

# Visual Acuity Outcomes of Two Target Locations for Inlay Implantation in Post-LASIK Patients

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# Purpose

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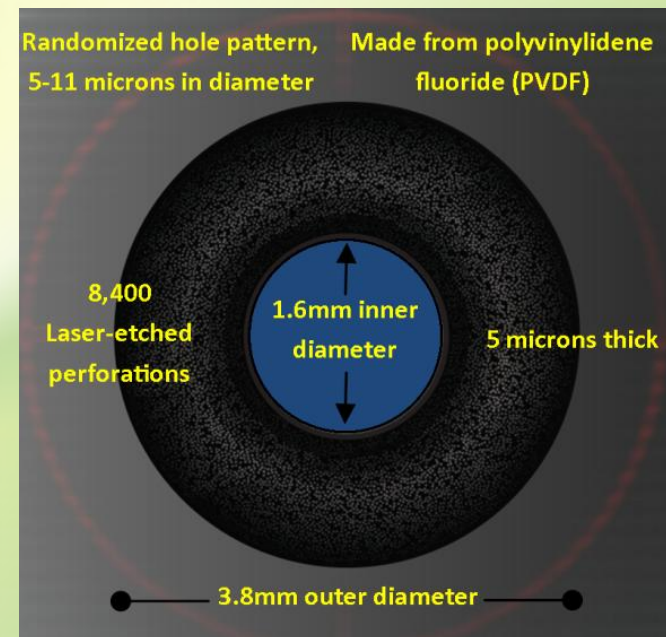
- To compare the visual acuity outcomes of two target locations for inlay implantation for post-LASIK presbyopes

# Kamra Corneal Inlay (Acufocus, Inc., CA, USA)

- The inlay is an investigational device in the United States and is limited by federal law to investigational use for the surgical treatment of presbyopia. . It is not available for sale in the United States.
- The inlay is available for use in Japan.
- The central aperture increases the depth of field. The patient is able to achieve improved vision for near with minimal effect on distance vision.
- Several published papers reported the KAMRA corneal inlay is effective for the treatment of presbyopia<sup>1-4</sup>.

## References.

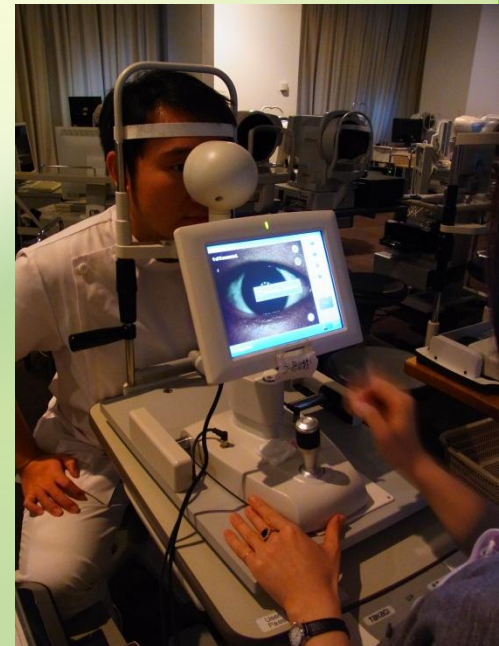
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- 2.Seyeddain, O, et al. Small-aperture corneal inlay for the correction of presbyopia. 3-year follow-up. J Cataract Refract Surg. 2012 Jan;38:35-45.
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# AcuTarget Diagnostics (Acufocus, Inc., CA, USA)

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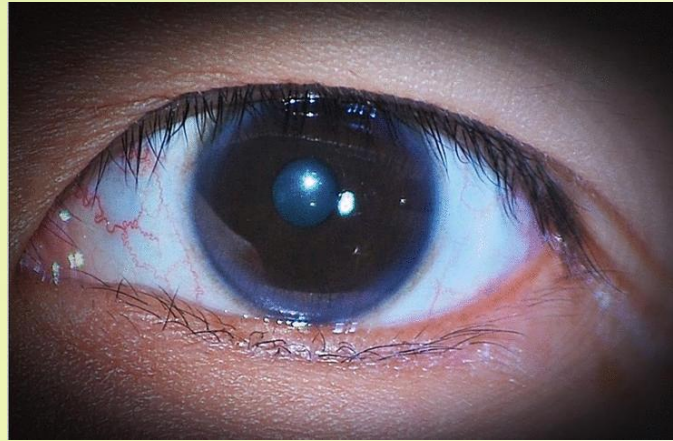
- A table-top device designed to identify and document the desired inlay placement location.
- The new generation device provides the following:
  - Objective assessment of visual quality
  - Tear-film quality over time and the resulting visual impact
  - Pseudo-accommodation measurement with visual demonstration of pre and post-op depth-of-focus
  - Inlay position guidance
  - Assessment of targeted versus achieved inlay placement
  - Enhanced patient understanding and commitment to post-op care



# Inlay Centration

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- In any refractive surgery procedure, centration is important in order to give our patients the best visual outcome with fewer complaints post-operatively...



