American Society of Cataract and Refractive Surgery

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Course 09-206
Room 244

“Solving the High Myopia Problem with Phakic IOLs”

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Monday, May 9, 2016
10.00 AM – 11.30 AM
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**PRL™ 15 Years Surgical Technique Evolution What Is New To Make It Safer?**

*Dimitrii Dementiev MD*

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**REFRACTIVE SURGERY TARGET**

- SAFETY
- HIGH QUALITY OF VISION
- HIGH PRECISION & PREDICTABILITY
- REVERSIBILITY
- SIMPLICITY
- QUICK REHABILITATION
- VERSATILITY

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**REFRACTIVE SURGERY**

**PHAKIC IMPLANTS**

- **ANTERIOR CHAMBER**
- **POSTERIOR CHAMBER**
- REVERSIBLE
- HIGH PREDICTABILITY
- HIGH QUALITY OF VISION
- NO TISSUE REMOVAL
- HIGH REFRACTIVE ERROR CAN BE CORRECTED

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**PHAKIC IOLs**

**ANTERIOR CHAMBER**

- Varioflex & Variflex implant; also known as the Artisan phakic IOL (AMO)
- Phakic (6.011)
- Vixentz (Ciba Vision/IOLTECH)
- I CARE (Cornel)
- ALVYFOG AC (ALCON)

**POSTERIOR CHAMBER**

- ICL (STAAR SURGICAL)
- PRL (CARL ZEISS/Meditec)

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**Visian ICL, Sierra Surgical FEATURES / APPLICATIONS**

- Material: Collamer (hydrogelic collagen)
- One-piece design, inner lens haptic design
- Prevalent in the market to avoid contact with the corneal area
- Risk of reposition is low
- Water 0.3 mm

**Optical Diameter**

- Mean: 15.5 mm
- Hyperopic model: 15.0 mm

**Displacement Range**

- Mean: 2 Diopters (D)
- Hyperopic: +0.5 to +2.0 D
- Low +2.0 D

*Diabetic indication*: 1.5 D.
1st Generation of PIOL implanted in 1987
pupil /PC positioning

**PRL™**
**Phakic Refractive Lens**
*Carl Zeiss, Meditec*

- **MATERIAL:** SILICONE
- **ONE PIECE DESIGN**
- **WIDTH:** 6.0 mm
- **OVERAL LENGTH:**
  - MYOPIQUE MODEL: 10.0 & 11.3 mm
  - HYPEROPIQUE MODEL: 10.6 mm
- **OPTICAL DIAMETER:**
  - HYPOPIQUE MODEL: 4.5 - 5.0 mm
  - HYPEROPIQUE MODEL: 4.5 mm
- **DIOPTRR RANGE:**
  - M: -3 until -20
  - H: +3 until +15
- **DIOPTRIC INCREMENT:** 0.5D.

**PRL “CONCEPT”**

1. Hydrophobic silicone RI 1.46
2. Radius of curvature = Lens RC
3. Hydrodynamics (pushed UP)
4. Natural "vaulting"

1. Touch of iris
2. No touch of lens

**SURGICAL TECHNIQUE**

- 2.8 mm standard clear cornea incision (TEMPORAL)
- PRL loading & insertion (self foldable)
- Atraumatic loading under the IRIS
- No stitch
10 years after PRL IMPLANTATION

- PREOP VIS 0.3 SPH-21.0
- 1993 PRL IMPLANTATION – INFLAMATION, RESOLVED WITH TX
- 1994 POSTOP VIS 0.7 S.G.
- 2004 VIS 0.3 S.G (CATARACT)

CONCERN / COMPLICATIONS

- GLAUCOMA?
- PIGMENT DESPERTION?

PIGMENT VACUUM PI

Kenneth J. Hoffer* Pigment vacuum iridectomy for phakic refractive lens implantation” J Cataract Refract Surg. 2001

PUPIOL OVALIZATION

Pupillary block, YAG LASER PI ???

