American Society of Cataract and Refractive Surgery

25-29 April, 2014
Boston, Massachusetts
Boston Convention Center

Course 27-411 BCEC
Room 206 AB

“Solving the High Myopia Problem With Phakic IOLs”

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Stephen G Slade MD FACS

Sunday, April 27, 2014
3.00 PM – 4.30 PM
Index

Posterior Chamber Phakic Refractive Lens (PRL): 12 Years Surgical Technique Evolution
*Dimitrii Dementiev MD*

- Pag. 3

Interest of the AC OCT and the study of Accomodation when Implanting Phakic IOLs
*Georges D Baikoff MD*

- Pag. 9

Achieving Success Safely with Phakic IOLs
*David R Hardten MD*

- Pag. 11

Management of Complications after Vivarte™ Phakic Anterior Chamber IOL Implantation
*Matteo Piovella MD, Fabrizio I. Camesasca MD*

- Pag. 16

Getting Started with the Staar ICL
*Stephen G Slade MD, FACS*

- Pag. 21

Uv-Absorbing Collamer™ Implantable Contact Lens (ICL™) For Correction of Myopia
*Stephen G Slade MD, FACS*

- Pag. 24

Tricks to obtain better results qith Acrysof Cachet Angle Supported anterior chamber IOL
*Luca Gualdi MD*

- Pag. 34

ADDRESSES

- Pag. 40
"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
  HYPEROPIC MODEL: 10.6 mm
- OPTICAL DIAMETER:
  MYOPIC MODEL: 4.5 - 5.0 mm
  HYPEROPIC MODEL: 4.5 mm
- DIOPTRE 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

PRL
MYOPIC RANGE
- FROM -3.0 DPTRS.
- TO -30.0 DPTRS.

HYPOROIC RANGE
- FROM +2.5 DPTRS
- TO +11.0 DPTRS

SURGICAL TECHNIQUE
- 2.0 mm standard clear cornea incision (TEMPORAL)
- PRL loading & insertion (self foldable)
- Atrumatic loading under the UKIS
- 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 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

PUPIL 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!!!

Possible reasons for decentration/sub-luxation

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

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

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

If so, not only limited cases at limited sites would be expected.
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 lenslet to make implantation or extraction through small incision without stromal and internal incarceration.

Reason 2: After 20 years of experience I believe Posterior chamber IOLs infected with endothelium centered that ACIOs are

Reason 3: More number of cases of IOLs are manufactured (ACO better) give good intraocular coherence in long term and resolve less cases of phacosopic phenomena than AC IOLs

Reason 4: Because the IOLs are placed under the iris, the complications like iris chafing are reduced.

Reason 5: IOL position in posterior chamber is a natural way, no one of us will like to make AC IOL repositioning for detached retina. Intermittent cell loss, iris denudation and light reflection after repositioning of AC IOL. IOL confirms it disadvantages.

CONCLUSION

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

ADVANTAGES OF PRL

- MYOPIA TILL -30.0d
- HYPEROPIA TILL 10.0D
- 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
“Interest Of The Ac Oct And The Study Of Accomodation When Implanting Phakic Iols”

Georges D Baikoff MD

Measurement of the anterior chamber’s internal diameter
One of the key points in improving anterior chamber angle-supported implant tolerance lies in correctly adapting its size with the anterior chamber’s internal diameter. Until today, we had to rely on approximate measuring methods, such as white-to-white, sometimes improved by using a graduated plastic sizer when inserting the implant. However, these measuring means are relatively inaccurate and do not give a precise evaluation of the anterior chamber diameter.

Figure 1 clearly demonstrates the interest of this type of anterior segment preoperative imaging (AC OCT, Scheimpflug, ultra high frequency ultrasound) to evaluate the internal diameter dimensions before surgery.

Fig 1 : Normal Anterior Segment

We were surprised when we compared the anterior chamber’s diameter on the 0°, 45°, 90° and 135° axes. The vertical diameter appeared larger than the horizontal diameter in 80% of the cases. The mean difference between the vertical and horizontal axis is more significant for eyes with small diameters than eyes with large diameters. The average distance is approximately 300 µm (Fig 2), which is more than the examination measuring or reproducibility error which is not more than 50µm. In the future, this phenomenon must be taken into account in order to chose the implant. If one chooses an implant slightly bigger than the horizontal diameter, it will have to be placed vertically and if one uses an implant that is almost the same size of the horizontal diameter, it should be placed horizontally.

Endothelium Safety distance
Retrospective studies have shown that a 1.5mm distance must be respected between the edge of the IOL’s optic and the corneal endothelium. This minimum safety distance avoids the risk of endothelial cell loss secondary to contact between the implant and the endothelium in particular when the patient rubs his eyes. Anterior segment imaging software should therefore include this safety distance.

