American Society of Cataract and Refractive Surgery

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San Diego Convention Center

Course 2698
Session 20-204
Room 7 B

“Solving the High Myopia Problem with Phakic IOLs”

Senior Instructor:
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Instructor:
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David R Hardten MD
Gregory Parkhurst MD
Matteo Piovella MD

Monday, April 20, 2015
10.00 AM – 11.30 AM
INDEX

Posterior Chamber Phakic Refractive Lens (PRL): 15 Years Surgical Technique Evolution

Dimitrii Dementiev MD

Management of Complications after Vivarte™ Phakic Anterior Chamber IOL Implantation

Matteo Piovella MD

Tricks to obtain better results with Acrysof Cachet Angle Supported anterior chamber IOL

Luca Gualdi MD

Solving High Myopia: Iris Fixated IOLs, Installation, Management and Removal

David R Hardten MD

ADDRESSES
“PRL™ 15 Year Surgical Technique Evolution What Is New To Make It Safer?”

Dimitrii Dementiev MD
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:
  - MYOPIC MODEL: 10.0 & 11.3 mm
  - HYPEROPIE MODEL: 10.6 mm
- OPTICAL DIAMETER:
  - MYOPIC MODEL: 4.5 - 5.0 mm
  - HYPEROPIE MODEL: 4.5 mm
- DIOPTER 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"

- Touch of iris
- No touch of lens

**PRL MYOPIC RANGE**

- FROM -3.0 DPTERS.
- TO -30.0 DPTERS.

**PRL HYPEROPIE RANGE**

- FROM +2.5 DPTERS
- TO +11.0 DPTERS

**SURGICAL TECHNIQUE**

- 2.0 mm standard clear cornea incision (TEMPORAL)
- PRL loading & insertion (self foldable)
- Atrumatic loading under the IRIS
- No stitch

**CONCERNS / COMPLICATIONS**

- CATARACT?
10 years after PRL IMPLANTATION

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

Deckert Dementrey MD

GLAUCOMA?
PIGMENT DESPERATION?
PIGMENT VACUUM PI

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

PUPIL OVALIZATION
Pupillary block, YAG LASER PI ???

- TOO SMALL
- NON PENETRATING


CONCERN / COMPLICATIONS

CONCERN / COMPLICATIONS

CONCERN / COMPLICATIONS

CONCERN / COMPLICATIONS

Possible reasons for PRL decentration/sub-luxation

1. Pre-existing zonular fragility/ dystrophy
   - Koch BK (Ed) Bitar Z. Zonular enchancement on the anterior capsular zonular-free zone J Cataract Refract Surg 1996

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

Can PRL haptic's edge damage zonule
by itself in follow up?

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

Cataract 6 years after ICL implantation
Why Posterior Chamber Phakic IOLs?

Reason 1: Perfect flexibility of implant to make operation or reoperation through small incision without extra- or intralenticular separation.

Reason 2: After 20 years of experience 1 bil eye Posterior chamber IOLs interfaced with endothelium better than Acrysof.

Reason 3: Surgical risk of ACIOl is not manifest unlike Phakic IOLs (PRL better) give good intracorneal coherence in long term and showed less cases of pseudophakic phacomorphic than AC IOl.

Reason 4: Because the PRLs are placed under the iris, natural activities like up and down are achieved.

Reason 5: PRL position in posterior chamber is a natural way, no one of us will like to make AC IOl, reoperation is needed surgery, intraocular cell loss, iris distortion and light reflection after implantation of AC IOl, PRL confirms it 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

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

CONCLUSION
- PRL IS IN EVOLUTION SINCE 1992
- PREVIOUS CONCERNS (CATARACT & GLAUCOMA) - NOT ANY MORE
- NEW CONCERN- POSTERIOR SEGMENT COMPLICATIONS
- SUBLUXATION TO VITREOUS (limited numbers)
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
Anterior Chamber Depth Determination

- Precise white-to-white preoperative measurement
- Important for patient selection
- IOL Master by Zeiss: Identify eyes out of range for IOL size
- W-T-W (surgical limbus add 1 mm): from 11.5 to 12.00 mm
- W-T-W (clear cornea add 0.5 mm): 10.60 – 12.00 mm

SURGICAL SIZER vs. VISANTE™
(24 eyes)
46% CORRECT IOL SIZE
54% WRONG IOL SIZE

Lenses explanted: 21

WRONG IOL SIZE: 54% = 13 Lenses:

