

Cataract & Refractive Surgery **TODAY**

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in Cataract Surgery

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Smaller Incisions, Safer Surgery

The clinical benefits of microincisional cataract surgery.

BY KERRY K. ASSIL, MD

Cataract surgery has evolved significantly in the past decade, and it continues to be one of the safest and most effective surgical procedures performed. In fact, enhanced safety and efficacy have been the motivating goals behind the movement in recent years to perform cataract surgery through incisions of 2.4 mm and smaller. As described in the following pages, smaller corneal incisions impart many benefits, from reducing the amount of fluid in the eye to generating less surgically induced astigmatism. In order to take full advantage of these microincisions, however, surgeons need a full package of complementary tools: a phaco system with advanced fluidics, gentler delivery systems for ultrasonic energy, ophthalmic viscosurgical devices with both cohesive and dispersive properties, and IOLs that can pass through such small incisions without stretching them.

My staff and I have adopted the microincisional cataract procedure utilizing the Micro-Implantation Cataract Suite (Figure 1) offered by Abbott Medical Optics Inc. (Santa Ana, CA). This suite provides us with all the tools we need for successful microincisional surgery. It comprises the WHITESTAR SIGNATURE Phacoemulsification System, the HEALON family of OVDs, the TECNIS 1-Piece IOLs, and the UNFOLDER Platinum 1 Series Implantation System. This article provides an overview of these technologies.

WHITESTAR SIGNATURE FUSION FLUIDICS

Advanced phaco fluidics has enabled cataract surgeons to perform phacoemulsification through incisions that are not much larger than the paracentesis site, without compromising the effectiveness or efficiency of the phaco procedure. With the WHITESTAR SIGNATURE Phacoemulsification System, I am able to routinely and easily perform surgery through 2.2- to 2.4-mm incisions without stretching or heating the wound and without compromising my irrigation parameters. I feel that the system's FUSION Fluidics offer power management that has improved the safety profile and efficiency of this surgical technique. Rather than merely responding to intraocular changes in pressure and flow, the fluidics proactively anticipates these changes and constantly adjusts to maintain stability in the anterior chamber. As a result, I no longer experience surge. I consistently have stable chamber fluidics and see much less shallowing of the chamber compared to other phaco technologies. In fact, I have

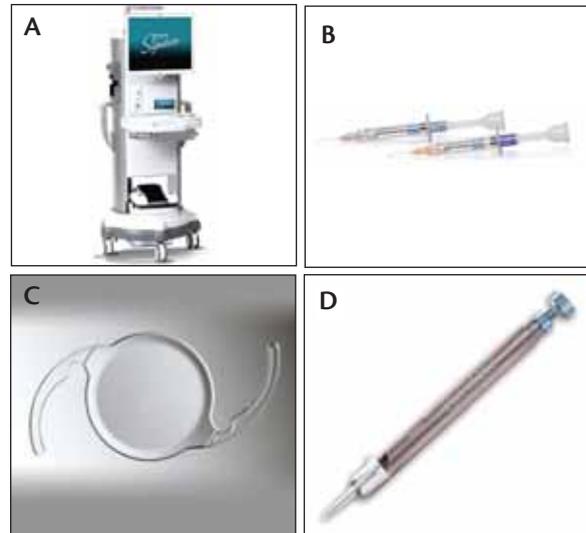


Figure 1. The AMO Micro-Implantation Cataract Suite: the WHITESTAR SIGNATURE Phacoemulsification System (A), HEALON5 and HEALON GV OVDs (B), The TECNIS 1-Piece IOL (C), and the UNFOLDER Platinum 1 Series Implantation System (D). (All manufactured by Abbott Medical Optics Inc., Santa Ana, CA.)

been able to lower the irrigation bottle without inducing chamber collapse. Also, I feel that the FUSION Fluidics results in less corneal edema postoperatively and helps protect against damage to the posterior capsule and loss of vitreous.

Another feature of the FUSION Fluidics I appreciate is the ability to use either peristaltic or venturi pumps at my discretion. The WHITESTAR SIGNATURE is the only phaco system currently available with a dual-pump pack that enables me to either pre-program one type of aspiration or switch between the two types using the foot pedal. The peristaltic fluidics are flow-based and enable flow up to 60 cc/min and a maximum vacuum of 650 mm Hg. The venturi fluidics are vacuum based, with a maximum vacuum of 600 mm Hg.

WHITESTAR SIGNATURE AND ELLIPS FX

The ELLIPS FX Transversal Ultrasound on the WHITESTAR SIGNATURE Phacoemulsification System is tailor-made for low-flow microincisional cataract surgery. The ELLIPS FX handpiece combines its elliptical/longitudinal movement with WHITESTAR Micropulse cutting technology. This

combination is designed to continuously emulsify cataractous material and simultaneously minimize occlusion of the phaco tip. The ELLIPS FX handpiece's transversal motion shears nuclear material with each pass, while the longitudinal movement keeps fragments from clogging the tip. The WHITESTAR Micropulse technology adds magnetic followability so that I am not chasing fragments around the eye. Furthermore, I can set the Transversal Ultrasound to run at continuous, pulse, or a combination of the two.

HEALON OVDs

The HEALON family of OVDs (Abbott Medical Optics Inc.) (Figure 1B) includes a range of viscosities to accommodate all aspects of the cataract procedure. The original HEALON OVD is a cohesive agent. HEALON5 OVD is viscoadaptive. It is designed with both cohesive and dispersive properties. It is very useful in creating the capsulorhexis. HEALON GV OVD is a high-viscosity cohesive agent that expands in the eye to maintain space. It has the highest molecular weight of any OVD currently available. For convenience, Abbott Medical Optics Inc. has packaged HEALON and HEALON5 OVDs together in the HEALON Ultimate Dual Pack.

IOL INJECTION AND INCISION SIZE

Currently, only a few IOLs will pass through incisions as small as 2.2 mm. One such lens platform is that of the TECNIS 1-Piece IOLs (Figure 1C), which pass through 2.2-mm incisions via the UNFOLDER Platinum 1 Series Implantation System (Figure 1D). The cartridge of this inserter has a beveled tip designed to fit microincisions and a proprietary coating inside that makes it easy for all dioptric powers of the TECNIS 1-Piece to pass into the eye. The new UNFOLDER Platinum 1 Series handpiece has a screw-style plunger rod with a rounded y-tip on the end that I can use to manipulate the lens into position after implantation. I find that the UNFOLDER Implantation System preserves the incision's integrity nicely; I have not seen any stretching of my wounds, and they self-seal with no leakage.

SUMMARY

I believe that not only will more ophthalmic surgeons learn about the benefits of microincisional cataract surgery and adopt the procedure, but the technology will continue to expand its advantages with further advancements. I look forward to these innovations as well as to accumulating clinical experience with the microincisional technique. ■

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APPROPRIATE OVDs CAN ASSIST MICROINCISIONAL CATARACT SURGERY

By Rosa Braga-Mele, MD

I find that using an appropriate OVD for each step of microincisional cataract surgery is an important component to high-quality outcomes. I use HEALON GV



Figure 1. HEALON GV deepens the anterior chamber and flattens the anterior capsule.

OVD (Abbott Medical Optics Inc., Santa Ana, CA) in most of my cases. HEALON GV nicely combines dispersive and cohesive properties to create adequate working space in the anterior chamber, coat the corneal endothelium effectively, and keep the iris stable throughout the procedure (Figure 1). It stays in the eye better than other cohesive viscoelastics I have used. Yet, even through microincisions, I find that HEALON GV is very easy to remove from underneath the IOL, around the capsular bag, and from the entry segment at the end of the procedure. Thus, it promotes chamber stability during surgery and minimizes IOP spikes postoperatively.

In difficult cases, I may use a combination of the viscoadaptive HEALON5 OVD (Abbott Medical Optics Inc.) and HEALON GV in the donut technique.¹ I first layer HEALON5 on the iris, and then I add HEALON GV in the center of the HEALON5 to create and maintain space. This technique prevents HEALON5 from leaking out of the eye if it gets fractured by ultrasonic forces. I have found this combination to be very effective in unstable eyes.

It is logical to complement microincisional surgery with the microimplantation of an IOL so as not to have to enlarge or stretch the wound. I currently operate through 2.2-mm incisions, because that is the smallest size that the majority of IOLs can pass through via an injector, and it does not restrict my technique. Again, I most often use HEALON GV to implant these IOLs, because it facilitates an easy and reproducible delivery. ■

1. Scott WJ. HEALON 5 Viscoat donut. *Cataract & Refractive Surgery Today*. 2006;6(9):63-64.

Clinical Advantages of 21-Gauge Phacoemulsification

Recent technological advances maximize the benefits of this technique.

