
INNOVATION DRIVES PERFORMANCE

Expert views on Vivinex[®] iSert[®] IOL

September 2016



HOYA
SURGICAL OPTICS

CONTENTS

Editorial

by R. Menapace, Vienna (Austria)

3

Analysis of the optical biomaterial purity of a new hydrophobic intraocular lens

by PR. Merz, Heidelberg (Germany), E. Friedmann, Heidelberg (Germany), G.U. Auffarth, Heidelberg (Germany)

4

Secondary cataract prevention to date: A history. Still a current issue.

by F. Lignereux, Nantes (France)

5

Surface modified IOL to prevent PCO – 4 years results with HOYA Vivinex®

by H. Matsushima, Dokkyo (Japan)

7

Advantages of blue light filtration – 2016 update

by C. Dot, Lyon (France)

8

The importance of incision structure and size in cataract surgery

by V. Guerzider, Nantes (France)

10

Rotational stability is key factor for Toric implanation success – New Vivinex® Toric platform preliminary rotational study results

by R. Menapace, Vienna (Austria)

11

Authors are solely responsible for scientific results published.
Authors have received consulting fees for their article.

EDITORIAL

Rupert Menapace, MD | Vienna (Austria)



The Vivinex® IOL is not just another new lens. It was conceived to fulfil the requirements of an optimal IOL platform:

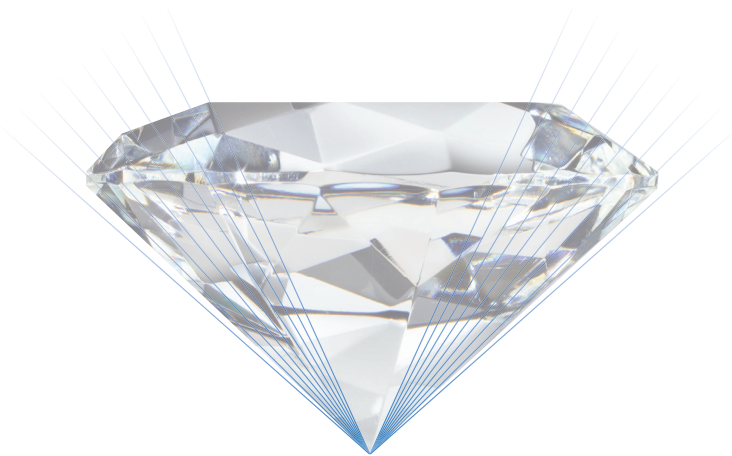
The material should be perfectly biocompatible, transparent and stable with no glistenings, resistant to damage when folded or compressed for injection through incisions of 2 mm and smaller, unfold smoothly but still fast enough, and effectively inhibit PCO formation

The haptics of the single-piece construction should allow for stable autocentration without inducing capsular ovalization or traction folds, easily adapt to varying capsular bag diameters, provide a broad contact

angle with the capsular bag equator for maximum rotational stability, and should be none-angulated for minimum axial movement when compressed by capsular shrinkage. The optic should provide perfect image quality and be forgiving with regard to decentration and tilt of the capsular bag, and its rim should minimize dysphotopsia while the posterior edge should be perfectly sharp to withhold LEC migration.

All that should be packed in a preloaded system which can be activated and the lens inserted in 3 simple movements. With the new Vivinex® IOL, HOYA has set out to meet these goals, and the following contributions shall mirror the clinical proof-of-concept.

Sabine M. Schrieffl, Christina Leydolt, Rupert Menapace. Rotational stability of a single-piece hydrophilic acrylic intraocular lens from end of surgery to 6 months postoperatively. British Journal of Ophthalmology (submitted)



ANALYSIS OF THE OPTICAL BIOMATERIAL PURITY OF A NEW HYDROPHOBIC INTRAOCULAR LENS



P. R. Merz
University Hospital Heidelberg,
Germany



E. Friedmann
University Hospital Heidelberg,
Germany



G. U. Auffarth
University Hospital Heidelberg,
Germany

INTRODUCTION

New Intraocular lenses (IOLs) have to meet a number of requirements to be successful on the market. Properties of a successful IOL include excellent biomaterial optical purity to guarantee long-term transparency, refractive reliability, stable foldability, pre-loaded delivery, excellent capsular bag performance and sharp edge technology for PCO prevention. The long-term transparency can be especially affected by various changes in the lens after implantation, including lens opacification, posterior capsule opacification, fibrosis and glistenings. Glistenings are fluid-filled microvacuoles that - depending on the IOL material - can form within the polymer matrix of the IOL when it is exposed to an aqueous environment^[1]. They have been reported in hydrophobic acrylic IOLs^[1,2-6].

To independently determine the optical purity of the IOL material from Vivinex® iSert® XY1 (HOYA) in comparison to CT LUCIA 601P (Zeiss), AcrySof SN60WF (Alcon), Tecnis ZCB00 (AMO), Avanssee PN6A (Kowa) and Aktis NS-60YG (Nidek) five IOLs of each model with a labelled power of +20.0 D were subjected to an accelerated *in vitro* glistening formation procedure^[1]. Glistenings were counted as microvacuoles MVs/mm² and the severity of glistenings was graded according to the Miyata Scale^[7].

ACCELERATED IN VITRO GLISTENING FORMATION PROCEDURE

The IOLs were immersed in saline at 45°C for 24h. Afterwards the temperature was reduced to 37°C using a water bath. The lenses were incubated at 37°C for 2.5h. Lens samples were subsequently analyzed and measured under the microscope using a digital camera. The evaluation of the number of glistenings was performed with the DT-Max iSolution (IMT i-Solution Inc., UK) image processing software. To the density we assigned a grade of glistenings severity according to the Miyata scale^[7]. IOLs with glistenings of grade 0 (< 50 MVs/mm²), IOLs with glistenings of grade 1 (> 50 MVs/mm² and < 100 MVs/mm²), IOLs with glistenings of grade 2 (> 100 MVs/mm² and < 200 MVs/mm²) and IOLs with glistenings of grade 3 (> 200 MVs/mm²).

