Refractive Surgery Update: Alternative Options and What’s New

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Other Corrective Options and Newer Procedures

- Phakic IOLs
- Clear Lens Extraction
- Nothing is always an option!
- Presbyopic Corneal Inlays
- SMILE procedure

Phakic IOL

- a.k.a. Implantable Lens
- Placed either between the cornea and iris or just behind the iris

Corrects moderate to severe myopia
- Up to -20.00 D (Verisyse and Visian ICL)
- Typical results: 20/40 vision or better uncorrected

How much?
$5000-6000 per eye
Clear Lens Extraction

- a.k.a. Refractive Lens Exchange
- Typically for >45 years old (presbyopia) and high hyperopia
- Remove the lens and replace with an intraocular lens (IOL)
  - Procedure is identical to cataract surgery
  - Difference is remove a clear lens rather than a cloudy lens

KAMRA® Inlay by AcuFocus

KAMRA® Inlay Design

- Inlay improves near vision by extending depth of focus
- Central aperture is a hole in the inlay and has no power
- Inlay provides an unobstructed pathway for focused light to reach the retina

Inlay Design

- Diameter: 3.8mm
- Aperture: 1.6mm
- Thickness: 6 μm
- Made from Polyvinylidene Fluoride (PVDF)

Permeability

- 8,400 micro-perforations (5-11 μm)
- Pseudo-random pattern
- Maximize nutrient flow
- Minimize visual symptoms

Extending the Depth of Focus

- Presbyopia: Lens cannot accommodate
- With Inlay: Lens cannot accommodate

Where the KAMRA® inlay falls within the Patient Spectrum

- LASIK: Ages 20 – 40
- KAMRA Inlay: Ages 40 – 60
- IOLs: Ages 60+

Near vision loss begins
KAMRA® Inlay Indications for Use

- Patient who is between 45 and 60 years old
- Cycloplegic refraction between +0.50 D and -0.75 D with less than or equal to 0.75 D of refractive cylinder
- Patient does not require glasses or contact lenses for clear distance vision
- Patient requires near correction of +1.00 D to +2.50 D of reading add

KAMRA® Inlay Patient-Exclusion Criteria

- 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

Surgical Procedure

- Description: A femtosecond laser created pocket in the stroma at a depth of 200-250μm with femtosecond laser spot/line settings of <6x6 or equivalent is recommended.

Implanted KAMRA® Inlay

- Pocket Emmetropic KAMRA (PEK)

Ophthalmic Assessments and the KAMRA® Inlay

The following ocular assessments are possible with the KAMRA inlay in situ:

- Fundus photography
- OCT
- Visual field assessment
- Intracocular pressure measurement
- Contrast sensitivity testing
- Gonioscopy

What Patients Can Expect

- Not like LASIK
- Resume most activities the next day
- Clarity of vision may occur within the first 24 hours, but generally takes 1-3 months (80% of patients)
- Vision may fluctuate for the first few months
- Magnification or LIGHT may still be needed for
  - Seeing tiny print, reading in dim light, conditions, or performing a near task for an extended period of time
- Under promise, over deliver
Visual Recovery

- Takes time and careful management
- Reassure patients regarding the recovery process and their progress
- Adherence to the therapeutic and dry eye regimen post-operatively can accelerate the healing process

Uncorrected Visual Acuity - Early Recovery (N=667)

Data courtesy of Dr. Minoru Tomita

Inlay is Removable

- Additive procedure
- Does not restrict future options
- Post-removal vision returns to baseline/LASIK target within 6 months
- Inlays have been successfully removed out to 4 years post op

Data from the Global KAMRA® Data Registry

9,000 commercially performed procedures around the world, including more than 700 with a 3-year follow-up

Inlay is Removable

- If a cataract develops, there are several options:
  - Phacoemulsification and monofocal IOL implantation can be performed with the inlay in situ
  - Inlay can be removed and replace after monofocal IOL implantation
  - Inlay can be removed and a PC-IOL implanted

KAMRA® Inlay Summary

- The KAMRA® inlay is an effective solution for presbyopia to bridge the gap between LASIK and cataract surgery
- The small aperture inlay reliably extends depth of focus providing uninterrupted vision from near to far
- Maintains stereopsis and binocular vision, regardless of monocular implantation
- The effect is proven to be stable over time
- Design does not interfere with ocular assessments or secondary surgical procedures

Other Corneal Inlays

- Raindrop Near Vision inlay (ReVision Optics)
- Flexivue Micro lens (Presbyia)
- InVue intracorneal microlens (Biovision)
ReLEx® SMILE procedure

- Refractive Lenticule Extraction
- Small Incision Lenticule Extraction
- Developed by Zeiss - 3rd generation of LVC (launched 2011)
- Micro-invasive refractive surgery
- Correction of myopia without a flap
- Clinical trials currently in U.S.

SMILE procedure

BENEFITS
- No flap = no flap-related complications
- Small incision of 2-4 mm
- Cornea remains intact as much as possible
- Improved predictability of the vision correction outcome
- Reduction in incidence of infection and epithelial in-growth
- Reduction in post-op dry eye

Figure 1: Distribution of post-refractive dry eye disease. The severity of dry eye disease was scored according to an overall index (range, 0-4) including signs and symptoms in small incision lenticule extraction (SMILE) and LASIK cases 1 month (A) and 6 months (B) after the surgery. The mean score was significantly higher in the LASIK than in the SMILE group at 6 months postoperatively (P < 0.01).

Clinical Outcomes and Efficacy Rates
- 95% of treated eyes achieve at least 20/30 UCVA at distance at 3 months for even moderate to high myopia levels
- 95% of eyes are +/- 0.50D from refractive target
- Only 1-2% of eyes losing 2 or more lines of BCSVA
- Refractive stability is typically achieved at 1 week
Carl Zeiss Meditec
- ~20,000 procedures performed by Dec 2012
- ~50,000 procedures performed by July 2013
- ~200,000 worldwide since Feb 2015

More research needed...

The Three Keys to Successful Surgery Outcomes
1. Successful Pre-operative Evaluation
2. Successful Surgery
3. Successful Recovery Period

Thank You and Questions?