Myopia, The Refractive Market and Phakic IOLs in Modern Refractive Surgery

David W. Friess, OD, FAAO

Head of Global Professional Affairs
Staar Surgical Company

President, OCCRS
Optometric Cornea, Cataract and Refractive Society

Financial Interest Disclosures

• STAAR Surgical Co. – Employee, Shareholder
• Optimus Clinical Partners LLC – President/Owner
Phakic IOL Product Information

• ATTENTION: Reference the Visian ICL™ and Verisyse™ Product Information for a complete listing of indications, warnings and precautions.

Refractive Market Statistics

• Includes US/Canada/Mexico LASIK, PRK/surface ablation, phakic IOLs, and refractive lens exchange
• 2007 1M+ refractive procedures
• 2013 600,000²
• 2015 vision correction market in the US²:
  – Over 60% require vision correction (nearly 200M people)
  – Spectacles, contact lenses
  – Refractive surgery penetration remains at less than 3%
  – 600,000 refractive procedures in 2015
• 2016 Q1 Market Scope:
  – 172,000 refractive procedures

Refractive Opportunity: Boomers vs. Millennials

- US Census Bureau Estimates¹:
  - 74.8 million Millennials in 2014. Ages 18 to 34 in 2015.
  - By 2015, Millennials increased to 75.3 million and became the biggest group.

1. http://www.pewresearch.org/fact-tank/2015/01/16/this-year-millennials-will-overtake-baby-boomers/

Myopia Research and Coverage in Mainstream Media

- Huffington Post, 03/22/2016: Nearsightedness Has a Far-Reaching Impact As the Myopia Epidemic Spreads Around the Globe
  - References new research from the Brien Holden Vision Institute (AUS) study on the prevalence of myopia

  - Myopia is projected to affect almost half of the world’s population by 2050 — a sevenfold increase
  - 5 billion with myopia
  - 1 billion with high myopia (>6D)
  - United States and Canada increase to 260 million, or close to half of the population, up from 89 million in 2000
  - High myopia cases increase by five times to 66 million
Key Myopic Treatment Goals

- Desire treatments with...
  - High Safety Index Postop BCVA/Preop BCVA
  - High Efficacy Index Postop UCVA/ Preop BCVA
  - Attempted vs. Achieved Rx - accurate and stable
  - Low rate of complications
  - Preserve corneal integrity and lens for future procedures
  - Low dry eye risk
  - Similar treatment across a broad range of refractions
  - High patient satisfaction

Phakic IOLs

- Variable materials
  - Plastic
  - Silicone
  - Collagen (Collamer) - STAAR Visian ICL

- Variable designs

  Anterior Chamber
  - Acrysof, Alcon
  - GBR, IOL Tech
  - Kelman Duet, Tekia
  - MemoryLens, Ciba
  - NewLife, IOL Tech
  - NuVita, B&L
  - ThinOptX
  - Vision Membrane
  - 6H2, Oll

  Iris Supported
  - Artison, Ophtec
  - Verisyse, AMO

  Posterior Chamber
  - PRL, Ciba
  - Visian ICL, STAAR
FDA Approvals for Phakic IOLs for Myopia

- 2004 – Verisyse® anterior chamber phakic IOL (AMO, Inc.)
- 2005 – Visian ICL™ posterior chamber phakic IOL (STAAR Surgical Co.)

Verisyse™
Anterior chamber iris fixated phakic IOL (AMO, Inc.)

8.5mm one piece PMMA
5.0mm and 6.0mm optic

Louis J. Catania © 2007 Nicolitz Eye Consultants
Verisyse® Phakic IOL Product Labeling

• Indication:
• Verisyse® intraocular lenses are indicated for the reduction or elimination of myopia in adults with myopia ranging from -5.0 to -20.0 diopters with less than or equal to 2.5 diopters of astigmatism at the spectacle plane and whose eyes have an anterior chamber depth greater than or equal to 3.2 millimeters; and, patients with documented stability of refraction for the prior 6 months, as demonstrated by spherical equivalent change of less than or equal to 0.50 diopters.

