APACRS EyeWorld Asia-Pacific
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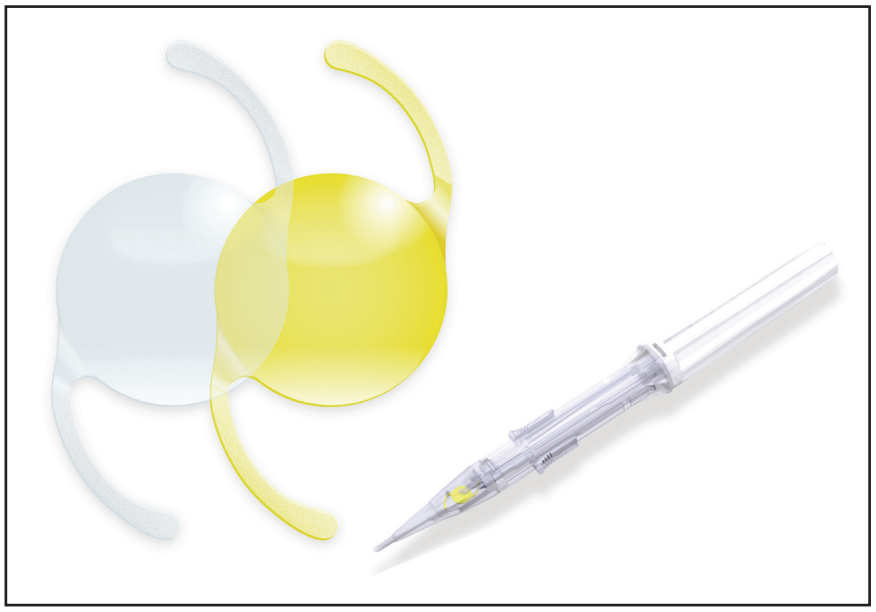
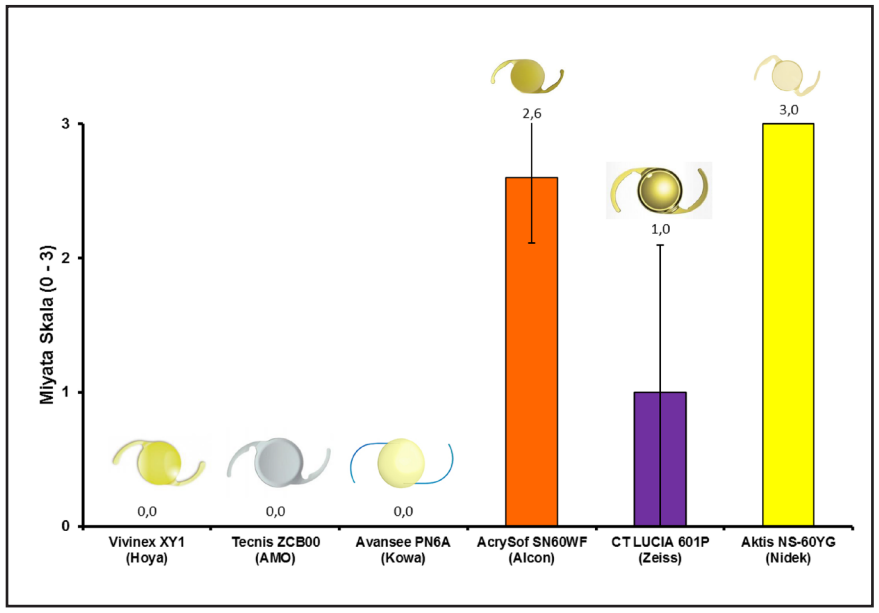
New hydrophobic lens and innovative technology highlighted in symposium



The Vivinex™ IOL and iSert®

Source: HOYA



Average Miyata grading

Source: Gerd Auffarth, MD

A symposium sponsored by HOYA Surgical Optics (Singapore) at the Asia-Pacific Association of Cataract & Refractive Surgeons (APACRS) meeting in July in Nusa Dua, Bali focused on "Innovative Technology and Long-Term Clinical Outcomes in Cataract Surgery." The session was moderated by **Soon Phaik Chee, MD**, Singapore.

During the session, **Gerd Auffarth, MD**, Heidelberg, Germany, spoke about improvements in acrylic material. Material is important because patients are getting younger, he said, so if the material deteriorates over time, that's not ideal. Properties of a good intraocular lens include excellent biomaterial (optical purity), foldability and pre-loaded delivery, optical quality and refractive reliability, excellent capsular bag performance, and sharp edge technology for PCO prevention, he said.

Hydrophobic acrylic IOL material has already been in the research field for more than 30 years, Dr. Auffarth said, and there have been many problems with the material, particularly because of glistening formation. These lenses were initially very stiff but have changed over time, he said. Glistenings are specific to hydrophobic material.

Dr. Auffarth spoke about the Vivinex™ lens (HOYA), which is made of hydrophobic material. It can be inserted through a small incision and can be injected nicely into the capsular bag with control, he said. The material is not as hard as other hydrophobic materials, so it slides well into the injector, he added.

In order to address the potential for glistening complications, Dr. Auffarth said the lens was tested with a specific treatment process and graded for glistenings. This testing method includes putting the lenses in an oven for a 24-hour period to accelerate the glistening process. Then, the lenses go into a controlled cooling process for several hours. The lenses are treated this way and put under a microscope. Photographs are taken, and software analyzes the number of glistenings and the size of the glistenings. The HOYA Vivinex™ lens, Dr. Auffarth said, showed "essentially zero glistenings."

With this process, there is a reproducible setup for experimental glistening formation, he said.

It's ideal for comparative studies and identifies significant differences among various materials and manufacturers, Dr. Auffarth added. There are great variations among hydrophobic IOLs from different manufacturers, but the Vivinex™ IOL has shown to be glistening free, he said.