- TOO SMALL
- NON PENETRATING

CONCERN / COMPLICATIONS

POSITION IN PC


CONCERN / COMPLICATIONS

POSITION IN PC

- DECENTRATION
- SUBLUXATION TO VITREOUS!

Possible reasons for PRL decentration/sub-luxation

1. Pre-existing zonular fragility/ dystrophy

2. YAG-laser iridectomy

3. Surgical trauma

4. May PRL haptics damage zonule (?)

HYPEROPIC PRL PIGGY BACKI (Dr. Hoyos courtesy)
Possible reasons for
decentration/sub-luxation

- YAG laser iridectomies may break zonulas
  - ENERGY?
  - NUMBER OF PULSES?
  - DARK IRIS!

PRL FURTHER ROTATION CAN
MAKE THE ZONULAR HOLE
BIGGER!!!

Gentle Manipulation Under Iris

PREVENTS ZONULAR DAMAGE

- Surgical trauma
- Very careful haptics loading under the iris is a crucial point of surgical technique
- No force to zonular!!! Fold but not move
- Avoid rotation in the PC

Possible reasons for
decentration/sub-luxation

- POSSIBLE INCREASE OF ZONULAR
damage after YAG-Laser PI - PRL
ROTATION

Possible reasons for
decentration/sub-luxation

If so, not only limited cases at limited sites
would be reported.
ICL DISPLACEMENT TO THE VITREOUS REPORT

- JCRS 08.2005 published similar complication with ICL
- All posterior chamber phakic IOLs can go to the vitreous???
  - WRONG CANDIDATE
  - SURGERY!!!

Complex KC treatment
1. INTACS - corneal stabilization
2. PRL - refractive error correction

Complex KC treatment
1. INTACS
2. PRL
**Why Posterior Chamber Phakic IOLs?**

- **Reason 1:** Perfect flexibility of implant set to ease implantation or explantation through small incision without stress and visual stagnation.
- **Reason 2:** After 20 years of experiences 1 bil eye Posterior chamber IOLs intact with endothelium better than ACIOls.
- **Reason 3:** Collagen (PRL better) give good intracorneal adherence in long term and scarcely less cases of photophobia phenomena than AC IOls.
- **Reason 4:** Because the IOls are placed under the iris, they can avoid complications like iris-lense, iris-narrowing and light reflection after implantation of AC IOls.
- **Reason 5:** IOL position in posterior chamber is natural way, no one of us will like to make AC IOls implantation in distant surgery. Intermediol cell loss, iris deformation and light reflection after implantation of AC IOls, IOLs confirms its disadvantages.

**ADVANTAGES OF PRL**
- **MYOPIA TILL -30.00d**
- **HYPEROPIA TILL 10.00d**
- **HIGH QUALITY OF VISION**
- **NO CATARACTS IN 13 YEARS,**
  **THINNER THAN ANY OTHER PIOL**
- **HYDROPHOBIC MATERIAL**
- **NO ADHESION TO TISSUE**
- **EASY REVERSIBLE**
- **HIGH PRECISION OF POWER**
  **CALCULATION-PREDICTABILITY**
- The **HIGHEST PATIENT SATISFACTION**

**CONCLUSION**

- **PRL IS IN EVOLUTION SINCE 1992**
- **PREVIOUS CONCERNS (CATARACT & GLAUCOMA) - NOT ANY MORE**
- **NEW CONCERN: POSTERIOR SEGMENT COMPLICATIONS**
- **SUBLUXATION TO VITREOUS (limited numbers)**

**PRL FUTURE APLICATION**

- **CAN BE EVEN THINNER THAN TODAY**
- **VACUUM DELIVERY SYSTEM FOR IMPLANTATION THROUGH LESS THAN 2.0 mm INCISION**
- **PRESBYOPIE PROJECT WITH PRL**

POSSIBLE CHANGES in PRL

- THINNER HAPTICS
  • LESS SURGICAL TRAUMA DURING IMPLANTATION

- SOFT HAPTICS EDGE
  • LESS WEIGHT IN PC

THANK YOU
“Solving the High Myopia Problem With Phakic IOls”

