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Cataract & Refractive Surgery TODAY EUROPE

The Future of Cataract Surgery

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Focusing on the Patient

Laser cataract surgery with Bausch + Lomb's new femtosecond laser produces superior results to standard cataract surgery.

BY PAVEL STODULKA, MD

The history of cataract surgery extends more than 2,000 years, but it wasn't until the mid 1700s that any significant changes were made to the technique of cataract extraction. Physicians began using intracapsular cataract extraction around 1753, a technique that has since been superseded by extracapsular cataract extraction and now phacoemulsification. If we take a closer look at the recent history of cataract surgery, however, more has changed in the past 50 years than it has in the entire existence of this procedure. Perhaps one of the most extreme changes, one that we are all currently witnessing together, is the advent of laser cataract surgery.

Now is an exciting time to be practicing cataract surgery, as the number of innovations in this field is steadily increasing. For instance, we can perform phacoemulsification and implant a premium IOL through a sub–2-mm incision, decreasing the amount of surgically induced astigmatism we leave on the eye and offering patients a customized solution for their visual needs with a variety of IOLs. We can also combine anterior and posterior surgery when necessary, eliminating the need for the patient to return to the operating room for a subsequent procedure. And, what I am most enthusiastic about, we now have access to a femtosecond laser platform that is capable of performing cataract, refractive, and therapeutic procedures.

ANOTHER STEP FORWARD

I strongly believe that the future of cataract surgery should keep the patient as the central focus of our efforts. A patient-centric approach includes utilizing the latest technology to provide the best possible outcomes. That is why the femtosecond laser for cataract surgery is another step forward in ophthalmology, as it provides greater precision compared with manual cataract surgery techniques.

Technologies such as the Victus Femtosecond Laser Platform (Bausch + Lomb) can be used to not only create a more precise, controllable, and centered capsulotomy, but they may also reduce phaco energy and decrease the time of manual intraocular surgery, improve IOL placement, and enhance patient outcomes.[1-3] The future of cataract surgery is in precision and customization. This can best be achieved by using the femtosecond laser to complete three basic steps in cataract surgery: incisions (including corneal relaxing incisions), capsulotomy, and lens fragmentation (Figure 1). Laser-assisted cataract surgery might make the learning curve shorter for new cataract surgeon.

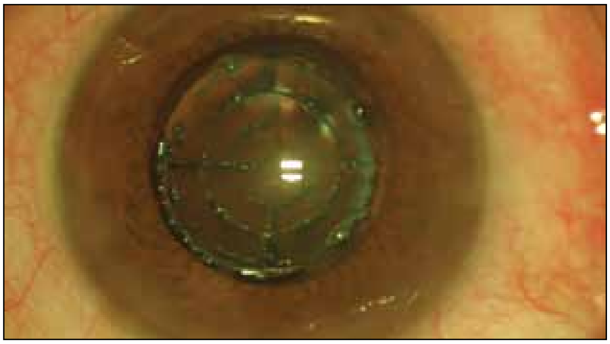

Figure 1. A circular cross pattern is used to fragment the lens using the Victus femtosecond laser.

What is unique about the Victus platform compared with other femtosecond lasers on the market is that it is capable of multiple functions. Therefore, in addition to its cataract surgery functions, the Victus can also be used to create a LASIK flap and to perform astigmatic keratotomy (Figure 2) as well as Intracor. We use the combination of laser corneal relaxing incisions with laser capsulotomy and lens fragmentation quite often. This laser received the Conformité Europeénne (CE) Mark in November 2011.

MICS

Microincision cataract surgery (MICS) is also an important step forward in our ability to offer patients optimal care. I like this technique because it decreases the incidence of surgically induced astigmatism, and my patients like this technique because visual recovery is quick. With that said, we must remember that MICS procedures are only successful when sophisticated tools and technologies are used efficiently during surgery. For instance, the Stellaris (Bausch + Lomb), with highly balanced fluidics as well as its dual-linear wireless footpedal, enables extremely fast and effective MICS surgery. Dr. Devgan provides an overview of the use of the Stellaris Vision Enhancement System for cataract surgery on page 7.

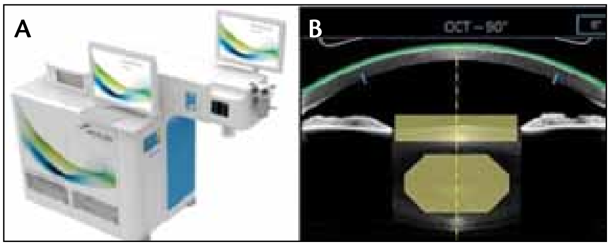

Figure 2. (A) The Victus femtosecond laser. (B) Astigmatic keratotomy, as performed with the Victus.

Figure 3. Bausch + Lomb has a complete range of single-use instruments, such as the bimanual I/A system and phaco tip shown here.

Additionally, an easy transition from anterior to posterior procedures is important in some cases. I have frequently used the Stellaris to perform combined vitreoretinal cataract surgery. The advantage of this platform is that only one pack and interface is needed to perform high-speed transconjunctival sutureless vitrectomy followed by 1.8-mm MICS. It is a minimally invasive, sutureless procedure that can be performed under intraocular anesthesia and as an outpatient procedure. Dr. Bashshur provides an overview of the use of the Stellaris PC for retinal surgery on page 10.

With a fast visual rehabilitation time, combined vitreoretinal cataract surgery is again beneficial to both the surgeon and the patient. Combined vitreoretinal cataract surgery increases patient comfort and safety and efficacy of medical care. I project that there will be an increased use of this combined procedure across Europe as well as worldwide.

OTHER FACTORS

Keeping the patient in focus also requires the use of high-quality IOLs and state-of-the-art surgical instruments. For starters, in most cases there is no need to increase incision size above 2 mm, as many of today's IOL cartridges are designed for MICS. A wound-assisted IOL injection under irrigation is a common practice today, but I would like to heed warning that pushing an IOL through a really tight incision can still be dangerous and counterproductive. I prefer a slightly larger but proper wound over a smaller incision that is torn wider by excessive pressure during implantation. When in doubt, do not be afraid to increase the incision size slightly.

There are also a lot of exciting things going on with IOL designs. Appropriate lenses have a square edge, minimize the incidence of halos and glare, and provide patients with excellent clarity and visual acuity at near, intermediate, and far distances. There are many options to choose from today, but one of the most promising new monofocal lenses is the enVista (Bausch + Lomb). Drs. Spalton and Tetz discuss their experiences with this lens starting on pages 12 and 14.

Lastly, with increasing evidence showing that single-use instruments are safer for our patients, I believe that we will continue to see an increase in their use. We already have several helpful disposable instruments, including phaco tips (Figure 3) and sleeves, and undoubtedly we should see others—maybe a disposable phaco probe—in the near future.

