AMETROPIC PRESBYOPIA
Combined LASIK/corneal inlay procedure ‘wows’ patients with early outcomes
by Cheryl Guttmann Krader in Milan

Simultaneous LASIK and monocular implantation of a small aperture corneal inlay (Kamra, AcuFocus) is a very safe and effective treatment for presbyopia and ametropia, according to a study presented by David Allamby MD, at the XXX Congress of the ESCRS.

Dr Allamby, director, Focus Clinics, London, UK, reported outcomes for a series of 57 presbyopic patients with refractive prescriptions ranging from moderate myopia to moderate hyperopia. Some 89 per cent of patients underwent combined LASIK and Kamra implantation ("CLK") for treatment of presbyopia and ametropia while the remaining 11 per cent were treated only for presbyopia using the pocket emmetropic Kamra ("PEK") procedure. In all patients, the inlay procedure was unilateral with placement in the non-dominant eye.

All 57 patients were seen at three months after surgery. The results of testing in the inlay eyes showed mean near UCVA (measured at 40cm) was J1 and mean distance UCVA was 20/30. Outcomes at six months showed further improvement. Among the 20 patients seen at six months, the inlay eyes had a mean near UCVA of J1 and mean distance UCVA of 20/25, reported Dr Allamby.

"The small aperture corneal inlay has become our preferred option for correcting presbyopia in patients aged 45 to 60 who have a clear lens. The surgery itself presents a little bit of a learning curve. However, once that’s overcome, there is a real wow factor for this procedure because of the near vision improvement achieved on post-op day one, and data from the Salzburg group show that the benefit is maintained with follow-up to five years,” he said.

The inlay procedure has several advantages for presbyopia correction compared with monovision or blended vision, including better distance visual acuity in the reading eye, better stereopsis, and better intermediate vision, he commented.

All of the patients were operated on at Focus Clinic by Dr Allamby or Ali Mearza MD. Patients were eligible for an inlay procedure if they had a clear lens, pupil diameter of 7.0mm or less, and were in the age range between 45 and 65 years old, although the series included one 69-year-old who had a very clear crystalline lens. The usual selection criteria for LASIK were applied, including an estimated residual stromal bed thickness of at least 300 microns.

For the 57 patients in the series, preoperative sphere ranged from -6.25 D to almost -3.0 D (median -0.5 D) and cylinder ranged up to -1.75 D (median -0.5 D).

Nearly half of the patients (48 per cent) were hyperopes (SE ≥+0.75 D), 30 per cent of the patients were myopes (SE ≤-0.75 D), and the rest were emmetropes (SE -0.5 to +0.5 D).

Initially, based on the manufacturer’s recommendation, target refraction was -1.0 D for emmetropes and -0.75 D for all other eyes so that even some emmetropes underwent CLK to achieve the myopic target instead of having the PEK procedure. However, when it was noted that the refractive outcome was too myopic in some hyperopes, the target refraction was adjusted to -0.75 D for all eyes. For the full CLK cohort, mean target refraction was -0.77 D and mean achieved refraction was -1.1 D.

At baseline, mean near UCVA was J13 for the emmetropes and hyperopes and J2 for the myopes. At three months, near UCVA in the inlay eye was J5 in one patient (two per cent) and J3 or better in all of the rest, with 65 per cent of eyes achieving J1 or better. The patient with J5 vision underwent inlay explantation.

“Our criteria for explantation are if the patient is not seeing J3 or better and is expressing dissatisfaction. It is important to have a ‘plan B’ for managing patients who are dissatisfied with the outcome of the inlay procedure, and ours is to convert to monovision,” Dr Allamby said.

Baseline mean distance UCVA for all eyes was 20/40 (20/41 for the emmetropes and hyperopes and 20/120 for the myopes). At three months, distance UCVA was 20/30 or better in 57 per cent of inlay eyes and 20/40 or better in 88 per cent, but it ranged up to 20/100 (one eye, two per cent), reported Dr Allamby.

“The latter case was related to dryness, and we see improvement of distance UCVA over time as post-LASIK dryness resolves. At six months, distance UCVA for the implanted eyes averaged 20/25 and was 20/30 or better in 90 per cent of eyes. In the few patients in our series with longer follow-up and based on international data, it appears that distance vision continues to improve through one year, typically 20/20,” he said.

Safety was good. Mean distance BCVA was 20/16 at baseline and reduced by an average of two letters after the procedure.

Dr Allamby also noted that the list of potential candidates for presbyopia correction with the small aperture corneal inlay continues to expand and now includes eyes that have had previous refractive surgery by LASIK, radial keratotomy or conductive keratoplasty.

“We have operated on eyes in all of those categories at our clinic with good outcomes. We are also expanding our treatments with PLK2, where first thin-flap LASIK is performed, followed four weeks after with implantation of the inlay via a pocket,” Dr Allamby said.

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**Graphs showing outcomes:**
- **Age distribution:** n=57 (46-69) mean=55
- **3m UCNVA – KAMRA eye:**
  - 20/16: 30%, 20/20: 30%, 20/25: 20%, 20/30: 20%, 20/40: 20%
  - mean = 20/21 (J1)
- **6m UCDVA - KAMRA eye:**
  - 20/16: 42%, 20/20: 50%, 20/25: 50%, 20/30: 50%, 20/40: 50%
  - mean = 20/25

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Courtesy of David Allamby MD.