APACRS EyeWorld Asia-Pacific
The Newsmagazine of the Asia-Pacific Association of Cataract & Refractive Surgeons
Supplement to EyeWorld Asia-Pacific Fall 2013

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Advances in the technology of illumination, IOLs, and femtosecond cataract surgery

Cataract experts from around the globe met to discuss the latest innovations in both anterior and posterior segment ophthalmic surgery at the 28th Asia-Pacific Academy of Ophthalmology (APAO) Congress in Hyderabad, India on 17 January 2013. The following is a summary of the findings from the leading faculty on the latest developments in the industry.

Diverse surgical benefits of Stellaris PC Vision Enhancement System

An ophthalmic microsurgical system needs to fulfill the advanced technological requirements for the high performance demands of both vitreoretinal and cataract surgery. The Stellaris PC technology not only leverages Bausch + Lomb's legacy of vitreoretinal surgical innovation, but also provides the demonstrated excellence of the Stellaris phacoemulsification platform.

Narciso F. Atienza Jr., MD, Quezon City, Philippines, spoke about the versatility of the Stellaris for comprehensive vitreoretinal surgical needs in a single platform during his talk at this symposium.

Vitreoretinal visualization

The technology for vitrectomy has come a long way since the procedure was first performed in 1964, when surgery was done manually with an "open sky" technique, sometimes using Weck-cel sponges and scissors, Dr. Atienza said.

The procedure has moved on from its garage days. Visualization of the posterior chamber is one of the most significant evolutions for performing vitrectomy. Mercury halide, xenon, and now mercury vapor light sources provide superb illumination, while wide-angle lenses and co-axial microscopy provide surgeons with comprehensive views of the posterior chamber surface.

The Stellaris PC is the only vitreoretinal surgical system that comes with a dual light source and surgeon-selected color filters that allow for differentiated viewing designed to enhance the surgeon's ability to see ocular tissue better under various surgical conditions.

The "main advantage" of the Stellaris PC when performing vitrectomies, according to Dr. Atienza, is in illumination.

The Stellaris PC incorporates both xenon and mercury vapor light sources in one machine, combining these light sources with various filters—yellow, green, and amber—to increase the visibility during surgery.

In the past, unfiltered xenon light sources induced glare and, more importantly, phototoxicity after a certain amount of time in surgery. Phototoxicity is reduced by using a 435-nm wavelength filter. Changing filters are designed to provide a higher safety profile for prolonged surgical time, while also helping visualize the retina and posterior segment structures during surgery.[1]

Without a filter, he said, xenon illumination induces phototoxicity in about 11 minutes—assuming a 10-mm distance between the end of the light pipe and the macula. With a green filter, it takes 15 minutes, 8 seconds; with amber, it takes 52 minutes, 4 seconds; with yellow, it takes 8 hours, 10 minutes, 12 seconds.

By incorporating a mercury vapor light source, the Stellaris adds another layer of safety: The mercury vapor light source minimizes the potential for phototoxicity with prolonged surgery.

Vitrectomy versatility

Another key element of the Stellaris PC platform is its versatility to be used for simple vitreoretinal cases as well as

Chairperson

Chee Soon Phaik, MD, head and senior consultant, cataract service, Singapore National Eye Centre, and associate professor, Department of Ophthalmology, National University of Singapore

Speakers

Narciso F. Atienza Jr., MD, MBA, DPBO, FPCS, chief of retina and vitreous surgery, Cardinal Santos Medical Center, St. Luke's Medical Center, Quezon City, Philippines

Mohan Rajan, MBBS, DO, DNB, MNAMS, MCh, FACS, chairman and medical director, Rajan Eye Care Hospital, Chennai, India

David Spalton, MD, PhD, professor of ophthalmology, King's College, London, and emeritus consultant, St. Thomas' Hospital

Kasu Prasad Reddy, MD, founder, Maxivision, Hyderabad, India

Dr. Atienza's use of color filters during surgery

Yellow:
- When performing surgery beyond 2 hours

Green:
- When needing contrast between tissue and blood

Amber:
- Use for membrane peeling and visualization of the cleave of the diabetic membranes
- When using vital staining dyes such as brilliant blue
- During macular hole or macular surgery

more complicated cases seen in a retina specialty practice. This adaptable platform is built to suit any surgeon according to his or her technique.