Matteo Piovella MD

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Medical Director
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Dr. Piovella has the following financial interests or relationships to disclose:

As consultant:
- Aerem Solinurino
- Alcon Medical Optics
- Alcon
- Carl Zeiss Meditec

As speaker:
- ESCMID (European Society of Clinical Microbiology and Infectious Diseases)
- Galler Therapeutics
- Teurelense

FRL IMPLANT

Vivarte™ evaluation
15 minutes after surgery

Vivarte™/I/ER
Anterior Chamber Phakic IOL

- Optic diameter: 5.5 mm
- Overall diameter: 12.0, 12.5, 13.0 mm
- Refractive index: 1.47
- Dioptric range: -7.0 to -35.0 D
- Increments: 0.5 D steps

- Precise white-to-white preoperative measurement
- Important for patient selection

- IOL Master by Zeiss: identify eye out of range for IOL size

- W-T-W (surgical limbus add 1 mm): from 11.6 to 12.66 mm
- W-T-W (clear cornea add 0.5 mm): 10.56 – 12.06 mm
Surgical Size Vs. Visante™ (24 eyes)

40% Correct IOL Size
34% Wrong IOL Size

Lenses explanted: 21

34% Wrong IOL Size

Wrong IOL Size: 13 Lenses:

11

Lenses explanted: 21
4 less explanted for different motivations

1 IOLs due to too short haptics
4 IOLs due to two long haptics
4 Lens due to AC diameter too big
12 correct size IOLs: 1 due to iridocyclitis

Vivaré™ IOL Removal
TERRIFIC BCVA!!!!
LogMAR

Vivaré™ GBR IOL Removal
Dramatic EC Counts!!

ECC: ≤ 1500/mm²
Vivarte™ IOL Removal

Vivarte™ IOL
IOL Removal – MD, 50 y.o., female

Vivarte™ IOL
Phakic Anterior Chamber IOL – 12 years follow-up

Vivarte™ IOL
Phakic Anterior Chamber IOL
IOL explanted 5 years after surgery

Vivarte™ IOL
Phakic Anterior Chamber IOL
IOL explanted 10 years after surgery

M.D. (60y.o.) cell 1191 (pre-op 2005)
Date of surgery: March 2011
Date of explantation: May 2013

V.V. (42y.o.) cell 1523 (pre-op 2270)
Date of surgery: October 2011

E.C.C Prep: LE n: 2204
Post-op VA: LC 1.6 +1.00 +1.00 (60)
IOL Dislocation
LC progressive ECC reduction
(after 6 years n = 1694)

Explantation was performed at: day 1441
B.S. (36 y.o) cell 1349 (preop 2481) Date of surgery Feb 2002 Date of Explanation Jan 2009

Vivarte™ Phakic Anterior Chamber IOL IOL explanted 7 years after surgery

M.G. (26 y.o) cell 2469 (preop 2467) Date of surgery March 2002 – 11 years follow-up

Pupil Ovalization:
\[ n = 7 \ (20.6\%) \]
Grade 1 (<0.5 mm): \( n = 4 \)
Grade 2 (<1 mm): \( n = 3 \)

Vivarte 12 Years After Surgery

25 eye in follow up 12 years after surgery 410Ls well tolerated - 21 IOLs explanted

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<tr>
<th>ID</th>
<th>REVA</th>
<th>ECD PRE</th>
<th>ECD</th>
<th>% ECD REDUCTION</th>
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<td>G.S.</td>
<td>20.20</td>
<td>2311</td>
<td>1872</td>
<td>-20.03</td>
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<td>G.S.</td>
<td>20.20</td>
<td>2319</td>
<td>2277</td>
<td>-1.45</td>
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<td>P.A.</td>
<td>20.20</td>
<td>2310</td>
<td>2008</td>
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Vivarte™ IOL
EC Counts : 12 Years Follow Up

LE 3 years after implantation:
VA 1.0 -0.50 -1.00 (20), ECC 1058

Phakic IOL PRL removal
3 years p.o.