KEEP THE PATIENT IN FOCUS

The bottom line is that, regardless of the innovations we are lucky enough to currentlyhave for cataract surgery, we must always remember to keep the patient in focus. Implementing the use of laser cataract surgery, performing MICS, and implanting innovative IOL designs are only a tip of the iceberg for what is required to keep our patients happy. However, these tools will only help us to succeed in paying attention to every aspect of surgery and meeting the individual visual requirements of every patient and safety of our surgery. ■

Pavel Stodulka, MD, is with the Gemini Eye Centre, Zlin, Czech Republic. Dr. Stodulka states that he is a speaker for and consultant to Bausch + Lomb. He may be reached at e-mail: Stodulka@lasik.cz.

1. Nagy Z. Comparative analysis of femtolaser-assisted and manual capsulorhexis during phacoemulsification. Presented at: the XXVIII Congress of the European Society of Cataract and Refractive Surgeons; September 5, 2010; Paris.
2. Koch D. The use of OCT-guided femtosecond laser to facilitate cataract nuclear disassembly and aspiration. Presented at: the XXVIII Congress of the European Society of Cataract and Refractive Surgeons; September 5, 2010; Paris.
3. Batlle J. Prospective randomized study of size and shape accuracy of OptiMedica femtosecond laser capsulotomy vs. manual capsulorhexis. Presented at: the XXVIII Congress of the European Society of Cataract and Refractive Surgeons; September 5, 2010; Paris.

The Ideal Anterior Segment Workstation

The versatility of the Victus provides surgeons with a single platform that can be used to perform cataract, refractive, and therapeutic procedures.

BY SHERAZ M. DAYA, MD, FACP, FACS, FRCS(Ed), FRCOphth

The concept of laser cataract surgery is no longer new, as many surgeons worldwide have now had the opportunity to not only garner early experiences but to also purchase these laser systems for their own practices. What is new, however, is the idea of using a single femtosecond laser platform for cataract, refractive, and therapeutic procedures. With the Victus Femtosecond Laser Platform (Bausch + Lomb), surgeons now have that option.

I recently traveled to Hyderabad, India, to gain firsthand experience with this laser before having one installed in my own practice. Following the direction of Kasu Prasad Reddy, MD, who has the most widespread experience with the Victus with more than 500 laser cataract surgery procedures to date, I successfully created perfect capsulotomies as well as nuclear fracture. Not only was I instantly impressed with the surgical outcomes this technology affords as well as the streamlined cataract surgery process, but I was also intrigued that this one laser is capable of refractive surgery procedures, namely LASIK and Intracor, and therapeutic procedures such as corneal transplantation and tunnels for intrastromal corneal ring segment placement.

Not only does the Victus have a curved patient interface, and an optical coherence tomography (OCT) device that is used to map the dimensions of the anterior segment, but the interface has intelligent pressure sensors. These are designed to reduce the pressure placed on the cornea for strainless contact and avoidance of corneal deformity, which can affect the accuracy of the OCT (Figure 1).

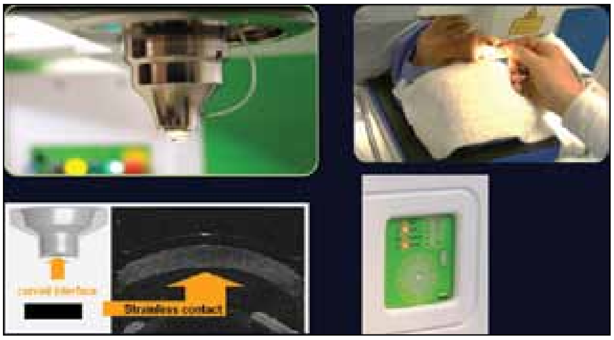

Figure 1. The Victus has a curved patient interface with intelligent pressure sensors, which are designed to reduce pressure on the cornea.

CATARACT APPLICATIONS

The reason I traveled to Hyderabad was to perform my first laser cataract surgery procedures. The Victus is capable of forming the capsulotomy, which I found to be the biggest thrill in using the laser; it can efficiently fracture the nucleus using a variety of cuts including radial, ring, and quadrant cuts (Figure 2); and it can also be used to create two- and three-step geometric incisions as well as corneal incisions.

My first case with the Victus was a grade 4+ cataract. By the time I had injected the ophthalmic viscosurgical device (OVD), I realized just how easy the capsule would come off. As soon as I removed the capsulorrhexis from the eye (Figure 3), I unraveled it, leaving an almost-perfect circle. I then continued to fragment the lens using the laser. Dr. Reddy developed the quadrant cut to aid in fracturing a hard lens, such as the one I had in this case. This cut fragments a single quadrant that can be removed to ease subsequent phaco chop maneuvers. However, I chose not to use the quadrant cut and instead chose a combination of rings and radial cuts to really get a feel for what this laser could do. I was fascinated to see that the Victus was capable of dismantling and fragmenting the lens in such a hard cataract.

During my initial cases, I realized that having a nucleus break into many pieces is not advisable, because sharp fragments can hit and damage the endothelium and potentially puncture the capsule posteriorly. Instead, it is best in a hard lens to confine lens dismantling to a few segments rather than trying to break it up into little pieces.

CLINICAL STUDIES

I have not used the Victus on enough eyes to warrant clinical study at this point; however, there is a lot of great work done by Dr. Reddy as well as Gerd U. Auffarth, MD, PhD. In a single-center, multisurgeon study, Dr. Reddy's team determined the precision of the capsulotomy in terms of diameter (intended vs actual), circularity, and centration. A total of 31 eyes were treated with femtosecond capsulotomy, and 31 were treated with manual capsulotomy (n=31). Figure 4 shows the overall precision of the capsulotomy in both groups.

With an intended diameter of 5.5 mm, the Victus only devi-

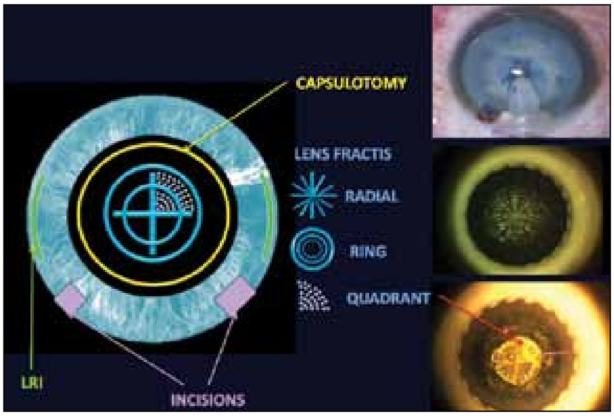

Figure 2. Cataract applications with the Victus include capsulotomy; LRIs and other incisions; and lens fragmentation with radial, ring, or quadrant cuts.

ated by 0.12 mm, indicating excellent accuracy and predictability of rhexis diameter with the femtosecond laser. Comparing circularity among the femtosecond and manual capsulotomies, where 1.0 is equivalent to a perfect circle, the Victus achieved 0.97 ±0.01 compared with 0.93 ±0.04 in the manual group (P<.001). Additionally, the deviation from perfect centration was less in the Victus group than it was in the manual group (95 ±37 µm vs 160 ±90 µm; P<.001).

