

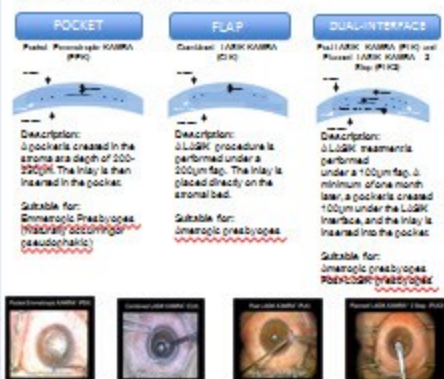
## PURPOSE

To assess the effectiveness of implantation of a small aperture corneal inlay for treatment of presbyopia.

## METHODS

Analysis of global outcomes for patients between the ages of 45-65 implanted with a small aperture intra-corneal inlay for correction of presbyopia. The inlay is 5 microns thick, measures 3.8mm in total diameter and has a central aperture (or hole) measuring 1.6mm in diameter. There are 8,400 micro-perforations, ranging in size from 5-11 microns, distributed throughout the inlay annulus in a pseudorandom pattern to allow metabolite diffusion. The small aperture design addresses presbyopia by expanding depth of focus. The inlay was implanted monocularly in the non-dominant eye in either a femtosecond laser-created corneal pocket or under a LASIK flap at a depth of 200µm. (Fig. 1)

Figure 1. Inlay Surgical Procedures



## RESULTS

At the time of this analysis, 7,566 implanted eyes of 7,566 patients were treated with the small aperture inlay. At 12 months post-op, 1,438 of those patients were available for assessment. At 12 months post-op, mean uncorrected near visual acuity (UCNVA) across all procedures was between 0.1 and 0.2 logMAR. (Fig. 2) UCNVA improved from a mean of J8 to J2 in the inlay eye between preop and 1 month. Mean uncorrected distance visual acuity was between -0.037 and 0.023 logMAR at 12 months. (Fig. 3)

Figure 2. UCNVA Across All Procedures Inlay Eye

\* Mean near visual acuity across all procedures at 12 months are between 0.1 and 0.2 logMAR (N=1,438)

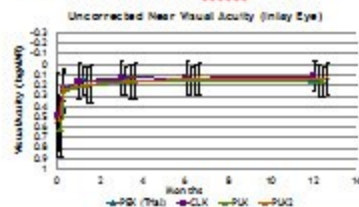


Figure 3. UCDA Across All Procedures Inlay Eye

\* At 12 months, mean UCDA for all procedures is between -0.037 and 0.023 logMAR (N=1,438)

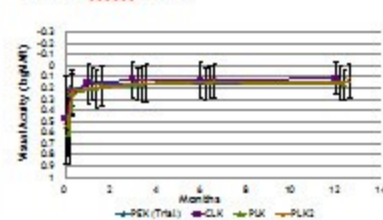
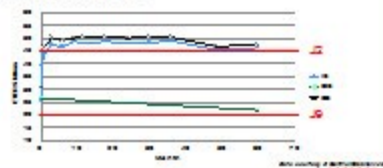


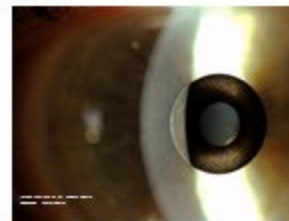
Figure 4. Long-Term Results:

## Uncorrected Near VA at 5 Years

- UCNVA improved from a mean of J8 to J2 in the inlay eye between preop and 1 month. This result is maintained out to 5 years.
- Vision in the inlay eye and with both eyes (BE) is unaffected by the progression of presbyopia.
- UCNVA in the untreated fellow eye (FE) shows a mean loss of 1 line over the same time period.



## Inlay In Vitro



## DISCUSSION

- Results from earlier generation small-aperture inlays demonstrate the visual result are maintained out to 5 years. (Fig. 4)
- Globally, surgeons are moving toward pocket and dual interface procedures and away from flap-based procedures.

## SUMMARY

Use of a small aperture inlay effectively addresses presbyopia by providing excellent simultaneous near and distance vision.