INNOVATIVE TECHNOLOGY AND LONG-TERM CLINICAL OUTCOMES IN CATARACT SURGERY

At a symposium held at the Gran Teatre del Liceu in Barcelona, Spain, with around 400 attendees, a panel of experts in cataract surgery, biochemistry and optics presented the theories behind the design of the HOYA Vivinex™ iSert® intraocular lens (IOL) implantation system and reported the clinical results achieved with the lens so far.

Introducing the symposium, session-moderator Prof Rupert Menapace MD, PhD, Medical University of Vienna, Austria, noted that the Vivinex™ iSert® was conceived to fulfil the requirements of an optimum IOL platform.

Those requirements include a stable biocompatible material that is resistant to posterior capsule opacification (PCO) and without glistenings, and provides good compressibility for injections through incisions less than 2.0mm. The ideal IOL should have single-piece design. Its haptics should be sturdy and have a broad contact angle to the capsular bag equator that provide stable autocentration and maximum rotational stability.

Furthermore, the IOL should have an optical design that is forgiving of decentration and tilt. Moreover, the optic edge should induce minimum dysphotopsia but be perfectly sharp to prevent lens epithelial cell migration. All that should be packed in a preloaded system which can be prepared and injected with three simple hand movements.

IMPORTANCE OF LENS MATERIAL IN IOL PERFORMANCE

Prof Gerd Auffarth MD, PhD, University of Heidelberg, Germany, followed with a presentation that highlighted the stability and optical purity of the Vivinex™ IOL material, describing how it resists the formation of glistenings and preserves lens clarity.

He noted that glistening are microvacuoles of aqueous that develop within an IOL's material. They were first described in the very early days of hydrophobic IOLs. They tend to increase in number over time, gradually decreasing lens clarity, and in some cases necessitating lens explantation.

Various manufacturers have developed new hydrophobic lens materials that are more resistant to the formation of glistenings, Prof Auffarth said. He presented a study which showed that an experimental glistening-inducing process resulted in virtually no glistenings in Vivinex™ XY1 and AMO TECNIS® ZCB00 lenses, but in significantly greater amounts of glistenings in Alcon lenses.

Prof Auffarth's team immersed five lenses of each type in saline solution at 45°C for 24 hours and then reduced the temperature to 37°C for 2.5 hours using a water bath. They then analysed the samples using dedicated software.

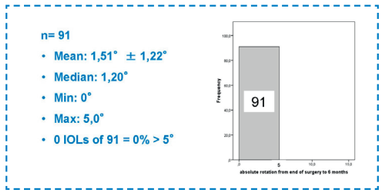
They found that the Vivinex™ and the TECNIS® IOLs had less than 25 microvacuoles per square millimetre (MVs/mm2) in all the lenses tested, but in the Alcon SN60WF IOLs the microvacuole density ranged from 133MVs/mm2 to 394MVs/mm2.

PCO REDUCTION THROUGH SURFACE MODIFICATION

Experimental evidence also shows that the adhesiveness-increasing surface modification of the Vivinex™ IOL material inhibits the development of PCO, said Prof Hiroyuki Matsushima MD, PhD, Dokkyo Medical University, Japan.

Research has shown that, although a square-edged optic does slow the development of PCO, it does not prevent it completely. IOL surface modification is an alternative approach to PCO prevention that has been used in several IOL designs. They include techniques to render them either more adhesive or less adhesive to lens epithelial cells (LECs).

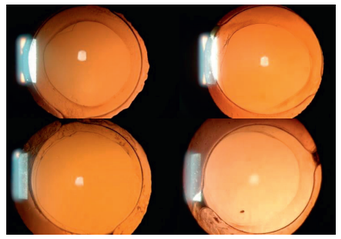
Prof Matsushima noted that in an in vivo rabbit-eye study, examination of lens sections at two weeks postoperative showed



Evaluation of rotation from end of surgery to 4-6 months

	Microvacuoles/mm²	Grade according to Miyata et al. [1] (Scale from 0 to 3)
HOYA Vivinex™ XY1	< 50	Grade 0
Alcon AcrySof® IQ SN60WF	> 200	Grade 3
AMO TECNIS® ZCB00	< 50	Grade 0

[1] Miyata A, Uchida N, Nakajima K, Yaguchi S. Clinical and experimental observation of glistening in acrylic intraocular lenses. Jpn J Ophthalmol. 2001



Vivinex™ iSert® – prevention of PCO

that the layer of LECs was only 17 microns in eyes with hydrophobic acrylic IOLs that had undergone the adhesiveness-increasing UV/ozone surface modification used in the manufacture of the Vivinex™ IOL. That compared to a thickness of 60 microns in eyes implanted with control lenses, and 80 microns in eyes implanted with lenses that had undergone adhesiveness-decreasing MPC (2-Methacryloyloxyethyl Phosphorylcholine) treatment ($P < 0.05$).