In a separate study, Dr. Reddy and his colleagues studied lens fragmentation and effective phaco time. A total of 64 and 67 eyes with grades 1 to 5 cataracts underwent femtosecond-assisted lens fragmentation or a manual technique, respectively. What they found was that the Victus laser was good at cutting the lens, even hard lenses, and that all cataract grades showed a reduction of effective phaco time. This was most noticeable in lower grades of cataract, which is likely associated with the need to phaco large quadrants as compared to smaller quadrants in soft cataracts.

Professor Auffarth also performed his own study, determining the strength of a capsulorrhexis created with the femtosecond laser as well as with a manual technique. In a nutshell, Professor Auffarth demonstrated that more force was required to stretch the laser-created capsulorrhexis (113 ±12 mN vs 73 ±22 mN; P<.05).

OTHER APPLICATIONS

Arcuate incisions can be performed at the time of cataract surgery with the Victus, one of the advantages being that the incisions are created using OCT image guidance. Traditionally incisions are made penetrating the epithelial surface, but they can also be created intrastromally, very much like Intracor. While these might not be as effective, they are likely to be more biomechanically stable long term.

In addition to cataract surgery, the Victus can also be used for refractive surgery. Figure 5 depicts three refractive applications for the Victus: Intracor, astigmatic keratotomy and corneal incisions, and the LASIK flap.

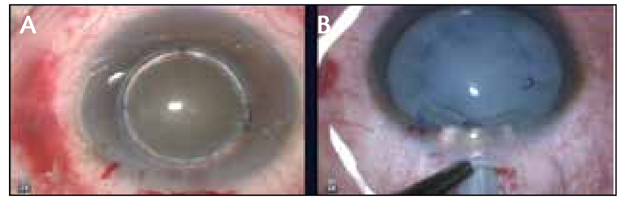

Figure 3. (A) The capsulorrhexis is created and then (B) removed from the eye.

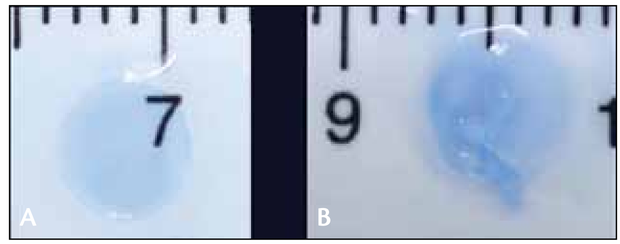

Figure 4. Overall precision of capsulorrhexis with the (A) Victus as compared with a (B) manual technique.

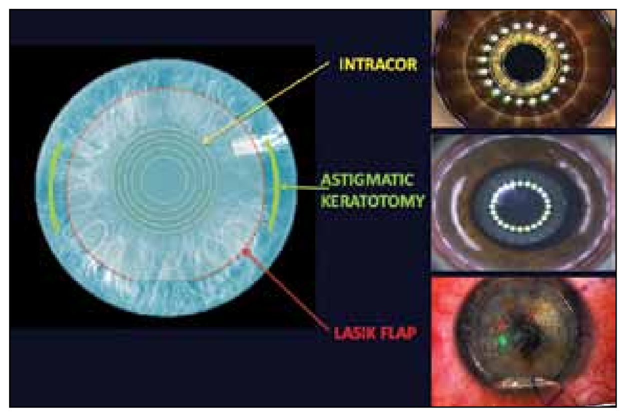

Figure 5. Refractive applications with the Victus include Intracor, astigmatic keratotomy, and LASIK flap creation.

CONCLUSION

To summarize, the Victus laser has many options for the anterior segment surgeon who does refractive surgery, cataract surgery, and corneal transplants. It is the ideal anterior segment workstation, as there is a considerable advantage to having one laser that does multiple things.

For cataract surgery, the Victus produces easy, reliable, and safe outcomes and enhances the surgical steps for capsulotomy and lens fragmentation. Compared with manual capsulotomy, the Victus offers surgeons the possibility for higher predictability of the rhexis diameter, of the circularity of the rhexis, and of the rhexis centration. This technology also reduces effective phaco time and is able to fragment even the hardest of cataracts. ■

Sheraz M. Daya, MD, FACP, FACS, FRCS(Ed), FRCOphth, is Director and Consultant of Centre for Sight, East Grinstead, United Kingdom. Dr. Daya states that he is a consultant to Bausch + Lomb and Technolas Perfect Vision GmbH. He may be reached at e-mail: sdaya@centreforsight.com.

The Future of Cataract Surgery is Now

Using today's new technologies in the operating room is more precise, less invasive, and produces better visual outcomes.

BY UDAY DEVGAN, MD, FACS, FRCS

As surgeons, we are always looking forward. We keep our eyes on technology and innovation and strive to produce the best postoperative results for our patients. Sometimes, however, if we look too far ahead, we can miss the exceptional technology that we currently have at our fingertips. I believe that the future of cataract surgery is now, as several technologies have allowed me to implement more precise, less invasive cataract surgery with optimal visual results.

Ever since Charles D. Kelman, MD, introduced the concept of phacoemulsification in 1967, surgeons have continued to perfect the technique, producing more precise outcomes using the latest phacoemulsification systems and devices. Flash forward to 2012, where there are three distinct technologies that continue to help us improve surgical outcomes: femtosecond lasers for cataract surgery, phacoemulsification systems capable of microincision cataract surgery (MICS), and high-quality IOLs and instruments.

LASER CATARACT SURGERY: MORE PRECISE

It is apparent that we are on the brink of widespread use of laser cataract surgery. Clinical experience was limited to a handful of surgeons initially, but today the technology is becoming available in more practices. Starting in 2011, I began to implement and integrate laser cataract surgery in my own practice. The Victus femtosecond laser platform (Bausch + Lomb) is the first combination laser capable of both cataract and refractive applications; it received the Conformité Européene (CE) Mark in November 2011. Additionally, the Victus is approved for capsulotomy, lens fragmentation, astigmatic keratotomy, LASIK flap creation, and is also used to perform Intracor procedures.

Capsulotomy. Compared with a manual capsulorrhexis, laser capsulotomy with the Victus produces a precisely circular and well-centered rhexis.