RESULTS

Stereomicroscopic images (**Fig.1**) of all the study IOLs were taken immediately after incubation and the images were analyzed with image processing methods in the frame of the i-Solution software for calculation of total amount of microvacuoles within the lens material. These values were converted to MVs/mm² (**Fig.2**). The severity of the glistenings was graded according to the Miyata Scale^[7] (**Fig.1**).

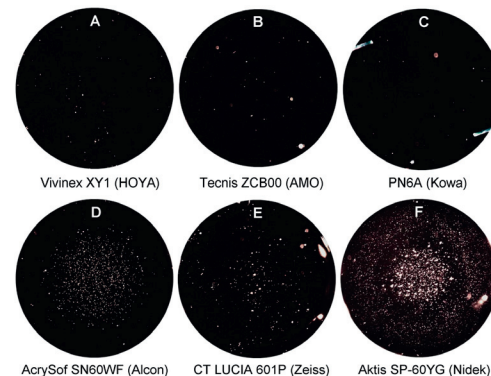


Figure 1: Microscopic images of representative IOLs after glistening induction
A: Vivinex® iSert® XY1 (HOYA) – Severity grade 0, B: Tecnis ZCB00 (AMO) – Severity grade 0, C: AvansseePreset PN6A (Kowa) – Severity grade 0, D: AcrySof SN60WF (Alcon) – Severity grade 2-3, E: CT LUCIA 601P (Zeiss) – Severity grade 0-1, F: Aktis SP NS-60YG (Nidek) – Severity grade 3+

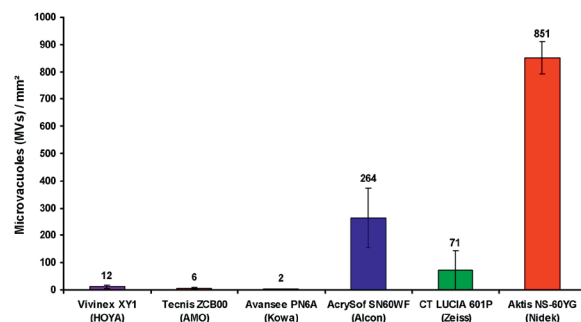


Figure 2: Mean Glistenings values measured in units of microvacuoles / mm² for each IOL type

The new Vivinex® iSert® XY1 lenses showed a very low number of glistenings (11.6 ± 5.7 MV/mm²) corresponding to severity grade 0 on the Miyata Scale and can therefore be claimed to be “glistening-free”. The Tecnis ZCB00 (8.0 ± 2.8 MV/mm²) as well as the PN6A (2.2 ± 0.7 MV/mm²) showed a comparable low number of glistenings as the Vivinex® iSert® XY1 IOLs and also correspond to severity grade 0 “glistening-free”. The CT LUCIA 601P (71.0 ± 71.6 MV/mm²) showed inconsistent results and in average referred to grade 0-1 on the Miyata Scale. The AcrySof SN-60WF (264.4 ± 110.3 MV/mm²) showed a significant number of glistenings and refers to grade 2-3 on the Miyata scale. The Aktis SP-60YG (851.4 ± 59.4 MV/mm²) had the worst performance with a severity grade 3+ on the Miyata scale.

The evaluation has been sponsored by HOYA.

1. Thoms BE, Callaghan TA. Evaluation of *in vitro* glistening formation in hydrophobic acrylic intraocular lenses. *Clin Ophthalmol*. 2013; 7:1529-34.
2. Ronbeck M, Behndig A, Taube M, Koivula A, Kugelberg M. Comparison of glistenings in intraocular lenses with three different materials: 12-year follow-up. *Acta Ophthalmol*. 2013; 91(1):66-70.
3. Miyata A, Yaguchi S. Equilibrium water content and glistenings in acrylic intraocular lenses. *J Cataract Refract Surg*. 2004; 30(8):1768-72.
4. Monestam E, Behndig A. Impact on visual function from light scattering and glistenings in intraocular lenses, a long-term study. *Acta Ophthalmol*. 2011; 89(8):724-8.
5. Dhaliwal DK, Mamalis N, Olson RJ et al. Visual significance of glistenings seen in the AcrySof intraocular lens. *J Cataract Refract Surg*. 1996; 22(4):452-7.
6. Werner L. Glistenings and surface light scattering in intraocular lenses. *J Cataract Refract Surg*. 2010; 36(8):1398-420.
7. Miyata A, Uchida N, Nakajima K, Yaguchi S. Clinical and experimental observation of glistening in acrylic intraocular lenses. *Jpn J Ophthalmol*. 2001; 45(6):564-9.

P. R. Merz | The David J Apple International Laboratory for Ocular Pathology, University Hospital Heidelberg, Im Neuenheimer Feld 400, 69120 Heidelberg, Germany

E. Friedmann | Institute of Applied Mathematics, University Hospital Heidelberg, Im Neuenheimer Feld 205, 69120 Heidelberg, Germany

Gerd U. Auffarth, MD, PhD is Chairman of the Department of Ophthalmology at the University of Heidelberg and Director of the International Vision Correction Research Center & David J. Apple Laboratory for Ocular Pathology in Heidelberg, Germany.

Professor Auffarth states that he has received research grants, travel expenses and lecture fees from HOYA. He has no financial interest in the product or in the company.

SECONDARY CATARACT PREVENTION TO DATE: A HISTORY. STILL A CURRENT ISSUE.

François Lignereux, MD | Nantes (France)



Secondary cataract corresponds to the crystalline posterior capsule opacification left in place after cataract surgery. This is known as posterior capsule opacification (PCO) and causes discomfort and low visual acuity following the surgical procedure. The incidence of PCO gives rise to a wide range of results and assessments.