First, the Stellaris PC platform features high cut rates. Dr. Atienza spoke about the importance of balancing speed of the cut rate without sacrificing efficiency. In the past, high cut rate platforms would heat up and lose efficiency during the procedure. The first three-port vitrectomy machines had a cut rate of 300 cuts per minute (cpm). The first electric cutter from Bausch + Lomb (Rochester, N.Y., U.S.), while more efficient than the first pneumatic cutters, could only cut up to 1,500 cpm. "Beyond that the probe would become very hot during surgery," said Dr. Atienza.

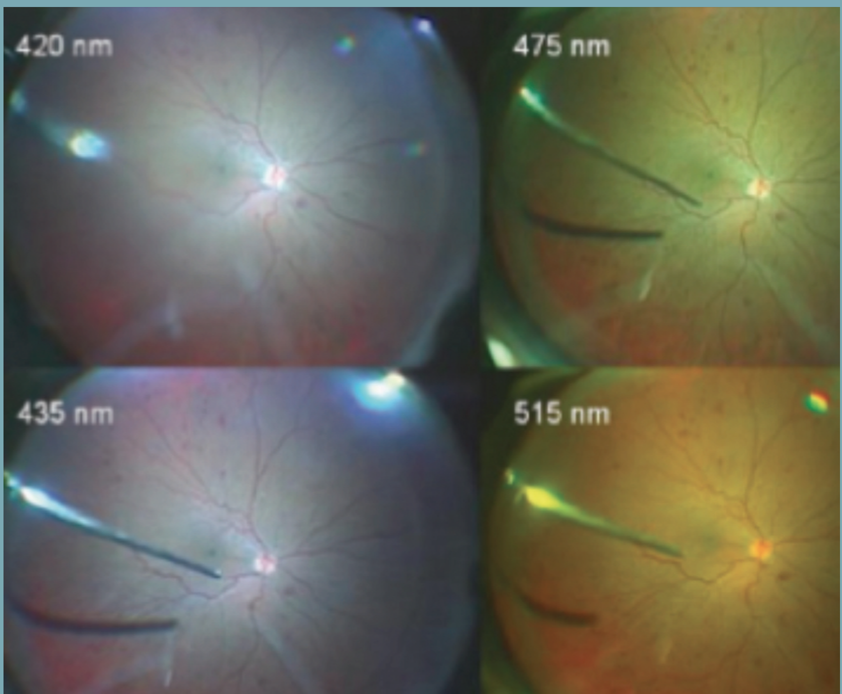
However, today with the Stellaris PC system, we can achieve cut rates up to 5,000 cuts per minute (cpm) without sacrificing efficiency. This permits surgeons to reduce overall surgery time and maximize the efficiency of the technology.

In addition to this high cutting rate, the Stellaris PC allows surgeons a platform for the smallest incisions for both retinal and cataract surgeries. It is capable of 1.8 mm micro-implantation cataract surgery (MICS) phacoemulsification as well as a complement to Bausch + Lomb's existing proprietary 25-gauge system of instruments for retinal surgery, along with standard 23- and 20-gauge instruments.

The Stellaris PC system also has light-weight, ultrahigh-speed vitrectomy probes for conventional and transconjunctival vitrectomy (TSV).

When performing surgery, Dr. Atienza uses a 5,000 cpm dual linear mode for procedures with a vacuum of 300 mm Hg for a 20-gauge needle and 550 mm Hg for his 23-gauge needle. The vented air fluid infusion system permits an air fluid exchange at 30 mm Hg, and the whole procedure is under his full control with the use of the precise Stellaris PC footswitch.

"The Stellaris PC Vision Enhancement System is a versatile system that you can use for both simple cases and more complicated cases," said Dr. Atienza. "It is an excellent, adaptable platform to suit any surgeon preference," he said.



Various color filters with the Stellaris PC

Refining the quality of vision with the enVista IOL

In order to maximize the quality of vision with IOLs, surgeons need to not only use the best materials, but they also need to use the highest engineered designs, said **David Spalton, MD**, London.

Maximizing success with IOL materials

The two key elements to maximizing visual quality with IOL materials include using the right polymer and avoiding the development of glistenings postoperatively.