Lens fragmentation. On one hand, phacoemulsification is a proven and safe technique for fragmenting the nucleus. However, on the other, laser lens fragmentation

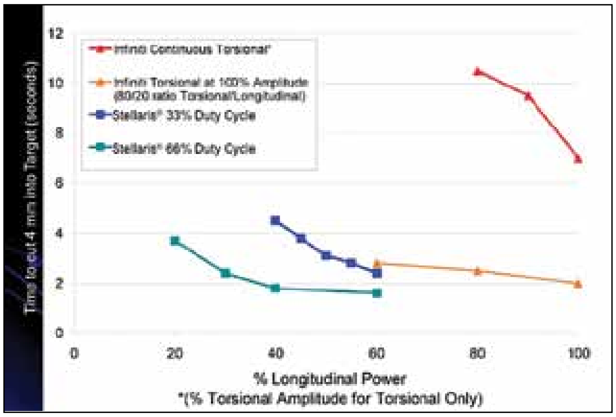

Figure 1. Comparison of cutting time with the Stellaris at 33% and 66% duty cycles and the Infiniti (Alcon Laboratories, Inc.) with continuous torsional and an 80/20 ratio of torsional and longitudinal.

has the capacity to reduce effective phaco time, regardless of the cataract grade.

Cataract aspiration. Using a standard cataract surgery approach, phacoemulsification is followed by aspiration of the nucleus. During laser cataract surgery, however, laser fragmentation can be performed prior to phacoemulsification to further reduce effective phaco time during subsequent fragmentation.

IOL implantation. Just as with any cataract procedure, the IOL is implanted via a (micro)incision. The advantage of using a femtosecond laser is that the precisely shaped and centered capsulotomy will provide the basis for consistent IOL placement in the capsular bag.

MICS: LESS INVASIVE SURGICAL TECHNIQUE

Although MICS may not seem as exciting as laser cataract surgery, it is equally as important to producing quality results after cataract surgery. I have been using the Stellaris Vision Enhancement System (Bausch + Lomb) so that I can safely and efficiently perform sub–2-mm incision cataract surgery. This system, which is capable of working with incisions as small as 1.8 mm, can per-

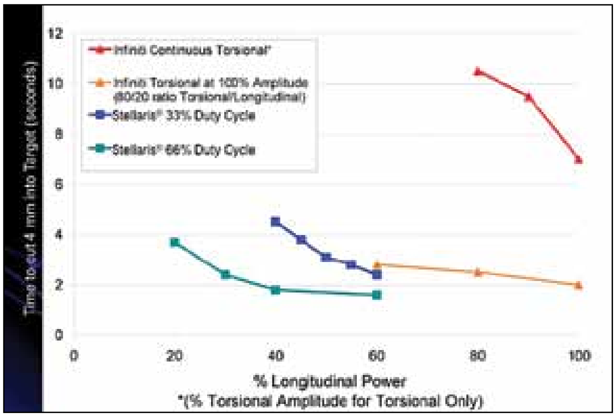

Figure 2. Comparison of thermal rise time with Stellaris longitudinal phaco and Infiniti torsional ultrasound.

form in flow mode, like a peristaltic pump, or in vacuum mode, like a venturi pump. I can also modify any aspect of phacoemulsification power delivery with the Stellaris to support my specific technique or use pre-set options with optimized settings for most phaco techniques. The result is efficient and safe phacoemulsification with minimal surge.

I recently participated in a field study along with 45 other investigators from across Europe, North America, and Asia to assess the performance of the Stellaris Vision Enhancement system. Nearly 1,500 cases were included, of which 385 were performed with a standard coaxial phacoemulsification technique, 811 with a coaxial MICS technique, and 284 with a bimanual MICS technique. Surgeons indicated that the Stellaris' fluidics performance was good to excellent with flow and vacuum modules, that phaco power efficiency was as good or better for MICS procedures compared with small-incision cataract surgery, and that ease of use improved from their previous system. A comparison of cutting time and thermal rise can be found in Figures 1 and 2.

The Stellaris platform includes several advances in phacoemulsification technology, including StableChamber Fluidics to minimize surge, decrease fluid flow-through, and stabilize the anterior chamber. StableChamber Fluidics is designed for safe, efficient, and predictable flow or vacuum modes to enhance chamber stability throughout the procedure. Using the StableChamber feature, I can balance fluidics to support coaxial MICS, and I can choose between two modules, the Advanced Flow Module (AFM) and the Vacuum Fluidics Module (VFM). The AFM allows me to toggle intraoperatively between flow and vacuum modes, and the latest-generation VFM delivers exceptional accuracy and efficiency (Figure 3).

Another advantage of the Stellaris is its sleek ultrasound tip design, corresponding with reductions in incision size. I have had to make no change to my technique to transition to MICS with the Stellaris. Additionally, the

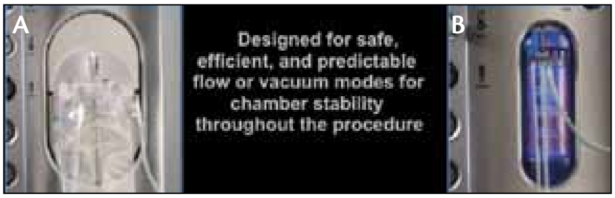

Figure 3. The Stellaris has customizable StableChamber Fluidics. (A) Advanced Flow Module allows surgeons to toggle intraoperatively between flow and vacuum modes. (B) Vacuum Fluidics Module is the latest-generation vacuum fluidics system; it delivers exceptional accuracy and efficiency.

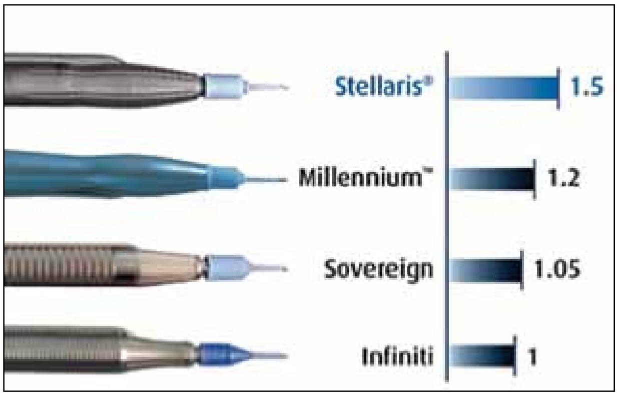

Figure 4. The Stellaris handpiece has an increased stroke length compared with the Millenium (Bausch + Lomb), Sovereign (Abbott Medical Optics Inc.), and Infiniti handpieces.

increased stroke length of the phaco tip (Figure 4) optimizes mechanical cutting. This handpiece uses a frequency of 28 kHz to maximize cavitation, producing tight, focused, and consistent stroke delivery. Additionally, the Stellaris reduces energy exposure, translating into maximized efficiency of cavitation and mechanical energy and minimizing energy loss to thermal or streaming effects.

Another feature of the Stellaris is its Attune Energy Management System, which can be used to customize ultrasound delivery with dual-linear control of aspiration and ultrasound, enabling efficient cataract removal with minimal energy. Attune has a programmable advanced waveform modulation that includes variable waveform duration and depth.

BETTER OUTCOMES: IOLs AND INSTRUMENTATION

I cannot forget to mention the importance of high-quality IOLs and instruments in boosting cataract surgery results. In addition to a wide range of single-use instruments already available, Bausch + Lomb now has an extensive line of single-use instruments that are compatible with MICS, including forceps and knives.