Over the past 20 years or so, it has arisen between 28 to 38% after 3 to 5 years of postoperative evolution^[1-2]. Following a significant decrease before the 2000s, incidence has stabilized. It is still the primary complication of cataract surgery with clinical and economic issues.

PCO is caused by the multiplication and metaplasia of the remaining cells producing capsular fibrosis and Elschnig pearls. It increases over time. The advent of standardized phacoemulsification with meticulous cleaning of the capsular bag limits the quantity of posterior capsular residue and residual equatorial cells. The principal means of fight-

CONCLUSION

Using a methodology which is now well-established in our laboratory, we studied glistening in a number of hydrophobic lens models. Although *in vitro* analysis might provide an assessment of the tendency of a material to form glistenings, the correlation between *in vitro* test results and *in vivo* observations remains unclear^[1,3]. In recent years the demand is steadily increasing for highly-developed long-term transparency in IOL materials. In our *in vitro* study the new Vivinex® iSert® XY1 (HOYA) developed only a low number of glistenings and can therefore be termed “glistening-free”.

ing PCO is to limit the migration and proliferation of lens epithelial cells. The choice of the intraocular lens (IOL) is now the main factor in fighting PCO.

WHAT FACTORS INFLUENCE THE EXTENT OF PCO?

IOL geometry

The choice of a single-piece or three-piece IOL is a subject of debate in the incidence of PCO. The trend is to one-piece IOLs despite their lower resistance to haptic compression and reduced optic pressure on the posterior capsule.

Haptic angulation

Haptic geometry and angulation may improve the capsular bag tension and therefore create a better contact between the posterior capsule and IOL posterior side.

The 360° square-edge concept

This is the 1990s significant discovery and determining factor. Its effect was twofold: that of a physiological barrier through inhibition of contact preventing cell migration, and, just as important, the compression effect on the posterior capsule. The fast fusion of the two capsule layers creates a complete capsule folding at the edge of the IOL.

The IOL material

The choice of materials is between PMMA (almost obsolete for capsular bag implantation), silicone (less and less in use) and acrylics, including both hydrophilic and hydrophobic groups.

Hydrophobic acrylic is now recommended, due to its adhesive properties.

The sandwich theory developed by Linnola^[3] encompasses all prior concepts.

The combination of a square-edged hydrophobic acrylic IOL inserted into a capsular bag with a smaller capsulorhexis than the diameter of the optic isolates the interior of the bag from the aqueous humor. The optic is then pushed backwards by the bag's contraction, limiting migration and cell proliferation.

The hydrophobic IOL posterior side treatment

This treatment is intended to improve the PCO prevention concept and make a stronger adhesion between the posterior capsular and the treated posterior side of the hydrophobic IOL. The properties of the extracellular matrix adhesion proteins are exploited (particularly one of its proteins: fibronectin, which is a real biological glue). By

modifying the polar endings of the material surface, the IOL surface treatment increases capsular adhesion^[4].

This procedure has been tested in a study on rabbit eyes implanted with argon plasma irradiated surface IOL. This method was associated with an etching effect that can promote IOL surface deterioration and less effective results in preventing PCO formation than UV-Ozone treatment^[4].

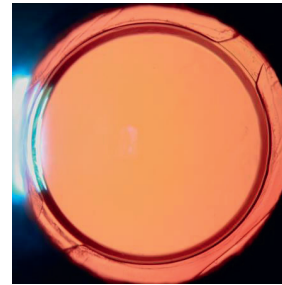


Image 1: Total absence of PCO 10 months after surgery with HOYA Vivinex® IOL (F. Lignereux)

More recently, HOYA has patented UV-Ozone treatment developed by Pr Matsushima^[4] to increase in the affinity of the treated posterior IOL surface for proteins adhesion. The Vivinex® IOL, single-piece hydrophobic acrylic with 360° square edges has benefited from this treatment.

As a user of the Vivinex® IOL since 2015 when available on the French market, I can attest its effectiveness in preventing secondary cataract as shown in the retro-illumination picture taken 10 months after surgery.

CONCLUSION

Minimizing the incidence of PCO can only be envisaged with high-quality surgery and capsular bag implantation. The choice of the IOL, in terms of material, design and improved biocompatibility (a recent factor in improvement), is an overriding element in this quest.

1. Schaumberg DA, Dana MR, Christen WG, Glynn RJ. A systematic overview of the incidence of posterior capsule opacification. *Ophthalmology*. 1998 Jul;105(7):1213-21.

2. Fong CS, Mitchell P, Rochtchina E, Cugati S, Hong T, Wang JJ. Three-year incidence and factors associated with posterior capsule opacification after cataract surgery: The Australian Prospective Cataract Surgery and Age-related Macular Degeneration Study. *Am J Ophthalmol*. 2014 Jan;157(1):171-9.

3. Linnola RJ. Sandwich theory: bioactivity-based explanation for posterior capsule opacification. *J Cataract Refract Surg*. 1997 Dec;23(10):1539-42.

4. Matsushima H et al. Active Oxygen processing for acrylic IOL to prevent PCO. *J Cataract Refract Surg*. 2006; 32:1035-40.

François Lignereux, MD | Polyclinique de l'Atlantique – Nantes (France).

Dr Lignereux has received travel expenses and lecture fees from HOYA. He has no financial interest in the products or the company.

SURFACE MODIFIED IOL TO PREVENT PCO – 4 YEARS RESULTS WITH HOYA VIVINEX®



Hiroyuki Matsushima, MD, PhD | Dokkyo Medical University, Tochigi (Japan)

Square edge is effective for the prevention of secondary cataracts. However, long-term prevention of 5 years or longer is often difficult to achieve. Therefore, other concepts are required for the long-term prevention of secondary cataracts. Vivinex® iSert® (XY-1, HOYA) is a square edge IOL made of a new hydrophobic acrylic material with grade zero glistening and surface scattering. It is a new type of intraocular lens (IOL) with the added value of preventing secondary cataracts applying not only on square edge but also on surface modification.

