


Louis D Nichamin Thierry Amzallag

Akreos scores highly for stability and centration

Dermot McGrath
in London

ONE-YEAR results from the FDA clinical trial of the Akreos Adapt IOL (Bausch & Lomb) indicate that the implant delivers excellent visual acuity results and is associated with a low risk of adverse events, according to Louis D "Skip" Nichamin MD.

"Our 12-month data show that the Akreos hydrophilic acrylic IOL has met or exceeded all of the key FDA requirements for efficacy and safety and we are hopeful that the lens will be approved in the relatively near future for use in the US," said Dr Nichamin, medical monitor for the FDA study and director at the Laurel Eye Clinic in Brookville, Pennsylvania.

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Addressing a session on intraocular lenses during the XXIV Congress of the ESCRS, Dr Nichamin said that the design properties of the Akreos enable the IOL to achieve excellent stability and centration in the capsular bag.

"This is a one-piece hydrophilic acrylic intraocular lens with four closed-loop haptics and a refractive index of 1.46 in order to minimise glare and internal reflections. It has a 6.0mm optic and is available in three different lens diameters to provide optimal centration and stability in the bag, ostensibly with uniform tension on the capsule in all eyes," he said.

Different diameter lenses

Dr Nichamin presented 12-month follow-up data for 329 eyes from the prospective trial that was carried out at 14 different clinical centres in the US. The Akreos Adapt IOL was implanted unilaterally in all cataract patients and the results were compared with historical control outcomes, the two main parameters of which were best-corrected visual acuity of 20/40 or better and the recording of adverse events.

Results exceeded FDA control guidelines

Although an injector and sub-3.0mm incision can be used with the Akreos, the study protocol called for forceps and in-the-bag implantation. The results for best-corrected visual acuity matched or exceeded those in the FDA guidelines, noted Dr Nichamin.

"Looking at all the enrolled patients, we see that 96 per cent achieved BCVA greater than or equal to 20/40, which exceeds the historic control rate and roughly 50 per cent of patients achieved 20/20, again beating or matching the historical control rate," he said.

The incidence of adverse events also comfortably met the FDA grid requirements, with one per cent of patients affected by transient cystoid macular oedema and less than one per cent requiring medication to deal with elevated IOP.

Dr Nichamin noted that the idea of introducing three different lens diameter sizes arose in part from studies carried out by Dr Rupert Menapace and colleagues at the Medical University of Vienna, Austria.

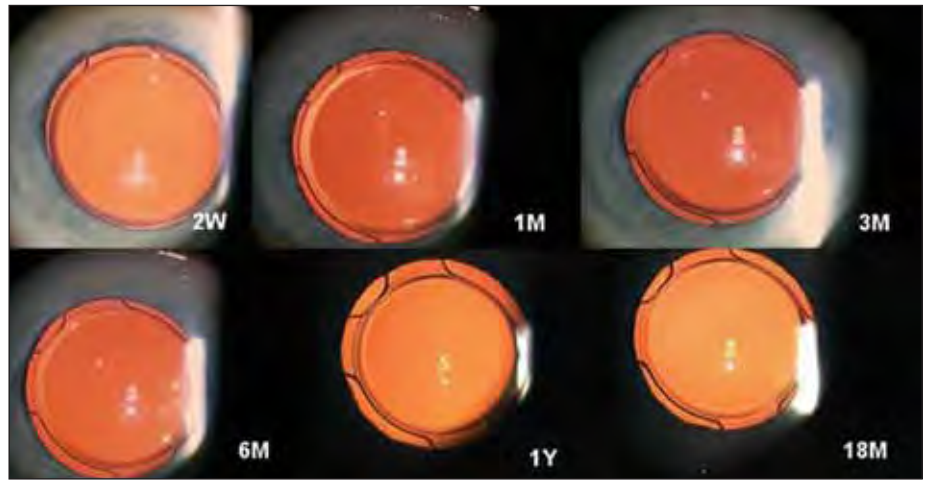
"Their research showed that capsular bag diameter correlates negatively with corneal power but positively with axial length. So the idea is to have a slightly larger diameter for longer myopic eyes, an intermediate diameter for emmetropic eyes and a slightly smaller diameter for the shorter hyperopic eyes," he said.

The smallest-diameter version for hyperopic eyes (axial length of 23mm) measures 10.5mm, the intermediate size for emmetropic eyes (axial length of 24 to 25mm) is 10.7mm, and the largest IOL for myopic eyes (axial length of 26mm) measures 11mm. The corresponding available dioptre ranges for the three different size implants are 22.5 to 30 D, 15.5 to 22 D, and 10 to 15 D, respectively.

Summing up, Dr Nichamin said that the Akreos Adapt IOL has demonstrated its ability to deliver excellent visual acuity outcomes with no significant implant-related adverse events. He said that its unique haptic design allows it to achieve impressive centration and stability in the capsular bag and it should prove a useful addition to any cataract surgery practice.

Foldable Akreos ideal for MICS

In a separate presentation, French ophthalmologist Thierry Amzallag MD reported the one-year follow-up results from a pilot trial of a new thinner version of the Akreos IOL that will enable surgeons to implant the lens through a sub-2.0mm incision.



Courtesy of Thierry Amzallag MD

Patient 14 from 2 weeks to 18 months

"The latest microincision techniques allow cataract removal through sub-2.0mm incisions but new IOLs are required to maximise the benefits of these smaller incisions. In my experience many of the currently available microincision IOLs do not always behave as safely as standard IOLs especially regarding posterior capsule opacification and capsular shrinkage," he said.

Dr Amzallag said that the new Akreos Micro-Incision Lens, by contrast, provides excellent intracapsular stability, very good visual acuity results, stable refraction and a good safety profile.

> "This lens has been designed to be suitable for microincision surgery thanks to its highly foldable hydrophilic acrylic material which has an excellent long-term safety record"
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"This lens has been designed to be suitable for microincision surgery thanks to its highly foldable hydrophilic acrylic material which has an excellent long-term safety record. The central optic thickness has been reduced by 25 per cent compared to the current design of the Akreos Adapt IOL. The lens has also been designed for maximum stability inside the capsular bag thanks to its unique haptics which avoid transfer of forces towards the optic during postoperative capsular bag contraction," he said.

The lens is available in three diameters –10.5mm, 10.7mm, and 11.0mm – depending on the power. As with other IOLs in the Akreos range, the Micro-Incision Lens has a continuous 360° barrier edge to prevent lens epithelial cells from migrating onto the optic surface and causing posterior capsule opacification.

Excellent in-the-bag stability and centration

The IOL is designed for insertion with a 1.8 Viscoglide cartridge and the Viscoject Lens Injection System (Medicel AG, Widnau, Switzerland).

Dr Amzallag presented results from his single-centre, single-surgeon study of 20 patients who were randomised to receive the IOL with two implantation techniques: standard insertion with the Medicel injector (group 1) and a wound-assisted technique where the injector was not introduced into the anterior chamber (group 2).

In the first group, the mean incision size after implantation was 2.22mm, while the mean incision size for the second group was 1.86mm. Overall, patients showed a mean gain of six lines of UCVA, with good predictability of refractive outcome, good early postoperative visual acuity and excellent refractive stability after one year.

Dr Amzallag said that the safety data for the lens was also very impressive.

"Our studies showed only minimal movement of the optic and the total optic decentration after one year is just 0.11mm, so it is clear that the lens is very stable inside the capsular bag. The PCO rates, which were evaluated by an independent team using EPCO 2000 software, were excellent and are comparable with results from the best standard IOLs available on the market," he concluded.

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