Another MICS-capable, single-use instrument is the CapsuleGuard I/A Handpiece (Bausch + Lomb; Figure 5). Its smooth and soft design promotes ease of use, and its

Figure 5. The CapsuleGuard I/A Handpiece is safe and gentle in the eye.

silicone-coated tip, as compared with metal tips, better facilitates capsular cleaning. The tip of the CapsuleGuard I/A Handpiece has adhesive properties, which facilitate cortex removal and positioning of the IOL in the capsular bag. It is safe and gentle in the eye.

Lastly, the Akreos MI60 IOL (Bausch + Lomb; Figure 6) is extremely stable in the eye, thanks to a new haptic design that uses four angulated haptics (10°) to provide four zones of support. This acrylic lens resists tearing and is suitable for injection through a sub–2-mm incision. Its continuous 360° barrier and haptics design help to prevent posterior capsular opacification. Another IOL from Bausch + Lomb, the enVista, is also designed to help prevent PCO. To learn more about this lens, read Dr. Spalton's article on page 12 and Dr. Tetz's article on page 14.

CONCLUSION

Femtosecond lasers have already begun to enhance our cataract surgery results, and as we gain more experience with this technology our techniques will continue to evolve. When used in conjunction with current phacoemulsification technology, such as the Stellaris Vision Enhancement System, and state-of-the-art instruments and IOL designs, including the Akreos and enVista, we can further improve surgical accuracy for our patients and provide better visual outcomes than ever before. ■

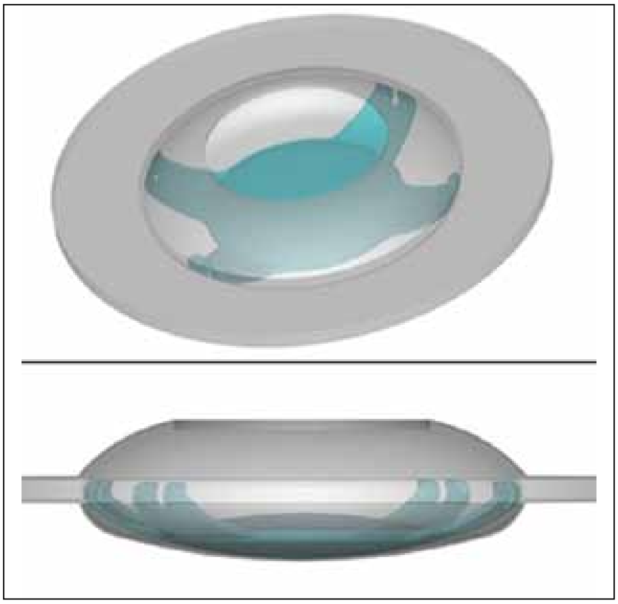

Figure 6. The Akreos' new haptic design ensures that the IOL is extremely stable in the eye.

Uday Devgan, MD, is in private practice in Los Angeles and Beverly Hills, California. He is also the Chief of Ophthalmology at Olive View UCLA Medical Center and an Associate Clinical Professor at the UCLA School of Medicine. Dr. Devgan states that he is a consultant to and speaker for Bausch + Lomb. Dr. Devgan may be reached at tel: +1 310 696 0330; e-mail: devgan@gmail.com; Web: www.DevganEye.com.

Achieving Optimal Outcomes in Combined Surgery

Surgeons can seamlessly transition between cataract and retinal surgery with the Stellaris PC.

BY ZIAD BASHSHUR, MD

A large consideration for surgeons who perform combined cataract and retinal surgery is how easy the transition between procedures is. With the Stellaris PC (Bausch + Lomb), transitioning from cataract to retinal surgery is seamless, and there is no need to change screens between procedures.

WHY USE A COMBINED PROCEDURE?

The advantages of a combined procedure are plentiful. For starters, patient satisfaction improves, mainly because there are fewer visits to the operating room and quicker visual rehabilitation, and health care costs are reduced.[1] Additionally, removing the crystalline lens before vitrectomy enables vitreous support for lens extraction, a clear view of the retina, full access to the vitreous base without risk of damaging the lens, and more effective gas tamponade.

Some surgeons would argue that, with a longer operating time than a traditional anterior or posterior procedure, this combined surgical technique runs the risk of an increased risk of complications including anterior chamber fluctuation during vitrectomy, a higher incidence of postoperative inflammation, biometric surprises, and IOL subluxation.[2] Although I have noticed that set-up is more complex for a combined procedure compared with vitrectomy alone, I believe that the extra time is justified, as the vitrectomy and cataract platforms of the Stellaris PC are stable and provide me with the option to use a sutureless technique. Additionally, I have noticed significant improvements in both anterior and posterior procedures, thanks to separate infusion lines for phaco and vitrectomy.

Another reason that I prefer to use a combination anterior/posterior approach to surgery is because it eliminates the risk of cataract formation or progression after pars plana vitrectomy, especially in patients over the age of 50 years. In this population, the risk of cataract formation after vitrectomy is sixfold that for patients under the age of 50 years.[3] In fact, approximately 80% of patients who are 50 years or older will develop a cataract within the first 2 years after vitrectomy.[4] Additionally, the use of intraocular gas tamponade during vitrectomy causes the risk for nuclear sclerosis to increase by 60%,[3] and there are a higher rate of surgical challenges and risks of intra- and postoperative complications, as well as retinal detachment, in previously vitrectomized eyes due to structural changes.[5] By performing vitrectomy directly after cataract surgery, these risks decrease or are eliminated altogether.

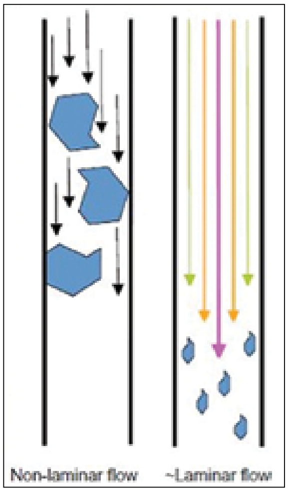

Figure 1. High cut rates produce smaller vitreous bites. With laminar flow, there is near-zero velocity at the wall, increasing to max at the center of the flow.

CATARACT SURGERY

As a vitreoretinal surgeon, I prefer to implant a premium IOL, as high-quality IOLs tend to create a better window to the back of the eye. In every case, the selected IOL should minimize the risk for posterior capsular opacification and glistenings, and it should also produce low silicone oil adhesion of the lens. A number of newer IOLs offer excellent optical clarity, and my preference is for the Akreos AO MICS IOL (Bausch + Lomb). Due to the smaller cataract incision and excellent stability of the IOL, it is possible to perform aggressive maneuvers during vitrectomy, such as scleral indentation, without fear of anterior chamber shallowing or lens decentration.

For an overview of how the Stellaris PC can be used for cataract surgery, see Dr. Devgan's article on page 7.