BY TAL RAVIV, MD

I have been performing microincisional cataract surgery since the technology first became available on the WHITESTAR SIGNATURE Phacoemulsification System via the Micro-Implantation Cataract Suite (Abbott Medical Optics Inc., Santa Ana, CA), and I have experience with other manufacturers' microincisional platforms through the teaching hospital where I operate and also train ophthalmic residents. I have found numerous surgical benefits from operating through 2.2- to 2.4-mm microincisions, as this article describes.

BENEFITS OF MICROINCISIONAL CATARACT SURGERY

Less Induced Astigmatism

Surgically induced astigmatism is something all ophthalmologists have become more aware of in recent years, with the increased use of toric IOLs as well as the advent of coaxial microincisional technologies. Studies have conclusively shown that cataract surgery performed through microincisions induces less astigmatism compared with traditional incisions of 2.75 mm and larger. Masket showed that reducing the incision from 3.0 to 2.2 mm diminished surgically induced astigmatism from a mean of 0.67 to 0.35 D.¹ Similarly, Can et al showed a reduction from 0.46 to 0.24 D of induced astigmatism by switching from a 2.8- to a 2.2-mm incision.²

Most surgeons know that entering different values for surgically induced astigmatism into a toric IOL calculator can take an eye from a standard to a toric IOL, or vice versa. Likewise, when calculating limbal relaxing incisions (LRIs) for multifocal IOLs, preoperative with-the-rule astigmatism of 0.25 to 0.50 D can quickly increase to 0.75 D or more with a temporal 2.75-mm incision. Here, a more astigmatically neutral 2.2-mm incision can make the difference between a happy and an unhappy patient.

Improved Surgical Dynamics

The less-invasive nature of the microincisional procedure offers several surgical advantages. First, a 21-gauge phaco needle passed through a 2.2- or 2.4-mm incision has a narrower profile and is much more nimble to maneuver in the

eye than a "fatter," traditional 19- or 20-gauge needle. The 21-gauge needle gives the surgeon a greater degree of control during sculpting and chopping. Second, smaller incisions allow less outflow of viscoelastic and fluid during instrument transitions and thereby increase the stability of the anterior chamber. Similarly, with incision sizes resembling paracenteses more than traditional wounds, iris prolapse becomes less and less of an issue. This is especially appreciable when performing microincisional phacoemulsification on a floppy iris.

THE WHITESTAR SIGNATURE PHACO SYSTEM

The main challenges manufacturers faced when they designed microincisional phaco systems was how to lower the thermal effects of the ultrasound and maintain flow rates so that cataract surgery was safer for the eye, while still maintaining sufficient irrigation to keep the anterior chamber formed and provide for efficient lens removal. With smaller-diameter phaco needles, the laws of physics dictate that for the same bottle height, less irrigation flows into the eye.

What I like about the WHITESTAR SIGNATURE System is that I need not change my traditional phaco and fluidic settings when I perform microincisional surgery. Using the 21-gauge needle through a 2.2-mm incision provides for a remarkably stable chamber, thanks to behind-the-scenes sensors and surge-protecting algorithms such as Advanced Chamber Stabilization Environment (CASE) technology.

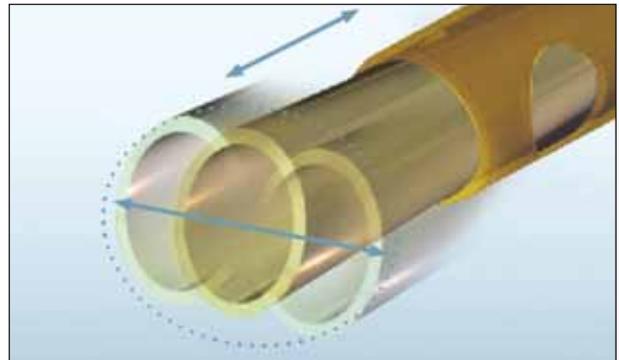


Figure 1. The ELLIPS FX handpiece moves longitudinally and horizontally.

Along with advanced phaco modulations such as transversal ultrasound, I feel that all the components of this system work in concert to make surgery both faster and safer.

Phaco Technology

The WHITESTAR SIGNATURE's ELLIPS Transversal Ultrasound blends traditional longitudinal and horizontal (side-to-side) ultrasound so that the phaco tip shears and emulsifies nuclear material constantly. The phaco tip moves in two directions: side-to-side (horizontally) as well as forward and backward (longitudinally) (Figure 1). This dual motion gives the phaco needle an overall elliptical pattern and allows nuclear fragments to stay at the tip without chattering at or clogging it. Last year, the company introduced its second-generation transversal handpiece,

the ELLIPS FX, which features a higher oscillation rate combined with a longer stroke-path. ELLIPS FX significantly improved the cutting ability for an even smoother, non-occluding phaco.

Due to ELLIPS FX's minimally repulsive nature, I am able to significantly reduce my fluidic settings without relinquishing phaco dynamics. Having worked with the WHITESTAR SIGNATURE System in the teaching hospital, I have found that surgeons who use it are able to lower their standard vacuum and flow rates by approximately 30% without any noticeable difference in emulsification efficiency. Because the ELLIPS FX handpiece eliminates fragment repulsion at the phaco tip, we do not need to use high vacuum. This feature was important when I switched from 2.75-mm incisions to 2.4 and 2.2 mm, because I did not need to change my phaco settings. I was able to use a lower flow rate without seeing any shallowing of the chamber.

Since ELLIPS FX ultrasound already incorporates longitudinal motion within its elliptical path, I have never experienced occlusion with it, even with grade 4 to 5 nuclear sclerosis. Whereas most users of the INFINITI Vision System (Alcon Laboratories, Inc., Fort Worth, TX) need to switch to some combination of added longitudinal ultrasound for very dense lenses, such an option is not necessary with the SIGNATURE's 100% transversal ELLIPS FX platform.

The WHITESTAR SIGNATURE System comes with a 19-, 20-, and now a 21-gauge phaco needle. This system can be used with a straight or curved tip. I initially used the 20-gauge needle with a 2.75-mm incision, but now with

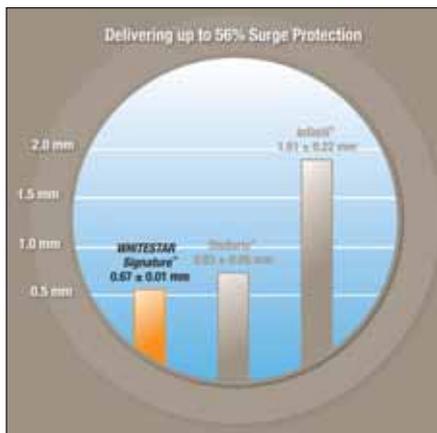


Figure 2. In an independent study, the WHITESTAR SIGNATURE System generated 56% less postocclusion surge than the INFINITI Vision System (Alcon Laboratories, Inc., Fort Worth, TX) and 19% less surge than the STELLARIS system (Bausch + Lomb, Rochester, NY).³

incisions of 2.2 and 2.4 mm, I use the 21-gauge needle and new sleeve. I find this combination allows for plenty of inflow irrigation fluid and efficient phacodynamics, even through a 2.2-mm incision. My technique of supracapsular phacoemulsification for soft lenses and vertical chop for denser lenses remains unchanged by the incision size.

Fluidics

One of my favorite features of the WHITESTAR SIGNATURE with ELLIPS FX is that it is the only phaco system that offers easily interchangeable venturi and peristaltic fluidics. With the nonrepulsive nature of ELLIPS FX, more surgeons are trying venturi fluidics with low levels of vacuum (traditional longitudinal

ultrasound required high levels of vacuum, such as 500 mm Hg, which some physicians perceived as unstable). I currently set my venturi vacuum to 200 mm Hg both with traditional, 2.75-mm incisions and those that are 2.2 to 2.4 mm. There is also a vacuum boost feature that allows me to increase the vacuum linearly to 300 mm Hg by using the yaw feature of the foot pedal. By never going higher than 300 mm Hg, I am able to attain the superb followability of venturi without any chamber or capsular instability (Figure 2).

