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B+L launches enVista, discusses VICTUS, Lotemax


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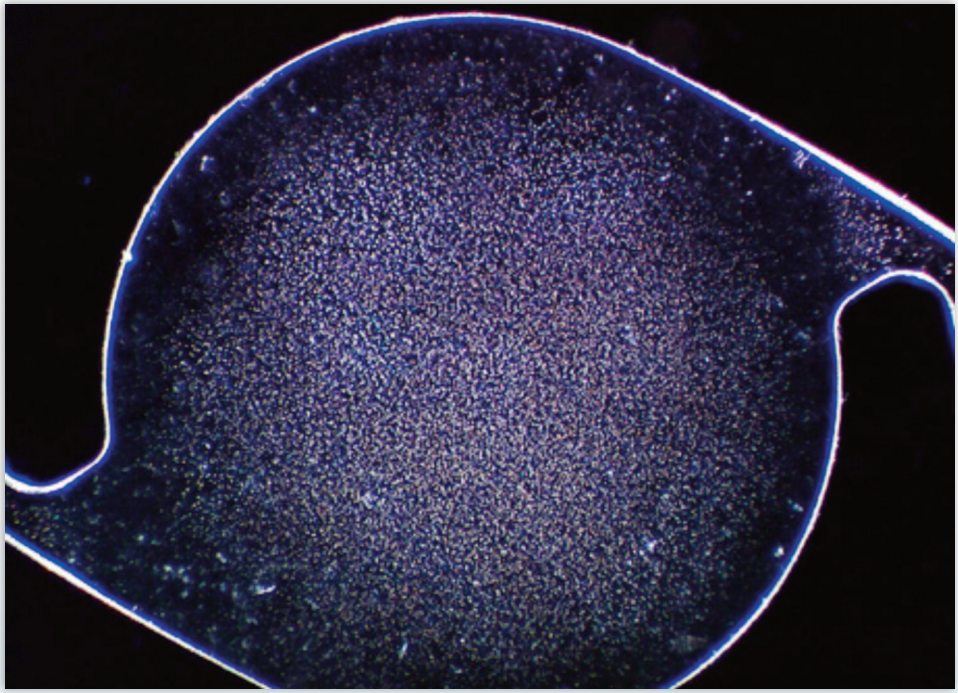
Sponsored by Bausch + Lomb.

Soon-Phaik Chee, F.R.C.Ophth., Singapore National Eye Centre, may not be a refractive surgeon, but the femtosecond laser for cataract surgery could turn her into one. It's an exciting time to be a cataract surgeon regardless of what country you practice in. During a symposium held at the annual meeting of the Asia-Pacific Association of Cataract and Refractive Surgeons, in conjunction with the Korean Society of Cataract and Refractive Surgery, attendees heard three very specific reasons why: enVista, VICTUS, and Lotemax (Bausch + Lomb, B+L, Rochester, N.Y.). The symposium was sponsored by B+L.



Photograph of a single-piece acrylic IOL showing intra-optical glistenings

enVista

"The enVista is not just a typical piece of plastic," said **Dylan Chan, M.D.**, a Hong Kong-based ophthalmologist. "It's the first-ever single-piece hydrophobic acrylic intraocular lens clinically proven to be glistening free."

There are two key words here: hydrophobic and glistenings. What makes something hydrophobic?

"Anything on Earth can be classified as hydrophilic or hydrophobic," said Dr. Chan. "If something is hydrophilic, it forms hydrogen bondings with water and can be wetted completely and homogenously by water. Hydrophobic means it doesn't like water, and H_20 beads off it. An intraocular lens made by hydrophilic material has higher water content, typically between 20% and 30%. Hydrophobic acrylic material, on the other hand, contains around 0.35% to 0.5% water."

What are glistenings? Glistenings are small fluid-filled pockets that form within the superficial layer of an IOL, potentially causing a portion of light coming into the eye to be scattered in all directions. This phenomenon can negatively affect visual acuity, according to a pilot study by Christiansen et al, published in the *Journal of Cataract & Refractive Surgery* (2001; 27: 728-33).[1]

High surface hardness is a special feature of the enVista, said Dr. Chan, noting that it's 10 times harder than other lenses tested. The same material used for the enVista is available in Japan and other markets as a three-piece IOL known as Eternity (Santen, Osaka, Japan) or XACT (Advanced Vision Science, Goleta, Calif.). In addition, the lens is specifically designed to reduce PCO with modified C-haptics and a complete 360-degree square edge design.[2] The lens has a 12.5 mm overall length with a refractive index of 1.54. The most striking feature of the lens, though, is its glistening-free material.