RETINAL SURGERY

One of the biggest advantages of the Stellaris PC for posterior surgery is its high cut rate. At 5,000 cuts per minute, the system reduces the size of the vitreous bites so that they behave more like a low-viscosity

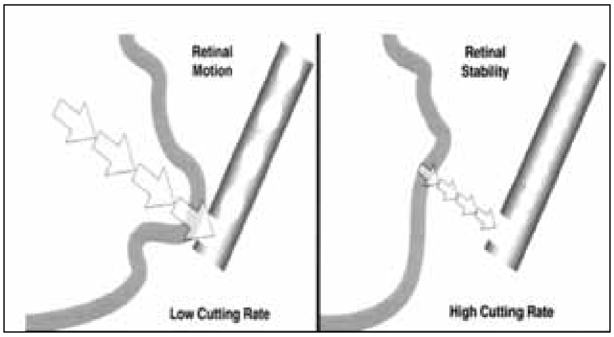

Figure 2. Greater stability in the posterior chamber results from the reduction of turbulance and a smaller change in volume per time period.

Figure 3. Three surgeon-controlled filters provide optimized visualization and additional safety and differentiated viewing.

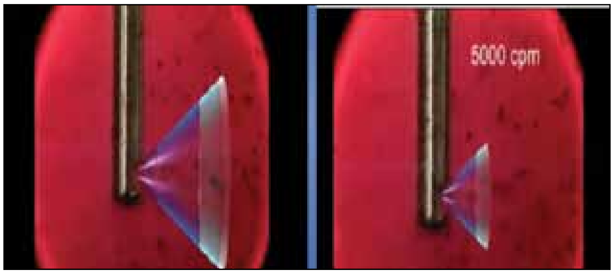

Figure 4. The cone of influence is smaller when 25-gauge vitrectomy is used.

fluid to enhance efficiency and laminar flow (Figure 1). Higher cut rates also result in reduced traction and better fluidics[6,7] due to the low viscosity-like fluid. In turn, stable fluidics optimizes preset port open time, allowing me to focus on the patient, not the equipment. It also allows me to use the wireless, dual-linear footpedal like an accelerator to control vacuum and manage flow. Another advantage of a high cut rate is that turbulance is further reduced, as the smaller vitreous bites can be removed with each cut, producing smaller changes in volume per time period. This results in greater posterior chamber stability (Figure 2).

The Stellaris PC also boasts enhanced visualization, including three surgeon-controlled filters for additional safety and differentiated viewing (Figure 3), dual independent lamps featuring the choice between the broad-spectrum white light of a xenon or the efficient luminosity of a mercury vapor, and chandelier lights for bimanual surgery. This advanced illumination system is extremely important with wide-field viewing, and it allows me to complete more precise removal of the peripheral vitreous.

I also like that the Stellaris PC platform provides the flexibility for me to use 20-, 23-, or 25-gauge instrumentation. My preference is for 25-gauge surgery, because the stiffer shaft allows excellent eye movement and I can easily rotate it up to the anterior chamber. Additionally, it has the feel of 23-gauge surgery but with a smaller incision size, and it provides better control of fluidics with its ultra-high cut rates, reduction of wound leakage, smaller probe, and reduced sphere of influence (Figure 4).

Compared with 20-gauge surgery, the advantages of 25-gauge, as well as 23-gauge, surgery include a reduction of surgically induced astigmatism, contributing to faster visual recovery and a faster surgical technique due to the reduction of time to open and close.[7] Additionally, 25-gauge cutters can be used as a pick, forceps, aspirating/backflush cannula, and scissors. There is, however, a learning curve associated with the use of 25-gauge instrumentation.

CONCLUSION

Performing a combination anterior and posterior surgical procedure is not for every surgeon; however, for those who do use this technique, I recommend the Stellaris PC. This versatile cataract and vitrectomy platform offers surgeons improved fluidics for cataract surgery, improved 25-gauge instrumentation for vitrectomy, and is a user-friendly system with an ergonomic design. The combination of anterior and posterior features in a single machine maximizes space in my operating room and, more importantly, comes with a less expensive price tag compared with purchasing two individual systems for different tasks. ■

Ziad Bashshur, MD, is an Associate Professor, Department of Ophthalmology, American University of Beirut. Dr. Bashshur states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: zb00@aub.edu.lb.

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A Glistening-Free IOL Platform: Innovating the Meaning of Quality Vision

A description of the unique enVista lens and how combining it with laser cataract surgery produces excellent results.

BY DAVID SPALTON, FRCS, FRCP, FRCOPHTH

I started phaco surgery in the early 1990s and over this time, I have developed and tweaked my surgical technique to provide my patients with the best quality of vision achievable. In order to do this, I offer patients a range of what I believe are the best IOL designs as well as the latest advances in surgical technology. Part of this equation is using a lens design that offers patients excellent vision without introducing artifacts such as glistenings.

Today, I am enthusiastic about the enVista IOL (Bausch + Lomb; Figure 1), because this is a single-piece, glistening-free hydrophobic, acrylic IOL.

Figure 1. The enVista IOL is designed to be glistening free.

LENS DESIGN

The lens material of the enVista is bioengineered with several unique properties. It is a totally novel polymer consisting of hydroxyethyl methacrylate (HEMA), a polyethylene glycol phenylether acrylate styrene copolymer, crosslinked with ethylene glycol dimethacrylate, and an ultraviolet (UV) blocker (data on file with Bausch + Lomb). This combination produces an IOL with high biocompatibility and a high refractive index of 1.54.[1] The polymer has 4% water content and is packaged in 0.9% sterile saline solution to keep the lens fully hydrated (Figure 2). This packaging maintains equilibrium water content at all times and ensures the enVista IOL will not gain or lose water after implantation and, in return, avoids the formation of intralenticular microvacuoles or glistenings once inside the eye. The optic is 6.0 mm in diameter, with an overall haptic diameter of 12.5 mm and is available from 0.00 to 34.00 D with 1.00 D increments from 0.00 to 10.00 D and from 30.00 to 34.00 D and in 0.50 D increments between 10.00 and 30.00 D. Some other noteworthy features of the enVista IOL are described below.

PCO prevention. This IOL has been specifically designed to minimize posterior capsular opacification (PCO). The quality of the posterior square edge of an IOL is extremely important in preventing PCO;[2] as the bag collapses and fibroses around the IOL in the first 3 to 4 weeks after surgery, the posterior square edge is pushed against the posterior capsule. This produces a mechanical pressure barrier to the migration of lens epithelial cells and, to do this effectively, an IOL must have a sharply defined square edge.

Almost all IOLs are now marketed as having a square edge, but not all are equally effective. At our center, we developed a method to quantify the edge characteristics of an IOL by measuring the local radius of curvature at the junction of the posterior optic surface and the edge of the IOL. Environmental scanning electron microscopy (SEM), which produces exceptionally high-quality SEM images without deforming or dehydrating the material, showed the enVista IOL has an edge sharpness that meets our criteria for PCO prevention.