Visian ICL™ V4 Design
Posterior Chamber Phakic IOL

ICL Design

- Posterior Chamber Phakic IOL
- Haptics placed in sulcus - stability
- Optic Vault by design
  - 500 um over the central crystalline lens
- Orientation marks for proper placement and alignment in injector
- Small incision refractive surgery
- Foldable and injectable through a 3.5mm or less incision
Collamer Summary

• Collagen matrix
• Hydrophilic
• Biocompatibility
• Refractive index = 1.44
• Elastic: Gentle unfolding
• Tensile strength: Strong, resists tearing
• UV blocking chromophore
• Lathe cut design
• Stored in BSS
Peripheral Iridotomy

- Two YAG iridotomies (0.5mm; placed superiorly, 90 degrees apart) should be performed 2 to 3 weeks prior to surgery with confirmation of the patency of the iridotomies prior to lens implantation.

**Orientation Marks**

- Trailing Left
- Leading Right
- Direction of Implantation
Visian ICL – Implantable Collamer Lens

Indications for Use

• The Visian ICL is indicated for use in adults 21-45 years of age:
  1. For the correction of myopia in adults with myopia ranging from -3.0D to ≤-15.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
  2. For the reduction of myopia in adults with myopia ranging from greater than -15.0D to -20.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
  3. With an anterior chamber depth (ACD) of 3.00mm or greater, and a stable refractive history (within 0.5 Diopter for 1 year prior to implantation).

STAAR FDA MiCL Directions for Use (DFU)
Visian ICL™ (Implantable Collamer Lens) for Myopia
For the correction / reduction of moderate to high myopia

- FDA Directions for Use (DFU) Device Description

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Dioptic Power (D)</th>
<th>Overall Diameter (mm)</th>
<th>Optic Diameter (mm)</th>
<th>Haptic Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICL 12.1</td>
<td>-3.0 to +16.00</td>
<td>12.1</td>
<td>4.9 – 5.8</td>
<td>Flat, plate</td>
</tr>
<tr>
<td>ICL 12.6</td>
<td>-3.0 to +16.00</td>
<td>12.6</td>
<td>4.9 – 5.8</td>
<td>Flat, plate</td>
</tr>
<tr>
<td>ICL 13.2</td>
<td>-3.0 to +16.00</td>
<td>13.2</td>
<td>4.9 – 5.8</td>
<td>Flat, plate</td>
</tr>
<tr>
<td>ICL 13.7</td>
<td>-3.0 to +16.00</td>
<td>13.7</td>
<td>4.9 – 5.8</td>
<td>Flat, plate</td>
</tr>
</tbody>
</table>

Contraindications

- The Visian ICL is contraindicated in patients:
  1. With an anterior chamber depth (ACD) of <3.00mm;
  2. With anterior chamber angle less than Grade III as determined by gonioscopic examination;
  3. Who are pregnant or nursing;
  4. Less than 21 years of age;
  5. Who do not meet the minimum endothelial cell density.
Packer, 2016: Meta-Analysis of ICL Papers

- Broad range of corrections
- High quantity of vision
- High quality of vision
- Low incidence of complications with good patient selection
- High benefit to risk ratio


VISIAN ICL™ QUALITY OF LIFE VS. GLASSES, CONTACT LENSES AND LASIK

<table>
<thead>
<tr>
<th></th>
<th>QIRC Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post ICL (n=34)</td>
<td>53.8</td>
</tr>
<tr>
<td>Other Refractive (n=104)</td>
<td>50.2</td>
</tr>
<tr>
<td>Contact Lenses (n=104)</td>
<td>46.7</td>
</tr>
<tr>
<td>Spectacles (n=104)</td>
<td>44.1</td>
</tr>
</tbody>
</table>

**WELL ESTABLISHED BENEFITS**

- **Efficacy Index**: Post-op UCVA/Pre-op BCVA

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Efficacy Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visian ICL™</td>
<td>0.96 – 1.01&lt;sup&gt;1, 2, 3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

