platform. I value its repeated consistency in terms of its folding, loading, implantation, unfolding, centering and fixation, and I am not alone. The consistent and reliable performance of this lens is a major reason why there have been more than 70 million AcrySof lenses implanted worldwide.[7] ■

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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 pre-operative 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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