Although I favor venturi fluidics for quadrant removal, supracapsular, and I/A settings, I use peristaltic fluidics for impaling and chopping the nucleus. In peristaltic mode, I use the more traditional settings of 350 mm Hg of vacuum, an aspiration rate of approximately 26 mL/min, and 50% transversal ultrasound. For a dense nucleus, I increase the FX to 60. Then, I revert to venturi fluidics for quadrant removal settings. So, I get the best of both worlds in one case for ultimate surgical safety. ■

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1. Masket S, Wang L, Belani S. Induced astigmatism with 2.2- and 3.0-mm coaxial phacoemulsification incisions. *J Refract Surg.* 2009;25(1):21-24.
 2. Can I, Takmaz T, Yildiz Y, et al. Coaxial, microcoaxial, and biaxial microincision cataract surgery: prospective comparative study. *J Cataract Refract Surg.* 2010;36(5):740-746.
 3. Data adapted from: Georgescu D, Kuo AF, Kinard KI, Olson RJ. A fluidics comparison of Alcon Inifiniti, Bausch & Lomb Stellaris, and Advanced Medical Optics Signature phacoemulsification machines. *Am J Ophthalmol.* 2008;145(6):1014-1017.

Optimal Vision at All Distances

The importance of the preoperative interview, counseling, and IOL selection for success with multifocal implants.

BY LAWRENCE B. KATZEN, MD

Multifocal IOLs give today's cataract patients the possibility of achieving good vision at all distances. I have found that proper patient selection and a thorough preoperative interview and counseling session make the difference in selecting the most appropriate implant for each individual and thereby generating a high level of patient satisfaction after surgery. Managing patients' expectations is the key to this process.

Multifocal lenses are hailed for their ability to provide good vision at both near and far distances, but they are sometimes criticized for vision that is less crisp than monofocal implants or for imparting visual symptoms such as halos and glare. I have personally implanted more than 700 presbyopic IOLs, and my overall clinical impression is that patient satisfaction is extremely high with the TECNIS Multifocal IOL (Abbott Medical Optics Inc., Santa Ana, CA). To confirm this impression scientifically, colleagues and I initiated a retrospective review to objectively document the effectiveness of this lens in reducing the need for spectacles at all three ranges of vision.

RETROSPECTIVE REVIEW

I participated in a multicenter, retrospective study that compared the outcomes of individuals implanted (either unilaterally or bilaterally) with the TECNIS Multifocal IOL (models ZMA00 or ZMB00) and the ACRYSOF IQ ReSTOR IOL +3.0 D (model SN6AD1; Alcon Laboratories, Inc., Fort Worth, TX). Outcome measures included UCVA and BCVA at near (14 to 16 inches), intermediate (28 to 32 inches), and distance. Following are preliminary results from a single site in this study (that of William B. Trattler, MD, of Miami).¹ Dr. Trattler's team found that 78% of the eyes implanted with the TECNIS Multifocal IOL achieved a UCVA of 20/25 or better at near at a minimum of 3 months after surgery, compared with 66% of those that received the ACRYSOF IQ ReSTOR IOL +3.0 D (Figure 1). At intermediate distance, 50% of the TECNIS Multifocal IOL recipients achieved 20/25 UCVA, compared with approximately 20% of the eyes implanted with the ACRYSOF IQ ReSTOR IOL +3.0 D (Figure 2). These findings suggest that the TECNIS Multifocal IOL provides better uncorrected near and intermediate visual performance than the ACRYSOF IQ ReSTOR IOL +3.0 D.

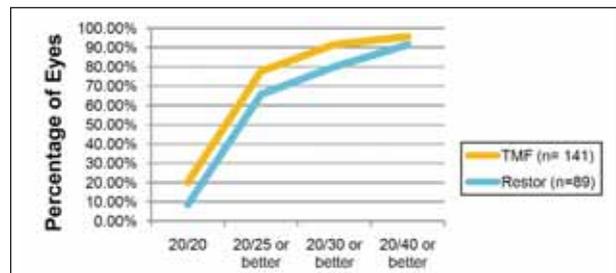


Figure 1. Near UCVA in subjects implanted with the TECNIS Multifocal IOL versus the ACRYSOF IQ ReSTOR IOL +3.0 D.¹

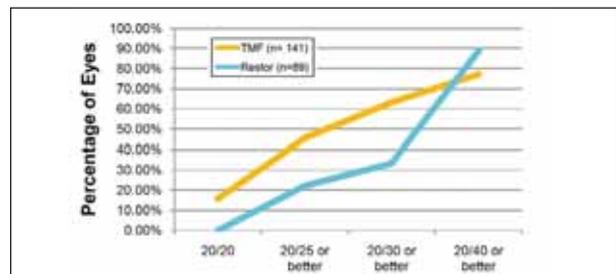


Figure 2. Intermediate UCVA with the TECNIS Multifocal IOL versus the ACRYSOF IQ ReSTOR IOL +3.0 D.¹

CLINICAL EXPERIENCE

I have been able to achieve more predictable refractive results with premium multifocal IOLs by optimizing the A-constant, addressing corneal astigmatism, and paying meticulous attention to the eye's keratometry and optical biometry preoperatively. Because the optic of the TECNIS 1-Piece Multifocal IOL is fully diffractive, it is rare that recipients of this lens are unable to read in dim light. I believe that certain physical characteristics of the TECNIS 1-Piece IOL contribute to its consistently good results. First, the lens corrects 0.27 μm of spherical aberration (the amount contained in the average adult cornea), which is intended to leave patients with zero spherical aberration. Second, the TECNIS 1-Piece IOL minimizes chromatic aberration, because its proprietary hydrophobic acrylic material has one of the highest Abbe numbers (55) of any IOL. Third, the posterior surface of the TECNIS 1-Piece IOL features a full diffractive posterior optic, which is designed

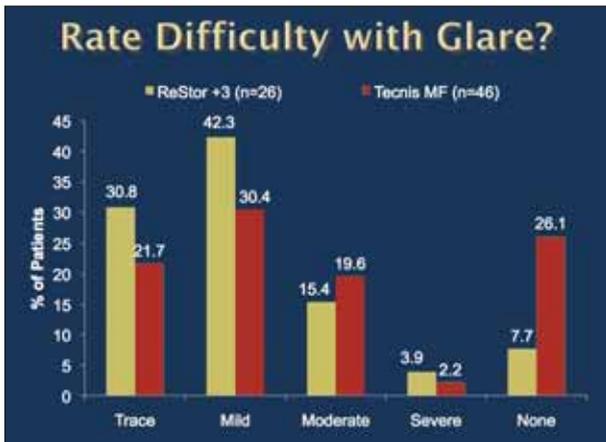


Figure 3. Data from Dr. Katzen's cohort of the study show the outcomes of patients implanted with the TECNIS Multifocal IOL and the ACRYSOF IQ ReSTOR IOL+3.0 D. A greater number of TECNIS patients reported no difficulty with glare than recipients of the ACRYSOF IQ ReSTOR IOL +3.0 D at a minimum of 3 months postoperatively.²

to provide patients with pupillary independence. This feature is especially important for close-range reading in dim light. My personal experience with the TECNIS 1-Piece has been very good.

PATIENT COUNSELING

Despite the high performance of the TECNIS 1-Piece Multifocal IOL at all viewing distances, a large part of patients' success, in my opinion, is the physician's awareness of their individual needs combined with sufficient counseling before surgery. Patients who are used to wearing bifocals see exceedingly well with this lens. Other patients must be advised that all multifocal lenses contain "sweet spots" of viewing distances, meaning that they must learn where to hold materials in order to see them most clearly. Also, some patients may notice a limitation in their intermediate vision compared with progressive spectacles. In regard to reading distance with the TECNIS Multifocal IOL, our experience has been that recipients' reading range is from 13 to 24 inches. Those who spend more time performing near-vision tasks such as reading or needlepoint are often very happy with the TECNIS Multifocal IOL, which has a +4.00 D add.

