Clinical experience of 9,000 small aperture Inlays for presbyopia correction

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Shinagawa LASIK Center in Tokyo, JAPAN

1,060,666 Femto LASIK cases since being established in 2004.

- Shinagawa LASIK Center in Tokyo with 5 branch clinics.
- We have a total of 131 doctors.
- Our clinics perform approx. 70% of the LASIK procedures in Japan.
Awards: High Volume Center

“Ziemer Award in 2009 through 2011 for the highest number of refractive treatments worldwide”

“SCHWIND AMARIS Award for the highest treatment volume worldwide in 2011”


“For the highest treatment volume worldwide on the ALLEGRETTO Wave EYE-Q laser system” (2006 through 2008)
Laser Systems at Shinagawa LASIK Center

Femtosecond Lasers
- FEMTO LDV™ & Crystal Line™ (Ziemer, Switzerland)
- IntraLase FS60™ & iFS (AMO, USA)

21 Units

Excimer Lasers
- AMARIS (SCHWIND, Germany)
- Refractive Suite (Alcon, US)
- Visx star S4 IR (AMO, USA)

14 Units

1 Unit

Other procedures also available:
- Surface ablation (PRK, LASEK, EpiLASIK)
- Intracorneal Ring Segment
- Phakic IOL
- Multi-focal IOL
- KAMRA® Intracorneal Inlay
- CK (Conductive Keratopasty)
Surgical Procedures

- **Pocket Emmetropic KAMRA (PEK)**: Implantation of an inlay into a femtosecond created lamellar pocket.
- **Combined LASIK KAMRA (CLK)**: Combination of a LASIK procedure with inlay implantation post-ablation.
- **Post-LASIK KAMRA (PLK)**: Creation of a lamellar pocket 100 microns below a previous LASIK flap for inlay implantation.
- **Planned LASIK KAMRA – 2 Step (PLK2)**: Planned traditional thin flap LASIK procedure followed by insertion of an inlay into a lamellar pocket 1 month after primary LASIK procedure.

※Over 15,000 inlays have been implanted worldwide and 9 ophthalmologists have the KAMRA inlay in their own eye.
Shinagawa History with KAMRA Vision

JUNE 2009
1st PEK Procedures Performed
100+ Procedures To Date

AUGUST 2009
1st CLK Procedures Performed
4500+ Procedures To Date

NOVEMBER 2010
1st PLK Procedures Performed
1000+ Procedures To Date

MAY 2011
1st PLK2 Procedures Performed
3400+ Procedures To Date

Over 9,000 Procedures as of July 2012
Volume by Surgical Procedure

9,035 Karma procedure as of July 2012.
**KAMRA corneal inlay:**

- **Aperture:** 1.6mm
- **Total diameter:** 3.8mm
- **Made from Polyvinylidene Fluoride (PVDF)**
- **8,400 holes**
  - (5 to 11 micron)
- **Thickness:** 5 microns
KAMRA corneal inlay (cont.):

The central aperture increases the depth of field. The patient is able to achieve improved vision for near and intermediate with minimal affect on distance vision. (Data source: AcuFocus, Inc.)

Several published reports showed the KAMRA intracorneal inlay is an effective method for the treatment of presbyopia\(^1-4\).

Result of a Combined LASIK KAMRA (CLK) procedure for Ametropic Presbyopes
Purpose

• To evaluate the outcomes of using KAMRA intracorneal inlay (AcuFocus Inc., Irvine, CA) implantation with simultaneous LASIK for the treatment of presbyopia with refractive errors.

• The KAMRA inlay is currently under US IDE clinical trial. It is available for use in Japan.

• This study is followed by Ethical Board Committee in Japan. All the patients read and signed an informed consent form.
INCLUSION CRITERIA:

- **Age:** 40-65 yr.
- **Spherical Equivalent:** -9.0 to +3.0 D with ≤ -3.0 D cylinder in inlay eye
- **Corneal Thickness:** > 470μm (*residual bed thickness > 280 μm*)
- **Keratometry:** 39 D to 47 D
- **Topography:** *no irregular patterns*
- **Endothelial Cell Density:** > 2000 cells/mm²
- **No severe dry eye** (*slit lamp, BUT more than 5sec, Phenol red > 7mm*)
- **No ocular/cornea disease/immune system disorder, etc** (*same as LASIK*)

### Preoperative Data for the Implanted Eye

<table>
<thead>
<tr>
<th>n</th>
<th>Patient Age (Mean ± SD) (Range (y.o.))</th>
<th>UDVA (Snellen)</th>
<th>UNVA (Jaeger)</th>
<th>SE (D) (Mean ± SD) (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3015*</td>
<td>51.6 ± 5.8 (40 to 65)</td>
<td>20/125</td>
<td>J6 (75% myopic)</td>
<td>-2.84 ± 2.71 (-9.00 to +3.00)</td>
</tr>
</tbody>
</table>

* Patient data from August 2009 to August 2012
**SURGICAL PROCEDURE:**

- Subjects were implanted monocularly with the inlay in their non-dominant eye.
  - **Non-Dominant Eye:** A 200μm flap was created with a femtosecond laser and an excimer laser ablation performed. Target post-op refraction was -0.75D in the inlay eye. After the refractive correction, a corneal inlay was implanted.
  - **Dominant Eye:** When necessary, the fellow eye was treated with LASIK with a target post-op refraction of plano. A target flap thickness of 100μm was used in this eye.