Surface modification refers to a technique that imparts a new function exclusively to the material surface through chemical reactions and coating of the material surface to increase the overall value of the material. UV/ozone-treated Vivinex® iSert® successfully increased adhesion between the IOL and the posterior capsule of the lens. The UV/ozone (ultraviolet lights of two different wave lengths) irradiation produces active species and thereby introduces oxygen-containing functional groups such as OHCOOH groups on the material surface, which enhance protein adsorption and cell adhesion (Figure 1). The processed IOL

shows an increased level of adhesion to the posterior capsule of the lens via fibronectin and lens epithelial cells, preventing lens epithelial cells remaining around the IOL from growing and extending toward the posterior capsule of the lens. The efficacy and *in vivo* safety of this surface modification in the prevention of secondary cataracts was repeatedly verified in animal experiments before a clinical trial was conducted.

Figure 2 shows the clinical trial results at the fourth year after the operation in 30 patients with Vivinex® iSert® inserted in one of their eyes and the control devoid of any surface modification in the other eye. The results showed that virtually no YAG laser posterior capsulotomy was made in the Vivinex® iSert® eyes, while 65.3% of the control eyes underwent YAG capsulotomy the demonstrating high efficacy in preventing secondary cataracts. In the future, it is anticipated that this new technology will be applied not only to single-focus IOL, but also to value-added IOL, such as toric and multifocal IOLs.

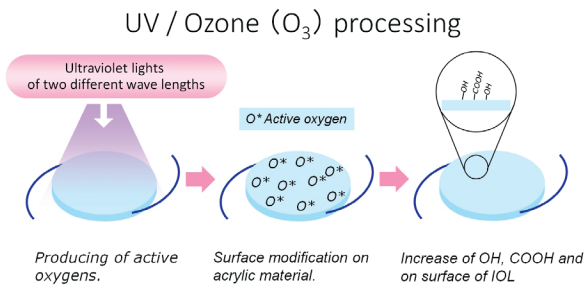


Figure 1

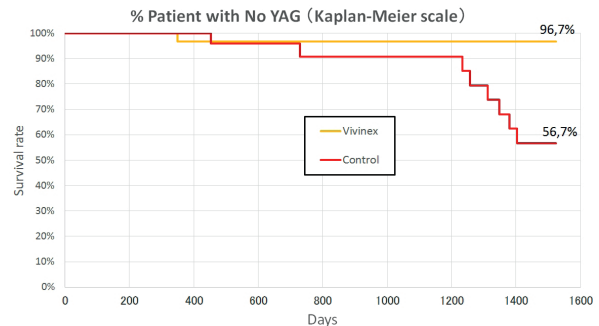


Figure 2

Hiroyuki Matsushima, MD, PhD | Dokkyo Medical University, Tochigi (Japan)

Professor Matsushima has received travel expenses and lecture fees from HOYA. He has no financial interest in the products or the company.

ADVANTAGES OF BLUE LIGHT FILTRATION – 2016 UPDATE

Corinne DOT, MD, PhD | Lyon (France)



The phototoxicity of blue light (BL) is a topic which emerged in ophthalmology in the 2000s, with the arrival on the market of the first yellow IOL to filter part of the BL transmitted to the retina. Since then literature has brought us significant steps forward in basic and clinical research for better understanding of ocular protection interest.

What is blue light? BL corresponds to the beginning of the visible light spectrum, which enables us to perceive the world around us in colour. The wavelengths of the visible light spectrum go from 400 nm to 700 nm, with BL corresponding to a window around 400–500 nm (between ultra-violet and green light) [Fig. 1].

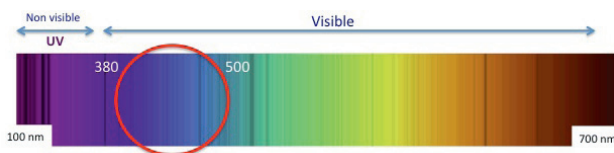


Figure 1: Electromagnetic light spectrum, with BL corresponding to the 380–500 nm window (red circle)

In everyday life, we are exposed to this BL essentially through the sun’s rays, including within vehicles. LED lighting is another source of BL (ambient lighting, electronic devices), although these sources have a much lower luminance compared with the sun (ratio of 2 to 100)⁽¹⁾⁽²⁾.

What is the current data on the chronic retinal phototoxicity of BL? The phototoxicity of type II BL, still known as “blue-light hazard”, damages retinal pigment epithelium (RPE) cells, mediated by RPE lipofuscin chromophores (A2E), which peak of absorption is 430–440 nm⁽³⁾⁽⁴⁾⁽⁵⁾. More recent work has shown that the maximum phototoxicity on the RPE observed *in vitro* is for wavelengths of 415 to 455 nm⁽⁶⁾. As such, we are confronted with phototoxicity from the beginning of the BL spectrum.

While BL may be toxic, it is nonetheless useful! Thanks to the melanopsin containing ganglion cells (GC) discovered in 2002 (2% of our GCs), the eye is considered to be a light sensor which is sensitive to a wavelength of 480 nm (end of the blue spectrum). Their cerebral projections do not go through visual anatomic routes and concern cerebral structures involved in sleep, awareness, mood, synchronisation of the biological clock, pupillomotor reflex...⁽⁷⁾⁽⁸⁾ The naturally yellow tint of the aging crystalline lens ensures such selective protection for our retina: it partially

blocks ‘toxic’ BL at the beginning of the spectrum and instead transmits ‘useful’ BL from the end of the spectrum.

What happens when we perform cataract surgery on a patient? We remove the yellow crystalline lens, which is natural protection for the retina. The majority of BL is then transmitted to the retina if a white UV-blocking IOL is chosen. This effect is described in British literature by the expression “dramatic change in ocular transmittance in pseudophakic eyes” [Table 1].