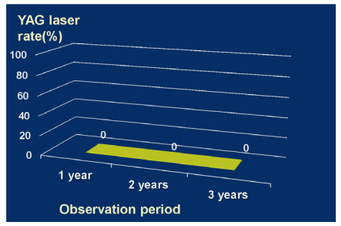
CLINICAL OUTCOMES WITH THE VIVINEX™ ISERT®

Clinical evidence is now showing good long-term resistance to PCO in eyes implanted with the Vivinex™ IOL, Prof Hiroko Bissen-Miyajima MD, PhD, Tokyo, Japan reported at the Barcelona symposium.

She reported the results of a multicentre clinical trial involving 180 eyes of 90 patients implanted with two hydrophobic acrylic IOLs, the Vivinex™ (SP2) lens, through a 2.0mm incision, and the approved AF-1 3-piece IOL, through a 2.5mm incision, as the control.

At one year, visual acuity was 1.0 or better in 86.4% of eyes in the Vivinex™ group and in 81.8% of the AF-1 group. However, in the AF-1 group, the percentage of PCO was 13.15%, compared to only 1.78% in the Vivinex™ group ($p<0.001$).

Furthermore, in 27 patients implanted with the Vivinex™ lens and followed for three years, 63% remained completely free of PCO, the remaining eyes had only mild opacity in the periphery and the YAG laser rate remained at zero.



Nd:YAG Laser Capsulotomy Rate of Vivinex™ iSert®

ROTATIONAL STABILITY

Prof Menapace returned to the podium and presented the results of a study which demonstrated that the haptic design of the Vivinex™ IOL provides the lens with excellent rotational stability.

"The Vivinex™ IOL has demonstrated an unsurpassed rotational stability, making it an excellent platform for a toric IOL," he said.

The study involved 120 eyes of 66 patients implanted with the Vivinex™ lens. In all eyes, Prof Menapace's team used a video clip at the end of surgery with the patient supine and still on the operating table to define the baseline meridional position of IOL in relation to fixed anatomical reference points, including scleral vessels and limbal vascular arcades.

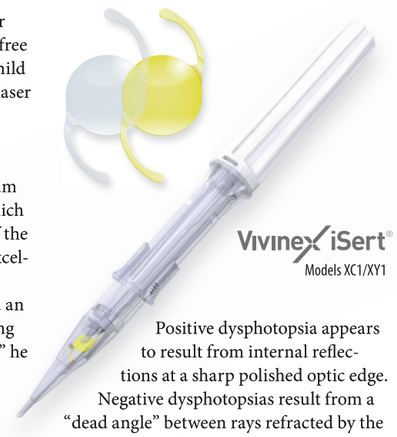
They used the same reference points in their follow-up photographs and used Photoshop software to calculate changes in the IOL's meridional position. They found that the mean amount of rotation occurring between the end of surgery and four to six months' follow-up, the mean amount of IOL rotation since surgery was still only 1.5 degrees and no eyes had more than five degrees of rotation.

UNDERSTANDING AND MINIMISING NEGATIVE DYSPHOTOPSIA

Modifying the optical properties of an IOL's optic edge may reduce the amount of dysphotopsia patients experience postoperatively, said Prof Achim Langenbucher PhD, Saarland University, Homburg, Germany.

Those which follow IOL implantation may be broken down into two main categories –positive dysphotopsia, which appear as bright arcs, stripes or rings, typically in the central or mid-peripheral visual field; and negative dysphotopsia, caused by light entering aberrantly from the temporal side and perceived as sickle or arc-shaped shadows.

Research indicates that IOL optic edge design is the main reason for dysphotopsia.

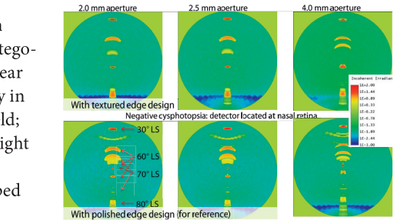


Positive dysphotopsia appears to result from internal reflections at a sharp polished optic edge.

Negative dysphotopsias result from a "dead angle" between rays refracted by the IOL and un-refracted grazing rays, or from rays refracted by the IOL's front surface exits partially via the optic edge and partially via the IOL's back surface.

Based on these findings, HOYA has designed the Vivinex™ IOL to have a textured optic edge to eliminate internal reflections and prevent positive dysphotopsia. It also has a thin optic edge to reduce the dead angle between refracted and direct rays and scatter the grazing rays through the translucent capsule to reduce the dysphotopic shadow. Texturing of the optical edge reduces negative dysphotopsia still further by scattering rays exiting the lens at the optic edge.

In optical simulations with the Vivinex™ lens, detectors at the nasal retina confirm that its optic edge design reduces both positive and negative dysphotopsia substantially compared to a lens with standard sharp polished edge. The simulations also showed that the lens is highly tolerant of decentration in terms of its modular transfer function.



HOYA Vivinex™ with textured optic edge shows less negative dysphotopisa than the reference lens with polished optic edge

Rupert Menapace MD, PhD
Medical University of Vienna, Austria

Gerd U. Auffarth MD, PhD
University of Heidelberg, Germany

Hiroyuki Matsushima MD, PhD
Dokkyo Medical University, Japan

Hiroko Bissen-Miyajima MD, PhD
Tokyo Dental College Suidobashi Hospital, Tokyo, Japan

Achim Langenbucher PhD
Saarland University, Homburg/Saar, Germany