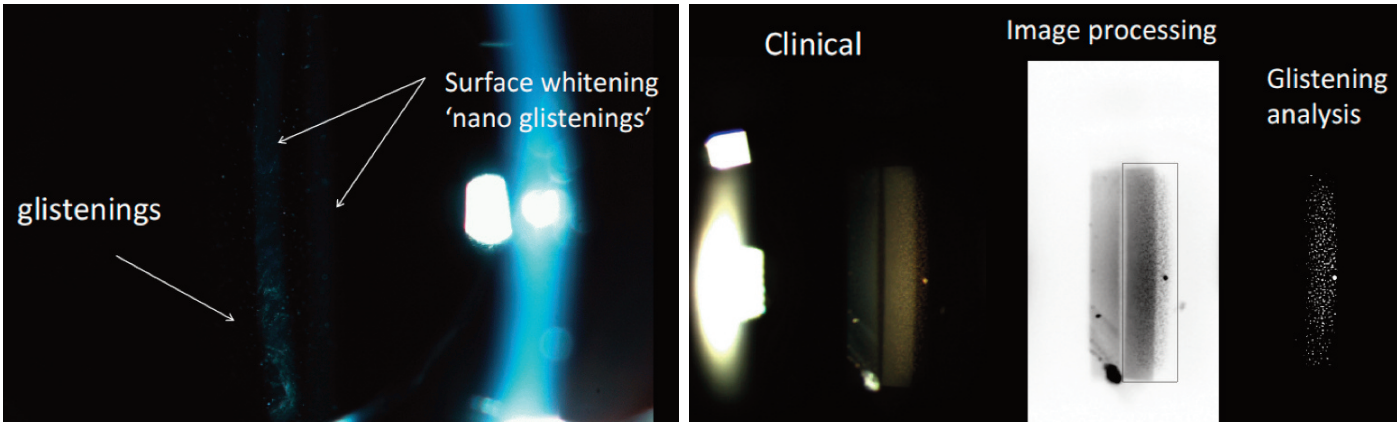
IOLs can be divided into two types based on polymer structures: hydrophilic and hydrophobic.

"Hydrophobic lenses have a lot of advantages," said Dr. Spalton. "They have a high refractive index, very good optical quality, and excellent biocompatibility as they never calcify. They also tend to be better at preventing posterior capsular opacification, and they have a very good surface for further engineering, such as making a toric or diffractive surface."

B+L's enVista lens is made from a "novel, new hydrophobic polymer," said Dr. Spalton. The polymer is significantly harder than competitor hydrophobic lenses, making it scratch resistant. It also has a high tensile strength, is less prone to YAG laser pitting, and has a more controlled unfolding in the eye after implantation.

Another significant element that distinguishes the enVista from other IOLs is that it is glistening free postoperatively. The main reason for this is that the enVista is prehydrated to equilibrium in saline by packing the lens in 0.9% saline and an optimum water content of 4%. Therefore, when the enVista is ready to be implanted in the eye, it is fully hydrated and doesn't create the glistening microvacuoles seen with some other IOLs.

If a hydrophobic acrylic IOL is not fully hydrated before being implanted in an eye, months after implantation, water begins to permeate potential spaces in a hydrophobic polymer's three-dimensional structure. These IOLs are thus prone to develop microvacuoles, spread uniformly throughout the lens material, increasing in number over time before reaching a plateau. These microvacuoles vary in size from 5-15 microns and often increase in incidence for about a year postoperatively.



Glistenings at the slit lamp and the analysis of glistenings from image processing