Uncorrected: 1 EYE TOO SHORT
DIFFERENCE = 0.50mm

Uncorrected: 3 EYES TOO BIG
DIFFERENCE= 1.19mm, 0.33mm, 0.41mm

4 IOLs TOO LONG (NEEDED INFERIOR SIZE) FOR EYE SIZE
DIFFERENCE= 0.66mm, 0.37mm, 0.42mm, 0.31mm

5 IOLs TOO SHORT (SUPERIOR SIZE REQUIRED)
DIFFERENCE= 0.71mm, 0.59mm, 0.58mm, 0.32mm, 0.32mm.

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

Vivarte™/IGBR IOL Removal
TERRIFIC BCVA!!!!!
LogMAR

Vivarte™ IOL Removal
Dramatic EC Count!!!
**ECC**: ≤ 1500/mm²

**Vivarte™ IOL Removal**

**Vivarte™ Needed bigger size IOL**

**Vivarte™ IOL**

Date of surgery March 2000
Date of explantation May 2007

ECC Preop: LE = 2394
Postop VA: LE 1.0 + 1.50 + 1.00 (60)
IOL Decentration
LE progressive ECC reduction
(18 years: n = 1098)

Explantation was performed at: Jono 1447

**Phakic Anterior Chamber IOL - 12 years follow-up**

**Vivarte™**

V.V. (42yo) cell 1923 (precop 2279) Date of surgery October 2001

**Vivarte™**

V.V. (42yo) cell 081 (precop 2577) Date of surgery Dec 2001
Date of Explantation: March 2010

**Vivarte™ IOL Removal - MD, 60 y.o., Female**

12
Pupil Ovalization:
n = 7 (20.6%)
Grade 1 (<0.5 mm): n = 4
Grade 2 (<1 mm): n = 3

Temporal Incision needed bigger size IOL

1 DAY PO
1 YEAR PO
2 YEARS PO
1 MONTH PO
4 YEARS PO
### Vivarte™ IOL
**EC Counts: 12 Years Follow Up**

#### 4 Lenses data

<table>
<thead>
<tr>
<th>ID</th>
<th>ID2OA</th>
<th>ID2FRE</th>
<th>ECC</th>
<th>% ECC Reduction</th>
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<td>V1</td>
<td>2270</td>
<td>1903</td>
<td>1903</td>
<td>-15.38</td>
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<td>V2</td>
<td>2541</td>
<td>1472</td>
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<td>P.A.</td>
<td>2008</td>
<td>2201</td>
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<td>-04.83</td>
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#### 25 eye in follow up
12 years after surgery
4 IOLs well tolerated - 21 IOLs explanted

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### Phakic IOL PRL removal
4 years p.o.

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

- No lens-induced warpage

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

### Vivarte™ IOL
Patient Satisfaction

- Patient satisfaction was evaluated at 360 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
Vivante™ IOL
Long-Term Management

- Refractive surgery patients require constant follow-up in time and proper technology (Visante™)
- 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
“Tricks to obtain better results with Acrysof Cachet angle supported anterior chamber IOL”
Luca Gualdi MD

I have no financial interests or relationships to disclose.

<table>
<thead>
<tr>
<th>Age</th>
<th>Minimum Cell Density (cells/mm²)</th>
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<tr>
<td>21 – 25</td>
<td>3,750</td>
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<tr>
<td>26 – 30</td>
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<td>2,500</td>
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<tr>
<td>41 – 45</td>
<td>2,200</td>
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<tr>
<td>≥46</td>
<td>2,000</td>
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Patient selection tricks

Endothelium selection tricks

Endothelial Cell Density Requirements
Tricks to obtain a correct White-to-white (W-W) distance
Intra-operative tricks

WITHOUT
vasoconsitistor drops

WITH
vasoconsitistor drops

Tricks to how to correct Astigmatism

BIOPTICS

Es. - 4.5 sf. - 3 cil (10D)

= 0 sf. - 3 cyl (180)

= 0
CONCLUSIONS

A correct pre-operative selection is very important to obtain the best result. With some tricks, you can avoid mistakes which can compromise the final and long-term result, giving to the patient less glasses dependence and better quality of life.

Grazie per l'attenzione!
“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 small role in the management of higher refractive errors
- Technique is learnable by intraocular surgeons
- Verisyse and IOL Vision 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 NLE or cataract surgery

Why a phakic IOL?
- High Corneal with Retention of Accommodation
- Removable (no tissue removed)
- Both IOLs in clinical trials >90% at 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

Pre-Verisyse or Visian Planning

Ultrasound Biomicroscopy (UBM)

Suggested Safety Parameters

- OCT – Anterior Chamber Dimensions
- A 5 mm safety distance
- Old or accommodated crystalline lens

- Anterior movement of lens at about 20 minutes per year
- Ballant G: JORS 2008; 20 Nov
Eventually Cataract
Eventually All Phakic IOLs Will be removed

Steps To Removal
I prefer Superior Scleral Incision for Removal of Verisyse
Then Clear Cornea for IOL

Conclusions
Phakic IOLs
- Excellent addition to comprehensive refractive practice
  - LASIK
  - PRK
  - Phakic IOLs
  - Natural Lens Replacement
  - Presbyopic IOLs
  - Refractive Cataract Surgery
- Enhancement possible with PRK or LASIK
  - Rates low (<10%)
- Eventually Cataract Removal
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