Transmission to the retina	UV	BL
Phakic adult (60 years old)	1–2%	40%**
Phakic child	5%	65%**
Aphakia	40 % ↑	95% ↑
Pseudophakic IOL without blue filter	<5%	95% ↑
Pseudophakic Yellow IOL	<5%	26 to 50 % at 430 nm* ↓

Table 1: Transmission of UV light and BL to the retina according to the age and state of the crystalline lens**⁽⁹⁾

*variable transmission of 430 nm rays depending on yellow IOL models, according to manufacturer information (e.g.: Hoya Vivinex XY1: 26%, Alcon SN WF: 29%, Croma Eyecee one 45%).

In addition, the transmission curves of BL to the retina are not strictly super-imposable between all different IOL, and as such, the level of retinal protection may vary depending the IOL chosen⁽¹⁰⁾. This information is confirmed and illustrated in the curves of figure 2.

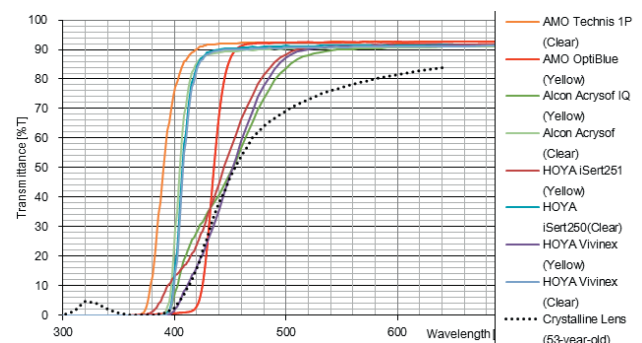


Figure 2: Percentage of light transmitted through an IOL depending on the wavelength (Hoya R&D information reprinted with permission). We can see that BL transmission curves for the Vivinex® IOL (purple curve) and for a 53 year-old crystalline lens (dotted) are super-imposable around the “toxic” 430 nm +/- 20 nm area, showing the excellent profile and quality of retinal protection of this IOL. Transmission of the end of the spectrum (around 480 nm), light which is “useful” for cognitive functions and circadian rhythm is also very well respected.

What is the clinical impact of a yellow IOL on the retina?

To date no prospective study has been carried out in order to demonstrate the presumed protective effect of a yellow IOL on age-related macular degeneration. A prospective randomised Japanese study is starting in Japan. The AREDS study (report 25) sowed doubts in 2009 by concluding a lack of obvious effect of cataract surgery on the risk of progression towards AMD⁽¹¹⁾. There are many confusing factors regarding this subject, in particular, the assessment of exposure to the sun, food, genetics... And other clinical studies have shown contradictory results⁽¹²⁻¹⁵⁾.

Wang et al. reported increased pigment epithelial damage and drusen in the operated eye in a study on 1244 pairs of eyes over 3 years⁽¹⁶⁾. Nagai et al. reported a decrease in the progression of autofluorescence and progression towards AMD among patients at 2 years implantation with yellow IOL in a smaller number of patients⁽¹⁷⁾.

Furthermore, fundamental *in vitro* and *in vivo* information shows consistent factors to support this hypothesis. *However, it must be remembered that the cumulative dose of toxic rays is certainly variable from one subject to the another and that it is reached following several years of exposure. As such, it seems important to consider the age of the IOL and each patient's ocular risks factors on a case by case basis when choosing IOL.*

Finally, a recent review of the literature by Davison et al. concludes that yellow IOL does not negatively impact visual acuity, colour vision, night vision, circadian rhythm, sleep quality, contrast vision or glare⁽¹⁸⁾. These reassuring results on performances in the cognitive sphere are once again consistent with existing knowledge: the transmission spectrum of yellow IOL respects the wavelength transmission of 480 nm (useful BL).

CONCLUSIONS

Recent findings enabled us to establish an array of positive presumptions for yellow IOL in favour of macular protection following cataract surgery, even more in case of early surgery and long life expectancy. This information is to be taken into account specifically as cataract refractive surgery increases among patients undergoing surgery at a younger age.