I have found that a key factor in ensuring patients' satisfaction with a multifocal lens is to properly educate them on the possible visual side effects of these implants, such as halos and glare, especially around lights at night (Figures 3 and 4). First, my staff and I explain that these symptoms are a common side effect of the surgery, and that they often dissipate over time. We also give our candidates the opportunity to view simulations or an artist's

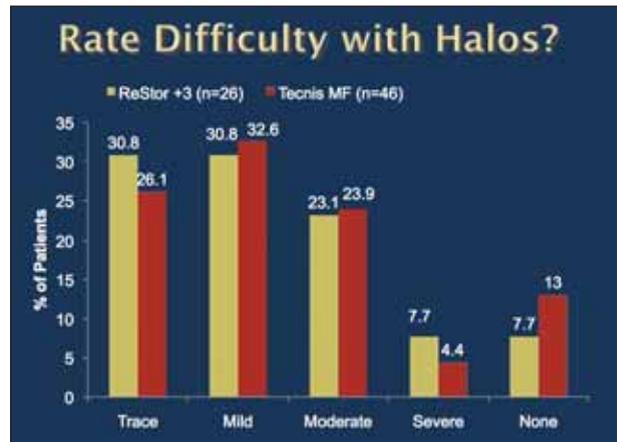


Figure 4. The author's cohort revealed that the TECNIS Multifocal group had a lower rate of severe halos and a comparable rate of moderate, mild, and trace halos compared with the ACRYSOF IQ ReSTOR IOL +3.0 D.²

drawings of these halos prior to surgery, to give them an idea of the effect. This is an excellent way to screen individuals who might be intolerant of this visual symptom. Furthermore, I feel it is important to question multifocal IOL recipients about their experience with halos 1 week after their first eye has been implanted and before performing surgery on the second eye. If the patient is suffering from severe symptoms at that time, I want to address the problem before implanting the second eye. Thanks to our preoperative education, almost all patients are able to tolerate the neuroadaptation period without a problem; we have not yet had to explant a TECNIS Multifocal IOL.

POTENTIAL FOR GROWTH

As more patients seek functional, spectacle-free vision at multiple distances, multifocal lenses will continue to grow in popularity. When patients are properly selected and counseled prior to surgery, they can be highly satisfied with the flexibility and freedom from eyeglasses they achieve with the TECNIS Multifocal IOL. From this study, my colleagues and I have concluded that patients who are motivated to reduce their dependence on spectacles can achieve a high level of satisfaction with the TECNIS Multifocal implant. This lens has been effective in reducing spectacle dependence for distance, near, and intermediate vision. ■

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1. Trattler B, Buznego C, Perez G, et al. Retrospective Evaluation of Tecnis Multifocal Intraocular Lenses Following Phacoemulsification. Poster presented at: the ESCRS Annual Meeting; September 17-21, 2011; Vienna, Austria.
 2. 127 Data on file. Santa Ana, CA: Abbott Medical Optics Inc. TECNIS MIOL Glare and Halo Comparative Results.

Better Near Visual Acuity With an Aspheric Multifocal IOL

An evaluation of the TECNIS Multifocal IOL and the Crystalens AO IOL.

BY FARRELL "TOBY" TYSON, MD

Recently, colleagues and I conducted a study designed to compare the visual outcomes of patients implanted bilaterally with the TECNIS Multifocal IOL (Abbott Medical Optics Inc., Santa Ana, CA) and the CRYSTALENS AO Aberration-free Accommodating IOL (Bausch + Lomb, Rochester, NY) after cataract surgery. This article reports on the 6-month data of 40 enrolled subjects in this prospective, nonrandomized study.

METHODS

Each patient attended five visits: preoperative (both eyes evaluated), operative (each eye evaluated), and 1, 3, and 6 months postoperative (both eyes evaluated). At the time of this writing, 40 individuals have completed the 6-month visit. The mean ages were 67 for the TECNIS Multifocal IOL group (n=20) and 66.7 years for the CRYSTALENS AO group (n=20), and all subjects had bilateral cataracts for which we planned phacoemulsification extraction and posterior IOL implantation. The visual potential of each eye was 20/25 or better after removal of the cataract and implantation of the IOL. The preoperative distance BCVA was worse than 20/40 Snellen, and the mean preoperative spherical equivalent was -1.194 (standard deviation, 2.5) in the TECNIS group and -0.669 (SD, 1.3) in the CRYSTALENS group. Each eye's naturally dilated pupil size (in dim light with no dilation medications) was > 4.0 mm, and their preoperative corneal astigmatism was 1.00 D or less. Other than the cataract, every eye was healthy.

OUTCOMES

Figure 1 shows the 1-, 3-, and 6-month outcomes for near UCVA in both study groups. By 6 months, the difference in near visual performance between the two groups was statistically significant ($P=.007$), with those in the TECNIS Multifocal IOL group achieving almost 20/23 UCVA, and the CRYSTALENS AO recipients reaching approximately 20/33 UCVA. The two groups achieved a similar visual performance at intermediate and distance viewing.

SUBJECTIVE RESULTS

We also administered a subjective questionnaire to patients to judge their visual performance at 6 months. When we asked the subjects how easy it was to perform near, intermediate, and distance tasks without glasses, a nearly equal percentage of patients in the two cohorts reported that seeing objects in the distance was easy or very easy, but a greater percentage of TECNIS Multifocal recipients experienced ease with intermediate tasks (working at a computer or reading at arms' length), and almost twice as many TECNIS Multifocal IOL subjects reported

(Continued on page 13)

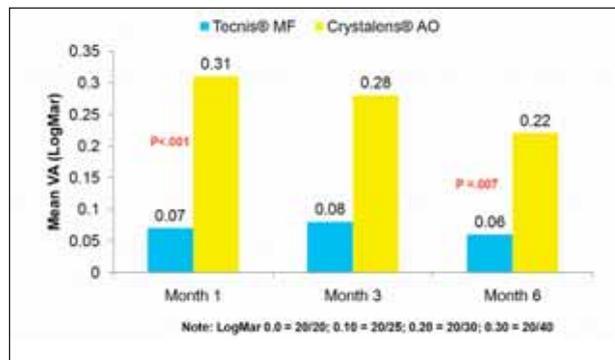


Figure 1. Near UCVA at 6 months after implantation of the TECNIS Multifocal and CRYSTALENS AO IOLs.¹

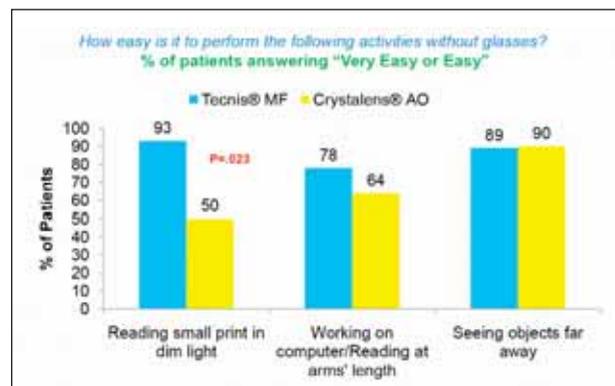


Figure 2. Patients' reporting of ease of performing near, intermediate, and distance tasks without glasses.¹

Dry Eye More Prevalent Than Expected in Cataract Patients

A recent study shows why all cataract patients should be tested for dry eye preoperatively.

BY WILLIAM B. TRATTLER, MD

Dry eye and ocular surface disease are important conditions to identify in patients who are scheduled for cataract surgery. Failure to identify and treat cataract surgical patients with these conditions can result in reduced accuracy in selecting the IOL's power and in identifying and treating astigmatism. Postoperatively, patients with inadequately treated dry eye syndrome may notice fluctuations in their vision as well as the classic ocular symptoms of dry eye. Because preoperative testing and postoperative results can be significantly affected by untreated or undertreated dry eye, it makes sense to be extremely vigilant in identifying patients at the initial consultation.

PREVALENCE OF DRY EYE IN THE CATARACT POPULATION

In a study of 100 patients (200 eyes) scheduled for cataract surgery at two centers, Carlos Buznego, MD, Jodi Luchs, MD, and I diagnosed 59% with blepharitis.¹ Moreover, my clinic was one of nine sites that participated in the Prospective Health Assessment of Cataract Patients Ocular Surface (PHACO) study,² the goal of which was to determine the prevalence of dry eye in patients undergoing cataract surgery. The study enrolled 136 patients (272 eyes) scheduled for cataract surgery whose average age was 70 years. All the patients presented for dry eye examination prior to starting any ocular drops. We evaluated tear break-up time, corneal staining, and Schirmer's scores to determine the instance of corneal dryness, and each patient answered a subjective questionnaire.

We found that dry eye was much more common than we expected in this population, although the subjects rarely reported symptoms of discomfort. For example, 59% of the individuals said that they never experienced foreign body sensation, and only 13% said that they felt it half or most of the time.

Although there has been little consensus about what constitutes a normal versus abnormal tear break-up time, I feel that 7 to 10 seconds indicates a healthy tear film (Figure 1). Out of the 272 eyes in this study, however, 171 (62.9%) had a tear break-up time of less than 5 seconds.



Figure 1. Tear break-up as seen under corneal staining.