**Laser Technology used:**
- **Femtosecond:** Ziemer LDV Z6 or IntraLase iFS
- **Excimer:** WaveLight Allegretto or Schwind Amaris

| Non-dominant eye (Implanted eye) | • Flap thickness: **200μm**  
|                                | • Post-op Target refraction: **-0.75 Diopter** |
| Dominant eye:                  | • Flap thickness: **100μm**  
|                                | • Post-op Target refraction: **Plano** |
| Follow-up exams:               | • 1, 3, 6 months and 1 year |
Surgical Video: CLK
**UDVA: Implanted Eyes (Snellen)**

- **Mean UDVA improved 8 lines** from preoperative 20/125 to 20/20 at 1 year ($p=0.0001$).

- **74% of the patients achieved 20/20 or better** and **82% of patients are 20/25 or better at 1 year in their inlay eye.**
Mean UNVA improved 3 lines from preoperative J6 to J2 at 1 year ($p=.0001$).

77% of patients achieved J2 or better and 56% achieved J1 or better at 1 year in their inlay eye.
At 1 year, **93% of the patients are satisfied with their vision** without reading glasses.

Only 10% (3%: often, 7%: sometimes) of the patients need reading glasses.
Corneal Inlay
For
Post-LASIK Presbyopic Patients
Tomita Method for Post-LASIK Implantation (PLK)

Subjects and Methods:

• Between November 2010 and August 2012, 3782 Post-LASIK presbyopic patients were implanted with a Kamra inlay in their non-dominant eye.

• A corneal pocket was created with a femtosecond laser, below the prior LASIK interface, and the inlay was inserted.

• In some cases, the prior LASIK flap was lifted and a minor laser enhancement was performed to achieve a post-op refraction of plano.

(Implanted eye):

<table>
<thead>
<tr>
<th>Non-dominant eye</th>
<th>Pocket created 200-250μm deep</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Target post-op refraction: Plano</td>
</tr>
</tbody>
</table>

Follow-up period: 6 months
Inclusion Criteria:

- Age: 40-65 yr
- CDVA both eyes: > 20/25
- UNVA implanted eye: < J3
- At least 1 month post-LASIK
- Corneal thickness: > 450 μm
- Topography: no irregular patterns
- Endothelial Cell Density: > 2000 cells/mm²
- No severe dry eye (slit lamp, TBUT more than 5sec, Phenol red more than 10mm)
- No ocular, corneal disease or immune system disorders, etc (same as LASIK)
Preoperative Implanted Eye Data

Previous LASIK Surgery

Mean attempted correction : • -3.37 ± 3.26 D
Mean attempted flap thickness : • 97.6 ± 5.7 μm

Before KAMRA Inlay Surgery

<table>
<thead>
<tr>
<th>n</th>
<th>Age (y.o)</th>
<th>UDVA (Snellen)</th>
<th>UNVA (Jaeger)</th>
<th>SE (D) (Mean ± SD) (Range)</th>
<th>CDVA</th>
<th>CNVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>3782</td>
<td>52.6 ± 5.4</td>
<td>20/16</td>
<td>J6</td>
<td>-0.12 ± 0.47 (-2.38 to +2.38)</td>
<td>20/12.5</td>
<td>J1</td>
</tr>
</tbody>
</table>
Adjustable Femto LDV™ pocket software was used to create a pocket for insertion of the corneal inlay.
Surgical Video
**OCT Scan**

- Image shows that the previous LASIK flap was made at about 100µm and the Kamra inlay was implanted at 200µm depth.
### Results: Implanted Eye

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>IE UDVA</th>
<th>IE UNVA 30cm</th>
<th>SE (Diopter)</th>
<th>CDVA</th>
<th>CNVA 30cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>3782</td>
<td>20/16</td>
<td>J6</td>
<td>-0.12 ± 0.47</td>
<td>20/12.5</td>
<td>J1</td>
</tr>
<tr>
<td>1M</td>
<td>3369</td>
<td>20/20</td>
<td>J2</td>
<td>-0.91 ± 0.62</td>
<td>20/16</td>
<td>J1</td>
</tr>
<tr>
<td>3M</td>
<td>2663</td>
<td>20/20</td>
<td>J2</td>
<td>-0.72 ± 0.72</td>
<td>20/16</td>
<td>J1</td>
</tr>
<tr>
<td>6M</td>
<td>1938</td>
<td>20/20 (-1 line) (p&lt;.0001)</td>
<td>J2 (+3 lines) (p&lt;.0001)</td>
<td>-1.01 ± 0.66 (p&lt;.0001)</td>
<td>20/16 (+ 0) (p=.0005)</td>
<td>J1 (+ 0) (p=.0372)</td>
</tr>
</tbody>
</table>

- **Mean UDVA changed 1 line from 20/16 to 20/20 at 6 months.**
- **Mean UNVA improved 3 lines from preoperative J6 to J2.**
- **Mean CDVA changed 1 line from 20/12.5 to 20/16.**
- **No change in CNVA.**
At 6 months, mean UDVA changed 1 line from preoperative 20/16 to 20/20. 80% achieved 20/20 or better and 86% achieved 20/25 or better.
At 6 months, mean UNVA improved 3 lines from preoperative J6 to J2. 67% achieved J2 or better and 80% achieved J3 or better.
At 6 months, **93% of the patients are satisfied with their vision without reading glasses**

Only 7% (3.5%:often, 3.5%:sometimes) of the patients need reading glasses
Conclusions – KAMRA surgery CLK and PLK

• In the CLK group, at 1-year, mean UDVA gained 8 lines to 20/20 and mean UNVA improved 3 lines to J2.

• In the Post-LASIK group, at 6-months, mean UDVA declined 1 line to 20/20 and mean UNVA improved 3 lines to J2.

• For both procedures, patients reported high satisfaction and reduced dependence on reading glasses.

• KAMRA intracorneal inlay implantation is a good treatment option for both ametropic and Post-LASIK presbyopic patients.
Thank you!