- Recentration may be needed for unsatisfactory visual outcome after the first surgery.<sup>5</sup>

## References

# Pupil Center<sup>6-8</sup>

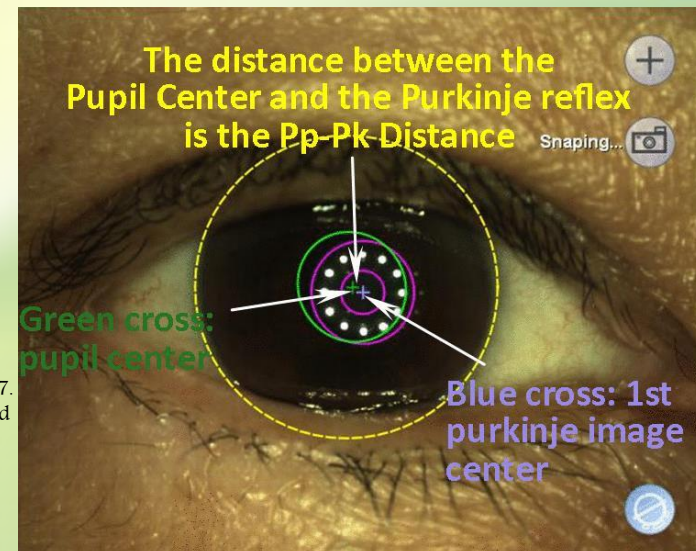
- Some eye-tracking devices use pupil boundaries as standard references.
- Common ablation areas are usually pupil-guided, since the entrance pupil can be well-represented by circular or oval apertures.
- The pupil center defines the principal line-of-sight in a fixating patient
- However, the pupil center shifts with changes in pupil size

# Purkinje Reflex<sup>9-10</sup>

- AKA coaxially-sighted corneal light reflex, lies nearer to the corneal intercept of the visual axis than the pupil center
- With the cornea as the main refractive surface, the reflex represents a more stable centration reference; and is therefore preferred over the pupil center.

## References:

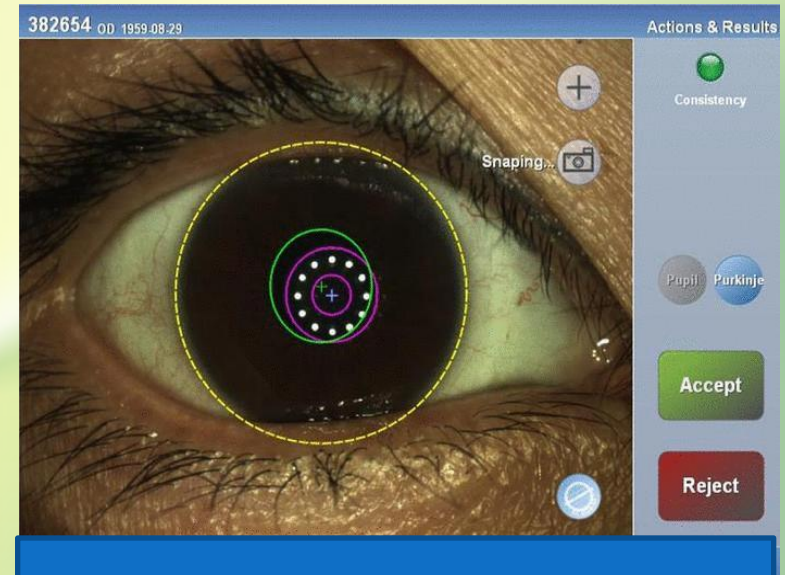
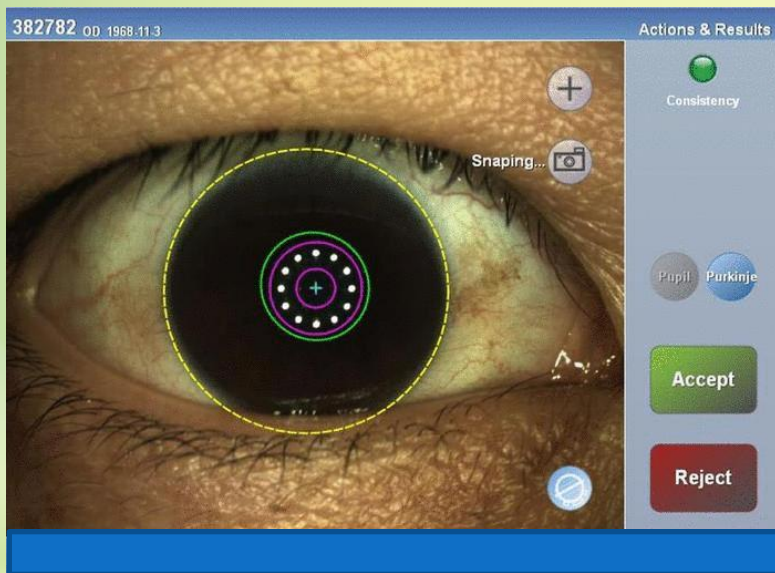
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# Pp-Pk Distance

In small pupil center-to-purkinje reflex (Pp-Pk) distances, the inlay may be placed on either one of these two locations.

