Refractive surgery at all stages of life: *Incorporating the 7 refractive procedures into your practice*

Lance Kugler, MD, PCEO
Stage One

Age: 40’s

Reading glasses & Bifocals
DLS: Stages

Stage One

Age: 40’s

Reading glasses & Bifocals

Stage Two

Age: 50-60

Lens Optics

Degrade & Poor Night Vision
DLS: Stages

Stage One
- Age: 40’s
- Reading glasses & Bifocals

Stage Two
- Age: 50-60
- Lens Optics Degrade & Poor Night Vision

Stage Three
- Age: 70’s
- Cataract
DLS: Slit Lamp

Stage One

Stage Two

Stage Three
DLS: Diagnostics

HD Analyzer
iTrace
Objective measure of vision quality

- Grade DLS
- Assess tear film
- Analyze corneal irregularities
- Assess aqueous and vitreous

Double Pass Principal
HD Analyzer

- Visually explain “20/20” quality
- Corneal vs. Lens refractive surgery
- Predict outcomes
- Sets realistic expectations
- Visual performance is changing over time
OSI: Quantifies the degree of intraocular scattering

Image Convolution:
Converts OSI into image of vision quality

HD Analyzer

OSI: 3.5

Predicted VA:
Decimal 0.4
Snellen 20/50
**HD Analyzer**

**OSI: Objective Scatter Index**

- **OSI = 0.4**
- **OSI = 2.3**
- **OSI = 3.2**
- **OSI = 6.2**

**OSI Range**

- **0** Normal
- **2** Increased (early cataract)
- **4** Abnormal (significant opacification)

**Surgery**

- Consider intervention
- Classical indication
DLS: Stages

Stage One
OSI = 1.5

Stage Two
OSI = 2.8

Stage Three
OSI = 9.0
iTrace

“5-in-1” System

- Optical Alignment Measurement
- Separation of Corneal vs Lens
- Toric/MF precision planning
- Post Operative Assessment

Ray tracing aberrometry
iTrace: Optical Alignment
iTrace: Improve Toric Precision
iTrace: DLS Analysis
iTrace: Opacity Map
Refractive procedures

1. LASIK
2. Advanced Surface Ablation (ASA)
3. SMILE
4. ICL
5. Corneal Inlays
6. Refractive Lens Exchange (RLE)
7. Corneal Crosslinking (CXL)
LASIK / ASA

- Becoming a mature procedure
- 98% satisfaction rate
- PROWL study overwhelmingly positive
- Several studies comparing to contact lenses
- Patient selection
- Alternatives
Risk for microbial keratitis: Comparative metaanalysis of contact lens wearers and post-laser in situ keratomileusis patients

Presented as a poster at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, New Orleans, Louisiana, USA, May, 2016.

Jordan Masters, MD, Mehmet Kocak, PhD, Aaron Waite, MD
From the Department of Ophthalmology (Masters, Waite), Hamilton Eye Institute, and the Department of Preventive Medicine (Kocak), University of Tennessee Health Science Center, Memphis, Tennessee, USA
Responses at year 3 to the following question: “At this time, do you believe that LASIK works better for you than contact lenses?”

- Strongly agree: 87.0%
- Agree: 10.0%
- Not sure: 1.7%
- Disagree: 0.6%
- Strongly disagree: 0.3%
Average yearly percentage rates of reported infections, abrasions, and ulcers in the study

- **Contacts Continued**
  - Infections: 8.8%
  - Abrasions: 5.2%
  - Ulcers: 1.6%

- **All LASIK Patients**
  - Infections: 3.5%
  - Abrasions: 1.4%
  - Ulcers: 0.3%
Topography-guided LASIK: Contoura
WaveLight Topography-Guided LASIK

• Topography-guided custom ablation treatments (T-CAT)
  – Performed internationally since 2003
  – Primary eyes
  – Previously operated symptomatic eyes
    • Decentered ablations
    • Small optical zones
    • Residual or induced corneal irregularities.
T-CAT Software
Study Laser Notebook

- Calculates treatment plan by combining manifest refraction data and corneal irregular shape data from topographer
- Four to eight images preferred
- Selection of single or median (averaged) image
T-CAT Software
Study Laser Notebook

- Best fitting asphere (least square fit) subtracted from median height profile

![Height Profile](Image)

- Zernike fit into resulting profile
- Modification of sphere and cylinder/axis Zernike terms based on Manifest Refraction (MR)
## Contoura results

<table>
<thead>
<tr>
<th></th>
<th>20/20</th>
<th>20/12</th>
<th>Cyl +/- 0.50D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WO</strong></td>
<td>93.8%</td>
<td>19.3%</td>
<td>97.4%</td>
</tr>
<tr>
<td><strong>Contoura</strong></td>
<td>92.7%</td>
<td>31.6%</td>
<td>80.5%</td>
</tr>
</tbody>
</table>
SMILE: Small Incision Lenticule Extraction

Video

Real smile video
SMILE: FDA Indications

-1.00 D to -8.00D
≤ -0.50D cylinder
MRSE ≤ -8.25D
22 years
Central corneal thickness > 500 um
SMILE:

- One Laser
- No flap
- Better biochemical stability?
- Less interaction with corneal nerves?
1. The strongest area of cornea: Mid-periphery (8~12 mm)
2. The interior part of the cornea is progressively weaker than the surface: Weakening of strength by 9% and 32% were observed following execution of flap cut to the depth of 90µm and 160µm respectively.
3. Side cut to the same depths can induce similar changes as flap: Weakening of strength by 9% and 33% were observed following execution of side cuts only to the depth of 90µm and 160µm
**SMILE**: Corneal Biomechanics

