Welcome to:

National Keratoconus Institute
Dedicated to State of the Art Management of Keratoconus and Keratoectasia

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Post-Intacs CL Fitting Strategies and Outcome

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ICRS (Intrastromal Corneal Ring Segment):
- Oklahoma optometrist first conceptualized the idea in 1978
- One of the early medical champions of contact lenses in the U.S.
- Developed CorneaScope in late 1960s - led to today's topography

Gene Reynolds, O.D.
1921 - 1994

ICRS Developmental Milestones: Device Types
- Kera Rings (360°)
- Intacs
- Ferrera Ring
- Bisantis Periopic Implants
  - PMMA proves biocompatible

1984 Adjustable Ring

ICRS Developmental Milestones
- 1985 – First pre-clinical studies on Dr. Reynolds’ device
- 1991 – First human clinical trials begun in Brazil
- 1996 – U.S. myopia clinical trial begun, 150° ICRS
- CE Mark approval in Europe (-1D to -4.50D)
- 1997 – Joseph Colin, MD inserts first ICRS for KC
- 1999 – FDA approval for myopia (-1D to -3D)
- 2004 – FDA approved HDE Use for KC/Ectasia

ICRS Developmental Milestones: Intacs® SK
- SK series approved for KC under HDE
  - 400SK: K 57- 62D, & Cyl < 5D
  - 450SK: K > 62D, & Cyl > 5D

SK (400 or 450SK)
Non-SK Series

Courtesy: Josef Ruckhofer, MD
Courtesy: Rex Hamilton, MD
UCLA Jules Stein

10/14/2013
**ICRS Intacs® Features and Mechanisms**

- 150 deg arc length
- PMMA
- 70-80% peripheral depth
- OZ: 6mm vs. 7 mm
- Refractive procedure via Addition
  - Potentially reinforces corneal biomechanics unlike incision or ablation

Barracker’s law of thickness
- $\alpha$ thickness, and
- $1/\alpha$ diameter
- Shortened arc length in central cornea
  - Central flattening,
  - Midperipheral steepening,
  - Centripetal apical shift
- Potential structural support
  - Stability? (Bedi et al, 2012)

**ICRS Intacs®: Implantation Techniques**

- Manual or Femto-assisted channels
  - Laser is delivered to precise depth
    - More reproducible?
    - Less complications?
    - Better fitting channels?
    - Faster recovery?

Customized channel dimensions
- Decreases surgical Risks
- More reproducible results

**ICRS Intacs®: Common Post-Op Mx Protocol**

- BSCL/bandage lens x 1 day
- Topical Fluoroquinolone
  - Q2hr x 1 day
  - QID x 1 wk
- Topical steroid
  - Q2hr x 1 day
  - QID x2wk, BID x 1 wk, OD x1 wk
- Topical NSAID (Rarely needed)
  - BID x 5 days
- NPAT PRN
- Oral analgesics (Rarely needed)

≥ 21 years y/o,
- CT ≥ 450mi at incision site,
- Clear central cornea,
- Contact lens “challenged” and considering PK,
- BCVA <20/25,
- Topo $K_{max} \leq 65$D (ie, Pentacam)
- Corneal cylinder less than 6D (Sim K or Topography)
ICRS

**Intacs®: NKCI Indications & Expectations**

- **Primary Goals:**
  - Enhance CL options and tolerance
  - Defer need for corneal transplant

- **Secondary Goals:**
  - Improve UCVA and BCSVA
  - 80.5% and 68.3% with improved UCVA and BCVA with 2 yrs f/u in 200 eyes (Colin J and Malal F, 2007)
  - 85.23% and 87.9% with improved UCVA and BCVA with 5 yrs f/u in 186 eyes (Ibrahim TA, 2006)

  - 19.7% gained > 3 lines of BCVA
  - 68.2% gained 1-3 lines of BCVA

- **ICRS Post-Op Fitting Considerations**:
  - Advancements in CL device materials/designs
  - 12-26% KC patients seek surgical Tx
  - PKP most common
  - Alternative corneal keratorefractive Tx
    - Incisional, Ablative, Thermal, Additive
    - In 58 eyes, mean pre-op UCVA of 20/200 improves to post-op UCVA of 20/50 but BCVA mostly unchanged
  - 72.2% reported significant VA improvement

- **ICRS Post-Op Fitting Considerations**:
  - Greatest flattening effects over segments
  - ICRS (ie, Intacs®) creates midperipheral elevation

  - Apical bearing/Decentration/Edge lift, Vs.