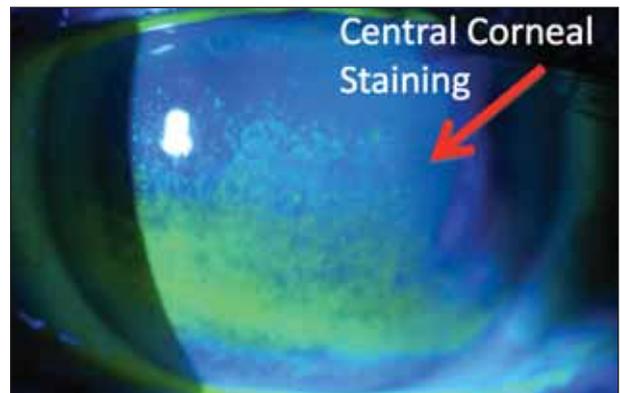


Figure 2. Central corneal staining as an indication of dry eye.

Additionally, 209 eyes (76.8%) showed positive corneal staining, and 136 eyes (50%) showed central corneal staining (Figure 2). In Schirmer's testing, 132 eyes (48.5%) had a score of 10 or less, and 58 eyes (21.3%) scored less than 5.

PRESURGICAL TREATMENT OF THE OCULAR SURFACE

As a result of these studies, I have become more proactive in testing and treating my cataract patients. Because even mild dry eye can affect cataract surgical outcomes, however, the key is identification—to test for dry eye syndrome early in the preoperative examination, before we take these

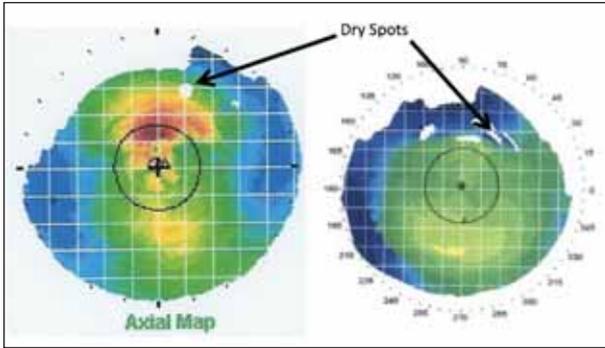


Figure 3. Topography readily identifies preoperative dry eye.

patients' measurements for cataract surgery. Topography is an excellent tool for identifying corneal dryness (Figure 3).

It is important to delay the surgery until the ocular surface is healthy enough to generate accurate measurements and withstand the procedure. Of course, patients are often anxious to schedule the surgery. Therefore, my protocol is to begin treating ocular surface disease with a topical steroid and topical cyclosporine (for aqueous deficiency) or azithromycin ophthalmic solution 1% (for blepharitis). I also like to use BLINK Tears (Abbott Medical Optics Inc., Santa Ana, CA), because I find it gives patients fast and long-lasting relief from dry eye symptoms.

As part of a 943-patient study I conducted with Dr. Buznego, I observed a significant mean reduction in patients' overall symptoms of dry eye from mild-to-moderate to trace-to-mild after switching them to BLINK Tears for 1 month.³ BLINK Tears' unique viscoadaptive formula mimics the structure of natural tear mucin, thereby helping to restore the tear film and provide patients with immediate and sustained comfort with less blur.⁴⁻⁶ Then, I ask the patient to return in 7 to 14 days for repeat testing. I often see a significant improvement in their visual outcome. ■

BLINK is a trademark owned by or licensed to Abbott Laboratories, its subsidiaries, or affiliates. All other trademarks are the intellectual property of their respective owners.

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TREATING THE OCULAR SURFACE TO OPTIMIZE CATARACT OUTCOMES

By Marguerite B. McDonald, MD

Although multifocal IOLs provide many patients with an excellent quality of vision, they are also unforgiving of the unintended higher-order aberrations that a dry ocular surface can present. Optimizing the ocular surface prior to implantation will help ensure success with these lenses.

As part of dry eye therapy, BLINK Tears (Abbott Medical Optics Inc., Santa Ana, CA) has shown effective clinical performance. BLINK Tears' unique viscoadaptive formula mimics natural tear mucin by binding 1,000 times its volume of water to help thicken and stabilize the tear film.¹⁻⁵ In studies, BLINK Tears extended the tear break-up time (TBUT) to eight times longer than SYSTANE Ultra (Alcon Laboratories, Inc., Fort Worth, TX). Patients with a mean TBUT of <10 seconds were randomized to use one of the two drops for 1 month. Results showed a mean TBUT improvement of 2.4 seconds with BLINK Tears versus 0.3 seconds with SYSTANE Ultra ($P=.003$).

BLINK Tears has also been shown to provide patients with immediate comfort from surface dryness with improved visual clarity. Patients rated BLINK Tears to be 50% more comfortable than SYSTANE Ultra upon instillation.⁶ In a study of 943 subjects, 70% of all patients found BLINK Tears to be comfortable or extremely comfortable compared to previously used tears products when performing their daily activities such as driving at night, watching TV, reading, and working at a computer,⁷ and 67% experienced greater visual clarity/sharpness with BLINK Tears versus previously used brands.⁷ Another study showed that BLINK Tears significantly reduced fluorescein corneal staining by 94% from baseline after 3 weeks compared to saline, which showed no signs of improvement.⁸ ■

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Glistenings in IOL Materials

Physicians must take IOL material into account when counseling patients.

BY MARK PACKER, MD, CPI

Several years ago, considerable discussion took place within ophthalmology regarding the merits of acrylic versus silicone IOLs. In recent years, all the attention has focused on optical design. With multifocal and accommodating IOLs now on the market, professional conversation has turned to determining which precise lens is best for the individual in order to provide patients with better vision after cataract surgery than ever before. As we conquer postoperative visual symptoms such as halo and glare, the next step in helping patients achieve emmetropia may be to return the discussion to lens material.

CHROMATIC ABERRATIONS AND VISUAL SYMPTOMS

When I first started implanting multifocal aspheric lenses, I was determined to choose the aspheric lens that most closely matched the cornea. However, experience taught me that something else seemed to be a more important factor, because even when I matched asphericity to the cornea, percentages of certain groups of patients still complained of visual symptoms. I had more complaints from patients who received aspheric lenses made out of material that produced higher rates of fluid-filled vacuoles, known as *glistenings*, or chromatic aberrations (Figure 1). These patients did not complain of halos, but rather about something they called “waxy vision”—the perception that their vision was not crisp. I came to realize that when I implanted IOLs that were made out of material that has fewer chromatic aberrations, my patients seemed more pleased with their results.

THE TECNIS MULTIFOCAL IOL

Various IOL materials contain different amounts of chromatic aberration. A material with a low amount of chromatic aberration produces a much higher level of contrast. In a very real way, higher contrast equals a higher quality of vision.¹ IOL materials available today are not all created equal. Similar to the materials used for eye glasses and contact lenses, every material refracts light slightly differently depending upon its inherent wavelengths. The Abbe rating is a measure of a materials' dispersion of light in relation to its refractive index, or the variation of the refractive index with wavelength. This rating allows us to recognize that yellow light is refracted differently from blue light, which is refracted differently from violet light. An Abbe number is calculated by a relative equation of three key spectral lines



Figure 1. Glistenings occur increasingly over time in some implanted hydrophobic acrylic lens materials, as pictured here.

that are at different wavelengths, and the numbers range from 20 to 90 in most types of material used in optical systems. The higher the Abbe number, the lower a material's amount of chromatic aberration.

The natural crystalline lens has an Abbe number of 47. The TECNIS Multifocal IOL

(Abbott Medical Optics Inc.; Santa Ana, CA) is made of an acrylic IOL material with a very high Abbe number (55), which means it has fewer chromatic aberrations and therefore provides a higher quality of vision.^{2,3} Clinically, I receive fewer postoperative complaints when I implant the TECNIS Multifocal IOL versus other premium refractive lenses, and I believe the reason is the lens' crisp quality of vision. Thus, I feel that using such a high-quality IOL is a preventative strategy that allows me to avoid postoperative problems, especially for those patients who pay for premium surgery.

