Corneal Inlays for the Treatment of Presbyopia

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Corneal inlays

’60s concept


--- need to improve near and intermediate vision with little compromise of distant vision (MONOVISION)

--- preference of corneal over intraocular procedure (MULTIFOCAL)

--- are highly biocompatible

--- removable (LASER)
Corneal Inlays

*Refractive Optics Inlays* -

alter index of refraction with a bifocal optic

*Flexivue microlens (Presbia)*

*Icolens (Neoptics)*
- transparent, 3.2-mm diameter hydrogel implant

- 0.15 mm opening in the center to facilitate fluid and nutrient flow.

- lens thickness varies between 15 and 20 μm depending on add power

- add power from +1.25 to +3.5 D, in 0.25-D steps

- implantation in a corneal pocket at a depth of 280–300 μm
Icolens

Preloaded delivery system for safe, simple and precise lens placement:

- Reduced risk of infection
- Improved quality and precision of procedure
- Reduced procedure time

Lens preloaded during assembly in a sterile vial

Clipping preloaded lens onto the delivery system

Illustration showing the placement of the lens into the corneal pocket
**Bifocal design produces two images at the foveal level:**

- one image results from the combined refractive effects of area of the cornea that surrounds the lens and the central zone of the lens

- one image from the peripheral zone of the lens

**Neuroadaptation** aids in using both images by choice

**Disadvantage**
pupil smaller than 3.0 mm == the peripheral plus power of the lens obstructed by iris
**Corneal Reshaping Inlays**

- same refractive index
- changes corneal curvature creating hyperprolate shape

*Raindrop (Revision Optics)*
2 mm in diameter and 32 µm thick in the center

implantation under a 130 - to 150 µm LASIK flap
Multifocality

1 Near
2 Intermediate
3 Distance

Corneal Cross-section
Small Aperture Inlays

small aperture - principal of pinhole optics

Kamra Inlay (Acufocus)
KAMRA Inlay Design

- Central aperture is a hole in the inlay and has no power

Inlay Design

3.8mm Diameter

1.6mm Aperture

8,400 holes (5-11 μm)

5 μm thick

Made from Polyvinylidene Difluoride (PVDF)
KAMRA Inlay

PVDF polyvinylidene fluoride - biocompatible
- mechanical strength
- consistent thin films
- UV resistance
Small aperture
Depth of Focus

- The inlay uses small aperture technology to extend depth of focus and improve near vision in presbyopic patients without limiting distance vision.
The Acufocus approach

KAMRA™

AcuTarget

Femtosecond corneal pocket software
(Pocket Emmetropia Kamra)
Exclusion Criteria

- Prior corneal procedures (Except LASIK and PRK)
- Any ocular or systemic disease that is a contraindication for corneal refractive procedures including:
  - Keratoconus
  - Uncontrolled and/or severe dry eye
  - Cataracts
  - Macular degeneration
  - Corneal dystrophy or degeneration
  - Amblyopia or Strabismus
- Patients with unrealistic expectations
- Patients with psychological conditions
most common sideeffect: nutritional problems - haze

glare and halo, dry eye, and night vision problems

increased concentration

line of sight

instrumentation - Acutarget
Advantages of Pocket Procedures

• Significantly improved refractive stability and predictability
• Minimal effect on corneal strength
• Simplified procedure
• Easy centration
• Improved healing and visual outcomes
Reduced Incidence of Dry Eye

- Based on clinical trial results, there appears to be a higher incidence of SPK (dry eye) after a flap procedure than a pocket based procedure.

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Pre-Op</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
<th>12M</th>
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</thead>
<tbody>
<tr>
<td>POCKETS</td>
<td>n/N</td>
<td>5/508</td>
<td>25/505</td>
<td>29/499</td>
<td>13/487</td>
<td>16/479</td>
</tr>
<tr>
<td>%</td>
<td>1%</td>
<td>5%</td>
<td>4.2%</td>
<td>5.8%</td>
<td>3.3%</td>
<td></td>
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<tr>
<td>FLAPS</td>
<td>n/N</td>
<td>4/185</td>
<td>19/184</td>
<td>12/177</td>
<td>9/169</td>
<td>12/160</td>
</tr>
<tr>
<td>%</td>
<td>2.2%</td>
<td>2.8%</td>
<td>10.3%</td>
<td>6.8%</td>
<td>7.5%</td>
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</table>

LASIK was not performed in the flap cases presented here.
<table>
<thead>
<tr>
<th>Author/Study</th>
<th>Inlay type</th>
<th>Study population</th>
<th>Follow-up</th>
<th>UCNVA</th>
<th>UCIVA</th>
<th>UCDVA</th>
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</thead>
<tbody>
<tr>
<td>Bouzoukis et al.</td>
<td>Refractive optic (InVue)</td>
<td>45 emmetropes</td>
<td>1 year</td>
<td>98% 20/32 or better</td>
<td>Not reported</td>
<td>93% 20/40 or better</td>
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<tr>
<td>Limnopoulou et al.</td>
<td>Refractive optic (Flexivue)</td>
<td>47 emmetropes</td>
<td>1 year</td>
<td>Mean 20/25; 75% 20/32 or better</td>
<td>Not reported</td>
<td>Mean 20/50</td>
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<tr>
<td>Porter et al.</td>
<td>Corneal reshaping inlay (Raindrop)</td>
<td>18 Hyperopes</td>
<td>1 month</td>
<td>Avg five-line gain; 78% 20/25 or</td>
<td>Avg four-line gain</td>
<td>Mean 20/25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>better</td>
<td></td>
<td></td>
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<tr>
<td>Lang et al.</td>
<td>Corneal reshaping inlay (Raindrop)</td>
<td>25 Hyperopes</td>
<td>1 month</td>
<td>80% J1 or better</td>
<td>Avg five-line gain Mean</td>
<td>Avg two-line gain</td>
</tr>
<tr>
<td></td>
<td>(with LASIK)</td>
<td></td>
<td></td>
<td></td>
<td>20/25</td>
<td></td>
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<tr>
<td>Tomita et al.</td>
<td>Small-aperture inlay (Kamra current generation)</td>
<td>180 Hyperopes;</td>
<td>6 months</td>
<td>Mean gain: seven lines (hyperopes); six lines (emmetropes); two lines (myopes)</td>
<td>Not reported</td>
<td>100% 20/20 or better</td>
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<tr>
<td></td>
<td></td>
<td>Emmetropes;</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Myopes</td>
<td></td>
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<tr>
<td>Drexl et al.</td>
<td>Small-aperture inlay (Kamra current generation)</td>
<td>24 Emmetropes</td>
<td>1 year</td>
<td>Mean J2 92% J3 or better</td>
<td>Mean 20/25 surgical eye, 20/20 binocular 67% 20/20 or better</td>
<td>Mean 20/20</td>
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<tr>
<td>Yilmaz et al.</td>
<td>Small-aperture inlay (Kamra earlier generation)</td>
<td>39 Emmetropes &amp; Post-LASIK emmetropes</td>
<td>4 years</td>
<td>Mean J1 96% J3 or better</td>
<td>Not reported</td>
<td>100% 20/40 or better</td>
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<tr>
<td>Seyeddain et al.</td>
<td>Small-aperture inlay (Kamra earlier generation)</td>
<td>32 Emmetropes</td>
<td>3 years</td>
<td>Mean J1 97% J3 or better</td>
<td>Mean 20/25; 91% 20/32 or better</td>
<td>Mean 20/20; 100% 20/32 or better</td>
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</tbody>
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