  - Midperipheral impingement? Improved bearing and position?

- **ICRS Post-Op Fitting Considerations**:
  - Pre-op Expectations Management!!
  - Pre-op CL history

  - Implantation Strategies
    - Depth
    - Number of Segment(s)

  - ICRS Designs
    - Location of Elevation (ie, OZ)
    - Magnitude of Elevation (ie, Intacs® SK)

  - Post-Op VA Responses
    - Duration of Stabilization period

- **ICRS Post-Op Fitting Considerations**:
  - Apical shift post-ICRS may help to offset challenges in post-ICRS fitting
    - Rearrangement of elevated point(s)
    - Elevation within area of max. sagittal depth
ICRS
Post-Op Fitting Considerations: Timing
- Alios et al (2005) described 3 mths stabilization
  - May take up to 12 mths for advanced KC
  - Post-ICRS fitting can be effective in deferring transplantation in severe KC (Ucakhan O et al, 2006)
- Post-ICRS Fitting Goals
  - Pre-Op goals: BCLVA, tolerance/wear time, I/R
  - Prevent (or minimize) positive pressure on ICRS
    - Maintain dynamic tear exchange
    - Maintain optimum ocular health

ICRS
Post-Op CL Fitting Strategies
- Segment Alignment
  - Soft CL
  - Corneal GP
- Segment Bandage
  - Piggyback system
  - Recess lens system
- Segment Vaulting
  - Shadow Vaulting (hybrid/mini-scleral)
  - Full Vaulting (scleral)

ICRS
Seg Alignment: Soft CL
- “Satisfactory” Post-Op BSCVA
  - Reduced HOA-related symptoms
  - Aspheric, Toric, & Multifocal
  - BC /PC selection
  - Manual Keratometry
  - Topography
  - Tomography/Elevation

ICRS
Seg Alignment: Soft Custom KC CL
- Improved OZ optical features
  - Enhanced CT profile: Gradient CT control, Or
  - Large OZ: Sag depth to better drape entire cornea, and
  - High Sph and Cyl Rx

ICRS
Seg Alignment: Soft Custom KC CL
- Independent PC fitting zone
  - Align with disproportional periphery
    - Reverse Geometry
    - Edge Sector control
  - Limbal stem cell health
- Fitting curves essential to KC SCL performances

ICRS
Seg Alignment: GPs
- Pending ICRS design and numbers of Segment, conventional GPs may not clear elevated zones
  - Localized binding, reduced dynamic tear exchange keratitis, erosion, chronic hypoxia

ICRS Seg Alignment: GPs
- Modern larger diameter GPs with multiple PC zones
  - Enhanced Sag depth/BOZD
  - Quadrant-specific & Reverse Geo. designs
  - Modify PC systems to aid centration/tear dynamics

ICRS Seg Bandage: Piggyback System
- If GP mechanical bearing can not be avoided, minimize positive pressure over ICRS segment via higher DK soft/soft custom lens
  - Patient Comfort
  - Centration
  - CLVA
  - Tear exchange
  - Ocular surface health

ICRS Seg Bandage: Recessed Piggyback
- Straight Walled
- Angle Walled
- Overhang

ICRS Seg Vaulting: Hybrid
- Reverse Geometry with 6.5mm OZ
  - New SK series (400/450): 6mm OZ
    - Limited vaulting?
  - Non-SK series: 7mm OZ
    - Alignment with soft skirt?
  - Hyper dK generation can reduce hypoxic concerns
    - GP: Dk 130
    - Soft Skirt: Dk 84