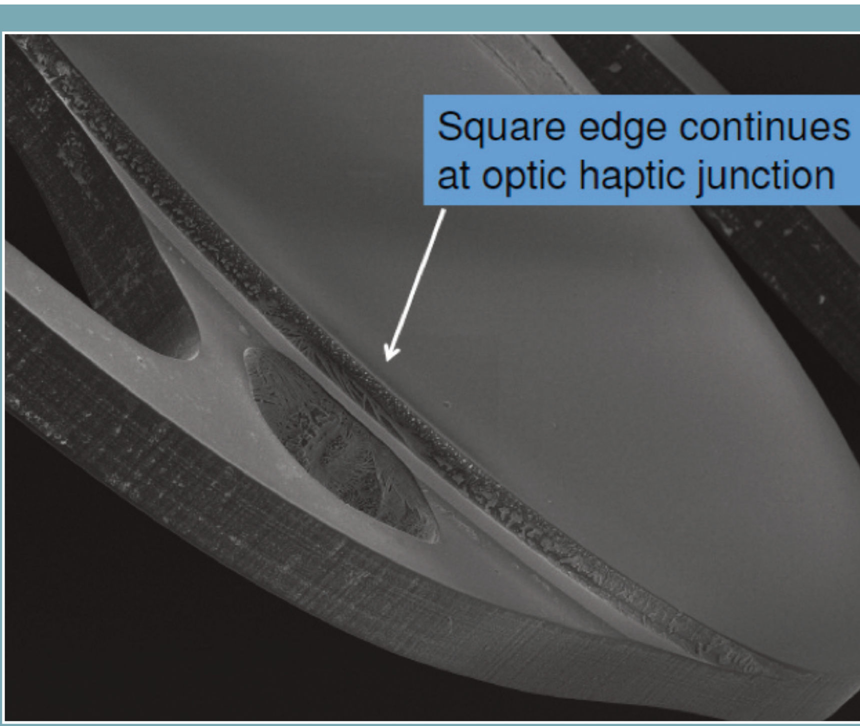
These microvacuoles are referred to as "glistenings" because there is a difference in refractive index between water and polymer that is easily seen at the slit lamp. Dr. Spalton stated that these glistenings "can certainly be a problem in some eyes." The enVista is the only lens currently FDA approved with labeling that states, "No glistenings of any grade were reported for any subject at any visit in the clinical study."

The clinical impact of IOL design: PCO prevention

Another important factor in the success of IOLs is a sharp square edge barrier, which is the single most important factor to prevent postoperative posterior capsule opacification. However, not all IOL square edges are the same, said Dr. Spalton.

Dr. Spalton reported, in the *Journal of Cataract & Refractive Surgery* (April 2008, p. 677-86), a method of measuring square edges using electron microscopy. The enVista's barrier edge is comparable to other lenses known to have good PCO prevention.

In some IOLs, the square edge has an Achilles' heel defect at the optic-haptic junction, where the lens epithelial cells (LECs) can migrate across this junction. What is critical for PCO prevention is that the barrier edge should extend through the optic-haptic junction to stop this effect of cells migrating through the optic-haptic junction onto the posterior capsule. "The enVista has a 360-degree square edge designed to prevent migration of the cells onto the posterior capsule through the optic-haptic junction," Dr. Spalton said.



View of the square edge maintained for 360 degrees, through the optic-haptic junction

The junction itself has been purpose-designed. Fenestrations are engineered into the haptics so that as the capsular bag constricts after surgery, the strain is taken up in the haptic and not transmitted into the optic of the lens—the optic is thus protected from optical power modifying contortion.

In addition, as the haptic takes up the strain of the contracting capsular bag, the lens moves backward slightly. This pushes the IOL against the posterior capsule, enhancing the square edge barrier effect.

Aspheric neutrality

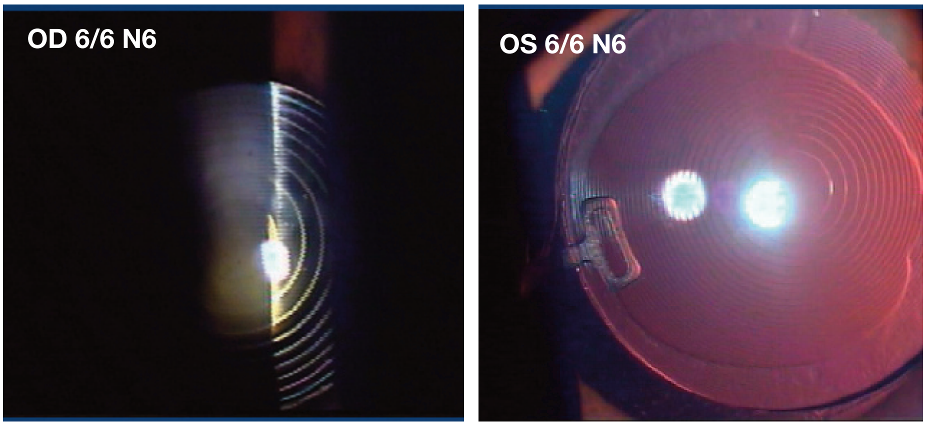
Like other Bausch + Lomb lenses, the enVista's optic design is aspherically neutral. "This is because the human eye is a decentered optical system by definition," said Dr. Spalton. "The lens is not aligned on the pupillary axis.