Another essential point is that the edge profile should continue under the optic-haptic junction to prevent migration of lens epithelial cells along this pathway onto the posterior capsule, the so called Achilles Heel effect. Figure 3 shows the posterior surface of the enVista IOL and its 360º barrier.

An aberration-free aspheric optic. This lens has an aspherically neutral, aberration-free optic, making the IOL resistant to aberrations induced by decentration. Compared to a standard spherical IOL, an aberration-free aspheric optic reduces spherical aberration (SA) and improves retinal image quality,

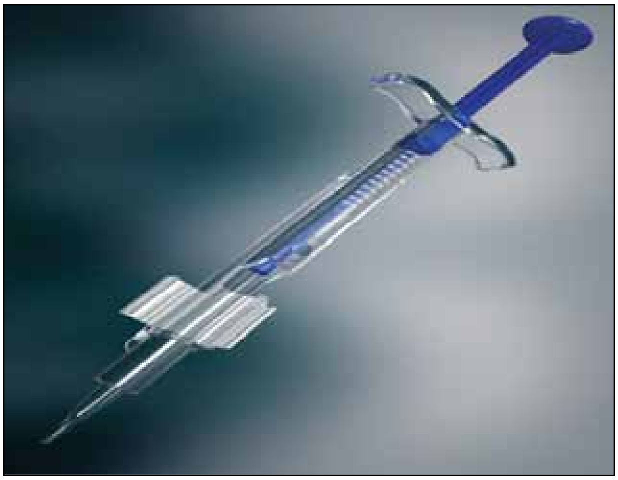

Figure 2. The lens is packaged in normal saline solution and is injectable through a 2.2-mm incision.

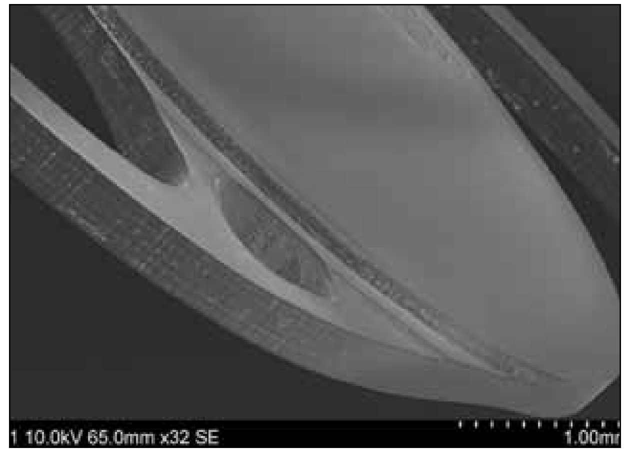

Figure 3. This image shows the posterior surface of the enVista IOL and its 360˚ degree sharp edge.

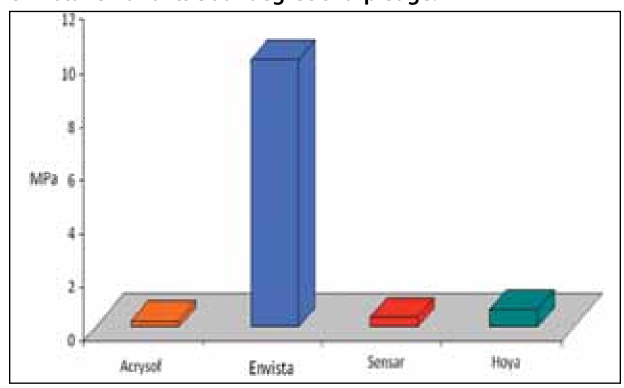

Figure 4. Nano indentation shows the increased surface hardness of the enVista material compared with other leading hydrophobic acrylic materials.

but unlike aspheric IOLs with negative SA, and aberration-free aspheric optic does not compromise depth of field.[3]

A durable surface. A noticeable feature of this polymer is that the surface is extremely hard and durable and is more resistant to scratching from instruments during insertion compared with other hydrophobic acrylic lenses (Figure 4) such as the AcrySof (Alcon Laboratories, Inc.), Sensar (Abbott Medical Optics Inc.), and the AF-1 (Hoya Corp.).

A glistening-free material. Glistenings are microvacuoles in the IOL caused by water migrating into the IOL and filling potential spaces in the polymer matrix. Because of the difference in refractive index, glistenings are seen as tiny sparkling spots, and they tend to be uniformly sized between 5 and 15 µm and evenly dispersed throughout the IOL material. These formations start to appear within a few months of surgery, with numbers typically plateauing approximately 1 year after implantation, as the material becomes fully hydrated. Glistening formation is influenced by a variety of factors such as IOL material, manufacturing processes, packaging, and temperature changes; clinically they seem to be a more common phenomenon in eyes with glaucoma or damaged blood aqueous barriers. They have been seen in most IOL polymers but are seen most commonly in AcrySof IOLs.[4]

The enVista material has been proven to be glistening-free in two different well-controlled clinical studies that were used in support of registration in the United States (data on file with Bausch + Lomb). This because it is prehydrated to an equilibrium water content of 4% and packaged in of physiologic saline solution, so that hydration is maintained at equilibrium and long-term water absorption is prevented after the lens is implanted.[5]

CONCLUSION

As one of the clinical investigators for the enVista IOL, I have been associated with the development of this IOL for several years. It offers impressive results and should make an ideal platform for toric or multifocal designs.

Implanting the enVista IOL complements today's advances in surgical technology, and it will be fascinating to see how this translates into the advent of laser cataract surgery. In the previous articles, my colleagues discussed the advantages of using the Victus femtosecond laser, another innovation that enhances surgical results. ■

David Spalton, FRCS, FRCP, FRCOphth, is a Consultant Ophthalmic Surgeon at St. Thomas' Hospital, London. Dr. Spalton states that he is a consultant to Bausch + Lomb and AVS Santen. He may be reached at e-mail: profspalton@gmail.com.

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Clinical Application of the New Glistening-Free IOL

One-year follow-up with the enVista is promising.

BY MANFRED R. TETZ, MD

The number of IOLs that cataract surgeons have at their disposal is continually growing. With such an overwhelming array of options, it can be a daunting task to decide what lenses to routinely use. I usually like to evaluate lens designs based on the lens material, injectability, rotational stability, and sharp microedge design for prevention of posterior capsular opacification (PCO). If the lens meets these criteria, I will consider adding it to my armamentarium.

Approximately 6 years ago, I was asked by Advanced Vision Science, Inc., to evaluate the safety and efficacy of a new glistening-free lens material. Implanting an aspheric monofocal lens called the AVS IOL in 172 eyes, I reported no incidence of early- or late-onset glistenings, with follow-up extending to 2 years in this population. These represent the first implants of this material in Europe.

