Implantation of the add-on Scharioth Macula Lens (SML, Medicontur) can improve the near visual acuity of pseudophakic patients with age-related macular degeneration (AMD) without impairing their distance visual acuity, according to the results of a prospective European multicentre clinical trial presented at the XXXIV Congress of the ESCRS in Copenhagen, Denmark.

A number of external magnifying devices are currently available for use, but all of these restrict field of view, causing discomfort and therefore limited acceptance by patients. With this in mind, an increasing amount of focus has been placed on visual rehabilitation of these patients using optical principles.

A variety of intraocular implants including intraocular telescopic systems and intraocular lenses (IOLs) have recently become available. Most of these intraocular magnifying IOLs are based on the Galilean telescope principle and have the downsides of requiring a very large incision to implant them and they severely impact the visual field.

This new IOL represents an alternative to external low vision aids for macular disease patients, which can be uncomfortable, inconvenient and awkward to use in public. They are also much easier to implant and remove than intraocular telescope IOLs, said Sathish Srinivasan MD, FRCSEd, FRCPht, FACS, University Hospital Ayr, UK.

"The injectable add-on SML appears to be safe and effective in the short- to medium-term in improving the corrected near visual acuity (CNVA) in patients with AMD, and our data also suggests that the corrected distance visual acuity (CDVA) remains unaffected," added Dr Srinivasan. The prospective multicentre European study involved 35 pseudophakic patients with dry or inactive wet AMD, recruited over seven clinical centres in six countries. All satisfied the inclusion criteria of being over 55 years of age and having a CDVA of 0.1 to 0.4 (decimal). In addition, all were able to achieve an improvement of at least three lines of CNVA when tested with a +6.0D reading addition at 15cm, compared to when tested with a +2.5D reading addition at 40cm with a ETDRS near vision chart.

**IMPLANTATION IN THE SULCUS**

Dr Srinivasan and his associates implanted the SML in the ciliary sulcus in one eye of each patient using a 2.75mm incision and a customised injector system. The implant has a bifocal optic, with a central 1.5mm diameter optical zone equivalent to +10D add and providing a mathematically calculated two-fold magnification on average. The peripheral zone of the lens is optically neutral, although other dioptic powers are possible. In addition, the optic of the lens has polished round edges to reduce photic phenomena.

At a follow-up of three months, the mean decimal CNVA had improved from 0.25 preoperatively to 0.55. In addition, mean best corrected distance visual acuity remained stable throughout follow-up, and was 0.16 at one day, 0.19 at one week, 0.2 at one month, and 0.19 at three months. There were no intraoperative complications. Two patients underwent SML explantation due to postoperative glares and halos.

"Three months’ data from our prospective multicentre trial indicates that the SML is safe and effective in eyes with macular disease," Dr Srinivasan concluded.

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