"The effect of spherical aberration is if you have a completely compensating lens, you will get a very good image if there's no decentration at all," he said. "As soon as you start to get some decentration—around 300 to 500 microns from clinical experience—the image starts to degrade with an aspherically compensated lens. This is designed to provide much better preservation of the image with decentration with the enVista aspherically neutral optic."

An aberration-free optic is thus "less sensitive to tilt and decentration, and there is an increased depth of field—all of which are important qualities for the patient," he said.[2]

Toric design

A final critical element of lens design is the development of a toric surface to address preoperative astigmatism. Today, the enVista series of IOLs includes a toric lens. Using the key elements of the enVista platform with a



Multifocal patient with a ReSTOR IOL (OD) with glare complaints and a non-ReSTOR IOL (OS) with no glare complaints

toric surface, Dr. Spalton said that clinical trials have shown the enVista Toric to have "very good rotational stability" after implantation. "The average post-operative rotational stability is 3 to 4 degrees [mean of 3.6]," he said. "Almost all patients with the enVista had less than 10 degrees of rotation."[3]

Meanwhile, data from the enVista Toric registry have shown the lens to provide excellent correction of refractive residual astigmatism. Data has shown significant reduction in refractive astigmatism, with mean absolute cylinder as low as an average of 0.25 D in patients. These outcomes are largely due to the contributions from all the various material and design elements of the enVista platform.

"This is a new generation lens," said Dr. Spalton. "It has important clinical characteristics and performance, particularly the absence of glistenings, the good PCO performance, the hard surface that doesn't get scratched, and toric outcomes that are excellent."

Using multiple advantages of enVista for success with diverse patients

The profile of the cataract patient is changing, said **Mohan Rajan, MBBS, DO, DNB, MNAMS, MCh, FACS**, Chennai, India. According to Dr. Rajan, cataract patients today tend to be younger, with an active lifestyle; they are economically independent, ready to spend on themselves; are educated, hugely aware of the variety of new possibilities; and, perhaps most significantly, they are highly demanding, with demanding lifestyles.

For these reasons, visual quality is more important than ever. "It is important for us also to deliver great support where cataract surgery is concerned," he said.

In the past a 6/6 outcome had been regarded as universally acceptable, and the patients were sent on their way. Today, however, patients who have 6/6 vision but are unhappy with the visual outcome are not uncommon. Therefore, Dr. Rajan has brought some of these 6/6 unhappy patients back to the clinic to determine why they were dissatisfied.

Case 1: Impact of glistenings on contrast sensitivity

In one patient, Dr. Rajan had implanted an SN60 IQ lens (Alcon, Fort Worth, Texas, U.S.) in one eye and an enVista in the other. Both eyes were 6/6, however the patient was unhappy with the vision from the SN60 IQ lens and happy with the enVista lens eye. Upon further examination, it was determined that there was a 25% reduction in contrast sensitivity in the IQ lens eye.

Upon slit lamp examination of the IQ lens eye Dr. Rajan noted "a lot of sparks on the lens, beautifully described as glistenings." No glistenings were noted in the enVista eye. "The mistake is to put an IQ lens in one eye and an enVista IOL in the other eye," he said. "If both eyes had IQ lenses, the patient would not have had a point of comparison."

Because of the glistenings in one eye, he said, the patient not only suffered from a decrease in contrast sensitivity, but also some light scatter effects like glare. "This is the clinical implication of glistenings," he said.