- Seeing well “right off the table”<sup>4</sup>

---

1. UCVA = Uncorrected Visual Acuity. BCVA = Best Corrected Visual Acuity.

---

**US MILITARY WARFIGHTERS**<sup>1</sup>

- Retrospective, interventional consecutive case series assessing short-term (3 months) clinical outcomes after Visian ICL™ implantation in US military warfighters

  - 135 eyes of 69 patients who were not good candidates for laser vision correction
  - Age: 30.9 +/- 6.6 years
  - Pre-Op MRSE: -6.00 +/- 1.92 D (range: -2.63 to -11.50 D)

US MILITARY WARFIGHTERS

- ICL Predictability:
  - 90% +/- 0.50 D
  - 99% +/- 0.75 D

- ICL Visual Acuity

VISIAN ICL™ VS. WFG-LASIK: CONTRAST SENSITIVITY (HIGH MYOPIA)

- ICL: Significant increase ($p < 0.001$)
- WFG-LASIK: Significant decrease ($p = 0.001$)


VISIAN ICL™ VS. WFG-LASIK: CONTRAST SENSITIVITY (LOW TO MODERATE MYOPIA)

- ICL: Significant increase ($p < 0.001$)
- WFG-LASIK: No change ($p = 0.11$)

Publication Review:
A prospective comparison of phakic collamer lenses and wavefront-optimized laser-assisted in situ keratomileusis for correction of myopia.


Study Methods

• Refractive Surgery Center, Carl R Darnall Army Medical Center, Fort Hood, TX
• Prospective, non-randomized comparison of 48 military personnel (95 eyes) who underwent either Visian ICL implantation or wavefront-optimized LASIK with WaveLight Allegretto Eye-Q 400 Hz excimer laser system
  – All the patients completed the 3-month follow-up period
• Subjects were included with:
  – Stable refractive error (change of spherical equivalent < 0.50 D for at least 1 year)
  – Myopia > −3.00 D (range: −3.00 D to −11.50 D) with astigmatism < 3.00 D
Study Methods

• Age was comparable between the two groups
  – ICL = 27.6 ± 7.3 years (range = 19 – 46 years)
  – LASIK = 27.0 ± 5.9 years (range = 20 – 41 years)
• No significant difference between two groups in preoperative spherical equivalent
  – ICL = −6.10 ± 1.76 D (range: −3.25 D to −11.50 D)
  – LASIK = −6.04 ± 1.72 D (range: −3.00 D to −9.50 D)
• Scotopic pupil diameters were also comparable
  – ICL = 6.37 ± 1.01 mm (range = 4.5 – 8 mm)
  – LASIK = 6.23 ± 0.88 mm (range = 4 – 8 mm)


Study Methods

• Rabin Super Vision Test
  – Precision Vision, LaSalle, IL, USA
  – High-contrast visual acuity
  – Letter contrast sensitivity
Study Methods

- Rabin Super Vision Test was used to compare the visual acuity and CS in each group under normal and low light conditions, using a filter for simulated vision through night vision goggles (NVG).
  - NVGs present particularly challenging viewing conditions
    - low luminance
    - loss of color discrimination
    - diminished contrast
  - Testing was conducted with best spectacle correction, first using NVG with low-luminance filter, then without filter (method used to prevent learning)

Study Results

- All surgeries were uneventful, and no vision-threatening complications were seen throughout the observation period
- Both groups were comparable with respect to preoperative visual acuities and contrast sensitivities
Study Results: Super Vision Acuity (SVa)

- Statistically significant improvement from preoperative-to-postoperative level observed in both groups.
- At 3 months, mean improvements in SVa (LogMAR) in the ICL and LASIK groups were comparable (P=0.154; error bars represent SD).

