Scleral spacing implants show promise as presbyopia treatment

BY Dermot McGrath

*in Athens*

EARLY clinical results suggest the scleral spacing procedure (SSP) using PresView Scleral Implants (Refocus Group) appears to be a safe, effective and reversible technique to improve near visual acuity without affecting distance visual acuity in emmetropic presbyopia, according to Barrie D Soloway MD, FACS.

Addressing delegates on presbyopia during the ESCRS W inter Refractive Meeting, Dr Soloway said that initial results from ongoing FDA clinical trials of the scleral implants in the US have given investigators good grounds for optimism.

“We are seeing over the course of our study in the US, with slightly less than half of the patients enrolled, a significant improvement in near vision with every metric that we are measuring with them with yet with no change in the uncorrected distance visual acuity. We think we have the genesis of a very safe, effective and reversible procedure and we really think that the FDA’s willingness to give us approval to perform binocular surgery with these implants is evidence of that,” he said.

Discussing the technique, Dr Soloway, medical director of Refocus Group, the maker of the scleral implants used in the procedure, director of vision correction at The New York Eye and Ear Infirmary, and assistant professor of ophthalmology at The New York Medical College, explained that it addresses the problem of presbyopia in a very different way than many of the IOL - or laser-based procedures for the cornea.

“We have primarily static corruptions like multifocality, monovision, bifocal contact lenses or implants, as well as lens-related surgery using implants such as the Crystalens or the Synchrony IOL which can help to achieve more of a dynamic correction. Scleral spacing procedures try to address the problem by improving the focusing ability for near without compromising the distance vision,” he said.

Dr Soloway stressed the immense challenge facing surgeons dealing with this particular category of patient. “We must not forget that we are talking here about presbyopia in the emmetrope. It is a very difficult group of patients to satisfy – these are not hyperopes receiving a bicofolous implant or doing some sort of laser procedure. These are patients that are very uncompromising on their distance visual acuity and do not really want to lose any of that acuity. The scleral spacing procedure tries to achieve this by using four PresView scleral implants to alter the configuration of the sclera around the lens equator, giving the eye more of an ability to have a good near focus without compromising the distance vision,” he said.

Discussing the clinical performance of the implants, Dr Soloway said that Phase I of the FDA study was completed between 2000 and 2002 and demonstrated the safety of the implants on 29 eyes of 29 subjects over two years. Results of Phase II of the trials were reported in September 2005 for the first 44 eyes at six months from patients undergoing SSP for presbyopia. These patients, along with 23 randomised, non-surgical control patients at six months, were monitored for reading and near acuity using standard near vision reading charts pre-operatively and at three – and six-month intervals. SSP patients experienced an average of three lines of improvement in six months, though several patients showed improvement of five lines or better. As expected, control patients not undergoing the SSP procedure showed no improvement in their close-up reading vision, said Dr Soloway. About 90 per cent of the surgical patients reported that their close-up vision was either better or significantly better. No patient in either group showed any deterioration of uncorrected distance acuity or contrast sensitivity.

Dr Soloway said that Phase III trials of the SSP procedure began in 2005, with additional investigators being added and the FDA giving the go-ahead to treat the second eye. Patients in the ongoing study are between 50 to 60 years of age, with distance corrected acuity of 20/20 and require at least 1.25 D add to achieve 20/25 near vision. The distance-corrected visual acuity has to be 20/20, and the patients must not have had a previous ocular surgery in order to reduce the confounding effects of any multifocality or change in sphericity in the cornea after LASIK.

Dr Soloway said that 183 eyes of 134 patients have been enrolled thus far in the surgical arm of the study. Of those patients, 158 eyes have six-month follow-up data and six-month data was also available from 31 out of 32 eyes from phase II in the control arm, he added. “We have a number of patients with 20/30 and 20/40 vision and more than 90 per cent of the patients are 20/63 or better and almost 75 per cent have 20/30 or better vision.”

Dr Soloway noted that the implants are now inserted with the help of an automated scleratome (PresView Scleratome), which has made the surgery easier and more efficient. “The scleratome definitely facilitates the surgery by improving the accuracy, positioning and the reproducibility of putting the implants in the proper position in the four oblique quadrants,” he said.

He also noted that modifications to the design of the implant should help to avoid problems of subluxation that had occurred with first-generation models of the implant. “We brought in a third-party research engineer to develop a more stable implant at the beginning of last year. The adaptive design of this modified implant really made a big difference in terms of the lateral stability. It eliminated the complexity of the nylon suture and it restored the underside vault to really give us a better visual result, while maintaining the tunnel anatomy and the reversibility of the procedure,” he said.

Looking to the future, Dr Soloway said that researchers are currently looking at ways in which OCT data can be used to optimise the position of the implants with regard to each patient’s individual anatomy. Other refinements being examined include using a locking and docking station to ensure optimal scleratome positioning of the tunnel, and the development of a self-contained disposable miniaturised scleratome. He also added that applications using PresView implants for transconjunctival surgery for presbyopia as well as in glaucoma surgery are currently under investigation in Canada.

The scleral spacing procedure continues to generate controversy. The mechanism of action is unclear. Adverse effects reported in previous case reports include anterior segment ischemia, inflammation, and irritation.

The PresView procedure is still considered experimental in the US and Canada. It has recently received marketing approval in the EU.

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