Phakic IOL ICL removal
2 years p.c. Female, 49 years old

Phakic IOL FRL removal
5 years p.o.

Vivarte™ IOL
Patient Satisfaction

- Patient satisfaction was evaluated at 309 days with a written questionnaire
- All patients were satisfied with the results of surgery
- Twenty-eight patients were actively driving a car
- They reported a better night vision than respect to spectacles or contact lenses

Vivarte™ IOL
Long-Term Management

- Refractive surgery patients require constant follow-up in time and proper technology (Vivarte™)
- All people require follow-up in time (AAD PPP suggest a visit every three years even for a healthy eye
- Patients with phakic IOL require follow-up examination every six months
- This information should be clearly shared with the patient preoperatively and stated in the informed consent
OCT Visante™
has the same priority role
for AC Segment Measures
as well as Corneal Map rule
for laser refractive surgery

Thank you for your attention
“Solving High Myopia: Iris Fixated IOLs, Installation, Management and Removal”

David R Hardten MD

Initial Step: Commit to their Usefulness

Why Phakic IOLs?
- They play a real role in the management of higher refractive error
- Technique is learnable by intracocular surgeons
- Verisyse and ICL, Vism IOL now approved
- Two implants increases options
- This is technology that can be additive to the technology needed by patients seeking LASIK
- This is technology that can be additive to the surgeon doing NLR or cataract surgery

Why a phakic IOL?
- High Corrections with Retention of Accommodation
  - Removable (no tissue removed)
  - Both IOLs in clinical trials >90% ± 1 D of target
  - Both IOLs in clinical trials >90% 20/40 or better UCVA
  - Improvements in BCVA on average
  - Low risk of complications

Complications

Complications can Occur

Ultrasound Biomicroscopy (UBM)

Pre-Verisyse or Visian Planning

Suggested Safety Parameters

OCT – Anterior Chamber Dimensions

free zone
Pre-Verisyse or Visian Planning

Advanced Software Developments

Verisyse Enclavation

Phakic IOLs
- Preoperative PI's critical
- Two paracenteses
- 10 and 2 o'clock
- Orient towards the midperipheral iris
- Wound should be relatively short
  Long wounds make lens insertion more difficult

Verisyse Enclavation

Key Steps to Insertion

Phakic IOLs
- Memorize AC depth
- Preview position of claws
- Small portion of iris
- Watch natural lens during enclavation
- Lift iris into claw
- Refill AC to proper depth when evaluating operation
Laser Vision Correction Enhancements

- LVC after ph-IOL
  - 22 eyes with at least 1 mo follow-up (mean 5 mos)
  - Mean SE post IOL = 0.12 ± 0.31 D
  - Mean AE (D) = 0.25 ± 0.31 D
  - UCVA 20/25 or better = 63%
  - UCVA 20/10 or better = 55%
  - In eyes with original BCVA 20/20
    - UCVA 20/25 or better = 54%
    - UCVA 20/20 or better = 100%
  - No eyes with loss of BCVA

Eventually Cataract

Eventually All Phakic IOLs Will be removed

Conclusions

Phakic IOLs
- Excellent addition to comprehensive refractive practice:
  - LASIK
  - Phakic IOLs
  - Natural Lens Replacement
  - Prephakic IOLs
  - Refractive Cataract Surgery
- Enhancement possible with PRK or LASIK
- Retic Inlay (<10%)
- Eventually Cataract Removal

Case Example – LVC after Verisyse

Wavefront Treatment after Verisyse

- MR: 2.50 ± 1.25 ± 25
- WR: 3.50 ± 2.11 ± 30
- HOA: 3.06 µ
- Corne: 14.1 µ
- Temp: 6.78 µ
- SA: 6.94 µ

Preop PRK – Custom
Postoperative UCVA = 20/10

Steps To Removal

I prefer:
- Superior Scleral Incision for Removal of Verisyse

Then Clear Cornea for IOL
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