Corneal Inlay Comes of Age

AcuFocus’ first symposium on the KAMRA inlay took place in September 2011. Per Ed Peterson, CEO, there are close to 6,000 commercial patients with the implant, which will likely increase to 10,000 in the next six months. Highlights from the session are below:

Gunther Grabner, MD, has enrolled 32 patients in his arm of the U.S. FDA study. With 36-48 months follow-up, reported distance vision has not been impacted and near vision improved to J2 and remained stable. Intermediate vision also remained stable, at 20/25.

George O. Waring IV, MD, described major milestones in the development of the KAMRA inlay. The current inlay is the 6th generation of the small aperture inlay from AcuFocus representing years of science-based design evolution. The final model is 3.8mm in diameter with a 1.6mm center aperture and is 5 microns thin. It is highly permeable and implanted deep in the stroma, without disrupting the catabolic, metabolic, and hydrational flows as a result of the 8,400 microperforations pseudo-randomly placed throughout the inlay. Additionally, surgical techniques have evolved to allow the inlay to correct presbyopia in emmetropes, ametropes, post-LASIK and pseudophakic patients.

The U.S. clinical trial for correction of presbyopia in emmetropes has enrolled 507 patients at 24 sites worldwide. John Vukich, MD, reported on the 2-year results to date (n=99). The mean uncorrected VA was J3 for near, with an average 3.5 lines gain from baseline; 20/25 for intermediate; and 20/20 for distance. Best-corrected distance vision (CDVA) is 20/20 or better in all implanted eyes. The binocular uncorrected vision (UDVA) is unchanged from preop to 24 months postop (20/16), and the binocular photopic and mesopic contrast sensitivity is within normal limits.

“These patients are remarkably free of complaints for dim light conditions, they are relatively asymptomatic in terms of discerning which eye had the implant,” he said. Dr. Vukich has been so impressed with the visual outcomes and quick recovery times he will be undergoing KAMRA inlay implantation in his non-dominant eye in November 2011 in Japan.

Minoru Tomita, MD has implanted more than 3,000 KAMRA inlays, and is the first surgeon to evaluate simultaneous LASIK and KAMRA (Sim-LASIK) surgery as well as post-LASIK implantation of a KAMRA inlay. Results from Sim-LASIK (n=2271), 76% of the patients achieved 20/20 UDVA at 1 year; 82% of patients were 20/25 or better at 1 year. Further, 50% achieved J1, and 80% achieved J3 (measured at 30cm). A patient questionnaire showed 87% were satisfied or very satisfied with their vision and did not need reading glasses at 1 year.

In a series of Post-LASIK patients (n=562), about 20% of these patients needed an enhancement before KAMRA implantation. The Adjustable Femto LDV pocket software was used to create the pocket at 200-250 microns, or about 100 microns deeper than the original LASIK flap. (This can be confirmed via OCT.) Mean UNVA improved from J8 to J2 at 3 months, with no change in UDVA (20/16).
Damien Gatineel, MD, moderated the last session which included an interview of three recent KAMRA inlay patients, surgeons Dean Corbett, MD, Robert Rivera, MD, and Rick Wolfe, MD. At baseline Dr. Corbett was +1.75D in the non-dominant eye, +0.75D in the fellow eye. Dr. Rivera was -.50/+1 in both eyes; astigmatism was with-the-rule. Dr. Wolfe was a 20/15 emmetrope with “absolutely no near vision” and called his condition “the desperation of the emmetropic presbyope.”

Postoperatively, Dr. Corbett went from a “poor” 6/12 to 6/6 or 6/6.5 “on a good day.” Dr. Rivera’s UDVA is equally good, and sometimes believes the KAMRA eye has better distance. Dr. Wolfe’s UDVA is 6/4.8, an increase of about 2 letters.

None of the physicians considered lensectomy approaches, nor did they consider non-reversible surgeries. Dr. Rivera shared that one the major factor influencing his decision to the inlay was the maintenance of distance vision. Performing surgery is not problematic, although they needed to reposition themselves at the microscope a bit.