Hiroko Bissen-Miyajima, MD, PhD, Tokyo, presented on clinical data with a new IOL material to reduce PCO with a hydrophobic acrylic lens. Dr. Bissen-Miyajima first discussed HOYA and its recognition in Japan before specifically discussing the Vivinex™ lens, sharing clinical outcomes and 3-year follow-up data from studies of this lens.

Everyone wants cataract surgery with less PCO, she said. A square edge is known to reduce PCO, but it's not perfect. With the Vivinex™ the posterior surface of the IOL is modified to increase adhesion to the posterior capsule. Dr. Bissen-Miyajima shared a video from Prof. Hiroyuki Matsushima (Japan) detailing the way the surface of the IOL is modified to improve adsorption of adhesive proteins through a simple and effective UV ozone treatment.

Dr. Bissen-Miyajima described outcomes from a 3-year follow-up of a clinical trial from 2009 to 2011 in Japan. The trial was a multicenter, single-blinded, parallel-group study looking at 180 eyes of 90 patients. The study featured a group with the Vivinex™ IOL, a hydrophobic acrylic IOL with a sharp frosted edge with an incision size of 2.0 mm, and a control group with a hydrophobic acrylic IOL with an incision size of 2.5 mm.

Results indicated that eyes with the Vivinex™ showed a lower rate of PCO and lower density of the posterior capsule compared to the control group. Additionally, results showed that glistenings were reduced in the Vivinex™ eyes compared to the control group.

The lens has been approved in Japan since 2012. It offers an easy implantation through a less than 2 mm incision, Dr. Bissen-Miyajima said.

Dr. Bissen-Miyajima concluded that the 3-year results from this new material show good visual acuity, less PCO, and less glistening.

Rupert Menapace, MD, Vienna, Austria, spoke about rotational stability, which he said is crucial when you use a lens platform for toric lenses. If you misalign a lens by 10 degrees, you lose one-third of the corrective power, he said. If you misalign by 30 degrees, you lose all the corrective power, and greater than that there will be significant rotation of the axis, Dr. Menapace cautioned.

Causes of toric IOL misalignment could be attributed to primary malpositioning, Dr. Menapace said. This could be from erroneous calculation of the target axis, erroneous or imprecise marking of the target axis, or imprecise alignment of the toric IOL with axis marks. Secondary rotation of the toric IOL in the capsular bag could also cause misalignment.

In the literature, a lot of information on rotational stability shows methods regarding how physicians can assess the position of the lens and when they start controlling the rotation baseline, Dr. Menapace said. It's necessary to have this information on rotational stability at the end of surgery while the patient is still on the table, he added. However, published data on rotational stability are incomplete and irrelevant, Dr. Menapace said. True rotational stability is actually worse than published, he said, and outliers with almost all "big players" on the market can occur. What counts is the positional change from the end of surgery to 1 month, not the deviation from the intended axis or from 1 hour, 1 day, or even later. "What counts [are] outliers and not mean values and standard deviations," he said. It's especially important to begin looking at this while the patient is still on the table because in many published studies, the first hour after surgery is disregarded, Dr. Menapace said, and this is when rotations are most frequent and pronounced.

Looking at data at 4 to 6 months on rotational stability, the Vivinex™ lens was the only product investigated that did not exhibit a single case of an outlier rotating more than 5 degrees, Dr. Menapace said. Vivinex showed an excellent rotational stability with an average of 1.54 degrees and a range of up to 5 degrees collected on 103 eyes, which is better than other tested hydrophobic lenses. Dr. Menapace added that companies must provide relevant information, and he recommended that surgeons minimize the need for rotation by using brands with proven rotational stability. Inform patients about possible rotation and possible need for surgical correction, he said. Surgeons should also optimize surgical technique by avoiding dispersive OVDs, allowing haptics to completely unfold, and flattening the chamber and leaving the eye normotonic at the end of surgery. He stressed the importance of seeing all patients at 2 weeks postop to detect any outliers and to reposition the toric IOL between 2 to 4 weeks when needed.

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> ***–Hiroko Bissen-Miyajima, MD, PhD***

Suhas Haldipurkar, MD, Hiroko Bissen-Miyajima, MD, Soon Phaik Chee, MD, Rupert Menapace, MD, and Gerd Auffarth, MD, presented at a symposium sponsored by HOYA Surgical Optics at the 2016 Asia-Pacific Association of Cataract & Refractive Surgeons meeting.

Source: HOYA

Finally, **Suhas Haldipurkar, MD**, Mumbai, India, spoke about spherical aberration. There is a quest for better quality for the patient, he said. If you look at aspheric and spherical lenses, Dr. Haldipurkar said that aspheric will give better quality, but the depth of focus is slightly less. At the same time, you cannot ignore the size of the pupil, he said, because a larger pupil will deteriorate the quality of vision. Additionally, total aberrations of the eye increase three-fold between the ages of 20 and 70.

When implanted in the capsular bag, the IOL center is typically 0.36 mm from the visual axis, which makes the IOL slightly decentered on the visual axis, Dr. Haldipurkar said. This natural physiologic misalignment degrades the image quality with traditional negative aspheric IOLs in spite of the excellent optics, he said.

Dr. Haldipurkar then discussed the HOYA IOL with patented Aspheric Balanced Curve Design (ABC Design) and results from studies comparing that IOL to others. This IOL performed "equally well" in eyes with angle alpha greater than 0.4 mm, he said. The IOL is also less affected by decentration, Dr. Haldipurkar added. The IOL provides unique control of higher order aberrations to reduce the effect of decentration, he said, and it provides minimal distortion in the center, where it really matters.