- [1] Wachler BS. Assessment of levels of ultraviolet A light protection in automobile windshields and side windows. *JAMA ophthalmol.* 2016. doi:10.1001/jamaophthalmol.2016.1139
- [2] Renard G, Leid J. The dangers of blue light : true story I *J Fr Ophthalmol.* 2016 ;39(5):483-8.
- [3] Sparrow JR, Nakanishi K, Parish CA. The lipofuscin fluorophore A2E mediates blue light-induced damage to retinal pigmented epithelial cells. *Invest Ophthalmol Vis Sci.* 2000;41(7):1981-9.
- [4] Ruffolo JJ Jr, Ham WT Jr, Mueller HA, Millen JE. Photochemical lesions in the primate retina under conditions of elevated blood oxygen. *Invest Ophthalmol Vis Sci.* 1984 ;25(8):893-8.
- [5] Ham WT Jr, Mueller HA, Ruffolo JJ Jr, Guerry D 3rd, Guerry RK. Action spectrum for retinal injury from near-ultraviolet radiation in the aphakic monkey. *Am J Ophthalmol.* 1982 ;93(3):299-306.
- [6] Arnault E, Barrau C, Nanteau C, Gondouin P, Bigot K, Viénot F, Gutman E, Fontaine V, Villette T, Cohen-Tannoudji D, Sahel JA, Picaud S. Phototoxic action spectrum on a retinal pigment epithelium model of age-related macular degeneration exposed to sunlight normalized conditions. *PLoS One.* 2013 ; 23;8(8):e71398.
- [7] Gronfier C. Consequences and physiological effects of light - sleep and biological clock in night and shift work. *Arch. Mal.Prof Environ.* 2009 ; 70,253-261.
- [8] Hattar S, Kumar M, Park A, Tong P, Tung J, Yau KW, Berson DM. Central projections of melanopsin-expressing retinal ganglion cells in the mouse. *J Comp Neurol.* 2006 ; 20;497(3):326-49.
- [9] Behar-Cohen F1, Martinson C, Viénot F, Zissis G, Barlier-Salsi A, Cesarini JP, Enouf O, Garcia M, Picaud S, Attia D. Light-emitting diodes (LED) for domestic lighting: any risks for the eye? *Prog Retin Eye Res.* 2011;30(4):239-57.
- [10] Tanito M, Okuno T, Ishiba Y, Ohira A. Transmission spectrums and retinal blue-light irradiance values of untinted and yellow-tinted intraocular lenses. *J Cataract Refract Surg* 2010; 36 :299-307.
- [11] Chew EY, Sperduto RD, Milton R et al. Risk of advanced age-related macular degeneration following cataract surgery in the age-related eye disease study. *Ophthalmology.*2009 ;116(2) : 297-303.
- [12] Sui GY, Liu GC, Liu GY, Gao Y, Deng Y, Wang WY, Tong SH, Wang L. Is sunlight exposure a risk factor for age-related macular degeneration? A systematic review and meta-analysis. *Br J Ophthalmol.* 2013;97(4):389-94.
- [13] El Chehab H, Blein JP, Herry JP, Chave N, Ract-Madoux G, Agard E, Guarracino G, Swalduz B, Mourgues G, Dot C. Ocular phototoxicity and altitude among mountain guides. *J Fr Ophthalmol.* 2012;35(10):809-15.
- [14] Taylor HR, West S, Muñoz B, Rosenthal FS, Bressler SB, Bressler NM. The long-term effects of visible light on the eye. *Arch Ophthalmol.* 1992;110(1):99-104
- [15] Wang JJ, Klein R, Smith W et al. Cataract Surgery and the 5-Year Incidence of Late-Stage Age-Related Maculopathy Pooled Findings from the Beaver Dam and Blue Mountains Eye Studies. *Ophthalmol.* 2003;110:1960 -1967
- [16] Wang JJ, Fong C, Rothchina E et al. Risk of Age-related Macular Degeneration 3 Years after Cataract Surgery: Paired Eye Comparisons. *Ophthalmol.* 2012;119:2298-2303.
- [17] Nagai H, Hirano Y, Yasukawa T. Prevention of increased abnormal fundus autofluorescence with blue light-filtering intraocular lenses. *J Cataract Refract Surg* 2015; 41:1855-1859.
- [18] Davison JA, Patel AS, Cunha JP, Schwiegerling J, Muftuoglu O. Recent studies provide an updated clinical perspective on blue light-filtering IOLs. *Graefes Arch Clin Exp Ophthalmol.* 2011;249(7):957-68.

Corinne DOT, MD, PhD | Professor at the French military health service Academy - Val de Grâce - Paris
Head of the Ophthalmology department -Desgenettes military hospital - Lyon (France)

Links of interest: consultant with Alcon, Allergan, Bayer, Novartis, Hoya. Professor Dot has received travel expenses and lecture fees from HOYA. She has no financial interest in the products or the company.

THE IMPORTANCE OF INCISION STRUCTURE AND SIZE IN CATARACT SURGERY

Vincent Guerzider, MD | Nantes (France)



For several decades, incisions made in cataract surgery have been getting smaller and their architecture has also changed. The ideal incision must be sealed during the procedure to maintain the stability of the anterior chamber as well as to reduce the risk of endophthalmitis after surgery, also to allow intraoperative manoeuvrability and induce as less astigmatism as possible. These elements will be determined by the size, location, architecture and integrity of the incision during the cataract removal phases (vulnerability through mechanical or thermal actions) and then during implantation.

SIZE OF THE INCISION

Over time size has reduced from 6 mm to 3 mm, and nowadays mini-incisions are approximately 2.5 mm and micro-incisions less than 2 mm are possible. The majority of surgeons operate through 2.2 mm incisions. Improvements in coaxial phacoemulsification made surgery possible with less than 2 mm incision but for incisions under 1.8 mm, biaxial phacoemulsification must be used (infusion and ultrasounds produced by two different probes). Biaxial surgery has even been carried out with incisions of 0.7 mm^[1]. However, despite some advantages, biaxial phacoemulsification is still less frequently used than micro-coaxial for several reasons: a substantial learning curve; the stability of the anterior chamber (and therefore intraoperative safety) is more difficult to achieve with this method; specific instruments are required (capsulorhexis forceps with distal opening) or requiring cystitome capsulorhexis to be carried out (more difficult); and the duration of the operation is longer^[2]. But most of all, the implantation requires enlarging the initial incision since current IOLs are not adapted to incisions smaller than 1.4 mm.

Incision size will determine the surgically induced astigmatism (SIA) and therefore will determine postoperative refraction. Numerous publications on SIA compare different incision locations and use various calculation methods, making it difficult or even impossible to compare the results. It is therefore difficult to provide precise figures, but it is accepted that the smaller the incision, the lesser the degree of the astigmatism. The average SIA figures are 0.76 D for 3.2 mm clear corneal incisions, 0.25 D for 2.2 mm incisions and 0.18 D for 1.8 mm incisions.

But SIA does not only depend on the size of the incision. In addition to intraoperative manoeuvres (it is not only the initial size of the incision that determines its integrity, but also the distortion of it during surgery^[3] and wound heal-

ing, SIA also depends upon the location and architecture of the incision.

LOCATION OF THE INCISION

This impacts significantly SIA. Superior area incisions result in the greatest astigmatism, followed by superotemporal, nasal, superonasal and finally temporal incisions being the least astigmatogenic, as they are the furthest from the corneal apex^[4]. Furthermore, temporal incisions result in fewer high-order optical aberrations (coma and trefoil) than superior incisions^[5].