Case 2: Impact of glistenings on multifocals

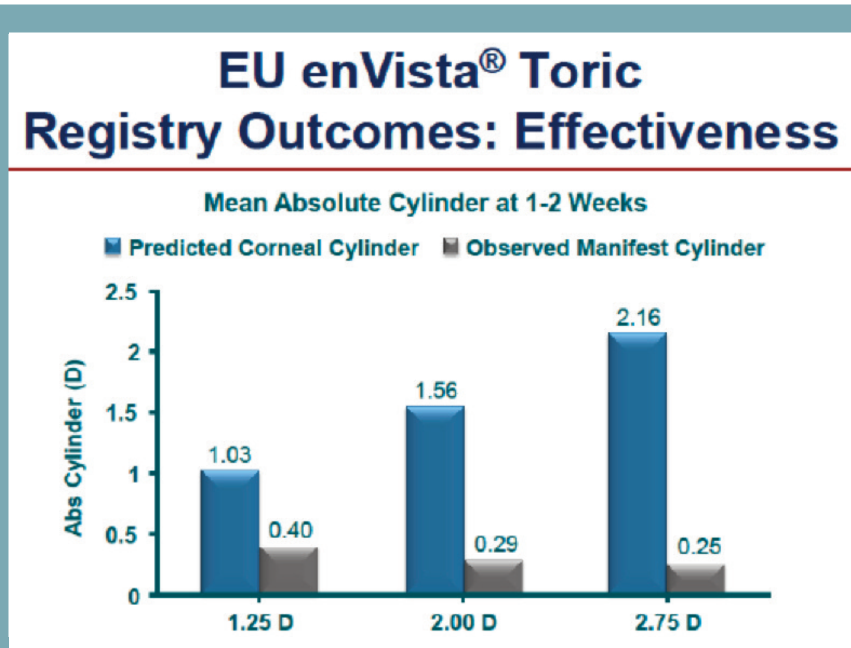
In another case, Dr. Rajan implanted multifocal lenses in both eyes, however one eye had a ReSTOR (Alcon) and the other eye did not have an Alcon multifocal IOL. Glistenings were observed in the eye with the ReSTOR IOL, but not in the other eye. The patient complained of glare coming from the ReSTOR IOL eye.

Because the patient only experienced glare in one eye, it could clearly not have been caused by the multifocal component. He concluded that the glare was likely due to the glistenings he found in one of the lenses.

"The water vacuoles affect contrast sensitivity," he said. "That is the cause of the misty vision these patients complain of."

True impact of glistenings

Dr. Rajan commented that the enVista IOL is unique since it was purpose-de-



Effectiveness of toric correction with the enVista Toric signed to be glistenings free. To confirm this, the enVista is the only glistenings-free IOL on the market today, based on long-term data.

But, Dr. Rajan asked, do glistenings really affect patients' visual acuity? Many people ask, "Does it matter clinically?" "It matters a lot," he said. "Glistenings can be very severe and degrade visual acuity and quality."

Glistenings, he explained, increase light scatter. "That is what is bothering to the patient," he said. "Similar to a multifocal lens, the patients can have glare and haloes along with the decreased quality of vision. Scatter increases between 2.5 and 4.5 orders —that is, between 300 and 3,000 times the level when the glistenings are not present."[4]

Case 3: Hydrophobic vs. hydrophilic materials

Dr. Rajan also has experience implanting hydrophilic lenses. In one case, a hydrophilic acrylic lens opacified after about 10 years in the patient's eye. The calcified lens was so opaque that his optometrist thought it was a recurrent mature cataract.

Dr. Rajan explanted the lens and replaced it with an enVista hydrophobic lens. The patient's postop visual recovery, he said, was significantly improved.

Other IOL keys to success: Aspheric neutrality and small incision capabilities

"What does the patient want today?" he asked. "The patient wants not only good uncorrected vision, but also good quality of vision." This, he said, is achieved using aspherically neutral lenses. Aberration-neutral lenses, he said, are designed to provide excellent contrast sensitivity.

Another advantage that the enVista lens has provided in Dr. Rajan's practice is that it can be implanted through small incision cataract surgery. "We implant it through a 2.2-mm incision," he said. "The lens demonstrates controlled unfolding, which is very important. It gives you ample time to go under the lens to remove the viscoelastic." The small incision permits the least amount of surgically induced astigmatism in this age of microincision cataract surgery.

Putting it all together

Dr. Rajan started implanting enVista lenses in February 2012. Since then, he and his colleagues have implanted the lens in 220 eyes, 30 bilaterally, 190 unilaterally, with a minimum follow-up of one month and a maximum of 10 months.

Serial photographs of their cases at various postoperative timeframes show "beautiful centration, excellent biocompatibility with clear anterior and posterior surfaces … and the absence of glistenings."

The best-corrected visual acuity was 6/5 in almost all the patients, and all of them were satisfied. Moreover, said Dr. Rajan, "in almost a year of follow-up, we have not had to use the YAG laser in any of these lenses."

Dr. Rajan attributes these results to the multiple advantages of the enVista platform. The main advantages are glistening-free vision, good biocompatibility, strong durability, better contrast sensitivity, ability to inject through a small incision, and effective PCO prevention.

"Choose the best quality IOL," he said. "My top priority would be enVista."