A NOVEL POLYMER

This novel glistening-free lens material is created by combining hydroxyethyl methacrylate (HEMA) and a polyethylene glycol phenylether acrylate copolymer and crosslinking them with ethylene glycol dimethacrylate. The result is the enVista IOL, a lens with high biocompatibility and a high refractive index (1.54). The A constant of the enVista is 118.7, the overall diameter is 12.5 mm, and the optic is 6.0 mm. It is available in 1.00 D increments from 0.00 to 9.00 D and from 31.00 to 34.00 D and in 0.50 D increments from 10.00 to 30.00 D.

This hydrophobic acrylic one-piece monofocal IOL has a modified C-shaped haptic design and a 360° square edge to prevent PCO and a low water content that makes the lens stable, flexible, resistant to abrasion, and biocompatible. It also finds a stable position within the capsular bag and is not prone to IOL rotation. One of the most unique elements of the enVista IOL is that it is packaged in 0.9% sterile saline solution. This allows the lens to maintain its equilibrium (low) water content, avoiding the formation of interlenticular glistenings once the IOL is implanted in the eye.

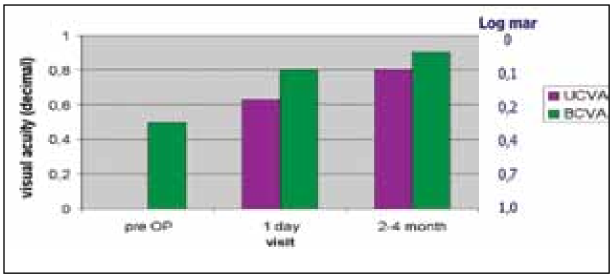

Figure 1. In this study, all eyes achieved a BCVA of 0.4 or better logMAR, and 85% achieved a BCVA of at least 0.1 logMAR.

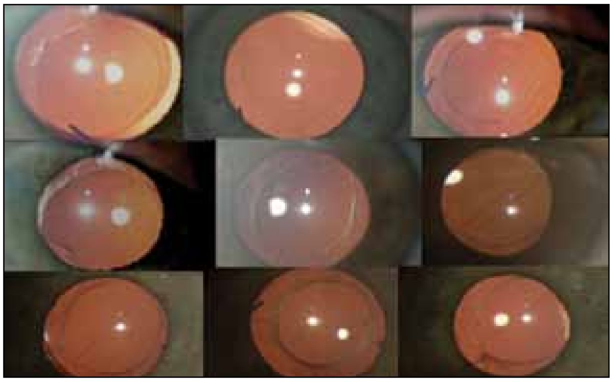

Figure 2. As seen in these images, no glistenings were documented on slit-lamp examination.

CLINICAL ANALYSIS

After studying the AVS IOL, I was asked to conduct a separate study on the enVista. I initially implanted the enVista in 14 eyes. During 2- to 4-month follow-up, the lens remained stable and viable in the capsular bag. I also conducted additional studies since this time, including a clinical findings study based on the follow-up implantation of 102 enVista IOLs and an experimental scanning electron microscopy (SEM) study on the IOL's 360° square-edge design. All of these studies have had positive outcomes. In these analyses, the enVista proved to be durable, it held up to posterior capsular opacification (PCO), and it provided patients with optical clarity and high-quality vision.

With regard to the initial enVista study, the average age of

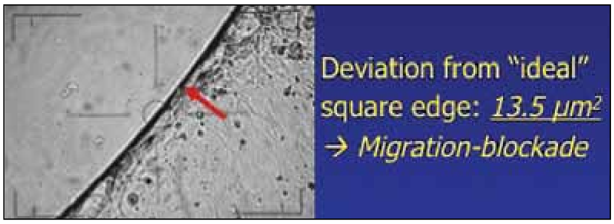

Figure 3. The deviation from the ideal square edge for migration blockade is 13.5 µm².

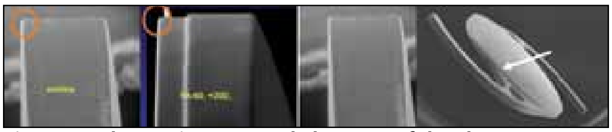

Figure 4. The enVista currently has one of the sharpest square edges of hydrophobic IOLs. The sharp edge extends 360º.

patients was 66.1 years (range, 35–81 years). Clinical examinations including UCVA and BCVA, refraction, intraocular pressure, and slit-lamp examination were performed preoperatively and at 1 day and at 2 to 4 months postoperatively. Complications and adverse events were also reported.

Following implantation of the enVista, all patients achieved excellent postoperative visual acuity. All eyes achieved a BCVA of 0.4 logMAR or better, with 85% achieving 0.1 logMAR or better. The mean BCVA before surgery was 0.30 logMAR and improved to 0.1 logMAR the day after surgery. Between 2 and 4 months after surgery, the mean BCVA had improved to 0.0. The mean UCVA also improved postoperatively, from 0.2 the day after surgery to 0.1 at 2 to 4 months after surgery (Figure 1).

No glistenings were documented on slit-lamp examination at any point in the follow-up (Figure 2), a finding that was identical to what we reported for the 172 eyes implanted with the AVS IOL. Additionally, I found that the enVista was resistant to abrasion and surgical surface damage during injection, and there were also no marks or surface scratches on the lens and no broken haptics.

My next study of the enVista IOL included 102 eyes, and follow-up extended to 1 year. Again, there were no clinical discernable glistenings, no surface scratches from injection or implantation, and no broken haptics. After 1 year, only one of the eyes required a Nd:YAG capsulotomy, indicating a low early PCO rate.

ADVANTAGES OF A 360º EDGE

Research has shown that the most important barrier to PCO is a square-edge design extending 360º. However, not all lenses with a square edge are equally effective at preventing PCO. I have conducted several studies on edge designs over the years,[1-3] and what I have found is that the ability of the IOL's edge to stop lens epithelial cell growth largely depends on the area of deviation from a 90º angle. The ideal experimental deviation from a completely square edge is 13.5 µm² for cell migration blockade (Figure 3). The enVista showed some of the most square edges of all acrylic IOLs tested by SEM. During our analyses, we thus found that, at 38 µm², the enVista had one of the sharpest square edges for a hydrophobic IOL (Figure 4).

CONCLUSION

I have implanted many different IOLs in my patients over the years. Today, the IOL that is high on my list is the enVista. As a hydrophobic acrylic, one-piece, aspheric lens, I have found it to be the ideal platform. Its low water content reduces the risk of glistenings as well as discoloration after implantation and offers patients the best optical clarity. Additionally, I feel confident implanting this lens through a small incision, knowing that the lens will be resistant to optic surface scratches and haptic damage. ■

Manfred R. Tetz, MD, Professor of Ophthalmology, is Director of his private practice, Eye Center-Spreebogen, in Berlin, and Scientific Director of the Berlin Eye Research Institute. Professor Tetz states that he has no financial interest in the companies or products mentioned. He has, however, been a consultant to Abbott Medical Optics Inc., and performed studies with various OVD manufacturers. Professor Tetz may be reached at tel: +49 30 398098 0; e-mail: info@augentagesklinik-spreebogen.de.

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