Fig 2 : AC Diameter with the AC OCT

Endothelium Safety distance
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Studying accommodation and crystalline lens ageing has shown that the crystalline lens increases in volume with age and during accommodation. Developing software that simulates anterior segment distortions with the variations of the crystalline lens volume should allow us to define a safety free zone in the anterior chamber where the optic of the implant should be situated in order to reduce the risk of complications, because of contact with the endothelium (forward movement) or with the crystalline lens (backward movement).

**Possibility of contact crystalline lens / implant.**

Having studied numerous series of phakic implants, we were able to show evidence of contact of different models of implants with the crystalline lens. Having dilated a hyperopic patient with an ARTISAN implant, we discovered a contact between the lower edge of the implant and the crystalline lens. Likewise, during accommodation, the posterior face of a hyperopic patient’s PRL phakic implant came into contact with the crystalline lens. In a patient implanted 10 years ago, we noticed that the crystalline lens came into contact with the implant’s posterior face because the crystalline lens had increased in volume with age.

These different elements should encourage manufacturers to include in their software the profiles of the different implants available so as to be able to simulate their position in the anterior segment either accommodated or unaccommodated. Charts simulating anterior segment ageing would give us an indication of how long an implant will be tolerated.

**Can anterior segment imaging indicate that one particular implant is preferable over another?**

Studying accommodation in an albino patient showed that all the structures of the anterior uvea are malleable and mobile. The only stable elements of the anterior segment are the cornea and the uvea insertion at the corneo-scleral junction, that is to say the irido-corneal angle. The iris, the sulcus, the ciliary body and the crystalline lens show significant modifications during accommodation.

In our opinion, these elements define the irido-corneal angle as the most stable structure and the least affected by accommodation. This could be another fact in favour of angle-supported implants, as long as the problem of pupil ovalisations has been definitely solved as they are the result of inaccurate preoperative measurements.

Studies are underway concerning anterior segment modifications observed with iris-fixated implants and will no doubt give rise to new safety criteria.

Studying the ciliary body and the sulcus in an albino patient showed evidence of important diameter variations of these two structures during accommodation. It is therefore very difficult to try and imagine, even with techniques visualising the posterior segment, that an exact measurement of the posterior sulcus’ diameter can be obtained. It is also probable that, just like the anterior chamber diameter, the posterior sulcus’ diameter is variable according to its axes. Anterior segment imaging techniques should also be able to define eyes at risk with posterior chamber implants that are responsible for developing cataracts as illustrated by Gonvers.

**Conclusions**

In the light of these studies, it appears that the AC OCT or other similar techniques (Scheimpflug, ultra high frequency ultrasound) available in everyday practice are going to become essential when scheduling a phakic implant in a patient where LASIK is contraindicated. A static and dynamic study of the anterior segment, and new software is going to become necessary to simulate the anatomical relationship of the implant and the anterior chamber during accommodation and ageing. The safety distances required in the anterior segment will be specified and we will probably be able to predict a safety period during which the implant will be well tolerated and after which it will probably be necessary to remove it.
“Solving High Myopia with Phakic IOLs: Comprehensive Refractive Surgical Practice”

David R Hardten MD
Advanced Software Developments

Pentacam – Extrapolation to Vision
- Scleral Vanes
- C/D Ratio
- Enhanced Emphasis
- Diff. in Probed

Nomogram Based on UBM

<table>
<thead>
<tr>
<th>Lens Type</th>
<th>Phakic IOL Power</th>
<th>Length of IOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Lent 10</td>
<td>AI</td>
<td>120</td>
</tr>
<tr>
<td>10 to 12</td>
<td>AI</td>
<td>120</td>
</tr>
<tr>
<td>10 to 12</td>
<td>AI</td>
<td>128</td>
</tr>
<tr>
<td>10 to 12</td>
<td>AI</td>
<td>120</td>
</tr>
<tr>
<td>10 to 12</td>
<td>AI</td>
<td>132</td>
</tr>
<tr>
<td>10 to 12</td>
<td>AI</td>
<td>132</td>
</tr>
</tbody>
</table>

Are There Enough Patients to Be Worthwhile?

Pre-presbyopic patient myopia -8 to -20 D
- Affects ~3.5% of US population
- Overrepresented in patients seeking refractive surgery
- More disabled - more motivated
- These patients are highly energetic ambassadors for the rest of your practice
- If you are known as helping the most highly disabled patients – good for word of mouth

Optimizing Efficiency

Specialized Format for Implementation
- This is a relatively low volume procedure in your practice
- Need to have systems in place to allow efficiency
- Staff training is vital
  - First responder training – yes we do it!
  - Technical training – careful MR & CR & IOL calculations
  - Counselor training – normal postop course similar to cataract surgery, with about 1-2 weeks between eyes
- Prepare in advance consent forms, postop instructions, follow-up visits, etc.

