THE NEW HOYA VIVINEX™ ISERT® IOL PLATFORM

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With the Vivinex™ intraocular lens (IOL), HOYA has developed a new IOL material platform that is intended to fulfill the following requirements and conditions:

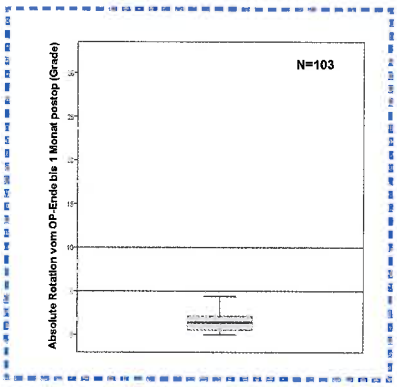
- Hydrophobic acrylate
- Glistening-free and biocompatible
- PCO inhibiting
- Robust and compressible (for safe implantation through incision size as small as 2.0mm)
- Fast and controlled unfolding inside the eye
- Stable anchoring of the IOL haptics in the capsular bag (for good predictability of the post-operative axial position and refraction with as little dispersion as possible)
- Minimization of aberrations caused by decentration and tilting (coma in particular)
- Rotational stability (as toric IOL)
- Compensation of inherent decentration and tilting of the capsular bag relative to the visual axis by IOL optic
- Sharp-edged, thin optic edge for inhibition of PCO and prevention of dysphotopsia and volume reduction
- Preloaded delivery of the IOL in a disposable injector system

What is particular about the new lens material is the special surface treatment with ozone and UV light, which creates a stronger adhesion of the IOL to the posterior capsule. In animal experimentation, this reduced the layer thickness of the lens epithelial cells in the space behind the lens by a quarter. In this way, the migration inhibiting effect of the sharp optic edge should be enhanced by a direct material effect hindering proliferation.

In the laboratory, the development of glistening, even under stress conditions, was negligible. Decentration and tilting had comparatively few negative effects on the image quality, and there are few cases of dysphotopsia at a diagonal light incidence.

During a pilot study in Japan on 30 eyes, only one YAG capsulotomy was required within three years postoperatively and two thirds of the eyes displayed a completely clear posterior capsular bag.

The new Vivinex™ IOL is currently undergoing systematic clinical testing at the University hospital in Vienna, encompassing all of the criteria previously mentioned. The rotational stability has already been measured exactly, from the end of the surgery on. The regenerative cataract is compared with market-leading IOLs in a bilateral benchmark study utilizing objective, automated scoring of high-quality retroillumination photographs. The indication for a possible YAG laser capsulotomy is standardized and the calculation of the capsulotomy rates is carried out in consideration of the failure of the treated eyes, using an algorithm developed specifically for this purpose. Fibrotic PCO and glistening are quantified using a subjective scoring process.



Rotation for 103 eyes < 5° (median 1,5 ± 1,2°)

We were able to certify an outstanding rotational stability to the Vivinex™ lenses: In over 100 eyes, no rotations of more than 5° were measured, with a median of 1.5 ± 1.2° (diagram 1). This is owed to the overall diameter and the haptic tension, such as the adhesive power and coarseness of the haptic surfaces. Right from the first week, the refraction remained stable. The target refraction was reached exactly, with an SD of 0.5 diopters. Most eyes developed a slightly diffuse fibrosis of the rhexis leaf with no shrinking tendency; no increase in lens epithelial cells on the IOL optic was observed. It is still too early for an assessment of the regenerative cataract; up to now, the posterior capsule has remained clear. The injector system is easy to use and works very well if filled with BSS or Ringer; it is activated in 3 steps, it is easy to guide into a 2.0 mm incision and the injection of the implant is very controlled. With gentle counterclockwise rotations, the proximal haptics can be maneuvered in one movement into the fornix of the capsular bag.

In summary, the iSert® injector system, preloaded with the Vivinex™ IOL, combines the possibility of swift, safe implantation in one movement into the capsular bag with highly promising implant performance that could set new standards in rotational stability and cataract prevention.

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