VICTUS: The exciting future of cataract surgery

When **Kasu Prasad Reddy, MD**, Hyderabad, India, watched his first femtosecond cataract surgery performed on an intumescent lens, he was extremely impressed. "What a fascinating technology this is," he thought to himself. He became dedicated to helping develop the next generation of this technology along with Bausch + Lomb.

Dr. Reddy was among the few to be there from the very beginning—performing his first femtosecond cataract surgery using the Technolas Perfect Vision prototype in November 2010.

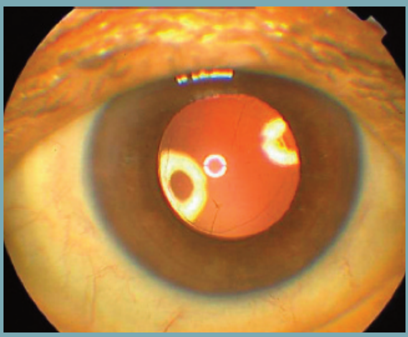
He is now using the latest version of this technology called the Bausch + Lomb VICTUS femtosecond cataract surgery platform. This technology includes several important elements focused on improving outcomes over manual phacoemulsification.

Improving capsulotomy to optimize effective lens position

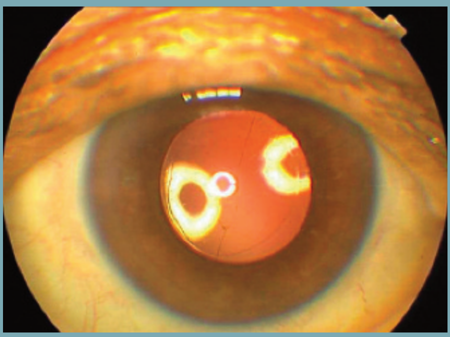
Dr. Reddy believes that the biggest unknown in IOL power calculations is the effective lens position (ELP). The ELP is the science of predicting where the IOL will rest in the eye and the visual system after implantation in the capsular bag. "There's been a lot of research about this, and having a good capsulotomy and a nice capsular bag undoubtedly help with this particular issue. The goal should be a well-centered capsulotomy with an overlap of 0.5 mm on the optic of the IOL," he said.

The VICTUS platform features key elements necessary for a precise capsulotomy—an easy, pupil-centered docking device, an OCT image-guided computer controlled system. The VICTUS also has a solid graphic user interface to permit optimal customization of the capsulotomy. All of this adds up to a fast and accurate procedure in which it is easy to extract the free floating capsule. Dr. Reddy said he can also simply aspirate the anterior capsule with the phaco tip.

