OPHTHALMO CHIRURGIE

Supplement
No. 3/2018

Kaden Verlag

An innovative concept as the standard of tomorrow?

ASPIRA-aXA: product launch of a novel IOL with a 7 mm optic

→ How can patients, as well as surgeons, benefit from an intraocular lens (IOL) with an enlarged optic? And how stable is a lens with specially designed cut-out haptics in the capsular bag? These, and additional topics, were discussed at this year's DOC-Symposium held by HumanOptics AG. Next to moderator Professor Manfred Tetz, MD (Berlin, Germany), highly recognized experts met to share their first clinical experience following implantation of the new ASPIRA-aXA IOL.

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Figure 1: Professor Matthias Bolz (Linz, Austria), Professor Manfred R. Tetz (Berlin, Germany), Anja Liekfeld, MD (Potsdam, Germany), and Professor Gernot I. W. Duncker (Halle, Germany) during the Symposium.

XL optic in a preloaded system

At the beginning of the scientific event, M. Tetz introduced the design of the ASPIRA-aXA. The monofocal one-piece posterior chamber lens is made of a glistening-free hydrophilic acrylate and manufactured 100 % in Germany. The lens has an aberration-free aspheric optic and a total diameter of 11.0 mm. Currently, the ASPIRA-aXA is available from 10 to 30 D (in 0.5 D steps). M. Tetz explained that the IOL has two innovative design features: its enlarged 7.0 mm optic diameter that offers numerous advantages and applications from standard cataract surgery to combined phaco-vitrectomy procedures, and the special cut-out haptic design that provides the best conditions for high stability and predictable refractive results. Due to the wide-open area (gap) within the haptic, the lens "does not present as rigid and bulky", instead it is flexible and fits well into the capsular bag, said M. Tetz. The innovative design also allows small incisions between 2.0 mm and 2.7 mm, depending on the implantation technique. Finally, and particularly relevant for a surgeon, the IOL comes already preloaded in the Safeloader® system supplied by HumanOptics. The lens is stored in its container separately from the injector to ensure minimum contact with the cartridge coating. Just prior to surgery, an easy rotary motion loads the IOL from the container into the injector. This system is intuitive, with maximum handling simplicity.

High stability provided by cut-out haptics

As emphasized by Professor Gernot I. W. Duncker, MD (Halle, Germany), the new haptic design combines the flexibility of a C-loop haptic with the stability of a plate haptic. The ASPIRA-aXA has a quattro point contact zone aimed at providing good centration and stability within the capsular bag. The early prospective clinical results presented by G. Duncker corroborated this assumption. After implantation of the ASPIRA-aXA (provided with markings) the mean absolute rotation from end of surgery to three months postoperatively was only 1.8° ± 2.0. The refractive results were extremely satisfactory (mean spherical equivalent: -0.04 ± 0.47 D) and close to the desired target refraction (-0.02 ± 0.15 D). No patient reported any disturbing light phenomena after implantation.

A possible solution for pseudophakic dysphotopsia?

ASPIRA-aXA finally may offer a solution regarding dysphotopsia, said G. Duncker. Using simulated beam paths through the optical system of the hu-

man eye, he explained how an IOL with a 7.0 mm optic can reduce the incidence of positive and negative dysphotopsia compared to a standard 6.0 mm optic. Interfering light phenomena are caused, among other things, by multiple reflections at the IOL optical edge. Depending on the angle of incidence, incoming light is either not interrupted and passes by the optic edge, or is scattered at the edge of the lens, even in small pupils. Due to the enlarged lens optic, less scattering phenomena are to be expected even in large pupils. G. Duncker recommended implanting ASPIRA-aXA in the second eye, if the patient already suffers from pseudophakic dysphotopsia. If that second eye then does not perceive light phenomena postoperatively, he would suggest a lens exchange with ASPIRA-aXA in the first eye.