It seems only logical that clearer IOL materials will result in improved visual clarity for patients. Thus, I feel that the first place we can look to improve postoperative clarity is in reducing the occurrence of glistenings in lens material. Glistenings are not inherent in all IOLs; certain lens materials and methods of production are able to reduce or eliminate these little vacuoles we see under the slit lamp. Although glistenings have yet to show a significant impact on visual acuity in a clinical setting, they remain an undesirable cosmetic defect in IOLs.⁴ As we implant more multifocal lenses, I have a growing concern about the long-term visual consequences of glistenings, because their formation progresses over time. Examination of a patient who had cataract surgery 20 years previously will often show a lens scattered with a significant number of these vacuoles. While the patient still may not complain of visual impairment, we are certain these vacuoles produce backscatter, and we fear that this may lead to diminished functional vision.^{5,6} Moreover, there is an incremental amount of evidence that these vacuoles may cause some loss of high-frequency contrast sensitivity.^{7,8}

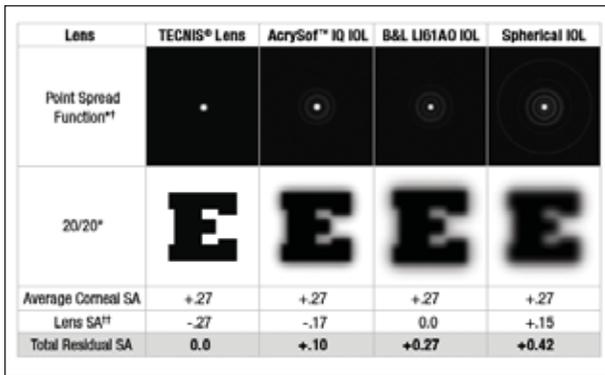


Figure 2. The TECNIS IOL’s aspheric optics counter corneal spherical aberration for improved visual function.

Because multifocal implants already divide light, what additional impact might light scatter have? There is concern that these imperfections will eventually lead to a demonstrable reduction of functional vision, most likely in terms of contrast sensitivity.

The scattering of light caused by a cataract does not allow the eye to see the edges between dark and light; it effectively removes contrast. Aspheric IOLs have grown exponentially in popularity over the last few years, because it was noted that the correction of spherical aberration improves contrast sensitivity and thus functional vision (Figure 2). I believe that the next frontier in improving visual contrast is removing chromatic aberration. The duochrome test used during refraction is a method of testing chromatic aberration. Increased chromatic aberration corresponds to greater differences of refractive index between the colors red on one end and violet on the other. As the distance between the two extremes enlarges before the eye reaches focus, the more contrast is diminished.⁹ ■

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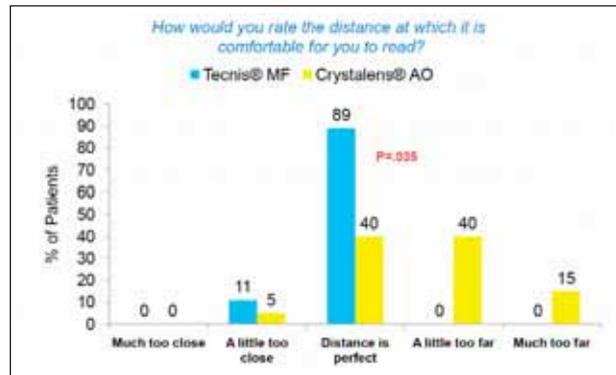


Figure 3. Patients’ comfort with their reading distance.¹

(Continued from page 9)

ease with reading small print in dim light (Figure 2). When we asked the subjects the distance at which reading was comfortable, 89% of the TECNIS Multifocal IOL subjects responded that they felt the distance at which they could read comfortably was perfect, versus 40% of those in the CRYSTALENS AO group ($P=.035$). Of the remaining Crystalens recipients, 55% felt that their reading distance was either a little or much too far (Figure 3).

Finally, we asked the patients how much their uncorrected vision fluctuated during activities. Although a similar percentage of patients in each group said that their vision fluctuated not at all or only some of the time during distance viewing, only 45% of the CRYSTALENS AO patients reported none or some fluctuation when using a computer, compared with 80% of individuals who received the TECNIS Multifocal IOL. Likewise, 89% of patients implanted with the TECNIS Multifocal IOL experienced none or some fluctuation when reading small print in dim light, versus 61% of the CRYSTALENS AO subjects.

CONCLUSIONS

These preliminary results show that the TECNIS Multifocal IOL provides statistically significantly better vision at near than the CRYSTALENS AO, although both lenses offer similarly excellent vision at distance and intermediate. Furthermore, the TECNIS Multifocal IOL seemed to provide greater visual flexibility for patients; a greater percentage of TECNIS patients reported more ease reading small print in dim light and reading at arms’ length. Follow-up for this study is ongoing. ■

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Using Purkinje Images to Improve IOL Centration

Recreating the angle of the light source and patient's gaze intraoperatively are the keys to making this method reproducible.

BY DANIEL H. CHANG, MD

IOL centration has been an underexplored area in cataract surgery, in large part because we surgeons have lacked a reproducible way to find the center of the pupil and match it to the center of the lens. However, the aspheric and diffractive optics embedded in some multifocal IOLs can be sensitive to decentration and therefore have made the correct positioning of these lenses important to successful outcomes.

THE SCIENCE OF DIFFRACTIVE OPTICS

Diffractive multifocal optics, such as those found in the TECNIS Multifocal IOL (Abbott Medical Optics Inc., Santa Ana, CA), allow patients the possibility of high-quality distance and near vision via higher-order optics that create two distinct focal points. The location of the focal points and the balance of light between them are determined by the spacing and height of the diffractive rings. The effective spacing and height of these rings is also a reason that the performance of multifocal diffractive IOLs can be affected by decentration and tilt. Patients see best with these lenses when the center of the optic is aligned with the center of the pupil, because an equal amount of light will hit the optic from all directions. When this happens, recipients of multifocal diffractive IOLs experience the optimal visual quality and the least visual side effects such as glare and halos. Theoretically, decentered diffractive optics can contribute to nighttime visual effects, and severe decentration can induce astigmatism or coma.

A NEW METHOD TO CENTER IOLS

How Purkinje Images Work

I have learned that it is possible to improve lens centration by using normally ignored reflections of the eye—Purkinje images. Named after the Czech anatomist of the same name, Purkinje images are reflections formed by the anterior and posterior surfaces of the cornea (Figure 1A) as well as the anterior and posterior surfaces of the lens (Figure 1B). These reflections depend on a variety of factors, including the curvature of the interface, the angle of the light entering the eye, and the relative reflectivity of the interface,

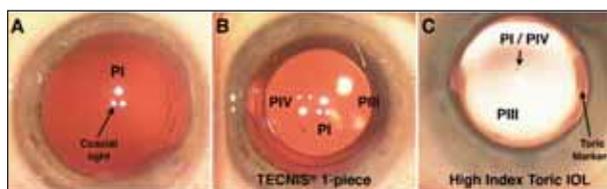


Figure 1. Purkinje images in aphakic (A) and pseudophakic (B, C) eyes. The bottom left light (of PI) is coaxial to the camera taking these photos. High refractive index materials, such as in this toric IOL, can create bright reflections that obscure the other Purkinje images (C).

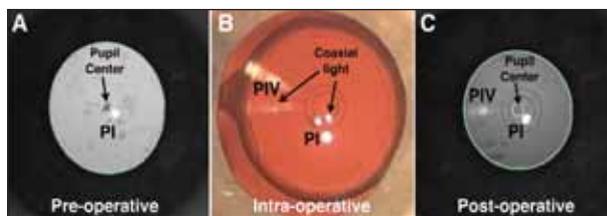


Figure 2. A preoperative image demonstrates the location of PI relative to the center of the undilated pupil (A). The same eye is shown intraoperatively (rotated 180° to match the orientation of the pre- and postoperative images) after implantation of a TECNIS 1-Piece Multifocal IOL. The patient was asked to fixate on the upper-right (coaxial) light (B). A postoperative image of the same eye shows a minimal IOL decentration of only 0.16 mm (C).

which is related to the index of refraction of the two materials. In Figure 1C, a toric IOL made from material with a high refractive index (such as the ACRYSOF Toric IOL [SN60TT; Alcon Laboratories, Inc., Fort Worth, TX], with a refractive index of 1.55) exhibits significant reflection from the anterior surface of the lens.

There are four distinct Purkinje images, three of which are typically seen intraoperatively (Figure 1). The first image (PI) is the reflection from the outer surface of the cornea. The second (PII) is the reflection from the inner surface of the cornea; PII can only be seen surgically with an air bubble in the anterior chamber. The third Purkinje image (PIII) is the

reflection from the anterior surface of the lens, and the fourth Purkinje image (PIV) is the reflection from the posterior surface of the lens. Unlike the others, PIV is an inverted image. Intraoperatively, if we can control how we illuminate the eye and the direction of the patient's gaze, then we can obtain a lot of information about a lens implant from these reflections.

While the concept of using the Purkinje reflections postoperatively to evaluate positioning of IOLs has been discussed previously,¹⁻³ this application requires specialized research equipment and has thus far been of limited clinical utility. However, a simple understanding of some basic concepts about Purkinje reflections is sufficient to allow surgeons to use this information intraoperatively to improve IOL positioning and centration.