ARCHITECTURE OF THE INCISION

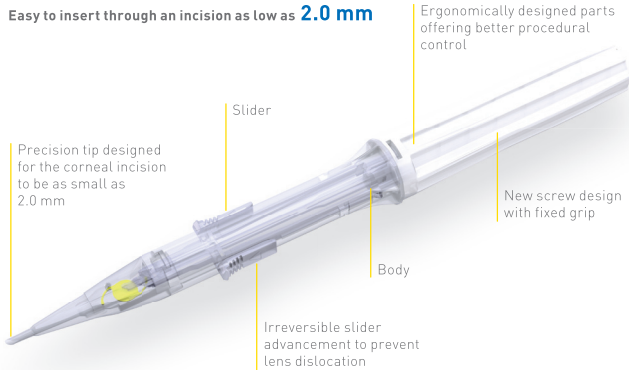
Using horizontal and vertical cutting portions, multi-plane incisions are supposed to increase resistance to leakage during surgery, and coaptation of these different planes is supposed to reduce the risk of endophthalmitis. The short nature and bad construction of the incision are factors that determine the risk of endophthalmitis^[6]. Several studies have investigated the architecture of incisions. Results are difficult to compare due to the number of parameters involved (size, location of the incision, whether or not a phaco probe sleeve is used, type of phaco handpiece tip needle, etc.). The studies use primarily anterior segment OCT. They measure the epithelial and endothelial gap, change in the alignment of the roof and floor of incision endothelial side, potential Descemet's membrane detachment and coaptation of the incisional tunnel. A slight endothelial gap is often found, with no clinical repercussions, regardless of the surgical technic used^[7].

FEMTOSECOND LASER

Using surgical calibrated knives with reference points enables the procedure to be reproducible and allows the incision tunnel to be calibrated during "manual" surgery. However, although the advantages of using the femtosecond laser for cataract surgery have not yet been proven, it does clearly make it possible to make incisions of the perfect size (in length and width), very precise architecture (on three perfectly-defined planes) and suitable location on any axis. In spite of this precision and reproducibility capacity, there is no difference in SIA when we compare manual clear corneal incisions made by an experienced surgeon with the same type of incisions made using a femtosecond laser^[8].

Furthermore, **THE IMPLANTATION**, source of incisional trauma, is a major part of the procedure. Preloaded IOLs are relatively new. They are mechanically reliable, reduce handling errors, are microbiologically safe and save time. Until recent time, it was still difficult to have preloaded hydrophobic IOLs available for small incisions with all the aforementioned here listed advantages of small incisions. For the most part, preloaded systems are now adapted for 2.2 mm incisions or even less, such as the HOYA Vivinex®

Hydrophobic IOL in a preloaded system for implantation starting at 2.0 mm. After quick and simple handling to prepare the preloaded iSert® system, the cartridge tip is fully inserted into the anterior chamber to avoid any concerns about wound implantation. A minimal incision stretch may occur but it remains fully sealed at the end of the procedure. The implantation effects on the incision are therefore perfectly managed and reproducible.



- New iSert® offers easy handling and a better surgical comfort
- Very small incision size reduces the risk of surgically-induced astigmatism

1. Agarwal A. Microphacoit: cataract surgery with a 0.7 mm tip. In: Sachdev MS, Sethi HS, Gadia R, Agarwal A, Dada T, eds. *Techniques of Cataract Surgery*. New Delhi, India, Jaypee Brothers, 2007; 242-248.
2. Can I, Takmaz T, Yildiz Y, Bayhan HA, Soyugelen G, Bostanci B. Coaxial, microcoaxial, and biaxial microincision cataract surgery: prospective comparative study. *J Cataract Refract Surg*. 2010;36:740-6.
3. Vaishali Vasavada, Abhay R. Vasavada, Viraj A. Vasavada, Samaresh Srivastava, Devarshi U Gajjar, Siddharth Mehta. Incision integrity and postoperative outcomes after microcoaxial phacoemulsification performed using 2 incision-dependent systems. *J Cataract Refract Surg*. 2013; 39: 563-571.
4. Dewey S, Beiko G, Mele B, Nixon D, Raviv T, Rosenthal K. Microincisions in cataract surgery. *J Cataract Refract Surg*. 2014; 40: 1549-1557
5. Song IS, Park JH, Park JH, Yoon SY, Kim JY, Kim MJ, Tchah H. Corneal coma and trefoil changes associated with incision location in cataract surgery. *J Cataract Refract Surg*. 2015; 41: 2145-51
6. Belazzougui R, Dupont Monod S, Baudouin C, Labbé A. Analyse architecturale des incisions cornéennes par OCT Visante® au cours des endophtalmies aiguës après chirurgie de la cataracte. *J Fr Ophthalmol*. 2010; 1: 10-15.
7. Dupont-Monod S, Labbé A, Fayol N, Chassignol A, Bourges JL, Baudouin C. *In vivo* architectural analysis of clear corneal incisions using anterior segment optical coherence tomography. *J Cataract Refract Surg*. 2009; 35: 444-450.
8. Vasilios F, Diakonis, Nilufer Yesilirmak, Florence Cabot, Vardhaman P, Kankariya, George A, Kounis, Daniel Warren, Ibrahim O, Sayed-Ahmed, Sonia H, Yoo, and others. Comparison of surgically induced astigmatism between femtosecond laser and manual clear corneal incisions for cataract surgery. *J Cataract Refract Surg*. 2015; 41: 2075-2080

Vincent Guerzider, MD | Polyclinique de l'Atlantique – Nantes (France).

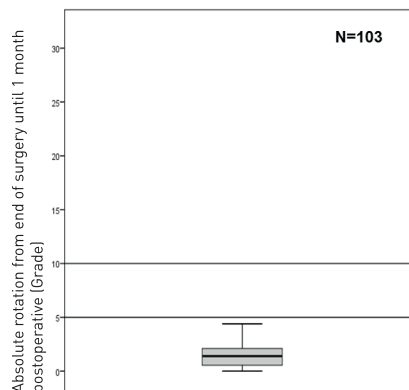
Dr Guerzider has received travel expenses from HOYA.

