

MULTIFOCAL AMD LENS

An injectable add-on IOL is a promising alternative to telescopic implants for some patients. *Howard Larkin reports*

A

single-piece, add-on multifocal lens in clinical trials in Europe has restored functional near vision without sacrificing distance vision or field of vision in patients with advanced age-related macular degeneration (AMD), Sathish Srinivasan MD told the American Academy of Ophthalmology 2017 meeting in New Orleans.

Other advantages of the sulcus-supported Scharioth Macula Lens (Medicontur, Zsambek, Hungary) over telescopic implants include insertion through a much smaller incision (2.2mm clear corneal wound), greater tolerance of decentration and complete reversibility, said Dr Srinivasan, of University Hospital Ayr, Ayr, Scotland, UK, and as it is an add-on lens it can be implanted in patients who were previously pseudophakic.

Developed by Gabor B Scharioth MD, PhD, Recklinghausen, Germany, this hydrophilic acrylic Scharioth lens consists of a 6.0mm plano optic with a central 1.5mm optical zone with a +10.0 D. This square-shaped IOL has rounded edges and is supported by a four-point haptic for stable fixation in the ciliary sulcus. (Scharioth GB, *J Cataract Refract Surg*, 2015 Aug;41:1559-63). Implanted unilaterally in the better-seeing eye, this design allows patients to retain a full field of vision as well as good distance vision – distinct advantages over telescopic designs, Dr Srinivasan

said. The hydrophilic material consists of 25% water and has very low chromatic aberration.

The lens is inserted with a standard injection cartridge and placed in the ciliary sulcus through a 2.2mm incision, compared with 6.0mm-to-12.0mm for telescopic devices, Dr Srinivasan noted. As a result, surgery is much easier, and the lens can be explanted much more easily than can a telescopic lens.

"A big advantage is if it doesn't work you just remove it," he emphasised.

Rounded edges of the four haptics keep the lens centred without risk of distorting the iris or causing pigment dispersion, while a concave-convex design keeps it clear of the iris and the primary IOL in the capsular bag. These features make the lens more stable in the eye than multi-piece telescopic alternatives, Dr Srinivasan added.

TRIAL RESULTS

In an ongoing prospective European multi-centre clinical trial launched in October 2015, 35 of a planned 60 patients so far have been implanted, of which 25 now have at least one year of follow-up. All treated patients were aged 55 or older, pseudophakic and had dry or treated wet macular degeneration that had been stable for at least six months before surgery. These patients had preoperative corrected near visual acuity ranging from 20/50 to 20/200. They also showed an improvement of at least three ETDRS lines with a +2.5D add at 40cm, and a +6.0D add at 15cm, indicating they could benefit from the magnification the lens provides, Dr Srinivasan said.

Patients with active wet AMD, severe zonulopathy, iris neovascularisation, uveitis, anterior chamber depth of less than 2.8mm or previous complicated cataract surgery were excluded.

Three months after surgery, mean corrected distance visual acuity was 0.18 decimal, or about 20/110 – identical with mean preoperative values. Mean uncorrected near vision acuity at 15cm was nearly 0.7, or about 20/30, three months after surgery, up from corrected near acuity values of about 0.25 with a +2.5D add at 40cm, and 0.6 with a +6.0D add at 15cm. These gains were sustained for the 25 patients with 12 months' follow-up.

Intraocular pressure remained stable at 12 months in all patients, and no cases of iris capture, chafing or dislocation were reported. However, three patients reported distance vision issues including glare and halos, leading to explantation in two cases. Vitreous loss occurred during implantation in one patient.

"The Scharioth Macula Lens seems to increase near vision consistently without affecting distance vision. Patient selection is key, and postoperative visual training for patients to help them to read at 15cm rather than 30 or 40cm seems to really help," Dr Srinivasan reported.

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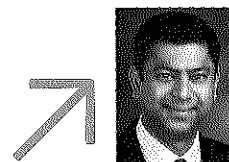
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