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

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 centration
Steps to Efficiency

Become proficient at the surgery - practice

Intraoperative Efficiency

Flow in OR
- Work into cataract day
- Average time for case is about 2x cataract
- We schedule the same as for a cataract
- Schedule 1 phakic IOL and then 3 cataracts on rotating basis
- Allows us to still maintain flow of the day
  - Extra prep work: PI's and Block for Verisyse
  - Extra post-op work: IOP and AC check for Visian
- If ultra-efficient turnover, may want to time differently in your OR schedule to allow 2x time for the phakic IOLs

Postoperative Care

Phakic IOLs
- Very similar to cataract surgery
- We use Zymar, Pred Forte, Acular LS QID until out
- Follow-up 1 day, 1 week, 1 month
- Second eye typically at 1 month for Verisyse, 1 week for Visian
- Early astigmatism resolves over 4-6 weeks for Verisyse
- Spectacle help when needed
- Endothelial counts every 1-2 years

Laser Vision Correction Enhancements

LVC after ph-IOL
- 22 eyes with at least 1 mo (mean 5 mos)
- Mean SE inc (μ) = +0.1 ± 0.31 D
- Mean Astig = +0.25 ± 0.31 D
- UCVA 20/20 or better = 86%
- UCVA 20/25 or better = 94%
- UCVA 20/30 or better = 96%
- UCVA 20/40 or better = 96%
- In eyes with original BCVA 20/20
  - UCVA 20/20 or better = 70%
  - UCVA 20/25 or better = 94%
  - UCVA 20/30 or better = 100%
  - No eyes with loss of BCVA

Case Example – LVC after Verisyse

Wavefront Treatment after Verisyse
MRC -2.70 x 1.25 x 20
WR -3.53 x 2.11 x 38
HCA: 0.68 μ
Cornea: 0.41 μ
Twist: 0.73 μ
SA: 0.19 μ
Postop PRK - Custom
UCVA = 20/20

Case Selection
Peaks
- Choose patients with reasonable expectations
- Young myope - about -12 D is ideal
- WTR astigmatism is ideal for Verisyse
- ATR astigmatism in older patient ideal for Visian
- OK with occasional spectacle wear
- Use peribulbar block for your first cases – especially with the Verisyse
Promotion of Phakic IOLs

**Marketing**
- Low yield on marketing this specific technology
- Synergistic with overall refractive surgery marketing plan
- Differentiates your practice from LASIK only practices
- Media coverage works well for special interest story
- Internal preparation key to success
  - Happy patient as advocate
  - Staff knowledge in place before external marketing

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
- Risks low (<10%)
“Management Of Complications After Vivarte™ Phakic Anterior Chamber IOL Implantation”

Matteo Piovella MD Fabrizio I. Camesasca MD
Vivarte™ IOL Removal
Dramatic ECC Counts!!

When lens removal needs to be considered

**ECC: ≤ 1500/mm²**

Vivarte™ Needed bigger size IOL

M.D. (50yo) c/2002 (preop 23/37) Date of surgery March 2002
Date of explantation May 2007

ECC Preop: LE n= 2304
Postop VA: LE 1.0 +1.00 +1.00 (60)
IOL Descent
LE progressive ECC reduction
(after 4 years n = 1068)

Explantation was performed at: day 1447
M.G. (26y.o) cell 246S (preop 2487)
Date of surgery: March 2002 – 11 years follow-up

Vivarte 12 Years After Surgery

Temporal Incision
Needed bigger size IOL

1 DAY PO
1 MONTH PO
1 YEAR PO
2 YEARS PO
4 YEARS PO

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

Vivarte™ IOL
EC Counts - 12 Years Follow Up

<table>
<thead>
<tr>
<th>ID</th>
<th>BCVA</th>
<th>ECC PRE</th>
<th>ECC</th>
<th>% ECC Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.V</td>
<td>2040</td>
<td>2270</td>
<td>1923</td>
<td>-15.28</td>
</tr>
<tr>
<td>C.S.</td>
<td>2020</td>
<td>2531</td>
<td>1872</td>
<td>-26.03</td>
</tr>
<tr>
<td>C.B.</td>
<td>2020</td>
<td>2586</td>
<td>2277</td>
<td>-4.96</td>
</tr>
<tr>
<td>P.A.</td>
<td>2025</td>
<td>3085</td>
<td>2008</td>
<td>-34.93</td>
</tr>
</tbody>
</table>

EC Counts
% ECC Reduction

IOL explanted in 18 cases

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

Phakic IOL PRL removal
4 years p.o.

No lens-induced warpage
Phakic IOL ICL removal
2 years p.o. Female, 49 years old

Vivaris™ 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

Vivaris™ IOL
Long-Term Management

- Refractive surgery patients require constant follow-up in time and proper technology (Vivaris™)
- All people require follow-up in time (AAO 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 Vitaris™ has the same priority role for AC Segment Measures as well as Corneal Map rule for laser refractive surgery
“Getting Started With The Staar ICL”

Stephen G. Slade MD, FACS

Thanks for the opportunity to talk about Staar. I’ve been looking forward to giving this talk. I’m sorry I can’t be there personally but hopefully I can convey my thoughts on the ICL through my slides. It’s a product that I believe in. And it’s a product I want for my patients.