The enVista avoids glistenings through pre-hydration and packaging in 0.9% saline. In saline, the enVista IOL with 4% water content is in equilibrium with its environment, which means there is no water movement in and out of the IOL. Advantages of hydration to equilibrium include:

- It eliminates the driving force for water diffusion, thus eliminating potential for haze/glistenings and other material defects.
- The small amount of water required for total hydration does not affect the hydrophobic nature of the material. This is supported by contract angle measurements, which demonstrate that an IOL made with the enVista material has similar or greater surface energy compared with other hydrophobic IOLs that are packaged in a dry state.
- The surface properties of the enVista IOL are more stable after implantation compared with other hydrophobic IOLs that are packaged dry.

Peter Heiner, M.D., Vision Eye Institute, Australia, also weighed in on the enVista, sharing his early experiences with the lens, as well as the injector system. Two injectors are currently validated for use, a 2.2 mm and 2.6 mm injector from Medicel (Wolfhalden, Switzerland). The injector used depends on physician incision size preference.

"I would recommend the use of the 2.2 mm injector," said Dr. Heiner. "It is important when using the injector (loading the lens) to ensure the trailing haptic is not caught by the plunger. Take a little time loading the lens and make sure you're happy it's progressing properly before you insert it into the eye," he said.

"As the lens warms within the eye itself," Dr. Heiner noted, "it becomes easier to handle and centers well."

He also gave an overview of field observation study results. "It's early data with this lens, but we've had good unaided and corrected visual results."

The lens is currently undergoing FDA review in the U.S. and is already available in Australia and New Zealand. It was recently launched in South Korea and has been released in Europe.

VICTUS

An estimated 20 million baby boomers and seniors have cataracts, and more than 15 million cataract surgeries are performed worldwide each year. Cataract surgery is considered one of the safest surgical procedures today, but "how can we do cataract surgery better?" Dr. Chee asked during her talk, *New paradigms in vision rejuvenation on femto cataract surgery*.

"We know there has been a trend toward smaller incisions because this means less invasive surgery for our patients, as well as faster healing and visual recovery. A small incision is more capable of being astigmatically neutral with potentially less risk of endophthalmitis," she said.

But is a 2.2 mm incision small enough? Dr. Chee prefers a 1.8 mm using the Stellaris platform (B+L).

"There is a unique needle on the Stellaris 1.8 mm platform," she explained. "The internal lumen provides normal aspiration. The company is able to achieve such a small incision because its needle wall is much thinner than the standard needle. So the external diameter is that of a 20-gauge, but the internal diameter is that of a 21-gauge. The sleeve is also slightly different because it's rather thin."

The Stellaris 1.8 mm platform is able to handle dense cataracts with ease, but the 1.8 mm incision is not without challenges.

"We'd all agree it's making the capsulorhexis," she said. "We want to make sure our capsulorhexis ends up circular and centered well on the lens. Those of you who find this may be a challenging step, why not look to innovations in cataract surgery?"

One such innovation is the VICTUS Femtosecond Laser Platform, a first-of-its-kind technology that's capable of performing cataract, refractive, and therapeutic procedures all in one. Dr. Chee has performed cataract surgeries with the laser in India. She plans on going back to the country to perform additional surgeries with the platform. The laser is not currently approved for use in Singapore, where Dr. Chee is based. It's also not approved in the United States.

Dr. Chee noted how impressed she was with the docking system and how quickly the laser made the capsulorhexis and four-section cut.

"I'm a cataract surgeon and have never done refractive surgery in my life," she said. "Everything went quite smoothly. This capsulorhexis was beautiful. The capsulotomy created with this system is round and centered, much rounder than a manual procedure."

Ideally, surgeons should aim for a 5.5 diameter for the capsulotomy opening for a 6 mm optic, but Dr. Chee favors a smaller size.

"When we center the capsulotomy we are actually centering on the pupil," she explained. "However, if you think about it carefully, the lens centers in the bag. Optimally, you would want to center the capsulorhexis on the bag. Therefore instead of using 5.5 mm for a targeted diameter for the capsular opening, I would favor a smaller diameter in case your pupil and your bag are not in line."