Figure 2: ASPIRA-aXA

Panoramic view of the fundus

Based on impressive fundus images after implantation of ASPIRA-aXA, Professor Matthias Bolz, MD (Linz, Austria) explained why he calls the lens "panoramic IOL". Funduscopy through the enlarged IOL optic reveals a panoramic view, up to the outermost edge of the retinal periphery. In general, vitreoretinal diseases often develop concurrently with cataract in advanced age. Thus, M. Bolz believes that ASPIRA-aXA will play a significant role in the future, especially in hybrid surgery such as combined phaco-vitrectomy. He would implant the lens even in patients with increased risk of retinal diseases since the implementation of therapeutic measures, especially in peripheral retinal diseases, is made much easier by the enlarged view of the fundus. Therefore, this view with the "panoramic IOL" is not only relevant for funduscopy but also in diagnostics such as fluorescein angiography and retinal surgery. Next to his study results, the speaker presented two cases which were not included in the study. Both were implantations of the XL-optic followed by vitrectomy. This presentation emphasized the advantage of the panoramic view, as the surgeon did not have to look next to the optic edge to see the outer periphery. M. Bolz described his implantation technique consisting of a large capsulorrhexis (between 5.7 and 6.5 mm) and a smooth and steady implantation through an incision size of 2.4 mm using the Safeloader autoloading system. In addition to his own first study data, with excellent results in terms of rotational stability and postoperative refraction, M. Bolz also presented the clinical results of Eckhard Becker, MD (Oranienburg, Germany). E. Becker has the longest clinical experience with the lens and has carried out more than 500 implantations since the CE marking of the ASPIRA-aXA in 2016. In a prospective randomized post-market follow-up study with currently 65 eyes per group, E. Becker compared the performance of the ASPIRA-aXA with that of a 6.0 mm optic IOL with C-loop haptics. The results showed that three months postoperatively, visual outcomes and contrast sensitivity under different lighting conditions were very good and not significantly different

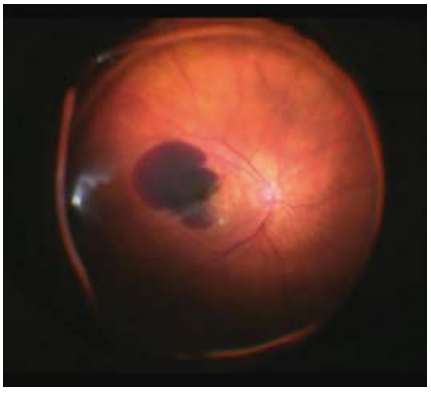

Figure 3: Vitrectomy with ASPIRA-aXA

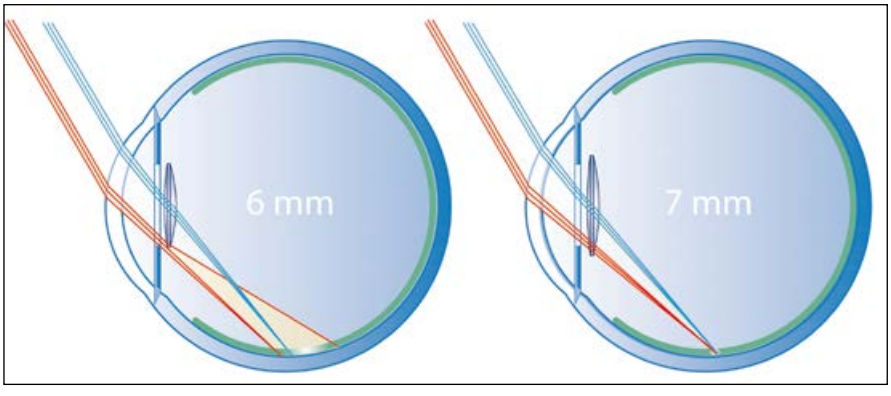

Figure 4: Simulated beam paths at an angle of 60° and a pupil size of 6 mm where beams pass the 6 mm IOL or get scattered at its edge (left); beams are refracted even at the edge of the 7 mm IOL (right).

between the groups. However, in terms of photic disturbances, significantly lower glare sensitivity and lower incidence of negative dysphotopsia were found in the ASPIRA-aXA group compared to the control group. No intra- and postoperative complications were reported, and in both study centers (Linz and Oranienburg) the levels of patient satisfaction were high.

Traumatic mydriasis as a special indication

An illustrative case presentation was given by Anja Liekfeld, MD (Potsdam, Germany) at the end of the session. An 82-year-old male patient with a cataract in the right eye suffered from contusio bulbi due to a sports accident in 1992, resulting in a traumatic mydriasis without disturbing glare sensitivity. The left, non-traumatized eye was already pseudophakic and supplied with a 6.0 mm optic IOL. Preoperative right eye pupillometry (scotopic 6.87 mm; mesopic 6.61 mm; photopic 6.48 mm) indicated that the patient would not be optimally treated by a conventional 6.0 mm optic IOL. Thus, A. Liekfeld found the ASPIRA-aXA to be the best option in this case. Implantation ran smoothly and the IOL was immediately perfectly centered. Postoperative outcomes were excellent and the patient was extremely satisfied and did not report dysphotopsia when asked, said the speaker. This case report showed that the XL optic not only performs well in vitreoretinal diseases, but also in other particular cases which cannot be treated optimally with standard IOLs. For the future, her wish would be the development of a multifocal IOL based on the ASPIRA-aXA platform. A. Liekfeld sees refractive lens surgery as another field of application for the ASPIRA-aXA, since especially young patients with large pupils would benefit from an XL optic.

