Implantable Telescope Helps Most AMD Patients

BY JANE SALODOF MACNEIL
Contributing Writer

NEW ORLEANS — Preliminary results from the phase II/III trial of an implantable miniature telescope suggest the experimental prosthetic device can enhance the vision of end-stage advanced macular degeneration and Stargardt's disease patients for whom no effective treatments currently exist.

Of 202 patients who wore the telescope for 6 months, 89% were able to improve their distance or near vision by at least two lines in the reading of an eye chart, according to investigator Jeffrey S. Heier, M.D., a vitreoretinal specialist at Ophthalmic Consultants of Boston and Tufts University, Boston. About half had a three-line improvement, he said.

Not all patients could tolerate the lens, however. Investigator Paul R. Lichter, M.D., director of the University of Michigan Kellogg Eye Center, reported that 11 of the first 217 implantations had to be aborted and that two telescopes were removed because of device failures.

The two researchers presented similar data from the ongoing trial at the annual meeting of the American Academy of Ophthalmology. The researchers were consultants to VisionCare Ophthalmic Technologies of Saratoga, Calif., which was cofounded by the telescope's inventors, Isaac Lipshitz, M.D., and Yossi Gross.

The implantable miniature telescope is said to give patients a wider visual field than external telescopes currently in use for advanced macular degeneration (AMD). Eye movement and visual appearance are also described as more natural.

Surgeons at 28 centers implanted the telescopes in one eye in each of 218 patients. Participants had to have a cataract in their study eye to be eligible for the trial. Their average age was 76, and they entered with best-corrected distance vision between 20/80 and 20/800.

Dr. Lichter noted that the telescope is not an intraocular lens. It required a 10- to 12-mm incision and was inserted with posterior pressure to avoid corneal touch. He described the surgery as three times as difficult as a cataract operation, with surgical success dependent on the surgeon's developing mastery of the technique.

The telescope will not help everyone with advanced AMD. Patients must be committed to learning how to use the telescope, including visual rehabilitation.

"Experience counts. There was higher cell loss in the first three cases," Dr. Lichter said, referring to the one study end point with notably poor results. Mean endothelial cell loss was 22% at 6 months, whereas the study goal had been less than 17% at 2 years.

In the 11 eyes where implantation was aborted, Dr. Lichter reported eight capsular tears (half of which occurred during extraction), two suprachoroidal hemorrhages, and one suspected suprachoroidal hemorrhage.

Common complications were elevated intraocular pressure and corneal edema during the first month of follow-up. Less than 5% of patients had adverse events, according to the analysis, and no postoperative retinal complications were reported. Only 2% of patients lost two or more lines of vision 6 months after implantation.

Dr. Lichter and Dr. Heier each stressed that the telescope will not help everyone with advanced AMD. Patients must be committed to learning how to use the telescope, they said, citing six visual rehabilitation sessions scheduled in addition to postoperative visits.

"It is important that patient selection be very, very careful," Dr. Lichter said. "Patients have to understand this is not a cure, and optimal outcome requires fairly intense visual rehabilitation."

A panel of experts responded positively to Dr. Heier's presentation. They expressed concerns about safety but applauded the possibility of a new treatment for AMD.

Cynthia A. Toth, M.D., of Duke University Eye Center in Durham, N.C., said VisionCare's data were difficult to assess because the statistical analysis only included patients who wore the telescope for 6 months.

VisionCare has announced plans to file a U.S. Food and Drug Administration premarket approval application for the telescope in the first half of 2005. ■