Refractive Surgery

<table>
<thead>
<tr>
<th>Corneal Modeling</th>
<th>Subtractive</th>
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<tbody>
<tr>
<td>RK, Intacs</td>
<td>LASIK</td>
</tr>
<tr>
<td>CK</td>
<td>myopia/astigmatism</td>
</tr>
<tr>
<td>SES</td>
<td>PRK</td>
</tr>
<tr>
<td></td>
<td>low myopia</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Lens Based, Additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phakic IOLS</td>
</tr>
<tr>
<td>myopia, hyperopia</td>
</tr>
<tr>
<td>Aphakic IOLs</td>
</tr>
<tr>
<td>Crystalens, presbyopia</td>
</tr>
<tr>
<td>Keratophakia</td>
</tr>
<tr>
<td>hyperopia, myopia ?</td>
</tr>
</tbody>
</table>

Where does the ICL fit in?

You can actually view refractive surgery in my fairly simplistic way by putting all the procedures into three modes of action. Corneal Modeling or “bending” such as RK, CK, Intacs, never really has worked out. Subtraction techniques have such as LASIK and PRK have worked but not for larger amounts and not as well for hyperopes or presbyopia. But the Staar lens is different and is part of the lens based, or adding power to the eye group. In Ophthalmology this has become the major area of interest. Aphakic IOLS like the crystalens and Restor, and keratophakia like Intralens and what we are talking about today, phakic IOLS....The Staar ICL It’s important to realize the advantages of these additive technologies: Don’t alter the cornea, They have a large degree of reversibility or at least removability. That’s important for safety and potential presbyopic uses. They are not “dose dependent”. The more myopia you treat with LASIK, the more risks. From the eye’s point of view, a –3 is the same as a –12. They are wonderfully stable.

I know you have seen some great data from Steve Schallhorn and I didn’t want to make that the focus of my talk but just look at three graphs to illustrate my point about the stability of additive technologies in general but the Staar in particular. Look at these flat lines over time from the Staar FDA study in regards to UCVA, BCVA and their actual refraction over time out to 3 years. The ICL is away from healing surfaces, it is amazing stable.

You don’t see that with corneal surgery. And don’t forget the average amount of myopia in the study was over 10 diopters. When we look at the change in lines of best spectacle corrected visual acuity, 49% of eyes gained one or more lines of acuity at 3 years. The technology delivers better vision than they were able to get with glasses, ever. Some of this is due to decreased minification but from the patient’s perspective, they don’t care where it comes from.
When contrast sensitivity was repeated in the presence of a glare source, there was a significant improvement at all 4 spatial frequencies from 3 cycles per degree. Now on to the surgery. This is a very attractive and fun surgery. It is, in a word, elegant. It is basically cataract surgery with all the messy steps in the middle left out. It is quick. I suspect when we are able to do these routinely, we will do these faster than a LASIK. My friend Eric Mertens, a surgeon in Belgium, routinely does these in three minutes, bilaterally, 3 minutes an eye. 7 minutes and he is done. Surgeons embrace it, they get it. They come to the courses I teach already convinced, just like the LASIK courses after we got going. Interestingly, we now have surgeons in the courses who have taken the Artisan course but haven’t started and are taking the Staar course. 

I ask them why and they say, well, we’re just waiting for Staar.

**Reduced working area**
- Use the extreme, center when working in small anterior chamber
- The highest peak of the crystalline lens will result in a capsular bag applanation tear
- ASCs that occur within 6 months of surgery are considered traumatic

**ICL Pearls**
- Loading is key ½ Occucoat ½ BSS
- Stab wound first, then viscoelastic and incision
- Fill AC with viscoelastic 80% full, not packed
- Inner width of incision no more than 3 mm, create a trapezoidal shape, anterior entry
- Pulse the lens in
- Careful and complete viscoelastic removal

Let’s review the downside, the FDA complications. The Panel got it as far as cataracts went, they hardly spent any time at all asking us about this. Indeed, we only had 3 eyes in the 559 eye cohort that required cataract extraction and all three did well. Three is close to what you would expect in this population of high myopes to develop over time naturally. Our study showed this is largely a learning curve issue, all the surgeon’s were implanting their first lenses typically with large gaps of time between surgeries. Indeed the complications were clustered early in a surgeon’s experience and clustered around one or two surgeons in the group. When we have surgeon’s doing these on a routine basis, the results will improve dramatically.
I’d like you to keep this photograph in mind, since over half of the anterior subcapsular opacities we are going to describe were no greater than this clinical standard. In fact, only 1 eye in the study had ASC of grade 2 or higher. To summarize our findings on lens opacities, only 3 cataract extractions were performed in the study population of 526 eyes. One was related to the inadvertent injection of a topical preserved miotic inside the eye, one was a nuclear cataract that occurred in one of the two patients that had bilateral nuclear opacities, and the third case was an anterior subcapsular opacity that did progress to the level of clinical significance. Best corrected visual acuity was unchanged or improved for all 3 eyes.