In large pupil center-to-purkinje reflex (Pp-Pk) distances, this study compares the visual acuity outcomes of inlays placed at the purkinje reflex, or halfway between the pupil center and the purkinje reflex (aka midpoint).



# Patients & Methods

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- 2,074 post-LASIK presbyopic eyes for inlay implantation
- Time frame: April 2011 to December 2012, with 6-months follow-up
- The implanted inlays were calculated for Pupil Center-to-Purkinje Reflex Distance (Pp-Pk) using the AcuTarget Diagnostics Unit's 1-month results.
- The distances were classified into small Pp-Pk ( $\leq 300\mu\text{m}$ ) and large Pp-Pk ( $> 300\mu\text{m}$ ).
- Each was further classified into Inlay-to-Midpoint Distance (I-M) and Inlay-to-Purkinje Reflex Distance (I-Pk) at 0-100 $\mu\text{m}$ , 101-200 $\mu\text{m}$ , 201-300 $\mu\text{m}$ , 301-400 $\mu\text{m}$ .



# Outcome Measures

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- Change in Uncorrected Near Visual Acuity (UNVA) after 6 months
- Change in Uncorrected Distance Visual Acuity (UDVA) after 6 months
- I-M vs I-Pk at 0-100 $\mu\text{m}$ , 101-200 $\mu\text{m}$ , 201-300 $\mu\text{m}$ , 301-400 $\mu\text{m}$
- Shapiro-Wilk Test for normality of data;  
Kruskal-Wallis Test for comparison between and within subgroups

# Results – UNVA

For Pp–Pk  $\leq$  300 $\mu$ m

Inlay-to-Midpoint (IM) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	J6	J2
101-200 $\mu$ m	J6	J2
201-300 $\mu$ m	J6	J2
301-400 $\mu$ m	J6	J2

Inlay-to-Purkinje (IPk) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	J6	J2
101-200 $\mu$ m	J6	J2
201-300 $\mu$ m	J6	J2
301-400 $\mu$ m	J6	J2

For Pp–Pk  $>$  300 $\mu$ m

Inlay-to-Midpoint (IM) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	J6	J2
101-200 $\mu$ m	J6	J2
201-300 $\mu$ m	J6	J2
301-400 $\mu$ m	J6	J2

Inlay-to-Purkinje (IPk) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	J6	J2
101-200 $\mu$ m	J6	J2
201-300 $\mu$ m	J6	J2
301-400 $\mu$ m	J6	J2

<sup>†</sup> no statistical difference in the change in UNVA for IM vs IPk at 0–100 $\mu$ m, 101–200 $\mu$ m, 201–300 $\mu$ m, 301–400 $\mu$ m ( $p > 0.05$  for all)

# Results – UDVA

For Pp-Pk  $\leq$  300 $\mu$ m

Inlay-to-Midpoint (IM) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	20/16	20/20
101-200 $\mu$ m	20/16	20/20
201-300 $\mu$ m	20/16	20/20
301-400 $\mu$ m	20/16	20/20

Inlay-to-Purkinje (IPk) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	20/16	20/20
101-200 $\mu$ m	20/16	20/20
201-300 $\mu$ m	20/16	20/20
301-400 $\mu$ m	20/16	20/20

For Pp-Pk  $>$  300 $\mu$ m

Inlay-to-Midpoint (IM) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	20/16	20/20
101-200 $\mu$ m	20/16	20/20
201-300 $\mu$ m	20/16	20/20
301-400 $\mu$ m	20/16	20/20

Inlay-to-Purkinje (IPk) Distance	Mean Preop	Mean postop (6 mos) <sup>†</sup>
0-100 $\mu$ m	20/16	20/20
101-200 $\mu$ m	20/16	20/20
201-300 $\mu$ m	20/16	20/20
301-400 $\mu$ m	20/16	20/20

<sup>†</sup> no statistical difference in the change in UDVA for IM vs IPk at 0-100 $\mu$ m, 101-200 $\mu$ m, 201-300 $\mu$ m, 301-400 $\mu$ m ( $p > 0.05$  for all)

# Conclusions

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- The Kamra corneal inlay is a good surgical option for post-LASIK presbyopes, providing a mean improvement of 3 lines in UNVA (J2), and a minimal change in UDVA (20/20).
- The post-LASIK inlay implantation is safe and effective, with visual improvements maintained throughout the time frame of the study.
- In post-LASIK presbyopes, both the purkinje reflex and the midpoint between the purkinje reflex and pupil center yield similar and good outcomes in UNVA. Small deviations from either target location do not significantly affect the results.