Dr. Chee pointed out that although a skilled surgeon can create manually what looks to be a round capsulorhexis, the manual capsulorhexis cannot stand up to the femtosecond-created capsulorhexis when compared side-by-side. To prove this, she gave an overview of a study conducted by **K. P. Reddy, M.D.**, in Hyderabad, India. He evaluated patients with a 5.5 mm capsulorhexis. Thirty-one had a manual capsulorhexis and 31 had their capsulorhexis performed with the VICTUS.

"Preliminary results demonstrate that a femtosecond laser platform has the capability to produce a capsulorhexis that has a more precise diameter, better accuracy, and predictability for centration, as compared with a manual tear," she said.[3]

"For those surgeons concerned about time added, performing the capsulotomy takes about 7 seconds, and using the femto laser adds a few minutes to the procedure overall.

The interface is really simple for the refractive surgeon. I did not feel there was a steep learning curve."

In addition to being designed to provide a more precise capsulorhexis, the VICTUS has a real-time OCT that shows the cuts as the procedure progresses. Dr. Chee said the other main advantage of the laser is it helps aspirate both the extremely soft and hard cataract.

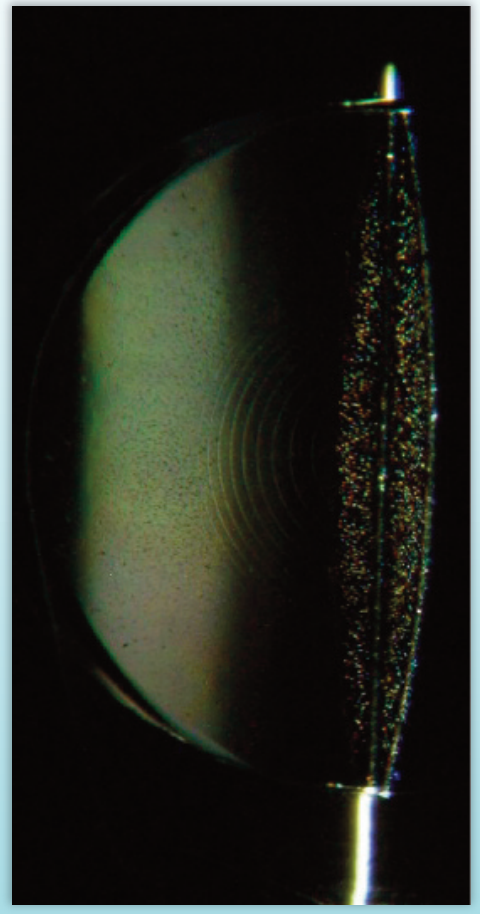
"With a hard cataract we know it isn't the easiest," she said. "It's difficult to chop and crack. In this case, with the aid of a laser to divide it into four or create rings, you can easily aspirate it. I'm looking forward to creating femto-based incisions for 1.8 mm phaco in the future."

Lotemax

"Why do we need another topical steroid?" asked **Sunil Shah, M.D.**, an ophthalmologist based in the United Kingdom, in his lecture, *Management of ocular inflammatory response*. "We've got quite a few available, we know they work, we can choose between the strength of the steroids, and we know what the adverse effects are. We all have our favorite ones. So why is B+L trying to introduce a new steroid when the market is already full?"

Some of the concerns about ophthalmic steroids are an elevation in IOP, cataract formation, infection aggravation, and a delay in healing. But what if physicians had a steroid that was potent but limited IOP elevation and didn't cause cataracts?

With Lotemax (loteprednol etabonate ophthalmic suspension), he said, that's what they get. "Why is Lotemax different?" Dr. Shah asked. "It's a very simple change in the chemical structure where we have an ester group there instead of a ketone group. It's a fairly simple chemical structure change. But that makes this drug the only one that has an ester group at the C-20 position. All the other steroids that we are able to use are ketone derivatives."



