PHAKIC IOLs
Angle-supported lens found safe and effective at four and five years in clinical trials
by Howard Larkin in Chicago

An angle-supported phakic intraocular lens (IOL) provided stable and predictable refractive results with acceptable endothelial cell loss and minimal intraocular inflammation for up to five years, according to four- and five-year results of prospective trials reported at the ASCRS symposium. Studies of the Alcon AcrySof Cachet Phakic Lens are ongoing to assess longer term outcomes and risks, presenters said.

“After five years’ follow-up what is amazing is the iris ovalisation. Only two cases of small ovalisation of less than 1.0mm,” in 360 subjects, said Beatrice Cochenier MD, PhD, of Brest University, France, who reported on global prospective trials for the Cachet. These and other promising safety results at five years are a marked improvement over several phakic IOLs that were pulled from the market in France after three years, she noted.

Studies also were reported from the US and Canada. Methodology and exclusion criteria were similar in all the studies. Participants were at least 18 years of age with stable moderate to high myopia. Excluded were patients with previous ocular surgery, glaucoma, cataract, astigmatism of greater than 2.0 D, mesopic pupil size of less than 3.2 mm and anterior chamber depth of less than 570 μm. The Monarch II IOL Delivery System was used to deliver the lens into the anterior chamber.

In a US phase 1 and II prospective clinical trial involving 60 eyes in 60 patients, 93 per cent achieved 20/40 or better uncorrected and 64 per cent 20/20 or better uncorrected at five years, said Jeffrey D Horn MD, Tennessee, US. All patients achieved 20/30 or better corrected with 95 per cent reaching 20/20 and 73 per cent 20/16 or better corrected. For the group, mean five-year uncorrected VA was 0.06 +/- 0.20 logMAR, or a little better than 20/25, with mean corrected VA -0.10 +/- 0.09 logMAR, or about 20/16, Dr Horn said. Refractions were also predictable and stable for the period, said Dr Horn, who is a consultant for Alcon.

At five years, 84 per cent were within 0.5 D of the target refraction and 96 per cent within 1.0 D. The patients were moderate to high myopes with a preoperative mean spherical equivalent of -10.09 +/- 2.13 D, ranging from about -8.0 to -12.5 D, and results were for first eye implants only.

At the fourth year follow-up of a five-year Canadian prospective study of 73 second eye Cachet implants, 97 per cent achieved 20/40 or better uncorrected and 75 per cent 20/20 or better, said Thaddeus T Demong MD of the University of Calgary, Canada. All patients achieved 20/32 corrected with 96 per cent reaching 20/20 and 77 per cent 20/16 corrected. Mean uncorrected distance visual acuity was -0.04 +/- 0.16 logMAR, or slightly better than 20/20, which was better than mean corrected distance visual acuity preoperatively, Dr Demong noted.

Refractive predictability was also good in the Canadian study, with 74 per cent within 0.5 D and 95 per cent within 1.0 D of target at four years, said Dr Demong, who is a member of an Alcon advisory board. The Canadian patients also were moderate to high myopes with a preoperative mean spherical equivalent of -10.5 +/- 2.2.

“Similar to Dr Horn’s presentation we find the refraction remains stable to four years,” Dr Demong said. The interim results reported were from a study involving 120 patients overall of which 105 received bilateral Cachet implants.

Low endothelial cell loss Four-year safety results were also promising in the Canadian trial, according to a poster presented by Simon P Holland MB, FRCS, Canada. Mean chronic annualised percentage change in central endothelial cell density in 57 patients was -1.22 per cent from six months to four years postoperatively. From the preoperative stage to four years, 42 per cent of 73 subjects had no change in corrected visual acuity, while the remaining patients gained one or more lines. At four years none of 95 patients had aqueous cells or flare, corneal or peripheral oedema, or corneal haze. The study is ongoing and five-year results will also be published.

Similar safety results were reported for a five-year global prospective trial involving 360 first-eye implants reported by Dr Cochenier.

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