ROTATIONAL STABILITY IS KEY FACTOR FOR TORIC IMPLANATION SUCCESS – NEW VIVINEX® TORIC PLATFORM PRELIMINARY ROTATIONAL STUDY RESULTS



Rupert M. Menapace, MD | Vienna (Austria)

One clock hour of misalignment with regard to the steep corneal meridian annihilates the corrective power of a toric IOL (TIOL). Perfect assessment of and TIOL positioning on the target axis are prerequisites for obtaining optimum astigmatic correction. However, rotational stability once positioned in the capsular bag is another key parameter. Publications disregard early positional changes during the first hour, day, or even week.



Therefore, we conducted a series of rotational studies with various IOLs assessing the change of meridional IOL position from the very end of surgery to one hour, (one day), one week and 3-6 months^[1]. The haptic insertions were used as reference marks on the IOL, and fixed scleral vessels as references on the globe. Zero-degree video recording and retroillumination photography were used for imaging, and Photoshop software for evaluation.

The Vivinex® IOL was the only one IOL that did not show a single case of secondary rotation greater than 5° during 3-6 months overall, with a mean amount of only 1.5 ± 1.2°. Other IOL brands revealed secondary rotation of greater than 10° in 3 up to 10% of the cases, which translates into a one third loss in corrective power. In cases, IOLs rotated by more than 30° and 40°, resulting in complete failure of correction or even induction of astigmatism in another axis. The most frequent and pronounced rotations and specifically outliers occurred during the first hour, the time window not considered by publications.

In summary, true rotational stability is a key issue with TIOs; published material largely disregards early rotation; our studies have shown that rotations predominantly occur during the first hour after surgery; surgeons and patients should be aware and informed about the likelihood and specific incidence of clinically significant rotation of every TIO brand; if rotational outliers are known to occur with a specific brand, every patient must be called about 2 weeks after surgery to rule out such rotation and allow for surgical correction before the IOL is fixed in a fibrosed capsular bag.

1. Rotational stability of a single-piece hydrophilic acrylic intraocular lens from end of surgery to 6 months postoperatively. Sub-Title: Most IOL rotation happens in the first hour after surgery, indicating that previous studies with a baseline at 1 hour or later may underreport IOL rotation. Authors: Sabine M. Schrieff, Christina Leydolt, Rupert Menapace; British Journal of Ophthalmology

Rupert M. Menapace, MD | Ophthalmologist and Eye Surgeon. Chief Surgeon at the Department of Ophthalmology & Optometry, Medical Director of the "Outpatient Cataract Surgery Unit", Head of the "Cataract & Intraocular Lens Service", University of Vienna Medical School (MUW, www.meduniwien.ac.at), Vienna General Hospital ("Allgemeines Krankenhaus", AKH).

Professor Menapace has received travel expenses and lecture fees from HOYA. He has no financial interest in the products or the company.

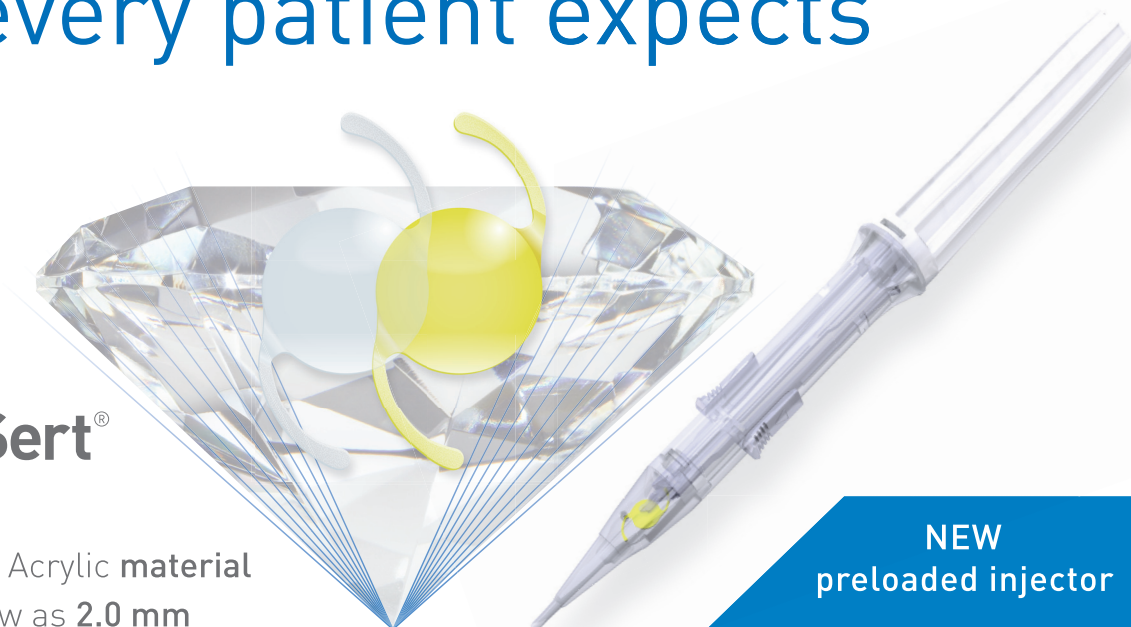
Long-term quality of vision is what every patient expects

Vivinex[®] iSert[®]

Models XC1/XY1

New Hydrophobic Acrylic material

Incision size as low as **2.0 mm**



**NEW
preloaded injector**

Singularly Focused. Globally Powered.™

Some of the products and/or specific features as well as the procedures featured in this document may not be approved in your country and thus may not be available there. Design and specifications are subject to change without prior notice as a result of ongoing technical development. Please contact our regional representative regarding individual availability in your respective market. The trademarks and logos used in this document are the property of HOYA Surgical Optics or the respective owner.

©2016 HOYA Surgical Optics. All rights reserved.

HOYA
SURGICAL OPTICS