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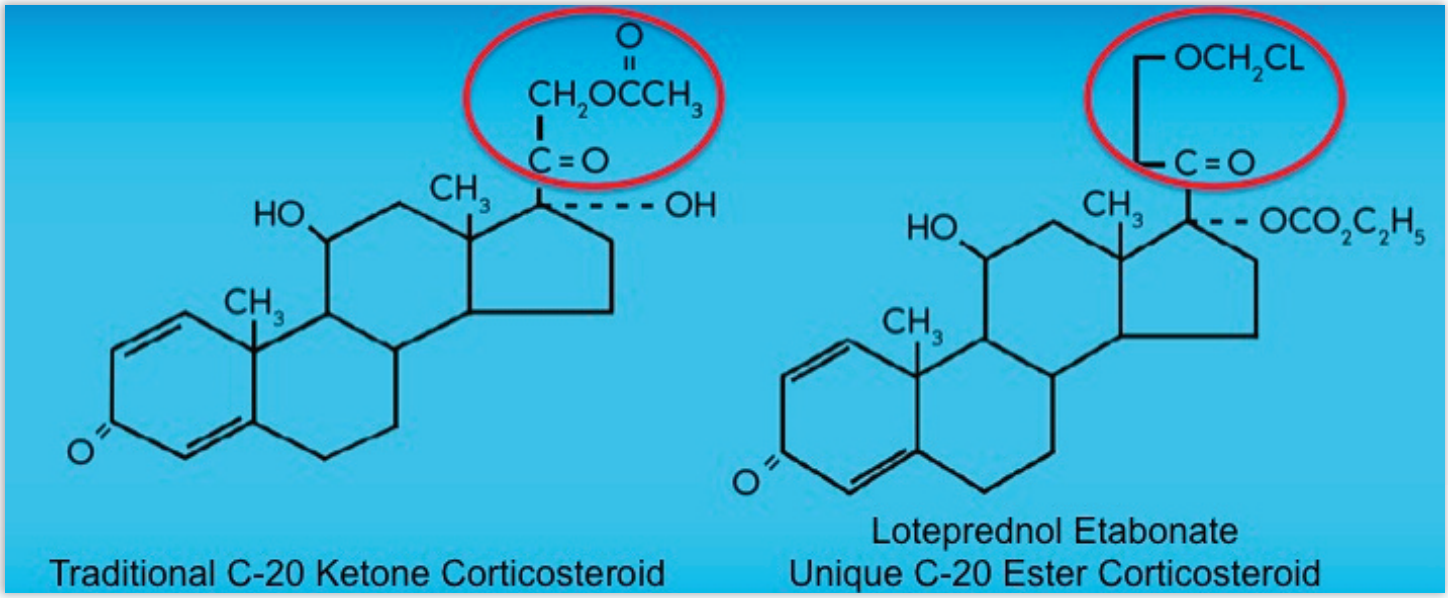

Loteprednol etabonate replaces the number 20 position ketone with an ester group, allowing for rapid and predictable inactivation of unbound drug and reduced risk for elevation of IOP

Lotemax is a next-generation ester ophthalmic steroid with unique safety characteristics due to a controlled metabolic profile, according to B+L. Lotemax has also been found to be highly lipid soluble, enhancing its penetration into cells and enabling it to exert anti-inflammatory activity within the eye.

Lotemax is indicated for the treatment of steroid-responsive inflammatory conditions associated with the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe. In clinical studies, Lotemax resolved or controlled inflammation in 95% of post-op patients following cataract surgery vs. 65% for placebo. Lotemax has also been proven effective for giant papillary conjunctivitis. Furthermore, all other steroids metabolize in the liver, but Lotemax primarily metabolizes locally in the eye.

The steroid drop significantly reduces IOP elevation, has significantly less propensity to form posterior subcapsular cataracts, and is as effective if not more effective than current drops on the market, Dr. Shah said. For example, as compared with prednisone acetate, there's a three times greater pressure rise with prednisone acetate than with Lotemax.

"I'm not saying there is no pressure rise with Lotemax—there's still a risk. But this is significantly reducing that risk," he said. "In patients who are steroid responders, a group we all have a problem with, in one particular study the known steroid responders started with an intraocular pressure of 17.4 and that rose to a mean of 21.5, whereas in the prednisone acetate group, the pressure rose to 27. If you can keep your mean pressure in the normal range in these higher risk patients, it's worth considering."

"My personal experience is it's an effective drug, it significantly reduces the patients who have IOP pressure rise, and it's extremely well tolerated," Dr. Shah said. "It's worth considering for all cases. It's new to Asia, but is the number one branded steroid in the U.S. That speaks for itself."

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