Advantages of Combined procedures
- The ICL is not dose-dependent
- Preserve corneal tissue, improved ablation profiles
- Maintain maximum optical zones
- Leave options open for retreatment
- Avoid pushing any one procedure to the limit
- Rapid recovery
Reproducibility, better quality of VA

And many of the patients will actually get both. There are many advantages to using both technologies in one eye, Bioptics……. READ SLIDE

I know you all have figured out you have the chance to get a piece of every myope with the ICL and Intralase but you may not have thought of the group that will get both. Many patients that have ICLs will get touched up with LASIK and many of the higher myopes will get both as a surgical plan, a combined procedure. This will grow both procedures, LASIK and ICL. People will come in hearing of ICL and be better LASIK candidates, we’ll avoid the patients pushed past the limits. We will end up doing more of both. They are very complementary, almost symbiotic procedures. Most important in Refractive Surgery is the patient’s perspective. How they view a procedure, how they describe it to their friends. Refractive is ELECTIVE surgery and the patient has the vote.

LASIK worked because it was what patients want laser surgery to be, a quick, relatively painless procedure with a rapid, relatively comfortable return to great vision. The WOW factor is key, all things equal, the patient that sees sooner, especially right after surgery, will be “WOWED” the most and will talk the most to his friends. And word of mouth referrals is most practices life blood.

Surgeon’s Perspective
Metal Keratomes—ECCE—StaarICL—Phaco
Intralase—Artisan (removal)

This is an exercise to try to illustrate my point about surgeon perspective and patient perspective and their preferences. There are 8 ophthalmic procedures or devices here, just think for a minute of how you would group them into two equal groups of four. What fits? Don’t try to group them by intraocular, extraocular or an ophthalmic sort,
but just into two groups, how a patient might view them. For example, you would put LASIK in one group and PRK in the other, which group would you put Phaco in?

**Surgeon’s Perspective**
- ECCE
- Metal Keratomes
- Artisan
- Phaco
- Intralase

Staar ICL

This is how patients have grouped them, in the real world, into choices they want and choices they don’t want. They prefer phaco over ECCE, etc. Now no one every published a paper showing phaco was better scientifically than ECCE or LASIK was better than PRK but the patients chose.

Once two technologies are in the same ballpark, in a way it is out of our hands, the patients elect. They’ll elect the ICL over the Artisan. I am sure of that. And surgeons will be happy with that choice because they will choose the ICL as well. And those surgeon’s are already in your camp, you don’t have to recruit new ones. The same docs who chose Intralase have chosen or will choose the ICL. It is no coincidence Dave Dulaney, the first guy to buy an Intralase laser in the US is also the largest Staar ICL implanter in the trials.

Howard Gimbel calls the ICL “The best thing since Phaco”.

**“UV- Absorbing Collamer™ Implantable Contact Lens (ICL™) For The Correction Of Myopia”**

*Stephen G. Slade MD FACS*

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**Indication for Use**

STAAR Myopic Implantable Contact Lens (ICL™) is indicated for placement in the posterior chamber of the phakic eye for
- Correction of moderate to high myopia
- –3.0 D to –20.0 D
- 21 to 45 years of age

**Implantable Contact Lens (ICL)**
- ICL design similar to standard plate haptic intraocular lenses for cataract surgery
- Forward vault to minimize contact of the ICL with the central anterior capsule
- Collamer material - hydrophillic, biocompatible
- Safety of the collamer material established in an approved PMA for a standard PC IOL (P990013)

**STAAR Implantable Contact Lens Version 4**

**A Prospective Multicenter Clinical Trial to Evaluate the Safety and Effectiveness of an Implantable Contact Lens (ICL) for the Correction of Moderate to High Myopia**

**Study Design**
- Prospective, multicenter study of patients with myopia from –3.0D to –20.0D
- Assessment of ICL outcomes based on comparison to baseline and FDA guidance
- Schedule of study visits:
  - Preoperative/2 hours postoperative/Days 1 and 7
  - Months 1, 3, 6, 12, 24 & 36

**Eligibility Criteria**
- 21 to 45 years of age
- BSCVA 20/100 or better
- ≤ 2.5D of refractive cylinder
- Stable refraction (change in MRSE of ≤ 0.5D)
- No previous refractive surgery
  - (except for astigmatic keratotomy)
  - No visually significant lens opacities
Effectiveness Parameters