![SVa (LogMAR) comparison](image1.png)


Study Results: Super Vision Contrast (SVc)

- Postoperative improvement from preoperative levels was statistically significant in both groups.
- Statistically significant greater improvement for normal illumination and night vision simulation in the ICL compared to LASIK group.

![SVc (LogCS) comparison](image2.png)

Study Results: Super Vision Acuity with Goggles (SVaG)

- At 3 months, mean improvement in SVaG (LogMAR) in the ICL group was statistically significantly greater than the mean improvement in the LASIK group (P=0.032*; error bars represent SD).


Study Results: Super Vision Contrast with (low luminance) Goggles (SVcG)

- At 3 months, mean improvement in SVcG (LogCS) was statistically significantly greater in the ICL group as compared to the LASIK group (P=0.024*; error bars represent SD).

Conclusion

- In this study, low-luminance visual acuity and low-luminance CS significantly improved following ICL implantation, and the improvements were significantly better than those observed after wavefront-optimized LASIK.


AS A COMPREHENSIVE REFRACTIVE PRACTICE...

...your responsibility is to understand the potential risks¹:

- Early IOP Spike
- Late Cataract

...and be prepared to manage them.

¹ STAAR FDA MIKL Directions for Use (DFU)
EARLY IOP SPIKE

- FDA Study MICL DFU: “Raised IOP Requiring Intervention”
  - 3.2% (n = 17/526) additional LPI
  - 0.6% (n = 3/526) repeat irrigation and aspiration at 1 day post-op

- Mitigation/Management:
  - Important to monitor IOP at 24 hours postoperatively
  - Importance of patent LPIs
  - Thorough removal of OVD

- Literature:
  - Incidence of pupillary block 0.01, 3, 4, 5 — 0.7%2

5. STAAR MICL Directions for Use (DFU)
INCIDENCE OF MICL/V4 ASC CATARACTS

<table>
<thead>
<tr>
<th>ASC and Cataract Surgery</th>
<th>N</th>
<th>MRSE (D)</th>
<th>Follow Up</th>
<th>Clinically Significant ASC</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAAR FDA MICL DFU</td>
<td>526</td>
<td>-10.06</td>
<td>3 years</td>
<td>0.4%</td>
</tr>
<tr>
<td>Kamiya Arch Ophthalmol 2009</td>
<td>56</td>
<td>-9.83</td>
<td>4 years</td>
<td>1.8%</td>
</tr>
<tr>
<td>Sanders J Refract Surg 2007</td>
<td>311</td>
<td>-10.06</td>
<td>5 years</td>
<td>1.3%</td>
</tr>
<tr>
<td>Alfonso J Cataract Refract Surg 2011</td>
<td>188</td>
<td>-10.76</td>
<td>5 years</td>
<td>0.5%</td>
</tr>
<tr>
<td>Alfonso J Cataract Refract Surg 2015</td>
<td>1531</td>
<td>-7.27</td>
<td>5 years</td>
<td>1.4%</td>
</tr>
<tr>
<td>Brar EC Ophthalmology 2015</td>
<td>615</td>
<td>NR</td>
<td>5 years</td>
<td>0.7%</td>
</tr>
<tr>
<td>Schmidinger Ophthalmology 2010</td>
<td>84</td>
<td>-16.40</td>
<td>6 years</td>
<td>17%</td>
</tr>
<tr>
<td>Lee Clin Exp Ophthalmol 2015</td>
<td>281</td>
<td>-8.74</td>
<td>7 years</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Phakic IOLs for Myopia

- Well established benefits
- Low rate of complications
- Broad range of treatment
- Preservation of corneal or lenticular tissue
- High patient satisfaction and improvement in quality of life
Summary: Myopia, The Refractive Market and Phakic IOLs in Modern Refractive Surgery

- Myopia affects a large and growing demographic in need of vision correction
- Refractive surgery is a viable option for many patients
- Phakic IOLs have a long history with high benefit to risk ratio
- Keys include proper patient selection, meticulous surgery and good clinical follow-up to ensure patient satisfaction and quality of life is delivered

Thank you