ICRS Seg Vaulting: Hyper Dk Hybrid

Courtesy of SynergEyes®

RGP Characteristics

<table>
<thead>
<tr>
<th>Material</th>
<th>Overname (SK)</th>
<th>Ultevname (SK)</th>
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<tbody>
<tr>
<td>Reflective Index</td>
<td>1.462</td>
<td>1.462</td>
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<tr>
<td>Modulus (MPa)</td>
<td>1350</td>
<td>1334</td>
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<tr>
<td>Water Vapour Transmission</td>
<td>95%</td>
<td>97%</td>
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<tr>
<td>UVB Transmittance</td>
<td>98%</td>
<td>98%</td>
</tr>
<tr>
<td>UVA Transmittance</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td>UVB Transmittance (300-380)</td>
<td>98%</td>
<td>98%</td>
</tr>
<tr>
<td>UVB Transmittance (380-400)</td>
<td>98%</td>
<td>98%</td>
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<tr>
<td>Wetting Angle</td>
<td>40°</td>
<td>34°</td>
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<tr>
<td>Specific Gravity</td>
<td>1.33</td>
<td>1.33</td>
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<tr>
<td>Hardness (shore 0)</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Dk (Oxygen Permeability)</td>
<td>100</td>
<td>300</td>
</tr>
</tbody>
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Courtesy of SynergEyes®
ICRS
Seg Vaulting: Hyper Dk Hybrid

Soft Skirt Characteristics
Material Comparison

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<tr>
<th>Material</th>
<th>ClearKera (CK)</th>
<th>UltraHealth (UH)</th>
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<tr>
<td>Nucleus (Mpa)</td>
<td>9.2 – 9.6</td>
<td>8.9 – 9.6</td>
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<tr>
<td>Refractive Index</td>
<td>1.409</td>
<td>1.408</td>
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<tr>
<td>Water Content</td>
<td>7.9%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Dk (Oxygen-Permeability)</td>
<td>64</td>
<td>84</td>
</tr>
</tbody>
</table>

Courtesy of SynergEyes®

ICRS
Seg Vaulting: Scleral Lenses

- Sustainable corneal clearance extending to limbal region with scleral alignment
  - “Liquid bandage” overlies insert segment(s)

ICRS
Post-Intacs® CL Fitting: Literature

- At 6 months after Intacs implantation, 12 of 13 (92.3%) were successfully fit with contact lenses
  - 58% (7/13) had soft toric lenses,
  - 17% (2/13) had GP lenses,
  - 25% (3/12) had hybrid contact lenses.

Chang C, Shin A, & Hersh P: Retrospective review of consecutive post-Intacs/CXL Tx
- 25 KC & 8 Ectasia eyes
- 13 Females & 20 Males
- Mean age = 37.1 y/o (22 – 56)
- Pre-op CL tolerance: 48.1%
  - General (CLEI): 57.7%
  - Non-surgical (CLEI): 63.4%

ICRS
A Post-Intacs® CLF Study

<table>
<thead>
<tr>
<th>Material</th>
<th>CL Tolerance at Presentation</th>
<th>s/p CXL-Intacs</th>
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<tbody>
<tr>
<td>CXL/Tacs</td>
<td>48.1%*</td>
<td>100% (33/33)</td>
</tr>
<tr>
<td>LogMAR Habitual VA</td>
<td>0.44 (20/55.6)</td>
<td>0.17 (20/29.6)</td>
</tr>
</tbody>
</table>

*Tolerance is defined as patients who present with CLs on eyes regardless of functional wear time.
ICRS
A Post-Intacs® CLF Study: Conclusion

- Patients seeking surgical consultations exhibit lower contact lens tolerance
- Modern surgical interventions such as ICRS potentially compliment contact lens fitting outcome
  - Pre-Op Hx/Expectations/Educations
  - 3 Months stabilization (up to 12 months in some)
- Specialty lens devices, including GPs, continue to be effective post-Intacs visual rehabilitation tools


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