New one-piece IOL shows encouraging 12-month results, says study

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THE TECNIS® 1-Piece intraocular lens (IOL) by Advanced Medical Optics (AMO) with innovative features including a 360° continuous posterior square edge and a Tri-fix™ design, while also incorporating a proven second-generation hydrophobic acrylic material has been shown to be safe and effective in a recent US FDA study.

The multicentre, unilateral, open-label, FDA clinical investigation was conducted with the spherical version of the one-piece, investigational, monofocal lens. There were 123 cataract patients in six investigational sites who received the lens. Emmetropia was the targeted refraction for all but three patients.

The TECNIS® 1-Piece has been designed to minimise posterior capsule opacification (PCO) development and enhance the ease of implantation. It has a 13.0mm overall length with a 6.0mm optic and the lens has a frosted edge to minimise edge glare. The benefits of this one-piece design includes polished haptic loops and reduced central thickness that facilitate coplanar delivery into the bag. The hydrophobic material has an excellent track record of being glistening and vacuole free while allowing transmission of healthy blue light. The lens clearly reveals the combined benefits of the 360° posterior square edge and the posterior pressure of the Tri-fix™ design maximises the barrier effect to lens epithelial migration. Even early implantations from 2005, in their 21st month, are still showing clear posterior capsules,” said Don Nixon MD, Royal Victoria Hospital, Barrie, Canada.

The mean patient age in the FDA study was 71.9 years, ranging from 48 to 94 years. Investigators at the various study sites followed the patients for one year after IOL implantation. Study parameters included visual acuity, occurrence of optical/visual symptoms (haloes/glare), the incidence of postoperative complications, and adverse effects. They implemented the FDA Grid for posterior chamber IOLs as a historical control.

At four to six months after surgery, 99.2 per cent of all patients achieved a best-corrected distance visual acuity (BCDVA) of 20/40 or better versus 92.5 per cent of the control group. Moreover, 83.5 per cent achieved a BCDVA of 20/20 or better.

At 12 months, 100 per cent of the patients had a BCDVA of at least 20/40. BCDVA was at least 20/20 in 82.9 per cent of the study participants. Uncorrected distance visual acuity (UCDVA) was at least 20/40 in 91.5 per cent.

Adverse events included four patients who developed cystoid macular oedema (CME) during the course of the study for a cumulative CME rate of 3.3 per cent. One subject had persistent CME at one year, for a rate of 0.9 per cent. One patient underwent a lens exchange at the time of surgery secondary to a torn haptic related to improper folding. Finally, there was one patient who underwent a pars plana vitrectomy with an epiretinal membrane peel.

Interestingly, the YAG capsulotomy rate was very low at 2.56 per cent at one year, which may be attributable to a combination of the Tri-fix™ design along with the continuous 360° square edge, he said. Photographic comparisons from the time of insertion, six months, and one year postoperatively showed evidence of minimal or no movement of the intraocular lens.

The TECNIS® 1-Piece is produced with a novel surface treatment designed to reduce the surface tackiness of the acrylic material and aid in unfolding the one-piece lens. Moreover, the square posterior edge geometry of the lens body is designed to inhibit the development of PCO, thanks to the uninterrupted barrier edge that blocks cell migration onto the posterior capsule, he observed.

This lens which has just been released onto the European market was designed to respond to perceived weaknesses in the existing one-piece IOLs available both from a biomechanical as well as a biomaterial point of view. Finally, incorporated in the optic design is the TECNIS® platform to rejuvenate vision by targeting zero spherical aberration, further enhancing visual function and performance. This fusion of optical clarity, full light transmissibility, and minimising spherical aberration seems to make the most sense to fill the expectations of both surgeons and patients today. Personally, I look forward to being able to incorporate the TECNIS® 1-Piece as part of my clinical practice in the near future.

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