SMILE: Less Interaction with corneal nerves

SMILE: Clinical Outcomes


Corneal Inlays

1. KAMRA
2. Raindrop
Corneal Inlays: KAMRA
**Corneal Inlays: KAMRA Design**

- **Inlay Design**
  - Diameter: 3.8mm
  - Aperture: 1.6mm
  - 8,400 holes (5-11 µm)
  - Thickness: 6 µm
  - Made from Polyvinylidene Difluoride (PVDF)

- **Pocket Emmetropic KAMRA (PEK)**
  - Epithelium
  - Endothelium
  - Pocket: 200-250µm
Corneal Inlays: KAMRA Case Study

Keys to success

- -0.75 Target
- Centration
- Deeper placement (250-300um from endo)
- Dry eye treatment
Long-Term Results:

Uncorrected Near VA at 5 Years

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

1. KAMRA
2. Raindrop
Corneal Inlays: Raindrop
Raindrop® Near Vision Inlay

- Physiologically transparent, biocompatible hydrogel corneal inlay
- Size: 2 mm diameter, 30 microns thickness
- Similar water content and refractive index as the cornea
- Implanted under a femtosecond laser corneal flap (30% of the corneal thickness) and centered over light-constricted pupil
- Placed in the non-dominant eye
- Removable, if needed
Topography of Profocal Cornea

Pre-Op Non-dominant Eye

After Raindrop

3 Months Postop
The Raindrop Near Vision Inlay is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent (MRSE) of +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.
Patient Selection:
Contraindications, Warnings, and Precautions

• Raindrop Patient Should Not Have…
  • Abnormal corneal topography of eye to be implanted
  • Corneal thickness that does not allow for a minimum of 300 microns of stromal bed thickness below the flap;
  • Active eye infection or inflammation
  • Dry eye syndrome
  • Moderate to severe MGD
  • Keratoconus or keratoconus suspect
  • Corneal dystrophy or degeneration
  • History of herpetic eye infection
  • Uncontrolled diabetes
  • Glaucoma, including history of IOP rise due to steroids
  • Previous eye surgery, including LASIK, PRK, cataracts
  • Any sight-threatening or sight-compromising condition
INDICATIONS FOR USE AND SUMMARY OF IMPORTANT INFORMATION FOR THE RAINDROP® NEAR VISION INLAY

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: Please see Professional Use Information and/or Patient Information Brochure for a complete list of Potential Risks, Warnings and Precautions.

INDICATIONS FOR USE: The Raindrop Near Vision Inlay is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent (MRSE) of +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.

SUMMARY OF IMPORTANT INFORMATION

The Raindrop Near Vision Inlay may not eliminate the need for reading glasses.

Implantation of the Raindrop Near Vision Inlay has the potential to cause vision and eye symptoms; dry eyes; decreased vision; decreased contrast sensitivity; problems with the cornea, such as clouding, thinning, scarring, and inflammation; eye infection; increased eye pressure; and the need for another eye surgery, such as removal or replacement of the inlay, or other treatment.

You should not have the Raindrop Near Vision Inlay implanted if you have severe dry eye; have an active eye infection or active inflammation; have signs of corneal disease characterized by general thinning and cone-shaped protrusion in the center of the cornea (keratoconus) or keratoconus suspect; have abnormal features of the outer part of the eye (cornea) to be implanted; have active abnormal immune response (autoimmune) or connective tissue diseases; do not have enough corneal thickness to safely have the procedure performed; have a recent herpes eye infection or problems resulting from a previous infection; have uncontrolled build-up of high pressure in the eye (glaucoma); have uncontrolled high blood sugar (diabetes).

Before having the Raindrop Near Vision Inlay procedure you should have a complete eye examination and talk with your eye care provider about alternative treatments, potential benefits, complications, risks, healing time, and any other concerns you have about having the procedure.
## Corneal Inlay: Overview

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<thead>
<tr>
<th></th>
<th>KAMRA</th>
<th>RAINDROP</th>
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<tbody>
<tr>
<td>How does it work?</td>
<td>Pinhole</td>
<td>Profocal Cornea:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Steepen central cornea</td>
</tr>
<tr>
<td>Where is it placed?</td>
<td>Stromal Pocket</td>
<td>Under LASIK flap</td>
</tr>
<tr>
<td>Ideal Refraction in</td>
<td>Slightly myopic (-0.75 D ideal)</td>
<td>Slightly hyperopic (+0.50 D ideal)</td>
</tr>
<tr>
<td>Non-Dominant eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous Corneal</td>
<td>Yes</td>
<td>No (not yet .... Soon. :)</td>
</tr>
<tr>
<td>Refractive Surgery</td>
<td></td>
<td></td>
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</tbody>
</table>
1. **RLE**

   *Refractive Lens Exchange*

   *(aka DLR, LLR, CLE)*

   - Mono
   - Toric *(Alcon, *Tecnis*, *TruLign*)*
   - Multifocal
     - TMF
     - Symfony
     - ReStor / ActiveFocus
   - Accommodating
     - CrystaLens / TruLign
TECNIS® Monofocal IOL

Distinct single focus

TECNIS® Multifocal IOL

Two Distinct foci

TECNIS® Symfony IOL

Elongated focus
DLS Surgical Solutions: Stage Three

- **RLE**  Refractive Lens Exchange
- **RELACS**  Refractive Laser Assisted Cataract Surgery
  - OptiMedica Catalys Laser System
  - LenSx Laser System
  - WaveTec ORA
The result? In a study of 215 prior myopic LASIK patients, over 45% more reached their intended refractive target when the ORA™ System was used compared to conventional preoperative IOL power calculation methods.*2
In your ocular

Continuous confirmation of magnitude and axis of astigmatism

Lens power data verification displayed right before your eyes
WaveTec ORA™

On your monitor

Robust data for comprehensive astigmatism management
WaveTec ORA™