- Decrease in refractive myopia
- Improvement in uncorrected visual acuity
- Predictability of refractive outcome
- Refractive stability
- Patient satisfaction

Safety Parameters

- Preservation of best corrected visual acuity
- Slit lamp findings
- Intraocular pressure
- Contrast sensitivity with & without glare
- Incidence of complications & adverse events
- Endothelial cell analysis

Accountability

539 Eyes of 305 Subjects implanted in the U.S.
13 eyes of 11 subjects did not meet entry criteria
Safety and Effectiveness 526 Eyes of 294 Subjects

At 3 years:
- 44 not yet eligible
- 4 discontinued
- 33 lost-to-follow-up
- 76 missed visit
- 157 w/o 3-year visit

At Three Years

369 Eyes Available (77.2%)

Demographic & Baseline Information (526 eyes of 294 subjects)

<table>
<thead>
<tr>
<th>GENDER</th>
<th>Female</th>
<th>178</th>
<th>60.5%</th>
<th>Male</th>
<th>116</th>
<th>39.5%</th>
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<tbody>
<tr>
<td>RACE</td>
<td>Caucasian</td>
<td>249</td>
<td>84.7%</td>
<td>Black</td>
<td>6</td>
<td>2.0%</td>
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<td></td>
<td>Hispanic</td>
<td>23</td>
<td>7.8%</td>
<td>Other</td>
<td>16</td>
<td>5.4%</td>
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<tr>
<td>AGE</td>
<td>Mean (SD)</td>
<td>36.5(5.8)</td>
<td></td>
<td>Range</td>
<td>22 to 45</td>
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<tr>
<td>PREOP.</td>
<td>MRSE</td>
<td>-10.1 (3.7)</td>
<td></td>
<td>Mean (SD)</td>
<td>-3.00 to -20.00 D</td>
<td>Range</td>
</tr>
</tbody>
</table>

Uncorrected Distance Visual Acuity

- UCVA 20/40 & 20/20 or better over time
- UCVA at 3 years
  - All eyes
  - Eyes with preoperative BSCVA 20/20 or better
  - Eyes targeted for emmetropia (±0.50 D)

Stratified by preoperative myopia

Uncorrected Distance Visual Acuity Over Time

Uncorrected Distance Visual Acuity at 3 Years
Refractive Predictability and Stability

- Attempted vs achieved MRSE
  - Within ± 0.50D of target MRSE at 3 years
  - Within ± 1.00D of target MRSE at 3 years
- Mean MRSE over time
- Stability of MRSE
Safety Outcomes
Best corrected visual acuity
Complications and adverse events
Lens opacities
Inflammation
Patient symptoms
Contrast sensitivity
Endothelial cell analysis
## Postoperative Complications 5/526 (<1.0%)
- 1 macular hemorrhage at 1 week;
- BSCVA 20/20 at 3 years
- 1 subretinal hemorrhage at 3 months;
- BSCVA 20/50 pre- and postoperative
- 3 retinal detachments (RD)
  *1 rd (macula off) repaired with silicone oil, resulting in nuclear opacification; bscva cf (MRSE –16.25 D)
  *2 other RDs; final BSCVA within 1 line of preoperative BSCVA (MRSE –9.5 D, –17.75 D)

## Late Intraocular Pressure Rises 5/526 (<1.0%)
IOP >25 mmHg or increase >10 mmHg from baseline at 3 months or later
3 eyes - IOP of 17, 22, and 26 mmHg at last visit without treatment; patients continue to be monitored
2 eyes - IOP controlled to 20 mmHg and 18 mmHg with topical beta blocker

## Acute Intraocular Pressure Rises 20/526 (3.8%)
- Majority of cases reported during first 1-2 days postoperative; no reports after 21 days postoperative
- 17 eyes - additional YAG iridotomy or enlargement of existing iridotomy
- 3 eyes - AC irrigation for removal of retained viscoelastic

## Secondary ICL Surgical Procedures 16/526 (3.0%)
- ICL repositioning 4 eyes
- ICL replacement (sizing) 8 eyes
- ICL replacement (wrong power) 1 eye
- ICL removal/cataract extraction 3 eyes

## Nuclear Opacities 5/526 (<1.0%)
1 case occurred following retinal detachment repair with silicone oil (~16.25 D myopia)
4 eyes of 2 patients
Nuclear opacity occurred bilaterally and simultaneously between 2 and 3 years
Both patients were high myopes (~14 D to ~17 D myopia)
1 eye required cataract extraction; final BSCVA 20/25

## Anterior Subcapsular Opacities 14/526 (2.7%)
12 of 14 cases asymptomatic and visually insignificant
11 of 14 cases observed within 6 months of surgery, ie, surgery related
6 of 14 cases - ICL was removed and replaced during initial surgery Associated with learning curve
3 of 14 cases observed at 1-2 years; associated with poor vault, but asymptomatic