CHALLENGES TO FINDING THE PUPILLARY CENTER

There are two challenges to finding the center of the pupil intraoperatively. First, it is difficult to triangulate the center of a pupil that is between 6 and 8 mm in diameter; it is much easier to find the center of a pupil that is between 2 and 3 mm in size. Second, the center of the pupil can change with dilation. As the pupil enlarges or shrinks, the center can shift up to almost 1 mm based on the anatomy of the eye.⁴ Thus, the center of the dilated pupil may not necessarily match the center of the undilated pupil.

The direction in which the patient is gazing during surgery can affect the location of the Purkinje image. I have found, however, that if I control the direction of the light source, I can closely identify the center of the pupil. By shining a light at an eye from a given orientation and looking at the reflection from a given position, the Purkinje image shows up reproducibly on the eye, regardless of the state of dilation.

REPRODUCIBLE APPROACH

In short, I capture a preoperative image of the undilated pupil using a coaxial light source, and then I recreate the same coaxial illumination and viewing intraoperatively and align the implant relative to that image. Figure 2 demonstrates this approach. I take a picture of the pupil preoperatively using the ATLAS topographer (Carl Zeiss Meditec Inc., Dublin, CA) with the camera and the light source located coaxially to the patient's fixation. I can mark the pupil center, and I can see the location of the Purkinje image relative to the pupil's center. In Figure 2A, I can see that the center of the pupil is slightly superior and temporal to the Purkinje image (PI) in this right eye. In the OR, I use the bright coaxial

light to illuminate and align the Purkinje image. I then displace the implant the same way off the Purkinje image. In this case, I center the TECNIS Multifocal IOL superiorly and temporally to the coaxial light, in alignment with the pupil's center as determined preoperatively while undilated.

The patient's line of sight must be aligned with the microscope's coaxial light. If the patient is able to fixate, the location of PI will be consistent with the preoperative photograph and can be used as a marker to locate the undilated pupillary center. If the patient does not voluntarily fixate, we can use the third and the fourth Purkinje images (PIII and PIV) to determine fixation once the IOL has unfolded inside the capsular bag.

OUTCOMES

Of course, there are other factors that influence final lens placement, such as how the implant sits in the bag. With this relatively simple technique, however, I have been able to improve my accuracy of centering the lens on the undilated pupil. In an initial case series of 22 eyes, I achieved an average decentration of just under 0.2 mm, with the greatest decentration being just over 0.4 mm. Previous studies have shown best average decentrations of 0.2 to 0.4 mm, with outliers up to 1.0 mm.¹⁻³

CONCLUSIONS

Overall, I have found that Purkinje images are quite helpful in finding the center of a dilated pupil, and they can be excellent markers. I am hopeful that this approach proves to be a viable, reproducible IOL placement technique that simplifies what has previously been an ambiguous art. Increasing the accuracy of IOL centration allows our patients to capitalize on the benefits of diffractive multifocal implants and simultaneously avoid potential visual side effects. ■

Parts of this article have been adapted from: Chang DH. Centering IOLs using Purkinje images. Cataract & Refractive Surgery Today. 2011;11(6):35-37.

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Important Safety Information – TECNIS® Monofocal IOL

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

Indications: TECNIS® 1-Piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

Warnings: Physicians considering lens implantation under any of the conditions described in the Directions for Use labeling should weigh the potential risk/benefit ratio prior to implanting a lens.

Precautions: Do not sterilize or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or over 45°C.

Adverse Events: The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece lens was macular edema, which occurred at a rate of 3.3%. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

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

Important Safety Information – TECNIS® Multifocal 1-Piece IOL

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

Indications: TECNIS® multifocal intraocular lenses are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag.

Warnings: Physicians considering lens implantation under any of the conditions described in the Directions for Use labeling should weigh the potential risk/benefit ratio prior to implanting a lens. Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Under low-contrast conditions, contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions. Patients with a predicted postoperative astigmatism > 1.0D may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence. Care should be taken to achieve centration, as lens decentration may result in patients experiencing visual disturbances, particularly in patients with large pupils under mesopic conditions.

Precautions: The central one millimeter area of the lens creates a far image focus, therefore patients with abnormally small pupils (~1mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however, because this multifocal design has not been tested in patients with abnormally small pupils, it is unclear whether such patients will derive any near vision benefit. Autorefractors may not provide optimal postoperative refraction of multifocal patients; manual refraction is strongly recommended. In contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Care should be taken when performing wavefront measurements as two different wavefronts are produced (one will be in focus (either far or near) and the other wavefront will be out of focus); therefore incorrect interpretation of the wavefront measurements is possible. The long-term effects of intraocular lens implantation have not been determined; therefore implant patients should be monitored postoperatively on a regular basis.

Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively. Do not sterilize or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or over 45°C. Emmetropia should be targeted as this lens is designed for optimum visual performance when emmetropia is achieved.

Adverse Events: The most frequently reported adverse event that occurred during the clinical trial of the TECNIS® Multifocal lens was surgical reintervention, which occurred at a rate of 3.7% (lens-related: 0.6%; non-lens related: 3.2%). Surgical reintervention included lens exchange, retinal repair, iris prolapse/wound repair, trabeculectomy, lens repositioning, and lens removal due to patient dissatisfaction. The second most frequent adverse event was macular edema, which occurred at a rate of 2.6%. Other reported reactions were hypopyon and endophthalmitis, each occurring at a rate of 0.3%.

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

Important Safety Information – UNFOLDER® Platinum 1 Series Implantation System

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

Indications: The UNFOLDER® Platinum 1 Series Implantation System is used to fold and assist in inserting TECNIS® 1-Piece intraocular lenses (IOL), ONLY into the capsular bag.

Warnings: The UNFOLDER® Platinum 1 Implantation System should only be used with TECNIS® 1-Piece IOLs. Do not use if the cartridge tip is cracked or split prior to implantation. Never release the plunger until the optic body has been completely released from the cartridge tube. The lens and cartridge should be discarded if the lens has been folded within the cartridge for more than 5 minutes. If the IOL is not properly placed in the cartridge, the IOL may be damaged and/or implanted upside down. The Model 1MTEC30 cartridge is intended for single use only. AMO single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient or the user. Do not attempt to modify or alter this device or any of the components, as this can significantly affect the function and/or structural integrity of the design. Use of methyl cellulose viscoelastics is not recommended as they have not been validated with this implantation system. Do not implant lens if rod tip becomes jammed in the cartridge.

Precautions: The use of viscoelastics is required when loading the IOL into the cartridge. For optimal performance use the AMO HEALON® family of viscoelastics. Do not use balanced salt solution. The combination of low operating room temperatures and high IOL diopter powers may require a slower delivery. Do not use if any component of this implantation system has been dropped or inadvertently struck while outside of the shipping case. Do not store the cartridges at temperatures under 5°C or over 30°C.

Contraindications: Do not use the handpiece if the rod tip appears nicked or damaged in any way.

Important Safety Information – WHITESTAR Signature® System

The WHITESTAR Signature® System is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery. Risk and complications may include broken ocular capsule or corneal burn. Please reference the WHITESTAR Signature® System Operator's Manual for more information on intended use, warnings and precautions.

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

Warnings and Cautions: All personnel who might operate this equipment must read and understand the instructions in the operator's manual before the system is used. Failure to do so might result in the improper operation of the system. This device is only to be used by a trained licensed physician. The fluid level in the balanced salt solution bottle must be monitored by the surgical nursing staff. The result of a low bottle or an empty bottle affects the fluid balance and the intra-ocular pressure (IOP) while aspirating. The low or empty bottle can result in the inadvertent chamber shallowing or collapse, the Aspiration of tissue, or an ultrasonic wound heating commonly called wound burn (extreme case). The surgical staff must monitor the fluid level at all times. DO NOT use the System in the presence of flammable anesthetics, or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as a fire could result. The unit might interfere with any cardiac pacemaker fitted to the patient; therefore qualified advice must be obtained prior to such use. The output power selected must be as low as possible for the intended purpose. Do not use the system near conductive materials such as metal bed parts, inner spring mattresses, or similar items. Replace electrode cables on evidence of deterioration. Not recommended for use in condensing environments. If exposed to a condensing environment, allow the system to equilibrate to typical operating room conditions prior to use. This high frequency surgical equipment is specified for use without a neutral electrode. Failure of the high frequency surgical equipment could result in an unintended increase of output power. Sterility assurance is the responsibility of the user. All non-sterile accessories must be sterilized prior to use. Prior to using any invasive portions of the hand-piece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. If any questionable characteristics are noted, use a backup handpiece for surgery. Use of contaminated or damaged system accessories can cause patient injury. Use of non-AMO approved products with the WHITESTAR Signature® System, can affect overall system performance and is not recommended. AMO cannot be responsible for system surgical performance if these products are utilized in surgery.

