INLAY SHOWS PROMISE

Corneal implant for presbyopia appears to sharpen near vision with only small sacrifice of distance vision in treated eye

by Roibeard O’Hineachain in Paris

The KAMRA™ (AcuFocus, Inc) corneal inlay, which uses a small aperture to improve near and intermediate vision in presbyopes, has produced promising results in a series of patients taking part in an international FDA trial, reports Gunther Grabner MD, University Eye Clinic, Paracelsus University, Salzburg, Austria at the XXVIII Congress of the ESCRS.

“The AcuFocus KAMRA inlay is effective, minimally invasive and well tolerated with stable results,” he said.

Promising results in FDA trial

Dr Grabner presented the results achieved in a series of 32 patients who underwent the procedure as part of a multicentre FDA study that is taking place at centres in the US, Europe and Asia. The patients in the study were presbyopic emmetropes aged between 45 and 55 years of age. All had a spherical equivalent within half a dioptre of emmetropia, required a reading add between 1.0 D and 2.5 D with uncorrected visual acuity 20/20 in both eyes. None had undergone prior eye surgery or had any other eye disease.

At 36 months of follow-up Dr Grabner’s cohort achieved a mean gain of 4.6 lines of uncorrected near visual acuity and the mean uncorrected distance visual acuity was 20/20. He noted that one of the FDA’s criteria for approval of the device as a treatment for presbyopia was that 75 per cent must be J3 or better. In fact, 98 per cent of patients in the study achieved J3 or better and half achieved J1, he pointed out.

In addition, uncorrected intermediate visual acuity was 20/32 or better in 95 per cent of eyes and 20/20 or better in 50 per cent of eyes.

Preoperative uncorrected distance visual acuity was 20/20 or better in all eyes. However, at six months’ follow-up it was 20/20 in two-thirds of eyes, 20/25 or better in 88 per cent, and 20/32 or better in all eyes. However, binocular distance visual acuity remained unchanged and uncorrected near and distance visual acuity remained stable throughout follow-up.

“The loss of uncorrected distance visual acuity in this trial is less than that reported with older inlay designs. This may be due to the enhancing effect of its design on distance visual acuity which may be an advantage to this technology,” Dr Grabner said.

Complications included one case of epithelial ingrowth that required a repeated flap lift plus suturing. There were also two cases with decentred inlays. In those patients, Dr Grabner lifted the flap and re-centred the inlay about half a millimetre towards the line of sight. Over the following two years, near and distance visual acuity steadily improved to acceptable levels. There were also a couple of patients who had problems with dry eye after the procedure.

“The inlay is mainly used in older patients, who will therefore be more prone to dry eye problems, especially women. It is important to test for and counsel patients about dry eye before surgery. For example, a patient who has a poor Schirmer’s test score should be advised that they will require eye drops for a minimum of six months,” he said.

Improved design now available

The current inlay measures 3.8mm in diameter with a central 1.6mm aperture and is five microns thick. It is composed of an opaque polyvinylidene fluoride material with 8400 laser etched micro-perforations designed to allow for optimal nutrient flow.

Other developments include the KAMRA AccuTarget System, a device to assist surgeons with precise inlay centration guidance and assessment.

It identifies both the 1st Purkinje reflex and the pupil centroid preoperatively and provides a visual guide for placement of the inlay during surgery. Postoperatively, the AccuTarget System identifies the actual inlay placement versus the preoperative target.

Laser manufacturers have also developed new technologies to support corneal inlay implantation within a pocket, for example the Ziemer femtosecond laser is now capable of reliably creating a pocket or flap at a target depth of 200-220mm. The IntraLase also has new pocket software that looks very promising, Dr Grabner said. He added that the deeper placement of the inlay should protect against complications of the anterior cornea such as corneal thinning that have happened with older inlay designs that resulted in removal.

“Although I have not taken one out in over 80 patients, some with over four years of follow-up, I like the fact that I can take it out if need be. In my opinion, this is an advantage over other presbyopia-correcting technologies,” Dr Grabner added.