## Clinically Significant Anterior Subcapsular Opacities 2/526 (0.4%)
2 cases progressed to clinically significant opacity* requiring cataract extraction
1 case (previously described) - inadvertent use of preserved miotic agent (topical Carbachol) in intraocular irrigating solution; BSCVA 20/20 preoperative and post-cataract extraction
1 case - opacity observed 6 months post-operatively; cataract surgery performed at 16 months - BSCVA 20/40 preoperative and post-cataract extraction
*Clinically significant opacity: LOCS AS score >0.5 with ≥2 lines loss BSCVA, increase in glare or ICL removal/cataract extraction
Summary – Lens Opacities Nuclear & Anterior Subcapsular
- Only 3 eyes (3/526 or 0.6%) underwent cataract extraction
- Good clinical outcomes – BSCVA unchanged or improved for all 3 eyes

Eyes With Persistent Loss of BSCVA ≥ 2 Lines 5/526 (<1.0%)
- 1 retinal detachment (macula off)
  *Observed 31 months postoperative, repaired with silicone oil
  *Dense cataract formation with BCVA CF
  * 1 case requiring cataract extraction; final BSCVA 20/25
  * 2 cases – no intervention
  - 1 anterior subcapsular cataract
    * Inadvertent use of preserved miotic agent in the intraocular irrigating solution; BSCVA 20/20 post-cataract extraction

Inflammation
- Postoperative inflammation measured by
  - Slit lamp examination (all eyes)
  - Laser cell-flare meter (substudy)
- No inflammatory response observed after the first postoperative week

Patient Symptoms
- Subjective questionnaire was administered at baseline and postoperatively
- Patients were asked to rate the following symptoms as absent, mild, moderate, marked, or severe:
  - Glare
  - Halos
  - Double vision
  - Night vision difficulties
  - Night driving difficulties

Contrast Sensitivity Methods
- Mesopic contrast sensitivity
  - 73 study eyes implanted at 2 clinical sites
  - Stereo Optical Inc. Optec X1600F2 Vision Tester
  - Tested at 3 cd/m2 following 10 minutes of dark adaptation
  - With and without glare source of 10 lux
  - Calibrated for 20 feet (6 meters)
Specular Microscopy Reading Center Methods

- Images were received from 12 investigators at 9 clinical sites
- Single masked reader analyzed all images
- Endothelial images were scanned and then analyzed with Konan KSS-300 software
- Approximately 1,300 images were analyzed in the study
- Mean number of cells per image = 93

Specular Microscopy Reading Center Estimates of Precision

- Best case - 2% for a single clinical site, single photographer, and a single reader
  For multicenter study, precision varies from 8% to 10% with a single reader

Specular Microscopy Outcomes

Endothelial cell density = cells/mm²
% Hexagonality or pleomorphism
Coefficient of variation or polymegathism
As a general rule, studies indicate that stressed corneas have:
- % Hex <45
- CV >45

Examples where endothelial morphology has been demonstrated to be the most sensitive measure of corneal endothelial stability:
- Pseudophakic bullous keratopathy
- Diabetes
- Contact lens wearers

Specular Microscopy Outcomes

Past studies have shown that endothelial morphology is the best indicator of corneal endothelial stress or instability
Corneal Endothelium in Diabetics
- Corneal endothelium in a diabetic cohort, as compared to normal controls
  - No significant difference in endothelial cell density
  - Significant decrease in % hexagonality
  - Significant increase in coefficient of variation

Corneal Endothelium in Long-term Contact Lens Wearers
- Corneal endothelium in contact lens wearers as compared to controls
  - No significant difference in endothelial cell density
  - Significant decrease in % hexagonality
  - Significant increase in coefficient of variation
  MacRae et al. Ophthalmology 1994;101:365-370

- The past three conditions demonstrate that corneal endothelial morphologic changes are the first indicators of endothelial stress.
% Hexagonality and coefficient of variation are more sensitive indicators of endothelial stability than endothelial cell density

Summary - Specular Microscopy
- Cumulative (total) mean loss 8.4% to 9.7% over 4 years
- Stabilization of endothelial cell loss suggested at 4 years
- No clear mechanism for chronic loss due to ICL
- % Hexagonality, CV data in the ICL study cohort does not support chronic endothelial stress, as previously reported in pseudophakic bullous keratopathy, diabetes, contact lens wear

Long-Term Considerations
Lack of longitudinal control data in peer-reviewed literature, particularly in high myopia
Consideration should be given to non-homogeneity of corneal endothelium when extrapolating endothelial cell density over time
Endothelial cell migration must be considered in long-term endothelial cell modeling - from higher-density periphery to lower-density central endothelium
The higher endothelial cell density found in the paracentral and peripheral cornea affords an additional reassurance of safety for the endothelium in patients implanted with the ICL