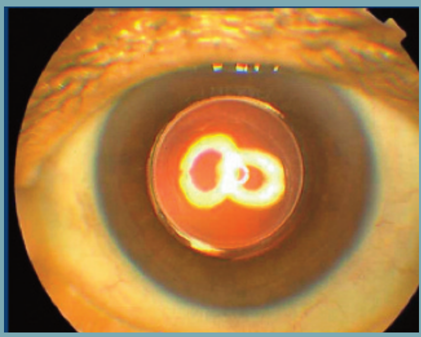
3 months postop



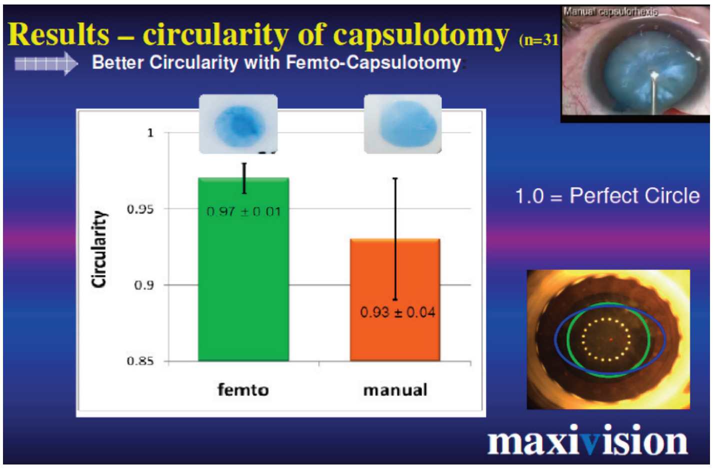
4 months postop



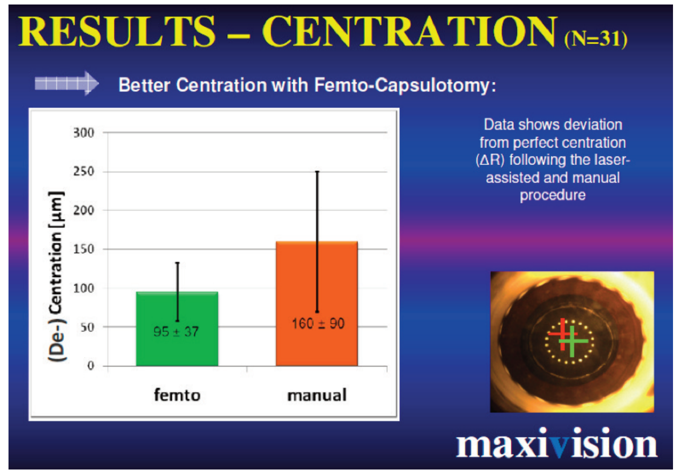
6 months postop



Serial photographs of an eye implanted with enVista at various postoperative timeframes



Comparison between the circularity of femto and manual capsulotomies



Comparison between the centration of femto and manual capsulotomies

Dr. Reddy and his colleagues have used the VICTUS successfully in cases with hazy corneas, a poor red reflex, positive pressure in the eye, specular pressures, cystatome issues, capsular forceps issues, and other situations that create poor visibility and make performing a good capsulotomy a challenge.

The laser begins cutting from within the lens through the capsule and any anteriorly inserted zonular fibers, thus avoiding risks such as catching zonular fibers, which can happen in a manual capsulorhexis situation.

In all of these cases, the laser is designed to create the same perfect capsulorhexis every time, according to Dr. Reddy.

In order to compare their results with a manual procedure, they initiated a study of 31 patients, where one eye had a laser capsulotomy and the other eye had a manual capsulotomy. Their goal was to create a 5.5-mm diameter capsulotomy. The cases in the laser group had an average of a 5.50 +/–0.12 mm diameter capsulotomy.

The study also compared the circularity of the capsulotomy. The laser group had 0.97 +/–0.01 circularity versus 0.93 +/–0.04 for the manual group. "The circularity of the laser capsulotomy is unbelievable," said Dr. Reddy. "I'm experienced enough to say I can do a nice capsulotomy, but my 'nice capsulotomy' will never be as perfect as the femtosecond capsulotomy."

Centration was also better, with femtosecond laser capsulotomies deviating on average 95±37 microns from perfect centration, compared with manual capsulotomies, which deviated by 160±90 microns.

Optimal lens fragmentation

Another key element of the VICTUS platform is the ability to reliably fragment the nucleus, even in the most challenging situations, without dropping the nucleus, in Dr. Reddy's experience. This fragmentation results in easier cracking of the nucleus and reduction of overall phaco time during the lens removal portion of the cataract procedure.

Dr. Reddy has tried various patterns for nucleus fragmentation. For grade 1 and 2 cataracts, he recommends using a concentric ring pattern with the femtosecond laser; for grades 3, 4, and 5, he usually uses a cross, dividing the cataract nucleus into quadrants. With these patterns, he has used the VICTUS in some of the most challenging situations, including cases with zonular dehiscence, intumescent cataracts, subluxated cataracts, and pediatric situations.

Dr. Reddy and his colleagues have used VICTUS in more than 1,120 eyes. In all of these eyes, he and his colleagues have never once had a nucleus drop. "I was able to stay more than 1,000 microns away from the posterior capsule, and I give total credit to the machine, which has helped me achieve many things without complications," he said.

Conclusion

"The VICTUS platform is a very versatile system," he said. "Not only does it do cataracts, I've performed LASIK flaps with this, and now I'm doing corneal incisions. It also does astigmatic keratotomies, and there are some therapeutic applications."

The system also includes an intelligent pressure sensor system with a curved patient interface designed to minimize corneal deformation and prevent corneal folds, and an attached microscope that gives surgeons like Dr. Reddy the option of performing different procedures in the same OR.

Dr. Reddy believes that the adoption of laser cataract surgery with the VICTUS will be similar to the learning curve for the IntraLase laser (Abbott Medical Optics, Santa Ana, Calif., U.S.) for LASIK. This will be the future of cataract surgery and bring safety and efficacy outcomes to a new level never seen before, he thinks.

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