Contraindications and Adverse Events: Risks and complications may include broken ocular capsule or corneal burn. Please reference the WHITESTAR Signature® Operators Manual for more information on intended use, warnings and precautions. US Federal law restricts this device to sale, distribution and use by or on the order of a physician or other licensed eye care practitioner.

Important Safety Information – HEALON® Ophthalmic Viscoelastic Device (OVD)

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

Indications: The HEALON® OVD is indicated for use as a surgical aid in cataract extraction (intra- and extracapsular), IOL implantation, corneal transplant, glaucoma filtration and retinal attachment surgery. In surgical procedures in the anterior segment of the eye, instillation of the HEALON® OVD serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with less trauma to the corneal endothelium and other surrounding tissues. Furthermore, its viscoelasticity helps to push back the vitreous face and prevent formation of a postoperative flat chamber. In posterior segment surgery the HEALON® OVD serves as a surgical aid to gently separate, maneuver and hold tissues. The HEALON® OVD creates a clear field of vision thereby facilitating intra- and post-operative inspection of the retina and photocoagulation.

Precautions: Those normally associated with the surgical procedure being performed. Overfilling the anterior or posterior segment of the eye with the HEALON® OVD may cause increased intraocular pressure, glaucoma, or other ocular damage.

Postoperative intraocular pressure may also be elevated as a result of pre-existing glaucoma, compromised outflow and by operative procedures and sequelae thereto, including enzymatic zonolysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber. Since the exact role of these factors is difficult to predict in any individual case, the following precautions are recommended:

- Don't overfill the eye chambers with the HEALON® OVD (except in glaucoma surgery).
- In posterior segment procedures in aphakic diabetic patients special care should be exercised to avoid using large amounts of the HEALON® OVD.
- Remove some of the HEALON® OVD by irrigation and/or aspiration at the close of surgery (except in glaucoma surgery).
- Carefully monitor the intraocular pressure, especially during the immediate postoperative period. If significant rises are observed, treat with appropriate therapy.

Care should be taken to avoid trapping air bubbles behind the HEALON® OVD. Because the HEALON® OVD is a highly purified fraction extracted from avian tissues and is known to contain minute amounts of protein, the physician should be aware of potential risks of the type that can occur with the injection of any biological material. Because of reports of an occasional release of minute rubber particles, presumably formed when the diaphragm is punctured, the physician should be aware of this potential problem. Express a small amount of the HEALON® OVD from the syringe prior to use, and carefully examine the remainder as it is injected. Reprocessed cannulas should not be used. Sporadic reports have been received indicating that the HEALON® OVD may become cloudy or form a slight precipitate following instillation into the eye. The clinical significance of these reports, if any, is not known since the majority received to date do not indicate any harmful effects on ocular tissues. The physician should be aware of this phenomenon and, should it be observed, remove the cloudy or precipitated material by irrigation and/or aspiration. In vitro laboratory studies suggest that this phenomenon may be related to interactions with certain concomitantly administered ophthalmic medications. Use only if solution is clear.

Adverse Events: The HEALON® OVD is extremely well tolerated after injection into human eyes. A transient rise of intraocular pressure postoperatively has been reported in some cases. In posterior segment surgery intraocular pressure rises have been reported in some patients, especially in aphakic diabetics, after injection of large amounts of the HEALON® OVD. Rarely, postoperative inflammatory reactions (iritis, hypopyon) as well as incidents of corneal edema and corneal decompensation have been reported. Their relationship to the HEALON® OVD has not been established.

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

Important Safety Information – HEALONS® Ophthalmic Viscoelastic Device (OVD)

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

Indications: The HEALONS® OVD is intended for use in anterior segment ophthalmic surgical procedures of the human eye. The HEALONS® OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALONS® OVD can also be used to efficiently separate and control ocular tissues. The HEALONS® OVD is not designed to have any pharmacological effect.

Precautions: Precautions normally considered during ophthalmic surgical procedures should be taken. Special care should be taken to ensure complete removal of the HEALONS® OVD from the entire eye including behind the lens and the chamber angles. Complete removal of the HEALONS® OVD is important to avoid intraocular pressure peaks postoperatively. Due to the greater viscosity and higher concentration of sodium hyaluronate in the HEALONS® OVD, the rise in the postoperative intraocular pressure may be higher with the HEALONS® OVD than if the same volume of other sodium hyaluronate viscoelastic products, with lower zero shear viscosity, is left in the anterior segment of the eye. Before initiating phacemulsification, use irrigation/aspiration to create a fluid-filled space above the lens. This reduces the risk of initial visco-occlusion of the phaco tip or the irrigation line which could cause phaco tip heating. Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure and complications in surgical procedures may also lead to increased intraocular pressure; consequently, extra care should be taken in patients with these conditions. Prophylactic pressure-lowering treatment should always be considered and especially in cases where the HEALONS® OVD has to be left in the eye for clinical reasons.

Adverse Events: Increased intraocular pressure has been reported after use of sodium hyaluronate solutions. Increased intraocular pressure is likely to occur if the HEALONS® OVD is not removed as completely as possible. Clinical judgment concerning the use of this product should be considered in cases where thorough removal may not be possible. The precautions noted above should be taken to manage any increased postoperative intraocular pressure and to reduce the likelihood of occurrence of related postoperative complications such as optic neuropathy, pupillary atonia and dilation, and iris atrophy. Rarely, postoperative inflammatory reactions (iritis, hypopyon, endophthalmitis) following the use of sodium hyaluronate, as well as incidents of corneal edema and corneal decompensation, have been reported. Their relationship to sodium hyaluronate has not been established.

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

Important Safety Information – HEALON GV® Ophthalmic Viscoelastic Device (OVD)

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

Indications: The HEALON GV® OVD is indicated for use in anterior segment ophthalmic surgical procedures. The HEALON GV® OVD creates and maintains a deep anterior chamber, to facilitate manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALON GV® OVD also can be used to efficiently maneuver, separate and control ocular tissues.

Precautions: Precautions normally considered during ophthalmic surgical procedures should be taken. Postoperative intraocular pressure may be increased if the HEALON GV® OVD is left in the eye. Due to the greater viscosity of the HEALON GV® OVD, this increase in postoperative IOP may be higher than that caused by leaving the same amount of other sodium hyaluronate viscoelastic products, with lower zero shear viscosity, in the anterior chamber. Since rises in postoperative intraocular pressure, including cases of significant elevation and subsequent complications, have been reported, the following precautions are strongly recommended:

- Special care should be taken to ensure as complete removal as possible by continuing to irrigate/aspirate after you see displacement of the initial bolus of viscoelastic from the eye, continued irrigation/aspiration should facilitate removal of viscoelastic which may remain in the anterior segment.
- Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure and complications in surgical procedures also may lead to increased intraocular pressure, consequently, extra care should be taken in patients with these conditions.
- Carefully monitor intraocular pressure, particularly during the early postoperative period.
- Treat with appropriate intraocular pressure lowering therapy, if required.

The HEALON GV® OVD is a highly purified fraction extracted from avian tissues which may contain minute amounts of protein. The potential risks associated with the injection of biological material should be considered. Express a small amount of the HEALON GV® OVD from the syringe prior to use and carefully examine it during use to avoid injecting minute rubber particles which may be released when the syringe diaphragm is punctured. Sodium hyaluronate solution may appear cloudy or form precipitates when it is injected. Based on in vitro laboratory studies, this phenomenon may be related to interactions with concomitantly used ophthalmic medications or detergents which remain in reused cannulas. Reprocessed cannulas should not be used.

Adverse Events: Increased intraocular pressure has been reported after use of the HEALON GV® OVD. Increased intraocular pressure is likely to occur if the HEALON GV® OVD is not removed as completely as possible. Clinical judgment concerning the use of this product should be considered in cases where thorough removal may not be possible. The precautions noted above should be taken to manage any increased postoperative intraocular pressure and to reduce the likelihood of occurrence of related postoperative complications such as optic neuropathy, pupillary atonia and dilation, and iris atrophy. Rarely, postoperative inflammatory reactions (iritis, hypopyon, endophthalmitis) following the use of sodium hyaluronate, as well as incidents of corneal edema and corneal decompensation, have been reported. Their relationship to sodium hyaluronate has not been established.

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