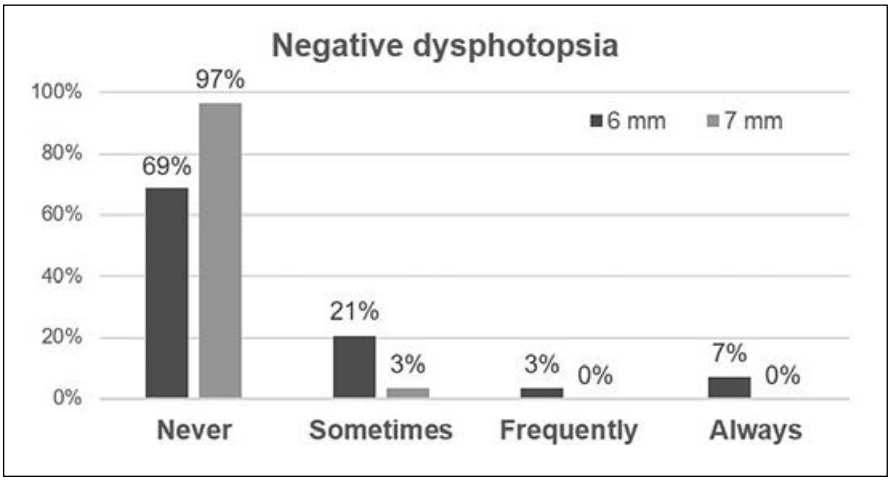

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Figure 5: Percentage of negative dysphotopsia in eyes with 6 mm IOL (black) and eyes with 7 mm IOL (grey)

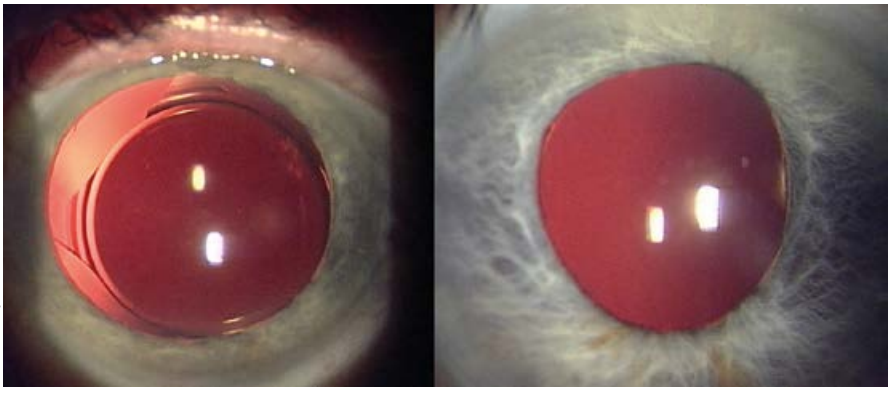

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Figure 6: Aspira-aXA in an eye with traumatic mydriasis; left: 1 day postoperative; right: 4 weeks postoperative

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Figure 7: Speakers Professor Matthias Bolz (Linz, Austria), Professor Gernot I. W. Duncker (Halle, Germany), and Anja Liekfeld, MD (Potsdam, Germany) next to moderator Professor Manfred R. Tetz (Berlin, Germany) and CEO of HumanOptics AG Pierre Billardon, Pharm D

Overall, the experts agreed that the study results obtained so far are promising, and indicate that the ASPIRA-aXA has a great potential to become a standard implant in cataract and refractive surgery.

In closing the symposium, M. Tetz referred to another innovation by HumanOptics, the Custom*Flex*® Artificial*Iris*. The Artificial*Iris* is intended for use as an iris prosthesis in the ciliary sulcus or capsular bag for the treatment of complete or partial iris defects such as aniridia in children and adults. Each iris is based on a patient accepted photography of the fellow eye. Its cosmetic appearance is therefore highly satisfactory with a realistic adaptation of the natural iris. The product is made of a biocompatible foldable silicone, and is versatile in implantation techniques. This unique product received CE-marking in 2011 and was granted breakthrough device designation by the U.S. Food and Drug Administration (FDA) in 2017. To qualify for such designation, a device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. On May 30, 2018, the FDA approved the first stand-alone prosthetic iris in the United States.

M. Tetz mentioned that the combination of the new ASPIRA-aXA and the Artificial*Iris* could be seen as a holistic approach to patient care in certain cases.

OPHTHALMO-CHIRURGIE supplement in collaboration with HumanOptics AG, Erlangen
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