**Summary – Specular Microscopy**
- Between the 3-year and 4-year interval, stability of the corneal endothelium appears to be achieved
- Stable endothelial morphology over time suggests absence of stress on the endothelium
- These data consistent with corneal endothelial remodeling and stabilization
- Provide reasonable assurance of safety for the Staar ICL

**To extend follow-up on endothelial cell morphometry observed to date, the sponsor is committed to:**
-Increasing the number of specular microscopic images analyzed at 4 years in the PMA cohort
-Collecting data at 5 years post-implantation
Continuing to use the same rigor and precision to evaluate the endothelium

**Uncorrected Distance Acuity**
- 39% of patients >15 D achieved UCVA 20/40 or better
- Limited potential for UCVA of 20/40 or better in this group
  - Pre-operative visual acuity
  - Limited range of lens powers

**ICL for Myopia >15 D**
- Challenges of treating high myopes
  - Significant variability in manifest refraction
  - Vertex distance (1 mm = 0.5 D)
  - Poor preoperative visual acuity with best spectacle correction

**Complications & Adverse Events RD, Lens Opacities, Loss of BSCVA ≥2 Lines 6/52 (12.4%)**
- 2 retinal detachments
  - 1 eye (macula off) repaired with silicone oil, followed by nuclear opacity with visual loss (CF)
- 1 eye - 1 line loss in BSCVA
- 3 eyes (2 patients) nuclear opacities
  - 1 cataract extraction – no loss in BSCVA
  - 1 anterior subcapsular opacity – cataract extraction performed with no loss in BSCVA
Risk-Benefit Considerations for ICL in Myopes >15 D

- All patients with myopia >15 D willing to undergo surgery again, satisfied with surgery
- Substantial improvement in UCVA
- Gain in lines of BSCVA in over half of eyes with myopia >15 D
- Increased risk of retinal detachment and nuclear opacity, independent of the ICL

Increased risk of complications in our highest myopia cohort must be considered in this context.

Summary

- The effectiveness data presented in the PMA establish the effectiveness of the Myopic ICL for the correction of myopia between −3.0 to −20.0 D
- Clinical outcomes presented in this PMA substantiate the overall safety of the Myopic ICL in this moderate to high myopic patient population
- Endothelial cell data provide reasonable level of assurance for safety

Patients with myopia >15 D are at greater risk of complications irregardless of ICL and enjoy the greatest benefit.

Staar Myopic ICL

- Long-term surveillance of study patients for endothelial analysis
- Well developed training program
- Labeling to encompass recommendations by FDA Medical Reviewer and Panel Reviewers
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.

Patient selection tricks

Endothelial Cell Density Requirements

<table>
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<tr>
<th>Age</th>
<th>Minimum Cell Density (cells/mm²)</th>
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<tbody>
<tr>
<td>21 – 25</td>
<td>3,750</td>
</tr>
<tr>
<td>26 – 30</td>
<td>3,300</td>
</tr>
<tr>
<td>31 – 35</td>
<td>2,900</td>
</tr>
<tr>
<td>36 – 40</td>
<td>2,500</td>
</tr>
<tr>
<td>41 – 45</td>
<td>2,200</td>
</tr>
<tr>
<td>≥46</td>
<td>2,000</td>
</tr>
</tbody>
</table>
...but...

Tricks to obtain a correct White-to-white (W-W) distance
Right optic compression in the angle

4 types of IOL dimensions with 0.5mm steps from 12.5 to 14 mm (0.75-1.00mm more than the measurement taken with UMIVISANTE, biometry, tomography or IOL MASTERS:

<table>
<thead>
<tr>
<th>Anterior Chamber Diameter (mm)</th>
<th>Model Designation</th>
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<tbody>
<tr>
<td>11.20 – 11.30</td>
<td>L12200</td>
</tr>
<tr>
<td>11.70 – 11.80</td>
<td>L12700</td>
</tr>
<tr>
<td>12.30 – 12.40</td>
<td>L13500</td>
</tr>
<tr>
<td>12.70 – 13.20</td>
<td>L14600</td>
</tr>
</tbody>
</table>

Stable material (ACRYSOF®): transparent, resistant, Reliability index 1.0, single-piece, UVR absorbing, hydrophobic, 2.0mm incision, no stability, no incisionry required.

Plastic angle-supported IOL

Flexible, allowing moving. Inclination: INSTABILITY

Phaco: angle-supported IOL

Acrysoft Crystalear: Bridge strength: INSTABILITY

“SAFETY” DISTANCES

Distances: 1.00 mm, 1.50 mm, 2.00 mm.
Intra-operative tricks

WITH vasoeconstrictor drops

WITHOUT vasoeconstrictor drops

Tricks to how to correct Astigmatism

BIOOPTICS

Es. - 10 sf. - 3 cm (100)

= 0 sf. - 3 cm (100)

= 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!
<table>
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<tr>
<th>Name</th>
<th>Address</th>
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